GAMBRO

Artis

Operator's Manual

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Questions or comments about this publication can be directed to your Local Representative.

This Operator's Manual is made up of the chapters listed in the table below. Each chapter is identified by its own code and revision.

Refer to the table below for the correct code and revision of each chapter in this Operator's Manual.

Chapter	Code	Revision
Cover	OP_9032935900_0C	Rev. /
Table of Contents	OP_9032935900_0T	Rev. /
Introduction	OP_9032935900_0I	Rev. /
Chapter 1	OP_9032935900_01	Rev. /
Chapter 2	OP_9032935900_02	Rev. /
Chapter 3	OP_9032935900_03	Rev. /
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Chapter 17	OP_9032935900_17	Rev. /
Appendix A	OP_9032935900_AA	Rev. /
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NOTE

Ensure that no chapter is removed from the manual because that might affect the understanding of the Artis Operator's Manual.

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Introduction

Operator's Manual symbols

Following the main symbols used in this Operator's Manual:

⚠WARNING

Used to underline very important information related to the patient or operator safety and to avoid machine malfunctions.
Read carefully before operating the machine.

NOTE

Reminder on suitable actions to perform in particular situations to ensure the correct functioning of the machine.
Read carefully before operating the machine.

Intended Use

The Artis® Dialysis System is intended for use as a single patient machine to perform High and Low Flux Hemodialysis (HD) and Hemodiafiltration (HDF) therapies.
The Artis Dialysis System is intended to be used in Double Needle and Single Needle mode. The Single Needle mode is supported for HD therapies and can be performed with one pump in case of emergency or with two pumps in standard mode.
The Artis Dialysis System is intended to be used with high and low permeability dialyzers.

The Artis Dialysis System is intended to be used by trained operators under a prescription from a physician, in a chronic dialysis facility and at Limited Care Centers.

The Artis Dialysis System is also intended for on-line preparation of substitution fluid to be used in HDF treatments. The system produces dialysis and substitution fluids at a desired temperature, conductivity and pressure within given specifications, and supervises the delivery of fluids.

Moreover, the Artis Dialysis System, if properly configured, can deliver Acetate-Free Biofiltration with controlled delivery of potassium (AFB K) therapy, characterized by a buffer-free dialysis fluid, a highly biocompatible hemodialyzer, a post-dialyzer infusion of a sodium bicarbonate substitution fluid from bags, and a variable concentration of potassium in the dialysis fluid.

Configuration of the machine for delivering AFB K therapy is restricted to the countries where mandatory regulatory activities have been completed.

The AFB K therapy is not approved for use in Canada.

⚠WARNING

Patient counselling and teaching of treatment techniques are directly under the supervision and discretion of the physician.

The Artis Dialysis System is designed to control and supervise the extracorporeal circuit. To prevent blood coagulation, heparin may be delivered through a Heparin delivery system.

The Artis Dialysis System is designed and validated to support the Gambro BiCart® Cartridge and the Gambro BiCartSelect® system (i.e. the SelectCart® cartridge and SelectBagOne® or SelectBag® Citrate container concentrate).

Configuration of the machine for preparation of dialysis fluid using the BiCartSelect® system is restricted to the countries where mandatory regulatory activities have been completed.

The BiCartSelect® system is not approved for use in Canada.

⚠WARNING

Gambro does not accept responsibility for use of other non-liquid concentrate containers.

⚠WARNING

The appropriate Dialyzer and Blood Tubing System must be selected according to the patient's size and weight and to the treatment type.
The decision must be taken by a physician.

⚠WARNING

Fluid balance deviations can exceed a level that can be tolerated by low-weight patients, even if deviations are within the specified Artis Dialysis System accuracy value, and in particular for patients whose weight is equal or lower than 25 kg.
The treatment of these patients shall be performed under the full supervision of the physician.
In these cases, the use of an additional device to measure the weight loss is recommended.

⚠WARNING

The use of procedures or accessory devices not recommended by the manufacturer may result in patient injury or death.
The manufacturer will not be responsible for patient safety if the procedures described in this Operator's Manual are not carefully followed and if procedures are performed by not trained and qualified personnel.
Depending on the circumstances, the use of accessories or disposables other than those specified in this manual may reduce the manufacturer warranties for the Artis Dialysis System.

Spare Parts

The Manufacturer will maintain spare parts availability for ten years after the end of production of the Artis Dialysis System. At the end of that time the involved product is considered obsolete and therefore it must be disposed of according to local applicable regulations. The final user will be informed about spare parts that are no longer available through the tecnical service or the commercial representative.

For questions, ask for information from the Local Representative.

Dialysis and Substitution Fluids

The Artis Dialysis System allows the use of two or three ultrafilters, according to its configuration.

The Artis Dialysis System performs the dialysis fluid preparation in two ultrafilters steps:

1. Filtration of inlet water which prevents bacterial contamination of the interior of the machine.
2. Filtration of the dialysis fluid through the dialysis fluid filter which removes possible bacteria and endotoxins originating from the concentrates.

For on-line preparation of the substitution fluid (for HDF Post Treatment) of the Artis Dialysis System a third step is added:

3. Filtration of filtered dialysis fluid in a single-use filter which result in non-pyrogenic substitution fluid.

Inlet Water requirements

The chemical and macrobiological properties of the water can contribute to achieve and maintain the proper quality of dialysis fluid.

The water quality depends on the technical water supply system. It is very important to properly maintain the water supply system and the water distribution loop.

The inlet water must comply with valid quality standards for water for dialysis (refer to the "Chapter 17: Specifications" of this Operator's Manual).

To improve the macrobiologic water quality, a water ultrafilter designed for this purpose performs ultrafiltration of the inlet water before it is used to prepare dialysis fluid. The water ultrafilter, if provided, is placed on the back of the Artis Dialysis System.

Dialysis Fluid for HD Treatments

Artis Dialysis System prepares dialysis fluid from treated water and concentrates.

The dialysis fluid can be made using:

- dry concentrates (such as the BiCartSelect system products);
- a liquid A-concentrate and a dry bicarbonate concentrate (such as the BiCart Cartridge).

For further details refer to the "Concentrates, accessories and disposables" section below.

On-line dialysis and substitution fluid for HDF Post Treatment

For HDF Post Treatment, the Artis Dialysis System prepares substitution fluid on-line from ultrafiltered dialysis fluid, which in turn is made of ultrafiltered water and concentrates.

The dialysis fluid should be made from dry concentrates (such as the BiCart Select® products) or from an A-concentrate and a dry bicarbonate concentrate (such as the BiCart cartridge). Refer to the "Concentrates, accessories and disposables" section below.

The Artis Dialysis System's on-line preparation of substitution fluid is based on the following:

1. Ultrafiltration of the dialysis fluid ensuring a bacterial count <0.1 CFU/ml and endotoxin level <0.03 EU/ml.
2. Final sterile filtration of the dialysis fluid with a single-use filter integrated in the Ultra Cassette.

On-line preparation of substitution fluid requires a certain disinfection routine of the machine. For further details refer to "Chapter 13: Disinfection/Rinse" of this Operator's Manual.

The ultrafilters must be disinfected, changed and otherwise handled in a correct way to ensure required efficiency. (Refer to the "Chapter 8: Special Procedures" of this Operator's Manual and the package insert of the ultrafilters).

Infusion flow and potassium delivery for AFB K Treatment

AFB and AFB K Treatments, due to the absence of acetate, the use of the bioactive membrane (Evodial) and the Potassium profiling, can limit the onset of cardiovascular risk factors as electrolyte disorders - acid-base imbalance, inflammatory processes including oxidative stress, dyslipidaemia, hyperhomocysteinaemia, left ventricular hypertrophy (LVH) and cardiac arrhythmias.

The Acetate-Free Biofiltration (AFB) is a low-volume Hemodiafiltration Treatment, characterised by the total absence of any buffer in the dialysis fluid (Safebag KV concentrate solution, no acetate) and by the continuous infusion of a sterile solution of sodium bicarbonate (Hospasol infusion bag) in post-dilution mode.

The AFB K Treatment is an AFB therapy which allows the controlled delivery of potassium ion concentration in the dialysis fluid. Two modes of treatment are allowed:

- K Constant mode
- K Profile mode

K Constant Mode

AFB K Treatment in K Constant mode allows to set a constant value of potassium (K+) concentration in the dialysis fluid. The large range of settable values and the possibility of changing from one to another profile during the treatment, shall become the new gold standard of safety and personalization avoiding the use of K+ concetrate solution.

K Profile Mode

AFB K Treatment in K Profile mode allows to automatically deliver the K+ concentration, according to a potassium profile exponential shape curve, aiding a gradual removal of potassium in hypercaliemic patients, often subject to the so-called electric imbalance syndrome.

NOTE

Refer to the Artis AFB K Treatment Operator's Manual for details on the AFB K machine configuration and on the AFB K Treatment procedures.
Alarms related to the AFB K Treatment are described both in this Operator's Manual and in the Artis AFB K Treatment Operator's Manual.

NOTE

In order to perform the AFB K Treatment, the Artis Dialysis System must have the proper hardware and software machine configuration.
Call for service technician if it is necessary to update the machine with the dedicated hardware and software configuration.

Ultrafilters, frequency of change

It is recommended to replace the U9000 ultrafilters following the instructions provided in the U9000 Ultrafilter Instruction for use.

U9000 Ultrafilters can not tolerate more than twelve Chemical Disinfection programs with Hypochlorite.

U9000 Ultrafilters must be changed when the maximum allowed number of chemical disinfection programs with hypochlorite have been performed.

For instructions on how to change the ultrafilters, refer to the "Chapter 8: Special Procedures" of this Operator's Manual.

Warnings

Introduction

1. Patient counselling and teaching of treatment techniques are directly under the supervision and discretion of the physician.

2. Gambro does not accept responsibility for use of other non-liquid concentrate containers.

3. The appropriate Dialyzer and Blood Tubing System must be selected according to the patient's size and weight and to the treatment type.
The decision must be taken by a physician.

4. Fluid balance deviations can exceed a level that can be tolerated by low-weight patients, even if deviations are within the specified Artis Dialysis System accuracy value, and in particular for patients whose weight is equal or lower than 25 kg.
The treatment of these patients shall be performed under the full supervision of the physician.
In these cases, the use of an additional device to measure the weight loss is recommended.

5. The use of procedures or accessory devices not recommended by the manufacturer may result in patient injury or death.
The manufacturer will not be responsible for patient safety if the procedures described in this Operator's Manual are not carefully followed and if procedures are performed by not trained and qualified personnel.
Depending on the circumstances, the use of accessories or disposables other than those specified in this manual may reduce the manufacturer warranties for the Artis Dialysis System.

6. Incorrect choice of dialysis fluid concentrate may cause incorrect composition of the dialysis fluid.

7. The Artis Dialysis System has been tested and validated for use with the concentrates, accessories and disposable listed above.
Gambro does not accept any responsibility or liability for use of concentrates, accessories and disposables other than those specified above.
The use of different kinds of concentrates, accessories and disposables may reduce Gambro's warranties for the Artis Dialysis System.

8. The Artis Dialysis System will perform as designed only if it is used and maintained in accordance with Gambro's instructions. Any warranties made by Gambro are void if the equipment is not used in accordance with the instruction provided.
Gambro will not accept responsibility for any damage or injury resulting from improper use or maintenance or unauthorized repair.
Gambro does not recognise the owner of a product as an authorised service representative.
If repairs of the machine have been attempted by anyone other than qualified personnel belonging to the service representative in your country, under no circumstances will the manufacturer be liable for indirect or consequential damages of any kind, its liability hereby being limited solely to repair or replacement.

This warranty is in lieu of any other expressed or implied warranties, including any implied warranty saleability or suitability of use and of any other obbligation on the part of the manufacturer.

9. This Operator's Manual contains a number of references to concentrates, disposables, accessories and spare parts for use with Artis Dialysis System.
The Artis Dialysis System has been tested and validated for use with concentrates, disposables, accessories and spare parts listed in this manual.
The Manufacturer does not accept responsibility or liability for use of concentrates, disposables or accessories other than those specified in this manual, for use of not genuine spare parts and for use/mounting of those components not in accordance with the official Gambro Instruction for Use accompanying those components.
Depending on the circumstances, use of concentrates, disposables or accessories other than those specified in this Operator's Manual, use of not genuine spare parts and use/mounting of those components not in accordance with the above mentioned Instruction for Use may reduce the Manufacturer's warranties for the Artis Dialysis System.

Chapter 1: General Description

1. To correctly operate the machine, pay careful attention to the messages displayed in the Message Area of the Touch Screen.

2. If both the Acustical Buzzer T1 Test and the Acustical Speaker T1 Test fail (both the auditory signal sources are malfunctioning), a malfunction occurs so that it is not possible to use the Artis Dialysis System. In this case, call for Service Technician.
If only one of the T1 Tests fails (only one of the auditory signal source is malfunctioning), it is the operator's responsibility to decide whether to proceed with the current treatment after having checked that the machine is able to sound properly. Also in this case, call for Service Technician to troubleshoot the problem as soon as possible.

3. During the Visible T1 Test, check that brief visual signal is triggered by the machine (Status Lights at the top of the machine lighten with red and yellow lights).
If the visual signal is not triggered, the signalling device (Status Lights) is malfunctioning. In this case, call for Service Technician.
DO NOT use the Artis Dialysis System in the absence of the visual alarm signal.

4. Setting the Upper Intervals of A/V alarm limits to their extreme values might render the Alarm Management System useless.
An improper setting of these intervals may prevent the Alarm Management System to detect possible alarm conditions related to air embolism in case of catheter or to blood loss.

5. Setting the Lower Intervals of A/V alarm limits to their extreme values might render the Alarm Management System useless.
An improper setting of these intervals may prevent the Alarm Management System to detect possible alarm conditions related to mechanical damage of vascular access or to blood loss.

6. Setting the Ven Treatment Max Limit to its extreme values might render the Alarm Management System useless.

An improper setting of this limit may prevent the Alarm Management System to detect possible alarm conditions related to blood loss.

7. Setting the Ven Treatment Min Limit to its extreme values might render the Alarm Management System useless.
An improper setting of this limit may prevent the Alarm Management System to detect possible alarm conditions related to blood loss.

8. Setting the Art Treatment Max Limit to its extreme values might render the Alarm Management System useless.
An improper setting of this limit may prevent the Alarm Management System to detect possible alarm conditions related to air embolism in case of catheter or to blood loss.

9. Setting the Art Treatment Min Limit to its extreme values might render the Alarm Management System useless.
An improper setting of this limit may prevent the Alarm Management System to detect possible alarm conditions related to mechanical damage of vascular access.

10. A dedicated alarm (Low blood pump speed *#204*) exists in order to avoid blood loss due to coagulation resulting from interruption of blood flow.

11. Monitoring of the Venous Pressure could not always detect the disconnection of a venous needle from its access site, which may result in extracorporeal blood loss to the environment. When a venous needle disconnects from its access, pressure at the venous monitoring side may only decrease by the pressure maintained within the patient's access site. This pressure drop may be less than the width of the machine's venous pressure alarm window: in this particular case the disconnection of a venous needle from its access site is not detectable by the machine, even if pressure alarms and alarm windows are properly set.
To reduce the risk of needles disconnection:

- ensure that venous needle and line are firmly secured to the access site area according to your clinic's protocol;
- ensure that the patient's access is visible at all times during the dialysis treatment;
- inspect frequently the patient's access;
- adjust properly the venous pressure alarm window: the venous pressure alarm lower limit should be set as closely as practical to the actual patient’s venous pressure value without generating excessive nuisance alarms.

Chapter 2: Installation

1. Check the continuity and the reliability of the ground connection.

2. Verify the quality of the protective earth ground at the time of installation.

3. Pay attention to connect correctly the batteries. An incorrect connection to the proper battery pin causes an irremediable damage to the power supply also if the machine is not connected to the main line.

4. This operation must be performed by authorized personnel. If Service is performed by unauthorized personnel, the manufacturer cannot accept any responsibility for any damage which may occur, and such damage is not covered by the warranty.

5. ***DO NOT*** use this machine near flammable gas or flammable anaesthetic mixtures with air, with oxygen or with nitrous oxide.

Chapter 3: Machine Dressing and Priming

1. Never insert fingers in the Arterial and Venous line clamps.
Keep the Arterial and Venous pump covers closed during the function check process since the pumps will be tested during this phase.

2. If an alarm is triggered during the loading phase, ***DO NOT*** use the Artis Dialysis System. Call for service technician.

3. Incorrect choice of dialysis fluid concentrates may cause incorrect composition of the dialysis fluid.
Check that the prescribed concentrates for the specific treatment are used.

4. If a "BiCart Select " or "BiCart Citrate" concentrate combination has been set, ensure that the correct concentrate disposables, BiCart Cartridge, SelectCart Cartridge and SelectBag container, have been set.
In particular, ensure that the SelectBag prescribed for the treatment corresponds to the SelectBag container that has been installed on the machine and to the SelectBag type that has been set.

5. Setting the "TMP Upper Limit", "TMP Upper Limit (Volume Control)" or the "TMP Upper Limit (Pressure Control)" to their extreme values might render the Alarm Management System useless.
An improper setting of these limits may prevent the Alarm Management System to detect possible alarm conditions related to blood loss or to blood clotting.

6. It is the operator's responsibility to check the compliance of the Central Concentrate Delivery system with IEC 601.1.1 standard.

7. It is the operator's responsibility to properly connect the Artis Dialysis System to a Central Concentrate Delivery system and to check that the connection works properly.

8. When installing the acid container, be careful to avoid that the concentrate splashes into your eyes.
Acid concentrate may cause chemical injury if comes in contact with eyes.

9. Before installing and using a BiCart Cartridge:

- Follow the Instructions for Use
- Check that the cartridge is undamaged
- Check for the expiration date on the BiCart Cartridge label

For the storage temperature refer to the Instructions for Use of BiCart Cartridge.

10. Use ***ONLY*** BiCart Cartridges new or that have not been drained.

11. Use ***ONLY*** SelectCart Cartridges new.

12. When installing the SelectBag container, avoid touching the plastic spike of the machine.

13. When installing the SelectBag container, be careful to avoid fluid from the SelectBag product splashing into your eyes.
Acid concentrate may cause chemical injury if comes in contact with eyes.

14. To avoid hazardous side effects during the treatment, parameters set must be suitable for the patient's needs and tolerance.
It is the operator's responsibility to check that the prescription parameters are suitable for the treated patient.

15. Setting the "Pre-Dialyzer Limit", the "Online Substitution Rate" or the "TMP Set" to their extreme values might render the Alarm Management System useless.
An improper setting of these limits may prevent the Alarm Management System to detect possible alarm conditions related to blood loss or to blood clotting.

16. The use of the Gambro/Hospal Blood Tubing Systems designed for the Artis Dialysis System has been tested and validated to provide safe and proper functioning of the system.
The Manufacturer has not validated the use of Blood Tubing Systems other than those specified in this manual.
The Manufacturer does not assume responsibility or liability for use of Blood Tubing Systems other than the Gambro/Hospal Blood Tubing Systems. It is the responsibility of the user to validate that other blood lines provide safe and effective performance.

17. The appropriate Dialyzer and Blood Tubing System must be selected according to the patient's size and weight and to the treatment type.
The decision must be taken by a physician.
Before installing Gambro/Hospal Dialyzers and Blood Tubing System carefully read the related Instructions for Use.

18. After a Heat or a Heat Disinfection with CleanCart Cartridge program, hot water can remain inside the Dialysis Fluid Tubes.
Pay attention when disconnecting the Dialysis Fluid Tubes from the machine since hot water could drip from the Dialysis Fluid Tube Connectors.

19. A damaged pump rotor will not work properly. This could result in patient serious injury.
Visually inspect the pump rotor each time you load any of Infusion, Ultra, SNDP or Blood Cassettes.
If the pump rotor is damaged, ***DO NOT*** use the machine for treatment, ***DO NOT*** repair and call for service.

20. Improper connections of the extracorporeal circuit may cause potential safety hazards, that might not be detected by the machine: for instance, hemolysis caused by kinks, clamps or other restrictions on the lines, blood loss to the environment/air into the blood circuit due to a leakage in the extracorporeal circuit.

21. The operator must take proper precaution in order to prevent coagulation in the extracorporeal circuit due to an improper connection of the circuit.
Coagulation may lead to:

- inadequate delivery of dialysis;
- risk associated with propagation of blood clots to the patient;
- disabling of the air detector function if blood clots aggregate in the chambers.

22. Leakages of the dialysis fluid circuit (Dialysate connectors and Ultra port) may cause safety hazards that might not be detected by the machine, for instance hypovolemia due to improper fluid balance.

23. In case of hardware malfunction or if the loading procedure is not completed within 2 minutes, the Cassette Holder will automatically retract.
DO NOT insert fingers behind the cassette to avoid injury to your fingers.

24. Before inserting the Venous Patient line in the Air Detector clean and dry it. Fluid and gel substances applied on the Air Detector may reduced the Air Detector sensitivity causing patient injury or death.
Refer to the "13.10 External Cleaning" paragraph, in the "Chapter 13: Disinfection/ Rinse" of this Operator's Manual, for the description of how to clean the Air Detector.

25. Use an aseptic technique when connecting/disconnecting the priming connectors of the Arterial and Venous Patient lines to/from the EvaClean ports in order to avoid any potential contamination of the lines.

26. Verify that fluid is not present in the EvaClean ports by visual inspection before inserting the priming connectors.
If fluid is present in the ports for more than six seconds after opening the doors, ***DO NOT USE*** the EvaClean.

27. The EvaClean option must be cleaned each time the patient connection procedure is performed keeping the Venous Patient line into the EvaClean Blue port until the machine detects blood.
In this case, manually clean the EvaClean option before performing another patient treatment.
(Refer to the "Chapter 8: Special Procedures" of this Operator's Manual).

28. In case of hardware malfunction or if the loading procedure is not completed within 2 minutes, the Blood and Ultra cassette holders will automatically retract.
DO NOT insert fingers behind the cassette to avoid injury to your fingers.

29. ***DO NOT*** connect the Ultra Inlet line to the Ultra port by rotating the Ultra Inlet line.
If rotating the Ultra Inlet line to connect it to the Ultra port, the green Ultra Inlet line connector will not be properly secured to the Ultra port. This may result in the Ultra Inlet line partial/complete disconnection from the Ultra port during the dialysis treatment.
Leakages from the Ultra port may cause safety hazards that might not be detected by the machine, for instance hypovolemia due to improper fluid balance during treatment.

30. In case of hardware malfunction or if the loading procedure is not completed within 2 minutes, the Cassette holders will automatically retract.
DO NOT insert fingers behind the cassette to avoid injury to your fingers.

31. Ensure that the Heparin line is securely connected to the heparin syringe and that the syringe is correctly installed on its holder.
Incorrect installation of the heparin syringe may cause an incorrect delivery of the heparin during treatment.

32. Reverse Ultrafiltration of fluid from the dialysis fluid compartment into the blood compartment of the dialyzer may occur when High Flux dialyzers are used. Because of their high ultrafiltration coefficients, high flux dialyzers will quickly transfer fluid across the membrane in response to pressure differences between the dialysis fluid compartment and the blood compartment.

33. If using an Evodial dialyzer, do not perform the “Priming Booking” procedure. Wait for the end of dialysis fluid preparation:

• To open the clamps on the Venous Infusion line and on the Prime line;

• To press the “Auto-Prime” button.

The choice of the “Priming Booking” procedure with the Evodial dialyzer might cause an incorrect priming of the dialyzer that could lead to:

• Air in the dialyzer;

• An incorrect level of fluid in the Arterial and Venous chambers at the end of the priming procedure;

• More possibilities that an “Air in Venous Line (#4)” alarm occurs during the treatment.

34. Choosing a Type of Priming and a Priming Volume not proper for the type of dialyzer used might cause an incorrect priming of the dialyzer that could lead to:

• Air in the dialyzer;

• An incorrect level of fluid in the Arterial and Venous chambers at the end of the priming procedure;

• More possibilities that an “Air in Venous Line (#4)” alarm occurs during the treatment.

35. Before patient connection, verify that no air is present in the Venous Patient line. If air is present perform an Extra Prime or a Reset Prime procedure.
Air remained in the Venous Patient line has to be removed before connecting the patient to avoid risk of air embolism.

36. If during the Isolated UF process the "Heparin" action button is activated/ reactivated, its action indicator becomes green, but the heparin delivery program does not start/restart until the end of the Isolated UF process.
If during the Isolated UF process the heparin settings are changed, these settings are not implemented until the end of the Isolated UF process.
To activate the heparin delivery program and/or change its settings, press the "Heparin" action button and/or change the heparin program settings before pressing the "Start Treatment" button.

37. If the dialysis fluid flow is deactivated and the "Heparin" action button is activated/reactivated in this phase, its action indicator becomes green, but the heparin delivery program does not start/restart until the dialysis fluid flow is activated.
If the dialysis fluid flow is deactivated and the heparin settings are changed in this

phase, these settings are not implemented until the dialysis fluid flow is activated.
To activate the heparin delivery program and/or change its settings, proceed as follows:

- Press the "Dialysis Fluid" action button to activate the dialysis fluid flow;
- Change the heparin delivery program settings and/or press the "Heparin" action button to activate the heparin delivery program;
- Press the "Dialysis Fluid" action button to deactivate again the dialysis fluid flow.

Chapter 4: HD-DN Treatment

1. After a Chemical Disinfection program, a test for residuals of disinfectant must be performed before the following patient connection to avoid the risk of blood hemolysis due to the exposure of the patient to the chemical residues.

2. The Patient Connection and Rinseback modes require additional attention: to facilitate their execution, some safety checkings are temporary deactivated and left to the responsibility of the operator (e.g., the extracorporeal A/V pressure limits are expanded to the maximum).

3. During patient connection/disconnection, follow your facility's policies and procedures for managing patient's vascular access and Venous and Arterial Patient lines used for hemodialysis.
The use of central venous catheters with atrial location leads to additional hazardous situations with respect to the other types of vascular access, due to their proximity to the heart.
In particular, if the patient's catheter disconnects from the patient lines or the integrity of the catheter is compromised in any other way, follow your facility's policy for preventing air embolism and infection, including clamping the patient's lines immediately.

4. Eventual electrical current leakages from the dialysis machine or from other electrical equipments are associated to an increased risk of patient electric shock in case central venous catheters with atrial location are used.
To avoid this risk, ensure that the potential equalization conductor is connected to the proper means on the Artis Dialysis System rear panel.

5. Before patient connection, verify that no air is present in the Venous Patient line. If air is present perform an Extra Prime or a Reset Prime procedure.
Air remained in the Venous Patient line has to be removed before connecting the patient to avoid risk of air embolism.

6. The EvaClean option must be cleaned each time the patient connection procedure is performed keeping the Venous Patient line into the EvaClean Blue port until the machine detects blood.
In this case, manually clean the EvaClean option before performing another patient treatment.
(Refer to the "Chapter 8: Special Procedures" of this Operator's Manual).

7. An incorrect pump segment unloading procedure could damage the pump rotor.
A damaged pump rotor will not work properly. This could result in patient serious injury.

8. In case of hardware malfunction or if the unloading procedure is not completed within 2 minutes, the Cassette Holder will automatically retract.
DO NOT insert fingers behind the cassette to avoid injury to your fingers.

Chapter 5: Hemodiafiltration On-line

1. After a Chemical Disinfection program, a test for residuals of disinfectant must be performed before the following patient connection to avoid the risk of blood hemolysis due to the exposure of the patient to the chemical residues.

2. The Patient Connection and Rinseback modes require additional attention: to facilitate their execution, some safety checkings are temporary deactivated and left to the responsibility of the operator (e.g., the extracorporeal A/V pressure limits are expanded to the maximum).

3. During patient connection/disconnection, follow your facility's policies and procedures for managing patient's vascular access and Venous and Arterial Patient lines used for hemodialysis.
The use of central venous catheters with atrial location leads to additional hazardous situations with respect to the other types of vascular access, due to their proximity to the heart.
In particular, if the patient's catheter disconnects from the patient lines or the integrity of the catheter is compromised in any other way, follow your facility's policy for preventing air embolism and infection, including clamping the patient's lines immediately.

4. Eventual electrical current leakages from the dialysis machine or from other electrical equipments are associated to an increased risk of patient electric shock in case central venous catheters with atrial location are used.
To avoid this risk, ensure that the potential equalization conductor is connected to the proper means on the Artis Dialysis System rear panel.

5. Before patient connection, verify that no air is present in the Venous Patient line. If air is present perform an Extra Prime or a Reset Prime procedure.
Air remained in the Venous Patient line has to be removed before connecting the patient to avoid risk of air embolism.

6. The EvaClean option must be cleaned each time the patient connection procedure is performed keeping the Venous Patient line into the EvaClean Blue port until the machine detects blood.
In this case, manually clean the EvaClean option before performing another patient treatment.
(Refer to the "Chapter 8: Special Procedures" of this Operator's Manual).

7. An incorrect pump segment unloading procedure could damage the pump rotor.
A damaged pump rotor will not work properly. This could result in patient serious injury.

8. In case of hardware malfunction or if the unloading procedure is not completed within 2 minutes, the Blood and Ultra cassette holders will automatically retract.
DO NOT insert fingers behind the cassette to avoid injury to your fingers.

Chapter 6: HD-SN Treatment

1. After a Chemical Disinfection program, a test for residuals of disinfectant must be performed before the following patient connection to avoid the risk of blood hemolysis due to the exposure of the patient to the chemical residues.

2. The Patient Connection and Rinseback modes require additional attention: to facilitate their execution, some safety checkings are temporary deactivated and left to the responsibility of the operator (e.g., the extracorporeal A/V pressure limits are expanded to the maximum).

3. During patient connection/disconnection, follow your facility's policies and procedures for managing patient's vascular access and Venous and Arterial Patient lines used for hemodialysis.
The use of central venous catheters with atrial location leads to additional hazardous situations with respect to the other types of vascular access, due to their proximity to the heart.
In particular, if the patient's catheter disconnects from the patient lines or the integrity of the catheter is compromised in any other way, follow your facility's policy for preventing air embolism and infection, including clamping the patient's lines immediately.

4. Eventual electrical current leakages from the dialysis machine or from other electrical equipments are associated to an increased risk of patient electric shock in case central venous catheters with atrial location are used.
To avoid this risk, ensure that the potential equalization conductor is connected to the proper means on the Artis Dialysis System rear panel.

5. Before patient connection, verify that no air is present in the Venous Patient line. If air is present perform an Extra Prime or a Reset Prime procedure.
Air remained in the Venous Patient line has to be removed before connecting the patient to avoid risk of air embolism.

6. The EvaClean option must be cleaned each time the patient connection procedure is performed keeping the Venous Patient line into the EvaClean Blue port until the machine detects blood.
In this case, manually clean the EvaClean option before performing another patient treatment.
(Refer to the "Chapter 8: Special Procedures" of this Operator's Manual).

7. An incorrect pump segment unloading procedure could damage the pump rotor.
A damaged pump rotor will not work properly. This could result in patient serious injury.

8. In case of hardware malfunction or if the unloading procedure is not completed within 2 minutes, the holders will automatically retract.
DO NOT insert fingers behind the cassette to avoid injury to your fingers.

Chapter 8: Special Procedures

1. Failure to remove the Arterial and Venous Patient lines from the Arterial and Venous Line Clamps or failure to unclamp the Arterial and Venous Patient lines can result in rupture of blood lines or dialyzer when hand cranking the Arterial Pump.

2. While manually returning blood, watch the Venous Patient line for air.
Do not perform air restitution.

3. It is the operator's responsibility to decide for how long a period the blood can be recirculated into the circuit.

4. During patient connection/disconnection, follow your facility's policies and procedures for managing patient's catheter and Venous and Arterial Patient lines used for hemodialysis.
In particular, if the patient's catheter disconnects from the patient lines or the integrity of the catheter is compromised in any other way, follow your facility's policy for preventing air embolism and infection, including clamping the patient's lines immediately.

5. Wait at least 5 seconds after switching OFF the machine before turning it ON again.

6. The use of a Fast Recovery procedure must be limited to exceptional cases where the normal recovery procedure can not be performed in accordance with the standard use of the machine, but where the current dialysis treatment must be continued.

7. The Fast Recovery procedure can only be performed if the dialysis treatment has already started, after the confirmation of the Patient Connection, and has been interrupted before the emptying procedure.

8. If after a Fast Recovery procedure, the same problem reoccurs during the restarted dialysis treatment, the cause is not a temporary malfunction. In this case, the Artis Dialysis System must be turned OFF and the patient manually disconnected.
Call for a service technician.

9. Before installing and using a BiCart Cartridge:

- Follow the Instructions for Use
- Check that the cartridge is undamaged
- Check for the expiration date on the BiCart Cartridge label

For the storage temperature refer to the Instructions for Use of BiCart Cartridge.

10. ***Use ONLY*** BiCart Cartridges new or that have not been drained.

11. When installing the acid container, be careful to avoid that the concentrate splashes into your eyes.
Acid concentrate may cause chemical injury if comes in contact with eyes.

12. If pH supervision is not available on your machine the presence of hypochlorite in the hydraulic circuit can not be detected by the Artis Dialysis System. Ensure that the correct Acid concentrate has been connected to the machine. Using improper fluid in the dialysis fluid circuit may lead to improper dialysis fluid to be delivered to the patient, thus resulting in patient injury or death.

13. Use ***ONLY*** SelectBag new.

14. When installing the SelectBag container, avoid touching the plastic spike of the machine.

15. When installing the SelectBag container, be careful to avoid fluid from the SelectBag product splashing into your eyes.
Acid concentrate may cause chemical injury if comes in contact with eyes.

16. ***Use ONLY*** SelectCart Cartridges new.

17. Before performing the Cassette Repositioning procedure, ensure that the arterial and venous chambers are no more than half full of fluid in order to avoid possible patient blood loss.

18. Before performing the Ultra Cassette Repositioning procedure, ensure that the chamber is no more than half full of fluid in order to avoid possible patient blood loss.

19. If the SN Cassette Repositioning procedure is performed during patient connection and before blood is detected by the machine, the Arterial and Venous line clamps are not automatically closed.
In this case, proceed as follows:

- Manually clamp the Arterial and Venous lines;
- Perform the SN Cassette Repositioning procedure;
- After the procedure has been successfully completed, unclamp the Arterial and Venous lines.

20. Before performing the SN Cassette Repositioning procedure, ensure that the chamber is no more than half full of fluid in order to avoid possible patient blood loss.

21. The Patient Connection and Rinseback modes require additional attention: to facilitate their execution, some safety checkings are temporary deactivated and left to the responsibility of the operator (e.g., the extracorporeal A/V pressure limits are expanded to the maximum).

22. In case of hardware malfunction or if the unloading procedure is not completed within 2 minutes, the Cassette Holder will automatically retract.
DO NOT insert fingers behind the cassette to avoid injury to your fingers.

23. In case of hardware malfunction or if the loading procedure is not completed within 2 minutes, the Cassette Holder will automatically retract.
DO NOT insert fingers behind the cassette to avoid injury to your fingers.

24. In case of hardware malfunction or if the unloading procedure is not completed within 2 minutes, the Blood and Ultra cassette holders will automatically retract.
DO NOT insert fingers behind the cassette to avoid injury to your fingers.

25. In case of hardware malfunction or if the loading procedure is not completed within 2 minutes, the Blood and Ultra cassette holders will automatically retract.
DO NOT insert fingers behind the cassette to avoid injury to your fingers.

26. Setting the "Pre-Dialyzer Limit" and the "TMP Set" to their extreme values might render the Alarm Management System useless.
An improper setting of these limits may prevent the Alarm Management System to detect possible alarm conditions related to blood loss or to blood clotting.

27. In case of hardware malfunction or if the loading procedure is not completed within 2 minutes, the Ultra Cassette holder will automatically retract.
DO NOT insert fingers behind the SNSP Conversion kit to avoid injury to your fingers.

28. Improper connections of the extracorporeal circuit may cause potential safety hazards, that might not be detected by the machine: for instance, hemolysis caused by kinks, clamps or other restrictions on the lines, blood loss to the environment/air into the blood circuit due to a leakage in the extracorporeal circuit.

29. The patient must not be connected to the machine during the “Manual cleaning procedure for the EvaClean option”.

30. ***DO NOT USE*** the priming connector or the syringe used for the “Manual cleaning procedure for the EvaClean option” for patient related uses or any sterile connections.

31. ***DO NOT LEAVE*** undiluted bleach in the flow circuit of the machine.

32. Following the EvaClean bleach procedure, before performing a Chemical Disinfection using a chemical other than Bleach, perform either a Rinse or a Heat disinfection or a Heat with CleanCart-C disinfection program.

33. After a Chemical Disinfection program, a test for residuals of disinfectant must be performed before the following patient connection to avoid the risk of blood hemolysis due to the exposure of the patient to the chemical residues.

34. When performing the “Adjust Chamber Levels” special procedure, always attach a sterile syringe to the access line before unclamping it and pay attention to the blood level in the chambers.
In case of central venous catheter with atrial location, don’t let the Arterial Chamber opened to air as the blood level in the Arterial Chamber may significantly decrease causing air to reach the patient’s vascular access.

35. When performing the “Adjust Expansion Chamber Levels” special procedure, always attach a sterile syringe to the Service Line before unclamping it and pay attention to the blood level in the chambers.

36. An incorrect pump segment unloading procedure could damage the pump rotor. A damaged pump rotor will not work properly. This could result in patient serious injury.

Chapter 9: BPM

1. Carefully follow the instructions for use supplied with the BPM kit to install and use the BPM system.

2. The BPM must be used only with adult patients or with children with a pediatric cuff but not with infant patients (neonatal).

3. Avoid compression or restriction of pressure tubes.

4. Check (e.g. by observing the limb concerned) that the patient’s blood circulation is not affected by the blood pressure measurements.

5. The BPM should be tested and re-calibrated at least every 4000 working hours or at least once a year or any time irregular performance is suspected or observed.

6. The composition of the BPM Cuff (insulating material) protects the BPM “Applied Part” (Type BF) against the effect of a defribillator discharge.

7. In the event of accidental wetting of the cuff or the hydraulic connections, wipe immediately to prevent moisture from entering the machine.

8. In order to be in full conformity with the indications of the European Medical Device Directive 93/42, the manufacturer advises the user that the information originating from the BPM ***CAN NOT*** be used as a unique source of information to induce any therapeutic or pharmacological actions.

9. Setting the Diastolic/Systolic Upper and Lower, Max Heart Rate and Min Heart Rate alarm limits to their extreme values might render the Alarm Management System useless.
An improper setting of these limits may prevent the Alarm Management System to detect possible alarm conditions related to hypertension, hypotension or cardiac arrhythmia.

Chapter 10: Hemoscan™ Monitoring System

1. It is the physician responsibility to verify the alignment of the Hemoscan measurements to local laboratory equipment (percentage Blood Volume change formula may be used). In any case the information originating from Hemoscan system can not be used as unique source of information to induce any therapeutical or pharmacological action (e.g. erythropoietin administration, plasma expanders infusions, etc...).

2. The Hemoscan system can be used only with a specific Blood Tubing System equipped with a Hemoscan cuvette.
Refer to the " Chapter 17: Specifications" of this manual for the list of Blood Tubing Systems equipped with Hemoscan cuvette.
Use of different Blood Tubing Systems can cause alarms or wrong measurements of Hemoscan Monitoring System due to differences in the characteristic of the line (materials, geometry and so on).

3. Setting the Alarm Limit to its extreme values might render the Alarm Management System useless.
An improper setting of this limit may prevent the Alarm Management System to detect possible alarm conditions related to hypovolemia or hypervolemia (patient fluid overload).

Chapter 11: Hemocontrol™ Biofeedback System

1. In case a single bolus of medicines has to be injected through the red injection port on the Arterial Patient Line, the Hemocontrol function must be set in Stand-by mode by pressing the related button before performing the injection.
Indeed medicines injections may result in incorrect sodium concentration and/or ultrafiltration driven by the Hemocontrol function.

Chapter 12: Diascan™ Monitoring System

1. The Ionic Kt/V computation is based on the Distribution volume value. The machine automatically calculates the patient's distribution volume if a value different from "No Entry" has been selected for the Distribution formula parameter in the *Distribution Volume Settings* sub-screen. The Distribution formula and related parameters must be entered and confirmed by the operator. It is the operator's responsibility to assess the clinical validity of these parameters.

2. The physician is responsible for the clinical adequancy of the parameters set for the correct dialysis dose, based upon the Diascan measurements. Do not use the

Diascan System as the only source of clinical information to initiate therapeutic or pharmacologic actions (e.g. change in blood flow rate, dialysis fluid flow rate, dialyzer, treatment time, etc...).

Chapter 13: Disinfection/Rinse

1. Follow the manufacturer's instructions when performing the disinfections and rinse procedures on the Artis Dialysis System.

2. No other maintenance than that mentioned in this chapter will be performed by the operator of the machine. The casing must ***ONLY*** be opened by a fully trained service technician.

3. Before using a disinfectant product, the user must take note of necessary precautions.
The manufacturer's instructions and recommendations must be followed.
Local regulations regarding the use of different chemicals must be followed.

4. To prevent damaging the machine, ***DO NOT LEAVE*** disinfectant solutions in the machine for periods over the following limits:

• 20 min for Sodium Hypochlorite based solutions at Disinfectant strength (Max. 0.2% concentration)

• 20 min for Citric Acid based solutions at Disinfectant strength (Max. 2% concentration)

• 20 min for Sodium Carbonate based solution at Disinfectant strength (Max. 0.5% concentration)

• 72 hours for Peracetic Acid based solutions at Disinfectant strength (Max. 0.10% concentration)

5. After a Chemical Disinfection program, a test for residuals of disinfectant must be performed before the following patient connection to avoid the risk of blood hemolysis due to the exposure of the patient to the chemical residues.

6. Before starting a Heat disinfection, ensure that:
• The EvaClean doors are firmly closed;
• The Ultra Door is firmly closed;
• The BiCart Cartridge, SelectCart Cartridge and SelectBag holder arms are closed.

7. Before performing an Integrated Heat disinfection, ensure that the Water Inlet Tube has been properly replaced, according to the CWP Instructions for Use.
The Water Inlet Tube supplied with the machine is not hot water resistant.

8. The Artis Dialysis System is not able to detect if a Heat Disinfection has been performed using a BiCart Cartridge rather than a CleanCart C Cartridge.
If unintentionally a Heat Disinfection using a BiCart Cartridge has been performed, perform a new Heat Disinfection program using a CleanCart C Cartridge.

9. ***DO NOT*** remove any connector during a Heat disinfection.

10. Before starting a Chemical Disinfection or a Rinse program, ensure that the EvaClean doors are firmly closed.

11. To clean the Touch Screen use ***ONLY*** the following disinfectants:

- Ethanol (60 or 70%).
- Isopropanol (60%).

12. To clean the external surface of the Artis Dialysis System, use only disinfectants/detergents suggested in this Operator's Manual.
Use of other chemicals to clean the Artis Dialysis System might cause ineffective disinfection or damage the plastic parts of the machine.
In particular, avoid chemicals containing benzene, toluene, xylene, acetone or similar solvents. .

13. Any liquid spilt on the machine must immediately be removed to prevent it from seeping into the machine.

14. To prevent cross-contamination problems resulting, for example, from blood leakage from the blood line or from the dialyzer, the components listed above must be cleaned by immersing them into a disinfectant solution or by exposing them to a steam sterilization procedure (121°C for at least 30 minutes).
Careful attention must be paid to dismounting and re-mounting Dialysis Fluid Tube Connectors, Concentrate Connectors and Chemical Connectors in order to avoid damages to those components and leakages from those components.

15. To prevent damage to the components listed above, ***DO NOT*** leave them immersed in the disinfectant solution for a prolonged period; the proper immersion time is related to the disinfectant dilution used.
When the dilution is the same as that used in the machine during disinfection programs, follow the same time limits:

- 4 hours for: Amuchina™, Instrunet HD™ and Sodium Hypochlorite at Disinfectant strength (1:25 dilution);
- 24 hours for: Dialox™, Acetoper™, Peresal™, Actril® and Renalin®;
- One week for: Sodium Hypochlorite at Bacteriostatic strength (1:750 dilution).

(For further information refer to the "Chapter 17: Specifications" of Artis Operator's Manual).

16. A damaged pump rotor will not work properly. This could result in patient serious injury.
Visually inspect the pump rotor each time you load any of Infusion, Ultra, SNDP or Blood Cassettes.
If the pump rotor is damaged, ***DO NOT*** use the machine for treatment, ***DO NOT*** repair and call for service.

17. Stagnant water may contaminate the machine. If machine is stored for more than 7 days, the water line should be disinfected and rinsed.

18. After a prolonged period of storage, Service must be called to return the machine to proper working order.
Storage at temperatures below 0 °C is allowed only if the hydraulic circuit has been completely emptied.

19. Never put any solutions inside the BPM cuff. If this occurs, dry the inside of the cuff before usage.

Chapter 14: Communication System

1. The Artis Dialysis System makes available the dialysis related data through connection to various external devices for storage and display. This information cannot be considered as the sole data source to induce any therapeutic or pharmacological action on the patient. It is the responsability of the user to verify any data that would imply taking therapeutic or pharmacological actions.

2. Exalis software allows information to be gathered about individuals and the user must be aware that the use of the information processed or generated by the software is restricted in most countries by legal dispositions such as the Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995.
The user shall therefore take all necessary measures to ensure the confidentiality of the information which is monitored by means of Exalis.

3. When the Exalis system is connected to machines via Ethernet, it is mandatory that Exalis Server PC's and any machine reside on a dedicated subnetwork: the machines and the Exalis servers have to be the ONLY devices present within it.

4. Exalis software must be installed on a dedicated PC. The presence of software tools other than Exalis software might affect the proper working of Exalis software. It is responsibility of the user to verify the proper working of the Exalis software when other software tools, previously or subsequently installed on the same PC, are present.

5. The Exalis software must be used exclusively with the authority of a physician, who is the sole responsible for the use of the information processed by the software.

6. The Artis Dialysis System can be programmed by receiving data through connections to the Exalis system. As soon as the Artis Dialysis System receives data from the network, it checks for its correctness and displays safety relevant parameters on the touch screen. It is responsibility of the user to verify this data before confirming it.

Chapter 15: Report Environment

1. The Artis Dialysis System makes available the dialysis related data through connection to various external devices for storage and display. This information cannot be considered as the sole data source to induce any therapeutic or pharmacological action on the patient. It is the responsibility of the user to verify any data that would imply taking therapeutic or pharmacological actions

Chapter 16: Alarms, Information Signals and Troubleshooting

1. If in your dialysis facility equipments with different alarm systems are installed, pay attention to the potential hazards associated to a not correct evaluation of the alarms generated by the different equipments.

2. During a ***PAUSE*** status, the user is responsible for monitoring the parameters that have been paused.

3. Press the Reset button to clear the alarm only after having removed the causes of the alarm, as described on the message displayed on the Alarm/Information Message Area.

4. The "DIALYSATE PH HIGH (#40)" alarm could be triggered in case a chemical disinfectant has been used instead of Acid concentrate during a dialysis treatment. This may lead to improper dialysis to be delivered to the patient, thus resulting in patient injury or death.

5. After a "BLD Sensitivity Loss (#170)" alarm perform a Chemical Disinfection program before starting a new treatment.

6. The "DIALYSATE PH LOW (#368)" alarm could be triggered in case a chemical disinfectant has been used instead of Acid concentrate during a dialysis treatment. This may lead to improper dialysis to be delivered to the patient, thus resulting in patient injury or death.

7. The "Acid/Safebag AFB Concentrate Error (#369)" alarm could be triggered in case a chemical disinfectant has been used instead of Acid concentrate during a dialysis treatment.
This may lead to improper dialysis to be delivered to the patient, thus resulting in patient injury or death.

8. If both the Acustical Buzzer T1 Test and the Acustical Speaker T1 Test fail (both the auditory signal sources are malfunctioning), a malfunction occurs so that it is not possible to use the Artis Dialysis System. In this case, call for Service Technician.
If only one of the T1 Tests fails (only one of the auditory signal source is malfunctioning), it is the operator's responsibility to decide whether to proceed with the current treatment after having checked that the machine is able to sound properly. Also in this case, call for Service Technician to troubleshoot the problem as soon as possible.

9. The Hemoscan system can be used only with a specific Blood Tubing System equipped with a Hemoscan cuvette.
Refer to the " Chapter 17: Specifications" of this manual for the list of Blood Tubing Systems equipped with Hemoscan cuvette.
Use of different Blood Tubing Systems can cause alarms or wrong measurements of Hemoscan Monitoring System due to differences in the characteristic of the line (materials, geometry and so on).

10. When this alarm is triggered, the Chemical Disinfection process has not been correctly performed because the disinfectant tank is empty.
Repeat the Chemical Disinfection process using a tank containing enough disinfectant solution.

Chapter 17: Specifications

1. The Artis Dialysis System must be used under the supervision of a physician.

2. Do not use the Artis Dialysis System near flammable gas or flammable anesthetic mixtures with air, with oxygen or with nitrous oxide.

3. Possible hazards may arise from equipment (other than the accessories listed below) being connected to the machine, which may cause the permitted leakage current to be exceeded.

4. The Artis Dialysis System should not be used adjacent to or stacked with other equipments.

However, if adjacent or stacked use is necessary, the Artis Dialysis System has to be observed to verify normal operation in the configuration in which it will be used for treatment.

5. Wait at least 5 seconds after switching OFF the machine before turning it ON again.

6. The correct installation of a MEDICAL ELECTRICAL SYSTEM requires that each SYSTEM component be individually connected to the main power.
It is strongly recommended: **NOT TO USE MULTIPLE PORTABLE SOCKET-OUTLETS**.
However, if using multiple portable socket-outlets, they must comply with the IEC 60601-1-1 Standard and must **NOT BE PLACED ON THE FLOOR**.

7. Check that the Artis Dialysis System is properly grounded.
Do not remove the panels. If necessary, ask qualified staff to open panels.
Disconnect the machine from the supply mains before every cleaning, checking or maintenance operation.

8. The Artis Dialysis System is provided with energy cells (batteries). When replacing these components, follow local regulations for proper disposal.

9. Before moving the Artis Dialysis System, check that all the locks are released and remove infusion bags or any other weights or hanging objects from the Infusion Pole, the chemical container shelf or the AFB K Scale and close the AFB K Scale.

10. To avoid jolting, carefully move the Artis Dialysis System by using the handles on the rear panel.
The machine could be damaged if handled in an improper way.

11. If condensation of Artis Dialysis System occurs when moving it between locations with different temperatures and high relative humidity (e.g. outdoor and indoor locations), the inside of the machine shall be allowed to dry before switching it on.

12. During transportation and storage the Artis Dialysis System has to be kept in its original packing.

13. All external equipments connected to the Artis Dialysis System must be compliant with IEC 60950 or IEC 60601 series. Equipment not complying with IEC 60601 shall be kept outside the patient environment, as defined in the standard.
Any person who connects external equipments to signal input, signal output or other connectors has formed a Medical Electrical system and is therefore responsible for the system to comply with the requirements of IEC 60601-1-1. If in doubt, contact qualified technician or your local representative.

14. Do not assemble, install or use the Artis Dialysis System before having carefully read this Operator's Manual.

15. It is recommended to use concentrates which conform to the requirements of the European Pharmacological Standards.
The control of alarm threshold and dialysis fluid conductivity precision is of major medical importance in ensuring a safe dialysis treatment.

16. Attention must be given to the safety hazards related to incorrect choice of dialysis fluid concentrates.

17. When the temperature of the dialysis fluid exceeds the alarm threshold, the auditory and visual alarm signals are triggered.

18. When the dialysis fluid flow exceeds the alarm threshold, the auditory and visual alarm signals are triggered.

19. When the dialysis fluid pressure exceeds the alarm threshold, the auditory and visual alarm signals are triggered.

20. If pH supervision is not available on your machine, possible user error leading to the presence of hypochlorite in the hydraulic circuit can not be detected by the Artis Dialysis System. Using improper fluid in the dialysis fluid circuit may lead to improper dialysis to be delivered to the patient, thus resulting in patient injury or death.
Carefully consider your dialysis facility practises and policies regarding the use of disinfectants to decide about the availability of pH supervision on your Artis Dialysis System.

21. When the pH of the dialysis fluid exceeds the alarm threshold, the auditory and visual alarm signals are triggered. The alarms are not activated in AFB K Treatment.

22. Carefully read the BiCart Cartridge Instructions for Use before using the concentrate disposable.
Refer to this Operator's Manual for the procedures related to the use of the BiCart Cartridge with the Artis Dialysis System.

23. If the difference between the accumulated weight loss rate measured by the Ultrafiltration System and the accumulated weight loss rate measured by the Protective System of the machine is greater than ±80 ml an audible and visual alarm is triggered.
When this alarm is activated the Venous Pump, if running, is stopped and the dialysis fluid goes into bypass.

24. A Safety Test of the Blood Leak Optical Sensor is automatically performed each time the machine enters the Preparation mode.
When the Blood Leak sensor test fails audible and visual alarms are triggered .

25. In the "Isolated UF" process or with the hydraulic circuit in bypass, the Blood Leak Alarm may be delayed, due to operating conditions and dialyzer characteristics.

26. Contact with cleaning and/or disinfection chemicals may pose a risk of burns, skin irritation or other adverse reactions. Always follow the chemical manufacturer's instructions when handling these products or cleaning spills.

27. To prevent damaging the machine, do not leave disinfectant solutions in the machine for periods over the following limits:

• 20 min for Sodium Hypochlorite based solutions at Disinfectant strength (Max. 0.2% concentration)

• 20 min for Citric Acid based solutions at Disinfectant strength (Max. 2% concentration)

• 20 min for Sodium Carbonate based solution at Disinfectant strength (Max. 0.5% concentration)

• 72 hours for Peracetic Acid based solutions at Disinfectant strength (Max. 0.10% concentration).

28. After a Chemical Disinfection program, a test for residuals of disinfectant must be performed before the following patient connection to avoid the risk of blood hemolysis due to the exposure of the patient to the chemical residues.

29. The use of the Blood Cassettes designed for Artis Dialysis System has been tested and validated to provide safe and proper functioning of the system.

30. The appropriate Dialyzer and Blood cassette must be selected according to the patient's size and weight and to the treatment type.
The decision must be taken by a physician.
Before installing Gambro/Hospal Dialyzers and Blood Cassettes carefully read the related Instructions for Use.

31. This Operator's Manual contains a number of references to accessories and disposables for use with Artis Dialysis System. The Artis Dialysis System has been tested and validated for use with accessories and disposables listed in this manual. The manufacturer has not validated the use of accessories or disposables other than those specified in this manual. The Manufacturer does not accept responsibility or liability for use of accessories or disposables other than those specified in this manual. Depending on the circumstances, use of accessories or disposables other than those specified may also reduce the Manufacturer's warranties for the Artis Dialysis System.

32. The Manufacturer recommends the use of a dialyzer with dialysis fluid and blood connections that comply with ISO 8637.

33. When using the Artis Dialysis System, stop the Blood Pumps before touching the Blood Pump Rotors.
Do not touch the blocking system.

34. A dedicated warning (Low Blood Pump Speed #204) exists in order to avoid blood loss due to coagulation resulting from interruption of blood flow.

35. These diameters have been taken from samples from many countries and are correct at the time of printing. However, the manufacturer cannot be held responsible for changes in syringe dimensions that may occur. The user should periodically check the correlation between the stated and the actual diameters.

36. ***DO NOT USE*** syringes without luer lock connection.

37. The syringe infusion pump described above must be used ***ONLY*** for the infusion of heparin.

38. Modification of the Blood Flow Rate causes a fluctuation in the Arterial Pressure and therefore an alarm may be triggered.
To prevent such an effect, following any start/stop of the Arterial pump or change in the Blood Flow Rate the Arterial pressure Alarm Window is automatically set

wider for 30 seconds, in HD-DN and HD-DNDP Treatments, for 120 seconds, in HDF Post Treatments and AFB K treatments or for 60 seconds, in HD-SN Treatments. Its lower value is set to -400 mmHg while the upper value is set to +150 mmHg.

39. Modification of the Blood Flow Rate causes a fluctuation in the Venous Pressure and therefore an alarm may be triggered.
To prevent such an effect, following any start/stop of the Arterial pump or change in the Blood Flow Rate the Venous pressure Alarm Window is automatically set wider for 30 seconds, in HD-DN and HD-DNDP Treatments, for 120 seconds, in HDF Post and AFB K Treatments or for 60 seconds, in HD-SN Treatments. Its lower value is set to -50 mmHg, while the upper limit is set to +450 mmHg.

40. Monitoring of the Venous Pressure could not always detect the disconnection of a venous needle from its access site, which may result in extracorporeal blood loss to the environment. When a venous needle disconnects from its access, pressure at the venous monitoring side may only decrease by the pressure maintained within the patient's vascular access. This pressure drop may be less than the width of the machine's venous pressure alarm window: in this particular case the disconnection of a venous needle from its access site is not detectable by the machine, even if pressure alarms and alarm windows are properly set.
To reduce the risk of needles disconnection:

• ensure that venous needle and line are firmly secured to the access site area according to your clinic's protocol;

• ensure that the patient's access is visible at all times during the dialysis treatment;

• inspect frequently the patient's access;

• adjust properly the venous pressure alarm window: the venous pressure alarm lower limit should be set as closely as practical to the actual patient's venous pressure value without generating excessive nuisance alarms.

41. The user must take precautions against the hazard of cross-contamination between patients by using only extracorporeal circuits that are not damaged.

42. No other maintenance procedures than those mentioned above will be performed by the operator of the machine. The machine panels must ***ONLY*** be opened by a fully trained service technician.

43. Stagnant water may contaminate the machine. If the machine is stored for more than 7 days, the water tube should be disinfected and rinsed before using it for treatment.

44. The manufacturer does not accept any responsibility for damages caused by any operation carried out on the machine by unauthorized staff.

45. Before replacing or checking any component in the Hydraulic Circuit, a Descaling procedure (i.e. a Heat with CleanCart-C disinfection) must be performed.

Concentrates, accessories and disposables

Below is the list of concentrates, accessories and disposables available for Artis Dialysis System:

Concentrates

Liquid Concentrates

2xx series 7xx series 8xx series	Liquid A-concentrate for preparation of bicarbonate dialysis fluid together with BiCart Cartridge or with bicarbonate hemodialysis concentrate D 200 (Sodium Bicarbonate 8,4%).
3xx series	Liquid A- and B- concentrates for preparation of bicarbonate dialysis fluid.
SelectBag One series	Liquid A-concentrate for preparation of bicarbonate dialysis fluid together with SelectCart and BiCart Cartridges.
SelectBag Citrate series	Citric Acid concentrate for preparation of bicarbonate dialysis fluid together with SelectCart and BiCart Cartridges.
Safebag KV: • KV93G • KV95G	Concentrate to be used in AFB K Treatments.

Non-Liquid Concentrates

BiCart Cartridge	Dry bicarbonate concentrate for preparation of bicarbonate dialysis fluid together with proper liquid A-concentrate or SelectCart Cartridge or SelectBags.
SelectCart Cartridge	Dry sodium chloride concentrate for preparation of bicarbonate dialysis fluid together with SelectBags or BiCart Cartridge

⚠WARNING

Incorrect choice of dialysis fluid concentrate may cause incorrect composition of the dialysis fluid.

Solution for infusion

Hospasol Bag: • Hospasol 145 • Hospasol 167	Bag to be used in AFB K Treatments.

ArtiSet Blood Tubing System

Code	Description
113908	ArtiSet HD DN HC (FULL)
113810	ArtiSet HD DN (BASE)
112559	ArtiSet ULTRA HC
114533	ArtiSet HD SN HC
113898	Evoset AFB K Infusion

Gambro Accessories

ArtiSet SNSP Conversion kit	Kit used in HD-SNSP Treatment.
SNSP Expansion Chamber Holder	Holder used to support the SNSP Expansion Chamber during HD-SNSP Treatment
GMB SP 402	Line for microbiological sampling.
SP-339G	Prime Line

Ultrafilters

U 9000®	Ultrafilter used as water filter and dialysis fluid filter.

Dialyzers

Dialyzers	Most types of dialyzers, except plate filters, can be used. However, it is essential to verify that the specifications and instructions for use of the dialyzers are not in discrepancy with those given for Artis Dialysis System, with regards to e.g. the recommended priming procedure. The connectors and the ports of the filter must comply with ISO 8637 and EN 1283.
Evodial: • Evodial 1.6 • Evodial 2.2	Dialyzer to be used in AFB K Treatments.

BPM accessories

Gambro Cuff

No. 1 (10 - 19 cm) No. 2 (18 - 26 cm) No. 3 (25 - 35 cm) No. 4 (33 - 47 cm)	Cuffs used for measuring blood pressure together with the Artis Dialysis System.

Gambro BPM Tube

No. 1 (3,5 cm) No. 2 (1,5 cm)	Tubes used for measuring blood pressure together with the Artis Dialysis System.

⚠WARNING

The Artis Dialysis System has been tested and validated for use with the concentrates, accessories and disposable listed above.
Gambro does not accept any responsibility or liability for use of concentrates, accessories and disposables other than those specified above.
The use of different kinds of concentrates, accessories and disposables may reduce Gambro's warranties for the Artis Dialysis System.

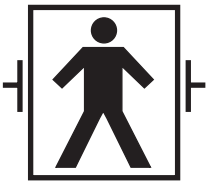
NOTE

- The operator should make sure to have a current list of available concentrates, accessories and disposables.
- The operator should follow the facility procedures for proper disposal of used blood cassette, dialyzers and other disposables per local regulations.

List of symbols

Warning, consult accompanying documents

Type B Equipment.
Provides an adequate degree of protection against electric shock, particularly regarding allowable LEAKAGE CURRENTS and reliability of the protective EARTH connection.



Defibrillation-Proof Type BF Applied Part

OFF (Main power disconnected)

ON (Main power connected)

Alternating Current

Protective Earth (ground)

Year of Manufacturing

Name and address of the Manufacturer

Follow instruction for use

Equipotentiality.

Conforms to requirements in EC Council directive 93/42/ EEC, of 14 June 1993, concerning Medical Devices.
0086 identifies BSI, British Standards Institution, as the Notified Body that has issued the CE Certificate against MDD 93/42/EEC Annex II for the 'design, development and manufacturing of renal replacement therapy equipment systems' after having positively assessed the quality management system of the Manufacturer.

Handle with care

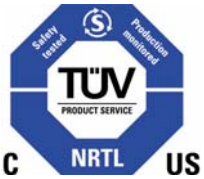
This way up

Keep dry

This symbol indicates that:
- the equipment may not be disposed of together with other municipal waste;
- the equipment was placed on the market after 13 August 2005.

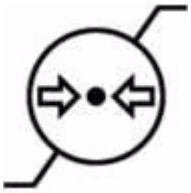
Do not re-use

Non-ionizing electromagnetic radiation



Indicates that the equipment complies with applicable UL and CSA standards for the Safety of Medical Electrical Equipment.

Only for 115V machine configuration.



Permitted pressure area

Permitted humidity area

Electrostatic sensitive devices.
Symbol used to indicate packages containing electrostatic sensitive devices, or to identify a device or connector that has not been tested for immunity to electrostatic discharge.

Do not stack

Addresses

For technical assistance, contact your Local Service Representative.

Belgium	**GAMBRO NV** Ikaroslaan, 61 1930 Zaventem Tel. ++32 2 711 21 11 Fax ++32 2 711 22 95
Canada	**GAMBRO Inc.** 2 East Beaver Creek Road Building #4 Richmond Hill Toronto CA-ONTARIO L4B 2N3 Tel: 1 - 905 762 06 90 Fax: 1 - 905 762 06 85
Denmark	**GAMBRO Danmark** Jydekrogen 8 2625 Vallensbæk Tel: +43 62 05 00 Fax.: +43 62 07 49
Finland	**GAMBRO Lundia AB, filial i Finland** PO Box 30, Sahaajankatu 24 FIN-00880 Helsinki FINLAND Tel: +358 9 759 4120 Fax: +358 9 781 146
France	**GAMBRO SAS** 1-3 Boulevard Charles de Gaulle 92700 Colombes Tel.: ++33/(0)1 41 91 31 00 Fax: ++33/(0)1 47 81 51 85
Germany	**GAMBRO Hospal GmbH** Danziger Strasse 23 DE-82194 Gröbenzell Tel: ++49-8142 6519 0 Fax: ++49-8142 6519 194

Italy	**Hospal S.p.A** Via Ferrarese, 219/9 I - 40128 Bologna Tel. ++39/051 63 82 411 Fax ++39/051 32 74 77
Netherlands	**GAMBRO-Hospal BV** Lijndonk 4 4825BG Breda Tel: ++31(0)881426200 Fax: ++31(0)881426250
Norway	**GAMBRO Norge NUF** Bjellandveien 24 N – 3172 Vear Tel. + 47 33 30 14 20 Fax. +47 33 30 14 35
Portugal	**Gambro Lundia AB Sucursal em Portugal** Lagoas Park Edificio 5A Piso 0 2740 - 298 Porto Salvo Portugal Tel. +351 21 487 6810 Fax. +351 21 487 6838/39
Russia	**Gambro Lundia Export** Box 101 01 SE-220 10 LUND Tel: 46 - 46 16 90 00 Fax: 46 - 46 16 96 10
Slovenia	**Gambro Lundia Export** Box 101 01 SE-220 10 LUND Tel: 46 - 46 16 90 00 Fax: 46 - 46 16 96 10
Spain	**GAMBRO LUNDIA A.B. Sucursal en España** C/ Nápoles 249, 1º 08013 Barcelona Tel +34934570074 Fax. +34934577672

Sweden	**GAMBRO Lundia AB** **GAMBRO Svenska Försäljning** P O Box 10101 Scheelevägen 34 SE-220 10 Lund Sweden Tel: +46 46 16 90 00 Fax: +46 46 16 96 20

Warranty

All products manufactured by Gambro are warranted against defects in workmanship and materials.

While the machine is within the stated warranty period, no service repairs on it should be attempted. Any unauthorized work will immediately void the warranty.

If additional information or assistance is required or the information provided is not sufficient, contact the Service Representative in your country and request additional information or assistance.

If any information in this manual is found to be in error, or if there are any additions or deletions that you feel will improve the manual, please forward your comments to the Service Representative in your country.

Gambro and/or its affiliates accept responsibility for the safety, reliability and performance of this equipment only if:

- Operational procedures, calibrations and repairs are carried out by appropriately qualified personnel;
- All equipment modifications are authorized in writing by Gambro and carried out by appropriately qualified persons;
- The electrical installation of the relevant room complies with all applicable local electrical codes and IEC requirements, and
- The equipment is used in accordance with the published instructions for use

⚠WARNING

The Artis Dialysis System will perform as designed only if it is used and maintained in accordance with Gambro's instructions. Any warranties made by Gambro are void if the equipment is not used in accordance with the instruction provided.
Gambro will not accept responsibility for any damage or injury resulting from improper use or maintenance or unauthorized repair.
Gambro does not recognise the owner of a product as an authorised service representative.
If repairs of the machine have been attempted by anyone other than qualified personnel belonging to the service representative in your country, under no circumstances will the manufacturer be liable for indirect or consequential damages of any kind, its liability hereby being limited solely to repair or replacement.
This warranty is in lieu of any other expressed or implied warranties, including any implied warranty saleability or suitability of use and of any other obbligation on the part of the manufacturer.

NOTE

The Artis Dialysis System was designed and has been built to comply with the product specifications listed in this Operator's Manual (Refer to the "Chapter 17: Specifications" of this Operator's Manual). Gambro is committed to continuously improving this product. The improvement process may result in modifications to both the product specifications and consequently to the equipment produced in the future. These changes or improvements may or may not be applicable or usable with previously produced equipment. Where possible, improvements will be made available at reasonable prices. Any such improvement shall not be construed as corrections of any perceived deficiency.

⚠WARNING

This Operator's Manual contains a number of references to concentrates, disposables, accessories and spare parts for use with Artis Dialysis System.
The Artis Dialysis System has been tested and validated for use with concentrates, disposables, accessories and spare parts listed in this manual.
The Manufacturer does not accept responsibility or liability for use of concentrates, disposables or accessories other than those specified in this manual, for use of not genuine spare parts and for use/mounting of those components not in accordance with the official Gambro Instruction for Use accompanying those components.
Depending on the circumstances, use of concentrates, disposables or accessories other than those specified in this Operator's Manual, use of not genuine spare parts and use/ mounting of those components not in accordance with the above mentioned Instruction for Use may reduce the Manufacturer's warranties for the Artis Dialysis System.

NOTE

This publication contains information which is the property of Gambro. Whoever receives this manual accepts that drawings and information contained herein must not be disclosed to others without the express written permission of Gambro. Do not attempt to assemble, install, or operate the machine until all the contents of this manual are thoroughly understood.

Major Changes in Operator's Manual from software version 8.08

Complete Manual

The whole Operator's Manual has been updated adding instructions and specifications related to the following new features introduced in the Artis software from version 8.08:

- HD-DNDP Treatment
- Optional skip of some Function Checks after the first treatment of the day
- Availability of the Chemical Disinfection with hypochlorite
- Use of SelectBag Citrate

Chapter 3: Machine Dressing and Priming

This chapter is new. It contains instructions related to the machine dressing procedure and to the priming phase.

A new warning has been added to the "3.5.2 Loading of the Blood and Ultra Cassette" section in order to alert the operator against the possible hazardous situations due to an improper connection of the Ultra Inlet line to the Ultra Port.

Chapter 5: Hemodiafiltration On-line

This chapter is new. It was obtained by merging two chapters: "Chapter 4: Hemodiafiltration On-line in Volume Control Mode" and "Chapter 5: Hemodiafiltration On-line in Pressure Control mode".

This chapter now contains the description of the HDF Post Treatment, both in Pressure and Volume Control modes.

Chapter 8: Special Procedures

The "Adjust Arterial/Venous chamber levels" section has been updated.

Chapter 16: Alarms, Information Signal Troubleshooting

New alarms related to the Arterial Chamber Blood Level have been added.

Chapter 1: General Description

1.1 Structure of the machine

The Artis Dialysis System consists of the machine in use with a blood cassette appointed for the machine, a dialyzer, a heparin syringe, a BiCart Cartridge, a SelectCart Cartridge, a SelectBag One or SelectBag Citrate Container and other dialysis fluid concentrates.

The Artis Dialysis System has a modular structure. It is made up of five modules that carry out indipendent functions. The modules are described below.

1.1.1 Master Module

This module manages the functioning of all machine processes. It allows the operator to communicate with the machine via a color Touch Screen, through which it is possible to:

- Activate/deactivate functions
- Visualize and set parameter values
- Receive operator instructions, Alarm and Information messages

1.1.2 Hydraulic Module

This module manages/supervises the dialysis/substitution fluid preparation and the measurement and control of ultrafiltration.

The Artis Dialysis System is a single-pass system, i.e. dialysis fluid passes through the circuit only once.

Dialysis fluid preparation is a continuous process. Its conductivity is affected by the parameters preset or selected by the operator.

1.1.3 Blood Module

The blood module manages all the processes related to therapies and modes of the machine.

The main functionalities of this module are:

- To route arterial blood from the patient
- To mix blood with heparin and substitution fluid
- To move blood to the dialyzer
- To monitor arterial and venous pressures
- To return the blood to the patient.

The unit mades up of the Master, Hydraulic and Blood Modules is called the Control System.

1.1.4 Protective Module

This module supervises all processes related to the patient-safe condition in order to prevent hazardous situations. It also manages the alarm conditions that may occur during a treatment.

For further details on the Protective System, refer to the “17.4 Protective System” section of this Operator’s Manual.

1.1.5 Bio Module

This module manages the processes related to the Hemoscan function.

1.2 Description of the machine

A detailed description of components of the Artis Dialysis System is reported in the sections below.

1.2.1 Machine Components - Front Panel

The Front Panel components of the Artis Dialysis System are shown and described below:

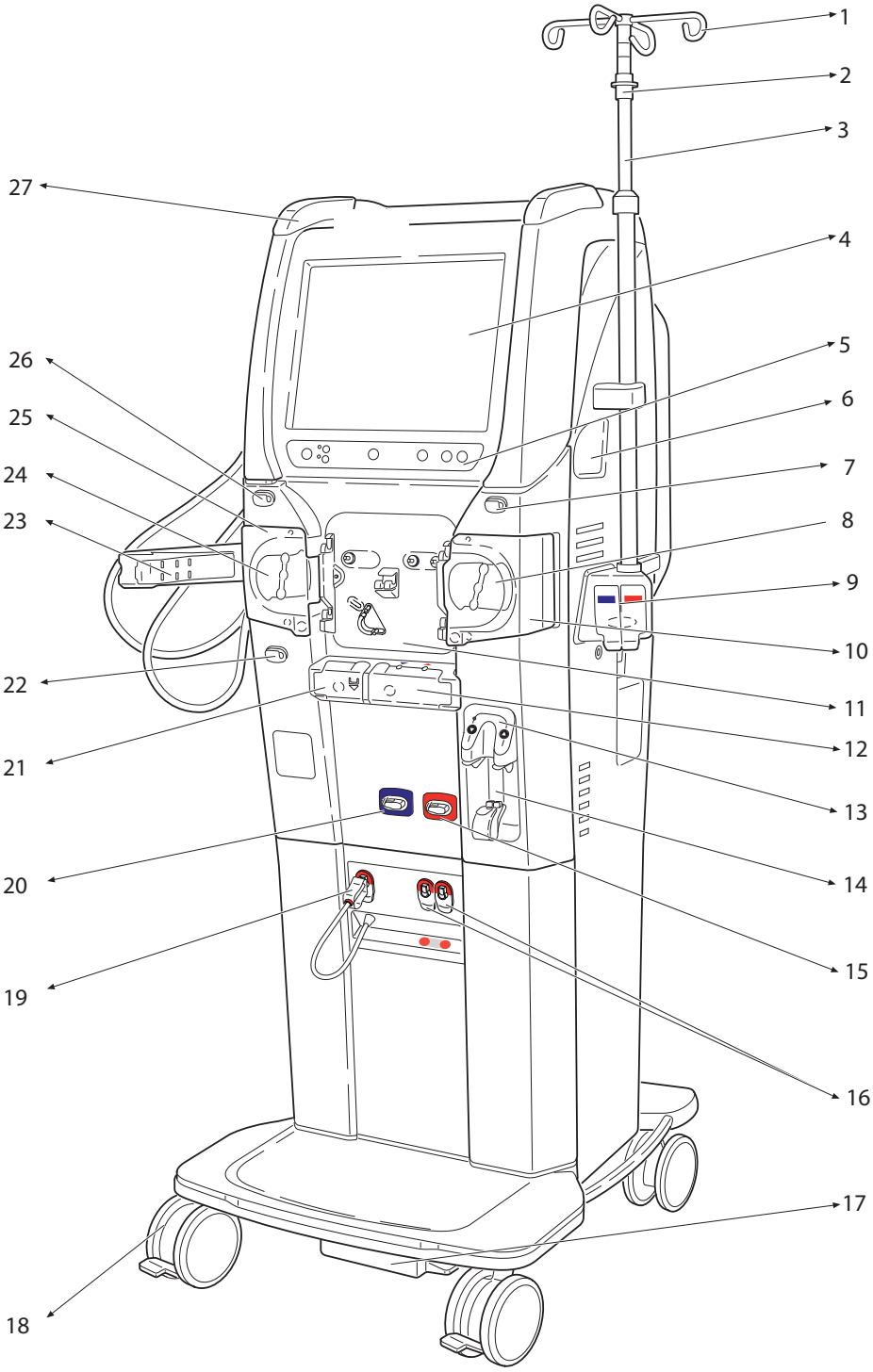


Figure 1-1. Front Panel

Table 1: Front Panel

COMPONENTS	DESCRIPTION
1. Infusion Pole Hooks	Used to hold the infusion saline bags
2. Infusion Pole Adjustment Knob	Knob which allows to adjust the infusion pole at the desired height
3. Infusion Pole	Adjustable pole, on the right side of the Artis Dialysis System, intended for holding the infusion bags
4. Touch Screen	Sensitive screen that allows the operator to interact with the Artis Dialysis System by giving and receiving operating instructions and setting parameters
5. Hard Key Panel	Panel located under the Touch Screen whose keys are used to control the machine/Arterial pump functions and to mute alarms
6. Card Reader	The Card Reader allows the upload/download of the patient prescription data into/from the machine by means of a Patient Card. The Patient Card is a contactless device.
7. Prime Line Guide	Guide used for securing the prime line to the machine.
8. Arterial Pump	Peristaltic pump that routes the blood from the patient to the extracorporeal circuit
9. EvaClean Ports	Ports used to connect the arterial and venous patient lines to the EvaClean option during priming procedure for proper disposal of waste fluids
10. Arterial Pump Cover	Protective cover. It must be closed when the pump is running
11. Cassette Panel	Appointed area for holding/loading/unloading the Blood, Ultra, Infusion and SN Cassettes
12. Sensor Bar Door	Cover which protects the Air detector/Hemoscan/ Blood sensor
13. Heparin Panel	Panel appointed to manage the heparin syringe positioning
14. Heparin Syringe Plunger	Movable device used for delivering of heparin into the extracorporeal circuit
15. Arterial Line Clamp	Automatic occlusive clamp that closes the arterial patient line when needed

Table 1: Front Panel

COMPONENTS	DESCRIPTION
16. Front Central Concentrate Connector Ports 1 & 2	Intended for connecting the machine to a central delivery system
17. Battery Holder	Housing for backup battery
18. Lockable Wheels	Wheels that can be locked during treatments
19. Acid Pick-up Tube Connector	Connector appointed to connect the acid pick-up tube to its related concentrate connector port or to a concentrate canister
20. Venous Line Clamp	Automatic occlusive clamp that closes the venous patient line when needed
21. Ultra Door	Cover which protects the Ultra port
22. Venous Dialyzer Line Guide	Guide used for securing the Venous Dialyzer line to the machine
23. Dialyzer Holder	Movable device appointed to hold the dialyzer in place during treatments
24. Venous Pump	Peristaltic pump used during HD-SN Treatment and for administering substitution fluid during HDF Post Treatment.
25. Venous Pump Cover	Protective cover. It must be closed when the pump is running
26. Arterial Dialyzer Line Guide	Guide used for securing the Arterial Dialyzer line to the machine
27. Status Lights	They illuminate to give general indications of the machine operating conditions

1.2.1.1 Cassette Panel

The Cassette Panel components are shown and described below.

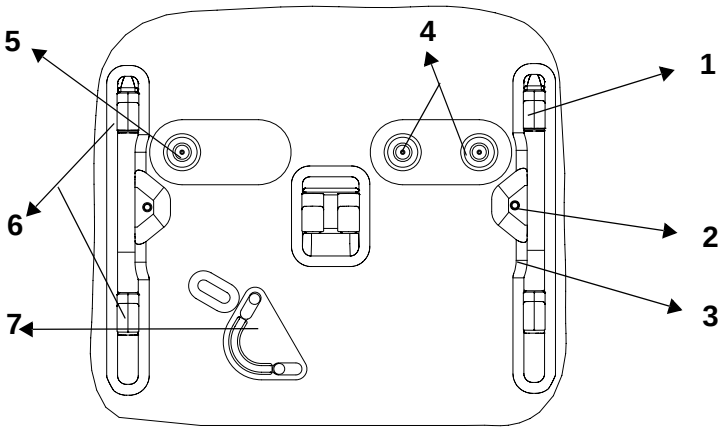


Figure 1-2. Cassette Panel

Table 2: Cassette Panel

COMPONENTS	DESCRIPTION
1. Cassette Holder	Three hooks used for holding the blood cassette in place
2. Cassette Sensor	Sensor that detects the presence of the blood cassette on the cassette panel
3. Heparin Line Guide	Two hooks used for securing the heparin line to the machine
4. Pressure Transducers	Sensors that read the arterial and venous pressure in the cassette chambers
5. Pressure Transducer	Sensor that reads the pre-dialyzer pressure in the Ultra cassette chambers and the post-dialyzer pressure in the Post-Dialyzer Expansion Chamber.
6. Ultra Cassette Holder	Three hooks used for holding the SNSP Conversion kit, SN Cassette and the Ultra Cassette in place.
7. Automatic Pinch Clamp	Clamp on the Cassette Panel that directs the substitution fluid pre or post.

1.2.1.2 Sensor Bar

The Sensor Bar components are shown and described below.

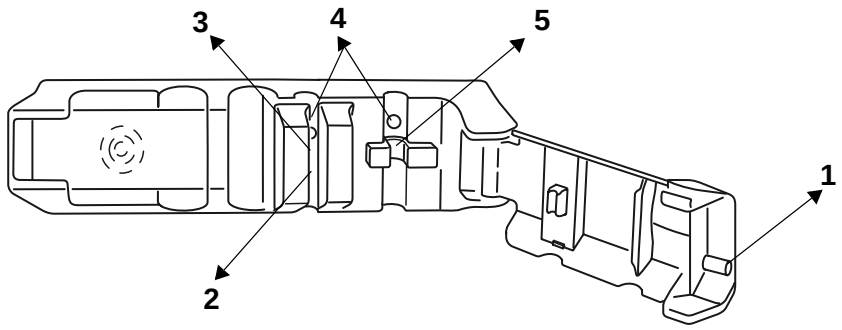


Figure 1-3. Sensor Bar

Table 3: Sensor Bar

COMPONENTS	DESCRIPTION
1. Sensor Bar Door Sensor	Magnetic sensor that detects the status of the sensor bar door (opened/closed).
2. Blood Sensor	An optical sensor, located in the Sensor Bar, that detects the presence of blood in the Venous Patient line.
3. Air Detector	Ultrasonic sensor that detects macro and micro air in blood in the Venous Patient line of the Blood Cassette.
4. Line Presence Sensors	Sensors that detect the presence of the Arterial and Venous Patient lines.
5. Hemoscan Sensor	Sensor that continuously measures the hemoglobin concentration, calculating the relative change in the patient's blood volume during dialysis treatments.

1.2.1.3 Ultra Door

The Ultra Door components are shown and described below.

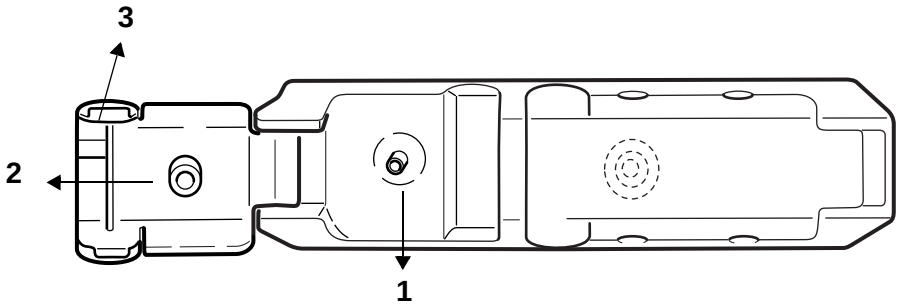


Figure 1-4. Ultra Door

Table 4: Ultra Door

COMPONENTS	DESCRIPTION
1. Ultra Port	Allows the passage of on-line prepared substitution fluid into the Ultra Inlet line.
2. Ultra Door Seal	Seals the Ultra port when on-line therapy is not performed.
3. Ultra Door Sensor	Magnetic sensor that detects the status of the Ultra door (opened/closed).

1.2.2 Machine Components - Rear Panel

The Rear Panel components of the Artis Dialysis System are shown and desribed below.

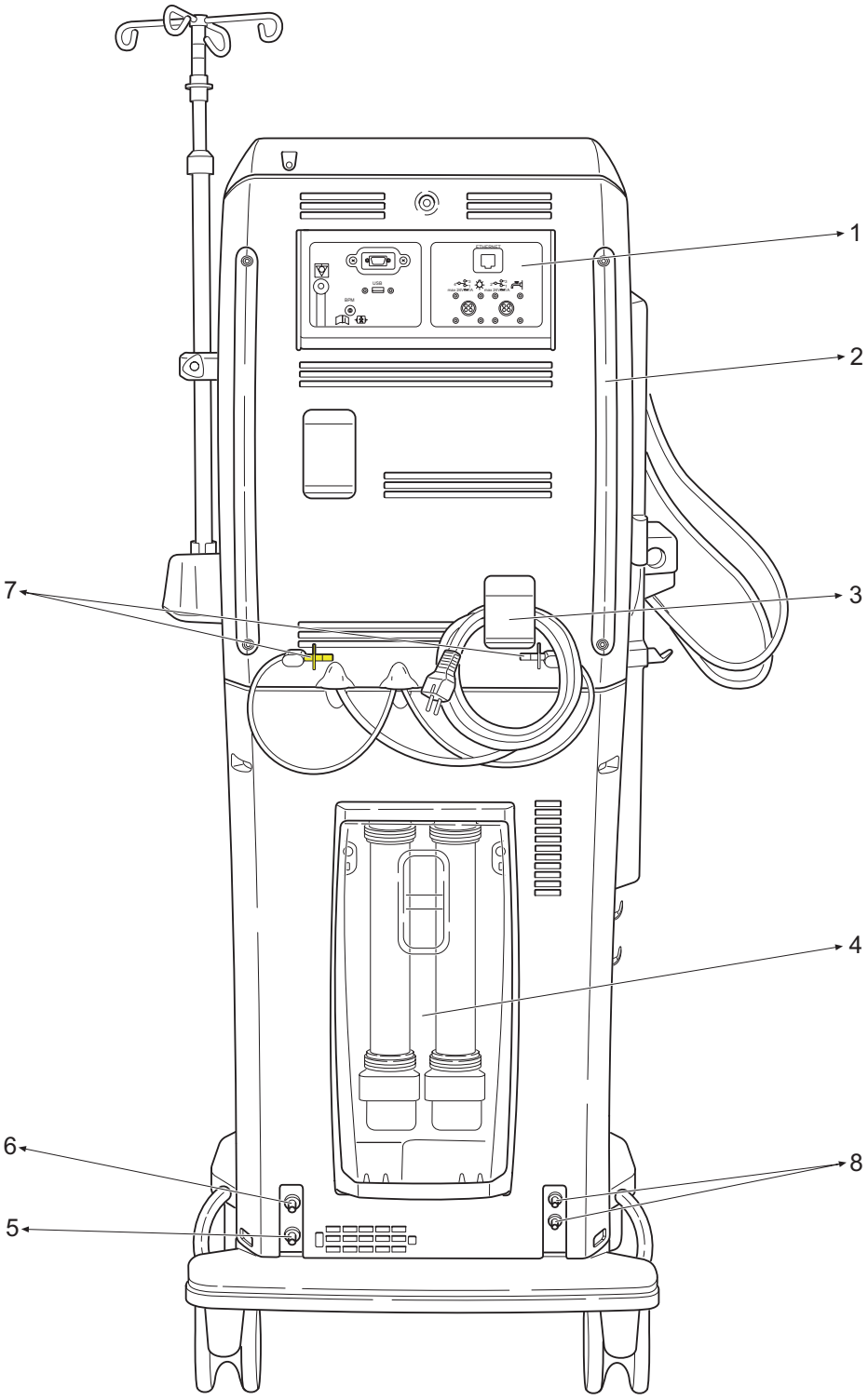


Figure 1-5. Rear Panel

Table 5: Rear Panel

COMPONENTS	DESCRIPTION
1. Connectivity Panel	Panel containing the following connectors: • A standard 10 Base T Ethernet connection; • A connection used to connect the machine to an external software application; • A USB port; • BPM connector used for the BPM Cuff; • A Potential Equalization Connection mean; • A Hour Meter.
2. Handles	Used to move the machine
3. Cable Holders	Used to roll up tubes or cables
4. Ultrafilter Cover	Plastic cover that protects the ultrafilters from foreign objects. The cover must be closed during operations
5. Drain Port	Port that connects the drain tube to the machine
6. Water Inlet Port	Port that connects the water inlet tube to the machine
7. Yellow/Clear Disinfectant Connector	Intended for connecting the disinfectant tube to the wand inserted into the disinfectant canister
8. Rear Central Concentrate Connector Ports 1 & 2	Intended for connecting the machine to a central delivery system

1.2.3 Machine Components - Left Panel

The Left Panel components of the Artis Dialysis System are shown and described below:

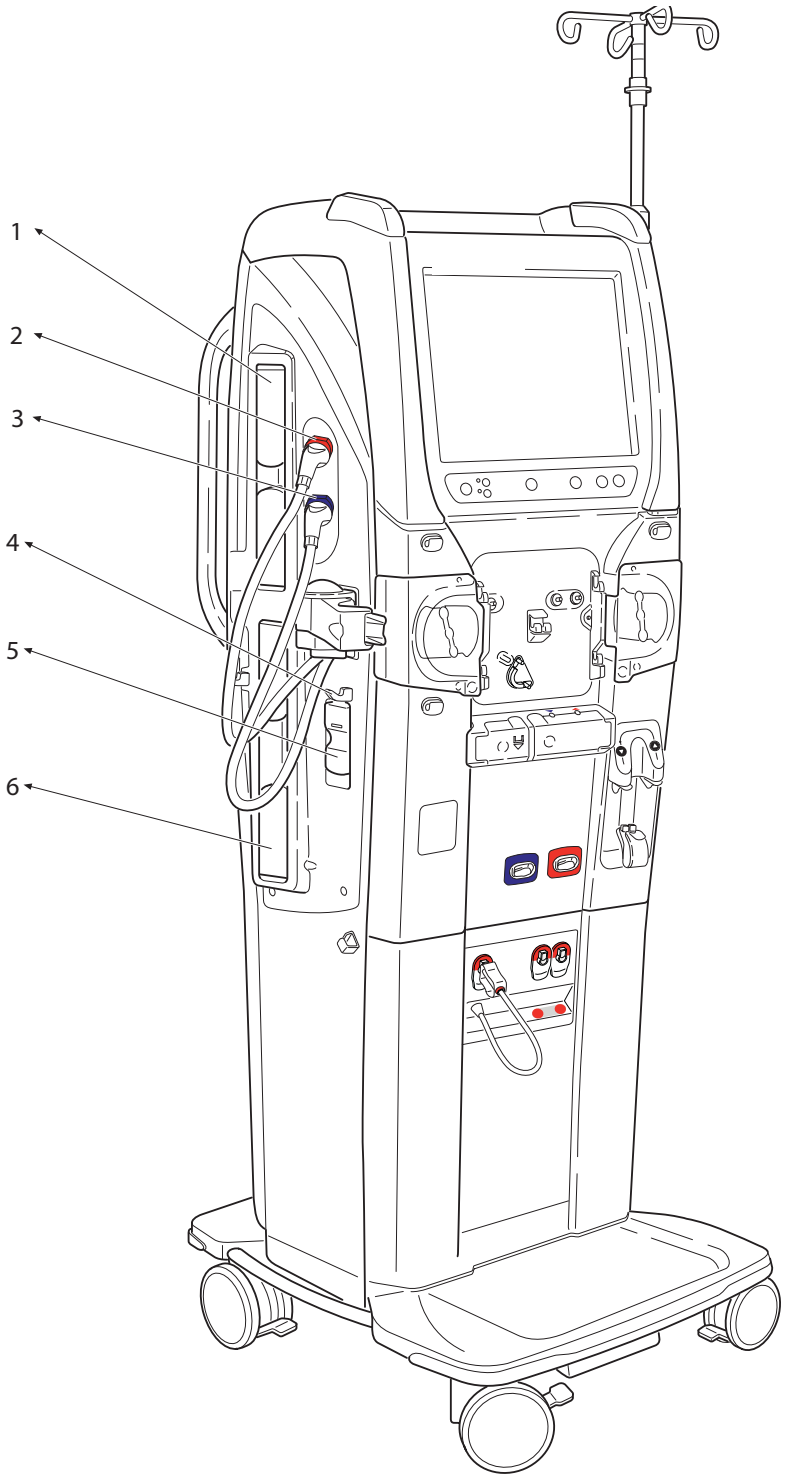


Figure 1-6. Left Panel

Table 6: Left Panel

COMPONENTS	DESCRIPTION
1. BiCart Cartridge Holder	Holder appointed for the BiCart Cartridge and for the CleanCarts®
2. Red Dialysis Fluid Tube	Tube through which the dialysis fluid passes from the dialyzer to the machine
3. Blue Dialysis Fluid Tube	Tube through which the dialysis fluid passes from the machine to the dialyzer
4. SoftPac Hooks	Hooks appointed to hold the SoftPac
5. SelectBag Holder	Holder appointed for the SelectBag
6. SelectCart Cartridge Holder	Holder appointed for the SelectCart Cartridges

1.3 Operator interface

Artis Dialysis System Operator Interface consists of:

- A colour Touch Screen;
- A Hard Key Panel;
- A Heparin Panel.

1.3.1 Artis Dialysis System Touch Screen

The Touch Screen allows the operator to interact with the machine, giving on-line detailed operating instructions. Instructions include the following screens/areas:

- Operating screens and sub-screens providing step-by-step instructions the operator follows each time in setting up, administering and ending patient treatments;
- Alarm/Information Messages Area providing Alarm/Information Messages when alarm situations occur or an Information Message is triggered;
- Help windows providing additional information on alarms, Information Messages and Special Procedures.

The Artis Dialysis System User Interface is made up of five main screens and several sub-screens.

During normal operations, the Artis Dialysis System Touch Screen has the following layout:

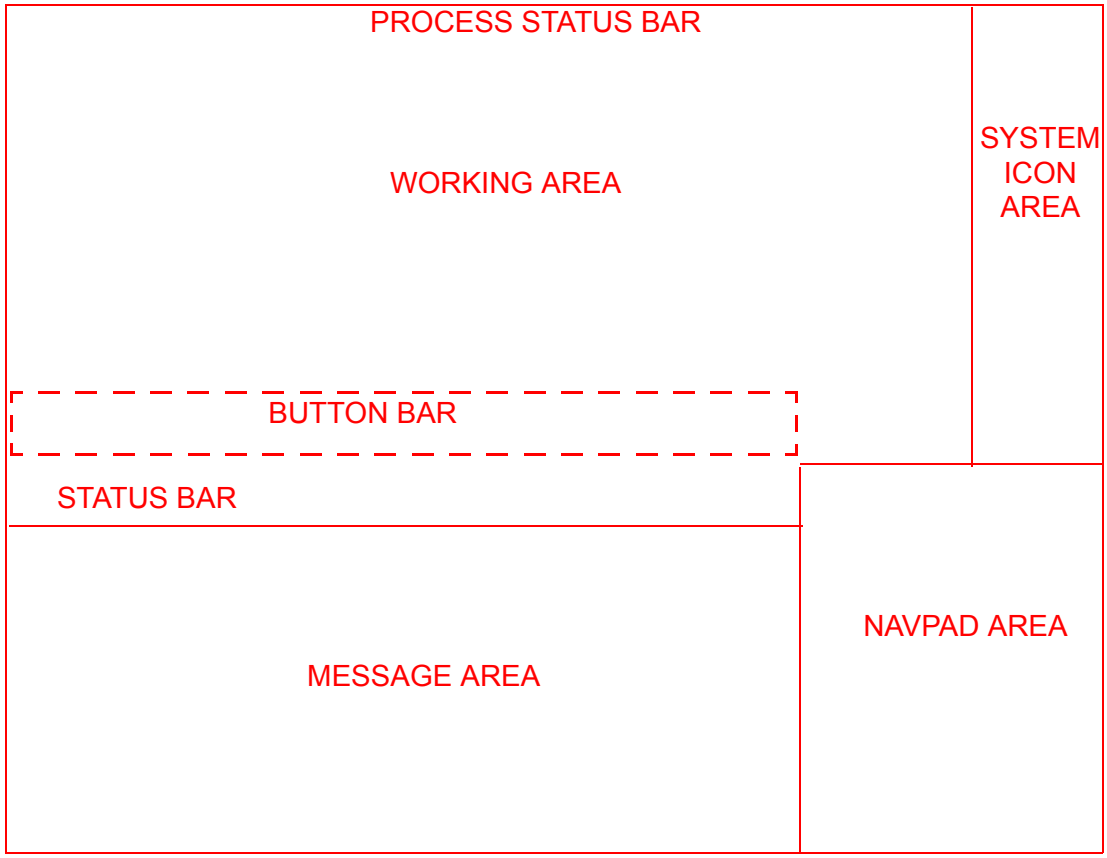


Figure 1-7. Touch Screen Layout

WORKING AREA

In this area the operator can visualize the screens containing data, graphs and icons related to the current treatment.

In this area also the Function sub-screens are displayed. In this case the working area covers the system icon area.

BUTTON BAR

The Button Bar is mainly divided in three parts:

1. Left part: displays three buttons related to the blood function;
2. Central part: displays one button (“Transition” button) that allows the next process/procedure. This button is displayed but not always available. When it becomes darker the machine is ready for the next procedure;
3. Right part: displays three buttons related to the fluid function.

On the Button Bar all the Action/Function/Command buttons are located.

The *ACTION* button allows the operator to activate/deactivate functions. This type of button has an action indicator on its top that can be grey, yellow or green:

- when it is grey, it means that the process/feature is not activated;
- when it is yellow, the machine is performing self-checks and the process/feature will be activated at the end of the checks;
- when it is green, it means that the process is running or that the feature is activated.

The *FUNCTION* button opens the Function sub-screens where it is possible to set/change specific function parameters.

The *COMMAND* button allows to start the next function.

PROCESS STATUS BAR

At the top of the Working Area a “Process Status Bar” indicates the progress status of the ongoing phase. The bar is made up of the Remaining Time value and of a progress bar. As the process goes on, the *Remaining Time* value decreases while the blue bar increases.

During the “Function check/preparation” phase this bar shows the *Percent Complete* percentage: in this case, as the process goes on, both the *Percent Complete* value and the blue progress bar increase.

STATUS BAR

This bar displays messages related to the current status of Artis Dialysis System.

MESSAGE AREA

Step-by-step information on how to carry out necessary actions are provided in this area.

⚠WARNING

To correctly operate the machine, pay careful attention to the messages displayed in the Message Area of the Touch Screen.

NAVPAD AREA

This cruciform area displays the five NavPad buttons that allow to switch from a screen to another (refer to the "1.4.1 NavPad Area" section of this chapter).

TIME BUTTON

In the right bottom corner of the Touch Screen the "Time" button displays the actual time in "h:min" format.

Pressing this button a manual reading of the current treatment parameters will be provided in the Event List of the *Report* screen. Refer to the "Chapter 15: Report Environment" of this Operator's Manual.

SYSTEM ICON AREA

It displays the icon related to the machine functions such as network, patient card, USB, bar code reader, plan of care, battery and time.

Below follows a detailed description of the main system icons:

Icons	Description
	This icon indicates that the machine is connected to the supply mains.
	This icon indicates that the Battery is in use in case of the Power Failure.
	This icon indicates that the Timer function is activated. When the timer expires, a Notification is displayed in the Message Area.
	This icon indicates that the AFB K Scale is connected to the machine. If the AFB K Scale is disconnected, the icon disappears.

1.3.1.1 Alarm/Information Messages Area

In the event of an alarm, an Alarm/Information Messages Area will appear, covering the Status Bar and the Message Area, with the following layout:

Figure 1-8. Alarm/Information Messages Area

SWITCH FUNCTION

When the Alarm/Information Messages Area is displayed hidding the operator messages, it is possible to switch from the Alarm/Information Messages Area to the Message Area and viceversa proceeding as follows:

1. Press the “Switch” button appearing on the right top part of the Alarm/ Information Messages Area:

- The Message Area will be displayed thus showing the hidden operator messages.

2. To come back to the Alarm/Information Messages Area press the “Return” button displayed on the right top part of the Message Area:

- The Alarm/Information Messages Area will be displayed again.

MUTE ICON

This icon appears on the Alarm/Information Messages Area when the mute function is activated by the operator pressing the related key on the Hard Key Panel:

The Progress Bar at the top of this icon shows the remaining time of the mute function.

TEXT AREA

If more than one alarm or Information Message is triggered, they are all listed in this area.

Below the Text Area, three colour-coded tabs allow the operator to visualize all the alarms and/or Information Messages that have been triggered.

The alarms and Information Messages are grouped as follows:

- Red tab: displays alarms with high priority
- Yellow tab: displays alarms with medium and low priority
- Blue tab: displays Information Messages

In each tab, no more than three Alarms/Information Messages are displayed at a time. In case that more than three alarms/Information Messages are present, the Scroll Buttons can be used to scroll the list.

Each time the Alarm/Information Message Area is displayed, if one of the tabs is empty it is grey-coloured. Otherwise, if the tab contains at least one alarm/ information message it is highlighted, according to the specific colour related to the priority level (refer to the "16.2.1 Priority Levels" section in the "Chapter 16: Alarms, Information Signals and Troubleshooting" of this Operator's Manual for further details).

SCROLL BUTTONS

The Scroll Buttons can be used to scroll the alarm list.

CONFIRM/PAUSE ALARM/RESET BUTTON

The Confirm/Pause Alarm/Reset buttons are displayed on the right of the alarm list only if the alarm/Information Message needs to be confirmed, paused or reset. Each function is referenced by a specific symbol, drawn into the button:

Symbols	Function
	**RESET**
	**PAUSE ALARM**
	**CONFIRM**

Refer to the "Chapter 16: Alarms, Information Signals and Troubleshooting" for further details on this functions.

"HELP" BUTTON

Selecting an Alarm/Information Message on the text area and pressing the "***HELP***" button, the Help Window will open.

HELP WINDOWS

When pressing the Help button, two types of Help Windows can open:

- A small Help Window that covers the Alarm/Information Messages Area, as shown in the image below.

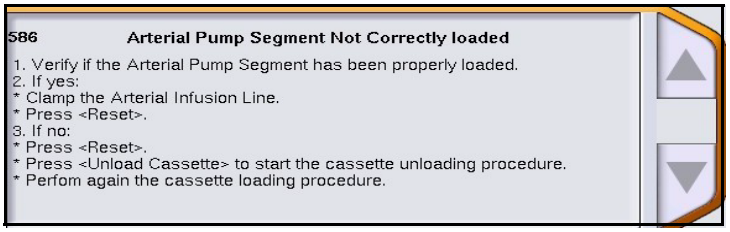


Figure 1-9. Example Help Window

On this area, further information on possible causes and solutions of the selected alarm will be provided.

- A "step-by-step" Help Window that covers a dedicated area. Refer to the "STEP-BY-STEP HELP WINDOWS" section.

Press the ***CLOSE*** button to switch back to the Alarm/Information Messages Area.

NOTE

If an alarm occurs with a higher priority while the operator is displaying the Help Window, the window will be automatically closed.

STEP-BY-STEP HELP WINDOWS

The Help Windows containing step-by-step instructions have the following configuration:

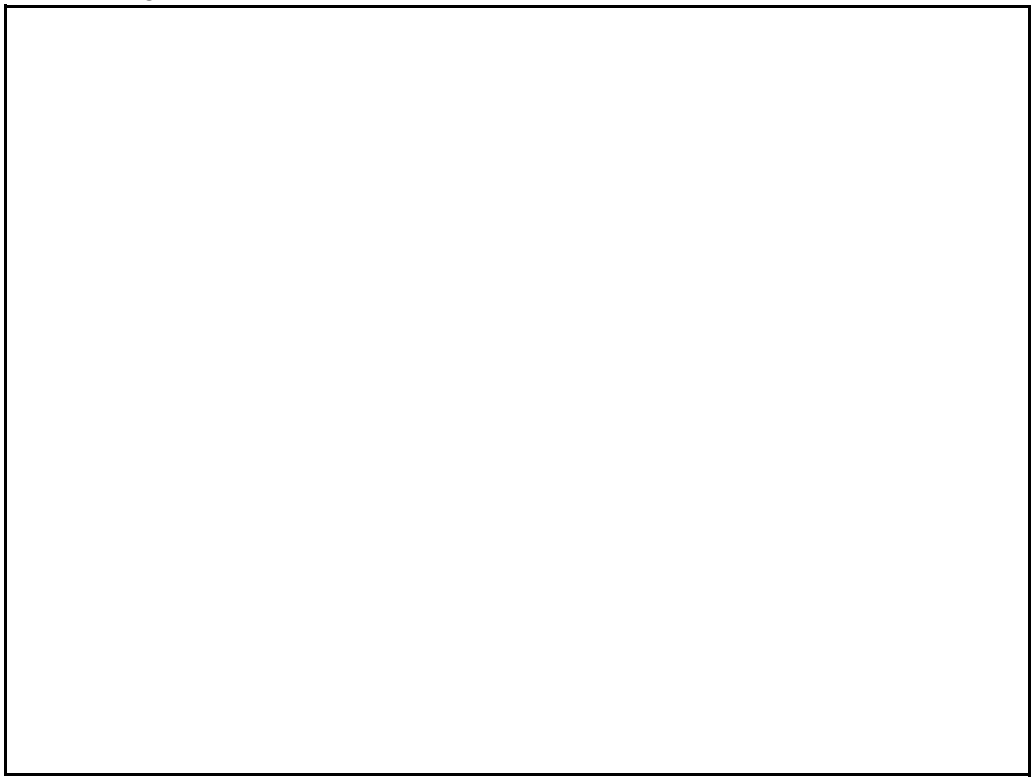


Figure 1-10. Example of Help Window - *Air in Venous Line* Alarm

As shown in the figure above, this window is configured in the following way:

- On the top of the window, there is the alarm message;
- On the left side of the window, there is the ordered sequence of actions the operator has to perform to solve the alarm;
- On the right side of the window, a series of images shows the operator the proper way to perform the actions described in the checklist. The image related to a specific step are shown when the related step is selected;
- On the bottom part of the window, the ***CLOSE*** button is available to allow the operator to close the pop-up window;
- To move from one step to another, select the related step or press the ***NEXT*** button, if available on the bottom part of the window;
- Just below the pop-up window, on the right side, the Arterial and Venous Pressures, the UF Rate and the UF Volume values are displayed throughout the procedure, only in case of "Air in Venous Line (#4)" alarm.

1.3.1.2 Special Procedure windows

When a Special Procedure is selected and confirmed in the “Special Procedures” selectpad, a pop-up window will appear giving the operator step-by-step instructions on how to perform the procedure.

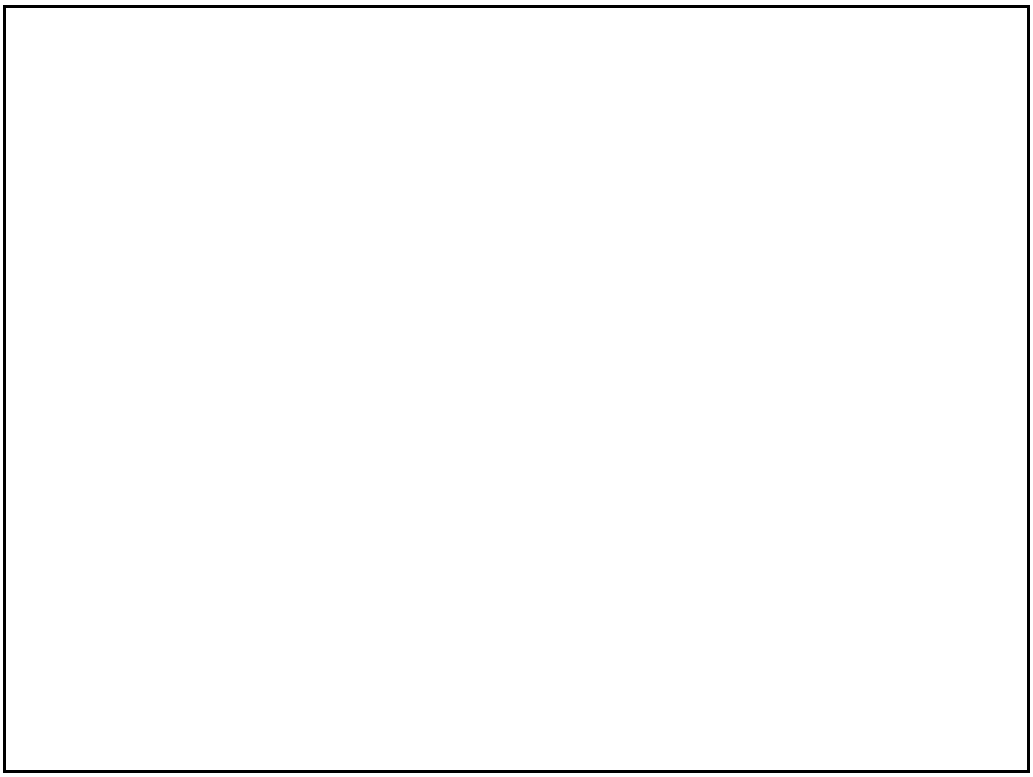


Figure 1-11. Special Procedure Window - Example

As shown in the exemplifying figure above, the Special Procedure window is configured in the following way:

- On the top of the window, there is the name of the selected Special Procedure
- On the left side of the window, a checklist is present containing the ordered sequence of actions the operator has to perform to carry on the Special Procedure selected;
- On the right side of the window, a series of images will show the operator the right way to perform the actions described in the checklist;
- On the bottom part of the window, the ***CONFIRM, CLOSE*** or ***NEXT*** buttons will be available;
- Just below the pop-up window, on the right side, the Arterial and Venous Pressures, the UF Rate and the UF Volume values are displayed throughout the procedure.

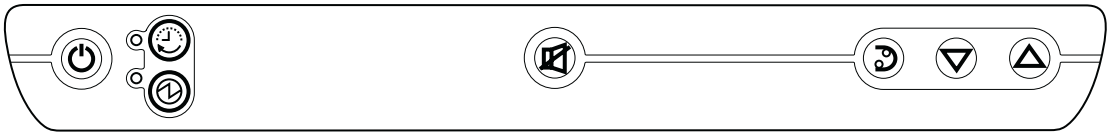
From time to time, the following symbols will be displayed next to the steps in the checklist:

Table 7: Special Procedure Window Symbols

Symbols	Description
	This symbol indicates that the yellow-highlighted step has to be performed by the operator
	This symbol indicates that the machine is performing the highlighted step
	This symbol indicates that the step has been successfully accomplished. In this case, the step in the checklist switches to grey.

1.3.2 Hard Key Panel

The Hard Key Panel is located below the Touch Screen:



Or:

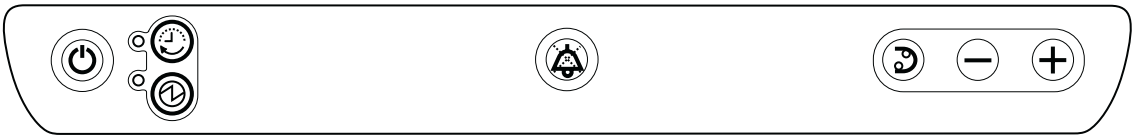


Figure 1-12. Hard Key Panel

It is made of the following keys:

Table 8: Hard Key Panel

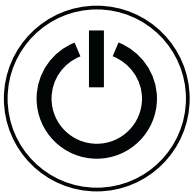
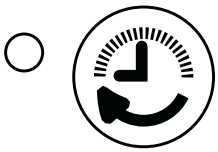
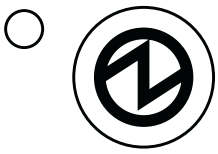
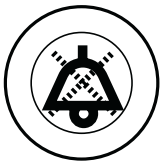
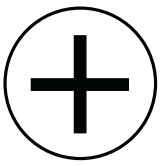
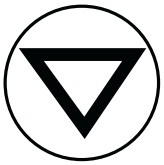
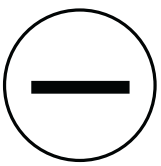
Keys	
	**On/Off Key:** it handles the on/off function of the machine when the machine is energized.
	**Autostart Indicator:** It is yellow-lit when any Disinfection/Rinse program and/or function test has been scheduled to automatically start at a predefined time.
	**Main Switch On Indicator:** It gives information about energizing state of the machine: the led is green-lit when the Artis Dialysis System is connected to the supply mains and the Main Switch button is ON.

Table 8: Hard Key Panel

Keys	
 or: 	**Mute Key:** it is used to mute an audible alarm.The key is green-lit during the alarm. The light switches off when it is pressed.
	**Blood Pump ON/OFF Key:** used to manually start/stop the Arterial and Venous Pumps. This key is not available until the "Connect Patient" action button is pressed and confirmed.
 or: 	**Blood Flow Increase Key:** used to manually increase the Arterial Pump speed: • If it is pressed with a single press the speed increases of 10 ml/min; • If it is pressed continuously the pump speed increases continuously. The Blood Flow Increase Key is not available until the "Connect patient" button is pressed and confirmed.
 or: 	**Blood Flow Decrease Key:** used to manually decrease the Arterial Pump speed: • If it is pressed with a single press the speed decreases of 10 ml/min • If it is pressed continuously the pump speed decrease continuously. The Blood Flow Decrease Key is not available until the "Connect patient" button is pressed and confirmed.

1.3.3 Heparin Panel

The Heparin Panel is placed above the Heparin Syringe Holder (see “Figure 1-1. Front Panel”).

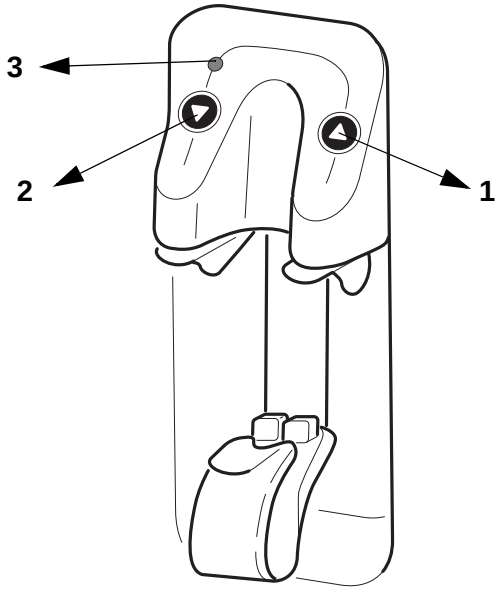


Figure 1-13. Heparin Panel

Table 9: Heparin Panel

COMPONENTS	DESCRIPTION
1. Heparin Syringe Positioning Key: Arrow Up Button	Key used to move up the Heparin Syringe Plunger.
2. Heparin Syringe Positioning Key: Arrow Down Button	Key used to move down the Heparin Syringe Plunger.
3. Heparin Indicator	Indicator that lightens when the heparin function is activated.

NOTE

The use of a 10 ml syringe size requires the installation of an appropriate Heparin Pump Assembly.
Call for service technician to replace the Heparin Pump Assembly installed on the machine with the Heparin Pump Assembly appropriate for a 10 ml syringe size.

NOTE

The maximum opening of the Heparin Syringe Plunger related to the 10 ml syringe size is shorter than the maximum opening of the Heparin Syringe Plunger related to the 30 ml syringe size.
When the maximum opening is reached, the "Heparin Pump Lower Limit Reached (#69)" alarm occurs.

NOTE

An audible signal can be triggered following the selection of a key when:

- The machine has not been temporarily able to detect correctly the key previously selected; in this case, wait at least 5 seconds before pressing the key again to let the machine recognize the selection;
- A superimposed window is present on the Touch Screen and the selection of that key is not requested by the superimposed window;
- The Blood Flow Increase or Decrease key is pressed but a manual increment/decrement of Arterial Pump speed is not allowed during the current machine phase.

1.4 Operating Modes

When the Artis Dialysis System is switched on (the main switch on indicator is green-lit), the machine starts loading the software program and begins the function check sequence. A progress bar and the software revision are displayed on the Touch Screen.

Further details about the function check sequence are only available in a specific Service page.

As soon as a certain number of function checks have been performed, the machine displays the following *Overview* screen:

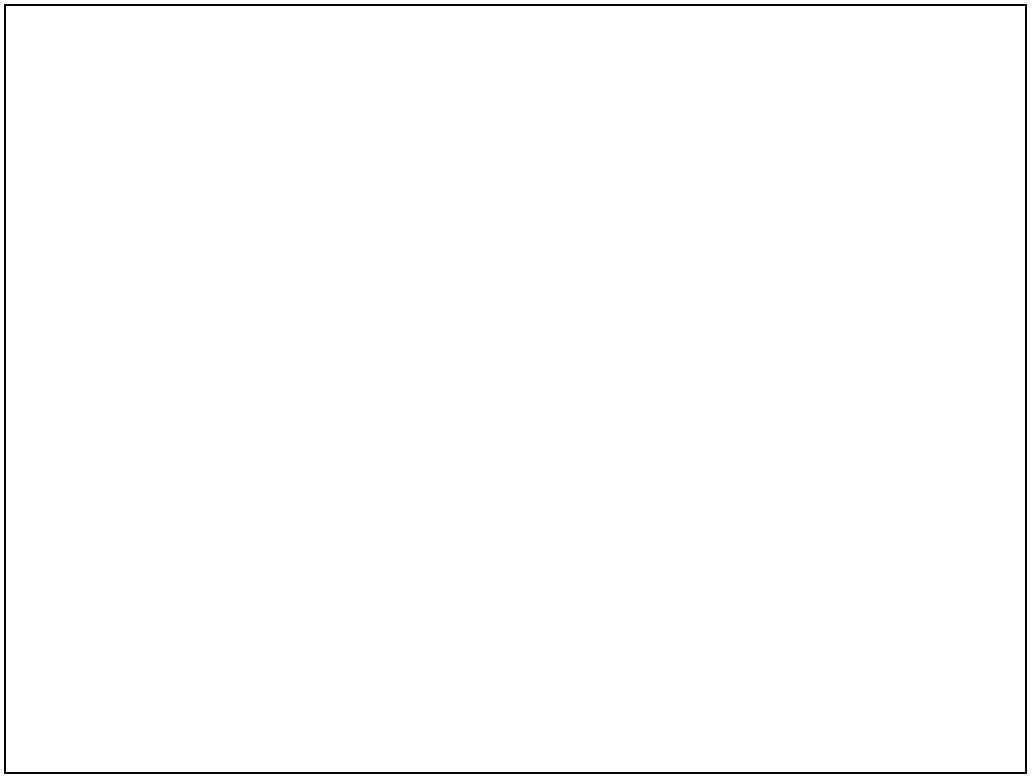


Figure 1-14. Overview Screen - Startup Mode

All the parameter values and functions pre-set during machine configuration and available Action/Function buttons are displayed in the working area.

The operator can select which procedure to perform as described in the following sections of this Operator's Manual. The specific function of each Action/Function button is explained as well as the operations to be carried out.

To switch from a screen to another one press the corresponding NavPad button on the NavPad Area (refer to the "1.4.1 NavPad Area" section of this chapter).

1.4.1 NavPad Area

The cruciform NavPad Area contains five NavPad buttons:

Figure 1-15. NavPad Area

Each screen is associated with a colour and an icon reproduced on the related button:

Table 10: NavPad buttons

NavPad buttons	
	The Overview NavPad button opens the **Overview screen** (refer to the "1.4.3 Overview Screen" section of this chapter for further details). The screen is associated with the blue colour.
	The Prescription NavPad button opens the **Prescription screen** (refer to the "1.4.4 Prescription Screen" section of this chapter for further details). The screen is associated with the light blue colour.

Table 10: NavPad buttons

NavPad buttons	
	The Blood NavPad button opens the **Blood screen** (refer to the “1.4.5 Blood Screen” section of this chapter for further details). The screen is associated with the red colour.
	The Report NavPad button opens the **Report screen** (refer to the “1.4.7 Report Screen” section of this chapter for further details). The screen is associated with the yellow colour.
	The Fluid NavPad button opens the **Fluid screen** (refer to the “1.4.6 Fluid Screen” section of this chapter for further details). The screen is associated with the green colour.

The frame of each screen has the same colour of the corresponding NavPad button.

When a screen is opened, the corresponding NavPad button is highlighted.

NOTE

When the Function sub-screens are opened the NavPad buttons are disabled.

1.4.2 Parameter Modification

The Artis Dialysis System user interface provides several button types:

- *Set button:* used for setting/change parameter values
- *Value box:* it displays the parameter values
- *Action button:* used for activating a function
- *Function button:* used for opening a Function sub-screen
- *Command button:* used for starting the next function

To set or change a parameter value, press the corresponding set button on the Touch Screen: according to the parameter type, the proper pop-up window will open.

The following windows are available:

- **Numeric Keypad:** it opens each time a set button related to a numeric value is pressed
- **Time Keypad:** it opens each time a set button related to a time value is pressed
- **Selectpad:** it opens each time it is possible to set the parameter value only selecting a predefined option from a list

NOTE

The pop-up windows will allow to insert only values included in the valid range established for the selected parameter.

1.4.2.1 Keypads

To change a time or a numeric parameter, proceed as follows:

1. Press the set button. The keypad opens:

- The parameter name and its current value are displayed;
- The unit of measurement is indicated.

2. Press the digit buttons to enter the new value:

- If an invalid value is entered, a popup window will open showing the allowed range.

NOTE

It is possible to change a value also using the increase/decrease buttons.
In this case the old value will be raised/reduced of a predefined amount.

- If the parameter is related to a rate (for ex. the “UF Volume” related to the “UF Rate”) the new calculated rate is also displayed on the keypad window.

3. Press the ***CONFIRM*** button to confirm the new value and close the keypad.

According to the parameter, the following buttons can also be available on the kaypad:

- The decimal "." and sign "+/-" buttons (only if they are allowed for the parameter);
- The "AM/PM" button (only if the machine is configured to display the time using this format).

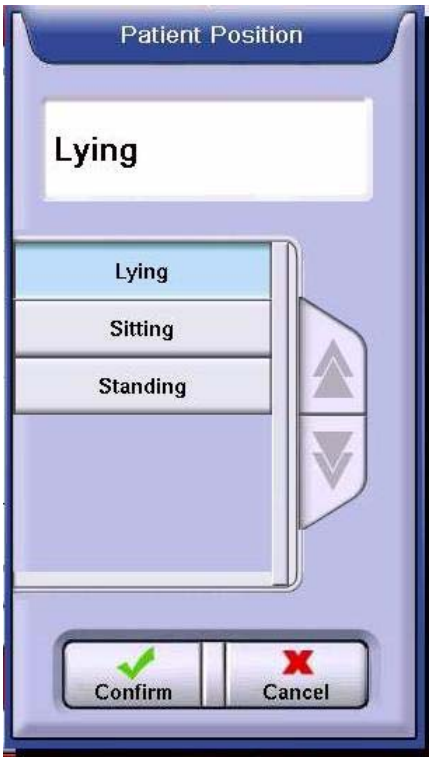
The "C"(Erase) button will erase the last character.

The ***CANCEL*** button will close the keypad without saving the new data.

1.4.2.2 Selectpad

Some parameter values can be changed only selecting the desired value from a predefined list:

1. Press the set button. The selectpad opens:



   - The parameter name and its current value are displayed;
   - The list of all the possible options is displayed.

2. Select the desired option from the list: it is possible to select only one value;
   - The selected value is marked in the list and is displayed in the text area.
3. Press the ***CONFIRM*** button to set the new parameter and close the window.

If the option list contains more than six elements, the “Scroll Buttons” will allow the operator to scroll the list.

The ***CANCEL*** button will close the keypad without saving the new data.

1.4.3 Overview Screen

When the machine is switched on or the Overview NavPad button is pressed, the following screen is displayed, with the proper configuration:

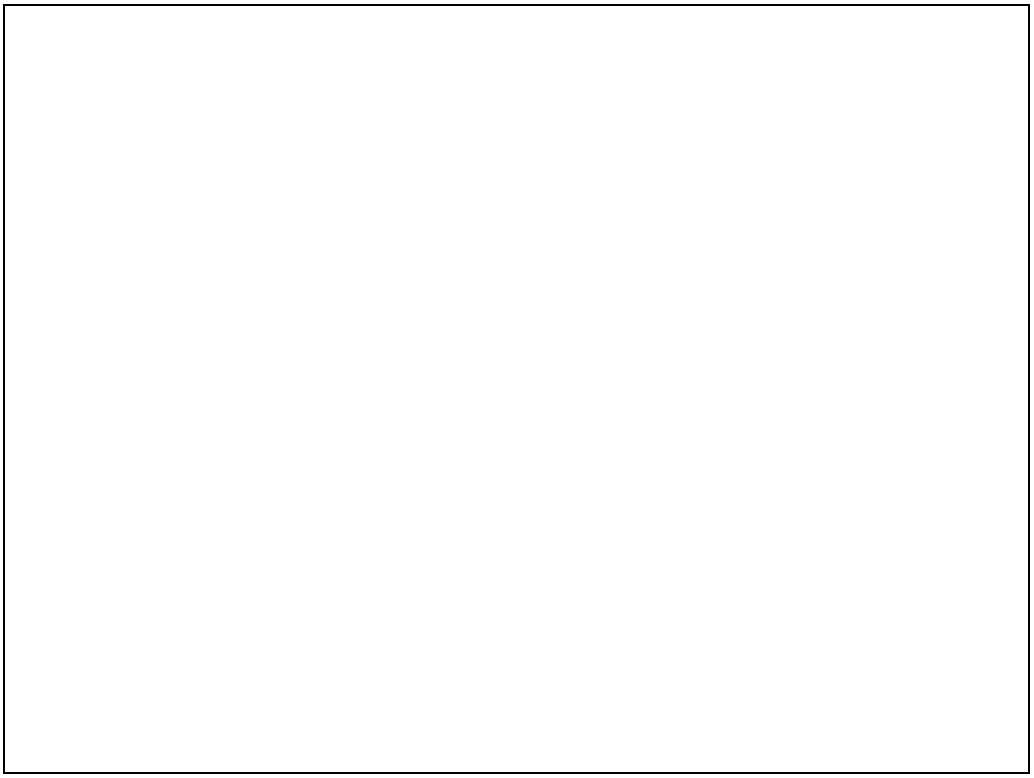


Figure 1-16. Overview Screen

The *Overview* screen can display the following elemets according to the machine/ treatment settings:

Table 11: Overview Screen Parameters

Parameters	
1. Remaining Time (h:mm) / Percent Complete (%)	Displays the remaining time/percentage of the ongoing process.
2. Arterial Pressure (mmHg)	Displays the Arterial Pressure Alarm Limit window
3. Venous Pressure (mmHg)	Displays the Venous Pressure Alarm Limit window

Table 11: Overview Screen Parameters

Parameters	
4. Blood Flow (mL/min)/Qb (mL/min)/Mean Blood Flow (mL/min)	Displays two values: • In the middle of the button, the Actual blood flow rate/pump speed value, during HD Treatments and HDF Post Treatments. During HD-SN Treatment this button displays the actual Mean Blood Flow value. • At the top right corner, the blood flow rate, pump speed value or mean blood flow set by the operator
5. Stroke Volume (mL) *(Only in HD-SN Treatment)*	Displays the actual Stroke Volume during HD-SN Treatment
6. Acc Priming Volume	Displays the volume processed during the priming process
7. Acc Rinseback Volume	Displays the volume processed during the rinseback process
8. Pre Dialyzer Pressure	Displays the current pre dialyzer pressure
9. TMP	Displays the current TMP pressure
10. QF/QB	Displays the ratio between the total UF Rate and the actual Blood Flow rate
11. UF Rate (L/h)	Displays the calculated UF Rate
12. Acc UF Volume (L)	Displays the accumulated UF Volume
13. Flow Path Diagram	Displays the blood and dialysis fluid flow status

Table 12: Overview Screen Buttons

Buttons	
1. Expand A/V Limits/ Close A/V Limits	Expand the A/V pressure alarm limit windows/Adjustes and closes the arterial and venous pressure limits
2. Unload Cassette	Starts the unloading cassette procedure
3. BPM	Starts/Stops the BPM function
4. Connect Patient	Allows the patient connection procedure. This button needs to be confirmed
5. Reconnect Patient	Allows the patient connection at the end of the Pause Treatment procedure. This button needs to be confirmed

Table 12: Overview Screen Buttons

Buttons	
6. Special Procedures	Allows special procedures during treatment session
7. Continue Treatment	Resumes the treatment after that the “Stop Treatment” button has been pressed
8. New Treatment	Starts a new dialysis session
9. Start Treatment	Starts the dialysis session
10. Stop Treatment	Stops the treatment session
11. Disconnect Patient	Allows the patient disconnection procedure. This button needs to be confirmed
12. Dialysis Fluid	Starts/Stops the dialysis fluid flow through the dialyzer
13. Drain Cartridge	Starts the cartridge draining procedure
14. Empty Circuit	Starts the emptying of the extracorporeal circuit.
15. UF	Activates/Deactivates the ultrafiltration process
16. Resume Treatment	Resumes treatment after the Pause Treatment procedure
17. Auto-Prime	Starts/Stops the priming procedure
18. Extra Prime	Starts/Stops the Extra Priming procedure
19. Extra Rinseback	Starts/Stops an additional rinseback procedure
20. Rinseback	Starts/Stops the rinseback process
21. Disinfect / Rinse	Opens the *Disinfec/Rinse Settings* sub-screen

Table 13: Icons

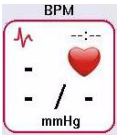
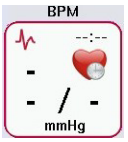
Icons[a]	
	***Heparin.*** This icon is displayed on the top of the Blood Flow Path.
	***Hemoscan.*** This icon appears on the left side of the *Overview* screen when the Hemoscan function is activated.
	***Diascan.*** This icon appears on the right side of the *Overview* screen when the Diascan function is activated.
	***Hemocontrol.*** This icon appears on the right side of the *Overview* screen when the Hemocontrol function is activated.
	***Manual BPM***. This icon appears on the left side of the screen when a single BPM measure is activated. The beating heart in the icon means that the BPM measurement is ongoing.
	***Automatic BPM.*** This icon appears when an automatic BPM measurement type is activated. The beating heart in the icon means that the BPM measurement is ongoing.
	***Isolated UF***. This icon appears on the *Overview* screen when the Isolated UF function is activated.
	***Low Consumption State.*** This icon appears on the *Overview* screen when the Low Consumption State function is activated.
	***Ultra Control.*** The green Ultra Control icon indicates that the Ultra Control scan function is activated. In particular: The Ultra Control icon is green and blinking when: • A manual Ultra Control scan is activated; • An automatic Ultra Control scan starts. After an automatic Ultra Control scan the Ultra Control icon becomes green and fixed to indicate that: • The TMP value has been automatically found by the machine; • The current Ultra Control modality is the automatic one.

Table 13: Icons

Icons[a]	
	***Ultra Control.*** The Ultra Control icon is grey when one of the following conditions occurs: • In case of automatic Ultra Control modality active, the grey fixed icon replaces the green and fixed one when the automatic modality is disabled to indicate that the TMP has been automatically found by the machine and that the current Ultra Control modality is the manual one • In case of manual Ultra Control scans, after every scan, the grey fixed icon replaces the blinking one to indicate that the TMP has been automatically found by the machine and that the current Ultra Control modality is the manual one.
	***AFB K Profile.*** [b] If the AFB K Treatment in K Profile mode is selected, this icon appears on the right side of the *Overview* screen as soon as the "K Initial" and the "K Final" parameters are confirmed.

a. Icons are displayed on the *Overview* screen when the related functions are activated and disappear when the functions are deactivated

b. To make the K Profile function available during the AFB K Treatment, the "K Profile Use" option has to be set as "YES" in the Service 2 menu.

1.4.3.1 Flow Path Diagram

The Flow Path Diagram is a graphical object, always displayed on the *Overview* screen, which shows the status of blood and dialysis fluid flows during all machine/treatment phases.

The Flow Path Diagram is made of two main paths:

1. ***Blood Path***, on the left side of the diagram, that represents the status of the blood flow;

2. ***Dialysis Fluid Path,*** on the right side of the diagram, that represents the status of the dialysis fluid flow.

Below the main flow path diagram configurations are described:

Table 14: Flow Path Diagram

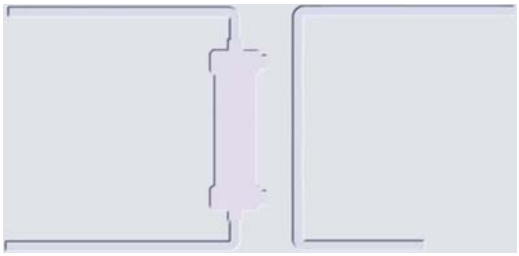
Flow Path Diagram	
	**Startup Mode** The diagram has this configuration when the machine has been switched on and it is performing the function checks. The Blood Cassette and concentrates are not yet attached.

Table 14: Flow Path Diagram

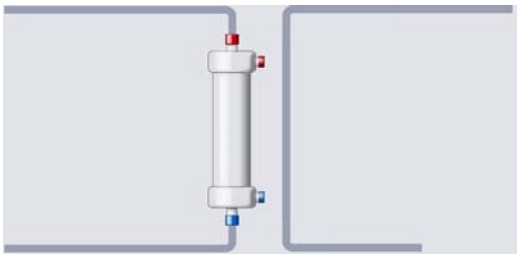
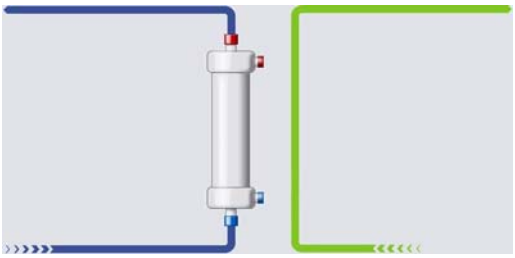
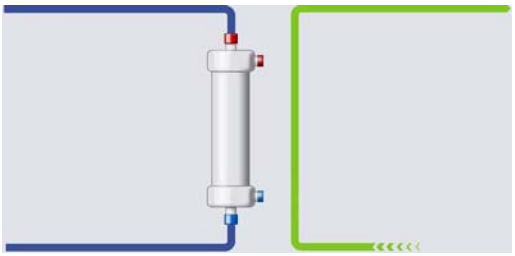
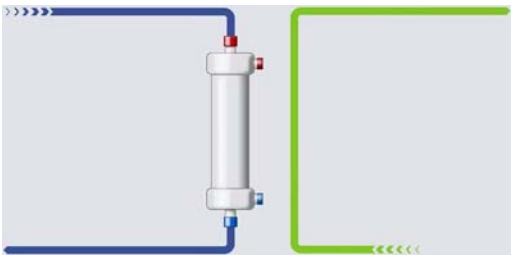
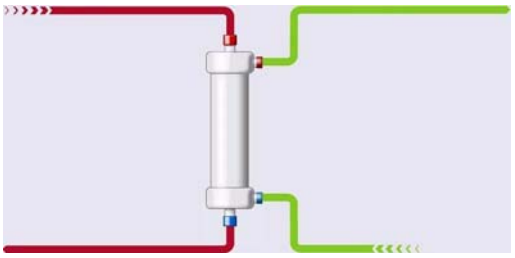
Flow Path Diagram	
	**Preparation/Emptying** The diagram has this configuration when the machine enters the Preparation mode and the Blood Cassette is attached or when the emptying of the concentrates is ongoing.
	**Priming phase** The diagram has this configuration when the machine is performing the priming process.
	**Priming/Rinseback accomplished** The diagram has this configuration when the first priming has been successfully accomplished or when the rinseback process is ended.
	**Patient connected** The diagram has this configuration when the patient has been connected but the machine has not detected blood yet.
	**HD Treatments** The diagram has this configuration when a HD treatments is ongoing.

Table 14: Flow Path Diagram

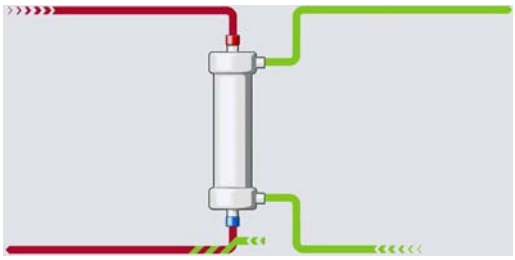
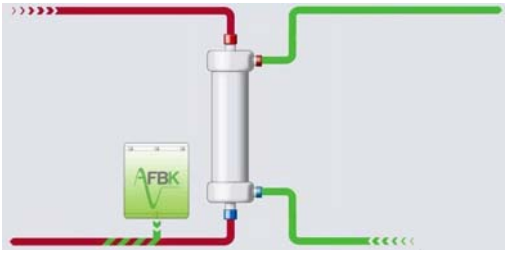
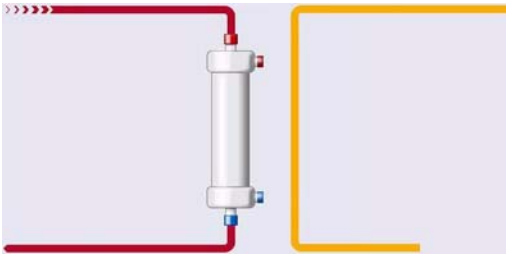
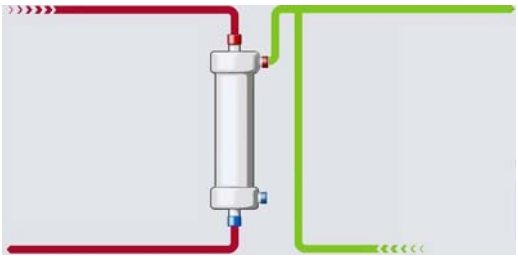
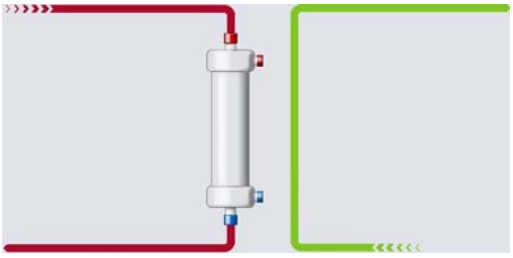
Flow Path Diagram	
	**HDF Post Treatment** The diagram has this configuration when a HDF Post Treatment is ongoing.
	**AFB K Treatment** The diagram has this configuration when an AFB K Treatment both in K Constant and K Profile mode is ongoing.
	**Incorrect Fluid composition** The diagram has this configuration when an alarm related to incorrect fluid composition is triggered during a treatment
	**Dialysis Fluid Deactivated** The diagram has this configuration when the *Dialysis Fluid* button is deactivated during a treatment
	**Rinseback** The diagram has this configuration during the rinseback process.

Table 14: Flow Path Diagram

Flow Path Diagram	
	**Chemical Disinfection** The diagram has this configuration during a disinfection program.
	**Heat Disinfection** The diagram has this configuration during a heat disinfection program.
	**Rinse** The diagram has this configuration during a rinse process.

1.4.4 Prescription Screen

When a patient's card is used or the Prescription NavPad button is pressed, the following screen is displayed:

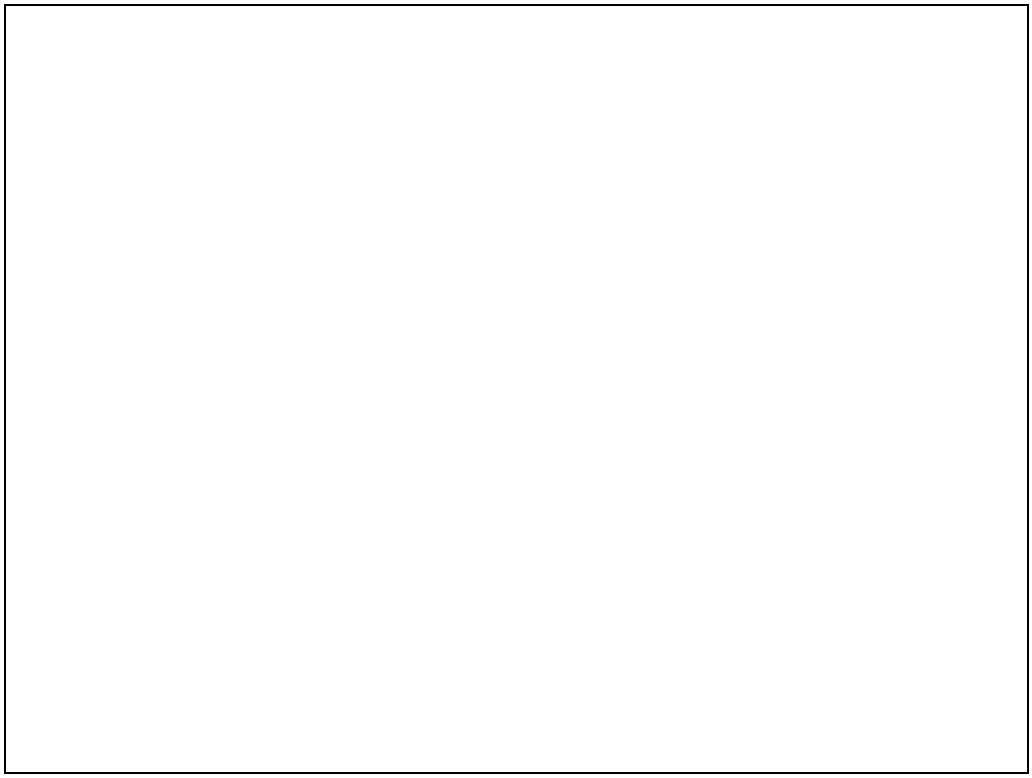


Figure 1-17. Prescription Screen

The *Prescription* screen can display the following parameters and buttons according to the treatment settings:

Table 15: Prescription Screen Parameters

Parameters	
1. Treatment Type	Displays the type of current treatment.
2. Needle Mode	Displays the type of needle mode selected for the current treatment.
3. Parameter Value List	Displays the list of parameters related to the current treatment
4. Activated Functions List	Displays the list of functions that can be activated for the current treatment. Each time a new function is activated the related action indicator switches to green.

Table 16: Prescription Screen Buttons

Buttons	
1. Treatment	Opens the Treatment Settings sub-screen

Table 16: Prescription Screen Buttons

Buttons	
2. Pt. Card Edit	Opens the Patient Card Edit sub-screen
3. Distrib Vol Settings	Opens the Distribution Volume Settings sub-screen
4. Timer Settings	Opens the Timer Settings sub-screen
5. Patient ID	This button is active only if the Exalis feature has been enabled in the Service menu. It opens a keyboard where Patient ID can be entered to download patient prescription parameters from the Exalis system, if available.

1.4.4.1 Timer Settings

The timer setting function allows to display a reminder message on the Alarm/ Information Messages Area when a predefined timer expires.

Up to 3 reminder messages can be set at the same time.

To set the message and the time proceed as follows:

1. On the *Prescription* screen press the "Timer Settings" button. The following sub-screen opens:

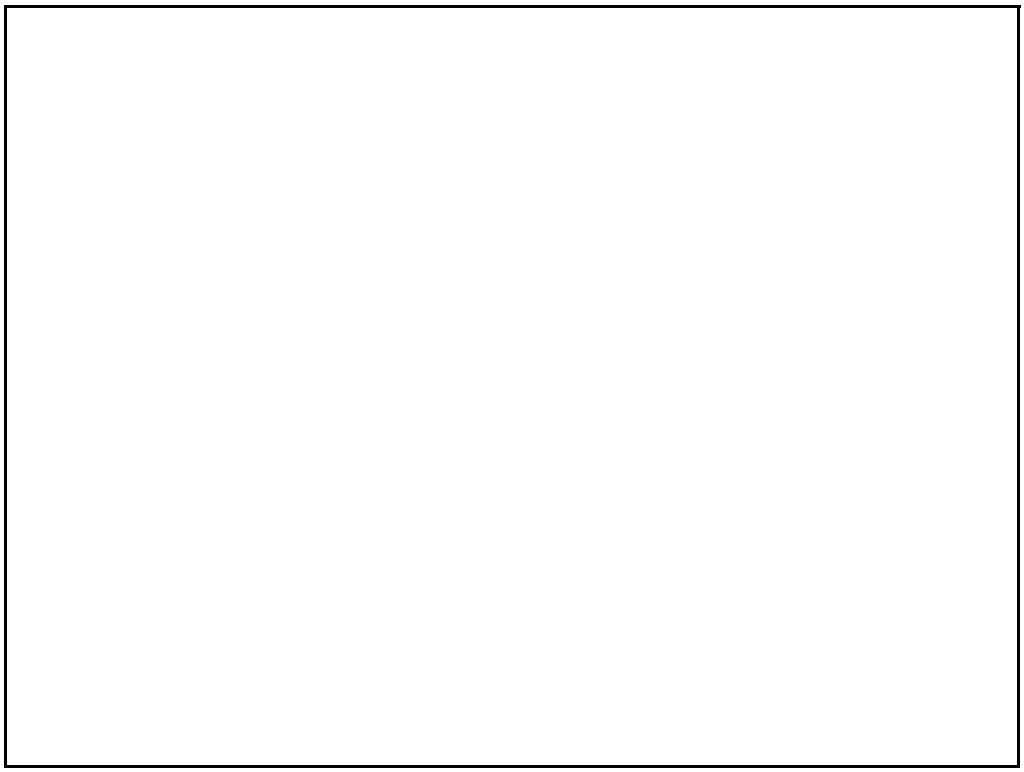


Figure 1-18. Timer Settings Sub-screen

2. Press the "Timer Reminder" button: a numeric keypad opens;

3. In the keypad enter the desired time and press the ***CONFIRM*** button;

4. Press the “Message to display when the Timer Expires” button: a Keyboard opens;

5. Write the reminder message and press the ***CONFIRM*** button to set the reminder message;

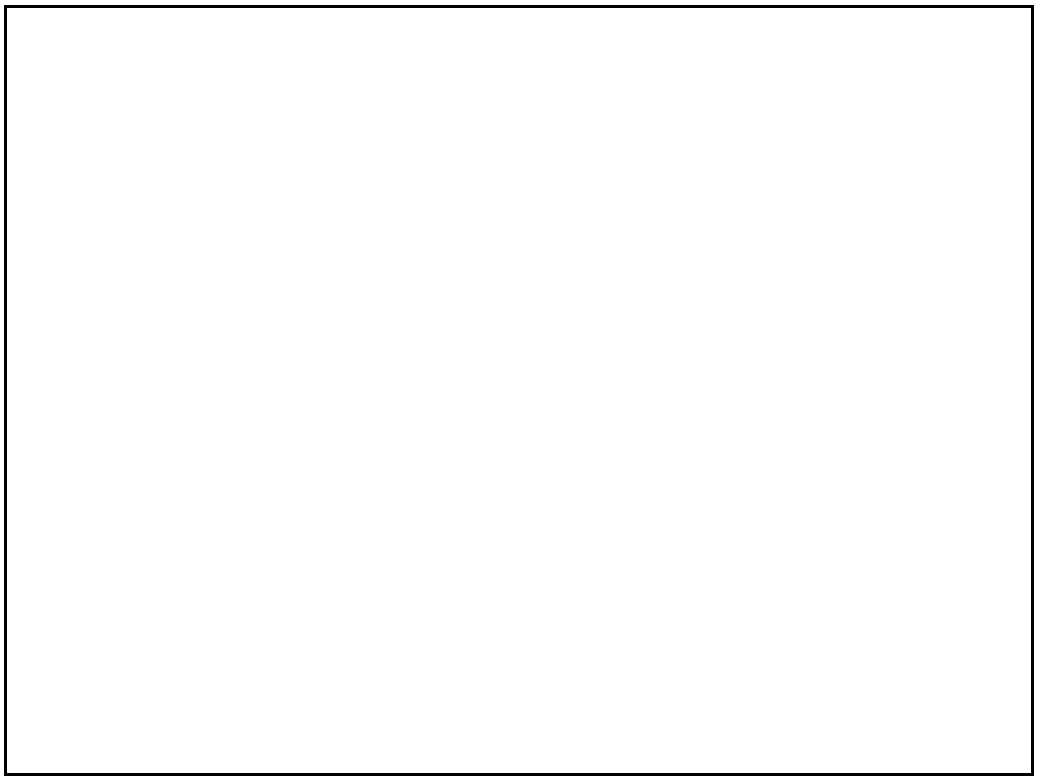
6. Press the “Activate” button to activate the function:

   • The “Activate” button switches to “Deactivate” button;

   • The “Deactivate” action indicator switches to green;

   • The “Time Remaining” value starts decreasing;

   • The Timer Settings sub-screen is displayed as follows:



   • The timer icon is displayed on the *Overview* screen.

   Up to 3 reminder messages can be set at the same time.

7. If needed, press the “Repeat” button to repeat the activation of the timer function once the set timer expires:

   • The “Repeat” action indicator switches to green.

8. Press the ***CLOSE*** button to switch to the *Prescription* screen.

When the set time expires:

- The reminder message will be displayed on the Alarm/Information Messages Area;
- A ***CONFIRM*** button will be displayed on the Alarm/Information Messages Area;
- The "Deactivate" button switches to "Activate" button;
- The "Activate" action indicator switches to grey;
- The timer icon on the *Overview* screen is hidden.

9. Press the ***CONFIRM*** button to erase the message.

1.4.5 Blood Screen

When the Blood NavPad button is pressed, the following screen is displayed:

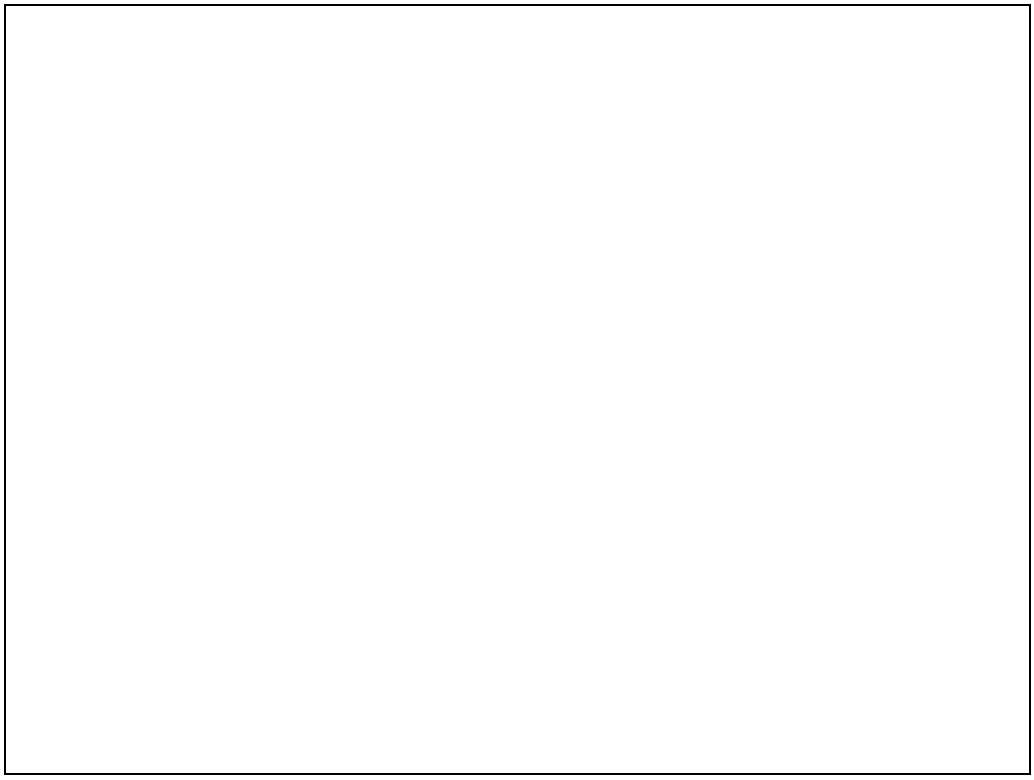


Figure 1-19. Blood Screen

On the *Blood* screen the following parameters and buttons can be displayed according to the treatment settings:

Table 17: Blood Screen Parameters

Parameters	
1. Blood Flow (mL/min)/ Mean Blood Flow (mL/ min)	Displays the actual blood flow/mean blood flow rate
2. Accumulated Blood Volume (L)	Displays the accumulated volume of treated blood
3. Post-dialyzer Pressure *(Only in HD-DNDP Treatment)*	Displays the Post-dialyzer pressure in HD-DNDP Treatment
4. Arterial Pressure (mmHg)	Displays the current arterial pressure
5. Venous Pressure (mmHg)	Displays the current venous pressure

Table 17: Blood Screen Parameters

Parameters	
6. Stroke Volume (mL) *(Only in HD-SN Treatment)*	Allows to set the stroke volume in HD-SN Treatment.
7. Arterial Pressure Bargraph	Allows to set the arterial pressure high and low alarm limits
8. Venous Pressure Bargraph	Allows to set the venous pressure high and low alarm limits
9. Pressure Graph	Displays the arterial and venous pressure curves during treatment

Table 18: Blood Screen Buttons

Buttons	
1. BPM Settings	Opens the BPM Settings sub-screen
2. A/V Limit Settings	Opens the A / V Limit Settings sub-screen
3. Expand A/V Limits/ Close A/V Limits	Expand the A/V pressure alarm limit windows/Adjustes and closes the arterial and venous pressure limits
4. Hemoscan Settings	Opens the Hemoscan Settings sub-screen
5. Heparin Settings	Opens the Heparin Settings sub-screen
6. Blood Settings	Opens the Blood Settings sub-screen
7. Priming Settings	Opens the Autopriming Settings sub-screen
8. Rinseback Settings	Opens the Rinseback Settings sub-screen

1.4.6 Fluid Screen

When the Fluid NavPad button is pressed, the following screen is displayed:

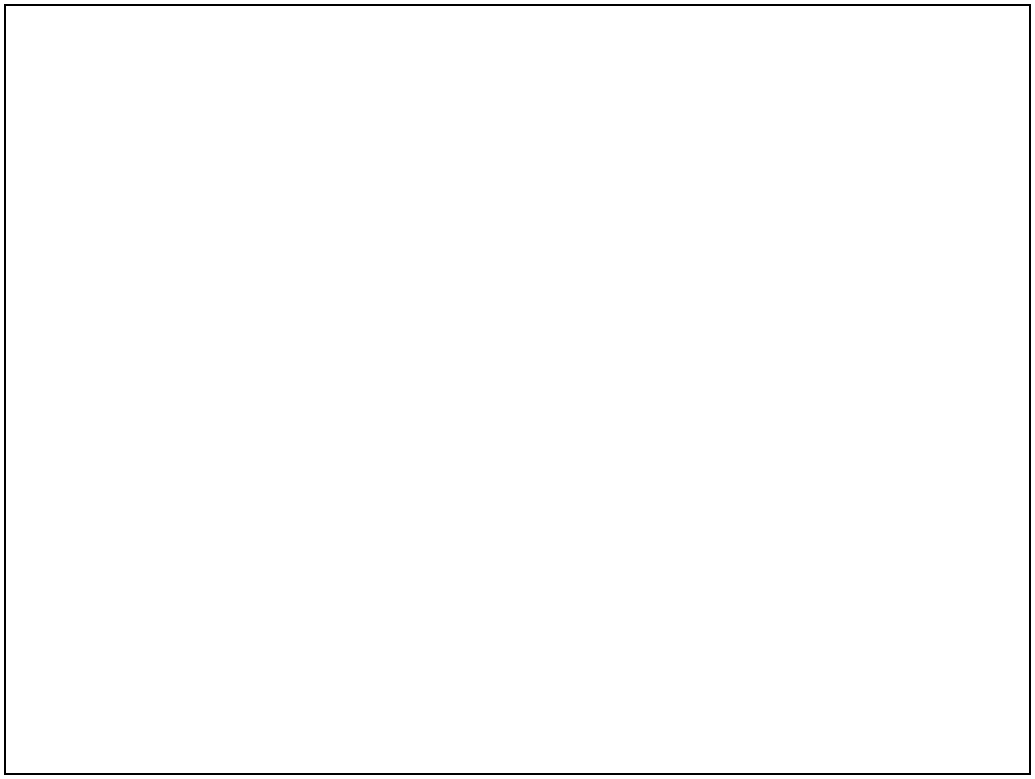


Figure 1-20. Fluid Screen

On the *Fluid* screen the following parameters and buttons can be displayed according to the treatment settings:

Table 19: Fluid Screen Parameters

Parameters	
1. Real TX Time (h:min)	Displays the effective treatment time (without bypass time)
2. Acc UF Volume (L)	Displays the accumulated UF Volume
3. Acc Online Bolus (mL)	Displays the total amount of substitution fluid boluses delivered during the treatment.
4. UF Rate (L/h)	Displays the calculated UF Rate
5. Acc Subst Vol (L)	Displays the total amount of substitution fluid delivered during the treatment.
6. Estimated Substitution Vol. (L)	Displays the estimated infused volume of substitution fluid.
7. TMP Actual (mmHg)	Displays the actual TMP pressure
8. Actual Substitution Rate	Displays the actual rate of the substituion volume

Table 19: Fluid Screen Parameters

Parameters	
9. Graph	Displays the TMP pressure and UF curves during treatment
10. Treatment Time (h:min)	Sets the total treatment time
11. UF Volume (L)	Sets the UF Volume value
12. Online Bolus Volume (mL)	Sets the amount of substituion fluid that is delivered each time the "Online Bolus" button is pressed.
13. TMP Set (mmHg)	Sets the TMP value.
14. Online Substitution Rate (mL/min)	Sets the Substitution Flow Rate, expressed in mL/min, based on the Blood Flow rate and the UF Rate, and depending on the hematocrit and the protein content of the patient's blood.

Table 20: Fluid Screen Buttons

Buttons	
1. Fluid Settings	Opens the Fluid Settings sub-screen
2. Diascan Settings	Opens the Diascan Settings sub-screen. This button becomes available after the Diascan function has been activated.
3. Hemocontrol Settings	Opens the Hemocontrol Settings sub-screen. This button becomes available after the Hemocontrol function has been activated.
4. Ultra Control Settings	Opens the Ultra Control Settings sub-screen.
5. Online Bolus	Delivers the amount of substitution fluid displayed on the "Online Bolus" set button.

1.4.7 Report Screen

When the Report NavPad button is pressed, the following screen is displayed:

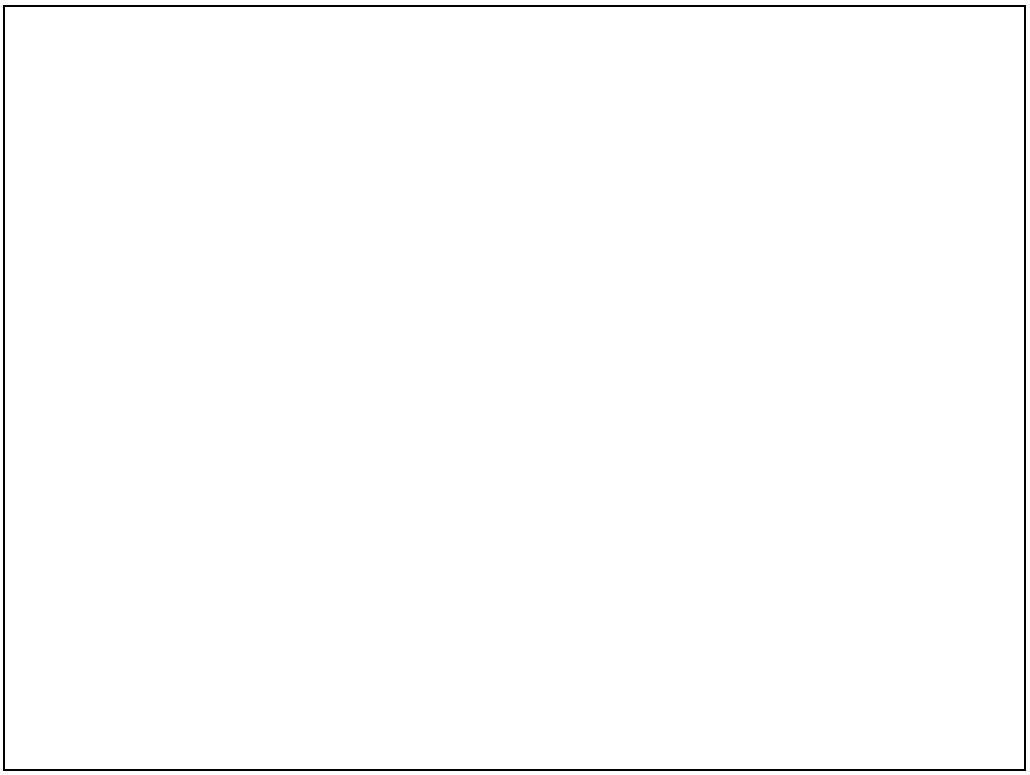


Figure 1-21. Report Screen

On the *Report* screen the following elements are displayed:

Table 21: Report Screen Parameters

Parameters	
1. Event List	Displays a list of the automatic and manual readings

Table 22: Report Screen Buttons

Buttons	
1. Print Me	Allows the operator to create the Print Me Report file.
2. New Reading	Performs an additional reading of the current treatment parameters
3. New Event	Opens the *Event* sub-screen
4. Blackbox	Opens a keypad to enter the password that allows to switch to the *BlackBox* environment
5. Hygiene	Opens the *Hygiene* sub-screen

Table 22: Report Screen Buttons

Buttons	
6. LCD Test	Allows the operator to perform the test of the Touch Screen pixels
7. Screen Cleaning	Allows the operator to clean the Touch Screen
8. System Data	Opens the Service pages where machine data are displayed
9. Service	Opens a keypad to enter the password that allows to switch to the Service menus.

For further details on this screen refer to the "Chapter 15: Report Environment" of this Operator's Manual.

1.5 Ultrafiltration Control System

During treatments the UF Rate is always calculated according to the following formula:

$$\text{UF Rate} = \frac{\text{UF Volume}}{\text{Treatment Time}}$$

where Ultrafiltration volume means the total patient weight loss during treatment and UF Rate means patient weight loss per time unit.

Treatment time and UF volume can be set by the operator within predefined limits and the UF Rate is automatically calculated each time these two parameters are changed during a treatment.

The Artis Dialysis System Control System controls the UF Rate in order to keep constant the UF volume set by the operator throughout the treatment.

If the Artis Dialysis System is not able to achieve the set UF volume within the remaining time, an attention alarm is triggered. For the troubleshooting of this alarm, refer to the related section in the "Chapter 16: Alarms, Information Signals and Troubleshooting" of this Operator's Manual.

In HDF Post Treatment in volume control mode, also the TMP will be automatically controlled by the Artis Dialysis System in order to achieve the desired UF Rate

The upper alarm limit for the TMP can be set by the operator on the *Fluid* screen. For further information, refer to the related section in the "Chapter 17: Specifications" of this Operator's Manual.

1.5.1 Protective System for Ultrafiltration

The protective system for ultrafiltration, also called the UF Supervision system, measures the accumulated ultrafiltration volume during a treatment independently by the control system mentioned in the section above.

Troughout the treatment, the actual accumulated UF Volume estimated by the Protective system will be compared with the expected patient weight loss set by the operator. If the difference between these two values exceeds a predefined limit, an alarm is triggered. For further information, refer to the related section in the "Chapter 17: Specifications" of this Operator's Manual.

For a complete list of all the alarms related to the UF Supervision system and their troubleshootings, refer to the "Chapter 16: Alarms, Information Signals and Troubleshooting" of this Operator's Manual.

1.6 Function Checks

The Artis Dialysis System automatically carries out a series of function checks in order to check all the components and processes that make a dialysis treatment safe.

The most of the function checks are performed each time the Artis Dialysis System is switched ON, before the patient connection phase.

If the machine is properly configured, the "Temperature" and "Conductivity Cell sensors" Function Checks can be performed before the first treatment of the day and skipped for the following three treatments in the same day, thus reducing the dialysis fluid preparation time. The skipped Function Checks do not affect in any way the safety of the Artis Dialysis System. However, a complete sequence of all the function checks will be always performed:

- At least once a day;
- After the "Temperature" and "Conductivity Cell sensors" Function Checks have been skipped for three consecutive patient connections;
- If a "Data Correctness Check Failure (#630)" alarm is triggered.

The "Conductivity Cell sensors" Function Check will be always performed if the type of concentrate used is different from the one used for the previous treatment. In particular, the check is performed if, for example, the current treatment uses a BiCart/BiCart Select concentrate while the previous treatment used AFB/AFB K concentrates or viceversa.

When the Function Checks are in progress, the "Function Check in progress..." operator message is displayed.

The Function Checks are interrupted and restarted when:

- an alarm is triggered by the machine;
- the operator loads/unloads a Blood Tubing System;
- a special procedure is performed.

To avoid interrupting the Function Checks excution, do not operate the machine when the "Function Check in progress..." operator message is displayed.

The list of all the function checks performed by the machine is available on the Service Data pages.

The list of the function checks is the following:

Table 23: Function Checks

	Test	Description	Failure results
1	CPU	Tests the CPU proper conditions.	The machine stops.
2	EEPROM	Tests congruency of CRC values.	The machine stops.
3	Arterial pump/ AD sensor	Tests the proper functioning of the Arterial Pump and of the Air Detector.	The machine repeats the test after the alarm has been confirmed by the operator.
4	RAM	Tests the RAM proper working conditions.	The machine stops.

Table 23: Function Checks

	Test	Description	Failure results
5	Battery	Tests the battery charge level.	An alarm is triggered.
6	Acustical Buzzer Test	Tests the acustic buzzer proper functioning. *(See* **WARNING 1** *below)*	An alarm is triggered
7	Acustical Speaker Test	Tests the acustic speaker proper functioning. *(See* **WARNING 1** *below)*	An alarm is triggered.
8	Visible T1 Test	Tests the status lights proper functioning. *(See* **WARNING 2** *below)*	None
9	Cut 24 Volt	The system tests its capability to switch the 24 volt supply OFF.	The machine stops.
10	Venous Line Clamp	Tests the Venous Line Clamp proper functioning.	The machine stops.
11	Switch sensors	Tests the proper functioning of the line presence sensors located in the Venous and Arterial Line clamps and in the Sensor Bar.	The machine prevents to proceed with Dialysis Fluid preparation phase until the test has been successfully accomplished. The operator will be forced to unload the cassette and then load it again.
12	Valves Command	Tests the proper functioning of the hydraulic valves command.	The machine stops.
13	Temperature	Tests the temperature sensors	The machine repeats the test after the alarm has been confirmed by the operator.
14	Conductivity Cell sensors (A, B, Sel)	Tests the right functioning of the cell sensors	The machine repeats the test after the alarm has been confirmed by the operator.
15	Flowmeters test	Tests the Flowmeters proper functioning	The machine repeats the test after the alarm has been confirmed by the operator.
16	Blood Leak Detector (BLD)	Tests the Blood Leak Detector functioning	The machine stops

Table 23: Function Checks

	Test	Description	Failure results
17	Venous pressure sensor	Tests the proper functioning of the sensor that measures the Venous Pressure.	The machine repeats the test after the alarm has been confirmed by the operator and the cassette has been unloaded and then loaded again.
18	Arterial Pressure sensor	Tests the proper functioning of the sensor that measures the Arterial Pressure.	The machine repeats the test after the alarm has been confirmed by the operator and the cassette has been unloaded and then loaded again.
19	Pre-dialyzer pressure sensor	Tests the proper functioning of the sensor that measures the Pre-dialyzer Pressure.	The machine repeats the test after the alarm has been confirmed by the operator and the cassette has been unloaded and then loaded again.
20	Sharp Temperature	Tests the Dialysis Fluid Temperature	The machine repeats the test after the alarm has been confirmed by the operator.
21	FPGA Test	Tests that the FPGA is properly working.	The machine stops
22	Water Presence Test	Tests the proper functioning of the sensor that detects the presence of excessive water (Wet Sensor).	The machine stops
23	Pinch Valve Test *(Only in HDF Post Treatment)*	Tests the proper functioning of the Automatic Pinch Valve	The machine stops

⚠ WARNING 1

If both the Acustical Buzzer T1 Test and the Acustical Speaker T1 Test fail (both the auditory signal sources are malfunctioning), a malfunction occurs so that it is not possible to use the Artis Dialysis System. In this case, call for Service Technician.
If only one of the T1 Tests fails (only one of the auditory signal source is malfunctioning), it is the operator's responsibility to decide whether to proceed with the current treatment after having checked that the machine is able to sound properly. Also in this case, call for Service Technician to troubleshoot the problem as soon as possible.

⚠ WARNING 2

During the Visible T1 Test, check that a brief visual signal is triggered by the machine (Status Lights at the top of the machine lighten with red and yellow lights).
If the visual signal is not triggered, the signalling device (Status Lights) is malfunctioning. In this case, call for Service Technician.
DO NOT use the Artis Dialysis System in the absence of the visual alarm signal.

1.7 A/V pressure alarm limit settings

The arterial and venous pressure alarm limits can be set: on the *Overview* screen, on the A / V Limit Settings sub-screen and on the *Blood* screen.

The pressure alarm limits can be set/changed by the operator during the treatment within predefined ranges, as detailed in the sections below.

1.7.1 Low/High A/V Limit Settings

To change the upper and lower alarm limit values, proceed as follows:

1. Open the *Blood* screen:

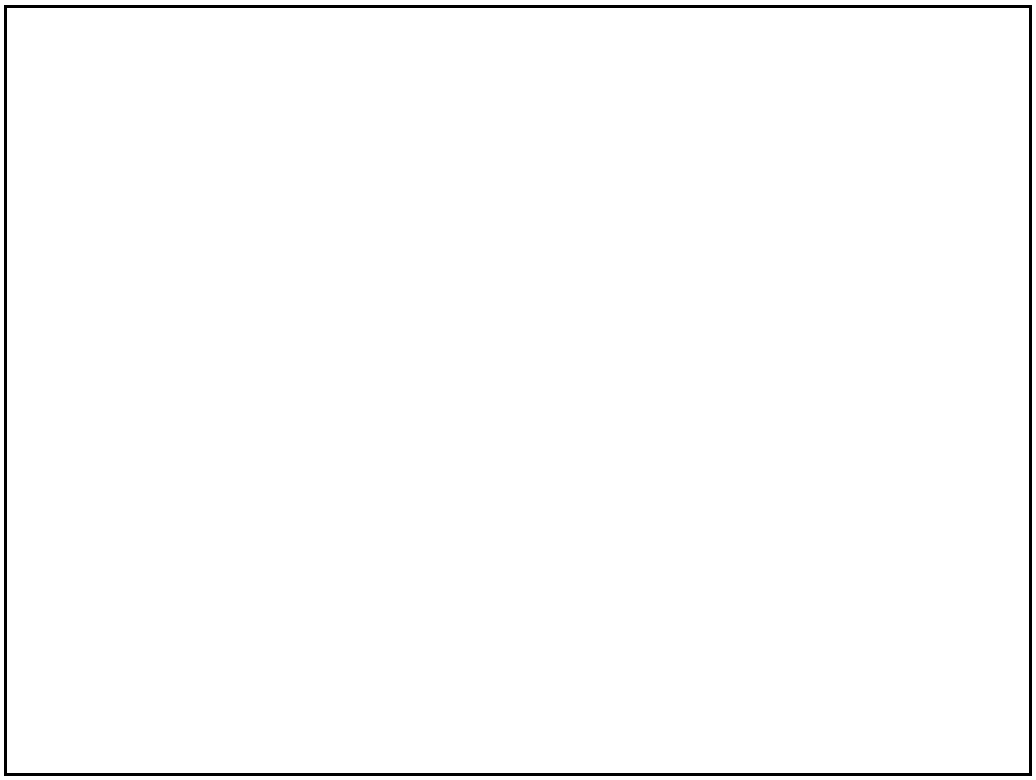
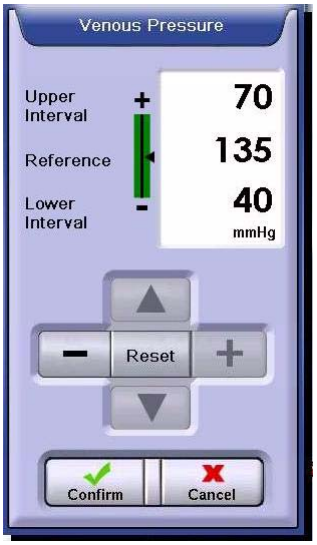


Figure 1-22. Blood Screen

2. Press on the arterial or venous pressure bargraph: the following keypad opens:



- The “Reference” value displays the current arterial/venous pressure.
- The “Upper Interval” value defines the upper interval within which the patient’s pressure is allowed to change without triggering alarms. The high arterial/venous pressure alarm limit will be calculated as: Reference Pressure Value + Upper Interval Value.

⚠WARNING

Setting the Upper Intervals of A/V alarm limits to their extreme values might render the Alarm Management System useless.
An improper setting of these intervals may prevent the Alarm Management System to detect possible alarm conditions related to air embolism in case of catheter or to blood loss.

- The “Lower Interval” value defines the lower interval within which the patient’s pressure is allowed to change without triggering alarms. The low arterial/venous pressure alarm limit will be calculated as: Reference Pressure Value - Lower Interval Value.

⚠WARNING

Setting the Lower Intervals of A/V alarm limits to their extreme values might render the Alarm Management System useless.
An improper setting of these intervals may prevent the Alarm Management System to detect possible alarm conditions related to mechanical damage of vascular access or to blood loss.

3. Press the "Plus / Minus" buttons to widen/restrict the arterial/venous alarm window, in steps of 5 mmHg. These buttons are dimmed when it is no more possible to widen or restrict the alarm limit window.

4. Press the "Arrow up / Arrow down" button to move the arterial/venous alarm limit window. This buttons are dimmed when it is no more possible to move the alarm limit window up or down.

5. Press the "***RESET***" button to reset the alarm window to the default arterial/ venous pressure alarm limit values.

6. Press the "***CONFIRM***" button to set the new alarm window values for the arterial/venous pressure.

The default values for the Upper and Lower limits of the arterial and venous pressures are the following:

Arterial Pressure	
Default Upper Limit	+ 60 mmHg
Default Lower Limit	- 60 mmHg

Venous Pressure	
Default Upper Limit	+ 70 mmHg
Default Lower Limit	- 40 mmHg

The upper and lower arterial and venous pressure alarm limits can be set only within the limits set for the Arterial and Venous Treatment Max/Min Limits.

It is possible to open the pressure keypad and set the upper/lower A/V pressure alarm limits also on the A / V Limit Settings sub-screen.

1.7.2 Max. and Min. Treatment Pressure Alarm Limits

To change the maximum and minimum treatment pressure limits, proceed as follows:

1. Open the A / V Limit Settings sub-screen, pressing the “A/V Limit Settings” button on the *Blood* screen:

Figure 1-23. A/V Limit ASettings Sub-screen

2. Press the “Ven Treatment Max Limit” button: a keypad opens. In the keypad, set the maximum limit allowed for the venous pressure during the treatment and press the ***CONFIRM*** button.

⚠WARNING

Setting the Ven Treatment Max Limit to its extreme values might render the Alarm Management System useless.
An improper setting of this limit may prevent the Alarm Management System to detect possible alarm conditions related to blood loss.

3. Press the “Ven Treatment Min Limit” button: a keypad opens. In the keypad, set the minimum limit allowed for the venous pressure during the treatment and press the ***CONFIRM*** button.

⚠WARNING

Setting the Ven Treatment Min Limit to its extreme values might render the Alarm Management System useless.
An improper setting of this limit may prevent the Alarm Management System to detect possible alarm conditions related to blood loss.

4. Press the "Art Treatment Max Limit" button: a keypad opens. In the keypad, set the maximum limit allowed for the arterial pressure during the treatment and press the ***CONFIRM*** button.

⚠WARNING

Setting the Art Treatment Max Limit to its extreme values might render the Alarm Management System useless.
An improper setting of this limit may prevent the Alarm Management System to detect possible alarm conditions related to air embolism in case of catheter or to blood loss.

5. Press the "Art Treatment Min Limit" button: a keypad opens. In the keypad, set the minimum limit allowed for the arterial pressure during the treatment and press the ***CONFIRM*** button.

⚠WARNING

Setting the Art Treatment Min Limit to its extreme values might render the Alarm Management System useless.
An improper setting of this limit may prevent the Alarm Management System to detect possible alarm conditions related to mechanical damage of vascular access.

It is also possible to set the Arterial/Venous treatment Max/Min. limits on the Parameter Value list on the *Prescription* screen.

1.7.3 A/V Pressure Alarm Limit Management

The Artis Dialysis System provides two ways to manage the A/V pressure alarm limits:

- A manual expand/close function
- An automatic expand/close function

1.7.3.1 Manually Expand/Close the pressure alarm limits

The Artis Dialysis System allows the operator to manually expand and close the pressure alarm windows using appropriate buttons, as detailed below.

The "Close A/V Limits" and the "Expand A/V Limits" action buttons will be available during the treatment on the *Overview* and on the *Blood* screens.

The "Expand A/V Limits" action button is available when the A/V pressure alarm limits are centralised around the current patient's pressures.

Open the arterial and venous pressure windows as follows:

1. Press the "Expand A/V Limits" action button:
   - The venous pressure alarm lower limit is automatically set to +10 mmHg;

- The venous pressure alarm upper limit is automatically set to +450 mmHg;
- The arterial pressure alarm lower limit is automatically set to -400 mmHg;
- The arterial pressure alarm upper limit is automatically set to +150 mmHg;
- The “Expand A/V Limits” button changes in “Close A/V Limits” button.

2. When the patient’s arterial and venous pressures are stable, press the “Close A/V Limits” button to redefine and close the arterial and venous pressures alarm limit windows.

It is necessary to manually close the A/V pressure limits in the following cases:

- At the beginning of a treatment, after the “Start Treatment” button has been pressed (refer to the “4.2 Start Treatment” section of this Operator’s Manual);
- After the A/V pressure limits have been manually expanded by the operator;
- At the end of the Fast Recovery special procedure, after the “Start Treatment” button has been pressed (refer to the “8.5 Fast Recovery” section of this Operator’s Manual);
- When the “Pressure Alarm Limits Still Expanded (#525)” alarm occurs (refer to the "Chapter 16: Alarms, Information Signals and Troubleshooting" of this Operator’s Manual).

1.7.3.2 Automatic Expand/Close of the pressure alarm limits

The A/V pressure alarm limits are automatically expanded and then closed by the Artis Dialysis System in the following cases:

- Each time the Arterial pump speed is increased/decreased;
- At the end of the Cassette Repositioning special procedure;
- After a venous or arterial pressure alarm has been solved;
- After an “Air in Venous Line (#4)” alarm has been solved.

1.8 Adjust the Arterial pump speed

It is possible to adjust the Arterial pump speed from the Hard Key panel, using the Blood Flow Increase/Decrease keys.

Each time the Arterial pump speed is adjusted during a treatment the arterial and venous pressure alarm limits are automatically expanded and set to the following values:

Arterial Pressure	
Maximum	+ 150 mmHg
Minimum	- 400 mmHg

Venous Pressure	
Maximum	+ 450 mmHg
Minimum	+ 10 mmHg

After 30 seconds (in HD-DN and HD-DNDP Treatments) or after 120 seconds (in HDF Post and AFB K Treatments) the Arterial pump speed has been adjusted, the arterial and venous pressure limits are automatically closed.

If the Arterial pump speed is set to zero by the operator, the machine will automatically set the UF rate to its minimum value.

When the Arterial pump speed is reset to a value greater than zero, the UFR returns to the value set by the operator.

⚠WARNING

A dedicated alarm (Low blood pump speed *#204*) exists in order to avoid blood loss due to coagulation resulting from interruption of blood flow.

1.9 Adjust the Mean Blood Flow in HD-SN Treatment

The Mean Blood Flow in a HD-SN Treatment can be adjusted in the following ways:

- Using the Blood Flow Increase/Decrease keys on the Hard Key Panel. In this case, the ratio Arterial Flow / Venous Flow is kept constant.
- During the treatment, using the “Arterial Flow” and “Venous Flow” buttons on the Blood Settings sub-screen. Each time the set Mean Blood Flow is changed during the treatment in this way the ratio Arterial Flow / Venous Flow is changed.

Each time the Mean Blood Flow is adjusted during a HD-SN Treatment, the arterial and venous pressure alarm limits are automatically expanded and set to the following values:

Arterial Pressure	
Maximum	+ 150 mmHg
Minimum	- 400 mmHg

Venous Pressure	
Maximum	+ 450 mmHg
Minimum	+ 10 mmHg

After 60 seconds the Mean Blood Flow has been adjusted, the arterial and venous pressure limits are automatically closed.

If the Mean Blood Flow is set to zero by the operator, the machine will automatically set the UF rate to its minimum value.

When the Mean Blood Flow is reset to a value greater than zero, the UFR returns to the value set by the operator.

⚠WARNING

A dedicated alarm (Low blood pump speed #204) exists in order to avoid blood loss due to coagulation resulting from interruption of blood flow.

1.10 Monitoring of Venous Pressure and Venous Needle Dislodgement

The Artis Dialysis System is provided with a venous pressure monitoring system able to trigger an alarm condition in case that the patient venous pressure falls below the venous pressure alarm threshold set by the operator.

User has to be aware that venous pressure monitoring system is not always able to detect the pressure drop caused by a venous needle dislodgement. This particular situation is described in the literature[1].

To reduce the risk related to a Venous Needle Dislodgement event, carefully follow the guidelines below:

1. Ensure that the venous needle and the venous patient line are adequately fixed to the patient according to your facility's protocol.

2. Make sure that the patient's access is visible at all times during the dialysis treatment.
   Do not cover the access with clothing, blankets, linens.

3. Visually inspect the patient's access frequently for needle security and site bleeding.
   Pay a special attention to patients who are moving a lot during the dialysis treatment.

4. Recommend patient to inspect its access site frequently.

5. Properly adjust the venous pressure alarm windows. In particular, it is recommended that the lower venous alarm limit is set as close as possible to the actual value of the patient venous pressure.

1. Sandroni S. Venous needle dislodgement during hemodialysis: An unresolved risk of catastrophic hemorrhage. Hemodialysis International (abstract) 2005; 9: 33-34.
   Medical Device Safety Reports. Undetected venous line needle dislodgement during hemodialysis.Health Devices 1998; 27: 404-406.

⚠WARNING

Monitoring of the Venous Pressure could not always detect the disconnection of a venous needle from its access site, which may result in extracorporeal blood loss to the environment. When a venous needle disconnects from its access, pressure at the venous monitoring side may only decrease by the pressure maintained within the patient's access site. This pressure drop may be less than the width of the machine's venous pressure alarm window: in this particular case the disconnection of a venous needle from its access site is not detectable by the machine, even if pressure alarms and alarm windows are properly set.

To reduce the risk of needles disconnection:

- ensure that venous needle and line are firmly secured to the access site area according to your clinic's protocol;
- ensure that the patient's access is visible at all times during the dialysis treatment;
- inspect frequently the patient's access;
- adjust properly the venous pressure alarm window: the venous pressure alarm lower limit should be set as closely as practical to the actual patient’s venous pressure value without generating excessive nuisance alarms.

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Chapter 2: Installation

This chapter contains instructions to install the Artis Dialysis System.

The installation of the machine has to be perfomed by a qualified Service technician.

2.1 Unpacking instructions

When unpacking the Artis Dialysis System, perform the following checks:

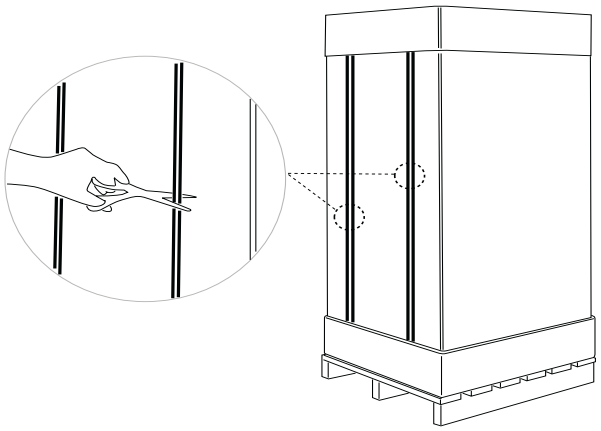
- The shipping container is not damaged;
- If the shipping container is damaged, notify the transporter before opening.

Carefully take the machine out of its packaging, proceeding as follows:

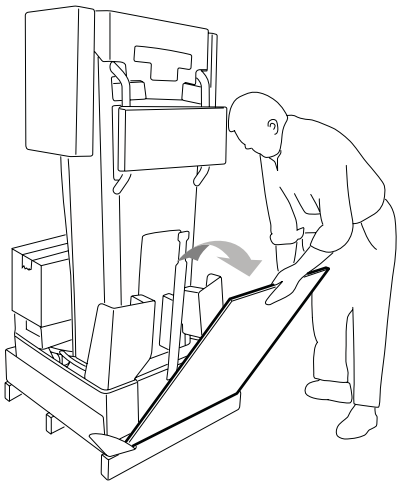
NOTE

The Artis Dialysis System shipping carton, foam packing and other packaging materials should be disposed of according to the local regulations.

1. Cut the strapping kit and remove the external protection (see A);
2. Pull down the panel on the rear side of the machine, as shown in the Figure B. Use it to pull the machine out of its packaging;
3. Remove the wrapping protections and the plastic bag (see C and D);
4. Remove the “Shipping List - Accessory Box” containing the components required to install the machine;
5. Gently raise the machine up and, at the same time, pull out the cartoon protection placed under the machine, to release the wheels (see E);
6. Release the brake of the lockable wheels by pulling all the locks completely up (see F);
7. Verify that the slipway is well positioned on the pallet and pull the machine outwards (see F).



A



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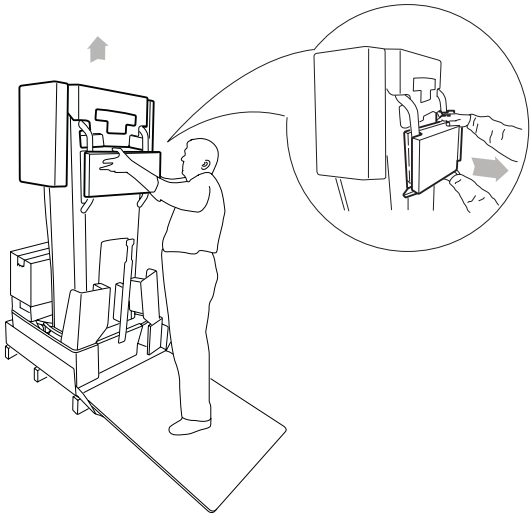

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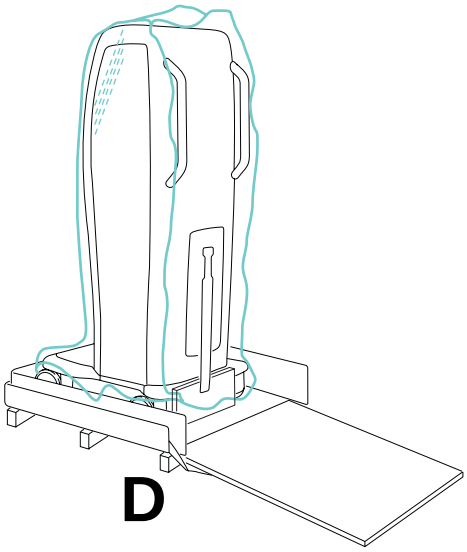
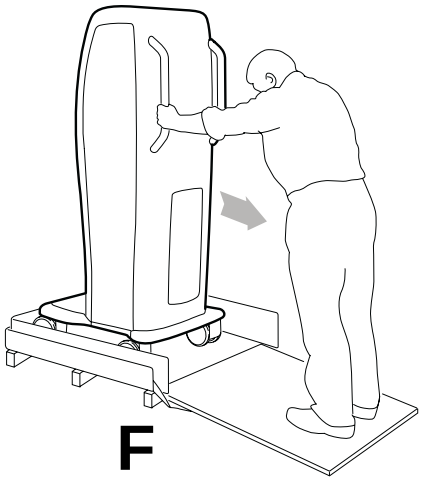


D

E



F

2.2 Shipping List

Refer to the “17.1.8 Shipping List” section of this Operator’s Manual for the contents of the machine packaging.

2.3 Installation

Proceed as described in the following paragraphs to install the Artis Dialysis System.

2.3.1 Supply Mains

Connect the power cord to a grounded, hospital-grade main power outlet (suitable for continuous operation) according to the voltage and current rating listed on the identification plate at the rear of the Artis Dialysis System. The electrical power requirements can be found in "Chapter 17: Specifications", of this Operator’s Manual.

⚠WARNING

Check the continuity and the reliability of the ground connection.

⚠WARNING

Verify the quality of the protective earth ground at the time of installation.

The Artis Dialysis System has a means on the rear panel for the connection of a Potential Equalization Conductor. If required connect the Potential Equalization Conductor to the means.

NOTE

The potential equalization connection should be installed when using the machine for treatments on patients with central venous catheter.

To make the Potential Equalization Connection available, contact your Local Representative.

2.3.2 Water inlet connection

Connect the 8x14 meshed tube to the Water Inlet Port on the rear of the Artis Dialysis System (see "Figure 2-1. Rear View"). The Water Inlet Port symbol, located on the label on the rear panel, shows where the Water Inlet Tube is to be connected.

Attach the Water Inlet Tube to the treated water for hemodialysis, using a stainless steel tube clamp.

Requirements for water for hemodialysis can be found in "Chapter 17: Specifications", of this Operator's Manual. The quality of the incoming water used by the Artis Dialysis System must comply with ISO 13959 standard.

2.3.3 Drain Tube connection

Connect the 8x14 tube, contained in the shipping carton, onto the drain port on the rear panel of the Artis Dialysis System (see "Figure 2-1. Rear View"). The Drain Port symbol, located on the label on the rear panel, show where the Drain Tube must be connected.

Connect the Drain Tube to a drainage system that satisfies the following requirements:

- Maximum Drain Outlet height above floor level: 1.3 m (51 inches).
- Maximum Drain Flow Rate: 1.2 l/min.
- Resistant to treated water and chemicals used for disinfection.
- Resistant to high temperature (~100°C) water, drained during the heat disinfection process.

The connection of the drain has to be carried out, as described in the applicable local and international standards, with an external pressure connector in order to avoid back flow. Mantain an air clearance between the drain connector of the machine and the drain itself.

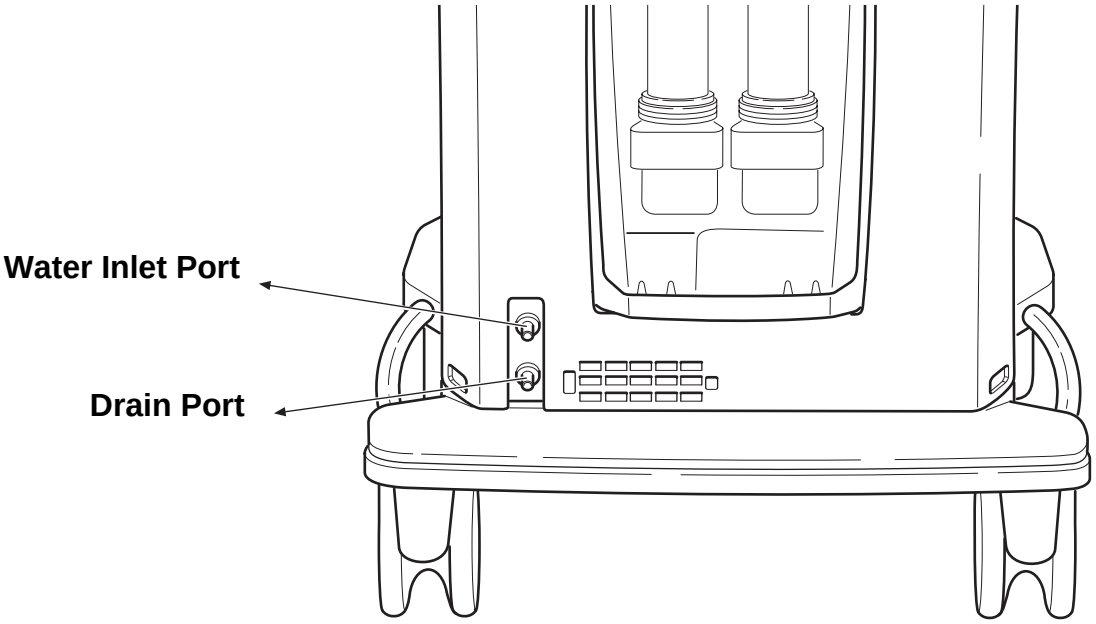


Figure 2-1. Rear View

2.3.4 Dialysis Fluid Tubes connection

Remove the protection on the female Dialysis Fluid connectors and place them on their safety couplings on the machine.

2.3.5 Install the Infusion Pole

(only if the Artis Dialysis System is not in AFB K configuration)

To install the Infusion Pole:

1. Attach the infusion bag holder to the pole;
2. Open the Infusion Pole locking latch and insert the pole in its holder;
3. Close the Infusion Pole locking latch.

2.3.6 Install the AFB K Infusion Pole and Scale

(only if the Artis Dialysis System is in AFB K configuration)

To install the AFB K Infusion Pole and Scale:

1. Remove the plastic protective caps located on the right and left machine sides;
2. Install the AFB K Infusion and Scale Support;
3. Install the AFB K Scale;
4. Insert the AFB K Infusion Pole in its holder

2.3.7 Battery connection

To connect the Lead Batteries, proceed as follows:

1. Check that the machine is switched OFF;
2. Remove the Battery Pack Panel;
3. Unscrew the four screws to remove the Battery protection panel;
4. Remove the two white terminal protections on both batteries;
5. Connect the Red wire to the "+" Battery Pin (Red colour coded);
6. Connect the Black wire to the "-" Battery Pin (Black colour coded);
7. Place the Battery protection panel and the Battery Pack Panel.

⚠WARNING

Pay attention to connect correctly the batteries. An incorrect connection to the proper battery pin causes an irremediable damage to the power supply also if the machine is not connected to the main line.

2.3.8 Protections on Coriolis and Loader Compressor

Proceed as follows to setup the Flowmeters and the Loader Compressor:

1. Remove the protection above and beside the Coriolis Flowmeter;
2. Locate the Loader Compressor in the front blood panel and cut the tie wrap that holds the white clip around the Loader Compressor. Discard the tie wrap and the white clip.

2.3.9 Ultrafilters

Install the U9000 ultrafilters proceeding as described below:

1. Access the Ultrafilter's compartment and remove the ultrafilters that are installed on the machine. These ultrafilters have only the purpose to seal the hydraulic circuit and avoid contamination during shipment so they must be discarded;
2. New U9000 ultrafilters, not provided with the machine, must be installed.

2.3.10 BPM Cuff

Connect the BPM cuff.

2.3.11 Time/Date

Set current time and date.

2.3.12 Application of silicone compound to the pressure pods

Apply Silicon Compound to the Arterial, Venous and System Pressure Pod O-Rings.

2.3.13 Top Tray

Lay the Top Tray on the top of the machine.

2.3.14 Chemical Container Shelf

(This component is optional)

Install the Chemical Container Shelf.

2.3.15 Concentrate Wands

Place the concentrate wands in the related supports on the left side of the machine.

2.4 First service

⚠WARNING

This operation must be performed by authorized personnel. If Service is performed by unauthorized personnel, the manufacturer cannot accept any responsibility for any damage which may occur, and such damage is not covered by the warranty.

2.4.1 General

Open the machine panels and visually inspect the hydraulics and electronics for any loose connections or damage from shipment.

2.4.1.1 Install the pH Probe (optional)

If required by the dialysis facility install the pH probe as described in the Artis Service Manual.

2.4.2 Functional Check

⚠WARNING

DO NOT use this machine near flammable gas or flammable anaesthetic mixtures with air, with oxygen or with nitrous oxide.

Prior to the first patient use, the Artis Dialysis System must be tested by a trained Service technician.

- Perform the complete installation procedure provided in the Artis Service Manual Maintenance.

The machine is calibrated by the manufacturer to guarantee the operating range described in the "Chapter 17: Specifications" of this Operator's Manual for the specified concentrates.

2.4.3 Machine disinfection

Before performing the first treatment with the Artis Dialysis System, proceed as follows:

1. Perform the Water Inlet Tube disinfection procedure. Refer to the "Chapter 13: Disinfection/Rinse" of this Operator's Manual.

2. Notify the operator that the machine must be disinfected again prior to use.

3. Notify the operator that a post-dialyzer dialysis fluid sample should be cultured for machine bioburden levels, as per AAMI and CDC guidelines. Follow your facility protocol for collecting and culturing the sample.

Chapter 3: Machine Dressing and Priming

3.1 First Checks

Before switching the Artis Dialysis System ON, perform the following checks:

- That the power cord is connected to a mains supply with protective earth;
- That the machine is connected to the water supply and that the water is on;
- That the Drain Tube is properly connected to the drain system;
- That the Dialysis Fluid Tubes are connected to their safety couplings on the machine;
- That the Ultra door and the Sensor Bar door are closed;
- That the EvaClean doors are firmly closed;
- That the machine is connected to a network, if nedeed.

⚠WARNING

- Never insert fingers in the Arterial and Venous line clamps.
- Keep the Arterial and Venous Pump covers closed during the function check process since the pumps will be tested during this phase.

3.2 Start the machine

3.2.1 Main power off

To start the Artis Dialysis System when the main power is off, press the *Main Switch* key:

- The “Main Switch On” indicator lights up;
- A screen containing an increasing progress bar and the software revision is displayed on the Touch Screen;
- The default settings are applied;
- The Alarm Management System is checked. Verify that:
  - > A continuous buzzer sound is triggered for about 2 seconds;
  - > Status Lights are red-lightened for 2 seconds;
  - > Status Lights are yellow-lightened for 2 seconds.

- The Artis Dialysis System enters the Function Check/Preparation mode. Verify that no T1 Test alarm related to Alarm Management System is triggered;
- If the Artis Dialysis System was switched OFF during a Chemical Disinfection program, an automatic Rinse starts. For further details, refer to the related section in the " Chapter 13: Disinfection/Rinse" of this Operator's Manual;
- If the Artis Dialysis System was stored filled with a chemical disinfectant, an automatic Rinse starts. For further details, refer to the related section in the " Chapter 13: Disinfection/Rinse" of this Operator's Manual.

⚠WARNING

If an alarm is triggered during the loading phase, ***DO NOT*** use the Artis Dialysis System. Call for service technician.

3.2.2 Low power mode

To start the Artis Dialysis System, when the main power is on and the machine is in "Low Power" mode (the Main Switch On indicator is ligthened), press the *On/Off* key: the *Overview* screen is displayed with the proper configuration.

3.2.3 Autostart

It is possible to schedule the automatic start of the dialysis fluid preparation from the Service 1 menu.

The scheduled dialysis fluid preparation starts only if the machine is in a "Display-Off" or in "Low Power" mode.

When the time set for autostart is reached, the machine:

- Switches the Touch Screen on;
- Enters the Function Check/Preparation mode.

3.2.4 Function Check/Preparation

The most of the function checks are performed each time the Artis Dialysis System is switched ON, before the patient connection phase. If the machine is properly configured, some of the function checks can be performed before the first treatment of the day and skipped for the following three treatments in the same day. For further details, refer to the "1.6 Function Checks" section of this Operator's Manual.

If any of the function checks fails (except for the Heparin delivery and other optional devices function checks) it will not be possible to start the treatment.

As soon as a certain number of function checks has been performed, the *Overview* screen will appear, with the following configuration:

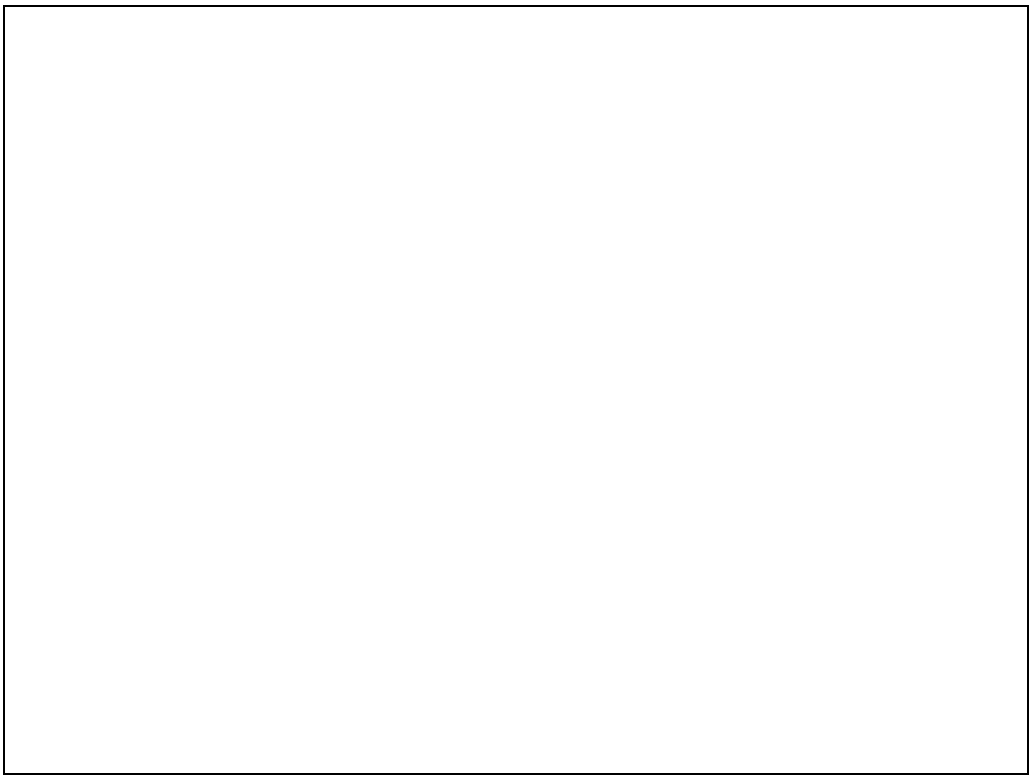


Figure 3-1. Overview Screen - Machine start-up

The dialysis fluid preparation starts as soon as the concentrates are connected to the machine.

When the preparation starts, the “Percent Complete” percentage and the blue bar will start increasing thus indicating the progress of this phase.

NOTE

If a chemical disinfection was performed on the machine, the “Residual Check Reminder (#582)” Information Message appears. To solve the alarm, refer to the #582 alarm troubleshooting in the “Chapter 16: Alarms, Information Signals and Troubleshooting” of this Operator’s Manual.

3.3 Concentrate Disposables

It is possible to connect the concentrate disposables to the machine before or after switching it ON.

After having switched ON the machine, if the concentrate disposables are not installed within a preset time, the related alarms are triggered.

The same alarms are triggered also in case that the concentrate connectors position is not appropriate for the set treatment type and concentrate combination. In these cases, connect the appropriate concentrate disposables as described in the sections below.

3.3.1 Select concentrate parameters

The Artis Dialysis System allows to choose between different concentrate combinations: "BiCart + A Concentrate", "BiCart Select" or "BiCart Citrate".

To change/update the concentrate combination and related parameters, proceed as follows:

1. Press the "Fluid Settings" button on the *Fluid* screen to open the following sub-screen:

Figure 3-2. Example of Fluid Settings Sub-screen

2. Check/change the parameters according to the values listed in the table below:

Table 1: Fluid Settings Parameters

Button	Definition	Values
Concentrate Combination	Sets the concentrate combination according to which the machine prepares the prescribed type of Dialysis Fluid. When this parameter has been set, the other related parameters (*Acid, BiCart, SelectBag One, SelectBag Citrate, SelectCart*) become available.	• BiCart + A Concentrate • BiCart Select • BiCart Citrate
Acid	Sets the type of Acid concentrate to be used during the treatment.	• Depend on the Acid concentrates set in the Service menu
BiCart	Sets the BiCart Cartridge to be used during the treatment.	• BiCart
SelectBag One *(Only in BiCart Select treatments)*	Sets the type of SelectBag One product to be used during the treatment.	• Depend on the SelectBag One products set in the Service menu
SelectBag Citrate *(Only in BiCart Citrate treatments)*	Sets the type of SelectBag Citrate product to be used during the treatment.	• Depend on the SelectBag Citrate products set in the Service menu
SelectCart *(Only in BiCart Select or BiCart Citrate treatments)*	Sets the SelectCart Cartridge to be used during the treatment.	• SelectCart
Sodium	Sets the Sodium concentration value to reach in the Dialysis Fluid.	• 130 mmol/L to 160 mmol/L
Bicarbonate	Sets the Bicarbonate concentration value to reach in the Dialysis Fluid.	• 24 mmol/L to 38 mmol/L
Temperature	Sets the Temperature of the Dialysis Fluid.	• 35,5 °C to 39,5 °C
Dialysis Fluid Flow	Sets the Dialysis Fluid Flow.	• 300 mmL/min to 800 mL/min
TMP Upper Limit	Sets the upper allowed limit for the TMP pressure during HD-DN or HD-SN treatments.	• 0 to 300 mmHg
TMP Upper Limit (Volume Control)	Sets the upper allowed alarm limit for the TMP pressure during a HDF Post Treatment in Volume Control mode.	• 0 to 500 mmHg (depends on the value set in the Service menu)

Table 1: Fluid Settings Parameters

Button	Definition	Values
TMP Upper Limit (Pressure Control)	Sets the upper allowed alarm limit for the TMP pressure during a HDF Post Treatment in Pressure Control mode.	• 0 to 450 mmHg (depends on the value set in the Service menu)
pH *(if available)*	Displays the current dialysis fluid pH	/

⚠WARNING

Incorrect choice of dialysis fluid concentrates may cause incorrect composition of the dialysis fluid.
Check that the prescribed concentrates for the specific treatment are used.

⚠WARNING

If a "BiCart Select " or "BiCart Citrate" concentrate combination has been set, ensure that the correct concentrate disposables, BiCart Cartridge, SelectCart Cartridge and SelectBag container, have been set.
In particular, ensure that the SelectBag prescribed for the treatment corresponds to the SelectBag container that has been installed on the machine and to the SelectBag type that has been set.

⚠WARNING

Setting the "TMP Upper Limit", "TMP Upper Limit (Volume Control)" or the "TMP Upper Limit (Pressure Control)" to their extreme values might render the Alarm Management System useless.
An improper setting of these limits may prevent the Alarm Management System to detect possible alarm conditions related to blood loss or to blood clotting.

NOTE

In case of BiCart Select or BiCart Citrate treatment, during the dialysis fluid preparation do not set the Dialysis Fluid Flow parameter to 300 mL/min. If the prescribed Dialysis Fluid Flow for the treatment is 300 mL/min, adjust the parameter value at the end of the preparation phase.

NOTE

If performing a treatment using the BiCart Select System, the dialysis fluid preparation followed by the autopriming process will last approximately 27 minutes.
This time could be shorter if the “Conductivity Cell sensors” and “Temperature” Function Checks are skipped.

NOTE

As soon as the dialysis fluid preparation starts it is no longer possible to change the concentrate combination.

3.3.2 Connect concentrates

According to the selected concentrate combination, proceed as described in the sections below to connect the concentrates.

3.3.2.1 Central Concentrate Delivery System

The Artis Dialysis System allows to use a Central Concentrate Delivery system for delivering of A-concentrate during a treatment, complying with specifications reported in the related section of the “Chapter 17: Specifications” of this Operator’s Manual.

The Central Concentrate Delivery system can be used only in combination with BiCart Cartridges.

A Central Concentrate tube suitable for the Artis Dialysis System must be used to connect the Central Concentrate Delivery system to the Artis Dialysis System.

⚠WARNING

It is the operator’s responsibility to check the compliance of the Central Concentrate Delivery system with IEC 601.1.1 standard.

Before Connecting a Central Concentrate Delivery System

To use a Central Concentrate Delivery system for delivering of A-concentrate with the Artis Dialysis System, it is necessary that the machine is properly configured by a trained service technician.

For further details refer to the related sections of the Artis Service Manual Maintenance.

3.3.2.2 BiCart and Central Concentrate Delivery System

⚠WARNING

It is the operator's responsibility to properly connect the Artis Dialysis System to a Central Concentrate Delivery system and to check that the connection works properly.

To use the Central Concentrate Delivery system, proceed as follows:

1. Ensure that one end of a Central Concentrate tube, suitable for the Artis Dialysis System, is connected to the A1 or A2 port of the Central Concentrate Delivery system
2. Ensure that the other end of the Central Concentrate tube is connected to the Rear Central Concentrate Connector Port 1 or 2, according to the pre-set configuration
3. Connect the Acid pick-up tube to the Front Central Concentrate Connector Port 1 or 2, according to the pre-set configuration. Ensure to hear a "clicking" sound when connecting the Acid pick-up tube to the Front Central Concentrate Connector Port.
4. Install a BiCart Cartridge as described in the "3.3.3.1 BiCart Cartridge" section of this chapter
5. Ensure that the SelectBag and SelectCart Cartridge holders are closed.

3.3.2.3 BiCart + A Concentrate

To perform a dialysis treatment using a container of A-concentrate and a BiCart Cartridge, proceed as follows:

1. Disconnect the Acid pick-up tube connector from the lower part of the machine front panel and connect it to the wand inserted in the Acid concentrate container or in the concentrate bag;

⚠WARNING

When installing the acid container, be careful to avoid that the concentrate splashes into your eyes.
Acid concentrate may cause chemical injury if comes in contact with eyes.

2. Install the BiCart Cartridge (refer to the "3.3.3.1 BiCart Cartridge" section below in this chapter);
3. Check that the SelectBag and SelectCart Cartridge holders are closed.

3.3.2.4 BiCart Select

To perform a dialysis treatment using a BiCartSelect System, proceed as follows:

1. Install the BiCart Cartridge (refer to the “3.3.3.1 BiCart Cartridge” section below);
2. Install the SelectCart Cartridge (refer to the “3.3.3.2 SelectCart Cartridge” section below);
3. Install the SelectBag container (refer to the “3.3.3.3 SelectBag container” section below);
4. Check that the Acid pick-up tube connector is connected to its concentrate connector port. Ensure to hear a “clicking” sound when connecting the Acid pick-up tube to its concentrate connector port.

3.3.3 Install Concentrate Disposables

3.3.3.1 BiCart Cartridge

To install a BiCart Cartridge proceed as follows:

1. Open both arms of the BiCart Cartridge holder. To fully open the upper arm, pull the arm out slightly, then tip it upward;
2. Place the bottom of the BiCart Cartridge into the hole in the lower arm;
3. Hold the BiCart Cartridge in an upright position and press down firmly on the upper arm of the BiCart Cartridge holder. The spike inside the hole of the upper arm pierces the top port of the BiCart Cartridge. At the same time, the BiCart Cartridge moves downward and the spike in the lower arm pierces the bottom port;
4. The BiCart Cartridge is automatically primed.

⚠WARNING

Before installing and using a BiCart Cartridge:
• Follow the Instructions for Use
• Check that the cartridge is undamaged
• Check for the expiration date on the BiCart Cartridge label
For the storage temperature refer to the Instructions for Use of BiCart Cartridge.

⚠WARNING

Use ***ONLY*** BiCart Cartridges new or that have not been drained.

3.3.3.2 SelectCart Cartridge

To install a SelectCart Cartridge proceed as follows:

1. Open both arms of the SelectCart Cartridge holder. To fully open the upper arm, pull the arm out slightly, then tip it upward;
2. Place the bottom part of the SelectCart Cartridge into the hole in the lower arm;
3. Hold the SelectCart Cartridge in an upright position and press down firmly on the upper arm of the SelectCart Cartridge holder. The spike inside the hole of the upper arm pierces the top port of the SelectCart Cartridge. At the same time, the SelectCart Cartridge moves downward and the spike in the lower arm pierces the bottom port;
4. The SelectCart Cartridge is automatically primed.

⚠WARNING

Use ONLY SelectCart Cartridges new.

NOTE

Before installing and using a SelectCart Cartridge, follow the Instructions for Use of the SelectCart Cartridge.

3.3.3.3 SelectBag container

To install a SelectBag container proceed as follows:

1. Open the protective cap of the SelectBag container;
2. Open the SelectBag holder arm as shown in "Figure 1" below;
3. Place the SelectBag container into the SelectBag holder ensuring that the SelectBag connector fits the shaped housing of the holder (see "Figure 2" below);
4. Press down the SelectBag holder arm so that the membrane of the SelectBag container is penetrated by the spike (see "Figure 3" below).

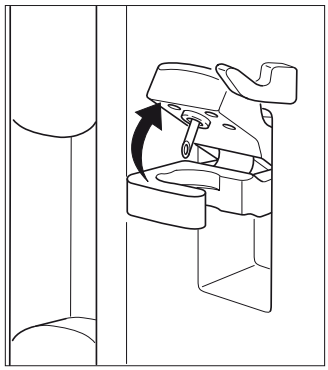


Figure 1

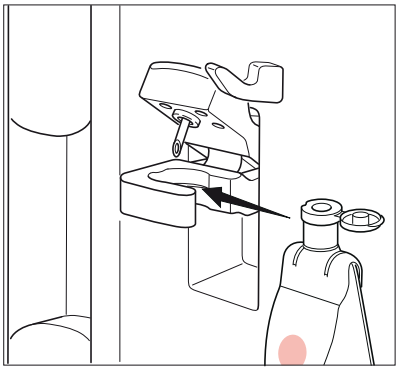


Figure 2

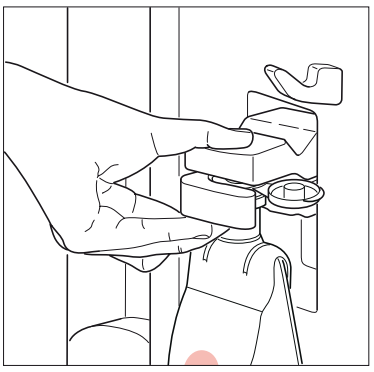


Figure 3

⚠WARNING

When installing the SelectBag container, avoid touching the plastic spike of the machine.

⚠WARNING

When installing the SelectBag container, be careful to avoid fluid from the SelectBag product splashing into your eyes.
Acid concentrate may cause chemical injury if comes in contact with eyes.

NOTE

Before installing and using a SelectBag container, follow the Instructions for Use of the SelectBag container.

3.4 Prescription Parameters Setting

⚠WARNING

To avoid hazardous side effects during the treatment, parameters set must be suitable for the patient's needs and tolerance.
It is the operator's responsibility to check that the prescription parameters are suitable for the treated patient.

3.4.1 Needle Mode Choice

The Artis Dialysis System is intended to be used in Double Needle and Single Needle mode.
The Double Needle mode is supported in:

- HD-DN Treatment (Single Pump with the HD-DN Blood Tubing System)
- HD-DNDP Treatment (Double Pump with the HD-SN Blood Tubing System). This treatment can be performed through the "Switch to DN" special procedure available during the HD-SN Treatment.
- HDF Post Treatment (with the HDF Post Blood Tubing System)
- AFB K Treatment (with the AFB K Blood Tubing System).

The Single Needle mode is supported in:

- HD-SN Treatment (Double Pump with the HD-SN Blood Tubing System)
- HD-SNSP Treatment (Single Pump with the HD-DN Blood Tubing System plus the SNSP Conversion Kit). This treatment can be performed through the "Switch to SNSP" special procedure available during the HD-DN Treatment

During the HD-SN and HD-DNDP Treatments, it is possible to switch from a needle mode to another without changing the HD-SN Blood Tubing System through the dedicated special procedures.

For further details refer to the related section in the "Chapter 8: Special Procedures" of this Operator's Manual.

3.4.2 Set Treatment Type

Before starting the treatment, check/adjust prescription parameters as follows:

1. Press the "Treatment" button on the *Prescription* screen to enter the Treatment Settings sub-screen;
2. On this sub-screen, press the treatment "Type" button and select the desired option on the Selectpad:

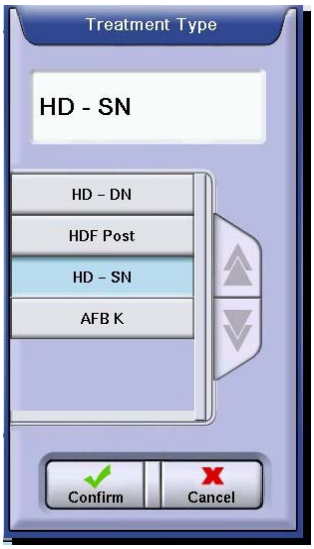


Figure 3-3. Example of Treatment Settings Sub-screen

The selected treatment type must be aligned with the type of Blood Tubing System installed on the machine. Refer to the “17.3.1 ArtiSet Blood Tubing System” section of this Operator’s Manual.

3. Press the ***CONFIRM*** button on the Selectpad: the keypad closes and a *Confirm* window opens requiring to confirm some of the following prescription parameters, according to the set treatment: “Dialysis Fluid Flow”, Pre-Dialyzer Limit”, “Online Substitution Rate” and “TMP Set”;

4. Check/adjust the parameter values, using the set buttons;

5. When all the proper values have been set, press the ***CONFIRM*** button to confirm them and to close the *Confirm* window;

6. If a HDF Post Treatment has been set, press the “Control Mode” button on the *Treatment Settings* sub-screen to open the following Selectpad:

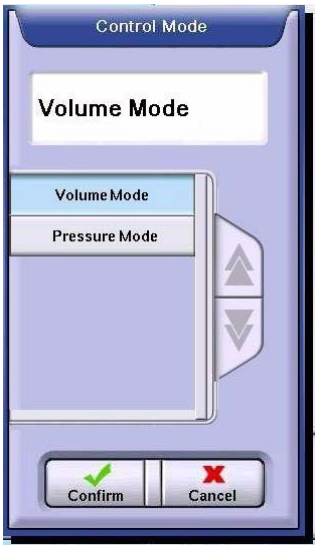


Figure 3-4. Treatment Settings Sub-screen - Set Control Mode

7. Select the desired option from the Selectpad and press the ***CONFIRM*** button to confirm it. The keypad closes and a *Confirm* window opens requiring to confirm some of the following prescription parameters, according to the set treatment: "Dialysis Fluid Flow", Pre-Dialyzer Limit", "Online Substitution Rate" and "TMP Set";

8. Check/adjust the desired values, using the set buttons;

⚠WARNING

Setting the "Pre-Dialyzer Limit", the "Online Substitution Rate" or the "TMP Set" to their extreme values might render the Alarm Management System useless.
An improper setting of these limits may prevent the Alarm Management System to detect possible alarm conditions related to blood loss or to blood clotting.

9. When all the proper values have been set, press the ***CONFIRM*** button to confirm them and to close the *Confirm* window;

10. Press the ***CLOSE*** button to switch to the *Prescription* screen:

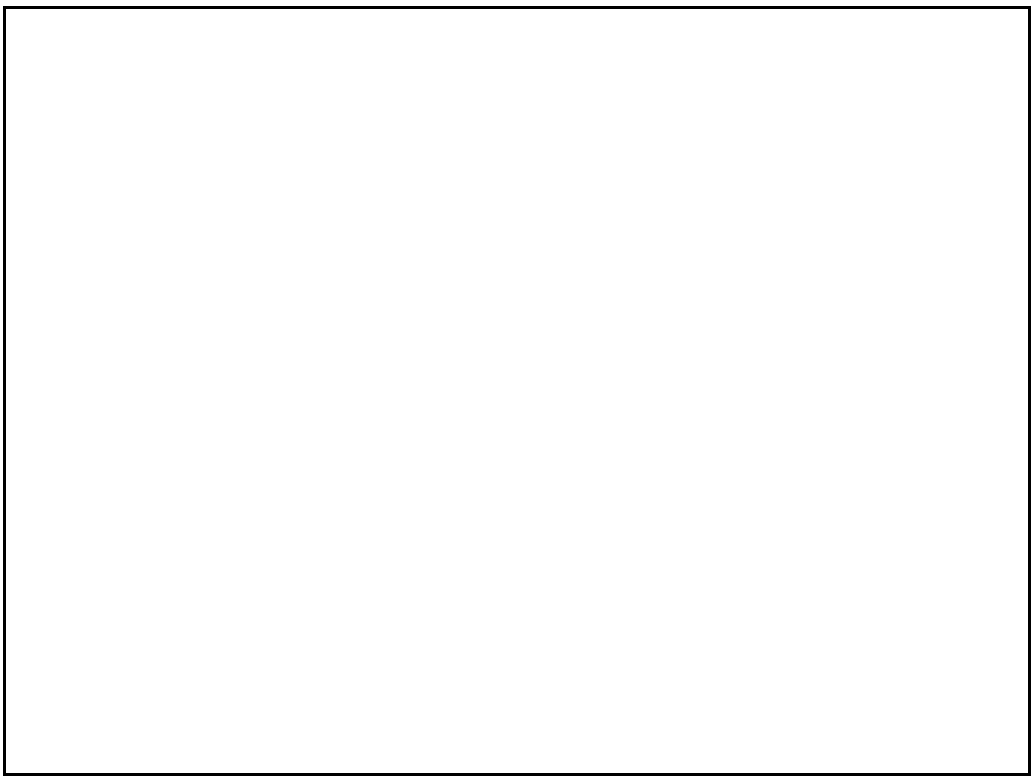


Figure 3-5. Example of Prescription Screen

The symbol means that these parameters must be confirmed before starting the treatment. The “Connect Patient” button will be available only after the “Treatment Time”, “UF Volume” and “Stroke Volume” (*only in HD-SN Treatment*) parameters have been set and confirmed. After they have been confirmed the mandatory symbol disappears from the *Parameter Value* list.

11. On the *Prescription* screen, set at least the following parameters in the *Parameter Value list:*

    • Treatment Time

    • UF Volume

    • Stroke Volume (*only in HD-SN Treatment*)

As soon as the UF volume and Treatment Time are entered and confirmed the UF rate is automatically calculated via the following formula:

$$\text{UF Rate} = \frac{\text{UF Volume}}{\text{Treatment Time}}$$

NOTE

- The "UF Volume" and "Treatment Time" values can also be checked/changed on the *Fluid* screen.
- The "Stroke Volume" value can also be checked/changed on the *Blood* screen.

12. Activate the required optional functions, such as BPM, Hemoscan™, Diascan, Isolated UF, Ultra Control (available only in HDF Post Treatment in Pressure Control mode) Hemocontrol and Heparin delivery, through the "Activated Functions" list. For further details on settings and activation of these functions, refer to the related sections of this Operator's Manual.

It is possible to manually set the prescription parameters or retrieve them from the Exalis software database. The "Patient ID" button will be available on the Prescription screen only if the Exalis system has been enabled in the Service menu.
For further details on Exalis software refer to the "Chapter 14: Communication System" of this Operator's Manual.

3.4.2.1 Change the Treatment Type before patient connection

It is possible to change the treatment type, as described in the "3.4.2 Set Treatment Type" section above:

- In HD-DN and HD-SN Treatment, at any moment until the "Connect Patient" button is pressed and confirmed;
- In HDF Post Treatment, until the "Auto-Prime" button is pressed.

If the cassette has already been installed, proceed as follows to change the treatment type:

1. Press the "Special Procedures" button on the *Overview* screen.
   If the button is dimmed, during the Autopriming procedure, pause the Autopriming to make the button undimmed.
2. Select and confirm the "Unload Cassette" option in the selectpad.
   If the "Unload Cassette" option is not available, during the Low Consumption state, exit the low consumption state to make the "Unload Cassette" option available in the selectpad.
3. Unload the cassette following the operator's messages in the Message Area;
4. Change the treatment type as described in the "3.4.2 Set Treatment Type" section or retrieve it from the Exalis database or from a Patient Card;
5. Proceed as described in the sections below.

3.4.3 Set Substitution Fluid Parameters in HDF Post Treatment

For a HDF Post Treatment, set/adjust the substitution fluid parameters on the following *Fluid* screen:

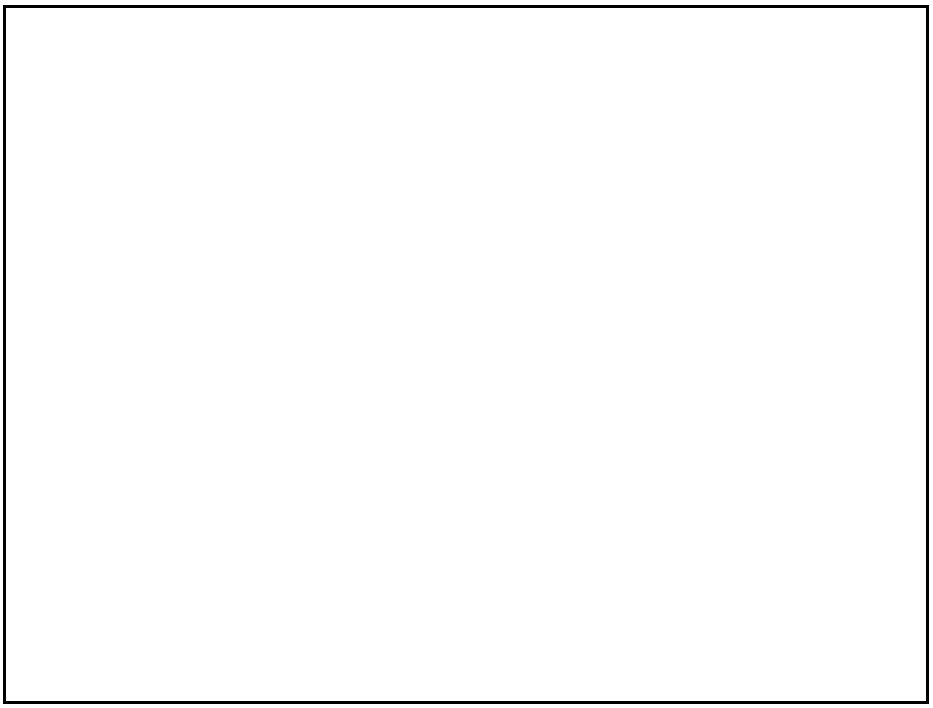


Figure 3-6. Example of Fluid Screen in Volume Control mode

Table 2: Substitution Fluid Parameters

PARAMETERS	DESCRIPTION
Online Bolus Volume **(mL)**	Sets the amount of substitution fluid delivered each time the “Online Bolus” action button is pressed. The “Online Bolus” action button will be available on this screen as soon as the “Start Treatment” button is pressed and until the “Stop Treatment” button is confirmed. During an online bolus delivery, the Venous Pump speed starts at a preset value.
Online Substitution Rate **(mL/min)**	Sets the Substitution Flow Rate, expressed in mL/min, based on the Blood Flow rate and the UF Rate. It depends on the hematocrit and the protein content in the patient’s blood. The Infusion Volume displayed on the keypad is calculated according to the Online Substitution Rate and to the Treatment Time and taking into account the time of Auto-test performed by the machine.
TMP Set **(mmHg)**	Sets the TMP pressure value to apply during the HDF Post Treatment in Pressure Control mode.

During HDF Post Treatment, the "Estimated Substitution Vol." button is displayed on the *Fluid* screen. This button contains the estimated value of substitution fluid that will be delivered in the remaining time at the end of treatment, considering the current Venous Pump speed and the Auto-test time.

In HDF Post Treatment in Volume Control, post-dilution mode, the recommendation is that Q_F does not exceed a preset percentage (default 40%) of Q_B, where:

- Q_F is the weight loss rate plus the substitution flow rate
- Q_B is the actual blood flow rate.

Also the patient's blood hematocrit concentration has a direct influence on the ratio Q_F/Q_B.

According to the dilution ratio suitable for the patient' s blood characteristics, the Online Substitution (expressed in mL/min) value can be calculated applying the following formula:

Online Substitution Rate= (Q_b* Dilution Ratio) - UF Volume (expressed in mL/min)

3.4.4 Set the TMP Upper Limit

To check/set the “TMP Upper Limit”, “TMP Upper Limit (Volume Control)” or the “TMP Upper Limit (Pressure Control)”, proceed as follows:

1. Open the Fluid Settings sub-screen pressing the “Fluid Settings” button on the *Fluid* screen;

Figure 3-7. Example of Fluid Settings Sub-screen

2. On this sub-screen, press the “TMP Upper Limit”, “TMP Upper Limit (Volume Control)” or the “TMP Upper Limit (Pressure Control)” button: a keypad opens;
3. On the keypad, enter the desired value for the TMP Upper Limit;

⚠WARNING

Setting the “TMP Upper Limit”, “TMP Upper Limit (Volume Control)” or the “TMP Upper Limit (Pressure Control)” to their extreme values might render the Alarm Management System useless.
An improper setting of these limits may prevent the Alarm Management System to detect possible alarm conditions related to blood loss or to blood clotting.

4. Press the ***CONFIRM*** button on the keypad to confirm the entered value.

3.5 Extracorporeal Circuit Preparation

The extracorporeal circuit preparation includes:

- Loading of the Blood Tubing System;
- Heparin Syringe Installation;
- Dialyzer installation.

⚠WARNING

The use of the Gambro/Hospal Blood Tubing Systems designed for the Artis Dialysis System has been tested and validated to provide safe and proper functioning of the system. The Manufacturer has not validated the use of Blood Tubing Systems other than those specified in this manual. The Manufacturer does not assume responsibility or liability for use of Blood Tubing Systems other than the Gambro/Hospal Blood Tubing Systems. It is the responsibility of the user to validate that other blood lines provide safe and effective performance.

⚠WARNING

The appropriate Dialyzer and Blood Tubing System must be selected according to the patient's size and weight and to the treatment type.
The decision must be taken by a physician.
Before installing Gambro/Hospal Dialyzers and Blood Tubing System carefully read the related Instructions for Use.

⚠WARNING

After a Heat or a Heat Disinfection with CleanCart Cartridge program, hot water can remain inside the Dialysis Fluid Tubes. Pay attention when disconnecting the Dialysis Fluid Tubes from the machine since hot water could drip from the Dialysis Fluid Tube Connectors.

⚠WARNING

A damaged pump rotor will not work properly. This could result in patient serious injury.
Visually inspect the pump rotor each time you load any of Infusion, Ultra, SNDP or Blood Cassettes.
If the pump rotor is damaged, ***DO NOT*** use the machine for treatment, ***DO NOT*** repair and call for service.

⚠WARNING

Improper connections of the extracorporeal circuit may cause potential safety hazards, that might not be detected by the machine: for instance, hemolysis caused by kinks, clamps or other restrictions on the lines, blood loss to the environment/air into the blood circuit due to a leakage in the extracorporeal circuit.

⚠WARNING

The operator must take proper precaution in order to prevent coagulation in the extracorporeal circuit due to an improper connection of the circuit.
Coagulation may lead to:
- inadequate delivery of dialysis;
- risk associated with propagation of blood clots to the patient;
- disabling of the air detector function if blood clots aggregate in the chambers.

⚠WARNING

Leakages of the dialysis fluid circuit (Dialysate connectors and Ultra port) may cause safety hazards that might not be detected by the machine, for instance hypovolemia due to improper fluid balance.

NOTE

If a Blood Tubing System is already installed when the machine is switched ON, it is necessary to unload it and then install it again to allow the dialysis fluid preparation to start.

NOTE

If the Blood Tubing System loading fails, always perform the following steps to complete the loading procedure:
- Unload the Blood Tubing System;
- Install again the Blood Tubing System.

3.5.1 Loading of the Blood Cassette

Refer to the "Figure 3-8. Machine Dressing - Example with HD DN HC (FULL)" for references to the Blood Tubing System components.

NOTE

If the "113810 - ArtiSet HD DN (BASE)" Blood Tubing System is used, ensure that the Hemoscan and the Hemocontrol functions are disenabled.
Since the Hemoscan cuvette is not present on this Blood Tubing System, the Hemoscan and the Hemocontrol functions can not be activated throughout the treatment.

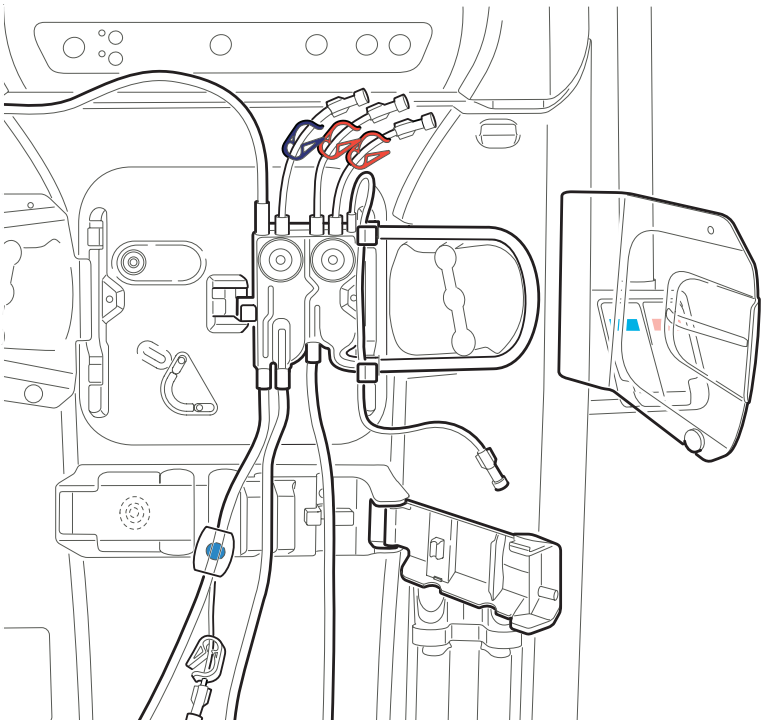
To install the Blood Cassette, proceed as follows:

1. Open the *Overview* screen. Follow the messages on the Message Area to install the cassette;
2. Hang a saline bag appropriate for the priming of the Extracorporeal Circuit on the Infusion Pole. Check that the saline amount in the bag is enough to complete the priming procedure;
3. Open the Sensor Bar door;
4. Open the Arterial Pump cover:
   - The machine pushes out the cassette holder ;
   - The Arterial Pump rotor is in a horizontal position. This is the default position after switching the machine on and each time the Arterial Pump cover is closed.
5. Extract the cassette from its package without removing the SteriWraps on the lines;
6. Hang the Blood Cassette on the Cassette holder;

WARNING

In case of hardware malfunction or if the loading procedure is not completed within 2 minutes, the Cassette holder will automatically retract.
DO NOT insert fingers behind the cassette to avoid injury to your fingers.

7. Route the heparin line through its guides on the Cassette panel;

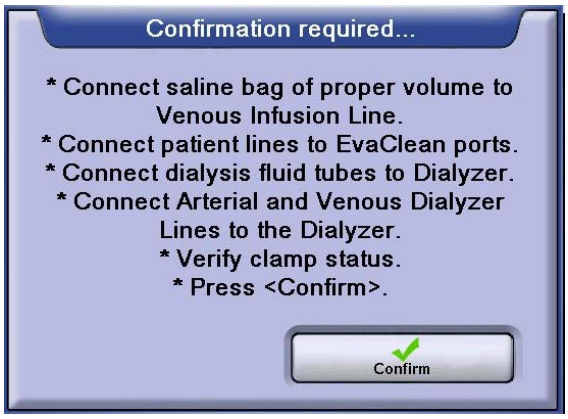


8. Close the Arterial Pump cover: the machine automatically loads the Blood Cassette and the pump segment;
9. Route the Arterial Patient line through the Hemoscan sensor;
10. Route the Venous Patient line through the air detector/blood sensor;

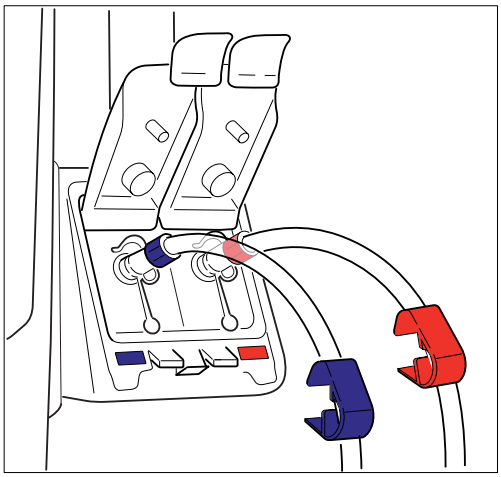
⚠WARNING

Before inserting the Venous Patient line in the Air Detector clean and dry it. Fluid and gel substances applied on the Air Detector may reduced the Air Detector sensitivity causing patient injury or death.
Refer to the “13.10 External Cleaning” paragraph, in the “Chapter 13: Disinfection/Rinse” of this Operator’s Manual, for the description of how to clean the Air Detector.

11. Close the Sensor Bar door;
12. Insert the Arterial and Venous Patient lines in their respective automatic clamps. Wait for the following *Confirm* window before proceeding with cassette installation:



13. Remove the SteriWrap from the Arterial Patient line;
14. Open the EvaClean doors and insert the Arterial Patient line into the EvaClean Red port using the priming connector. When inserting the priming connector keep the clear cap downward to avoid blocking the EvaClean Blue door when closed. Refer to the following figure for the correct insertion:



15. Remove the SteriWrap from the Venous Patient line;
16. Insert the Venous Patient line into the EvaClean Blue port using the priming connector. When inserting the priming connector keep the clear cap downward to avoid blocking the EvaClean Red door when closed;

⚠WARNING

Use an aseptic technique when connecting/disconnecting the priming connectors of the Arterial and Venous Patient lines to/from the EvaClean ports in order to avoid any potential contamination of the lines.

⚠WARNING

Verify that fluid is not present in the EvaClean ports by visual inspection before inserting the priming connectors.
If fluid is present in the ports for more than six seconds after opening the doors, ***DO NOT USE*** the EvaClean option.

⚠WARNING

The EvaClean option must be cleaned each time the patient connection procedure is performed keeping the Venous Patient line into the EvaClean Blue port until the machine detects blood. In this case, manually clean the EvaClean option before performing another patient treatment.
(Refer to the “Chapter 8: Special Procedures” of this Operator’s Manual).

17. Clamp the Venous and Arterial Infusion lines;
18. Connect the dialyzer as described in the “3.5.6 Dialyzer Installation” section;
19. Remove the cap from the Arterial Dialyzer line and insert the line into the upper dialyzer blood port. Before connecting the Arterial Dialyzer line to the dialyzer, rotate the line counter-clockwise (about 1 full turn) to prevent kinking;
20. Route the Arterial Dialyzer line through the corresponding guide of the Artis Dialysis System, avoiding covering the Hard Key panel with the line;
21. Remove the cap from the Venous Dialyzer line and insert the line into the lower dialyzer blood port. Before connecting the Venous Dialyzer line to the dialyzer, rotate the line clockwise (about 1 full turn) to prevent kinking;
22. Route the Venous Dialyzer line through the corresponding guide of the Artis Dialysis System;
23. Adjust the dialyzer position to prevent sharp bends in tubes and to prevent tubes from interfering with Artis Dialysis System or its parts. Ensure that lines are untangled;
24. Connect the Dialysis Fluid Tubes to the dialyzer;
25. Connect the prime line to the saline bag, then route the prime line through its guide on the machine;
26. If needed, fill a syringe with the amount of heparin solution prescribed for a single treatment and before connecting it to the Heparin line remove any air from the syringe;
27. Remove the cap from the Heparin line and connect the line to the heparin syringe. ***Do not*** remove the no-return valve connected at the end of the

Heparin line. Install the syringe as described in the "3.5.5 Heparin syringe installation" section;

28. Press the ***CONFIRM*** button on the *Confirm* window.

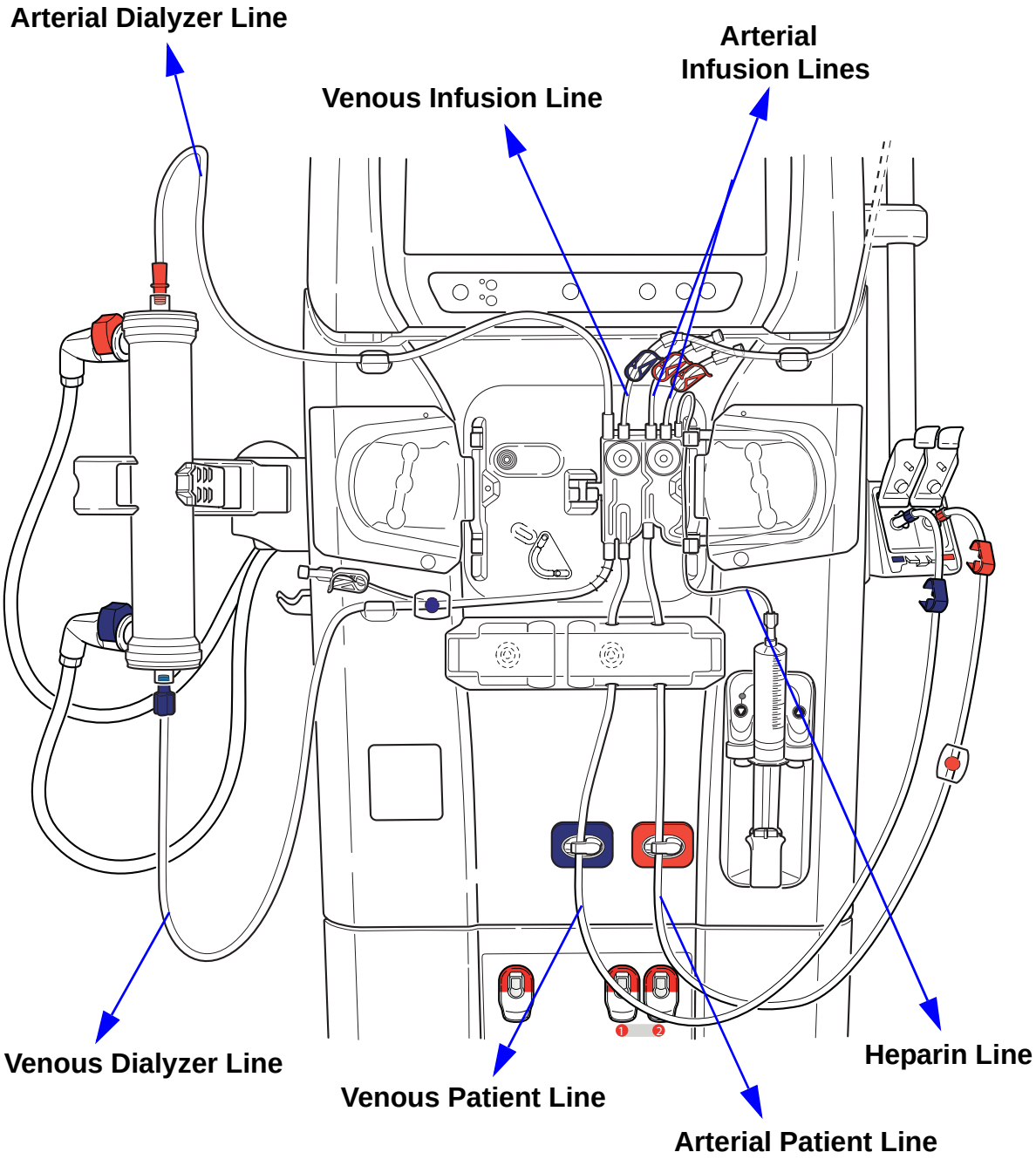


Figure 3-8. Machine Dressing - Example with HD DN HC (FULL)

After the cassette installation has been completed and confirmed, it is possible to unload the Blood cassette at any moment before or after the dialysis fluid preparation is completed.

If the loading procedure fails, it must be restarted from the beginning.

3.5.2 Loading of the Blood and Ultra Cassettes

Refer to the “Figure 3-9. Machine Dressing - Ultra Cassette” for references to the Blood Tubing System components.

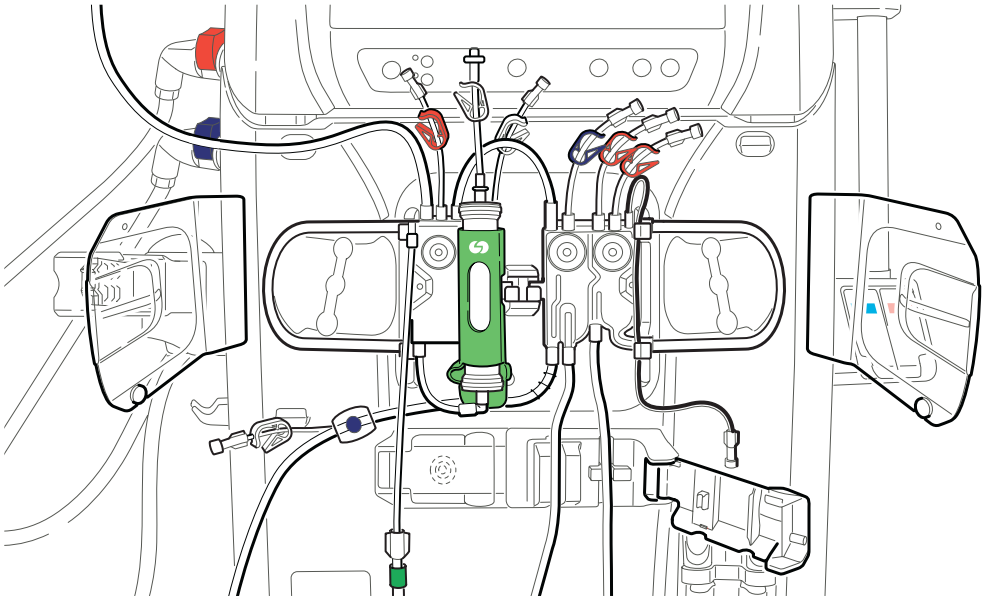
To install the cassette, proceed as follows:

1. Open the *Overview* screen. Follow the messages on the Message Area to install the cassette;
2. Open the Sensor Bar door;
3. Open the Arterial and Venous Pump covers:
   - The machine pushes out the blood and ultra cassette holders;
   - The Arterial and Venous Pump rotors are in a horizontal position. This is the default position after switching the machine on and each time the Arterial and Venous Pump covers are closed.
4. Extract the cassette from its package without removing the SteriWraps on the lines;
5. Hang the Blood and Ultra Cassettes on their respective holders;

⚠WARNING

In case of hardware malfunction or if the loading procedure is not completed within 2 minutes, the Blood and Ultra cassette holders will automatically retract.
DO NOT insert fingers behind the cassette to avoid injury to your fingers.

6. Route the heparin line through its guides on the Cassette panel;



7. Close the Arterial and Venous Pump covers: the machine automatically loads the Blood and Ultra Cassettes and the pump segments;

8. Route the Arterial Patient line through the Hemoscan sensor;

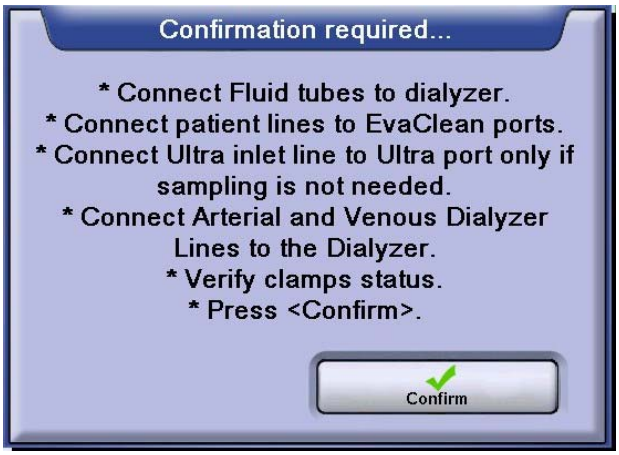
9. Route the Venous Patient line through the air detector/blood sensor;

⚠WARNING

Before inserting the Venous Patient line in the Air Detector clean and dry it. Fluid and gel substances applied on the Air Detector may reduce the Air Detector sensitivity causing patient injury or death.
Refer to the "13.10 External Cleaning" paragraph, in the "Chapter 13: Disinfection/Rinse" of this Operator's Manual, for the description of how to clean the Air Detector.

10. Close the Sensor Bar door;

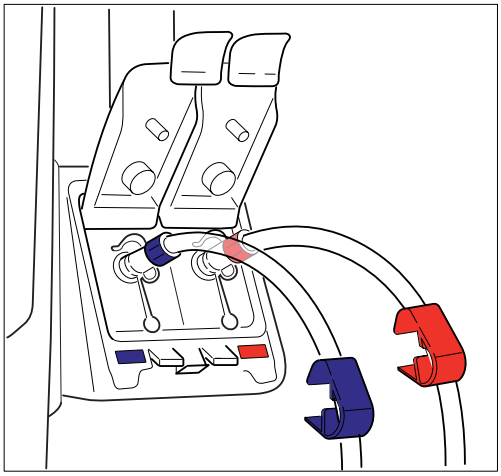
11. Insert the Arterial and Venous Patient lines in their respective automatic clamps. Wait for the following *Confirm* window before proceeding with the cassette installation:



12. Connect the Dialysis Fluid Tubes to the dialyzer;

13. Remove the SteriWrap from the Arterial Patient line;

14. Open the EvaClean doors and insert the Arterial Patient line into the EvaClean Red port using the priming connector. When inserting the priming connector keep the clear cap downward to avoid blocking the EvaClean Blue door when closed. Refer to the following figure for the correct insertion:



15. Remove the SteriWrap from the Venous Patient line;

16. Insert the Venous Patient line into the EvaClean Blue port using the priming connector. When inserting the priming connector keep the clear cap downward to avoid blocking the EvaClean Red door when closed;

⚠WARNING

Use an aseptic technique when connecting/disconnecting the priming connectors of the Arterial and Venous Patient lines to/from the EvaClean ports in order to avoid any potential contamination of the lines.

⚠WARNING

Verify that fluid is not present in the EvaClean ports by visual inspection before inserting the priming connectors.
If fluid is present in the ports for more than six seconds after opening the doors, ***DO NOT USE*** the EvaClean option.

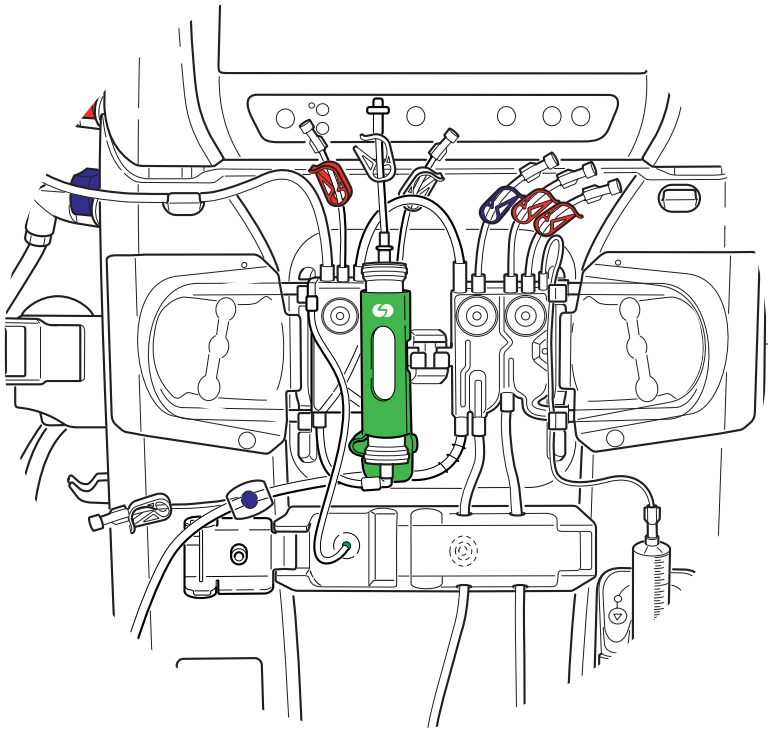
⚠WARNING

The EvaClean option must be cleaned each time the patient Connection procedure is performed keeping the Venous Patient line into the EvaClean Blue port until the machine detects blood. In this case, manually clean the EvaClean option before performing another patient treatment.
(Refer to the “Chapter 8: Special Procedures” of this Operator’s Manual).

17. Open the Ultra door;

18. Remove the cap from the Ultra Inlet Line;

19. Screw tight the green Ultra Inlet line connector to the Ultra port, avoiding rotating the Ultra Inlet line. Ensure that the Ultra Inlet line is not twisted. For the proper connection of the green Ultra Inlet line connector to the Ultra port refer to the following image:



⚠WARNING

DO NOT connect the Ultra Inlet line to the Ultra port by rotating the Ultra Inlet line.
If rotating the Ultra Inlet line to connect it to the Ultra port, the green Ultra Inlet line connector will not be properly secured to the Ultra port. This may result in the Ultra Inlet line partial/complete disconnection from the Ultra port during the dialysis treatment. Leakages from the Ultra port may cause safety hazards that might not be detected by the machine, for instance hypovolemia due to improper fluid balance during treatment.

NOTE

If no dialysis fluid sample is needed, connect the green Ultra Inlet Line connector to the Ultra Port before pressing the ***CONFIRM*** button on the *Confirm* window.
Otherwise, press the ***CONFIRM*** button on the *Confirm* window without connecting the green Ultra Inlet Line connector. In this case, do not remove the cap on the Ultra Inlet Line.

20. Clamp the Rinseback/Ultra Service lines and the Artrial/Venous Infusion lines. Unclamp the Ultrafilter Degassing line: this clamp must be kept opened throughout the priming procedure;

21. If needed, fill a syringe with the amount of heparin solution prescribed for a single treatment and before connecting it to the Heparin line remove any air from the syringe;

22. Remove the cap from the Heparin line and connect the line to the heparin syringe. ***Do not*** remove the no-return valve connected at the end of the Heparin line. Install the syringe as described in the “3.5.5 Heparin syringe installation” section;

23. If not already done, connect the dialyzer as described in the “3.5.6 Dialyzer Installation” section;

24. Remove the cap from the Arterial Dialyzer line and insert the line into the upper dialyzer blood port. Before connecting the Arterial Dialyzer line to the dialyzer, rotate the line counter-clockwise (about 1 full turn) to prevent kinking;

25. Route the Arterial Dialyzer line through the corresponding guide of the Artis Dialysis System, avoiding covering the Hard Key panel with the line;

26. Remove the cap from the Venous Dialyzer line and insert the line into the lower dialyzer blood port. Before connecting the Venous Dialyzer line to the dialyzer, rotate the line clockwise (about 1 full turn) to prevent kinking;

27. Route the Venous Dialyzer line through the corresponding guide of the Artis Dialysis System;

28. Adjust the dialyzer position to prevent sharp bends in tubing and to prevent tubes from interfering with Artis Dialysis System or its parts. Ensure that lines are untangled;

29. Press the ***CONFIRM*** button on the *Confirm* window.

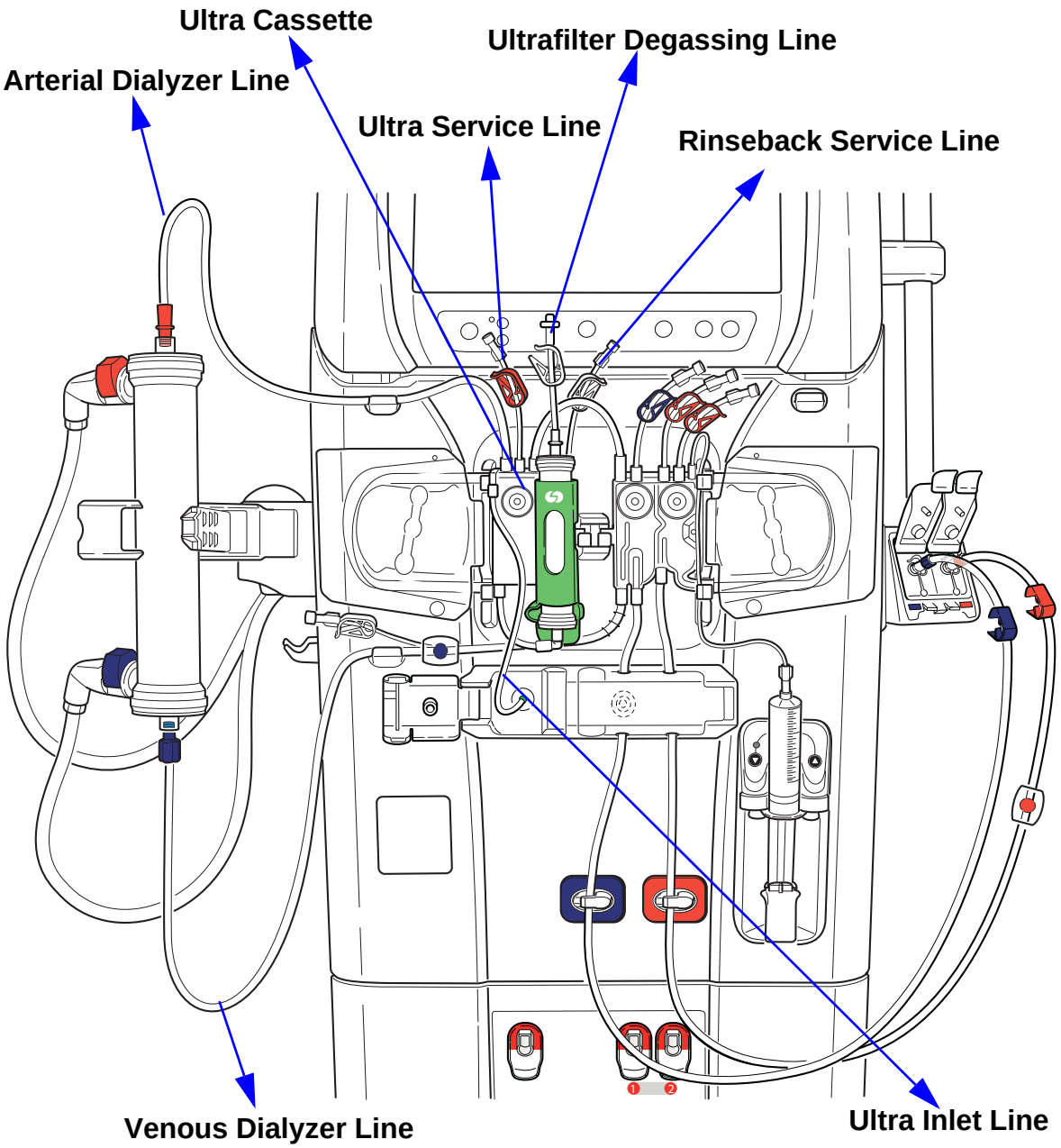


Figure 3-9. Machine Dressing - Ultra Cassette

After the cassette installation has been completed and confirmed, it is possible to unload the Blood and Ultra cassettes at any moment before or after the dialysis fluid preparation is completed.

If the loading procedure fails, it must be restarted from the beginning.

3.5.3 Loading of the Blood and SN Cassettes

Refer to the “Figure 3-10. Machine Dressing - Blood and SN Cassettes” for references to the Blood Tubing System components.

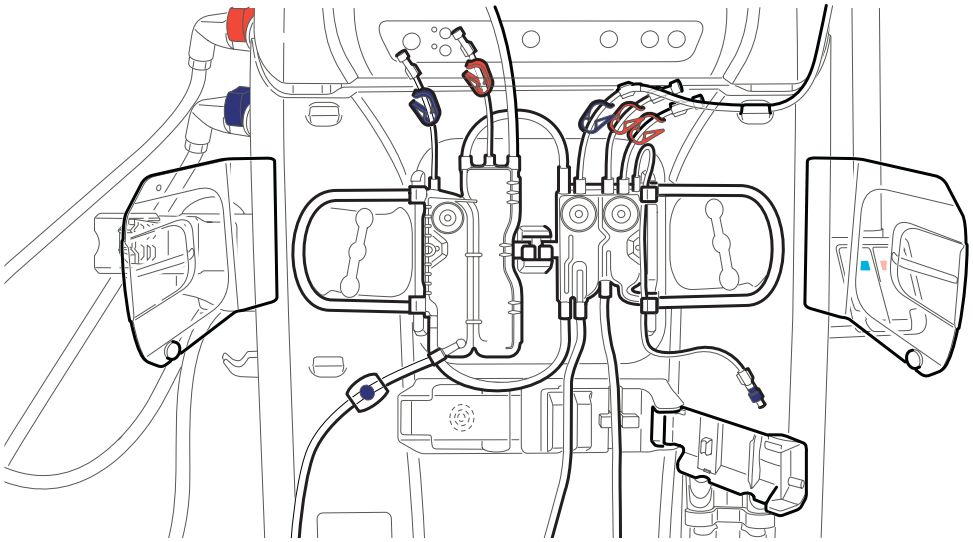
To install the cassette, proceed as follows:

1. Open the *Overview* screen. Follow the messages on the Message Area to install the cassette;
2. Hang a saline bag appropriate for the priming of the extracorporeal circuit on the Infusion Pole. Check that the saline amount in the bag is enough to complete the priming procedure;
3. Open the Sensor Bar door;
4. Open the Arterial and Venous Pump covers:
   - The machine pushes out the blood and ultra cassette holders;
   - The Arterial and Venous Pump rotors are in a horizontal position. This is the default position after switching the machine on and each time the Arterial and Venous pump covers are closed.
5. Extract the Cassette from its package without removing the SteriWraps on the lines;
6. Hang the SN and Blood cassettes on their respective holders;

⚠WARNING

In case of hardware malfunction or if the loading procedure is not completed within 2 minutes, the Cassette holders will automatically retract.
DO NOT insert fingers behind the cassette to avoid injury to your fingers.

7. Route the Heparin line through its guides on the Cassette panel;

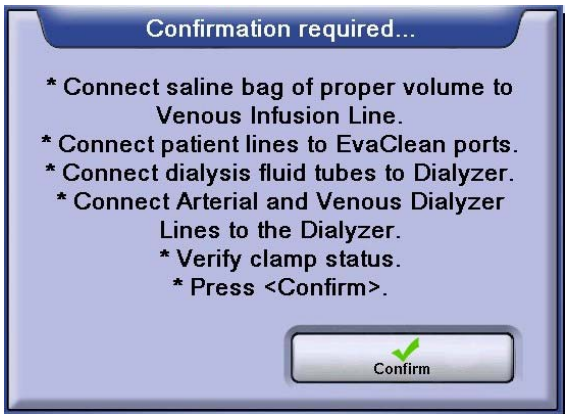


8. Close the Arterial and Venous Pump covers: the machine automatically loads the Blood and SN Cassettes and the pump segments;
9. Connect the Prime Line to the saline bag, then route the Prime Line through its guide on the machine;
10. Route the Arterial Patient line through the Hemoscan sensor;
11. Route the Venous Patient line through the air detector/blood sensor;

⚠WARNING

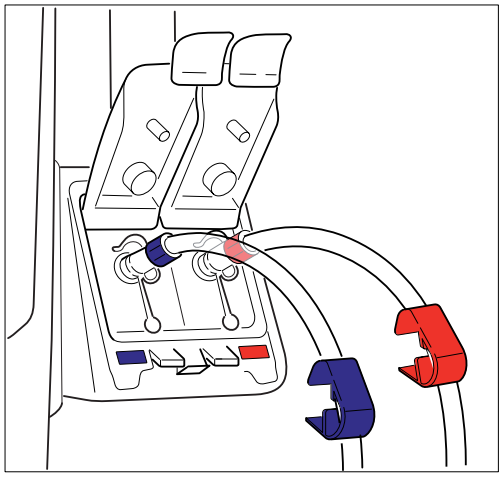
Before inserting the Venous Patient line in the Air Detector clean and dry it. Fluid and gel substances applied on the Air Detector may reduced the Air Detector sensitivity causing patient injury or death.
Refer to the "13.10 External Cleaning" paragraph, in the "Chapter 13: Disinfection/Rinse" of this Operator's Manual, for the description of how to clean the Air Detector.

12. Close the Sensor Bar door;
13. Insert the Arterial and Venous Patient lines in their respective automatic clamps. Wait for the following *Confirm* window before proceeding with cassette installation:



14. Remove the SteriWrap from the Arterial Patient line;

15. Open the EvaClean doors and insert the Arterial Patient line into the EvaClean Red port using the priming connector. When inserting the priming connector keep the clear cap downward to avoid blocking the EvaClean Blue door when closed. Refer to the following figure for the correct insertion:



16. Remove the SteriWrap from the Venous Patient line;

17. Insert the Venous Patient line into the EvaClean Blue port using the priming connector. When inserting the priming connector keep the clear cap downward to avoid blocking the EvaClean Red door when closed;

⚠WARNING

Use an aseptic technique when connecting/disconnecting the priming connectors of the Arterial and Venous Patient lines to/from the EvaClean ports in order to avoid any potential contamination of the lines.

⚠WARNING

Verify that fluid is not present in the EvaClean ports by visual inspection before inserting the priming connectors.
If fluid is present in the ports for more than six seconds after opening the doors, ***DO NOT USE*** the EvaClean option.

⚠WARNING

The EvaClean option must be cleaned each time the Patient Connection procedure is performed keeping the Venous Patient line into the EvaClean Blue port until the machine detects blood. In this case, manually clean the EvaClean option before performing another patient treatment.
(Refer to the "Chapter 8: Special Procedures" of this Operator's Manual).

18. Clamp the SN Service lines and the Arterial/Venous Infusion lines;
19. Connect the dialyzer as described in the "3.5.6 Dialyzer Installation" section;
20. Remove the cap from the Arterial Dialyzer line and insert the line into the upper dialyzer blood port. Before connecting the Arterial Dialyzer line to the dialyzer, rotate the line counter-clockwise (about 1 full turn) to prevent kinking;
21. Route the Arterial Dialyzer line through the corresponding guide of the Artis Dialysis System, avoiding covering the Hard Key panel with the line;
22. Remove the cap from the Venous Dialyzer line and insert the line into the lower dialyzer blood port. Before connecting the Venous Dialyzer line to the dialyzer, rotate the line clockwise (about 1 full turn) to prevent kinking;
23. Route the Venous Dialyzer line through the corresponding guide of the Artis Dialysis System;
24. Adjust the dialyzer position to prevent sharp bends in tubes and to prevent tubes from interfering with Artis Dialysis System or its parts. Ensure that lines are untangled;
25. Connect the Dialysis Fluid Tubes to the dialyzer;
26. If needed, fill a syringe with the amount of heparin solution prescribed for a single treatment and before connecting it to the Heparin line remove any air from the syringe;
27. Remove the cap from the Heparin line and connect the line to the heparin syringe. ***Do not*** remove the no-return valve connected at the end of the Heparin line. Install the syringe as described in the "3.5.5 Heparin syringe installation" section;
28. Press the ***CONFIRM*** button on the *Confirm* window.

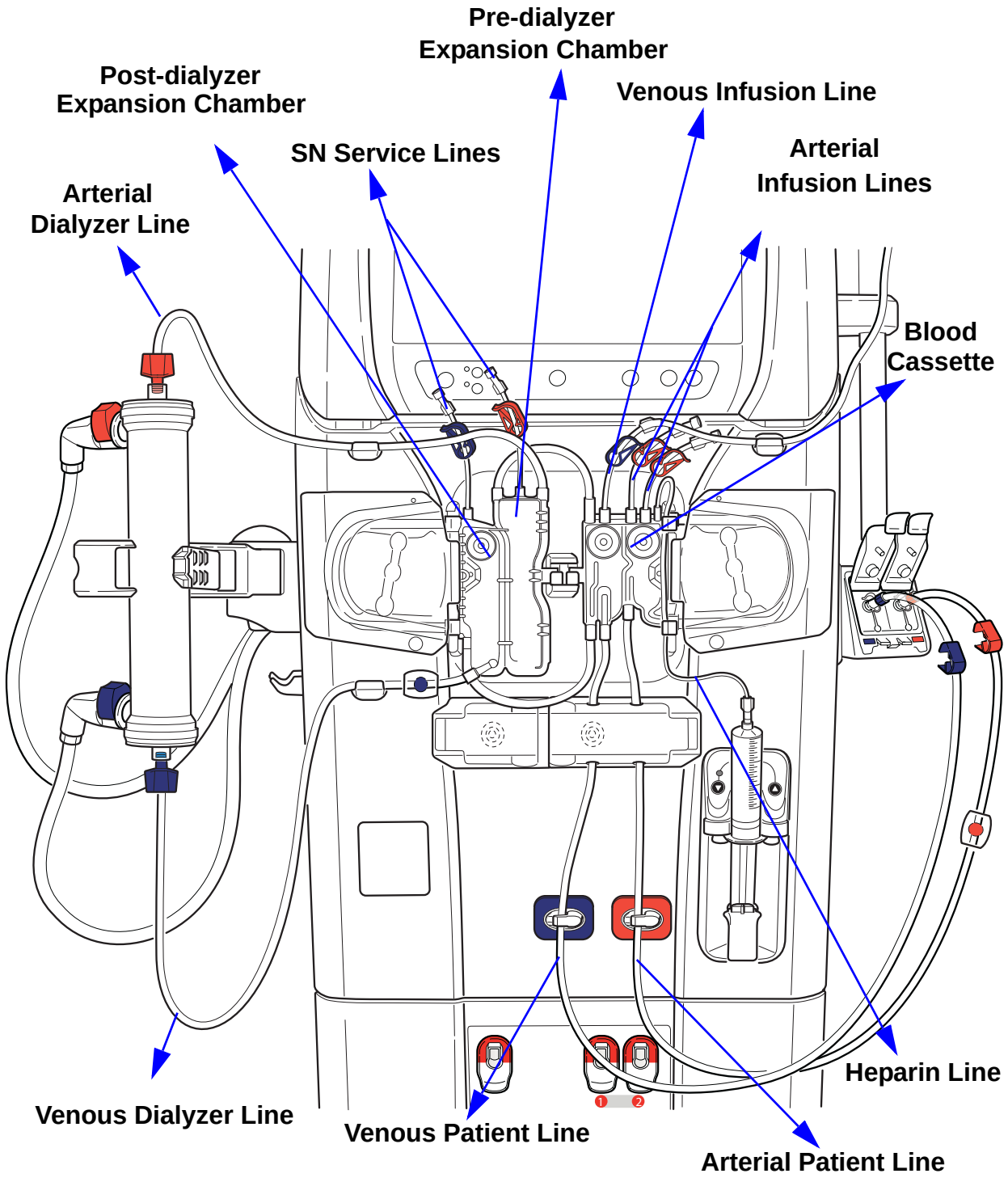


Figure 3-10. Machine Dressing - Blood and SN Cassettes

After the cassette installation has been completed and confirmed, it is possible to unload the cassette at any moment before or after the dialysis fluid preparation is completed.

If the loading procedure fails, it must be restarted from the beginning.

3.5.4 Dialysis Fluid Sampling

It is possible to take a dialysis fluid sample before pressing the "Auto-Prime" button.
The "Sampling" button will be available again after confirming the "Disconnect Patient" button and until the "Drain Cartridge" button is pressed.

3.5.4.1 HD-DN and HD-SN Treatment

To take a dialysis fluid sample in HD-DN or HD-SN Treatment, proceeding as described in the "8.26 Microbiological Sampling of dialysis fluid" section of this Operator's Manual.

3.5.4.2 HDF Post Treatment

To take a dialysis fluid sample in HDF Post Treatment, proceeding as follows:

1. Do not connect the green Ultra Inlet Line connector to the Ultra port and keep the cap on the Ultra Inlet line;

2. Press the ***CONFIRM*** button on the *Confirm* window displayed at the end of the Extracorporeal Circuit installation;

3. Proceed as described in the "8.26 Microbiological Sampling of dialysis fluid" section of this Operator's Manual.

3.5.5 Heparin syringe installation

After the heparin syringe has been connected to the Heparin line, proceed as follows to install the syringe:

1. Push down the heparin syringe plunger lock;

2. Press the arrow down button in the heparin panel to move down the heparin syringe plunger;

3. Place the wings of the syringe against the plastic clips of the heparin syringe holder. Press the syringe slightly down and then push it so that the syringe wings fit between the plastic clips of the heparin syringe holder;

4. Adapt the heparin syringe plunger to the syringe lenght, using the arrow down/up buttons in the heparin panel, so that the syringe piston lays on the base of the heparin syringe plunger;

5. Push up the heparin syringe plunger lock to lock the syringe in place;

6. Verify that the Heparin line is unclamped.

The instructions related to the heparin syringe installation are available on the Heparin Settings sub-screen.

⚠WARNING

Ensure that the Heparin line is securely connected to the heparin syringe and that the syringe is correctly installed on its holder. Incorrect installation of the heparin syringe may cause an incorrect delivery of the heparin during treatment.

3.5.6 Dialyzer Installation

It is possible to install the dialyzer before switching the Artis Dialysis System on or anyway before starting the Autopriming.

To install the dialyzer, proceed as follows:

1. Rotate the dialyzer holder placing its movable arm in the right operating position with the red label on its top;

2. Insert the dialyzer in treatment position between the arm and the clip attached to the arm. Push slightly the dialyzer to insert it into the dialyzer holder: the dialyzer is held in position between the holder arm and the clip.

⚠WARNING

Reverse Ultrafiltration of fluid from the dialysis fluid compartment into the blood compartment of the dialyzer may occur when High Flux dialyzers are used. Because of their high ultrafiltration coefficients, high flux dialyzers will quickly transfer fluid across the membrane in response to pressure differences between the dialysis fluid compartment and the blood compartment.

3.6 Autopriming

The "Auto-Prime" button becomes available:

- After that the Artis Dialysis System has successfully performed its internal checks at the end of the Blood Tubing System loading procedure
- As soon as the Hemoscan cuvette calibration has been successfully performed

3.6.1 Autopriming Booking

As soon as the Blood Tubing System has been installed, it is possible to book the autopriming procedure that will be automatically performed as soon as the dialysis fluid preparation is successfully completed.

When performing a HDF Post Treatment the priming of the Extracorporeal Circuit can be performed with the substitution fluid prepared by the Artis Dialysis System from normally used concentrates. In this case, the substitution fluid contains electrolytes and bicarbonate.

⚠WARNING

If using an Evodial dialyzer, do not perform the "Priming Booking" procedure.
Wait for the end of the dialysis fluid preparation:
- To open the clamps on the Venous Infusion line and on the Prime Line;
- To press the "Auto-Prime" button.

The choice of the "Priming Booking" procedure with the Evodial dialyzer might cause an incorrect priming of the dialyzer that could lead to:
- Air in the dialyzer;
- An incorrect level of fluid in the Arterial and Venous chambers at the end of the priming procedure;
- More possibilities that an "Air in Venous Line (#4)" alarm occurs during the treatment.

NOTE

If the blood volume measurements have to be performed during the treatment, activate the Hemoscan function before pressing the "Auto-Prime" button (refer to the "Chapter 10: Hemoscan™ Monitoring System" of this Operator's Manual).

HD-DN or HD-SN Treatment

To book the autopriming procedure, proceed as follows:

1. Open the clamps on the Venous Infusion line and on the Prime line;

2. Ensure that the saline bag is hanging correctly on the Infusion Pole;

3. Press the “Auto-Prime” button:

   • The “Auto-Prime” action indicator switches to yellow;

   • The dialysis fluid preparation continues;

   • The following *Overview* screen is displayed:

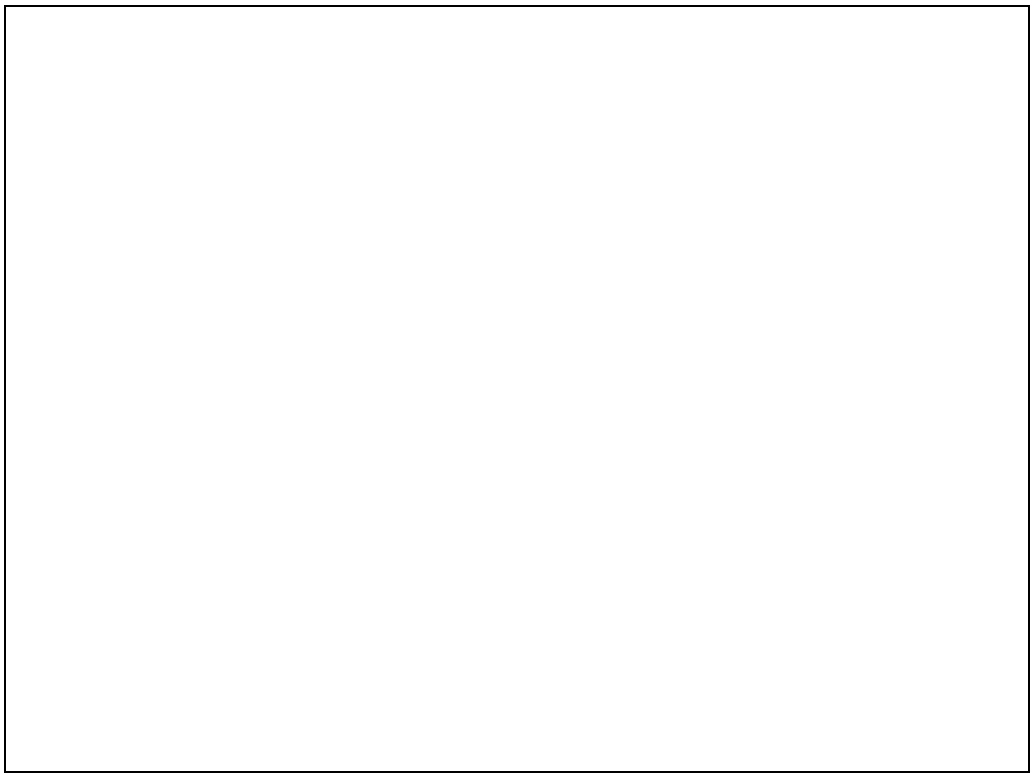


Figure 3-11. Overview Screen - Autopriming booked

NOTE

If the “Auto-Prime” button is not pressed during the dialysis fluid preparation:
• The dialysis fluid preparation goes on;
• The machine waits for the “Auto-Prime” button to be pressed to activate the autopriming process.

If the activated “Auto-Prime” button is pressed, the Autopriming booking is interrupted.

HDF Post Treatment

To book the autopriming procedure, proceed as follows:

1. Ensure that the clamps on the Arterial/Venous Infusion lines and on the Rinseback/Ultra service lines are closed and that the Ultrafilter Degassing line is unclamped;
2. Press the "Auto-Prime" action button:
   - The "Auto-Prime" action indicator switches to yellow;
   - The dialysis fluid preparation continues.

If the activated "Auto-Prime" button is pressed, the Autopriming booking is interrupted.

3.6.2 Check priming parameters

To check the priming parameters, proceed as follows:

1. On the *Blood* screen, press the "Priming Settings" button. The following sub-screen opens:

Figure 3-12. Example of Autopriming Settings Sub-screen

Table 3: Autopriming Settings Buttons

Button	Definition	Values
Type *(Not currently available)*	Sets the type of priming to perform.	/
Pump Speed	Sets/displays the pump speed during the priming procedure.	• 10 mL/min to 350 mL/min *(default 250 mL/min)*

Table 3: Autopriming Settings Buttons

Button	Definition	Values
Volume	Sets the volume of priming solution to process during the priming procedure.	• 1100 mL (or 850 mL, *can be preset only in HD-DN Treatment*) to 4000 mL *(the default value is preset in Service menu)*
UF rate	Sets the UF rate value during the priming procedure.	• 1.0 L/h to 4.0 L/h *(default 1.0 L/h)*
Extra Volume	Sets the volume of priming solution that is processed each time an Extra Prime is performed.	• 250 mL to 4000 mL *(default 250 mL)*
Reset Prime	Resets all the priming parameters. This button becomes available after the priming procedure has been accomplished or interrupted.	/
Acc. Volume	Displays the volume of solution processed during the priming and the extra priming (if performed) procedures.	/
Autopriming Mode *(only in HD-DN and HD-SN treatments)*	Displays the current type of priming.	• High Volume • Low Volume *(only in HD-DN Treatment)*
Acc UF during Priming	Displays the Accumulated UF volume during the priming procedure.	/
Remaining Time	Displays the time remaining to complete the priming process.	/

Priming Volume Setting in HD-DN and HD-SN Treatment

Set the “Priming Volume” parameter according to the type of priming chosen (i.e. default priming equal to High Volume or Low Volume):

Default Priming Volume	Priming Volume
High Volume	Priming Volume of the dialyzer[a] + 500 ml
Low Volume	Priming Volume of the dialyzer[a] + 250 ml

a. Refer to the Dialyzer Instruction for Use for the recommended dialyzer Priming Volume.

⚠WARNING

Choosing a Type of Priming and a Priming Volume not proper for the type of dialyzer used might cause an incorrect priming of the dialyzer that could lead to:
- Air in the dialyzer;
- An incorrect level of fluid in the Arterial and Venous chambers at the end of the priming procedure;
- More possibilities that an "Air in Venous Line (#4)" alarm occurs during the treatment.

NOTE

If using an Evodial 2.2 dialyzer, set the Priming Volume according to the following:

- High Volume: 2000 mL of Priming Volume
- Low Volume: 1750 mL of Priming Volume

Priming Volume Setting in HDF Post Treatment

When setting the "Priming Volume" parameter, consider that this value should be at least equal to the Priming Volume of the dialyzer + 500 ml.

Refer to the Dialyzer Instructions for Use for the recommended dialyzer priming volume.

NOTE

If the "Priming Volume" parameter has been set to a value lower than 1100 ml, the priming procedure will be anyway performed using 1100 ml of solution.

NOTE

If using an Evodial 2.2 dialyzer, set the Priming Volume to 2000 mL.

3.6.3 Start the priming process

HD-DN or HD-SN Treatment

As soon as the dialysis fluid preparation is completed after the priming process has been booked or as soon as the "Auto-Prime" button is pressed:

- The Arterial Pump starts running in a clockwise direction;
- The priming process automatically starts ;
- The "Auto-Prime" action indicator switches to green;

- The “Remaining Time” value starts decreasing while the blue progress bar starts increasing;
- If the heparin delivery function has been activated, the Heparin line will be primed during the priming process;
- The following *Overview* screen is displayed:

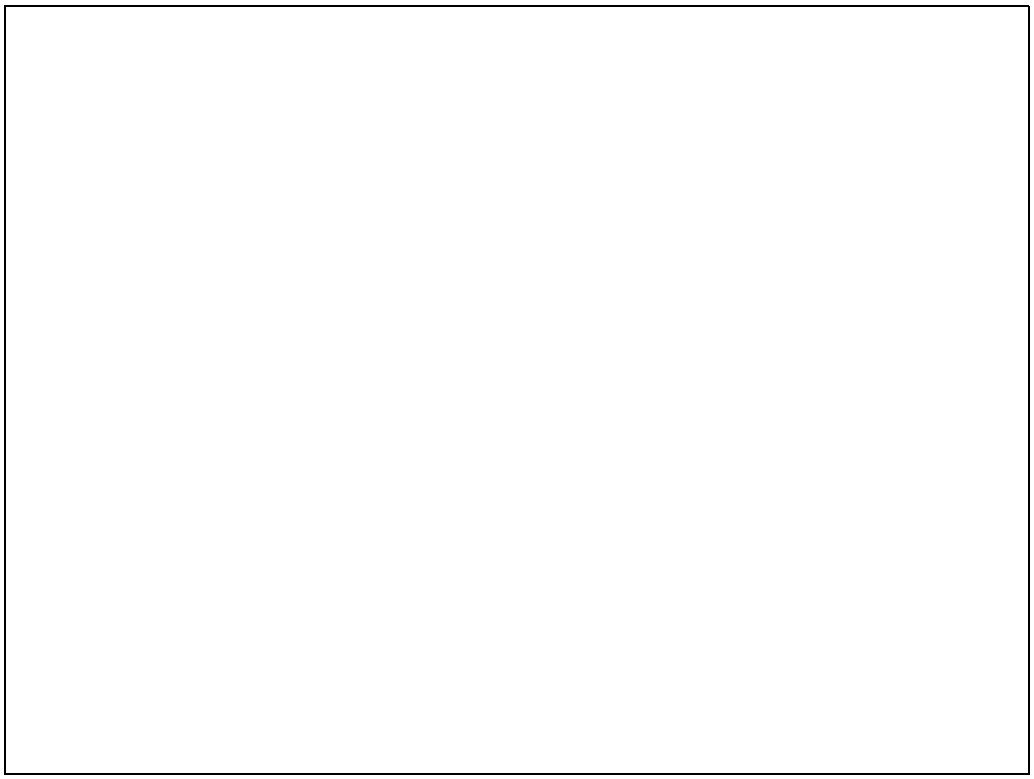


Figure 3-13. Overview Screen - Priming mode

Throughout the priming procedure the “Acc Priming Volume” will be displayed on the *Overview* screen. At the end of the priming procedure, this value will be updated adding the “Acc UF during Priming” value.

HDF Post Treatment

To start the Autopriming, proceed as follows:

1. Ensure that the clamps on the arterial/venous infusion lines and on the Rinseback/Ultra service lines are closed and that the Ultrafilter Degassing line is unclamped;
2. Press the “Auto-Prime” button: a *Confirm* window opens if the green Ultra Inlet Line connector has not been connected to the Ultra port
3. Open the Ultra door;
4. Connect the green Ultra Inlet Line connector to the Ultra port;
5. Press the ***CONFIRM*** button on the *Confirm* window:

- The priming process automatically starts ;
- The "Auto-Prime" action indicator switches to green;
- The "Remaining Time" on the *Overview* screen value starts decreasing while the blue progress bar starts increasing;
- If the heparin delivery function has been activated, the Heparin line will be primed during the priming process.

NOTE

If in HDF Post Treatment, during the Autopriming, conductivity alarms occur preventing the completion of the priming process, consider reducing the Sodium and Bicarbonate prescription settings.
Before starting the patient connection phase, check and if necessary adjust the Sodium and Bicarbonate prescription settings.

3.6.4 Autopriming Paused

Automatic Pause

Autopriming procedure is automatically paused by the Artis Dialysis System in the following cases:

- Each time an alarm is triggered during the Autopriming
- Each time the Arterial and Venous Pumps stop due to:
  - >Operator's intervention
  - >Alarm conditions

After the cause has been solved, the Autopriming procedure is automatically resumed according to defined rules.
In this case, verify that an adequate amount of saline solution is available.

Manual Pause

It is also possible to manually pause the Autopriming procedure before the priming volume has been achieved, pressing the activated "Auto-Prime" action button:

• The following *Overview* screen is displayed:

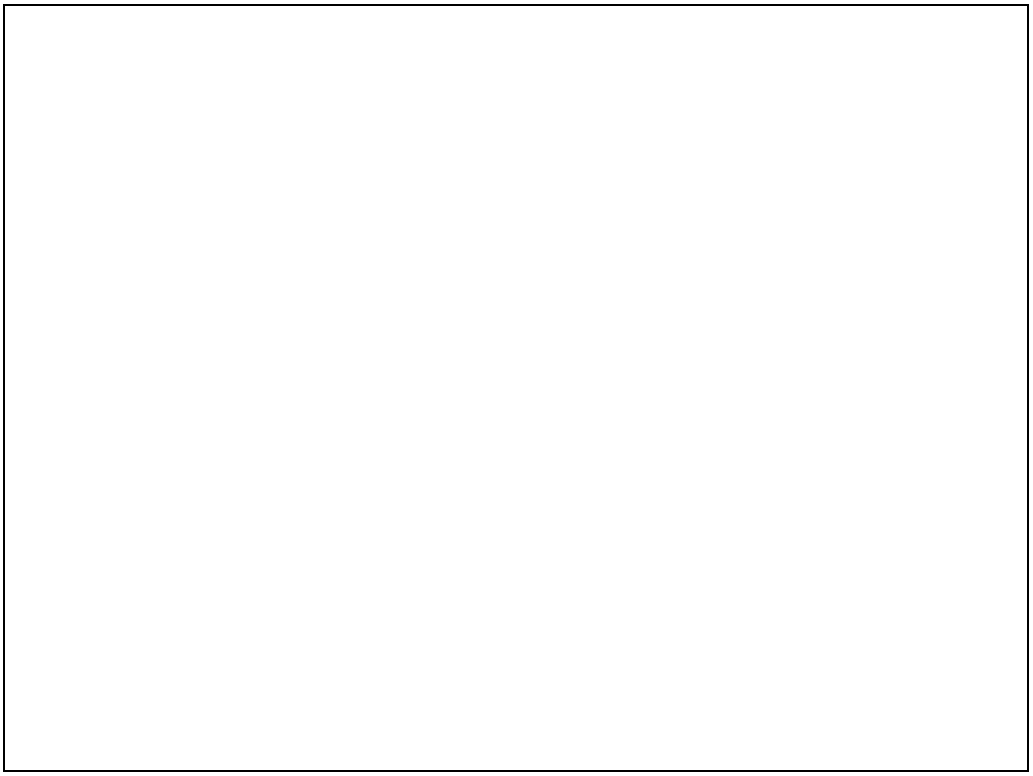


Figure 3-14. Overview Screen - Priming not completed

• The Arterial Pump stops;

• The Venous Pump stops, if a HDF Post or a HD-SN treatment is performed;

• The priming process is paused;

• The message on the Message Area blinks;

• On the Autopriming Settings sub-screen, the “Reset Prime” button is available;

• The “Special Procedures” button is undimmed.

When the “Auto-Prime” button is pressed to restart priming, the machine will resume the process according to defined rules.

3.6.5 Autopriming Completed

As soon as the priming sequence has been successfully completed, the priming process ends:

- The "Priming Completed (#560)" Information Message is triggered
- The Arterial Pump stops
- The Venous Pump stops (if in HDF Post or in HD-SN Treatment)
- On the Autopriming Settings sub-screen, the "Reset Prime" button is available

1. Press the ***CONFIRM*** button to reset the Information Message
2. If in HDF Post Treatment, clamp the Ultrafilter Degassing line
3. Check the fluid level in the Venous and Arterial Chambers and adjust it if necessary. (Refer to the related section in the "Chapter 8: Special Procedures" of this Operator's Manual).

⚠WARNING

Before patient connection, verify that no air is present in the Venous Patient line. If air is present, perform an Extra Prime or a Reset Prime procedure.
Air remained in the Venous Patient line has to be removed before connecting the patient to avoid risk of air embolism.

NOTE

At the end of the priming procedure, internal functional checks will be performed.

3.6.6 Extra Priming

As soon as the priming process has been successfully accomplished, it is possible to start an extra priming, if needed, proceeding as follows:

1. Check for the amount of saline solution, if in HD-DN or HD-SN Treatment;
2. Press the "Extra Prime" Action button: a *Confirm* window opens;

NOTE

The "Extra Prime" button will be available only after the T1 Arterial Pump/ABD test has been successfully accomplished.

3. Press the ***CONFIRM*** button on the *Confirm* window:
   - The extra priming process starts;

• The “Remaining Time” value starts decreasing while the blue progress bar starts increasing.

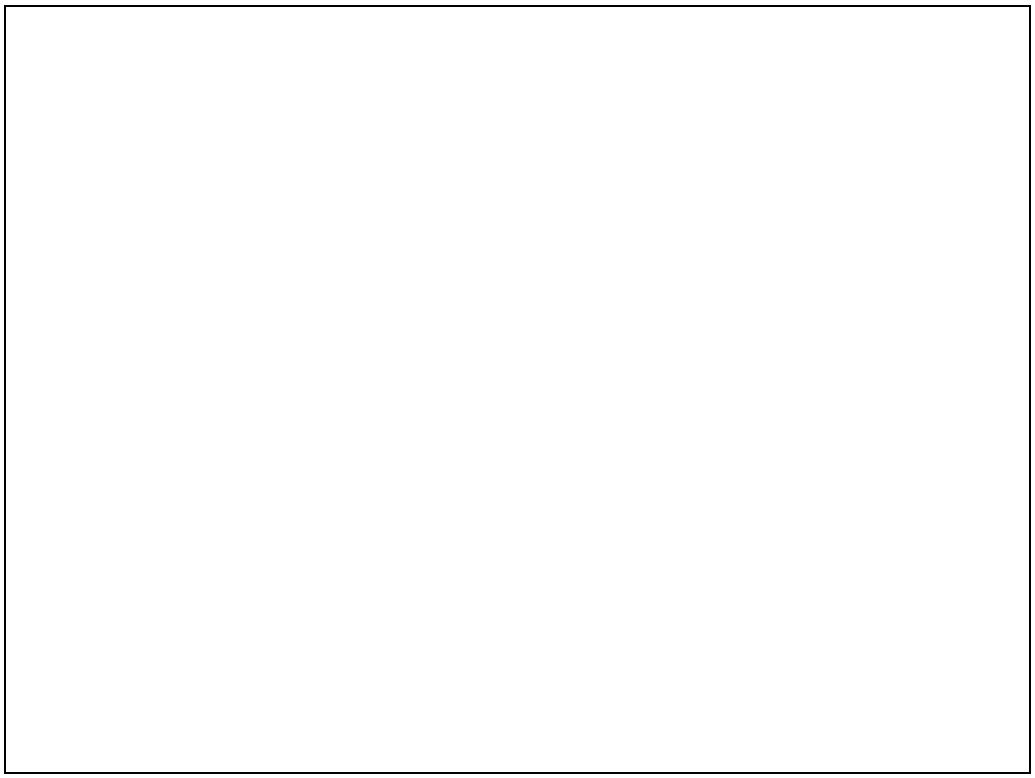


Figure 3-15. *Overview* Screen - Extra Priming in progress

⚠WARNING

Before patient connection, verify that no air is present in the Venous Patient line. If air is present perform an Extra Prime or a Reset Prime procedure.
Air remained in the Venous Patient line has to be removed before connecting the patient to avoid risk of air embolism.

3.6.6.1 Extra Priming Stopped

To stop the extra priming process, press the activated "Extra Prime" action button:

- The extra priming process stops;
- The Arterial Pump stops;
- The Venous Pump stops, if a HDF Post treatment cassette is installed;
- The “Priming Completed (#560)” Information Message appears.

When the “Extra Prime” button is pressed and confirmed to restart the priming, the machine will resume the process according to defined rules.

3.6.6.2 Extra Priming Completed

When the extra prime volume (Extra Volume parameter value) has been achieved, the process stops:

- The "Priming Completed (#560)" Information Message appears;
- The Arterial pump stops;
- The Venous Pump stops, if a HDF Post treatment cassette is installed;
- The "Extra Prime" action indicator switches to grey;
- The "Connect Patient" button is available.

NOTE

The "Extra Prime" action button can be pressed as many times as requested, before connecting the patient to the Artis Dialysis System.

1. Press the ***CONFIRM*** button to reset the Information Message
2. Check the fluid level in the Venous and Arterial Chambers and adjust it if necessary. (Refer to the related section of the "Chapter 8: Special Procedures" of this Operator's Manual)

3.6.7 Reset Prime

As soon as the first priming sequence is accomplished or it is interrupted, the "Reset Prime" button is available on the Autopriming Settings sub-screen. This button allows to repeat the priming procedure.

Repeat the priming procedure as follows:

1. Press the "Priming Settings" button on the *Blood* screen to enter the Autopriming Settings sub-screen;
2. Press the "Reset Prime" button to reset the priming parameter values;
3. Check for the amount of saline solution, if a HD-DN or HD-SN Treatment cassette is installed;
4. On the *Overview* screen, press the "Auto-Prime" button again: the priming process restarts according to defined rules.

3.6.8 Low Consumption

After the priming process has been completed, the Artis Dialysis System will be able to enter the Low Consumption state after a preset time (from 1 to 10 minutes), if the feature has been enabled and configured in the Service menu.

The aim of the feature is to reduce water and concentrate consumption.

When the machine enters the Low Consumption state:

- The Dialysis Fluid Flow is 300 mL/min
- The following *Overview* screen is displayed:

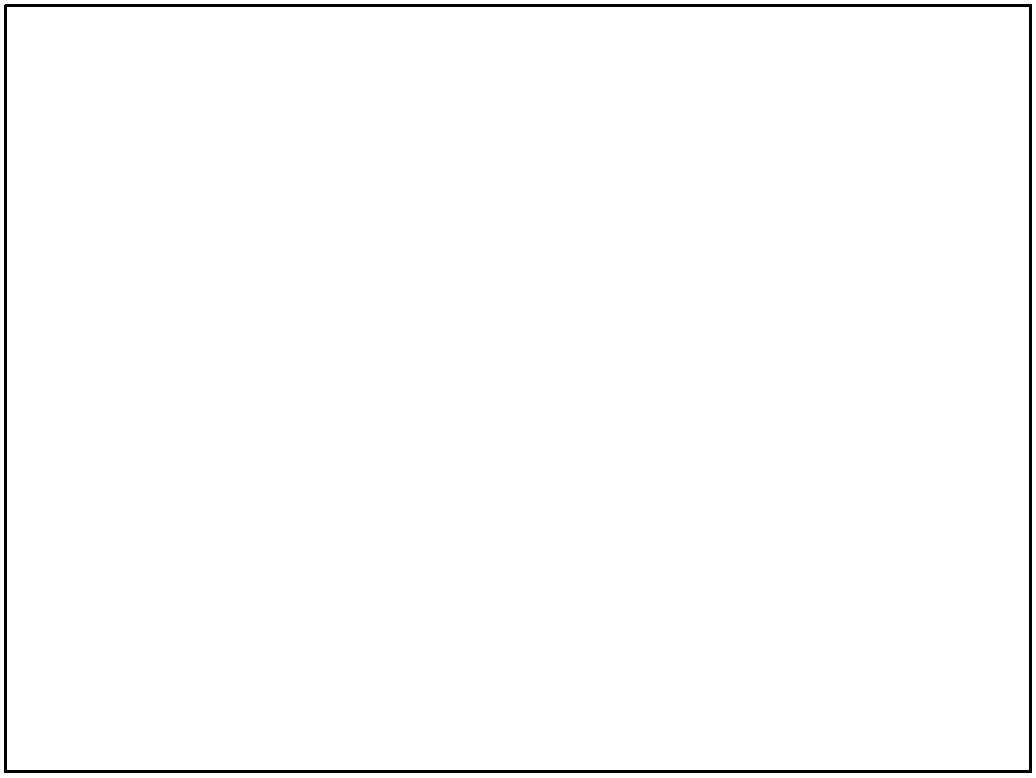


Figure 3-16. Low Consumption State

3.6.8.1 Resume fluid preparation

To resume the dialysis fluid preparation, proceeed as follows:

1. Press the "End Low Consumption" button on the *Overview* screen: a *Confirm* window opens;

2. Press the ***CONFIRM*** button on the *Confirm* window:

   - The "End Low Consumption" button is hidden;
   - The Low Consumption icon is hidden;
   - The "Extra Prime" and "Connect Patient" buttons are displayed but they are dimmed;
   - The dialysis fluid preparation is resumed.

When the dialysis fluid preparation is accomplished the "Extra Prime" and "Connect Patient" buttons are enabled.

NOTE

Once the Dialysis Fluid preparation is resumed, if neither the "Extra Prime" nor the "Connect Patient" button has been pressed, the Artis Dialysis System re-enters the Low Consumption state after an interval of 5 minutes plus the Low Consumption preset time.

3.7 Heparin delivery system

The Artis Dialysis System provides the following heparin delivery programs:

Program	Initial Bolus	Delivery Method	Manual Bolus
Linear	Yes	Constant Rate	Yes
Intermittent	Yes	Bolus delivered at programmed intervals of time	Yes
Manual	NO	Manual	Yes

A single extra bolus of heparin can be delivered to the patient during the treatment if an automatic heparin Administration Type has been set (refer to the “3.7.5.2 Extra Bolus Delivery” section below).

Each program can be activated or deactivated, and related parameters modified, anytime during the start up phase or during the treatment.

3.7.1 Heparin line priming

The Artis Dialysis System allows to perform an automatic or a manual heparin line priming process.

The heparin volume necessary for priming the Heparin line is 0.6 mL. This volume will not be added to the “Acc Heparin” value.

3.7.1.1 Automatic priming

It is possible to perform the automatic priming only if the heparin delivery function is activated before starting the first priming procedure. In this case, as soon as the operator press the “Auto-Prime” action button the Heparin line is primed and the indicator on the Heparin Panel lights up green.

3.7.1.2 Manual priming

The manual priming of the heparin line can be carried out by means of the heparin syringe positioning keys on the Heparin panel.

This type of priming can be performed if the heparin function has been activated after starting the first priming procedure.

3.7.2 Set the Heparin Parameters

To check/set the values related to the heparin delivery system, enter the Heparin Settings sub-screen as follows:

1. Press the "Heparin Auto Start" button in the "Activated Functions" list on the *Prescription* screen during the set-up procedure. The Heparin Settings sub-screen opens:

Figure 3-17. Heparin Settings Sub-screen

It is also possible to open the Heparin Settings sub-screen pressing the "Heparin Settings" button on the *Blood* screen.

This sub-screen displays different buttons and parameters according to the set Administration Type.

In the following table all the heparin buttons/parameters are listed.

PARAMETER	DESCRIPTION	VALUES
Administration Type	Allows to select the desired heparin delivery type.	• Linear • Intermittent • Manual
Initial Dose (mL)	Sets the initial amount of heparin solution that will be delivered as soon as the set heparin delivery program starts. When the dose has been delivered, this button will be disenabled.	• 30 mL syringes: 0.0 mL to 12.0 mL *(default 0.0 mL)* • 10 mL syringes: 0.0 mL to 4.0 mL *(default 0.0 mL)*

PARAMETER	DESCRIPTION	VALUES
Dose Rate (mL/h)	Sets the heparin rate during the treatment. This button is available if a Linear Administration Type has been selected.	• 30 mL syringes: 1.5 mL/h to 10.0 mL/h *(default 1.5 mL/h)* • 10 mL syringes: 0.5 mL/h to 4.0 mL/h *(default: 1.5 mL/h)*
Stop Time (h:min)	Sets the difference, in hour and minutes, between the end of the treatment time and the end of the heparin delivery.	• 0 to 8:00
Dose Size (mL)	Sets the amount of the automatically given doses. This button is available if an Intermittent Administration Type has been selected.	• 30 mL syringes: 0.5 mL to 12.0 mL *(default 1.0 mL)* • 10 mL syringes: 0.5 mL to 4.0 mL *(default: 1.0 mL)*
Time Interval (h:min)	Sets the time interval, in hour and minutes, between the automatically given doses. This button is available if an Intermittent Administration Type has been selected.	• 0:05 to 2:00 *(default 2:00)*
Bolus Size (mL)	• **"**Linear***" or "***Intermittent***"** Administration Type***:*** Sets the amount of heparin solution delivered each time the "Extra Bolus" action button is pressed • **"**Manual***"*** Administration Type***:*** Sets the amount of heparin solution delivered each time the "Extra Bolus" action button is pressed.	• 30mL syringes: 0.5 mL to 12.0 mL *(default 1.0 mL)* • 10mL syringes: 0.5 mL to 4.0 mL *(default: 1.0 mL)*
Manual Bolus (mL)	Sets the amount of a manual delivered bolus of heparin solution. This button is displayed when a Manual Administration Type is set and remains available until the rinseback phase starts.	/
Extra Bolus	Allows to deliver a single heparin bolus. The operation must be confirmed pressing the ***CONFIRM*** button on the *Confirm* window. This button will be available as soon as blood is detected into the Venous Patient line and until the "Stop Treatment" button is pressed.	• ON • OFF
Acc Heparin (mL)	Displays the accumulated amount of heparin that has been delivered, including bolus doses.	/
Syringe Type	Displays the syringe type set in the Service 2 menu.	The syringe type can be set only in Service 2 menu

PARAMETER	DESCRIPTION	VALUES
Heparin	Activate/deactivate the heparin delivery.	• ON • OFF

3.7.3 Activate a delivery program

After setting the heparin parameters, it is possible to activate the delivery program pressing the "Heparin" action button on the Heparin Settings sub-screen:

Figure 3-18. Heparin Settings Sub-screen - Heparin Delivery Program activated

- The heparin icon is displayed on the *Overview* screen;
- The "Heparin Auto Start" action indicator on the "Activated Functions" list on the *Prescription* screen switches to green.
- When a Manual Administration Type is activated, the "Manual Bolus" button becomes available on the Heparin Settings sub-screen after blood has been detected by the machine and all the heparin parameters related to the automatic distibution types are hidden.

⚠WARNING

If during the Isolated UF process the "Heparin" action button is activated/reactivated, its action indicator becomes green, but the heparin delivery program does not start/restart until the end of the Isolated UF process.
If during the Isolated UF process the heparin settings are changed, these settings are not implemented until the end of the Isolated UF process.
To activate the heparin delivery program and/or change its settings, press the "Heparin" action button and/or change the heparin program settings before pressing the "Start Treatment" button.

⚠WARNING

If the dialysis fluid flow is deactivated and the "Heparin" action button is activated/reactivated in this phase, its action indicator becomes green, but the heparin delivery program does not start/ restart until the dialysis fluid flow is activated.
If the dialysis fluid flow is deactivated and the heparin settings are changed in this phase, these settings are not implemented until the dialysis fluid flow is activated.
To activate the heparin delivery program and/or change its settings, proceed as follows:
- Press the "Dialysis Fluid" action button to activate the dialysis fluid flow;
- Change the heparin delivery program settings and/or press the "Heparin" action button to activate the heparin delivery program;
- Press the "Dialysis Fluid" action button to deactivate again the dialysis fluid flow.

NOTE

If the patient prescription parameters are set via a Patient Card or via the network connection, the heparin parameters will be automatically set and the heparin delivery program will be automatically activated.

NOTE

If the Heparin Delivery system has not been activated, the “Heparinization Not Initiated (#71)” alarm is triggered as soon as the “Start Treatment” button is pressed.
This alarm will not be triggered if the prescription is downloaded from the Exalis System or if using a Patient Card.

3.7.4 Heparin delivery

3.7.4.1 Automatic delivery program

If an Administration Type Linear or Intermittent has been set, the delivery starts in Patient Connection phase as soon as one of the following conditions is satisfied:

- Before the machine detects blood: the Arterial Pump runs and 30 mL of saline/blood have been processed;
- The Arterial Pump runs and blood is detected into the Venous Patient line.

As soon as the program starts:

- The initial dose is delivered;
- The “Initial Dose” button is disenabled;

- The "Extra Bolus" button is displayed and it will be available until the rinseback procedure starts.
  The "Extra Bolus" button is not available during an Intermittent delivery program while heparin is delivered.
- The heparin syringe positioning keys are disenabled;
- The set heparin program continues throughout the treatment until the remaining treatment time minus the heparin stop time is equal to zero.

NOTE

If the "Stop Treatment" button is pressed and then the treatment is continued, the bolus is delivered even if the programmed time interval is not elapsed.

3.7.4.2 Manual delivery program

If a Manual Administration Type has been set and a manual bolus has to be delivered during the treatment, proceed as follows:

1. Open the Heparin Settings sub-screen;
2. Check the "Manual Bolus" amount;
3. Press the "Manual Bolus" action button: a *Confirm* window opens;
4. Press the ***CONFIRM*** button on the *Confirm* window:
   - The "Manual Bolus" action indicator switches to green and the button is dimmed;
   - The set amount is delivered;
   - The delivered amount will be added to the "Acc Heparin" volume.

Each time the "Manual Bolus" button is pressed and confirmed the complete manual bolus dose is delivered.

When the requested dose has been delivered, the "Manual Bolus" action indicator button switches to grey and the button becomes available.

3.7.5 Operations during the delivery program

Anytime before the end of the heparin delivery program, it is possible to perform the following actions:

- Manually stop the delivery program
- Deliver a manual bolus
- Change the heparin program

3.7.5.1 Deactivate a Delivery Program

To manually stop an heparin delivery program, proceed as follows:

1. Press the activated "Heparin" action button:

   - The delivery program stops;
   - The indicator on the Heparin Panel turns off;
   - The heparin syringe positioning keys are activated;
   - The heparin icon on the *Overview* screen is hidden;
   - The “Heparin Auto Start” action indicator on the “Activated Functions” list on the *Prescription* screen switches to grey;
   - The “Heparin” action indicator on the Heparin Settings sub-screen switches to grey.

NOTE

When the heparin delivery program is manually stopped, the “Acc Heparin” value is not set to zero.
When the program is restarted, the heparin volume delivered will be added to the previously accumulated heparin volume.

3.7.5.2 Extra Bolus Delivery

To deliver a single heparin bolus to the patient during the treatment, proceed as follows:

1. Press the “Extra Bolus” button on the Heparin Settings sub-screen and confirm the operation pressing the ***CONFIRM*** button on the *Confirm* window:

Figure 3-19. Extra Bolus Delivery Confirm

NOTE

The "Extra Bolus" button is not available during the intermittent delivery program while heparin is delivered.

- The "Extra Bolus" action indicator switches to green;
- The requested bolus is delivered;
- The bolus amount will be added to the "Acc Heparin" volume.

As soon as the bolus amount has been delivered, the "Extra Bolus" indicator switches to grey.

Each time the "Extra Bolus" button is pressed the whole "Bolus Size" is delivered.

It is possible to interrupt the bolus delivering after the ***CONFIRM*** button on the *Confirm* window has been pressed, proceeding as follows:

1. Press the activated "Extra Bolus" button:
   - The machine immediately stops the bolus delivering;
   - The "Extra Bolus" action indicator switches to grey.

3.7.5.3 Change the Heparin Delivery Program

To change the heparin delivery program, proceed as follows:

1. Press the "Administration Type" button on the Heparin Settings sub-screen: a selectpad opens;
2. Select the desired Administration Type and press the ***CONFIRM*** button on the selectpad:
   - The heparin delivery is stopped;
   - The indicator on the Heparin Panel turns off;
   - The heparin syringe positioning keys are activated;
   - The heparin icon on the *Overview* screen is hidden;
   - The "Heparin Auto Start" action indicator on the "Activated Functions" list on the *Prescription* screen switches to grey;
   - The "Heparin" action indicator switches to grey.
3. Check the heparin parameters;
4. Press the "Heparin" button: the heparin program starts again with the new parameter.

NOTE

When the heparin delivery program is manually stopped, the “Acc Heparin” value is not set to zero.
When the program is restarted, the heparin volume delivered will be added to the previously accumulated heparin volume.

3.7.6 Delivery Program Completed

The machine will automatically stop the heparin delivery as soon as the remaining treatment time minus the heparin stop time is equal to zero.

When the heparin delivery program has been completed the “Heparin infusion complete (#518)” Information Message is triggered:

- The delivery program stops;
- The heparin icon on the *Overview* screen is hidden;
- The “Heparin” action indicator on the Heparin Settings sub-screen switches to grey.

1. Press the ***CONFIRM*** button to reset the Information Message.

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Chapter 4: HD-DN Treatment

After the operations described in the “Chapter 3: Machine Dressing and Priming” have been performed, proceed as described in the sections below to connect the patient and perform the treatment.

4.1 Connect the Patient

The “Connect Patient” button becomes available:

- After the BLD T1 Test has been successfully completed;
- After the Artis Dialysis System exits from the Low Consumption State, if active.

When the machine is ready for patient connection, the following *Overview* screen is displayed:

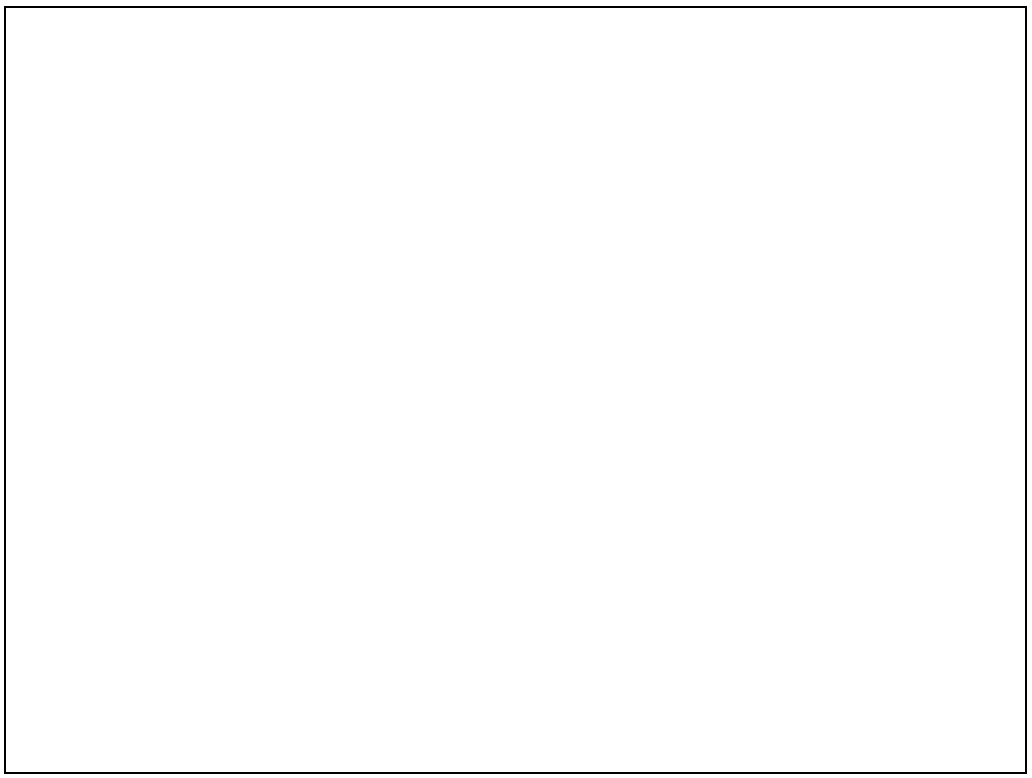


Figure 4-1. Overview Screen - Waiting for patient

⚠WARNING

After a Chemical Disinfection program, a test for residuals of disinfectant must be performed before the following patient connection to avoid the risk of blood hemolysis due to the exposure of the patient to the chemical residues.

⚠WARNING

The Patient Connection and Rinseback modes require additional attention: to facilitate their execution, some safety checkings are temporary deactivated and left to the responsibility of the operator (e.g., the extracorporeal A/V pressure limits are expanded to the maximum).

⚠WARNING

During patient connection/disconnection, follow your facility's policies and procedures for managing patient's vascular access and Venous and Arterial Patient lines used for hemodialysis.
The use of central venous catheters with atrial location leads to additional hazardous situations with respect to the other types of vascular access, due to their proximity to the heart.
In particular, if the patient's catheter disconnects from the patient lines or the integrity of the catheter is compromised in any other way, follow your facility's policy for preventing air embolism and infection, including clamping the patient's lines immediately.

⚠WARNING

Eventual electrical current leakages from the dialysis machine or from other electrical equipments are associated to an increased risk of patient electric shock in case central venous catheters with atrial location are used.
To avoid this risk, ensure that the potential equalization conductor is connected to the proper means on the Artis Dialysis System rear panel.

⚠WARNING

Before patient connection, verify that no air is present in the Venous Patient line. If air is present perform an Extra Prime or a Reset Prime procedure.
Air remained in the Venous Patient line has to be removed before connecting the patient to avoid risk of air embolism.

NOTE

If the Patient Connection is delayed, the dialysis fluid contained in the dialyzer could get cold.
In order to warm the dialysis fluid before connecting the patient, perform an Extra Priming procedure.

To connect the patient, proceed as follows:

1. Clamp the Venous Infusion line and disconnect the saline bag;
2. Enter and confirm mandatory prescription parameters on the *Prescription* screen, if not already done;
3. Ensure that all the required functions have been activated;
4. Press the “Connect Patient” command button: the following *Confirm* window opens:

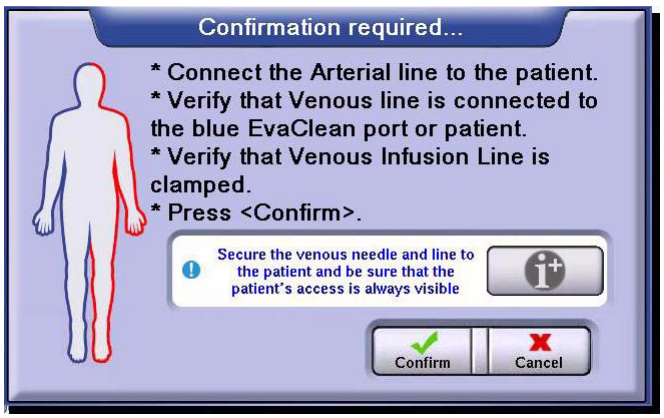
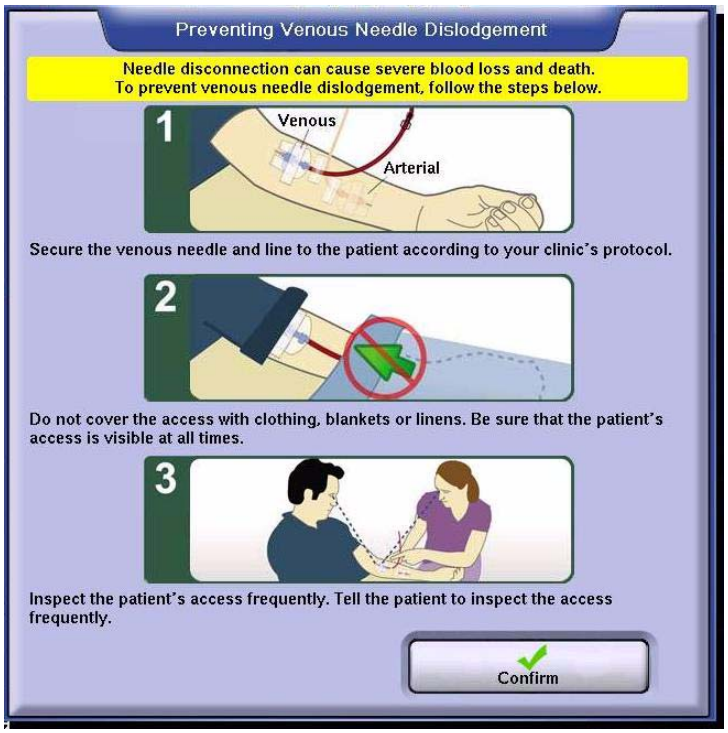


Figure 4-2. Confirm Patient Connection

Pressing the “i+” button the following window is displayed:



Press the ***CONFIRM*** button to close the window and to come back to the patient connection *Confirm* window;

5. Remove the Arterial Patient line from the EvaClean port, unscrew the priming connector from the line and discard it;

6. Close the EvaClean Red door,

7. Connect the Arterial Patient line to the patient's vascular access, according to the clinical policy;

8. Connect the Venous Patient line to the patient or to a waste bag (in these cases, close the EvaClean Blue door) or keep the Venous Patient line into the EvaClean Blue port;

⚠WARNING

The EvaClean option must be cleaned each time the patient connection procedure is performed keeping the Venous Patient line into the EvaClean Blue port until the machine detects blood. In this case, manually clean the EvaClean option before performing another patient treatment.
(Refer to the "Chapter 8: Special Procedures" of this Operator's Manual).

9. Press the ***CONFIRM*** button on the *Confirm* window:

   • The *Confirm* window closes;

   • The blood pump ON/OFF and the blood flow Increase/Decrease keys are activated;

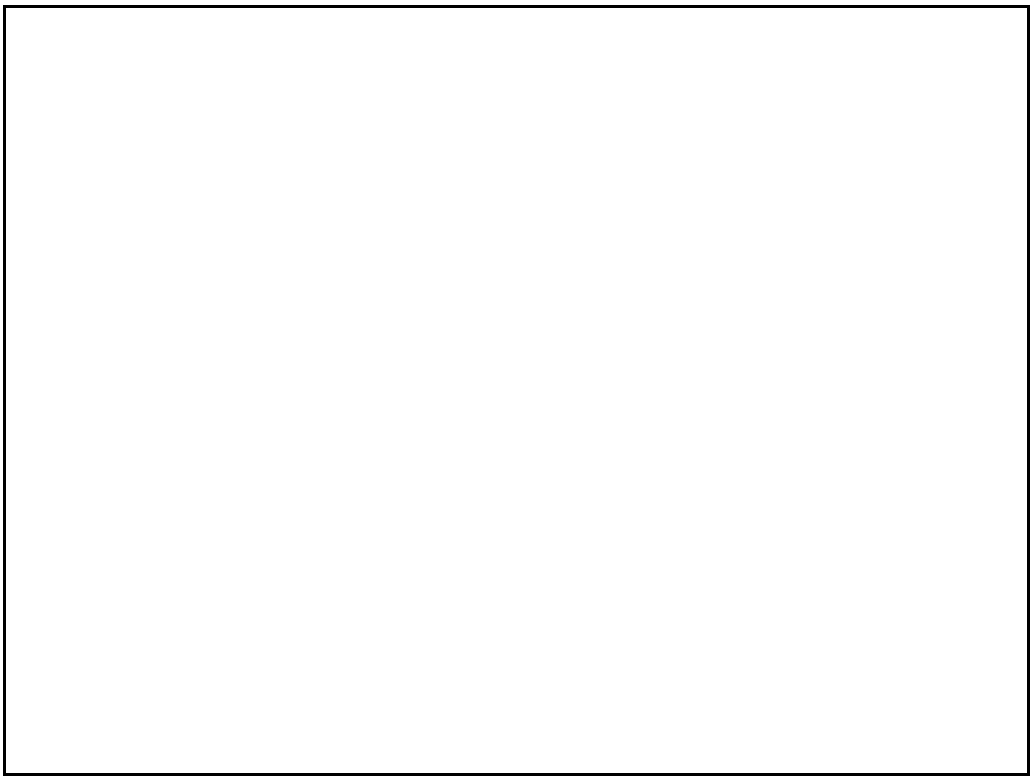
   • The arterial and venous clamps are closed.

10. Press the blood pump ON/OFF key to start the Arterial Pump;

NOTE

If the EvaClean Red door is still opened, an alarm is triggered and the Arterial Pump stops. The operator has to proceed with proper connection, close the EvaClean door and manually restart the Arterial Pump.

As soon as blood is detected, the following *Overview* screen is displayed:



- The Arterial Pump stops;
- If in HD-DNDP Treatment, the Venous Pump stops too;
- The arterial and venous pressure Bar Graphs start monitoring with open limits;
- The blood path switches to red.

11. If the Venous Patient line is already connected to the patient, skip steps 12, 13, 14 and 15.
    Otherwise, remove the Venous Patient line from the EvaClean port or from the waste bag, unscrew the priming connector from the line and discard it;
12. Discard the waste bag if used;
13. Close the EvaClean Blue door if not already done;
14. Connect the Venous Patient line to the patient's vascular access;
15. Start the dialysis treatment (refer to "4.2 Start Treatment" section).

NOTE

If the EvaClean Blue door is still opened, an alarm is triggered and the Arterial Pump stops. The operator has to proceed with proper connection, close the EvaClean door and manually restart the Arterial Pump.

4.1.1 Special Procedures

During the Connect Patient phase the following special procedures are available:

- Change Acid
- Change BiCart
- Change SelectCart
- Change SelectBag
- Skip Treatment
- Cassette Repositioning
- SN Cassette Repositioning (*only in HD-DNDP Treatment)*
- Switch to SN (*only in HD-DNDP Treatment)*
- Change Circuit
- Pause Treatment *(only after blood has been detected by the machine)*

NOTE

Complete the "Change Circuit" procedure (until the "Start Treatment" button is pressed) before starting a "Pause Treatment" procedure.

To perform these procedures refer to the related sections in the "Chapter 8: Special Procedures" of this Operator's Manual.

4.1.2 Change Treatment Type

To change to a HD-SN Treatment during the Connect Patient phase, perform a "Change Circuit" procedure as described in the "8.13 Change Circuit in HD-DN Treatment" section of this Operator's Manual.

4.2 Start Treatment

NOTE

If it is necessary to infuse saline solution to the patient during the treatment, the Arterial Infusion lines can be used.

To start a HD-DN Treatment, proceed as follows:

1. Press the blood pump ON/OFF key to start the Arterial Pump;
   - The Arterial Pump starts at a pre-set speed in a counter-clockwise direction;
   - The “Start Treatment” button becomes available.
2. Press the “Start Treatment” button to start the treatment: the “UF” and the “Dialysis Fluid” buttons become available and their indicators are yellow.
3. Press the blood flow Increase/Decrease keys to adjust the pump speed;
4. As required by the operator message, press the “Close A/V Limits” button as soon as the arterial and venous pressures are stable: an operator message is displayed indicating that the machine is performing its internal checks;
5. As required by the operator message, check the blood levels in the Arterial and Venous Chambers.
   For further details, refer to the “8.28 Adjust Arterial/Venous chamber levels” section of this Operator’s Manual.

NOTE

Blood levels too low in the Arterial or Venous Chambers may cause air to enter the dialyzer thus resulting in dialysis efficacy reduction and/or “Air in Venous Line (#4)” alarm occurrence.

When the machine is ready:

- The UF process starts;
- The “UF” and “Dialysis Fluid” action indicators switch to green;
- The “Real TX Time” value on the *Fluid* screen starts increasing;

- The following *Overview* screen is displayed:

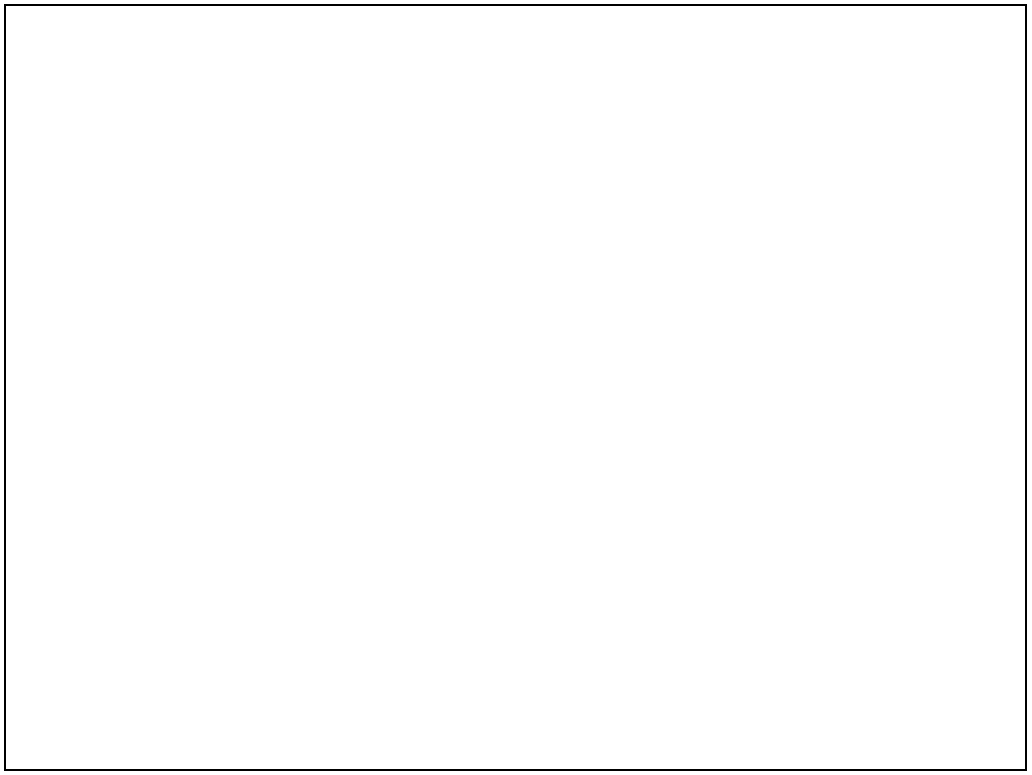


Figure 4-3. Overview Screen - HD-DN Treatment in progress

The "Acc UF Volume" value box will display the accumulated UF volume during the treatment.

4.3 Operations during treatment

Below is a list of the main operations that can be performed on the Artis Dialysis System when a treatment is ongoing.

4.3.1 Special Procedures

As soon as the treatment starts and until the “Stop Treatment” button is pressed and confirmed, the following special procedures are available:

- Change Acid
- Change BiCart
- Change SelectCart
- Change SelectBag
- Switch to SNSP (*only in HD-DN Treatment*)
- Pause Treatment
- Change Circuit
- Cassette Repositioning
- SN Cassette Repositioning (*only in HD-DNDP Treatment*)
- Switch to SN (*only in HD-DNDP Treatment*)
- Adjust the Arterial/Venous Chamber Levels
- Adjust the Expansion Chamber Levels *(only in HD-DNDP Treatment)*

To perform these procedures refer to the related sections in the “Chapter 8: Special Procedures” of this Operator’s Manual.

4.3.2 Deactivate UF process

To deactivate the ongoing UF process, press the activated “UF” action button on the *Overview* screen:

- The “UF” action indicator switches to grey;
- The ultrafiltration process is stopped.

Press the dectivated “UF” button to restart the UF process.

4.3.3 Deactivate Dialysis Fluid flow

To deactivate the dialysis fluid flow, press the "Dialysis Fluid" action button:

- The dialysis fluid goes in bypass;
- The "Dialysis Fluid" action indicator switches to grey;
- The updating of the "Real TX Time" value is interrupted.

To activate the Dialysis Fluid flow again, press the dectivated "Dialysis Fluid" button:

- The "Dialysis Fluid" action indicator switches to green;
- The updating of the "Real TX Time" value restarts.

4.3.4 Expand A/V Limits

The "Expand A/V Limits" button allows to open the arterial and venous pressure alarm windows.

When the "Expand A/V Limits" button is pressed on the *Overview* screen or on the *Blood* screen:

- The "Expand A/V Limits" button becomes "Close A/V Limits";
- The Arterial and Venous alarm windows open and they are automatically set at the following values:

Arterial Pressure	
Upper Limit	+ 150 mmHg
Lower Limit	- 400 mmHg

Venous Pressure	
Upper Limit	+ 450 mmHg
Lower Limit	+ 10 mmHg

When the arterial and venous pressures are stable, press the "Close A/V Limits" button to adjust and close the A/V pressure alarm limit windows.

For further details on this function refer to the "1.7.3.1 Manually Expand/Close the pressure alarm limits" section of this Operator's Manual.

4.3.5 Stop the Arterial Pump

To stop the pump during a treatment, press the blood pump ON/OFF key:

- The Arterial Pump stops.
  In HD-DNDP, the Venous Pump stops too;
- The "UF Rate" is set to zero;
- The "UF" and "Dialysis Fluid" action indicators switch to yellow;

- The updating of the “Real TX Time” value stops;
- The arterial and venous alarm limits are automatically set to the following values:

Arterial Pressure	
Upper Limit	+ 150 mmHg
Lower Limit	- 400 mmHg

Venous Pressure	
Upper Limit	+ 450 mmHg
Lower Limit	- 50 mmHg

These values are maintained for all the time the Arterial Pump is off and for 30 seconds after the Arterial Pump restarts.

To restart the pump, press again the blood pump ON/OFF key:

- The Arterial Pump restarts.
  In HD-DNDP, the Venous Pump restarts too;
- The treatment restarts;
- The updating of the “Real TX Time” value restarts.

4.3.6 Report Table

During a treatment it is possible to visualize a run-time dialysis report containing the data acquired throughout the treatment.

For further details on this function, refer to the “Chapter 15: Report Environment” of this Operator’s Manual.

4.4 Stop treatment

When the end conditions for the current treatment are reached, one or both the Information Messages "Treatment Time Complete (#51)" and "Fluid Removal Complete (#53)" are triggered.

The Treatment can also be manually stopped at any time by pressing the "Stop Treatment" action button.

To stop the treatment after the end conditions have been reached or before reaching the end conditions, proceed as follows:

1. Press the "Stop Treatment" button: a *Confirm* window opens;

2. Press the ***CONFIRM*** button on the *Confirm* window. The following *Overview* screen is displayed:

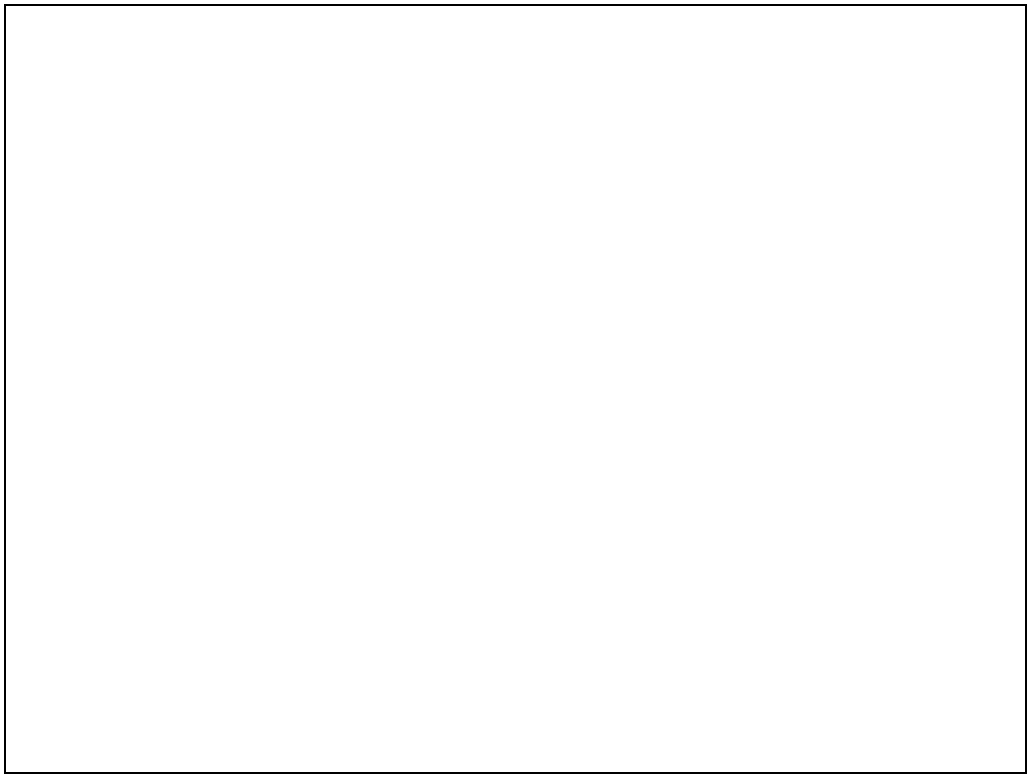


Figure 4-4. Overview Screen - Rinseback

3. Perform Rinseback proceeding as described in the "4.5 Rinseback mode" section or disconnect the patient as described in the "4.6 Patient Disconnection" section or continue the treatment as described in the "4.4.1 Continue treatment" section.

4.4.1 Continue treatment

To resume the treatment after the “Stop Treatment” button has been pressed and confirmed, proceed as follows:

1. Check the treatment parameters;

2. Press the “Continue Treatment” button:

   - The blood pump ON/OFF key and the blood flow Increase/Decrease keys are enabled;

   - The update of the “Remaining Time” value on the *Overview* screen restarts from where it was interrupted;

   - If the Hemoscan function was enabled, the blood volume measurements are resumed;

   - If the Isolated UF function was enabled, it is resumed.

3. Press the blood pump ON/OFF key to restart the Arterial Pump;

   - The Arterial Pump starts at the speed it had before stopping the treatment.
     In HD-DNDP, the Venous Pump starts too;

   - The treatment is resumed;

   - The “Treatment Time” and “UF Volume” parameters continue to be updated.

4. Adjust the pump speed.

4.5 Rinseback mode

It is possible to disconnect the patient without performing the rinseback procedure. In this case skip to the procedure described in the "4.6 Patient Disconnection" section.

Otherwise, follow the instructions below.

⚠WARNING

The Patient Connection and Rinseback modes require additional attention: to facilitate their execution, some safety checkings are temporary deactivated and left to the responsibility of the operator (e.g., the extracorporeal A/V pressure limits are expanded to the maximum).

⚠WARNING

During patient connection/disconnection, follow your facility's policies and procedures for managing patient's catheter and Venous and Arterial Patient lines used for hemodialysis.
In particular, if the patient's catheter disconnects from the patient lines or the integrity of the catheter is compromised in any other way, follow your facility's policy for preventing air embolism and infection, including clamping the patient's lines immediately.

4.5.1 Start Rinseback

To start the rinseback procedure, proceed as follows:

1. Clamp the Arterial Patient line and disconnect it from the patient;
2. Connect the Arterial Patient line to a saline bag appropriate for rinseback procedure;
3. Unclamp the Arterial Patient line and the Prime line;
4. If needed, change the values on the Rinseback Settings sub-screen. Open this sub-screen pressing the "Rinseback Settings" button on the *Blood* screen;
5. Press the "Rinseback" action button: a *Confirm* window opens;
6. Press the ***CONFIRM*** button on the *Confirm* window:
   - The "Rinseback" action indicator switches to green;
   - The Arterial Pump starts at the set value.
     In HD-DNDP, the Venous Pump starts too;

- The blood pump ON/OFF and blood flow Increase/Decrease keys are activated;
- The “Acc Volume” value in the Rinseback Settings sub-screen starts increasing;
- The “Acc Rinseback Volume” value in the *Overview* screen starts increasing.

During the Rinseback mode:

- The Arterial Pump speed can be adjusted anytime with the blood flow increase/decrease keys;
- The rinseback volume can be changed anytime.

NOTE

If an Air in Venous Line *(#4)* alarm occurs during a rinseback procedure, verify the presence of air in the Venous Patient line:
- If air is not present, perform the manual rinseback procedure.
- If air is still present, disconnect the patient without performing blood restitution.

4.5.2 Pause Rinseback

To pause the rinseback process, proceed as follows:

1. Press the activated “Rinseback” button;
   - The Arterial Pump stops.
     In HD-DNDP, the Venous Pump stops too;
   - The rinseback process stops;
   - The “Rinseback” indicator switches to grey.
2. Press again the “Rinseback” button to restart the process or proceed with patient disconnection.

4.5.3 Operations during Rinseback

During the Rinseback process, it is possible to perform the following special procedures:

- Change Acid
- Change BiCart
- Change SelectCart

- Change SelectBag
- Cassette Repositioning
- SN Cassette Repositioning *(only in HD-DNDP Treatment)*

To perform these procedures refer to the related sections in the "Chapter 8: Special Procedures" of this Operator's Manual.

During the Rinseback process, it is also possible to perform the Drain Cartridge procedure, as described in the "4.7 Drain Cartridge/Empty Circuit" section.

4.5.4 End Rinseback

The Rinseback process automatically ends when the rinseback volume has been reached.

It is also possible to manually stop the rinseback process pressing the activated "Rinseback" action button.

When the rinseback process is completed or it is stopped:

- The Arterial Pump automatically stops.
  In HD-DNDP, the Venous Pump stops too;
- The following *Overview* screen is displayed:

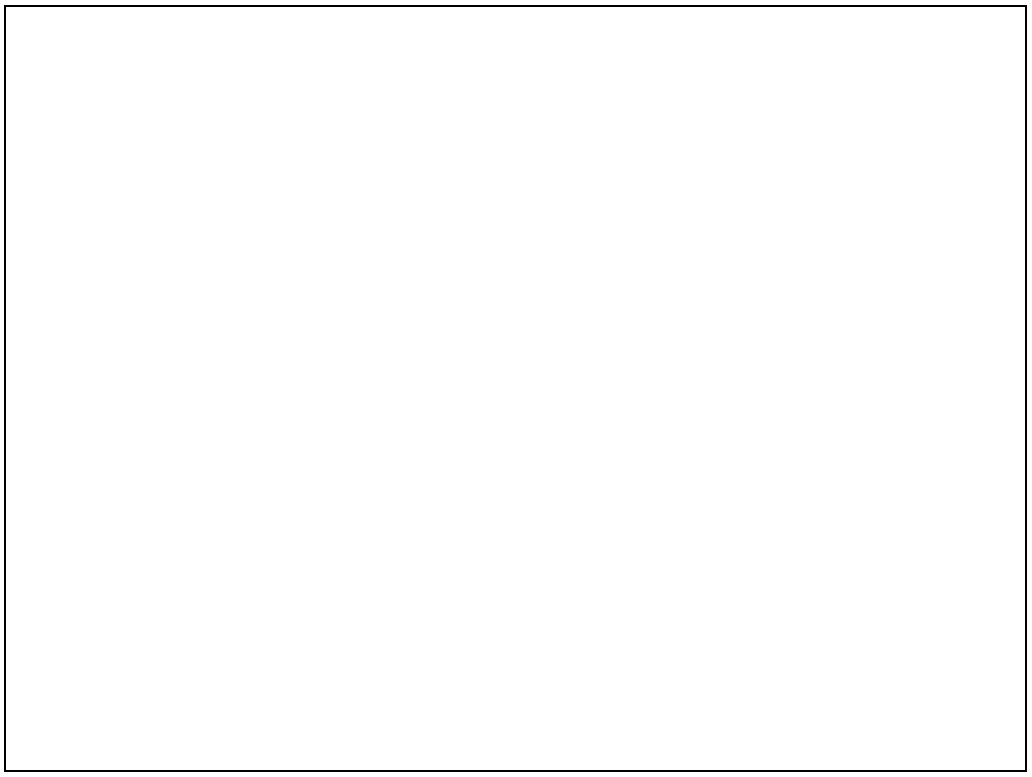


Figure 4-5. Overview Screen - Rinseback Completed

4.5.5 Additional rinseback

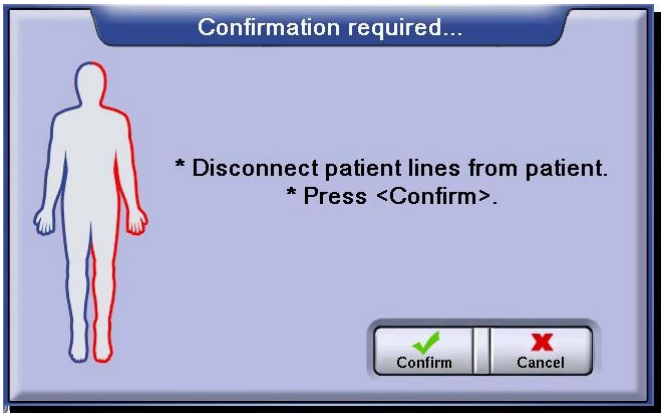
To perform an additional rinseback, proceed as follows:

1. Press the “Extra Rinseback” button:
   - The rinseback process starts again and an additional volume of 100 mL is processed;
   - The “Acc Volume” value in the Rinseback Settings sub-screen continues to increase;
   - The “Acc Rinseback Volume” value on the *Overview* screen starts increasing.
2. Refer to “4.5.4 End Rinseback” section.

4.6 Patient Disconnection

To disconnect the patient after the rinseback process has been completed or after the "Stop Treatment" button has been pressed and confirmed, proceed as follows:

1. Press the "Disconnect Patient" command button. A *Confirm* window opens;



2. Clamp the Venous Patient line and disconnect it from the patient;

3. Confirm patient disconnection pressing the ***CONFIRM*** button on the Confirm window: the following *Overview* screen is displayed:

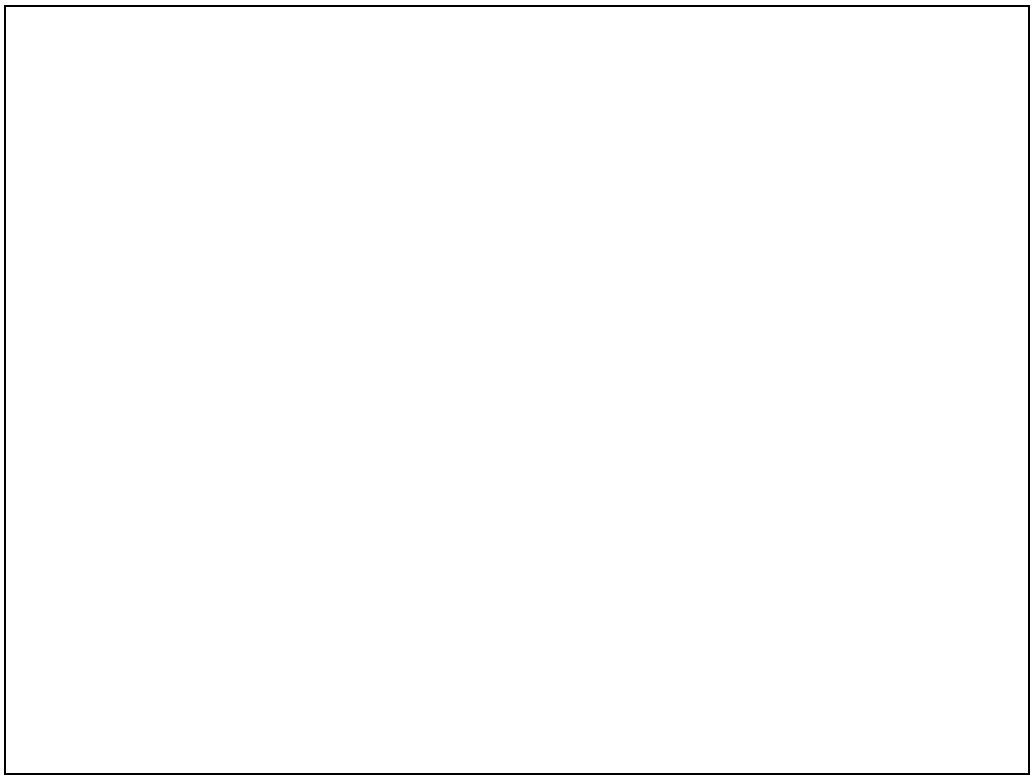


Figure 4-6. Overview screen - Patient disconnected

4.7 Drain Cartridge/Empty Circuit

The “Drain Cartridge” and “Empty Circuit” buttons allow to drain the concentrate disposables and empty the extracorporeal circuit after a treatment.

NOTE

To skip the BiCart Cartridge draining, proceed as follows:
- ***DO NOT*** perform the “Drain Cartridge” procedure;
- Remove the BiCart Cartridge from the BiCart Cartridge Holder;
- Close the BiCart Cartridge Holder arms;
- Place the caps on the cartridge.

NOTE

To skip the SelectCart Cartridge draining, proceed as follows:
- ***DO NOT*** perform the “Drain Cartridge” procedure;
- Remove the SelectCart Cartridge from the SelectCart Cartridge Holder;
- Close the SelectCart Cartridge Holder arms;
- Place the caps on the cartridge.

To start the draining process, follow the instructions on the Message area and proceed as follows:

1. Press the "Drain Cartridge" and the “Empty Circuit” buttons to perform both the draining and emptying procedures;

Or

1. Press the "Drain Cartridge" button to drain the BiCart and the SelectCart Cartridges (the SelectBag container will not be drained);

Or

1. Press the "Empty Circuit" button to empty the extracorporeal circuit only;

2. When required by the operator message, rotate the dialyzer, checking that the blue label is on the top of the dialyzer holder;

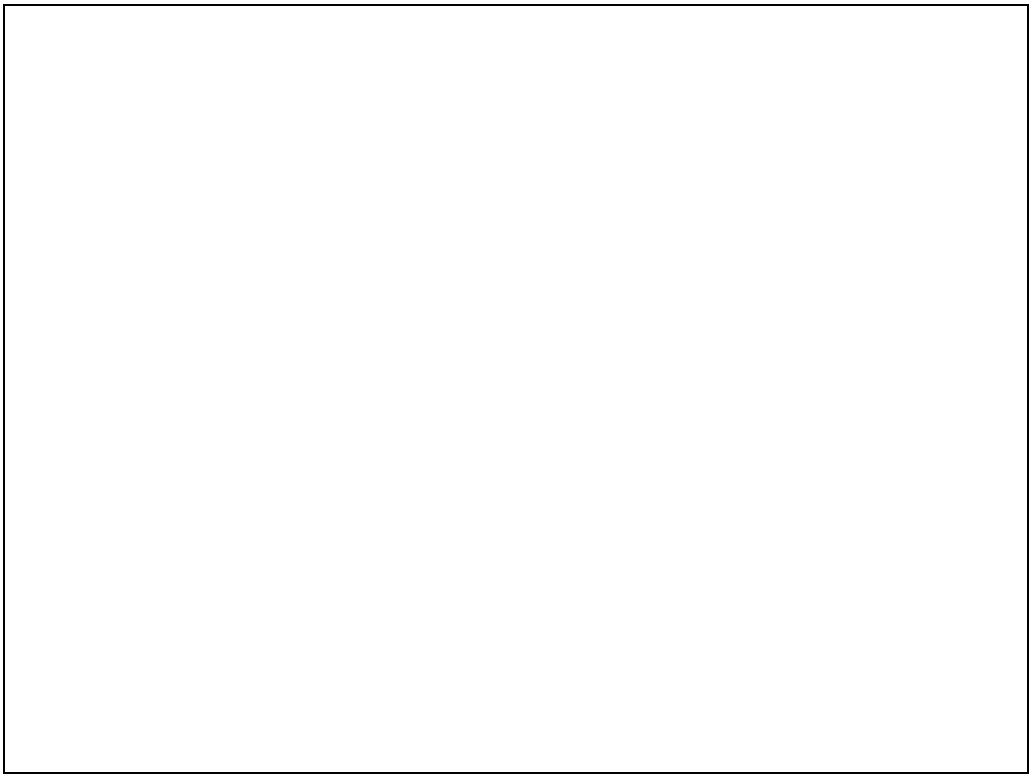


Figure 4-7. Overview screen - Drain Cartridge/Empty Circuit

3. Connect the Blue Dialysis Fluid Tube connector to its safety coupling in order to empty the dialyzer;

4. When required by the operator message, remove the empty cartridges;

5. Close the BiCart holder arms;

6. Close the SelectCart holder arms;

7. Remove the SelectBag container from its holder;

8. Close the SelectBag holder arm;

9. Connect the Acid pick-up tube connector to the concentrate connector port on the front panel of the machine. Ensure to hear a "clicking" sound when connecting the Acid pick-up tube to its concentrate connector port;

10. Connect the Red Dialysis Fluid Tube connector to its safety coupling.

4.8 Remove the Cassette

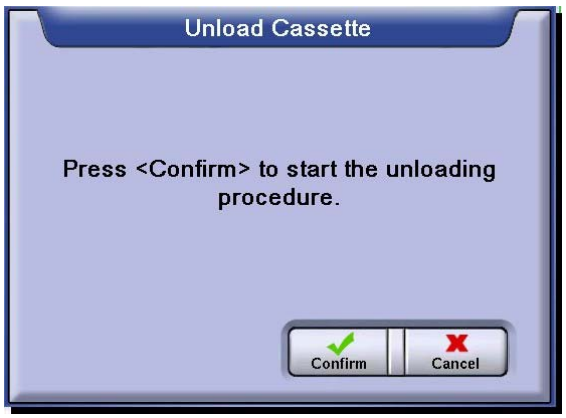
⚠WARNING

An incorrect pump segment unloading procedure could damage the pump rotor.
A damaged pump rotor will not work properly. This could result in patient serious injury.

4.8.1 Remove the cassette after a HD-DN Treatment

To remove the blood cassette follow the instruction displayed in the Message Area, proceeding as follows:

1. Press the "Unload Cassette" button. A *Confirm* window opens;



2. Press the ***CONFIRM*** button on the *Confirm* window;

3. Keep the Arterial Pump cover closed to allow the unload of the pump segment;

4. Open the Sensor Bar door;

   • The machine pushes out the cassette holder and starts unloading the pump segment. If the pump segment unloading procedure fails, proceed as decribed in the “8.29 Manual Pump Segment Unloading Procedure” section of this Operator’s Manual.

5. Remove the patient lines from the Sensor Bar and from the automatic clamps;

6. Close the Sensor Bar door;

7. When the Arterial Pump stops, open the Arterial Pump cover;

NOTE

After 45 seconds the Arterial Pump stops, if the cover is not opened an alarm will be triggered.

8. Remove the Heparin line from the Cassette Panel guides;

9. Remove the heparin syringe from its holder as described in the "4.8.3 Remove the Heparin Syringe" section;

10. Remove the cassette from the cassette holder.
DO NOT remove the cassette if the pump segment is still loaded into the pump rotor.
In case the automatic pump segment unloading procedure failed, proceed as decribed in the "8.29 Manual Pump Segment Unloading Procedure" section of this Operator's Manual;

⚠WARNING

In case of hardware malfunction or if the unloading procedure is not completed within 2 minutes, the Cassette holder will automatically retract.
DO NOT insert fingers behind the cassette to avoid injury to your fingers.

11. Remove the dialyzer from its holder;

12. Throw away the complete circuit;

13. Close the Arterial Pump cover: the machine automatically withdraws the cassette holder.

If the unloading procedure fails it is necessary to perform it again from the beginning.

When the cassette has been removed, switch the Artis Dialysis System OFF and then ON again before starting the next treatment or perform a Disinfection/Rinse program.

If a Disinfection/Rinse program needs to be performed, refer to the "Chapter 13: Disinfection/Rinse" of this Operator's Manual for its settings and activation. After the Disinfection program has been performed, switch the machine OFF and then ON again before starting the next treatment.

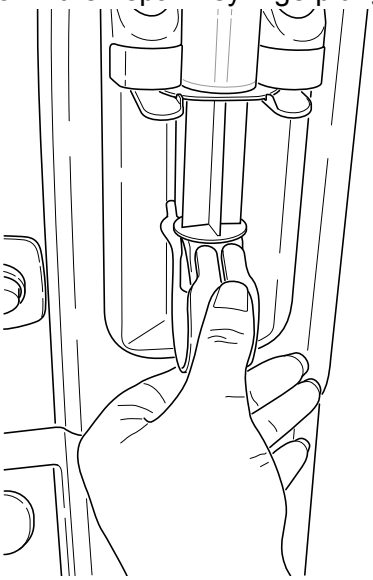
4.8.2 Remove the cassette after a HD-DNDP Treatment

At the end of the HD-DNDP Treatment, remove the SN and Blood Cassettes as described in the "6.8 Remove the Cassette" section of this Operator's Manual.

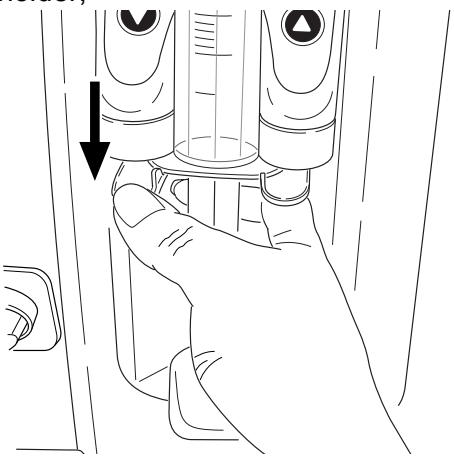
4.8.3 Remove the Heparin Syringe

To remove the heparin syringe, proceed as follows:

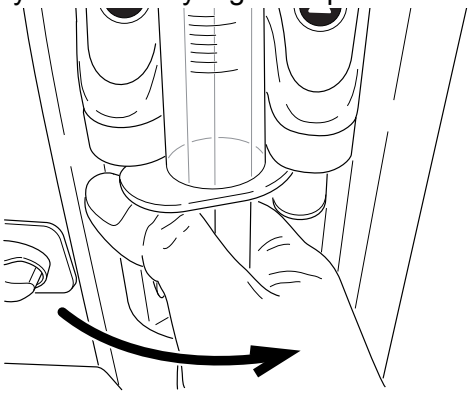
1. Push down the heparin syringe plunger lock to unlock the syringe;



2. Gently push down with one finger the plastic clip on the left of the heparin syringe holder;



3. Slightly rotate the syringe and pull it out from the heparin syringe holder.



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Chapter 5: Hemodiafiltration On-line

After the operations described in the “ Chapter 3: Machine Dressing and Priming” have been performed, proceed as described in the sections below to connect the patient and perform the treatment.

5.1 Connect the Patient

The “Connect Patient” button becomes available:

- After the BLD T1 Test has been successfully completed;
- After the Artis Dialysis System exits from the Low Consumption State, if active.

When the machine is ready for patient connection, the following *Overview* screen is displayed:

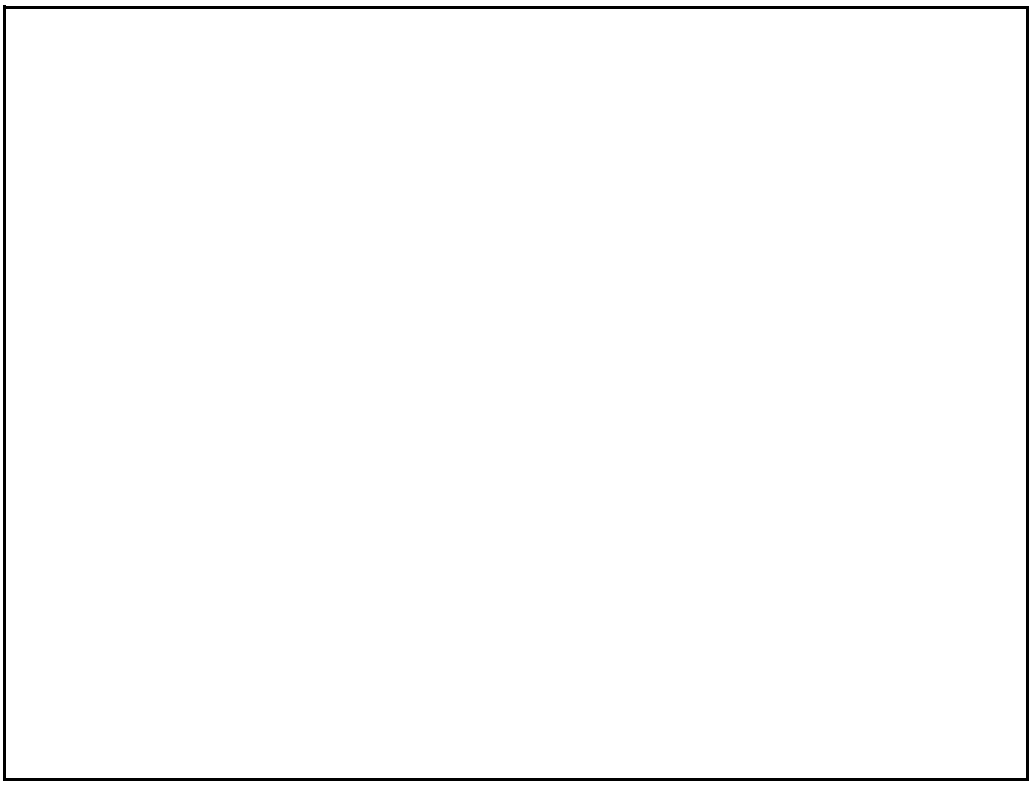


Figure 5-1. Overview Screen - Waiting for patient

⚠WARNING

After a Chemical Disinfection program, a test for residuals of disinfectant must be performed before the following patient connection to avoid the risk of blood hemolysis due to the exposure of the patient to the chemical residues.

⚠WARNING

The Patient Connection and Rinseback modes require additional attention: to facilitate their execution, some safety checkings are temporary deactivated and left to the responsibility of the operator (e.g., the extracorporeal A/V pressure limits are expanded to the maximum).

⚠WARNING

During patient connection/disconnection, follow your facility's policies and procedures for managing patient's vascular access and Venous and Arterial Patient lines used for hemodialysis.
The use of central venous catheters with atrial location leads to additional hazardous situations with respect to the other types of vascular access, due to their proximity to the heart.
In particular, if the patient's catheter disconnects from the patient lines or the integrity of the catheter is compromised in any other way, follow your facility's policy for preventing air embolism and infection, including clamping the patient's lines immediately.

⚠WARNING

Eventual electrical current leakages from the dialysis machine or from other electrical equipments are associated to an increased risk of patient electric shock in case central venous catheters with atrial location are used.
To avoid this risk, ensure that the potential equalization conductor is connected to the proper means on the Artis Dialysis System rear panel.

⚠WARNING

Before patient connection, verify that no air is present in the Venous Patient line. If air is present perform an Extra Prime or a Reset Prime procedure.
Air remained in the Venous Patient line has to be removed before connecting the patient to avoid risk of air embolism.

NOTE

If the Patient Connection is delayed, the dialysis fluid contained in the dialyzer could get cold.
In order to warm the dialysis fluid before connecting the patient, perform an Extra Priming procedure.

To connect the patient, proceed as follows:

1. Enter and confirm mandatory prescription parameters on the *Prescription* screen, if not already done;
2. Ensure that all the required functions have been activated;
3. Verify that no alarm is present;
4. Press the “Connect Patient” command button: the following *Confirm* window opens:

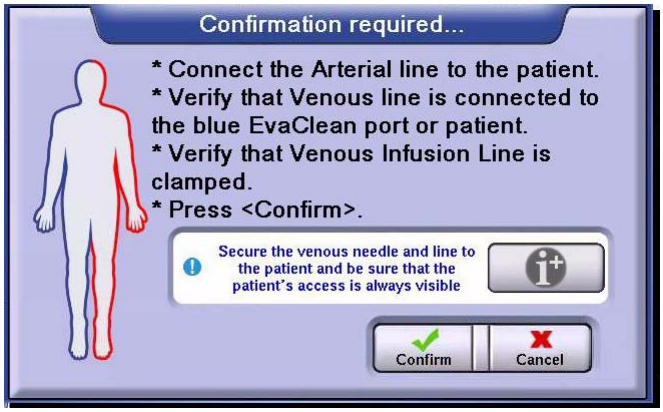
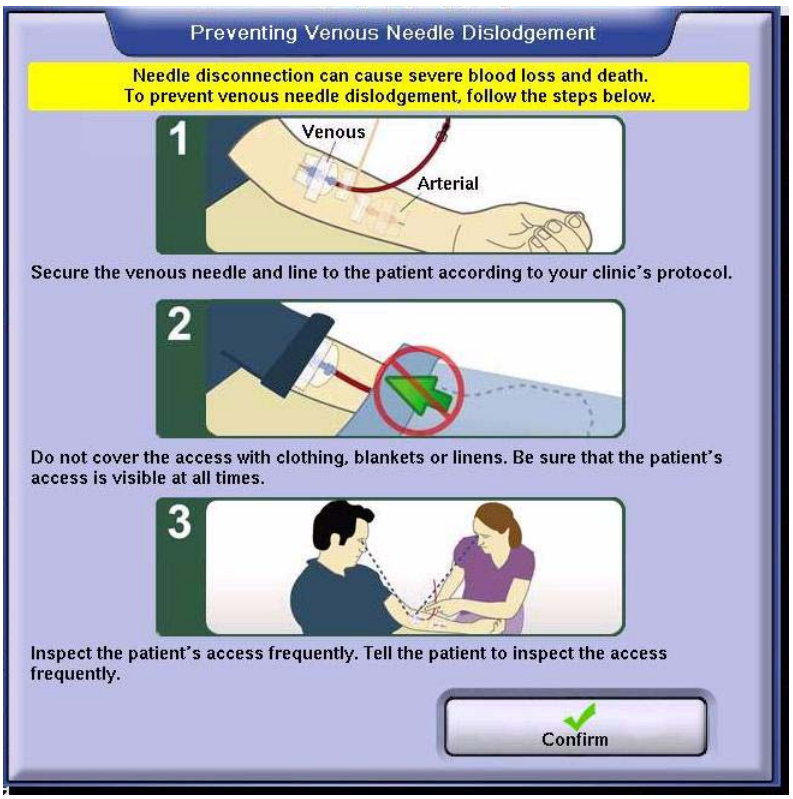


Figure 5-2. Overview Screen - Confirm Patient Connection

Pressing the “i+” button the following window is displayed:



Press the ***CONFIRM*** button to close the window and to come back to the patient connection *Confirm* window;

5. Remove the Arterial Patient line from the EvaClean port, unscrew the priming connector from the line and discard it;

6. Close the EvaClean red door;

7. Connect the Arterial Patient line to the patient's vascular access, according to the clinical policy;

8. Connect the Venous Patient line to the patient or to a waste bag (in these cases, close the EvaClean blue door) or keep the Venous Patient line into the EvaClean blue port;

⚠WARNING

The EvaClean option must be cleaned each time the patient Connection procedure is performed keeping the Venous Patient line into the EvaClean Blue port until the machine detects blood. In this case, manually clean the EvaClean option before performing another patient treatment.
(Refer to the " Chapter 8: Special Procedures" of this Operator's Manual).

9. Ensure that the Ultrafilter Degassing line is clamped;

10. Press the ***CONFIRM*** button on the *Confirm* window:

    - The *Confirm* window closes;
    - The blood pump ON/OFF and blood flow Increase/Decrease keys are activated;
    - The Arterial and Venous Clamps are closed.

11. Press the blood pump ON/OFF key;

NOTE

If the EvaClean Red door is still opened, an alarm is triggered and the Arterial Pump stops. The operator has to proceed with proper connection, close the EvaClean door and manually restart the Arterial Pump.

As soon as blood is detected, the following *Overview* screen is displayed:

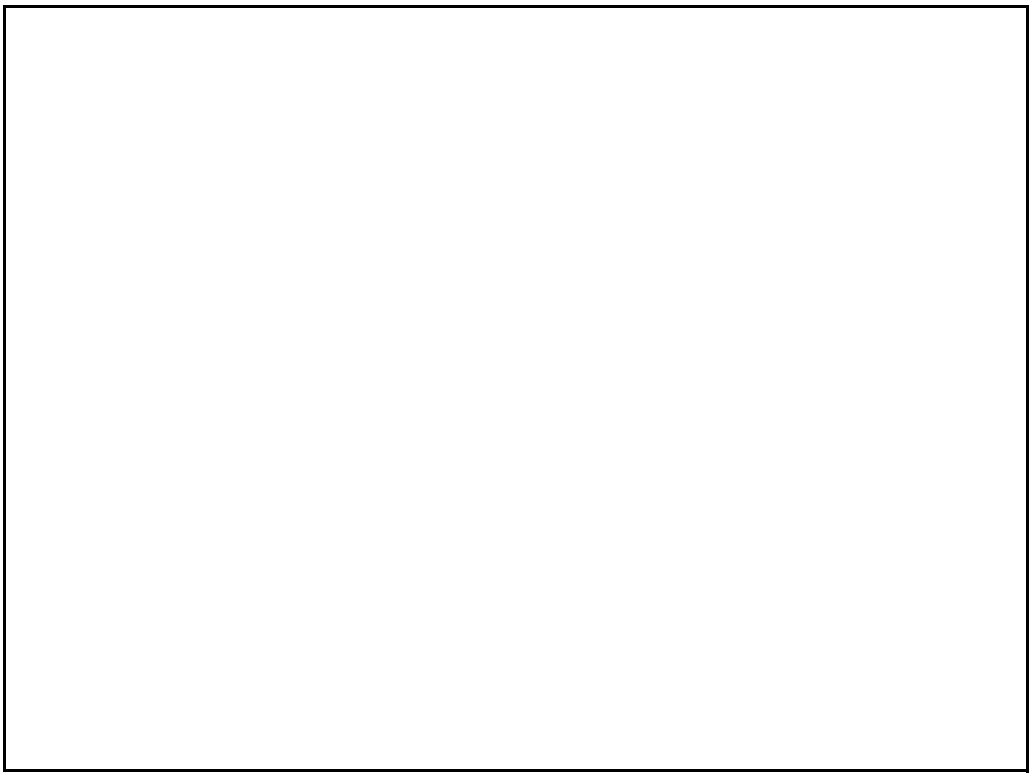


Figure 5-3. Overview Screen - Patient Connection

- The Arterial Pump stops;
- The arterial and venous pressure Bar Graphs start monitoring with open limits;
- The blood path switches to red.

12. If the Venous Patient line is already connected to the patient, skip steps 12, 13, 14 and 15.
    Otherwise, remove the Venous Patient line from the EvaClean port or from the waste bag, unscrew the priming connector from the line and discard it;
13. Discard the waste bag if used;
14. Close the EvaClean blue door if not already done;
15. Connect the Venous Patient line to the patient's vascular access, according to the clinical policy;
16. Start the dialysis treatment (refer to "5.2 Start Treatment" section).

NOTE

If the EvaClean Blue door is still opened, an alarm is triggered and the Arterial Pump stops. The operator has to proceed with proper connection, close the EvaClean door and manually restart the Arterial Pump.

5.1.1 Special Procedures

During the Connect Patient phase the following special procedures are available:

- Change Acid
- Change BiCart
- Change SelectCart
- Change SelectBag
- Skip Treatment
- Cassette Repositioning
- Ultra Cassette Repositioning
- Pause Treatment *(only after blood has been detected by the machine)*

NOTE

Complete the "Change Circuit" procedure (until the "Start Treatment" button is pressed) before starting a "Pause Treatment" procedure.

To perform these procedures refer to the related sections in the "Chapter 8: Special Procedures" of this Operator's Manual.

5.2 Start Treatment

NOTE

If it is necessary to infuse saline solution to the patient during the treatment, the Arterial Infusion lines can be used.

To start the dialysis treatment, proceed as follows:

1. Press the blood pump ON/OFF key;
   - The Arterial Pump starts at a pre-set speed in a counter-clockwise direction;
   - The “Start Treatment” button becomes available.
2. Press the “Start Treatment” button to start the treatment: the “UF”, “Dialysis Fluid” and “HDF Substitution” buttons are available and their indicators are yellow;
3. Press the blood flow Increase/Decrease keys to adjust the Arterial pump speed;
4. Press the “Close A/V Limits” button as soon as the arterial and venous pressures are stable: an operator message is displayed indicating that the machine is performing its internal checks;
5. As required by the operator message, check the blood levels in the Arterial and Venous Chambers.
   For further details, refer to the "8.28 Adjust Arterial/Venous chamber levels" section of this Operator’s Manual.

NOTE

Blood levels too low in the Arterial or Venous Chambers may cause air to enter the dialyzer thus resulting in dialysis efficacy reduction and/or “Air in Venous Line (#4)” alarm occurrence.

When the machine is ready:

- The hemodiafiltration starts;
- The “UF”, “Dialysis Fluid” and “HDF Substitution” action indicators switch to green;
- The “Real TX Time” value on the *Fluid* screen starts increasing;

• The following *Overview* screen is displayed:

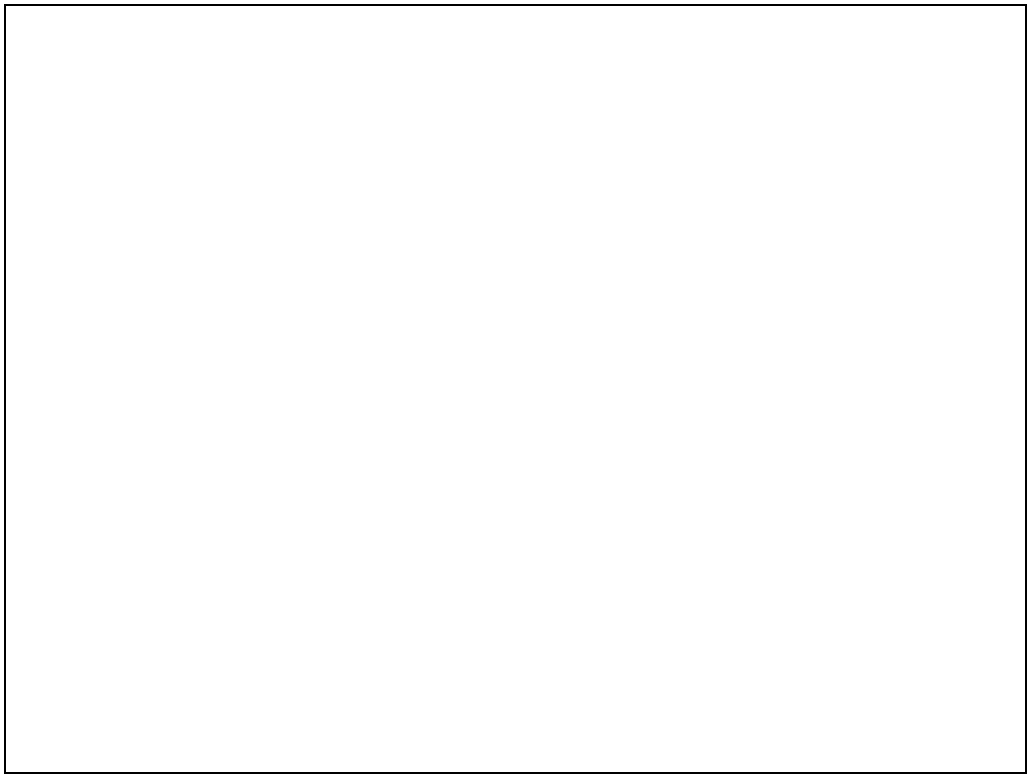


Figure 5-4. Overview Screen - HDF Post Treatment in progress

NOTE

The Venous Pump is controlled in the following way:
- The Venous Pump runs according to the substitution flow rate set value;
- The Venous Pump runs according to the preset Online Bolus Rate during bolus infusion.

NOTE

The Venous Pump is stopped during the following conditions:
- If the Arterial Pump stops;
- If the dialysis fluid is in bypass.

5.3 Operations during treatment

Below is a list of the main operations that can be performed on the Artis Dialysis System when a treatment is ongoing.

5.3.1 Special Procedures

As soon as the treatment starts and until the “Stop Treatment” button is pressed and confirmed, the following special procedures are available:

- Change Acid
- Change BiCart
- Change SelectCart
- Change SelectBag
- Pause Treatment
- Change Circuit
- Cassette Repositioning
- Ultra Cassette Repositioning
- Switch off OnLine
- Adjust the Arterial/Venous Chamber Levels

To perform these procedures refer to the related sections of the "Chapter 8: Special Procedures"" Chapter 8: Special Procedures" of this Operator’s Manual.

5.3.2 Deactivate UF process

To deactivate the ongoing UF process, press the activated “UF” action button on the *Overview* screen:

- The ultrafiltration process (substitution and weight loss) is interrupted;
- The “UF” and “HDF Substitution” action indicators switch to grey;
- The “UF Rate” is set to zero.

To restart the UF process:

1. Press the deactivated “UF” button to resume hemodialysis: the “UF” action indicator switches to green.
2. Press the “HDF Substitution” button to resume substitution:
   - The ultrafiltration process (substitution and weight loss) is restarted;
   - The “HDF Substitution” action indicator switches to green.

NOTE

If the substitution fluid infusion is stopped for more than 5 minutes an alarm is triggered.

5.3.3 Deactivate the HDF Substitution

To interrupt the ultrafiltration process, press the "HDF Substitution" button:

- The ultrafiltration process (substitution and weight loss) is interrupted;
- The "UF" and "HDF Substitution" action indicators switch to grey;
- The "UF Rate" is set to zero.

To activate the HDF Substitution, press the deactivated "HDF Substitution" button:

- The ultrafiltration process (substitution and weight loss) is restarted;
- The "HDF Substitution" and "UF" action indicators switch to green.

NOTE

If the substitution fluid infusion is stopped for more than 5 minutes an alarm is triggered.

5.3.4 Delivery of an Online Bolus

The "Online Bolus" action button will be available as soon as the "Start Treatment" button is pressed and until the "Stop Treatment" button is confirmed, except during the Special Procedures .

To deliver an Online Bolus to the patient, proceed as follows:

1. On the *Fluid* screen, check/set the "Online Bolus Volume" amount;
2. Press the "Online Bolus" button: a *Confirm* window opens;
3. Press the ***CONFIRM*** button:
   - The Venous Pump speed starts at a preset value;
   - The bolus delivery starts;
   - The "TMP Actual" value is set to zero;
   - The "Acc Online Bolus" value starts increasing;
   - The Arterial and Venous Pressure alarm limit window are opened.

During the delivery of the online bolus:

- The blood pump automatic control is active;
- The ultrafiltration process (substitution and weight loss) is stopped;

- The arterial and venous pressure alarm limits are expanded to the following values:

Arterial Pressure	
Upper Limit	+ 150 mmHg
Lower Limit	- 400 mmHg

Venous Pressure	
Upper Limit	+ 450 mmHg
Lower Limit	+ 10 mmHg

- If an automatic Ultra Control scan was scheduled, it is not activated. It will be activated 3 minutes after the end of the Online bolus delivery;
- The “UC Scan” button is dimmed;
- The following *Overview* screen is displayed:

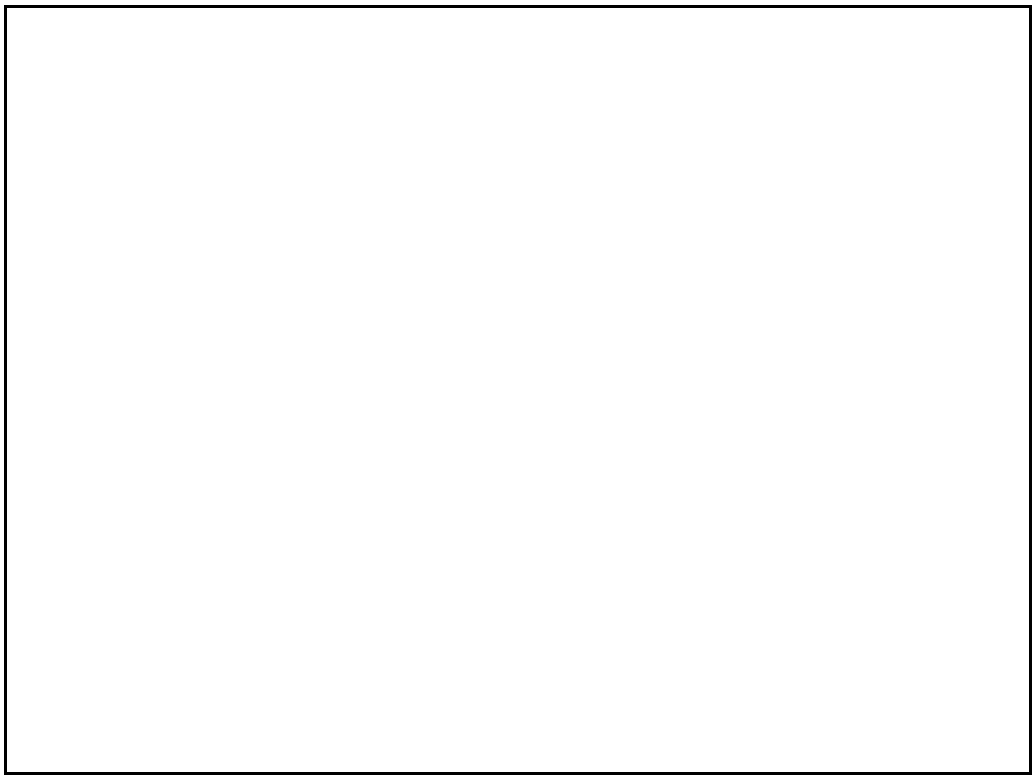


Figure 5-5. Online Bolus Infusion

- The “Dialysis Fluid” and “UF” buttons are dimmed and their action indicators are grey;
- The “Dialysis Fluid” button is dimmed.

5.3.4.1 Online Bolus Delivery Completed

As soon as the set Online Bolus volume has been delivered, the Artis Dialysis System performs the following operations:

- The Venous Pump stops;
- The "TMP Actual" value unfreezes.

To continue the treatment at the end of the online bolus delivery, proceed as follows:

1. To activate the ultrafiltration only, press the "UF" button on the *Overview* screen:
   - The ultrafiltration process restarts;
   - The operator message previously displayed disappears;
   - The "Online Bolus" value box disappears.
2. To activate the ultrafiltration and substitution, press the "HDF Substitution" button on the *Overview* screen:
   - The substitution process restarts;
   - The "UF" action indicator switches to green.

NOTE

If the substitution fluid infusion is stopped for more than 5 minutes an alarm is triggered.

5.3.4.2 Online Bolus delivery failure

The administration of the online bolus is suspended in the following cases:

- When one of the pumps stops;
- When an alarm is triggered related to the dialysis fluid (i.e. alarms related to the conductivity or temperature)

5.3.4.3 Stop an Online Bolus

To interrupt the online bolus delivery, proceed as follows:

1. Press the activated "Online Bolus" button:
   - The Venous Pump stops;
   - The TMP value is unfrozen.
2. Press the "Close A/V Limits" button on the *Overview* screen;

3. To activate the ultrafiltration only, press the “UF” button on the *Overview* screen:
   - The weight loss process restarts;
   - The operator message previously displayed disappears.
4. To activate the ultrafiltration and substitution, press the “HDF Substitution” button on the *Overview* screen:
   - The substitution process restarts;
   - The “UF” action indicator switches to green.

NOTE

If the substitution fluid infusion is stopped for more than 5 minutes an alarm is triggered.

5.3.5 Deactivate Dialysis Fluid flow

To deactivate the dialysis fluid flow, press the “Dialysis Fluid” action button:

- The ultrafiltration process (substitution and weight loss) is stopped;
- The “Dialysis Fluid” action indicator switches to grey;
- The “UF” and “HDF Substitution” buttons are dimmed and their action indicators switch to grey;
- The updating of the “Real TX Time” value is interrupted.

To activate the Dialysis Fluid flow again, press the dectivated “Dialysis Fluid” button:

- The “Dialysis Fluid” action indicator switches to green;
- The “UF” and “HDF Substitution” buttons are available and their action indicators are grey;
- The updating of the “Real TX Time” value restarts.

NOTE

If the substitution fluid infusion is stopped for more than 5 minutes an alarm is triggered.

5.3.6 Expand A/V Limits

The "Expand A/V Limits" button allows to open the arterial and venous pressure alarm windows.

When the "Expand A/V Limits" button is pressed on the *Overview* screen or on the *Blood* screen:

- The "Expand A/V Limits" button becomes "Close A/V Limits";
- The Arterial and Venous alarm windows open and they are automatically set at the following values:

Arterial Pressure	
Upper Limit	+ 150 mmHg
Lower Limit	- 400 mmHg

Venous Pressure	
Upper Limit	+ 450 mmHg
Lower Limit	+ 10 mmHg

When the arterial and venous pressures are stable, press the "Close A/V Limits" button to adjust and close A/V pressure alarm limit windows.

For further details on this function refer to the "1.7.3.1 Manually Expand/Close the pressure alarm limits" section of this Operator's Manual.

5.3.7 Ultra Control Function in Pressure Control Mode

If the Ultra Control function is activated in Service 2 menu, it is possible to perform manual or automatic Ultra Control scans during a HDF Post Treatment in Pressure Control mode.

5.3.7.1 Activate a Manual Ultra Control Scan

To activate a manual Ultra Control scan, proceed as follows:

1. On the *Prescription* screen select the “Ultra Control” option on the “Activated Functions” list or press the “Ultra Control Settings” button on the *Fluid* screen: the following sub-screen opens:

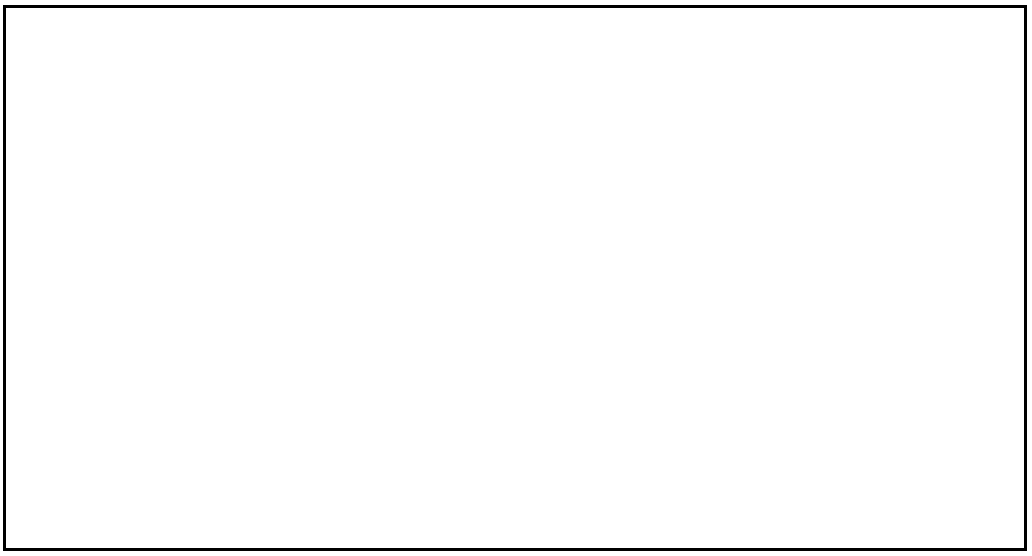


Figure 5-6. Ultra Control Settings

2. Press the “UC Scan” button:

   - The “UC Scan” action indicator switches to green;
   - The TMP pressure is increased starting from the TMP value set by the operator in order to find the optimum value for the current treatment phase;
   - The “TMP Set” button is dimmed but its value is updated run time with the set point value applied by the machine;
   - The Ultra Control icon displayed is the green blinking one.

NOTE

In case of a manual Ultra Control scan, if the Arterial Pump speed is increased or decreased more than 50ml/min after an Ultra Control scan has been performed, the "New Ultra Scan is suggested (#545)" alarm is triggered suggesting the user to perform a new Ultra Control scan in order to find the new optimum TMP value.

- If the Arterial Pump speed is decreased more than 50ml/min after an Ultra Control Scan has been performed, the "TMP Set" value is automatically reduced to the reference value (the value used as starting TMP value for the first Ultra Control scan).
- If the Arterial Pump speed variation is performed while an Ultra Control scan is in progress, the Ultra Control scan in progress is interrupted (refer to Ultra Control scan failure paragraph).

When the system finds the optimum TMP value:

- The "Ultra Scan completed (#544)" Information Message is triggered (only if it has been properly configured in the Service 2 menu).
- The "UC Scan" action indicator switches to grey;
- The "TMP Set" button becomes available on the *Fluid* screen and it is automatically updated with the TMP value found by the machine;
- The treatment continues with the new TMP value;
- The Ultra Control icon displayed is the grey fixed one.

Manual Ultra Control Scan Stopped

To stop a manual Ultra Control scan, proceed as follows:

1. Press the "UC Scan" button: a *Confirm* window opens;
2. Press the ***CONFIRM*** button on the *Confirm* window:
   - The "Ultra Scan aborted (#543)" Information Message is triggered (only if it has been properly configured in the Service 2 menu);
   - The "UC Scan" action indicator switches to grey;
   - The scan in progress is stopped;
   - The "TMP Set" button becomes available on the *Fluid* screen and it is automatically updated with the TMP value found by the machine;
   - The treatment continues with the new TMP value;
   - The Ultra Control icon displayed is the grey fixed one.

Manual Ultra Control Scan Failure

If the Ultra Control scan fails, the “Ultra Scan aborted (#543)” Information Message is triggered (only if it has been properly configured in the Service 2 menu).

The manual Ultra Control scan fails in the following cases:

- The Arterial pump speed increases more than 50 ml/min;
- The Arterial pump speed decreases more than 50 ml/min;
- The Pre-Dialyzer pressure exceeds the 80% of the “Pre-Dialyzer Limit” set by the operator;
- The found TMP value exceeds the current “TMP Upper Limit” value;
- The “TMP Set” value is too low;
- The operator switches from Pressure to Volume control mode;
- The “Remaining Time” value is 1:00;
- Maximum infusion rate is reached (330 ml/min);
- Maximum substitution volume is reached (49 L);
- The “HDF Substitution” or “UF” or “Dialysis Fluid” button is deactivated;
- Online Bolus is started;
- “Stop Treatment” button is pressed and confirmed;
- “Rinseback” button is pressed and confirmed;
- “Change Circuit” special procedure is selected and confirmed;
- “Pause Treatment” special procedure is selected and confirmed;
- “Change BiCart” special procedure is selected and confirmed;
- “Change SelectCart” special procedure is selected and confirmed;
- “Change SelectBag” special procedure is selected and confirmed;
- “Change Acid” special procedure is selected and confirmed;
- “Cassette Repositioning” or “Ultra Cassette Repositioning” special procedure is selected and confirmed;
- “Switch off OnLine” special procedure is selected and confirmed;
- The “UC Scan” button is deactivated.

5.3.7.2 Activate an Automatic Ultra Control Scan

The automatic Ultra Control scan function allows to perform scans during the treatment according to the following sequence:

- the first one is performed 3 minutes after the "UC Auto Scan" button has been pressed or 3 minutes after the "Start Treatment" button has been pressed and confirmed;
- the second one is performed 25 minutes after the end of the first scan;
- the third is performed 50 minutes after the end of the second scan;
- from the third scan on, automatic scans are performed 50 minutes after the end of the previous scan.

NOTE

If the "Isolated UF" function has been activated, the first automatic ultra scan starts 3 minutes after the end of the Isolated UF process.

NOTE

When the "Remaining Time" value is 1:00, the automatic Ultra Scan function is automatically disabled and the "UC Auto Scan" button is dimmed. If the operator increases the "Treatment Time" parameter value to a value greater than 1:30, the "UC Auto Scan" button becomes available.

To activate an automatic Ultra Control scan, proceed as follows:

1. On the *Prescription* screen select the "Ultra Control" option on the "Activated Functions" list or press the "Ultra Control Settings" button on the *Fluid* screen: the following sub-screen opens:

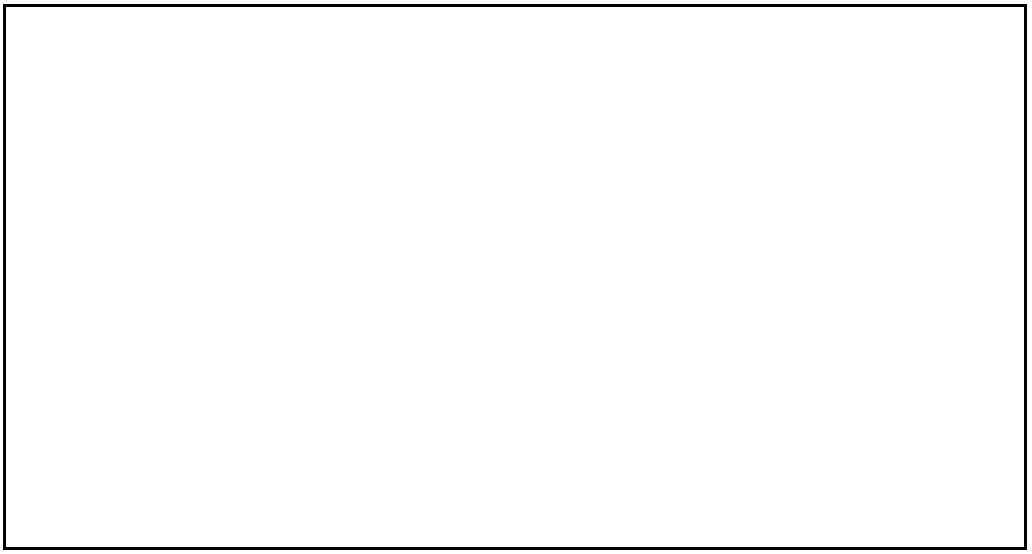


Figure 5-7. Ultra Control Settings

2. Press the “UC Auto Scan” button:

- The “UC Auto Scan” action indicator switches to green;
- The “UC Scan” button is dimmed;
- The Ultra Control icon displayed is the green fixed one.

When the automatic scan starts:

- The “UC Scan” button is activated and its action indicator switches to green;
- The TMP pressure is increased starting from the TMP value set by the operator in order to find the optimum value for the current treatment phase;
- The “TMP Set” button is dimmed but its value is updated run time with the set point value applied by the machine;
- The Ultra Control icon displayed is the green blinking one.

NOTE

In case of an automatic Ultra Control scan, if the Arterial Pump speed is increased or decreased more than 50ml/min after an Ultra Control scan has been performed, the machine starts a new automatic Ultra Control scan after 3 minutes to find the new optimum TMP.

- If the Arterial Pump speed is decreased more than 50ml/min after an Ultra Control scan has been performed, the “TMP Set” button on the *Fluid* screen is automatically updated with the reference TMP value (the value used as starting TMP value for the first Ultra Control scan) and the machine starts a new automatic Ultra Control scan after 3 minutes to find the new optimum TMP.
- If the Arterial Pump speed variation is performed while an automatic Ultra Control scan is in progress, the Ultra Control scan in progress is interrupted (see Ultra Control scan failure paragraph).

When the system finds the proper TMP value:

- The “Ultra Scan completed (#544)” Information Message is triggered (only if it has been properly configured in the Service 2 menu);
- The “UC Scan” action indicator switches to grey and the button is dimmed;
- The “TMP Set” button becomes available on the *Fluid* screen and it is automatically updated with the TMP value found by the machine;

- The treatment continues with the new TMP value;
- The Ultra Control icon displayed is the green fixed one.

The automatic Ultra Control Scan function is paused by the machine in the following cases:

- During the machine internal checks
- If an alarm occurs requiring the Venous pump to stop
- If the Ultra Control Scan function is paused for more than 5 minutes, the scan is not performed and the "Ultra Scan aborted (#543)" alarm is triggered (only if it has been properly configured in the Service 2 menu).

Automatic Ultra Control Scan Stopped

To stop an automatic Ultra Control scan, proceed as follows:

1. Press the "UC Scan" button: a *Confirm* window opens:
2. Press the ***CONFIRM*** button on the *Confirm* window:
   - The "Ultra Scan aborted (#543)" Information Message is triggered (only if it has been properly configured in the Service 2 menu);
   - The "UC Scan" action indicator switches to grey and the button is dimmed;
   - The scan in progress is stopped;
   - The "TMP Set" button becomes available on the *Fluid* screen and it is automatically updated with the TMP value found by the machine.

Automatic Ultra Control Scan Failure

If the Ultra Control scan fails, the "Ultra Scan aborted (#543)" Information Message is triggered (only if it has been properly configured in the Service 2 menu).

The Ultra Control scan fails in the following cases:

- The Arterial pump speed increases more than 50 ml/min;
- The Arterial pump speed decreases more than 50 ml/min;
- The Pre-Dialyzer pressure exceeds the 80% of the "Pre-Dialyzer Limit" set by the operator;
- The found TMP value exceeds the current "TMP Upper Limit" value;
- The "TMP Set" value is too low;

- The operator switches from Pressure to Volume control mode;
- The “Remaining Time” value is 1:00;
- Maximum infusion rate is reached (330 ml/min);
- Maximum substitution volume is reached (49 L);
- The “HDF Substitution” or “UF” or “Dialysis Fluid” button is deactivated;
- Online Bolus is started;
- “Stop Treatment” button is pressed and confirmed;
- “Rinseback” button is pressed and confirmed;
- “Change Circuit” special procedure is selected and confirmed;
- “Pause Treatment” special procedure is selected and confirmed;
- “Change BiCart” special procedure is selected and confirmed;
- “Change SelectCart” special procedure is selected and confirmed;
- “Change SelectBag” special procedure is selected and confirmed;
- “Change Acid” special procedure is selected and confirmed;
- “Cassette Repositioning” or “Ultra Cassette Repositioning” special procedure is selected and confirmed;
- “Switch off OnLine” special procedure is selected and confirmed;
- The “UC Auto Scan” button is deactivated;
- The “UC Scan” button is deactivated.

5.3.8 Stop the Arterial and Venous Pumps

To stop the pumps during a treatment, press the blood pump ON/OFF key:

- The Arterial and Venous Pumps stop;
- The updating of the "Real TX Time" value stops;
- The "Dialysis Fluid", "UF" and "HDF Substitution" action indicators switch to yellow
- The arterial and venous alarm limits are automatically set to the following values:

Arterial Pressure	
Upper Limit	+ 150 mmHg
Lower Limit	- 400 mmHg

Venous Pressure	
Upper Limit	+ 450 mmHg
Lower Limit	- 50 mmHg

These values are maintained for all the time the Arterial Pump is off and for 30 seconds after the Arterial Pump restarts.

To restart the pumps, press the blood pump ON/OFF key:

- The Arterial and Venous Pumps restart;
- The treatment restarts;
- The updating of the "Real TX Time" value restarts;
- The "Dialysis Fluid", "UF" and "HDF Substitution" action indicators switch to green;
- The arterial and venous pressure alarm windows are automatically closed when they are stable.

5.3.8.1 Blood Pump Automatic Control Function

Each time the Venous Pump is stopped during the treatment or during an online bolus delivery or when the "Switch off OnLine" special procedure is performed, the Blood Pump Automatic Control function starts and the following conditions are applied:

- The Arterial Pump flow is automatically controlled by the machine;
- The red frame around the "Blood Flow" field on the *Overview* screen becomes thicker:

- The Blood Pump Automatic Control function keeps the Venous Pump stopped until the control is completed.

To exit from the Blood Pump Automatic Control function press the Increase/ Decrease blood flow key to adjust the Arterial pump speed.

5.3.9 Change the Online Substitution Rate in Volume Control mode

To change the Online Substitution Rate, proceed as follows:

1. Open the *Fluid* screen;
2. Press the “Online Substitution Rate” set button: a keypad opens;
3. Set the desired value and press the ***CONFIRM*** button on the keypad to confirm the new value: the treatment continues with the new substitution fluid rate

5.3.10 Change the TMP value in Pressure Control mode

To change the TMP value, proceed as follows:

1. Open the *Fluid* screen or the Ultra Control Settings sub-screen;
2. Press the “TMP Set” button: a keypad opens;
3. Set the desired value and press the ***CONFIRM*** button on the keypad to confirm the new value: the treatment continues with the substitution fluid rate calculated according to the new TMP value

5.3.11 Report Table

During a treatment it is possible to visualize a run-time dialysis report containing the data acquired throughout the treatment.

For further details on this function, refer to the "Chapter 15: Report Environment" of this Operator’s Manual.

5.4 Stop treatment

When the end conditions for the current treatment are reached, one or both the Information Messages "Treatment Time Complete (#51)" and "Fluid Removal Complete (#53)" are triggered and the "UF" and "HDF Substitution" action indicators switch to grey.

The Treatment can also be manually stopped at any time by pressing the "Stop Treatment" action button.

5.4.1 Continue Total Ultrafiltration Process

When the "Total Treatment Time" has been reached, to continue the total ultrafiltration process (weight loss and substitution) proceed as follows:

1. Press the ***CONFIRM*** button to reset the Information Message;
2. Press the "UF" and "HDF Substitution" buttons to activate the total ultrafiltration again.

When the "UF Volume" has been reached, to continue the total ultrafiltration process (weight loss and substitution), proceed as follows:

1. Press the ***CONFIRM*** button to reset the Information Message;
2. Change the "UF Volume" and/ or "Treatment Time" parameters;
3. Press the "UF" and "HDF Substitution" buttons to activate the total ultrafiltration again.

5.4.2 Stop Treatment

To stop the treatment after the end conditions have been reached or before reaching the end conditions, proceed as follows:

1. Press the "Stop Treatment" button: a *Confirm* window opens;
2. Press the ***CONFIRM*** button on the *Confirm* window. The following *Overview* screen is displayed:

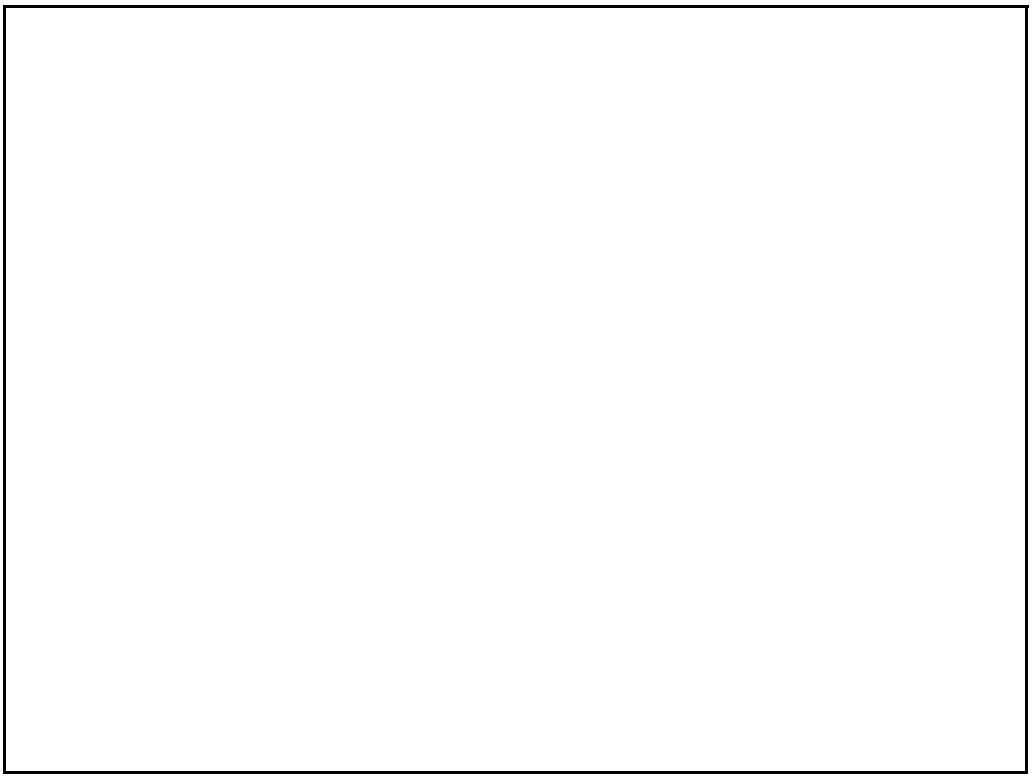


Figure 5-8. Overview screen - Rinseback

- The Arterial and Venous Pumps stop;
- The blood pump ON/OFF key and the blood flow Increase/Decrease keys are disabled.

3. Perform Rinseback proceeding as described in the "5.5 On-line Rinseback" section or disconnect the patient as described in the "5.6 Patient Disconnection" section or continue the treatment as described in the "5.4.3 Continue treatment" section.

5.4.3 Continue treatment

To resume the treatment after the "Stop Treatment" button has been pressed, proceed as follows:

1. Check the treatment parameters;

2. Press the "Continue Treatment" button:

   - The blood pump ON/OFF key and the blood flow Increase/Decrease keys are enabled;

   - The update of the "Remaining Time" value on the *Overview* screen restarts from where it was interrupted;

   - If the Hemoscan function was enabled, the blood volume measurements are resumed;

   - If the Isolated UF function was enabled, it is resumed;

   - If the Diascan function was enabled, it is resumed;

3. Press the blood pump ON/OFF key to restart the Arterial Pump;

   - The Arterial Pump starts at the speed it had before stopping the treatment;

   - The treatment is resumed;

   - The "Dialysis Fluid", "UF" and "HDF Substitution" action indicators switch to green;

   - The "Treatment Time" and "UF Volume" parameters continue to be updated.

4. Adjust the Arterial Pump speed.

5.5 On-line Rinseback

The substitution fluid produced by the Artis Dialysis System can be used as rinseback solution when an on-line treatment is performed.

It is possible to disconnect the patient without performing the rinseback procedure. In this case skip to the procedure described in the “5.6 Patient Disconnection” section.

Otherwise follow the instructions below.

⚠WARNING

The Patient Connection and Rinseback modes require additional attention: to facilitate their execution, some safety checkings are temporary deactivated and left to the responsibility of the operator (e.g., the extracorporeal A/V pressure limits are expanded to the maximum).

⚠WARNING

During patient connection/disconnection, follow your facility’s policies and procedures for managing patient’s catheter and Venous and Arterial Patient lines used for hemodialysis.
In particular, if the patient’s catheter disconnects from the patient lines or the integrity of the catheter is compromised in any other way, follow your facility’s policy for preventing air embolism and infection, including clamping the patient’s lines immediately.

5.5.1 Start Rinseback

NOTE

If an Air in Venous Line *(#4)* alarm occurs during a rinseback procedure, verify the presence of air in the Venous Patient line:
- If air is not present, perform the manual rinseback procedure.
- If air is still present, disconnect the patient without performing blood restitution.

NOTE

If during an On-line Rinseback process a conductivity alarm or other problems cause the Arterial and Venous Pumps to stop, perform a "Switch off OnLine" special procedure and proceed with Rinseback in HD-DN treatment.

NOTE

If an alarm occurs that prevent proceeding with the on-line rinseback procedure, proceed as follows:
- Perform a "Switch off OnLine" special procedure;
- Perform the Rinseback procedure as decribed in the "4.5 Rinseback mode" section of this Operator's Manual.

NOTE

If an alarm is present on the machine reset it before starting the On-line Rinseback procedure to avoid the risk of blood clotting.

NOTE

If it is necessary to perform rinseback using a saline bag, proceed as follows:
- Perform a "Switch off OnLine" special procedure;
- Perform rinseback as described in the "4.5 Rinseback mode" section of this Operator's Manual.

To start the rinseback procedure, proceed as follows:

1. Clamp the Arterial Patient line and disconnect it from the patient;

2. Connect the Arterial Patient line to the Rinseback Service line;

3. Unclamp the Rinseback Service line and the Arterial Patient line;

4. Check/change the values on the Rinseback Settings sub-screen. Open this sub-screen pressing the “Rinseback Settings” button on the *Blood* screen;

5. Press the “Rinseback” action button: a *Confirm* window opens

6. Press the ***CONFIRM*** button on the *Confirm* window:

   • The “Rinseback” action indicator switches to green;

   • The Arterial and Venous pumps start at the set value;

   • The blood pump ON/OFF and blood flow Increase/Decrease keys are activated;

   • The “Acc Volume” value in the Rinseback Settings sub-screen starts increasing;

   • The “Acc Rinseback Volume” value in the *Overview* screen starts increasing.

During the Rinseback mode:

• The Arterial Pump speed can be adjusted anytime with the blood flow increase/decrease keys;

• The rinseback volume can be changed anytime.

5.5.2 Pause Rinseback

To pause the rinseback process, proceed as follows:

1. Press the activated “Rinseback” button or the blood pump ON/OFF key;

   • The Arterial and Venous pumps stop;

   • The rinseback process stops;

   • The “Rinseback” indicator switches to grey.

2. Press again the “Rinseback” button or the blood pump ON/OFF key to restart the process or proceed with patient disconnection.

5.5.3 Operations during On-line Rinseback

During the Online Rinseback process, it is possible to perform the following special procedures:

- Change Acid
- Change BiCart
- Change SelectCart
- Change SelectBag
- Cassette Repositioning
- Ultra Cassette Repositioning
- Switch off OnLine

To perform these procedures refer to the related sections of the"Chapter 8: Special Procedures" of this Operator's Manual.

5.5.4 End Rinseback

The Rinseback process automatically ends when the rinseback volume has been reached.

It is also possible to manually stop the rinseback process pressing the activated "Rinseback" action button.

When the rinseback process is completed or it is stopped:

- The Arterial and Venous pumps automatically stop.
- The following *Overview* screen is displayed:

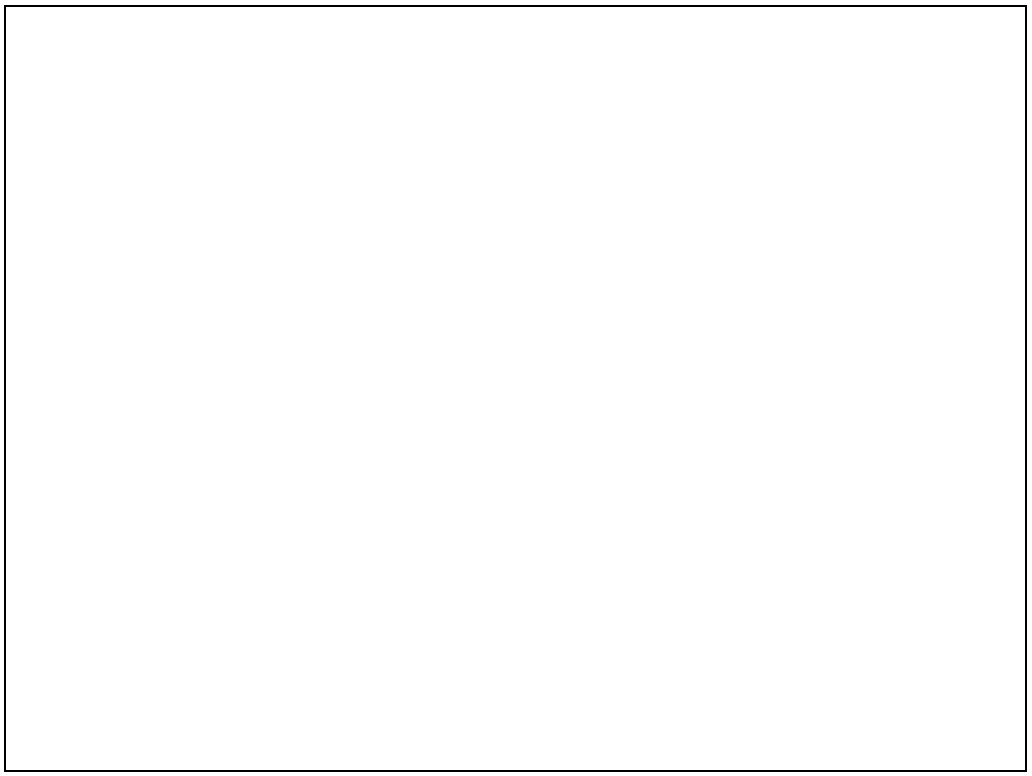


Figure 5-9. Overview Screen - Rinseback Completed

5.5.5 Additional rinseback

To perform an additional rinseback, proceed as follows:

1. Press the “Extra Rinseback” button or the blood pump ON/OFF key :

   • The rinseback process starts again and an additional volume of 100 mL is processed;

   • The “Acc Volume” value in the Rinseback Settings sub-screen continues to increase;

   • The “Acc Rinseback Volume” value on the *Overview* screen starts increasing.

2. Refer to “5.5.4 End Rinseback” section.

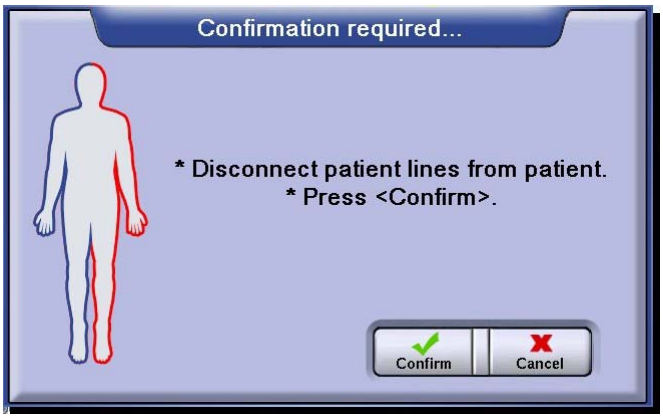
NOTE

If during an Extra Rinseback process a conductivity alarm or other problems cause the Arterial and Venous Pumps to stop, perform a "Manual Rinseback" special procedure.

5.6 Patient Disconnection

To disconnect the patient after the rinseback process has been completed or after the "Stop treatment" button has been pressed, proceed as follows:

1. Press the "Disconnect Patient" button. A *Confirm* window opens;



2. Clamp the Venous Patient line and disconnect it from the patient;
3. Confirm patient disconnection pressing the ***CONFIRM*** button on the Confirm window: the following *Overview* screen is displayed:

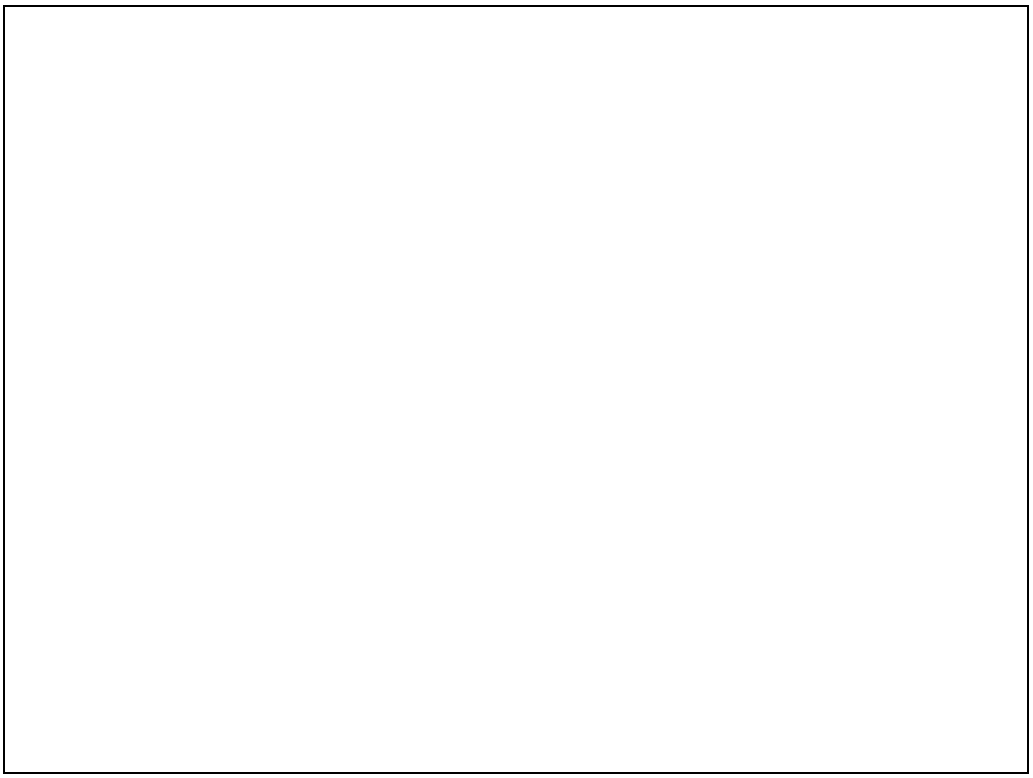


Figure 5-10. Overview Screen - Patient Disconnected

4. When required by the operator message, remove the Ultra inlet line from the Ultra port;
5. Close the Ultra door.

5.7 Drain Cartridge/Empty Circuit

The “Drain Cartridge” and ”Empty Circuit” buttons allow to drain the concentrate disposables and empty the extracorporeal circuit after the patient has been disconnected.

NOTE

To skip the BiCart Cartridge draining, proceed as follows:
- ***DO NOT*** perform the “Drain Cartridge” procedure;
- Remove the BiCart Cartridge from the BiCart Cartridge Holder;
- Close the BiCart Cartridge Holder arms;
- Place the caps on the cartridge.

NOTE

To skip the SelectCart Cartridge draining, proceed as follows:
- ***DO NOT*** perform the “Drain Cartridge” procedure;
- Remove the SelectCart Cartridge from the SelectCart Cartridge Holder;
- Close the SelectCart Cartridge Holder arms;
- Place the caps on the cartridge.

To start the draining process, follow the instructions on the Message area and proceed as follows:

1. Press the "Drain Cartridge" and the “Empty Circuit” buttons to perform both the draining and emptying procedures;

Or

1. Press the "Drain Cartridge" button to drain the BiCart and the SelectCart Cartridges (the SelectBag container will not be drained);

Or

1. Press the "Empty Circuit" button to empty the Extracorporeal Circuit only;

2. When required by the operator message, rotate the dialyzer, checking that the blue label is on the top of the dialyzer holder;

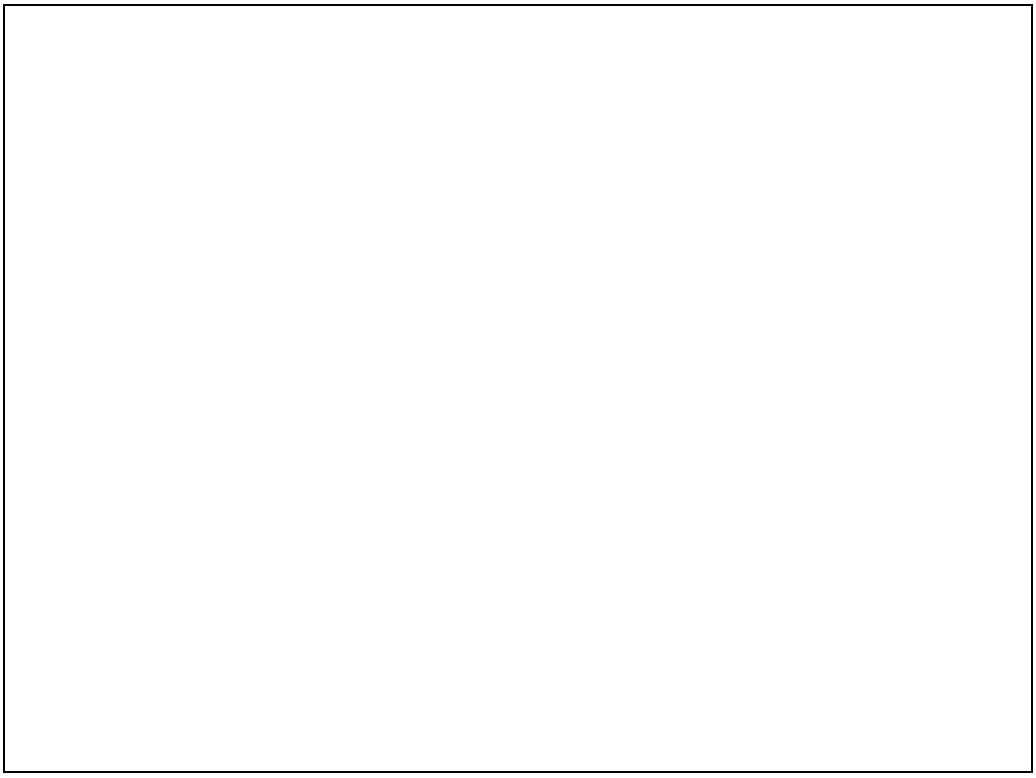


Figure 5-11. Overview Screen - Drain Cartridge/Empty Circuit

3. Connect the Blue Dialysis Fluid Tube connector to its safety coupling in order to empty the dialyzer;

4. When required by the operator message, remove the empty cartridges;

5. Close the BiCart holder arms;

6. Close the SelectCart holder arms;

7. Remove the SelectBag container from its holder;

8. Close the SelectBag holder arm;

9. Connect the Acid pick-up tube connector to the concentrate connector port on the front panel of the machine. Ensure to hear a "clicking" sound when connecting the Acid pick-up tube to its concentrate connector port;

10. Connect the Red Dialysis Fluid Tube connector to its safety coupling.

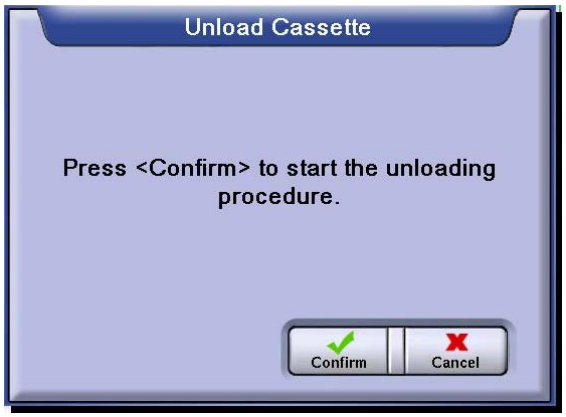
5.8 Remove the Cassette

⚠WARNING

An incorrect pump segment unloading procedure could damage the pump rotor.
A damaged pump rotor will not work properly. This could result in patient serious injury.

To remove the cassette follow the instruction displayed in the Message Area, proceeding as follows:

1. Press the "Unload Cassette" action button: a *Confirm* window opens;



2. Press the ***CONFIRM*** button on the *Confirm* window;

3. Keep the Arterial and Venous Pump covers closed to allow the unload of the pump segment;

4. Open the Sensor Bar door;

   • The machine pushes out the Blood and Ultra cassette holders and starts unloading the pump segment. If the pump segment unloading procedure fails, proceed as decribed in the “8.29 Manual Pump Segment Unloading Procedure” section of this Operator’s Manual.

5. Remove the patient lines from the Sensor Bar and from the automatic clamps;

6. Close the Sensor Bar door;

7. When the pumps stop, open the Arterial and Venous pump covers;

NOTE

After 45 seconds the Arterial Pump stops, if the covers are not opened an alarm will be triggered.

8. Remove the Heparin line from its guides;
9. Remove the heparin syringe from its holder. For further details, refer to the "4.8.3 Remove the Heparin Syringe" section of this Operator's Manual;
10. Remove the Blood and Ultra cassettes from the holders.
    DO NOT remove the Blood and Ultra cassettes if the pump segments are still loaded into the pump rotor.
    In case the automatic pump segment unloading procedure failed, proceed as decribed in the "8.29 Manual Pump Segment Unloading Procedure" section of this Operator's Manual;

⚠WARNING

In case of hardware malfunction or if the unloading procedure is not completed within 2 minutes, the Blood and Ultra cassette holders will automatically retract.
DO NOT insert fingers behind the cassette to avoid injury to your fingers.

11. Remove the dialyzer from its holder;
12. Throw away the complete circuit;
13. Close the Arterial and Venous pump covers; the machine automatically withdraws the Blood and Ultra cassette holders.

If the unloading procedure fails it is necessary to perform it again from the beginning.

When the Blood and Ultra cassettes have been removed, switch the Artis Dialysis System OFF and then ON again before starting the next treatment or perform a Disinfection/Rinse program.

If a Disinfection/Rinse program needs to be performed, refer to the "Chapter 13: Disinfection/Rinse" of this Operator's Manual for its settings and activation. After the disinfection program has been performed, switch the machine OFF and then ON again before starting the next treatment.

Chapter 6: HD-SN Treatment

After the operations described in the “Chapter 3: Machine Dressing and Priming” have been performed, proceed as described in the sections below to connect the patient and perform the treatment.

6.1 Connect the Patient

The “Connect Patient” button becomes available:

- After the BLD T1 Test has been successfully completed;
- After the Artis Dialysis System exits from the Low Consumption State, if active.

When the machine is ready for patient connection, the following *Overview* screen is displayed:

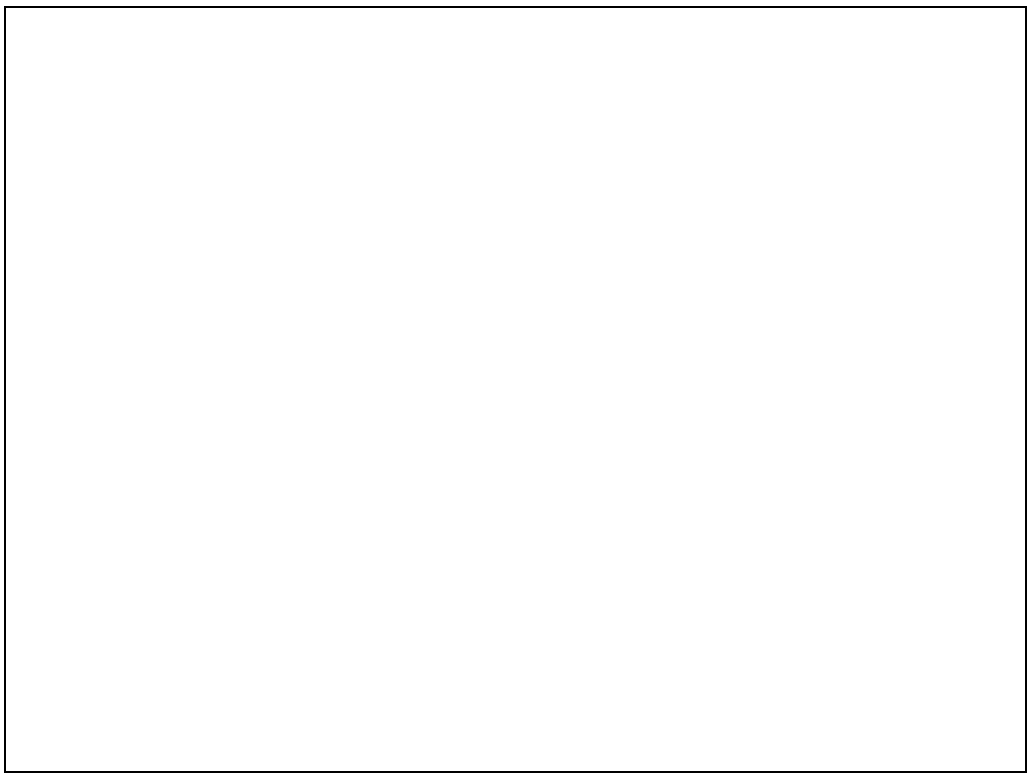


Figure 6-1. Overview Screen - Waiting for patient

⚠WARNING

After a Chemical Disinfection program, a test for residuals of disinfectant must be performed before the following patient connection to avoid the risk of blood hemolysis due to the exposure of the patient to the chemical residues.

⚠WARNING

The Patient Connection and Rinseback modes require additional attention: to facilitate their execution, some safety checkings are temporary deactivated and left to the responsibility of the operator (e.g., the extracorporeal A/V pressure limits are expanded to the maximum).

⚠WARNING

During patient connection/disconnection, follow your facility's policies and procedures for managing patient's vascular access and Venous and Arterial Patient lines used for hemodialysis.
The use of central venous catheters with atrial location leads to additional hazardous situations with respect to the other types of vascular access, due to their proximity to the heart.
In particular, if the patient's catheter disconnects from the patient lines or the integrity of the catheter is compromised in any other way, follow your facility's policy for preventing air embolism and infection, including clamping the patient's lines immediately.

⚠WARNING

Eventual electrical current leakages from the dialysis machine or from other electrical equipments are associated to an increased risk of patient electric shock in case central venous catheters with atrial location are used.
To avoid this risk, ensure that the potential equalization conductor is connected to the proper means on the Artis Dialysis System rear panel.

⚠WARNING

Before patient connection, verify that no air is present in the Venous Patient line. If air is present perform an Extra Prime or a Reset Prime procedure.
Air remained in the Venous Patient line has to be removed before connecting the patient to avoid risk of air embolism.

NOTE

If the Patient Connection is delayed, the dialysis fluid contained in the dialyzer and in the cassette could get cold.
In order to warm the dialysis fluid before connecting the patient, perform an Extra Priming procedure.

To connect the patient, proceed as follows:

1. Clamp the Venous Infusion line and disconnect the saline bag;
2. Enter and confirm mandatory prescription parameters on the *Prescription* screen, if not already done;
3. Ensure that all the required functions have been activated;
4. Press the “Connect Patient” command button: the following *Confirm* window opens:

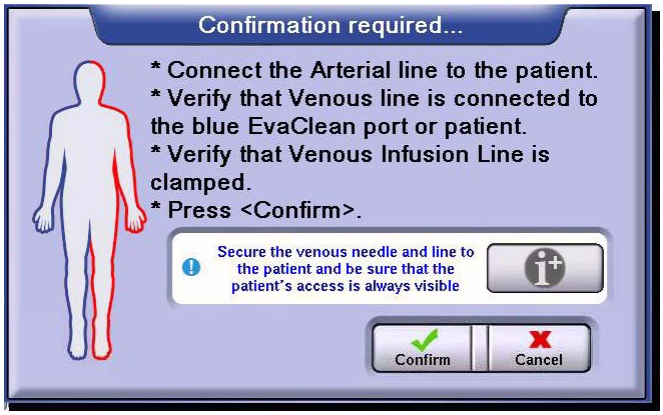
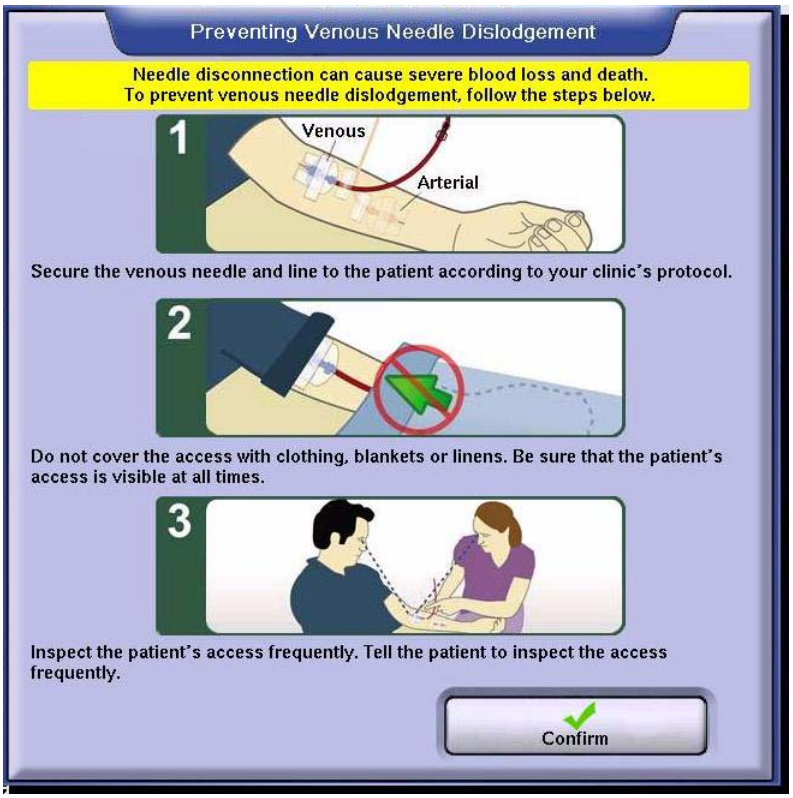


Figure 6-2. Confirm Patient Connection

Pressing the “i+” button the following window is displayed:



Press the ***CONFIRM*** button to close the window and to come back to the patient connection *Confirm* window;

5. Remove the Arterial Patient line from the EvaClean port, unscrew the priming connector from the line and discard it;

6. Close the EvaClean Red door;

7. Connect the Arterial Patient line to the patient's vascular access according to the clinical policy;

8. Connect the Venous Patient line to the patient or to a waste bag (in these cases, close the EvaClean Blue door) or keep the Venous Patient line into the EvaClean Blue port;

⚠WARNING

The EvaClean option must be cleaned each time the patient connection procedure is performed keeping the Venous Patient line into the EvaClean Blue port until the machine detects blood. In this case, manually clean the EvaClean option before performing another patient treatment.
(Refer to the "Chapter 8: Special Procedures" of this Operator's Manual).

9. Press the ***CONFIRM*** button on the *Confirm* window:

   • The *Confirm* window closes;

   • The blood pump ON/OFF and the blood flow Increase/Decrease keys are activated;

   • The Arterial and Venous clamps are closed.

10. Press the blood pump ON/OFF key to start the Arterial and Venous Pumps;

NOTE

If the EvaClean Red door is still opened, an alarm is triggered and the Arterial and Venous Pumps stop. The operator has to proceed with proper connection, close the EvaClean door and manually restart the Arterial and Venous Pumps.

As soon as blood is detected, the following *Overview* screen is displayed:

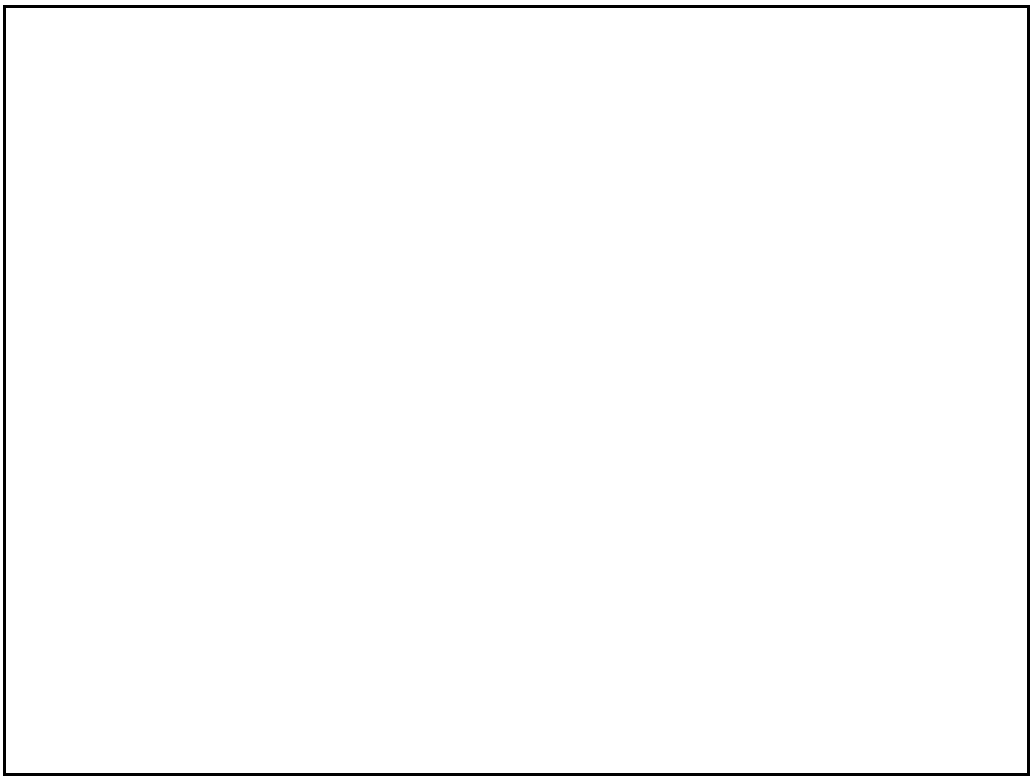


Figure 6-3. Overview Screen - Patient Connection

- The Arterial and Venous Pumps stop;
- The arterial and venous pressure Bar Graphs start monitoring with open limits;
- The blood path switches to red.

11. If the Venous Patient line is already connected to the patient the operator skips steps 11, 12, 13 and 14.
    Otherwise, remove the Venous Patient line from the EvaClean port or from the waste bag, unscrew the priming connector from the line and discard it;
12. Discard the waste bag if used;
13. Close the EvaClean Blue door if not already done;
14. Connect the Venous Patient line to the patient's vascular access according to the clinical policy;
15. Start the dialysis treatment (refer to "6.2 Start Treatment" section).

NOTE

If the EvaClean Blue door is still opened, an alarm is triggered and the Arterial and Venous Pumps stop. The operator has to proceed with proper connection, close the EvaClean door and manually restart the Arterial and Venous Pumps.

6.1.1 Special Procedures

During the Connect Patient phase the following special procedures are available:

- Change Acid
- Change BiCart
- Change SelectCart
- Change SelectBag
- Skip Treatment
- Cassette Repositioning
- SN Cassette Repositioning
- Switch to DN
- Pause Treatment *(only after blood has been detected by the machine)*

NOTE

Complete the "Change Circuit" procedure (until the "Start Treatment" button is pressed) before starting a "Pause Treatment" procedure.

To perform these procedures refer to the related sections in the "Chapter 8: Special Procedures" of this Operator's Manual.

6.2 Start Treatment

NOTE

If it is necessary to infuse saline solution to the patient during the treatment, the Arterial Infusion lines can be used.

To start the treatment, proceed as follows:

1. Press the blood pump ON/OFF key to start the Arterial and Venous Pumps;
   - The Arterial and Venous Pumps start at the default speeds;
   - The “Start Treatment” button becomes available.

NOTE

If the Arterial or Venous Flow values have been changed in the Blood Settings sub-screen, press once the blood flow increase key and then once the blood flow decrease key, before pressing the “Start Treatment” or the “Resume Treatment” button. Otherwise, a malfunction will be triggered.

2. Press the “Start Treatment” button to start the treatment:
   - the “UF” and the “Dialysis Fluid” buttons become available and their indicators are yellow;
   - If the Hemocontrol function was activated, the following *Confirm* window opens, informing the operator that the Hemocontrol function will be disenabled and that the displayed values of “UF Rate” and “Sodium” will be applied during the treatment.

   Press the ***Confirm*** button to close the window.

3. Press the blood flow Increase/Decrease keys to adjust the Mean Blood Flow;
4. As required by the operator message, press the “Close A/V Limits” button as soon as the arterial and venous pressures are stable: an operator

message is displayed indicating that the machine is performing its internal checks;

NOTE

Press the "Close A/V Limits" button during the Venous phase.
If these limits are closed during the Arterial phase, Arterial Pressure alarms will be triggered by the machine.

5. As required by the operator message, check the blood levels in the Arterial and Venous Chambers.
   For further details, refer to the "8.28 Adjust Arterial/Venous chamber levels" section of this Operator's Manual.

NOTE

Blood levels too low in the Arterial or Venous Chambers may cause air to enter the dialyzer thus resulting in dialysis efficacy reduction and/or "Air in Venous Line (#4)" alarm occurrence.

When the machine is ready:

- The UF process starts;
- The "UF" and "Dialysis Fluid" button indicators switch to green;
- The "Real TX Time" value on the *Fluid* screen starts increasing;
- The following *Overview* screen is displayed:

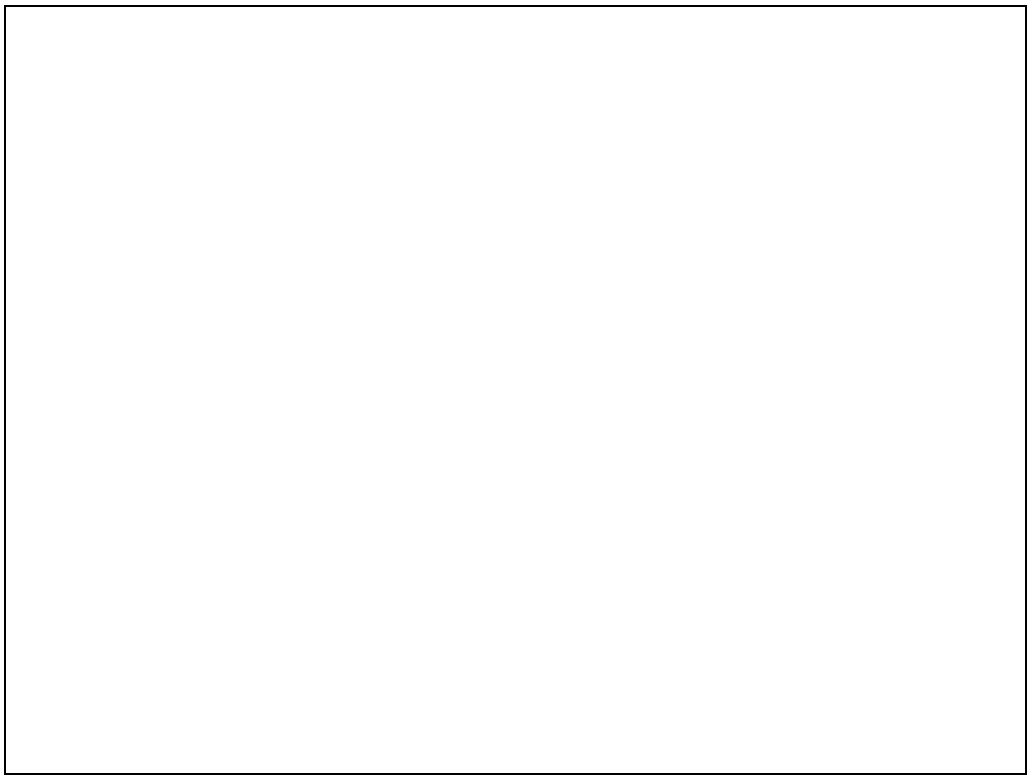


Figure 6-4. Overview Screen - HD-SN Treatment in progress

The “Acc UF Volume” value box will display the accumulated UF volume during the treatment.

The “Stroke Volume” value box will display the actual Stroke Volume during the treatment.

NOTE

In HD-SN Treatment, the difference between the actual and the set Mean Blood Flow rate might be greater than in HD-DN Treatment. The use of a small size needle in combination with an high Mean Blood Flow rate might result into an arterial pressure sensibly lower than in HD-DN Treatment, thus generating a lower actual Mean Blood Flow rate.

6.3 Operations during treatment

Below is a list of the main operations that can be performed on the Artis Dialysis System when a treatment is ongoing.

6.3.1 Special Procedures

As soon as the treatment starts and until the "Stop Treatment" button is pressed and confirmed, the following special procedures are available:

- Change Acid
- Change BiCart
- Change SelectCart
- Change SelectBag
- SN Cassette Repositioning
- Pause Treatment
- Cassette Repositioning
- Switch to DN
- Change Circuit
- Adjust the Arterial/Venous Chamber Levels
- Adjust the Expansion Chamber Levels

For further details on each of the special procedures listed above refer to the related section in the "Chapter 8: Special Procedures" of this Operator's Manual.

6.3.2 Change Blood Setting Parameters

As soon as blood is detected by the machine in the Venous Patient Line, the "Blood Settings" button becomes available in the *Blood Screen*.

To check/adjust the SN parameters in the Blood Settings sub-screen, proceed as follows:

1. Press the "Blood Settings" button in the *Blood Screen.* The following sub-screen opens:

Figure 6-5. HD-SN Treatment - Blood Settings Sub-screen

PARAMETER	DESCRIPTION	VALUES
SN Pressure Graph	Displays the post-dialyzer pressure variation during the treatment.	/
Arterial Flow[a]	Sets the Arterial Pump Speed.	• 30 to 580 mL/min in steps of 10 mL/min
Venous Flow[a]	Sets the Venous Pump Speed.	• 30 to 500 mL/min in steps of 10 mL/min
Stroke Volume	Displays the actual Stroke Volume.	/
Arterial Pressure	Displays the Arterial Pressure.	/
Venous Pressure	Displays the Venous Pressure.	/
SN Pressure Max	Displays the maximum value of the post-dialyzer pressure used during a SN cycle. This value is automatically calculated by the machine according to the Stroke Volume set by the operator.	/
SN Pressure	Dispalys the actual post-dialyzer pressure.	/
SN Pressure Min	Displays the minimum value of the post-dialyzer pressure used during a SN cycle. This value is always 40 mmHg during all cycles.	• 40 mmHg

a. Each time the Arterial Flow or Venous Flow values are changed during the treatment, the machine automatically recalculates the Mean Blood Flow.

When the Blood Settings sub-screen is displayed during a HD-SN Treatment, the blood flow increase/decrease keys on the Hard Key panel are disabled, whereas the blood pump ON/OFF key remains active.

Each time one of the SN parameters is changed by the operator during the treatment, some cycles are necessary to reach the new values.

6.3.2.1 Change the Stroke Volume

To change the Stroke Volume, proceed as follows:

1. Open the *Blood* screen;
2. Press the "Stroke Volume" button: a Keypad opens;
3. Enter the new stroke volume in the following range:
   - 20 mL to 60 mL (*default 30mL*)
4. Press the ***CONFIRM*** button on the keypad to confirm the new value.

Each time the Stroke Volume parameter is changed by the operator during the treatment, some cycles are necessary to reach the new value.

6.3.3 Deactivate UF process

To deactivate the ongoing UF process, press the activated "UF" action button on the *Overview* screen:

- The "UF" action indicator switches to grey;
- The ultrafiltration process is stopped.

Press the dectivated "UF" button to restart the UF process.

6.3.4 Deactivate Dialysis Fluid flow

To deactivate the Dialysis Fluid Flow, press the "Dialysis Fluid" action button:

- The dialysis fluid goes in bypass;
- The "Dialysis Fluid" action indicator switches to grey;
- The updating of the "Real TX Time" value is interrupted.

To activate the Dialysis Fluid Flow again, press the dectivated "Dialysis Fluid" button:

- The "Dialysis Fluid" action indicator switches to green;
- The updating of the "Real TX Time" value restarts.

6.3.5 Expand A/V Limits

The “Expand A/V Limits” button allows to open the arterial and venous pressure alarm windows.

When the “Expand A/V Limits” button is pressed on the *Overview* screen or on the *Blood* screen:

- The “Expand A/V Limits” button becomes “Close A/V Limits”;
- The Arterial and Venous alarm windows open and they are automatically set at the following values:

Arterial Pressure	
Upper Limit	+ 150 mmHg
Lower Limit	- 400 mmHg

Venous Pressure	
Upper Limit	+ 450 mmHg
Lower Limit	+ 10 mmHg

When the arterial and venous pressures are stable, press the “Close A/V Limits” button to adjust and close the A/V pressure alarm limit windows.

For further details on this function refer to the “1.7.3.1 Manually Expand/Close the pressure alarm limits” section of this Operator’s Manual.

6.3.6 Stop the Arterial and Venous Pumps

It is possible to stop the pumps during a treatment, proceeding as follows:

1. Press the blood pump ON/OFF key:
   - The Arterial and Venous Pumps are stopped;
   - The “UF Rate” is set to zero;
   - The “UF” action indicator switches to yellow;
   - The “Dialysis Fluid” action indicator switches to yellow;
   - The updating of the “Real TX Time” value stops;
   - The arterial and venous alarm limits are automatically set to the following values:

Arterial Pressure	
Upper Limit	+ 150 mmHg
Lower Limit	- 400 mmHg

Venous Pressure	
Upper Limit	+ 450 mmHg
Lower Limit	- 50 mmHg

These values are maintained for all the time the Arterial Pump is off and for 30 seconds after the Arterial Pump restarts.

To restart the pumps, press the blood pump ON/OFF key:

- The Arterial and Venous Pumps restart;
- The treatment restarts;
- The updating of the "Real TX Time" value restarts.

6.3.7 Report Table

During a treatment it is possible to visualize a run-time dialysis report containing the data acquired throughout the treatment.

For further details on this function, refer to the "Chapter 15: Report Environment" of this Operator's Manual.

6.4 Stop treatment

When the end conditions for the current treatment are reached, one or both the Information Messages “Treatment Time Complete (#51)” and “Fluid Removal Complete (#53)” are triggered.

The Treatment can also be manually stopped at any time by pressing the “Stop Treatment” action button.

To stop the treatment after the end conditions have been reached or before reaching the end conditions, proceed as follows:

1. Press the “Stop Treatment” button: a *Confirm* window opens;

2. Press the ***CONFIRM*** button on the *Confirm* window. The following *Overview* screen is displayed:

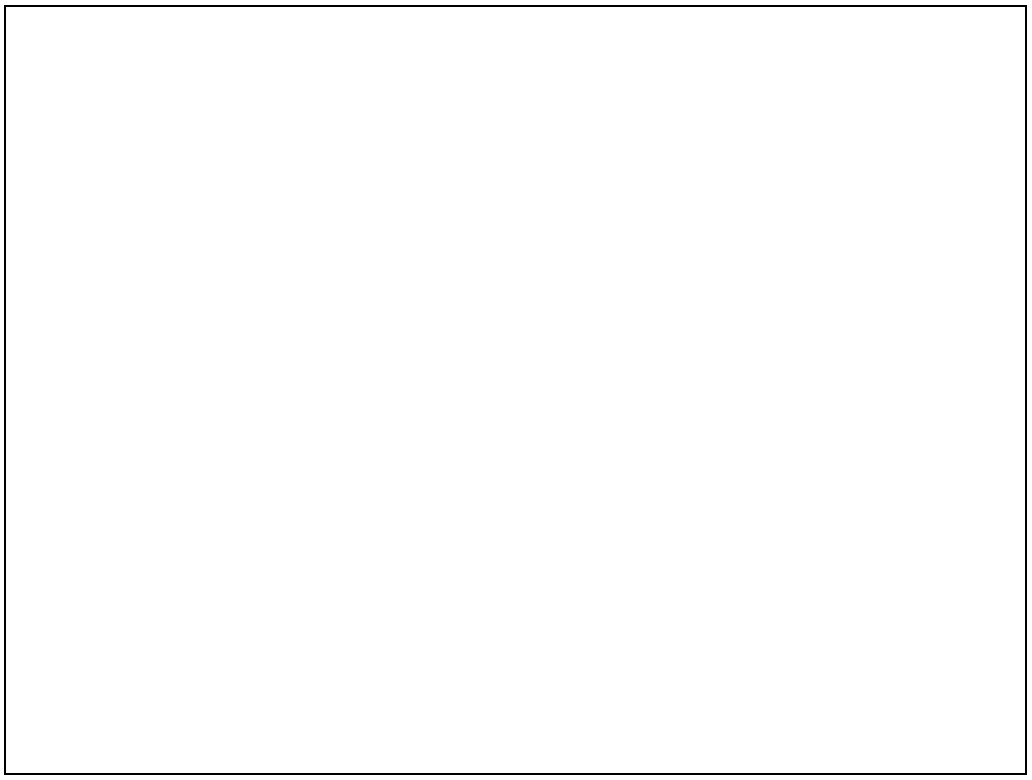


Figure 6-6. Overview Screen - Rinseback

3. Perform Rinseback proceeding as described in the “6.5 Rinseback mode” section or disconnect the patient as described in the “6.6 Patient Disconnection” section or continue the treatment as described in the “6.4.1 Continue treatment” section.

6.4.1 Continue treatment

To continue the treatment after the "Stop Treatment" button has been pressed and confirmed, proceed as follows:

1. Check the treatment parameters;

2. Press the "Continue Treatment" button:

   - The blood pump ON/OFF key and the blood flow Increase/Decrease keys are enabled;

   - The update of the "Remaining Time" value on the *Overview* screen restarts from where it was interrupted;

   - If the Isolated UF function was enabled, it is resumed.

3. Press the blood pump ON/OFF key to restart the Arterial Pump;

   - The Arterial Pump starts at the speed it had before stopping the treatment;

   - The treatment is resumed;

   - The "Treatment Time" and "UF Volume" parameters continue to be updated.

4. Adjust the pump speed.

6.5 Rinseback mode

It is possible to disconnect the patient without performing the rinseback procedure. In this case skip to the procedure described in the “6.6 Patient Disconnection” section below.

Otherwise, follow the instructions below.

⚠WARNING

The Patient Connection and Rinseback modes require additional attention: to facilitate their execution, some safety checkings are temporary deactivated and left to the responsibility of the operator (e.g., the extracorporeal A/V pressure limits are expanded to the maximum).

⚠WARNING

During patient connection/disconnection, follow your facility’s policies and procedures for managing patient’s catheter and Venous and Arterial Patient lines used for hemodialysis.
In particular, if the patient’s catheter disconnects from the patient lines or the integrity of the catheter is compromised in any other way, follow your facility’s policy for preventing air embolism and infection, including clamping the patient’s lines immediately.

6.5.1 Start Rinseback

To start the rinseback procedure, proceed as follows:

1. Clamp the Arterial Patient line and disconnect it from the patient;
2. Connect the Arterial Patient line to a saline bag appropriate for rinseback procedure;
3. Unclamp the Arterial Patient line and the Prime line;
4. If needed, change the values on the Rinseback Settings sub-screen. Open this sub-screen pressing the “Rinseback Settings” button on the *Blood* screen;
5. Press the “Rinseback” action button: a *Confirm* window opens;
6. Press the ***CONFIRM*** button on the *Confirm* window:
   - The “Rinseback” action indicator switches to green;
   - The Arterial and Venous Pumps start at the set value;
   - The blood pump ON/OFF and blood flow Increase/Decrease keys are activated;

- The "Acc Volume" value in the Rinseback Settings sub-screen starts increasing;
- The "Acc Rinseback Volume" value in the *Overview* screen starts increasing.

During the Rinseback mode:

- The Arterial Pump speed can be adjusted anytime with the blood flow increase/decrease keys;
- The rinseback volume can be changed anytime.

NOTE

If an Air in Venous Line *(#4)* alarm occurs during a rinseback procedure, verify the presence of air in the Venous Patient line:
- If air is not present, perform the manual rinseback procedure.
- If air is still present, disconnect the patient without performing blood restitution.

6.5.2 Pause Rinseback

To pause the rinseback process, proceed as follows:

1. Press the activated "Rinseback" button:
   - The Arterial and Venous Pump stop;
   - The rinseback process stops;
   - The "Rinseback" indicator switches to grey.
2. Press again the "Rinseback" button to restart the process or proceed with patient disconnection.

6.5.3 Operations during Rinseback

During the Rinseback process, it is possible to perform the following special procedures:

- Change Acid
- Change BiCart
- Change SelectCart
- Change SelectBag
- Cassette Repositioning
- SN Cassette Repositioning

For further details on each of the special procedures listed above refer to the related section in the " Chapter 8: Special Procedures" of this Operator's Manual.

During the Rinseback process, it is also possible to perform the Drain Cartridge procedure, as described in the "6.7 Drain Cartridge/Empty Circuit" section.

6.5.4 End Rinseback

The Rinseback process automatically ends when the rinseback volume has been reached.

It is also possible to manually stop the rinseback process pressing the activated “Rinseback” action button.

When the rinseback process is completed or it is stopped:

- The Arterial and Venous Pumps automatically stop;
- The following *Overview* screen is displayed:

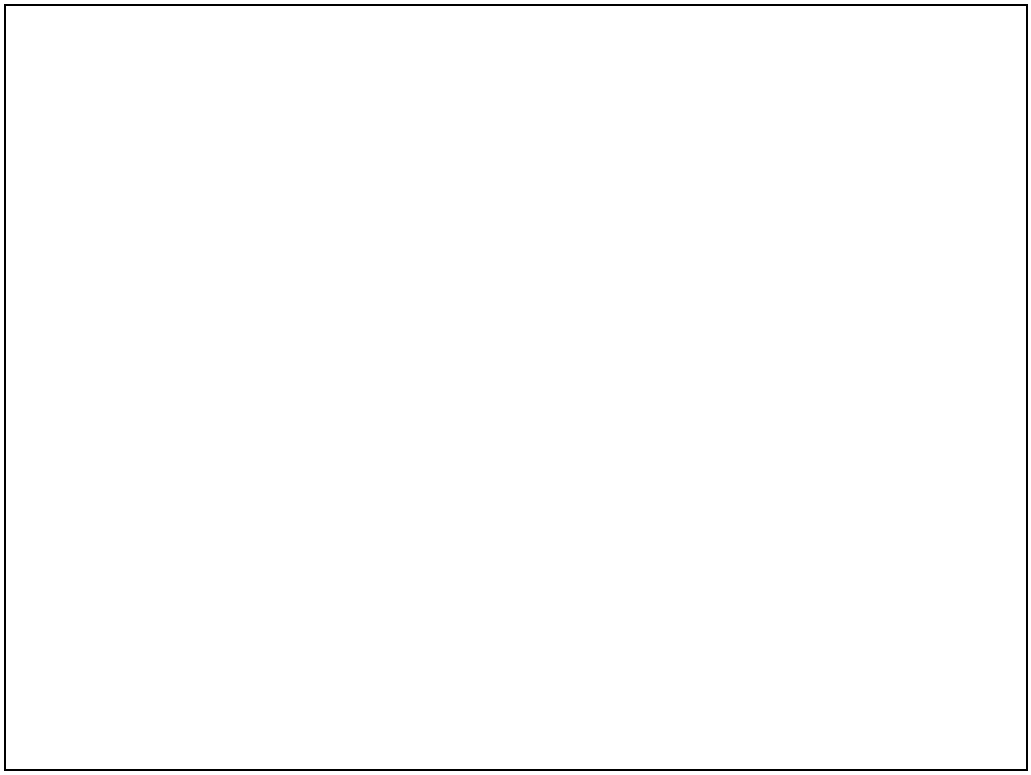


Figure 6-7. Overview Screen - Rinseback Completed

6.5.5 Additional rinseback

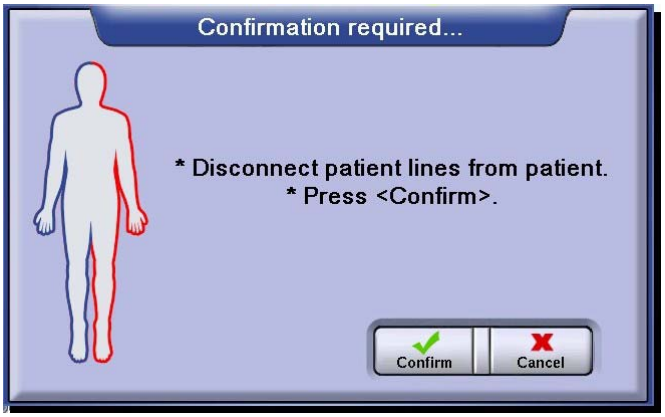
To perform an additional rinseback, proceed as follows:

1. Press the “Extra Rinseback” button:
   - The rinseback process starts again and an additional volume of 100 mL is processed;
   - The “Acc Volume” value in the Rinseback Settings sub-screen continues to increase;
   - The “Acc Rinseback Volume” value on the *Overview* screen starts increasing.
2. Refer to “6.5.4 End Rinseback” section.

6.6 Patient Disconnection

To disconnect the patient after the rinseback process has been completed or after the "Stop Treatment" button has been pressed and confirmed, proceed as follows:

1. Press the "Disconnect Patient" command button. A *Confirm* window opens;



2. Clamp the Venous Patient line and disconnect it from the patient;

3. Confirm patient disconnection pressing the ***CONFIRM*** button on the *Confirm* window:

   • The following *Overview* screen is displayed:

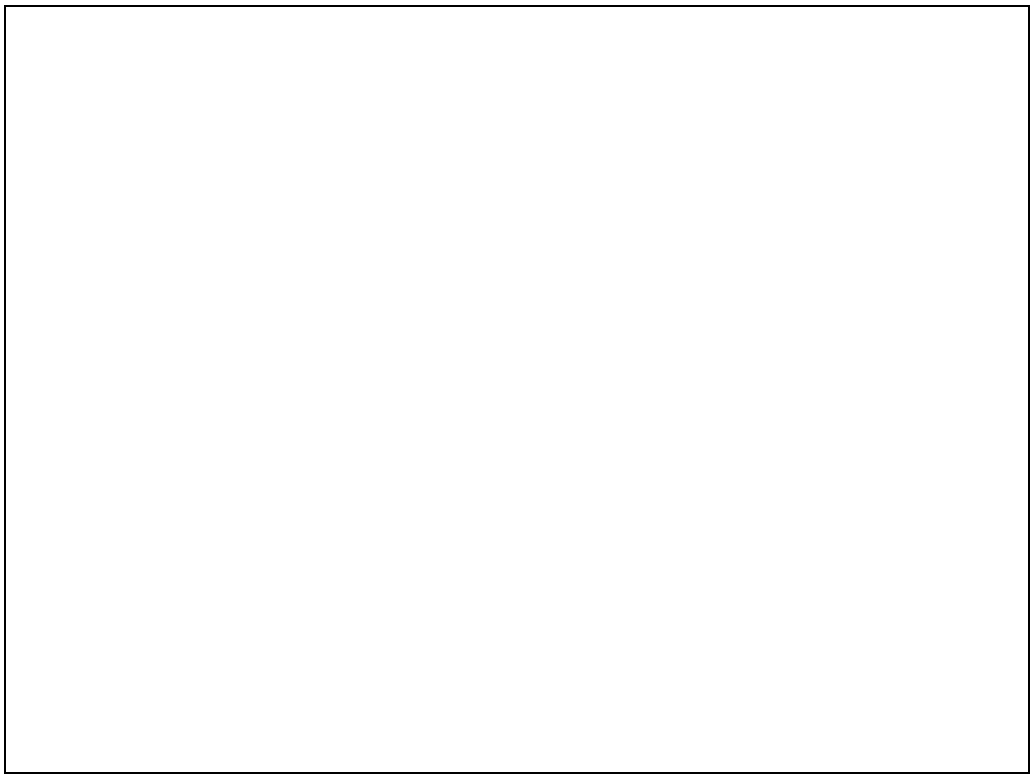


Figure 6-8. Overview Screen - Patient disconnected

6.7 Drain Cartridge/Empty Circuit

These two buttons allow to drain the concentrate disposables and empty the extracorporeal circuit after a treatment.

NOTE

To skip the BiCart Cartridge draining, proceed as follows:
- ***DO NOT*** perform the “Drain Cartridge” procedure;
- Remove the BiCart Cartridge from the BiCart Cartridge Holder;
- Close the BiCart Cartridge Holder arms;
- Place the caps on the cartridge.

NOTE

To skip the SelectCart Cartridge draining, proceed as follows:
- ***DO NOT*** perform the “Drain Cartridge” procedure;
- Remove the SelectCart Cartridge from the SelectCart Cartridge Holder;
- Close the SelectCart Cartridge Holder arms;
- Place the caps on the cartridge.

NOTE

It is possible to perform the Drain Cartridge procedure also during the rinseback process.

To start the draining process, follow the instructions on the Message area and proceed as follows:

1. Press the "Drain Cartridge" and the “Empty Circuit” buttons to perform both the draining and emptying procedures;

Or

1. Press the "Drain Cartridge" button to drain the BiCart and the SelectCart Cartridges (the SelectBag container will not be drained);

Or

1. Press the "Empty Circuit" button to empty the extracorporeal circuit only;

2. When required by the operator message, rotate the dialyzer, checking that the blue label is on the top of the dialyzer holder;

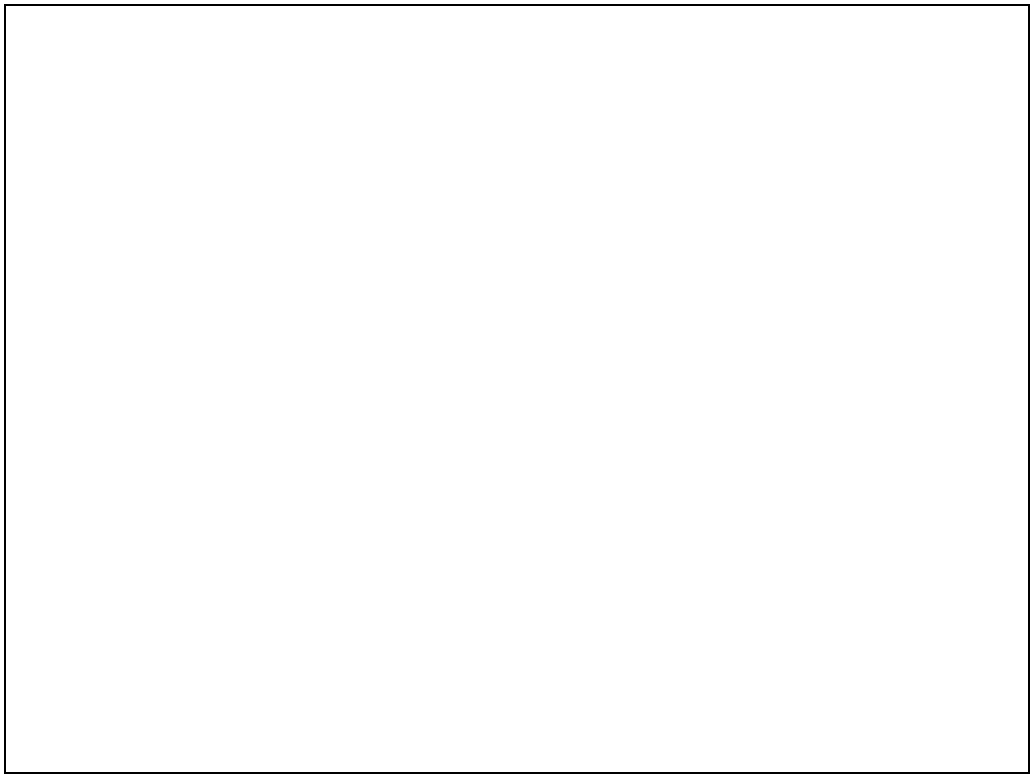


Figure 6-9. Overview Screen - Drain Cartridge/Empty Circuit

3. Attach the blue dialysis fluid tube connector to its safety coupling in order to empty the dialyzer;

4. When required by the operator message, remove the empty cartridges;

5. Close the BiCart Holder arms;

6. Close the SelectCart Holder arms;

7. Remove the SelectBag container from its holder;

8. Close the SelectBag Holder arm;

9. Connect the Acid pick-up tube connector to the concentrate connector port on the front panel of the machine. Ensure to hear a "clicking" sound when connecting the Acid pick-up tube to its concentrate connector port;

10. Connect the Red Dialysis Fluid Tube connector to its safety coupling.

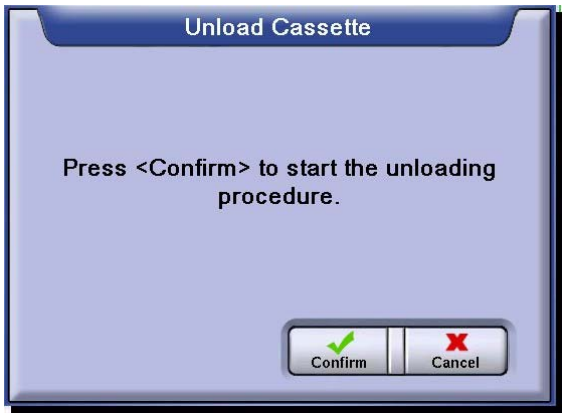
6.8 Remove the Cassette

⚠WARNING

An incorrect pump segment unloading procedure could damage the pump rotor.
A damaged pump rotor will not work properly. This could result in patient serious injury.

To remove the cassette follow the instruction displayed in the Message Area, proceeding as follows:

1. Press the "Unload Cassette" action button. A *Confirm* window opens;



2. Press the ***CONFIRM*** button on the *Confirm* window;

3. Keep the Arterial and Venous Pump covers closed to allow the unload of the pump segment;

4. Open the Sensor Bar door;

   • The machine pushes out the cassette holders and starts unloading the pump segments. If the pump segment unloading procedure fails, proceed as decribed in the “8.29 Manual Pump Segment Unloading Procedure” section of this Operator’s Manual.

5. Remove the patient lines from the Sensor Bar and from the automatic clamps;

6. Close the Sensor Bar door;

7. When the Arterial and Venous Pumps stop, open the Arterial and Venous Pump covers;

NOTE

After 45 seconds the Arterial and Venous Pumps stop, if the covers are not opened an alarm will be triggered.

8. Remove the heparin line from the Cassette Panel guides;

9. Remove the heparin syringe from its holder. For further details, refer to the "4.8.3 Remove the Heparin Syringe" section of this Operator's Manual;

10. Remove the cassettes from the Cassette holders.
    DO NOT remove the cassettes if the pump segments are still loaded into the pump rotor.
    In case the automatic pump segment unloading procedure failed, proceed as decribed in the "8.29 Manual Pump Segment Unloading Procedure" section of this Operator's Manual;

⚠WARNING

In case of hardware malfunction or if the unloading procedure is not completed within 2 minutes, the holders will automatically retract.
DO NOT insert fingers behind the cassette to avoid injury to your fingers.

11. Remove the dialyzer from its holder;

12. Throw away the complete circuit;

13. Close the Arterial and Venous Pump covers: the machine automatically withdraws the cassette holders.

If the unloading procedure fails it is necessary to perform it again from the beginning.

When the cassette has been removed, switch the Artis Dialysis System OFF and then ON again before starting the next treatment.

If a Disinfection/Rinse procedure needs to be performed, refer to the "Chapter 13: Disinfection/Rinse" of this operator's manual for its settings and activation. After the disinfection program has been performed, switch the machine OFF and then ON again before starting the next treatment.

Chapter 7: Isolated UF

7.1 General Description

The Isolated UF is a function that allows to perform only weight loss during a treatment (without substitution), i.e. there is no dialysis fluid flow through the dialyzer.

The under-pressure created on the dialysis fluid compartment of the dialyzer removes excess fluid from the blood.

7.2 Procedures

It is possible to activate the Isolated UF function only with the following treatment modes:

- Hemodialysis (HD-DN Treatment)
- Hemodialysis (HD-SN Treatment)
- Hemodialysis (HD-DNDP Treatment)
- Hemodiafiltration (HDF Post Treatment)

Following the operational procedures necessary to activate/deactivate the Isolated UF function.

7.2.1 Preset

To make the Isolated UF function available during the dialysis treatment, the proper service configuration has to be set up:

- The “Isolated UF Use” option of the “Installed Features” list is “YES”: the Isolated UF function is available in the treatment views and can be activated.
- The “Isolated UF Use” option is “NO”: the Isolated UF related buttons are not available in the treatment views and the Isolated UF function can not be activated.

7.2.2 Confirm Mandatory Parameters

Before setting the Isolated UF parameters on the Isolated UF Settings sub-screen, it is necessary to set and confirm the following parameters on the *Prescription* or on the *Fluid* screen:

- Treatment Time
- UF Volume

NOTE

- The “Isolated UF Volume” value can not be greater than the “UF Volume” value.
- The “Isolated UF Time” can not be greater than the “Treatment Time”.

NOTE

- The "Treatment Time" value has to include also the "Isolated UF Time" value.
- The "UF Volume" value has to include also the "Isolated UF Volume" value.

7.2.3 Activate the Isolated UF function

After being enabled in the Service menu, the Isolated UF function can be activated/deactivated, before starting the treatment, from the Isolated UF Settings sub-screen.

It is possible to open the settings sub-screen in the following ways:

- Pressing the "Isolated UF Settings" button on the *Fluid* screen
- Pressing the "Isolated UF" option on the "Activated Functions" list on the *Prescription* screen.

1. On the Isolated UF Settings sub-screen, check/change the Isolated UF parameters listed in the table below:

Figure 7-1. Isolated UF Settings Sub-screen

Table 1: Isolated UF Setting Parameters

Parameters	Description	Values	Conditions
Isolated UF Volume	Sets the total UF Volume to be processed during the Isolated UF process.	• 0 to 6 L	• UF Volume prescription > Isolated UF Volume
Isolated UF Time	Sets the total time of the Isolated UF process.	• 0 to 2 hours	• Treatment Time prescription > Isolated UF Time

As soon as the “Isolated UF Time” and the “Isolated UF Volume” are set, the “Isolated UF” action button becomes available.

After it has become available, the “Isolated UF” action button disappears each time one or both the “Isolated UF Time” and the “Isolated UF Volume” parameters are reset to zero.

NOTE

The “Isolated UF” action button will be dimmed during a Change Circuit procedure or after the “Stop Treatment” button has been pressed and confirmed. The button will be available again as soon as the treatment is resumed.

2. Press the “Isolated UF” action button to activate the function:
   - The Isolated UF function is activated;
   - The “Isolated UF” action indicator switches to green;
   - The Isolated UF icon is displayed on the *Overview* screen;
   - The “Isolated UF” action indicator on the “Activated Functions” list on the *Prescription* screen switches to green.
3. Press the ***CLOSE*** button to close the setting sub-screen.

As soon as the “Start Treatment” button is pressed to start the treatment, the Isolated UF process starts.

NOTE

If the Isolated UF function is enabled in the service environment but it is not activated before pressing the “Start Treatment” button, it will be no more possible to activate it for the current treatment.

NOTE

If the “UC Auto Scan” button has been pressed before pressing the “Start Treatment” button, the first automatic scan starts after 3 minutes the Isolated UF process has been accomplished or interrupted.

NOTE

It is not possible to activate an Isolated UF process after a Fast Recovery procedure.

7.2.4 Performing Isolated UF

After the "Start Treatment" button has been pressed, the Isolated UF function starts:

1. As required by the operator message, press the "Close A/V Limits" button when the arterial and venous pressures are stable;

    • The following *Overview* screen is displayed:

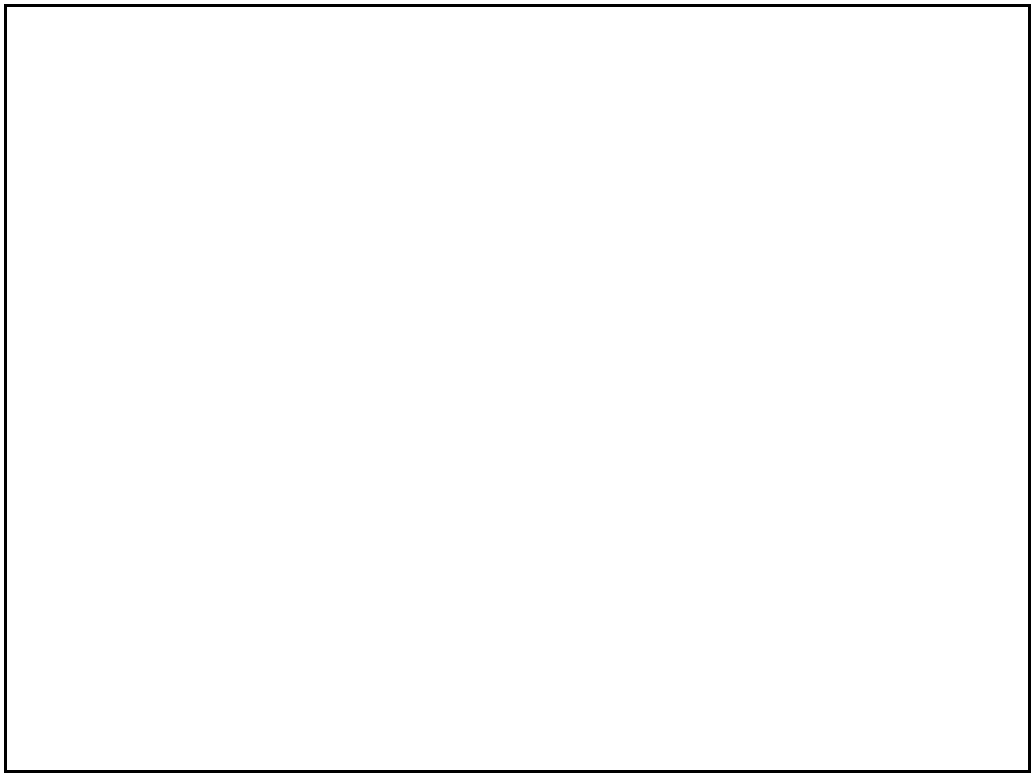


Figure 7-2. Isolated UF - Auto Test

The "Remaining Time" value on this screen shows the treatment remaining time. It is not referred to the remaining time of the Isolated UF function.

When the machine is ready:

• The "UF" button action indicator becomes green;

• The following *Overview* screen is displayed:

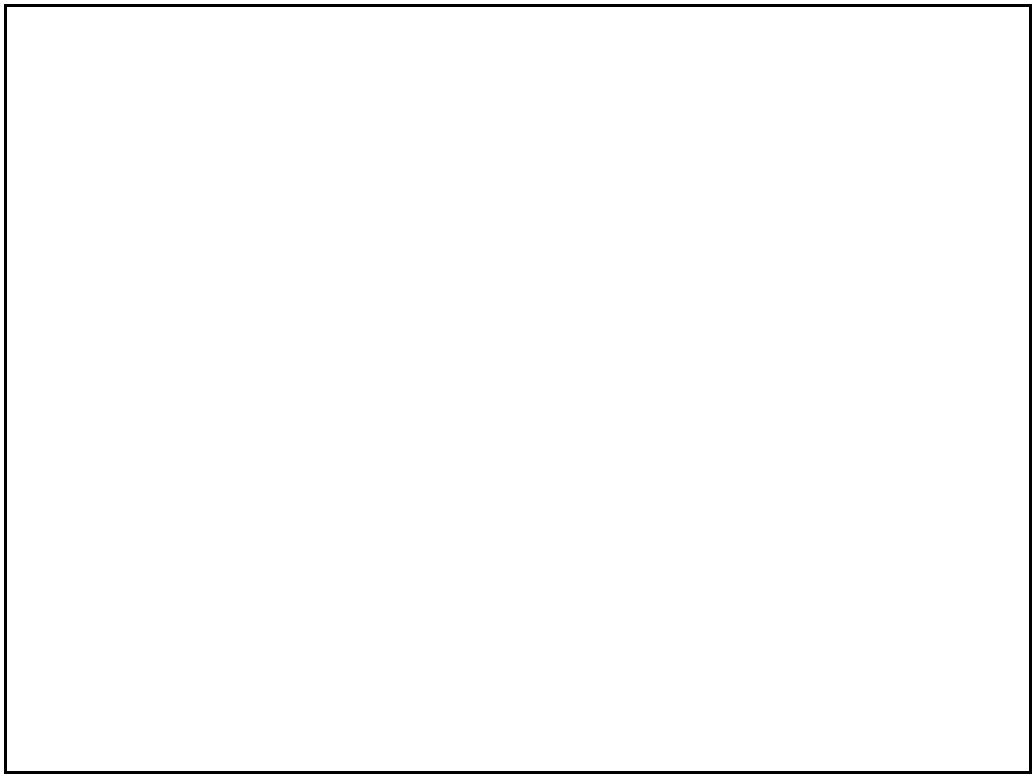


Figure 7-3. HD-DN Treatment - Isolated UF ongoing

NOTE

During the Isolated UF process, the “Pause Treatment”, “Change Circuit”, “Switch to DN” and “Switch to SN” special procedures are not available in the “Special Procedures” list. To perform these procedures it is necessary to stop the Isolated UF process, as described in the “7.2.6 Stop the Isolated UF function” section.

During the Isolated UF process, the Isolated UF Settings sub-screen will display the following parameters:

Table 2: Isolated UF Parameters

Parameters	Description
Real Isolated UF Time	Displays the real Isolated UF Time. The updating of this value is interrupted each time ultrafiltration is stopped due to an alarm situation, to a special procedure execution or to the stop of the Arterial pump.
Isolated UF Volume	Displays the actual Isolated UF Volume processed.
Isolated UF Rate	Displays the weight loss rate during the Isolated UF process.

NOTE

If during the Isolated UF process the difference between the set Isolated UF Volume and the volume calculated according to the remaining time is more than 100 g, the "Isolated UF target loss will not be achieved (#581)" alarm is triggered.
Refer to the " Chapter 16: Alarms, Information Signals and Troubleshooting" of this Operator's Manual.

7.2.5 Pause the Isolated UF function

The Isolated UF process will be automatically paused and the "Real Isolated UF Time" updating interrupted, in the following cases:

- when the "Stop Treatment" button is pressed and confirmed.
  In this case, the function will be resumed if the "Continue Treatment" button is pressed and the Arterial pump restarts.
  The function will be disabled if the "Rinseback" button is pressed and confirmed.
- when the "UF" button is pressed to deactivate ultrafiltration during the treatment. In this case, the "Remaining Time" value continues to be updated and the "Real Isolated UF Time" is frozen.
  As soon as the "UF" button will be pressed again the Isolated UF function will be automatically reactivated.

7.2.6 Stop the Isolated UF function

7.2.6.1 Stop Isolated UF process before it is accomplished

It is possible to deactivate the Isolated UF function during a treatment, proceeding as follows:

1. Press the “Isolated UF” button:
   - The following confirmation window is displayed:

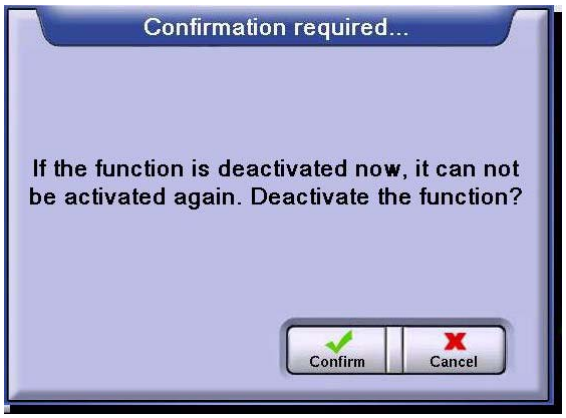


Figure 7-4. Isolated UF *Confirm* Window

2. Press the ***CONFIRM*** button to confirm function deactivation:
   - The “UF” and “Dialysis Fluid” buttons are displayed and their action indicators are green;
   - In a HDF Post Treatment, the “HDF Substitution” button is displayed and its action indicator is green;
   - The treatment starts;
   - The following sub-screen opens with a keypad displaying the set “UF Volume” according to which the machine calculates the UF Rate to use during the remaining treatment time, considering the accumulated “Isolated UF Volume”, too:

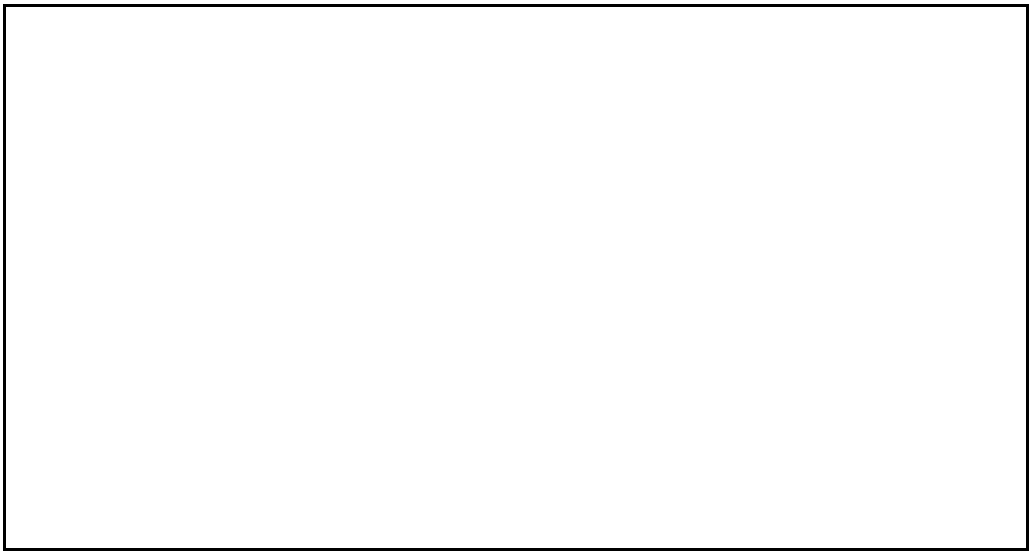


Figure 7-5. Isolated UF - UF Volume Confirmation

3. Check the total UF Volume value and change if necessary.

NOTE

The "UF Volume" value can not be set to a value lower than the accumulated "Isolated UF Volume".

NOTE

The "UF Rate" value displayed on the keypad is calculated as follows:
- (Total UF Volume - UF Volume accumulated during Isol. UF) / Remaining treatment time

If "UF Rate" value is "-.--" it means that the UF Rate calculated by the machine is outside the allowed limits.

4. Press the ***CONFIRM*** button on the keypad:
   - The sub-screen closes;
   - The standard treatment continues;
   - The "Isolated UF" button on the Isolated UF Settings sub-screen is no more available;
   - All the isolated UF parameter buttons are dimmed.

NOTE

Until the “UF Volume” on the keypad is not confirmed or the operator presses the ***CANCEL*** button *(active only if “*UF Rate*” value is “-.--”)* , the treatment starts with the UF Rate calculated according to the prescription without considering the time of the Isolated UF and the UF Volume accumulated during the Isolated UF procedure.

7.2.6.2 Stop the Isolated UF function after it is accomplished

When the time set for the “Isolated UF Time” parameter expires or the “Isolated UF Volume” is reached:

- The Isolated UF function is stopped;
- The “Isolated UF Completed (#570)” Information Message is triggered
- The icon on the *Overview* screen disappears;
- The “UF” button is dimmed;
- The “Isolated UF” button on the Isolated UF Settings sub-screen is hidden;
- All the isolated UF parameter buttons are dimmed.

To proceed with the HD-DN or HDF Post Treatment, perform the following tasks:

1. Press the ***CONFIRM*** button on the Alarm/Information Messages Area to reset the alarm:
   - The “UF” and “Dialysis Fluid” buttons are displayed and their action indicators are green;
   - In a HDF Post Treatment, the “HDF Substitution” button is displayed and its action indicator is green;
   - The treatment starts;
   - The following sub-screen opens with a keypad displaying the set “UF Volume” according to which the machine calculates the UF Rate to use during the remaining treatment time, considering the accumulated “Isolated UF Volume”, too:

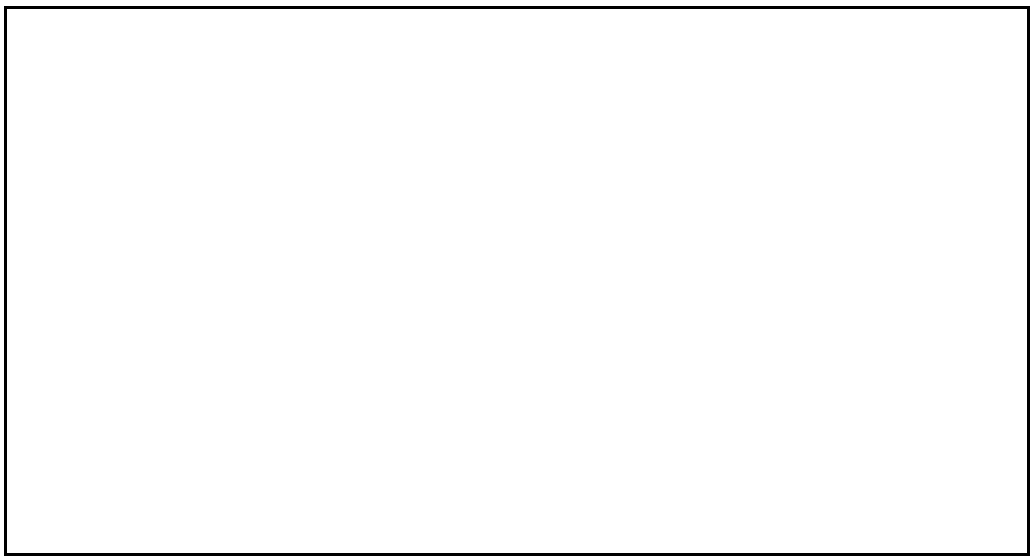


Figure 7-6. Isolated UF - UF Volume Confirmation

2. Check the total UF Volume value and change if necessary.

NOTE

The "UF Volume" value can not be set to a value lower than the accumulated "Isolated UF Volume".

NOTE

The "UF Rate" value displayed on the keypad is calculated as follows:
• (Total UF Volume - UF Volume accumulated during Isol. UF) / Remaining treatment time
If "UF Rate" value is "-.--" it means that the UF Rate calculated by the machine is outside the allowed limits.

3. Press the ***CONFIRM*** button on the keypad:

- The sub-screen closes;
- The standard treatment continues;
- The "Isolated UF" button on the Isolated UF Settings sub-screen is no more available;
- All the isolated UF parameter buttons are dimmed.

NOTE

Until the "UF Volume" on the keypad is not confirmed or the operator presses the ***CANCEL*** button *(active only if "*UF Rate*" value is "-.--")* , the treatment starts with the UF Rate calculated according to the prescription without considering the time of the Isolated UF and the UF Volume accumulated during the Isolated UF procedure.

Chapter 8: Special Procedures

8.1 Procedure for Power Failure (with battery backup)

NOTE

During a power failure the heater is turned off. This means that a low temperature alarm will occur within a minute after the power failure.

NOTE

If a Power Failure occurs during a Chemical Disinfection program, switch the machine OFF after 3 minutes.

NOTE

If the power failure lasts less than 5 minutes, once the supply mains returns:
- The “No Power - Using Battery Backup” alarm message disappears;
- The interrupted process automatically restarts and no operator intervention is required.

In case of a power failure, depending on the machine operating conditions, proceed as follows:

1. In Rinse or Disinfection: an alarm is triggered and the current process is stopped. After 5 minutes, the machine automatically switches OFF.

2. In Dialysis, during the HD-DN Treatment: press the “Stop Treatment” button, perform a Rinseback to return the blood and disconnect the patient; then switch the machine OFF.

3. In Dialysis, during the HDF Post Treatment: switch to HD-DN Treatment: using the “Special Procedures” button and then perform a rinseback. When the rinseback has been completed, disconnect the patient and switch the machine OFF.

NOTE

If a Power Failure occurs during a HDF Post Treatment and the machine is in On-line Rinseback mode, it is not possible to complete the Rinseback procedure.
In this case:
- Perform a "Switch off OnLine" special procedure;
- Perform a rinseback procedure as described in the "4.5 Rinseback mode" section of this Operator's Manual.

A message is also displayed in the Operator Message Area suggesting the proper action to be performed during each specific machine operating condition.

NOTE

In Rinse or Disinfection, if the "No Power - Using Battery Backup" alarm is displayed for more than 5 minutes, the machine will be automatically switched OFF. A continous audible signal, decreasing in tone, sounds for approximately 5 seconds once the machine is switched OFF.

NOTE

If the machine is switched OFF and bicarbonate dialysis fluid remains in the hydraulic circuit for more than 30 minutes, it is recommended that a rinse should be performed when the machine is switched back ON.

NOTE

Each time a power failure occurs, the Battery loses a quantity of its power and it has to be recharged by leaving the machine switched ON and connected to the supply mains.
The Battery Backup will be fully recharged at least after 12 hours from the previous power failure.

NOTE

When the machine remains switched OFF, the Battery gradually loses its charge.
After a long storage (at ambient temperature), before using again the machine, it is recommended to keep it switched ON for a minimum time of 2 hours for each month it has been left switched OFF.
If the storage temperature is greater than 25°C, the time necessary to recharge the Battery doubles.

NOTE

When the machine remains switched ON but not connected to the mains supply, the Battery gradually loses its charge.
Pay attention to unintentional disconnection of the machine from the mains supply when the machine is in a Display OFF mode because during this state the disconnection is not indicated by any visible or auditory signal.

NOTE

When a Power Failure occurs with the Battery Backup charged, the Alarm Management System continues working and keeping unchanged the alarm limits set by the operator.

8.1.1 Power Failure with battery not charged

If a Power Failure occurs during a treatment and the battery backup is not charged, the machine enters the “Safe State Activated” mode.

In this case, proceed as follows:

1. Perform a Manual Rinseback procedure;

2. When the power is ON again, switch the machine OFF.

8.2 Manual Rinseback procedure in HD-DN and HDF Post Treatments

In case of a machine malfunction, a power failure or other emergencies (included malfunctions of the automatic pinch clamp) that do not allow the automatic rinseback procedure, it is possible to manually return the blood to the patient, proceeding as follows:

1. Switch the Artis Dialysis System OFF;
2. Clamp the Venous Patient line under the Venous Line Clamp;
3. Clamp the Arterial Patient line and the patient's arterial access;
4. Hang a saline bag to the Infusion pole;
5. Disconnect the Arterial Patient line from the patient's arterial access (or from the Rinseback Service Line if in Online Rinseback mode). Return the blood to the patient according to the facility protocol;
6. Connect the Arterial Patient line to the saline bag;
7. Carefully remove the Venous Patient line from the Venous Line Clamp by pushing the push button down and moving the Venous Patient line to the left;
8. Carefully remove the Arterial Patient line from the Arterial Line Clamp by pushing the push button down and moving the Arterial Patient line to the left;
9. Open the Arterial Pump Cover and extract the crank of the Arterial Pump rotor;
10. Open the Sensor Bar door and check for any air bubble into the lines;

NOTE

During the manual rinseback procedure, the Alarm Management System is inactive.

11. Unclamp the Venous and Arterial Patient lines;

WARNING

Failure to remove the Arterial and Venous Patient lines from the Arterial and Venous Line Clamps or failure to unclamp the Arterial and Venous Patient lines can result in rupture of blood lines or dialyzer when hand cranking the Arterial Pump.

12. Check that all the cassette clamps are closed, except for the clamp on the line connected to the saline bag.
    If in Online Rinseback mode ensure that also the clamp on the Rinseback Service Line is closed;

13. When ready, slowly turn the Arterial Pump Crank counter-clockwise to return the blood to the patient;

⚠WARNING

While manually returning blood, watch the Venous Patient line for air.
Do not perform air restitution.

14. When the required amount of blood has been returned to the patient, clamp the venous patient line and disconnect it from the patient;

NOTE

To decide when to stop blood restitution, consider that in a HDF Post Treatment blood dilution could start more quickly than in a HD-DN Treatment.

15. Pull up the crank of the Arterial Pump rotor and close the Arterial Pump Cover.

NOTE

During the manual rinseback procedure, in HDF Post Treatment, you might observe red colouring of the ultrafilter due to diffusion effects.

8.3 Manual Rinseback procedure in HD-SN and HD-DNDP Treatments

In case of a machine malfunction, a power failure or other emergencies that do not allow the automatic rinseback procedure, it is possible to manually return the blood to the patient, proceeding as follows:

1. Switch the Artis Dialysis System OFF;
2. Clamp the Venous Patient line under the Venous Line Clamp;
3. Clamp the Arterial Patient line and the patient's arterial access;
4. Hang a saline bag to the Infusion pole;
5. Disconnect the Arterial Patient line from the patient's arterial access. Return the blood to the patient according to the facility protocol;
6. Connect the Arterial Patient line to the saline bag;
7. Carefully remove the Venous Patient line from the Venous Line Clamp by pushing the push button down and moving the Venous Patient line to the left;
8. Carefully remove the Arterial Patient line from the Arterial Line Clamp by pushing the push button down and moving the Arterial Patient line to the left;
9. Open the Venous Pump cover and manually extract the pump segment from the rotor;
10. Open the Arterial Pump Cover and extract the crank of the Arterial Pump rotor;
11. Open the Sensor Bar door and check for any air bubble into the lines;

NOTE

During the manual rinseback procedure, the Alarm Management System is inactive.

12. Unclamp the Venous and Arterial Patient lines;

⚠WARNING

Failure to remove the Arterial and Venous Patient lines from the Arterial and Venous Line Clamps or failure to unclamp the Arterial and Venous Patient lines can result in rupture of blood lines or dialyzer when hand cranking the Arterial Pump.

13. Check that all the cassette clamps are closed, except for the clamp on the line connected to the saline bag;

14. When ready, slowly turn the Arterial Pump Crank counter-clockwise to return the blood to the patient;

⚠WARNING

While manually returning blood, watch the Venous Patient line for air.
Do not perform air restitution.

15. When the required amount of blood has been returned to the patient, clamp the venous patient line and disconnect it from the patient;

16. Pull up the crank of the Arterial Pump rotor and close the Arterial Pump Cover.

8.4 Pause Treatment procedure

It is possible to temporarily disconnect the patient from the machine during the dialysis treatment and recirculate blood inside the circuit.

⚠WARNING

It is the operator's responsibility to decide for how long a period the blood can be recirculated into the circuit.

When starting the dialysis session again, the Artis Dialysis System will resume the treatment from where it was stopped.

8.4.1 Disconnect the Patient

⚠WARNING

During patient connection/disconnection, follow your facility's policies and procedures for managing patient's catheter and Venous and Arterial Patient lines used for hemodialysis.
In particular, if the patient's catheter disconnects from the patient lines or the integrity of the catheter is compromised in any other way, follow your facility's policy for preventing air embolism and infection, including clamping the patient's lines immediately.

To disconnect the patient, follow the next steps:

1. Press the "Special Procedures" button on the *Overview* screen and select the "Pause Treatment" option on the Selectpad;

NOTE

It is not possible to perform a "Pause Treatment" procedure during an Isolated UF process. To perform a "Pause Treatment" procedure it is necessary to previously stop the Isolated UF process.

2. Press the ***CONFIRM*** button on the selectpad: a *Confirm* window opens;

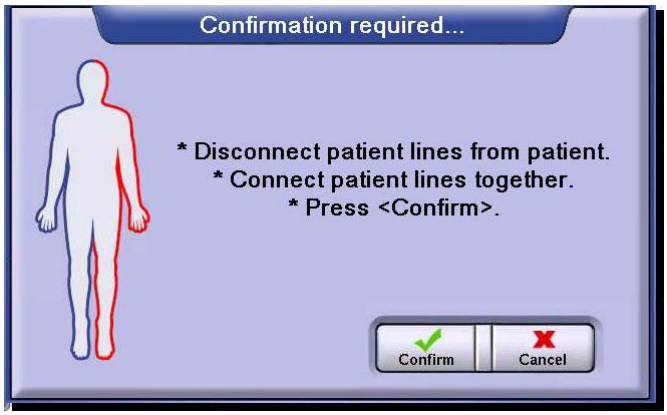


Figure 8-1. Pause Treatment - Disconnect Patient Confirm

NOTE

If in HD-SN Treatment, ***Do Not*** press the ***Cancel*** button on this *Confirm* window. This may lead to an incorrect updating of the "Mean Blood Flow" parameter.
If the ***Cancel*** button is pressed, proceed as follows:
- Select again the "Pause Treatment" option from the "Special Procedures" selectpad and confirm the procedure;
- Simulate a "Pause Treatment" procedure.

- The Arterial Pump automatically stops;
- If performing a HDF Post Treatment, a HD-SN Treatment or a HD-DNDP Treatment, also the Venous Pump stops;
- The following expanded limits are applied to the arterial and venous pressure windows:

Arterial Pressure		**Venous Pressure**	
Upper Limit	+ 150 mmHg	Upper Limit	+ 250 mmHg
Lower Limit	- 400 mmHg	Lower Limit	- 50 mmHg

- If a Linear or Intermittent Heparin delivery program was ongoing during treatment it is interrupted.

3. Clamp the Arterial and Venous Patient lines and the patient's vascular access;
4. Disconnect the patient and connect the Arterial and Venous Patient lines together using a sterile connector;
5. Press the ***CONFIRM*** button;

• The following *Overview* screen is displayed:

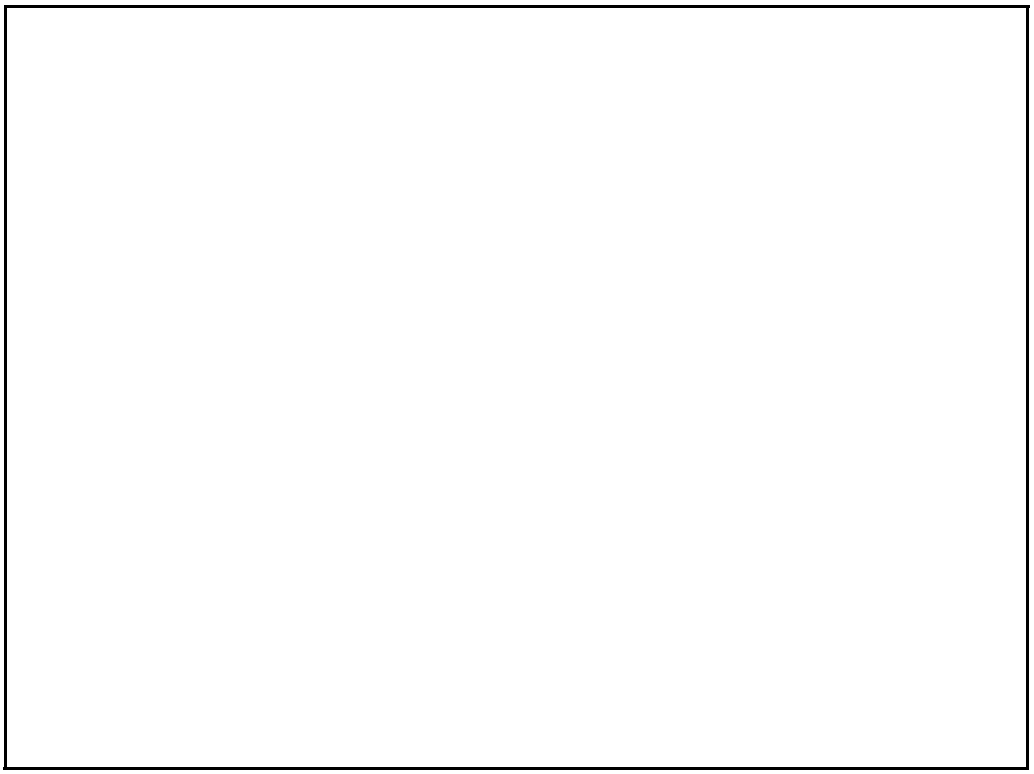


Figure 8-2. Pause Treatment - Patient Disconnected

• The updating of "Real TX Time" parameter is interrupted;

• The updating of the "Remaining Time" value is interrupted;

• The UF Rate is set to zero.

8.4.2 Recirculate Blood

To start the recirculation process, after the patient has been disconnected, proceed as follows:

1. Unclamp the Arterial and Venous Patient lines;
2. Press the blood pump ON/OFF key on the Hard Key panel to start the recirculation process:

   • The Arterial pump starts at a 100 ml/min blood flow.
   In HD-DNDP, the Venous Pump starts too;

   • The blood flow Increase/Decrease keys are disabled.

NOTE

If the recirculation phase lasts more than 5 minutes, the “Reminder - Still In Pause Therapy (#329)” alarm will be triggered. Refer to the “ Chapter 16: Alarms, Information Signals and Troubleshooting” of this Operator’s Manual for further explanation on this alarm.

• The following *Overview* screen is displayed:

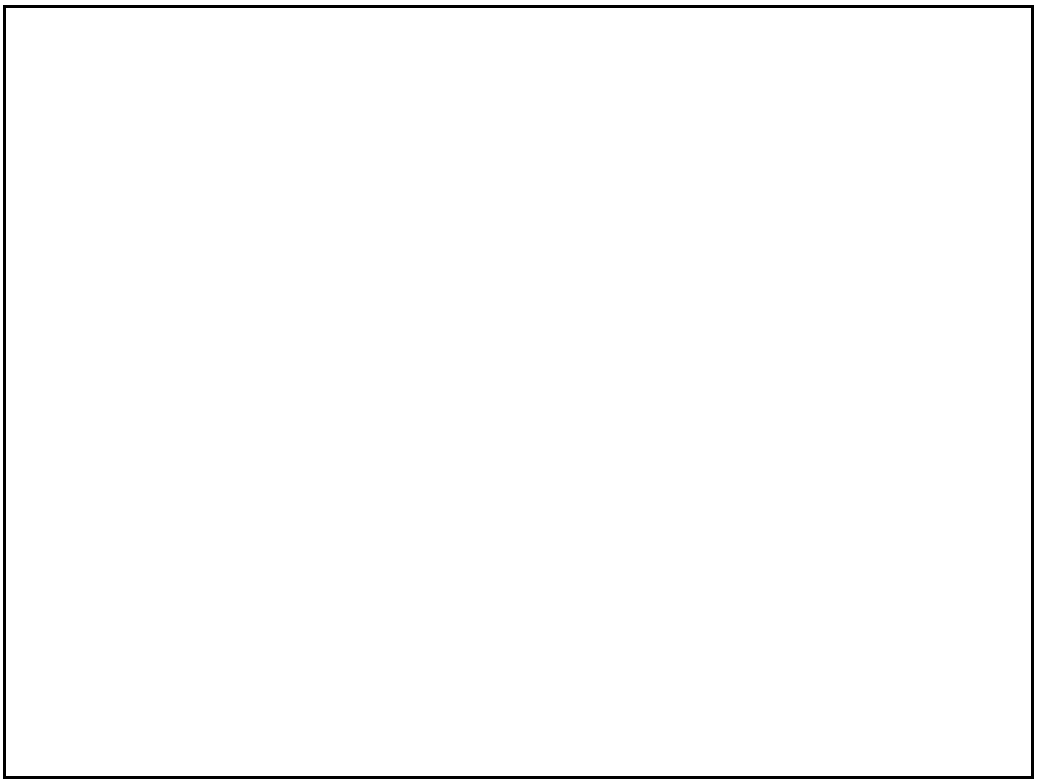


Figure 8-3. Pause Treatment - Recirculation

8.4.3 Reconnect the Patient

⚠WARNING

During patient connection/disconnection, follow your facility’s policies and procedures for managing patient’s catheter and Venous and Arterial Patient lines used for hemodialysis.
In particular, if the patient’s catheter disconnects from the patient lines or the integrity of the catheter is compromised in any other way, follow your facility’s policy for preventing air embolism and infection, including clamping the patient’s lines immediately.

When ready to reconnect the patient to the machine, proceed as follows:

1. Press the "Reconnect Patient" button:

   • The Arterial Pump automatically stops;

   • The following *Confirm* window is displayed:

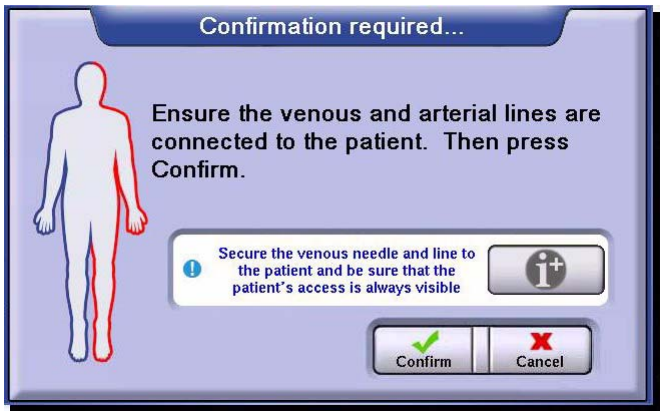
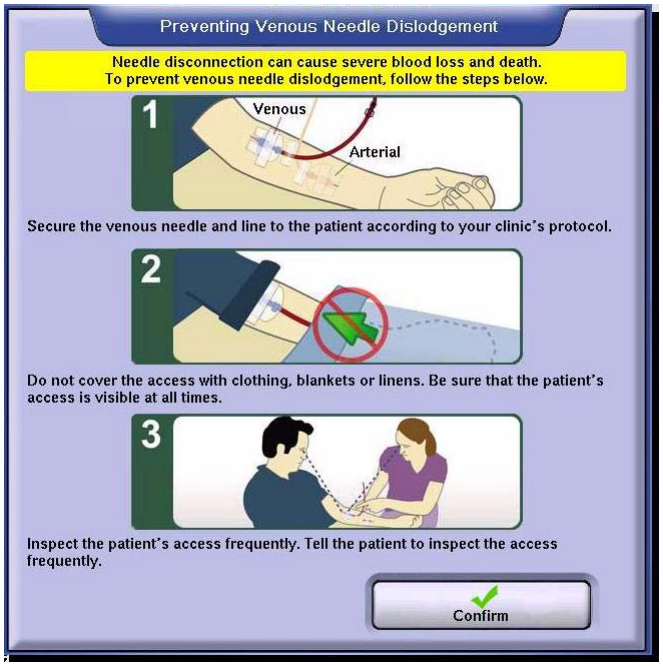


Figure 8-4. Pause Treatment - Reconnect Patient Confirm

Pressing the "i+" button the following window is displayed:



Press the ***CONFIRM*** button to close the window and to come back to the patient connection *Confirm* window;

2. Clamp the Arterial and Venous Patient lines;

3. Remove the connector from the patient lines and discard it;

4. Connect the Arterial and Venous Patient lines to the patient's vascular access;

5. Unclamp the Arterial and Venous Patient lines and the patient's vascular access;

6. Press the ***CONFIRM*** button: the blood pump ON/OFF and the blood flow Increase/Decrease keys are enabled.

7. As required by the operator message, press the blood pump ON/OFF key:

   • The Arterial pump starts at 100 mL/min;

   • If performing a HDF Post Treatment, a HD-SN Treatment or a HD-DNDP Treatment, also the Venous Pump starts;

   • The A/V pressure alarm limits are set to the previous treatment limits;

   • The "Resume Treatment" button becomes available on the *Overview* screen.

8. Adjust the pump speed;

NOTE

If the Arterial or Venous Flow values have been changed in the Blood Settings sub-screen, press once the blood flow increase key and then once the blood flow decrease key, before pressing the "Start Treatment" or the "Resume Treatment" button.
Otherwise, a malfunction will be triggered.

9. Press the "Resume Treatment" button:

   • The treatment is automatically resumed;

   • The updating of "Real TX Time" parameter restarts;

   • The updating of the "Remaining Time" value restarts;

   • If heparin delivery, Diascan, Hemoscan or Hemocontrol functions were activated before the Pause Treatment procedure they are resumed with the previous parameters.

   • If a manual Ultra Scan function was activated before the Pause Treatment procedure, an Information Message (New Ultra Scan is suggested *#545*) is displayed.

   • If an automatic Ultra Scan function was activated before the Pause Treatment procedure, it is suspended during the procedure and is activated again 3 minutes after the "Resume Treatment" button has been pressed.

10. Press the "Close A/V Limits" button as soon as the arterial and venous pressures are stable.

8.5 Fast Recovery

During a dialysis treatment certain conditions may cause the machine to halt:

- A "Safe State Activated" alarm condition (refer to the " Chapter 16: Alarms, Information Signals and Troubleshooting" of this Operator's Manual);
- A problem with the Power Supply which reduces the voltage to the machine's electronics;
- A "Malfunction" occurs.

In both cases, it is impossible to continue the dialysis treatment and the machine must be turned OFF.

If the machine halt was caused by a temporary malfunction or by unexpected operations, turning the machine OFF and then back ON may clear the incorrect condition.

⚠WARNING

Wait at least 5 seconds after switching OFF the machine before turning it ON again.

⚠WARNING

The use of a Fast Recovery procedure must be limited to exceptional cases where the normal recovery procedure can not be performed in accordance with the standard use of the machine, but where the current dialysis treatment must be continued.

⚠WARNING

The Fast Recovery procedure can only be performed if the dialysis treatment has already started, after the confirmation of the Patient Connection, and has been interrupted before the emptying procedure.

NOTE

It is the responsibility of the user to verify that the proper concentrates are used for the patient. This includes the choice of Acid Concentrate as well as Bicarbonate Concentrate. The checks on acid/bicarbonate concentrate conductivity, temperature, pH (if available) and PA/PB pump speed are disabled during a Fast Recovery procedure, in order to prevent the occurrence of the related alarms for about 3 minutes.
If during these 3 minutes the “Stop Treatment” button is pressed, the checks on acid/bicarbonate concentrate conductivity, temperature, pH (if available) and PA/PB pump speed are enabled again.

NOTE

After a Fast Recovery procedure, it is no more possible to activate an Isolated UF process.

To perform a Fast Recovery procedure, proceed as follows:

1. ***DO NOT*** open the Arterial Pump Cover;
2. ***DO NOT*** open the Sensor Bar door;
3. Clamp the venous patient line below the automatic venous clamp;
4. Switch the Artis Dialysis System OFF;
5. Switch the machine ON again: the following *Confirm* window will open asking the operator to confirm the Fast Recovery procedure:

WARNING

Wait at least 5 seconds after switching OFF the machine before turning it ON again.

Figure 8-5. Fast Recovery - Confirm Procedure

6. Press the ***CONFIRM*** button to start the recovery procedure.

• The following *Confirm* window opens:

Figure 8-6. Fast Recovery - Confirm Prescription

7. Check the prescription parameters;

8. Press the ***CONFIRM*** button:

• The Confirm Prescription window closes

NOTE

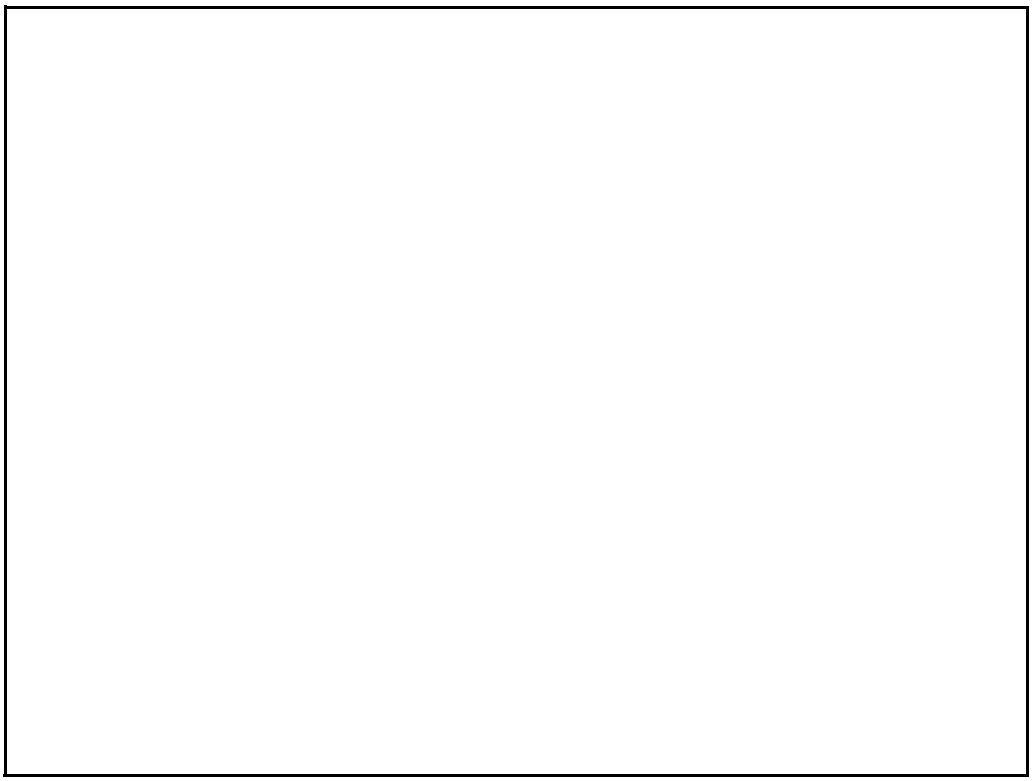
If in HD-SNSP Treatment, proceed as described in the "8.19.3 Connect the SNSP Conversion kit" section of this chapter.

NOTE

During a HDF Post Treatment, if performing a "Fast Recovery" procedure and then a "Skip Treatment" special procedure, after the Rinseback button has been pressed the Arterial and Venous Pumps will not start until the dialysis fluid conductivity is correct. In this case, since no alarm will be triggered by the machine, it is necessary to proceed as follows:

1. Perform a "Switch off OnLine" special procedure;
2. Continue performing the Rinseback procedure in HD-DN Treatment.

• The following screen opens:



9. Verify that the Arterial and Venous Patient lines are both connected to the patient;
10. Check for air in the Venous Patient line:
11. If no air is present, unclamp the Venous Patient line.
12. Press the blood pump ON/OFF key to start the Arterial pump:

NOTE

Following a Fast Recovery procedure, if the Arterial pump does not start when the blood pump On/Off key is pressed, perform a Manual Rinseback procedure.

• The Arterial pump starts

13. Adjust the Arterial Pump speed;

NOTE

If the Arterial or Venous Flow values have been changed in the Blood Settings sub-screen, press once the blood flow increase key and then once the blood flow decrease key, before pressing the “Start Treatment” or the “Resume Treatment” button.
Otherwise, a malfunction will be triggered.

NOTE

During the Fast Recovery procedure it is not possible to use a Patient Card to load the patient prescription.
If a Patient Card is placed near the Card Reader during a Fast Recovery procedure:
• The Prescription Review window will be displayed;
• Press the "Discard" button on the Prescription Review window.

14. Press the "Start Treatment" button to start the treatment:
    - The machine starts its internal checks;
    - The "UF" button becomes available and its action indicator is yellow;
    - The "Dialysis Fluid" button becomes available and its action indicator is yellow;
    - If performing a HDF Post Treatment, the "HDF Substitution" button becomes available and its action indicator is yellow;
    - When the machine completes its internal checks, the ultrafiltration process starts and the "UF" and "Dialysis Fluid" button indicators switch to green. In HDF Post Treatment, also the "HDF Substitution" button switches to green.
15. Press the "Close A/V Limits" as soon as the arterial and venous pressures are stable.
16. Check the blood levels in the Arterial and Venous Chambers.
    For further details, refer to the "8.28 Adjust Arterial/Venous chamber levels" section of this Operator's Manual.

NOTE

Blood levels too low in the Arterial or Venous Chambers may cause air to enter the dialyzer thus resulting in dialysis efficacy reduction and/or "Air in Venous Line (#4)" alarm occurrence.

17. In Pressure Control mode, press the "UC Scan" if a manual UltraControl scan is required or press "UC Auto Scan" buttons if automatic UltraControl scans are required.

⚠WARNING

If after a Fast Recovery procedure, the same problem reoccurs during the restarted dialysis treatment, the cause is not a temporary malfunction. In this case, the Artis Dialysis System must be turned Off and the patient manually disconnected.
Call for a service technician.

8.6 Change BiCart Cartridge

When the BiCart Cartridge is empty or needs to be changed, an alarm is triggered (BiCart cartridge empty *#21*). In this case perform the procedure described below.

8.6.1 Change Concentrate Disposable

To change an empty concentrate disposable, proceed as follows:

1. Press the “Special Procedures” button on the *Overview* screen;
2. Select the “Change BiCart” option on the selectpad and press the ***CONFIRM*** button to confirm the procedure;
   - The following window opens:

Figure 8-7. Change BiCart Cartridge procedure

3. Open the upper arm of the BiCart Cartridge holder;
4. Remove the BiCart Cartridge;
5. Install the new BiCart Cartridge;
6. Press down firmly on the upper arm of the BiCart Cartridge holder;
7. Press the ***CONFIRM*** button on the *Confirm* window:
   - The BiCart Cartridge priming process automatically starts;

• The *Confirm* window changes as follows:

• Dialysis fluid preparation is resumed;

• The alarm is automatically cleared.

8. Press the ***CLOSE*** button to close the window.

⚠WARNING

Before installing and using a BiCart Cartridge:
• Follow the Instructions for Use
• Check that the cartridge is undamaged
• Check for the expiration date on the BiCart Cartridge label
For the storage temperature refer to the Instructions for Use of BiCart Cartridge.

⚠WARNING

Use ONLY BiCart Cartridges new or that have not been drained.

NOTE

During a concentrate change procedure, when the "Change of concentrate in progress" message is displayed in the Message Area, it is not possible to start another concentrate change procedure.

NOTE

It is the responsibility of the user to verify that the proper concentrates are used for the patient. This includes the choice of Acid Concentrate as well as Bicarbonate Concentrate. The checks on acid/bicarbonate concentrate conductivity, temperature, pH (if available) and PA/PB pump speed are disabled during a BiCart Change procedure, in order to prevent the occurrence of the related alarms for about 6 minutes.

8.7 Change Acid

The "Change Acid" option is available in the Special Procedure selectpad from the machine start-up phase until the "Disconnect Patient" button is pressed and confirmed.

NOTE

Replace an empty acid container or bag only following the Change Acid special procedure described in this section.

⚠WARNING

When installing the acid container, be careful to avoid that the concentrate splashes into your eyes.
Acid concentrate may cause chemical injury if comes in contact with eyes.

To perform a Change Acid procedure, proceed as follows:

1. Press the "Special Procedures" button on the *Overview* screen: a selectpad opens;

2. Select the "Change Acid" option and press the ***CONFIRM*** button on the selectpad: the following window opens:

Figure 8-8. Change Acid - Step 1

3. Remove the empty acid container/bag ;

4. Connect a new acid container/bag to the Acid pick-up tube connector;

5. Press the ***CONFIRM*** button on the *Confirm* window:

    • The *Confirm* window changes as follows:

Figure 8-9. Change Acid - Step 2

NOTE

If pH supervision is available on your machine, the intermediate step 2 of the procedure will not be present on the window.

6. Check container/bag content ensuring that the correct Acid concentrate has been connected to the machine;

    • If the correct Acid concentrate has been connected to the machine proceed with step 7;

    • If the wrong Acid concentrate has been connected to the machine, follow the “8.7.1 Wrong concentrate solution” procedure

⚠WARNING

If pH supervision is not available on your machine the presence of hypochlorite in the hydraulic circuit can not be detected by the Artis Dialysis System. Ensure that the correct Acid concentrate has been connected to the machine. Using improper fluid in the dialysis fluid circuit may lead to improper dialysis fluid to be delivered to the patient, thus resulting in patient injury or death.

7. Press the ***CONFIRM*** button on the *Confirm* window.

    • The alarm is automatically cleared;

- The machine performs its internal self checks and the dialysis fluid preparation is resumed;

- The *Confirm* window changes as follows:

Figure 8-10. Change Acid - Step 3

8. Ensure that an Acid concentrate with the appropriate formulation has been connected;

9. Press the ***CLOSE*** button to complete the procedure.

NOTE

During a concentrate change procedure, when the "Change of concentrate in progress" message is displayed in the Message Area, it is not possible to start another concentrate change procedure.

8.7.1 Wrong concentrate solution

In case a wrong concentrate solution has been connected to the machine (i.e. connection of a chemical disinfectant rather than an Acid concentrate), proceed as follows:

1. Disconnect the Acid pick-up tube connector from the wand inserted in the wrong concentrate container/bag;

2. Connect the Acid pick-up tube connector to a new wand. DO NOT reuse the same wand;

3. Insert the new wand in the correct Acid concentrate container/bag;

4. Proceed with the procedure.

8.8 Change SelectBag container

When the SelectBag container is empty or needs to be changed, an alarm is triggered (SelectBag empty *#293*). In this case perform the procedure described below.

8.8.1 Change Concentrate Disposable

To change an empty concentrate disposable, proceed as follows:

1. Press the “Special Procedures” button on the *Overview* screen;
2. Select the “Change SelectBag” option on the selectpad and press the ***CONFIRM*** button to confirm the procedure;
   - The following window opens:

Figure 8-11. Change SelectBag procedure

3. Open the upper arm of the SelectBag holder;
4. Remove the SelectBag container from its holder;
5. Install a new SelectBag container;
6. Press down the SelectBag holder arm;
7. Press the ***CONFIRM*** button on the *Confirm* window:

8. The confirm window changes as follows:

- Dialysis fluid preparation is resumed;

9. Ensure that the correct SelectBag has been set.

10. The alarm is automatically cleared.

11. Press the ***CLOSE*** button to close the po-up window.

⚠WARNING

Use ONLY SelectBag new.

⚠WARNING

When installing the SelectBag container, avoid touching the plastic spike of the machine.

⚠WARNING

When installing the SelectBag container, be careful to avoid fluid from the SelectBag product splashing into your eyes.
Acid concentrate may cause chemical injury if comes in contact with eyes.

NOTE

Before installing and using a SelectBag container, follow the Instructions for Use of the SelectBag container.

NOTE

During a concentrate change procedure, when the “Change of concentrate in progress” message is displayed in the Message Area, it is not possible to start another concentrate change procedure.

NOTE

It is the responsibility of the user to verify that the proper concentrates are used for the patient. This includes the choice of Acid Concentrate as well as Bicarbonate Concentrate. The checks on acid/bicarbonate concentrate conductivity, temperature, pH (if available) and PA/PB pump speed are disabled during a Change SelectBag procedure, in order to prevent the occurrence of the related alarms for about 6 minutes.

8.9 Change SelectCart Cartridge

When the SelectCart Cartridge is empty or needs to be changed, an alarm is triggered (SelectCart cartridge Empty *#596*). In this case perform the procedure described below.

8.9.1 Change Concentrate Disposable

To change an empty concentrate disposable, proceed as follows:

1. Press the "Special Procedures" button on the *Overview* screen;
2. Select the "Change SelectCart" option on the selectpad and press the ***CONFIRM*** button to confirm the procedure;
    - The following window opens:

Figure 8-12. Change SelectCart Cartridge procedure

3. Open the upper arm of the SelectCart Cartridge holder;
4. Remove the SelectCart Cartridge from its holder;
5. Install a new concentrate cartridge;
6. Press down firmly on the upper arm of the SelectCart Cartridge holder;
7. Press the ***CONFIRM*** button on the *Confirm* window:
    - The SelectCart Cartridge priming process automatically starts;
    - The *Confirm* window changes as follows:

- Dialysis fluid preparation is resumed;

8. The alarm is automatically cleared.

9. Press the ***CLOSE*** button to close the pop-up window.

⚠WARNING

Use ONLY SelectCart Cartridges new.

NOTE

Before installing and using a SelectCart Cartridge, follow the Instructions for Use of the SelectCart Cartridge.

NOTE

During a concentrate change procedure, when the “Change of concentrate in progress” message is displayed in the Message Area, it is not possible to start another concentrate change procedure.

NOTE

It is the responsibility of the user to verify that the proper concentrates are used for the patient. This includes the choice of Acid Concentrate as well as Bicarbonate Concentrate. The checks on acid/bicarbonate concentrate conductivity, temperature, pH (if available) and PA/PB pump speed are disabled during a Change SelectCart Cartridge procedure, in order to prevent the occurrence of the related alarms for about 8 minutes.

8.10 Cassette Repositioning

Under certain conditions, one or both diaphragms of the Blood Cassette may move out of their neutral position, i.e. the position where they naturally fall when are not exposed to pressure. This causes pressure monitoring to become inaccurate and can result in pressure alarms or T1 Test failures.

The Cassette Repositioning procedure restores both diaphragms to their proper position. This procedure may be performed when certain alarms are triggered or if the operator suspects pressure monitoring to be inaccurate.

NOTE

If during a Cassette Repositioning procedure an hardware malfunction occurs so that the Cassette holder is not pushed out, perform a Manual Rinseback procedure.

8.10.1 Restore diaphragms proper position

⚠WARNING

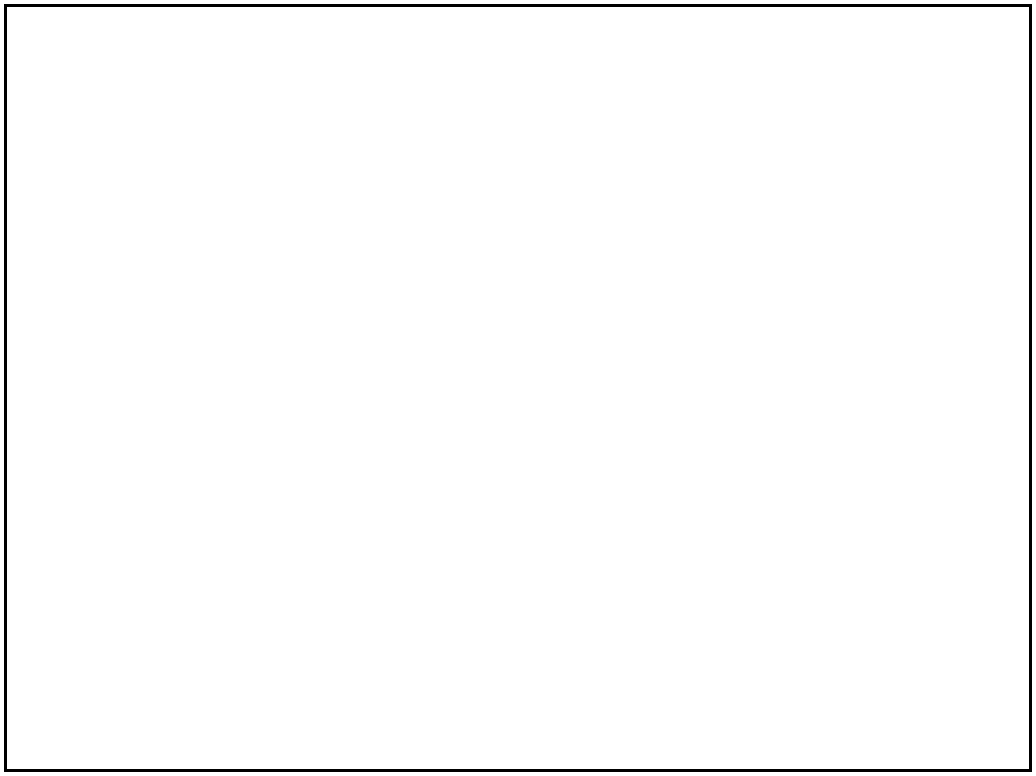
Before performing the Cassette Repositioning procedure, ensure that the arterial and venous chambers are no more than half full of fluid in order to avoid possible patient blood loss.

To restore both diaphragms to their proper position, proceed as follows:

1. Decrease the Arterial Pump speed;

2. Press the "Special Procedures" button on the *Overview* screen, select the "Cassette Repositioning" option from the Selectpad and press the ***CONFIRM*** button on the Selectpad:

   • The following pop-up window is displayed:



3. Press the ***CONFIRM*** button:

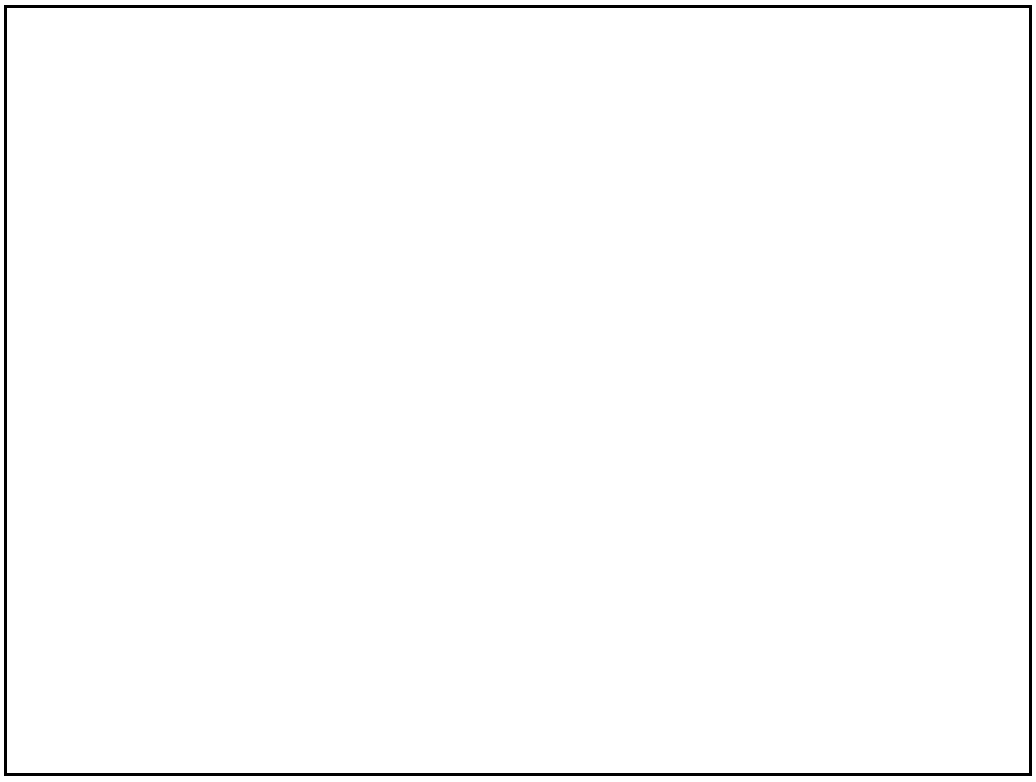
   • The Arterial pump stops;

   • The heparin delivery stops;

   • The automatic arterial and venous line clamps are closed;

   • The machine pushes out the cassette holder;

   • The pop-up window configuration changes as follows:



4. As required by the pop-up window, unscrew the Venous Infusion line and one of the Arterial Infusion line caps;

NOTE

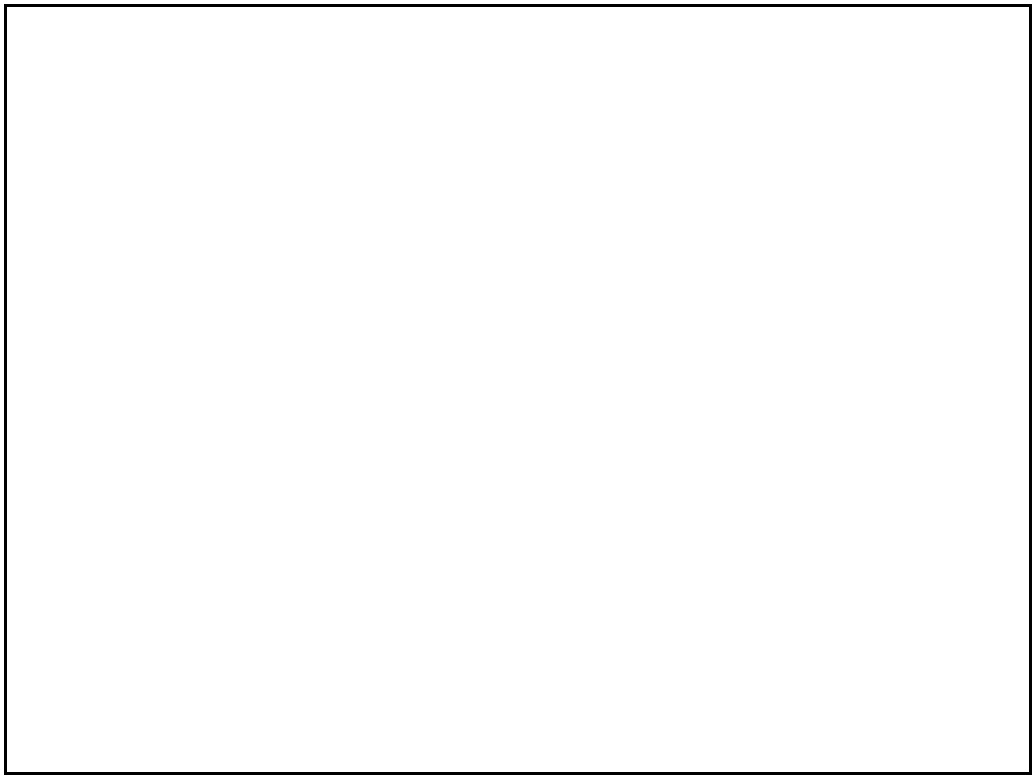
If in HD-SNSP Treatment, clamp the Venous Dialyzer line.

5. Attach a sterile syringe to the Venous Infusion line;

6. Unclamp the Venous Infusion line and the Arterial Infusion line;

7. Press the ***Next*** button;

    •The pop-up window configuration changes as follows:



8. Remove the syringe;

9. After the time indicated in the pop-up window is elapsed, press the ***CONFIRM*** button: the Cassette holder will be withdrawn;

NOTE

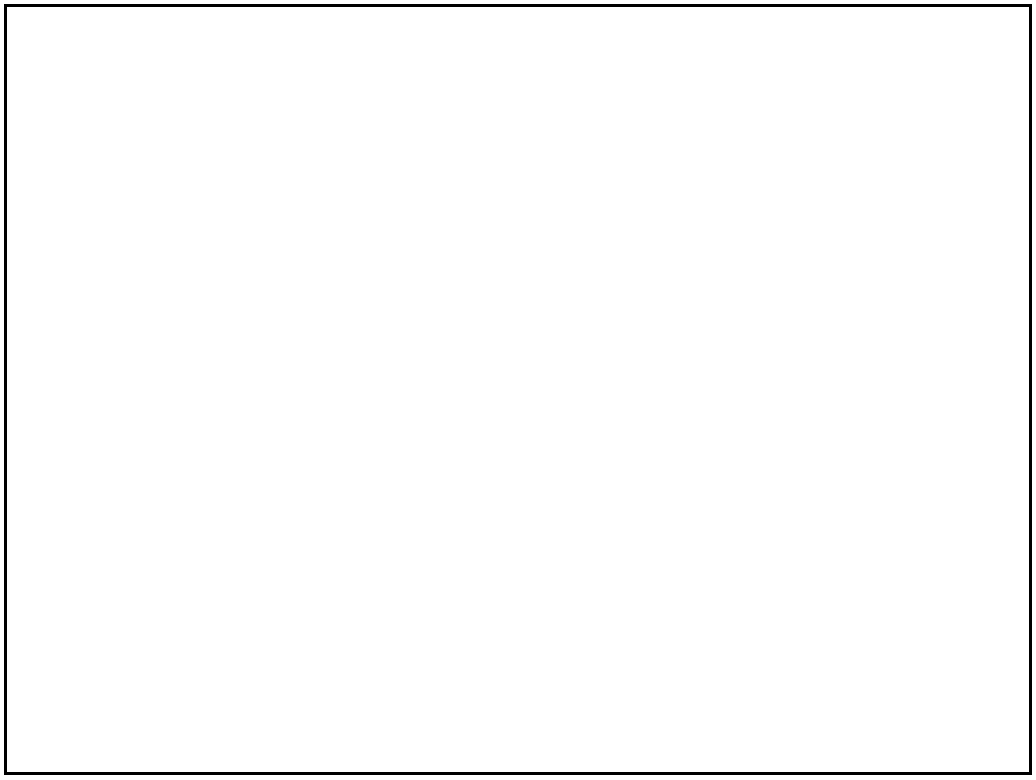
DO NOT activate a new Cassette Repositioning procedure while the machine is withdrawing the Cassette holders.

- The machine performs the pressure checks;

NOTE

If performing a ”Switch to SNSP” Special Procedure the automatic clamps are kept closed until the end of the Cassette Repositioning procedure.

- The heparin delivery program is resumed.
- The pop-up window configuration changes as follows:



10. Clamp the Venous Infusion line and the Arterial infusion line and replace the caps on the lines;
11. Press the ***CLOSE*** button to close the window;
12. Start the Arterial Pump pressing the blood pump ON/OFF key:
    - The automatic arterial and venous line clamps are opened.
13. If necessary, adjust the fluid level in the venous and arterial chambers.

NOTE

If the Cassette Repositioning procedure fails, a *Confirm* window opens requiring to restart the procedure. In this case press the ***CONFIRM*** button on the *Confirm* window:
- The Cassette Repositioning procedure will be automatically restarted.

At the end of the procedure, the machine will perform the following tasks:

1. Performs its internal checks. During this phase the "UF" and "Dialysis Fluid" action indicators are yellow;
2. When ready, resumes the treatment: the "UF" and "Dialysis Fluid" action indicators switch to green;
3. Automatically closes the arterial and venous pressure limits.

8.11 Ultra Cassette Repositioning

Under certain conditions the diaphragm of the Ultra Cassette may move out of its neutral position, i.e. the position where it naturally falls when not exposed to pressure. This causes pre-dialyzer pressure monitoring to become inaccurate and can result in pressure alarms or T1 Test failures.

The Ultra Cassette Repositioning procedure restores the diaphragm to its proper position. This procedure may be performed when certain alarms are triggered or if the operator suspects pre-dialyzer pressure monitoring to be inaccurate.

NOTE

If during an Ultra Cassette Repositioning procedure an hardware malfunction occurs so that the Ultra Cassette holder is not pushed out, perform a Manual Rinseback procedure.

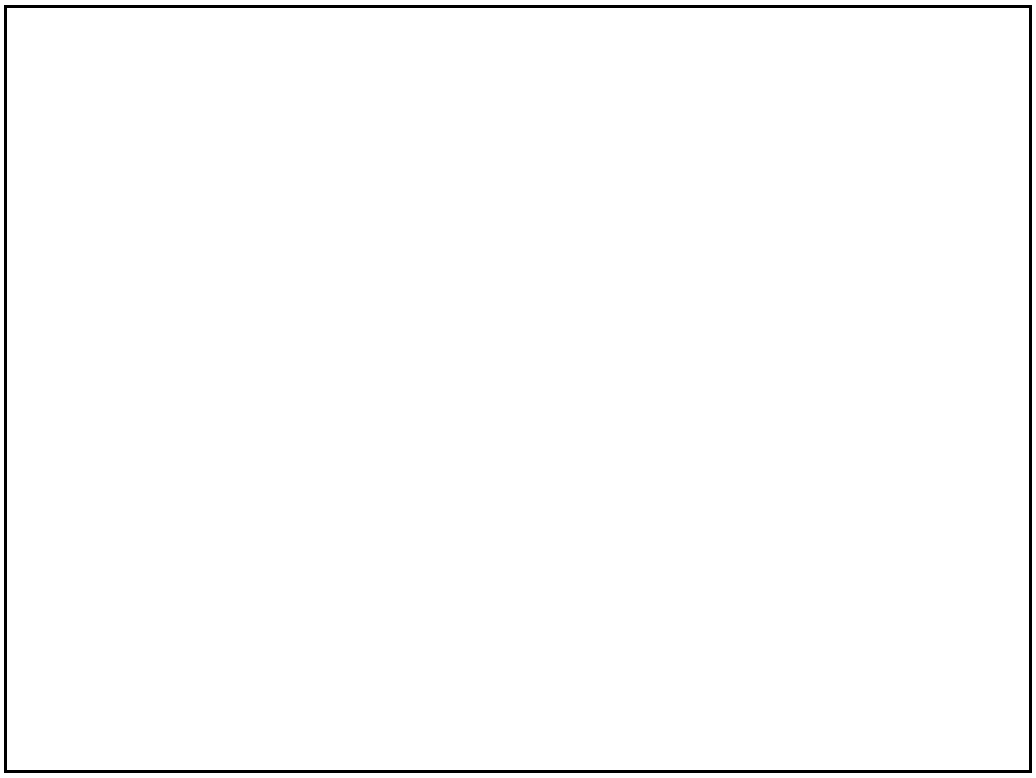
8.11.1 Restore diaphragm proper position

⚠WARNING

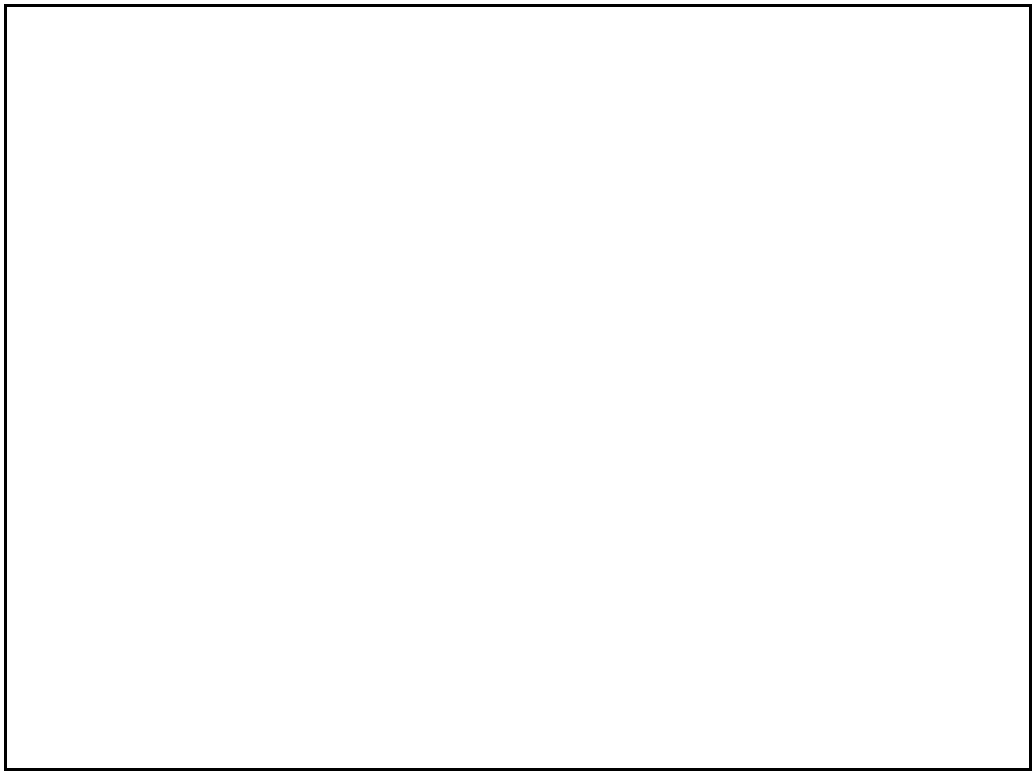
Before performing the Ultra Cassette Repositioning procedure, ensure that the chamber is no more than half full of fluid in order to avoid possible patient blood loss.

To restore the diaphragm to its proper position, proceed as follows:

1. Decrease the Arterial Pump speed;
2. Press the "Special Procedures" button on the *Overview* screen, select the “Ultra Cassette Repositioning” option from the Selectpad and press the ***CONFIRM*** button on the Selectpad:
   - The Arterial and Venous pumps stop;
   - The heparin delivery stops;
   - The following pop-up window is displayed:



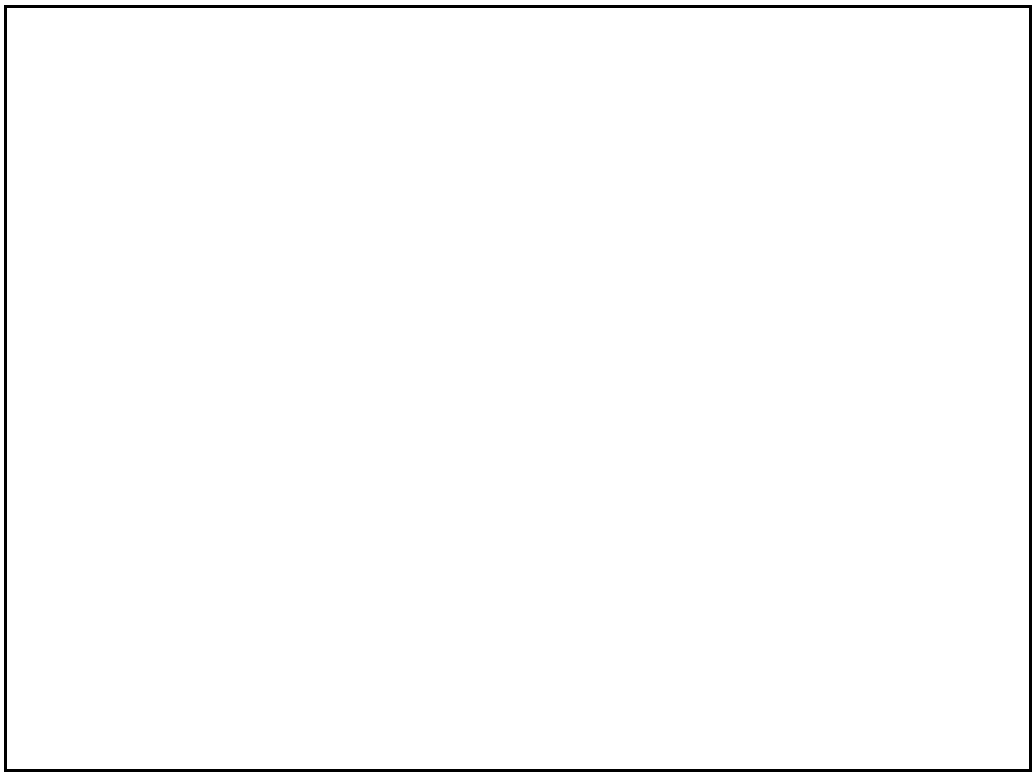
3. As soon as the pressures stabilizes and the pop-up window configuration changes as follows, press the ***CONFIRM*** button:



NOTE

If the “Cassette Repositioning Failed (#557)” alarm is triggered, the Ultra Cassette Repositioning procedure fails. In this case:
• Press the ***CONFIRM*** button to reset the alarm;
• Repeat the Ultra Cassette Repositioning procedure
Refer to “ Chapter 16: Alarms, Information Signals and Troubleshooting” of this Operator’s Manual for further information on this alarm.

- The automatic pinch valve is closed
- The machine pushes out the Ultra Cassette holder;
- The pop-up window configuration changes as follows:



- The Venous Pump rotor is set in horizontal position;
- The automatic pinch valve opens;
- The automatic arterial and venous clamps are closed;

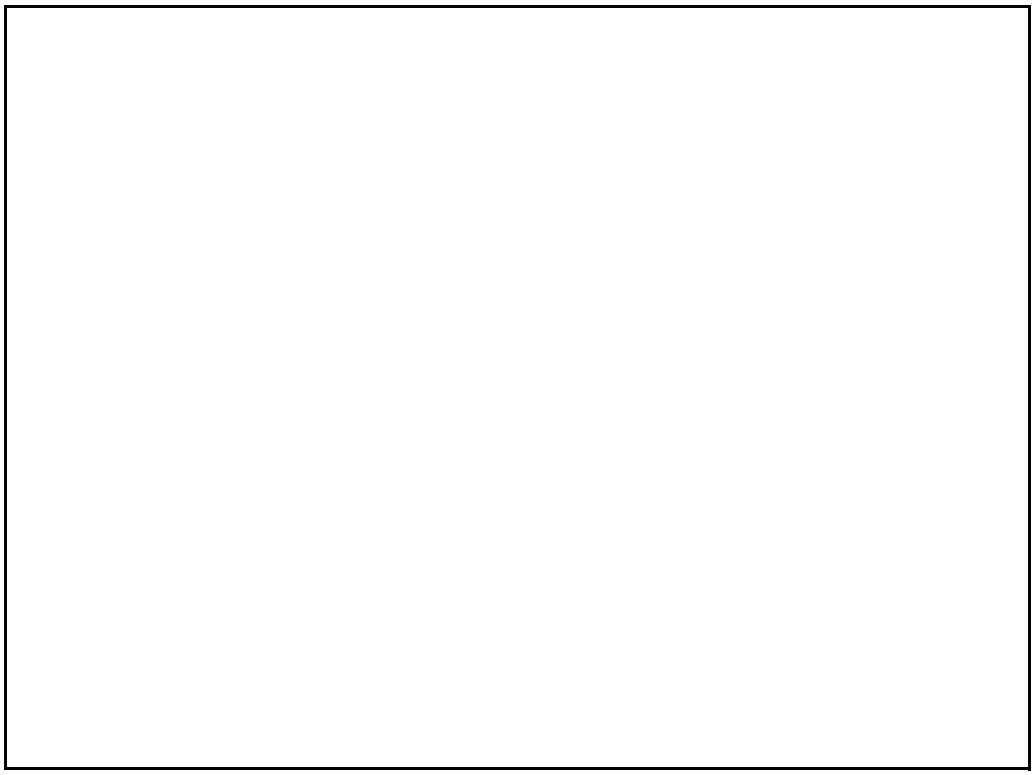
4. As required by the window, unscrew the cap on the Ultra Service line;

5. Attach a sterile syringe to the Ultra Service line;

6. Unclamp the Ultra Service line;

7. Press the ***Next*** button;

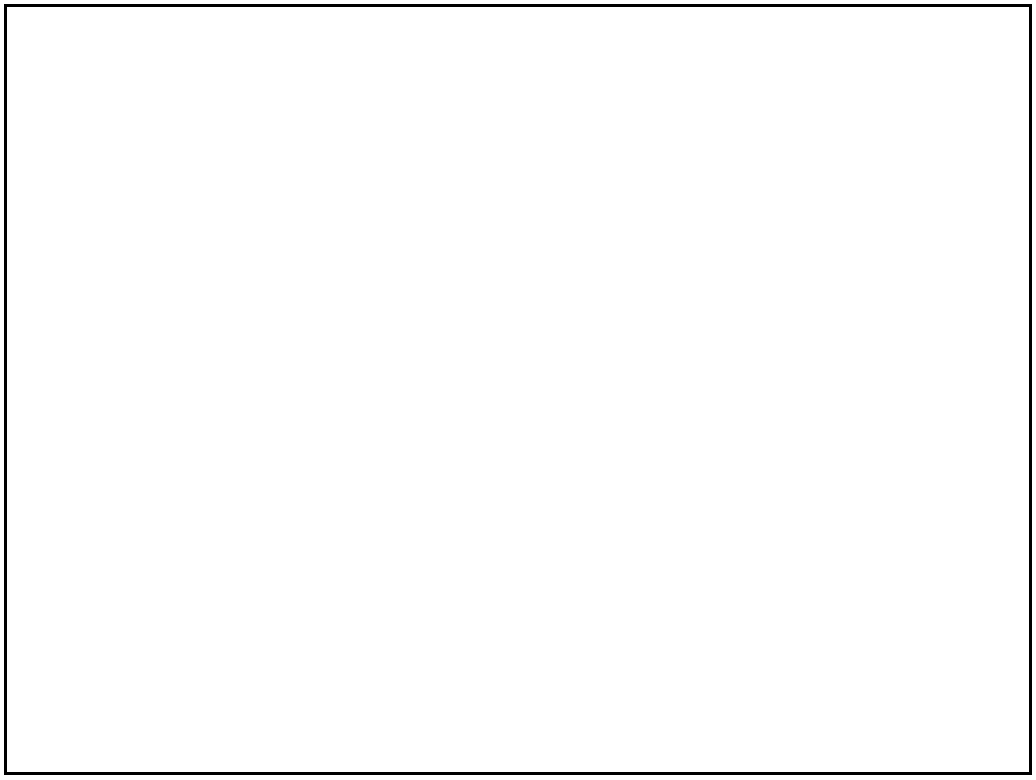
   • The pop-up window changes as follows:



8. Remove the syringe from the Ultra Service line;

9. After the time indicated in the *Confirm* window is elapsed, press the ***CONFIRM*** button: the Ultra Cassette holder will be withdrawn.

• The pop-up window configuration changes as follows;



NOTE

DO NOT activate a new Ultra Cassette Repositioning procedure while the machine is withdrawing the Cassette holders.

10. Clamp the Ultra Service line and replace the cap on the line;

11. Press the ***CLOSE*** button to close the window;

12. Start the Arterial Pump pressing the blood pump ON/OFF key;

    •The machine performs the pressure checks;

    • The automatic arterial and venous clamps are opened;

    • The heparin delivery program is resumed

13. If necessary, adjust the fluid level in the venous and arterial chambers.

NOTE

If the Ultra Cassette Repositioning procedure fails, a *Confirm* window opens requiring to restart the procedure. In this case press the ***CONFIRM*** button on the *Confirm* window:
- The Ultra Cassette Repositioning procedure will be automatically restarted.

At the end of the procedure, the machine will perform the following tasks:

1. Performs its internal checks. During this phase the "UF", "Dialysis Fluid" and "HDF Substitution" action indicators are yellow;

2. When ready, the treatment is resumed: the "UF", "Dialysis Fluid" and "HDF Substitution" action indicators switch to green;

3. Automatically closes the arterial and venous pressure limits.

8.12 SN Cassette Repositioning

Under certain conditions the diaphragm of the SN Cassette may move out of its neutral position, i.e. the position where it naturally falls when not exposed to pressure. This causes post-dialyzer pressure monitoring to become inaccurate and can result in pressure alarms or T1 Test failures.

The SN Cassette Repositioning procedure restores the diaphragm to its proper position. This procedure may be performed when certain alarms are triggered or if the operator suspects post-dialyzer pressure monitoring to be inaccurate.

NOTE

If during a SN Cassette Repositioning procedure an hardware malfunction occurs so that the holder is not pushed out, perform a Manual Rinseback procedure.

⚠WARNING

If the SN Cassette Repositioning procedure is performed during patient connection and before blood is detected by the machine, the Arterial and Venous line clamps are not automatically closed. In this case, proceed as follows:
- Manually clamp the Arterial and Venous lines;
- Perform the SN Cassette Repositioning procedure;
- After the procedure has been successfully completed, unclamp the Arterial and Venous lines.

8.12.1 Restore diaphragm proper position

⚠WARNING

Before performing the SN Cassette Repositioning procedure, ensure that the chamber is no more than half full of fluid in order to avoid possible patient blood loss.

To restore the diaphragm to its proper position, proceed as follows:

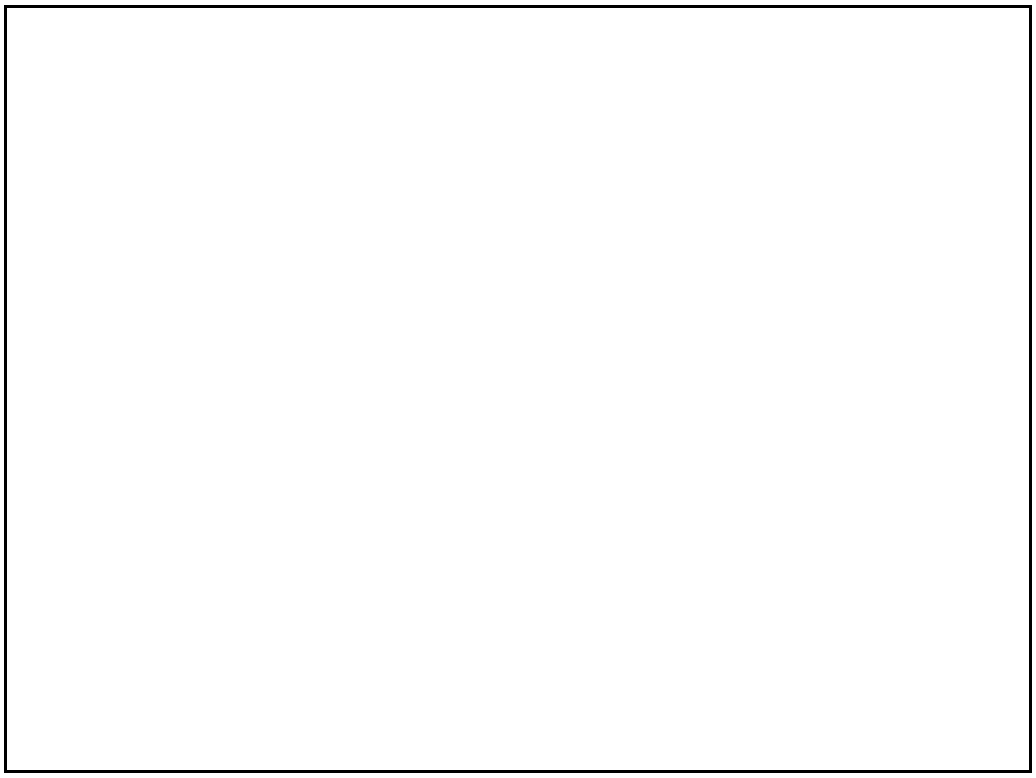
1. Decrease the Arterial Pump speed;

2. Press the "Special Procedures" button on the *Overview* screen, select the “SN Cassette Repositioning” option from the Selectpad and press the ***CONFIRM*** button on the Selectpad:

   - The Arterial or Venous pump stops;

   - The heparin delivery stops;

• The following pop-up window is displayed:

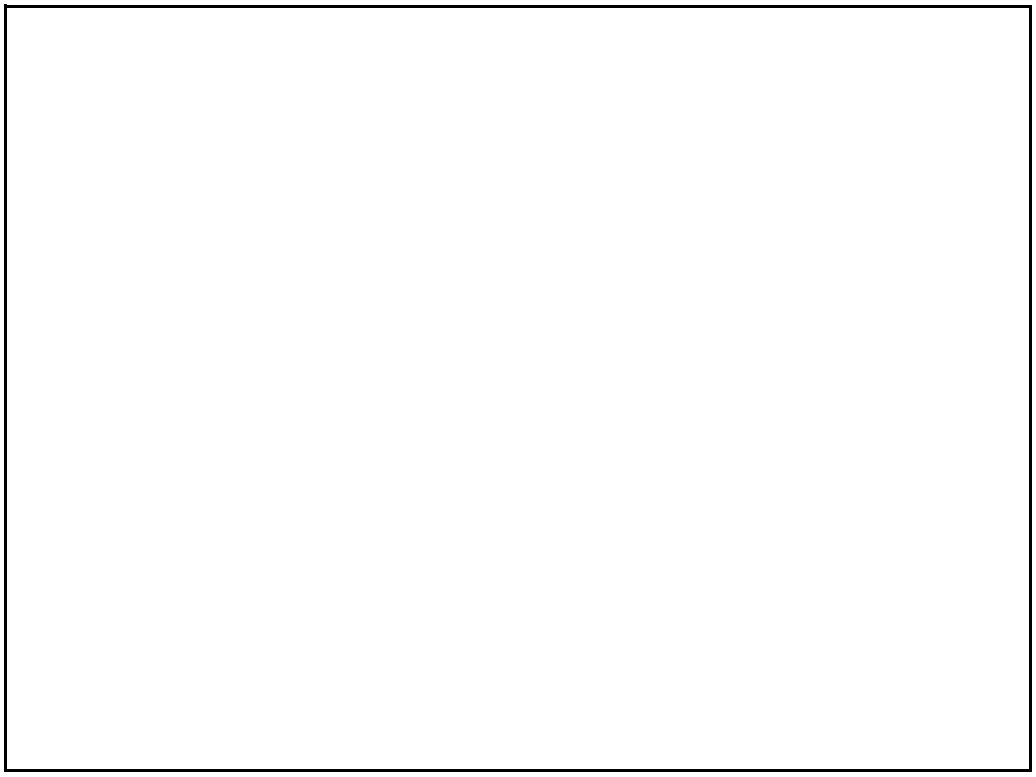


3. Press the ***CONFIRM*** button to complete the Venous phase in progress:

NOTE

If the "Cassette Repositioning Failed (#557)" alarm is triggered, the SN Cassette Repositioning procedure fails. In this case:
• Press the ***CONFIRM*** button to reset the alarm;
• Repeat the SN Cassette Repositioning procedure
Refer to " Chapter 16: Alarms, Information Signals and Troubleshooting" of this Operator's Manual for further information on this alarm.

• The pop-up window configuration changes as follows:



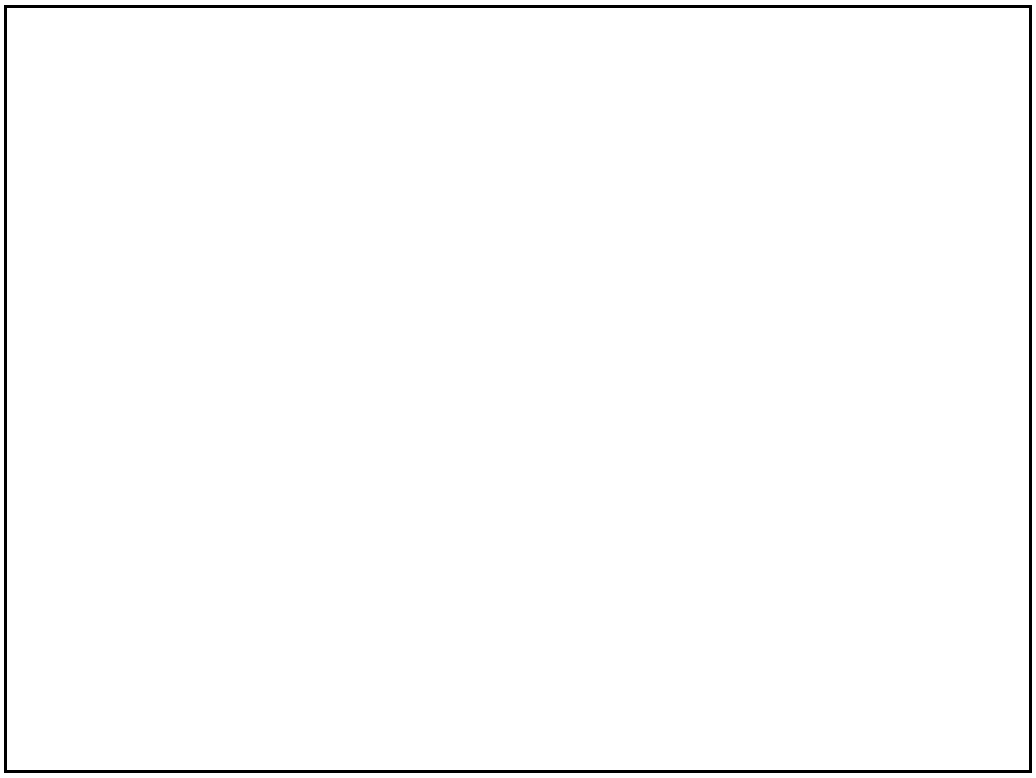
4. Press the ***CONFIRM*** button to start the SN Cassette Repositioning procedure:

   • The automatic pinch valve opens

   • The automatic arterial and venous clamps are closed

   • The machine pushes out the Ultra Cassette holder.

   • The pop-up window configuration changes as follows:



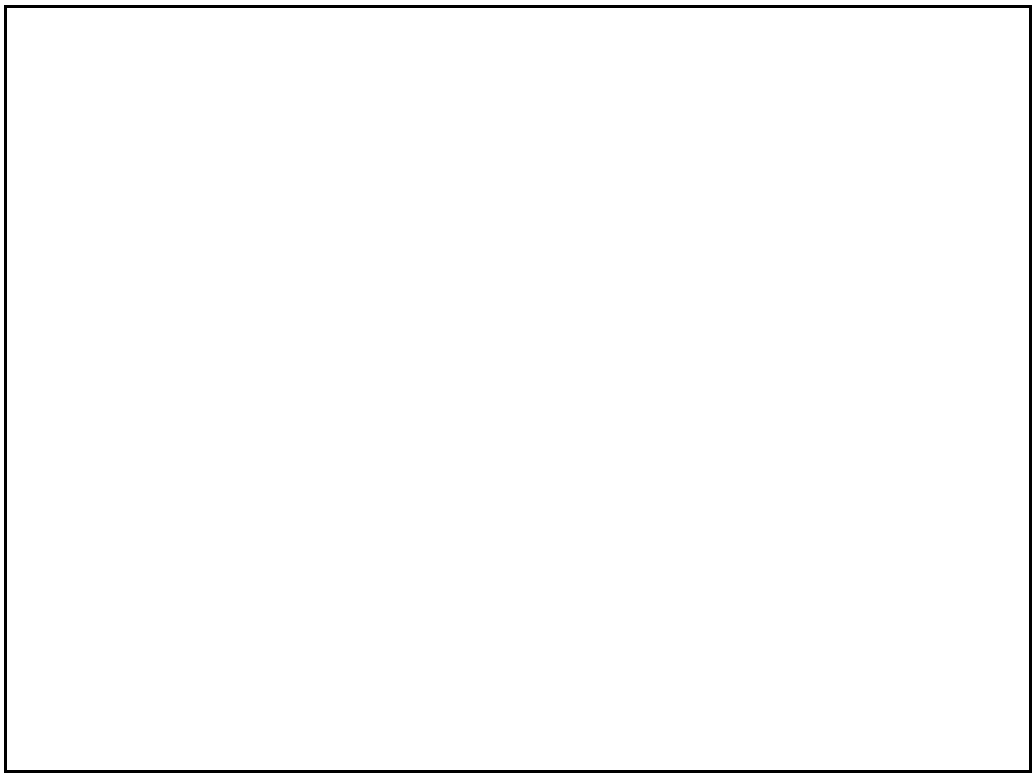
5. Unscrew the cap on the SN Venous Service line;

6. Attach a sterile syringe to the SN Venous Service line;

7. Unclamp the SN Venous Service line;

8. Press the ***Next*** button:

    • The pop-up window configuration changes as follows:



9. Remove the syringe;

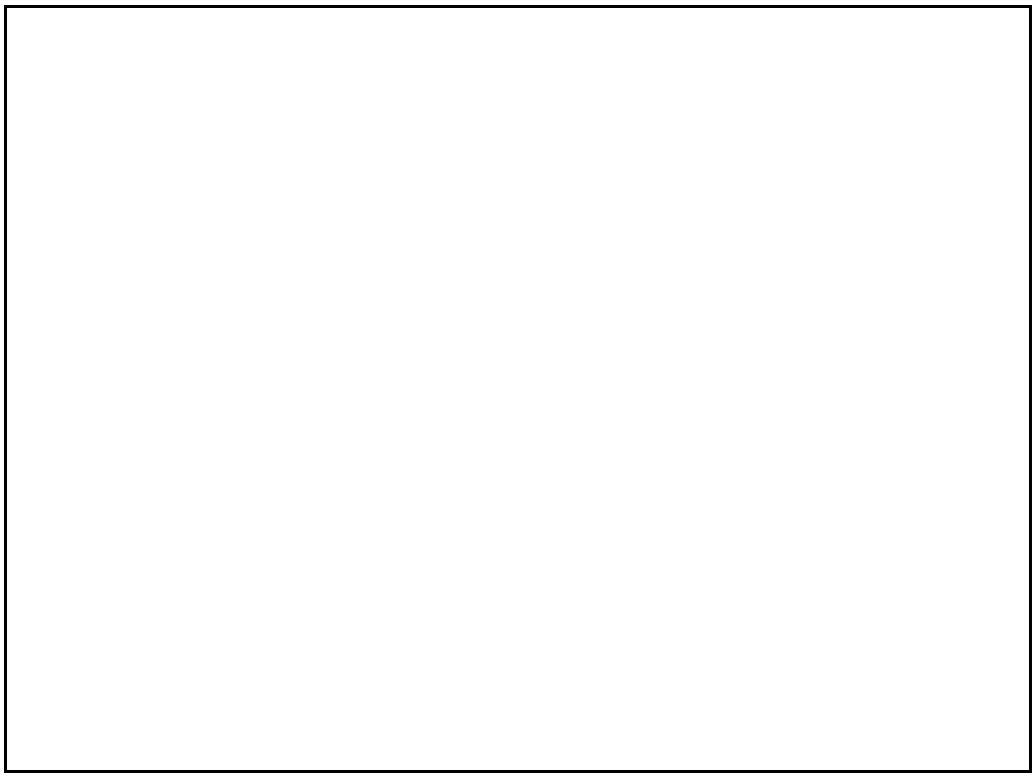
10. After the time indicated in the pop-up window is elapsed, press the ***CONFIRM*** button;

    • The machine quickly withdraw the Ultra Cassette holder;

NOTE

DO NOT activate a new SN Cassette Repositioning procedure while the machine is withdrawing the Cassette holders.

    • The pop-up window configuration changes as follows:



11. Clamp the SN Venous Service line and replace the cap on the line;
12. Press the ***CLOSE*** button to close the pop-up window;
13. Start the Arterial Pump pressing the blood pump ON/OFF key;
    - The machine performs the pressure checks;
    - The automatic arterial and venous clamps are opened;
    - The heparin delivery program is resumed.

NOTE

If the SN Cassette Repositioning procedure fails, a *Confirm* window opens requiring to restart the procedure. In this case press the ***CONFIRM*** button on the *Confirm* window:
- The SN Cassette Repositioning procedure will be automatically restarted.

At the end of the procedure, the machine will perform the following tasks:

1. Performs its internal checks. During this phase the "UF" and "Dialysis Fluid" action indicators are yellow;
2. When ready, the treatment is resumed: the "UF" and "Dialysis Fluid" action indicators switch to green;
3. Automatically closes the arterial and venous pressure limits.

8.13 Change Circuit in HD-DN Treatment

The Change Circuit procedure allows:

- to unload the extracorporeal circuit (Blood Cassette and dialyzer) during the Connect Patient phase or during the treatment
- to change to a HD-SN Treatment, if needed
- to install a new extracorporeal circuit.

The machine will store all the treatment data and resume them when dialysis is restarted.

This procedure can be performed as soon as the “Connect Patient” button is pressed and confirmed and until the “Stop Treatment” button is confirmed.

NOTE

It is not possible to perform a Change Circuit procedure during an Isolated UF process. To perform a Change Circuit procedure it is necessary to previously stop the Isolated UF process.

The Change Circuit procedure is made up of the following phases:

- Rinseback (if needed)
- Disconnect Patient
- Unload Cassette and change dialyzer
- Change to a HD-SN Treatment (if needed)
- Reprime
- Connect the patient

During the Change Circuit procedure in a HD-DN Treatment:

- The heparin delivery program, if active, is automatically paused. The program will be resumed as soon as blood will be detected again but no initial dose will be delivered.

NOTE

Before starting a Change Circuit procedure check that there is a sufficient amount of concentrates to perform the procedure.
The “Special Procedures” button containing the Change Acid and Change BiCart procedures is not available during some phases of the Change Circuit procedure.
If a conductivity alarm is triggered during the Change Circuit procedure due to empty concentrate disposables and the “Special Procedures” button is not available, it is necessary to switch the machine OFF and then ON again to make the “Special Procedures” button available.

8.13.1 Rinseback

⚠WARNING

The Patient Connection and Rinseback modes require additional attention: to facilitate their execution, some safety checkings are temporary deactivated and left to the responsibility of the operator (e.g., the extracorporeal A/V pressure limits are expanded to the maximum).

⚠WARNING

During patient connection/disconnection, follow your facility's policies and procedures for managing patient's catheter and Venous and Arterial Patient lines used for hemodialysis.
In particular, if the patient's catheter disconnects from the patient lines or the integrity of the catheter is compromised in any other way, follow your facility's policy for preventing air embolism and infection, including clamping the patient's lines immediately.

NOTE

It is possible to skip the rinseback phase and proceed with the "Patient disconnection" operation.

To start the Change Circuit procedure, follow the next steps:

1. Press the "Special Procedures" button on the *Overview* screen, select the "Change Circuit" option from the Selectpad and press the ***CONFIRM*** button:

NOTE

If the Hemocontrol function was activated, as soon as the Change Circuit procedure is confirmed, a *Confirm* window opens requiring to confirm the hemocontrol parameters.
In this case, press the ***CONFIRM*** button on the *Confirm* window to proceed with the special procedure: the Hemocontrol function is deactivated.

NOTE

If the Hemoscan or the Diascan function was activated, as soon as the Change Circuit procedure is confirmed:
- the Hemoscan function is automatically deactivated;
- the Diascan function is suspended. It will start again as soon as the treatment is resumed.

• The *Overview* screen has the following configuration:

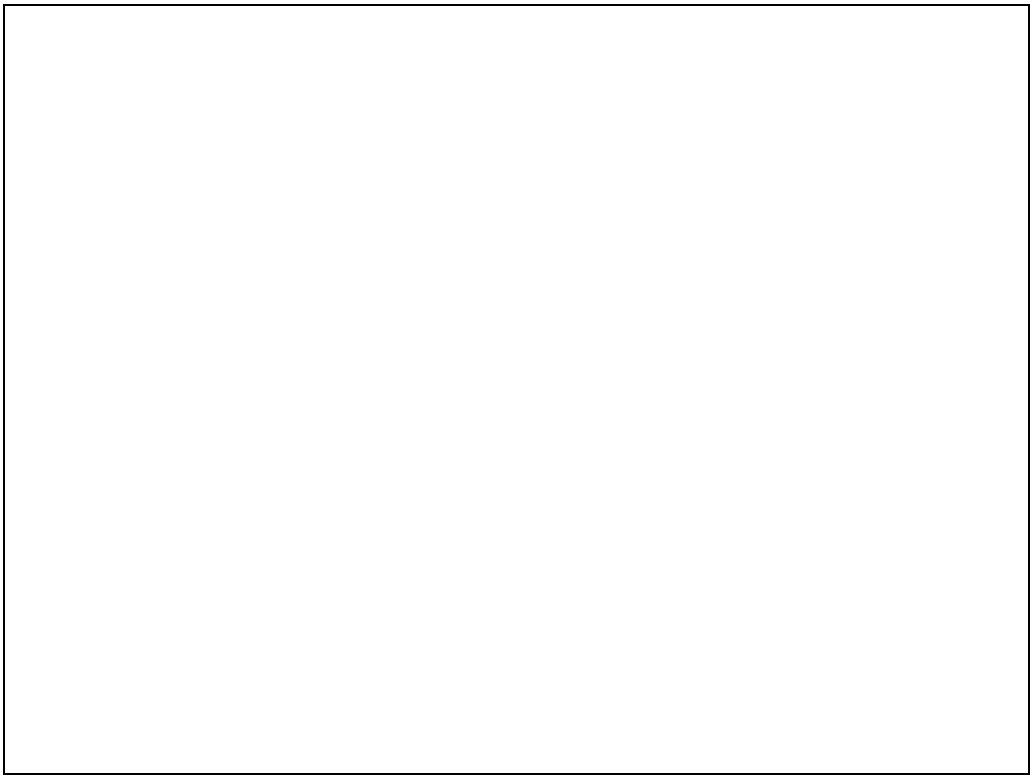


Figure 8-13. Change Circuit - Rinseback

• The Arterial Pump automatically stops;

• All the treatment data are stored in the machine memory.

2. Disconnect the Arterial Patient line from the patient;

3. Connect the Arterial Patient line to a saline bag appropriate for rinseback procedure;

4. Open the clamps on the Arterial Patient line and on the prime line;

5. Press the “Rinseback” Action button:

• A *Confirm* window opens

6. Press the ***CONFIRM*** button on the *Confirm* window:

- The Rinseback procedure starts;
- The "Rinseback" action indicator switches to green.

When the Rinseback volume has been processed, the procedure is completed:

- The Arterial pump automatically stops;
- The "Extra Rinseback" button becomes available.

8.13.2 Patient Disconnection

After the rinseback process has been completed, proceed as follows:

1. Press the "Disconnect Patient" Action button on the *Overview* screen;
2. Disconnect the Venous Patient line from the patient;

⚠WARNING

During patient connection/disconnection, follow your facility's policies and procedures for managing patient's catheter and Venous and Arterial Patient lines used for hemodialysis.
In particular, if the patient's catheter disconnects from the patient lines or the integrity of the catheter is compromised in any other way, follow your facility's policy for preventing air embolism and infection, including clamping the patient's lines immediately.

3. Press the ***CONFIRM*** button on the *Confirm* window:

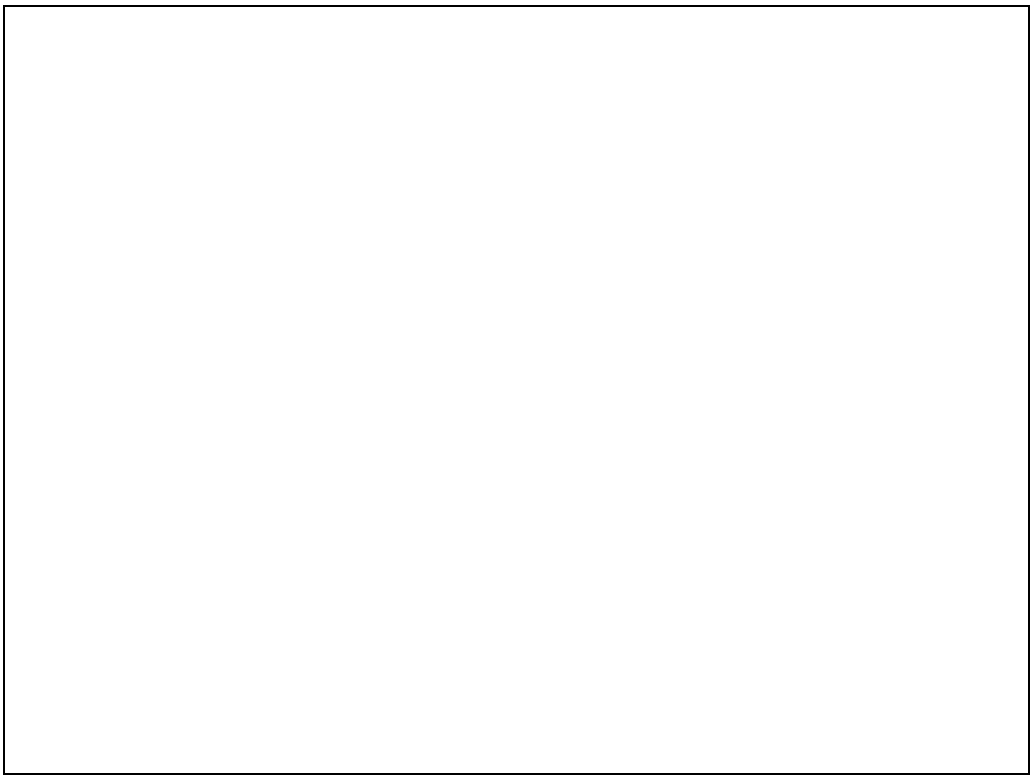


Figure 8-14. Change Circuit - Unload Cassette

8.13.3 Unload Blood Cassette

NOTE

If the hemoscan function was activated, it is automatically deactivated when unloading the Blood Cassette during treatment. All the blood volume data previously collected remain available.

To unload the Blood Cassette, proceed as follows:

1. Press the “Unload Cassette” Action button: a Confirm window opens;
2. Press the ***CONFIRM*** button in the *Confirm* window;
3. Keep the Arterial Pump cover closed to allow the unload of the pump segment;
4. Wait for the Arterial Pump to stop and open the Sensor Bar door;
    - The machine pushes out the cassette holder and unloads the pump segment.

5. Remove the Arterial and Venous Patient lines from the related automatic clamps;

6. Remove the Arterial and Venous Patient lines from the Sensor Bar;

7. Close the Sensor Bar Door;

8. When required by the operator message, open the Arterial Pump Cover;

9. Remove the heparin line from the related guides;

10. Remove the heparin syringe from its holder;

⚠WARNING

In case of hardware malfunction or if the unloading procedure is not completed within 2 minutes, the Cassette holder will automatically retract.
DO NOT insert fingers behind the cassette to avoid injury to your fingers.

11. Remove the Blood Cassette from the Cassette holder;

12. Remove the old dialyzer and install a new one (refer to the related section of "Chapter 4: HD-DN Treatment" of this Operator's Manual);

13. Close the Arterial Pump cover: the machine withdraws the Cassette holder.

8.13.4 Change to HD-SN Treatment

After the cassette has been unloaded, it is possible to change the treatment type in order to resume a HD-SN Treatment.

To change the treatment type, proceed as follows:

1. Change the treatment type and prescription as described in the "3.4 Prescription Parameters Setting" section of this Operator's Manual;

2. Install the new Blood and SN Cassettes and perform the Autopriming as described in the "3.5.3 Loading of the Blood and SN Cassettes" and "3.6 Autopriming" sections of this Operator's Manual;

3. Proceed with the HD-SN Treatment, as described in the "Chapter 6: HD-SN Treatment" of this Operator's Manual.

8.13.5 Install the new Blood Cassette

To install a new Blood Cassette and proceed with the HD-DN Treatment, proceed as follows:

1. Wait for the Cassette holder to withdraw then open the Sensor Bar door and the Arterial Pump Cover to install the new Blood Cassette;

2. Install the Blood Cassette on the Cassette holder;

⚠WARNING

In case of hardware malfunction or if the loading procedure is not completed within 2 minutes, the Cassette holder will automatically retract.
DO NOT insert fingers behind the cassette to avoid injury to your fingers.

3. Route the heparin line through its guides;

4. If needed, install a heparin syringe in its holder and connect the heparin line to the heparin syringe;

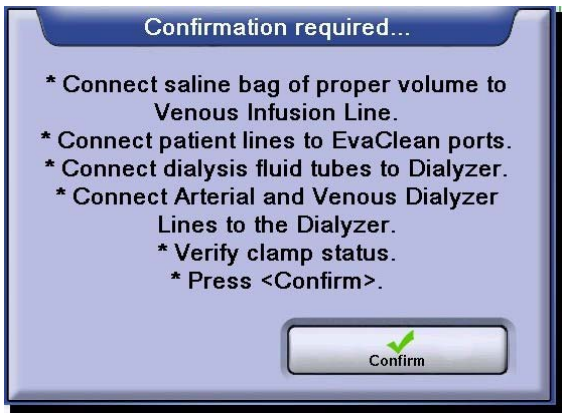
5. Close the Arterial Pump Cover;

6. Route the Venous Patient line through the air detector/blood sensor;

7. Route the Arterial Patient line through the Hemoscan sensor;

8. Close the Sensor Bar Door;

9. Insert the Arterial and Venous Patient lines in their respective automatic clamps: a *Confirm* window opens.



10. Connect the Arterial Patient line to the EvaClean red port. When inserting the priming connector keep the clear cap downward to avoid it could block the EvaClean blue door when closed;

11. Connect the Venous Patient line to the EvaClean blue port. When inserting the priming connector keep the clear cap downward to avoid it could block the EvaClean red door when closed;

12. Attach the Dialysis Fluid Tubes to the dialyzer:

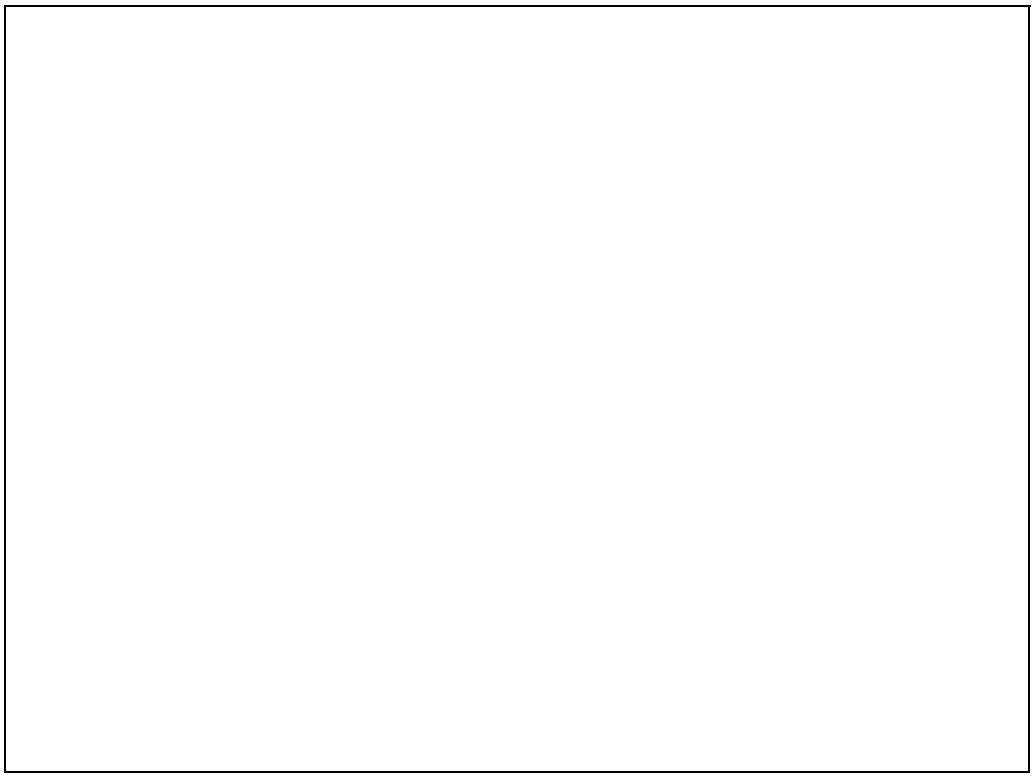
13. Connect the prime line to the saline bag, then route the prime line through its guide on the machine.

14. Clamp the Arterial infusion lines;

15. Press the ***CONFIRM*** button on the *Confirm* window: the machine verifies the correct cassette loading.

8.13.6 Priming

When the new extracorporeal circuit has been successfully installed and the cassette loading check has been successfully performed, the following *Overview* screen is displayed:



Proceed as follows:

1. Press the "Auto-Prime" action button and at the same time open the clamps on the venous infusion line and on the prime line:

NOTE

Before pressing the “Auto-Prime” action button, make sure that the saline bag is hanging correctly on the infusion pole and that a proper amount of solution is available.

- The priming process starts automatically;
- The heparin line, if attached, is automatically primed;
- The “Remaining Time” value starts decreasing while the blue progress bar starts increasing.

Throughout the priming procedure the “Acc Priming Volume” will be displayed on the *Overview* screen. It is also possible to visualize all the priming parameters in the Autopriming Settings sub-screen.

Alarm messages could be displayed in the following cases:

- The dialysis fluid tubes are not connected to the dialyzer after the “Auto-Prime” button has been pressed.
- The arterial and venous patient lines are not connected to the EvaClean ports after the “Auto-Prime” button has been pressed;
- The Arterial Infusion Lines have not been clamped.

NOTE

Each time an alarm is triggered during the priming phase, the process is automatically stopped. When the alarm is reset, the priming process starts according to defined rules.
Verify that an adequate amount of saline solution is available.

8.13.7 Connect the patient

Refer to the “4.1 Connect the Patient” section of this Operator’s Manual to reconnect the patient.

NOTE

If the Diascan function was activated, when resuming the treatment from a “Change Circuit” procedure, the Diascan function will be disabled and it will not be possible to reactivate the function.
Do not rely on the Diascan icon, which remains displayed on the *Overview* screen, and on the Diascan action indicator, which remains green.

8.14 Change Circuit in HDF Post Treatment

The Change Circuit procedure allows to change the extracorporeal circuit (Blood and Ultra cassettes and dialyzer) during a treatment and to install a new one. The machine will store all the treatment data and easily resume them when dialysis is restarted.

This procedure is available as soon as the "Start Treatment" button is pressed and until the "Stop Treatment" button is confirmed.

NOTE

It is not possible to perform a Change Circuit procedure during an Isolated UF process. To perform a Change Circuit procedure it is necessary to previously stop the Isolated UF process.

The Change Circuit procedure is made up of the following phases:

- Rinseback (if needed)
- Disconnect Patient
- Unload Cassette and change dialyzer
- Reprime
- Connect the patient

During the Change Circuit procedure in a HDF Post Treatment:

- The heparin delivery program, if active, is automatically paused. The program will be resumed as soon as blood will be detected again but no initial dose will be delivered.
- **In Pressure Control mode,** the "UC Scan" and "UC Auto Scan" buttons on the Ultra Control Settings sub-screen are not available. The buttons will be available again at the end of the procedure.

NOTE

Before starting a Change Circuit procedure check that there is a sufficient amount of concentrates to perform the procedure.
The "Special Procedures" button containing the Change Acid and Change BiCart procedures is not available during some phases of the Change Circuit procedure.
If a conductivity alarm is triggered during the Change Circuit procedure due to empty concentrate disposables and the "Special Procedures" button is not available, it is necessary to switch the machine OFF and then ON again to make the "Special Procedures" button available.

8.14.1 Rinseback

⚠WARNING

The Patient Connection and Rinseback modes require additional attention: to facilitate their execution, some safety checkings are temporary deactivated and left to the responsibility of the operator (e.g., the extracorporeal A/V pressure limits are expanded to the maximum).

⚠WARNING

During patient connection/disconnection, follow your facility's policies and procedures for managing patient's catheter and Venous and Arterial Patient lines used for hemodialysis.
In particular, if the patient's catheter disconnects from the patient lines or the integrity of the catheter is compromised in any other way, follow your facility's policy for preventing air embolism and infection, including clamping the patient's lines immediately.

NOTE

It is possible to skip the rinseback phase and proceed with the "Patient disconnection" operation.

NOTE

If an alarm occurs that prevent proceeding with the on-line rinseback procedure, proceed as follows:
- Switch to HD-DN Treatment: performing the "Switch off OnLine" Special Procedure;
- Perform the Rinseback procedure as described in the "4.5 Rinseback mode" section of this Operator's Manual.

NOTE

If an alarm is present on the machine reset it before starting the On-line Rinseback procedure to avoid the risk of blood clotting.

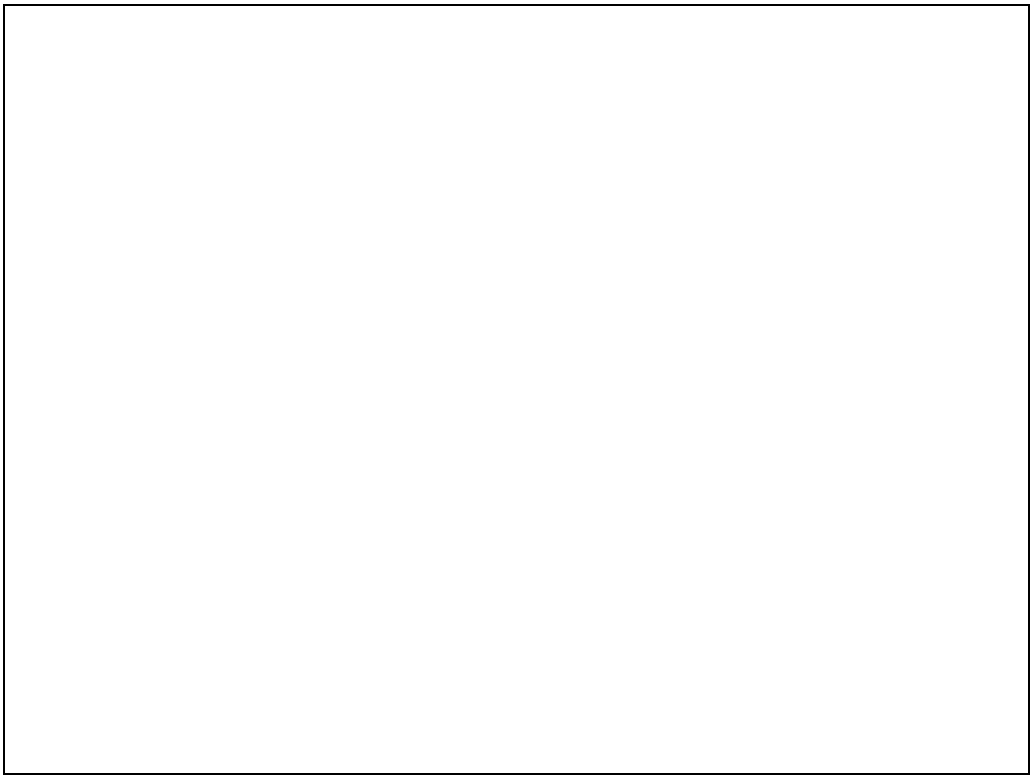
NOTE

If a conductivity alarm is triggered during the Rinseback phase of a "Change Circuit" procedure, the Arterial and Venous pumps do not start.
In this case, perform a Manual Rinseback procedure.

To start the Change Circuit procedure, follow the next steps:

1. Press the "Special Procedures" button on the *Overview* screen, select the "Change Circuit" option from the Selectpad and press the ***CONFIRM*** button:

   • The *Overview* screen has the following configuration:



   • The Arterial and Venous Pumps automatically stop;

   • All the treatment data are stored in the machine memory.

2. As required by the operator message, clamp the Arterial Patient line and disconnect it from the patient;
3. Connect the Arterial Patient line to the Rinseback Service line;
4. Unclamp the Rinseback Service line and the Arterial Patient line;
5. Check/change the values on the Rinseback Settings sub-screen. Open this sub-screen pressing the "Rinseback Settings" button on the *Blood* screen;

NOTE

- The Arterial Pump speed can be adjusted anytime during the rinseback mode with the blood flow increase/decrease keys.
- The rinseback volume can be changed anytime during the rinseback mode.

6. Press the "Rinseback" action button: a *Confirm* window opens

7. Press the ***CONFIRM*** button on the *Confirm* window:

   • The “Rinseback” action indicator switches to green;

   • The Arterial and Venous pumps start at the set value;

   • The blood pump ON/OFF and blood flow Increase/Decrease keys are activated;

   • The “Acc Volume” value in the Rinseback Settings sub-screen starts increasing;

   • The “Acc Rinseback Volume” value in the *Overview* screen starts increasing.

NOTE

If an Air in Venous Line *(#4)* alarm occurs during a rinseback procedure, verify the presence of air in the venous patient line:
• If air is not present, perform the manual rinseback procedure.
• If air is still present, disconnect the patient without performing blood restitution.

NOTE

If the hemoscan function was activated, it is automatically deactivated when unloading the Blood Cassette during treatment. All the blood volume data previously collected remain available.

When the Rinseback volume has been processed, the procedure is completed:

• The Arterial and Venous pumps automatically stop;

• The “Extra Rinseback” button becomes available.

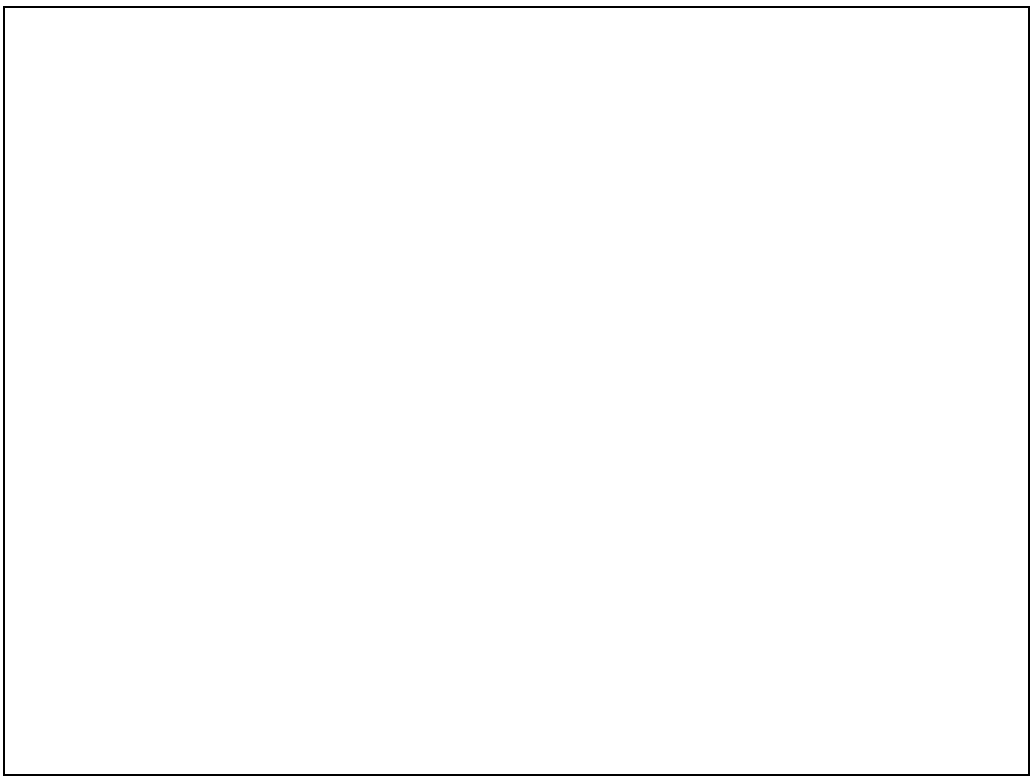
8.14.2 Patient Disconnection

After the rinseback process has been completed, proceed as follows:

1. Press the “Disconnect Patient” Action button on the *Overview* screen: a *Confirm* window opens;

2. Clamp the Venous Patient line and disconnect it from the patient;

3. Press the ***CONFIRM*** Action button on the *Confirm* window:



4. As required by the operator message, remove the Ultra Inlet line from the Ultra port;

5. Close the Ultra door.

8.14.3 Unload Blood and Ultra Cassettes

To unload the Blood and Ultra Cassette, proceed as follows:

1. Press the "Unload Cassette" Action button: a *Confirm* window opens;

2. Press the ***CONFIRM*** button on the *Confirm* window and follow the operator messages to unload the cassette;

3. Keep the Arterial and Venous Pump covers closed to allow the unload of the pump segment;

4. When required by the operator's message, open the Sensor Bar door;

   - The machine pushes out the cassette hooks and unloads the pump segments.

5. Remove the patient lines from the Sensor Bar and from the automatic clamps;

6. Close the Sensor Bar door;

7. Open the Arterial and Venous pump covers;

8. Remove the heparin line from its guides;

9. Remove the heparin syringe from its holder;

10. Remove the Blood and Ultra Cassettes from the related holders;

⚠WARNING

In case of hardware malfunction or if the unloading procedure is not completed within 2 minutes, the Blood and Ultra Cassette holders will automatically retract.
DO NOT insert fingers behind the cassette to avoid injury to your fingers.

11. Remove the dialyzer from its holder;

12. Throw away the complete circuit;

13. Close the Arterial and Venous Pump covers: the machine automatically withdraws the Blood and Ultra Cassette holders.

14. Install a new dialyzer;

15. When required by the operator's message, open the Sensor Bar door and Arterial and Venous Pump Covers to install the new cassette;

16. Install the Blood and Ultra Cassettes on the holders;

⚠WARNING

In case of hardware malfunction or if the loading procedure is not completed within 2 minutes, the Blood and Ultra cassette holders will automatically retract.
DO NOT insert fingers behind the cassette to avoid injury to your fingers.

NOTE

If the Blood and Ultra cassette loading fails, always perform the following steps to complete the loading procedure:
• Unload the Blood and Ultra cassettes;
• Install again the Blood and Ultra cassettes.

17. Route the heparin line through its guides;

18. Close the Arterial and Venous Pump Covers;

19. Route the Venous Patient line through the air detector/blood sensor;

20. Route the Arterial Patient line through the Hemoscan sensor:

21. Close the Sensor Bar Door;

22. Insert the Arterial and Venous Patient lines in their respective automatic clamps: a *Confirm* window opens

23. Connect the Dialysis Fluid Tubes to the dialyzer;

24. Remove the SteriWrap from the Arterial Patient line;

25. Open the EvaClean doors and insert the Arterial Patient line into the EvaClean red port using the priming connector. When inserting the priming connector keep the clear cap downward to avoid it could block the EvaClean blue door when closed;

26. Remove the SteriWrap from the Venous Patient line;

27. Insert the Venous Patient line into the EvaClean blue port using the priming connector. When inserting the priming connector keep the clear cap downward to avoid it could block the EvaClean red door when closed;

28. Clamp the Rinseback/Ultra service lines and the Artrial/Venous Infusion lines. Unclamp the Ultrafilter Degassing line: this clamp must be kept opened throughout the priming procedure;

29. If needed, fill a syringe with the amount of heparin solution prescribed for a single treatment and before connecting it to the heparin line remove any air from the syringe;

30. Remove the cap from the heparin line and connect the line to the heparin syringe;

31. If not already done, attach the dialyzer;

32. Remove the cap from the arterial dialyzer line and insert the line into the upper dialyzer blood port. Before attaching the Arterial Dialyzer line to the dialyzer, rotate the line counter-clockwise (about 1 full turn) to prevent kinking;

33. Route the arterial dialyzer line through the corresponding guide of the Artis Dialysis System, avoiding covering the Hard Key panel with the line;

34. Remove the cap from the venous dialyzer line and insert the line into the lower dialyzer blood port. Before attaching the Venous Dialyzer line to the dialyzer, rotate the line clockwise (about 1 full turn) to prevent kinking;

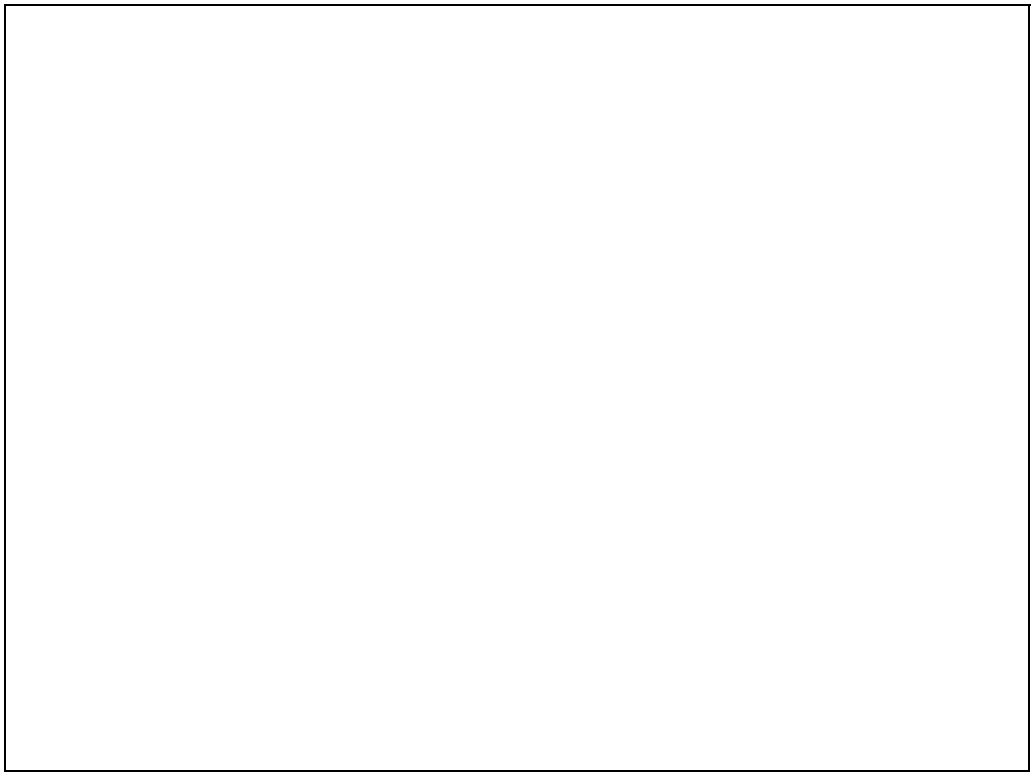
35. Route the venous dialyzer line through the corresponding guide of the Artis Dialysis System;

36. Adjust the dialyzer position to prevent sharp bends in tubing and to prevent tubes from interfering with Artis Dialysis System or its parts. Ensure that lines are untangled;

37. Press the ***CONFIRM*** button on the *Confirm* window: the machine verifies the correct cassette loading.

8.14.4 Priming

When the new extracorporeal circuit has been successfully installed and the cassette loading check has been successfully performed, the following *Overview* screen is displayed:



Proceed as follows:

1. Press the “Auto-Prime” action button:

   • A *Confirm* window opens

2. Open the Ultra door;

3. Remove the cap from the Ultra Inlet Line;

4. Screw tight the green Ultra Inlet line connector to the Ultra port, avoiding rotating the Ultra Inlet line. Ensure that the Ultra Inlet line is not twisted;

5. Press the ***CONFIRM*** button:

   •The priming process starts automatically;

   • The heparin line, if attached, is automatically primed;

   • The “Remaining Time” value starts decreasing while the blue progress bar starts increasing.

Throughout the priming procedure the "Acc Priming Volume" will be displayed on the *Overview* screen. It is also possible to visualize all the priming parameters in the Autopriming Settings sub-screen.

8.14.5 Connect the patient

Refer to the "5.1 Connect the Patient" section of this Operator's Manual to reconnect the patient.

If in Pressure Control mode, the "UC Auto Scan" action indicator on the Ultra Control Settings sub-screen will be grey at the end of the Change Circuit procedure.

NOTE

If the Diascan function was activated, when resuming the treatment from a "Change Circuit" procedure, the Diascan function will be disabled and it will not be possible to reactivate the function.
Do not rely on the Diascan icon, which remains displayed on the *Overview* screen, and on the Diascan action indicator, which remains green.

8.15 Change Circuit in HD-SN and HD-DNDP Treatments

The Change Circuit procedure allows to change the extracorporeal circuit (Blood, SN Cassettes and dialyzer) during a treatment and to install a new one.

This procedure can be performed as soon as the “Start Treatment” button is pressed and until the “Stop Treatment” button is confirmed.

NOTE

It is not possible to perform a Change Circuit procedure during an Isolated UF process. To perform a Change Circuit procedure it is necessary to previously stop the Isolated UF process.

The Change Circuit procedure is made up of the following phases:

- Rinseback (if needed)
- Disconnect Patient
- Unload Cassettes and change dialyzer
- Reprime
- Connect the patient

During the Change Circuit procedure, the heparin delivery program, if active, is automatically paused. The program will be resumed as soon as blood will be detected again but no initial dose will be delivered.

NOTE

Before starting a Change Circuit procedure check that there is a sufficient amount of concentrates to perform the procedure.
The “Special Procedures” button containing the Change Acid and Change BiCart procedures is not available during some phases of the Change Circuit procedure.
If a conductivity alarm is triggered during the Change Circuit procedure due to empty concentrate disposables and the “Special Procedures” button is not available, it is necessary to switch the machine OFF and then ON again to make the “Special Procedures” button available.

8.15.1 Rinseback

⚠WARNING

The Patient Connection and Rinseback modes require additional attention: to facilitate their execution, some safety checkings are temporary deactivated and left to the responsibility of the operator (e.g., the extracorporeal A/V pressure limits are expanded to the maximum).

⚠WARNING

During patient connection/disconnection, follow your facility's policies and procedures for managing patient's catheter and Venous and Arterial Patient lines used for hemodialysis.
In particular, if the patient's catheter disconnects from the patient lines or the integrity of the catheter is compromised in any other way, follow your facility's policy for preventing air embolism and infection, including clamping the patient's lines immediately.

NOTE

It is possible to skip the rinseback phase and proceed with the "Patient disconnection" operation.

NOTE

If a conductivity alarm is triggered during the Rinseback phase of a "Change Circuit" procedure, the Arterial and Venous pumps do not start.
In this case, perform a Manual Rinseback procedure.

Before starting the Change Circuit procedure in Single Needle Double Pump treatments:

1. Note the prescription parameters and their current values.

To start the Change Circuit procedure, follow the next steps:

1. Press the "Special Procedures" button on the *Overview* screen, select the "Change Circuit" option from the Selectpad and press the ***CONFIRM*** button.

- The *Overview* screen has the following configuration:

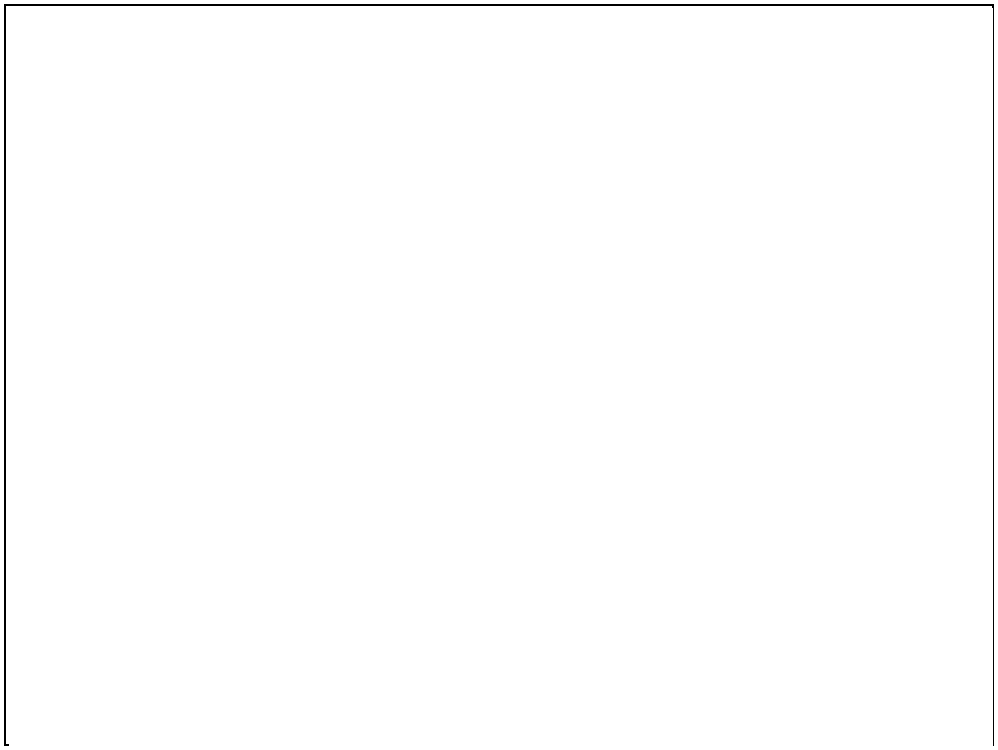


Figure 8-15. Change Circuit - Rinseback

- The Arterial Pump automatically stops;
- The Venous Pump automatically stops.

2. Disconnect the Arterial Patient line from the patient;
3. Connect the Arterial Patient line to a saline bag appropriate for rinseback procedure;
4. Open the clamps on the Arterial Patient line and on the prime line;
5. Press the “Rinseback” Action button:
   - A *Confirm* window opens.
6. Press the ***CONFIRM*** button on the *Confirm* window:
   - The Rinseback procedure starts;
   - The “Rinseback” action indicator switches to green.

When the Rinseback volume has been processed, the procedure is completed:

- The Arterial pump automatically stops;
- The Venous pump automatically stops;
- The “Extra Rinseback” button becomes available.

8.15.2 Patient Disconnection

After the rinseback process has been completed, proceed as follows:

1. Press the "Disconnect Patient" Action button on the *Overview* screen;
   - A *Confirm* window opens.
2. Disconnect the Venous Patient line from the patient;

⚠WARNING

During patient connection/disconnection, follow your facility's policies and procedures for managing patient's catheter and Venous and Arterial Patient lines used for hemodialysis.
In particular, if the patient's catheter disconnects from the patient lines or the integrity of the catheter is compromised in any other way, follow your facility's policy for preventing air embolism and infection, including clamping the patient's lines immediately.

3. Press the ***CONFIRM*** button on the *Confirm* window:

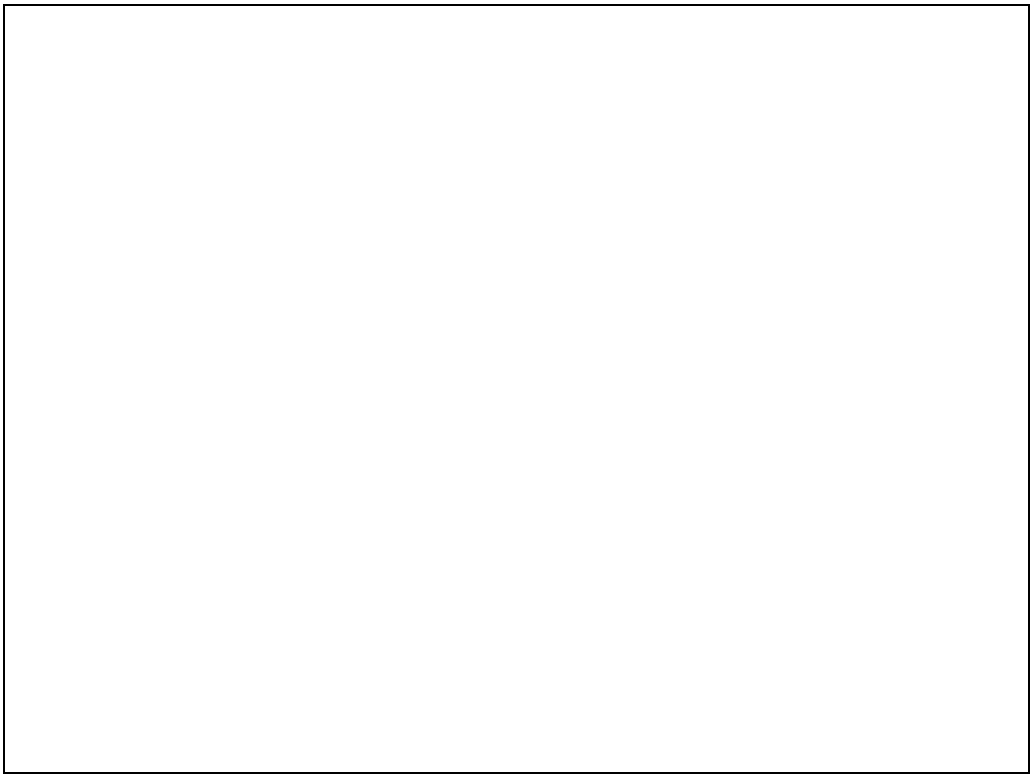


Figure 8-16. Change Circuit - Unload Cassette

8.15.3 Unload Blood and SN Cassettes

To unload the Blood and SN Cassettes, proceed as follows:

1. Press the “Unload Cassette” Action button: a *Confirm* window opens;
2. Press the ***CONFIRM*** button in the *Confirm* window;
3. Keep the Arterial and Venous Pump covers closed to allow the unload of the pump segments;
4. Wait for the Arterial and Venous Pumps to stop and open the Sensor Bar door;
   - The machine pushes out the Cassettes holders and unloads the pump segments.
5. Remove the Arterial and Venous Patient lines from the related automatic clamps;
6. Remove the Arterial and Venous Patient lines from the Sensor Bar;
7. Close the Sensor Bar Door;
8. When required by the operator message, open the Arterial and Venous Pump covers;
9. Remove the heparin line from the related guides;
10. Remove the heparin syringe from its holder;

⚠WARNING

In case of hardware malfunction or if the unloading procedure is not completed within 2 minutes, the Blood and SN Cassettes holders will automatically retract.
DO NOT insert fingers behind the cassettes to avoid injury to your fingers.

11. Remove the Blood and SN Cassettes from the Cassettes holders;
12. Remove the old dialyzer and install a new one (refer to the related section of “Chapter 6: HD-SN Treatment” of this Operator’s Manual);
13. Close the Arterial and Venous Pump covers;
14. Wait for the Cassettes holders to withdraw then open the Sensor Bar door, the Arterial and Venous Pump covers to install the new Blood and SN Cassettes;

15. Install the Blood and SN Cassettes on the Cassettes holders;

⚠WARNING

In case of hardware malfunction or if the loading procedure is not completed within 2 minutes, the Blood and SN Cassettes holders will automatically retract.
DO NOT insert fingers behind the cassettes to avoid injury to your fingers.

16. Route the heparin line through its guides;

17. If needed, install a heparin syringe in its holder and connect the heparin line to the heparin syringe;

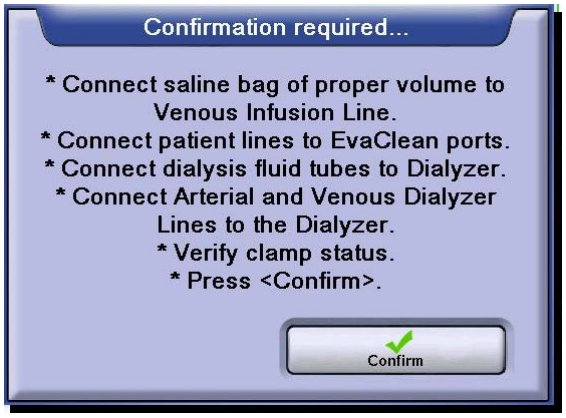
18. Close the Arterial and Venous Pump covers;

19. Route the Venous Patient line through the air detector/blood sensor;

20. Route the Arterial Patient line through the Hemoscan sensor;

21. Close the Sensor Bar Door;

22. Insert the Arterial and Venous Patient lines in their respective automatic clamps: a *Confirm* window opens.



23. Connect the Arterial Patient line to the EvaClean red port. When inserting the priming connector keep the clear cap downward to avoid it could block the EvaClean blue door when closed;

24. Connect the Venous Patient line to the EvaClean blue port. When inserting the priming connector keep the clear cap downward to avoid it could block the EvaClean red door when closed;

25. Attach the Dialysis Fluid Tubes to the dialyzer:

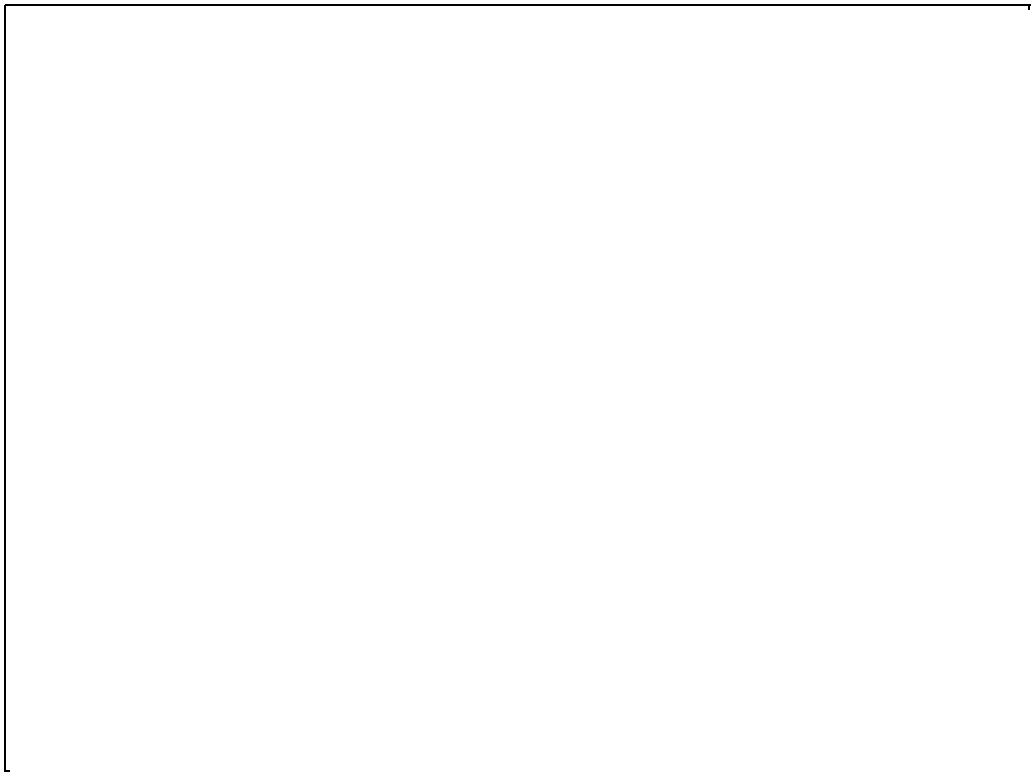
26. Connect the venous infusion line to a saline bag appropriate for the priming of the extracorporeal circuit.

27. Clamp the Arterial infusion lines;

28. Press the ***CONFIRM*** button on the *Confirm* window: the machine verifies the correct cassettes loading.

8.15.4 Priming

When the new extracorporeal circuit has been successfully installed and the cassettes loading check has been successfully performed, the following *Overview* screen is displayed:



Proceed as follows:

1. Press the “Auto-Prime” action button and at the same time open the clamps on the venous infusion line and on the prime line:

NOTE

Before pressing the “Auto-Prime” action button, make sure that the saline bag is hanging correctly on the infusion pole and that a proper amount of solution is available.

- The priming process starts automatically;
- The heparin line, if attached, is automatically primed;
- The “Remaining Time” value starts decreasing while the blue progress bar starts increasing.

Throughout the priming procedure the "Acc Priming Volume" will be displayed on the *Overview* screen. It is also possible to visualize all the priming parameters in the Autopriming Settings sub-screen.

Alarm messages could be displayed in the following cases:

- The dialysis fluid tubes are not connected to the dialyzer after the "Auto-Prime" button has been pressed.
- The Arterial and Venous Patient Lines are not connected to the EvaClean ports after the "Auto-Prime" button has been pressed;
- The Arterial Infusion Lines have not been clamped.

8.15.5 Connect the patient

Refer to the "6.1 Connect the Patient" section of this Operator's Manual to reconnect the patient.

8.16 Switch from HDF Post Treatment to HD-DN Treatment

In case it is necessary to stop the substitution delivery to the patient during a treatment or during an On-line Rinseback procedure, the machine allows to switch from a HDF Post Treatment to a HD-DN Treatment.

Switch from a HDF Post Treatment to a HD-DN Treatment as follows:

1. On the *Overview* screen, press the “Special Procedures” button and select the “Switch off OnLine” option;

2. Press the ***CONFIRM*** button to confirm the selection: a *Confirm* window opens;

3. Press the ***CONFIRM*** button in the *Confirm* window to start the treatment:

   - The machine switches to the HD-DN Treatment
   - The Automatic Pinch clamp is closed
   - The Venous Pump stops
   - In Pressure Control Mode, the “UC Scan” and the “UC Auto Scan” buttons on the Ultra Control Settings sub-screen are no more available.

4. Proceed with the HD-DN Treatment (refer to the “ Chapter 4: HD-DN Treatment” of this Operator’s Manual).

When the HD-DN Treatment ends, perform a rinseback procedure, if needed, as described in the related section of the “ Chapter 4: HD-DN Treatment” of this Operator’s Manual.

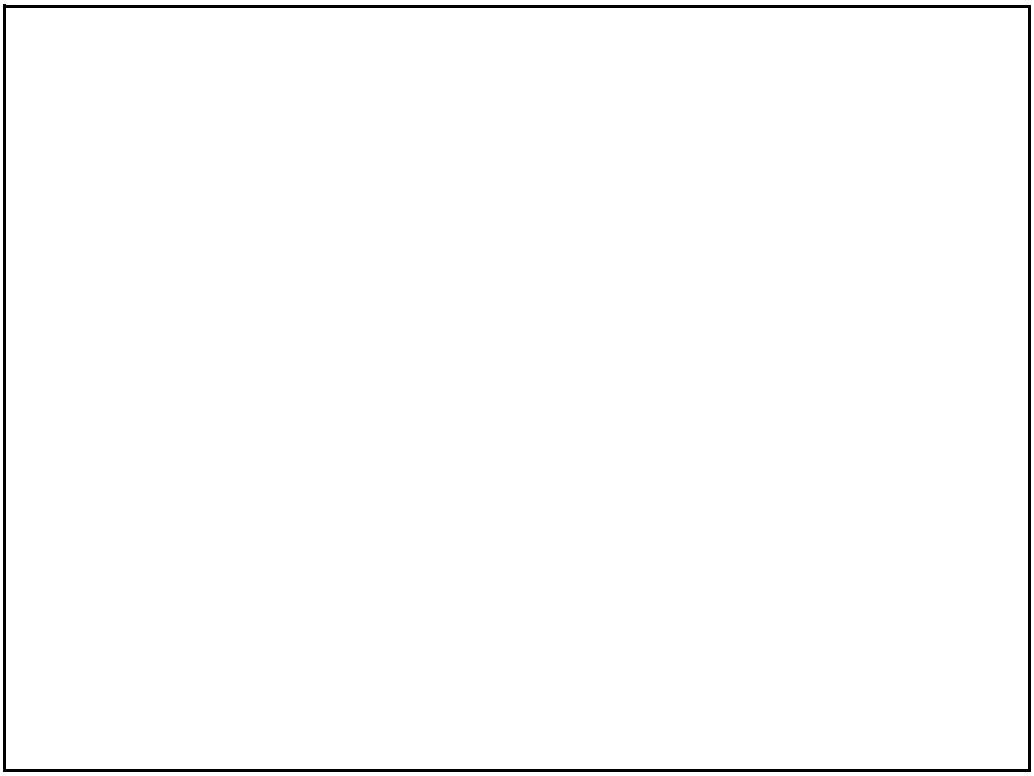
At the end of the rinseback procedure, disconnect the patient proceeding as follows:

1. Press the “Disconnect Patient” button on the *Overview* screen. A *Confirm* window opens;

2. Disconnect the patient per clinical policy;

3. Press the ***CONFIRM*** button on the *Confirm* window:

•The following *Overview* screen is displayed:



4. As required by the operator message, disconnect the Ultra Inlet line from the Ultra port;

5. Close the Ultra door;

6. Proceed with the Drain phase and the Unload Cassette procedures as described in the related sections of the "Chapter 5: Hemodiafiltration On-line" of this Operator's Manual.

8.17 Switch from a HDF Post Treatment in Pressure Control mode to Volume Control mode

During a HDF Post Treatment in Pressure Control mode, it is possible to switch to a HDF Post Treatment in Volume Control mode, proceeding as follows:

1. On the *Prescription* screen, press the “Treatment” button to open the Treatment Settings sub-screen;

2. Press the “Control Mode” button: the following Selectpad opens:

3. Select the “Volume” option and press the ***CONFIRM*** button on the Selectpad to confirm the new control mode. The keypad closes and the following *Confirm* window opens:

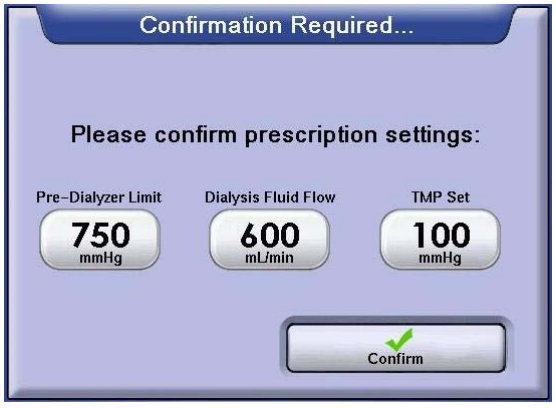


Figure 8-17. Confirm Prescription Settings

4. Check/adjust the “Pre-Dialyzer Limit”, “Dialysis Fluid Flow” and “TMP Set” values, using the set buttons;

⚠WARNING

Setting the "Pre-Dialyzer Limit" and the "TMP Set" to their extreme values might render the Alarm Management System useless.
An improper setting of these limits may prevent the Alarm Management System to detect possible alarm conditions related to blood loss or to blood clotting.

5. When all the proper values have been set, press the ***CONFIRM*** button to confirm them and to close the *Confirm* window:

   • The "UC Scan" and "UC Auto Scan" buttons are no more available on the Ultra Control Settings sub-screen;

   • The treatment continues in Volume Control mode.

8.18 Skip Treatment

During the Connect Patient phase the “Skip Treatment” special procedure is available until the “Start Treatment” button is pressed.

This procedure allows the operator to skip the treatment phase and to perform a patient disconnection.

Skip the treatment proceeding as follows:

1. Press the “Special Procedures” button and select the “Skip Treatment” option in the selectpad;

2. Confirm the selection pressing the ***CONFIRM*** button in the selectpad:

    • The machine enters the rinseback mode

3. Perform a patient disconnection procedure.

8.19 Switch to SNSP

The Artis Dialysis System allows to switch from a HD-DN Treatment to a HD-SNSP Treatment, if needed.

To perform the procedure it is necessary to have the SNSP Conversion kit and the following accessories:

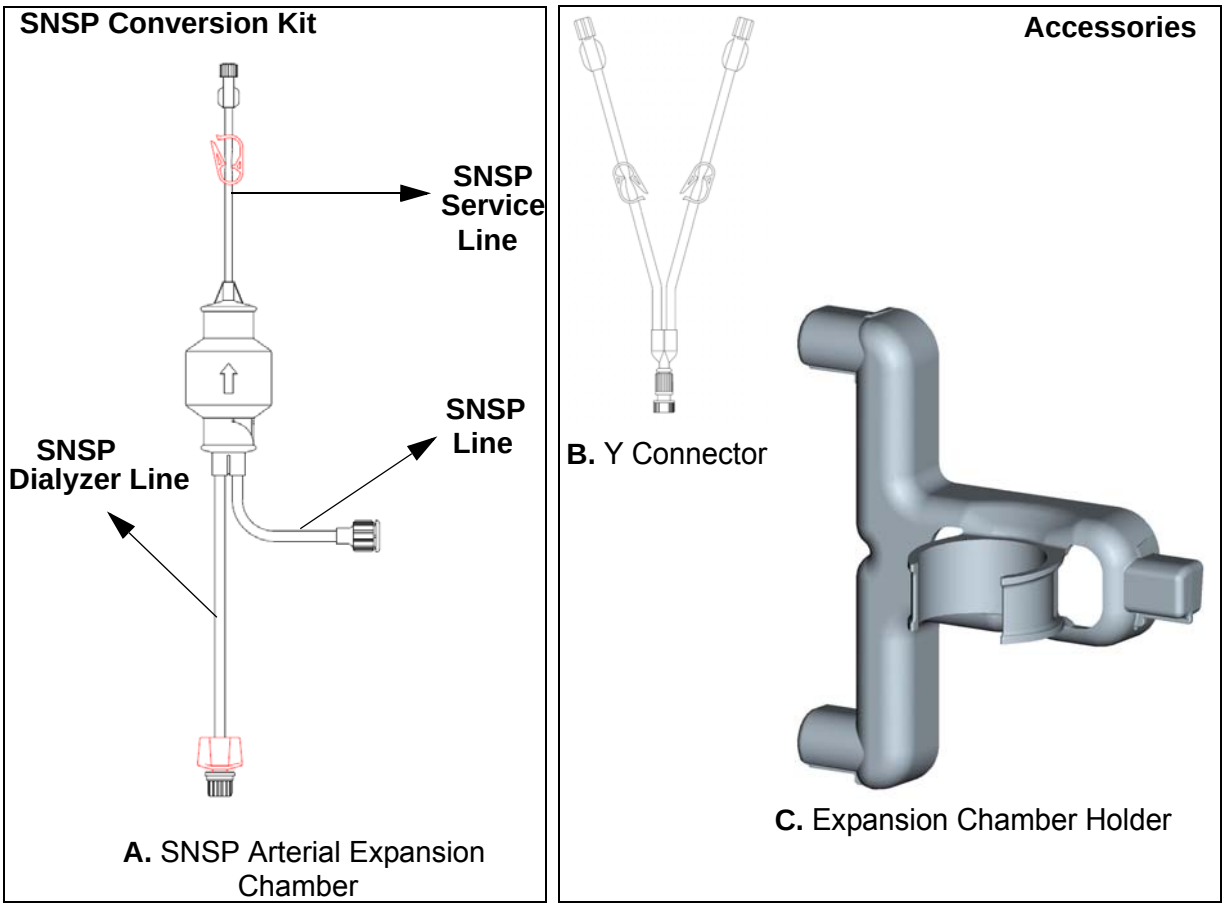


Figure 8-18. SNSP Conversion Kit and required accessories

8.19.1 Manual priming of the SNSP Conversion kit

Before starting the “Switch to SNSP” Special Procedure, it is necessary to manually priming the conversion kit, proceeding as follows:

1. Fill a sterile syringe of saline solution;
2. Unscrew the cap on the SNSP Service line;
3. Unclamp the SNSP Service Line;
4. Clamp the SNSP line;
5. Keeping the SNSP Dialyzer line at the same level of the expansion chamber, start injecting the saline solution into the expansion chamber through the SNSP service line until the SNSP Dialyzer line is completely full;
6. When completely full, clamp the SNSP Dialyzer line;
7. Continue injecting saline solution into the kit through the SNSP Service line until the expansion chamber is for 1/3 full of saline solution;
8. Close the clamp on the SNSP Service line;
9. Insert the SNSP Arterial Expansion Chamber in the Expansion Chamber Holder so that the arrow printed on the chamber is upward.

8.19.2 Install the SNSP Conversion Kit

After the SNSP Conversion kit has been manually primed, install it proceeding as follows:

1. Press the “Special Procedures” button on the *Overview* screen: a selectpad opens;
2. Select the “Switch to SNSP” option and press the ***CONFIRM*** button on the selectpad:

NOTE

If the Hemocontrol function was activated, a *Confirm* window opens requiring to confirm the hemocontrol parameters.
In this case, press the ***CONFIRM*** button on the *Confirm* window to proceed with the special procedure.
The Hemocontrol function is deactivated.

NOTE

The Hemoscan and the Diascan functions are automatically deactivated as soon as the Switch to SNSP procedure is confirmed.

- The treatment continues;
- The following *Overview* screen is displayed:

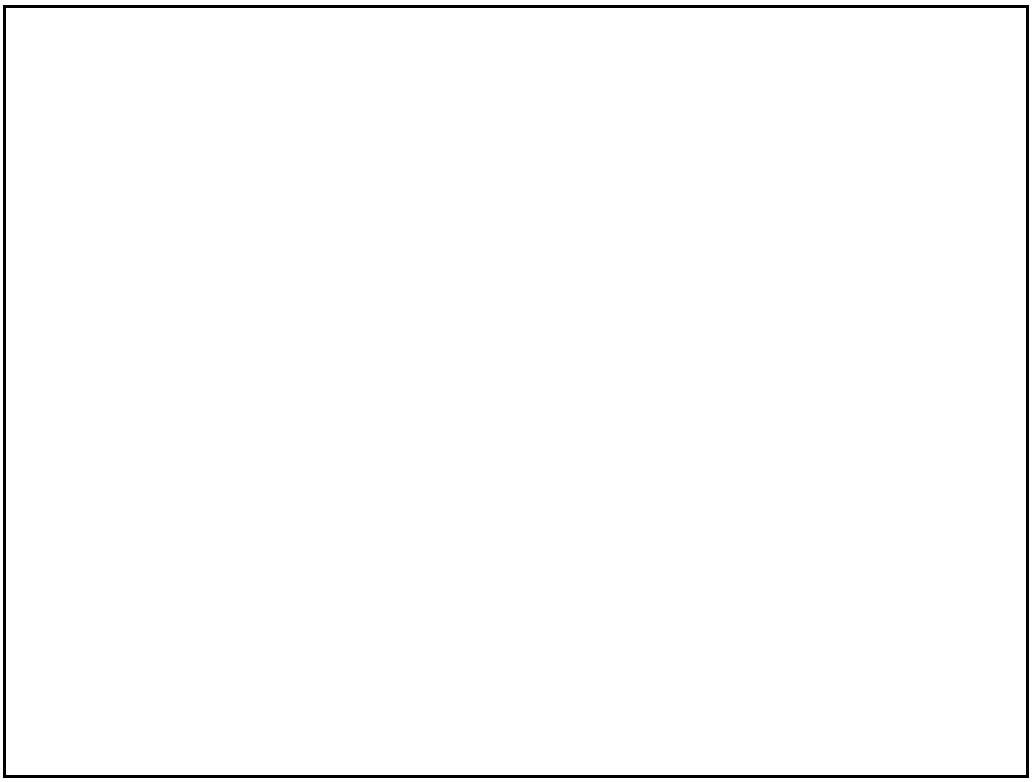


Figure 8-19. Load SNSP Conversion kit

NOTE

It is possible to restart the standard treatment pressing the "Continue Treatment" button.
After the Venous pump cover has been opened to start the SNSP Conversion kit installation procedure, it is no more possible to come back to the previous treatment mode.

3. Open the Venous Pump cover:

- The machine pushes out the Ultra Cassette holder

4. Hang the Expansion Chamber Holder on the Ultra Cassette holder;

⚠WARNING

In case of hardware malfunction or if the loading procedure is not completed within 2 minutes, the Ultra Cassette holder will automatically retract.
DO NOT insert fingers behind the SNSP Conversion kit to avoid injury to your fingers.

5. Close the Venous Pump cover:

   • The machine loads the SNSP Conversion kit

8.19.3 Connect the SNSP Conversion kit

Connect the Conversion kit to the dialyzer and to the Blood Cassette, proceeding as follows:

1. Press the blood pump ON/OFF key to stop the Arterial pump;

   • The Arterial pump stops;

   • The A/V Pressure limits open;

   • The following *Confirm* window opens:

Figure 8-20. "Switch to SNSP" - *Confirm* window

2. Connect both the patient lines to the Y connector according to clinical policy;

3. Connect the Y connector to the patient's vascular access according to clinical policy;

⚠WARNING

During patient connection/disconnection, follow your facility's policies and procedures for managing patient's catheter and Venous and Arterial Patient lines used for hemodialysis.
In particular, if the patient's catheter disconnects from the patient lines or the integrity of the catheter is compromised in any other way, follow your facility's policy for preventing air embolism and infection, including clamping the patient's lines immediately.

4. Clamp the Arterial and Venous Dialyzer Lines;

5. Disconnect the Arterial Dialyzer line from the dialyzer;

6. Unscrew the cap on the SNSP Line;

7. Connect the SNSP Line to the Arterial Dialyzer line of the Blood Cassette;

8. Unscrew the cap on the SNSP Dialyzer Line;

9. Connect the SNSP Dialyzer line to the dialyzer. Before attaching the SNSP Dialyzer line to the dialyzer, rotate the line counter-clockwise (about 1 full turn) to prevent kinking;

10. Ensure that there are no sharp bends in tubes and prevent tubes from interfering with Artis Dialysis System or its parts. Ensure that lines are untangled

⚠WARNING

Improper connections of the extracorporeal circuit may cause potential safety hazards, that might not be detected by the machine: for instance, hemolysis caused by kinks, clamps or other restrictions on the lines, blood loss to the environment/air into the blood circuit due to a leakage in the extracorporeal circuit.

11. Unclamp the Arterial and Venous Dialyzer line, the SNSP Dialyzer Line and the SNSP line.

Refer to the following image for the correct installation of the SNSP Conversion kit:

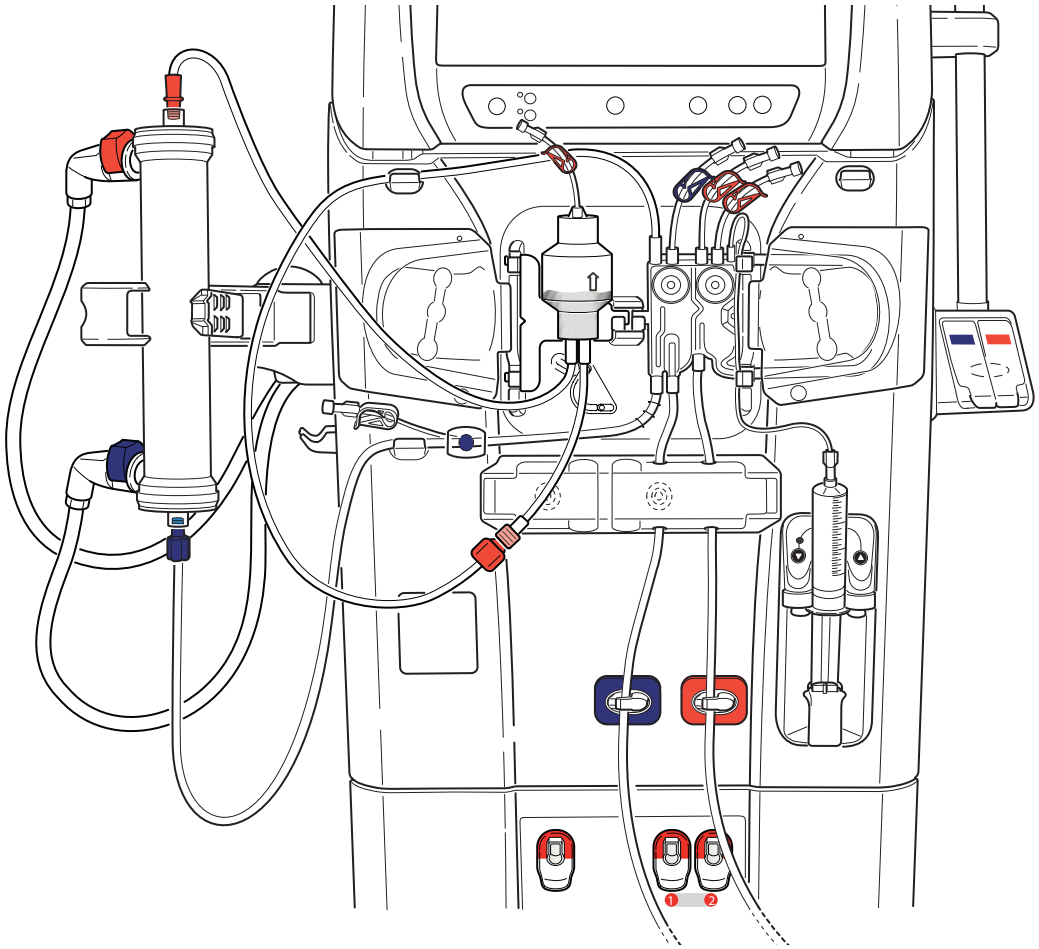


Figure 8-21. HD-SNSP Treatment - Conversion Kit Installation

12. Press the ***CONFIRM*** button on the *Confirm* window:

    • The Arterial Pump speed is automatically set to 50 mL/min;

    • The blood pump ON/OFF and blood flow Increase/Descrease keys are enabled.

8.19.4 Start HD-SNSP Treatment

To start the HD-SNSP Treatment, proceed as follows:

1. On the *Blood* screen, press the "Blood Settings" button to open the Blood Settings sub-screen:

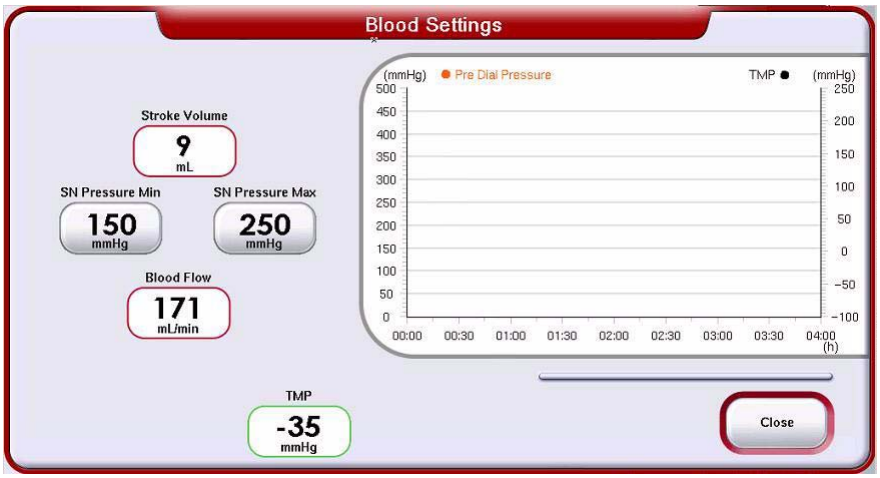


Figure 8-22. Blood Settings sub-screen

Table 1: Blood Settings Parameters

Parameter	Description	Values
Stroke Volume	Displays the actual Stroke Volume during the HD-SNSP Treatment.	/
Mean Blood Flow	Displays the actual mean blood flow, calculated by the machine via the following formula: • Stroke Volume / Treatment Time	/
TMP	Displays the actual TMP	/
SN Pressure Min	Sets the minimum value for the commutation pressure during the HD-SNSP Treatment	• 150 to 360 mmHg
SN Pressure Max	Sets the maximum value for the commutation pressure during the HD-SNSP Treatment	• 190 to 400 mmHg[a]

a. This range can vary according to the SN Pressure Min value set by the operator, in order to maintain the difference between the SN Pressure Min and SN Pressure Max values at least of *40*.

2. Check/set the "SN Pressure Min" and "SN Pressure Max" parameters;

3. Check that fluid level in the expansion chamber is about 1/3 of the height of the expansion chamber and and adjust it if necessary;

4. If no air is present in the lines, press the blood pump ON/OFF key to start the Arterial Pump;

NOTE

When the Arterial Pump starts, the first commutation cycle is performed using the following SN Pressure values:
• SN Pressure Min: 150 mmHg
• SN Pressure Max: 190 mmHg.
The subsequent cycles will be performed using the SN Pressure Min and SN Pressure Max values set by the operator.

5. Adjust the Arterial Pump speed;

6. Press the “Start SNSP Treatment” button on the *Overview* screen:

   • The HD-SNSP Treatment starts

   • The following *Overview* screen is displayed:

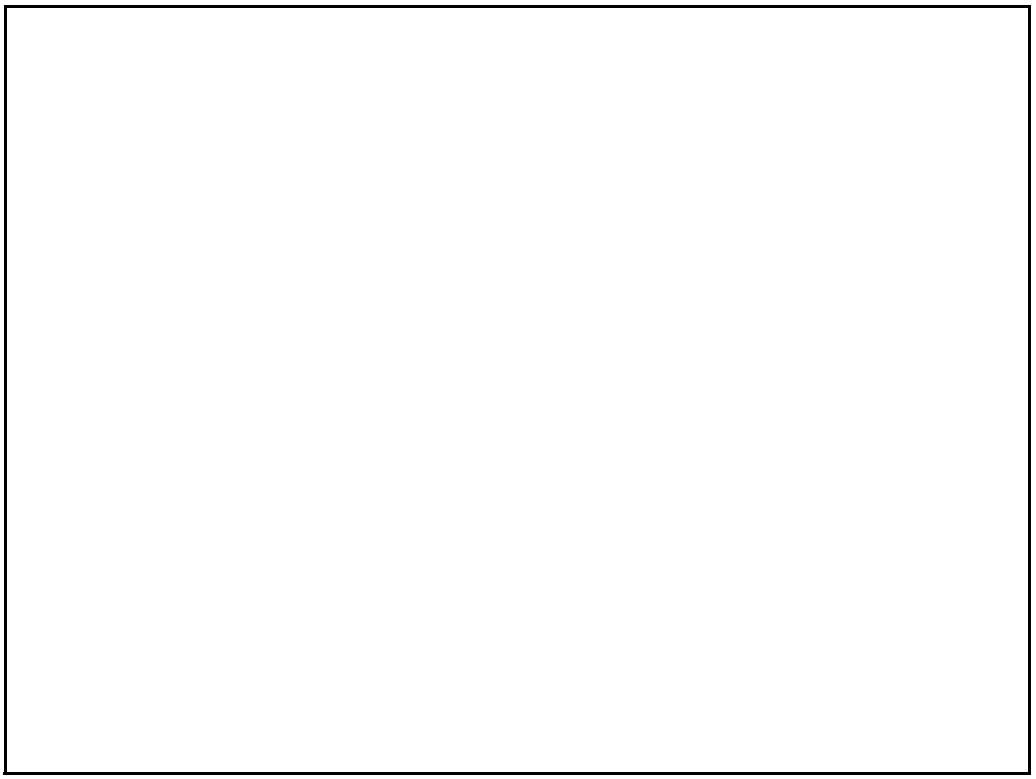


Figure 8-23. HD-SNSP Treatment

8.19.5 Special Procedures during HD-SNSP Treatment

During the HD-SNSP Treatment it is possible to perform the following Special Procedures:

- Change Acid
- Change BiCart
- Change SelectCart
- Change SelectBag
- Pause Treatment
- Cassette Repositioning

For each of these procedures, refer to the related section of this chapter.

8.19.6 End HD-SNSP Treatment

When the HD-SNSP Treatment is accomplished, one or more notification alarms are triggered.

To stop the HD-SNSP Treatment, perform the rinseback, disconnect patient and the drain/empty procedures, proceed as described in the related sections of the " Chapter 4: HD-DN Treatment" of this Operator's Manual.

8.19.7 Unload the Blood Cassette and the SNSP Conversion kit

After the HD-SNSP Treatment is accomplished and the patient has been disconnected, it is possible to unload the Blood Cassette and the SNSP Conversion kit.

To unload the Blood Cassette and the SNSP Conversion kit, proceed as follows:

1. Press the "Unload Cassette" action button. A *Confirm* window opens;
2. Press the ***CONFIRM*** button on the *Confirm* window;
3. Keep the Arterial Pump cover closed to allow the unload of the pump segment;
4. Open the Sensor Bar door:
   - The machine pushes out the Blood and Ultra Cassette holders and starts unloading the pump segment.
5. Remove the patient lines from the Sensor Bar and from the automatic clamps;

6. Close the Sensor Bar door. The following operator's message is displayed:

7. Open the Arterial and Venous Pump covers;
8. Remove the heparin line from the Cassette Panel guides;
9. Remove the heparin syringe from its holder as described in the "3. Slightly rotate the syringe and pull it out from the heparin syringe holder." section;
10. Remove the Blood Cassette from the Blood Cassette holder;
11. Remove the SNSP Conversion kit from the Ultra Cassette holder;
12. Remove the dialyzer from its holder;
13. Throw away the SNSP Conversion kit and the Expansion Chamber Holder;
14. Close the Arterial and Venous Pump covers: the machine automatically withdraws the Blood and Ultra Cassette holders.

8.20 Switch to DN

The "Switch to DN" Special Procedure allows to switch from a HD-SN to a HD-DNDP Treatment without changing the Blood Tubing System.

This procedure can be performed during a HD-SN Treatment, as soon as the "Connect Patient" button is pressed and confirmed and until the "Stop Treatment" button is confirmed.

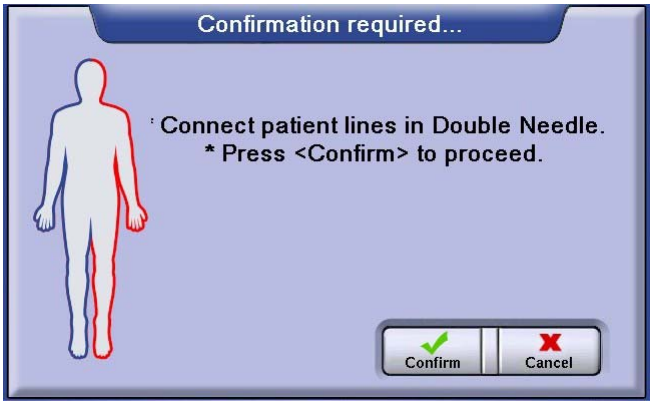
NOTE

It is not possible to perform a "Switch to DN" procedure during an Isolated UF process. To perform a "Switch to DN" procedure it is necessary to previously stop the Isolated UF process.

To perform the "Switch to DN" procedure, proceed as follows:

1. Press the "Special Procedures" button on the *Overview* screen: a selectpad opens;

2. Select the "Switch to DN" option and press the ***CONFIRM*** button on the selectpad. A *Confirm* window opens:



   - The Arterial and Venous Pumps stop
   - The Arterial and Venous Line Clamps are closed
   - The dialysis fluid goes in bypass
   - The blood pump ON/OFF key is disenabled
   - The Arterial and Venous Pressure Alarm Limits are opened

3. Connect the patient in double needle mode, according to the clinical policy;

4. Press the ***CONFIRM*** button to close the *Confirm* window:

- The “HD-DN (Double Pump)” status message is displayed
- The *Blood Settings* sub-screen is hidden
- The “Mean Blood Flow” and “Stroke Volume” values on the *Overview* screen are no longer available
- The “Blood Flow” value box is displayed on the *Overview* screen
- The “Post-dialyzer Pressure” value is displayed in the *Blood* screen
- If the Isolated UF, Hemoscan and/or Diascan functions were activated they continue to be available in HD-DNDP Treatment

5. Press the blood pump ON/OFF key to start the Arterial and Venous Pumps;
   - The Arterial and Venous Pumps start at a pre-set speed in a counter-clockwise direction;
   - The “Start Treatment” or the “Resume Treatment” button becomes available.
6. Press the “Start Treatment” or the “Resume Treatment” button to start the treatment: the “UF” and the “Dialysis Fluid” buttons become available and their indicators are yellow;
7. Press the blood flow Increase/Decrease keys to adjust the pump speed;
8. Press the “Close A/V Limits” button as soon as the arterial and venous pressures are stable: an operator message is displayed indicating that the machine is performing its internal checks;
9. Check the blood levels in the Arterial and Venous Chambers.
   For further details, refer to the “8.28 Adjust Arterial/Venous chamber levels” section of this Operator’s Manual.

NOTE

Blood levels too low in the Arterial or Venous Chambers may cause air to enter the dialyzer thus resulting in dialysis efficacy reduction and/or “Air in Venous Line (#4)” alarm occurrence.

When the machine is ready:

- The UF process starts;
- The “UF” and “Dialysis Fluid” action indicators switch to green;
- The “Real TX Time” value on the *Fluid* screen starts increasing;
- The “Acc UF Volume” value box on the *Overview* screen will display the accumulated UF volume during the treatment.

Continue the treatment as described in the “Chapter 4: HD-DN Treatment” of this Operator’s Manual, starting from the “4.3 Operations during treatment” section.

8.21 Switch to SN

The "Switch to SN" Special Procedure allows to switch from a HD-DNDP to a HD-SN Treatment without changing the Blood Tubing System.

This procedure can be performed during a HD-DNDP Treatment, as soon as the "Connect Patient" button is pressed and confirmed and until the "Stop Treatment" button is confirmed.

NOTE

It is not possible to perform a "Switch to SN" procedure during an Isolated UF process. To perform a "Switch to SN" procedure it is necessary to previously stop the Isolated UF process.

To perform the "Switch to SN" procedure, proceed as follows:

1. Press the "Special Procedures" button on the *Overview* screen: a selectpad opens;
2. Select the "Switch to SN" option and press the ***CONFIRM*** button on the selectpad. A *Confirm* window opens;
   - The Arterial and Venous Pumps stop
   - The Arterial and Venous Line Clamps are closed
   - The dialysis fluid goes in bypass
   - The blood pump ON/OFF key is disenabled
   - The Arterial and Venous Pressure Alarm Limits are opened
3. Connect the patient in single needle mode, according to the clinical policy;
4. Verify and confirm the Stroke Volume parameter. Only after confirming this value, the ***CONFIRM*** button will become available on the *Confirm* window;
5. If the Hemocontrol funtion was activated, on the *Confirm* window a message informs the operator that this function will be deactivated. In this case, verify the "UF Rate" and "Sodium" values;
6. Press the ***CONFIRM*** button to close the *Confirm* window:
   - The *Blood Settings* sub-screen is available as soon as the machine detects blood
   - The "Mean Blood Flow" and "Stroke Volume" values are displayed on the *Overview* screen
   - The "Blood Flow" value box is hidden
   - If the Isolated UF, Hemoscan and/or Diascan functions were enabled they continue to be available in HD-SN Treatment
7. Proceed as described in the "Chapter 6: HD-SN Treatment" of this Operator's Manual.

8.22 Change Heparin Syringe during a treatment

If the heparin syringe is emptied during the treatment the "Heparin pump overload (#55)" alarm is triggered and the heparin delivery program automatically stops. The treatment continues without delivering heparin.

To change the syringe and continue the treatment performing heparin delivery, proceed as follows:

1. Press the "Heparin Settings" button on the *Blood* screen or press the “Heparin Auto Start” button on the “Activated Functions” list on the *Prescription* screen to open the following sub-screen:

2. On the Heparin Settings sub-screen, press the "Heparin" button to deactivate the heparin delivery function:
   - The heparin syringe positioning keys are enabled
3. Clamp the heparin line;
4. Remove the syringe from the holder as described in the “3. Slightly rotate the syringe and pull it out from the heparin syringe holder.” section of this Operator's Manual;
5. Disconnect the syringe from the heparin line;
6. Fill the syringe with an amount of heparin prescribed for a single treatment;
7. Connect the heparin syringe to the heparin line;
8. Install the heparin syringe as described in the “3.5.5 Heparin syringe installation” section of this Operator's Manual;
9. Unclamp the heparin line;
10. On the Heparin Settings sub-screen check the heparin parameters and press the "Heparin" button to activate the heparin delivery.

8.23 Manual Cleaning procedure for the EvaClean Option

The EvaClean option must be cleaned each time the Patient Connection procedure is performed keeping the Venous Patient line into the EvaClean blue port until the machine detects blood. In this case, manually clean the EvaClean option before performing another patient treatment.

NOTE

Non-sterile components can be used to manually clean the EvaClean option.

To manually clean the EvaClean option, proceed as follows:

1. Open the EvaClean doors by gently lifting the EvaClean door tabs;
2. Using a syringe with a priming connector as an adapter, inject 15 ml of undiluted bleach (5.25%-6% sodium hypochlorite) into each of the two EvaClean ports after the machine has been switched ON;

⚠WARNING

The patient must not be connected to the machine during the "Manual cleaning procedure for the EvaClean option".

⚠WARNING

DO NOT USE the priming connector or the syringe used for the "Manual cleaning procedure for the EvaClean option" for patient related uses or any sterile connections.

3. Remove the syringe and the priming connector;
4. Disinfect the external surface of the EvaClean ports with a soft cloth dipped in the disinfectant solution used for the external cleaning of the machine (per clinical policy);
5. Remove the residual disinfectant remained on the EvaClean surface with a soft cloth dipped in water;
6. Close the EvaClean doors;
7. Perform a disinfection/rinse program in order to rinse the undiluted bleach from the EvaClean option.

⚠WARNING

DO NOT LEAVE undiluted bleach in the hydraulic circuit of the machine.

⚠WARNING

Following the EvaClean bleach procedure, before performing a Chemical Disinfection using a chemical other than Bleach, perform either a Rinse or a Heat Disinfection or a Heat with CleanCart-C disinfection program.

8.24 Residual Test after Chemical Disinfection

After a chemical disinfection program a test for residuals of disinfectant must be performed on the dialysis fluid.

Perform the test:

- Just before connecting the patient to the machine, if a chemical disinfection program with peracetic was performed;
- Before attaching the concentrates to the machine, if a chemical disinfection program with hypochlorite was performed.

⚠WARNING

After a Chemical Disinfection program, a test for residuals of disinfectant must be performed before the following patient connection to avoid the risk of blood hemolysis due to the exposure of the patient to the chemical residues.

8.24.1 How to obtain the dialysis fluid sample

Collect the dialysis fluid sample just before connecting the patient to the machine.

Proceed as follows to obtain a dialysis fluid sample:

1. Insert a 10 ml sterile syringe, without needle, into the sampling port on the blue dialysis fluid tube to the dialyzer;
2. Take about 10 ml of dialysis fluid for the test.

8.24.2 Perform the Test

To perform the test follow the instructions on the “Instruction for Use” of the strip.

Compare the reaction zone colour with the ones indicated on the strip instruction for use.

Peracetic Disinfectant

- If the strip indicates less than 1 ppm proceed connecting the patient to the machine;
- If the result of the sample cultured just before connecting the patient to the machine is greater than 1 ppm:

  a. Perform a Rinse;

  b. After the rinse has been accomplished, start the dialysis fluid preparation;

  c. Start autopriming with new concentrates, dialyzer and cassette(s);

d. Perform the residual test again just before connecting the patient.

- If the machine still shows disinfectant residuals, contact service technician.

Hypochlorite Disinfectant

- If the strip indicates less than 0.1 ppm proceed connecting the patient to the machine;
- If the result of the sample cultured just before connecting the patient to the machine is greater than 0.1 ppm:

  a. Perform a Rinse;

  b. After the rinse has been accomplished, start the dialysis fluid preparation;

  c. Start autopriming with new concentrates, dialyzer and cassette(s);

  d. Perform the residual test again just before connecting the patient.

- If the machine still shows disinfectant residuals, contact service technician.

8.25 Ultrafilter Change Procedure

It is recommended to replace the U9000 ultrafilters following the instructions provided in the U9000 Ultrafilter Instruction for Use.

U9000 Ultrafilters can not tolerate more than twelve Chemical Disinfection programs with Hypochlorite.

U9000 Ultrafilters must be changed when the maximum allowed number of chemical disinfection programs with hypochlorite has been performed.

U9000 Ultrafilters can not tolerate more than 150 Disinfection programs, including both Heat and Chemical disinfections.

U9000 Ultrafilters must be changed when the maximum allowed number of disinfection programs has been performed.

It is possible to perform the Ultrafilter Change procedure anytime before starting the priming procedure. However, the “Ultrafilters History” table will be always available during treatment, in the *Hygiene* sub-screen. To open this sub-screen, press the “Hygiene” button on the *Report* screen.

NOTE

Use gloves when performing the ultrafilter change procedure.

To change the ultrafilters, proceed as follows:

1. In the Report screen, press the “Hygiene” button to open the *Hygiene* sub-screen;

Figure 8-24. Hygiene sub-screen

2. Press the "Change Ultrafilters" button: a *Confirm* window opens;

3. Press the ***CONFIRM*** button to close the Confirm window: a new *Confirm* window opens;

4. Open the ultrafilter cover;

5. While holding the ultrafilter with one hand, push outward the latch under the lower arm of the ultrafilter holder;

6. Pull the arm downward;

7. Remove the ultrafilter pulling it gently downwards;

NOTE

When removing the old ultrafilter be careful not wetting excessively the machine with fluid dripping from the ultrafilter.

8. Dry the water on the tray under the ultrafilter holder;

9. Extract the ultrafilter from its package and unscrew the caps from the ports;

10. Insert the new ultrafilter into the holder checking that it is in the right position with the arrow on the label upward;

11. Push the lower arm upwards.
    Verify that the ultrafilter holder arm is firmly latched.

12. Label the ultrafilter with date for change;

13. Close the ultrafilter cover;

14. Press the ***CONFIRM*** button on the *Confirm* window:

    - The *Confirm* window closes;
    - The "Date of Installation", "Next Installation of Rear Ultrafilter", "Remaining Hypchlrt Disinfs" and "Remaining Disinfections" parameter values are reset;
    - The machine enters the "Display-Off" mode.

15. Switch the machine OFF and then switch it ON again: a heat disinfection program automatically starts.

8.25.1 Ultrafilter Change Reminder

It is possible to preset in the Service 2 menu the number of days (from 30 to 90) or of Hypochlorite disinfection programs (from 4 to 12) or of Disinfection programs (from 50 to 150), after which an alarm will be triggered requiring the operator to change the ultrafilters.

During the last three days or when only three Hypochlorite disinfection programs remain or when only three Disinfection programs remain, the “Ultrafilter Replacement Reminder (#402)” Information Message will appear each time the machine is switched ON. In this case, it is anyway possible to confirm the Information Message and perform dialysis treatments. For further details on this alarm refer to the related section of the “ Chapter 16: Alarms, Information Signals and Troubleshooting” of this Operator’s Manual.

When the preset number of days or of Hypochlorite disinfection programs or of Disinfection programs is expired, the “Treatment can not begin until the ultrafilters have been replaced (#571)” alarm will appear each time the machine is switched ON. When this alarm appears, it is not possible to start a dialysis treatment before changing the ultrafilters. For further details on this alarm refer to the related section of the “ Chapter 16: Alarms, Information Signals and Troubleshooting” of this Operator’s Manual.

8.26 Microbiological Sampling of dialysis fluid

> ***NOTE***
>
> If a dialysis fluid sample is needed take the sample before pressing the "Auto-Prime" button.

A pre-dialyzer dialysate sample has to be cultured monthly for machine bioburden levels from at least two machines of the dialysis facility; a dialysate sample should be cultured from each machine at least once per year, as per ANSI/AAMI standards. Other standards/technical documents requiring equivalent or higher level of effectiveness in microbiological sampling procedure could be adopted by government regulatory agencies.

Follow your facility protocol for collecting and culturing the sample.

In order to extend the time between the U9000 Ultrafilter replacement, the microbiological data should be collected at the end of the life cycle of the Ultrafilters before replacing them with new ones. Refer to the " Ultrafilters, frequency of change" section in the " Introduction" chapter of this Operator's Manual.

For instructions on how to change the ultrafilters refer to the "8.25 Ultrafilter Change Procedure" section in this chapter.

It is recommended to obtain the dialysis fluid samples from the Ultra port of the Artis Dialysis System.

The procedure below is an example on how to obtain a sample and can be adjusted to local conditions.

8.26.1 Material to be used for bacteriological sampling

The following materials must be used to obtain a dialysis fluid sample:

- In-Line Filtration Sampler MicropreSure equipped with 0.45 μm membrane from Millipore or similar;
- Sterile disposable sampling tube set from Gambro (GMB SP 402);
- 1 Measuring cylinder with at least 1000 ml volume (diameter: 5 cm);
- Isopropylic alcohol or similar;
- 2 Sterile and pyrogen free vials.

8.26.2 Performing bacteriological sampling

Proceed as described in the sections below to culture dialysis fluid samples for endotoxins and bacteriologic analysis.

8.26.2.1 Endotoxins sampling

The sample for endotoxins should be collected before the sampling for bacteriologic analysis.

Proceed as follows:

1. Collect a sample of the inlet water in a sterile and pyrogen free vial (100-150 ml) before starting the preparation of the dialysis fluid;
2. Send the sample to the laboratory for the analysis;
3. Start the preparation phase;
    - When the preparation is completed, the “Sampling” button becomes available on the *Overview* screen
4. Press the “Sampling” button: a *Confirm* window opens;
5. Open the Ultra door;
6. Spray the Ultra port with Isopropylic alcohol or similar disinfectant solution;
7. Aseptically connect the end of the Sampling line GMB SP 402 to the Ultra port;
8. Press the ***CONFIRM*** button on the *Confirm* window;
9. Let about 20-30 ml of dialysis fluid to spill out of the sampling line into a waste container;
10. Collect 10-50 ml of dialysis fluid into a pyrogen free sampling vial;
11. To stop the fluid flow, press again the “Sampling” button;
12. Close the vial and send it to the laboratory;
13. Remove the GMB SP 402 sampling line;
14. Close the Ultra door.

8.26.2.2 Bacteriologic sampling

After the sample for the endotoxins has been cultured, proceed as follows:

1. When the preparation phase is completed, press the "Sampling" button: a Confirm window opens;
2. Open the Ultra door;
3. Spray the Ultra port with Isopropylic alcohol or similar disinfectant solution;
4. Remove the yellow and blue caps from the MicropreSure filter. Do not throw the caps away;
5. Connect the MicropreSure filter to the conical ending of th GMB SP 402 sampling line (see "Figure 8-25. Sampling Materials");
6. Place the MicropreSure filter on the mesuring cylinder (see "Figure 8-25. Sampling Materials"). The MicropreSure filter is suitable for a cylinder of 5 cm of diameter;
7. Press the ***CONFIRM*** button on the *Confirm* window;
8. When about 980 ml of dialysis fluid have been collected, press the "Sampling" button to stop the fluid flow;
9. When the sampling line is empty, close the clamp on it;
10. Disconnect the GMB SP 402 Sampling line from the MicropreSure filter;
11. Close the MicropreSure filter with the yellow and blue caps;
12. Remove the MicropreSure filter from the cylinder;
13. Make a note of the actual filtered volume if different from what indicated in this procedure. Send this information to the laboratory;
14. Send the MicropreSure filter to the laboratory for the analysis.

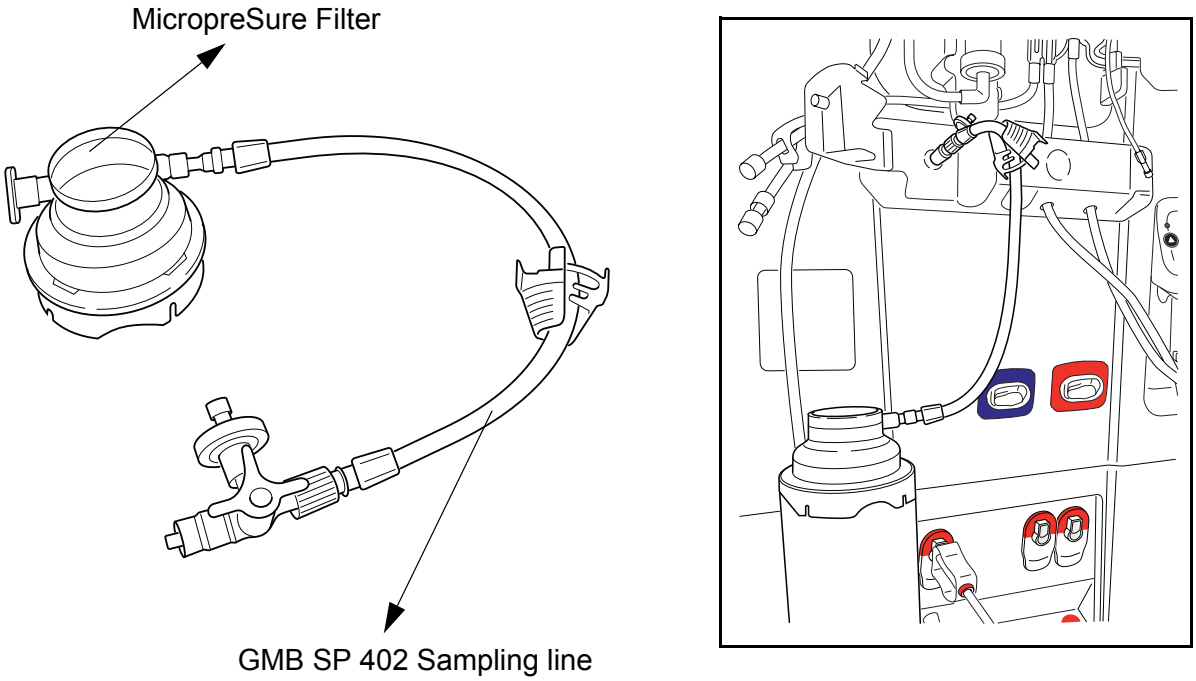


Figure 8-25. Sampling Materials

8.26.3 Sampling results from the bacteriological laboratory

The limits for the inlet water sample are the following:

- ***Bacteria:*** < 100 CFU/ml
- ***Endotoxins:*** <1 UI/ml

The limits for ultra-pure dialysis fluid after cultivation are the following:

- ***Bacteria:*** < 10 CFU/100 ml
- ***Endotoxins:*** <0,03 EU/ml

If the results are outside these limits, perform the following tasks:

- Check the sampling and laboratory routines;
- Perform a second sampling collection procedure;
- Check the disinfection routines of the machine.

8.26.4 Instructions for the bacteriological laboratory

Samples for bacteria.

Substrate: Tryptone Glucose Extract Agar (TGEA).

Incubation: 17-23 °C, 7 days.

1. Open the filter holder and transfer the filter ***aseptically*** to a TGEA plate, with the bacteria collecting side (filter inlet) upwards (see "A" and "B" below);
2. Make sure there is no air bubble between the filter and the TGEA plate;
3. Place the TGEA plates in a plastic bag to avoid contamination and to prevent the agar from drying.

A

B

Result: Note the number of CFU and if any species are dominating.

8.27 LCD Test

The LCD Test function allows the operator to check that the Touch Screen works in the proper way.

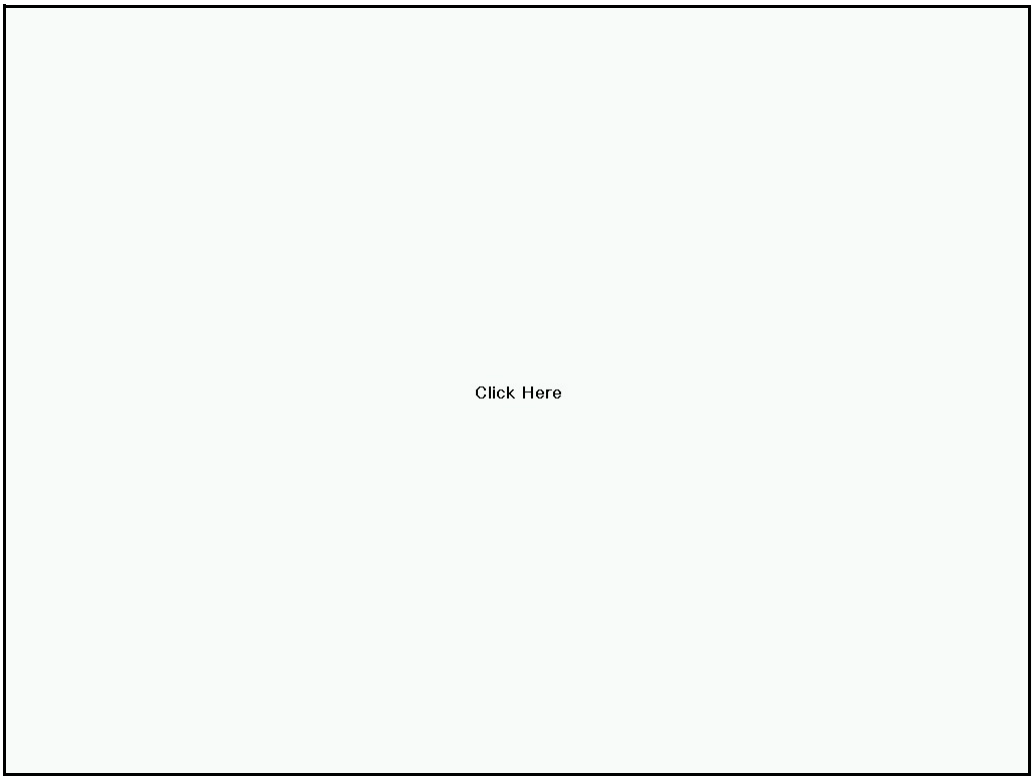
The test should be performed each time the operator observes or suspects that data are not correctly displayed on the Touch Screen.

To perform the test, proceed as follows:

1. On the *Report* screen, press the “LCD Test” button: a *Confirm* window opens;

2. Press the ***CONFIRM*** button on the *Confirm* window

   • The following screen is displayed:



3. Visually check that the screen is completely white and that no spots of different colours are present;

4. Press on the Touch Screen: the following screen is displayed:

5. Visually check that the screen is completely black and that no spots of different colours are present;

6. Press on the Touch Screen:

   - The machine automatically stops the procedure and returns to the previous operating status

If the Touch Screen is damaged, ask for a service technician to repair/change the LCD screen.

8.28 Adjust Arterial/Venous chamber levels

8.28.1 Before Treatment

After the priming process, the fluid level in the Arterial and Venous Chambers should be between the green lines drawn in the figure below:

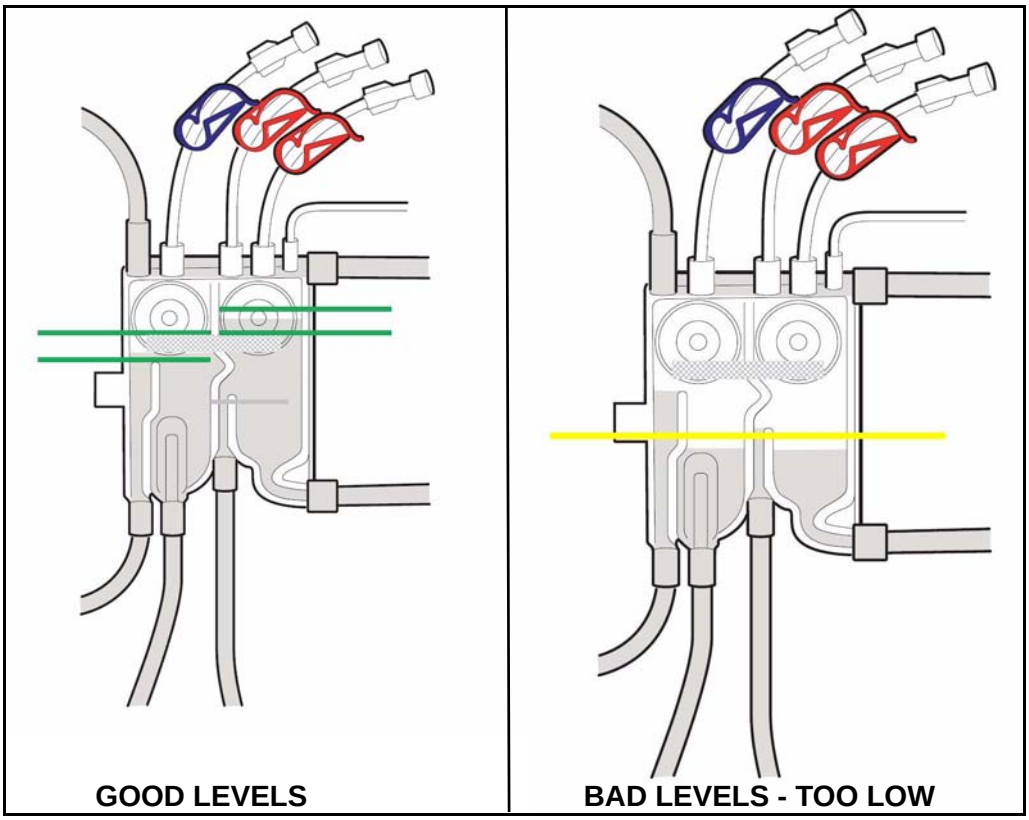


Figure 8-26. Adjust Arterial/Venous Chamber Levels - Before Treatment

Fluid levels in the chambers could be too low at the end of Autopriming in case one of the following conditions occurred during Autopriming:

- The saline bag was emptied during the priming
- The patient lines were not properly connected to EvaClean doors
- The infusion line clamps were not closed
- The priming volume was not appropriate for the dialyzer used

If fluid levels in the chambers are too low they have to be checked and adjusted before patient connection. To adjust them perform a Reset Prime as described in the dedicated sections of this Operator's Manual.

8.28.2 During treatment

During a treatment, the blood level in the arterial and venous chambers should be stabilized at the frosted line present on the chamber themselves, as shown in the figure below:

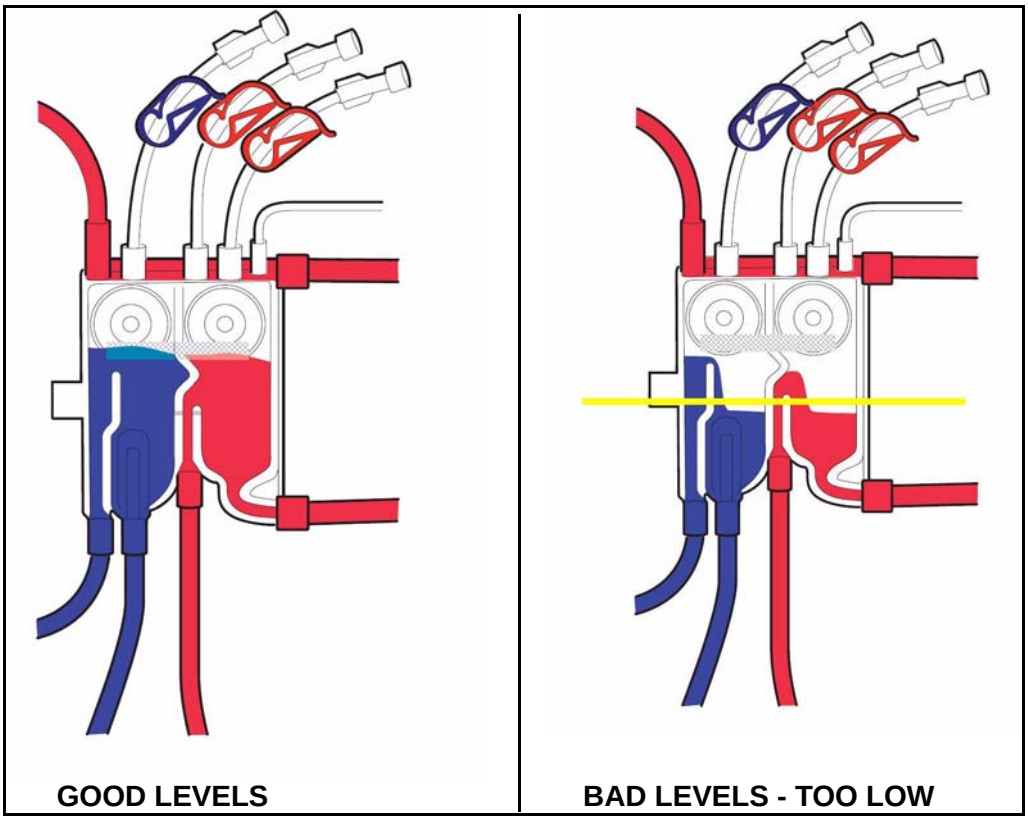
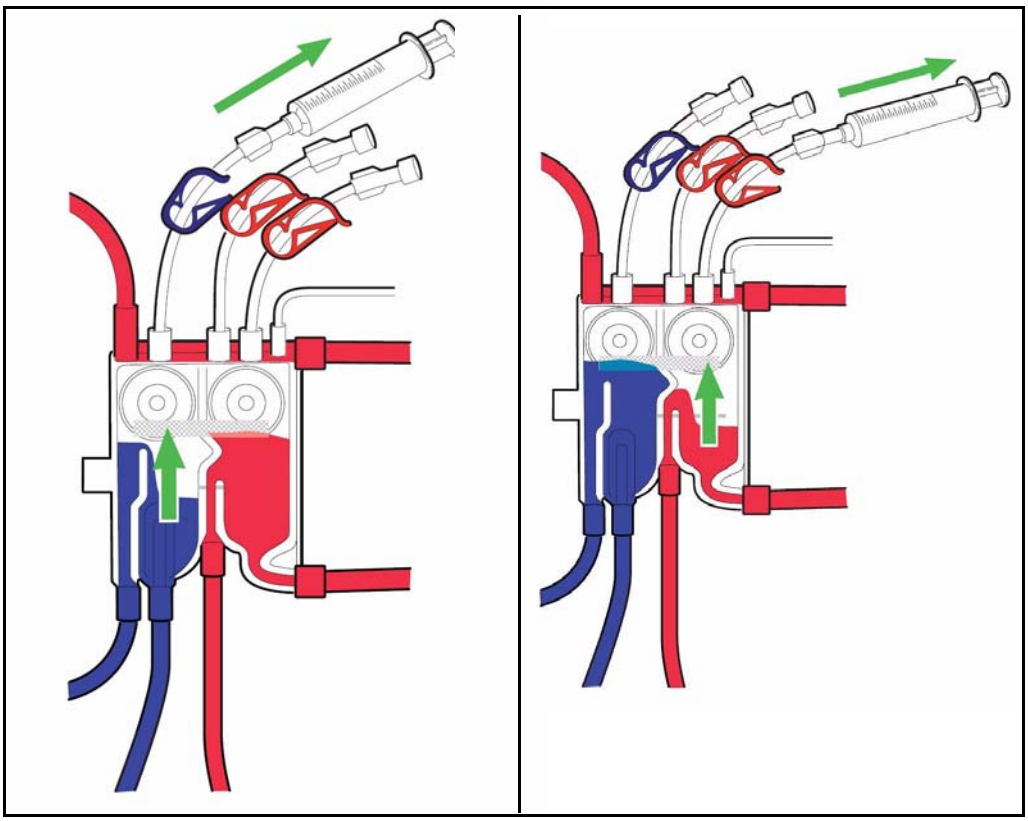


Figure 8-27. Adjust Arterial/Venous Chamber Levels - During Treatment

Adjust the level of the Arterial and Venous Chambers during a treatment, proceeding as follows:

1. Press the "Expand A/V Limits" button on the Overview screen
2. Ensure that the Infusion Line clamp of the chamber in which the level needs to be adjusted is closed
3. Remove the cap from Arterial or Venous Infusion Line
4. Attach a sterile luer-lock syringe (at least 20 ml) to the Infusion Line
5. Unclamp the Infusion Line
6. Adjust the level in the chamber, aspiring to increase or injecting to decrease



If in HD-SN Treatment:

- If the Arterial Chamber level needs to be adjusted, perform the adjustment during the Arterial phase (i.e., when the Arterial automatic clamp is open);
- If the Venous Chamber level needs to be adjusted, perform the adjustment during the Venous phase (i.e., when the Venous automatic clamp is open).

7. When the desired level is reached, clamp the Infusion line
8. Remove the syringe
9. Replace the cap on the Infusion line
10. Press "Close A/V Limits" button

⚠WARNING

When performing the “Adjust Chamber Levels” special procedure, always attach a sterile syringe to the Infusion line before unclamping it and pay attention to the blood level in the chambers. In case of central venous catheter with atrial location, don’t let the Arterial Chamber opened to air as the blood level in the Arterial Chamber may significantly decrease causing air to reach the patient’s vascular access.

8.28.3 Adjust Expansion Chamber Levels

8.28.3.1 During Treatment

The blood level in the Pre- and Post-Dialyzer Expansion Chambers is automatically controlled by the Artis Dialysis System during the priming process in order to maintain the blood on the same level into the two chambers. So, usually it does not need to be adjusted by the operator.

Anyway, if during the treatment the blood levels in the two Expansion Chambers need to be adjusted, proceed as described in the sections below.

⚠WARNING

When performing the "Adjust Expansion Chamber Levels" special procedure, always attach a sterile syringe to the Service Line before unclamping it and pay attention to the blood level in the chambers.

HD-SN Treatment

If during the HD-SN Treatment the blood levels into the two Expansion Chambers become greatly different from each other (for example after an alarm situation has been reset) it is possible to adjust them proceeding as follows:

1. Set the "Stroke Volume" value to 20 mL;
2. Set the "Mean Blood Flow" to 50 mL/min;
3. Wait at least that an Arterial and Venous cycle is completed before proceeding;
4. Press the blood pump ON/OFF key to stop the Arterial/Venous Pump;
5. Ensure that the SN Service Line clamps are closed;
6. Remove the cap on the SN Service line related to the Expansion Chamber where the blood level is higher;
7. Attach a sterile luer-lock syringe (at least 20 ml) to the SN Service Line;
8. Open the clamp of the SN Service Line;
9. Adjust the level in the Expansion Chamber in order to reach the same blood level into both the Expansion Chambers;
10. When the blood into the two Expansion Chambers is at the same level, close the SN Service Line clamp;
11. Remove the syringe;

12. Replace the cap of the line;

13. Press the blood pump ON/OFF key.

HD-DNDP Treatment

If during the HD-DNDP Treatment it is necessary to adjust the blood levels into the two Expansion Chambers, it is possible to adjust them proceeding as follows:

1. Ensure that the SN Service Line clamps are closed;

2. Remove the cap on the SN Service line related to the Expansion Chamber where the blood level needs to be adjusted;

3. Attach a sterile luer-lock syringe (at least 20 ml) to the SN Service Line;

4. Open the clamp of the SN Service Line;

5. Adjust the level in the Expansion Chamber aspirating to increase or injecting to decrease;

6. When the blood level in the chamber reaches 1/3 of its height, close the SN Service Line clamp;

7. Remove the syringe;

8. Replace the cap of the line.

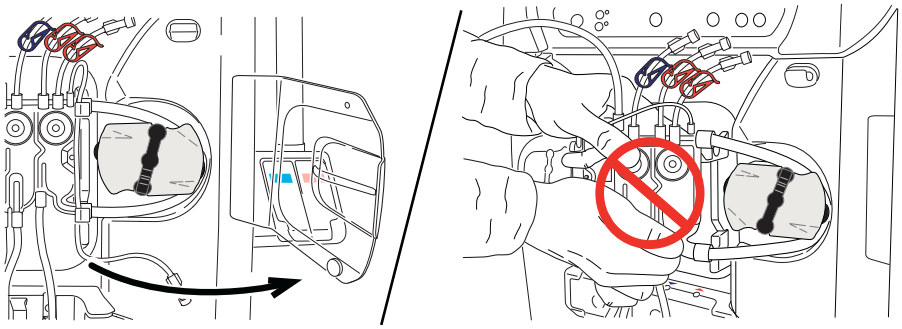
8.29 Manual Pump Segment Unloading Procedure

⚠WARNING

An incorrect pump segment unloading procedure could damage the pump rotor.
A damaged pump rotor will not work properly. This could result in patient serious injury.

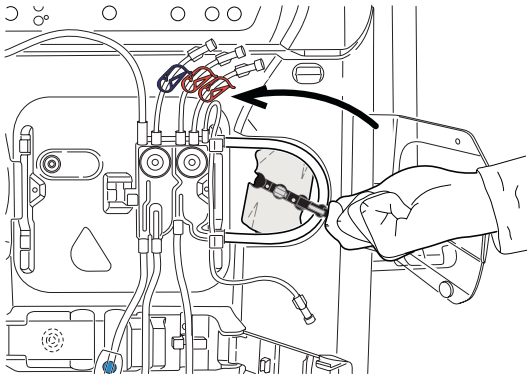
To manually unload the pump segment, proceed as follows:

1. Open the Pump Cover.
   DO NOT remove the cassette while the pump segment is still loaded into the pump rotor;



2. Extract the crank from the pump rotor;

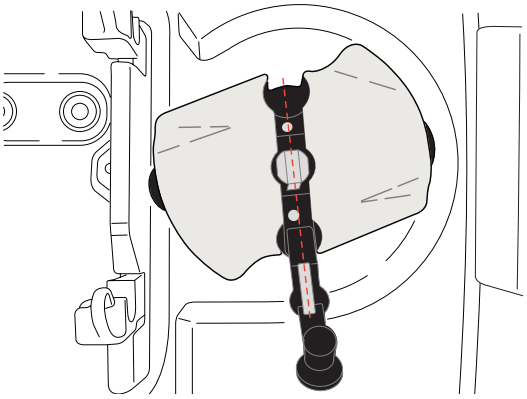
3. Turn the pump rotor in a counter-clockwise direction to unload the pump segment;



4. Extract the pump segment from the rotor;

5. Remove the cassette;

6. Turn the pump rotor in order to align the crank with its axis;



7. Close the crank

8. Close the Pump Cover.

8.30 Touch Screen frozen

8.30.1 During treatment

If the Touch Screen freezes or goes black or white while performing a treatment, perform a Fast Recovery procedure as described in the "8.5 Fast Recovery" section of this Operator's Manual.

In case the proper working conditions of the Touch Screen are not reestablished after the Fast Recovery procedure, proceed as follows:

1. Perform a Manual Rinseback procedure as described in the related sections of this Operator's Manual;

2. Switch the machine OFF;

3. Call for Service.

8.30.2 During Dialysis Fluid Preparation/Disinfection programs

If the Touch Screen freezes or goes black or white during the Preparation/ Function Check phase or while perfoming a Disinfection/Rinse program, switch the machine OFF and then ON again.

In case the proper working conditions of the Touch Screen are not reestablished after switching the machine OFF and ON, proceed as follows:

1. Switch the machine OFF;

2. Call for service.

Chapter 9: BPM

9.1 General

The Blood Pressure Monitor (BPM) measures patient arterial blood pressure using an inflatable pressure cuff. The blood pressure data is derived by the oscillometric method.

Once the BPM has acquired the pressure data, it analyzes them to obtain Systolic pressure, Diastolic pressure and Heart rates.

⚠WARNING

Carefully follow the instructions for use supplied with the BPM kit to install and use the BPM system.

The BPM can be manually or automatically activated:

- It is possible to manually activate the system during the following machine modes: Preparation, Treatment and Service (refer to the “9.4.2 Manual Measurement” section of this chapter);
- It is possible to automatically activate the option during the patient connection phase up to the end treatment phase (refer to the “9.4.3 Automatic Measurement” section of this chapter).

To verify which type of BPM has been installed, press the “System Data” button on the *Report* screen and, after selecting the fourth Service Data page, verify the “BPM Rel” value:

- If the “BPM Rel” value is “0504h”, the HDBPM is installed;
- If the “BPM Rel” value is “0704h”, the NiBPM is installed.

Following the main features of the BPM system.

9.1.1 Oscillometric Blood Pressure Measurement Method

The BPM uses a blood pressure cuff to apply pressure to the artery.

The arterial pressure pulses are coupled in the cuff and result in pulses (oscillations) modulating the cuff pressure. The maximum amplitude of these oscillometric pulses occurs at mean blood pressure.

The BPM plots the amplitude of the oscillometric pulses against the cuff pressure and then interpolates the systolic and diastolic blood pressures from the plot.

9.1.2 Assembly accuracy

The assembly accuracy meets the ANSI/AAMI standard SP10.

9.1.3 Overall System Accuracy

The overall system accuracy meets ANSI/AAMI SP10.

The following values are applied:

1. Maximum mean error of measurement: ±5 mmHg
2. Maximum standard deviation of error: 8 mmHg

Those accuracy values are obtained with a measurement device with the following accuracy:

- ±2% or ±3 mmHg, whichever is greater, over a range of 0 to 260 mmHg (compliant to ANSI/AAMI SP10).

9.1.4 Measurement ranges

The following measurement ranges are applied:

HDBPM	NiBPM
• Systolic: +60 to + 255 mmHg	• Systolic: +40 to + 260 mmHg
• Diastolic: +30 to +195 mmHg	• Diastolic: +20 to +200 mmHg
• Pulse rate: 30 to 200 beats per minute.	• Pulse rate: 30 to 220 beats per minute.

9.1.5 Cycle time

The typical measurement cycle time is approximately 35 s.

Anyway, the maximum cycle time will not be greater than 160 s.

9.1.6 Zero setting

The BPM is able to automatically set the pressure transducer channel to zero, at appropriate intervals at last staring after switching on the BPM system.

9.1.7 Conformity with international standards

The BPM complies with the applicable clauses of the following international standards:

Standards	
IEC 601-2-30	Medical electrical equipment. Part 2: Particular requirements for the safety of automatic cycling indirect blood pressure monitoring equipment.
EN 1060-1	Specification for non-invasive sphygmomanometers Part 1: General requirements
EN 1060-3	Non-invasive sphygmomanometers Part 3: Supplementary requirements for electro-mechanical blood pressure measuring system
EN 1060-4	Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers

9.1.8 Composition

HDBPM

The inflation bags and the tube in the BPM cuff are made of a latex-free material.

The external materials of the inflation bags that are in contact with the patient are made of Dupont Dacron Polyester with the hook and loop closures made of Dupont Nylon.

These materials have been tested by NAMSA (North American Science Associates) and are in compliance with bio-compatibility standards for irritation and skin sensitivity.

NiBPM

The cuff bladder and the cuff shell are made of nylon. The cuff hose is made of silicon.

All cuffs are latex and PVC free and have been tested for bio-compatibility.

9.1.9 Cuff cleaning

HDBPM

Small soiled or stained areas may be cleaned by gentle scrubbing with a sponge or cloth soaked in mild soap or water solution.

NiBPM

The cuff may be cleaned with a mild disinfectant spray, rinsed with distilled water, and line dry. Ensure that no liquid enters the bladder tubing.

Or:

Remove bladder to machine wash the cuff shell. Machine wash warm with a mild detergent (50 - 130°F, 10 - 54°C) and line dry.

9.1.10 Cuff pressure

The maximum cuff pressure is 300 mmHg.

An adult cuff will inflate from 50 to 250 mmHg in a maximum time of 10 s (at sea level, with a cuff for 24/32 cm arm circumference of 120 ml volume).

In the event of a total or partial power failure, the cuff automatically deflates to less than 15 mmHg within 30 s.

⚠WARNING

The BPM must be used only with adult patients or with children with a pediatric cuff but not with infant patients (neonatal).

⚠WARNING

Avoid compression or restriction of pressure tubes.

⚠WARNING

Check (e.g. by observing the limb concerned) that the patient's blood circulation is not affected by the blood pressure measurements.

⚠WARNING

The BPM should be tested and re-calibrated at least every 4000 working hours or at least once a year or any time irregular performance is suspected or observed.

⚠WARNING

The composition of the BPM Cuff (insulating material) protects the BPM "Applied Part" (Type BF) against the effect of a defribillator discharge.

⚠WARNING

In the event of accidental wetting of the cuff or the hydraulic connections, wipe immediately to prevent moisture from entering the machine.

⚠WARNING

In order to be in full conformity with the indications of the European Medical Device Directive 93/42, the manufacturer advises the user that the information originating from the BPM ***CAN NOT*** be used as a unique source of information to induce any therapeutic or pharmacological actions.

9.1.11 Patient factors that affect readings

Excess patient speech or movement can interfere with readings. Ensure that the patient is quiet and not moving during measurements, just as during manual readings.

NOTE

Avoid applying external pressure to the cuff during readings.

Some arrhythmias may cause pressure fluctuations that make difficult to obtain readings. In this case, blood pressure should periodically be verified using another method.

Verify the next points before applicating a blood pressure cuff:

- Do not apply a blood pressure cuff to an arm/limb with an access, e.g. fistula or graft.
- Do not apply a blood pressure cuff to an arm being monitored with a pulse oximetry sensor.
- Do not apply a cuff to an arm that has restricted blood flow.
- Avoid applying a cuff to an arm that has an intravenous line in place.

9.2 Cuff Selection

The cuff and the cuff hose are available in different sizes that can be ordered from your Gambro representative.

HDBPM

Use the circumference of the patient's arm to determine the proper cuff size, according to the table below:

Cuff Size	Arm Circumference (cm)	Service Code
CHILD	10 -19 (3.9-7.5 IN)	6975213
SMALL ADULT	18 - 26 (7.1-10.2 IN)	6975221
ADULT	25 - 35 (9.8-13.8 IN)	6975239
LARGE ADULT	33 - 47 (12.9-18.5 IN)	6975247

NiBPM

Use the circumference of the patient's arm to determine the proper cuff size, according to the table below:

Cuff Size	Arm Circumference (cm)	Service Code
CHILD	12 -19 (4.7-7.5 IN)	6993513
SMALL ADULT	17 - 25 (6.7-9.8 IN)	6993521
ADULT	23 - 33 (9.1-13.0 IN)	6993539
LARGE ADULT	31 - 40 (12.2-15.7 IN)	6993547
EXTRA LARGE ADULT	36 - 46 (14.1-18.1 IN)	6993596
THIGH	38 - 50 (15.0-19.7 IN)	6993554

When applying the cuff, ensure that it wraps at least halfway around the patient's arm.

NOTE

The table above contains a number of references to cuffs for use with the Blood Pressure Monitoring System (BPM). The Artis Dialysis System has been tested and validated for use with the cuffs listed in this table. The Manufacturer does not accept responsibility or liability for use of cuffs other than those specified.

9.2.1 Common errors in cuff size selection

It is important to use proper cuff size for accurate measurements. Infact, if the cuff bladder is too wide, the blood pressure reading will be erroneously low; if it is too narrow, the reading will be erroneously high.

For correction to blood pressure reading refer to “9.3.2 Correction of blood pressure readings” section of this chapter.

9.3 Cuff Application

After the proper cuff size has been selected, it is possible to applicate the cuff to the patient's arm, proceeding as follows:

1. Connect the BPM tube to the BPM connector on the rear connectivity panel of the Artis Dialysis System;

2. Squeeze air from cuff;

3. Place the white arrow on the cuff approximately over brachial artery;

4. Wrap the cuff snugly, placing its upper edge as high on arm as possible, with its lower edge 25 to 50 mm above the antecubital crease.

The cuff is correctly applied when the white arrow on the cuff is placed on the inner surface of the arm (not near antecubital crease).

9.3.1 Common errors in cuff application

Posible errors on blood pressure measurement can be caused by:

- Wrong cuff size
- Cuff full of air when first applied
- Cuff too low on arm (lower edge of cuff must not rest on antecubital crease)
- Cuff too loose.

9.3.2 Correction of blood pressure readings

When accurate blood pressure measurements are necessary, arm circumferences should be measured and corrections made using the following tables (where SBP and DBP respectively represent the Systolic and the Diastolic Adult Blood Pressure Cuffs):

Arm Circumference			
Bladder width (cm)	12 (4.7 in)	15 (5.9 in)	18 (7.1 in)
Ideal arm circumference (cm)	30 (11.8 in)	37.5(14.8 in)	45 (17.7 in)
Arm circumference range (cm) (inc)	• 26 - 33 • (10.2 - 12.9)	• 33 - 41 • (12.9 - 16.1)	• > 41 • > 16.1

Arm Circumference (cm)	SBP	DBP	SBP	DBP	SBP	DBP
26 (10.2 in)	+5	+3	+7	+5	+9	+5
28 (11.0 in)	+3	+2	+5	+4	+8	+5
30 (11.8 in)	0	0	+4	+3	+7	+4
32 (12.6 in)	-2	-1	+3	+2	+6	+4
34 (13.4 in)	-4	-3	+2	+1	+5	+3
36 (14.2 in)	-6	-4	0	+1	+5	+3
38 (14.9 in)	-8	-6	-1	0	+4	+2
40 (15.7 in)	-10	-7	-2	-1	+3	+1
42 (16.5 in)	-12	-9	-4	-2	+2	+1
44 (17.3 in)	-14	-10	-5	-3	+1	0
46 (18.1 in)	-16	-11	-6	-3	0	0
48 (18.9 in)	-18	-13	-7	-4	-1	-1
50 (19.7 in)	-21	-14	-9	-5	-1	-1

For correction of blood pressure readings in individual patients, positive numbers should be added to and negative numbers subtracted from the readings obtained. (The table data are taken from the American Heart Association).

9.4 BPM User Interface

The BPM option allows to perform manual or automatic measurements of the patient's blood pressure before, during or after a treatment.

Measures taken in manual mode can be labelled as *pre-* or *post-* according to the following definitions:

- ***Pre blood pressure:*** measurements taken starting from the Artis Dialysis System start-up until the selection of the confirm of the "Connect Patient" button;

- ***Post blood pressure:*** measurements taken starting from the selection of the "Stop treatment" button until the selection of the "Empty Circuit" button.

There are six labelled BPM positions: pre measurements for standing, sitting, lying and post measurements for standing, sitting and lying.

9.4.1 BPM Settings sub-screen

Activate the BPM option proceeding as follows:

1. Select the "Auto BPM" option from the "Activated Functions" list on the *Prescription* screen or press the "BPM Settings" button on the *Blood* screen: the following sub-screen opens:

Figure 9-1. BPM Settings Sub-screen

2. Check/modify the desired parameters:

PARAMETER	DESCRIPTION	VALUES
Patient Position	Sets the possible patient position during measurements.	• Lying • Sitting • Standing
Measure Interval	Sets the time between automatic measurements, expressed in minutes. This value defines the time interval between the beginning of a measurement and the beginning of the subsequent one.	• 0:05 to 1:00 h, in steps of 5 minutes
Max Heart Rate	Sets the maximum value allowed for the heart rate alarm limit	• 30 to 200 bpm, in steps of 1 bpm
Min Heart Rate	Sets the minimum value allowed for the heart rate alarm limit	• 30 to 200 bpm, in steps of 1 bpm
Systolic Upper	Sets the upper systolic alarm limit	• 60 to 255 mmHg, in steps of 5 mmHg
Systolic Lower	Sets the lower systolic alarm limit	• 60 to 255 mmHg, in steps of 5 mmHg
Diastolic Upper	Sets the upper diastolic alarm limit	• 30 to 195 mmHg, in steps of 5 mmHg
Diastolic Lower	Sets the lower diastolic alarm limit	• 30 to 195 mmHg, in steps of 5 mmHg

⚠WARNING

Setting the Diastolic/Systolic Upper and Lower, Max Heart Rate andMin Heart Rate alarm limits to their extreme values might render the Alarm Management System useless.
An improper setting of these limits may prevent the Alarm Management System to detect possible alarm conditions related to hypertension, hypotension or cardiac arrhythmia.

3. Refer to the following sections for activation/deactivation of the BPM option;

4. Press the “Close” button to close the BPM Settings sub-screen.

The blood pressure measurements and pulse rate are displayed in the “BPM” icon and in the BPM Graph.

9.4.1.1 BPM Graph

All the blood pressure measures taken during a treatment are plotted on the BPM Graph on the BPM Settings sub-screen.

The graph displays:

- On the horizontal axis, the treatment time;
- On the vertical axis, the mmHg for the blood pressure. The grading will be set to 25 - 300 mmHg.

The Graph displays the patient's systolic, diastolic blood pressures and the pulse rate values taken during treatment. In particular:

- The blue line represents the systolic pressure;
- The red line represents the diastolic pressure;
- The green line represents the pulse rate.

If a measurement check fails or is outside the alarm limits, there will be an interruption of the line in the graph.

9.4.2 Manual Measurement

To perform a manual blood pressure measurement, proceed as follows:

1. Apply the cuff to the patient's arm as described in the "9.3 Cuff Application" section above;
2. Press the "BPM" action button on the *Overview* screen or on the BPM Settings sub-screen:
   - The machine immediately starts the blood pressure measurement;
   - The "BPM " action indicator, both on the *Overview* screen and on the BPM Settings sub-screen, switches to green;
   - The heart in the BPM icon starts beating indicating that the measurement is ongoing.

NOTE

If the BPM Cuff is not connected to the Artis Dialysis System after the "BPM" action button has been pressed, an alarm will be triggered.

When the measures have been taken:

- The “BPM “ action indicators on the *Overview* screen and on the BPM Settings sub-screen switch to grey;
- The “BPM “ buttons on the *Overview* screen and on the BPM Settings sub-screen are disabled for 45 seconds;

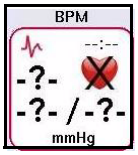
  If using a NiBPM, the buttons are disabled for 5 seconds. If more than six manual measures are requested with a in-between time interval lower than 30 seconds, the “BPM “ buttons will remain disabled for 45 seconds;
- The BPM icons on the *Overview* screen and on the BPM Settings sub-screen are updated with the new values;
- The BPM data are plotted on the graph (only if taken during treatment), stored on the *Report* screen and sent to the network connection (if available)

NOTE

- In case of multiple pre/post BPM measurements, the last BPM value for each labelled position will be reported to an external software.
- Every *pre-* and *post-* BPM measurement, labelled or not, will be displayed on the *Report* screen.

If the BPM system is not able to acquire a measure:

- The following icon is displayed on the *Overview* screen and on the BPM Settings sub-screen;



- No data is recorded;
- The “BPM Measurement failure or Out of Range (#31)” alarm is triggered. Press the ***CONFIRM*** button to clear the alarm.

9.4.2.1 Stop Measurement

To stop an ongoing manual measurement, press the activated “BPM” action button on the *Overview* screen or on the BPM Settings sub-screen:

- No data is recorded;

- The "BPM" action indicators on the *Overview* screen and on the BPM Settings sub-screen switch to grey;
- The "BPM" buttons on the *Overview* screen and on the BPM Settings sub-screen are disabled for 45 seconds.

9.4.3 Automatic Measurement

To activate an automatic blood pressure measurement during a treatment, proceed as follows:

1. Apply the cuff to the patient's arm as described in the "9.3 Cuff Application" section above;
2. Press the "Auto BPM" action button on the BPM Settings sub-screen.
   - The blood pressure measurement starts at the "Measure Interval" time;
   - The automatic BPM icons are displayed on the *Overview* screen and on the BPM Settings sub-screen;
   - The "Auto BPM" action indicator in the "Activated Functions" list on the *Prescription* screen switches to green.

NOTE

If the BPM Cuff is not connected to the Artis Dialysis System after the "BPM" action button has been pressed, an alarm will be triggered.

When the BPM measurement starts:

- The "BPM " action indicator, both on the *Overview* screen and on the BPM Settings sub-screen, switches to green;
- The heart in the BPM icon starts beating indicating that the measurement is ongoing.

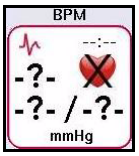
Each time new values are successfully acquired:

- The "BPM " action indicators on the *Overview* screen and on the BPM Settings sub-screen switch to grey;
- The BPM icons on the *Overview* screen and on the BPM Settings sub-screen are updated with the new values;
- The "BPM " buttons on the *Overview* screen and on the BPM Settings sub-screen are disabled for 45 seconds;

- The BPM data are plotted on the graph (only if taken during treatment), stored on the *Report* screen and sent to the network connection (if available).

If the BPM system is not able to acquire a measure:

- The following icon is displayed on the *Overview* screen and on the BPM Settings sub-screen;



- No data is recorded;

- The “BPM Measurement failure or Out of Range (#31)” alarm is triggered. Press the ***CONFIRM*** button to clear the alarm.

9.4.3.1 Pause Measurement

It is possible to pause and then resume the BPM measurement during a treatment, proceeding as follows:

1. Press the activated “Auto BPM” button;

2. Press the “Auto BPM” button again to resume automatic measurement.

9.4.3.2 Stop Measurement

The automatic measurement continues periodically until:

- The treatment time is complete;

- The operator presses the activated “Auto BPM” action button on the BPM Settings sub-screen.

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Chapter 10: Hemoscan™ Monitoring System

10.1 General Description

The Hemoscan™ Monitoring System is a continuous and non-invasive system to measure changes in the patient's blood volume during the dialysis treatment.

The Hemoscan Monitoring System is based on the measurement of the optical absorption caused by the blood flowing into the arterial patient line. The primary measure is the hemoglobin concentration (HGB), from which the percentage blood volume changes (BV) is derived , applying the following formula:

$$BV_t = \frac{HGB_0}{HGB_t} - 1$$

HGB_0 is the hemoglobin concentration value measured during the first minutes (approximately 5 minutes) after the start of the treatment. This value is used as a reference.

HGB_t is the hemoglobin concentration value automatically measured at regular intervals following the first hemoglobin concentration measurement (HGB_0).

When enabled, the Hemoscan system will perform the following operations:

- a self-test, at machine startup, to check the Hemoscan sensor proper working conditions;
- an autocalibration after the blood cassette installation, to ensure an accurate blood volume monitoring during the treatment.

The system supplies different kinds of information to the physician and the nurse:

- ***ON-LINE:*** the nurse can have an immediate and comprehensive look at the different signals coming from the patient. The alarm that can be set on blood volume is useful in the clinical surveillance.
- ***OFF-LINE***: the physician can analyze the trends of signals for different patients and relate them to the dialysis treatment.
- The Hemoscan system allows continuous monitoring of the blood volume change together with other machine and patient parameters during a dialysis session. These elements are displayed both in numerical and graphical forms. The graphs represent their progress during the dialysis treatment.

⚠WARNING

It is the physician responsibility to verify the alignment of the Hemoscan measurements to local laboratory equipment (percentage Blood Volume change formula may be used).
In any case the information originating from Hemoscan system can not be used as unique source of information to induce any therapeutical or pharmacological action (e.g. erythropoietin administration, plasma expanders infusions, etc...).

10.1.1 Hemoscan function specifications

In the following table the Hemoscan system specifications are reported:

Parameter	Value
Blood Volume Range of measurement	• -40% to +10%
Blood Volume Accuracy	• ±3 %
Blood Volume Resolution	• ±0.1%
Alarm Limit Range	• -30% to 0

The blood volume changes can be measured by the Hemoscan system only if the following parameters fall in the indicated ranges:

Parameter	Value
Hemoglobin Concentration Range	• 6 to 16 g/dl
Blood Flow Rate	• 180 to 580 ml/min
Blood Temperature	• 30 to 40°C

10.2 Procedures

⚠WARNING

The Hemoscan system can be used only with a specific Blood Tubing System equipped with a Hemoscan cuvette.
Refer to the “Chapter 17: Specifications” of this manual for the list of Blood Tubing Systems equipped with Hemoscan cuvette.
Use of different Blood Tubing Systems can cause alarms or wrong measurements of Hemoscan Monitoring System due to differences in the characteristic of the line (materials, geometry and so on).

It is possible to use the Hemoscan function only with the following treatment/ functions:

- Hemodialysis (HD-DN Treatment) using BiCart or BiCart Select
- Hemodiafiltration (HDF Post Treatment)
- HD-DNDP Treatment
- Hemocontrol
- Diascan
- HD-SN Treatment
- AFB K Treatment

Following the operational procedures necessary to activate/deactivate the Hemoscan system.

10.2.1 Preset

To make the Hemoscan system available during the dialysis treatment, the proper service configuration has to be set up:

- The “Hemoscan” option of the “Installed Features” list is “YES”: the Hemoscan function is available in the treatment views and can be activated.
- The “Hemoscan” option is “NO”: the Hemoscan related buttons are not available in the treatment views and the Hemoscan function can not be activated.

10.2.2 Self-test

At machine startup, an electronic self-test is performed by the Hemoscan system in order to check the proper working conditions of its sensor.

If the self-test fails an alarm is triggered. In this case, deactivate the Hemoscan function in order to solve the alarm.

In case of a Hemoscan self-test failure, the machine set-up phase will correctly continue but the Hemoscan function will not be activated.

10.2.3 Autocalibration

When enabled, the Hemoscan Monitoring System performs an autocalibration each time a new blood cassette is loaded.

The Hemoscan system calibration lasts about 20 seconds and requires that:

- A blood cassette has been successfully loaded by the machine;
- An empty Hemoscan cuvette is inserted into the proper Sensor Bar housing;
- The Sensor Bar door is securely closed.

If one of the previous conditions is not satisfied, the autocalibration fails or is suspended. Only if the Hemoscan function is activated, an alarm is triggered. In this case, either troubleshoot the alarm to complete the autocalibration (Refer to the "Chapter 16: Alarms, Information Signals and Troubleshooting" of this Operator's Manual) or deactivate the Hemoscan function.

NOTE

If the Hemoscan function has been activated, the "Auto-Prime" button will be available only after the Hemoscan sensor calibrations have been completed.

It is necessary to activate the Hemoscan function before pressing the "Start Treatment" button. Otherwise, it will not be possible to activate the function later on.

10.2.4 Activate the Hemoscan function

After being enabled in the service mode, the Hemoscan function can be activated/ deactivated from the Hemoscan Settings sub-screen.

It is possible to open the settings sub-screen in the following ways:

- Pressing the “Hemoscan Settings” button on the *Blood* screen
- Pressing the “Hemoscan” option on the “Activated Functions” list on the *Prescription* screen.

1. On the Hemoscan Settings sub-screen, check/change the alarm limit value. It is possible to adjust the alarm limit value anytime during the treatment:

Figure 10-1. Hemoscan Settings sub-screen

- The “Alarm Limit” value can be set in the range from 0% to - 30.0%, default value “- 20.0%”

⚠WARNING

Setting the Alarm Limit to its extreme values might render the Alarm Management System useless.
An improper setting of this limit may prevent the Alarm Management System to detect possible alarm conditions related to hypovolemia or hypervolemia (patient fluid overload).

NOTE

The "Alarm Limit" parameter is not available when the Hemocontrol function is activated. In this case the Blood Volume limits are the one set by the Hemocontrol function.

2. Press the "Hemoscan" button to activate the function:

   - The Hemoscan function is activated;
   - The "Hemoscan" button switches to green;
   - The Hemoscan icon is displayed on the *Overview* screen;
   - The "Hemoscan" action indicator on the "Activated Functions" list on the *Prescription* switches to green.

3. Press the ***CLOSE*** button to close the setting sub-screen.

As soon as the "Start Treatment" button is pressed to start the treatment, the Hemoscan function starts the blood volume measurements. During the monitoring phase, the Hemoscan Settings sub-screen will display the following parameters:

The ***Blood Volume*** value box shows the latest measurement value of the blood volume. This value will also be displayed on the *Overview* screen.

The ***Hemoscan Graph*** represents the blood volume values and the alarm limit (red line) in a graphical form. If a measurement fails, a gap will be displayed into the graph.

The "00:00" point on the horizontal axis represents the start treatment time (when the "Start Treatment" button is pressed).

The last blood volume measurement is taken when the "Stop Treatment" button is pressed and confirmed.

NOTE

If the Hemoscan function is enabled in the Service menu but it has not been activated before pressing the “Start Treatment” button, the function will be kept deactivated and it will be no more possible to activate it for the current treatment.

NOTE

If it is necessary to infuse medicines to the patient during the treatment, use the Arterial Infusion lines or the blue injection port on the Venous Patient Line.
Injecting medicins through the red port on the Arterial Patient Line could cause the blood volume measurement to be inaccurate.

10.2.5 Deactivate the Hemoscan function

The Hemoscan function will be automatically deactivated in the following cases:

- when starting a “Change Circuit” procedure: the data collected will be still available on the Hemoscan Settings sub-screen
- when unloading the blood cassette during a treatment: the data collected will be still available on the Hemoscan Settings sub-screen
- after a “Fast Recovery” procedure: the data collected will no longer be available

10.2.5.1 Before connecting a patient

To deactivate the Hemoscan function, press the activated “Hemoscan” button:

- The Hemoscan function is deactivated;
- The Hemoscan icon is hidden on the *Overview* screen;
- The “Hemoscan” action indicator on the “Activated Functions” list on the *Prescription* screen switches to grey.

It is possible to reactivate the Hemoscan function pressing the “Hemoscan” action button before pressing the “Start Treatment” button. Otherwise, the treatment will continue without the Hemoscan function.

10.2.5.2 During a treatment

It is possible to deactivate the Hemoscan function during a treatment, proceeding as follows:

1. Press the "Hemoscan" button:

   • The following confirmation window is displayed:

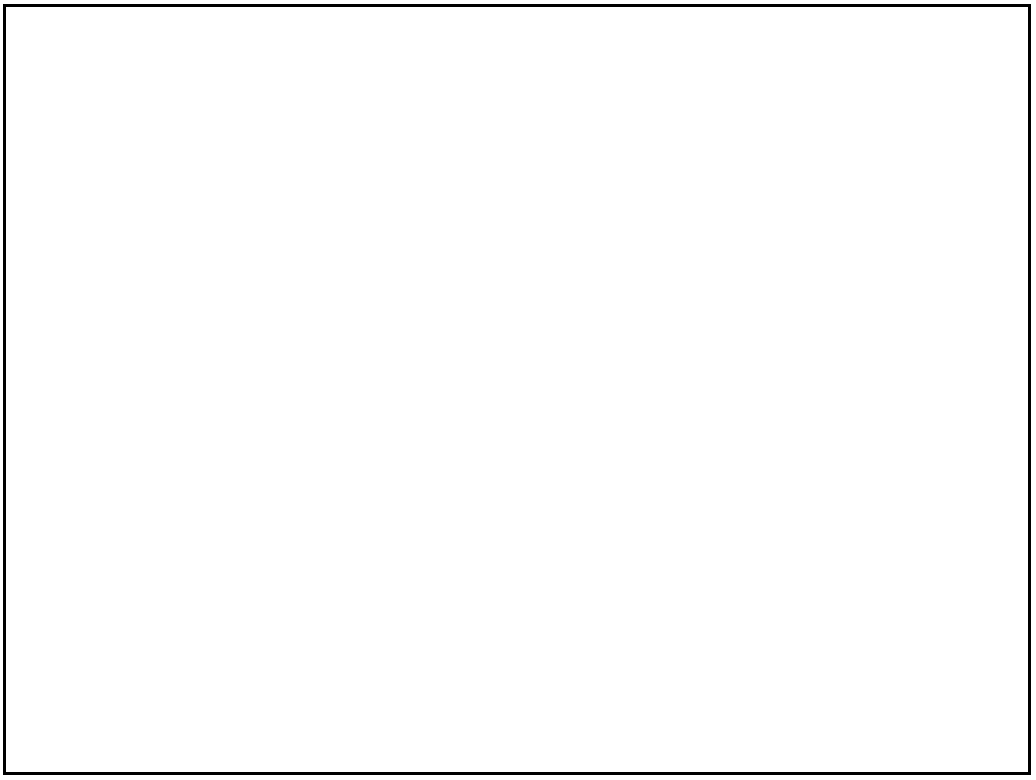


Figure 10-2. Hemoscan confirmation window

2. Press the ***CONFIRM*** button to confirm function deactivation:

   • The Hemoscan function is deactivated;

   • The Hemoscan icon is hidden on the *Overview* screen;

   • The "Hemoscan" action indicator on the "Activated Functions" list on the *Prescription* switches to grey.

   • The "Hemoscan" button on the Hemoscan Settings sub-screen is no more available;

   • The Hemoscan graph is available but it is no more updated;

   • The treatment continues without Hemoscan function.

3. Press the ***CLOSE*** button to close the settings sub-screen.

As suggested by the confirmation text, it is not possible to activate again a Hemoscan function if it has been deactivated during a dialysis treatment.

NOTE

When the Hemocontrol function is activated the “Hemoscan” button is not available and the Hemoscan function can not be deactivated.

NOTE

In order to deactivate the Hemoscan function when the Hemocontrol function is activated, deactivate the Hemocontrol function first.

10.2.6 Monitoring

After the “Start Treatment” button has been pressed, the Hemoscan system will acquire an initial value of hemoglobin concentration (HGB_0) used as reference value for the relative blood volume change measurements, as soon as the following conditions are satisfied:

- The autocalibration and self-test have been successfully accomplished;
- A blood cassette has been successfully loaded;
- A Hemoscan cuvette is inserted into the proper Sensor Bar housing;
- The Sensor Bar door is securely closed;
- Blood is detected and its flow rate is greater than 180 ml/min.

The blood volume changes during the treatment will be related to the reference value. If the patient’s blood volume decreases this will result in a negative percentage. Conversely an increased blood volume will be shown as a positive percentage.

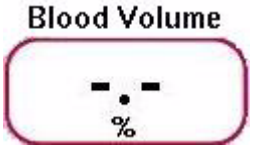
The calculation of the reference value lasts about 4 minutes. After this phase the computation of the Blood Volume (BV) starts.

NOTE

- During the “Pause Treatment” procedure the Hemoscan function is paused and then reactivated when the treatment is resumed.
- If the Hemoscan function was enabled, the blood volume measurements will restart when pressing the “Resume Treatment” button.

10.3 Blood Volume Measurement Alarms

In the table below different incorrect conditions for blood volume and HGB signals are listed which can occur during a dialysis treatment, together with the possible causes and solutions:

Icon	Problem	Possible solutions
	HGB out of the monitoring range	• Verify the Lab value of the patient's hemoglobin concentration. If the value falls within the monitoring range [6-16] g/dl deactivate the Hemoscan function.
	Sensor Bar Door open	• Close the Sensor Bar door.
	Measuring conditions not satisfied	• Ensure that the Hemoscan cuvette is correctly inserted in the Sensor Bar housing. • Set the blood flow rate higher than 180 ml/min. • Deactivate the Hemoscan function.
	BV% out of the monitoring range	• Verify the patient's blood values. • Ensure that the Hemoscan cuvette is correctly inserted in the Sensor Bar housing. • Deactivate the Hemoscan function.

Chapter 11: Hemocontrol™ Biofeedback System

11.1 General Description

The Hemocontrol™ Biofeedback System allows to automatically profile the following prescription parameters according to specific patient prescription and to the relative Blood Volume changes measured by the Hemoscan system:

- Dialysis Fluid sodium concentration
- Ultrafiltration Flow Rate (UF Rate), i.e. weight loss rate

It extends the medical prescription of the dialysis session to a significant parameter of the patient state, i.e. Blood Volume.

The change in Blood Volume is a reliable representation of the difference between the water removed by ultrafiltration and the capability of the body to refill the vascular compartment, usually called Plasma Refilling Rate.[1]

Unlike a conventional-type dialysis where all the treatment parameters are constant (as in the case of standard dialysis), the Hemocontrol performs a modulation of Weight Loss Rate and Dialysis Fluid sodium concentration, not only depending on the medical prescription but also depending on the state of the patient.

Besides, continuous modulation realizes the best possible compromise between the above targets and allows compensations for any sudden variations in Blood Volume, thus considerably reducing the hypotensive phenomena linked to hypovolemia.

To achieve these targets, Hemocontrol carries out the following steps:

- Offers the possibility to set the UF Volume and Equivalent dialysate sodium concentration at the end of dialysis (EqNa), the desired value of Blood Volume change (BV%) at the end of dialysis;
- Traces a curve for each parameter (UF Volume, BV%, EqNa) which leads to the final values set by the operator;
- Uses the Blood Volume change measurement originating from Hemoscan and the UF Volume and EqNa values calculated by the machine;
- Realizes continuous and automatic modulation of UF Rate and dialysis fluid sodium concentration (Na);
- Warns the operator if achievement of the prefixed targets should be not possible.

Because of the dynamic management of the actual UF Rate and Na values, the safety criteria are extended through the introduction of a safety band as an alternative to the characteristic fixed values of standard dialysis.

1. W.H. Horl, K.M. Koch, Robert M. Lindsay, C. Ronco, J.F. Winchester. Replacement of renal function by dialysis. 5th Revised Edition.
   E.J. Topol, R.M. Califf. Textbook of Cardiovascular Medicine. 3rd Edition.

11.2 Treatment Modes

It is possible to use the Hemocontrol function only with the following treatments/ functions:

- Hemodialysis (HD-DN Treatment) using BiCart or BiCart Select
- HD-DNDP Treatment
- Diascan
- Hemoscan

It is not possible to use the Hemocontrol function with the following treatments/ functions:

- Hemodiafiltration (HDF Post Treatment)
- AFB K
- Isolated UF
- HD-SN Treatment

For proper functioning of the Hemocontrol system it is necessary that the Hemoscan Monitoring System is enabled and proper functioning on the machine. For further details on this function refer to the "Chapter 10: Hemoscan™ Monitoring System" of this Operator's Manual.

NOTE

When the Hemocontrol function is activated, the Hemoscan function is automatically activated.

Following the operational procedures necessary to activate/deactivate the Hemocontrol system.

11.2.1 Preset

To make the Hemocontrol system available during the dialysis treatment, the proper service configuration has to be set up in the Service menu.

The Hemocontrol function is available in the treatment views and can be activated if both the following configurations are set:

- The "Hemoscan" option of the "Installed Features" list is "YES";
- The "Hemocontrol Use" option of the "Installed Features" list is "YES".

11.3 Hemocontrol Function Use

After being enabled in Service menu, the Hemocontrol function can be activated/ deactivated in the Treatment environment from the Hemocontrol Settings sub-screen.

Follow the instruction in the sections below to activate Hemocontrol function.

11.3.1 Set the Distribution Volume parameter

Before activating the Hemocontrol function set the Distribution Volume of the patient proceeding as follows:

1. Press the “Distrib Vol Settings” button on the *Prescription* screen: the Distribution Volume Settings sub-screen opens:

2. On this sub-screen press the “Distribution Volume Entry” button: a Selectpad opens:

Figure 11-1. Distribution Volume Settings sub-screen

The Hemocontrol Biofeedback System provides the following formulas to calculate the patient Distribution Volume.

Table 1: Distribution Volume Formulas

Distribution Volume Entry	**Patient parameters displayed**
Watson	Patient Height, Patient Dry Weight, Patient Gender, Patient Age
Hume	Patient Height, Patient Dry Weight, Patient Gender
Mellits-Cheek	Patient Height, Patient Dry Weight, Patient Gender
Percentage	Patient Dry Weight, Percent. Distrib. Vol.
No Entry	/

3. On the Selectpad select the desired formula and press the ***CONFIRM*** button to confirm the choice:

   • The Selectpad closes;

   • The Distribution Volume Settings sub-screen is updated with the parameters related to the selected formula:

4. Set the patient's parameter values by pressing the related buttons: a Keypad opens.

Refer to the table below to enter the patient's parameter values.

Table 2: Distribution Volume Parameters

Parameter	Range	Incr.	Default value	Unit of measure
Patient Gender	M/F	N.A.	M	--
Patient Age	15-150	1	45	years
Patient Height	1-250	1	165	cm
Patient Dry Weight	25-250	1	65	kg
Percent. Distrib. Vol.	20-80	1	55	%

5. On the keypad enter the parameter value then press the ***CONFIRM*** button:
   - The “Distribution Volume” parameter is automatically calculated by the machine and is displayed on the Distribution Volume Settings sub-screen.

NOTE

If the “No Entry” option is selected as “Distribution Volume Entry“, the “Distribution Volume” value is not calculated.

NOTE

It is not possible to confirm a “Distribution Volume” value which is greater than the “Patient Dry Weight” value.

NOTE

If the Hemocontrol function has been activated, the Distribution Volume Entry can not be changed after the “Start Treatment” button has been pressed.

6. Press the ***CLOSE*** button to close the setting sub-screen.

NOTE

If the calculated “Distribution Volume” is higher than the “Patient Dry Weight”, the “--” value is displayed in the “Distribution Volume” button.
In this case, change the formula related parameters to set a valid value

11.3.2 Confirm Mandatory Parameters

Before activating the Hemocontrol function, the "Treatment Time" and the "UF Volume" parameters must be set and confirmed on the *Prescription* screen. The confirmation of these parameters is a mandatory action:

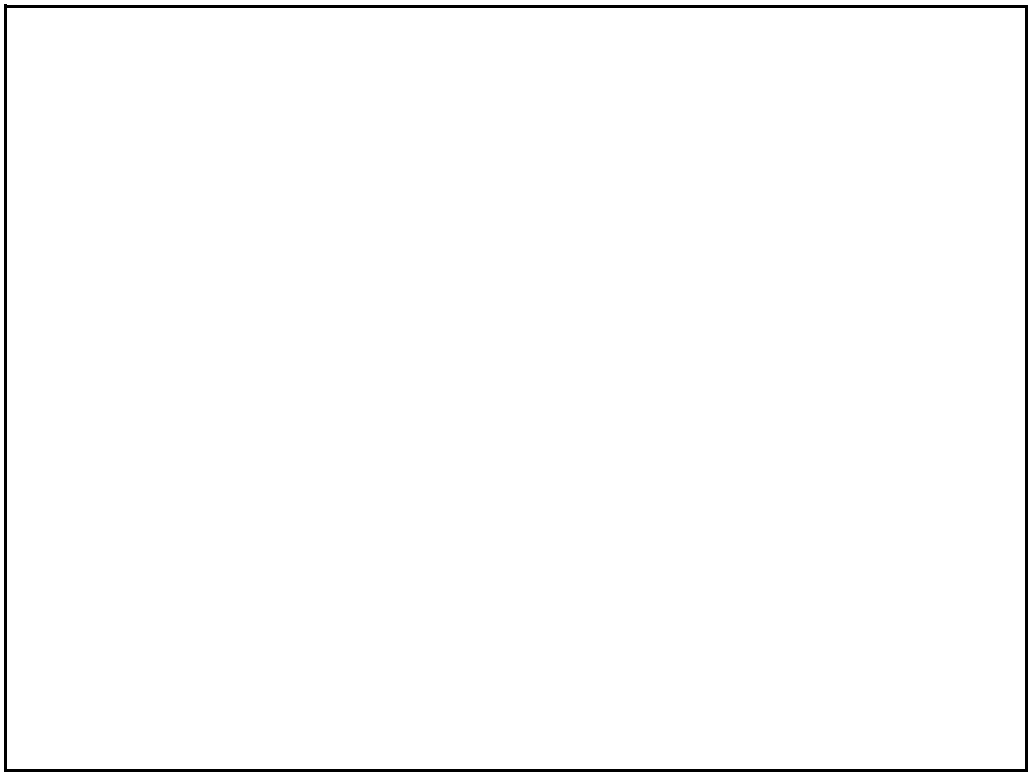


Figure 11-2. Prescription Screen - Mandatory Parameters

To confirm the parameters proceed as follows:

1. Press the "Treatment Time" parameter on the "Parameter Value" list: a Keypad opens.

2. Set the "Treatment Time" parameter value on the keypad then press the ***CONFIRM*** button: the Keypad closes.

3. Press the "UF Volume" parameter on the "Parameter Value" list: a Keypad opens.

4. Set the "UF Volume" parameter value on the Keypad then press the ***CONFIRM*** button: the keypad closes.

11.3.3 Set the Hemocontrol parameters

To set the Hemocontrol parameters open the Hemocontrol Settings sub-screen by pressing the “Hemocontrol Settings” button on the *Fluid* screen or by selecting the “Hemocontrol” option in the “Activated Functions” list on the *Prescription* screen. The following sub-screen opens:

Figure 11-3. Hemocontrol Settings sub-screen

NOTE

The “Hemocontrol” action button is not displayed in the Hemocontrol Settings sub-screen if a “Distribution Volume Entry” has not be set and if the mandatory parameters have not been confirmed.

Table 3: Hemocontrol Parameters

Parameter	Description	Range	Unit of measure
Final BV	Defines the Blood Volume change value to be reached at the end of dialysis. (See the formula below).	• -30.0 to 0.0	%
UF Volume	Defines the total weight loss to be reached at the end of dialysis.	• 0.0 to 24.00	L

Parameter	Description	Range	Unit of measure
Equivalent Na	Defines the final equivalent dialysis fluid sodium concentration. The Equivalent Na value should be equal to the Sodium value which would be set in a standard dialysis. The Equivalent Na actual range depends on the "Na Limits" parameter setting.	• 135 to 150	mmol/L
Forecast BV	Defines the forecast value for the Final BV parameter at the end of dialysis	/	%
Forecast UF vol	Defines the forecast value for the UF Volume parameter at the end of dialysis	/	L
Forecast Na	Defines the forecast value for the Equivalent Na parameter at the end of the dialysis	/	mmol/L
Final BV/UF vol	Defines the ratio between the Final Blood Volume and the UF Volume.	• - 50.0 to 0.0	%/L
Max Initial UF	Defines the maximum value of UF Rate that can be modulated by the Hemocontrol. (See the formula below)	• 0.12 to 3.00	L/h
Na Limits	Defines the band in which the Hemocontrol can modulate the sodium concentration in dialysis fluid. Only bands compatible with the current "Equivalent Na" parameter setting are available for selection. (See the graphs below)	• Narrow (-5 to +10) • Standard (-5 to +15) • Large (-7 to +18)	mmol/L
Max UF Coeff	Defines the coefficient to calculate the "Max Initial UF" parameter from the "UF Volume" parameter.	• 1.2 to 2.0	N.A
Stand-by	Allows to pause the Hemocontrol modulation for 5 minutes. After this time has elapsed, the modulation is automatically resumed.	/	/

11.3.3.1 Final BV formula

The formula relative to the “Final BV” parameter follows:

$$\text{Final BV} = \textit{Final (BV/UF)} \times \text{UF Volume}$$

11.3.3.2 Max Initial UF formula and UF rate band

The formula relative to the “Max Initial UF” parameter follows:

$$\text{Max Initial UF} = \text{Max UF Coeff} \times \left(\frac{UFVolume}{TreatmentTime} \right)$$

The Hemocontrol function automatically modulates the “UF Rate” parameter within the UF rate band.

Refer to the graph below for a detailed description of the maximum UF Rate band.

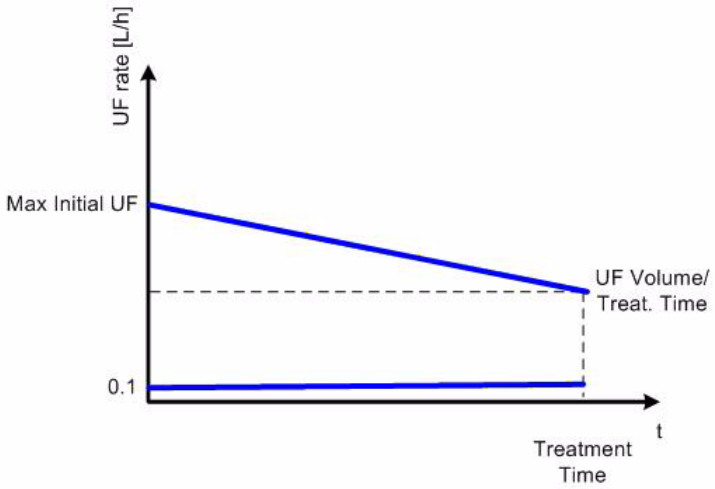


Figure 11-4. UF rate band

11.3.3.3 Sodium bands

The Hemocontrol function automatically modulates the “Sodium” parameter within the Sodium bands.

NOTE

The modulation of the dialysis fluid sodium concentration within the Sodium bands is further restricted in order to never exceed the conductivity range: 13.4 to 15.6 mS/cm.

Refer to the graphs below for detailed description of the Sodium bands.

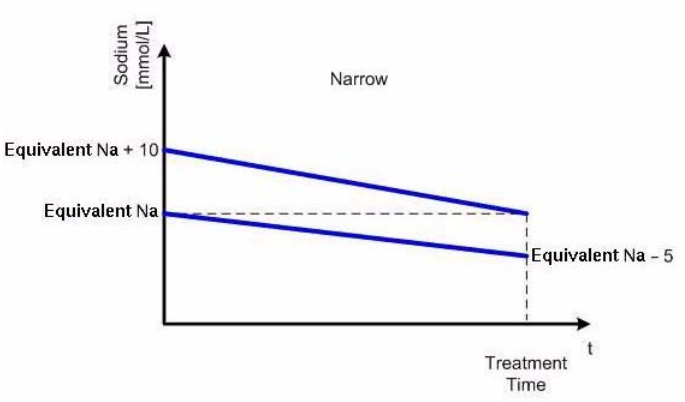


Figure 11-5. Sodium Narrow Band

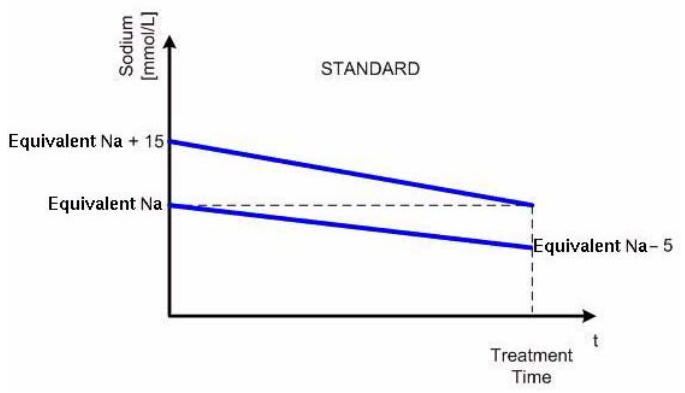


Figure 11-6. Sodium Standard Band

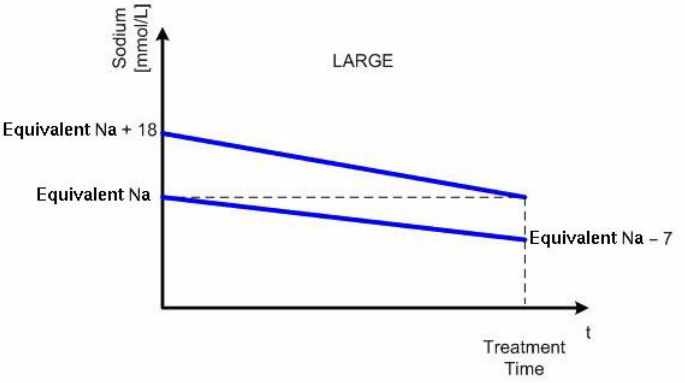


Figure 11-7. Sodium Large Band

Some Hemocontrol parameters can be modified before the "Start Treatment" button has been pressed but not after the start of the treatment. On the contrary, some parameters can not be modified before the start of the treatment but only after the "Start Treatment" button has been pressed.

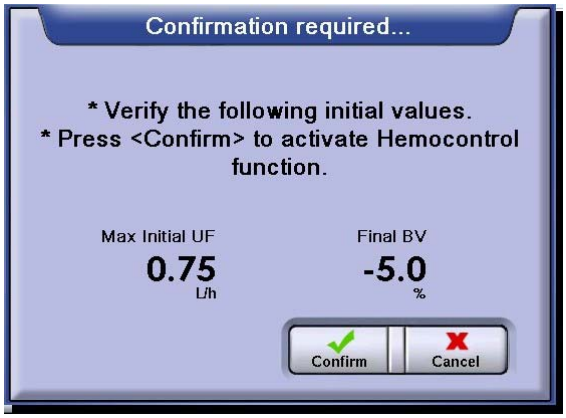
The following table lists the parameters that can be modified before and after the start of the treatment, and the parameters that are automatically calculated by the machine:

Parameter	Before treatment start	After treatment start
Settable by the operator	• Final BV/UF vol • Max UF Coeff	• Final BV • Max Initial UF
Automatically calculated by the machine	• Final BV • Max Initial UF	• Final BV/UF vol • Max UF Coeff

11.3.4 Activate the Hemocontrol function

After the “Distribution Volume” formula, the mandatory parameters and the Hemocontrol parameters have been set, proceed as follows:

1. In the Hemocontrol Settings sub-screen, press the “Hemocontrol” button to activate the Hemocontrol function. A *Confirm* window opens:



   - The calculated “Max Initial UF” and “Final BV” values are displayed on the *Confirm* window.

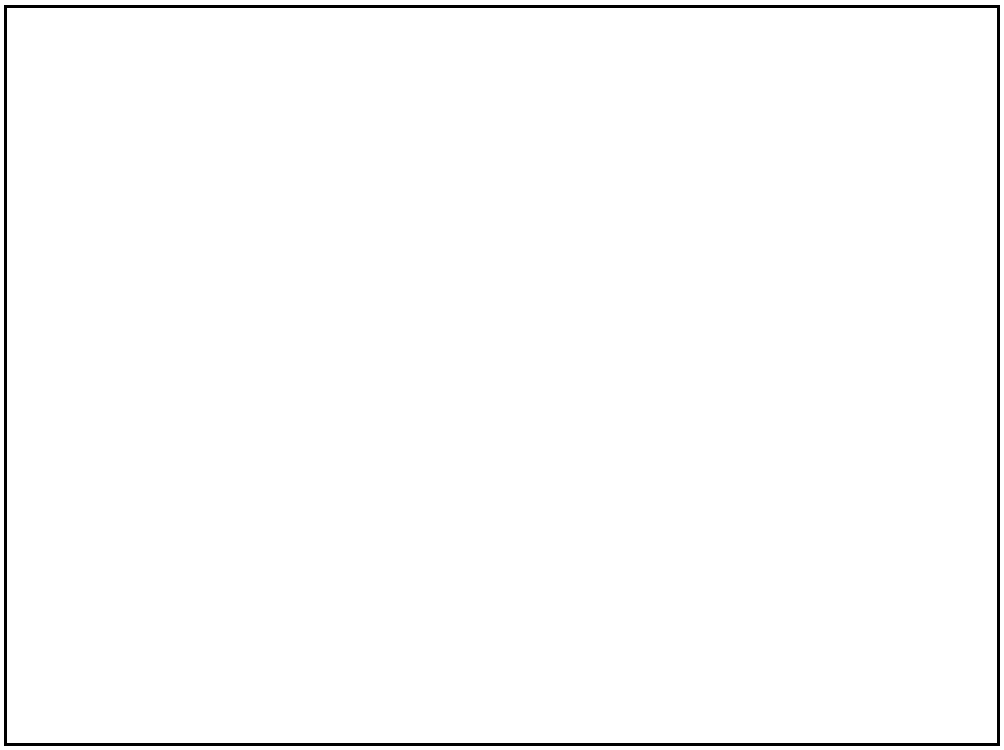
2. Check the parameters on the *Confirm* window and press the ***CONFIRM*** button to confirm Hemocontrol function activation:

   - The Hemocontrol action indicator switches to green;
   - The Hemoscan function is automatically activated and can not be manually deactivated by the operator;
   - It is no more possible to change the “Sodium” parameter on the Fluid Settings sub-screen.

NOTE

After Hemocontrol function activation, as soon as the “UF Volume” parameter is entered, the “Max Initial UF” and the “Final BV” values are automatically calculated by the machine.

• The following *Overview* Screen is displayed:



NOTE

It is not possible to activate the Hemocontrol function after the "Start Treatment" button has been pressed.

NOTE

The Hemocontrol function can be activated only if the Hemoscan function has been enabled in Service menu.

After the Hemocontrol function has been activated:

• All the Hemocontrol-related parameters are marked with a dedicated icon: 

On the *Overview* screen:

• The Hemoscan icon is dispalyed on the left side of the screen;

• The Hemocontrol icon is displayed on the right side of the screen;

• The Hemocontrol chart panel is displayed on the left side of the screen: 

11.3.5 Modulation

As soon as the “Start Treatment” button is pressed and confirmed, the Hemocontrol function starts setting the “UF Rate” and “Sodium” values.

The Hemocontrol Settings sub-screen is updated as follows:

Figure 11-8. Hemocontrol Settings sub-screen - Modulation

- The “Stand-by” button becomes available;
- The “Final BV” and the “Max Initial UF” parameters can be set;
- The “Final BV/UF vol” and the “Max UF Coeff” parameters become read-only values;
- The machine starts updating the “Acc UF” and “BV%” graphs. Refer to the “11.4 Hemocontrol Graphs” section of this chapter.

After 45’ minutes from the pressure of the “Start Treatment” button:

- The machine starts updating the “Diff. BV/UF” graph. Refer to the “11.4 Hemocontrol Graphs” section of this chapter.
- The “Forecast BV”, “Forecast UF vol” and the “Forecast Na” parameter values are updated for the first time.
- The machine starts updating the Hemocontrol chart panel on the *Overview* screen.
- The machine activates the Hemocontrol-related Smartscan/ Information messages.

NOTE

When the relative Blood Volume change measure is not available, the Hemocontrol algorithm is automatically paused.

11.3.6 Stand-by

The "Stand-by" button can be used to pause the modulation of the "UF Rate" and "Sodium" parameters performed by the Hemocontrol function.

WARNING

In case a single bolus of medicines has to be injected through the red injection port on the Arterial Patient Line, the Hemocontrol function must be set in Stand-by mode by pressing the related button before performing injection.
Indeed medicines injections may result in incorrect sodium concentration and/or ultrafiltration profiling driven by the Hemocontrol function.

NOTE

When the Hemocontrol function is paused ("Stand-by" button activated or BV% not available), the ultrafiltration flow rate and the dialysis fluid sodium concentration are automatically set by the system in order to achieve the "UF Volume" and the "Equivalent Na" targets.
The target values can be achieved presuming that the ultrafiltration flow rate and the dialysis fluid sodium concentration values set by the system are maintained constant until the end of the treatment.

11.4 Hemocontrol Graphs

11.4.1 Fluid Screen

On the *Fluid* screen, the following graph is displayed showing the following values:

- UF Rate
- Sodium (Na)

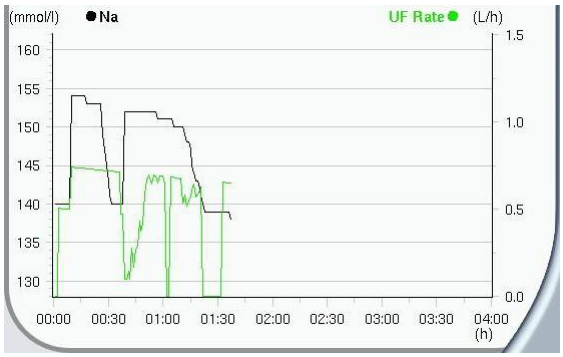


Figure 11-9. Hemocontrol - Fluid Screen

11.4.2 Hemocontrol Settings sub-screen

On the Hemocontrol Settings sub-screen, the following graphs are displayed:

- Acc UF
- BV%
- Diff BV/UF

11.4.2.1 Acc UF

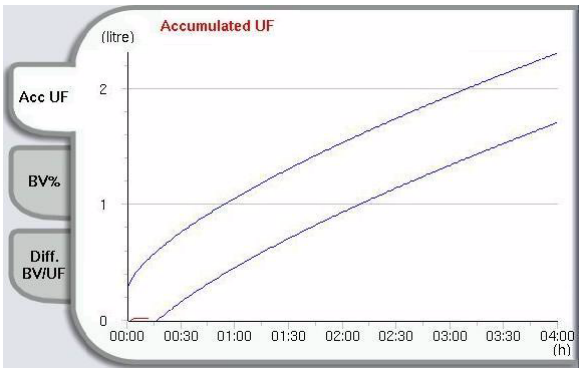


Figure 11-10. Hemocontrol - Acc UF Graph

This graph shows:

- The allowed band for the UF Volume (blue lines).
  The upper limit band is defined by adding +0.3L to the curve traced by the Hemocontrol system according to parameters set by the operator. The lower limit band is defined by subtracting -0.3L from the curve traced by the Hemocontrol system in relation to the parameters set by the operator.

- During treatment, the current accumulated UF Volume will be displayed (red line). If this value is out of the allowed band the related Information Message will be triggered. The Information Message is not triggered during the first 45' minutes of the treatment.

11.4.2.2 BV%

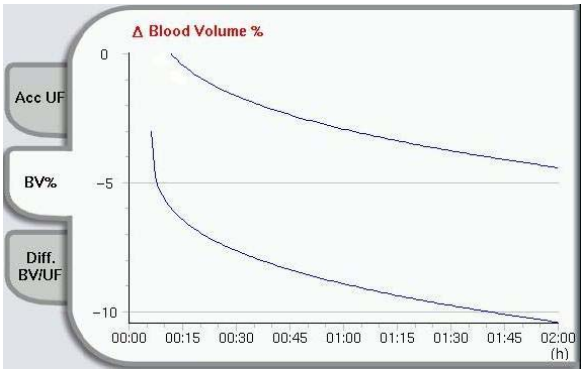


Figure 11-11. Hemocontrol - BV% Graph

The "BV%" graph is plot as soon as the information on the Blood Volume change is available. Refer to the Hemoscan Chapter of this Operator's Manual.

This graph shows:

- The allowed band for the BV% (blue lines).
  The upper limit band is defined by adding +3.0% to the curve traced by the Hemocontrol system according to parameters set by the operator. The lower limit band is defined by subtracting -3.0% from the curve traced by the Hemocontrol system in relation to the parameters set by the operator.

- During treatment, the current BV% will be displayed (red line). If this value is out of the allowed band the related Information Message will be triggered. The Information Message is not triggered during the first 45' minutes of the treatment.

11.4.2.3 Diff BV/UF

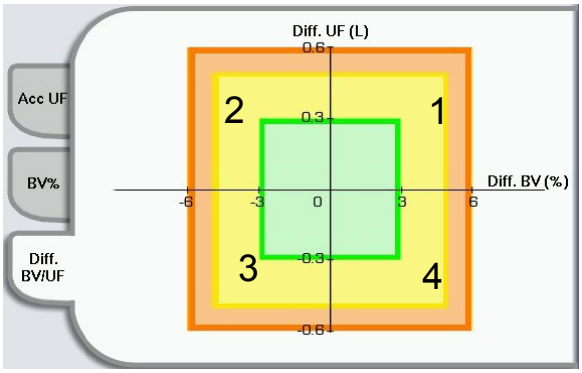


Figure 11-12. Hemocontrol - Diff BV/UF Graph

This graph shows:

Diff. BV%: The deviation of the current values for the Blood Volume change with respect to the current target calculated by the Hemocontrol algorithm.

Diff. UF: The deviation of the current values for the accumulated UF Volume with respect to the current target calculated by the Hemocontrol algorithm.

The update of the “Diff. BV/UF” graph will start after 45 minutes the “Start Treatment” button has been pressed.

On the “Diff. BV/UF” graph, the state indicator ● represents the current status compared with the expected response. When displayed outside the green area, tolerance limits are exceeded and the prescription may not be reached at the end of the treatment. In this situation, the Artis Dialysis System warns the operator by displaying an Information Message.

Refer to the table below for actions to be taken in case the state indicator is outside the green area.

NOTE

A prescription adjustement shall be considered only after a careful assessment of patient’s status and blood pressure.

Table 4: Diff. BV/UF Graph

Quadrant	Meaning	Action
Quadrant 1	A reduction in BV% has occurred, lower than expected and thus a higher Accumulated UF volume (weight loss) is reached. If the state indicator is stable in this quadrant, the "Hemocontrol: Refilling rate better than expected (#635)" Information Message is triggered. The risk of hyperhydration episodes is higher when the state indicator moves towards the orange area of this quadrant.	If this state persists, the prescription cannot be reached: set a greater (absolute) Final BV value and/or a greater UF Volume value, according to the patient's blood pressure.
Quadrant 2	This corresponds to a condition where the BV% reduction and the Accumulated UF volume are higher than expected. If the state indicator is stable in this quadrant, the "Hemocontrol: Unusual Status (#636)" Information Message is triggered. The state indicator could only be temporary in this quadrant.	If the state persists in this quadrant, deactivate the Hemocontrol function.
Quadrant 3	A reduction in BV% has occurred, higher than expected and thus a lower Accumulated UF Volume is reached. If the state indicator is stable in this quadrant, the "Hemocontrol: Refilling rate lower than expected (#637)" Information Message is triggered. The risk of hypotensive episodes is higher when the state indicator moves towards the orange area of this quadrant.	If this state persists, the prescription cannot be reached: set a lower Final BV value and/or a lower UF Volume value, according to the patient's blood pressure.
Quadrant 4	Both the reduction in BV% and the Accumulated UF Volume are lower than expected. If the upper limit of the "Max Initial UF" parameter is too low, the state indicator is stable in this quadrant. If the state indicator is stable in this quadrant, the "Hemocontrol: UF Volume may not be reached (#638)" Information Message is triggered.	If the state persists in this quadrant, set a greater "Max Initial UF" parameter value, according to the patient's blood pressure.

NOTE

When the Hemocontrol function is paused ("Stand-by" button activated or BV% not available), the forecast values and the values displayed on the graph on the Hemocontrol Settings sub-screen could be inaccurate.

NOTE

It takes up to 30 minutes to see the full effect of a Hemocontrol prescription adjustment.

11.5 Hemocontrol Chart Panel

The Hemocontrol chart panel is displayed on the *Overview* screen.

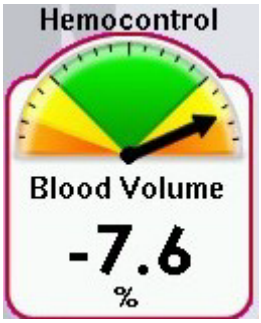


Figure 11-13. Hemocontrol - Chart Panel

The chart panel shows:

- A simplified representation of the “Diff. BV/UF” graph, where the state indicator is represented by a black arrow;
- The current Blood Volume value.

If the black arrow is within the green area:

- The treatment is proceeding according to the Hemocontrol prescription;
- The Accumulated UF Volume and the BV% values are within the allowed bands.

If the black arrow is within the yellow or the orange area:

- The Hemocontrol prescription may not be reached at the end of the treatment time;
- The Accumulated UF Volume and/or the BV% values are outside the allowed bands;
- Information Message related to the Hemocontrol function will be triggered. In this case the operator has to monitor the situation and to evaluate whether to wait for the patient to come back within the green area or to adjust the Hemocontrol prescription.

NOTE

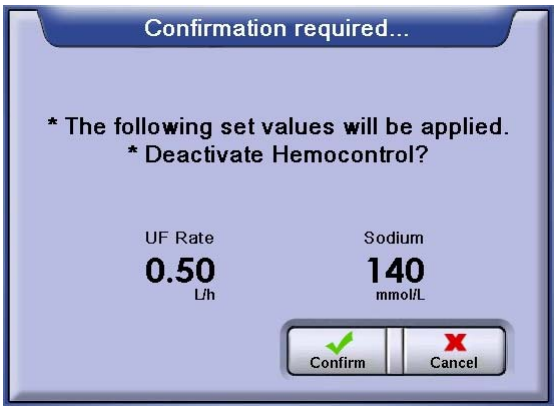
When the black arrow on the Hemocontrol chart panel goes outside the green area, enter the Hemocontrol Settings sub-screen and check the “Diff. BV/UF” graph.

11.6 Deactivate the Hemocontrol function

11.6.1 Before starting the treatment

To deactivate the Hemocontrol function before pressing the "Start Treatment" button, proceed as follows:

1. Press the "Hemocontrol" button on the Hemocontrol Settings sub-screen. A *Confirm* window opens:



2. Press the ***CONFIRM*** button on the *Confirm* window to deactivate the function:

   - The "UF Rate" and "Sodium" parameters are set to the values displayed on the *Confirm* window;
   - The Hemocontrol function is deactivated;
   - The Hemocontrol icon is hidden on the *Overview* screen;
   - The "Hemocontrol" action indicator on the "Activated Functions" list on the *Prescription* screen switches to grey.

NOTE

In case of Hemoscan autocalibration failure it is recommended to deactivate the Hemoscan and the Hemocontrol functions before the patient connection phase.

It is possible to activate the Hemocontrol function again pressing the "Hemocontrol" button on the Hemocontrol Settings sub-screen anytime before starting the treatment. Otherwise, the treatment will start without the Hemocontrol function.

11.6.2 During a treatment

To deactivate the Hemocontrol function during a treatment, proceed as follows:

1. Press the “Hemocontrol” button on the Hemocontrol Settings sub-screen. A *Confirm* window opens:

2. Press the ***CONFIRM*** button on the *Confirm* window to deactivate the function:

   • The “UF Rate” and “Sodium” parameters are set to the values displayed on the *Confirm* window;

   • The Hemocontrol function is deactivated.

   • As indicated in the *Confirm* window, if the Hemocontrol function is deactivated during a treatment it will be no more possible to activate it again for the same treatment.

NOTE

In case of Hemoscan autocalibration failure it is recommended to deactivate the Hemoscan and the Hemocontrol functions before the patient connection phase.

NOTE

In order to deactivate the Hemoscan function when the Hemocontrol function is activated, deactivate the Hemocontrol function first.

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Chapter 12: Diascan™ Monitoring System

12.1 General Description

The Diascan™ Monitoring System allows real time, non-invasive and automatic monitoring of patient's and dialyzer's parameters that can be computed from conductivity measurements on the dialysis fluid side.

The clinical purpose of this monitoring is to provide a measure of dialysis efficacy for quality control purposes.

The basic principle of this monitoring system is to periodically measure, during the dialysis treatment, the dialysis fluid conductivity at the dialyzer outlet, following an adjustment of the inlet dialysis fluid conductivity. During the measurement, the inlet conductivity is automatically adjusted by 1.0 mS/cm for 2 minutes. As a result of this adjustment in conductivity, a mathematical model computes several parameters relevant to the dialysis process:

- The ***IONIC CLEARANCE***: average Clearance of ionized substances; this value is strongly correlated to Urea Clearance. This is a relevant parameter of the clearance actually obtained from the patient, since it includes effects of fistula recirculation and ultrafiltration rate on solute removal during dialysis.

- The ***PLASMA CONDUCTIVITY***: an expression of the effective plasma ionic concentration. This is a factor that governs the intra/extra cellular fluid shifts.

- The ***PLASMA SODIUM CONCENTRATION***: estimated sodium concentration in plasma, calculated by the machine from the Plasma Conductivity value.

Three other parameters derive from the IONIC CLEARANCE:

- The ***DEPURATED VOLUME***: volume of body water completely cleared of solute during the treatment, with reference to small molecular weight solutes. The computation is based on repeated Clearance measures and on the assessment of the effective dialysis time.

- The ***IONIC KT/V***: this value is computed by dividing the "Depurated Volume" by the urea Distribution Volume ("Distribution Volume"), which is automatically calculated by machine after selecting the desired formula to calculate the patient distribution volume. The "Distribution Volume Entry" and related parameters are to be established by the physician. The Ionic Kt/V allows the physician to understand if the dialysis dose achieved (which is influenced by different factors such as dialysis fluid flow and blood flow, type of dialyzer and time) is adequate for the patient.

- The ***IONIC MASS BALANCE***: this estimation is based on the continuous dialysis fluid outlet conductivity measurement, for each patient. It correlates to the sodium mass balance.

⚠WARNING

The Ionic Kt/V computation is based on the Distribution Volume value. The machine automatically calculates the patient's distribution volume if a value different from "No Entry" has been selected for the Distribution formula parameter in the Distribution Volume Settings sub-screen. The Distribution formula and related parameters must be entered and confirmed by the operator. It is the operator's responsibility to assess the clinical validity of these parameters.

NOTE

The Plasma Conductivity, Plasma Sodium Concentration and Ionic Mass Balance values are calculated through mathematical models: this value is not measured directly on the patient's blood by the machine. The "Plasma Conduct." value displayed during treatment expresses an estimation of the patient Plasma Conductivity value with the purpose of allowing a qualitative evaluation of the plasma ionic concentration.

⚠WARNING

The physician is responsible for the clinical adequancy of the parameters set for the correct dialysis dose, based upon the Diascan measurements. Do not use the Diascan system as the only source of clinical information to initiate therapeutic or pharmacologic actions (e.g. change in blood flow rate, dialysis fluid flow rate, dialyzer, treatment time, etc...).

The "Ionic Mass Balance" and "Plasma Sodium Conc." values are only displayed on the *Report* screen.

12.1.1 Diascan function specifications

In the following table the Diascan system specifications are reported:

Parameter	***Range***	***Accuracy***	***Resolution***
Ionic Dialysance	0 to 500 ml/min	±7 ml/min[a]	1 ml/min
Plasma Sodium Conc.	130 to 160 mmol/l	±3 mmol/l[a]	1 mmol/l
Plasma Conduct.	13 to 16 mS/cm	± 0.05 mS/cm	0.01 mS/cm
Ionic Mass Balance	-800 to 800 mmol (HD-DN)[b]	±25 mmol[a]	1 mmol
Depurated Volume	0 to 200 litres	±2 L[a]	0.1 L
Kt/V	0 to 3	-	0.01

a. Standard Error for a 4 hour dialysis.
b. Positive values correspond to solutes removed from the patient.

Accuracy is guaranteed in all the treatment modes for blood flows 200 to 500 ml/min and dialysis fluid flows 300 to 800 ml/min, except in HD-SN Treatment where accuracy is not guaranteed.

The conductivity of the dialysis fluid can be measured by the Diascan system only if the following parameters fall in the indicated ranges:

Parameter	**Range**
Temperature	30-45 °C
Conductivity	13 to 16 mS/cm (0.05 mS/cm)

12.2 Procedures

It is possible to use the Diascan function with HD-DN, HD-DNDP and HDF Post Treatments, using BiCart or BiCart Select, and with AFB K Treatments (K Constant mode). The Diascan function can be also used when performing the HD-SN Treatment but the accuracy of the Diascan measurement is not guaranteed.
The Diascan function is compatible with the following functions:

- Isolated UF
- Hemoscan
- Hemocontrol

If both the Hemocontrol and the Diascan functions are activated, the Sodium profiling will be frozen when the inlet conductivity is adjusted by Diascan during the measurement.

12.2.1 Preset

To make the Diascan system available during the dialysis treatment, the proper service configuration has to be set up:

- The "Diascan Use" option of the "Installed Features" list is "YES": the Diascan function is available in the treatment views and can be activated.
- The "Diascan Use" option is "NO": the Diascan related buttons are not available in the treatment views and the Diascan function can not be activated.

In the Service menu it is also possible:

- to set the "Interval" parameter (15 or 30 minutes) which defines the time interval between two subsequent Diascan measurements. Its default value is 15 minutes;
- to set the default value of "Target Kt/V" parameter

12.2.2 Initial Auto-Calibration

The Diascan Monitoring System performs an initial Auto-Calibration process to verify the proper functioning of the conductivity measuring system. Failure of the procedure will not affect the dialysis treatment.

The initial Auto-Calibration is performed only once a day before starting the first dialysis treatment or each time a complete sequence of Function Checks is performed due to the “Data Correctness Check Failure (#630)” alarm. For further details refer to the “1.6 Function Checks” section in the "Chapter 1: General Description” of this Operator’s Manual.

When the Diascan Auto-Calibration is in progress, the “Function Check in progress...” operator message is displayed.

The Diascan Auto-Calibration is interrupted and restarted when:

- an alarm is triggered by the machine;
- the operator loads/unloads a Blood Tubing System;
- a special procedure is performed.

To avoid interrupting the Diascan Auto-Calibration, do not operate the machine when the “Function Check in progress...” operator message is displayed.

At the end the Auto-Calibration process, two results are possible:

- Auto-Calibration successfully completed: the Diascan Monitoring System is ready for use;
- Auto-Calibration failed: the “Diascan: Autocalibration Failure (#528)” alarm will be triggered. In this case, refer to the related section of the "Chapter 16: Alarms, Information Signals and Troubleshooting” of this Operator’s Manual for further explanations on this alarm.

12.3 Activate the Diascan function for the current treatment

After being enabled in the Service menu, the Diascan function can be activated/ deactivated in the Treatment environment from the Diascan Settings sub-screen.

Follow the instruction in the sections below to activate Diascan function.

12.3.1 Distribution Volume Parameters

The operator is requested to set the "Distribution Volume" of the patient in order to obtain a correct dialysis dose value (Kt/V) from the Diascan function.

The Diascan system automatically calculates the "Distribution Volume" only if a "Distribution Volume Entry" is selected by the operator in the Distribution Volume Settings sub-screen.

To set the formula, proceed as follows:

1. On the *Prescription* screen press the "Distrib Vol Settings" button to enter the Distribution Volume Settings sub-screen.

2. On the Distribution Volume Settings sub-screen press the "Distribution Volume Entry" button: a Selectpad opens listing the available formulas.

Figure 12-1. Distribution Volume Settings sub-screen

3. On the Selectpad select the desired formula and press the ***CONFIRM*** button to confirm the choice:

   • The Selectpad closes;

- The Distribution Volume Settings sub-screen is updated with the parameters related to the selected formula:

4. Set the patient's parameter values by pressing the related buttons: a Keypad opens.

5. On the keypad enter the parameter value then press the ***CONFIRM*** button:

   - The "Distribution Volume" parameter is automatically calculated by the machine and is displayed on the Distribution Volume Settings sub-screen.

NOTE

If the calculated "Distribution Volume" is higher than the "Patient Dry Weight", the "--" value is displayed in the "Distribution Volume" button.
In this case, change the formula related parameters to set a valid value

- The Kt/V parameters are available on the Diascan Settings sub-screen.

The Diascan Monitoring System provides the following formulas to calculate the Patient Distribution Volume:

Table 1: Distribution Volume Formulas

Distribution Volume Entry	**Patient parameters displayed**
Watson	Patient Height, Patient Dry Weight Patient Gender, Patient Age
Hume	Patient Height, Patient Dry Weight Patient Gender,
Mellits-Cheek	Patient Height, Patient Dry Weight Patient Gender,
Percentage	Patient Dry Weight, Percent. Distrib. Vol.
No Entry	/

Refer to the table below to enter the patient's parameter values:

Table 2: Distribution Volume Parameters

Parameter	**Range**	**Incr.**	**Default value**	**Unit of measure**
Patient Gender	M/F	N.A.	M	--
Patient Age	15-150	1	45	years
Patient Height	1-250	1	165	cm
Patient Dry Weight	25-250	1	65	kg
Percent. Distrib. Vol.	20-80	1	55	%

12.3.2 Diascan Parameter Settings

To set/check the Diascan parameters, after the distribution formula has been selected, proceed as follows:

1. Open the Diascan Settings sub-screen pressing the “Diascan Settings” button on the *Fluid* screen or selecting the “Diascan” option in the “Activated Functions” list on the *Prescription* screen. The following screen opens:

Figure 12-2. Diascan Settings sub-screen

Table 3: Diascan Parameters

Parameter	Decription	Ranges	Unit of measure
Clearance Low Limit	Defines the lower limit allowed for the Clearance parameter.	• 0 to 500 mL/min	mL/min
Target Kt/V	Defines the Dialysis Dose to be achieved during dialysis. The “Target Kt/V” parameter is available only if a value different from “No Entry” has been selected for “Distribution Volume Entry” parameter in the Distribution Volume Settings sub-screen.	• 0.1 to 3.0	/
Clearance	Displays the latest clearance value calculated by the machine.	/	mL/min

Table 3: Diascan Parameters

Parameter	Decription	Ranges	Unit of measure
Kt	Displays the Depurated Volume value calculated by the machine. The "Depurated Volume" parameter is available only if the "No Entry" value has been set for "Distribution Volume Entry" parameter in the Distribution Volume Settings sub-screen.	/	L
Forecast Kt	Displays the volume of body water completely cleared of solute during the treatment, estimated on the current Clearance value and the set "Treatment Time" value. The "Forecast Kt" parameter is available only if the "No Entry" value has been set for "Distribution Volume Entry" parameter in the Distribution Volume Settings sub-screen	/	L
Kt/V	Displays the Dialysis Dose value calculated as the ratio between the "Depurated Volume" (Kt) and the "Distribution Volume" (V). The "Kt/V" parameter is available only if a "Distribution Volume" value has been set in the Distribution Volume Settings sub-screen.	/	/

Table 3: Diascan Parameters

Parameter	Decription	Ranges	Unit of measure
Forecast Kt/V	Displays the forecast value of the Dialysis Dose at the end of the ”Treatment Time”. The "Forecast Kt/V" parameter is available only if a “Distribution Volume” value has been set in the Distribution Volume Settings sub-screen.	/	/
Time to Target Kt/V	Displays the time necessary to reach the ”Target Kt/V” value set by the operator. The "Time to Target Kt/V" parameter is available only if a “Distribution Volume” value has been set in the Distribution Volume Settings sub-screen.	/	h:min
Plasma Conduct.	Displays the Plasma Conductivity calculated by the machine through mathematical models. It expresses an estimation of the patient Plasma Conductivity value with the purpose of allowing a qualitative evaluation of the plasma ionic concentration.	/	mS/cm

2. Check/change the parameter values;
3. On the Diascan Settings sub-screen press the “Diascan” button to activate the function:
   - The Diascan function is activated;
   - The “Diascan” action indicator switches to green;
   - The Diascan icon is displayed on the Diascan Settings sub-screen and on the *Overview* screen ;
   - The “Diascan” action indicator on the “Activated Functions” list on the *Prescription* screen switches to green;
   - When the “Start Treatment” button is pressed the Diascan function starts

NOTE

If the Diascan function is enabled in the Service menu but it is not activated before pressing the "Start Treatment" button, it will be no more possible to activate the Diascan function for the current treatment.

4. Press the ***CLOSE*** button to close the setting sub-sreen.

"Clearance Low Limit" Setting

If the "Clearance" value calculated during the Diascan measurement is below a threshold value, the "Smartscan - Diascan: Low Clearance (#530)" Information Message is triggered.

The threshold value can be set:

- Manually, by setting the "Clearance Low Limit" parameter in the Diascan Settings sub-screen;
- Automatically at 55% of the Blood Flow value, in case no value for the "Clearance Low Limit" parameter has been entered (the "-" value is displayed in the "Clearance Low Limit" button).

"Forecast Kt/V" Setting

If the Forecast Kt/V value calculated during the Diascan measurement is below the value displayed in the "Target Kt/V" button, the "Smartscan - Diascan: Low KT/V (#531)" Information Message is triggered. This Information Message is triggered only if at least two Diascan measurements have been completed without failures.

The Forecast Kt/V value is automatically calculated according to the "Target Kt/V" parameter value set by the operator through the "Target Kt/V" button in the Diascan Settings sub-screen.

The default value of the "Target Kt/V" parameter can be modified in the Service menu.

12.3.2.1 Diascan Settings (No Distribution Volume available)

If the “No Entry” value is set for the “Distribution Volume Entry” parameter or an invalid value has been calculated by the system, the Kt parameters are displayed on the Diascan Settings sub-screen and the graph is accordingly updated.

In this case, during the treatment the system:

- each minute, after the first Diascan measurement, calculates and updates the ”Forecast Kt” value and the graph;
- each time a Diascan measure is taken, updates the ”Clearance” and ”Forecast Kt” parameters and the graph.

12.3.2.2 Diascan Graph

All the clearance measures taken during a treatment are plotted on the Diascan Graph displayed on the Diascan Settings sub-screen:

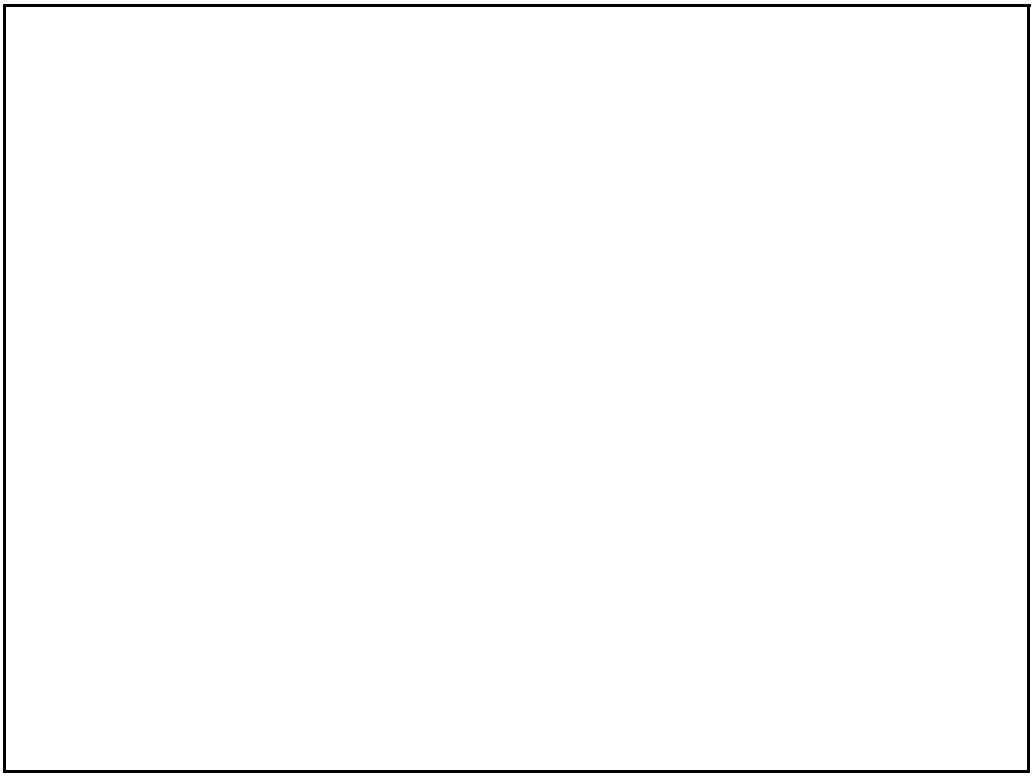


Figure 12-3. Diascan Settings during treatment

The Diascan Graph displays:

- On the horizontal axis, the treatment time;
- On the left vertical axis, the Clearance and the Actual Blood Flow rate (Qb) values;
- On the right vertical axis, the Dialysis Dose Kt/V or the Depurated Volume Kt values according to the "Distribution Volume Entry" parameter that has been entered or not;
- The blue points represent the Clearance;
- The red line represents the Actual Blood Flow rate value if in HD-DN Treatment and the Mean Blood Flow rate value if in HD-SN Treatment.
- The green line represents the Kt (or Kt/V) value.

The "00:00" point on the horizontal axis represents the start treatment time (when the "Start Treatment" button is pressed).

12.3.3 Deactivate the Diascan function

The Diascan function can be manually or automatically deactivated, as described in the following sections.

12.3.3.1 Automatic deactivation

The Diascan function will be automatically deactivated in the following cases:

- When the “Rinseback” or the “Disconnect Patient” buttons are pressed and confirmed;
- After a “Fast Recovery” procedure. In this case, the data collected will no longer be available.

In these cases, it will be no more possible to activate the Diascan function for the rest of the treatment.

12.3.3.2 Manual deactivation before connecting a patient

To deactivate the Diascan function, press the activated “Diascan” button on the Diascan Settings sub-screen:

- The Diascan function is deactivated;
- The “Diascan” button switches to grey;
- The Diascan icon is hidden on the Diascan Settings sub-screen and on the *Overview* screen;
- The “Diascan” action indicator on the “Activated Functions” list on the *Prescription* screen switches to grey;
- The Diascan graph is available but it is no more updated.

It is possible to reactivate the Diascan function pressing the “Diascan” action button before pressing the “Start Treatment” button. Otherwise, the treatment will continue without the Diascan function.

12.3.3.3 Manual deactivation during a treatment

It is possible to deactivate the Diascan function during a treatment, proceeding as follows:

1. Press the activated “Diascan” button on the Diascan Settings sub-screen:
   - The following *Confirm* window is displayed:

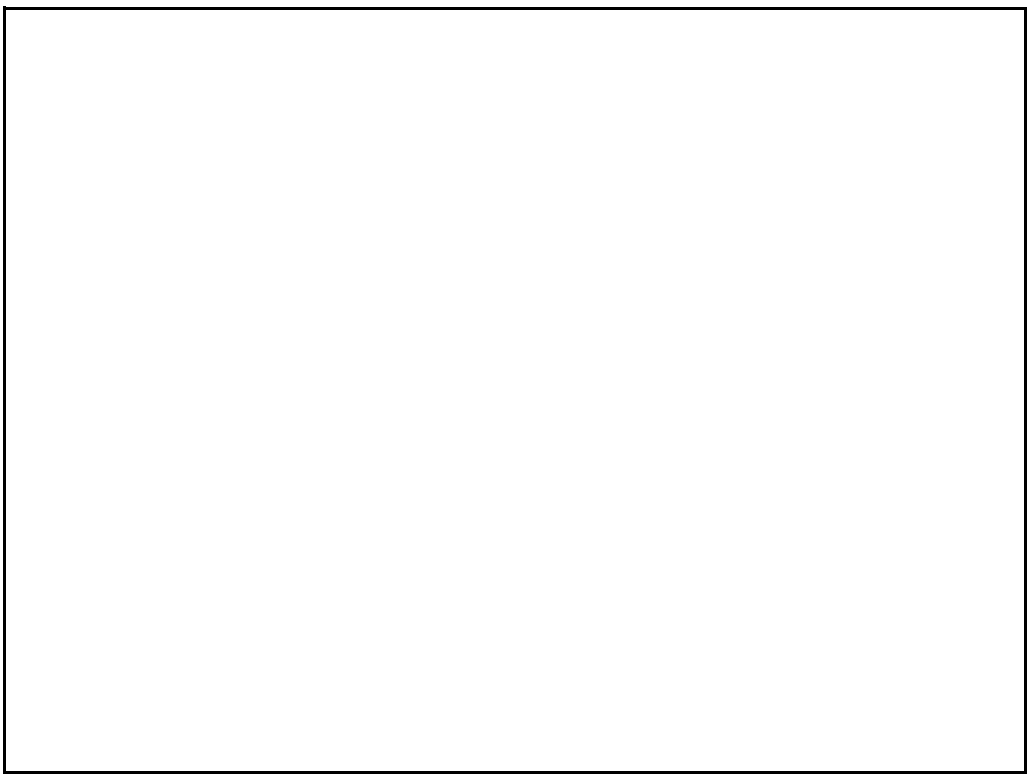


Figure 12-4. Diascan Deactivation - Confirm Window

2. Press the ***CONFIRM*** button to confirm the function deactivation:

- The Diascan function is deactivated;
- The Diascan icon is hidden on the *Overview* screen;
- The "Diascan" action indicator on the "Activated Functions" list on the *Prescription* screen switches to grey;
- The "Clearance Low Limit", "Target Kt/V" (if present) and "Diascan" buttons on the Diascan Settings sub-screen are no more available;
- The Diascan graph is available but it is no more updated;
- The treatment continues without Diascan function.

3. Press the ***CLOSE*** button to close the settings sub-screen.

As suggested by the confirmation text, it is not possible to activate again the Diascan function if it has been deactivated during a dialysis treatment.

12.3.4 Monitoring

After the “Start Treatment” button has been pressed, the Diascan system will acquire a Diascan measurement, as soon as the following conditions are satisfied:

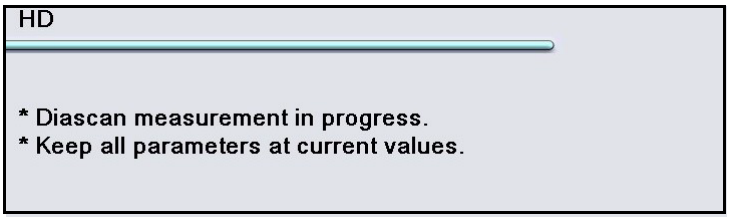
- The autocalibration has been successfully accomplished;
- Blood is detected and its flow rate is greater than or equal to 80 ml/min. Diascan measurements are not performed if the Blood flow rate is lower than 80 ml/min.

The Diascan measurements are automatically performed at the frequency of 15 minutes (this value can be preset).

When the Hemocontrol function is activated, the Diascan measurements are automatically performed each 30 minutes, independently from the preset “Interval“ parameter.

When the Isolated UF function is activated, the first Diascan measurement is performed at the end of the Isolated UF process.

A proper operator message will inform the operator that a Diascan measurement is in progress and that it is not recommended to change the related parameters.



During the measurement (about 11 min), the final conductivity is controlled by the Diascan Monitoring System.

12.3.4.1 Measurement Failure

The Diascan measurement will be interrupted during the measurement if:

NOTE

The Diascan System may not be able to perform measurement if the dialysis fluid flow rate is set below 500 ml/min and a dialyzer with a large membrane area is used.
In case of repeated measurement failures, it is recommended to increase the dialysis fluid flow rate or to deactivate the Diascan function.

- The Actual Blood Flow rate changes for more than 30 ml/min, in HD-DN Treatment, because of a change of the Arterial Pump speed or a fluctuation of the arterial pressure;

- The Mean Blood Flow value or the Arterial Pump speed change for more than 30ml/min in HD-SN Treatment;
- The Dialysis Fluid flow changes;
- The Sodium or Bicarbonate (concentration) change;
- The "Stop Treatment" button is pressed and confirmed;
- Any of the Special Procedures is started and confirmed;
- An alarm is triggered that causes the dialysis fluid bypass; An alarm is triggered that causes the stop of the Arterial Pump;
- In HDF Post Treatment, the "Infusion Flow" rate changes for more than 200 mL/min;
- In HDF Post Treatment, with Ultra Control function activated, a manual Ultra Control scan is performed;
- The estimated "Ionic Clearance" is greater than the current Blood Flow rate;
- In treatments with Hemocontrol function activated, the "Stand-by" button is selected.

NOTE

During the "Pause Treatment" procedure the Diascan function, if active, is paused.
The Diascan measurements will restart as soon as the "Continue Treatment" button is pressed.

When a Diascan measurement fails, a "Diascan: Measurement Failure (#529)" alarm is triggered. Refer to the "Chapter 16: Alarms, Information Signals and Troubleshooting" of this Operator's Manual for the troubleshooting of this alarm.

Chapter 13: Disinfection/Rinse

This chapter provides information about the hygiene and maintenance actions that can be performed by the operator on the Artis Dialysis System.

This information includes:

- The description of all the disinfection and rinse programs allowed on the Artis Dialysis System
- Step-by-step instructions to perform each of the disinfection/rinse programs
- Procedures and agents to clean the external surface of the Artis Dialysis System

⚠WARNING

Follow the manufacturer's instructions when performing the disinfections and rinse procedures on the Artis Dialysis System.

⚠WARNING

No other maintenance than that mentioned in this chapter will be performed by the operator of the machine. The casing must **ONLY** be opened by a fully trained service technician.

A post-dialyzer dialysis fluid sample should be cultured monthly for machine bioburden levels, as per AAMI and CDC guidelines. Follow your facility protocol to collect and culture the samples.

13.1 Disinfection Protocol

The Artis Dialysis System provides several methods to disinfect its internal circuit. The choice of which of these methods to use is the responsibility of the facility. The Manufacturer validates the methods suggested based on in-vitro laboratory testing for adequate concentration or temperature distribution to obtain microbial efficacy and hydraulic circuit material compatibility. However, the frequency of disinfection should be based upon allowable bacterial and/or endotoxin limits in water and dialysis fluid, trending of microbiological monitoring results, applicable regulatory requirements and facility practices.

Frequency of disinfection or the method used may need to be changed if results do not meet either the facility or regulatory body requirements (if applicable). Testing for residual chemicals must be done before the following patient connection (refer to the related section of the " Chapter 8: Special Procedures" of this Operator's Manual).

The Artis Dialysis System can accommodate chemical disinfection as frequently as between each treatment or daily. As a minimum, a daily disinfection (chemical, or heat) is recommended.

Heat disinfection is also an option, and in addition a deproteinization procedure (for example: bleach) should be done at least two times per week if heat disinfection is the primary (between each patient treatment or daily minimum) disinfection method. This is to ensure that any accumulated organic material is periodically removed from the hydraulic circuit. Such material can potentially reduce the effectiveness of a disinfection process.

The Artis Dialysis System offers a unique method to protect the hydraulic circuit from microbial contamination with the preparation of a bacteriostatic level of disinfectant. This can be useful for overnight or weekend storage, and in clinical setting where the time between uses is variable.

The disinfection procedure in Artis Dialysis System will reduce the number of organisms in the hydraulic circuit according to the standards for the intended markets.

In order to maintain high microbiological quality of the dialysis fluid, it is important that the operator is attentive to hygiene and maintenance of the machine. There are factors and procedures that affect the hygiene of the internal circuit and consequently the quality of the prepared dialysis/substitution fluid.

NOTE

It is recommended to alternate the disinfection methods and/or the disinfectants in order to optimize the disinfection of the machine.

NOTE

The test procedure used for verification of the effectiveness of disinfection or sterilization is available on request.

NOTE

For a correct maintenance of the Artis Dialysis System, it is recommended to follow a disinfection protocol which provides at least the use of *Heat* and *Heat with CleanCarts* disinfections.

13.1.1 Schedule for hygiene and maintenance

Follow the schedule in the table below for a correct maintenance of the Artis Dialysis System:

Disinfect Program	Frequency	Cycle Time	Chemical Solution
Heat	Daily; between two subsequent treatments	34 min	/
Integrated Heat	Daily; between two subsequent treatments in place of a Heat disinfection	34 min	/
Heat + CleanCart C	Daily; following the last treatment of the day	44 min	CleanCart C
Heat + CleanCart A	At least once a week in place of the Chemical disinfection with hypochlorite	44 min	CleanCart A
Bacteriostatic Chemical Disinfection	For week end storage	16 min (Chemical disinfection) + 27 min (Rinse)	Low Peracetic
Bacteriostatic Chemical Disinfection	For week end storage	16 min (Chemical disinfection) + 38 min (Rinse)	Peracetic
Chemical Disinfection	At least once a week	16 min (Chemical disinfection) + 94 min (Rinse)	Hypochlorite[a]

Disinfect Program	Frequency	Cycle Time	Chemical Solution
Chemical Disinfection	Daily; between two subsequent treatments in place of the Heat disinfection	16 min (Chemical disinfection) + 27 min (Rinse)	Low Peracetic
Chemical Disinfection	Daily; between two subsequent treatments in place of the Heat disinfection	16 min (Chemical disinfection) + 38 min (Rinse)	Peracetic
Rinse	/	16/27/38 min	/
Rinse CCK	/	4 min	/

a. U9000 Ultrafilters can not tolerate more than twelve Chemical Disinfection programs with Hypochlorite.
U9000 Ultrafilters must be changed when the maximum allowed number of chemical disinfection programs with hypochlorite have been performed.

13.2 Disinfection/Rinse available programs

The Artis Dialysis System allows the following disinfection/rinse programs:

CHEMICAL DISINFECTIONS

A. ***Chemical disinfection***. The disinfectant solution is uptaken from a chemical canister connected to the Yellow or Clear connector on the rear of the machine. The disinfection cycle includes all the hydraulic circuit. During a chemical disinfection program the machine is filled with disinfectant solution. The solution is then distributed into all the hydraulic circuit and after the dwell time has elapsed (the time the hydraulic circuit is filled with disinfectant solution) the machine is rinsed and drained

B. ***Bacteriostatic.*** The machine is left filled with diluted chemical disinfectant. The uptake of disinfectant is the same described for the Chemical Disinfection. This disinfection process involves all the hydraulic circuit. The bacteriostatic chemical disinfection is useful for weekend storage. This program can be activated following the last treatment of the week and leaving the machine internal circuit full of a chemical at a bacteriostatic concentration

HEAT DISINFECTIONS

C. ***Heat disinfection.*** This process is performed circulating hot water through the hydraulic circuit.

D. ***Heat disinfection with CleanCart C***. This process is performed flushing dissolved CleanCart C powder (citric acid) and hot water in the hydraulic circuit.

E. ***Heat disinfection with CleanCart A***. This process is performed flushing dissolved CleanCart A powder (sodium carbonate) and hot water in the hydraulic circuit.

During heat disinfection programs the water is heated up and flushed through the hydraulic circuit of the machine. The program starts with a high flow rinse process in order to remove possible residues from concentrates used in the dialysis treatment. When the hydraulic circuit has been in contact with hot water for a proper dwell time, the whole circuit is drained.

NOTE

Do not switch the machine OFF during a Heat disinfection program. If it is necessary to turn the machine OFF, follow the instructions on the “13.6 End of a Disinfection/Rinse Program” section below.
If the machine is switched OFF during a Heat disinfection an alarm will occur as soon as the machine is switched ON again.

RINSE

F. ***Rinse.*** Fresh water flushes the hydraulic circuit.

During treatments or disinfection programs using chemical agents, residuals remain on the hydraulic circuit of the machine. The rinse process provides a method to remove all these residuals. The duration of the rinse program depends on the type of chemical agents that must be removed.

The Artis Dialysis System allows to manually activate a rinse program between treatments in order to remove the concentrate residuals. It is possible to preset the duration of the Rinse program only in Service menu, choosing between the following options: 16 minutes, 27 minutes or 38 minutes.

13.2.1 Chemical disinfectants

The chemical disinfectant solutions listed below are recommended for use with Artis Dialysis System:

Solutions based on peracetic acid	
Active ingredients:	Peracetic acid and hydrogen peroxide.
Trade names:	Dialox™

Solutions based on sodium hypochlorite	
Active ingredients:	Sodium Hypochlorite.
Trade names:	Bleach, Amuchina

⚠WARNING

- Before using a disinfectant product, the user must take note of necessary precautions.
- The manufacturer's instructions and recommendations must be followed.
- Local regulations regarding the use of different chemicals must be followed.

⚠WARNING

To prevent damaging the machine, ***DO NOT LEAVE*** disinfectant solutions in the machine for periods over the following limits:
- 20 min for Sodium Hypochlorite based solutions at Disinfectant strength (Max. 0.2% concentration)
- 20 min for Citric Acid based solutions at Disinfectant strength (Max. 2% concentration)
- 20 min for Sodium Carbonate based solution at Disinfectant strength (Max. 0.5% concentration)
- 72 hours for Peracetic Acid based solutions at Disinfectant strength (Max. 0.10% concentration)

⚠WARNING

After a Chemical Disinfection program, a test for residuals of disinfectant must be performed before the following patient connection to avoid the risk of blood hemolysis due to the exposure of the patient to the chemical residues.

NOTE

The dilution ratio and dwell time for the chemical disinfections are defined by the manufacturer.

NOTE

In order to perform a chemical disinfection program using a disinfectant canister, it is necessary to install the Chemical Container Shelf.
For further information on the availability of this component, contact your Local Representative.

13.2.2 Disinfection/Rinse History Table

The Disinfection/Rinse History Table showed in the Disinfect / Rinse Settings sub-screen, stores the last 50 Disinfection/Rinse programs performed on the machine.

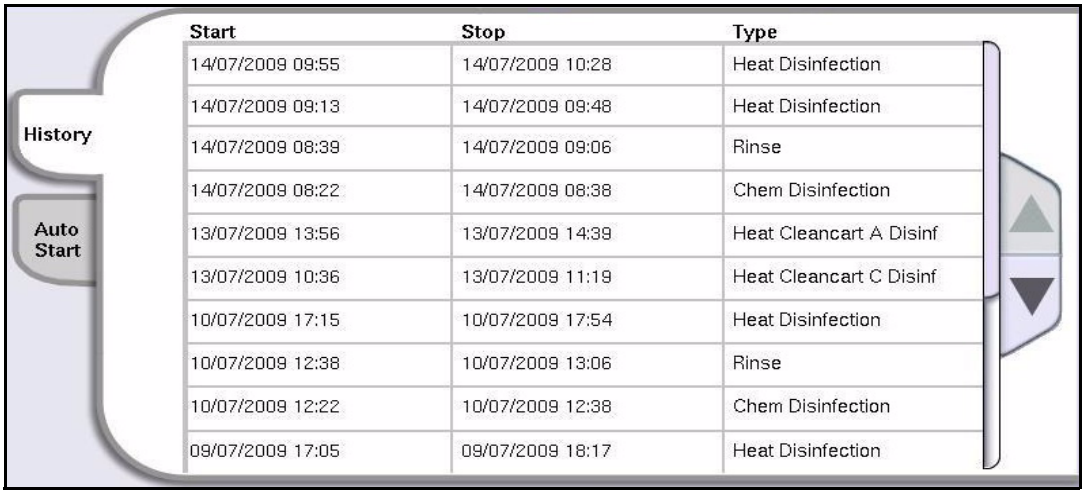


Figure 13-1. Disinfection/Rinse History Table

The "Disinfection/Rinse History Table" is always available during treatments, in the *Hygiene* sub-screen. To open this sub-screen, press the "Hygiene" button on the *Report* screen.

The table includes the following columns:

- ***Start***: contains the date and time of the Disinfection/Rinse program start
- ***Stop***: contains the status of the Disinfection/Rinse program after it has been accomplished or while it is in progress. The default status showed in this column at the beginning of each Disinfection/Rinse program is "Not Completed". At the end of the program this column content will be updated as described in the "Table 1: Stop Statuses" below.
- ***Type***: contains the type of Disinfection/Rinse program performed

According to how the Disinfection/Rinse program ended, the ***Stop*** column can show one of the following statuses:

Table 1: Stop Statuses

Disinfection/Rinse Program End	Stop Status
Default status showed at the beginning of each Disinfection/ Rinse program.	Not Completed
Program successfully performed	Date and time of the program ending

Table 1: Stop Statuses

Disinfection/Rinse Program End	Stop Status
An alarm occurred during the Disinfection/Rinse program	Failed due to Alarm
The operator pressed the “Disinf/ Rinse” button to stop the program before it was completed	User Stop
The machine was switched OFF (pressing the *Main Switch* key or following a Power Failure) while the Disinfection/Rinse program was in progress	Not Completed
This status is displayed while the Rinse program following a Chemical Disinfection program is in progress	Rinse Required
This status is displayed at the end of a Chemical Disinfection program if the “Chemical process not properly performed: disinfectant tank empty (#533)” alarm was triggered during the disinfection program.	Completed with alarms

13.3 Before starting a Disinfection/Rinse Program

Before starting a Disinfection/Rinse program, perform the following checks:

- That the Dialysis Fluid Tubes are connected to their safety couplings;
- That the Sensor Bar door is closed;
- That the Ultra door is closed;
- That the Acid pick-up tube is connected to its concentrate connector port. Ensure to hear a "clicking" sound when connecting the Acid pick-up tube to its concentrate connector port;
- That the EvaClean doors are firmly closed;
- That the machine is connected to the water supply system and that the water is on;
  OR
  That the machine is connected to the CWP, if an Integrated Heat Disinfection must be performed. To connect the machine to the CWP follow the CWP Instructions for Use;
- If an Integrated Heat Disinfection must be performed, check that the Water Inlet Tube has been properly replaced, according to the CWP Instructions for Use. The Water Inlet Tube supplied with the machine is not hot water resistant. If the appropriate tube has not been installed, it must be installed before starting an Integrated Heat Disinfection program;
- That the BiCart Cartridge, SelectCart Cartridge and SelectBag holder arms are closed.

⚠WARNING

Before starting a Heat disinfection, ensure that:
- The EvaClean doors are firmly closed;
- The Ultra Door is firmly closed;
- The BiCart Cartridge, SelectCart Cartridge and SelectBag holder arms are closed.

⚠WARNING

Before performing an Integrated Heat disinfection, ensure that the Water Inlet Tube has been properly replaced, according to the CWP Instructions for Use.
The Water Inlet Tube supplied with the machine is not hot water resistant.

According to the required Disinfection/Rinse program, perform the following additional tasks:

Disinfection/Rinse Program	Machine preparation
• Heat disinfection • Integrated Heat disinfection • Rinse	No additional tasks required.
• Heat disinfection with CleanCart C Cartridge • Heat disinfection with CleanCart A Cartridge	1. Open the BiCart Cartridge holder arms and insert a CleanCart C/A cartridge. 2. Close the BiCart Cartridge holder pressing firmly the upper and lower arms in order to ensure that the spikes inside the upper and lower arms of the BiCart Cartridge holder pierce the ports of the CleanCart cartridge. *See WARNING below*
• Bacteriostatic disinfection with Low Peracetic • Bacteriostatic disinfection with Peracetic • Chemical disinfection with Low Peracetic • Chemical disinfection with Peracetic	1. On the rear panel of the machine, place the disinfectant canister, containing enough disinfectant solution to perform the program, on the Chemical Container Shelf 2. Connect the Clear connector on the rear panel of the machineto the wand inserted into the disinfectant canister
• Chemical disinfection with Hypochlorite	1. On the rear panel of the machine, place the disinfectant canister, containing enough disinfectant solution to perform the program, on the Chemical Container Shelf 2. Connect the Yellow connector on the rear panel of the machine to the wand inserted into the disinfectant canister

⚠WARNING

The Artis Dialysis System is not able to detect if a Heat Disinfection has been performed using a BiCart Cartridge rather than a CleanCart C Cartridge.
If unintentionally a Heat Disinfection using a BiCart Cartridge has been performed, perform a new Heat Disinfection program using a CleanCart C Cartridge.

13.4 Set and start a Disinfection/Rinse Program

NOTE

The disinfection programs available in the Disinfect / Rinse Settings sub-screen are configurable in the Service menu.

NOTE

It is possible to activate a disinfection/rinse program ***ONLY*** before starting a dialysis and/or after the treatment has been accomplished.

To activate the desired disinfection program, proceed as follows:

1. Open the Disinfect / Rinse Settings sub-screen pressing the "Disinfect / Rinse" button on the *Overview* screen:

Figure 13-2. Disinfect/Rinse Settings Sub-screen

- The last 50 Disinfection/Rinse programs are stored in the "Disinfection/Rinse History" table.

2. Press the "Process Type" button: a Selectpad opens with available Disinfection/Rinse programs:

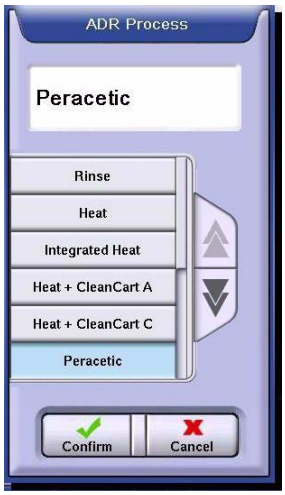


Figure 13-3. Disinfection/Rinse Selectpad

3. Select the desired program and press the ***CONFIRM*** button:

   • The Selectpad closes;

   • The "Process Type" button label is updated with the selected program name;

   • The "Disinf/Rinse" button is available;

   • The "Time" button becomes available displaying the total time of the selected program;

   • In case of a Chemical Disinfection, the "Disinf. from" button becomes available too, displaying the rear connector related to the Disinfection program selected.

4. Press the "Disinf/Rinse" button to activate the new program;

   • The selected Disinfection/Rinse program starts;

   • The "Disinf/Rinse" action indicator switches to green;

   • The "Process Type" button is dimmed.

NOTE

If the drainage of dialyzer and concentrate disposables has not been performed yet it must be done before starting a hygienic program. In this case, the "Empty Circuit" and "Drain Cartridge" action buttons will be available on the *Overview* screen.

5. Press the ***CLOSE*** button to switch to the *Overview* screen.

13.5 Disinfection/Rinse program in progress

While the program is in progress:

- The Status Message Bar indicates the name of the program in progress;
- The "Remaining Time" blue progress bar on the *Overview* screen increases;
- The "Remaining Time" value on the *Overview* screen descreases.

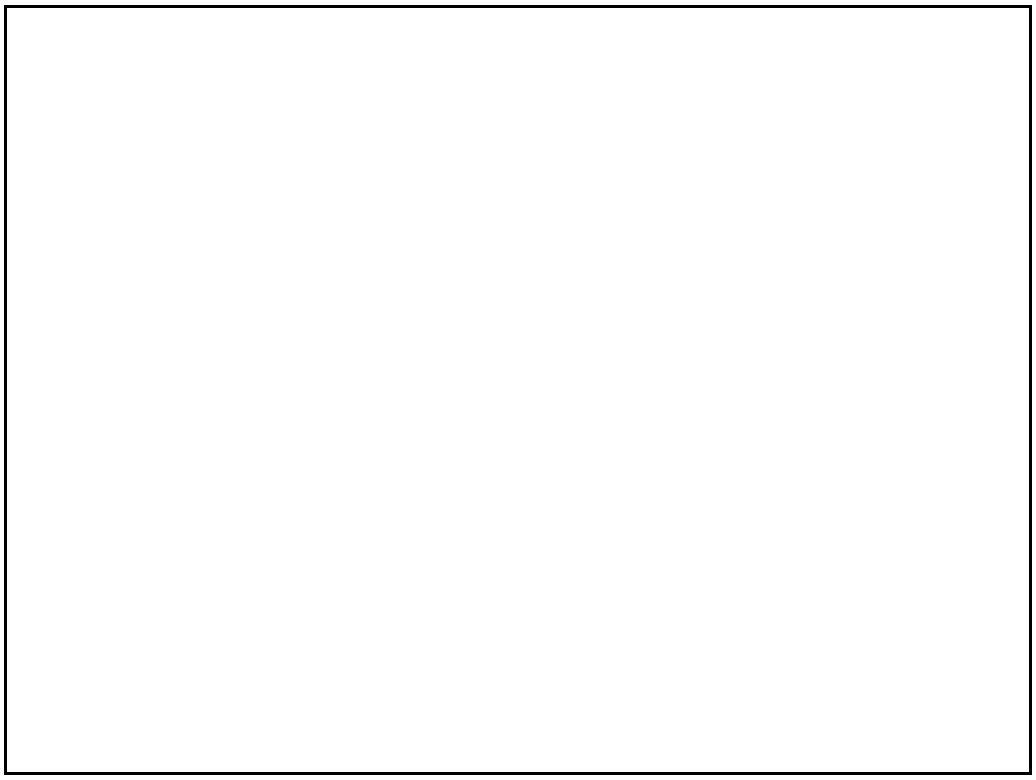


Figure 13-4. Disinfection/Rinse program in progress - Example

Heat Disinfection in progress

During the Heat Disinfection programs heat water flows in the hydraulic circuit. In order to alert the operator the following message appears:

⚠WARNING

DO NOT remove any connector during a Heat disinfection.

13.6 End of a Disinfection/Rinse Program

The Disinfection/Rinse program stops when:

- The “Remaining Time” value is equal to “0:00”;
- The machine goes into an alarm condition. When the alarm is reset the process starts from the point it was interrupted;
- The activated “Disinf/Rinse” action button is pressed and confirmed.

NOTE

If the “Disinf/Rinse” action button is pressed while a Chemical Disinfection is ongoing, an automatic Rinse program starts anyway but the process is not considered complete.
The rinse time depends on the type of Chemical Disinfection program performed. Refer to the "13.1.1 Schedule for hygiene and maintenance" table for rinse times.

Disinfection/Rinse Program	End Status
• Heat disinfection • Integrated Heat disinfection • Rinse	• The “Remaining Time” value is equal to “0:00”; • The “Remaining Time” progress bar is completely blue. • Touch Screen enters in “Display-Off” mode . • The machine enters in “Low Power” mode. 1. Press the “On/Off” key to exit the “Low Power” mode. *See NOTE 1 below*
• Heat disinfection with CleanCart C Cartridge • Heat disinfection with CleanCart A Cartridge	• The “Remaining Time” value is equal to “0:00”; • The “Remaining Time” progress bar is completely blue. • Touch Screen enters in “Display-Off” mode . • The machine enters in “Low Power” mode. 1. Remove the CleanCart Cartridge from the holder; 2. Close the BiCart Cartridge Holder arms; 3. Press the “On/Off” key to exit the “Low Power” mode

Disinfection/Rinse Program	End Status
• Bacteriostatic disinfection with Low Peracetic • Bacteriostatic disinfection with Peracetic	• The "Remaining Time" value is equal to "0:00"; • The "Remaining Time" progress bar is completely blue. • Touch Screen enters in "Display-Off" mode . • The machine enters in "Low Power" mode. 1. Disconnect the Clear rear disinfectant connector from the wand inserted into the disinfectant canister 2. Press the "On/Off" key to exit the "Low Power" mode: a Rinse program starts. *(The rinse time depends on the chemical solution used during disinfection program)* 3. At the end of the Rinse program, switch the machine OFF *See NOTE 2 below*
• Chemical disinfection with Low Peracetic • Chemical disinfection with Peracetic	• An automatic Rinse program starts. *(The rinse time depends on the chemical solution used during disinfection program)* At the end of the automatic Rinse program: • The "Remaining Time" value is equal to "0:00"; • The "Remaining Time" progress bar is completely blue. • Touch Screen enters in "Display-Off" mode . • The machine enters in "Low Power" mode. 1. Disconnect the Clear rear disinfectant connector from the wand inserted into the disinfectant canister 2. Press the "On/Off" key to exit the "Low Power" mode *See NOTE 3 below*
• Chemical disinfection with Hypochlorite	• An automatic Rinse program starts. *(The rinse time depends on the chemical solution used during disinfection program)* At the end of the automatic Rinse program: • The "Remaining Time" value is equal to "0:00"; • The "Remaining Time" progress bar is completely blue. • Touch Screen enters in "Display-Off" mode . • The machine enters in "Low Power" mode. 1. Disconnect the Yellow rear disinfectant connector from the wand inserted into the disinfectant canister 2. Press the "On/Off" key to exit the "Low Power" mode *See NOTE 3 below*

⚠WARNING

After a Chemical Disinfection program, a test for residuals of disinfectant must be performed before the following patient connection to avoid the risk of blood hemolysis due to the exposure of the patient to the chemical residues.

NOTE 1

If a Rinse process is deactivated by the operator before being accomplished, the machine will anyway perform an emptying of the hydraulic circuit before completely stopping the process.

NOTE 2

Following a Bacteriostatic Chemical Disinfection, the "Autoscheduled Disinfection/Rinse Program not Performed (#562)" alarm will appear if a Disinfection/Rinse program has been scheduled using the *Autostart* function.
In this case, press the ***RESET*** button to remove the alarm.

NOTE 3

If a switch off of the machine occurs before accomplishing a Chemical Disinfection, at the power on the Rinse program related to the interrupted program will automatically start.

Automatic Rinse

An automatic Rinse program is set to start at the end of each Chemical Disinfection program.

NOTE

- The Artis Dialysis System does ***NOT*** allow the operator to stop a Rinse program following a Chemical Disinfection.
- The duration of automatic rinse processes is defined by the manufacturer and can not be pre-set or modified by the operator.

NOTE

When a Chemical Disinfection is interrupted before its accomplishment, an automatic Rinse program is anyway performed and can not be stopped by the operator.

13.7 Rinse CCK

A Rinse program can be performed in order to remove concentrates from the Central Concentrate Tube.

To carry out the Central Concentrate Tube Rinse program the proper configuration of the tubes must be set.

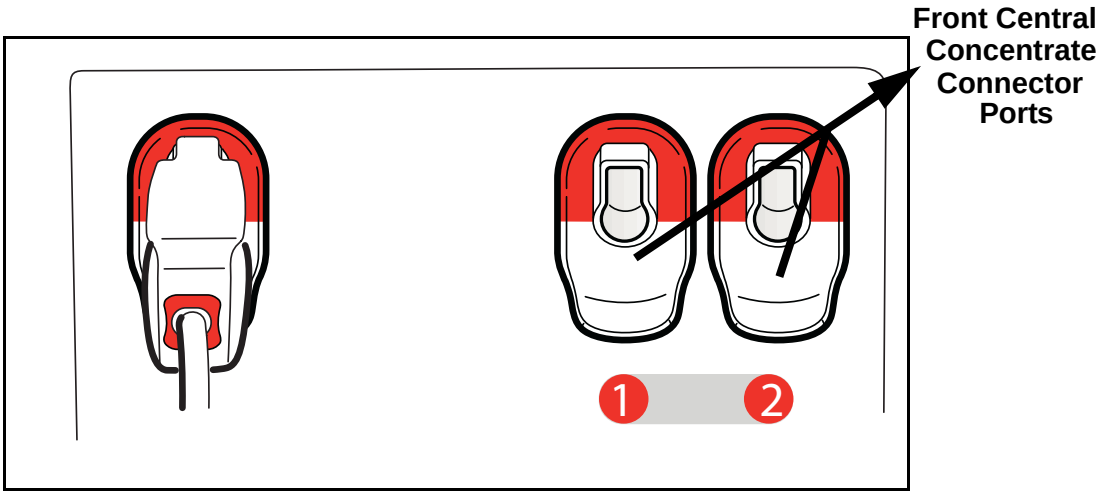


Figure 13-5. Concentrate Connectors Panel

13.7.1 Before starting a Rinse CCK

Before starting a Rinse CCK program, check:

- That the Dialysis Fluid Tubes are connected to their safety couplings;
- That the Sensor Bar door is closed;
- That the Ultra door is closed;
- That the EvaClean doors are firmly closed;
- That the machine is connected to the water supply system and that the water is on;
- That the BiCart Cartridge, SelectCart Cartridge and SelectBag holder arms are closed.

⚠WARNING

Before starting a Chemical Disinfection or a Rinse program, ensure that the EvaClean doors are firmly closed.

13.7.2 Start a Rinse CCK

To perform this program proceed as follows:

1. Switch the machine ON;

2. Open the Disinfect / Rinse Settings sub-screen pressing the Disinfect / Rinse button on the *Overview* screen;

3. Press the “Process Type” button: a selectpad opens;

4. Select the “Rinse CCK” option and press the ***CONFIRM*** button on the selectpad: the “CCK Rinse Time” and “CCK Configuration” buttons are displayed

5. If needed, press the “CCK Configuration” button: on the selectpad select the desired option and press the ***CONFIRM*** button;

NOTE

If the Artis Dialysis System is in AFB K configuration, ***do not*** select the “Two Concentrate Connector” option in the CCK Configuration selectpad, since this concentrate connector is not available on the AFB K Concentrate Connector Panel.
If the “Two Concentrate Connector” option is selected, the “Hydraulic Centralise Acetate Connector Type Two (#566)” alarm will be triggered and the rinse process will not be performed.

6. Connect the Acid pick-up tube:

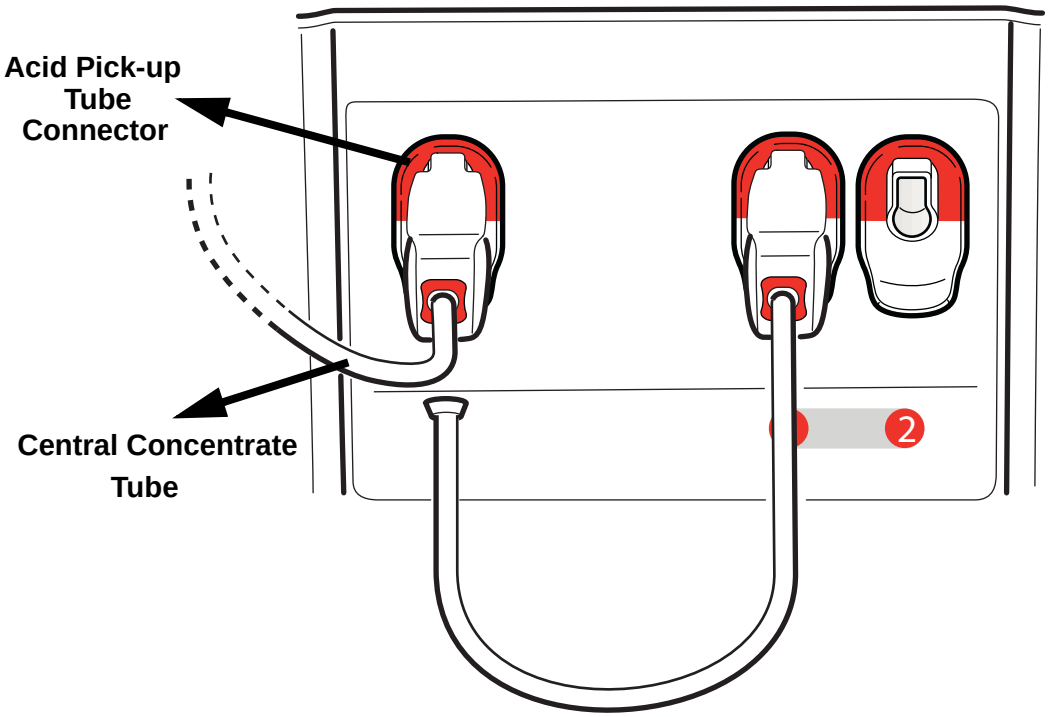
   - to the Front Central Concentrate Connector Port 1 if the selected “CCK Configuration” option is “One Concentrate Connector”;

   - to the Front Central Concentrate Connector Port 2 if the selected “CCK Configuration” option is “Two Concentrate Connector”;

   - to the Front Central Concentrate Connector Port, after having selected the “One Concentrate Connector” option, if the Artis Dialysis System is in AFB K configuration.

   Ensure to hear a “clicking” sound when connecting the Acid pick-up tube to a Central Concentrate Connector Port.

7. Connect the central concentrate tube to the Acid pick-up tube connector on the Concentrate Connector Panel;



8. Ensure that the other end of the Central Concentrate Tube is connected:

   - to the Rear Central Concentrate Connector Port 1 if the selected "CCK Configuration" option is "One Concentrate Connector";
   - to the Rear Central Concentrate Connector Port 2 if the selected "CCK Configuration" option is "Two Concentrate Connector";
   - to the (only) Rear Central Concentrate Connector Port, if the Artis Dialysis System is in AFB K configuration.

9. Press the "Disinf/Rinse" button to start the Rinse program:

   - The "Disinf/Rinse" action indicator switches to green;
   - The Rinse program starts: it last 4 minutes

At the end of the Rinse program, the Touch Screen enters a "Display-Off" mode and the machine enters the "Low Power" mode: press the "On/Off" key to exit the "Low Power" mode.

13.8 Autostart

It is possible to schedule the automatic start of a Disinfection/Rinse program from the Service 1 and Service 2 menus.

The scheduled Disinfection/Rinse program starts only when the machine is in a “Display-Off” mode (the Touch Screen is switched off and the machine is energized) or if it has been in “Low Power” mode (the machine is not energized but the Main Switch is ON) for at least five minutes.

13.8.1 Before starting an automatic program

Before the machine starts the scheduled program, perform the following checks:

- That the machine is connected to the water supply and that the water is on;
- That the appropriate disinfectant canister or cartridge is connected to the machine.

13.8.2 Start a scheduled Disinfection/Rinse Program

When a Rinse program is scheduled and the machine is in “Low Power” mode:

- Five minutes before starting the program, the machine automatically exits the “Low Power” mode and enters a “Display-Off” mode;
- At the preset time, the scheduled program starts.

NOTE

If the “ON/OFF” key on the Hard Key panel is pressed while the machine is in ”Display-Off” mode, the scheduled Disinfection/Rinse program does not start.
Instead, the machine enters the Function Check/Preparation mode.

When the Disinfection/Rinse program starts:

- The values on the Disinfect / Rinse Settings sub-screen are updated according to the started Disinfection/Rinse program;
- The “Disinf/Rinse” action indicator switches to green.

If the system is not able to start the scheduled program, an alarm is triggered.

13.8.3 Program Completed

When the Disinfection/Rinse program has been successfully accomplished, the Touch Screen goes into “Display-Off” mode and after a preset time the machine enters the “Low Power” mode:

1. Press the “On/Off” key to exit the “Low Power” mode.
2. Verify that the scheduled Disinfection/Rinse program has been successfully accomplished in the disinfection history table on the Disinfect / Rinse Settings sub-screen.

13.9 Water Inlet Tube disinfection

The Water Inlet Tube, between the water supply system and the end of the tube connected to the inlet port of the heater exchanger, is not automatically cleaned/ disinfected by the machine.

To disinfect this tube follow the instructions below.

13.9.1 Disinfection procedure

If the machine is stored or switched OFF for a long period of time, it is recommended to perform the following procedure:

1. Assemble the Water Inlet Tube disinfection tool as shown in "Figure 13-6. Water Inlet Tube disinfection tool". Contact your Local Representative for information on how to obtain this device or the components to assemble it;

2. Prepare a dilute peracetic (Oxagal or Dialox) solution (2 ml of solution in 50 ml of room-temperature treated water) in a chemical resistant container;

NOTE

The disinfectant solution must be prepared and used immediately.

3. Turn the water supply system off;

4. Disconnect the machine's water tube from the water supply system and connect it to the connector on the disinfection tool (on the left side of the device, as shown in "Figure 13-6. Water Inlet Tube disinfection tool");

5. Insert the free end (disinfectant suction tube) of the pump device into the disinfectant solution container;

6. Switch the machine on and open the Disinfect / Rinse Settings sub-screen. Press the "Process Type" button, select the "Peracetic" option and ***CONFIRM*** the selection;

7. Press the "Disinf/Rinse" button to activate the disinfection program;

8. When the machine triggers the alarm related to the absence of water, use the syringe on the pump device to pump 150 ml of disinfectant solution into the inlet water tube;

NOTE

Point the syringe downward during the emptying phase to prevent air from entering the water inlet tube.

9. Turn the machine off and leave the tube filled with the disinfectant solution for 15 minutes;

10. Carefully disconnect the inlet water tube from the pump device;

11. After the dwell time has elapsed, switch the machine on;

12. When the alarm related to the absence of water is triggered, connect the water inlet tube to the water supply system and open the water: an automatic rinse procedure will start;

NOTE

The purpose of this operation is to empty the end of the water inlet tube to avoid that the disinfectant comes into contact with the water supply system flowpath.

13. Perform a Chemical Disinfection (refer to the "13.3 Before starting a Disinfection/Rinse Program" section of this chapter);

WARNING

After a Chemical Disinfection program, a test for residuals of disinfectant must be performed before the following patient connection to avoid the risk of blood hemolysis due to the exposure of the patient to the chemical residues.

14. Start the dialysis treatment.

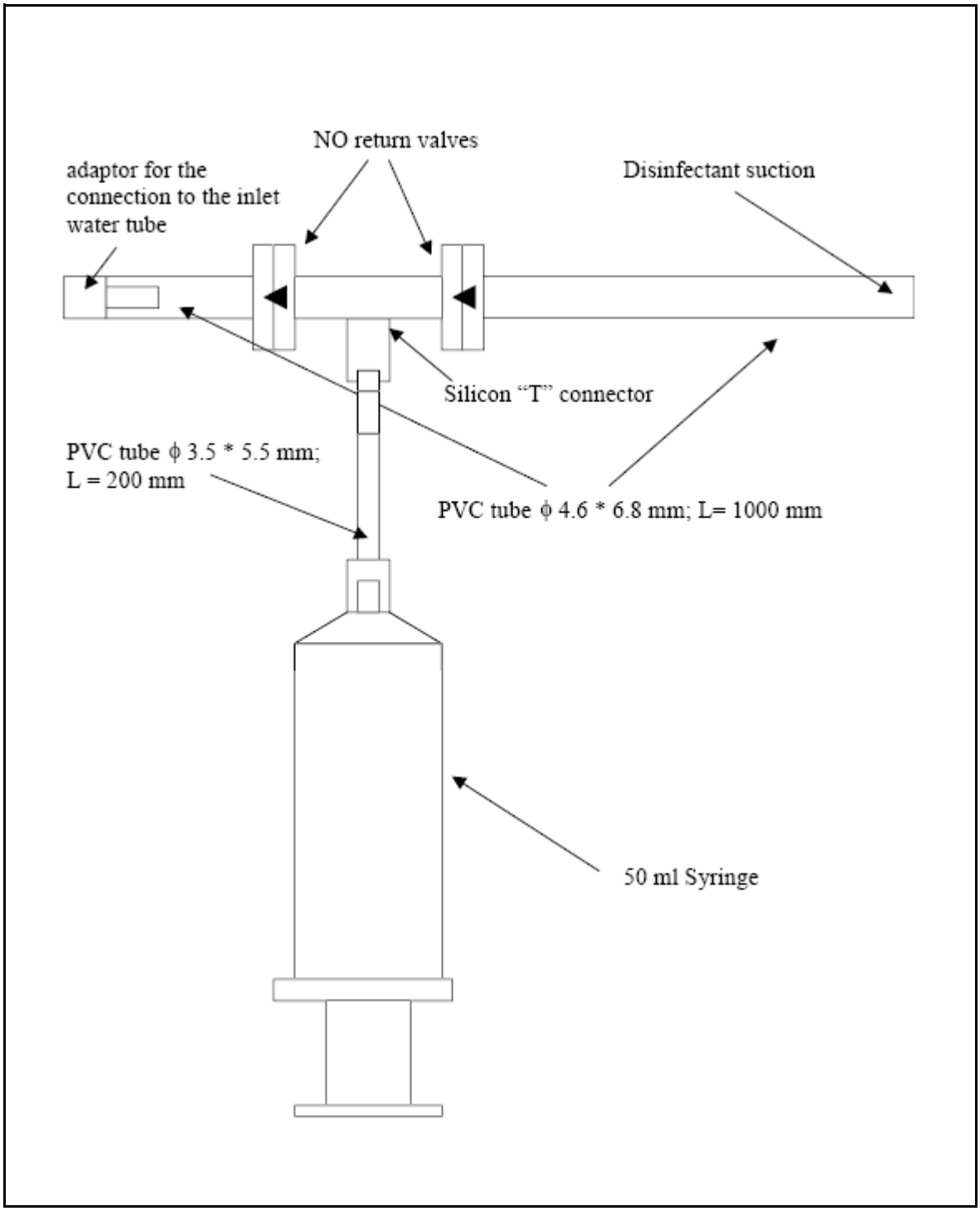


Figure 13-6. Water Inlet Tube disinfection tool

13.10 External Cleaning

Artis Dialysis System must be cleaned as often as required by operating conditions and the facility's protocol.

The machine has been designed to function with a minimum of maintenance. The ambient conditions, as well as frequency and duration of use determine the required cleaning frequency.

The external surfaces of the machine to be cleaned are:

- Arterial and Venous Pumps
- Arterial and Venous Line Clamps
- Sensor Bar
- Air detector
- Blood sensors
- Hemoscan sensor
- Heparin syringe holder
- Arterial and Venous pressure sensors
- Pre-dialyzer sensor
- BiCart cartridge, SelectCart cartridge, SelectBag holders
- Dialyzer holder
- EvaClean ports and doors
- Touch Screen
- Bart code reader
- Card reader
- Automatic Pinch Clamp

Particles and dust on the external surface of the machine can be removed with a soft cloth or brush.

All other deposits can be removed with a soft cloth dipped in the following detergent/disinfectant solutions:

- Ethanol (60% or 70%).
- Isopropanol 60%.
- Liquid soap, except for the Touch Screen
- Sodium hypochlorite (NaClO) of 1,5% available chlorine, except for the Touch Screen, Arterial and Venous Pumps, Air Detector, Blood Sensor, Hemoscan Sensor, Arterial and Venous Line Clamps and Automatic Pinch Clamp

⚠WARNING

To clean the Touch Screen use ***ONLY*** the following disinfectants:
• Ethanol (60 or 70%).
• Isopropanol (60%).

⚠WARNING

To clean the external surface of the Artis Dialysis System, use only disinfectants/detergents suggested in this Operator's Manual.
Use of other chemicals to clean the Artis Dialysis System might cause ineffective disinfection or damage the plastic parts of the machine.
In particular, avoid chemicals containing benzene, toluene, xylene, acetone or similar solvents.

⚠WARNING

Any liquid spilt on the machine must immediately be removed to prevent it from seeping into the machine.

NOTE

DO NOT immerse the machine components listed above in disinfectant solutions.

NOTE

In case salt deposits are present on the Sensor Bar, the machine could not be able to detect the Sensor Bar door status (opened/closed).
To avoid this, carefully clean the Sensor Bar

NOTE

If residual detergent/disinfectant remains on the surface of the machine after external cleaning, it has to be removed with a soft cloth dipped in water to avoid damaging or discoloring the plastic parts of the machine.
Detergents/disinfectants have to be removed from the external surface of the machine only after the minimum dwell time for cleaning is elapsed (refer to the detergent/disinfectant instructions for use for the minimum dwell time recommended to guarantee an effective cleaning).

13.10.1 External components Cleaning

It is advisable to clean periodically the following external components of the machine, immersing them in a disinfectant solution:

- Dialysis Fluid Connectors
- Concentrate Connectors
- Chemical Connectors

To clean these components proceed as follows:

1. Immerse them in a disinfectant solution;

NOTE

The lenght of the immersion depends on the disinfection solution used.

2. Thoroughly rinse them with treated water to remove all disinfectant residuals, prior to using them during dialysis.

The frequency of this cleaning procedure depends on the use of the machine, on the operating conditions and the ambient conditions.

⚠WARNING

To prevent cross-contamination problems resulting, for example, from blood leakage from the blood line or from the dialyzer, the components listed above must be cleaned by immersing them into a disinfectant solution or by exposing them to a steam sterilization procedure (121°C for at least 30 minutes).
Careful attention must be paid to dismounting and re-mounting Dialysis Fluid Tube Connectors, Concentrate Connectors and Chemical Connectors in order to avoid damages to those components and leakages from those components.

⚠WARNING

To prevent damage to the components listed above, ***DO NOT*** leave them immersed in the disinfectant solution for a prolonged period; the proper immersion time is related to the disinfectant dilution used.
When the dilution is the same as that used in the machine during disinfection programs, follow the same time limits:

- 4 hours for: Amuchina™, Instrunet HD™ and Sodium Hypochlorite at Disinfectant strength (1:25 dilution);
- 24 hours for: Dialox™, Acetoper™, Peresal™, Actril® and Renalin®;
- One week for: Sodium Hypochlorite at Bacteriostatic strength (1:750 dilution).

(For further information refer to the " Chapter 17: Specifications" of Operator's Manual).

13.11 Screen Cleaning

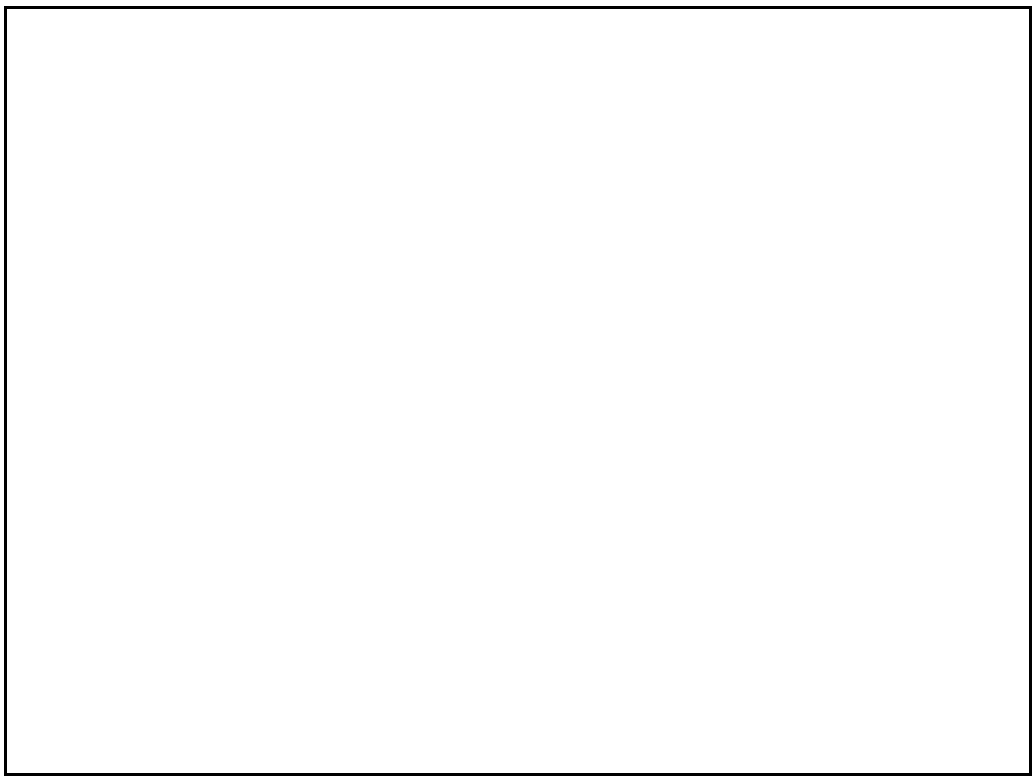
A special feature is available on the machine to allow the operator to clean the Touch Screen also when the machine is switched on. It is possible to perform this procedure during every machine status.

To clean the Touch Screen when the machine is switched on, proceed as follows:

1. On the *Report* screen, press the “Screen Cleaning” button:

   • A *Confirm* window opens

2. Press the ***CONFIRM*** button on the *Confirm* window. The following window is displayed:



   • The Touch Screen is temporarily disenabled (12 seconds) allowing the operator to clean it

3. Clean the Touch Screen with a soft cloth.

After 12 seconds have elapsed the Touch Screen is automatically enabled again.

13.12 Visual inspection

The machine must be periodically inspected (at least once a week) to check for:

- Broken or damaged switches
- Broken or twisted power cord
- Cracks in the structure
- Corroded metal parts
- Unattached loose or missing hardware
- Arterial and Venous Pump rotor damage and that the rotor surface remains smooth

⚠WARNING

A damaged pump rotor will not work properly. This could result in patient serious injury.
Visually inspect the pump rotor each time you load any of Infusion, Ultra, SNDP or Blood Cassettes.
If the pump rotor is damaged, ***DO NOT*** use the machine for treatment, ***DO NOT*** repair and call for service.

- Damage to the arterial and venous pressure transducers and that their surface is smooth

If any of the damage listed above is noted, avoid using the machine, until the damage has been repaired and the machine is in proper working order.

13.13 Cassette Panel O-Rings Inspection and Greasing

Inspection and greasing of the O-Rings of the Cassette Panel are required once a week or after the “(#644) Pressure Transducer: Greasing Required“ alarm. Follow the steps below to proceed:

- Check the three O-Rings on the Cassette Panel pressure transducers for nicks, damage, or wear and replace them if necessary;
- Grease the three O-Rings to improve the seal to the Cassette and reduce wear of O-Rings.

To inspect and grease the O-Rings proceed as follows:

1. Remove possible grease in excess using an alcool based solution (refer to the list of chemicals for external cleaning suggested on this section);
2. Check, that the O-Ring surface and the metal stems are free from any extraneous particles and check for nicks, damage or wear. Replace the O-Rings if necessary;
3. Apply a very thin coating of silicon grease (spare part code 6975395) all around the three O-Rings. The silicon grease can be applied either manually or using a grease Dispenser. Refer to the two procedures described below.

13.13.1 Manual Greasing procedure

To perform a manual greasing, proced as follows:

1. Place a small quantity of silicon grease on your finger and apply it uniformly all around the O-Rings.
2. Pay careful attention to ensure that no grease enters inside the metal stems: grease in the stems may result in false pressure readings.

13.13.2 Procedure with Grease Dispenser

To use a Grease Dispenser to perform the greasing procedure, proceed as follows:

1. Ensure that no grease is present on the Grease Dispenser (spare part code 6977854) around the Grease Dispenser pin;
2. Screw the Grease Dispenser to the silicon grease tube and then insert the pin of the Grease Dispenser in the pressure coupling hole;
3. Press firmly to fit the Grease Dispenser against the pressure coupling;
4. Press the silicon grease tube to allow a thin quantity of grease exits and rotate the tube twice;
5. Remove the Grease Dispenser;
6. Verify that a thin quantity of grease has been applied all around the O-Ring;
7. Check, that the front of the couplings and the holes in the metal steams are free from any extraneous particles and exceeding grease.

13.14 Storage

When the machine is planned not to be in use for a long period of time, it must be kept in a safe place such as a closet free from dust:

- Avoid storing in busy areas where the machine may be moved or knocked over.
- Avoid storing in conditions of high humidity.

If the machine will be stored for an extended period, it is suggested to carry out a chemical bacteriostatic disinfection at least once per week. To perform chemical disinfection refer to "13.4 Set and start a Disinfection/Rinse Program" paragraph of this chapter.

⚠WARNING

Stagnant water may contaminate the machine. If machine is stored for more than 7 days, the water line should be disinfected and rinsed.

⚠WARNING

After a prolonged period of storage, Service must be called to return the machine to proper working order.
Storage at temperatures below 0 °C is allowed only if the hydraulic circuit has been completely emptied.

13.15 BPM cuff

Use a damp cloth with 70% ethyl alcohol or 30% to 50% isopropyl alcohol to clean the surface of the BPM cuff.

⚠WARNING

Never put any solutions inside the BPM cuff. If this occurs, dry the inside of the cuff before usage

The cloth cover of the cuff is removable and washable.

In the cloth bag there are two holes: the larger hole is used to put the rubber bladder through while the smaller one is for the rubber tube. (See “A.” in the figure below)

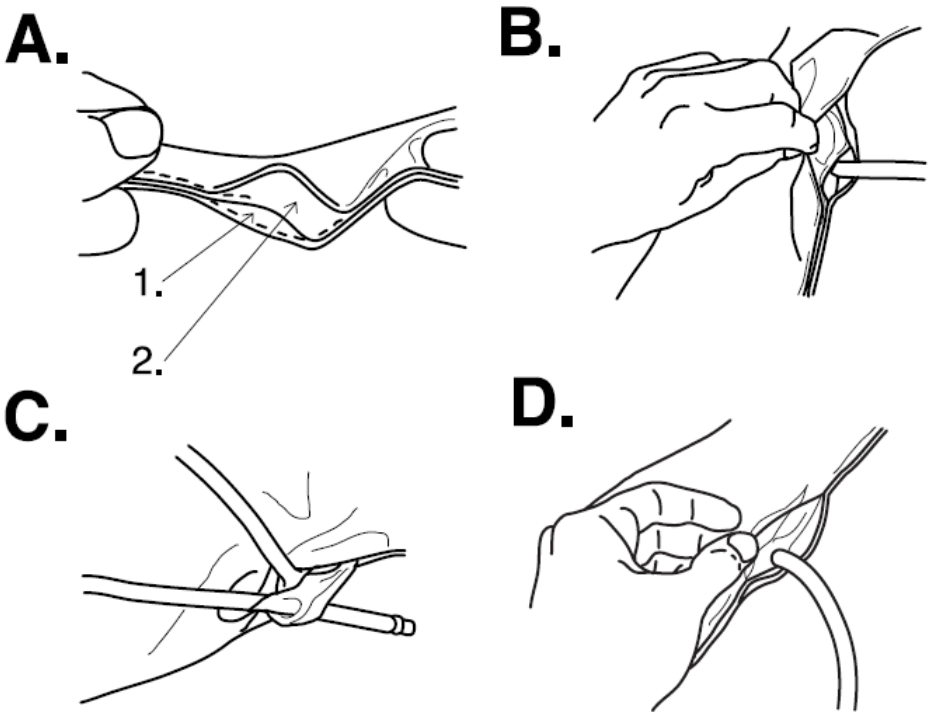
To take the rubber bladder out of the cloth bag, proceed as follows:

1. Put the rubber tube inside the bag and pull out the inside cloth to make the hole larger (see “B.” and “C.” in the figure below);

2. Take the rubber bag out of the larger hole (see “D.” in the figure below);

3. Reverse the order when putting the rubber bladder in the cloth bag;

4. When the cloth bag of the cuff is removed, pay attention to the hole through which the rubber tube of the rubber bladder goes. Unless the hole is used, the rubber bag gets out of the cloth bag, leading to blow out.



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Chapter 14: Communication System

14.1 General Description

The Artis Dialysis System can be connected to different external devices for storage and display of dialysis related data. All the communication software systems, such as Exalis Dialysis Management Tool, that can be connected to the Artis Dialysis System, are managed through the Artis Communication System.

This system is able to transfer through the network data acquired during a dialysis treatment and it is designed to be compatible with different data acquisition systems.

Moreover, the Artis Dialysis System is able to display a run-time dialysis report containing the data acquired throughout the treatment. For further information on this feature, refer to the “Chapter 15: Report Environment” of this Operator’s Manual.

NOTE

The communication system features are linked to an external system able to acquire data from the Artis Dialysis System. This chapter refers to the “Exalis Dialysis Management Tool” running on a Personal Computer connected to the Artis Dialysis System. Refer to the software's manual for a detailed description of the program.

⚠WARNING

The Artis Dialysis System makes available the dialysis related data through connection to various external devices for storage and display. This information cannot be considered as the sole data source to induce any therapeutic or pharmacological action on the patient. It is the responsibility of the user to verify any data that would imply taking therapeutic or pharmacological actions.

⚠WARNING

Exalis software allows information to be gathered about individuals and the user must be aware that the use of the information processed or generated by the software is restricted in most countries by legal dispositions such as the Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995. The user shall therefore take all necessary measures to ensure the confidentiality of the information which is monitored by means of Exalis.

14.2 Patient Card

The Artis Dialysis System allows the operator to retrieve patient data and prescription from a card.

The card can be used:

- as a "Patient ID Card": this is the only available option if the machine is configured to communicate with the Exalis System.
  In this case, only the patient ID, name and surname are read from the card. The ID is then used to retrieve the patient data and prescription from the Exalis system;

- as a "Patient Prescription Card": all patient's data and prescription are automatically set.
  It is not possible to use the "Patient Prescription Card" if the machine is connected to the Exalis System.

To use a Patient Prescription Card or a Patient iD Card, it is necessary to configure the machine in a proper way in the Service 2 menu.

14.3 Exalis Functional Description

The Exalis software is an application used for downloading/transferring data from/ to the Artis Dialysis System.

NOTE

It is necessary that the Artis Dialysis System is properly configured to make available the connection with the Exalis system.

WARNING

When the Exalis system is connected to machines via Ethernet, it is mandatory that Exalis Server PC's and any machine reside on a dedicated subnetwork: the machines and the Exalis servers have to be the ONLY devices present within it.

WARNING

Exalis software must be installed on a dedicated PC. The presence of software tools other than the Exalis software might affect the proper working of Exalis software. It is responsibility of the user to verify the proper working of the Exalis software when other software tools, previously or subsequently installed on the same PC, are present.

14.3.1 Data Download

The Exalis system provides the following data acquisition methods.

Synchronous acquisition

The Exalis system is able to define a sampling time, typically 5 minutes, for each machine parameter that can be acquired. The Artis Dialysis System has a default pre-setting for this type of acquisition, which can be customized via Exalis itself. Refer to Exalis Operator's Manual for further explanations.

The table below lists all parameters available for acquisition.

Artis Dialysis System Parameters	Parameter Acquisition
Medication	Acquired according to Exalis setup
Intake	Acquired according to Exalis setup
Event	Acquired according to Exalis setup
Remaining time	Acquired according to Exalis setup
Current total weight loss	Acquired according to Exalis setup
Current weight loss rate	Acquired according to Exalis setup
Dialysis conductivity	Acquired according to Exalis setup
Bic 8.4% conductivity	Acquired according to Exalis setup
Dialysis temperature	Acquired according to Exalis setup
Dialysis flow rate	Acquired according to Exalis setup
Infusion pump setting	Acquired according to Exalis setup
Heparin pump rate	Acquired according to Exalis setup
Total blood	Acquired according to Exalis setup
TM pressure	Acquired according to Exalis setup
Venous Pressure	Acquired according to Exalis setup
Arterial Pressure	Acquired according to Exalis setup
pH *(optional)*	Acquired according to Exalis setup
Depurated blood volume KT	Acquired according to Exalis setup
Qf/Qb	Acquired according to Exalis setup
Qi/Qb	Acquired according to Exalis setup
TMP Set	Acquired according to Exalis setup
Scale	Acquired according to Exalis setup

Artis Dialysis System Parameters	Parameter Acquisition
K Concentration	Acquired according to Exalis setup
Effective dialysis time	Acquired according to Exalis setup
Total heparin infusion	Acquired according to Exalis setup
Accumulated Infusion Bolus	Acquired according to Exalis setup
Infused volume	Acquired according to Exalis setup
Pre-filter pressure	Acquired according to Exalis setup
Arterial flow S.N.	Acquired according to Exalis setup
Venous flow S.N.	Acquired according to Exalis setup
Stroke volume	Acquired according to Exalis setup
Diastolic Pressure	Acquired according to Exalis setup
Systolic Pressure	Acquired according to Exalis setup
Heart Rate	Acquired according to Exalis setup
Plasma Na Concentration	Acquired according to Exalis setup
Scale-bed weight	Acquired according to Exalis setup
Current Na Equivalent	Acquired according to Exalis setup
Desired Na Equivalent	Acquired according to Exalis setup
Actual blood volume	Acquired according to Exalis setup
BV Desired	Acquired according to Exalis setup
Ionic mass balance	Acquired according to Exalis setup
Ionic effective dialysance	Acquired according to Exalis setup
Real blood flow	Acquired according to Exalis setup
Plasma conductivity	Acquired according to Exalis setup
Dialyzer outlet pressure	Acquired according to Exalis setup
Blood Flow D/N-S/N	Acquired according to Exalis setup
KT/V	Acquired according to Exalis setup
TWL Desired	Acquired according to Exalis setup

Asynchronous acquisition

The Exalis software is able to acquire information about alarms and machine events (for example: incidents, given medicines, Snapshots taken from the *Report* screen, BPM measurements) occurred on the Artis Dialysis System. The Exalis software acquires the whole machine status at the occurrence of each event or alarm.

Operating phase acquisition

The Exalis software is able to acquire the start and the stop time of any operating phase of the machine (for example: Bic. Dialysis, Rinsing, Idle, Chemical Disinfection, Heat Disinfection).

Status acquisition

The Exalis software is able to acquire the machine status (for example: in dialysis, rinsing) together with the parameters listed in the table displayed in the previous page.

NOTE

The acquisition of both synchronous and asynchronous data occurs only between the following events:

- Start of treatment: dialysis phase running after pressing the "Start Treatment" button.
- Stop of treatment: start of rinseback process by pressing the "Rinseback" action button.

NOTE

If between the start and the end of synchronous and asynchronous data acquisition the connection with the Exalis software is continously unavailable, data will be stored on the internal memory of the Artis Dialysis System. Once the connection with the Exalis software is re-established, it will be possible to download synchronous and asynchronous data from the Artis Dialysis System. This is valid for up to 3 treatments.

14.3.2 Prescription Download with the Exalis System

The Exalis software is an application used for downloading data from the Artis Dialysis System and transferring data to the Artis Dialysis System.

The Exalis software is able to transfer to the Artis Dialysis System the prescription parameters of a patient stored in the Exalis database. Refer to the “14.5 Events Handled by the Communication System” section of this chapter.

NOTE

To make available the connection with the Exalis software, it is necessary that the Artis Dialysis System is properly configured.

NOTE

To fully accomplish the exchange of data between the Exalis software and the Artis Dialysis System, it is necessary to establish a connection between the Artis Dialysis System and the Exalis software and to verify the proper working of the connection.

14.4 Configuration of the machine Communication Environment

The following parameters must be set in the Service 2 menu, to make avaiable the Exalis communication on the Artis Dialysis System.

SUB-ENVIRONMENT	PARAMETER	DESCRIPTION	VALUES
Installed Features	**EXALIS**	Disables/enables communication with Exalis.	Yes/No (Default "No")
Exalis/Foxalis	**CCM IDENT**	Unique identifier of the Artis Dialysis System within the network system.	Selectable from 1 to 255. (Default 48)
Exalis/Foxalis	**STATION ID**	Allows to display each Artis Dialysis System location in the Exalis room overview window.	Selectable from 1 to 255. (Default 50)
Network	**IP ADDRESS 1st, 2nd, 3rd and 4th**	TCP/IP Configuration Address of the machine. Each Artis Dialysis System must have a unique identifier.	From 0 to 255 for the 1st, 2nd and 3rd field. From 1 to 254 for the 4th field. (Default 192.168.111.250)
Network	**SUBNET MASK**	Subnet Mask for the machine.	From 0 to 255 for each field. (Default 255.255.255.0.0)

14.5 Events Handled by the Communication System

Following a brief description of the events and parameters handled by the Artis Communication System and made available to any communication software systems, such as the Exalis Dialysis Management Tool.

14.5.1 Patient Login

The Patient Login is a unique event for each dialysis session, i.e, the logged in patient is not logged out until the session is concluded or a different patient is logged in.
Patient can be logged in only before the “Connect Patient” button is pressed and confirmed.

14.5.1.1 Patient Login by means of a Card

To perform a Patient Login by means of a Patient ID/Prescription Card, proceed as follows:

1. Press the Prescription NavPad button to enter the *Prescription* screen;

2. Place the card near the Card Reader on the right side of the machine:

   - If the machine is configured to communicate with Exalis system, the patient ID, name and surname are read from the card and the operator is prompted for confirmation. Once confirmed, the patient ID is used to retrieve prescription from Exalis System;

   - If the machine is not configured to communicate with Exalis system, the patient ID, name and surname and the patient prescription parameters are retrieved from the card (refer to the “14.6 Prescription download with the Patient Prescription Card” section below);

   - The Prescription Review window is displayed: it contains all the safety relevant prescription parameters as well as the Patient ID, The Patient Name and surname and the Date and Source of the prescription:

Figure 14-1. Prescription Review

The Prescription Review confirmation window displays:

- Safety relevant prescription parameters;
- The Patient Name;
- The Patient ID;
- The Prescription Date;
- The Prescription Source.

NOTE

Only applicable parameters are displayed.
For example, HDF-specific parameters are displayed only if "HDF Post" treatment type has been set , Hemocontrol-specific parameters are displayed only if Hemocontrol is active and so on.

14.5.1.2 Manual Patient Login with Exalis software

It is possible to perform a manual patient login if the Patient ID/Prescription card is not available and the machine is configured to communicate with the Exalis System.

To manually perform a Patient Login, proceed as follows:

1. Press the Prescription NavPad button to enter the *Prescription* screen;

2. On the *Prescription* screen press the “Patient ID” button:

   • A keyboard is displayed allowing the operator to enter the Patient ID:

3. Enter the Patient ID and press the ***CONFIRM*** button:

   • The related patient prescription parameters are retrieved from the network;

   • The system checks that all the prescription values are within the allowed ranges and that they are aligned with functionalities available on the machine;

   • The Prescription Review window is displayed:

Figure 14-2. Prescription Review

The Prescription Review confirmation window displays:

- Safety relevant prescription parameters;
- The Patient Name;
- The Patient ID;
- The Prescription Date;
- The Prescription Source.

NOTE

Only applicable parameters are displayed.
For example, HDF-specific parameters are displayed only if "HDF Post" treatment type has been set , Hemocontrol-specific parameters are displayed only if Hemocontrol is active and so on.

14.5.2 Pre/Post Dialysis Data Handling

This option allows the operator to record data related to the patient blood pressure before and after the dialysis treatment.

The acquisition system will store the following pre/post data:

- Pre and Post Lying Systolic
- Pre and Post Lying Diastolic
- Pre and Post Lying Pulse Rates
- Pre and Post Sitting Systolic
- Pre and Post Sitting Diastolic
- Pre and Post Sitting Pulse Rates
- Pre and Post Standing Systolic
- Pre and Post Standing Diastolic
- Pre and Post Standing Pulse Rates

Depending on the operating phase of the equipment, the system allows the operator to input data.

14.5.2.1 Pre Dialysis Data

Pre-dialysis data can be entered after the Patient Login procedure.

To enter pre-dialysis data, proceed as follows:

1. On the *Prescription* screen press the “Auto BPM” option on the “Activated Functions” list: the BPM Settings sub-screen opens.
2. On this sub-screen press the “Patient Position” button: a selectpad opens.
3. On the selectpad select the desired patient position then press the ***CONFIRM*** button.
4. On the BPM Settings sub-screen press the “BPM” action button to activate a manual BPM measurement or press the “Auto BPM” action button to activate an automatic measurement:
   - The system will automatically acquire BPM measurements;
   - BPM measurements will be displayed in the table on the *Report* screen. Refer to “Chapter 15: Report Environment” for further explanations of the use of the *Report* screen.
   - BPM measurements will be made available for network acquisition.

14.5.2.2 Post Dialysis Data

Post-dialysis data can be entered between the pressure of the "Stop Treatment" button and the machine switch-off.

To enter post-dialysis data, proceed as follows:

1. On the *Prescription* screen press the "Auto BPM" option on the "Activated Functions" list: the BPM Settings sub-screen opens.

2. On this sub-screen press the "Patient Position" button: a selectpad opens.

3. On the selectpad select the desired patient position then press the ***CONFIRM*** button.

4. On the BPM Settings sub-screen press the "BPM" action button to activate a manual BPM measurement or press the "Auto BPM" action button to activate an automatic measurement:

   • The system will automatically acquire BPM measurements;

   • BPM measurements will be displayed in the table on the *Report* screen. Refer to "Chapter 15: Report Environment" for further explanations of the use of the *Report* screen.

   • BPM measurements will be made available for network acquisition.

14.5.3 Event/Intervention Marking

The Artis communication system allows to store specific patient-related events, which have occurred during the dialysis treatment. The events recorded are made available for network acquisition.

This feature is active only when the acquisition is running: starting from the confirmation of the "Connect Patient" button (Start of data acquisition) until the confirmation of the Rinseback process (Stop of data acquisition).

The data recorded is entered and displayed on the *Report* screen. (Refer to the "Chapter 15: Report Environment" of this Operator's Manual).

14.6 Prescription download with the Patient Prescription Card

The Artis Dialysis System allows the user to start a dialysis treatment with prescription retrieved from a Patient Prescription Card.

To download patient prescription from a card, proceed as follows:

1. Perform a Patient Login by means of a Card as described in the section above;

2. On the Prescription Review window check the prescription parameters and press the ***CONFIRM*** button when done:

> ***NOTE***
>
> ***Do Not*** confirm the Prescription Review window if the “Isolated UF Time” and/or the “Isolated UF Volume” parameter values are equal to zero.
> In this case, the machine might not be able to properly perform the Isolated UF process. Perform a Fast Recovery procedure to re-establish the proper machine working conditions.

   - The Prescription Review window closes;
   - All the parameters in the *Prescription* screen are updated;
   - The *Prescription* screen is displayed

3. On the *Prescription* screen, press the “UF Volume” parameter: a keypad opens;

4. Set/check the UF Volume value and press the ***CONFIRM*** button on the keypad:

   - The confirmation of the “UF Volume” parameter is a mandatory action. This mandatory parameter is identified with the following icon: 

14.7 Patient ID Card and Patient Prescription Card Management

The Patient ID Card and the Patient Prescription Card are managed only through the machine.

It is possible to write, modify and delete the data contained in the card by means of the Artis Dialysis System User Interface.

14.7.1 Write an Empty card

It is possible to save data on an empty card, procceding as follows:

1. Open the *Prescription* screen;

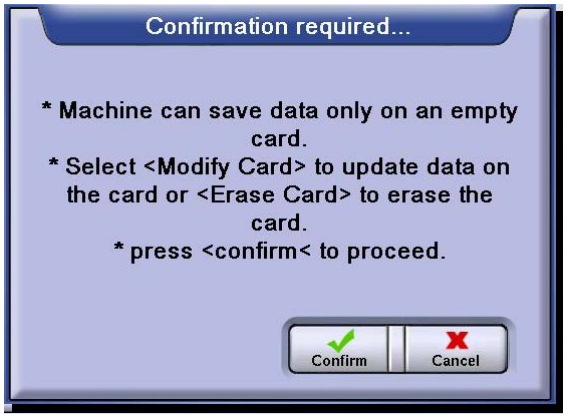
2. Press the "Pt. Card Edit" button:

    •The Patient Card Edit sub-screen opens

Figure 14-3. Patient Card Edit Sub-screen

3. Press the "New Card" button:

    • The following window opens:



4. Press the ***CONFIRM*** button on the window to start the procedure:

   •The "Pt Id", "Pt Name" and "Pt Surname" parameters on the Patient Card Edit sub-screen become available

5. Edit the "Pt Id", "Pt Name" and "Pt Surname" parameters:

   • If the machine is not configured to communicate with the Exalis System (the card is thus a Patient Prescription Card), all other prescription parameters on the Patient Card Edit sub-screen are enabled;

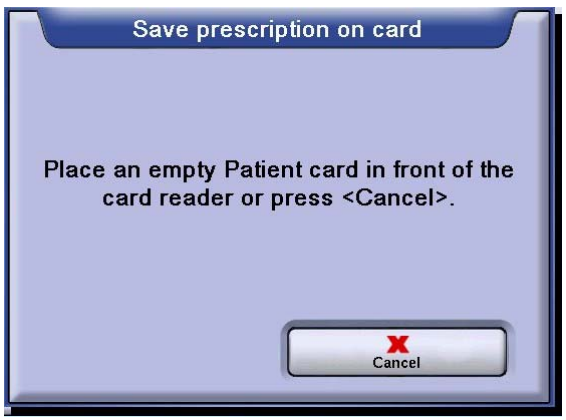
   • The "Save" button is enabled

6. If the machine is not configured to communicate with the Exalis System (the card is thus a Patient Prescription Card), edit the prescription parameters:

   • The system calculates derived values and perform congruency checks on the edited parameters

7. Press the "Save" button;

   •The following window opens:



8. Place an empty card near the Card Reader:

   • The data is saved on the card;

   • The following window opens

9. Press the ***CONFIRM*** button:

   • The window closes;

   • The Patient Card Edit sub-screen closes;

   • The *Prescription* screen is displayed.

14.7.2 Modify a Card

It is possible to modify data contained in a card, proceeding as follows:

1. Open the *Prescription* screen;

2. Press the "Pt. Card Edit" button:

   •The Patient Card Edit sub-screen opens

3. Press the "Modify Card" button:

   • The following window opens:

4. Place a card near the Card Reader:

   • All the data contained on the card are loaded and displayed on the Patient Card Edit sub-screen

   • All the parameter buttons on the Patient Card Edit sub-screen are enabled;

   • The “Save” button is enabled

5. Modify the parameters;

NOTE

If the machine is configured to communicate with the Exalis System, it is only possible to modify the Patient Name and Surname.

   • The system calculates derived values and perform congruency checks on the edited parameters

6. Press the “Save” button;

7. A new window opens requiring to place the previous card near the Card Reader;

8. Place the same card near the Card Reader:

   • The new prescription parameters and the patient data are saved on the card;

   • The following window opens

9. Press the ***CONFIRM*** button on the window:

   • The window closes;

   • The *Prescription* screen is dispalyed

14.7.3 Erase a Card

It is possible to delete all the data contained in a card, proceeding as follows:

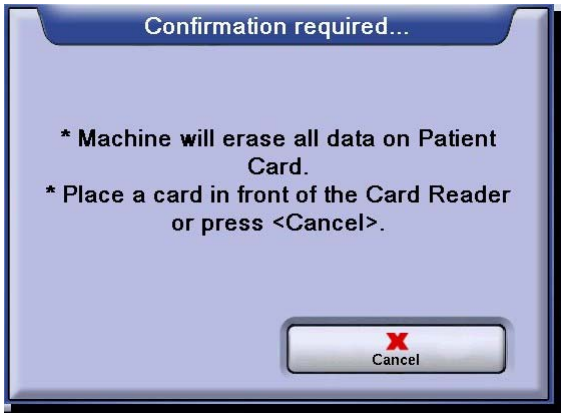
1. Open the *Prescription* screen;

2. Press the "Pt. Card Edit" button:

   •The Patient Card Edit sub-screen opens:

3. Press the "Erase Card" button:

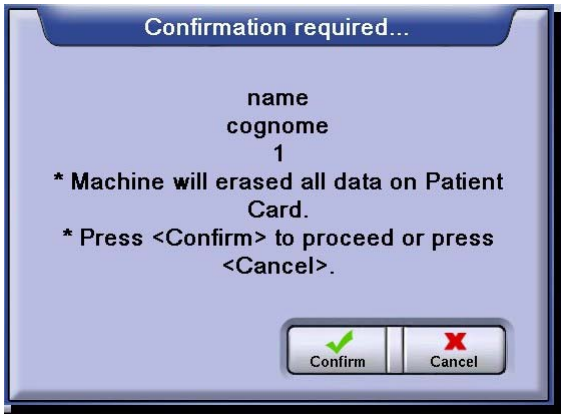
   • The following window opens:



4. Place a card near the Card Reader:

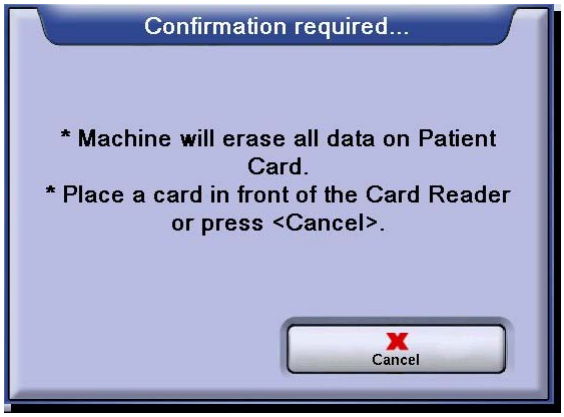
   • The system loads the data contained in the card

   • The following window opens:



5. Press the ***CONFIRM*** button on the window;

   • The following window opens



6. Place the card near the Card Reader;

   • All the data on the card are deleted;

   • A *Confirm* window opens informing the operator that the card has been successfully emptied

7. Press the ***CONFIRM*** button;

   • The window closes

   • The *Prescription* screen is displayed

14.8 Prescription download with the Exalis System

⚠WARNING

The Exalis software must be used exclusively with the authority of a physician, who is the sole responsible for the use of the information processed by the software.

The Artis Dialysis System allows the user to start a dialysis treatment with a treatment prescription retrieved from the Exalis Dialysis Management Tool.

To download patient prescription from the Exalis database, proceed as follows:

1. Perform a Manual Patient login as described in the section above;

2. On the Prescription Review window check the prescription parameters and press the ***CONFIRM*** button when done:

   • The system checks that the prescription is not corrupted;

   • All the parameters are loaded;

   • The Prescription Review window closes.

⚠WARNING

The Artis Dialysis System can be programmed by receiving data through connections to the Exalis system. As soon as the Artis Dialysis System receives data from the network, it checks for its correctness and displays safety relevant parameters on the Touch Screen. It is responsibility of the user to verify this data before confirming it.

3. On the *Prescription* screen, press the "UF Volume" parameter: a keypad opens;

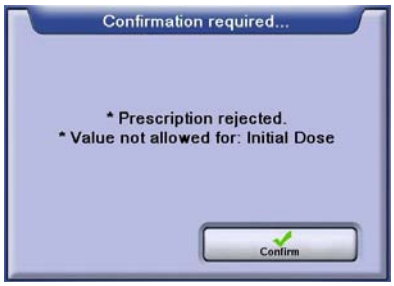
4. Set/check the UF Volume value and press the ***CONFIRM*** button on the keypad:

   • The confirmation of the "UF Volume" parameter is a mandatory action. This mandatory parameter is identified with the following icon: 

14.9 Error Messages related to Computer/Card Prescription Download

If an error occurs during the transfer of the prescription parameters, a proper confirmation window opens or a proper warning message is triggered.

Refer to the table below for specific actions to be taken to solve the situation.

PROBLEM	MACHINE ACTION	MESSAGE DISPLAYED	SUGGESTED ACTION
The Patient ID entered on the keyboard or loaded from a Card is not available in the Exalis system or no prescription for the entered Patient ID is available within the Exalis system.	A confirmation window opens.		Press the ***CONFIRM*** button and repeat the Patient ID entry procedure.
At least one of the prescription parameters is out of range.	• A confirmation window opens listing at least the first three out of range parameters; • The prescription is discarded.	 Example with the “Initial Dose” parameter.	Press the ***CONFIRM*** button and check values entered in Exalis for the wrong parameter. If using a Patient Prescription Card: • Press the ***CONFIRM*** button; • Set the proper parameter value on the machine; • Try again to load the card.

PROBLEM	MACHINE ACTION	MESSAGE DISPLAYED	SUGGESTED ACTION
At least one of the prescription parameters is not aligned with the functionalities available on the machine.	• A confirmation window opens listing the first detected invalid setting; • The prescription is discarded.	 Example with "Treatment Type" parameter.	Press the ***CONFIRM*** button and check settings entered in Exalis for the invalid parameter. If using a Patient Prescription Card: • Press the ***CONFIRM*** button; • Set the proper parameter on the machine • Try again to load the card
When the Patient ID is entered and confirmed, the network connection is not available.	• A confirmation window opens; • The prescription is not loaded.		Press the ***CONFIRM*** button and check the network connection between the Exalis software and the Artis Dialysis System.
After confirming the Patient ID, the system is not able to retrieve prescription parameters from the network in the required time.	An alarm message is displayed.		Press the ***RESET*** button and repeat the prescription parameter load procedure.

PROBLEM	MACHINE ACTION	MESSAGE DISPLAYED	SUGGESTED ACTION
An error occurs while reading a Patient ID/ Prescription Car	• A confirmation window opens; • The card is not read.		If the error occurs before the Patient Connection procedure, press the ***CONFIRM*** button and repeat the procedure; If the error occurs after the Patient Connection procedure, press the ***CONFIRM*** button to clear the window and do not present the Patient Card again.

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Chapter 15: Report Environment

To enter the *Report* screen, press the Report NavPad button on the NavPad area. The following screen is displayed with the proper configuration:

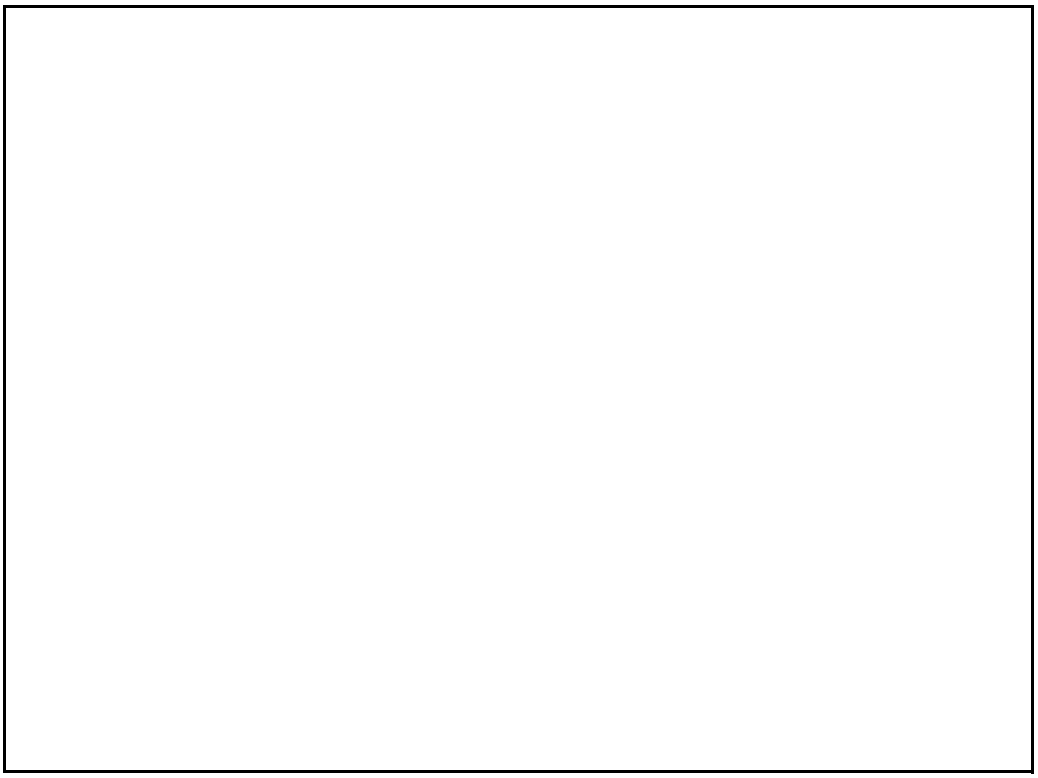

Figure 15-1. Report screen

On the *Report* screen the following buttons and parameters can be displayed:

Table 1: Report Screen Parameters

Parameters	
1. Event List	Displays a list of the automatic and manual readings

Table 2: Report Screen Buttons

Buttons	
1. Print Me	Allows the operator to create the Print Me Report file
2. New Reading	Performs an additional reading of the current treatment parameters
3. New Event	Opens the Event sub-screen

Table 2: Report Screen Buttons

Buttons	
4. Blackbox	Opens a keypad to enter the password that allows to switch to the *BlackBox* environment.
5. Hygiene	Opens the *Hygiene* sub-screen
6. LCD Test	Allows the operator to perform the test of the Touch Screen pixels
7. Screen Cleaning	Allows the operator to clean the Touch Screen
8. System Data	Opens the Service pages where machine data are displayed
9. Service	Opens a keypad to enter the password that allows to switch to the Service menus.

It is possible to preset the type of parameters that have to be displayed in the Event list, according to the clinical requests. The readings of these parameters are automatically carried out each 30 minutes during the dialysis session or can be manually performed by pressing the "New Reading" button or the "Time" button (refer to "15.2.1 Print Me" section of this chapter).
The Event list can record up to maximum 100 events.

All the treatment-related parameters, manually or automatically acquired, are stored in this table and are available for network acquisition through the Exalis System.

Data collected during a treatment are available on the *Report* screen until one of the following events occurs:

- A new prescription is selected and confirmed on the network
- The "Connect Patient" button is pressed and confirmed

In these cases, the Event list is emptied and is filled in with the data of the new dialysis session.

15.1 Report sub-screens

A detailed description of the *Report* sub-screens is reported in the sections below.

15.1.1 Event sub-screen

The incidents, actions and medications occurred during a treatment must be manually entered by the operator in the Event sub-screen.

To enter a new event, proceed as follows:

1. Press the “New Event” button on the *Report* screen. The following sub-screen is displayed:

Figure 15-2. Event sub-screen

The Event sub-screen contains the following tables:

- Incident table: this table lists several options of incident.
- Various table: this table lists several types of various events (e.g. Pre/ Post Weight)
- Medication / Intake table: this table lists several options of medications.

Enter and confirm the new event as detailed in the sections below.

Each time an event is confirmed, the “Event” list on the *Report* screen is accordingly updated.

To close the Event sub-screen without saving the incident/medication entered, press the ***CLOSE*** button.

Autochart Function

The Autochart function allows to automatically record events at regular intervals (30 minutes).

It is also possible to set the interval time for an automatic event recording by pressing the "AutoChart Time" button.

Each time an event is recorded, the "Event" list on the *Report* screen is accordingly updated.

15.1.1.1 Incident table

The Incident table has the following configuration:

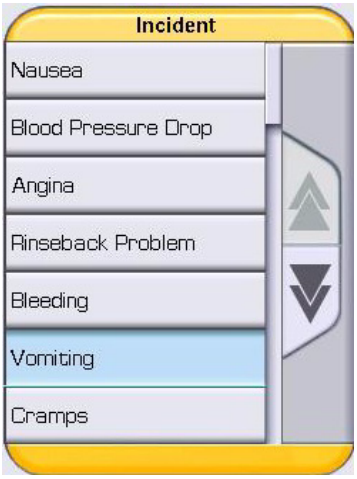

Figure 15-3. Incident table

To enter an incident proceed as follows:

1. Select the required incident in the list;
2. Press the "Confirm Event" button to confirm the incident:
   - The "Event" list on the *Report* screen is accordingly updated;
   - The Event sub-screen closes;
   - The *Report* screen is displayed.

15.1.1.2 Various table

The Various table has the following configuration:

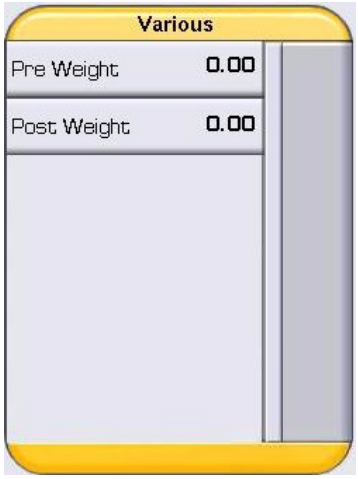

Figure 15-4. Various table

To enter a various event proceed as follows:

1. Select the desired option in the list: a keypad opens;
2. In the keypad, set the patient weight and press the ***CONFIRM*** button to confirm it;
3. Press the “Confirm Event” button to confirm the event:
   - The “Event” list on the *Report* screen is accordingly updated;
   - The Event sub-screen closes;
   - The *Report* screen is displayed.

15.1.1.3 Medication/Intake table

The Medication / Intake table has the following configuration:

Figure 15-5. Medication/Intake table

To enter a medication administered to the patient (if any), proceed as follows:

1. Select the required medication: a keypad opens;
2. In the keypad, set the dose administered and press the ***CONFIRM*** button to confirm it;
3. Press the "Confirm Event" button to enter the medication:
   - The "Event" list on the *Report* screen is accordingly updated;
   - The Event sub-screen closes;
   - The *Report* screen is displayed.

15.2 Report Functionalities

All the functionalities available on the *Report* screen are described below.

15.2.1 Print Me

This button becomes available on the Report Environment only after it has been set and activated on the Service menu by a service technician.

It allows to create the Print Me Report file containing a subset of the current treatment parameters.

NOTE

The Print Me function requires that the Print Me Manager software is installed and running in your dialysis unit.
For further information on the availability in your country of this function, contact your local representative.

⚠WARNING

The Artis Dialysis System makes available the dialysis related data through connection to various external devices for storage and display. This information cannot be considered as the sole data source to induce any therapeutic or pharmacological action on the patient. It is the responsibility of the user to verify any data that would imply taking therapeutic or pharmacological actions.

The Print Me Report is a non-editable PDF file that can be stored, printed or sent via e-mail.

15.2.1.1 How to create a report

At the end of a treatment

To create a report at the end of a dialysis session, press the “Print Me” button after post treatment measurements have been taken.

While a treatment is ongoing

To create a report while a treatment is ongoing, proceed as follows:

1. Press the “New Reading” button
2. Press the “Snapshot” button to update treatment-related parameter values;
3. Press the “Print Me” button to create the report.

NOTE

It is possible to create a Print Me report before switching the machine OFF.
Infact, each time the machine is switched ON, the Print Me report will lost all data. The same will happen after a Fast Recovery procedure.

15.2.2 New Reading

This button allows to take an additional reading of the current parameters value.

Each time this button is pressed, all the current treatment parameters are displayed on the "Event" list of the Report screen.

Manual and automatic readings are differently labeled in the "Event" list:

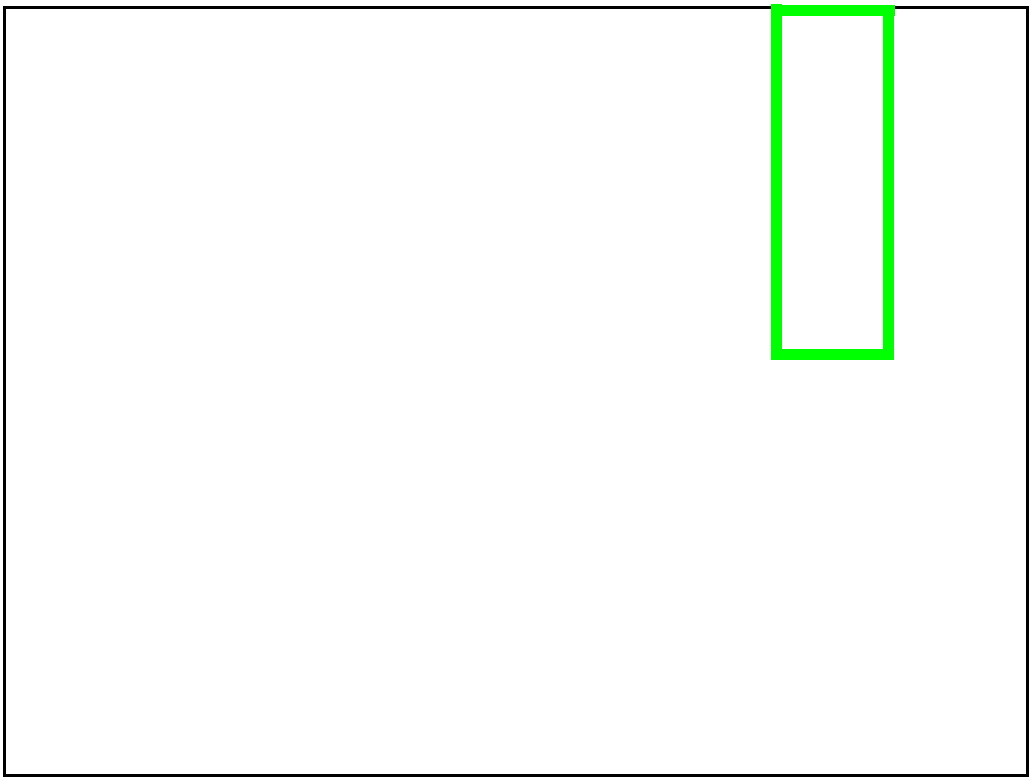

Figure 15-6. New Reading

- Manual reading are identified with the "Snapshot" label;
- Automatic readings are identified with the name of the event.

Snapshot Label

Pressing the “Snapshot” label on the Event List, the following sub-scren opens:

Figure 15-7. ModifySnapShot Event sub-screen

On this sub-screen it is possible to modify the Snapshot Event, proceeding as described in the “15.1.1 Event sub-screen” section of this chapter.

When pressing the “Confirm Event” button to confirm changes, the Event List on the *Report* screen is updated with the new event inserted.

Time Button

It is possible to take a manual reading of the current prescription parameters also pressing the “Time” button in the right bottom corner of the Touch Screen.

Autochart Function

The Autochart function allows to automatically record events at regular intervals (30 minutes).

It is also possible to set the interval time for an automatic event recording by pressing the “AutoChart Time” button.

Each time an event is recorded, the “Event” list on the *Report* screen is accordingly updated.

15.2.3 BlackBox Button

This button allows to enter the BlackBox environment after typing the specific password.

The BlackBox recorder is a service feature installed on the Artis Dialysis System allowing to periodically store the machine data (such as alarms, machine/patient parameter values and so on) and make them available to the service technician.

Data are logged according to the BlackBox recorder configuration: the list of data to log in the BlackBox is set by the service technician.

NOTE

When the maximum BlackBox memory size is reached, the system overwrites data starting from the oldest ones.

The occurrence of an alarm is a type of data included in the manufacturer's default list of data to be logged.

NOTE

Each time the machine is switched OFF or in case of a Power Failure with battery backup not charged, the BlackBox recorder could not be able to keep track of the data occurred within the last ten minutes.

15.2.4 Hygiene

The "Hygiene" button allows to open the Hygiene sub-screen where information about Ultrafilters and Disinfections are available.

For further details on these functionalities, refer to the "8.25 Ultrafilter Change Procedure" and "13.2.2 Disinfection/Rinse History Table" sections of this Operator's Manual.

15.2.5 LCD Test

For details on this functionality, refer to the related section of the "Chapter 8: Special Procedures" of this Operator's Manual.

15.2.6 Screen Cleaning

For details on this functionality, refer to the related section of the "Chapter 13: Disinfection/Rinse" of this Operator's Manual.

15.2.7 System Data

This function allows to display all the service-related data during treatment, without entering the Service menu. It is not possible to change data on this view but only to display them.

Data are divided in four Service Data pages and collected according to the main module they belong to.

To display the Service Data pages, proceed as follows:

1. Press the “System Data” button on the *Report* screen: the following sub-screen opens

Figure 15-8. Service Data sub-screen

2. Select the desired page pressing the related numeric button on the left side of the sub-screen;
3. Press the ***CLOSE*** button to exit from the sub-screen and switch to the *Report* screen.

15.2.8 Service

This button allows service technician to enter the Service menus.

This functionality is detailed in the “Artis Service Manual Maintenance”.

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Chapter 16: Alarms, Information Signals and Troubleshooting

16.1 Alarm Management System

The Artis Dialysis System is provided with an Alarm Management System that allows the machine to recognize and control various types of malfunctions and faults and to determine that a potential or actual hazard exists.

Three types of indicators are available to point out an alarm condition to the operator:

- **Auditory alarm signal** issued by an internal acustic speaker;
- **Visual alarm signal** issued by the Status Lights at the top of the machine;
- **Alarm Message** displayed in the Alarm/Information Message Area. Each alarm is referenced by a technical number and an alarm message.
  For further details on the Alarm/Information Message Area, refer to the “1.3.1.1 Alarm/Information Messages Area” section of the "Chapter 1: General Description” of this Operator’s Manual.

NOTE

If more than one alarm occurs at the same time, they are automatically prioritized by the system.

The machine will restart the interrupted action only after all the alarms have been solved.

Alarm Signals are triggered as soon as the alarm condition is detected by the Alarm Management System.

⚠WARNING

If in your dialysis facility equipments with different alarm systems are installed, pay attention to the potential hazards associated to a not correct evaluation of the alarms generated by the different equipments.

16.2 Alarm Classification

16.2.1 Priority Levels

Artis alarms are categorized based on their *priority*, which indicates the importance of an alarm and the urgency to address it.

In particular, the priority of each alarm has been assigned taking into account both the severity of the potential consequences of operator's failure to respond to the cause of the alarm and how fast these consequences may start to happen.

There are three alarm messages priorities: *High*, *Medium* and *Low*.

Each alarm priority is represented by a set of specific properties which are:

HIGH PRIORITY

- Recurring high sound, 10 sound pulses repeated every 7 seconds;
- Red flashing light;
- Alarm message displayed with white text on red background.

MEDIUM PRIORITY

- Recurring medium sound, 3 sound pulses repeated every 7 seconds;
- Yellow flashing light;
- Alarm message displayed with black text on yellow background.

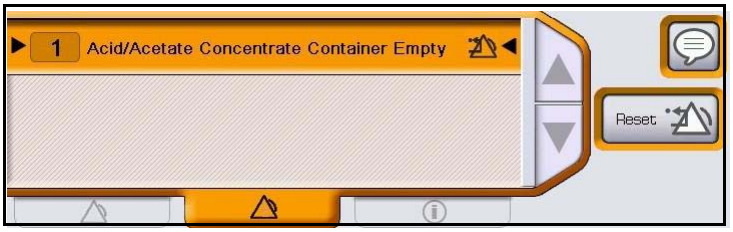
LOW PRIORITY

- Recurring low sound, 2 sound pulses repeated every 17 seconds;
- Yellow constant light;
- Alarm message displayed with black text on yellow background.

16.2.1.1 Alarm Messages in the Alarm/Information Message Area

Below some examples of different priority alarm messages, as they are displayed in the Alarm/Information Message Area.

High Priority Alarm Message



Medium Priority Alarm Messages

Low Priority Alarm Messages

In case that more alarms with different priorities are triggered at the same time, they are displayed in two different tabs according to their priority:

- Red tab: displays alarms with high priority
- Yellow tab: displays alarms with medium and low priority

NOTE

In each tab, no more than three alarms at a time can be displayed. The Scroll Buttons can be used to scroll the alarm list.

In this case, the Alarm Management System will automatically trigger the Auditory and Visual Alarm signals and will show the Alarm Message tab related to the alarm(s) with higher priority.

The operator will be anyway able to:

- visualize all the alarms with the same priority using the scroll buttons;

- visualize all the alarms with different priorities using the two colour-coded tabs at the bottom of the Alarm/Information Message Area.

Each time the Alarm/Information Message Area is displayed, if one of the tabs is empty it is grey-coloured. Otherwise, if the tab contains at least one alarm/information message it is highlighted, according to the specific colour related to the priority level.

For further details on the Alarm/Information Message Area refer to the "1.3.1.1 Alarm/Information Messages Area" section of this Operator's Manual.

16.2.2 Auditory Alarm Signal characteristics

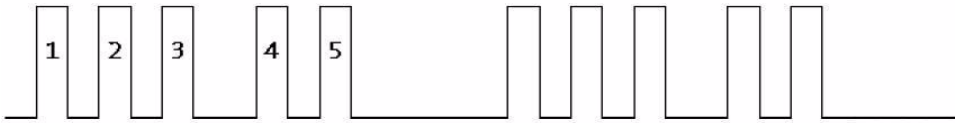
The Auditory Alarm Signals have the characteristics listed in the table below:

Characteristics	High	Medium	Low
Number of Pulses per Burst	10	3	2
Interburst Interval	approx. 4 seconds	approx. 6 seconds	approx. 16 seconds
Volume	approx. 69 dB(A)	approx. 68 dB(A)	approx. 67 dB(A)

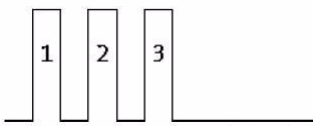
NOTE

The Volume measures have been performed in compliance with the IEC 60601-1-8 standard.

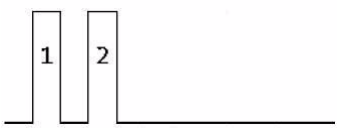
Burst graphical representation for High Priority alarms



Burst graphical representation for Medium Priority alarms



Burst graphical representation for Low Priority alarms



16.2.3 Intelligent Alarm System

The Artis Alarm Management System is able to recognize if two or more alarm conditions are triggered related to the same cause.

In this case, the Alarm Management System distinguishes the alarms as follows:

- The Main Alarm
- The alarm(s) resulting from the Main Alarm

When alarms of this type occur the Alarm Management System only displays the Main Alarm(s) in the Alarm/Information Message Area.

The table below lists the Main Alarms managed by the Artis Alarm Management System:

MAIN ALARMS	RESULTING ALARMS
BiCart cartridge empty (#21)	• Incorrect conductivity measured (#375) • Incorrect bicart/blue concentrate tube concentration (#366) • Dialysis fluid temp low (#377) • Dialysis fluid flow low (#373) • Conductivity too low (#462) • Acid/Safebag AFB Concentrate Error (#369) • Bicarbonate/Safebag K Concentrate Error (#370) • Dialysis fluid temp too low (#461) • Dialysate pH low (#368) *(optional)* • Dialysate pH high (#40) *(optional)* • Conductivity from Bicart/blue concentrate tube too Low (#464) • Incorrect fluid conductivity detected (#496) • Select Concentrate Error (#590)
Acid/Acetate Concentrate Container Empty (#1)	• Incorrect conductivity measured (#375) • Incorrect bicart/blue concentrate tube concentration (#366) • Dialysis fluid temp low (#377) • Dialysis fluid flow low (#373) • Conductivity too low (#462) • Acid/Safebag AFB Concentrate Error (#369) • Bicarbonate/Safebag K Concentrate Error (#370) • Dialysis fluid temp too low (#461) • Dialysate pH low (#368) *(optional)* • Dialysate pH high (#40) *(optional)* • Conductivity from Bicart/blue concentrate tube too Low (#464) • Incorrect fluid conductivity detected (#496)

MAIN ALARMS	RESULTING ALARMS
Incorrect concentrate connector (#2)	• Incorrect conductivity measured (#375) • Incorrect bicart/blue concentrate tube concentration (#366) • Dialysis fluid temp low (#377) • Dialysis fluid flow low (#373) • Conductivity too low (#462) • Acid/Safebag AFB Concentrate Error (#369) • Bicarbonate/Safebag K Concentrate Error (#370) • Dialysis fluid temp too low (#461) • Dialysate pH low (#368) *(optional)* • Dialysate pH high (#40) *(optional)* • Conductivity from Bicart/blue concentrate tube too Low (#464) • Incorrect fluid conductivity detected (#496)
Insufficient water supply (#100)	• Incorrect conductivity measured (#375) • Incorrect bicart/blue concentrate tube concentration (#366) • Dialysis fluid temp low (#377) • Dialysis fluid flow low (#373) • Conductivity too low (#462) • Acid/Safebag AFB Concentrate Error (#369) • Bicarbonate/Safebag K Concentrate Error (#370) • Dialysis fluid temp too low (#461) • Dialysate pH low (#368) *(optional)* • Dialysate pH high (#40) *(optional)* • Conductivity from Bicart/blue concentrate tube too Low (#464) • Incorrect fluid conductivity detected (#496) • Select Concentrate Error (#590)
SelectCart cartridge Empty (#596)	• Incorrect conductivity measured (#375) • Incorrect bicart/blue concentrate tube concentration (#366) • Dialysis fluid temp low (#377) • Dialysis fluid flow low (#373) • Conductivity too low (#462) • Acid/Safebag AFB Concentrate Error (#369) • Bicarbonate/Safebag K Concentrate Error (#370) • Dialysis fluid temp too low (#461) • Dialysate pH low (#368) *(optional)* • Dialysate pH high (#40) *(optional)* • Conductivity from Bicart/blue concentrate tube too Low (#464) • Incorrect fluid conductivity detected (#496) • Select Concentrate Error (#590)

MAIN ALARMS	RESULTING ALARMS
SelectBag empty (#293)	• Incorrect conductivity measured (#375) • Incorrect bicart/blue concentrate tube concentration (#366) • Dialysis fluid temp low (#377) • Dialysis fluid flow low (#373), • Conductivity too low (#462) • Acid/Safebag AFB Concentrate Error (#369) • Bicarbonate/Safebag K Concentrate Error (#370) • Dialysis fluid temp too low (#461) • Dialysate pH low (#368) *(optional)* • Dialysate pH high (#40) *(optional)* • Conductivity from Bicart/blue concentrate tube too Low (#464) • Incorrect fluid conductivity detected (#496) • Select Concentrate Error (#590)
Incorrect conductivity measured (#375)	• Incorrect fluid conductivity detected (#496)
Safebag - K Compartment Empty (#610)	• Incorrect conductivity measured (#375) • Incorrect bicart/blue concentrate tube concentration (#366) • Dialysis fluid temp low (#377) • Dialysis fluid flow low (#373) • Conductivity too low (#462) • Acid/Safebag AFB Concentrate Error (#369) • Bicarbonate/Safebag K Concentrate Error (#370) • Dialysis fluid temp too low (#461) • Dialysate pH low (#368) *(optional)* • Dialysate pH high (#40) *(optional)* • Conductivity from Bicart/blue concentrate tube too Low (#464) • Incorrect fluid conductivity detected (#496) • Select Concentrate Error (#590)
Safebag - AFB Compartment Empty (#611)	• Incorrect conductivity measured (#375) • Incorrect bicart/blue concentrate tube concentration (#366) • Dialysis fluid temp low (#377) • Dialysis fluid flow low (#373) • Conductivity too low (#462) • Acid/Safebag AFB Concentrate Error (#369) • Bicarbonate/Safebag K Concentrate Error (#370) • Dialysis fluid temp too low (#461) • Dialysate pH low (#368) *(optional)* • Dialysate pH high (#40) *(optional)* • Conductivity from Bicart/blue concentrate tube too Low (#464) • Incorrect fluid conductivity detected (#496) • Select Concentrate Error (#590)

MAIN ALARMS	RESULTING ALARMS
Scale Measurement Error (#98)	• Infusion Flow Rate Error (#99)
Arterial Chamber: Level Adjustment Required (#642)	• Low Arterial Chamber Level (#643)

16.3 Information Signals

Information Signals are triggered to give the operator advices or notices on some machine events.

Information Signals are divided into Notifications and Smartscan Messages; they are both displayed on the Alarm/Information Messages Area together with a recurring notice sound.

- *NOTIFICATIONS* are usually related to customizable reminder events or machine events requiring the operator's attention in order to move forward in the treatment workflow;
- *SMARTSCAN MESSAGES* are triggered by Smartscan criteria enabled on the machine.

Information Signals are referenced by:

- **A Message** displayed in the Alarm/Information Message Area;
- **An Auditory signal** issued by an internal acustic speaker.

16.3.1 Information Signals in the Alarm/Information Message Area

Information Signals are blue colour-coded.

Below some examples of Information Signals, as they are displayed in the Alarm/Information Message Area:

Notification

Smartscan Message

In case that Alarms and Information Signals are triggered at the same time, the Alarm Management System will automatically trigger the Auditory and Visual Alarm signals and will show the Alarm Message tab related to the alarm(s) with higher priority.

In this case, the operator will be anyway able to:

- visualize all the alarms with the same priority using the scroll buttons;
- visualize all the alarms with different priorities using the two colour-coded tabs at the bottom of the Alarm/Information Message Area;
- visualize all the Information Signals using the blue colour-coded tab at the bottom of the Alarm/Information Message Area.

If alarms are not present, the tabs are grey-coloured. Otherwise, they are highlighted, according to the specific colour related to the priority level.

For further details on the Alarm/Information Message Area refer to the "1.3.1.1 Alarm/Information Messages Area" section of this Operator's Manual.

16.3.2 Auditory Information Signals characteristics

The Information Signals are notified by specific melodies, different from the Auditory Alarm Signals, with the following Volumes:

Characteristic	Notifications	Smartscan Messages
Volume	53 dB(A)	57 dB(A)

The Auditory Information Signal is issued every 90 seconds.

NOTE

The Volume measures have been performed in compliance with the IEC 60601-1-8 standard.

16.4 Levels of operator intervention

When an alarm condition occurs or an Information Signal is triggered, the operator may be able to manually deal with the problem.

The specific actions to take are described for each individual alarm. Four types of intervention are possible:

- MUTE
- CONFIRM
- PAUSE ALARM
- RESET

16.4.1 Mute

It is possible to temporarily (for 2 minutes) deactivate the Auditory Alarm Signal, by pressing the ***MUTE*** key on the Hard Key Panel.

It is important to consider that during the MUTE status:

- The LED on the MUTE key switches ON.
- The Auditory Alarm Signal is deactivated.
- The Visual Alarm Signal remains active.
- The Message remains displayed in the Alarm/Information Message Area.

It is possible to remove the MUTE status:

- Automatically: when the time has elapsed.
- Manually: pressing again the MUTE key.

NOTE

If a new alarm is triggered, different from the previous one, during a MUTE status, the MUTE status will be automatically removed.

MUTE ICON

This icon appears on the Alarm/Information Message Area when the mute function is activated by the operator pressing the related key on the Hard Key Panel:

At the top of this icon, a Progress Bar is displayed showing the remaining time of the mute function.

16.4.2 Confirm

The ***CONFIRM*** operation forces a removing of the Information Signal. It clears the Auditory Information Signals.

After having looked over the Information Signal, the operator can confirm the Information Signal pressing the ***CONFIRM*** button, displayed on the right top side of the Alarm/Information Message Area.

The ***CONFIRM*** button that appears in the Alarm/Information Message Area is referenced by the following symbol:

16.4.3 Pause Alarm

The Artis Dialysis System allows to ***Pause*** only the alarm related to a Blood Leak Detection.

The ***Pause*** of this alarm can be performed to give the possibility to ignore it and to continue the treatment. *It is useful every time a recovery of a dangerous situation requires the machine working, to reactivate some functionality that was stopped due to the alarm presence.*

To pause the alarm, press the ***PAUSE ALARM*** button displayed in the Alarm/Information Message Area when the Blood in Dialysate alarm is triggered.

It is important to consider that during a pause period:

- Some of the safety mechanisms are disabled for a limited period of time (2 minutes);
- The Auditory and Visible Alarm Signals are maintained;
- The Alarm Message is still displayed in the Alarm/Information Message Area.

If one or more additional faults cause an alarm during the ***PAUSE*** state, the description relative to each fault is displayed in the Alarm/Information Message Area.

⚠WARNING

During a ***PAUSE*** status, the operator is responsible for monitoring of the parameters that have been paused.

The ***PAUSE ALARM*** button that appears in the Alarm/Information Message Area is referenced by the following symbol:

16.4.4 Reset

Automatic Reset

Some alarms can be automatically ***RESET*** by the machine when there are no more failures.

The ***RESET*** operation consists of an automatic removing of the alarm after that the conditions that generated the alarm are satisfied again for a specified time interval dependent on the alarm itself.

After an automatic reset, the Auditory and Visible Alarm Signals are cleared and the functionalities previously stopped are restored again.

Manual Reset

Some alarms can be manually reset pressing the Reset button that appears in the Alarm/Information Message Area.

This button is referenced by the following symbol:

⚠WARNING

Press the Reset button to clear the alarm only after having removed the causes of the alarm.
Refer to the related troubleshooting for a detailed description of how to remove the alarm cause.

16.5 Guidelines to respond to an Alarm/Information Signal

In case of an Alarm/Information Signal condition, the operator should perform the following actions:

1. Press the ***MUTE*** key to silence the Auditory Signal, if desired.

2. Observe the message in the Alarm/Information Message Area on the left bottom of the Touch Screen.

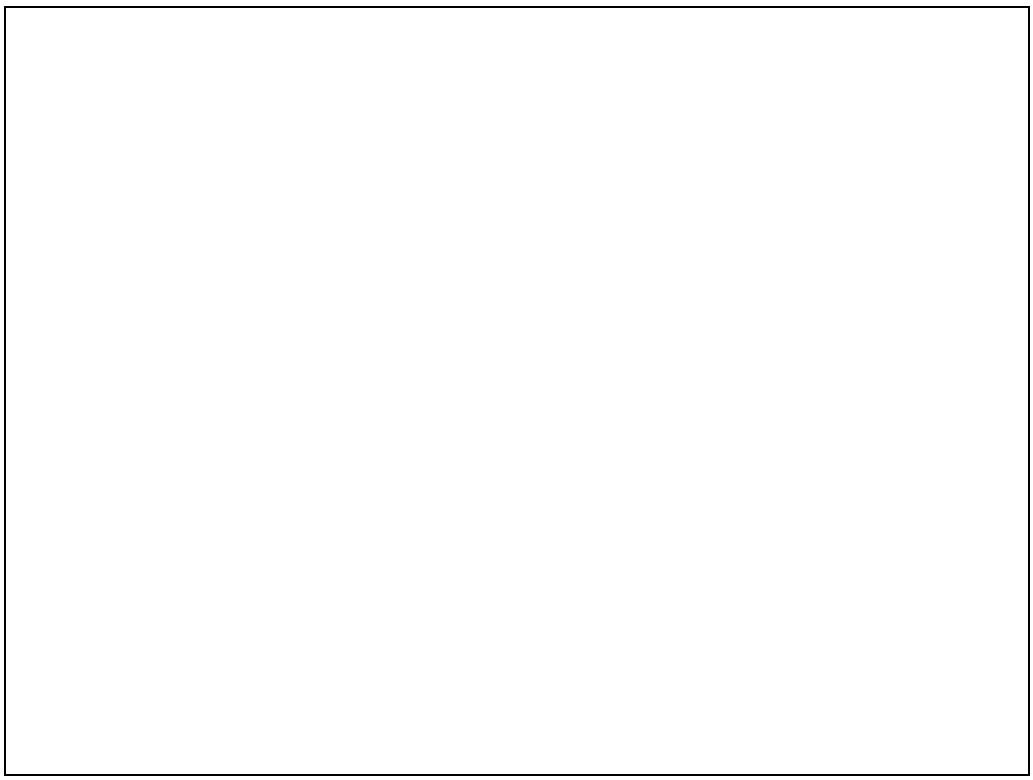


Figure 16-1. Alarm/Information Message Area - Example

3. If more than three Alarm/Information Signals in the same list are triggered, it is possible to scroll the list up and down using the Scroll Buttons.

4. If Alarm/Information Signals of different lists are triggered, it is possible to switch between the three tabs displayed at the bottom of the Alarm/Information Messages Area.

5. Determine the cause of the Alarm/Information Signal. If uncertain about the cause or the appropriate response to the alarm, refer to the “16.7 Operator Alarm and Information Signals Troubleshooting” section in this chapter for possible causes and solutions. If an Alarm Information Area is available, the ***HELP*** button is displayed.

6. Correct the cause of the alarm as described in “16.7 Operator Alarm and Information Signals Troubleshooting”.

7. If required press the Reset or the ***CONFIRM*** button.

NOTE

If nothing is placed between the operator and the Status Lights the Visual Alarm and Information Signals are visible from a distance of 4 meters.

If nothing is placed between the operator and the Artis Touch Screen, the messages displayed in the Alarm/Information Message Area are visible from a distance of 1 meter.

16.6 Alarms/Information Messages

Messages displayed on the Alarm/Information Message Area can be grouped into three categories:

- *Operator Alarms* requiring the operator's intervention.
- *Malfunction Alarms* requiring the service technician's intervention.
- *Information Messages* requiring the operator's attention in order to move forward in the treatment workflow.

For a detailed list of these alarms refer to the "16.6.1 Operator Alarms, Malfunctions and Information Messages List" table.

16.6.1 Operator Alarms, Malfunctions and Information Messages List

The table below contains a list of all the Operator Alarms, Malfunctions and Information Messages in numerical order, indicating:

- The message displayed on the Alarm/Information Message Area;
- The Technical Code;
- The Priority Level;
- The possibility or not to manually ***RESET*** the Operator Alarms or to ***CONFIRM*** the Information messages
- The type of message: Operator, Malfunction or Information
- The reference to the page of this chapter where it is possible to find the related troubleshooting

NOTE

Alarms related to pH supervision are available only if pH probe is installed on your Artis Dialysis System.

ALARM MESSAGE	CODE	PRIORITY	RESET/ CONFIRM	TYPE	TROUBLE-SHOOTING
Acid/Acetate Concentrate Container Empty	1	MEDIUM	NO	Operator	Page 31
Incorrect Red Concentrate Connector Position	2	LOW	NO	Operator	Page 33
Incorrect SelectCart Holder Arms Position	3	LOW	NO	Operator	Page 34
Air in Venous Line	4	HIGH	NO	Operator	Page 35

ALARM MESSAGE	CODE	PRIORITY	RESET/ CONFIRM	TYPE	TROUBLE-SHOOTING
MALFUNCTION	6	HIGH	/	Malfunction	Page 313
MALFUNCTION	7	HIGH	/	Malfunction	Page 313
Blood pump cover open	8	HIGH	NO	Operator	Page 36
Pump speed too high	10	HIGH	YES	Operator	Page 37
Arterial pressure out of range	11	HIGH	YES	Operator	Page 38
Blood pump speed error	12	HIGH	YES	Operator	Page 39
Blood pump rotor error	13	HIGH	YES	Operator	Page 40
Incorrect Blue Concentrate Connector Position	18	LOW	NO	Operator	Page 41
BiCart cartridge empty	21	MEDIUM	NO	Operator	Page 42
Incorrect BiCart Holder Arms Position	22	LOW	NO	Operator	Page 43
Incorrect bicart/blue concentrate tube concentration	23	LOW	NO	Operator	Page 44
Blood in dialysate	28	HIGH	NO	Operator	Page 45
BPM failure	30	MEDIUM	YES	Operator	Page 46
BPM Measurement failure or Out of Range	31	MEDIUM	YES	Operator	Page 47
Air In Hydraulic Pathway (LD1)	33	LOW	NO	Operator	Page 48
Hydraulic Sensor Dirty (LP)	34	LOW	NO	Operator	Page 49
Air in Hydraulic Pathway (LD2)	35	LOW	NO	Operator	Page 50
Dialysate pH high *(optional)*	40	LOW	NO	Operator	Page 51
MALFUNCTION	43	MEDIUM	/	Malfunction	Page 313
Dialysis fluid flow high	44	LOW	NO	Operator	Page 53
BPM Diastolic pressure alarm	46	HIGH	YES	Operator	Page 54
MALFUNCTION	48	MEDIUM	/	Malfunction	Page 313
MALFUNCTION	49	MEDIUM	/	Malfunction	Page 313
Treatment Time Complete	51	/	YES	Information	Page 55
Fluid Removal Complete	53	/	YES	Information	Page 56
Heparin pump overload	55	MEDIUM	NO	Operator	Page 57
Heparin infusion complete	58	/	YES	Information	Page 58

ALARM MESSAGE	CODE	PRIORITY	RESET/ CONFIRM	TYPE	TROUBLE-SHOOTING
MALFUNCTION *(See **NOTE1** below)*	59	MEDIUM	/	Malfunction	Page 313
UF target will not be achieved	60	LOW	NO	Operator	Page 59
CFD1 Ultrafilter Lower Switch Error	61	LOW	NO	Operator	Page 60
Incorrect conductivity measured	62	LOW	NO	Operator	Page 61
MALFUNCTION	63	MEDIUM	/	Malfunction	Page 313
Safe State Activated Cause: *(See **NOTE2** and **NOTE3** below)*	64	HIGH	/	Malfunction	Page 313
BPM Heart rate alarm	66	HIGH	YES	Operator	Page 62
MALFUNCTION	67	MEDIUM	/	Malfunction	Page 313
TMP High	68	HIGH	YES	Operator	Page 63
Heparin pump lower limit reached	69	/	YES	Information	Page 64
Heparinization Not Initiated	71	LOW	YES	Operator	Page 65
Infusion Settings Invalid Prescription	79	MEDIUM	NO	Operator	Page 66
Low Temperature	81	LOW	NO	Operator	Page 67
MALFUNCTION	84	MEDIUM	/	Malfunction	Page 313
Dialyzer Inlet Pressure High	87	HIGH	YES	Operator	Page 68
Dialyzer Outlet Pressure High	88	HIGH	YES	Operator	Page 69
MAXIMUM TEMPERATURE LIMIT	90	MEDIUM	NO	Operator	Page 70
Max Weight On The Scale	92	MEDIUM	YES	Operator	Page 71
Dialyzer Inlet Pressure Low	94	HIGH	YES	Operator	Page 72
Dialyzer Outlet Pressure Low	95	HIGH	YES	Operator	Page 73
Infusion Flow Rate Error	99	LOW	NO	Operator	Page 74
Insufficient water supply	100	MEDIUM	NO	Operator	Page 75
Infusion Settings Outside Prescription	102	/	YES	Information	Page 76
MALFUNCTION	104	MEDIUM	/	Malfunction	Page 313

ALARM MESSAGE	CODE	PRIORITY	RESET/ CONFIRM	TYPE	TROUBLE-SHOOTING
MALFUNCTION	106	MEDIUM	/	Malfunction	Page 313
MALFUNCTION	108	MEDIUM	/	Malfunction	Page 313
MALFUNCTION	110	MEDIUM	/	Malfunction	Page 313
MALFUNCTION	111	MEDIUM	/	Malfunction	Page 313
MALFUNCTION *(optional)*	112	LOW	/	Malfunction	Page 313
MALFUNCTION *(optional)*	113	LOW	/	Malfunction	Page 313
Dialyzer Pressure Maximum	114	LOW	YES	Operator	Page 77
Dialyzer Pressure Minimum	115	LOW	YES	Operator	Page 79
MALFUNCTION	120	HIGH	/	Malfunction	Page 313
MALFUNCTION	130	MEDIUM	/	Malfunction	Page 313
MALFUNCTION	131	MEDIUM	/	Malfunction	Page 313
BPM Systolic pressure alarm	132	HIGH	YES	Operator	Page 80
Dialysis fluid temp high	134	LOW	NO	Operator	Page 81
Ultrafilter TMP High	138	MEDIUM	YES	Operator	Page 82
TMP Low	142	LOW	YES	Operator	Page 83
UF rate higher than expected	145	LOW	YES	Operator	Page 84
Dialysate Pressure High	146	LOW	YES	Operator	Page 85
MALFUNCTION	148	HIGH	/	Malfunction	Page 313
Venous pump cover is open	149	HIGH	NO	Operator	Page 86
Venous pressure out of range	153	HIGH	YES	Operator	Page 87
Venous pressure too high	154	HIGH	YES	Operator	Page 88
Venous pressure high	155	HIGH	YES	Operator	Page 90
Venous pump speed error	157	HIGH	YES	Operator	Page 91
Venous pump rotor error	158	LOW	YES	Operator	Page 92
MALFUNCTION	159	HIGH	/	Malfunction	Page 313
Scale Measurement Error	161	MEDIUM	NO	Operator	Page 93
MALFUNCTION	167	LOW	/	Malfunction	Page 313
BLD Sensitivity Loss	170	MEDIUM	YES	Operator	Page 94
MALFUNCTION	173	MEDIUM	/	Malfunction	Page 313

ALARM MESSAGE	CODE	PRIORITY	RESET/ CONFIRM	TYPE	TROUBLE-SHOOTING
MALFUNCTION	182	MEDIUM	/	Malfunction	Page 313
Backup battery failure	183	LOW	YES	Operator	Page 95
MALFUNCTION	185	MEDIUM	/	Malfunction	Page 313
MALFUNCTION	190	MEDIUM	/	Malfunction	Page 313
HEMOSCAN: Minimum Blood Volume	191	HIGH	NO	Operator	Page 96
Low blood pump speed	204	HIGH	YES	Operator	Page 97
Incorrect venous or arterial line position in clamp	205	HIGH	NO	Operator	Page 98
Fluid path obstruction	206	MEDIUM	YES	Operator	Page 99
HEMOSCAN: DARK Out of Range	223	LOW	NO	Operator	Page 100
HEMOSCAN: Communication Error	224	HIGH	NO	Operator	Page 101
HEMOSCAN: TEST Out of Range	225	LOW	NO	Operator	Page 102
HEMOSCAN: L/H Out of Range	226	LOW	NO	Operator	Page 103
Smartscan - Hemocontrol: High Na Concentration	231	/	YES	Information	Page 104
Smartscan - Hemocontrol: Low Na Concentration	232	/	YES	Information	Page 105
Hemocontrol: BV% not available	234	LOW	YES	Operator	Page 106
AFBK: ByPass too Frequent	291	MEDIUM	YES	Operator	Page 107
SelectBag empty	293	MEDIUM	NO	Operator	Page 108
MALFUNCTION	295	MEDIUM	/	Malfunction	Page 313
Bioslave Subsystem Communication Error	296	MEDIUM	NO	Operator	Page 109
BIO SLAVE ERROR	297	HIGH	NO	Operator	Page 110
MALFUNCTION	300	MEDIUM	/	Malfunction	Page 313
MALFUNCTION	301	MEDIUM	/	Malfunction	Page 313
Still in bypass	302	MEDIUM	YES	Operator	Page 111
MALFUNCTION	304	HIGH	/	Malfunction	Page 313

ALARM MESSAGE	CODE	PRIORITY	RESET/ CONFIRM	TYPE	TROUBLE-SHOOTING
ARTERIAL PRESSURE HIGH	305	HIGH	YES	Operator	Page 112
Arterial Pressure Below Treatment Min. Limit	306	HIGH	YES	Operator	Page 113
Patient connected	308	MEDIUM	YES	Operator	Page 114
Wrong A/V or System Pressure Offset	319	LOW	YES	Operator	Page 115
MALFUNCTION	320	HIGH	/	Malfunction	Page 313
MALFUNCTION	327	MEDIUM	/	Malfunction	Page 313
Reminder - Still In Pause Therapy	329	LOW	YES	Operator	Page 116
Blue Dialysis Fluid Tube Incorrect Position	330	LOW	NO	Operator	Page 117
Red Dialysis Fluid Tube Incorrect Position	331	LOW	NO	Operator	Page 118
Venous Pressure Not Increasing	351	HIGH	YES	Operator	Page 119
No power - Using battery backup	353	MEDIUM	NO	Operator	Page 120
Blood Sensed in Venous Line	359	HIGH	YES	Operator	Page 121
Pump speed too low	362	HIGH	YES	Operator	Page 122
Blood Pump Rotor Error	363	HIGH	YES	Operator	Page 123
Venous line not in patient sensor	364	HIGH	NO	Operator	Page 124
Incorrect bicart/blue concentrate tube concentration	366	LOW	NO	Operator	Page 125
Dialysate pH low *(optional)*	368	LOW	NO	Operator	Page 126
Acid/Safebag AFB Concentrate Error	369	LOW	NO	Operator	Page 128
Bicarbonate/Safebag K Concentrate Error	370	LOW	NO	Operator	Page 130
Dialysis fluid flow low	373	LOW	NO	Operator	Page 131
Incorrect conductivity measured	375	LOW	NO	Operator	Page 132
Dialysis fluid temp low	377	LOW	NO	Operator	Page 133

ALARM MESSAGE	CODE	PRIORITY	RESET/ CONFIRM	TYPE	TROUBLE-SHOOTING
UF rate lower than expected	379	LOW	YES	Operator	Page 134
Venous pressure low	382	HIGH	YES	Operator	Page 135
Arterial pressure low	384	HIGH	YES	Operator	Page 136
Air In Blood T0 Failure	385	HIGH	YES	Operator	Page 137
MALFUNCTION	395	MEDIUM	/	Malfunction	Page 313
MALFUNCTION	396	MEDIUM	/	Malfunction	Page 313
Na or Bic Settings result in conductivity out of range	401	LOW	NO	Operator	Page 138
Ultrafilter Replacement Reminder	402	/	YES	Information	Page 139
Incorrect Green Concentrate Connector Position	404	LOW	NO	Operator	Page 140
MALFUNCTION	410	MEDIUM	/	Malfunction	Page 313
Incorrect SelectBag Holder Arm Position	411	LOW	NO	Operator	Page 141
Venous Flow Minimum	412	HIGH	YES	Operator	Page 142
Venous Flow Maximum	413	HIGH	YES	Operator	Page 143
No Power - Using Battery Backup	415	MEDIUM	YES	Operator	Page 144
Left Blue EvaClean door incorrect position	416	HIGH	NO	Operator	Page 145
Right Red EvaClean door incorrect position	417	HIGH	NO	Operator	Page 146
T1 Test Pre Filter Pressure	418	LOW	YES	Operator	Page 147
T1 Test Arterial Pump/ABD	419	LOW	YES	Operator	Page 148
T1 Test Flow Meters	422	LOW	YES	Operator	Page 149
On-line door incorrect position	423	LOW	NO	Operator	Page 150
Sensor Bar Door Open	424	LOW	NO	Operator	Page 151
Dialysis fluid flow too low	425	LOW	YES	Operator	Page 152
MALFUNCTION	426	MEDIUM	/	Malfunction	Page 313
MALFUNCTION	434	LOW	/	Malfunction	Page 313
T1 Test Acoustical Buzzer Failed	438	LOW	YES	Operator	Page 153

ALARM MESSAGE	CODE	PRIORITY	RESET/ CONFIRM	TYPE	TROUBLE-SHOOTING
MALFUNCTION	440	HIGH	/	Malfunction	Page 313
MALFUNCTION	441	HIGH	/	Malfunction	Page 313
MALFUNCTION	442	HIGH	/	Malfunction	Page 313
Smartscan - Not Performing UF	443	/	YES	Information	Page 154
T1 Test Temperature Failed	444	LOW	YES	Operator	Page 155
T1 Test Conductivity Cells Failed	445	LOW	YES	Operator	Page 156
T1 Test Venous Pressure	446	LOW	YES	Operator	Page 157
T1 Test Arterial Pressure	447	LOW	YES	Operator	Page 158
Comunication Protective Cond. Cell Stopped	449	LOW	YES	Operator	Page 159
Comunication Select Cond. Cell Stopped	450	LOW	YES	Operator	Page 160
T1 Test Acoustic Speaker	451	HIGH	YES	Operator	Page 161
PDr Pressure High	452	LOW	YES	Operator	Page 162
PDr Pressure Low	453	LOW	YES	Operator	Page 163
Insert the HEMOSCAN cuvette	454	/	NO	Information	Page 164
Arterial pressure high	457	HIGH	YES	Operator	Page 165
Venous Pressure Below Treatment Min. Limit	459	HIGH	YES	Operator	Page 166
Dialysis fluid temp too high	460	LOW	NO	Operator	Page 167
Dialysis fluid temp too low	461	LOW	NO	Operator	Page 168
Conductivity too low	462	LOW	NO	Operator	Page 169
Conductivity too high	463	LOW	NO	Operator	Page 170
Conductivity from Bicart/blue concentrate tube too Low	464	LOW	NO	Operator	Page 171
Conductivity from Bicart/blue concentrate tube too High	465	LOW	NO	Operator	Page 172
MALFUNCTION	466	HIGH	/	Malfunction	Page 313
Leakages Test (A) Failure	467	LOW	YES	Operator	Page 173
Leakages Test (B) Failure	468	LOW	YES	Operator	Page 174

ALARM MESSAGE	CODE	PRIORITY	RESET/ CONFIRM	TYPE	TROUBLE-SHOOTING
Leakages Test (C) Failure	469	LOW	YES	Operator	Page 175
Leakages Test (D) Failure	470	LOW	YES	Operator	Page 176
Venous pressure Not Decreasing	472	HIGH	YES	Operator	Page 177
HEMOSCAN Autocalibration Failure	473	LOW	NO	Operator	Page 178
Preparation not Completed - Incorrect Condition on D1 Flow Rate	474	LOW	YES	Operator	Page 179
Preparation not Completed - Incorrect Condition on TcA	475	LOW	YES	Operator	Page 180
Preparation not Completed - Incorrect Condition on Acid/ AFB Distribution	476	LOW	YES	Operator	Page 181
Preparation not Completed - Incorrect Condition on Bicarbonate/AFB Distribution	477	LOW	YES	Operator	Page 182
Preparation not Completed - Incorrect Condition on Select Distribution	478	HIGH	YES	Operator	Page 183
Reminder - Still In Isolated UF	479	MEDIUM	YES	Operator	Page 184
MALFUNCTION	480	MEDIUM	/	Malfunction	Page 313
MALFUNCTION	481	HIGH	/	Malfunction	Page 313
MALFUNCTION	484	MEDIUM	/	Malfunction	Page 313
MALFUNCTION	485	MEDIUM	/	Malfunction	Page 313
MALFUNCTION	486	LOW	/	Malfunction	Page 313
MALFUNCTION	487	HIGH	/	Malfunction	Page 313
MALFUNCTION	488	HIGH	/	Malfunction	Page 313
MALFUNCTION	489	HIGH	/	Malfunction	Page 313
MALFUNCTION	490	MEDIUM	/	Malfunction	Page 313
MALFUNCTION	491	MEDIUM	/	Malfunction	Page 313
MALFUNCTION	492	MEDIUM	/	Malfunction	Page 313
MALFUNCTION	493	MEDIUM	/	Malfunction	Page 313
MALFUNCTION	494	HIGH	/	Malfunction	Page 313

ALARM MESSAGE	CODE	PRIORITY	RESET/ CONFIRM	TYPE	TROUBLE-SHOOTING
MALFUNCTION	495	HIGH	/	Malfunction	Page 313
Incorrect fluid conductivity detected	496	LOW	NO	Operator	Page 185
MALFUNCTION	497	MEDIUM	/	Malfunction	Page 313
Leakages Test (E) Failure	498	LOW	YES	Operator	Page 186
Leakages Test (F) Failure	499	LOW	YES	Operator	Page 187
Leakages Test (G) Failure	500	LOW	YES	Operator	Page 188
Reminder - Wrong Dip Switches	502	HIGH	YES	Operator	Page 189
Wrong Arterial and Venous Treatment Limits	503	MEDIUM	YES	Operator	Page 190
Low Disinfectant Level in last Clean Cart Process	504	LOW	YES	Operator	Page 191
UF Deviation	505	MEDIUM	NO	Operator	Page 192
Flowmeter Alignment Failed	506	LOW	YES	Operator	Page 193
Blood Cassette presence required	507	HIGH	NO	Operator	Page 194
Wrong disposable configuration on Ultra Cassette holder	508	HIGH	NO	Operator	Page 195
Blood Lines Clamped	509	HIGH	YES	Operator	Page 196
MALFUNCTION	510	MEDIUM	/	Malfunction	Page 313
MALFUNCTION	511	MEDIUM	/	Malfunction	Page 313
Smartscan - Low QB	512	/	YES	Information	Page 197
Smartscan - Low QD	513	/	YES	Information	Page 198
Smartscan - High QD	514	/	YES	Information	Page 199
Saline Bag Not Connected	515	LOW	YES	Operator	Page 200
Venous Line Clamped or Saline Bag Empty	516	LOW	YES	Operator	Page 201
Arterial Line Clamped	517	LOW	YES	Operator	Page 202
Line Not Connected in EvaClean Port or Access Line Open	518	LOW	YES	Operator	Page 203
Arterial Infusion Line Open	519	LOW	YES	Operator	Page 204

ALARM MESSAGE	CODE	PRIORITY	RESET/ CONFIRM	TYPE	TROUBLE-SHOOTING
Venous Pump Rotor Error	521	HIGH	YES	Operator	Page 205
Pre-Dialyzer Pressure out of range	522	HIGH	YES	Operator	Page 206
MALFUNCTION	523	HIGH	/	Malfunction	Page 313
Hemoconcentration Risk	524	MEDIUM	YES	Operator	Page 207
Pressure Alarm Limits Still Expanded	525	LOW	NO	Operator	Page 208
Reminder - HDF Substitution Still Disabled	526	MEDIUM	YES	Operator	Page 209
TMP Upper Limit	527	HIGH	NO	Operator	Page 210
Diascan: Autocalibration Failure	528	LOW	NO	Operator	Page 211
Diascan: Measurement Failure	529	LOW	YES	Operator	Page 212
Smartscan - Diascan: Low Clearance	530	/	YES	Information	Page 213
Smartscan - Diascan: Low KT/V	531	/	YES	Information	Page 214
Time Out on Data Reception	532	LOW	YES	Operator	Page 215
Chemical process not properly performed: disinfectant tank empty	533	LOW	YES	Operator	Page 216
Disinfection not Properly Performed	534	MEDIUM	YES	Operator	Page 217
MALFUNCTION	535	MEDIUM	/	Malfunction	Page 313
Diascan measurement error	536	LOW	YES	Operator	Page 218
MALFUNCTION	537	HIGH	/	Malfunction	Page 313
MALFUNCTION	538	MEDIUM	/	Malfunction	Page 313
Water Leakage	539	MEDIUM	NO	Operator	Page 219
Dialysate Pressure Low	540	LOW	YES	Operator	Page 220
Pre Filter Pressure High	541	HIGH	YES	Operator	Page 221
Incorrect Cassette line connections or clamps status	542	LOW	YES	Operator	Page 222
Ultra Scan aborted	543	/	YES	Information	Page 223
Ultra Scan completed	544	/	YES	Information	Page 224

ALARM MESSAGE	CODE	PRIORITY	RESET/ CONFIRM	TYPE	TROUBLE-SHOOTING
New Ultra Scan is suggested	545	/	YES	Information	Page 225
On-Line Fluid Volume Exceeded Maximum Limit	546	HIGH	NO	Operator	Page 226
Patient Venous Line Incorrect Position	547	LOW	YES	Operator	Page 227
Leakages H	548	LOW	YES	Operator	Page 228
Leakages I	549	LOW	YES	Operator	Page 229
Power Failure: Check Power Supply	550	MEDIUM	YES	Operator	Page 230
80% Maximum Substitution Volume Reached	551	/	YES	Information	Page 231
90% Maximum Substitution Volume Reached	552	/	YES	Information	Page 232
Maximum Substitution Volume Reached	553	MEDIUM	YES	Operator	Page 233
Hemocontrol Error	554	MEDIUM	YES	Operator	Page 234
Scale Stability not Reached	555	MEDIUM	YES	Operator	Page 235
Ultra Inlet Tube Clamped	556	LOW	YES	Operator	Page 236
Cassette Repositioning Failed	557	HIGH	YES	Operator	Page 237
Reminder:	558	/	YES	Information	Page 238
Preparation Completed	559	/	YES	Information	Page 239
Priming Completed	560	/	YES	Information	Page 240
Autoscheduled Disinfection/ Rinse Program not Performed	562	MEDIUM	YES	Operator	Page 241
CDF2 Ultrafilter Lower Switch error	563	LOW	NO	Operator	Page 242
Ultrafilter Cover Error	564	LOW	NO	Operator	Page 243
Hydraulic Centralise Acetate Connector Type One	565	LOW	NO	Operator	Page 244
Hydraulic Centralise Acetate Connector Type Two	566	LOW	NO	Operator	Page 245
TMP Set too Low	567	LOW	NO	Operator	Page 246
Wrong Check Red Concentrate Connector	568	LOW	NO	Operator	Page 247

ALARM MESSAGE	CODE	PRIORITY	RESET/ CONFIRM	TYPE	TROUBLE-SHOOTING
Wrong Check Blue Concentrate Connector	569	LOW	NO	Operator	Page 248
Isolated UF Completed	570	/	YES	Information	Page 249
Treatment can not begin until the ultrafilters have been replaced	571	LOW	NO	Operator	Page 250
MALFUNCTION	572	LOW	/	Malfunction	Page 313
Low Heparinization	573	MEDIUM	YES	Operator	Page 251
Wrong Single Needle Clamps Position	574	HIGH	YES	Operator	Page 252
MALFUNCTION	575	MEDIUM	/	Malfunction	Page 313
Preparation can not proceed until dressing is complete	576	/	NO	Information	Page 253
Smartscan - Low Real Qb	577	/	YES	Information	Page 254
Wrong Disinfectant used in Chemical Disinf.	578	MEDIUM	YES	Operator	Page 255
On line blood restitution: wrong Ultra Cassette configuration	579	HIGH	YES	Operator	Page 256
On line Prime - Incorrect Ultra or Blood cassette configuration	580	LOW	YES	Operator	Page 257
Isolated UF target loss will not be achieved	581	LOW	NO	Operator	Page 258
Residual Check Reminder	582	/	YES	Information	Page 259
Air detector cleaning required	583	HIGH	YES	Operator	Page 260
Air detector inspection required	584	HIGH	YES	Operator	Page 261
Saline Bag Empty	585	LOW	YES	Operator	Page 262
Arterial Pump Segment Not Correctly loaded	586	LOW	YES	Operator	Page 263
Venous Infusion Line Open	587	HIGH	YES	Operator	Page 264
Chemical Disinfection not Properly Performed: wrong disinfectant used	588	MEDIUM	YES	Operator	Page 265
Post Filter Pressure High	589	HIGH	YES	Operator	Page 266
Select Concentrate Error	590	LOW	NO	Operator	Page 267

ALARM MESSAGE	CODE	PRIORITY	RESET/ CONFIRM	TYPE	TROUBLE-SHOOTING
MALFUNCTION	591	MEDIUM	/	Malfunction	Page 313
SN: Pressure not increasing	592	HIGH	YES	Operator	Page 268
SN: Pressure not decreasing	593	HIGH	YES	Operator	Page 269
SN Service Line(s) on SN Cassette open	594	LOW	YES	Operator	Page 270
Maximum Blood Volume Reached	595	HIGH	YES	Operator	Page 271
SelectCart cartridge Empty	596	MEDIUM	NO	Operator	Page 272
End of Hospasol Bag	597	LOW	YES	Operator	Page 273
Bicart Change Failed	598	MEDIUM	YES	Operator	Page 274
SelectCart Change Failed	599	MEDIUM	YES	Operator	Page 275
SelectBag Not Connected	600	LOW	YES	Operator	Page 276
MALFUNCTION	601	MEDIUM	/	Malfunction	Page 313
Bicarbonate/Select Conductivity Set too Low	602	LOW	NO	Operator	Page 277
Bicarbonate/Select Conductivity Set too High	603	LOW	NO	Operator	Page 278
Smartscan - High Sodium setting	606	/	YES	Information	Page 279
Scale Measurement Error	609	MEDIUM	NO	Operator	Page 280
Safebag - K Compartment Empty	610	MEDIUM	NO	Operator	Page 281
Safebag - AFB Compartment Empty	611	MEDIUM	NO	Operator	Page 282
Infusion Settings Still Outside Prescription	612	LOW	YES	Operator	Page 283
Infusion Settings Out of Range	613	MEDIUM	NO	Operator	Page 284
Infusion Cassette not Connected to Blood Cassette	614	LOW	YES	Operator	Page 286
Hospasol Infusion Line Clamped	615	LOW	YES	Operator	Page 287
Degassing Line on Infusion Cassette Clamped	616	LOW	YES	Operator	Page 288

ALARM MESSAGE	CODE	PRIORITY	RESET/ CONFIRM	TYPE	TROUBLE-SHOOTING
EvaClean Doors Incorrect Position	617	LOW	YES	Operator	Page 289
Scale Acquisition Failure	618	HIGH	YES	Operator	Page 290
MALFUNCTION	619	MEDIUM	/	Malfunction	Page 313
End of Hospasol Bag	620	LOW	YES	Operator	Page 291
End of Hospasol Bag or Hospasol Infusion Line Clamped	621	LOW	YES	Operator	Page 292
Infusion Chamber Pressure too High	622	LOW	YES	Operator	Page 293
K Profile Error	623	MEDIUM	YES	Operator	Page 294
No Hospasol Bag on Scale	624	LOW	YES	Operator	Page 295
Hospasol Low Weight Limit Reached	625	/	YES	Information	Page 296
Infusion Volume Error	626	MEDIUM	NO	Operator	Page 297
MALFUNCTION *(See **NOTE4** below)*	627	HIGH	/	Malfunction	Page 313
Saline solution has entered in the Hospasol bag	628	MEDIUM	YES	Operator	Page 298
MALFUNCTION	629	MEDIUM	/	Malfunction	Page 313
Data Correctness Check Failure	630	LOW	YES	Operator	Page 299
Unreliable Post-dialyzer Pressure	631	HIGH	YES	Operator	Page 299
Venous Flow too high	632	HIGH	YES	Operator	Page 301
Venous Flow Over allowed Range	633	HIGH	YES	Operator	Page 302
Venous Flow too low: SN cassette inspection required	634	HIGH	YES	Operator	Page 303
Hemocontrol: Refilling rate better than expected	635	/	YES	Information	Page 304
Hemocontrol: Unusual Status	636	/	YES	Information	Page 305
Hemocontrol: Refilling rate lower than expected	637	/	YES	Information	Page 306

ALARM MESSAGE	CODE	PRIORITY	RESET/ CONFIRM	TYPE	TROUBLE-SHOOTING
Hemocontrol: UF Volume may not be reached	638	/	YES	Information	Page 307
Arterial Chamber: Level Adjustment Required *(See NOTE5 below)*	642	HIGH	YES	Operator	Page 308
Low Arterial Chamber Level *(See NOTE5 below)*	643	MEDIUM	YES	Operator	Page 310
Pressure Transducer: Greasing Required	644	LOW	YES	Operator	Page 312

NOTE 1

If the alarm number code 59 occurs during treatment:

1. Switch the machine OFF;
2. Perform a *Manual Rinseback* procedure as described in the "8.2 Manual Rinseback procedure in HD-DN and HDF Post Treatments" section of this Operator's Manual.

NOTE 2

Next to "Cause:" the explanation of the alarm causes is reported.

NOTE 3

During rinseback, if the alarm number code 64 occurs with the attribute "Cause: excessive Rinseback Volume":

1. Switch the machine OFF;
2. Disconnect the patient.

NOTE 4

If the malfunction number code 627 occurs at the end of the treatment:

1. Switch the machine OFF;
2. Switch the machine ON again.

NOTE 5

The "Arterial Chamber: Level Adjustment Required (#642)" and "Low Arterial Chamber Level (#643)" alarms will be triggered only if they have been previously enabled in the Service menu.

16.7 Operator Alarm and Information Signals Troubleshooting

The Alarm/Information Message Area gives all the necessary instructions to respond to most of the alarm situations. Under certain circumstances, however, the Alarm Mangement System could not give detailed information.

Therefore, additional information is provided in this section for each of the alarms listed in the previous table.

The alarms below are listed according to their technical code number.

ACID/ACETATE CONCENTRATE CONTAINER EMPTY 1

Reason	The Acid concentrate canister/bag is either empty or not properly connected; as a result the Acid Pump cannot reach the set conductivity value.
Machine Actions	• The dialysis fluid goes into Bypass; • The Acid Pump (PA) is stopped.

Possible Cause	**Suggested Action**
1. The Acid concentrate canister/bag is empty.	1. Press the “Special Procedures” button. Select the “Change Acid” option to change the Acid concentrate canister/ bag. Perform the “Change Acid” special procedure as described in the "Change Acid” section of this Operator’s Manual.
2. Massive air leak from the Acid concentrate canister/bag.	2. Check the Acid concentrate canister/ bag. Press the “Special Procedures” button. Select the “Change Acid” option to change the Acid concentrate canister/ bag. Perform the “Change Acid” special procedure as described in the "Change Acid” section of this Operator’s Manual.

Possible Cause (Continued)	Suggested Action (Continued)
3. The Acid pick-up tube connector is not connected to the concentrate canister/ bag.	3. Check that the Acid pick-up tube connector is properly connected to the concentrate canister/bag. Press the "Special Procedures" button. Select the "Change Acid" option to change the Acid concentrate canister/ bag. Perform the "Change Acid" special procedure as described in the "Change Acid" section of this Operator's Manual.
	Call for Service if the alarm persists.

INCORRECT RED CONCENTRATE CONNECTOR POSITION 2

Reason	The Red Concentrate Connector is in the wrong position or is not fully inserted into its Concentrate Connector Port.
Machine Actions	In DIALYSIS: • The phase currently running stops; • The concentrate pump PA is stopped; • The dialysis fluid goes into Bypass; • The infusion flow is interrupted; • The Venous Pump is stopped. In ADR: • The phase currently running stops; • All the pumps are stopped.

Possible Cause	**Suggested Action**
1. The Red Concentrate Connector is in the wrong position.	1. In Dialysis (BiCart treatments): Verify that the Red Concentrate Connector is connected to the Acid concentrate canister/bag.
2. The Red Concentrate Connector is not fully inserted into its Concentrate Connector Port.	2. In ADR, Select and AFB K Treatment: Verify that the Red Concentrate Connector is securely connected to its Concentrate Connector Port.
	Call for Service if the alarm persists.

INCORRECT SELECTCART HOLDER ARMS POSITION 3

Reason	The Select Cart Holder Arms are in the wrong position or not closed securely.
Machine Actions	• The phase currently running stops; • All the pumps are stopped; • The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. The Select Cart Holder Arms are in the wrong position, or not closed securely.	1. Verify the correct position of the Select Cart Holder Arms in relation to the machine phase. In Dialysis, Rinsing and Disinfection: Position the connector correctly.
	Call for Service if the alarm persists.

AIR IN VENOUS LINE 4	
Reason	Air has been detected in the Venous Patient Line.
Machine Actions	• The Arterial and the Venous Pumps are stopped; • The Venous Line Clamp is closed; • The UF Rate is automatically set to zero; • The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. Air in the Venous Patient Line.	1. Clamp the Venous Patient Line under the Venous Line Clamp; 2. Clamp the venous dialyzer line; 3. Attach a sterile luer-lock syringe to the venous infusion line; 4. Unclamp the venous infusion line and gradually create a negative venous pressure (around *-80 mmHg*) with the syringe *(See **NOTE 1**)*; 5. When the machine opens the Venous Line Clamp, clamp the venous infusion line; 6. Unclamp the Venous Patient Line: air will be drawn into the venous chamber; 7. If bubbles are still present, repeat the procedure; 8. Start the Arterial pump by pressing the “Blood Pump On/Off” key on the hard key panel; 9. Immediately, unclamp the venous dialyzer line; 10. If needed, adjust the chamber levels *(See **NOTE 2**)*.
	Call for service if the alarm persists.

NOTE 1

Do not allow the venous pressure inside the venous chamber to decrease below -150 mmHg.

NOTE 2

Refer to "Chapter 8: Special Procedures” for better explanations on the adjust chamber levels procedure.

BLOOD PUMP COVER OPEN 8

Reason	The Arterial pump cover is open.
Machine Actions	• The Arterial Pump is stopped; • The UF Rate is automatically set to zero.

Possible Cause	**Suggested Action**
1. The Arterial pump cover is open.	1. Close the Arterial pump cover. Be sure the Arterial pump cover is securely latched.
2. The magnet is dirty.	2. Carefully clean the magnet placed behind the Arterial pump cover with a cloth dipped in a disinfectant solution.
	Call for Service if the alarm persists.

PUMP SPEED TOO HIGH 10

Reason	The Blood flow is higher than the Arterial Pump speed set value or than the maximum permitted value.
Machine Actions	• The Arterial and the Venous Pumps are stopped; • The Venous Line Clamp is closed; • The UF Rate is automatically set to zero.

Possible Cause	**Suggested Action**
1. The Arterial Pump speed is different from the set value.	1. Press the Reset button to restart the Arterial Pump.
	Call for Service if the alarm persists.

ARTERIAL PRESSURE OUT OF RANGE 11

Reason	The arterial pressure is beyond the upper or lower limit of the sensor.
Machine Actions	• The Arterial Pump is stopped; • The UF Rate is automatically set to minimum.

Possible Cause	**Suggested Action**
1. Restriction of blood flow from the Patient's Vascular Access or in the Arterial Patient Line.	1. Check for restriction of blood flow in the Arterial Patient Line, i.e. kinks, clamps, clotted arterial needle, poor flow from the Patient's Vascular Access; The alarm clears when the arterial pressure is in the proper range. When the pressure stabilizes, select the alarm in the Alarm/Information Message Area and press the Reset button to restart the Arterial Pump.
2. Arterial pressure decreased somewhat during a treatment due to hemoconcentration and/or inadequate heparin delivery to the patient and a resulting pressure drop increase for a given needle at a fixed blood flow rate.	2. Attention should be given to revaluation of the needle size, the blood flow rate and the heparin dosage; When the pressure stabilizes, select the alarm in the Alarm/Information Message Area and press the Reset button to restart the Arterial Pump.
	Call for Service if the alarm persists.

BLOOD PUMP SPEED ERROR 12

Reason	The Arterial Pump is not turning at the requested speed.
Machine Actions	• The Arterial Pump is stopped; • The UF Rate is automatically set to zero.

Possible Cause	**Suggested Action**
1. The pump segment is jamming the rotor of the Arterial Pump.	1. Verify the correct placement of the pump segment into the rotor. Press the Reset button to restart the Arterial Pump.
	Call for Service if the alarm persists.

BLOOD PUMP ROTOR ERROR 13

Reason	The arterial hall sensor is not detected properly.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The Arterial pump segment is not correctly inserted into the rotor.	1. Verify that the Arterial pump segment is correctly inserted into the rotor. Press the Reset button.
	Call for Service if the alarm persists.

INCORRECT BLUE CONCENTRATE CONNECTOR POSITION 18

Reason	The Blue Concentrate Connector is in the wrong position or not fully inserted into its Concentrate Connector Port.
Machine Actions	In DIALYSIS: • The concentrate pumps (PA, PB, PSel) shall be stopped; • The phase currently running stops; • The dialysis fluid goes into Bypass; • The infusion flow is interrupted; • The Venous Pump is stopped. In ADR: • The phase currently running stops; • All the pumps are stopped.

Possible Cause	**Suggested Action**
1. The Blue Concentrate Connector is in the wrong position.	1. In Dialysis (BiCart and BiCart Select treatments): Verify that the Blue Concentrate Connector is connected to its Concentrate Connector Port.
2. The Blue Concentrate Connector is not connected to its Safebag Connector.	2. In AFB K Treatment: Verify that the Blue Concentrate Connector is connected to its Safebag Connector.
3. The Blue Concentrate Connector is not fully inserted into its Concentrate Connector Port.	3. In ADR: Verify that the Blue Concentrate Connector is securely connected to its Concentrate Connector Port.
	Call for Service if the alarm persists.

NOTE

The use of liquid Bicarbonate concentrate is not currently available.

BICART CARTRIDGE EMPTY 21

Reason	The BiCart Cartridge is either empty or not connected properly; as a result the Bicarbonate Pump cannot reach the set conductivity value.
Machine Actions	• The Bicarbonate Concentrate Pump (PB) is stopped; • The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. The BiCart Cartridge is almost empty.	1. Press the "Special Procedures" button. Select the "Change BiCart" option to change the BiCart Cartridge. Perform the Change BiCart procedure as described in the "8.6 Change BiCart Cartridge" section of this Operator's Manual.
2. The Bicarbonate powder is not well distributed in the BiCart Cartridge.	2. Tap the bottom of the BiCart Cartridge to evenly distribute the powder. Press the "Special Procedures" button. Select the "Change BiCart" option to change the BiCart Cartridge. Perform the Change BiCart procedure as described in the "8.6 Change BiCart Cartridge" section of this Operator's Manual.
3. The BiCart Cartridge is in the wrong position.	3. Check the correct position of the BiCart into its holder. Press the "Special Procedures" button. Select the "Change BiCart" option to change the BiCart Cartridge. Perform the Change BiCart procedure as described in the "8.6 Change BiCart Cartridge" section of this Operator's Manual.
	Call for Service if the alarm persists.

INCORRECT BICART HOLDER ARMS POSITION 22

Reason	The BiCart Holder Arms are in the wrong position or not closed securely.
Machine Actions	In DIALYSIS: During the dialysis fluid preparation phase: • The phase currently running stops; • The concentrate pump PB is stopped. During treatment: • The phase currently running stops; • The dialysis fluid goes into Bypass. In ADR: • The phase currently running stops; • All the pumps are stopped.

Possible Cause	**Suggested Action**
1. The BiCart Holder Arms are in the wrong position, or not closed securely.	1. Verify the correct position of the BiCart Holder Arms in relation to the machine phase.
	Call for Service if alarm persists.

INCORRECT BICART/BLUE CONCENTRATE TUBE CONCENTRATION *23*

Reason	The conductivity measured in the first stage of the dialysis fluid preparation is above the permitted range.
Machine Actions	• The dialysis fluid goes into Bypass; • The infusion flow is interrupted; • The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. The Blue Concentrate Connector is not properly connected to its Safebag Connector.	1. Verify that the Blue Concentrate Connector is properly connected to its Safebag Connector.
2. Massive air leak from the Safebag KV concentrate solution.	2. Replace the Safebag KV concentrate solution as described in the "3.4 Change Safebag" section of the Artis AFB K Treatment Operator's Manual.
3. The BiCart Cartridge is not properly positioned in its holder.	3. Ensure the BiCart Cartridge is securely placed in its holder.
	Call for Service if the alarm persists.

BLOOD IN DIALYSATE 28	
Reason	Blood has been detected in the dialysate by the Blood Leakage Detector.
Machine Actions	• The Arterial and the Venous Pumps are stopped; • The Venous Line Clamp is closed; • The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. A break in the dialyzer membrane caused a blood leakage into the hydraulic circuit.	1. Press the ***PAUSE ALARM*** button. Some of the safety mechanisms shall be disabled for the subsequent 2 minutes. Visually check the dialysate for blood presence. If the results are positive, replace the dialyzer and the Blood Cassette. Follow the correct procedure to replace the extracorporeal circuit.
2. The blood leak sensor is dirty.	2. Press the ***PAUSE ALARM*** button. Some of the safety mechanisms shall be disabled for the subsequent 2 minutes. Visually check the dialysate for blood presence. If the results are negative and the alarm persists, stop the treatment. As soon as possible perform a chemical disinfection to clean the blood leak sensor.
3. Massive air leak from the Red/Blue dialysis fluid tube connectors, as the BLD sensor could confuse air with blood.	3. Press the ***PAUSE ALARM*** button. Some of the safety mechanisms shall be disabled for the subsequent 2 minutes. Deactivate the dialysis fluid flow by pressing the “Dialysis Fluid” action button. • the Dialysis Fluid goes into bypass; • the “Dialysis Fluid” action indicator switches to grey. Verify that the Red/Blue dialysis fluid tube connectors do not leak and are securely fitted to the dialyzer. Activate again the dialysis fluid flow by pressing the deactivated “Dialysis Fluid” action button. • the “Dialysis Fluid” action indicator switches to green.
	Call for Service if the alarm persists.

BPM FAILURE 30

Reason	The BPM System was calibrated incorrectly, is malfunctioning or is disconnected.
Machine Actions	• The Blood Pressure Monitoring system is stopped and the measurement is not available.

Possible Cause	Suggested Action
1. Temporary blockage of the device.	1. Press the Reset button to remove the alarm. Do not perform any other Blood Pressure measurements. If the BPM Mode parameter is set to Auto, set it to Manual. At the end of the treatment: • switch the machine OFF, wait a few seconds and then switch the machine back ON; • take a Blood Pressure to verify if the BPM device is functioning correctly: if the result is negative, a service technician assistance is required.
	Call for Service if the alarm persists.

BPM MEASUREMENT FAILURE OR OUT OF RANGE 31	
Reason	• The BPM System may have been unable to record a blood pressure measurement because of patient and/or Cuff conditions; • The BPM Tubing may be kinked or disconnected; • The BPM System may be leaking; • There may be a Hardware/Communication failure on the BPM System; • The measure of Systolic or Diastolic pressure or of Pulse Rate may be out of range.
Machine Actions	• The Blood Pressure Monitoring System is stopped and the measurement is not available.

Possible Cause	**Suggested Action**
1. The tubing of the BPM cuff is kinked or disconnected.	1. Verify that the external tubing of the BPM cuff is connected and that there are no leaks or kinks. Press the Reset button and retry the measurement.
2. The patient moved his arm too many times during the measurement. The BPM was unable to measure the blood pressure.	2. Press the Reset button and retry the measurement.
3. The external tubing of the BPM cuff or the BPM cuff itself is leaking.	3. Press the Reset button. Replace the tubing of the BPM cuff and the BPM cuff with a new one.
4. There is a communication problem between the BPM cuff and the machine.	4. Press the Reset button. Repeat the blood pressure measurement.
5. The measure of Systolic or Diastolic pressure or of Pulse Rate may be out of range.	5. Verify that the cuff is correctly applied to the patient and connected to the machine. Press the Reset button. Repeat the blood pressure measurement.
6. An automatic BPM measurement started while the “BPM” button was dimmed	6. Wait for the subsequent automatic measurement or, if needed, perform a new manual measurement as soon as the “BPM” button becomes available.
	Call for Service if the alarm persists.

AIR IN HYDRAULIC PATHWAY (LD1) 33

Reason	LD1 Level Sensor failed its test during dialysis preparation or an ADR process. The level sensor may have detected air, failed or needs to be cleaned.
Machine Actions	• The phase currently running stops; • The dialysis fluid goes into bypass.

Possible Cause	**Suggested Action**
1. Massive air leak from an empty concentrate canister.	1. Check for empty Acid, BiCart or Bicarbonate canister. The alarm clears before patient connection.
2. Dirty LD1 level detector.	2. Perform a RINSE or a Chemical Disinfection to clean the sensor from deposits.
3. The concentrate tube is not in the proper position for the current phase of the machine.	3. Verify the proper placement of the concentrate tube for the current phase of the machine.
4. The BiCart holder arms are not in the fully closed position.	4. Place the BiCart holder arms in the closed position.
	Call for Service if the alarm persists.

NOTE

The use of liquid Bicarbonate concentrate is not currently available.

HYDRAULIC SENSOR DIRTY (LP) 34

Reason	The LP Level Sensor failed its test during dialysis preparation or an ADR process. The level sensor may have detected air, failed or needs to be cleaned.
Machine Actions	• The phase currently running stops; • The dialysis fluid goes into bypass.

Possible Cause	**Suggested Action**
1. Dirty LP level detector.	1. Perform a RINSE or a Chemical Disinfection to clean the sensor from deposits.
	Call for Service if the alarm persists.

AIR IN HYDRAULIC PATHWAY (LD2) 35

Reason	The LD2 Level Sensor failed its test during dialysis preparation or a cleaning process. The Level Sensor may have detected air, failed or needs to be cleaned.
Machine Actions	• The phase currently running stops; • The dialysis fluid goes into bypass; • All the pumps are stopped.

Possible Cause	**Suggested Action**
1. Massive air leak from an empty concentrate canister.	1. Check for empty Acid, BiCart or Bicarbonate canister.
2. Dirty LD2 level detector.	2. Perform a RINSE or a Chemical Disinfection to clean the sensor of deposits.
3. The Concentrate tube is not in the proper position for the current phase of the machine.	3. Verify that the concentrate tubes are in the proper position for the current phase of the machine.
4. The BiCart holder arms are not in the fully closed position.	4. Move the BiCart holder arms to the closed position to remove the alarm and to allow cleaning of the complete circuit.
	Call for Service if the alarm persists.

NOTE

The use of liquid Bicarbonate concentrate is not currently available.

DIALYSATE PH HIGH 40 (optional)	
Reason	The dialysis fluid pH value exceeds the alarm threshold.
Machine Actions	• The dialysis fluid goes into Bypass; • The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. The machine has run out of concentrates.	1. Replace the empty canister, then wait a few seconds for the machine to stabilize.
2. There is an air leak from the Acid or Bicarbonate Pick-up tube connector/ BiCart.	2. Verify there are no air leaks from the the Acid and Bicarbonate Pick-up tube connectors/BiCart.
3. The Acid or Bicarbonate Pick-up tube connector has accumulated debris or salt crystals.	3. Rinse the accumulated debris from the Acid and Bicarbonate Pick-up tube connector.
4. The Acid or Bicarbonate Pick-up tube is not properly connected to the concentrate canister.	4. Verify that the Acid and Bicarbonate Pick-up tubes are securely connected and that no air bubbles are being drawn into the tube.
5. A chemical disinfectant has been connected to the machine instead of the A-concentrate. *(see WARNING below)*	**5. DURING PREPARATION** 1. Stop dialysis fluid preparation; 2. Remove the cassette and the dialyzer if yet installed; 3. Perform a Rinse programme; 4. Change both the Ultrafilters performing the procedure described in the “8.25 Ultrafilter Change Procedure” section of this Operator’s Manual **5. DURING TREATMENT** 1. Stop the treatment and disconnect the patient. 2. Perform a Rinse programme; 3. Change both the Ultrafilters performing the procedure described in the “8.25 Ultrafilter Change Procedure” section of this Operator’s Manual
6. The solution in the concentrate canister is not a solution correct for hemodialysis treatments (Refer to the "Chapter 17: Specifications”, in this Operator’s Manual).	6. Stop the dialysis preparation and replace the Blood Cassette and the dialyzer with a new Blood Cassette and a new dialyzer. Run a complete RINSE procedure. Replace the solution with the correct solution and then restart the dialysis preparation.

Possible Cause (Continued)	Suggested Action (Continued)
7. The solution in the concentrate canister is not correct or diluted.	7. Verify that the solution concentration is correct and if needed replace it with a correct solution.
8. The Acid Pick-up tube connector is not securely connected to its concentrate connector port (if using concentrate from a central delivery system).	8. Verify that the Acid Pick-up tube connector is securely connected to its concentrate connector port. Ensure to hear a "clicking" sound when connecting the Acid pick-up tube to its concentrate connector port.
9. An incorrect type of dialysis fluid concentrate could be selected on the Fluid Settings sub-screen.	9. Verify that the correct type of dialysis fluid concentrate has been selected on the Fluid Settings sub-screen, otherwise select the correct concentrate combination.
	Call for Service if the alarm persists.

⚠WARNING

The "DIALYSATE PH HIGH (#40)" alarm could be triggered in case a chemical disinfectant has been used instead of Acid concentrate during a dialysis treatment.
This may lead to improper dialysis to be delivered to the patient, thus resulting in patient injury or death.

DIALYSIS FLUID FLOW HIGH 44

Reason	The dialysis fluid flow is higher than the set value or than the maximum permitted flow.
Machine Actions	• The dialysis fluid goes into Bypass; • The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. Unstable dialysis fluid flow has been detected by the machine.	1. Wait for a while, if the problem persists call for service for recalibration of the flowmeter.
2. There are deposits or debris inside the flowmeters of the machine.	2. Perform a Descaling or a Chemical Disinfection.
	Call for Service if the alarm persists.

NOTE

The use of liquid Bicarbonate concentrate is not currently available.

BPM DIASTOLIC PRESSURE ALARM 46

Reason	The diastolic pressure measurement made by the BPM device is outside the configured limits.
Machine Actions	• The Blood Pressure Monitoring system is stopped and the measurement is not available.

Possible Cause	Suggested Action
1. The diastolic pressure measurement, made by the BPM device, is outside the alarm limits set by the operator in BPM Settings sub-screen.	1. Press the Reset button to remove the alarm message. Check in the BPM Settings sub-screen that the *"Diastolic upper" and "Diastolic lower"* pressure limits are not too much restrictive.
	Call for Service if the alarm persists.

TREATMENT TIME COMPLETE 51

Reason	Notification: the entered Treatment Time has elapsed.
Machine Actions	• The UF Rate is automatically set to zero.

Possible Cause	**Suggested Action**
1. The Treatment Time is complete.	1. Disconnect the patient.
2. Additional Treatment Time may be needed.	2. Increase the set Treatment Time to lengthen the treatment. Press the ***CONFIRM*** button to continue.
	Call for Service if the alarm persists.

FLUID REMOVAL COMPLETE 53

Reason	Notification: the patient's weight removal is complete.
Machine Actions	• The UF Rate is automatically set to minimum.

Possible Cause	Suggested Action
1. The programmed "Target UF Volume" has been reached.	1. Disconnect the patient or increase the set "Target UF Volume", then select the "UF" button.
	Call for Service if the alarm persists.

HEPARIN PUMP OVERLOAD 55

Reason	The heparin syringe has reached the upper limit or the Heparin Line is clamped.
Machine Actions	• The Heparin Pump is stopped.

Possible Cause	**Suggested Action**
1. The syringe holder has reached the upper hardware limit while the heparin program is active.	1. Disable the heparin program and use the down arrow key to exit from the error situation.
2. The syringe holder has reached the upper hardware limit while the heparin program is not active.	2. Use the down arrow key to exit from the error situation.
3. The syringe holder has reached the upper hardware limit and the Heparin syringe is empty.	3. Disable the heparin delivery program, use the down arrow key to exit from the error situation. Pull out the syringe from the holder, refill the syringe and place it back on the holder. Restart the program.
4. Blocked heparin line.	4. Disable the heparin program, verify if the heparin line is blocked and remove the possible obstruction. Enable the heparin delivery program.
5. The syringe is defective.	5. Disable the heparin delivery program, pull out the defective syringe, prepare a new filled one, place it back on the holder. Restart the program.
6. Incorrect position of the syringe.	6. Ensure that the syringe is properly placed into the syringe holder.
	Call for Service if the alarm persists.

HEPARIN INFUSION COMPLETE 58

Reason	The programmed heparin "Stop Time" has been reached.
Machine Actions	• The Heparin Pump is stopped.

Possible Cause	**Suggested Action**
1. The Heparin delivery program is complete.	1. Enter the Heparin Settings sub-screen. Deactivate the heparin delivery program to remove the alarm or in case the patient needs more heparin, set a new value for the heparin "Stop Time", lower than the previous one.
2. The programmed heparin "Stop Time" is greater than the programmed "Treatment Time".	2. Set a new value either for the heparin "Stop Time" or for the "Treatment Time", lower than the previous one.
	Call for Service if the alarm persists.

UF TARGET WILL NOT BE ACHIEVED 60

Reason	The remaining treatment time is not enough to reach the programmed “UF Volume”.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The programmed UF Volume has not been achieved due to many bypass conditions.	1. Modify the “Treatment Time” and/or “UF Volume” parameters.
2. The “UF” action button has been deactivated for too long, therefore the time left after its activation is not enough for the achievement of the set “UF Volume”.	2. Modify the “Treatment Time” and/or “UF Volume” parameters. Then select the “UF” action button.
	Call for Service if the alarm persists.

CFD1 ULTRAFILTER LOWER SWITCH ERROR 61

Reason	The CDF1 first ultrafilter lower connector microswitch (SWLOWUF1) is indicating an error condition.
Machine Actions	• In ADR: The phase currently running stops; • In Dialysis fluid preparation: The machine will not continue until the microprocessor receives the correct signal from the switch; • In DIALYSIS: The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. The CDF1 ultrafilter lower connector microswitch is indicating an error condition.	1. Check the correct position of the ultrafilter.
	Call for Service if the alarm persists.

INCORRECT CONDUCTIVITY MEASURED 62

Reason	The conductivity of the dialysis fluid is above the allowed limit.
Machine Actions	• The dialysis fluid goes into Bypass; • The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. The Acid or Bicarbonate concentrate canister is empty.	1. Supply appropriate concentrate to the relevant inlet connector. Wait for stability of the dialysis fluid flow.
2. The Acid or Bicarbonate pick-up tube connector(s) are not properly positioned into the concentrate canister(s).	2. Verify that the connector(s) are properly positioned into the proper canister(s). Wait for stability of the dialysis fluid flow.
3. Massive air leak from a concentrate canister.	3. Check and replace the concentrate canister. Wait for stability of the dialysis fluid flow.
4. The Acid or Bicarbonate pick-up tube connector(s) has accumulated debris or salt crystals.	4. Rinse the accumulated debris from the connector(s).
5. Inappropriate solution in the Acid concentrate canister.	5. Verify that appropriate concentrate has been used.
6. When using acid central delivery, the Acid or Bicarbonate pick-up tube connector is not securely connected to its concentrate connector port.	6. Verify that the Acid or Bicarbonate pick-up tube connector is properly positioned in its concentrate connector port.
	Call for Service if the alarm persists.

NOTE

The use of liquid Bicarbonate concentrate is not currently available.

BPM HEART RATE ALARM 66

Reason	The BPM heart rate measurement is outside the established limits.
Machine Actions	The Blood Pressure Monitoring system is stopped and the measurement is not available.

Possible Cause	Suggested Action
1. The BPM heart rate measurement is outside the established limits.	1. Press the Reset button to remove the alarm message. Check in the BPM Settings sub-screen that the *"Max Heart Rate"* and *"Min Heart Rate"* alarm limits are not too much restrictive.
	Call for Service if the alarm persists.

TMP HIGH 68

Reason	The TMP Upper Limit value has been exceeded.
Machine Actions	• The UF Rate is automatically set to zero; • The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. The TMP Upper Limit value is incorrect for the dialyzer used.	1. Press the Reset button. From the Fluid Settings sub-screen, verify that the correct TMP Upper Limit value was entered for the dialyzer used.
2. The blood flow rate is too high for the dialyzer used in the current operating condition.	2. Press the Reset button. Verify the correctness of the patient prescription (ultrafiltration rate). Decrease the blood flow, using the blood flow decrease key, if this operation is not in disagreement with the patient prescription (to decrease the venous pressure and avoid hemoconcentration).
3. The ultrafiltration value is too high for the dialyzer used in the current operating condition.	3. Press the Reset button. Verify the correctness of the patient prescription (ultrafiltration rate).
4. The transmembrane pressure is too high.	4. Press the Reset button. Consider increasing the dialysis fluid flow to increase the dialysis fluid pressure.
5. The extracorporeal circuit is clotting.	5. Press the Reset button. Check the extracorporeal circuit for clotting. Refer to your internal policy.
	Call for Service if the alarm persists.

HEPARIN PUMP LOWER LIMIT REACHED 69

Reason	The heparin pump has reached the lower limit.
Machine Actions	• The Heparin Pump is stopped.

Possible Cause	Suggested Action
1. The syringe holder has reached the lower hardware limit.	1. Use the up arrow key to exit from the error situation. Press the ***CONFIRM*** button.
	Call for Service if the alarm persists.

HEPARINIZATION NOT INITIATED 71

Reason	The Heparin Delivery Program has not been activated.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The heparin infusion was not enabled by the operator.	1. In Heparin Settings sub-screen: • Press the “Heparin” action button to enable the heparin delivery program and • Press the Reset button to remove the alarm.
2. No heparin delivery program is needed.	2. Press the Reset button to remove the alarm.
	Call for Service if the alarm persists.

INFUSION SETTINGS INVALID PRESCRIPTION *79*

Reason	The Bicarbonatemia Surveillance System (Caddy) has detected that the infusion prescription confirmed by the operator is not valid because it might result in a final bicarbonatemia target not acceptable for the patient or the Infusion Flow rate + UF Rate results to be out of the acceptable range established for this parameter.
Machine Actions	• The dialysis fluid goes into Bypass; • The infusion flow is interrupted; • The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. The infusion prescription is not valid and might result in a final bicarbonatemia target not acceptable for the patient.	1. Check the infusion prescription parameters (Blood Flow rate, Infusion Flow rate and UF Rate) and modify them in order to obtain a final bicarbonatemia target acceptable for the patient.
2. The Infusion Flow rate + UF Rate results to be out of the acceptable range established.	2. Modify the Infusion Flow rate so that the Infusion Flow rate + UF Rate falls in its acceptable range.
	Call for Service if the alarm persists.

LOW TEMPERATURE 81

Reason	This alarm appears if, in Chemical Disinfection with heating, the hydraulic circuit temperature falls below 32°C.
Machine Actions	• The process time will stop until the temperature measured in the hydraulic circuit reaches 32°C.

Possible Cause	**Suggested Action**
1. Temporary drop of the temperature.	1. No Action is required. The machine should heat automatically.
	Call for Service if the alarm persists.

DIALYZER INLET PRESSURE HIGH 87

Reason	Pressure higher than what is allowed has been detected at the Dialyzer Inlet Connector.
Machine Actions	• The phase currently running stops; • The P1 and P2 pumps are stopped; • All the pumps are stopped; • The dialysis fluid goes into Bypass.

Possible Cause	Suggested Action
1. The Red and Blue dialysis fluid tube connectors are in the wrong position.	1. Verify that the Red and Blue dialysis fluid tube connectors are in the proper position for the current phase of the machine, then press the Reset button.
2. The Red and Blue dialysis fluid tube connectors are in the proper position, but not well inserted.	2. Verify that the Red and Blue dialysis fluid tube connectors are well fitted to the dialyzer or to the machine, depending upon the phase of the machine at that time, then press the Reset button.
3. The external dialysis fluid tubes are kinked.	3. Verify that the external dialysis fluid tubes are not kinked, then press the Reset button.
4. Massive presence of air inside the hydraulic circuit.	4. Verify the presence of air in the external dialysis fluid tubes then press the Reset button.
5. The blood flow is too high, producing an overpressure within the hydraulic circuit.	5. Verify the correctness of the patient prescription (ultrafiltration rate). Decrease the blood flow, using the blood flow decrease key, if this operation is not in disagreement with the patient prescription, then press the Reset button.
6. Clotting or clogging in the blood side of the dialyzer.	6. Check for clotting or clogging in the blood side of the dialyzer. Replace the dialyzer if necessary then press the Reset button.
7. The dialysis fluid flow rate is not correct for the current dialyzer.	7. From the Fluid Settings sub-screen, reduce the dialysis fluid flow rate then press the Reset button.
8. Incorrect placement of the diaphragm between the Blood Cassette and the venous seal.	8. Press the Reset button. Perform a Cassette Repositioning Procedure (Refer to the "Chapter 8: Special Procedures", in this Operator's Manual).
	Call for Service if the alarm persists.

DIALYZER OUTLET PRESSURE HIGH 88

Reason

Pressure higher than what is allowed has been detected at the Dialyzer Outlet Connector.

Machine Actions

In DIALYSIS:
- If the pressure is greater than 450 mmHg, the UF pump is driven at the current value and the phase currently running stops;
- If the pressure is greater than 500 mmHg, the UF pump is driven at the current value and the phase currently running stops;
- All the pumps are stopped;
- The dialysis fluid goes into Bypass.

In ADR:
- The phase currently running stops;
- All the pumps are stopped.

Possible Cause	Suggested Action
1. The dialysis fluid tube connectors are in the wrong position.	1. Verify that the dialysis fluid tube connectors are in the proper position for the current phase of the machine, then press the Reset button.
2. The dialysis fluid tube connectors are in the proper position, but not well inserted.	2. Verify that the dialysis fluid tube connectors are well fitted to the dialyzer or to the machine, depending upon the phase of the machine at that time, then press the Reset button.
3. The external dialysis fluid tubes are kinked.	3. Verify that the external dialysis fluid tubes are not kinked, then press the Reset button.
4. The blood flow is too high, producing an overpressure on the hydraulic side of the machine.	4. Press the Reset button. Verify the correctness of the patient prescription (ultrafiltration rate). Consider reducing the blood flow if this operation is not in disagreement with the patient prescription.
5. Clotting or clogging in the blood side of the dialyzer.	5. Press the Reset button. Check for clotting or clogging in the blood side of the dialyzer. Replace the dialyzer if necessary.
6. Incorrect placement of the diaphragm between the Blood Cassette and the venous seal.	6. Press the Reset button. Perform a Cassette Repositioning Procedure (Refer to the "Chapter 8: Special Procedures”, in this Operator’s Manual).
	Call for Service if the alarm persists.

MAXIMUM TEMPERATURE LIMIT 90

Reason	The temperature measured by TP is greater than the following maximum values: • In DIALYSIS: 45°C • In Chemical Disinfection: 42°C • In Heat or Heat with CleanCart A/C: 110°C
Machine Actions	• The heater is turned off; • The phase currently running stops; • All the hydraulic pumps are stopped; • The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. The machine had a temporaneous unstable condition.	1. Verify the patient safety. Wait for the temperature to drop; the heater is automatically turned on.
2. The machine has malfunctioned.	2. Discontinue the dialysis treatment and call for Service.
3. The incoming water temperature is too high.	3. Check the incoming water temperature (Refer to the "Chapter 17: Specifications" in this Operator's Manual).
	Call for Service if the alarm persists.

MAX WEIGHT ON THE SCALE *92*

Reason	The weight of the Hospasol infusion bags hung on the AFB K scale exceeds the maximum value of 20 kg.
Machine Actions	• The dialysis fluid goes into Bypass; • The infusion flow is interrupted; • The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. The weight of the Hospasol infusion bags hung on the AFB K scale exceeds 20 kg.	1. Reduce the weight on the AFB K scale. Press the ***RESET*** button. If the alarm persists, check the weight of the Hospasol infusion bags, using a different scale. If the weight of the bags is less than 20 kg, the scale connected to the machine is defective. In this case, call for Service.
2. The Hospasol infusion bags are not properly installed.	2. Verify the proper installation of the Hospasol infusion bags on the AFB K scale. Press the ***RESET*** button.
	Call for Service if the alarm persists.

DIALYZER INLET PRESSURE LOW 94

Reason	Pressure lower than what is allowed has been detected at the Dialyzer Inlet Connector.
Machine Actions	In DIALYSIS: • The P1 and P2 pumps are stopped; • The dialysis fluid goes into Bypass. In ADR: • The phase currently running stops; • All the pumps are stopped.

Possible Cause	Suggested Action
1. Dialysis fluid tube connectors in the wrong position.	1. Verify the dialysis fluid tube connectors are in the proper position for the current phase of the machine, then press the ***RESET*** button.
2. Dialysis fluid tube connectors in the proper position, but not well inserted.	2. Verify the dialysis fluid tube connectors are well fitted to the dialyzer or to the machine, depending upon the phase of the machine at that time, then press the ***RESET*** button.
3. The external dialysis fluid tubes are kinked.	3. Verify the external dialysis fluid tubes are not kinked, then press the ***RESET*** button.
4. The UF Rate is too high for the dialyzer used.	4. Check the proper UF Rate for the dialyzer used. Consider reducing the blood flow if this operation is not in disagreement with the patient prescription, then press the ***RESET*** button.
5. Clotting or clogging in the blood side of the dialyzer.	5. Press the ***RESET*** button. Check for clotting or clogging in the blood side of the dialyzer. Replace the dialyzer if necessary.
6. The dialysis fluid flow is not correct for the current dialyzer.	6. Press the ***RESET*** button. Consider reducing the dialysis fluid flow rate.
	Call for Service if the alarm persists.

DIALYZER OUTLET PRESSURE LOW 95

Reason	Pressure lower than what is allowed has been detected at the Dialyzer Outlet Connector.
Machine Actions	In DIALYSIS: • If the pressure is lower than -350 mmHg, the UF Pump is stopped; • If the pressure is lower than -450 mmHg, the UF Pump is stopped; • All the pumps are stopped; • The dialysis fluid goes into Bypass. In ADR: • The phase currently running stops; • All the pumps are stopped.

Possible Cause	**Suggested Action**
1. The dialysis fluid tube connectors are in the wrong position.	1. Verify that the dialysis fluid tube connectors are in the proper position for the current phase of the machine, then press the ***RESET*** button.
2. The dialysis fluid tube connectors are in the proper position, but not well inserted.	2. Verify that the dialysis fluid tube connectors are well fitted to the dialyzer or to the machine, depending upon the phase of the machine at that time, then press the ***RESET*** button.
3. The external dialysis fluid tubes are kinked.	3. Verify that the external dialysis fluid tubes are not kinked, then press the ***RESET*** button.
4. The blood flow is too high, producing an overpressure on the hydraulic side of the machine.	4. Verify the correctness of the patient prescription (ultrafiltration rate). Consider reducing the blood flow if this operation is not in disagreement with the patient prescription press the ***RESET*** button.
5. Clotting or clogging in the blood side of the dialyzer.	5. Press the ***RESET*** button. Check for clotting or clogging in the blood side of the dialyzer. Replace the dialyzer if necessary.
6. Incorrect placement of the diaphragm between the Blood Cassette and the venous seal.	6. Press the ***RESET*** button. Perform a Cassette Repositioning Procedure (Refer to the "Chapter 8: Special Procedures", in this Operator's Manual).
	Call for Service if the alarm persists.

INFUSION FLOW RATE ERROR *99*

Reason	A difference greater than 100 grams has been detected between the calculated Infusion Volume, based on the Infusion Flow rate set, and the infusion fluid effectively delivered, measured by the scale.
Machine Actions	• The dialysis fluid goes into Bypass; • The infusion flow is interrupted; • The Venous Pump is stopped.

Possible Cause	Suggested Action
1. The Infusion flow is not correctly delivered.	1. Check that there are no obstructions or external leakages in the infusion fluid flow from the Hospasol infusion bags to the Infusion cassette. Press the "Special Procedures" button. Select the "Change Hospasol Bag" option. Perform the "Change Hospasol Bag" special procedure as described in the "3.5 Change Hospasol Bag" section of the Artis AFB K Treatment Operator's Manual without actually changing the bags.
2. An Hospasol infusion bag has been hung on or removed from the AFB K scale.	2. Check for Hospasol infusion bags hanged or removed. Press the "Special Procedures" button. Select the "Change Hospasol Bag" option. Perform the "Change Hospasol Bag" special procedure as described in the "3.5 Change Hospasol Bag" section of the Artis AFB K Treatment Operator's Manual.
	Call for service if the alarm persists.

INSUFFICIENT WATER SUPPLY 100

Reason	The Inlet Water pressure is low.
Machine Actions	• All the Hydraulic Pumps are stopped; • The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. Pressure drop in the water distribution system.	1. Verify that there is adequate water pressure in the water distribution system.
2. The water inlet tube is disconnected.	2. Connect the water inlet tube to the proper water valve.
3. The water valve is closed.	3. Verify the water valve is open.
4. The incoming water filter is clogging.	4. Check the water filter in the machine for clogging. A clogged filter will decrease the amount of water flowing through the system.
	Call for Service if the alarm persists.

INFUSION SETTINGS OUTSIDE PRESCRIPTION *102*

Reason	The Bicarbonatemia Surveillance System (Caddy) has detected a discrepancy between the Blood Flow rate, Infusion Flow rate and UF Rate that results to be outside the current infusion prescription and the patient final bicarbonatemia target is still inside the value acceptable for the patient.
Machine Actions	• The treatment continues with the current settings.

Possible Cause	Suggested Action
1. The Blood Flow rate is changed and results to be outside the current infusion prescription.	1. To keep the current infusion prescription: Press the ***CONFIRM*** button on the Alarm/Information Message Area. Press the ***CONFIRM*** button on the *Confirm* window.
2. The UF Rate is changed and results to be outside the initial infusion prescription.	2. To keep the current infusion prescription: Press the ***CONFIRM*** button on the Alarm/Information Message Area. Press the ***CONFIRM*** button on the *Confirm* window.
	Call for Service if the alarm persists.

DIALYZER PRESSURE MAXIMUM 114

Reason	The dialyzer inlet pressure, measured by the PI pressure sensor, OR the dialyzer outlet pressure, measured by the PO pressure sensor, has exceeded the maximum limit.
Machine Actions	• The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. The dialysis fluid tube connectors are not in the proper position or are not well inserted.	1. Verify that the dialysis fluid tube connectors are in the proper position and are well fitted to the dialyzer or to the machine, depending upon the phase of the machine at that time. Press the Reset button to remove the alarm message.
2. The external dialysis fluid tubes are kinked.	2. Verify that the external dialysis fluid tubes are not kinked. Press the Reset button to remove the alarm message
3. Massive presence of air inside the hydraulic circuit.	3. Verify the presence of air into the external dialysis fluid tube. Verify the dialysis fluid connectors are well fitted to the dialyzer or to the machine. Press the Reset button to remove the alarm message
4. The UF Rate is too low.	4. Verify the correctness of the patient prescription (ultrafiltration rate). Consider reducing the Arterial Pump speed if this operation is not in disagreement with the patient prescription. Press the Reset button to remove the alarm message
5. Clotting or clogging in the dialyzer and/ or Blood Cassette.	5. Press the Reset button to remove the alarm message Check for clotting or clogging in the blood side of the dialyzer or in the Blood Cassette. Replace the dialyzer and the Blood Cassette if necessary.

Possible Cause (Continued)	Suggested Action (Continued)
6. The dialysis fluid flow rate is not correct for the current dialyzer.	6. Consider reducing the dialysis fluid flow rate. Press the Reset button to remove the alarm message
7. Incorrect placement of the diaphragm between the Blood Cassette and the venous seal.	7. Press the Reset button to remove the alarm message Perform a Cassette Repositioning Procedure (Refer to the "Chapter 8: Special Procedures", in this Operator's Manual).
	Call for Service if the alarm persists.

DIALYZER PRESSURE MINIMUM 115	
Reason	The dialyzer inlet pressure, measured by PI sensor, OR the dialyzer outlet pressure, measured by PO sensor, are below the minimum limit.
Machine Actions	• The UF Rate is automatically set to zero.

Possible Cause	**Suggested Action**
1. The dialysis fluid tube connectors not in the proper position or are not inserted well.	1. Verify that the dialysis fluid tube connectors are in the proper position and are well fitted to the dialyzer or to the machine, depending upon the phase of the machine at that time. Press the Reset button to remove the alarm message
2. The external dialysis fluid tubes are kinked.	2. Verify that the external dialysis fluid tubes are not kinked. Press the Reset button to remove the alarm message
3. Massive presence of air inside the hydraulic circuit.	3. Verify the presence of air in the external dialysis fluid tubes. Verify the dialysis fluid connectors are well fitted to the dialyzer or to the machine. Press the Reset button to remove the alarm message
4. The UF Rate is too high for the dialyzer used.	4. Verify the correctness of the patient prescription (ultrafiltration rate). Consider increasing the Arterial Pump speed if this operation is not in disagreement with the patient prescription. Press the Reset button to remove the alarm message
5. Clotting or clogging in the dialyzer or the Blood Cassette.	5. Press the Reset button to remove the alarm message Check for clotting or clogging in the blood side of the dialyzer or in the Blood Cassette. Replace if necessary.
6. The dialysis fluid flow rate is not correct for the current dialyzer.	6. Press the Reset button to remove the alarm message Consider increasing the dialysis fluid flow rate.
	Call for Service if the alarm persists.

BPM SYSTOLIC PRESSURE ALARM 132

Reason	The systolic pressure measurement made by the BPM device is outside the configured limits.
Machine Actions	• The Blood Pressure Monitoring System is stopped and the measurement is not available.

Possible Cause	Suggested Action
1. The systolic pressure measurement made by the BPM device is outside the configured limits.	1. Press the Reset button to remove the alarm message. Check in the BPM Settings sub-screen that the *("Systolic upper"/"Systolic lower")* pressure limits are not too much restrictive.
	Call for Service if the alarm persists.

DIALYSIS FLUID TEMP HIGH 134

Reason	The temperature of the dialysis fluid is 2°C above the value set by the operator.
Machine Actions	• The dialysis fluid goes into Bypass; • The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. A temporary instability of the dialysis fluid flow.	1. Wait for stability of the system.
2. The temperature of the dialysis fluid has exceeded the safety limits.	2. Check the incoming water temperature (Refer to the "Chapter 17: Specifications" in this Operator's Manual).
3. The machine has recently been turned on and has not yet reached the operating temperature.	3. If the machine temperature remains high or low for more than 10 minutes, discontinue the dialysis treatment.
4. The machine has an internal malfunction.	4. Discontinue the dialysis treatment.
	Call for Service if the alarm persists.

ULTRAFILTER TMP HIGH 138

Reason	The pressure in the Ultrafilter is higher than 600 mmHg.
Machine Actions	• The dialysis fluid goes into Bypass

Possible Cause	**Suggested Action**
1. The Ultrafilter is obstructed.	1. *During Treatment*: • Press the Reset button; • Decrease the "Dialysis Fluid Flow" parameter in the *Fluid* screen to 350 mL/min, according to the patient's prescription; • Complete the treatment; • After the treatment has been completed, perform an "Ultrafilter Change Procedure" as described in the "8.25 Ultrafilter Change Procedure" section of this Operator's Manual. *During Disinfection/Rinse program*: • Press the Reset button; • Perform an "Ultrafilter Change Procedure" as described in the "8.25 Ultrafilter Change Procedure" section of this Operator's Manual.
	Call for Service if the alarm persists.

TMP LOW 142

Reason	The current TMP value is below the lowest TMP safety limit.
Machine Actions	• The UF Rate is automatically set to zero; • The Venous pump is stopped.

Possible Cause	**Suggested Action**
1. The dialyzer used is not correct for the current treatment.	1. Press the Reset button. Verify the correctness of the patient prescription (ultrafiltration rate). Increase the blood flow, using the blood flow increase key, if this operation is not in disagreement with the patient prescription. Comply with the specifications of the dialyzer.
2. The Arterial Pump is stopped.	2. Press the Reset button. Correct the action which caused the Arterial Pump to stop and restart the Arterial Pump.
3. The Red and Blue dialysis fluid tubes are blocked.	3. Press the Reset button. Check that the Red and Blue dialysis fluid tubes are not kinked or clamped.
4. The Blood Cassette is not well positioned or a pressure pod diaphragm has collapsed. The Pressure Sensor cannot read properly.	4. Press the Reset button. If the alarm condition persists, verify the Blood Cassette position. Verify that the pressure pod diaphragm is not collapsed. If required, perform a Cassette Repositioning Procedure (Refer to the "Chapter 8: Special Procedures", of this Operator's Manual).
	Call for Service if the alarm persists.

UF RATE HIGHER THAN EXPECTED 145

Reason	The ultrafiltration rate (UFR) is above the value confirmed by the operator or the maximum permitted value.
Machine Actions	• The Venous Pump is stopped; • The dialysis fluid goes into Bypass; • Calibration request.

Possible Cause	**Suggested Action**
1. Error in the Ultrafiltration Mass Balance in the Hydraulic Module, due to incorrect valves control.	1. Press the Reset button and continue the treatment.
2. Error in the Ultrafiltration Mass Balance in the Hydraulic Module, due to incorrect flowmeter reading.	2. Press the Reset button and continue the treatment.
3. Error in the Ultrafiltration Mass Balance in the Hydraulic Module, due to incorrect P2 pump flow or P2 reading.	3. Press the Reset button and continue the treatment.
4. The machine could not perform an alignment of the D2 flowmeter during the treatment and the Ultrafiltration Mass Balance could be incorrect.	4. Press the Reset button and continue the treatment.
	Call for Service if the alarm persists.

DIALYSATE PRESSURE HIGH 146

Reason	The pressure in the Ultrafilter is higher than the permitted limit.
Machine Actions	• The phase currently running stops; • The dialysis fluid goes into Bypass; • All the pumps are stopped.

Possible Causes	**Suggested Action**
1. The Ultrafilter is clogged.	1. Press the Reset button. During treatment: from the Fluid Settings sub-screen, decrease the dialysis fluid flow rate to continue with the dialysis process in progress. When the treatment is complete, perform the ultrafilter change procedure as described in the “8.25 Ultrafilter Change Procedure” section of this Operator’s Manual.
2. The Red and Blue dialysis fluid tube connectors are not properly positioned.	2. Verify that the Red and Blue dialysis fluid tube connectors are properly positioned to the dialyzer or to the machine, depending upon the current machine phase. Press the Reset button to restart the current operation of the machine.
	Call for Service if the alarm persists.

VENOUS PUMP COVER IS OPEN 149

Reason	The Venous Pump Cover is open.
Machine Actions	• The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. The Venous Pump Cover is open.	1. Close the Venous Pump Cover. Be sure the Venous Pump Cover is securely latched.
2. The magnet is dirty.	2. Carefully clean the magnet placed behind the Venous Pump cover with a cloth dipped in a disinfectant solution.
	Call for Service if the alarm persists.

VENOUS PRESSURE OUT OF RANGE 153	
Reason	The measured venous pressure is outside the permitted range.
Machine Actions	• The Arterial and the Venous Pumps are stopped; • The Venous Line Clamp is closed; • The UF Rate is automatically set to minimum; • The alarm limits are opened for both arterial and venous pressure.

Possible Cause	**Suggested Action**
1. Restriction of blood flow to the Patient's Vascular Access or in the Venous Patient Line.	1. Check for restriction of blood flow in the Venous Patient Line, i.e. kinks, clamps, clotted venous needle, poor flow to the Patient's Vascular Access; When the pressure stabilizes, select the alarm in the Alarm/Information Message Area and press the Reset button to restart the Arterial Pump. The alarm clears when the venous pressure is in the proper range.
2. Venous pressure has increased somewhat during a treatment due to hemoconcentration and/or inadequate heparin delivery to the patient, resulting in a pressure increase for a given needle at a fixed blood flow rate.	2. Attention should be given to revaluation of the needle size, the blood flow rate and the heparin dosage; When the pressure stabilizes, select the alarm in the Alarm/Information Message Area and press the Reset button to restart the Arterial Pump.
	Call for Service if the alarm persists.

VENOUS PRESSURE TOO HIGH 154

Reason	The measured venous pressure is above the maximum venous treatment limit.
Machine Actions	• The Arterial and the Venous Pumps are stopped; • The Venous Line Clamp is closed; • The UF Rate is automatically set to zero (typical value 100 ml/h); • The alarm limits are opened for both arterial and venous pressure.

Possible Cause	Suggested Action
1. Restriction of blood flow to the Patient's Vascular Access or in the Venous Patient Line.	1. Carefully check the Blood Cassette connections and assess the Patient's Vascular Access. Check for restrictions, such as: • kinks in the Venous Patient Line; • closed clamps; • clotted venous needle. If necessary decrease the blood flow per clinical policy. When the pressure stabilizes, select the alarm in the Alarm/Information Message Area and press the Reset button to restart the Arterial Pump. If the alarm persists: • attach a sterile syringe to the Venous Infusion Line; • open the clamp on the Venous Infusion Line to decrease the pressure; • when the pressure stabilizes, close the clamp on the Venous Infusion Line and remove the syringe; • select the alarm in the Alarm/Information Message Area and press the Reset button to restart the Arterial Pump.

Possible Cause (Continued)	Suggested Action (Continued)
2. The venous pressure has increased somewhat during a treatment due to hemoconcentration and/or inadequate heparin delivery to the patient, resulting in a pressure increase for a given needle at a fixed blood flow rate.	2. Attention should be given to the revaluation of the needle size, the blood flow rate and the heparin dosage; When the pressure stabilizes, select the alarm in the Alarm/Information Message Area and press the Reset button to restart the Arterial Pump. If the alarm persists: • attach a sterile syringe to the Venous Infusion Line; • open the clamp on the Venous Infusion Line to decrease the pressure; • when the pressure stabilizes, close the clamp on the Venous Infusion Line and remove the syringe; • select the alarm in the Alarm/ Information Message Area and press the Reset button to restart the Arterial Pump.
	Call for Service if the alarm persists.

VENOUS PRESSURE HIGH 155

Reason	The venous pressure is above the Venous Pressure Threshold as displayed in the Venous Pressure Alarm Window.
Machine Actions	• The Arterial and the Venous Pumps are stopped; • The Venous Line Clamp is closed; • The UF Rate is automatically set to zero; • The alarm limits are opened for both arterial and venous pressure.

Possible Cause	**Suggested Action**
1. The venous pressure is above the allowed limit.	1. Carefully check the Patient's Vascular Access, the Cassette connections and inspect for kinking of the Venous Patient Line. When the pressure stabilizes, select the alarm in the Alarm/Information Message Area and press the Reset button to restart the treatment. Press the "Close A/V Limits" button when the arterial and venous pressures are stable. 2. If the alarm persists: • attach a sterile syringe to the Venous Infusion Line; • open the clamp on the Venous Infusion Line to decrease the pressure; • when the pressure stabilizes, close the clamp on the Venous Infusion Line and remove the syringe; • select the alarm in the Alarm/ Information Message Area and press the Reset button to restart the Arterial Pump.
	Call for Service if the alarm persists.

VENOUS PUMP SPEED ERROR 157

Reason	The Venous Pump is not turning at the requested speed.
Machine Actions	• The Venous Pump stops.

Possible Cause	Suggested Action
1. The pump segment is jamming the rotor of the Venous Pump.	1. Verify the correct placement of the pump segment into the rotor. Press the Reset button to restart the Venous Pump.
	Call for Service if the alarm persists.

VENOUS PUMP ROTOR ERROR 158

Reason	The venous hall sensor is not detected properly.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The Venous Pump segment is not correctly inserted into the rotor.	1. Press the Reset button. Verify that the Venous Pump segment is correctly inserted into the rotor.
	Call for Service if the alarm persists.

SCALE MEASUREMENT ERROR *161*

Reason	A difference greater than 50 grams has been detected between the calculated Infusion Volume, based on the Infusion Flow rate set, and the infusion fluid effectively delivered, measured by the scale.
Machine Actions	• The dialysis fluid goes into Bypass; • The infusion flow is interrupted; • The Venous Pump is stopped.

Possible Cause	Suggested Action
1. An Hospasol infusion bag has been hung on or removed from the AFB K scale.	1. Check for Hospasol infusion bags hung or removed. Press the “Special Procedures” button. Select the “Change Hospasol Bag” option. Perform the special procedure as described in the “3.5 Change Hospasol Bag” section of the Artis AFB K Treatment Operator’s Manual.
2. The Infusion Flow is not correctly delivered.	2. Check that there are no obstructions or external leakages in the infusion fluid flow from the Hospasol infusion bags to the Infusion Cassette. Press the “Special Procedures” button. Select the “Change Hospasol Bag” option. Perform the special procedure as described in the “3.5 Change Hospasol Bag” section of the Artis AFB K Treatment Operator’s Manual without actually changing the bags.
3. The Hospasol Infusion Line is defective.	3. Replace the Infusion Cassette as described in the “3.3 Change Circuit” section of the Artis AFB K Treatment Operator’s Manual.
	Call for Service if the alarm persists.

NOTE

DO NOT hang or remove Hospasol infusion bags without first confirming the Change Hospasol Bag special procedure.
If during treatment the machine detects for four times a weight variation on the AFB K scale exceeding 50 grams without that the Change Hospasol Bag special procedure has been confirmed, the alarm “Infusion Volume Error (#626)” is triggered. The alarm “Infusion Volume Error (#626)” requires to disconnect the patient.

BLD SENSITIVITY LOSS 170

Reason	Deposits and/or debris collected on the Blood Leak Detector (BLD) are causing a loss of sensitivity.
Machine Actions	None.

Possible Cause	Suggested Action
1. An excessively high value is present at the receiver of the Optical Sensor, due to deposits on the detector.	1. Press the Reset button to remove the alarm. Perform a Chemical Disinfection procedure to clean the Sensor.
	Call for Service if the alarm persists.

⚠WARNING

After a "BLD Sensitivity Loss (#170)" alarm perform a Chemical Disinfection program before starting a new treatment.

BACKUP BATTERY FAILURE 183

Reason	The T1 test performed by the machine on the Backup Battery has failed.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The battery in the Battery Backup Kit needs to be replaced.	1. Press the Reset button to continue with the treatment without the Battery Backup. In case of Power Failure, refer to the “8.1.1 Power Failure with battery not charged” section of this Operator’s Manual.
	Call for Service if the alarm persists.

HEMOSCAN: MINIMUM BLOOD VOLUME 191

Reason	The Hemoscan sensor detects blood volume lower than the "Alarm Limit" set value.
Machine Actions	• The dialysis process continues *(See **NOTE**)*;

Possible Cause	**Suggested Action**
1. Great increase of the Hemoglobin concentration in the patient's blood since the start of the treatment.	1. Take the appropriate clinical action.
2. The Hemoscan "Alarm Limit" value is incorrect for this patient.	2. Change the "Alarm Limit" value in the Hemoscan Settings sub-screen.
	Call for Service if the alarm persists.

NOTE

This alarm occurs in order to signal to the operator possible patient's health risk.

LOW BLOOD PUMP SPEED 204

Reason	The Arterial Pump has been running at less than 50 ml/min for more than 30 seconds.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The Arterial Pump speed is less than 50 ml/min for more than 30 seconds.	1. Press the Reset button to remove the alarm. Increase the Arterial Pump speed to more than 50 ml/min.
	Call for Service if the alarm persists.

INCORRECT VENOUS OR ARTERIAL LINE POSITION IN CLAMP 205

Reason	The Venous/Arterial Patient Line has been incorrectly inserted into the Venous/Arterial Line Clamp.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The Venous Patient Line is not correctly inserted into the Venous Line Clamp.	1. Remove and correctly re-insert the Venous Patient Line into the Venous Line Clamp.
2. The Arterial Patient Line is not correctly inserted into the Arterial Line Clamp.	2. Remove and correctly re-insert the Arterial Patient Line into the Arterial Line Clamp.
3. The Arterial and Venous Patient Lines are bent because they have been closed in the Arterial/Venous Line clamps for a too long time.	3. Remove and correctly re-insert the Arterial and Venous Patient Lines into their respective line clamps.
	Call for Service if the alarm persists.

FLUID PATH OBSTRUCTION 206

Reason	There is an excessive pressure in the Drain Tube. (Due to Drain Tube kinking/obstruction or bad connection)
Machine Actions	• The dialysis fluid goes into Bypass; • The heater is turned off; • The phase currently running stops; • All the pumps are stopped.

Possible Cause	**Suggested Action**
1. Obstruction or kinking in the Drain Tube.	1. Press the Reset button. Verify that the Drain Tube is not kinked or obstructed in any way.
	Call for Service if the alarm persists.

HEMOSCAN: DARK OUT OF RANGE 223

Reason	Electronic malfunctioning of the Hemoscan Monitoring System.
Machine Actions	• None. • Hemoscan Monitoring disabled.

Possible Cause	Suggested Action
1. Internal malfunctioning of the Hemoscan Monitoring System.	1. From the Hemoscan Settings sub-screen, deactivate the Hemoscan function. In order to deactivate the Hemoscan function when the Hemocontrol function is activated, deactivate the Hemocontrol function first.
	Call for Service if the alarm persists.

HEMOSCAN: COMMUNICATION ERROR 224

Reason	Electronic malfunctioning of the Hemoscan Monitoring System.
Machine Actions	• None. • Hemoscan Monitoring disabled.

Possible Cause	Suggested Action
1. Internal malfunctioning of the Hemoscan Monitoring System.	1. From the Hemoscan Settings sub-screen, deactivate the Hemoscan function. In order to deactivate the Hemoscan function when the Hemocontrol function is activated, deactivate the Hemocontrol function first.
	Call for Service if the alarm persists.

HEMOSCAN: TEST OUT OF RANGE 225

Reason	Electronic malfunctioning of the Hemoscan Monitoring System.
Machine Actions	• None. • Hemoscan Monitoring disabled.

Possible Cause	Suggested Action
1. Internal malfunctioning of the Hemoscan Monitoring System.	1. From the Hemoscan Settings sub-screen, deactivate the Hemoscan function. In order to deactivate the Hemoscan function when the Hemocontrol function is activated, deactivate the Hemocontrol function first.
	Call for Service if the alarm persists.

HEMOSCAN: L/H OUT OF RANGE 226

Reason	Electronic malfunctioning of the Hemoscan Monitoring System.
Machine Actions	• None. • Hemoscan Monitoring disabled.

Possible Cause	Suggested Action
1. Internal malfunctioning of the Hemoscan Monitoring System.	1. From the Hemoscan Settings sub-screen, deactivate the Hemoscan function. In order to deactivate the Hemoscan function when the Hemocontrol function is activated, deactivate the Hemocontrol function first.
	Call for Service if the alarm persists.

SMARTSCAN - HEMOCONTROL: HIGH NA CONCENTRATION 231

Reason	The actual value of equivalent dialysis fluid sodium concentration has deviated from the path, calculated automatically by the system, by a quantity higher than the Na tolerance set.
Machine Actions	• None.

Possible Causes	**Suggested Action**
1. The actual value of equivalent dialysis fluid sodium concentration has deviated from the path, calculated automatically by the system, by a quantity higher than the Na limits set.	1. Press the ***CONFIRM*** button to clear the alarm. If the alarm persists, correct the Equivalent Na value in the Hemocontrol Settings sub-screen, as suggested by the indications displayed.
	Call for Service if the alarm persists.

SMARTSCAN - HEMOCONTROL: LOW NA CONCENTRATION 232

Reason	The actual value of equivalent dialysis fluid sodium concentration has deviated from the path, calculated automatically by the system, by a quantity lower than the Na tolerance set.
Machine Actions	• None.

Possible Causes	**Suggested Action**
1. The actual value of equivalent dialysis fluid sodium concentration has deviated from the path, calculated automatically by the system, by a quantity lower than the Na limits set.	1. Press the ***CONFIRM*** button to clear the alarm. If the alarm persists, correct the Equivalent Na value in the Hemocontrol Settings sub-screen, as suggested by the indications displayed.
	Call for Service if the alarm persists.

HEMOCONTROL: BV% NOT AVAILABLE 234

Reason	The HEMOSCAN™ is unable to supply a reliable Blood Volume.
Machine Actions	• None.

Possible Causes	**Suggested Action**
1. The HEMOSCAN™ is unable to supply a reliable Blood Volume.	1. Press the ***RESET*** button. Remove the causes which have stopped the measuring of the Blood Volume by the HEMOSCAN™ or wait.
2. The Hemoscan cuvette is not present on the Blood Tubing System used.	2. Deactivate first the Hemocontrol function (when activated) and then the Hemoscan function.
	Call for Service if the alarm persists.

AFBK: BYPASS TOO FREQUENT *291*

Reason	Bypass conditions occurred too frequently during treatment. As a result, the treatment time effectively performed is less than 90% of the total treatment time.
Machine Actions	• None

Possible Cause	Suggested Action
1. Bypass conditions occurred too frequently during treatment.	1. Press the ***RESET*** button.
	Call for Service if the alarm persists.

NOTE

The “AFBK: ByPass too Frequent (#291)” alarm is not triggered during the first hour of treatment.

SELECTBAG EMPTY 293

Reason	The SelectBag is either empty or not properly installed.
Machine Actions	• The SelectBag Pump (PSel) is stopped; • The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. The SelectBag is empty.	1. Press the "Special Procedures" button. Select the "Change SelectBag" option to change the SelectBag container. Perform the "Change SelectBag" special procedure as described in the "8.8 Change SelectBag container" section of this Operator's Manual.
2. The SelectBag is not properly connected.	2. Check that the SelectBag is properly installed on its holder. Press the "Special Procedures" button. Select the "Change SelectBag" option to change the SelectBag container. Perform the "Change SelectBag" special procedure as described in the "8.8 Change SelectBag container" section of this Operator's Manual.
	Call for Service if the alarm persists.

BIOSLAVE SUBSYSTEM COMMUNICATION ERROR 296

Reason	An internal communication problem between the Master Module and the Bio Module occurred.
Machine Actions	• None.

Possible Cause	Suggested Action
1. Temporary communication problem.	1. Wait a few seconds for the alarm to be cleared.
2. If the alarm persists and the machine stops functioning.	2. Perform a Fast Recovery procedure during a dialysis treatment as described in the “8.5 Fast Recovery” section of this Operator’s Manual.
	Call for Service if the alarm persists.

BIO SLAVE ERROR *297*

Reason	An internal communication problem between the Master Module and the Bioslave 2 Module occurred.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The Bioslave 2 module is not communicating.	1. Perform a Fast Recovery procedure as described in the "8.5 Fast Recovery" section of this Operator's Manual.
	Call for Service if the alarm persists.

STILL IN BYPASS 302	
Reason	The machine has been in BYPASS for more than 6 minutes, either because the operator has deselected the ”Dialysis Fluid” button, or due to an internal machine malfunction that is blocking the machine in bypass condition.
Machine Actions	• None. In DIALYSIS: The alarm is active when the machine is in FULL ACTIVITY with blood detected in the Venous Patient Line. The alarm will be displayed on the Touch Screen 6 minutes after the machine is in BYPASS.

Possible Cause	**Suggested Action**
1. Bypass has been selected and not cleared during the treatment.	1. Press the ***RESET*** button. Take the machine out of BYPASS by selecting the ”Dialysis Fluid” button.
2. The machine is stuck in bypass.	2. Press the ***RESET*** button. Perform a Fast Recovery procedure during a dialysis treatment as described in the “8.5 Fast Recovery” section of this Operator’s Manual.
3. The “Start Treatment” button has not been pressed.	3. Press the ***RESET*** button. Confirm the mandatory parameters (UF Volume and Treatment Time), if not already done, and then press the “Start Treatment” button.
4. Isolated UF function has not been properly stopped by the machine. This might occur when the “Isolated UF Completed (#570)” Information Message is confirmed while the machine is performing the Auto Test.	4. Press the ***RESET*** button. **IN HD TREATMENT:** 1. Press the “UF” button 2. Confirm the “Isolated UF Completed (#570)” Information Message 3. Confirm the “UF Volume Confirmation Required” *Confirm* window to continue the treatment **IN HDF POST TREATMENT:** 1. Press the “Dialysis Fluid” button 2. Confirm the “Isolated UF Completed (#570)” Information Message 3. Confirm the “UF Volume Confirmation Required” *Confirm* window to continue the treatment
	Call for Service if the alarm persists.

ARTERIAL PRESSURE HIGH 305

Reason	The measured arterial pressure is above the maximum arterial pressure threshold as displayed in the Arterial Pressure Alarm Window.
Machine Actions	• The Arterial and the Venous Pumps are stopped; • The Venous Line Clamp is closed; • The UF Rate is automatically set to zero; • The alarm limits are opened for both arterial and venous pressure

Possible Cause	**Suggested Action**
1. The Arterial Pressure Alarm Window needs to be set.	1. In the A / V Limit Settings sub-screen adjust the arterial pressure alarm limits; Press "Close A/V Limits" button: the machine automatically centralize the alarm window values around the current patient's arterial/venous pressures; When the pressure stabilizes, select the alarm in the Alarm/Information Message Area and press the Reset button to restart the Arterial Pump.
2. The Arterial Patient Line may have become disconnected from the patient.	2. Carefully check the Cassette connections and the Patient's Vascular Access; When the pressure stabilizes, select the alarm in the Alarm/Information Message Area and press the Reset button to restart the Arterial Pump.
3. Loss of diaphragm pressure between the Blood Cassette and the arterial pressure cone.	3. Perform a Cassette Repositioning Procedure, (Refer to the "Chapter 8: Special Procedures", in this Operator's Manual). When the pressure stabilizes, select the alarm in the Alarm/Information Message Area and press the Reset button to restart the Arterial Pump.
	Call for Service if the alarm persists.

ARTERIAL PRESSURE BELOW TREATMENT MIN. LIMIT 306

Reason	The measured arterial pressure is below the minimum arterial treatment limit.
Machine Actions	• The Arterial and the Venous Pumps are stopped; • The Venous Line Clamp is closed; • The UF Rate is automatically set to zero; • The alarm limits are opened for both arterial and venous pressure.

Possible Cause	**Suggested Action**
1. The Arterial Pump speed is too fast.	1. Consider decreasing the blood flow if this operation is not in disagreement with the patient prescription. When the pressure stabilizes, select the alarm in the Alarm/Information Message Area and press the Reset button to restart the Arterial Pump.
2. The Arterial Patient Line is kinked, clamped or restricted.	2. Check the Arterial Patient Line and the Patient's Vascular Access for restrictions, such as: • kinks in the Arterial Patient Line; • closed clamps; • clotted arterial needle; • poor flow from the Patient's Vascular Access. When the pressure stabilizes, select the alarm in the Alarm/Information Message Area and press the ***CONFIRM*** button to restart the Arterial Pump.
3. The arterial pressure decreased somewhat during a treatment due to hemoconcentration and/or inadequate heparin delivery to the patient, resulting in a reduced pressure for a given needle at a fixed blood flow rate.	3. Attention should be given to the revaluation of the needle size, the blood flow rate and the heparin dosage; When the pressure stabilizes, select the alarm in the Alarm/Information Message Area and press the ***CONFIRM*** button to restart the Arterial Pump.
	Call for Service if the alarm persists.

PATIENT CONNECTED 308

Reason	The Blood Sensor detected blood in the Venous Patient line.
Machine Actions	• The Arterial Pump stops.

Possible Cause	**Suggested Action**
1. The Blood Sensor detected blood in the Venous Patient line.	1. Verify that the Venous and Arterial Patient Lines are not attached to the patient. Press the Reset button to clear the message.
2. Blood Sensor is dirty or wet.	2. Clean or dry the Blood Sensor using a soft cloth. Press the Reset button to clear the message.
	Call for Service if the alarm persists.

WRONG A/V OR SYSTEM PRESSURE OFFSET 319

Reason	The initial Arterial and Venous Pressure offset are out of range or they aren't yet been calculated.
Machine Actions	• The machine will stop at this point and will not proceed any further into the test.

Possible Cause	**Suggested Action**
1. If the Blood Cassette is filled with saline, it is possible to have a pressure different from 0 mmHg.	1. Press the Reset button. Clamp the prime line, the Arterial infusion line and the Venous infusion line. Open the Venous infusion line and the Arterial infusion line to the atmosphere. The pressures displayed on the Touch Screen should decrease toward 0 mmHg.
2. The Blood Cassette was installed incorrectly during the Venous/Arterial Pressure T1 Test.	2. Press the Reset button. The Venous Patient Line must be inserted into the Air Detector and the Sensor Bar door closed. The Arterial Pump Cover must be closed. Reposition the Blood Cassette and restart the T1 test.
3. The Arterial Pump Cover is open.	3. Press the Reset button. Close the Arterial Pump Cover. Be sure the Arterial Pump Cover is securely latched.
4. The magnet is dirty.	4. Press the Reset button. Carefully clean the magnet located behind the Arterial Pump Cover, using a soft cloth dipped in Ethyl Alcohol (90°) or in Isopropyl Alcohol (70°).
	Call for Service if the alarm persists.

REMINDER - STILL IN PAUSE THERAPY 329

Reason	The machine remains in PAUSE TREATMENT for more than 5 minutes.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The operator has maintained the selection of PAUSE TREATMENT for more than 5 minutes.	1. Press the Reset button to remove the alarm. Interrupt the Pause Treatment procedure and continue the treatment.
	Call for Service if the alarm persists.

BLUE DIALYSIS FLUID TUBE INCORRECT POSITION 330

Reason	The Blue Dialysis Fluid Tube Connector is not in the position required for the current operating phase.
Machine Actions	• All the hydraulic pumps are stopped; • Waits until the connector is in right position; • The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. The Blue Dialysis Fluid Tube Connector is not in the position required for the current operating phase.	1. Verify the correct position of the Blue Dialysis Fluid Tube Connector for the current operating phase.
	Call for Service if the alarm persists.

RED DIALYSIS FLUID TUBE INCORRECT POSITION 331

Reason	The Red Dialysis Fluid Tube Connector is not in the position required for the current operating phase.
Machine Actions	• All the hydraulic pumps are stopped; • Waits until the connector is in right position; • The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. The Red Dialysis Fluid Tube Connector is not in the position required for the current operating phase.	1. Verify the correct position of the Red Dialysis Fluid Tube Connector for the current operating phase.
	Call for Service if the alarm persists.

VENOUS PRESSURE NOT INCREASING 351

Reason	In HD-SNSP Treatment, during the venous phase the venous pressure is not increasing as expected.
Machine Actions	• The Arterial Pump is stopped.

Possible Cause	Suggested Action
1. The venous pressure is not increasing as expected.	1. Check if the Blood Cassette is properly loaded on the Cassette holder and if it is properly connected to the venous pressure pod. Press the Reset button to restart the Arterial Pump and remove the alarm.
2. The Venous/Arterial Patient Lines or Venous/Arterial Dialyzer Lines could be kinked, clamped, restricted or have some leakages.	2. Check the Venous/Arterial Patient Lines, Venous/Arterial Dialyzer Lines and the Patient's Vascular Access for kinks, clamps or other restrictions. Press the Reset button to restart the Arterial Pump and remove the alarm.
3. The Blood Cassette and/or the SNSP conversion kit could have some leakages.	3. Check the line connections to these devices and ensure that the related clamps are closed. Press the Reset button to restart the Arterial Pump and remove the alarm.
	Call for Service if the alarm persists.

NO POWER - USING BATTERY BACKUP 353

Reason	The AC supply voltage has been interrupted in a machine equipped with the BATTERY BACKUP KIT.
Machine Actions	In RINSE: • The machine automatically switches OFF after 5 minutes. In DISINFECTION: • The heater is turned off.

Possible Cause	**Suggested Action**
1. Interruption of the AC supply voltage in RINSE or DISINFECTION.	1. Switch OFF the machine.
	Call for Service if the alarm persists.

BLOOD SENSED IN VENOUS LINE *359*

Reason	The Air Detector does not operate with the maximum sensitivity because the Venous Patient line or the Air Detector is dirty.
Machine Actions	• None

Possible Cause	Suggested Action
1. The Venous Patient line is dirty or the Air Detector is defective.	1. Open the Sensor Bar door; 2. Remove the Venous Patient line from the air detector/blood sensor; 3. Clean the Venous Patient line and the air detector/blood sensor; 4. Route again the Venous Patient line through the air detector/blood sensor; 5. Close the Sensor Bar door; 6. Press the ***RESET*** button to clear the “Blood Sensed in Venous Line (#359)” alarm; 7. If the “Blood Sensed in Venous Line (#359)” persists, repeat the procedure.
	Call for Service if the alarm persists.

PUMP SPEED TOO LOW 362

Reason	The Arterial pump speed is lower than the set value.
Machine Actions	• The Arterial and the Venous pumps are stopped; • The Venous Line Clamp is closed; • The UF Rate is automatically set to zero.

Possible Cause	**Suggested Action**
1. The Arterial Pump speed is incorrect.	1. Press the Reset button to restart the Arterial Pump.
2. The Arterial Pump speed is too high for the "SN Pressure Min" and "SN Pressure Max" parameter values set by the operator.	2. Decrease the Arterial Pump speed or consider changing the "SN Pressure Min" and "SN Pressure Max" parameter values. Press the Reset button to restart the Arterial Pump.
	Call for Service if the alarm persists.

BLOOD PUMP ROTOR ERROR 363

Reason	The Arterial Pump is not functioning properly.
Machine Actions	• The Arterial and the Venous Pumps are stopped; • The Venous Line Clamp is closed; • The UF Rate is automatically set to zero.

Possible Cause	**Suggested Action**
1. If the alarm is displayed for the first time.	1. Press the Reset button and continue the process.
2. If the alarm persists.	2. Perform a Fast Recovery procedure during a dialysis treatment as described in the “8.5 Fast Recovery” section of this Operator’s Manual. Then call for Service.

VENOUS LINE NOT IN PATIENT SENSOR 364

Reason	The machine is not detecting that the Venous Patient Line is present into the Air Detector housing or into the Venous Line Clamp (ONLY after Patient Connection).
Machine Actions	• The Arterial Pump is stopped; • The UF Rate is automatically set to minimum; • The Venous Line Clamp is closed.

Possible Cause	**Suggested Action**
1. The Venous Patient Line is not properly inserted into the Air Detector housing or into the Venous Line Clamp.	1. Verify that the Venous Patient Line has been inserted correctly into the Air Detector housing and into the Venous Line Clamp.
	Call for Service if the alarm persists.

INCORRECT BICART/BLUE CONCENTRATE TUBE CONCENTRATION *366*

Reason	The conductivity measured in the first stage of the dialysis fluid preparation is below the permitted range.
Machine Actions	• The dialysis fluid goes into Bypass; • The infusion flow is interrupted; • The Venous Pump is stopped.

Possible Cause	Suggested Action
1. The Safebag - K Compartment is almost empty.	1. Verify if the level of concentrate is adequate. If the Safebag - K compartment is almost empty, replace the Safebag as described in the “3.4 Change Safebag” section of the Artis AFB K Treatment Operator’s Manual.
2. The Blue Concentrate Connector is not properly connected to its Safebag Connector.	2. Verify that the Blue Concentrate Connector is properly connected to its Safebag Connector.
3. The Blue Concentrate Connector is not properly connected to its Concentrate Connector Port.	3. Verify that the Blue Concentrate Connector is properly connected to its Concentrate Connector Port.
4. Massive air intake from the Safebag - K Compartment.	4. Check the position of the Safebag KV concentrate solution on the Concentrate bag hooks.
5. The BiCart Cartridge is almost empty.	5. Verify if the level of concentrate is adequate. If the BiCart Cartridge is almost empty, replace the BiCart as described in the “8.6 Change BiCart Cartridge” section of the Artis Operator’s Manual.
6. The BiCart Cartridge is not properly positioned in its holder.	6. Ensure the BiCart Cartridge is securely placed in its holder.
	Call for Service if the alarm persists.

NOTE

The use of liquid Bicarbonate concentrate is not currently available.

DIALYSATE PH LOW 368 (optional)	
Reason	The dialysis fluid pH value is below the alarm threshold.
Machine Actions	• The dialysis fluid goes into Bypass; • The Venous pump is stopped.

Possible Cause	**Suggested Action**
1. The concentrate canisters are empty.	1. Verify that none of the concentrate canisters are empty.
2. A chemical disinfectant has been connected to the machine instead of the A-concentrate. *(see WARNING below)*	**2. DURING PREPARATION** 1. Stop dialysis fluid preparation; 2. Remove the cassette and the dialyzer if yet installed; 3. Perform a Rinse programme; 4. Change both the Ultrafilters performing the procedure described in the "8.25 Ultrafilter Change Procedure" section of this Operator's Manual **2. DURING TREATMENT** 1. Stop the treatment and disconnect the patient. 2. Perform a Rinse programme; 3. Change both the Ultrafilters performing the procedure described in the "8.25 Ultrafilter Change Procedure" section of this Operator's Manual
3. The solution in the concentrate canister is not correct or diluted.	3. Verify that concentrates are being used and are of the appropriate formulation for the selected treatment type. If using dialysis fluid concentrate solutions, replace the concentrates as needed, then wait a few seconds for the machine to stabilize. If using solutions other than concentrates during the dialysis fluid preparation: • Stop the dialysis preparation; • Replace the Blood Cassette and the Dialyzer; • Run a complete RINSE procedure; • Replace solutions; • Restart the dialysis fluid preparation.

Possible Cause (Continued)	Suggested Action (Continued)
4. Air leak from the Red/Blue pick-up tube connectors or the Red/Blue pick-up tube is not connected to the Concentrate Canister or the Red/Blue pick-up tube connector has accumulated debris or salt crystals.	4. If the alarm persists, verify that: • the Red and Blue pick-up tube connectors and Red and Blue pick-up tubes are free of leaks/holes and debris. • the Red/Blue pick-up tube connectors are securely connected to the appropriate concentrate connector port/ canister. If necessary, rinse the accumulated debris from the Connector(s).
	Call for Service if the alarm persists.

⚠WARNING

The “DIALYSATE PH LOW (#368)” alarm could be triggered in case a chemical disinfectant has been used instead of Acid concentrate during a dialysis treatment.
This may lead to improper dialysis to be delivered to the patient, thus resulting in patient injury or death.

ACID/SAFEBAG AFB CONCENTRATE ERROR *369*	
Reason	A discrepancy is indicated between the conductivity of the dialysis fluid both for the dialysis fluid flow and the rotation speed of the associated Pump(s). The actual Pump(s) speed does not match with the actual concentrate(s) used.
Machine Actions	• The dialysis fluid goes into Bypass. • The infusion flow is interrupted; • The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. A chemical disinfectant has been connected to the machine instead of the A-concentrate. *(see WARNING below)*	**1. DURING PREPARATION** 1. Stop dialysis fluid preparation; 2. Remove the cassette and the dialyzer if yet installed; 3. Perform a Rinse programme; 4. Change both the Ultrafilters performing the procedure described in the "8.25 Ultrafilter Change Procedure" section of this Operator's Manual **1. DURING TREATMENT** 1. Stop the treatment and disconnect the patient. 2. Perform a Rinse programme; 3. Change both the Ultrafilters performing the procedure described in the "8.25 Ultrafilter Change Procedure" section of this Operator's Manual
2. The type of the Acid/Safebag Concentrate solution used is incorrect.	2. Verify that the correct type of Acid/ Safebag Concentrate solution is being used. If the Acid canister/bag has to be replaced, perform the "Change Acid" special procedure as described in the "8.7 Change Acid" section of the Artis Operator's Manual. If the Safebag KV concentrate solution has to be replaced, perform the "Change Safebag" special procedure as described in the "3.4 Change Safebag" section of the Artis AFB K Treatment Operator's Manual. Wait a few seconds for the machine to stabilize.

Possible Cause (Continued)	Suggested Action (Continued)
3. The Acid/Safebag Concentrate solution selected in the *Fluid Settings* sub-screen is incorrect.	3. Verify that the correct type of Acid/ Safebag Concentrate solution has been selected on the *Fluid Settings* sub-screen, then wait a few seconds for the machine to stabilize.
4. The Red Concentrate Connector is not securely connected to its port/canister or the machine has been switched from the Central Concentrate to an individual Concentrate Canister.	4. Verify that the Red Concentrate Connector is securely connected to the appropriate port/canister.
5. The Green Concentrate Connector is not connected to its Safebag Connector or the frangible pin of the Safebag - AFB Compartment has not been broken.	5. In AFB K Treatment: Verify that the Green Concentrate Connector is connected to its Safebag Connector. Verify that the frangible pin of the Safebag - AFB Compartment has been broken.
6. The SelectCart powder has not been properly diluted in the SelectCart Cartridge.	6. Press the “Special Procedures” button. Select the “Change SelectCart” option. Perform the “Change SelectCart” special procedure as described in the “8.9 Change SelectCart Cartridge” section of this Operator’s Manual.
7. The Acid Pump speed is incorrect.	7. If the machine does not stabilize, call for Service.
	Call for Service if the alarm persists.

⚠WARNING

The “Acid/Safebag AFB Concentrate Error (#369)” alarm could be triggered in case a chemical disinfectant has been used instead of Acid concentrate during a dialysis treatment.
This may lead to improper dialysis to be delivered to the patient, thus resulting in patient injury or death.

BICARBONATE/SAFEBAG K CONCENTRATE ERROR *370*

Reason	A discrepancy is indicated between the conductivity of the dialysis fluid both for the dialysis fluid flow and the rotation speed of the associated Pump/Pumps. The actual Pump(s) speed does not match with the actual concentrate(s) used.
Machine Actions	• The dialysis fluid goes into Bypass; • The infusion flow is interrupted; • The Venous Pump is stopped (in HDF Post and AFB K Treatments).

Possible Cause	Suggested Action
1. The Blue Concentrate Connector, if present, is not securely connected to its its Concentrate Connector Port.	1. In Dialysis (BiCart treatments): Verify that the Blue Concentrate Connector is securely connected to its Concentrate Connector Port.
2. The Blue Concentrate Connector is not connected to its Safebag Connector or the frangible pin of the Safebag - K Compartment has not been broken.	2. In AFB K Treatment: Verify that the Blue Concentrate Connector is connected to its Safebag Connector. Verify that the frangible pin of the Safebag - K Compartment has been broken.
3. The type of Safebag KV concentrate solution used is incorrect.	3. Verify that the correct type of Safebag KV concentrate solution is being used. Replace the Safebag as described in the "3.4 Change Safebag" section of the Artis AFB K Treatment Operator's Manual. Wait a few seconds for the machine to stabilize.
4. The Safebag KV concentrate solution selected on the "Fluid Settings" sub-screen is incorrect.	4. Ensure that the correct type of Safebag KV concentrate solution has been selected on the "Fluid Settings" sub-screen, then wait a few seconds for the machine to stabilize.
5. The BiCart Cartridge powder has not been properly diluted in the BiCart Cartridge.	5. Press the "Special Procedures" button. Select the "Change BiCart" option. Perform the "Change BiCart" special procedure as described in the "8.6 Change BiCart Cartridge" section of this Operator's Manual.
6. The Bicarbonate Pump speed is incorrect.	6. If the machine does not stabilize, call for Service.
	Call for Service if the alarm persists.

DIALYSIS FLUID FLOW LOW 373

Reason	The dialysis fluid flow is lower than the set value or than the minimum permitted flow.
Machine Actions	• The dialysis fluid goes into Bypass; • The Venous pump is stopped.

Possible Cause	**Suggested Action**
1. There are deposits or debris inside the flowmeters of the machine.	1. Perform a Chemical Disinfection.
	Call for Service if the alarm persists.

INCORRECT CONDUCTIVITY MEASURED 375

Reason	The conductivity of the dialysis fluid is below the allowed limit.
Machine Actions	• The dialysis fluid goes into Bypass; • The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. Inappropriate solution in the Acid Concentrate Canister.	1. Verify that appropriate concentrate has been used for the selected treatment type.
2. Massive air leak from Concentrate Canisters/Connectors/Tubes or the Connectors are not securely connected to their Canisters/Ports or the Canisters/Connectors have accumulated debris or salt crystals.	2. If the alarm persists: • verify that Concentrate Canisters, Connectors and Tubes are free of leaks/ holes and debris; • verify that the Connectors are securely connected to the appropriate Canisters/ Ports; • if necessary, rinse the accumulated debris from the Canister(s)/Connector(s); • massive air leaks affect conductivity readings.
3. Inadequate Concentrates are being used.	3. If using dialysis fluid concentrate solutions, replace concentrates as needed then wait a few seconds for the machine to stabilize. If using solutions other than concentrates during dialysis fluid preparation: • stop the dialysis fluid preparation; • replace the Blood Cassette and the dialyzer; • run a complete ADR: RINSE procedure; • replace the solutions; • restart the dialysis fluid preparation.
4. The Acid or Bicarbonate Connector is not properly positioned into the Central Concentrate port.	4. Verify that the Acid or Bicarbonate Connector is properly positioned into the Central Concentrate port on the front panel.
	Call for Service if the alarm persists.

NOTE

The use of liquid Bicarbonate concentrate is not currently available.

DIALYSIS FLUID TEMP LOW 377

Reason	The temperature of the dialysis fluid is 2°C below the value set by the operator.
Machine Actions	• The dialysis fluid goes into Bypass; • The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. A temporary instability of dialysis fluid flow.	1. Wait a few seconds for the system to stabilize.
2. The temperature of the dialysis fluid has exceeded the safe limits.	2. Verify that the incoming water temperature is between 5.0°C - 32.2°C (41-90 degrees F). If the incoming water temperature exceeds the specified range, then adjust the temperature of the water source per clinical policy. If this alarm persists, then discontinue the dialysis treatment.
	Call for Service if the alarm persists.

UF RATE LOWER THAN EXPECTED 379

Reason	The ultrafiltration rate (UFR) is below the value confirmed by the operator or the minimum permitted value.
Machine Actions	• The Venous Pump is stopped; • The dialysis fluid goes into Bypass; • Calibration request.

Possible Cause	**Suggested Action**
1. Error in the Ultrafiltration Mass Balance in the Hydraulic Module, due to incorrect valves control.	1. Press the Reset button and continue the treatment.
2. Error in the Ultrafiltration Mass Balance in the Hydraulic Module, due to incorrect flowmeter reading.	2. Press the Reset button and continue the treatment.
3. Error in the Ultrafiltration Mass Balance in the Hydraulic Module, due to incorrect P2 pump flow or P2 reading.	3. Press the Reset button and continue the treatment.
4. The machine could not perform an alignment of the D2 flowmeter during the treatment and the Ultrafiltration Mass Balance could be incorrect.	4. Press the Reset button and continue the treatment.
	Call for Service if the alarm persists.

VENOUS PRESSURE LOW 382

Reason	The measured venous pressure is either below +10 mmHg or below the venous pressure threshold as displayed in the Venous Pressure Alarm Window.
Machine Actions	• The Arterial and the Venous Pumps are stopped; • The Venous Line Clamp is closed; • The UF Rate is automatically set to zero; • The alarm limits are opened for both arterial and venous pressure.

Possible Cause	**Suggested Action**
1. If <10 mmHg, the Venous Patient Line may have become disconnected from the patient.	1. Carefully check the Patient's Vascular Access, the Cassette connections and inspect for kinking of the Venous Patient Line. When the pressure stabilizes, select the alarm in the Alarm/Information Message Area and press the Reset button to restart the Arterial Pump.
	Call for Service if the alarm persists.

ARTERIAL PRESSURE LOW 384

Reason	The measured arterial pressure is below the minimum arterial pressure threshold, as displayed in the Arterial Pressure Alarm Window.
Machine Actions	• The Arterial and the Venous Pumps are stopped; • The Venous Line Clamp is closed; • The UF Rate is automatically set to zero; • The alarm limits are opened for both arterial and venous pressure.

Possible Cause	**Suggested Action**
1. The Arterial pressure alarm window needs to be set.	1. In the A / V Limit Settings sub-screen adjust the arterial pressure alarm limits; Press "Close A/V Limits" button: the machine automatically centralize the alarm window values around the current patient's arterial/venous pressures. When the pressure stabilizes, select the alarm in the Alarm/Information Message Area and press the Reset button to restart the Arterial Pump.
2. The Arterial Patient Line may have become disconnected from the patient.	2. Carefully check the Cassette connections and the Patient's Vascular Access. When the pressure stabilizes, select the alarm in the Alarm/Information Message Area and press the Reset button to restart the Arterial Pump.
3. The Arterial Patient Line is kinked, clamped or restricted.	3. Check the Arterial Patient Line and the Patient's Vascular Access for restrictions, such as: • kinks in the Arterial Patient Line; • closed clamps; • clotted arterial needle; • poor flow from the Patient's Vascular Access. When the pressure stabilizes, select the alarm in the Alarm/Information Message Area and press the Reset button to restart the Arterial Pump.
4. Loss of diaphragm pressure between the Blood Cassette and the arterial pressure cone.	4. Perform a Cassette Repositioning Procedure (Refer to the "Chapter 8: Special Procedures", in this Operator's Manual). When the pressure stabilizes, select the alarm in the Alarm/Information Message Area and press the Reset button to restart the Arterial Pump.
	Call for Service if the alarm persists.

AIR IN BLOOD T0 FAILURE 385

Reason	The T0 Test, related to the Air Detector sensor, has failed.
Machine Actions	• The Arterial Pump is stopped; • The Venous Line Clamp is closed; • The UF Rate is automatically set to minimum.

Possible Cause	Suggested Action
1. The T0 Test failed.	1. Press the Reset button to remove the alarm.
	Call for Service if the alarm persists.

NA OR BIC SETTINGS RESULT IN CONDUCTIVITY OUT OF RANGE 401

Reason	The Sodium or Bicarbonate Settings result in conductivity out of range.
Machine Actions	• The machine continues the treatment with the previous conductivity set; • The new set conductivity is not stored in the machine memory.

Possible Cause	**Suggested Action**
1. One of the formula input (Na set, HCO3 set, Concentrate set) causes the results out of range.	1. Change the value of the formula input.
	Call for Service if the alarm persists.

NOTE

The use of liquid Bicarbonate concentrate is not currently available.

ULTRAFILTER REPLACEMENT REMINDER 402

Reason	The machine notifies that the ultrafilters should be replaced.
Machine Actions	• The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. The ultrafilters should be replaced.	1. Press the ***CONFIRM*** button to remove the alarm. If needed, replace the ultrafilters with new ones (Refer to the “8.25 Ultrafilter Change Procedure” section of this Operator’s Manual).
	Call for Service if the alarm persists.

INCORRECT GREEN CONCENTRATE CONNECTOR POSITION 404

Reason	The Green Concentrate Connector is in the wrong position, for the treatment type set, or is not fully inserted into its Concentrate Connector Port.
Machine Actions	In AFB K Treatments: • The phase currently running stops; • The PA concentrate pump is stopped; • The dialysis fluid goes into Bypass and the infusion flow is interrupted. In ADR: • The phase currently running stops; • All the pumps are stopped.

Possible Cause	Suggested Action
1. The Green Concentrate Connector is not connected to its Safebag Connector.	1. In AFB K Treatments: Verify that the Green Concentrate Connector is connected to its Safebag Connector.
2. The Green Concentrate Connector is not fully inserted in its Concentrate Connector Port.	2. In ADR and all the other treatments: Verify that the Green Concentrate Connector is securely connected to its Concentrate Connector Port.
	Call for Service if the alarm persists.

INCORRECT SELECTBAG HOLDER ARM POSITION 411

Reason	The SelectBag holder is in the wrong position.
Machine Actions	In DIALYSIS: • All hydraulic module pumps are stopped; • The dialysis fluid goes into Bypass; • Waits until the connector is in right position. In ADR: • The phase currently running stops; • All the pumps are stopped.

Possible Cause	**Suggested Action**
1. The SelectBag holder is in the wrong position.	1. Check the position of the SelectBag holder.
	Call for Service if the alarm persists.

VENOUS FLOW MINIMUM 412

Reason	The venous blood flow is lower than the expected set value.
Machine Actions	• The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. The Venous Pump speed is different from the set value.	1. Press the Reset button to restart the Venous Pump.
	Call for Service if the alarm persists.

VENOUS FLOW MAXIMUM 413

Reason	The venous blood flow is greater than the expected set value.
Machine Actions	• The Venous Pump is stopped.

Possible Cause	Suggested Action
1. The Venous Pump speed is different from the set value.	1. Press the Reset button to restart the Venous Pump.
	Call for Service if the alarm persists.

NO POWER - USING BATTERY BACKUP 415

Reason	A power failure occurred and therefore the battery back-up is used.
Machine Actions	• The phase currently running stops; • The heater is turned OFF • All the pumps are stopped.

Possible Cause	**Suggested Action**
1. Interruption of the AC supply voltage in DIALYSIS, during the Dialysis Fluid preparation until patient connection.	1. Switch the machine OFF.
2. Interruption of the AC supply voltage in DIALYSIS, during the treatment.	2. Press the Reset button. Perform Rinseback to return the blood to the patient and then switch the machine OFF.
3. Interruption of the AC supply voltage in DIALYSIS, before the patient connection or after the patient disconnection.	3. Switch the machine OFF.
	Call for Service if the alarm persists.

LEFT BLUE EVACLEAN DOOR INCORRECT POSITION 416

Reason	The Left Blue EvaClean door position is wrong.
Machine Actions	The machine waits until the EvaClean Door is closed, in the meantime: In DIALYSIS: • All hydraulic module pumps are stopped; • The dialysis fluid goes into Bypass. In ADR: • The phase currently running stops; • All the pumps are stopped.

Possible Cause	**Suggested Action**
1. The Left Blue EvaClean door is open when it should be closed.	1. Verify that the door is closed.
2. The Left Blue EvaClean door is closed when it should be opened.	2. Verify that the door is opened.
	Call for Service if the alarm persists.

RIGHT RED EVACLEAN DOOR INCORRECT POSITION 417

Reason	The Right Red EvaClean door position is wrong.
Machine Actions	• The machine stops and waits for the EvaClean Door to be closed.

Possible Cause	**Suggested Action**
1. The Right Red EvaClean door is open when it should be closed.	1. Verify that the door is closed.
2. The Right Red EvaClean door is closed when it should be opened.	2. Verify that the door is opened.
	Call for Service if the alarm persists.

T1 TEST PRE FILTER PRESSURE 418

Reason	The acquired inlet pressure value is out of range respect to the set point.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The T1 test failed during preparation.	1. Press the Reset button. Verify that the dialysis fluid connectors are properly positioned to their bypass ports. Repeat the dialysis fluid preparation.
	Call for Service if the alarm persists.

T1 TEST ARTERIAL PUMP/ABD 419

Reason	The acquired flow value is out of range respect to the set point.
Machine Actions	• None. • If the alarm condition persists after the preparation phase, it will not be possible to start the treatment.

Possible Cause	Suggested Action
1. The T1 test failed during preparation.	1. Press the Reset button to remove the alarm. Perform an Extra Priming procedure.
	Call for Service if the alarm persists.

NOTE

This alarm appears also in case the Arterial Pump cover is opened and then closed while the machine is performing the T1 Arterial Pump/ABD test. In this case, pressing the ***CONFIRM*** button, the alarm message is removed but if the "Reset Prime" button is pressed, the priming procedure gets stuck.

To restore the priming procedure, proceed as follows:

1. Open the Arterial Pump Cover;
2. Close the Arterial Pump Cover;
3. Press the "Auto-Prime" button to start again the priming procedure.

T1 TEST FLOW METERS 422

Reason	The T1 test performed by the machine on the T1 Test Flow Meters has failed.
Machine Actions	• None. • If the alarm condition persists after the preparation phase, it will not be possible to start the treatment.

Possible Cause	Suggested Action
1. The T1 test Flowmeter failed.	1. Press the Reset button and wait for the new flowmeter test.
	Call for Service if the alarm persists.

ON-LINE DOOR INCORRECT POSITION 423

Reason	The Ultra Door position is wrong.
Machine Actions	• The phase currently running stops; • All the pumps are stopped; • The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. The Ultra Door is open when it should be closed.	1. Verify that the door is closed.
2. The Ultra Door is closed when it should be opened.	2. Verify that the door is opened.
	Call for Service if the alarm persists.

SENSOR BAR DOOR OPEN 424

Reason	The sensor detected that the Sensor Bar Door is open.
Machine Actions	• The phase currently running stops; • All the pumps are stopped.

Possible Cause	Suggested Action
1. The Sensor Bar Door is open when it should be closed.	1. Verify that the door is closed.
	Call for Service if the alarm persists.

DIALYSIS FLUID FLOW TOO LOW 425

Reason	The dialysis fluid flow is lower than the set value or than the minimum permitted flow.
Machine Actions	• The phase currently running stops; • All the pumps are stopped; • The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. There are deposits or debris inside the flowmeters of the machine.	1. Press the Reset button. Perform a Chemical Disinfection.
	Call for Service if the alarm persists.

T1 TEST ACOUSTICAL BUZZER FAILED 438

Reason	The acoustical buzzer T1 test failed.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The acoustical buzzer T1 test failed.	1. Press the Reset button.
	Call for Service if the alarm persists.

⚠WARNING

If both the Acustical Buzzer T1 Test and the Acustical Speaker T1 Test fail (both the auditory signal sources are malfunctioning), a malfunction occurs so that it is not possible to use the Artis Dialysis System. In this case, call for Service Technician.
If only one of the T1 Tests fails (only one of the auditory signal source is malfunctioning), it is the operator's responsibility to decide whether to proceed with the current treatment after having checked that the machine is able to sound properly. Also in this case, call for Service Technician to troubleshoot the problem as soon as possible.

SMARTSCAN - NOT PERFORMING UF 443

Reason	The "UF" button has been deselected during treatment.
Machine Actions	• None.

Possible Cause	Suggested Action
1. During treatment the operator has deselected the "UF" button (the machine doesn't apply UF for six consecutive minutes, so an alarm message will be displayed).	1. Press the ***CONFIRM*** button to remove the alarm message (pay attention that UF doesn't restart automatically).
	Call for Service if the alarm persists.

T1 TEST TEMPERATURE FAILED 444

Reason	The T1 test performed by the machine on the Temperature has failed.
Machine Actions	• None. • If the alarm condition persists after the preparation phase, it will not be possible to start the treatment.

Possible Cause	Suggested Action
1. The T1 test Temperature failed.	1. Press the Reset button and wait the machine to perform another Temperature test.
	Call for Service if the alarm persists.

T1 TEST CONDUCTIVITY CELLS FAILED 445

Reason	The T1 test performed by the machine on the Conductivity cells has failed.
Machine Actions	• None. • If the alarm condition persists after the preparation phase, it will not be possible to start the treatment.

Possible Cause	**Suggested Action**
1. The T1 test Conductivity failed.	1. Press the Reset button and wait the machine to perform another Conductivity test. If the alarm persists, call for service.
	Call for Service if the alarm persists.

T1 TEST VENOUS PRESSURE 446

Reason	The T1 test performed by the machine on the Venous pressure has failed.
Machine Actions	• None. • If the alarm condition persists after the preparation phase, it will not be possible to start the treatment.

Possible Cause	Suggested Action
1. The T1 test Venous pressure failed.	1. Press the Reset button and perform unload/load cassette for a new Venous pressure test.
	Call for Service if the alarm persists.

T1 TEST ARTERIAL PRESSURE 447

Reason	The T1 test performed by the machine on the Arterial pressure has failed.
Machine Actions	• None. • If the alarm condition persists after the preparation phase, it will not be possible to start the treatment.

Possible Cause	**Suggested Action**
1. The T1 test Arterial pressure failed.	1. Press the Reset button and perform unload/load cassette for a new Arterial pressure test.
	Call for Service if the alarm persists.

COMMUNICATION PROTECTIVE COND. CELL STOPPED 449

Reason	The communication between the Protective System and the conductivity cell Γp has failed.
Machine Actions	• None.

Possible Cause	Suggested Action
1. Temporary problem.	1. Press the Reset button to remove the alarm. If the problem persists, disconnect the patient.
	Call for Service if the alarm persists.

COMMUNICATION SELECT COND. CELL STOPPED 450

Reason	The communication between the Protective System and the conductivity cell ΓcP has failed.
Machine Actions	• None.

Possible Cause	Suggested Action
1. Temporary problem.	1. Press the Reset button to remove the alarm. If the problem persists, disconnect the patient.
	Call for Service if the alarm persists.

T1 TEST ACOUSTIC SPEAKER 451

Reason	The T1 Test related to the Acoustic Speaker is failed.
Machine Actions	• The buzzer is active.

Possible Cause	**Suggested Action**
1. Acoustic Speaker is defective.	1. Press the Reset button to remove the alarm.
	Call for Service if the alarm persists.

⚠WARNING

If both the Acustical Buzzer T1 Test and the Acustical Speaker T1 Test fail (both the auditory signal sources are malfunctioning), a malfunction occurs so that it is not possible to use the Artis Dialysis System. In this case, call for Service Technician.
If only one of the T1 Tests fails (only one of the auditory signal source is malfunctioning), it is the operator's responsibility to decide whether to proceed with the current treatment after having checked that the machine is able to sound properly. Also in this case, call for Service Technician to troubleshoot the problem as soon as possible.

PDR PRESSURE HIGH 452

Reason	The pressure of the dialysis fluid that is going to the drain, measured by the PD pressure sensor, is higher than the permitted value.
Machine Actions	• The phase currently running stops; • All the pumps are stopped; • The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. Temporary problem.	1. Press the Reset button to remove the alarm.
	Call for Service if the alarm persists.

PDR PRESSURE LOW 453

Reason	The pressure of the dialysis fluid that is going to the drain, measured by the PD pressure sensor, is lower than the permitted value.
Machine Actions	• The phase currently running stops; • All the pumps are stopped; • The dialysis fluid goes into Bypass.

Possible Cause	Suggested Action
1. Temporary problem.	1. Press the Reset button to remove the alarm.
	Call for Service if the alarm persists.

INSERT THE HEMOSCAN CUVETTE 454

Reason	The Hemoscan Cuvette is not inserted into the Sensor Bar door.
Machine Actions	• The appearance of the "Auto-Prime" Action button has been delayed. • None.

Possible Cause	**Suggested Action**
1. The cassette is loaded and the Sensor Bar door is open and/or the cuvette is not present.	1. Insert the Arterial Patient Line with the Hemoscan cuvette into the Sensor Bar. Firmly close the Sensor Bar door.
2. The Hemoscan cuvette is not present on the Blood Tubing System used.	2. Deactivate first the Hemocontrol function (when activated) and then the Hemoscan function.
	Call for Service if the alarm persists.

⚠WARNING

The Hemoscan system can be used only with a specific Blood Tubing System equipped with a Hemoscan cuvette.
Refer to the " Chapter 17: Specifications" of this manual for the list of Blood Tubing Systems equipped with Hemoscan cuvette.
Use of different Blood Tubing Systems can cause alarms or wrong measurements of Hemoscan Monitoring System due to differences in the characteristic of the line (materials, geometry and so on).

ARTERIAL PRESSURE HIGH 457

Reason	The measured arterial pressure is above the maximum arterial treatment limit.
Machine Actions	• The Arterial and the Venous Pumps are stopped; • The Venous Line Clamp is closed; • The UF Rate is automatically set to zero; • The alarm limits are opened for both arterial and venous pressure.

Possible Cause	**Suggested Action**
1. The Arterial Patient Line may have become disconnected from the patient.	1. Carefully check the Cassette connections and the Patient's Vascular Access. When the pressure stabilizes, select the alarm in the Alarm/Information Message Area and press the Reset button to restart the Arterial Pump.
2. The Arterial Pump speed is too low.	2. Consider increasing the blood flow if this operation is not in disagreement with the patient prescription. When the pressure stabilizes, select the alarm in the Alarm/Information Message Area and press the Reset button to restart the Arterial Pump.
	Call for Service if the alarm persists.

VENOUS PRESSURE BELOW TREATMENT MIN. LIMIT 459

Reason	The measured venous pressure is below the minimum venous treatment limit.
Machine Actions	• The Arterial and the Venous Pumps are stopped; • The Venous Line Clamp is closed; • The UF Rate is automatically set to zero (typical value 100 ml/h); • The alarm limits are opened for both arterial and venous pressure.

Possible Cause	**Suggested Action**
1. Restriction of blood flow to the Patient's Vascular Access or in the Venous Patient Line.	1. Carefully check the Blood Cassette connections and assess the Patient's Vascular Access. Check for restrictions, such as: • kinks in the Venous Patient Line; • closed clamps; • clotted venous needle. If necessary decrease the blood flow per clinical policy. When the pressure stabilizes, select the alarm in the Alarm/Information Message Area and press the Reset button to restart the Arterial Pump.
2. The venous pressure has decreased somewhat during a treatment due to hemoconcentration and/or inadequate heparin delivery to the patient, resulting in a pressure decrease for a given needle at a fixed blood flow rate.	2. Attention should be given to the revaluation of the needle size, the blood flow rate and the heparin dosage; When the pressure stabilizes, select the alarm in the Alarm/Information Message Area and press the Reset button to restart the Arterial Pump.
	Call for Service if the alarm persists.

DIALYSIS FLUID TEMP TOO HIGH 460

Reason	The temperature of the dialysis fluid measured by the ΓP conductivity cell is greater than 41°C.
Machine Actions	• The dialysis fluid goes into Bypass; • The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. A temporary instability of dialysis fluid flow.	1. Wait for stability of the system.
2. The temperature of the dialysis fluid has exceeded the safe limits.	2. Check the incoming water temperature (Refer to the "Chapter 17: Specifications" in this Operator's Manual).
3. The machine has recently been turned on and has not yet reached the operating temperature.	3. If the machine temperature remains high or low for more than 10 minutes, discontinue the DIALYSIS.
4. The machine has an internal malfunction.	4. Discontinue the DIALYSIS.
	Call for Service if the alarm persists.

DIALYSIS FLUID TEMP TOO LOW 461

Reason	The temperature of the dialysis fluid measured by the ΓP conductivity cell is lower than 32°C
Machine Actions	• The dialysis fluid goes into Bypass; • The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. There are deposits or debris inside the flowmeters of the machine.	1. Perform a Chemical Disinfection.
	Call for Service if the alarm persists.

CONDUCTIVITY TOO LOW 462

Reason	The measured conductivity is below the desired set point.
Machine Actions	• The dialysis fluid goes into Bypass; • The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. Inappropriate solution in the Acid Concentrate Canister.	1. Verify that concentrates are being used and are of the appropriate formulation for the selected treatment type.
2. Massive air leak from Concentrate Canisters/Connectors/Tubes or the Connectors are not securely connected to their Canisters/Ports or the Canisters/ Connectors have accumulated debris or salt crystals.	2. If the alarm persists: • verify that Concentrate Canisters, Connectors and Tubes are free of leaks/holes and debris; • verify that the Connectors are securely connected to the appropriate Canisters/ Ports; • If necessary, rinse the accumulated debris from the Canister(s)/ Connector(s); • massive air leaks affect the conductivity readings.
3. Inadequate Concentrates are being used.	3. If using dialysis fluid concentrate solutions, replace the concentrates as needed, then wait a few seconds for the machine to stabilize. If using solutions other than concentrates during the dialysis fluid preparation: • stop the dialysis fluid preparation; • replace the Blood Cassette and the dialyzer; • run a complete ADR: RINSE procedure; • replace the solutions; • restart the dialysis fluid preparation.
4. The Acid or Bicarbonate pick-up tube connector is not properly positioned into the Central Concentrate port.	4. Verify that the Acid or Bicarbonate pick-up tube connector is properly positioned into the Central Concentrate port on the front panel.
	Call for Service if the alarm persists.

NOTE

The use of liquid Bicarbonate concentrate is not currently available.

CONDUCTIVITY TOO HIGH 463

Reason	The measured conductivity is above the desired set point.
Machine Actions	• The dialysis fluid goes into Bypass; • The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. The Acid or Bicarbonate Concentrate canister is empty.	1. Supply appropriate concentrate to the relevant inlet connector. Wait for stability of the dialysis fluid flow.
2. The Acid or Bicarbonate pick-up tube connector(s) are not properly positioned to the concentrate Canister(s).	2. Verify the connector(s) are properly positioned to the proper Canister(s). Wait for stability of the dialysis fluid flow.
3. Massive air leak from the concentrate canister.	3. Replace the concentrate canister. Wait for stability of the dialysis fluid flow.
4. The Acid or Bicarbonate pick-up tube connector(s) has accumulated debris or salt crystals.	4. Rinse the accumulated debris from the connector(s).
5. Inappropriate solution in the Acid concentrate canister.	5. Verify that appropriate concentrate has been used.
6. When using central delivery acid, the Acid or Bicarbonate pick-up tube connector is not securely connected into its concentrate connector port.	6. Verify that the Acid or Bicarbonate pick-up tube connector is properly positioned in its concentrate connector port.
	Call for Service if the alarm persists.

NOTE

The use of liquid Bicarbonate concentrate is not currently available.

CONDUCTIVITY FROM BICART/BLUE CONCENTRATE TUBE TOO LOW *464*

Reason	The conductivity of the solution after the mixing of the bicarbonate and the select bag is below the setpoint fixed by the operator. In AFB K Treatments, the conductivity of the solution after the mixing of the Safebag - K Compartment is below the setpoint fixed by the operator.
Machine Actions	• The dialysis fluid goes into Bypass; • The infusion flow is interrupted; • The Venous Pump is stopped.

Possible Cause	Suggested Action
1. The BiCart Cartridge is almost empty.	1. Verify if the level of concentrate is adequate. If the BiCart Cartridge is almost empty, replace the BiCart as described in the related section of the “8.6 Change BiCart Cartridge” section of this Operator’s Manual.
2. The Safebag - K Compartment is almost empty.	2. In AFB K Treatments: If the Safebag KV concentrate solution is almost empty, replace the Safebag as described in the “3.4 Change Safebag” section of the Artis AFB K Treatment Operator’s Manual.
3. The Blue Concentrate Connector is not connected to its Safebag Connector or the frangible pin of the Safebag - K Compartment has not been broken.	3. In AFB K Treatments: Verify that the Blue Concentrate Connector is connected to its Safebag Blue Connector. Verify that the frangible pin of the Safebag - K Compartment has been broken.
4. The BiCart Cartridge is not well positioned in its holder.	4. Ensure the BiCart Cartridge is securely placed in its holder.
	Call for Service if the alarm persists.

NOTE

The use of liquid Bicarbonate concentrate is not currently available.

CONDUCTIVITY FROM BICART/BLUE CONCENTRATE TUBE TOO HIGH *465*

Reason	The conductivity of the solution after the mixing of bicarbonate and select bag is above the setpoint fixed by the operator. In AFB K Treatments, the conductivity of the solution after the mixing of the Safebag - K Compartment is above the setpoint fixed by the operator.
Machine Actions	• The dialysis fluid goes into Bypass; • The infusion flow is interrupted; • The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. The Blue Concentrate Connector is not connected to its Safebag Connector or the frangible pin of the Safebag - K Compartment has not been broken.	1. In AFB K Treatments: Verify that the Blue Concentrate Connector is connected to its Safebag Connector. Verify that the frangible pin of the Safebag - K Compartment has been broken.
2. The Green Concentrate Connector is not connected to its Safebag Connector or the frangible pin of the Safebag - AFB Compartment has not been broken.	2. In AFB K Treatments: Verify that the Green Concentrate Connector is connected to its Safebag Connector. Verify that the frangible pin of the Safebag - AFB Compartment has been broken.
3. The BiCart is not well positioned into its holder.	3. Ensure the BiCart is securely placed into its holder.
	Call for Service if the alarm persists.

NOTE

The use of liquid Bicarbonate concentrate is not currently available.

LEAKAGES TEST (A) FAILURE 467

Reason	Failure of the leakages test on the PO, PFS, PD pressure sensors: pressure sensor out of calibration.
Machine Actions	• The phase currently running stops; • All the pumps are stopped.

Possible Cause	Suggested Action
1. The Red and Blue Dialysis Fluid Tubes are not properly connected.	1. Verify that the Red and Blue Dialysis Fluid Tubes are properly connected. Press the Reset button to repeat the leakages tests.
2. Venous and/or Arterial Dialyzer Lines are not properly connected.	2. Verify that the Venous and Arterial Dialyzer Lines are properly connected. Press the Reset button to repeat the leakages tests.
3. Infusion and/or Service Line clamps are open.	3. Verify that the Infusion and Service Line clamps are securely closed. Press the Reset button to repeat the leakages tests.
4. In case the Ultra Cassette is installed and the Ultra Inlet Line is connected to the Ultra port, the Ultra Inlet Line is not properly connected.	4. Verify the Ultra Inlet Line is properly connected to the Ultra port. Press the Reset button to repeat the leakages tests.
5. The Venous and Arterial Patient Lines are not properly connected to the EvaClean ports.	5. Verify that the Venous and Arterial Patient Lines are properly connected. Press the Reset button to repeat the leakages tests.
6. The priming connectors are not properly connected to the patient lines or to the EvaClean ports.	6. Verify that the priming connectors are fully inserted into the patient lines. Verify that the priming connectors are properly connected to the EvaClean ports. Press the Reset button to repeat the leakages tests.
	Call for Service if the alarm persists.

LEAKAGES TEST (B) FAILURE 468

Reason	Failure of the leakages test on the R1 pressure regulator: pressure regulator out of calibration.
Machine Actions	• The phase currently running stops; • All the pumps are stopped.

Possible Cause	Suggested Action
1. The Red and Blue Dialysis Fluid Tubes are not properly connected.	1. Verify that the Red and Blue Dialysis Fluid Tubes are properly connected. Press the Reset button to repeat the leakages tests.
2. Venous and/or Arterial Dialyzer Lines are not properly connected.	2. Verify that the Venous and Arterial Dialyzer Lines are properly connected. Press the Reset button to repeat the leakages tests.
3. Infusion and/or Service Line clamps are open.	3. Verify that the Infusion and Service Line clamps are securely closed. Press the Reset button to repeat the leakages tests.
4. In case the Ultra Cassette is installed and the Ultra Inlet Line is connected to the Ultra port, the Ultra Inlet Line is not properly connected.	4. Verify the Ultra Inlet Line is properly connected to the Ultra port. Press the Reset button to repeat the leakages tests.
5. The Venous and Arterial Patient Lines are not properly connected to the EvaClean ports.	5. Verify that the Venous and Arterial Patient Lines are properly connected. Press the Reset button to repeat the leakages tests.
6. The priming connectors are not properly connected to the patient lines or to the EvaClean ports.	6. Verify that the priming connectors are fully inserted into the patient lines. Verify that the priming connectors are properly connected to the EvaClean ports. Press the Reset button to repeat the leakages tests.
	Call for Service if the alarm persists.

LEAKAGES TEST (C) FAILURE 469

Reason	Failure of the leakages test on the PDrain, PFS or PO pressure sensors: pressure failure.
Machine Actions	• The phase currently running stops; • All the pumps are stopped.

Possible Cause	Suggested Action
1. The Red and Blue Dialysis Fluid Tubes are not properly connected.	1. Verify that the Red and Blue Dialysis Fluid Tubes are properly connected. Press the Reset button to repeat the leakages tests.
2. Venous and/or Arterial Dialyzer Lines are not properly connected.	2. Verify that the Venous and Arterial Dialyzer Lines are properly connected. Press the Reset button to repeat the leakages tests.
3. Infusion and/or Service Line clamps are open.	3. Verify that the Infusion and Service Line clamps are securely closed. Press the Reset button to repeat the leakages tests.
4. In case the Ultra Cassette is installed and the Ultra Inlet Line is connected to the Ultra port, the Ultra Inlet Line is not properly connected.	4. Verify the Ultra Inlet Line is properly connected to the Ultra port. Press the Reset button to repeat the leakages tests.
5. The Venous and Arterial Patient Lines are not properly connected to the EvaClean ports.	5. Verify that the Venous and Arterial Patient Lines are properly connected. Press the Reset button to repeat the leakages tests.
6. The priming connectors are not properly connected to the patient lines or to the EvaClean ports.	6. Verify that the priming connectors are fully inserted into the patient lines. Verify that the priming connectors are properly connected to the EvaClean ports. Press the Reset button to repeat the leakages tests.
	Call for Service if the alarm persists.

LEAKAGES TEST (D) FAILURE 470

Reason	Failure of the leakages test on the PO, PFS and PD pressure sensors: negative calibration of pressure sensor.
Machine Actions	• The phase currently running stops; • All the pumps are stopped.

Possible Cause	Suggested Action
1. The Red and Blue Dialysis Fluid Tubes are not properly connected.	1. Verify that the Red and Blue Dialysis Fluid Tubes are properly connected. Press the Reset button to repeat the leakages tests.
2. Venous and/or Arterial Dialyzer Lines are not properly connected.	2. Verify that the Venous and Arterial Dialyzer Lines are properly connected. Press the Reset button to repeat the leakages tests.
3. Infusion and/or Service Line clamps are open.	3. Verify that the Infusion and Service Line clamps are securely closed. Press the Reset button to repeat the leakages tests.
4. In case the Ultra Cassette is installed and the Ultra Inlet Line is connected to the Ultra port, the Ultra Inlet Line is not properly connected.	4. Verify the Ultra Inlet Line is properly connected to the Ultra port. Press the Reset button to repeat the leakages tests.
5. The Venous and Arterial Patient Lines are not properly connected to the EvaClean ports.	5. Verify that the Venous and Arterial Patient Lines are properly connected. Press the Reset button to repeat the leakages tests.
6. The priming connectors are not properly connected to the patient lines or to the EvaClean ports.	6. Verify that the priming connectors are fully inserted into the patient lines. Verify that the priming connectors are properly connected to the EvaClean ports. Press the Reset button to repeat the leakages tests.
	Call for Service if the alarm persists.

VENOUS PRESSURE NOT DECREASING 472

Reason	In HD-SNSP Treatment, during the venous phase the venous pressure is not decreasing as expected.
Machine Actions	• The Arterial Pump stops.

Possible Cause	**Suggested Action**
1. The venous pressure is not decreasing as expected.	1. Check if the Blood Cassette is properly loaded on the Cassette holder and if it is properly connected to the venous pressure pod. Press the Reset button to remove the alarm.
2. The The Venous/Arterial Patient Lines or Venous/Arterial Dialyzer Lines could be kinked, clamped, restricted or have some leakages.	2. Check the The Venous/Arterial Patient Lines, Venous/Arterial Dialyzer Lines and the Patient's Vascular Access for kinks, clamps or other restrictions. Press the Reset button to remove the alarm.
	Call for Service if the alarm persists.

HEMOSCAN AUTOCALIBRATION FAILURE 473

Reason	Failure of the Hemoscan Autocalibration.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. Problem in the calculated coefficients in the autocalibration process of the Hemoscan.	1. Deactivate the Hemoscan.
	Call for Service if the alarm persists.

PREPARATION NOT COMPLETED - INCORRECT CONDITION ON D1 FLOW RATE 474

Reason	During preparation, the flow of the D1Control Flowmeter is not stable.
Machine Actions	• None.

Possible Cause	Suggested Action
1. Massive air in the hydraulic circuit.	1. Check that all the connectors are inserted in the machine. Then press the Reset button.
2. Probable tubing popping upstream the D1 Control Flowmeter.	2. Switch off the machine.
	Call for Service if the alarm persists.

PREPARATION NOT COMPLETED - INCORRECT CONDITION ON TcA 475

Reason	During preparation, the flow of the TcA Control Sensor is not stable.
Machine Actions	• None.

Possible Cause	Suggested Action
1. Probable drift of the Tp or TcA temperature sensor.	1. Press the Reset button. If the problem persist, switch off the machine and call for service.

PREPARATION NOT COMPLETED - INCORRECT CONDITION ON ACID/AFB DISTRIBUTION *476*

Reason	The dialysis fluid can not reach the condition required at the final stage of the dialysis fluid preparation.
Machine Actions	• None.

Possible Cause	Suggested Action
1. Massive air leak from the Red Concentrate Connector.	1. Check the Red Concentrate Connector. Press the ***RESET*** button.
2. Massive air leak from the Green Concentrate Connector.	2. Check the Green Concentrate Connector. Press the ***RESET*** button.
3. The Green Concentrate Connector is not connected to its Safebag Connector or the frangible pin of the Safebag - AFB Compartment has not been broken.	3. Check that the Green Concentrate Connector is properly connected to its Safebag Connector. Verify that the frangible pin of the Safebag - AFB Compartment has been broken. Press the ***RESET*** button.
	Call for Service if the alarm persists.

PREPARATION NOT COMPLETED - INCORRECT CONDITION ON BICARBONATE/ AFB DISTRIBUTION *477*

Reason	The dialysis fluid can not reach the condition required at the first stage of the dialysis fluid preparation.
Machine Actions	• None.

Possible Cause	Suggested Action
1. Massive air leak from the Blue Concentrate Connector.	1. Check the Blue Concentrate Connector. Press the ***RESET*** button.
2. The Blue Concentrate Connector is not connected to its Safebag Connector or the frangible pin of the Safebag - K Compartment has not been broken.	2. Check that the Blue Concentrate Connector is properly connected to its Safebag Connector. Verify that the frangible pin of the Safebag - K Compartment has been broken. Press the ***RESET*** button.
	Call for Service if the alarm persists.

NOTE

The use of liquid Bicarbonate concentrate is not currently available.

PREPARATION NOT COMPLETED - INCORRECT CONDITION ON SELECT DISTRIBUTION 478

Reason	The dialysate fluid cannot reach the required conductivity after the mixing with the SelectBag.
Machine Actions	• None.

Possible Cause	Suggested Action
1. Massive air leak from the SelectBag container.	1. Check that the SelectBag container is properly installed in its holder. Then press the Reset button.
2. The type of SelectBag that has been set does not match with the installed one.	2. Ensure that the proper SelectBag has been installed and that the proper type of SelectBag has been set. Then press the Reset button.
	Call for Service if the alarm persists.

REMINDER - STILL IN ISOLATED UF 479

Reason	Isolated UF process has not been deactivated more than 2 minutes after the "Isolated UF Time" has expired.
Machine Actions	• The UF Rate is automatically set to zero.

Possible Cause	Suggested Action
1. Isolated UF process has not been deactivated more than 2 minutes after the "Isolated UF Time" has expired or the "Isolated UF Volume" has been reached.	1. Press the ***Confirm*** button of the "Isolated UF Completed (#570)" Information Message; Press the Reset button of the "Reminder - Still in Isolated UF (#479)" alarm.
	Call for Service if the alarm persists.

NOTE

If the Reset button of the "Reminder - Still in Isolated UF (#479)" alarm is pressed without pressing the ***Confirm*** button of the "Isolated UF Completed (#570)" Information Message, the "Reminder - Still in Isolated UF (#479)" will be triggered again after 2 minutes.

INCORRECT FLUID CONDUCTIVITY DETECTED 496

Reason	The measured conductivity is outside the safety range limits.
Machine Actions	• The dialysis fluid goes into Bypass.

Possible Cause	Suggested Action
1. Acid concentrate not correctly supplied.	1. Supply appropriate concentrate to the relevant inlet connector. Wait for stable condition.
2. Massive air leak from the Acid Concentrate Canister.	2. Check and if necessary replace the Acid Concentrate Canister.
3. Acid pick-up tube connector not connected to the Concentrate Canister.	3. Verify the Acid pick-up tube connector is well fitted into the proper Canister.
4. Bicarbonate not correctly supplied.	4. Replace the BiCart according to the BiCart Change procedure.
5. The Bicarbonate powder is not well distributed in the BiCart Cartridge.	5. Tap the bottom of the BiCart Cartridge to evenly distribute the powder. Wait for stable condition.
6. The BiCart Cartridge is in the wrong position.	6. Ensure the BiCart is securely placed into its holder. Repeat the BiCart Change procedure.
	Call for Service if the alarm persists.

LEAKAGES TEST (E) FAILURE 498

Reason	Failure of the leakages test on delivery of dialysis fluid in the hydraulic circuit and control of the patient weight loss.
Machine Actions	• The phase currently running stops; • All the pumps are stopped.

Possible Cause	**Suggested Action**
1. The Red and Blue Dialysis Fluid Tubes are not properly connected.	1. Verify that the Red and Blue Dialysis Fluid Tubes are properly connected. Press the Reset button to repeat the leakages tests.
2. Venous and/or Arterial Dialyzer Lines are not properly connected.	2. Verify that the Venous and Arterial Dialyzer Lines are properly connected. Press the Reset button to repeat the leakages tests.
3. Infusion and/or Service Line clamps are open.	3. Verify that the Infusion and Service Line clamps are securely closed. Press the Reset button to repeat the leakages tests.
4. In case the Ultra Cassette is installed and the Ultra Inlet Line is connected to the Ultra port, the Ultra Inlet Line is not properly connected.	4. Verify the Ultra Inlet Line is properly connected to the Ultra port. Press the Reset button to repeat the leakages tests.
5. The Venous and Arterial Patient Lines are not properly connected to the EvaClean ports.	5. Verify that the Venous and Arterial Patient Lines are properly connected. Press the Reset button to repeat the leakages tests.
6. The priming connectors are not properly connected to the patient lines or to the EvaClean ports.	6. Verify that the priming connectors are fully inserted into the patient lines. Verify that the priming connectors are properly connected to the EvaClean ports. Press the Reset button to repeat the leakages tests.
	Call for Service if the alarm persists.

LEAKAGES TEST (F) FAILURE 499

Reason	Failure of the leakages test on delivery of dialysis fluid in the hydraulic circuit and control of the patient weight loss.
Machine Actions	• The phase currently running stops; • All the pumps are stopped.

Possible Cause	Suggested Action
1. The Red and Blue Dialysis Fluid Tubes are not properly connected.	1. Verify that the Red and Blue Dialysis Fluid Tubes are properly connected. Press the Reset button to repeat the leakages tests.
2. Venous and/or Arterial Dialyzer Lines are not properly connected.	2. Verify that the Venous and Arterial Dialyzer Lines are properly connected. Press the Reset button to repeat the leakages tests.
3. Infusion and/or Service Line clamps are open.	3. Verify that the Infusion and Service Line clamps are securely closed. Press the Reset button to repeat the leakages tests.
4. In case the Ultra Cassette is installed and the Ultra Inlet Line is connected to the Ultra port, the Ultra Inlet Line is not properly connected.	4. Verify the Ultra Inlet Line is properly connected to the Ultra port. Press the Reset button to repeat the leakages tests.
5. The Venous and Arterial Patient Lines are not properly connected to the EvaClean ports.	5. Verify that the Venous and Arterial Patient Lines are properly connected. Press the Reset button to repeat the leakages tests.
6. The priming connectors are not properly connected to the patient lines or to the EvaClean ports.	6. Verify that the priming connectors are fully inserted into the patient lines. Verify that the priming connectors are properly connected to the EvaClean ports. Press the Reset button to repeat the leakages tests.
	Call for Service if the alarm persists.

LEAKAGES TEST (G) FAILURE 500

Reason	Failure of the leakages test on the PDrain, PFS or PO pressure sensors: negative pressure failure.
Machine Actions	• The phase currently running stops; • All the pumps are stopped.

Possible Cause	Suggested Action
1. The Red and Blue Dialysis Fluid Tubes are not properly connected.	1. Verify that the Red and Blue Dialysis Fluid Tubes are properly connected. Press the Reset button to repeat the leakages tests.
2. Venous and/or Arterial Dialyzer Lines are not properly connected.	2. Verify that the Venous and Arterial Dialyzer Lines are properly connected. Press the Reset button to repeat the leakages tests.
3. Infusion and/or Service Line clamps are open.	3. Verify that the Infusion and Service Line clamps are securely closed. Press the Reset button to repeat the leakages tests.
4. In case the Ultra Cassette is installed and the Ultra Inlet Line is connected to the Ultra port, the Ultra Inlet Line is not properly connected.	4. Verify the Ultra Inlet Line is properly connected to the Ultra port. Press the Reset button to repeat the leakages tests.
5. The Venous and Arterial Patient Lines are not properly connected to the EvaClean ports.	5. Verify that the Venous and Arterial Patient Lines are properly connected. Press the Reset button to repeat the leakages tests.
6. The priming connectors are not properly connected to the patient lines or to the EvaClean ports.	6. Verify that the priming connectors are fully inserted into the patient lines. Verify that the priming connectors are properly connected to the EvaClean ports. Press the Reset button to repeat the leakages tests.
	Call for Service if the alarm persists.

REMINDER - WRONG DIP SWITCHES 502

Reason	The Dip Switch configuration detected by the machine is incorrect.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The machine is not properly configured.	1. Press the Reset button. If the alarm persists, switch off the machine and call for service.

WRONG ARTERIAL AND VENOUS TREATMENT LIMITS 503

Reason	This alarm occurs after that the alarm #525 has been triggered and not resolved within the due time (after 30 seconds in HD-DN and HD-DNDP Treatments, 120 seconds in HDF Post and AFB K Treatments or 60 seconds in HD-SN Treatments). The arterial and venous pressure treatment limits are open for a long time interval.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The "Close A/V Limits" button has not been pressed within the due time.	1. Press the Reset button to remove the alarm message.
2. The A/V pressure limits have not been automatically closed within the due time.	2. Carefully check the Patient's Vascular Access and inspect the Arterial and Venous Patient Lines; Press the Reset button to remove the alarm message.
3. The A/V pressures have exceeded the upper/lower intervals.	3. Carefully check the Patient's Vascular Access and inspect the Arterial and Venous Patient Lines; Press the Reset button to remove the alarm message.
	Call for Service if the alarm persists.

LOW DISINFECTANT LEVEL IN LAST CLEAN CART PROCESS 504

Reason	The CleanCart dilution is not properly performed. In case of CleanCart C, the decalcification may not be effective; in case of CleanCart A, the protein removal may not be effective. However, the disinfection performed by means of the heat effect is guaranteed.
Machine Actions	• None

Possible Cause	**Suggested Action**
1. The Clean Cart Holder Arms are in the wrong position or not securely closed.	1. Verify the correct position of the CleanCart Holder Arms in relation to the machine phase. Press the Reset button. Only if necessary, repeat the disinfection program in order to perform decalcification or protein removal.
	Call for Service if the alarm persists.

UF DEVIATION 505

Reason	The machine has detected an incorrect weight loss management.
Machine Actions	• The dialysis fluid goes into Bypass; • The Venous Pump is stopped; • Calibration request.

Possible Cause	**Suggested Action**
1. Error in the Ultrafiltration Mass Balance in the Hydraulic Module, due to incorrect valves control.	1. Press "Stop Treatment"; Perform a rinseback; Disconnect the patient.
2. Error in the Ultrafiltration Mass Balance in the Hydraulic Module, due to incorrect flowmeter reading.	2. Press "Stop Treatment"; Perform a rinseback; Disconnect the patient.
3. Error in the Ultrafiltration Mass Balance in the Hydraulic Module, due to incorrect P2 pump flow or P2 reading.	3. Press "Stop Treatment"; Perform a rinseback; Disconnect the patient.
4. The machine could not perform an alignment of the D2 flowmeter during the treatment and the Ultrafiltration Mass Balance could be incorrect.	4. Press "Stop Treatment"; Perform a rinseback; Disconnect the patient.
	Call for Service if the alarm persists.

FLOWMETER ALIGNMENT FAILED 506

Reason	Error in the Ultrafiltration Mass Balance in the Hydraulic Module.
Machine Actions	• The dialysis fluid goes into Bypass; • The Venous Pump is stopped; • Calibration request.

Possible Cause	Suggested Action
1. Temporary problem.	1. Press the Reset button. If the problem persists disconnect the patient.
	Call for Service if the alarm persists.

BLOOD CASSETTE PRESENCE REQUIRED 507

Reason	The Blood Cassette is not detected by the presence switch.
Machine Actions	• The Arterial and Venous Pumps stop.

Possible Cause	**Suggested Action**
1. The Blood Cassette was not loaded properly by the operator.	1. Load the Blood Cassette. If after the loading of the Blood Cassette the error persists, call for Service.
2. The Blood Cassette does not fit the pressure transducer.	2. Repeat the loading procedure for the Blood cassette.
	Call for Service if the alarm persists.

WRONG DISPOSABLE CONFIGURATION ON ULTRA CASSETTE HOLDER 508

Reason	The Ultra Cassette is not detected by the presence switch.
Machine Actions	• The Arterial and Venous Pumps stop.

Possible Cause	**Suggested Action**
1. The Ultra Cassette was not loaded properly by the operator.	1. Load the Ultra Cassette. If after the loading of the Ultra Cassette the error persists, call for Service.
2. The Ultra Cassette does not fit the pressure transducer.	2. Repeat the loading procedure for the Ultra cassette.
	Call for Service if the alarm persists.

NOTE

This alarm can be triggered also if the following sequence is performed:
1. “Switch off OnLine” special procedure;
2. “Change Circuit” special procedure;
3. Blood Cassette priming;
4. Reset Priming.

In this case, the machine gets stuck and to solve the problem it is necessary to switch the machine OFF and then ON again.

BLOOD LINES CLAMPED 509

Reason	The Blood lines are clamped or kinked.
Machine Actions	• The Arterial Pump is stopped; • The UF Rate is automatically set to zero; • The dialysis fluid goes into bypass.

Possible Cause	**Suggested Action**
1. The Blood lines are clamped or kinked.	1. Verify that the blood lines are not clamped or kinked, then press the Reset button to continue the process.
	Call for Service if the alarm persists.

SMARTSCAN - LOW QB 512

Reason	Smartscan has detected a Blood Flow value (QB) too low during the last 5 minutes, which may affect treatment efficiency.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The QB value, measured during the last 5 minutes, is lower then 50 ml/min.	1. Verify the Blood Flow parameter value and eventually adjust the prescription parameter values. Press the ***CONFIRM*** button.
	Call for Service if the alarm persists.

SMARTSCAN - LOW QD 513

Reason	Smartscan has detected a dialysis flow rate value (QD) lower than the optimal setting for the current Blood Flow during the last 10 minutes.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The dialysis flow rate value (QD) has been lower than the optimal setting for the current Blood Flow during the last 10 minutes.	1. Check and eventually increase the dialysis fluid flow rate value according to the prescription. Press the ***CONFIRM*** button.
	Call for Service if the alarm persists.

SMARTSCAN - HIGH QD 514

Reason	Smartscan has detected a dialysis flow rate value (QD) higher than the optimal setting for the current Blood Flow during the last 10 minutes.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The dialysis flow rate value (QD) has been higher than the optimal setting for the current Blood Flow during the last 10 minutes.	1. Check and eventually decrease the dialysis fluid flow rate value according to the prescription. Press the ***CONFIRM*** button.
	Call for Service if the alarm persists.

SALINE BAG NOT CONNECTED 515

Reason	The machine does not detect saline solution inside the Venous Patient Line during priming phase.
Machine Actions	• The phase currently running stops.

Possible Cause	**Suggested Action**
1. The machine does not detect saline inside the Venous Patient Line.	1. Check the Saline Bag clamp is open, then press the Reset button.
2. The machine does not detect saline inside the Venous Patient Line.	2. Check that the Venous Line Clamp is open, then press the Reset button.
3. The machine does not detect saline inside the Venous Patient Line.	3. Check that the pin of the Saline Bag is correctly broken, then press the Reset button.
	Call for Service if the alarm persists.

VENOUS LINE CLAMPED OR SALINE BAG EMPTY *516*

Reason	The Venous Patient Line is clamped or kinked; or the Saline Bag is either empty or not properly perforated by the spike of the Prime Line; or the Venous Infusion Line is clamped; or the Prime Line is either closed or obstructed.
Machine Actions	• The phase currently running stops.

Possible Cause	**Suggested Action**
1. The Venous Patient Line is clamped or kinked.	1. Check that the Venous Patient Line is not clamped or kinked, then press the Reset button.
2. The Saline Bag is empty.	2. Change the Saline Bag; Press the ***RESET*** button to clear the alarm.
3. The Saline Bag is not properly perforated by the spike of the Prime Line.	3. Ensure that the spike of the Prime Line is deeply inserted in the Saline Bag; Press the ***RESET*** button to clear the alarm.
4. The Venous Infusion line is clamped or the clamp on the Prime Line is closed.	4. Open the clamp on the Venous Infusion line or on the Prime line; Press the ***RESET*** button to clear the alarm.
5. The Prime Line is obstructed.	5. Adjust the Prime Line position to avoid obstructions; Press the ***RESET*** button to clear the alarm.
	Call for Service if the alarm persists.

ARTERIAL LINE CLAMPED 517

Reason	The Arterial Patient Line is clamped or kinked.
Machine Actions	• The phase currently running stops.

Possible Cause	**Suggested Action**
1. The Arterial Patient Line is clamped or kinked.	1. Check that the Arterial Patient Line is not clamped or kinked, then press the Reset button.
	Call for Service if the alarm persists.

LINE NOT CONNECTED IN EVACLEAN PORT OR ACCESS LINE OPEN 518

Reason	Line not connected or not correctly connected to the EvaClean Ports.
Machine Actions	• The phase currently running stops.

Possible Cause	**Suggested Action**
1. Line Not Connected to the EvaClean Ports.	1. Check that the arterial and Venous Patient Lines are correctly connected to the EvaClean port, then press the Reset button.
	Call for Service if the alarm persists.

ARTERIAL INFUSION LINE OPEN 519

Reason	The clamp on the Arterial Infusion Line is open.
Machine Actions	• The phase currently running stops.

Possible Cause	Suggested Action
1. One of the clamps on the Arterial Infusion Lines is open.	1. Check that the clamps on the Arterial Infusion Lines are securely closed, then press the Reset button.
	Call for Service if the alarm persists.

VENOUS PUMP ROTOR ERROR 521

Reason	The Venous Pump is in failure.
Machine Actions	• The Arterial and Venous Pumps stop.

Possible Cause	Suggested Action
1. The Venous Pump is stopped.	1. Press the Reset button to remove the alarm.
	Call for Service if the alarm persists.

PRE-DIALYZER PRESSURE OUT OF RANGE 522

Reason	The system pressure is beyond the upper or lower limit of the sensor.
Machine Actions	• The Arterial and Venous Pumps stop.

Possible Cause	**Suggested Action**
1. A safety condition has not been satisfied when an alarm occurred.	1. Adjust the pressure by using a sterile syringe until it falls in the permitted range. Press the Reset button. If necessary, perform a Cassette Repositiong procedure as described in the "8.10 Cassette Repositioning" section of this Operator's Manual.
	Call for Service if the alarm persists.

HEMOCONCENTRATION RISK 524

Reason	The Q_F/Q_B ratio exceeds the allowed range.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. Q_F/Q_B ratio Out of Range.	1. Press the Reset button. Increase the Arterial Pump speed.
2. Q_F/Q_B ratio Out of Range.	2. Press the Reset button. Decrease the Venous Pump speed.
	Call for Service if the alarm persists.

NOTE

The “Hemoconcentration Risk (#524)” alarm occurs the first time that the Q_F/Q_B ratio exceeds its allowed range.
Once the ***RESET*** button is pressed, it will not occur again (even if the Q_F/Q_B ratio remains out of range) unless the value of any of the following parameters is modified:

- Weight Loss Rate
- Substitution Flow Rate
- Actual Blood Flow Rate.

PRESSURE ALARM LIMITS STILL EXPANDED 525

Reason	• The operator has not pressed the "Close A/V Limits" button to close the pressure alarm limits within the due time (30 seconds in HD-DN and HD-DNDP Treatments; 120 seconds in HDF Post and AFB K Treatments or 60 seconds in HD-SN Treatments). • After a change of the blood flow rate, the machine was not able to automatically close the A/V pressure limits within the due time (30 seconds in HD-DN and HD-DNDP Treatments; 120 seconds in HDF Post and AFB K Treatments or 60 seconds in HD-SN Treatments) because the new A/V pressure values set are not consistent with the change of the blood flow rate, compared to the previous A/V pressure values set.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The "Close A/V Limits" button has not been pressed within the due time.	1. Press the "Close A/V Limits" button: the machine automatically centralizes the alarm window values around the current patient's arterial/venous pressures.
2. The A/V pressure limits have not been automatically closed within the due time.	2. Carefully check the Patient's Vascular Access and inspect the Arterial and Venous Patient Lines; Press the "Close A/V Limits" button: the machine automatically centralizes the alarm window values around the current patient's arterial/venous pressures.
3. The Arterial or Venous Pump has been stopped by the operator or due to an alarm condition and restarted again. The A/V pressures have therefore exceeded the upper/lower intervals.	3. Carefully check the Patient's Vascular Access and inspect the Arterial and Venous Patient Lines; Press the "Close A/V Limits" button: the machine automatically centralizes the alarm window values around the current patient's arterial/venous pressures.
	Call for Service if the alarm persists.

REMINDER - HDF SUBSTITUTION STILL DISABLED 526

Reason	During HDF Post treatment, the “HDF Substitution” button remains Off for more than 5 min.
Machine Actions	• None.

NOTE

This alarm is triggered in the following cases:
- At the beginning of the HDF Post treatment, if the “HDF Substitution” button is not pressed within five minutes. When the alarm is confirmed the alarm disappears even if the “HDF Substitution” button is not activated.
- Each time the “HDF Substitution” button is activated and then deactivated if it remains deactivated for 5 minutes. The alarm disappears when the ***RESET*** button is pressed to confirm the alarm.

Possible Cause	**Suggested Action**
1. HDF Substitution still disabled.	1. Press the ***RESET*** button to confirm the alarm; Press the “HDF Substitution” button to restart the infusion of substitution fluid.
	Call for Service if the alarm persists.

TMP UPPER LIMIT 527

Reason	During On Line treatment phases, the TMP value exceeds the permitted upper limit.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The TMP value is beyond the permitted upper limit.	1. Stop the UF and wait the TMP to drop. Check the pre dialyzer pressure to detect possible hemoconcentration. Check the "Treatment Time", "UF Volume", "UF Rate", "Online Substitution Rate" and "Blood Flow" paramete values. Press the "UF" and the "HDF Substitution" buttons.
	Call for Service if the alarm persists.

DIASCAN: AUTOCALIBRATION FAILURE 528

Reason	The DIASCAN autocalibration has failed: the autocalibration coefficient is out of the allowed range.
Machine Actions	• None.

Possible Cause	Suggested Action
1. There is a flowmeter/conductivity instability or the machine is not able to reach the set value.	1. Disable the Diascan deselecting the “Diascan” button.
	Call for Service if the alarm persists.

DIASCAN: MEASUREMENT FAILURE 529

Reason	The Diascan has not been able to complete a measurement.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The Diascan has not been able to complete a measurement.	1. To proceed with the Diascan measurement, press the Reset button.
2. The Diascan has not been able to complete a measurement.	2. To stop the Diascan measurement, disable the Diascan deselecting the "Diascan" button.
	Call for Service if the alarm persists.

SMARTSCAN - DIASCAN: LOW CLEARANCE 530

Reason	Smartscan has detected a Clearence value lower than 55% of the Blood Flow value or lower than the Clearence Low Limit set value.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The Dialysis Fluid Flow rate is low.	1. Consider increasing the Dialysis Fluid Flow if this operation is not in disagreement with the patient prescription. Press the ***CONFIRM*** button.
2. The Dialyzer has not been properly primed or it is clotting.	2. Verify that the Dialyzer has been properly primed. If the Dialyzer is clotting, determine reason for clotting. Press the ***CONFIRM*** button. If necessary, perform a Change Circuit procedure as described in the "Chapter 8: Special Procedures" of this Operator's Manual.
3. Problem with patient's access or needle placement. The level of recirculation is increased.	3. Check the patient's access for correct needle placement. Consider decreasing the Blood Flow if this operation is not in disagreement with the patient prescription. Press the ***CONFIRM*** button.
4. Low Real Blood Flow value resulting from kinking of a line in the blood circuit.	4. Carefully inspect for kinking of the line. Press the ***CONFIRM*** button.
5. Co-current connection of the Dialysis Fluid.	5. Verify that the Dialysis Fluid tube connectors are in the proper posistion. Press the ***CONFIRM*** button.
	Call for Service if the alarm persists.

SMARTSCAN - DIASCAN: LOW KT/V 531

Reason	Smartscan has detected a Forecast Kt/V value lower than 0,8 or lower than the Target Kt/V set value.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The current Clearance value is lower than 55% of the Blood Flow value.	1. Verify that the current Clearance value is adequate to the treatment, according to the dialyzer used and to the patient's vascular access. Press the ***CONFIRM*** button.
2. An incorrect Distribution Formula has been set.	2. Verify that the "Distribution Volume" parameter value is properly set for the patient. Press the ***CONFIRM*** button.
3. The Treatment Time set value is lower than the prescription set value.	3. Increase the "Treatment Time" parameter value if this operation is not in disagreement with the patient prescription. Press the ***CONFIRM*** button.
	Call for Service if the alarm persists.

TIMEOUT ON DATA RECEPTION 532

Reason	Temporary problem with the network.
Machine Actions	• None.

Possible Cause	Suggested Action
1. Temporary problem with the network.	1. Reload the prescription, then press the Reset button. If the alarm persists, switch off the machine.
	Call for Service if the alarm persists.

CHEMICAL PROCESS NOT PROPERLY PERFORMED: DISINFECTANT TANK EMPTY 533

Reason	Chemical Disinfection process not correctly performed because the disinfectant tank is empty. Repeat the Chemical Disinfection process.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The disinfectant tank is empty.	1. Check the level of the disinfectant tank: • I*f the disinfectant tank is empty*, press the Reset button and, at the and of the chemical disinfection procedure, replace the disinfectant tank with a new one. Repeat the disinfection procedure. • *If the disinfectant tank is full,* press the Reset button and call for service.
	Call for Service if the alarm persists.

⚠WARNING

When this alarm is triggered, the Chemical Disinfection process has not been correctly performed because the disinfectant tank is empty.
Repeat the Chemical Disinfection process using a tank containing enough disinfectant solution.

DISINFECTION NOT PROPERLY PERFORMED 534

Reason	The programmed disinfection process set by the operator has not been correctly performed because it was interrupted before the process completion or the disinfectant tank got empty during the disinfection process.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. Alarm 533 has been triggered and confirmed during a disinfection process.	1. Press the Reset button and start the process. If the alarm persists, call for service.
	Call for Service if the alarm persists.

DIASCAN MEASUREMENT ERROR 536

Reason	The Diascan has not been able to complete a measurement.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The Diascan has not been able to complete a measurement.	1. Press the Reset button and wait for the next Diascan measurement.
	Call for Service if the alarm persists.

WATER LEAKAGE 539

Reason	A leakage was detected by the Water Leakage sensor in the hydraulic circuit.
Machine Actions	• The dialysis fluid goes into Bypass.

Possible Cause	Suggested Action
1. A water leakage was detected in the hydraulic circuit.	1. If possible, start with the Rinseback procedure, otherwise switch off the machine.
	Call for Service if the alarm persists.

DIALYSATE PRESSURE LOW 540

Reason	The pressure in the Ultrafilter is lower than the permitted limit.
Machine Actions	• All the pumps are stopped; • The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. The Ultrafilter is clogged.	1. If in treatment, the dialysis process in progress can be continued by decreasing the dialysis fluid flow rate and pressing the Reset button to restart the current operation of the machine. When the treatment is complete, replace the Ultrafilter according to the procedure.
2. The Dialysis fluid connectors are not properly positioned.	2. Verify that the Dialysis fluid connectors are properly positioned to the dialyzer or to the machine, depending upon the phase of the machine at that time. Press the Reset button to restart the current operation of the machine.
	Call for Service if the alarm persists.

PRE FILTER PRESSURE HIGH 541

Reason	The Pre Filter Pressure is higher than the allowed limit.
Machine Actions	• The UF Rate is automatically set to zero; • The Arterial Pump is stopped; • The Venous Line Clamp is closed.

Possible Cause	**Suggested Action**
1. The Venous Patient Line is clamped or kinked.	1. Check that the Venous Patient Line is not clamped or kinked. Carefully check the Venous Patient Line connections. Press the Reset button.
	Call for Service if the alarm persists.

INCORRECT CASSETTE LINE CONNECTIONS OR CLAMPS STATUS 542

Reason	The Ultra/Blood Cassette Line connections or the Ultra/Blood Cassette Line Clamps status is incorrect.
Machine Actions	• All the pumps are stopped.

Possible Cause	**Suggested Action**
1. The Venous/Arterial Patient Lines have not been inserted in the EvaClean Ports.	1. Check that the Venous/Arterial Patient Lines are inserted in the EvaClean Ports. Then press the Reset button to remove the alarm.
2. The Venous/Arterial Dialyzer Line is not securely connected to the dialyzer.	2. Check that the Venous/Arterial Dialyzer Lines are firmly connected to the dialyzer. Then press the Reset button to remove the alarm.
3. The Ultra Inlet Line is not securely connected to the Ultra Port.	3. Check that the Ultra Inlet Line is firmly connected to the Ultra Port. Then press the Reset button to remove the alarm.
4. A line on the Ultra/Blood Cassette (Ultra Service Line, Rinseback Service Line or Venous/Arterial Infusion Lines) may be unclamped.	4. Check that the clamps on the Ultra Service Line, Rinseback Service Line and Venous/Arterial Infusion Lines are securely closed. Then press the Reset button to remove the alarm.
	Call for Service if the alarm persists.

ULTRA SCAN ABORTED 543

Reason	The Ultra Scan has been aborted: the TMP Set and the Upper Limit have been consequently updated.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The Ultra Scan has been aborted: the TMP set and the Upper Limit have been consequently up-dated.	1. Press the ***CONFIRM*** button to remove the alarm.
	Call for Service if the alarm persists.

ULTRA SCAN COMPLETED 544

Reason	The Ultra Scan has been completed: the TMP Set and the Upper Limit have been consequently updated.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The Ultra Scan has been completed: the TMP set and the Upper Limit have been consequently up-dated.	1. Press the ***CONFIRM*** button to remove the alarm.
	Call for Service if the alarm persists.

NEW ULTRA SCAN IS SUGGESTED 545

Reason	Notification: the Ultra Scan has been completed.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The Ultra Scan has been completed.	1. Perform a new scan and press the ***CONFIRM*** button to remove the alarm.
	Call for Service if the alarm persists.

ON-LINE FLUID VOLUME EXCEEDED MAXIMUM LIMIT 546

Reason	Notification: in On-line Rinseback, the maximum allowed On-Line Fluid Volume has been reached. This alarm is triggered if after the "Maximum Substitution Volume Reached (#553)" alarm the On-line Rinseback is continued and more than 1 liter of On-line Fluid is given to the patient.
Machine Actions	• The Arterial and Venous Pumps stop.

Possible Cause	Suggested Action
1. In On-line Rinseback, the maximum allowed On-Line Fluid Volume has been reached.	1. If it is necessary to continue the rinseback, proceed as follows: Switch to HD-DN Treatment, performing the "Switch off OnLine" Special Procedure; Perform the Rinseback procedure as described in the "4.5 Rinseback mode" section of this Operator's Manual. If it is not necessary to continue the rinseback, disconnect the patient.

PATIENT VENOUS LINE INCORRECT POSITION 547

Reason	The position of the Venous Patient Line is incorrect. Probably during priming the Venous Patient Line has not been inserted under the Venous Line Clamp.
Machine Actions	• The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. The Venous Patient Line has not been inserted under the Venous Line Clamp.	1. Carefully check that the Venous Patient Line is under the Venous Line Clamp. Then press the Reset button and continue the process.
	Call for Service if the alarm persists.

LEAKAGES H 548

Reason	Failure of the leakages test on the PDrain, PFS or PO: negative pressure failure on the internal bypass circuit.
Machine Actions	• The phase currently running stops; • All the pumps are stopped.

Possible Cause	**Suggested Action**
1. The Red and Blue Dialysis Fluid Tubes are not properly connected.	1. Verify that the Red and Blue Dialysis Fluid Tubes are properly connected. Press the Reset button to repeat the current leakages test.
2. The Venous and Arterial Patient Lines are not properly connected to the EvaClean port.	2. Verify that the Venous and Arterial Patient Lines are properly connected. Press the Reset button to repeat the current leakage test.
	Call for Service if the alarm persists.

LEAKAGES I 549

Reason	Failure of the leakages test on delivery of dialysis fluid in the hydraulic circuit and control of the patient weight loss.
Machine Actions	• The phase currently running stops; • All the pumps are stopped.

Possible Cause	Suggested Action
1. The Red and Blue Dialysis Fluid Tubes are not properly connected.	1. Verify that the Red and Blue Dialysis Fluid Tubes are properly connected. Press the Reset button to repeat the current leakages test.
2. The Venous and Arterial Patient Lines are not properly connected to the EvaClean port.	2. Verify that the Venous and Arterial Patient Lines are properly connected. Press the Reset button to repeat the current leakage test.
	Call for Service if the alarm persists.

POWER FAILURE: CHECK POWER SUPPLY 550

Reason	A Power Failure occurred during HDF Post treatment.
Machine Actions	• The heater is turned OFF.

Possible Cause	**Suggested Action**
1. A Power Failure occurred during HDF Post treatment or during an On-line Rinseback.	1. Check the power supply. In case no recovery is possible: • Press the Reset button to remove the alarm. • Switch to HD-DN treatment; • Perform a rinseback procedure; • Switch the machine OFF.
	Call for Service if the alarm persists.

80% MAXIMUM SUBSTITUTION VOLUME REACHED 551

Reason	The maximum substitution volume has been reached (allowed by the U2000 ultrafilter): the actual value reaches 80% of the maximum limit (50L).
Machine Actions	• None.

Possible Cause	Suggested Action
1. The maximum substitution volume has been reached: the actual value reaches 80% of the maximum limit (50L).	1. Press the ***CONFIRM*** button to remove the alarm.
	Call for Service if the alarm persists.

90% MAXIMUM SUBSTITUTION VOLUME REACHED 552

Reason	The maximum substitution volume has been reached (allowed by the U2000 ultrafilter): the actual value reaches 90% of the maximum limit (50L).
Machine Actions	• None.

Possible Cause	Suggested Action
1. The maximum substitution volume has been reached: the actual value reaches 90% of the maximum limit (50L).	1. Press the ***CONFIRM*** button to remove the alarm.
	Call for Service if the alarm persists.

MAXIMUM SUBSTITUTION VOLUME REACHED 553

Reason	Notification: the machine has stopped the substitution process in order to save the remaining one litre for performing on-line restitution.
Machine Actions	• The “HDF” button is locked.

Possible Cause	**Suggested Action**
1. The machine has stopped the substitution process in order to save the remaining one liter for performing on-line restitution.	1. Press the Reset button to remove the alarm.
	Call for Service if the alarm persists.

HEMOCONTROL ERROR 554

Reason	A failure on the Hemocontrol has been verified.
Machine Actions	The dialysis fluid goes into Bypass.

Possible Cause	Suggested Action
1. A failure on the Hemocontrol has been verified.	1. Deactivate the Hemocontrol, then press the Reset button.
	Call for Service if the alarm persists.

SCALE STABILITY NOT REACHED *555*

Reason	The AFB K scale can not reach the required stability condition after the “Change Hospasol Bag” special procedure has been performed.
Machine Actions	• None

Possible Cause	Suggested Action
1. The Hospasol infusion bags are not properly installed on the AFB K scale.	1. Verify the proper installation of the Hospasol infusion bags on the AFB K scale. Verify that Hospasol infusion bags do not move when hung on the AFB K scale. Press the ***RESET*** button.
2. An Hospasol infusion bag has been hung or removed from the AFB K scale after the “Change Hospasol Bag” special procedure has been performed.	2. Check for Hospasol infusion bags hung or removed. Press the ***RESET*** button.
	Call for Service if the alarm persists.

ULTRA INLET TUBE CLAMPED 556

Reason	The Ultra Inlet Line is clamped when it should not be.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The Ultra Inlet Line is clamped.	1. Press the Reset button. Check the Ultra Inlet Line and remove any clamps.
	Call for Service if the alarm persists.

CASSETTE REPOSITIONING FAILED 557

Reason	In HDF Post treatment, the Ultra Cassette Repositioning Procedure has failed.
Machine Actions	• None.

Possible Cause	Suggested Action
1. In HDF Post treatment, the Ultra Cassette Repositioning Procedure has failed.	1. Press the Reset button to remove the alarm and to restart the Arterial Pump.
	Call for Service if the alarm persists.

REMINDER: 558

Reason	Notification: the set time has elapsed for the note entered on the keyboard window.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The set time has elapsed for the note entered on the keyboard window.	1. Press the ***CONFIRM*** button to remove the alarm.
	Call for Service if the alarm persists.

PREPARATION COMPLETED 559

Reason	Notification: the preparation process has been completed.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The preparation process has been completed.	1. Press the ***CONFIRM*** button to remove the alarm.
	Call for Service if the alarm persists.

PRIMING COMPLETED 560

Reason	Notification: the Priming sub-process has been completed.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The Priming sub-process has been completed.	1. Press the ***CONFIRM*** button to remove the alarm.
	Call for Service if the alarm persists.

AUTOSCHEDULED DISINFECTION/RINSE PROGRAM NOT PERFORMED 562

Reason	The autoscheduled disinfection/rinse program has not been performed.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The autoscheduled disinfection/rinse program has not been performed.	1. Press the Reset button to remove the alarm message. Make sure that a Disinfection/Rinse program has been performed before starting a new treatment.
2. Following a Bacteriostatic Chemical disinfection, the scheduled Disinfection/ Rinse program has not been performed because the machine has automatically performed a Rinse process instead of the program scheduled.	2. Press the Reset button to remove the alarm.
	Call for Service if the alarm persists.

NOTE

This alarm will be triggered each time the machine is switched on during the day in which the scheduled process has not been performed (although the alarm message has been confirmed). The alarm will be definitely removed the day after the one the process has been scheduled, only if the alarm message has been confirmed, otherwise it will continue to be triggered also in the subsequent days.

CDF2 ULTRAFILTER LOWER SWITCH ERROR 563

Reason	The CDF2 second ultrafilter lower connector microswitch (SWLOWUF2) is indicating an error condition.
Machine Actions	• In ADR: The phase currently running stops. • In Dialysis fluid preparation: The machine will not continue until the microprocessor receives the correct signal from the switch; • In DIALYSIS: The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. The CDF2 ultrafilter lower connector microswitch is indicating an error condition.	1. Check the correct position of the ultrafilter.
	Call for Service if the alarm persists.

ULTRAFILTER COVER ERROR 564

Reason	The ultrafilter cover is not placed correctly.
Machine Actions	• In ADR: The phase currently running stops. • In Dialysis fluid preparation: The machine will not continue until the microprocessor receives the correct signal from the switch; • In DIALYSIS: The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. The ultrafilter cover is not placed correctly.	1. Check the correct position of the ultrafilter cover.
	Call for Service if the alarm persists.

HYDRAULIC CENTRALISE ACETATE CONNECTOR TYPE ONE *565*

Reason	The Hydraulic Centralise Acetate Connector Type One is not placed correctly.
Machine Actions	In ADR: • The phase currently running stops.

Possible Cause	Suggested Action
The Hydraulic Centralise Acetate Connector Type One is not placed correctly.	1. Check the correct position of the Hydraulic Centralise Acetate Connector Type One.
	Call for Service if the alarm persists.

HYDRAULIC CENTRALISE ACETATE CONNECTOR TYPE TWO *566*

Reason	The Hydraulic Centralise Acetate Connector Type Two is not placed correctly.
Machine Actions	In ADR: • The phase currently running stops.

Possible Cause	Suggested Action
1. The Hydraulic Centralise Acetate Connector Type Two is not placed correctly.	1. Check the correct position of the Hydraulic Centralise Acetate Connector Type Two.
	Call for Service if the alarm persists.

NOTE

If the Artis Dialysis System is in AFB K configuration, ***do not*** select the “Two Concentrate Connector” option in the CCK Configuration selectpad, since this concentrate connector is not available on the AFB K Concentrate Connector Panel.
If the “Two Concentrate Connector” option is selected, the “Hydraulic Centralise Acetate Connector Type Two (#566)” alarm will be triggered and the rinse process will not be performed.

TMP SET TOO LOW 567

Reason	During dialysis, the TMP set is lower than the actual TMP measured.
Machine Actions	• If the machine is performing UC scan, the procedure fails.

Possible Cause	**Suggested Action**
1. The TMP set is lower than the actual TMP measured.	1. Increase the TMP set value.
2. The TMP set is too low when the Venous Pump set is lower than 10ml/ min for 5 seconds in the TMP therapy.	2. Increase the TMP set value.
	Call for Service if the alarm persists.

WRONG CHECK RED CONCENTRATE CONNECTOR 568

Reason	The position of the Red Concentrate Connector is wrong.
Machine Actions	In DIALYSIS: • The dialysis fluid goes into Bypass; • The infusion flow is interrupted; • The Venous Pump is stopped. In ADR: • The phase currently running stops.

Possible Cause	**Suggested Action**
1. The Red Concentrate Connector is not placed correctly.	1. Check the correct position of the Red Concentrate Connector.
	Call for Service if the alarm persists.

WRONG CHECK BLUE CONCENTRATE CONNECTOR 569

Reason	The position of the Blue Concentrate Connector is wrong.
Machine Actions	In ADR: • The phase currently running stops.

Possible Cause	Suggested Action
1. The Blue Concentrate Connector is not placed correctly.	1. Check the correct position of the Blue Concentrate Connector.
	Call for Service if the alarm persists.

NOTE

The use of liquid Bicarbonate concentrate is not currently available.

ISOLATED UF COMPLETED 570

Reason	The machine notifies that the Isolated UF process has been completed.
Machine Actions	• The machine remains in Isolated UF with deactivated “UF” button.

Possible Cause	**Suggested Action**
1. The Isolated UF process has been completed.	1. Press the ***CONFIRM*** button to proceed with the next phase.
	Call for Service if the alarm persists.

NOTE

DO NOT perform any special procedure or press the “Stop Treatment” button before having pressed the ***CONFIRM*** button to reset the “Isolated UF Completed (#570)” Information Message.

If a special procedure is performed or the “Stop Treatment” button is pressed before confirming the “Isolated UF Completed (#570)” Information Message, when the treatment is resumed, the machine might not be able to retrieve the proper prescription parameters. In this case, perform a Fast Recovery procedure to reestablish the proper prescription parameters.

TREATMENT CAN NOT BEGIN UNTIL THE ULTRAFILTERS HAVE BEEN REPLACED 571

Reason	The machine notifies that the ultrafilters have to be replaced, otherwise the treatment cannot be performed.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The ultrafilters have to be replaced.	1. Replace the ultrafilters with new ones (Refer to the "8.25 Ultrafilter Change Procedure" section of this Operator's Manual).
	Call for Service if the alarm persists.

LOW HEPARINIZATION 573

Reason	The volume of the Heparin infused is lower than the expected value.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The volume of the Heparin infused is lower than the expected value.	1. Press the Reset button to remove the alarm.
	Call for Service if the alarm persists.

WRONG SINGLE NEEDLE CLAMPS POSITION 574

Reason	The Protective Subsystem has detected the Arterial and Venous line clamps open at the same time.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The Protective Subsystem has detected the Arterial and Venous line clamps open at the same time.	1. Press the Reset button to remove the alarm.
	Call for Service if the alarm persists.

PREPARATION CAN NOT PROCEED UNTIL DRESSING IS COMPLETE 576

Reason	The preparation can not proceed until the machine dressing procedure has been completed.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The machine dressing procedure is not been completed.	1. Complete the machine dressing procedure, then press the ***CONFIRM*** button on the *Confirm* window.
	Call for Service if the alarm persists.

SMARTSCAN – LOW REAL QB 577

Reason	The actual Blood Flow rate value is less than 90% of the Arterial Pump speed set value for more than three minutes.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The actual Blood Flow rate value is less than 90% of the Arterial Pump speed set value for more than three minutes.	1. Verify the set Arterial Pump speed and the arterial pressure. Decrease the arterial pressure or decrease the Arterial Pump speed. Press the ***CONFIRM*** button to remove the alarm.
	Call for Service if the alarm persists.

WRONG DISINFECTANT USED IN CHEMICAL DISINF. 578

Reason	A wrong conductivity has been detected during a Chemical disinfection process with peracetic/low peracetic. The machine assumes that a disinfection with hypochlorite has been performed and decreases of one the “Remaining Hypchlrt Disinfs” parameter value.
Machine Actions	• None

Possible Cause	**Suggested Action**
1. A wrong conductivity has been detected during a Chemical disinfection program with peracetic/low peracetic.	1. Press the Reset button to remove the alarm and let the disinfection program end.
	Call for Service if the alarm persists.

ON LINE BLOOD RESTITUTION: WRONG ULTRA CASSETTE CONFIGURATION 579

Reason	During the On-line Rinseback the Ultra or Blood cassette is not properly configured (Incorrect Ultra or Blood Cassette line connections or clamps status).
Machine Actions	• The dialysis fluid goes into Bypass; • The Venous Pump stops.

Possible Cause	**Suggested Action**
1. Incorrect Ultra or Blood Cassette line connections.	1. The Arterial patient line shall be connected to the Rinseback Service Line and the Clamp on the Rinseback Service Line shall be opened. Press the Reset button.
2. Incorrect clamps status.	2. The clamps of the Arterial infusion lines shall be closed. Press the Reset button.
3. The Rinseback Service Line is kinked.	3. Ensure that the Rinseback Service Line is not kinked. Press the ***Reset*** button.
	Call for Service if the alarm persists.

ON LINE PRIME - INCORRECT ULTRA OR BLOOD CASSETTE CONFIGURATION 580

Reason	During the On Line Priming the Ultra or Blood cassette is not properly configured (Incorrect Ultra or Blood Cassette line connections or clamps status).
Machine Actions	• The phase currently running stops.

Possible Cause	Suggested Action
1. During the On Line Priming the Ultra or Blood cassette is not properly configured.	1. Check that: • the Ultra Service Line clamp is closed and the cap is totally screwed; • the Rinseback Service Line clamp is closed and the cap is totally screwed; • the Venous and Arterial Infusion Line clamps are closed and the caps are totally screwed; • the Arterial and Venous Dialyzer Lines are properly connected to the dialyzer; • the Arterial and Venous Patient Lines are unclamped and properly connected to the EvaClean ports with the connector totally screwed; • the dialyzer, Ultra and Blood cassette are not re-used. Press the Reset button.
	Call for Service if the alarm persists.

ISOLATED UF TARGET LOSS WILL NOT BE ACHIEVED 581

Reason	The remaining Isolated UF time is not sufficient in order to be reached the programmed Isolated UF target loss.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The Isolated UF target loss will not be achieved.	1. Press the "Isolated UF" action button. 2. Reduce the Isolated UF parameter values: "Time" and/or "Volume".
	Call for Service if the alarm persists.

RESIDUAL CHECK REMINDER 582

Reason	Notification: A test for residues of disinfectant has to be performed just before connecting the patient to the machine or before attaching the concentrates to the machine.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. After chemical disinfection with peracetic and just before connecting the patient to the machine, a test for residuals of disinfectant on the dialysis fluid has to be performed.	1. Perform a test for residuals of disinfectant on the dialysis fluid (Refer to the “8.24 Residual Test after Chemical Disinfection” section of this Operator’s Manual).
2. After chemical disinfection with hypochlorite and before attaching the concentrates to the machine, a test for residuals of disinfectant on the dialysis fluid has to be performed.	2. Perform a test for residuals of disinfectant on the dialysis fluid (Refer to the “8.24 Residual Test after Chemical Disinfection” section of this Operator’s Manual).
	Call for Service if the alarm persists.

AIR DETECTOR CLEANING REQUIRED 583

Reason	The Air Detector does not work with the maximum sensitivity because the Venous Patient line or the Air Detector is dirty.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The Venous Patient Line is dirty or the Air Detector is defective.	1. Open the Sensor Bar door; 2. Remove the Venous Patient line from the air detector/blood sensor: an "Air in Venous Line (#4)" alarm will be triggered; 3. Carefully check that there is not air in the Venous Patient line; 4. Clean the Venous Patient line and the air detector/blood sensor; 5. Route again the Venous Patient line through the air detector/blood sensor; 6. Close the Sensor Bar door; 7. Solve the "Air in Venous Line (#4)" alarm as described in the related troubleshooting of this chapter; 8. Press the Reset button to clear the "Air detector cleaning required (#583)" alarm; 9. If the "Air detector cleaning required (#583)" alarm persists, stop the treatment and perform a Manual Rinseback procedure.
	Call for Service if the alarm persists.

AIR DETECTOR INSPECTION REQUIRED 584

Reason	The Air Detector does not work with the maximum sensitivity because the Venous Patient line or the Air Detector is dirty.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The Venous Patient Line is dirty or the Air Detector is defective.	1. Open the Sensor Bar door; 2. Remove the Venous Patient line from the air detector/blood sensor: an “Air in venous line (#4)” alarm will be triggered; 3. Carefully check that there is not air in the Venous Patient line; 4. Clean the Venous Patient line and the air detector/blood sensor; 5. Route again the Venous Patient line through the air detector/blood sensor; 6. Close the Sensor Bar door; 7. Press the Reset button to clear the “Air detector inspection required (#584)” alarm; 8. Solve the “Air in Venous Line (#4)” alarm as described in the related troubleshooting of this chapter; 9. If the “Air detector inspection required (#584)” alarm persists, stop the treatment and perform a Manual Rinseback procedure.
	Call for Service if the alarm persists.

SALINE BAG EMPTY 585

Reason	The Saline Bag is either empty or not properly perforated by the spike of the Prime Line; or the Venous Infusion Line is clamped; or the Prime Line is either closed or obstructed.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The Saline Bag is empty.	1. Change the Saline Bag; Press the Reset button to clear the alarm.
2. The Saline Bag is not properly perforated by the spike of the Prime Line.	2. Ensure that the spike of the Prime Line is deeply inserted in the Saline Bag; Press the Reset button to clear the alarm.
3. The Venous Infusion line is clamped or the clamp on the Prime Line is closed.	3. Open the clamp on the Venous Infusion line or on the Prime line; Press the Reset button to clear the alarm.
4. The Prime Line is obstructed.	4. Adjust the Prime Line position to avoid obstructions; Press the Reset button to clear the alarm.
	Call for Service if the alarm persists.

ARTERIAL PUMP SEGMENT NOT CORRECTLY LOADED 586

Reason	The Arterial Pump Segment has not been properly loaded in the pump rotor or the clamp on the Arterial Infusion line is open.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The Arterial Pump Segment has not been properly loaded in the pump rotor.	1. Press the Reset button to clear the alarm; 2. Press the “Unload Cassette” button; 3. Press the ***CONFIRM*** button to start the unloading procedure; 4. Unload the cassette; 5. Perform again the loading cassette procedure.
2. The clamp on the Arterial Infusion line is open.	1. Close the clamp on the Arterial Infusion line; 2. Press the Reset button to clear the alarm.
	Call for Service if the alarm persists.

VENOUS INFUSION LINE OPEN 587	
Reason	The clamp on the Venous Infusion Line is open.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The clamp on the Venous Infusion Line is open.	1. Close the clamp on the Venous Infusion Line; 2. Press the ***CONFIRM*** button to clear the alarm.
	Call for Service if the alarm persists.

CHEMICAL DISINFECTION NOT PROPERLY PERFORMED: WRONG DISINFECTANT USED 588

Reason	The chemical disinfection program set by the operator has not been properly performed because a wrong disinfectant solution was used.
Machine Actions	• None.

Possible Cause	**Suggested Action**
1. The chemical disinfection program set by the operator has not been properly performed because a wrong disinfectant solution was used.	1. Press the Reset button. Perform the Residual Test after chemical disinfection procedure according to the wrong disinfectant used, as described in the “8.24 Residual Test after Chemical Disinfection” section of this Operator’s Manual.
	Call for Service if the alarm persists.

POST FILTER PRESSURE HIGH 589

Reason	The Post-dialyzer Pressure is higher than 450 mmHg.
Machine Actions	• The Arterial and Venous Pumps are stopped. • The UF Rate is automatically set to zero. • The automatic Venous Line Clamp is closed.

Possible Cause	**Suggested Action**
1. The Venous Patient Line is kinked, clamped or restricted.	1. Carefully check the Venous Patient Lines and the patient's vascular access for kinks, clamps or other restrictions. Press the Reset button.
2. The diaphragm of the SN Cassette does not well stick to the Post-dialyzer pressure transducer.	2. Press the Reset button. Perform a SN Cassette Repositioning Procedure (Refer to the "Chapter 8: Special Procedures", in this Operator's Manual).
	Call for Service if the alarm persists.

SELECT CONCENTRATE ERROR 590

Reason	PSe pump speed is different from expected value for more then 5%
Machine Actions	• Venous Pump is stopped; • The dialysis fluid goes into Bypass.

Possible Cause	Suggested Action
1. The PSe pump speed is different from expected value.	1. If during treatment, switch the machine off, wait a few seconds and switch it on again. Perform a Fast Recovery procedure as described in the “8.5 Fast Recovery” section of this Operator’s Manual. If the alarm persists, manually perform blood restitution to the patient, and call for Service.
2. Inappropriate solution in the Acid Concentrate Canister.	2. Verify that appropriate concentrate has been used for the selected treatment type.

NOTE

The Venous Pump stops only if performing HDF Post treatment.

SN: PRESSURE NOT INCREASING 592

Reason	During a Single Needle treatment the SN pressure is not increasing as expected.
Machine Actions	• The Arterial Pump stops.

Possible Cause	**Suggested Action**
1. The SN pressure is not increasing as expected.	1. Check that the SN Cassette is properly loaded on the Cassette holder and that the pressure pods are properly connected to the pressure transducers. Press the Reset button to restart the Arterial Pump and remove the alarm.
2. The Venous/Arterial Patient Lines or Venous/Arterial Dialyzer Lines are kinked, clamped, restricted or have some leakeages.	2. Check the Venous/Arterial Patient Lines, Venous/Arterial Dialyzer Lines and the patient's vascular access for kinks, clamps or other restrictions. Press the Reset button to restart the Arterial Pump and remove the alarm.
3. The Blood Cassette and/or the SN cassette have some leakeages	3. Check the line connections to the cassettes and ensure that the related clamps are closed. Press the Reset button to restart the Arterial Pump and remove the alarm.
	Call for Service if the alarm persists.

SN: PRESSURE NOT DECREASING 593

Reason	During a Single Needle treatment the SN pressure is not decreasing as expected.
Machine Actions	• The Venous Pump stops.

Possible Cause	Suggested Action
1. The pressure pods of the SN cassette are not properly connected to the related pressure transducers.	1. Check that the SN Cassette is properly loaded on the Cassette holder and that the pressure pods are properly connected to the pressure transducers. Press the Reset button to restart the Venous Pump and remove the alarm.
2. The Venous Patient Line is kinked, clamped or restricted.	2. Check the Venous Patient Line and the patient's vascular access for kinks, clamps or other restrictions. Press the Reset button to restart the Venous Pump and remove the alarm.
	Call for Service if the alarm persists.

SN SERVICE LINE(S) ON SN CASSETTE OPEN *594*

Reason	During the priming process in Single Needle treatment, one of the SN Service lines is not clamped.
Machine Actions	• The Priming process stops.

Possible Cause	Suggested Action
1. One of the clamps of the SN Service Lines is open.	1. Check that the SN Service Lines are securely clamped. Press the Reset button.
	Call for Service if the alarm persists.

MAXIMUM BLOOD VOLUME REACHED 595

Reason	During the Arterial Phase of a Single Needle treatment, the maximum blood volume is reached before passing from the arterial to the venous phase.
Machine Actions	• The Arterial Pump stops.

Possible Cause	**Suggested Action**
1. The set Stroke Volume has been changed directly from maximum to minimum value or from minimum to maximum value.	1. Reduce the Stroke Volume parameter value. Press Reset button to restart the Arterial Pump and remove the alarm. Gradually increase the Stroke Volume and the Blood Flow parameter values.
2. The pressures are not properly measured in the Post-Dialyzer Expansion Chambers.	2. Press Reset button. Perform the “SN Cassette Repositioning” special procedure as described in the "Chapter 8: Special Procedures” of this Operator’s Manual.
	Call for Service if the alarm persists.

NOTE

If this alarm occurs in HD-SN Treatment and with the Isolated UF function activated, press the Reset button until the proper SN Pressure Max. limit is reached.

SELECTCART CARTRIDGE EMPTY 596

Reason	The SelectCart Cartridge is either empty or not properly installed.
Machine Actions	• The SelectBag Pump (PSel) is stopped; • The dialysis fluid goes into Bypass.

Possible Cause	Suggested Action
1. The SelectCart Cartridge is empty.	1. Press the "Special Procedures" button. Select the "Change SelectCart" option to change the SelectCart Cartridge. Perform the "Change SelectCart" special procedure as described in the "8.9 Change SelectCart Cartridge" section of this Operator's Manual.
2. The SelectCart Cartridge is not properly installed.	2. Check that the SelectCart Cartridge is properly installed on its holder. Press the "Special Procedures" button. Select the "Change SelectCart" option to change the SelectCart Cartridge. Perform the "Change SelectCart" special procedure as described in the "8.9 Change SelectCart Cartridge" section of this Operator's Manual.
	Call for Service if the alarm persists.

END OF HOSPASOL BAG *597*

Reason	The protective system of the machine has detected that the Hospasol infusion bag is empty.
Machine Actions	• The dialysis fluid goes into Bypass; • The infusion flow is interrupted; • The Venous Pump is stopped.

Possible Cause	Suggested Action
1. The Hospasol infusion bag is empty	1. Press the ***RESET*** button. Press the “Special Procedures” button. Select the “Change Hospasol Bag” option. Perform the “Change Hospasol Bag” special procedure as described in the “3.5 Change Hospasol Bag” section of the Artis AFB K Treatment Operator’s Manual.
	Call for Service if the alarm persists.

BICART CHANGE FAILED 598

Reason	The Change BiCart Cartridge special procedure has not been successfully accomplished.
Machine Actions	• The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. The Change BiCart Cartridge special procedure has not been successfully accomplished.	1. Press the Reset button. Perform again the "Change BiCart Cartridge" special procedure as described in the "8.6 Change BiCart Cartridge" section of this Operator's Manual.
	Call for Service if the alarm persists.

SELECTCART CHANGE FAILED 599

Reason	The Change SelectCart Cartridge special procedure has not been successfully accomplished.
Machine Actions	• The dialysis fluid goes into Bypass.

Possible Cause	Suggested Action
1. The Change SelectCart Cartridge special procedure has not been successfully accomplished.	1. Press the Reset button. Perform again the “Change SelectCart Cartridge” special procedure as described in the “8.9 Change SelectCart Cartridge” section of this Operator’s Manual.
	Call for Service if the alarm persists.

SELECTBAG NOT CONNECTED 600

Reason	The SelectBag is not properly installed or the SelectBag has been re-used.
Machine Actions	• The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. The SelectBag is not properly installed.	1. Verify that the SelectBag is properly installed on its holder. Press the Reset button.
2. The SelectBag is full of air.	2. Verify the SelectBag: • If air is present in the SelectBag, press the Reset button and then change the SelectBag performing the "Change SelectBag" special procedure as described in the "8.8 Change SelectBag container" section of this Operator's Manual.
	Call for Service if the alarm persists.

BICARBONATE/SELECT CONDUCTIVITY SET TOO LOW 602

Reason	The conductivity of the dialysis fluid solution after mixing of the bicarbonate and the SelectBag concentrates is below the expected value.
Machine Actions	• The Venous Pump is stopped; • The dialysis fluid goes into Bypass.

Possible Cause	Suggested Action
1. The BiCart Cartridge is almost empty.	1. Check the BiCart Cartridge. If necessary, perform the Change BiCart procedure as described in the “8.6 Change BiCart Cartridge” section of this Operator’s Manual.
2. Massive air leak from the BiCart Cartridge; the BiCart Cartridge is not properly positioned in its holder.	2. Ensure the BiCart Cartridge is securely placed in its holder.
3. The SelectBag container currently used is not the proper one.	3. Replace the wrong SelectBag container with the proper one. Perform a Change SelectBag procedure as described in “8.8 Change SelectBag container” section of this Operator’s Manual.
4. The SelectBag is not properly connected.	4. Check that the SelectBag is properly installed on its holder. Press the “Special Procedures” button. Select the “Change SelectBag” option to change the SelectBag container. Perform the “Change SelectBag” special procedure as described in the “8.8 Change SelectBag container” section of this Operator’s Manual.
	Call for Service if the alarm persists.

NOTE

The Venous Pump stops only if performing HDF Post treatment.

BICARBONATE/SELECT CONDUCTIVITY SET TOO HIGH 603

Reason	The conductivity of the dialysis fluid solution after mixing of the bicarbonate and the SelectBag concentrates is above the expected value.
Machine Actions	• The dialysis fluid goes into Bypass.

Possible Cause	**Suggested Action**
1. The BiCart Cartridge is almost empty.	1. Check the BiCart Cartridge. If necessary, perform the Change BiCart procedure as described in the "8.6 Change BiCart Cartridge" section of this Operator's Manual.
2. Massive air leak from the BiCart Cartridge; the BiCart Cartridge is not properly positioned in its holder.	2. Ensure the BiCart Cartridge is securely placed in its holder.
3. The SelectBag container currently used is not the proper one.	3. Replace the wrong SelectBag container with the proper one. Perform a Change SelectBag procedure as described in "8.8 Change SelectBag container" section of this Operator's Manual.
	Call for Service if the alarm persists.

NOTE

The Venous Pump stops only if performing HDF Post treatment.

SMARTSCAN - HIGH SODIUM SETTING 606

Reason	The "Sodium" parameter set value has been higher than 155 mmol/L for more than 90 minutes, consecutively.
Machine Actions	• None.

Possible Cause	Suggested Action
1. The "Sodium" parameter has been set to a value higher than 155 mmol/L for more than 90 minutes, consecutively.	1. Check that the current setting is in agreement with the patient prescription or set the "Sodium" parameter to a value equal to or lower than 155 mmol/L. Press the ***CONFIRM*** button.
	Call for Service if the alarm persists.

SCALE MEASUREMENT ERROR *609*

Reason	The protective system has detected a scale weight measurement error.
Machine Actions	• The dialysis fluid goes into Bypass; • The infusion flow is interrupted; • The Venous Pump is stopped

Possible Cause	Suggested Action
1. A scale measurement error has been detected.	1. Disconnect the patient. Call for Service.
	Call for Service if the alarm persists.

SAFEBAG - K COMPARTMENT EMPTY *610*

Reason	The K Compartement of the Safebag KV concentrate solution is either empty or not properly connected to the Blue Concentrate Connector. As a result, the PB concentrate pump can not reach the set conductivity value.
Machine Actions	• The dialysis fluid goes into Bypass; • The infusion flow is interrupted • The PB concentrate pump is stopped.

Possible Cause	Suggested Action
1. The K Compartment of the Safebag KV concentrate solution is empty.	1. Press the “Special Procedures” button. Select the “Change Safebag” option. Perform the “Change Safebag” special procedure as described in the “3.4 Change Safebag” section of the Artis AFB K Treatment Operator’s Manual.
2. The Blue Concentrate Connector is not connected to its Safebag Connector or the frangible pin of the Safebag - K Compartment has not been broken.	2. In AFB K Treatment: Verify that the Blue Concentrate Connector is properly connected to its Safebag Connector. Verify that the frangible pin of the Safebag - K Compartment has been broken.
3. The Bicarbonate Pump speed is incorrect.	3. If the machine does not stabilize, call for Service.
	Call for Service if the alarm persists.

SAFEBAG - AFB COMPARTMENT EMPTY *611*

Reason	The AFB Compartement of the Safebag KV concentrate container is either empty or not properly connected to the green concentrate connector. As a result the PA concentrate pump can not reach the set conductivity value.
Machine Actions	• The dialysis fluid goes into Bypass; • The infusion flow is interrupted; • The PA concentrate pump is stopped.

Possible Cause	Suggested Action
1. The AFB Compartment of the Safebag KV concentrate container is empty.	1. Press the "Special Procedures" button. Select the "Change Safebag" option. Perform the "Change Safebag" special procedure as described in the "3.4 Change Safebag" section of the Artis AFB K Treatment Operator's Manual.
2. The Green Concentrate Connector is not connected to its Safebag Connector or the frangible pin of the Safebag - AFB Compartment has not been broken.	2. Check that the Green Concentrate Connector is properly connected to its Safebag Connector. Verify that the frangible pin of the Safebag - AFB Compartment has been broken.
	Call for Service if the alarm persists.

INFUSION SETTINGS STILL OUTSIDE PRESCRIPTION *612*

Reason	The Bicarbonatemia Surveillance System (Caddy) has detected that either no action has been taken by the user within 60 seconds from the occurrence of the “Infusion Settings Outside Prescription (#102)” Information Message or, following a change to the Blood Flow rate or to the Infusion Flow rate, the Blood Flow rate or the Infusion Flow rate results to be outside the final bicarbonatemia target acceptable for the patient, but the machine can suggest an Infusion Flow rate.
Machine Actions	• The dialysis fluid goes into Bypass; • The infusion flow is interrupted; • The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. No action has been taken by the user within 60 seconds from the occurrence of the “Infusion Settings Outside Prescription (#102)” Information Message.	1. To keep the current infusion prescription: Press the ***RESET*** button on the Alarm/ Information Message Area. Press the ***CONFIRM*** button on the *Confirm* window.
2. The Blood Flow rate is changed and results to be outside the patient final bicarbonatemia acceptable for the patient, but the machine can suggest an Infusion Flow rate.	2. To keep the current infusion prescription: Press the ***RESET*** button on the Alarm/ Information Message Area. Press the ***CONFIRM*** button on the *Confirm* window.
3. The Infusion Flow rate is changed and results to be outside the patient final bicarbonatemia acceptable for the patient, but the machine can suggest an Infusion Flow rate.	3. To keep the current infusion prescription: Press the ***RESET*** button on the Alarm/ Information Message Area. Press the ***CONFIRM*** button on the *Confirm* window.
	Call for Service if the alarm persists.

INFUSION SETTINGS OUT OF RANGE *613*

Reason	The Bicarbonatemia Surveillance System (Caddy) has detected a discrepancy between the Blood Flow rate, Infusion Flow rate and UF Rate such that the system can not suggest an Infusion Flow rate.
Machine Actions	• The dialysis fluid goes into Bypass; • The infusion flow is interrupted; • The Venous Pump is stopped.

Possible Cause	Suggested Action
1. The Blood Flow rate is changed and the system can not suggest an Infusion Flow rate.	1. To keep the current infusion prescription: Decrease or Increase the Blood Flow rate in opposite direction to the Blood Flow rate change just done. Solve the "Infusion Settings Outside Prescription (#102) Information Message or the "Infusion Settings Still Outside Prescription (#612)" Alarm Message. To set a new infusion prescription: Press the "Infusion Settings" button to enter the *Infusion Settings* sub-screen. Modify the Blood Flow rate. Press the "Confirm Prescription" button.
2. The Infusion Flow rate is changed and the system can not suggest an Infusion Flow rate.	2. To set a new infusion prescription: Press the "Infusion Settings" button to enter the *Infusion Settings* sub-screen. Modify the Infusion Flow rate. Press the "Confirm Prescription" button.

Possible Cause (Continued)	Suggested Action (Continued)
3. The UF Rate is changed and an inconsistency is detected between the infusion prescription parameter values.	3. To keep the current infusion prescription: Decrease the Blood Flow value until the Information Message (#102) or the Alarm Message (#612) will be triggered. Solve the “Infusion Settings Outside Prescription (#102) Information Message or the “Infusion Settings Still Outside Prescription (#612)” Alarm Message. To set a new infusion prescription: Press the “Infusion Settings” button to enter the *Infusion Settings* sub-screen. Reduce the Infusion Flow rate. Press the “Confirm Prescription” button.
	Call for Service if the alarm persists.

INFUSION CASSETTE NOT CONNECTED TO BLOOD CASSETTE *614*

Reason	The AFB K Connection Line of the Infusion Cassette is not connected to the Service Line of the Venous Dialyzer Line.
Machine Actions	• The priming phase is stopped.

Possible Cause	Suggested Action
1. The AFB K Connection Line of the Infusion Cassette is not connected to Service Line of the Venous Dialyzer Line.	1. Verify the connection between the Infusion and the Blood Cassette. If necessary, connect the AFB K Connection Line of the Infusion Cassette to the Service Line of the Blood Cassette. Press the ***RESET*** button.
2. The clamp on the Service Line of the Venous Dialyzer Line is closed.	2. Verify that the clamp on the Service Line of the Venous Dialyzer Line is open. If necessary, open the clamp on the Service Line of the Venous Dialyzer Line. Press the ***RESET*** button.
	Call for service if the alarm persists.

HOSPASOL INFUSION LINE CLAMPED *615*

Reason	The Hospasol Infusion Line of Infusion Cassette is clamped.
Machine Actions	• The dialysis fluid goes into Bypass; • The infusion flow is interrupted; • The Venous Pump is stopped.

Possible Cause	Suggested Action
1. The clamps on the Hospasol Infusion Lines connected to Hospasol Bags are closed.	1. Verify that the clamps on the Hospasol Infusion Lines are open; if necessary open them. Press the ***RESET*** button.
2. The Hospasol Infusion Line is obstructed or kinked.	2. Carefully check the Hospasol Infusion Line for kinks. Check that the Hospasol Infusion Line is properly inserted in its guides on the machine. If necessary, insert the Hospasol Infusion Line in its guides. Press the ***RESET*** button.
	Call for service if the alarm persists.

DEGASSING LINE ON INFUSION CASSETTE CLAMPED *616*

Reason	The Infusion Cassette is not filled with the infusion fluid.
Machine Actions	• The dialysis fluid goes into Bypass; • The infusion flow is interrupted; • The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. The clamp on the Degassing Line of the Infusion Cassette is closed.	1. Verify that the clamp on the Degassing Line of the Infusion Cassette is open. If necessary, open the clamp on the Degassing Line. Press the ***RESET*** button.
	Call for service if the alarm persists.

EVACLEAN DOORS INCORRECT POSITION *617*

Reason	The Left Blue EvaClean door position is wrong; or the Right Red EvaClean door position is wrong; or both the EvaClean doors are in a wrong position.
Machine Actions	The machine waits until the EvaClean Door is closed, in the meantime: In DIALYSIS: • All hydraulic module pumps are stopped; • The dialysis fluid goes into Bypass. In ADR: • The phase currently running stops; • All the pumps are stopped.

Possible Cause	Suggested Action
1. The Left Blue EvaClean door is open when it should be closed.	1. Verify that the door is closed. Press the ***RESET*** button.
2. The Left Blue EvaClean door is closed when it should be opened.	2. Verify that the door is opened. Press the ***RESET*** button.
3. The Right Red EvaClean door is open when it should be closed.	3. Verify that the door is closed. Press the ***RESET*** button.
4. The Right Red EvaClean door is closed when it should be open.	4. Verify that the door is opened. Press the ***RESET*** button.
5. Both the EvaClean doors are open when they should be closed.	5. Verify that the doors are closed. Press the ***RESET*** button.
6. Both the EvaClean doors are closed when they should be open.	6. Verify that the doors are open. Press the ***RESET*** button.
	Call for Service if the alarm persists.

SCALE ACQUISITION FAILURE *618*

Reason	The reading acquired from the AFB K scale has an invalid value.
Machine Actions	• The dialysis fluid goes into Bypass; • The infusion flow is interrupted; • The Venous Pump is stopped.

Possible Cause	Suggested Action
1. The operator, while handling with the Hospasol infusion bags, bumps the AFB K scale pushing it up.	1. Pay attention to not bump and push up the AFB K scale, while handling with the Hospasol infusion bags. Press the ***RESET*** button.
2. The operator, while moving the machine, bumps the AFB K scale pushing it up.	2. Pay attention to not bump and push up the AFB K scale, while moving the machine. Press the ***RESET*** button.
3. A failure in the AFB K scale has occurred.	3. Press the ***RESET*** button. If the alarm persists, call for Service.
	Call for Service if the alarm persists.

END OF HOSPASOL BAG *620*

Reason	The control system has detected that the Hospasol infusion bag is empty.
Machine Actions	• The dialysis fluid goes into Bypass; • The infusion flow is interrupted; • The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. The Hospasol infusion bag is empty	1. Press the ***RESET*** button. Press the “Special Procedures” button. Select the “Change Hospasol Bag” option. Perform the “Change Hospasol Bag” special procedure as described in the “3.5 Change Hospasol Bag” section of the Artis AFB K Treatment Operator’s Manual.
2. The AFB K Connection Line is clamped	2. Unclamp the AFB K Connection Line. Press the ***RESET*** button.
	Call for Service if the alarm persists.

END OF HOSPASOL BAG OR HOSPASOL INFUSION LINE CLAMPED *621*

Reason	The Hospasol infusion bag is empty or the clamp on the Hospasol Infusion Line, connected to the Hospasol infusion bag, is closed or the Hospasol Infusion Line is kinked.
Machine Actions	• The dialysis fluid goes into Bypass; • The infusion flow is interrupted; • The Venous Pump is stopped.

Possible Cause	Suggested Action
1. The Hospasol infusion bag is empty.	1. Press the ***RESET*** button. Press the "Special Procedures" button. Select the "Change Hospasol Bag" option. Perform the "Change Hospasol Bag" special procedure as described in the "3.5 Change Hospasol Bag" section of the Artis AFB K Treatment Operator's Manual.
2. The clamp on the Hospasol Infusion Line is closed.	2. Verify that the clamp on Hospasol Infusion Line, connected to the Hospasol Infusion bag, is open. If necessary, open the clamp on the Hospasol Infusion Line. Press the ***RESET*** button.
3. The Hospasol Infusion Line is kinked.	3. Carefully check the Hospasol Infusion Line for kinks. Check that the Hospasol Infusion Line is properly inserted in its guides on the machine. If necessary, insert the Hospasol Infusion Line in its guides. Press the ***RESET*** button.
	Call for Service if the alarm persists.

INFUSION CHAMBER PRESSURE TOO HIGH *622*

Reason	The pressure inside the Infusion Cassette is too high.
Machine Actions	• The dialysis fluid goes into Bypass; • The infusion flow is interrupted; • The Venous Pump is stopped.

Possible Cause	Suggested Action
1. The Hospasol infusion bag is squeezed.	1. Pay attention while hanging the Hospasol infusion bags on the AFB K scale. Handle the Hospasol infusion bags without squeezing them. Press the ***RESET*** button.
	Call for service if the alarm persists.

K PROFILE ERROR *623*

Reason	The protective system has detected a discrepancy in the actual potassium profile curve.
Machine Actions	• The dialysis fluid goes into Bypass; • The infusion flow is interrupted; • The Venous Pump is stopped.

Possible Cause	Suggested Action
1. The protection module has detected a discrepancy in the actual potassium profile curve.	1. Press the ***RESET*** button. Press the "K Profile Mode" button on the *K Settings* sub-screen to deactivate the K Profile mode. Refer to the "2.14.2 Deactivate K Profile" section of the Artis AFB K Treatment Operator's Manual. Continue the treatment in K Constant mode.
	Call for Service if the alarm persists.

NO HOSPASOL BAG ON SCALE *624*

Reason	During the machine dressing procedure that precedes the priming procedure, the connection of the Hospasol Infusion Lines with the Hospasol infusion bags has been confirmed, but no Hospasol infusion bag has been hung on the AFB K scale.
Machine Actions	• None

Possible Cause	Suggested Action
1. The Hospasol Infusion bags have not been hung on the AFB K scale.	1. Press the ***RESET*** button. Hang the Hospasol infusion bags on the scale as described in the “2.4.2 Install Hospasol Infusion Bags” paragraph of the Artis AFB K Treatment Operator’s Manual.
2. The Hospasol infusion bag is empty.	2. Press the ***RESET*** button. Replace the empty Hospasol infusion bag and hang a new one as described in the “2.4.2 Install Hospasol Infusion Bags” paragraph of the Artis AFB K Treatment Operator’s Manual.
	Call for Service if the alarm persists.

HOSPASOL LOW WEIGHT LIMIT REACHED *625*

Reason	The weight of the Hospasol infusion bags hung on the scale is below the minimum value set in the Service 2 menu.
Machine Actions	• None

Possible Cause	Suggested Action
1. The Hospasol infusion bag is almost empty.	1. Press the ***CONFIRM*** button. Press the "Special Procedures" button. Select the "Change Hospasol Bag" option. Perform the "Change Hospasol Bag" special procedure as described in the "3.5 Change Hospasol Bag" section of the Artis AFB K Treatment Operator's Manual.
	Call for Service if the alarm persists.

INFUSION VOLUME ERROR *626*

Reason	A difference greater than 200 grams has been detected between the calculated Infusion Volume, based on the Infusion Flow rate set, and the infusion fluid effectively delivered, measured by the scale.
Machine Actions	• The dialysis fluid goes into Bypass; • The infusion flow is interrupted; • The Venous Pump is stopped.

Possible Cause	**Suggested Action**
1. The “Scale Measurement Error (#161) and/or the “Infusion Flow Rate Error (#99) alarm have been triggered several times.	1. Press the “Stop Treatment” button to stop the treatment. Perfom the rinseback and the patient disconnection procedures as described in the “2.16 Rinseback Mode” and “2.17 Patient Disconnection” sections of the Artis AFB K Treatment Operator’s Manual.
2. The Hospasol infusion bag has been hung or removed several times without performing the “Change Hospasol Bag” special procedure.	2. Press the “Stop Treatment” button to stop the treatment. Perfom the rinseback and the patient disconnection procedures as described in the “2.16 Rinseback Mode” and “2.17 Patient Disconnection” sections of the Artis AFB K Treatment Operator’s Manual.
	Call for Service if the alarm persists.

SALINE SOLUTION HAS ENTERED IN THE HOSPASOL BAG *628*

Reason	Some saline solution has entered in the Hospasol Bag and the Bicarbonate concentration could be changed.
Machine Actions	• None

Possible Cause	Suggested Action
1. The pump segment of the Infusion Cassette has not been loaded correctly.	**DURING PREPARATION** 1. Press the "Special Procedure" action button in the *Overview* screen and select the "Unload Cassette" procedure. Unload and discard the Infusion and Blood Cassettes before the end of the preparation phase. Discard those Hospasol bags whose Infusion Line was unclamped. Install a new Hospasol bag. Install new Blood and Infusion Cassettes. **DURING PRIMING** 1. Switch the machine OFF. Switch it ON again. Press the "Special Procedure" action button in the *Overview* screen and select the "Unload Cassette" procedure. Unload and discard the Infusion and Blood Cassettes. Discard those Hospasol bags whose Infusion Line was unclamped. Install a new Hospasol bag. Install new Blood and Infusion Cassettes.
	Call for Service if the alarm persists.

DATA CORRECTNESS CHECK FAILURE 630

Reason	A hardware malfunction caused the Data Correctness check to fail.
Machine Actions	• None

Possible Cause	Suggested Action
1. A hardware malfunction caused the Data Correctness check to fail.	1. Press the ***RESET*** button Because of this malfunction, the machine is not able to notify when ultrafilters have expired. Check the installation date of the ultrafilters and replace them if necessary. Call for service to repair the hardware malfunction. While the malfunction is present, the machine will perform all the Function Checks each time a new treatment is started, thus increasing the preparation time.

NOTE

Each time the Data Correctness Check fails, the Artis Dialysis System performs the complete sequence of Function Checks and the Diascan Auto-Calibration.

UNRELIABLE POST-DIALYZER PRESSURE 631

Reason	The Post-dialyzer pressure is out of allowed limits due to an improper position of the SN Cassette diaphragm or to the breakdown of the pressure sensor.
Machine Actions	• The Arterial and Venous Pumps stop • The Venous Line Clamp is closed • The dialysis fluid goes into Bypass

Possible Cause	Suggested Action
1. The Post-dialyzer pressure is out of allowed limits due to an improper position of the SN Cassette diaphragm or to the breakdown of the pressure sensor.	1. Adjust the Post-dialyzer pressure by using a sterile syringe until it reaches about 100 mmHg. Press the ***RESET*** button to clear the alarm and to restart the Arterial and Venous Pumps. Perform a "SN Cassette Repositioning" procedure as described in the "8.12 SN Cassette Repositioning" section of this Operator's Manual.
	If the alarm persists, switch the machine off and call for service.

VENOUS FLOW TOO HIGH 632

Reason	During HD-DNDP, the Venous Flow is greater than allowed limits.
Machine Actions	• The Arterial and Venous Pumps stop • The Venous Line Clamp is closed • The dialysis fluid goes into Bypass

Possible Cause	**Suggested Action**
1. During HD-DNDP, the Venous Flow is greater than allowed limits.	1. Press the Blood Flow Decrease key, to decrease the blood flow. Press the ***RESET*** button to clear the alarm and to restart the Arterial and Venous Pumps.
	If the alarm persists, switch the mahine off and call for service.

VENOUS FLOW OVER ALLOWED RANGE 633

Reason	The Post-dialyzer pressure is out of allowed limits due to an improper position of the SN cassette diaphragm or to the breakdown of the pressure sensor.
Machine Actions	• The Arterial and Venous Pumps stop • The Venous Line Clamp is closed • The dialysis fluid goes into Bypass

Possible Cause	**Suggested Action**
1. The Post-dialyzer pressure is out of allowed limits due to an improper position of the SN cassette diaphragm or to the breakdown of the pressure sensor.	1. Press the ***RESET*** button to clear the alarm and to restart the Arterial and Venous Pumps Perform a "SN Cassette Repositioning" procedure as described in the "8.12 SN Cassette Repositioning" section of this Operator's Manual.
	If the alarm persists, switch the machine off and call for service.

VENOUS FLOW TOO LOW: SN CASSETTE INSPECTION REQUIRED 634

Reason	During HD-DNDP, venous flow is below allowed range due to possible leakages in the SN cassette.
Machine Actions	• The Arterial and Venous Pumps stop • The Venous Line Clamp is closed • The dialysis fluid goes into Bypass

Possible Cause	**Suggested Action**
1. During HD-DNDP, venous flow is below allowed range due to possible leakages in the SN cassette.	1. Ensure that the SN Service Lines are clamped. Ensure that the Dialyzer lines are firmly connected to the dialyzer. Press the ***RESET*** button to clear the alarm and to restart the Arterial and Venous Pumps.
2. During HD-DNDP, in the blood side of the dialyzer clotting or clogging were formed.	2. If the alarm persists, check for clotting or clogging in the blood side of the dialyzer. Press the ***RESET*** button to clear the alarm and to restart the Arterial and Venous Pumps. Perform a Change Circuit procedure, if necessary.
	Call for Service if the alarm persists.

HEMOCONTROL: REFILLING RATE BETTER THAN EXPECTED 635

Reason	SmartScan detected a BV% reduction lower than expected, leading to higher Accumulated UF Volume.
Machine Actions	• None.

Possible Causes	Suggested Action
1. SmartScan detected a BV% reduction lower than expected, leading to higher Accumulated UF Volume.	1. Press the ***CONFIRM*** button to remove the Information Message. If this message reoccurs, consider one of the following options. Carefully evaluate the patient's clinical condition before adjusting the prescription parameters. Pay particular attention to the patient's blood pressure. ***OPTION 1*** STABLE BP, NO HYPOTENSION AND DRY WEIGHT TO BE MAINTAINED: Consider increasing Final BV. ***OPTION 2*** STABLE BP AND NO HYPOTENSION: Consider increasing UF Volume. ***OPTION 3*** AFFECTED BP AND/OR HYPOTENSION: Consider increasing Final BV, or Stand by (if infusion is required), or deactivate HemoControl.

NOTE

It takes up to 30 minutes to see the full effect of a Hemocontrol prescription adjustment.

HEMOCONTROL: UNUSUAL STATUS 636

Reason	HemoControl: Unusual state.
Machine Actions	• None.

Possible Causes	Suggested Action
1. HemoControl: Unusual state.	1. Press the ***CONFIRM*** button to remove the Information Message. Carefully evaluate the patient's clinical condition before adjusting the prescription parameters. Pay particular attention to the patient's blood pressure. ***OPTION 1*** HEMOCONTROL PRESCRIPTION RECENTLY MODIFIED: Wait (max 15 minutes). This could be a temporary situation following the adjustment of a setting ***OPTION 2*** HEMOCONTROL PRESCRIPTION NOT MODIFIED: If this state persists for more than 15 minutes, deactivate Hemocontrol.
	Call for Service if the alarm persists.

HEMOCONTROL: REFILLING RATE LOWER THAN EXPECTED 637

Reason	SmartScan detected a BV% reduction higher than expected, leading to a lower Accumulated UF Volume.
Machine Actions	• None.

Possible Causes	Suggested Action
1. SmartScan detected a BV% reduction higher than expected, leading to a lower Accumulated UF Volume.	1. Press the ***CONFIRM*** button to remove the Information Message. If this message reoccurs, consider one of the following options. Carefully evaluate the patient's clinical condition before adjusting the prescription parameters. Pay particular attention to the patient's blood pressure. ***OPTION 1*** STABLE BP, NO HYPOTENSION AND DRY WEIGHT TO BE MAINTAINED: Consider decreasing Final BV. ***OPTION 2*** AFFECTED BP AND/OR HYPOTENSION: Consider decreasing UF Volume, or Stand by (if infusion is required), or deactivate HemoControl.

NOTE

It takes up to 30 minutes to see the full effect of a Hemocontrol prescription adjustment.

HEMOCONTROL: UF VOLUME MAY NOT BE REACHED 638

Reason	SmartScan detected that the UF Volume may not be reached.
Machine Actions	• None.

Possible Causes	Suggested Action
1. SmartScan detected that the UF Volume may not be reached.	1. Press the ***CONFIRM*** button to remove the Information Message. Carefully evaluate the patient's clinical condition before adjusting the prescription parameters. Pay particular attention to the patient's blood pressure. Consider increasing Max Initial UF.

NOTE

It takes up to 30 minutes to see the full effect of a Hemocontrol prescription adjustment.

ARTERIAL CHAMBER: LEVEL ADJUSTMENT REQUIRED 642	
Reason	During the treatment, the blood level in the Arterial Chamber is too low or the pressure readings are inaccurate. The "Arterial Chamber: Level Adjustment Required (#642)" alarm will not be triggered in the following conditions: • Qb < 150 ml/min; • Arterial Pressure > -50mmHg; • Stroke Volume < 25 ml; • during HD-SNSP Treatments.
Machine Actions	• Arterial and Venous Pumps stop

Possible Cause	**Suggested Action**
1. During the treatment, the blood level in the Arterial Chamber is too low.	1. Ensure that the Infusion lines are clamped. Ensure that the saline bags or bottles connected to the cassette are not empty. Perform the following tasks: - Ensure that the Arterial Infusion Line is clamped. - Remove the cap from Arterial Infusion Line. - Take a sterile syringe. Ensure that its plunger is completely down. - Attach the syringe to the Arterial Infusion Line. - Press the **RESET** button to start the Arterial and Venous Pumps. - Decrease the Arterial Pump speed. - Unclamp the Arterial Infusion Line. If in HD-SN, unclamp the Arterial Infusion Line when the automatic arterial clamp opens. - Aspirate to increase the level. DO NOT INJECT AIR. - Adjust the level above the frosted line on the chamber. - Clamp the Arterial Infusion line. - Remove the syringe and replace the cap. - Adjust the Arterial Pump speed.

Possible Cause (Continued)	Suggested Action (Continued)
2. The blood level in the Arterial Chamber is correctly at the frosted line. The “Arterial Chamber: Level Adjustment Required (#642)” alarm is caused by inaccurate readings of the Arterial pressure due to an improper greasing of the Pressure Transducer.	2. Press the ***RESET*** button. *(See NOTE1)* To continue the treatment, perform a “Cassette Repositioning” special procedure, as described in the related section of the "Chapter 8: Special Procedures” in this Operator’s Manual. At the end of the treatment, grease the Pressure Transducers as described in the “13.13 Cassette Panel O-Rings Inspection and Greasing” section of the "Chapter 13: Disinfection/Rinse”.
	Call for Service if the alarm persists.

NOTE 1

If the ***RESET*** button is pressed without performing the level adjustment procedure, the “Arterial Chamber: Level Adjustment Required (#642)” alarm will no longer be triggered during the treatment.
If both the “Low Arterial Chamber Level (#643)” and the “Arterial Chamber: Level Adjustment Required (#642)” alarms are reset without performing the level adjustment procedure, at the end of the treatment the “Pressure Transducer: Greasing Required (#644)” alarm will be triggered.

LOW ARTERIAL CHAMBER LEVEL 643	
Reason	During the treatment, the blood level in the Arterial Chamber is lower than expected or the pressure readings are inaccurate. The "Low Arterial Chamber Level (#643)" alarm will not be triggered in the following conditions: • Qb < 150 ml/min; • Arterial Pressure > -50mmHg; • during HD-SNSP Treatments.
Machine Actions	• None

Possible Cause	**Suggested Action**
1. During the treatment, the blood level in the Arterial Chamber is lower than expected.	1. Ensure that the Infusion lines are clamped. Ensure that the saline bags or bottles connected to the cassette are not empty. Perform the following tasks: - Ensure that the Arterial Infusion Line is clamped. - Remove the cap from Arterial Infusion Line. - Take a sterile syringe. Ensure that its plunger is completely down. - Attach the syringe to the Arterial Infusion Line. - Press the **RESET** button to clear the alarm. - Decrease the Arterial Pump speed. - Unclamp the Arterial Infusion Line. If in HD-SN, unclamp the Arterial Infusion Line when the automatic arterial clamp opens. - Aspirate to increase the level. DO NOT INJECT AIR. - Adjust the level above the frosted line on the chamber. - Clamp the Arterial Infusion line. - Remove the syringe and replace the cap. - Adjust the Arterial Pump speed.

Possible Cause (Continued)	Suggested Action (Continued)
2. The blood level in the Arterial Chamber is correctly at the frosted line. The “Low Arterial Chamber Level (#643)” alarm is caused by inaccurate readings of the Arterial pressure due to an improper greasing of the Pressure Transducer.	2. Press the ***RESET*** button. *(See NOTE1)* To continue the treatment, perform a “Cassette Repositioning” special procedure, as described in the related section of the "Chapter 8: Special Procedures” in this Operator’s Manual. At the end of the treatment, grease the Pressure Transducers as described in the “13.13 Cassette Panel O-Rings Inspection and Greasing” section of the "Chapter 13: Disinfection/Rinse”.
	Call for Service if the alarm persists.

NOTE 1

If the ***RESET*** button is pressed without performing the level adjustment procedure, the “Low Arterial Chamber Level (#643)” alarm will no longer be triggered during the treatment.
If both the “Low Arterial Chamber Level (#643)” and the “Arterial Chamber: Level Adjustment Required (#642)” alarms are reset without performing the level adjustment procedure, at the end of the treatment the “Pressure Transducer: Greasing Required (#644)” alarm will be triggered.

PRESSURE TRANSDUCER: GREASING REQUIRED 644	
Reason	The Arterial and/or Venous and/or Pre-Dialyzer pressure readings might be inaccurate because the Pressure Transducers do not work properly.
Machine Actions	• None

Possible Cause	**Suggested Action**
1. The Arterial and/or Venous and/or Pre-Dialyzer pressure readings might be inaccurate because the Pressure Transducers do not work properly.	1. Press the **CONFIRM** button. Grease the Pressure Transducer proceeding as described in the "13.13 Cassette Panel O-Rings Inspection and Greasing" section in the "Chapter 13: Disinfection/Rinse" of the present Operator's Manual.

16.7.1 Malfunction Alarms

When a malfunction alarm occurs the following message is displayed in the Alarm/Information Message Area

MALFUNCTION

together with the technical code of the alarm.

When a Malfunction occurs:

- during a treatment: perform a Fast Recovery procedure as described in the “8.5 Fast Recovery” section of this Operator’s Manual.
  If the alarm persists, take note of the alarm code, switch the machine OFF and perform a Manual Rinseback procedure as described in the “8.2 Manual Rinseback procedure in HD-DN and HDF Post Treatments” section of this Operator’s Manual, then call for Service.
- during a Disinfection/Rinse program: take note of the alarm code, switch the machine OFF and call for Service.

16.7.2 MALFUNCTION 320

When the "Malfunction 320" is triggered by the Artis Dialysis System the following pop-up window appears on the Touch Screen:

Figure 16-2. Malfunction 320 - pop-up window

Following the troubleshooting related to this malfunction:

MALFUNCTION 320	
Reason	This is a special malfunction. The Main Board is blocked
Machine Actions	• GENERAL SAFE STATE • The Touch Screen is blocked

Possible Cause	**Suggested Action**
1. Main Board internal error.	1. If the alarm occurs during a disinfection/ rinse program, during the set-up or during the priming procedure, switch the machine OFF and after few seconds turn it ON again.
2. Main Board internal error.	2. If the alarm occurs during a tretament, perform a Fast Recovery procedure as described in the "8.5 Fast Recovery" section of this Operator's Manual.
	Call for Service if the alarm persists.

Chapter 17: Specifications

17.1 General Specifications

Following the main specifications related to Artis Dialysis System general characteristics are reported.

17.1.1 Name

Artis Dialysis System.

⚠WARNING

The Artis Dialysis System must be used under the supervision of a physician.

17.1.2 Standards and Classifications

The Artis Dialysis System complies with the following classifications and standards.

Equipment Classifications

- Class IIb (MDD 93/42/EEC)
- Class I, Applied Part Type B (EN 60601-1)
- Protection Class: IP21 (IEC 60529)
- Not suitable for use in the presence of flammable anesthetics, or anesthetic mixtures with air or with oxygen or nitrous oxide. (EN 60601-1)
- Continuous Operation (EN 60601-1)

⚠WARNING

Do not use the Artis Dialysis System near flammable gas or flammable anesthetic mixtures with air, with oxygen or with nitrous oxide.

CE Marking

- European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
  Notified body: British Standards Institution (BSI) with the notified body number 0086.

NOTE

- The CE marking by the manufacturer GAMBRO Dasco S.p.A. covers the equipment.
- The compatibility of the Artis Dialysis System with the accessories and disposables listed in this Operator's Manual has been verified during product validation.
- The CE-marking of this manual is only valid if the device which it describes is CE-marked.

International Standards

Medical Equipment Standards[a]	
IEC 60601-1	• MEDICAL ELECTRICAL EQUIPMENT - Part 1: General Requirements for safety (Equivalent to EN 60601-1)
IEC 60601-1-2	• MEDICAL ELECTRICAL EQUIPMENT - Part 1-2: General Requirements for safety - Collateral standard: Electromagnetic Compatibility - Requirements and tests (Equivalent to EN 60601-1-2)
IEC 60601-1-4	• MEDICAL ELECTRICAL EQUIPMENT - Part 1-4: General Requirements for safety - Collateral standard: Programmable electrical medical systems (Equivalent to EN 60601-1-4)
IEC 60601-1-6	• MEDICAL ELECTRICAL EQUIPMENT - Part 1-6: General Requirements for safety - Collateral standard: Usability (Equivalent to Harmonized standard EN 60601-1-6)
IEC 60601-1-8	• Medical electrical equipment - Part 1-8: General requirements for safety - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (Equivalent to EN 60601-1-8)
IEC 60601-2-16	• MEDICAL ELECTRICAL EQUIPMENT - Part 2-16: Particular Requirements for the safety of hemodialysis, haemodiafiltration and haemofiltration equipment (Equivalent to EN 60601-2-16)

Medical Equipment Standards[a] (Continued)	
IEC 60601-2-30	• MEDICAL ELECTRICAL EQUIPMENT - Part 2-30: Particular Requirements for safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment. (Equivalent to Harmonized standard EN 60601-2-30)
IEC 60320/C19	• Appliance and Interconnection Couplers
IEC 60529	• Degrees of protection provided by enclosures (IP Code)
EN 980	• Graphical Symbols for Use in the Labelling of Medical Devices
EN 1041	• Information supplied by the manufacturer with medical devices
EN 1060-1	• Non-invasive sphygmomanometers - Part 1: General requirements
EN 1060-3	• Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems
EN 1060-4	• Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers
EN 62304	• Medical device software - Software life-cycle processes
EN 62366	• Medical devices - Application of usability engineering to medical devices
European Pharmacopoeia	• 2.9.19 Particulate contamination: Sub-visible particles
EN ISO 11137-1	• Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 13485	• Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971	• Medical devices - Application of risk management to medical devices

Medical Equipment Standards[a] (Continued)	
ISO 594-2	• Conical fitting with a 6% (Luer) taper for syringes, needles and certain other medical equipment
ISO 13958	• Concentrates for haemodialysis and related therapies
ISO 13959	• Water for haemodialysis and related therapies
ANSI/AAMI SP10	• Manual, Electronic or automated sphygmomanometers.
ANSI AAMI RD52	• Dialysate for hemodialysis
ANSI/AAMI RD61	• Concentrates for haemodialysis
UL 60601-1	• MEDICAL ELECTRICAL EQUIPMENT - Part 1: General Requirements for Safety
CSA C22-2 N° 601-1-M90	• MEDICAL ELECTRICAL EQUIPMENT - Part 1: General Requirements for Safety
CAN/CSA C22-2N°601-2-16-92	• MEDICAL ELECTRICAL EQUIPMENT - Part 2: Particular requirements for safety of Hemodialysis Equipment.

a. Independent internationally recognized experts have rigorously checked conformity with these standards.

Essential Performance

For the purpose of EMC compliance, below the list of the essential performances of the Artis Dialysis System:

- Blood Flow
- Dialysis Fluid Flow
- Dialysis Fluid Composition
- Dialysis Fluid Temperature
- Substitution Fluid Flow
- Substitution Fluid Temperature
- Weight Loss
- Hemocontrol™ Biofeedback System

Refer to the specific sections of this chapter for further details on these performances.

Radio Frequency Interference and Electromagnetic Environment Requirements

The Artis Dialysis System needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Appendix A, of this Operator's Manual.

Portable and mobile RF communications equipment can affect the Artis Dialysis System.

RFID Module Characteristics

Parameter	*Values*
Frequency Range	• 13,56 MHz
Effective Radiative Power	• < 10 mW which corresponds to 42 dB μA/m at 10m
Type of Modulation	• ASK

FCC / Canada Radio Certification

The Artis Dialysis System has embedded a module approved with FCC ID: XD3-RFMOD, IC: 8313A-RFMOD.

These devices comply with part 15 of the FCC rules.

Changes or modifications not expressly approved by the party responsible for compliance could void user's authority to operate the equipment.

Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

17.1.3 Supply Mains

Main Characteristics

Parameter	*Values*
Mains Voltage	• 230/240 VAC (±10%) • 115 VAC (±10%)
Frequency	• 50/60 Hz (±5 Hz)
Power Consumption	• Max. 10 A at 230/240 VAC • Max. 16 A at 115 VAC
Power Cord	• Max. length 3 m.
Mains Connector	• Certified to IEC 60320/C19
Mains Plug	• Earthed plug, 250 V AC (10-16 A), • Earthed plug 125 VAC (20 A)
Dielectric Strength	• Complying with clause 20 of IEC 60601-1
Battery Back-up	• Voltage 24 volt, 7.2 Ah • Fuse: T 12 A

⚠WARNING

Possible hazards may arise from equipment (other than the accessories listed below) being connected to the machine, which may cause the permitted leakage current to be exceeded.

⚠WARNING

The Artis Dialysis System should not be used adjacent to or stacked with other equipments.
However, if adjacent or stacked use is necessary, the Artis Dialysis System has to be observed to verify normal operation in the configuration in which it will be used for treatment.

⚠WARNING

Wait at least 5 seconds after switching OFF the machine before turning it ON again.

⚠WARNING

The correct installation of a MEDICAL ELECTRICAL SYSTEM requires that each SYSTEM component be individually connected to the main power.
It is strongly recommended: **NOT TO USE MULTIPLE PORTABLE SOCKET-OUTLETS.**
However, if using multiple portable socket-outlets, they must comply with the IEC 60601-1-1 Standard and must **NOT BE PLACED ON THE FLOOR**.

⚠WARNING

- Check that the Artis Dialysis System is properly grounded.
- Do not remove the panels. If necessary, ask qualified staff to open panels.
- Disconnect the machine from the supply mains before every cleaning, checking or maintenance operation.

⚠WARNING

The Artis Dialysis System is provided with energy cells (batteries). When replacing these components, follow local regulations for proper disposal.

Power failure

In case of a mains power failure, an audible alarm is triggered and the red lamp is illuminated.

17.1.4 Physical Data

The physical data reported below must be considered approximated.

Parameter	***Dimensions***
Height (without Infusion Pole)	• 1550 mm
Height (in AFB K machine configuration)	• 1632 mm (AFB K Scale side) • 1763 mm (AFB K Infusion Pole side)
Infusion Pole Height	• 1500 to 2000 mm. Max. load 10 kg
AFB K Scale	• Max. load 20 kg
Width	• 500 mm (excluded the EvaClean connector and dialyzer holder) • 660 mm (when the dialyzer holder is turned in the position used for transportation)
Width of the base	• 700 mm
Depth	• 600 mm
Depth of the base	• 900 mm (included back-tray) • 700 mm (excluded back-tray)
Floor Area	• 0.405231 m^2
Dry Weight	• < 135 kg • < 140 kg (in AFB K)
Transportation	• in vertical position

Wheels and Portability

The Artis Dialysis System is provided with 4 double wheels: two lockable wheels on the front side and two wheels without brake on the rear side or four lockable wheels, according to the machine configuration.

The locks are foot-operated:

- to brake the machine, press all the locks completely down;
- to release the brake, pull all the locks completely up.

⚠WARNING

Before moving the Artis Dialysis System, check that all the locks are released and remove infusion bags or any other weights or hanging objects from the Infusion Pole, the chemical container shelf or the AFB K Scale and close the AFB K Scale.

⚠WARNING

To avoid jolting, carefully move the Artis Dialysis System by using the handles on the rear panel.
The machine could be damaged if handled in an improper way.

17.1.5 Environmental Data

Operational Mode

Parameter	***Values***
Ambient Temperature Range	• +18°C to +35°C (65°F to 94°F).
Relative Humidity Range	• 30 to 85 % rh
Air Pressure Range	• 795 to 1060 HPa

Storage and Transportation

Parameter	***Values***
Ambient Temperature Range	• -20°C to +70°C[a]
Relative Humidity Range	• 10 to 95% rh (non-condensing)
Air Pressure Range	• 500 to 1060 HPa

a. Temperatures above +50° C are allowed ONLY for maximum 12 hours

⚠WARNING

If condensation of Artis Dialysis System occurs when moving it between locations with different temperatures and high relative humidity (e.g. outdoor and indoor locations), the inside of the machine shall be allowed to dry before switching it on.

⚠WARNING

During transportation and storage the Artis Dialysis System has to be kept in its original packing.

17.1.6 Software revision

This Operator's Manual revision is related to the 8.09 software revision.

17.1.7 Connection of external equipment

⚠WARNING

- All external equipments connected to the Artis Dialysis System must be compliant with IEC 60950 or IEC 60601 series. Equipment not complying with IEC 60601 shall be kept outside the patient environment, as defined in the standard.
- Any person who connects external equipments to signal input, signal output or other connectors has formed a Medical Electrical system and is therefore responsible for the system to comply with the requirements of IEC 60601-1-1. If in doubt, contact qualified technician or your local representative.

The Artis Dialysis System is provided with a Connectivity Panel (see "Figure 17-1. Connectivity Panel") for connection of external equipments, including the following ports:

Connectivity Panel	
10/100 Base T Ethernet Port	• Used for connecting the machine to a Personal Computer to interface with the Communication System
RS232 Serial Port	• Used to connect the machine to an external software application
USB Port	• Used for flash memories *(only for service interventions)*
BPM Port	• Used for connecting the BPM Cuff
External Water Valve *(Not currently available)*	• Max voltage: 24 V DC • Max current: 500 mA
Hour Meter	• Displays the cumulative hours of machine operation (total time that power to the machine has been on)
Potential Equalization Connection mean	• Used for connecting a Potential Equalization Conductor to the machine

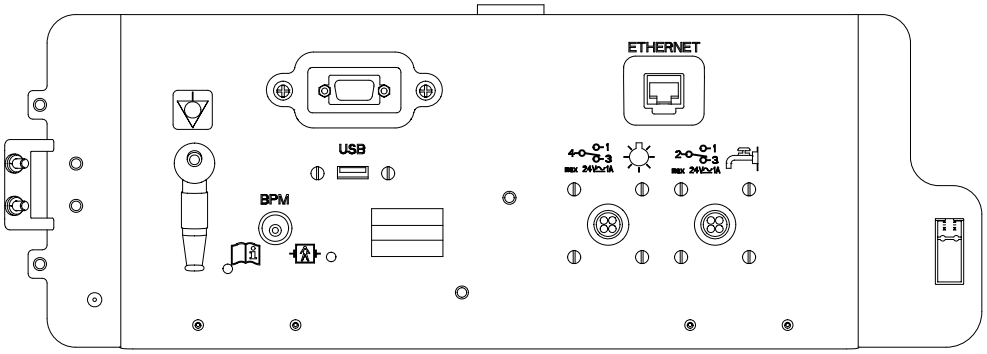


Figure 17-1. Connectivity Panel

17.1.8 Shipping List

The machine packaging contains the following components:

- Artis Dialysis System
- CD ROM of Artis Operator's Manual
- Installation Checklist
- Water Inlet and Drain Tubes
- Infusion Pole or AFB K Infusion Pole (maximum load: 10 kg or 22 lb) and Scale (depending on the Artis Dialysis System configuration)

NOTE

Adjustement of the infusion pole height must be done without bags on the hooks.

- Concentrate Wand
- BPM Cuff
- Top Tray
- BPM (Blood Pressure Monitoring)
- Central Concentrate Supply Kit

Accessories

- SNSP Expansion Chamber Holder
- CWP Adapter Kit
- AFB K Conversion Kit
- Chemical Container Shelf
- pH probe assembly
- Potential Equalization Connector

⚠WARNING

Do not assemble, install or use the Artis Dialysis System before having carefully read this Operator's Manual.

17.2 Hydraulic Circuit Specifications

17.2.1 Water Supply

The quality of the incoming water used by the Artis Dialysis System must comply with local standards and ISO 13959 standard.

Main Requirements

Parameter	***Value***	***Conditions***
Pressure	• 150 to 800 kPa	/
Inlet Water Demand (Flow Rate)	• ≥ 1 l/min	/
Temperature (Treatment)	• +5°C to +35°C • +10°C to +35°C • +16°C to +35°C	• Dialysis Fluid Flow Rate: 300 to 800 mL/min (230V) • Dialysis Fluid Flow Rate: 300 to 750 mL/min (115V) • Dialysis Fluid Flow Rate: 750 to 800 mL/min (115V)
Temperature	• +5°C to +93°C	/
Inlet Tube	• Length: 5 m • Internal diameter: 8 mm	/

Drain

Parameter	***Value***
Drain Flow Rate	• Max. 1.2 l/min
Drain Fluid Temperature	• Max. 90°C
Pressure	• 0 to 13 kPa
Drain Tube Length	• Max. 5 m
Drain Outlet Height	• Max. 1.3 m above floor level

Make the connection of the drain, as described in applicable local and international standards, with an external pressure connector to avoid back flow. Mantain an air clearance between the drain connector of the machine and the drain itself.

17.2.2 Concentrate Connectors

The concentrate and disinfectant connectors on the Artis Dialysis System are colour-coded as follows:

Connector	***Colour***
Acid Tube Connector	• Red, located on the machine front side
Blue Concentrate Connector	• Blue, located on the machine front side
Green Concentrate Connector	• Green, located on the machine front side
Disinfectant Tubes	• Yellow and Clear, located on the machine rear side

17.2.3 Dialysis Fluid

⚠WARNING

It is recommended to use concentrates which conform to the requirements of the European Pharmacological Standards.
The control of alarm threshold and dialysis fluid conductivity precision is of major medical importance in ensuring a safe dialysis treatment.

⚠WARNING

Attention must be given to the safety hazards related to incorrect choice of dialysis fluid concentrates.

Dialysis Fluid Temperature

Parameter	***Values***
Range	• +35°C (or +2°C above the inlet water temperature, whichever is greater) to +39.5°C
Accuracy	• +0.5°C/-1.8°C of the set value
Alarm Limits	• ±2 °C (+0.5°C) of the set value • Min. +34.5 °C (±0.5°C) • Max. +41 °C (±0.5°C)
Protection system type	• Monitoring of the dialysis fluid temperature

⚠WARNING

When the temperature of the dialysis fluid exceeds the alarm threshold, the auditory and visual alarm signals are triggered.

Dialysis Fluid Flow

Parameter	Values
Dialysis Fluid Flow Rate	• 300 to 800 mL/min, in steps of 50 mL/min • 500 mL/min (in AFB K Treatment)
Accuracy	• ± 2% of the set value
Alarm Limits	• ±10% (accuracy ±1%) of the set value • Min. 250 ml/min (±10 ml/min) • Max. 900 ml/min (±10 ml/min)

⚠WARNING

When the dialysis fluid flow exceeds the alarm threshold, the auditory and visual alarm signals are triggered.

NOTE

In AFB K Treatments, the Dialysis Fluid Flow Rate is fixed at 500 mL/min.

Dialysis Fluid Pressure

Parameter	Values
Permitted Values	• -350 to +480 mmHg
Accuracy	• ± 5 mmHg
Alarm Limits	• -350 to +480 mmHg

⚠WARNING

When the dialysis fluid pressure exceeds the alarm threshold, the auditory and visual alarm signals are triggered.

Degassing

Parameter	Values
Method of Degassing	• Heating in combination with vacuum pumping.
Pressure	• Dissolved gas in dialysis fluid < 7.0 mg/l.

pH Supervision

The pH supervision *is not available* in the default configuration of the Artis Dialysis System.

⚠WARNING

If pH supervision is not available on your machine, possible user error leading to the presence of hypochlorite in the hydraulic circuit can not be detected by the Artis Dialysis System. Using improper fluid in the dialysis fluid circuit may lead to improper dialysis to be delivered to the patient, thus resulting in patient injury or death.
Carefully consider your dialysis facility practises and policies regarding the use of disinfectants to decide about the availability of pH supervision on your Artis Dialysis System.

To decide about the availability of pH supervision on your machine, check if one of the following hazardous situations is present in your clinical environment:

Situation 1: Liquid A-concentrate in canister

Check if all the three conditions listed below are present at the same time in your clinical environment:

1. Liquid A-concentrate in canister
2. Sodium hypochlorite disinfectant in canister
3. Liquid A-concentrate and sodium hypochlorite disinfectant in canisters similar in shape, size and colour.

Situation 2: Central Delivery System of A-concentrate

Check if all the three conditions listed below are present at the same time in your clinical environment:

1. Liquid A-concentrate delivered from a central delivery system
2. Central delivery system disinfected with chemical disinfectants
3. Lack of safety measures to guarantee that the Artis Dialysis System is not connected to the central delivery system while the central delivery system is disinfected.

If situation 1 or situation 2 is present in your clinical environment, the availability of pH supervision on your Artis Dialysis System is requested as a countermeasure to guarantee safety in case of user error.

To make the pH supervision available contact your Local Representative.

pH supervision available

The pH Supervision is available only if the optional pH probe is installed on your machine. In this case, the following specifications are applied:

Parameter	***Values***
Range	• 1.0 to 13.0 pH units
Accuracy	• ±0.3 pH units
Alarm Limits	• 6.5 to 7.6 pH units (±0.1)

⚠WARNING

When the pH of the dialysis fluid exceeds the alarm limits, auditory and visual alarm signals are triggered. The alarms are not activated in AFB K Treatments.

17.2.4 Supported Concentrates

A-Concentrate with Bicart

Parameter	***Values***
Liquid concentrate	• SoftPac®: Acetic acid based concentrate for preparation of bicarbonate based HD, HF and HDF fluids.
Dry concentrate	• BiCart® Cartridge: Dry sodium bicarbonate concentrate for preparation of bicarbonate based HD, HF, HDF fluids.

Bicart Select System

Parameter	***Values***
Liquid concentrate	• SelectBag® One Product: Liquid A-concentrate for preparation of bicarbonate dialysis fluid together with SelectCart and BiCart Cartridges. • SelectBag® Citrate Product: citric A-concentrate for preparation of bicarbonate dialysis fluid together with SelectCart and BiCart Cartridges.

Parameter	***Values***
Dry concentrates	• BiCart® Cartridge: Dry sodium bicarbonate concentrate for preparation of bicarbonate based HD, HF, HDF fluids. • SelectCart® Cartridge: Dry sodium chloride concentrate for preparation of bicarbonate based HD, HF, HDF fluids.

Safebag KV Concentrate Solution

The Safebag KV concentrate solution is an acetate-free bag composed of two separate compartments (AFB and K Compartment), each of them containing a concentrated electrolyte solution. The fluid composition in both compartments is identical, except that the K Compartment contains potassium whereas the AFB Compatment is potassium-free.

Sodium and Bicarbonate Setting

Parameter	***Values***
Na+ (Sodium)[a]	• 130 to 160 mmol/l (±2.5%)
HCO3- (Bicarbonate)[a]	• 24 to 38 mmol/l (± 5%)
Accuracy	
Other Ions (Ca^{2+}, Mg^{2+}, Cl^-, CH_3COO^-, $C_6H_5O_7^{3-}$, Glucose)	• ± 5%
Na+ (Sodium)	• ± 2,5%
HCO3- (Bicarbonate)	• ± 5%
K^+ (Potassium)	• ± 5% or 0.1 mmol/l whichever is greater
Alarm Limits	
Other Ions (K^+, Ca^{2+}, Mg^{2+}, Cl^-, CH_3COO^-, $C_6H_5O_7^{3-}$, Glucose)	• ± 20%
Na+ (Sodium)	• ± 5%
HCO3- (Bicarbonate)	• ± 25%

a. Can be set by the operator.
The machine verifies the Sodium and Bicarbonate combination and accepts only values settings that result in an allowed final conductivity.

Central Concentrate Delivery

Parameter	***Values***
Pressure	• -20 kPa to +50 kPa

Final Conductivity

Parameter	*Values*
Setting values	• 13.3 to 15.7 mS/cm • 13.3 to 18.0 mS/cm (in AFB K Treatment)
Accuracy	• ± 0.1 mS/cm
Alarm Limits (difference between measured values and set points[a])	• ± 0.4 mS/cm of the set point (Protective System) • ± 0.2 mS/cm of the set point (Control System)
Alarm Limits (measured values)	• 12.5 to 16.5 mS/cm • 12.5 to 18.8 mS/cm (in AFB K Treatment)

a. The set point is given by the values set by the operator plus an adjustment coefficient calculated by the system.

Conductivity of the Bicarbonate Solution

BiCart Cartridges (sodium bicarbonate cartridge - see specific instruction sheet) can be used with the Artis Dialysis System.

⚠WARNING

Carefully read the BiCart Cartridge Instructions for Use before using the concentrate disposable.
Refer to this Operator's Manual for the procedures related to the use of the BiCart Cartridge with the Artis Dialysis System.

BiCart Solution Conductivity Monitor	
Parameter	*Value*
Conductivity values allowed	• 2.44 to 3.59 mS/cm
Accuracy	• ±0.1 mS/cm
Alarm Limits	• 2.24 to 3.79 mS/cm

Dialysis Fluid Pump Monitoring for Concentrate Exchange

The reference values for the speed of the acid/acetate and bicarbonate ceramic pumps are defined during the corresponding calibration processes (Stroke Volume editing) and represent the 0% functioning point.

A safety system is present to prevent concentrate errors, by generating an alarm in case the pump speeds are measured outside a range of ±10% for PA and of ±17% for PB.

17.2.5 Substitution Fluid

Parameter	***Value***
Substitution Fluid Flow Rate	• 1.2 to 19.8 l/h
Substitution Fluid Flow Rate Accuracy	• 10% of the substitution fluid flow rate or ±5 mL, whichever is greater, if Ultra Port pressure is from +50 mmHg to +300 mmHg; • 15% of the substitution fluid flow rate or ±10 mL, whichever is greater, if Ultra Port pressure is from +300 mmHg to +600 mmHg;
Online Produced Substitution Fluid	• Max. 50 litres, in post-dilution (49L for treatment, 1L for restitution)
Alarm Limits	• 10% (accuracy of ±5%) of the set substitution fluid flow rate or ±5 mL/min (accuracy of ±1 mL/min), whichever is greater
OnLine Bolus *(default)*	• 50 mL to 1000 mL, in steps of 10 mL (*default 150 mL*)
OnLine Bolus Rate *(default)* *Preset*	• 20 mL/min to 330 mL/min, in steps of 5 mL/min *(150 mL/min)*
Q_F/Q_B (in Post-dilution) *Preset*	• 30% to 50%, in steps of 1%, in Volume Control Mode. Default:40% • 30% to 60%, in steps of 1%, in Pressure Control Mode. Default:40%
Q_F/Q_B (in Pre-dilution) *Preset* *(not currently available)*	• 80% to 120%, in steps of 1%

NOTE

The On-line Substitution Fluid, prepared with inlet water conforming to ISO 13959 and concentrates conforming to European Pharmacopea, will have a microbiological fluid quality of:
• Bacterial content less than 10E-6 CFU/ml,
• Endotoxin content < 0.03 IU/ml measured with an LAL assay.

Volume Control Mode

Hemodiafiltration treatments performed by the Artis Dialysis System can be controllable in Volume Control Mode (Post dilution): the total weight loss, the Substitution Fluid Flow Rate and Treatment Time are set by the user while the TMP pressure varies accordingly to the total Ultra-filtration rate (weight loss rate + substitution fluid flow rate).

In online volume control treatments, the following ratios will always be displayed:

- Ratio between the total Ultra-filtration rate (weight loss rate + substitution fluid flow rate) and the Real Blood Flow Rate (Q_F/Q_B) in POST dilution mode
- Ratio between the Substitution Fluid Flow Rate and the Real Blood Flow Rate (Qi/Qb) in PRE dilution mode *(not currently available)*

TMP in Volume Control Mode

The operator will be able to set the maximum alarm limit for the TMP, during an Online treatment in volume control mode, in the following range:

- 0 mmHg to Absolute Maximum TMP, in steps of 5 mmHg

where the Absolute Maximum TMP is a pre-defined value set by a Service technician in the following range:

- 0 mmHg to +500 mmHg in steps of 5 mmHg

Pressure Control Mode

Hemodiafiltration treatments performed by the Artis Dialysis System can be controllable in Pressure Control Mode (Post dilution): the Total Weight Loss, the TMP and the Treatment Time are set by the user while the Substitution Pump Fluid Flow Rate varies accordingly to the TMP.

In online pressure control treatments, the following ratios will always be displayed:

- Ratio between the total Ultra-filtration rate (weight loss rate + substitution fluid flow rate) and the Real Blood Flow Rate (QF/QB) in POST dilution mode
- Ratio between the Substitution Fluid Flow Rate and the Real Blood Flow Rate (Qi/Qb) in PRE dilution mode*(not currently available)*

Pressure Control Mode with Ultra Control

Hemodiafiltration treatments performed by the Artis Dialysis System can be controllable in Pressure Control Mode (Post dilution) with Ultra Control: if the related functionality has been selected in the Service menu, then during the treatment, the machine allows manual Ultra Scans or automatic Ultra scans. During an Ultra Scan, the machine automatically increases the TMP from the initial value to the value that maximizes the total Ultra-filtration.

In case of manual Ultra Scans, the Ultra Scan process is activated by the user and automatically stopped by the machine as the optimum TMP is reached. A manual Ultra Scan can also be stopped by the user.

In case of automatic Ultra Scans, three Ultra Scan processes are automatically activated by the machine with a fixed timing and automatically stopped by the machine as the optimum TMP is reached. An automatic Ultra Scan can also be stopped by the user.

TMP in Pressure Control Mode

The operator will be able to set the maximum alarm limit for the TMP, during an Online treatment in volume control mode, in the following range:

- 0 mmHg to Absolute Maximum TMP, in steps of 5 mmHg

where the Absolute Maximum TMP is a pre-defined value set by a Service technician in the following range:

- 0 mmHg to +350 mmHg in steps of 5 mmHg

17.2.6 Ultrafiltration system

The accuracy of the Ultrafiltration system will be guaranteed in the following operating ranges:

Parameter	***Values***
Dialysis Fluid Flow	• 300 to 800 mL/min
UF Rate	• 0 to 3.0 L/h
UF Rate Accuracy	• ±50 ml/h
UF Volume	• 0 to 24 L, in steps of 0.05 L
UF Volume Accuracy	• ± 2.5% or ±50 ml/h * total treatment time, whichever is greater.
TMP	• -200 to +600 mmHg (±15 mmHg)
Treatment Time	• 00.10 to 08.00 (hour.minute), in steps of 5 minutes
Protein Content	• 0 to 120 mg/l
Protection System Type	• Monitoring of the ultrafiltration rate

⚠WARNING

If the difference between the accumulated weight loss rate measured by the Ultrafiltration System and the accumulated weight loss rate measured by the Protective System of the machine is greater than ±80 ml an audible and visual alarm is triggered.
When this alarm is activated the Venous Pump, if running, is stopped and the dialysis fluid goes into bypass.

NOTE

Besides the ultrafiltration, the patient's weight change during treatment is affected by other factors such as fluid and food intake, perspiration, drug administration, infusion priming and rinseback volumes, amongst others.
In addition, precise pre- and post-treatment weight are critical for the proper assesment of the ultrafiltration during the treatment. If these measurements are not accurate a discrepancy between the achieved ultrafiltration during treatment and the patient's weight changes will occur.

Ultrafiltration Supervision

Following the alarm limits for the Ultrafiltration System control:

Parameter	*Values*
UF Volume Supervision[a]	• < 540 ml
UF Rate Alarm Limits	• ±80 ml of the set value
UF Rate Measurement	• 0 to +3.0 l/h

a. It is defined as the difference between the Actual UF Volume and the UF Volume set by the operator.

17.2.6.1 Ultrafiltration system in AFB K Treatment

In AFB K Treatments, the UF Volume is calculated as follows:

$$\text{Total UF Volume} = \underset{\text{(Patient Weight Loss)}}{\text{UF Volume}} + \text{Total Infusion Volume}$$

According to that, the accuracy of the UF Volume can be calculated with the following formula:

$$\underset{\text{Accuracy}}{\text{Total UF Volume}} = \underset{\text{Accuracy}}{\text{UF Volume}} + \underset{\text{Accuracy}}{\text{Total Infusion Volume}}$$

Where:

UF Volume Accuracy = ± 2.5% or ±50 ml/h * total treatment time, whichever is greater (Refer to "17.2.6 Ultrafiltration system" paragraph)

Total Infusion Volume Accuracy = ± 0.3%

Infusion Flow

Parameter	*Values*
Infusion Flow Rate range	• 1 to 4.0 l/h

Parameter	*Values*
Infusion Flow + UF Rate	• ≤ 5 l/h
Total Infusion Volume Accuracy	• 100 g

17.2.7 Blood Leak Detection

Parameter	*Values*
Sensitivity	• > 0.35 ml/min , haematocrit 32%, ±2%
Detection Method	• Optical Infrared System

⚠WARNING

A Safety Test of the Blood Leak Optical Sensor is automatically performed each time the machine enters the Preparation mode.
When the Blood Leak sensor test fails audible and visual alarms are triggered .

⚠WARNING

In the "Isolated UF" process or with the hydraulic circuit in bypass, the Blood Leak Alarm may be delayed, due to operating conditions and dialyzer characteristics.

17.2.8 Disinfection

⚠WARNING

Contact with cleaning and/or disinfection chemicals may pose a risk of burns, skin irritation or other adverse reactions. Always follow the chemical manufacturer's instructions when handling these products or cleaning spills.

NOTE

It is recommended to alternate the disinfection methods and/or the disinfectants, in order to optimize cleaning, descaling and disinfection of the machine.
For additional information contact your local representative.

17.2.8.1 Chemical Disinfectants

Below is a list of the main chemical solutions validated for chemical disinfection of the Artis Dialysis System:

Active Ingredient	*Trade Names*
Sodium Hypochlorite	• Bleach® 5% • Amuchina™ 1.1%
Peracetic Acid	• Dialox™ 0,35% • Actril 0,06% • Renalin 4% • Oxagal 0,5%
Sodium Carbonate	• CleanCart A
Citric Acid	• CleanCart C

⚠WARNING

To prevent damaging the machine, do not leave disinfectant solutions in the machine for periods over the following limits:
- 20 min for Sodium Hypochlorite based solutions at Disinfectant strength (Max. 0.2% concentration)
- 20 min for Citric Acid based solutions at Disinfectant strength (Max. 2% concentration)
- 20 min for Sodium Carbonate based solution at Disinfectant strength (Max. 0.5% concentration)
- 72 hours for Peracetic Acid based solutions at Disinfectant strength (Max. 0.10% concentration)

17.2.8.2 Disinfection Programs

Following a list of the main disinfection programs allowable with the Artis Dialysis System.

The indicated “Total Time” parameter includes all the phases of the different disinfection processes (fill-up, circulation, drain and cooling).

Heat Disinfection

Parameter	*Values*
Temperature	• 95°C
Total Time	• 34 min

Heat Disinfection with CleanCarts

Parameter	*Values*
Heated Solution Concentration	• Max. 2%, CleanCart-C • Max. 0.5% CleanCart-A
Temperature	• 95°C
Total Time	• 44 min

Central Heat Disinfection

Parameter	*Values*
Temperature	• 95° C
Total Time	• 34 min

Chemical Disinfection - Peracetic Acid

Parameter	*Values*
Disinfectant Solution Concentration after 1:35 dilution	• Max. 0.10%
Disinfection Time	• 16 min.
Rinse Time	• 38 min.

Chemical Disinfection - Low Peracetic Acid

Parameter	*Values*
Disinfectant Solution Concentration after 1:35 dilution	• Max. 0.01%
Disinfection Time	• 16 min.
Rinse Time	• 27 min.

Chemical Disinfection - Sodium Hypochlorite

Parameter	*Values*
Disinfectant Solution Concentration after 1:35 dilution	• Max. 0.2%
Disinfection Time	• 16 min.
Rinse Time	• 94 min.

17.2.8.3 Rinsing

The Artis Dialysis System will automatically perform a Rinse process after any Chemical Disinfection Program and a drain of the circuit after any Rinse process.

It is also possible to manually activate a rinsing process after a dialysis treatment.

The effectiveness of Rinsing (measured just before connecting the patient to the machine) conforms to international standards for residual concentrations of disinfectant (European Pharmacological Standards and the ANSI - AAMI RD62):

- Peracetic maximum 1 ppm
- Sodium Hypochlorite maximum 0.1 ppm

NOTE

The test procedures for the measurement of disinfection and rinsing efficiency are available, upon request, from the manufacturer's quality control department.

WARNING

After a Chemical Disinfection program, a test for residuals of disinfectant must be performed before the following patient connection to avoid the risk of blood hemolysis due to the exposure of the patient to the chemical residues.

17.2.8.4 External Cleaning

It is possible to clean the Artis Dialysis System externally without affecting the original surface appearance using the following products:

- Ethanol (60% or 70%).
- Isopropanol 60%.
- Liquid soap, except for the Touch Screen
- Sodium hypochlorite (NaClO) of 1,5% available chlorine, except for the Touch Screen, Arterial and Venous Pumps, Air Detector, Blood Sensor, Hemoscan Sensor, Arterial and Venous Line Clamps and Automatic Pinch Clamp

17.3 Extracorporeal Blood Circuit

17.3.1 ArtiSet Blood Tubing System

The Blood Cassettes will allow the bloodlines to be positioned in a way designed to ensure a simple and effective system.

The following Blood Cassettes are available for the Artis Dialysis System:

Code	Application	Prime Line	Hemoscan Cuvette
113908	HD-DN (FULL)	YES	YES
113810	HD-DN (BASE)	YES	NO
112559	HDF Post	NO	YES
114533	HD-SN and HD-DNDP Treatment	YES	YES
113898	AFB K Treatment [a]	NO	NO

a. In AFB K Treatments, the Infusion Cassette must be used together with an ArtiSet HD DN HC Blood Tubing System.

NOTE

- Refer to the Blood Cassette labeling for technical specifications of the lines.
- Further information on suitable Blood Cassettes can be obtained by contacting your local representative.

⚠WARNING

The use of the Blood Cassettes designed for Artis Dialysis System has been tested and validated to provide safe and proper functioning of the system.

⚠WARNING

The appropriate Dialyzer and Blood cassette must be selected according to the patient's size and weight and to the treatment type. The decision must be taken by a physician.
Before installing Gambro/Hospal Dialyzers and Blood Cassettes carefully read the related Instructions for Use.

⚠WARNING

This Operator's Manual contains a number of references to accessories and disposables for use with Artis Dialysis System. The Artis Dialysis System has been tested and validated for use with accessories and disposables listed in this manual. The manufacturer has not validated the use of accessories or disposables other than those specified in this manual. The Manufacturer does not accept responsibility or liability for use of accessories or disposables other than those specified in this manual. Depending on the circumstances, use of accessories or disposables other than those specified may also reduce the Manufacturer's warranties for the Artis Dialysis System.

⚠WARNING

The Manufacturer recommends the use of a dialyzer with dialysis fluid and blood connections that comply with ISO 8637.

NOTE

Do not use plate-type dialyzer.

17.3.2 Arterial and Venous Pumps

The Artis Blood Module is made up of two peristaltic pumps designed for dialysis, with pump segment inserts of 6.36 x 9.54 mm (0.25x0.38 in).

To control the Arterial and Venous Pumps, the Blood Module is provided with:

- An Electronic Speed Control System to keep the speed constant, independently of load variations;
- A light on the Hard Key Panel illuminated when the Arterial and Venous Pumps are turning on (or when they are about to turn on, for example, after an automatic stop caused by an alarm);
- A Pump Direction Monitor;
- A system to automatically stop the Arterial and Venous Pumps and close the Venous Line Clamp in case of air or foam detection;
- A Safety Control when the Arterial and Venous Pump Covers are opened;
- Two cranks, one for each pump, for manual turning of the Arterial and Venous Pumps.

⚠WARNING

When using the Artis Dialysis System, stop the Arterial and Venous Pumps before touching the Arterial and Venous Pump Rotors.
Do not touch the blocking system.

Blood Pump Technical Characteristics

Parameter	***Value***	***Condition***
Speed of Pump Rotor	• 0 to 76 rpm approx.	/
Blood Flow Ramping Up *Can be preset*	• 25, 50 or 100 ml/min, per second	/
Max actual Blood Flow (at max rpm)	• 500 ml/min	• Arterial Pressure: 0 to -250 mmHg

17.3.3 Blood Flow

The Artis Dialysis System displays the following values related to the blood flow:

- The blood flow set value
- The blood flow actual value.

The blood flow set value represents the theoretical blood flow rate in the extra-corporeal circuit calculated from the speed of the Arterial Pump rotor and the geometric characteristics of the pump segment.

The blood flow actual value is the actual blood flow rate in the extra-corporeal circuit. The actual value is usually lower than the set value due to the negative pressure in the access line at the inlet to the pump. The negative pressure is caused by the rotation of the pump itself and pressure drop linked to the motion of blood in the line. The actual value coincides with the set value when the pump inlet pressure (arterial pressure) is zero.

The accuracy on the estimate, using GAMBRO Blood Cassette, is typically within ±10% in the following conditions:

- the pressure before the pump, given by the pressure in the arterial chamber of the cassette, is higher (less negative) than –150 mmHg and in the Actual Blood Flow range from 100 ml/min to 500 ml/min.

The blood flow actual value is estimated by means of a mathematical algorithm taking into account the pump segment characteristics of GAMBRO Blood Cassette, the current pump speed and the pressure values in the extra-corporeal circuit.

NOTE

The Artis Dialysis System will be able to calculate and display the accumulated blood volume in the range 0 to 999 liters.

⚠WARNING

A dedicated warning (Low Blood Pump Speed #204) exists in order to avoid blood loss due to coagulation resulting from interruption of blood flow.

HD-DN Treatment

Parameter	***Values***	***Conditions***
Adult Blood Cassette		
Actual Blood Flow	• 10 to 500 ml/min	• Arterial Pressure: 0 to -250 mmHg
Accuracy	• ±10% • ±20% or ±20 ml/min, whichever is greater	• Arterial Pressure: 0 to -150 mmHg • Total Treated Blood Volume: ≤120 litres • Actual Blood Flow: 100 to 500 ml/min • Arterial Pressure: 0 to -150 mmHg • Total Treated Blood Volume: 120 to 200 litres • Actual Blood Flow: 100 to 500 ml/min
Arterial Pump Speed	• 10 to 580 ml/min, in steps of 10 ml/min	/
Accumulated Blood Volume	• 0 to 999 litres (±20%)	/

HD-DNDP Treatment

Parameter	***Values***	***Conditions***
Adult Blood Cassette		
Actual Arterial Flow	• 20 to 500 mL/min	• Arterial Pressure: 0 to -250 mmHg
Actual Venous Flow	• 10 to 500 mL/min	• /

Parameter	*Values*	*Conditions*
Accuracy	• ±10% • ±20% or ±20 ml/min, whichever is greater	• Arterial Pressure: 0 to -150 mmHg • Total Treated Blood Volume: ≤120 litres • Actual Blood Flow: 100 to 500 ml/min • Arterial Pressure: 0 to -150 mmHg • Total Treated Blood Volume: 120 to 200 litres • Actual Blood Flow: 100 to 500 ml/min
Arterial Pump Speed	• 20 to 520 mL/min, in steps of 10 mL/min	/
Accumulated Blood Volume	• 0 to 999 litres (±20%)	/
Post-dialyzer Pressure	• -100 mmHg to +800 mmHg	/

NOTE

In HD-DNDP Treatment, the Venous Pump Speed is automatically controlled by the Artis Dialysis System, according to the Arterial Pump Speed.

HD-SNSP Treatment

Parameter	*Values*	*Conditions*
Mean Blood Flow	• 10 to 220 mL/min, in steps of 10 mL/min	/
Accuracy	• ±10 ml/min or ±20% whichever is greater	• Arterial Pressure: 0 to -150 • Treated Blood Volume: ≤ 120 L
SN Pressure Min	• 150 to 360 mmHg	/
SN Pressure Max	• 190 to 400 mmHg	/

NOTE

In HD-SN Treatment the stroke volume for each cycle is approximately 20 ml.

NOTE

During a HD-SNSP Treatment, the Artis Dialysis System will be able to automatically control the Arterial/Venous phase commutation according to pressure measurement in the Venous Patient Line (see " Venous Pressure Monitoring (HD-SNSP Treatment)" section in this chapter).

NOTE

In HD-SN Treatment, the blood recirculation rate at the level of the patient's vascular access is influenced by the needle type or catheter used. The blood recirculation rate is not due to the single needle cassette characteristics.

HD-SN Treatment

Parameter	***Values***	***Conditions***
Mean Blood Flow (*default*)	• 20 mL/min to 210 mL/min, in step of 10 mL/min *(50 mL/min)* • 20 mL/min to 170 mL/min, in step of 10 mL/min *(50 mL/min)* • 20 mL/min to 270 mL/min, in step of 10 mL/min *(50 mL/min)*	• Ratio between Venous Flow and Arterial Flow: 1.33 • Venous Flow 500 mL/min • Arterial Flow 250 mL/min • Venous Flow 500 mL/min • Arterial Flow 580 mL/min
Mean Blood Flow Accuracy	• ±10 ml/min or ±15%, whichever is greater	• Arterial Pressure between 0 and - 150 mmHg; • Treated Blood Volume: $\leq$ 120 L
Stroke Volume (*default*)	• 20 mL to 60 mL, in steps of 5 mL *(30 mL/min)*	/
Stroke Volume Accuracy	• ± 15% of the set value	/
Post-dialyzer Pressure	• -100 mmHg to +800 mmHg	/
Post-dialyzer Pressure Accuracy	• ±10 % • ±20 mmHg or ±10 %, whichever is greater	• Post-dialyzer Pressure: +300 mmHg to +800 mmHg • Post-dialyzer Pressure: -100 mmHg to +300 mmHg
Arterial Flow	• 30 to 580 mL/min in steps of 10 mL/min	/

Parameter	*Values*	*Conditions*
Venous Flow	• 30 to 500 mL/min in steps of 10 mL/min	/
Accumulated Blood Volume	• 0 to 999 litres (±20%)	/
QVen/QArt Ratio	• 0.50 to 2.00 *(default 1.33)*	/

NOTE

During a HD-SN Treatment, the Artis Dialysis System will be able to automatically control the Arterial/Venous phases commutation according to high and low Post-dialyzer pressure limits.

17.3.4 Heparin Delivery

The Artis Dialysis System may be supplied with a syringe type infusion pump which delivers heparin with a standard 30 ml syringe or a 10 ml syringe .

Parameter	*Values*
Heparin Delivery Management	• Linear: bolus delivered at a constant flow • Intermittent: bolus delivery at a set interval of time • Manual: single bolus delivered when the button is pressed • Extra Bolus: a bolus is delivered when the "Extra Bolus" Action button is pressed.
Syringe Size	• 30 mL • 10 mL
Heparin Delivery Rate (Linear Mode)	• 0 mL/h or 1.5 mL/h to 10.0 mL/h, in steps of 0.1 mL/h (30 ml syringe) • 0 mL/h or 0,5 mL/h to 4.0 mL/h, in steps of 0.1 mL/h (10 ml syringe)
Accuracy (on Accumulated Volume)	• ±1 ml or ±0.2 ml/h * heparinization time (h) or ±10% whichever is greater
Bolus Amounts *(default)*	• 0.5 to 12 mL, in steps of 0.1 mL *(1.0 mL)* (30 ml syringe) • 0.5 to 4 mL, in steps of 0.1 mL *(1.0 mL)* (10 ml syringe)
Bolus Delivery Rate	• 0.08 mL/s (30 ml syringe) • 0.04 mL/s (10 ml syringe)
Stop Time *(default)*	• 0 to total treatment time, in steps of 1 minute (30 min)

Parameter	Values
Max. Counter Pressure	• +900 mmHg
Heparin Delivery Alarm Limits	• Accumulated Heparin Volume: ±40% of the set Heparin Volume

NOTE

To prime the Heparin line, 0.6 ml of heparin will be injected into the Blood Cassette. This will happen regardless of the type of heparin delivery program selected.

Heparin Syringes

Following a list of the main syringes allowed on the Artis Dialysis System:

Syringe Name	Volume (ml)	Internal Diameter
TERUMO	30	23.1 mm (0.909 in)
BD 30 PLASTIPAK	30	21.6 mm (0.850 in)
PIC 30 LL	30	23.6 mm (0.929 in)
ICO GAMMA PLUS/ MONOSTERIL	30	23.9 mm (0.941 in)
PENTA 30	30	21.8 mm (0.858 in)
TERUMO	10	15.8 mm (0.622 in)
BD 10 PLASTIPAK	10	14.5 mm (0.570 in)

⚠WARNING

These diameters have been taken from samples from many countries and are correct at the time of printing. However, the manufacturer cannot be held responsible for changes in syringe dimensions that may occur. The user should periodically check the correlation between the stated and the actual diameters.

⚠WARNING

DO NOT USE syringes without luer lock connection.

⚠WARNING

The syringe infusion pump described above must be used **ONLY** for the infusion of heparin.

17.3.5 Hemoscan Sensor

The Artis Dialysis System provides a non-invasive mechanism to perform relative blood volume change measurements, according to the following specifications:

Parameter	***Values***
Blood Flow Rate	• 180 to 580 mL/min
Blood Temperature	• 30 to 40°C
Relative Blood Volume	• -40% to +10%
Accuracy (standard error)	• ±3%
Resolution	• 0.1%
Hemoglobin Value Range	• 6 to 16 g/dl

17.3.6 Blood Pressure Monitor (BPM)

The Blood Pressure Monitor is a non-invasive system to read the patient's blood pressure during a treatment (refer to the " Chapter 9: BPM" of this Operator's Manual).

In the table below the main specifications related to the blood pressure monitor option are reported.

The alarm limits below can be preset. The value put in brackets and in italics is the default value.

Parameter	***Values***
Systolic pressure range[a]	• +60 to +255 mmHg (BPM code 9032415600) • +40 to +260 mmHg (BPM code 9032622000)
Low alarm limit	• 60-255 mmHg *(90 mmHg)*
High alarm limit	• 60-255 mmHg *(200 mmHg)*
Diastolic pressure range[a]	• +30 to +195 mmHg (BPM code 9032415600) • +20 to +200 mmHg (BPM code 9032622000)
Low alarm limit	• +30 to +195 mmHg *(50 mmHg)*
High alarm limit	• +30 to +195 mmHg *(100 mmHg)*
Heart rate range[b]	• 30 to 200 bpm (BPM code 9032415600) • 30 to 220 bpm (BPM code 9032622000)
Low alarm limit	• 30 to 200 bpm *(40 bpm)*
High alarm limit	• 30 to 200 bpm *(120 bpm)*
Heart rate resolution	• 1 bpm
Cuff Pressure	• Max.: 300 mmHg
Cycle Time	• Typical cycle time: 35 s • Max.: < 160 s

a. Meets ANSI/AAMI SP-10. Mean error ±5 mmHg. Standard deviation 8 mmHg.
b. Heart Rate Accuracy: ±2% or ±3 bpm, whichever is greater

17.3.7 Automatic Functions

The following automatic functions are available with the Artis Dialysis System:

1. **HD-SNSP Treatment:** arterial/venous cycles occur through automatic blood pump transition when set venous pressure thresholds are reached.
2. **HD-SN Treatment:** arterial/venous cycles occur through automatic transition when the set Stroke Volume and the commutation pressure are reached.
3. **Linear or Intermittent *Heparin* Delivery:** through programming of the rate and timing of delivery.
4. **Heparin Bolus Injection Characteristics**
5. **Blood Sensor before Venous Line Clamp**: before blood detection by the Blood Sensor or before starting the dialysis treatment, some alarms are bypassed to allow easier filling of the extracorporeal and hydraulic circuits.
6. **Ultra Control:** in **HDF Post Treatment** with Pressure control mode, it is possible to activate the Ultra Control functionality (ref to "17.2.5Substitution Fluid" section of this chapter)
7. **Automatic Pump control:** in online treatments with Volume or Pressure control mode, each time that the substitution pump is stopped due to any reasons, the machine automatically decreases the Arterial Pump speed in order to avoid venous pressure peaks.

17.3.8 Main Surveillance Devices

Following the specifications related to the main surveillance devices available with the Artis Dialysis System.

Ultrasonic Air Detector

The Blood Module has an Air Detector consisting of:

- An Ultrasonic Sensor located into the right Sensor Bar;
- A Transducer which carries out the auto-test every 350 ms;
- A Visual and Audible Alarm which is activated if air is detected.

Parameter	***Values***
Detection Method	• An ultrasonic wave band crosses the fluid in the blood line. When air is present in the line, the signal received by the detector is modified in proportion to the volume of air present. When the signal goes above a fixed threshold, the microprocessor triggers a signal, which causes the Venous Line Clamp to close and the Arterial and Venous Pumps to stop.

Parameter	***Values***
Sensitivity	• Bubble volume ≥ 20 micro litres (±1 micro liter), at max. flow rate

Arterial Pressure Monitoring

The Arterial Pressure Sensor is used for measuring pre-pump arterial pressure in order to protect the patient from high negative arterial pressures between the patient and the Arterial pump.

During a treatment, an Arterial Pressure alarm will be triggered if the pressure measurements are not within the following ranges:

- Minimum and Maximum treatment limits;
- Minimum and Maximum Arterial pressure limits, calculated as:

  Max Arterial Limit = Operating value + Arterial Positive Offset

  Min Arterial Limit = Operating value - Arterial Negative Offset

NOTE

In case of Fast Recovery procedure, the Artis Dialysis System will automatically set the Extreme Alarm limits as the Minimum and Maximum Arterial pressure limits.

Parameter	***Values***
Operating Range	• -400 to +150 mmHg
Accuracy	• ±10 mmHg or ±10%, whichever is greater (in the range -400 mmHg to +20 mmHg) • ±20 mmHg (in the range +20 mmHg to +150 mmHg)
Offset Values *(Default)*[a]	• Positive: 10 to 100 mmHg, in steps of 5 mmHg *(80 mmHg or 100 mmHg in HD-SN Treatment)* • Negative: 10 to 80 mmHg, in steps of 5 mmHg *(40 mmHg or 80 mmHg in HD-SN Treatment)*
Treatment Limits*(Default)*[a]	• Min: -300 to -100 mmHg, in steps of 10 mmHg *(-300 mmHg)* • Max: -100 to +150 mmHg, in steps of 10 mmHg *(0 mmHg)*
Extreme Alarm Limits (outside the treatment mode)	• Min: -500 mmHg • Max: +300 mmHg
Maximum Arterial Alarm Limit[a]	• -100 to +150 mmHg, in steps of 10 mmHg

a. Can be preset

⚠WARNING

Modification of the Blood Flow Rate causes a fluctuation in the Arterial Pressure and therefore an alarm may be triggered.
To prevent such an effect, following any start/stop of the Arterial pump or change in the Blood Flow Rate the Arterial pressure Alarm Window is automatically set wider for 30 seconds, in HD-DN and HD-DNDP Treatments, for 120 seconds, in HDF Post Treatments and AFB K treatments or for 60 seconds, in HD-SN Treatments. Its lower value is set to -400 mmHg while the upper value is set to +150 mmHg.

Venous Pressure Monitoring (HD-DN and HD-DNDP Treatments)

During a treatment, a Venous Pressure alarm will be triggered if the pressure measurements are not within the following ranges:

- Minimum and Maximum treatment limits;
- Minimum and Maximum Venous pressure limits, calculated as:

  Max Venous Limit = Operating value + Venous Positive Offset

  Min Venous Limit = Operating value - Venous Negative Offset

Parameter	***Values***
Operating Range	• -100 to +450 mmHg
Accuracy	• ±10 mmHg or ±10%, whichever is greater (in the range -20 mmHg to +450 mmHg) • ±20 mmHg (in the range -100 mmHg to -20 mmHg)
Offset Values *(Default)*[a]	• Positive: 10 to 70 mmHg in steps of 5 mmHg *(70 mmHg)* • Negative:10 to 40 mmHg in steps of 5 mmHg *(40 mmHg)*
Treatment Limits*(Default)*[a]	• Min: 10 to 100 mmHg, in steps of 10 mmHg *(10 mmHg)* • Max: 150 to 400 mmHg, in steps of 10 mmHg *(300 mmHg)*
Extreme Alarm Limits (outside the treatment mode)	• Min: -300 mmHg • Max: +450 mmHg
Maximum Venous Pressure Alarm Limit *(Default)*[a]	• +150 to +350 mmHg, in steps of 10 mmHg *(300 mmHg)*

a. Can be preset

NOTE

A Safety Test of the Venous Pressure Monitoring System is automatically performed each time the machine enters the Preparation mode.

WARNING

Modification of the Blood Flow Rate causes a fluctuation in the Venous Pressure and therefore an alarm may be triggered.
To prevent such an effect, following any start/stop of the Arterial pump or change in the Blood Flow Rate the Venous Pressure Alarm Window is automatically set wider for 30 seconds, in HD-DN and HD-DNDP Treatments, for 120 seconds, in HDF Post and AFB K treatments or for 60 seconds, in HD-SN Treatments. Its lower value is set to -50 mmHg, while the upper limit is set to +450 mmHg.

WARNING

Monitoring of the Venous Pressure could not always detect the disconnection of a venous needle from its access site, which may result in extracorporeal blood loss to the environment. When a venous needle disconnects from its access, pressure at the venous monitoring side may only decrease by the pressure maintained within the patient's vascular access. This pressure drop may be less than the width of the machine's venous pressure alarm window: in this particular case the disconnection of a venous needle from its access site is not detectable by the machine, even if pressure alarms and alarm windows are properly set.
To reduce the risk of needles disconnection:

- ensure that venous needle and line are firmly secured to the access site area according to your clinic's protocol;
- ensure that the patient's access is visible at all times during the dialysis treatment;
- inspect frequently the patient's access;
- adjust properly the venous pressure alarm window: the venous pressure alarm lower limit should be set as closely as practical to the actual patient's venous pressure value without generating excessive nuisance alarms.

Venous Pressure Monitoring (HD-SNSP Treatment)

In ***HD-SNSP Treatment***, the Venous Pressure Sensor is used for measuring the blood pressure in the Venous chamber for Arterial Pump activation and deactivation, according to set venous pressure values:

Parameter	***Values***
Operating Range	• +150 to 400 mmHg, in steps of 10 mmHg
SN Pressure Min	• 150 to 360 mmHg
SN Pressure Max	• 190 to 400 mmHg
Alarm Limits	• +10 mmHg to +450 mmHg
Accuracy	• ±10 % (in the Operating Range +300 mmHg to +800 mmHg) • ±20 mmHg or ±10%, whichever is greater (in the Operating Range -100 mmHg to +300 mmHg)

⚠WARNING

The user must take precautions against the hazard of cross-contamination between patients by using only extracorporeal circuits that are not damaged.

Pre-Dialyzer Pressure

Parameter	***Values***
Operating Range	• -100 to +800 mmHg
Accuracy	• ±10% (in the Operating Range +300 mmHg to +800 mmHg) • ±20 mmHg or ±10%, whichever is greater (in the Operating Range -100 mmHg to +300 mmHg)
Alarm Limits *(Default)*	• 0 to +800 mmHg *(500 mmHg in HDF Post Treatment in Volume Control)*

Post-Dialyzer Pressure (HD-SN Treatment)

In HD-SN Treatment, the pressure transducer measures the blood pressure into the Post-Dialyzer Expansion Chamber in order to manage the Arterial and Venous phases.

Arterial and Venous phases are managed according to the *SN Pressure Max*. and *Min.* values calculated on the basis of the Stroke Volume set by the operator.

Parameter	***Values***
Operating Range	• -100 to +800 mmHg
Accuracy	• ±10 % (in the Operating Range +300 mmHg to +800 mmHg) • ±20 mmHg or ±10%, whichever is greater (in the Operating Range -100 mmHg to +300 mmHg)
Alarm Limits	• SN Pressure Max.: +450 mmHg (see ***NOTE1***)

NOTE

SN Pressure Min. is automatically controlled during the Venous phase and it can not be lower than 40 mmHg.
When this pressure is reached the machine automatically switches from the Venous phase to the Arterial one.

Hospasol Infusion Line Pressure (AFB K Treatment)

Parameter	***Values***
Operating Range	• -100 to +100 mmHg
Accuracy	• ±10 mmHg (in the Operating Range -50 mmHg to +100 mmHg) • ±20 mmHg (in the Operating Range -100 mmHg to -50 mmHg)
Alarm Limits	• -50 mmHg to +75mmHg

End of Infusion bag

The Artis Dialysis System is designed to trigger alarms if, in AFB K Treatment, the end of infusion bag is detected.
This criterion is active only after patient connection by monitoring the weight changes on the AFB K Scale.
If no weight changes are detected on the AFB K Scale, the Venous Pump is stopped within a interval time enough to avoid the emptying of the Infusion Cassette chamber.

Infusion Flow Rate

The Artis Dialysis System is designed to trigger alarms if, in AFB K Treatment, the Infusion Flow rate error exceeds specific values.
This criterion is active only after patient connection by comparing the weight changes on the AFB K Scale and the Infusion Fluid Volume given to the patient by means of the Venous Pump. The alarm is triggered each time the difference between these two values is greater than 50, 100 and 150 grams.

17.3.9 Safety system actuators

The Artis Dialysis System is supplied with the following safety system actuators:

Arterial Line Clamp	• Used for HD-SN Treatment
Venous Line Clamp	• Automatic closure when required by an alarm as part of a specific safety state; • Closure in HD-SN Treatment to reduce recirculation; • The Venous Line Clamp is fitted with a position sensor to ensure proper functioning of the clamp, and to assure that the Arterial Pump is stopped.

17.4 Protective System

The Protective System of the Artis Dialysis System grants safety under so called "single fault condition", as required by international regulations. The system supervises all the patient-safety relevant conditions and it can place the machine in a Specific Safe State when one of these conditions is not satisfied.

The conditions controlled are:

- Final Dialysis Fluid Conductivity
- Arterial and Venous Pumps flow and direction
- Bicarbonate Dialysis Fluid Conductivity
- Blood Leakage from the dialyzer
- Concentrate Container Error
- Dialysis Fluid Flow
- Dialysis Fluid pH (optional)
- End of Infusion Bag in AFB K Treatment/
- Heparin Delivery
- Maximum Dialyzer Pressure at the Dialyzer Inlet and Outlet
- Minimum Dialyzer Pressure at the Dialyzer Inlet and Outlet
- Infusion Weight in AFB K Treatment
- Presence of Air in the Venous Patient Line
- Dialysis Fluid Temperature
- Ultrafiltration Flow
- Ultrafiltrate Mass Balance
- Venous Pressure monitoring
- Arterial Pressure monitoring
- Pre-Dialyzer Pressure
- Incorrect Voltage
- Activity of Diascan System
- Control System Communications
- Correct Sequence of T1 Test
- Power Failure
- Long Bypass

- Pause Therapy
- TMP
- Blood Lines Clamped
- Water Leakage
- Activity of Hemocontrol System
- Activity of AFB K Scale/
- Activity of K Profile in AFB K Treatment
- Bicarbonatemia Surveillance in AFB K Treatment

Depending on the type of fault condition occurred, one or more of the following Specific Safe States are applied to the machine:

- Arterial Pump Stop
- Venous Pump Stop
- Venous Line clamp Closed
- Dialysis Fluid Bypass (to prevent it reaching the dialyzer)

Each time a Specific Safe State is applied, the related auditory and visual alarms are triggered.

In case that the Specific Safe State is not properly applied, the Protective System places the machine in a **General Safe State** and:

- Closes the Venous Line Clamp;
- Switches OFF the Power Supply to all the actuators, except to those for visual and audible alarms.

For further details about protective alarm limits, refer to the related sections of this chapter and of the “Chapter 16: Alarms, Information Signals and Troubleshooting”.

17.5 Disposal of discarded equipment

Discarded electromedical equipment may not be disposed of together with municipal waste but must be collected separately in order to guarantee ecologically correct disposal to prevent dispersion of potential pollutants into the environment.

Pay attention to the fact that some components of the machine (display, batteries, circuit boards, etc.) may contain toxic substances which, if released into the environment, pose a risk to the health of living organisms and the environment itself.

When discarding electromedical equipment used at or through healthcare facilities, it may be returned directly to the local representative/distributor who has supplied it.

When discarding electromedical equipment used in private households, it may be:

- returned free of charge to the distributor at the time of purchasing new equipment
- sent to the specialized collection centres free of charge.

Users who return electromedical equipment to the subjects identified above actively contribute to reuse, recycling and recovery of potentially still useable materials and components and to reduction of the potential risks to the environment and human health.

Abusive disposal of discarded equipment may be punishable by law.

17.6 Preventive maintenance

To keep the machine in good and safe working order, a periodical preventive maintenance of the Artis Dialysis System must be performed both by the operator and by an authorized service technician.

The operator is responsible for a regular preventive maintenance of the solely machine external surface, whereas the machine internal components preventive maintenance must be performed exclusively by an authorized service technician.

17.6.1 Preventive Maintenance performed by the operator

Depending on the ambient conditions, the frequency and the average duration of daily use of the Artis Dialysis System, the operator is required to perform periodical preventive maintenance procedures on the machine external surface. In particular, the operator has to perform:

- External cleaning of the machine surface and outside components. Refer to the “13.10 External Cleaning” section of this Operator’s Manual for the procedures and agents to be used.
- External disinfection of the water inlet tube. Refer to the “13.9 Water Inlet Tube disinfection” section of this Operator’s Manual for the related procedure.
- External cleaning of the Touch Screen. Refer to the “13.10 External Cleaning” section of this Operator’s Manual for the related procedure.
- Visual Inspection of the machine. Refer to the “13.12 Visual inspection” section of this Operator’s Manual for the related procedure.
- Cassette Panel O-Rings Inspection and Greasing. Refer “13.13 Cassette Panel O-Rings Inspection and Greasing” section Inspection and Greasing” of this Operator’s Manual for the related procedure.

⚠WARNING

No other maintenance procedures than those mentioned above will be performed by the operator of the machine. The machine panels must ***ONLY*** be opened by a fully trained service technician.

⚠WARNING

Stagnant water may contaminate the machine. If the machine is stored for more than 7 days, the water tube should be disinfected and rinsed before using it for treatment.

17.6.2 Preventive Maintenance performed by an authorized service technician

The ambient conditions, the frequency and the average duration of daily use of the Artis Dialysis System determine the maintenance frequency of the internal machine components; however when a maximum of 4,000 working hours have elapsed (or at least once a year) a technical preventive maintenance is required.

The components to be replaced and the calibrations and checks to be performed are specified in the Preventive Maintenance Checklist. A copy of the most recent Preventive Maintenance Checklist is included with every Preventive Maintenance kit. All the Preventive Maintenance programs have to be performed in accordance with the list included in the Preventive Maintenance Checklist, with the calibration/ test procedures described in this Service Manual and with the Instruction sheets procedures described in the Preventive Maintenance Booklet.

⚠WARNING

The manufacturer does not accept any responsibility for damages caused by any operation carried out on the machine by unauthorized staff.

⚠WARNING

Before replacing or checking any component in the Hydraulic Circuit, a Descaling procedure (i.e. a Heat with CleanCart-C disinfection) must be performed.

There are currently two Preventive Maintenance kits:

- PM1: "MAINTENANCE KIT1 AE" code 6999783
- PM2: "MAINTENANCE KIT2 AE" code 6999791

These two preventive maintenance have to be performed alternatively each 4000 hours or once a year whichever comes first.

The schedule for which kit to use is listed in the table below:

Preventive Maintenance Period	**PM1ST** (4000 hours)	**PM2ND** (8000 hours)	**PM3RD** (12000 hours)	**PM4TH** (16000 hours)
PM1: "MAINTENANCE KIT1 AE"	X		X	
PM2: "MAINTENANCE KIT2 AE"		X		X

NOTE

Each part present in the “Maintenance Kit1 AE” and “Maintenance Kit2 AE” is also available as single spare part kit.

For the complete list of all the components that have to be checked and/or replaced and for the complete description of the required test and calibration procedures, refer to the Preventive Maintenance Checklist provided with each Preventive Maintenance Kit and to the Artis Service Manual.

For detailed instructions of the replacement procedures of the single spare part kits, refer to the related Instruction Sheet described in the Preventive Maintenance Booklet.

Please find below the list of the spare parts included in the PM1/PM2 that have to be replaced:

Components to be replaced	**PM1**	**PM2**
PRESSURE TRANSDUCERS O-RINGS	X	X
EVACLEAN DOOR CAPS AND ULTRA PORT CAP	X	
ULTRA PORT CAP		X
EVACLEAN DOORS		X
SAMPLING PORT	X	
UPPER-LOWER SELECTCART AND UPPER BICART HOLDER ARMS O-RINGS		X
BICART AND SELECTCART HOLDER ARMS O-RINGS	X	
LOWER BICART HOLDER ARM SPIKE		X
FEMALE RED-BLUE DIALYSIS FLUID CONNECTORS O-RINGS	X	
MALE-FEMALE RED-BLUE DIALYSIS FLUID CONNECTORS/TUBES		X
ULTRAFILTERS HOLDERS O-RINGS AND X-RINGS	X	X
YELLOW-CLEAR DISINFECTANT CONNECTORS O-RINGS	X	X
ACID PICK-UP TUBE CONNECTOR O-RINGS	X	
ACID PICK-UP TUBE CONNECTOR O-RINGS AND THE FEMALE ACID CONCENTRATE CONNECTOR		X
250 MICRON FILTERS	X	X
50 MICRON FILTERS	X	X
FH2O FILTER		X

PRV PRESSURE REGULATOR MEMBRANE	X	X
NON RETURN VALVE(S)	X	X
ORDEG RESTRICTION	X	X
SILICONE CONNECTORS	X	X
AIR INTAKE FILTER	X	X
BLD VESSEL		X

Please find below the list of the spare parts that have to be ordered separately and replaced only if necessary:

Components to be replaced	**PM1**	**PM2**
TWIN ACTUATOR	X	X
Female Central Concentrate Connectors "FEM.CONC. CONNECTOR AE"		X
EVC and EVD 2-way valves "2WAY SOLENOID VALVE PEEK"	X	X
F5 and F6 filters "50 MICRON AE"	X	X
EVDS1, EVDS2 3-way valves "3WAY SOLENOID VALVE PEEK" and EVBP2 2-way valves "2WAY SOLENOID VALVE PEEK"	X	X

Below is a list of the main operations and verifications required during the Technical Preventive Maintenance program, updated at the date of printing of this manual:

- Perform the required cleaning;
- Verify, test and if necessary recalibrate or replace the following components: pressure regulators, pressure sensors, pH probe (only if installed), hemoscan, blood sensors and Scale sensor;
- Perform conductivity, temperature and TP temperature probe tests;
- Perform the Wet Sensor Assembly maintenance;
- Check the Power Supply Voltages;
- Perform the Arterial/Venous pump rotor occlusion test;
- Perform Protective Earth test;
- Perform the Power Failure & Battery Test (before, during and after the Simulated Dialysis Treatment);
- Use the Total Ultrafiltration Accuracy Test procedure to perform the simulated dialysis treatment) and execute the following operations:

- Verify the correct T1 Test execution.
- Run 10 minutes of simulated dialysis treatment with blood detection.
- Verify PA Error parameter = 0 ± 5 (1st Page of the Service Data screen).
- Verify PB Error parameter = 0 ± 8 (1st Page of the Service Data screen).
- Perform the Earth Leakage Current Test (< 300µA for 115V machines; <500 µA for 230/240V machines);
- Simulate an "Air in Venous Line" alarm and reset the alarm.

• Perform a Water Leakage Check in the Main Hydraulic Circuit.

• Notify the machine operator to perform a disinfection procedure prior to perform a dialysis treatment.

Periodic Electrical Safety Inspection

An Electrical Safety Inspection of the Artis Dialysis System is required at least once a year and according to the local policies. Only trained and qualified technicians are authorized to perform the safety inspection procedures.

The detailed list of the Electrical Safety Inspection is included in the Artis Service Manual.

17.7 Materials in contact with water, concentrates and dialysis fluid

Ceramic (alluminium oxide)
EPDM (Ethylene Propylene Terpolymer Rubber)
FKM (Fluoroelastomer)
Glass
Graphite
NBR (Acrylonitrile-butadiene Rubber)
Ni superalloy (Nickel)
PA (Polyamide)
PA + GF (Polyamide + Glass Fiber)
PAES
PC (Polycarbonate)
PE HD (Polyethilene high density)
PEEK (Polyether ether ketone)
PP (Polypropylene)
PP + GF (Polypropylene + Glass Fiber)
PPE+PS (Polyphenylene ethynylene + Polystyrene)
PPE+PS+GF (Polyphenylene ethynylene + Polystyrene + Glass Fiber)
PPSU (Radel)
PSU (Polysulfone)
PTFE (Polytetrafluoroethylene)
PUR (Polyurethane)
PVC (Polyvinyl chloride)
PVDF (Polyvinylidene Fluoride)
PVP (Polyvinylpyrrolidone)
Silicone
SS (Stainless Steel)
Ti (Titanium)
TPE (Thermoplastic Elastomer)

17.8 Diascan

The Diascan™ system will be available in the following treatment modes:

- Hemodialysis (HD-DN and HD-DNDP Treatment)
- Hemodiafiltration (HDF Post in Volume and Pressure Control Mode)
- HD-SN Treatment
- AFB K (K Constant mode)

Following the main specifications related to this functionality:

Parameter	*Range*	*Accuracy*	*Resolution*	*Conductivity*
Ionic Dialysance	0 to 500 ml/min	±7 ml/min[a]	1 ml/min	/
Plasma Sodium Concentration	130 to 160 mmol/l	±3 mmol/l[a]	1 mmol/l	/
Plasma Conduct.	13 to 16 mS/cm	± 0.05 mS/cm	0.01 mS/cm	13 to 16 mS/cm (0.05 mS/cm)
Ionic Mass Bal	-800 to 800 mmol (HD-DN)[b]	±25 mmol[a]	1 mmol	-
Depurated Vol	0 to 200 litres	±2 litres[a]	0.1 L	/
Kt/V	0 to 3	-	0.01	/

a.Standard Error for a 4 hour dialysis.
b.Positive values correspond to solutes removed from the patient.

Accuracy is guaranteed in all the treatment modes for blood flows 200 to 500 ml/min and dialysis fluid flows 300 to 800 ml/min, except in HD-SN Treatment where accuracy is not guaranteed.

The conductivity of the dialysis fluid can be measured by the DIASCAN™ system only if the following parameters fall in the indicated ranges:

Parameter	Range
Temperature Range	30-45 °C
Conductivity Range	13 to 16 mS/cm (0.05 mS/cm)

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Appendix A: Guidelines and Manufacturer's Declaration - Electromagnetic Emissions and Immunity

A.1 Guidance and manufacturer's declaration

A.1.1 Electromagnetic emissions

The Artis Dialysis System is intended for use in the electromagnetic environment specified in the table below.

The customer or the user of the Artis Dialysis System should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment - guidance
RF emission CISPR 11	Group 1	Artis Dialysis System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The Artis Dialysis System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

A.1.2 Electromagnetic immunity

The Artis Dialysis System is intended for use in the electromagnetic environment specified in the table below.

The customer or the user of the Artis Dialysis System should assure that it is used in such an environment.

Electromagnetic immunity			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	• ±6 KV contact • ±8 KV air	• ±6 KV contact • ±8 KV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	• ±2 KV for power supply lines • ±1 KV for input / output lines	• ±2 KV for power supply lines • ±1 KV for input / output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	• 1 KV line(s) to line(s) • 2 KV line(s) to earth	• 1 KV line(s) to line(s) • 2 KV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	• <5 % U_T (>95 % dip in U_T) for 0.5 cycles[a] • 40 % U_T (60 % dip in U_T) for 5 cycles[a] • 70 % U_T (30 % dip in U_T) for 25 cycles[a] • <5 % U_T (>95 % dip in U_T) for 5 s[a]	• <5 % U_T (>95 % dip in U_T) for 0.5 cycles[a] • 40 % U_T (60 % dip in U_T) for 5 cycles[a] • 70 % U_T (30 % dip in U_T) for 25 cycles[a] • <5 % U_T (>95 % dip in U_T) for 5 s[a]	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Artis Dialysis System requires continued operation during power mains interruptions, it is recommended that the Artis Dialysis System be powered from an uninterruptible power supply or a battery.

Electromagnetic immunity			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	• 3 A/m	• 30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

a. U_T is the a.c. mains voltage prior to application of the test level.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	• 3 Vrms • 150 KHz to 80 MHz • 3 V/m • 80 MHz to 2.5 GHz	• 10 Vrms • 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Artis Dialysis System including cables, than the recommended separation distance calculated from the equation applicable to frequency of the transmitter. Recommended separation distance d = 0.35 $\sqrt{P}$ *d* = 0.35 $\sqrt{P}$ *80 MHz to 800 MHz* *d = 0.7* $\sqrt{P}$ *800 MHz to 2.5 GHz* where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To asses the electromagnetic environment due to fixed transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Artis Dialysis System is used exceeds the applicable RF compliance level above, the Artis Dialysis System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Artis Dialysis System.
b. Over the frequency range 150 KHz to 80 MHz, field strength should be less than 10 V/m.

NOTE

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

A.2 Recommended separation distances between portable and mobile RF communications equipment and Artis Dialysis System

Artis Dialysis System is intended for use in the electromagnetic environment where radiated RF disturbances are controlled. The customer or the user of Artis Dialysis System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Artis Dialysis System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	**Separation distances according to frequency of transmitter (m)**		
W	**150 KHz to 80 MHz** $d = 0.35\sqrt{P}$	**80 MHz to 800 MHz** $d = 0.35\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 0.7\sqrt{P}$
0,01	0.04	0.04	0.07
0,1	0.11	0.11	0.22
1	0.35	0.35	0.70
10	1.11	1.11	2.21
100	3.50	3.50	7.00
For transmitters rated at maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			

NOTE

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, object and people.

Appendix B: Parameter List

B.1 Parameter List

The default values for each parameter of the Artis Dialysis System can be set only in the Service 2 menu by a qualified service technician.

In the following table an alphabetical list of all the parameters of the Artis Dialysis System is provided with a brief description, ranges, the unit of measurement and the default values.

PARAMETER	DESCRIPTION	VALUE/RANGE	UNIT
Acid	Presets the default acid type to be used for dialysis fluid preparation.	Default: C295/ G295	/
Administration Type	Presets the default heparin administration mode in dialysis.	Linear/ Intermittent/ Manual Default: Linear	/
ADR Autostart	Enables/disables the ADR Autostart function in Treatment Environment and accordingly updates the “Default Settings” parameter list.	No/Yes Default: Yes	/
AFB K Mode *(See Note 7)*	Presets the AFB K Treatment.	K Constant/K Profile Default: K Constant	/
Alarm Limit	Presets the alarm limit value for Hemoscan monitoring system.	-30 to 0 Default: -20	%
Art Level Check 1	Enables/disenables the check on the Arterial Chamber Level.	No/Yes Default: Yes	/
Art Level Check 2	Enables/disenables the check on the Arterial Chamber Level.	No/Yes Default: Yes	/
Art Treatment Max Limit	Presets the maximum arterial pressure limit default.	-100 to +150 Default: 0	mmHg
Art Treatment Min Limit	Presets the minimum arterial pressure limit default.	-300 to -100 Default: -300	mmHg
Autopriming Mode	Presets the autopriming type.	High Volume/Low Volume Default: High Volume	mL
Backend conn.	Enables/disables the Backend connection in Treatment Environment.	No/Yes Default: No	/

PARAMETER	DESCRIPTION	VALUE/RANGE	UNIT
Bicarbonate	Presets the bicarbonate concentration in the dialysis fluid.	24 to 38 Default: 34	mmol/L
BiCart	Presets the default BiCart type to be used for dialysis fluid preparation.	Default: BiCart	/
BiCart Citrate Use	Enables/disenables the BiCart Citrate function in Treatment Environment.	No/Yes Default: No	/
BiCart Select Use	Enables/disables the BiCart Select function in Treatment Environment.	No/Yes Default: No	/
Bolus Size	Presets the amount of the automatically delivered heparin dose (Linear, Intermittent and Manual Mode).	• 30 mL syringes: 0.5 to 12.0 Default: 1.0 • 10 mL syringes: 0.5 to 4.0 Default: 1.0	mL
BPM	Enables/disables the BPM function in Treatment Environment and accordingly updates the "Default Settings" parameter list.	No/Yes Default: Yes	/
Ca++	Presets the amount of calcium in an added solution and indicates the amount of calcium in a preinserted one.	0.00-655.35	mmol/L
Card Reader	Enables/disables the Card Reader function in Treatment Environment.	No/Yes Default: No	/
CCK Configuration	Presets the Acid Concentrate Connector to be used during rinse process.	One Concentrate Connector, Two Concentrate Connector Default: One Concentrate Connector	/
CCK Rinse Time *(See Note 1)*	Displays the default time for the Central Concentrate Tube rinse process.	4:00	min:s
CCM Ident	Presets the unique identifier of the Artis Dialysis System within the network system.	1 to 255 Default: 48	/

PARAMETER	DESCRIPTION	VALUE/RANGE	UNIT
CH3COO-	Presets the amount of acetate in an added solution and indicates the amount of acetate in a preinserted one.	0.0-6553.5	mmol/L
Cl-	Presets the amount of cloride in an added solution and indicates the amount of cloride in a preinserted one.	0.0-6553.5	mmol/L
ConcentrateCombination	Presets the concentrate type to be used during the treatments.	• BiCart + A Concentrate • BiCart Select • BiCart Citrate *(See Note 6)* Default: BiCart + A Concentrate	/
Conc. Install Delay	Presets the maximum time the machine allows the operator for configuring concentrates before triggering the alarms.	3 to 15 Default: 15.00	min:s
Control Mode	Presets the control mode during the on-line treatments (HDF Post Treatment).	Volume Mode/ Pressure Mode Default: Pressure Mode	/
Date Display	Presets the mode the current date is displayed.	DD/MM/YYYY (for instance) Default: DD/MM/YYYY	/
Day *(see Note 9)*	Presets the current day of the month.	1 to 31 Default: 1	/
Delay for Low Consumption	Presets the time interval between the end of the prime process and the beginning of the Low Consumption State.	1:00 - 10:00 Default: 2.00	min:s
DHCP Enable *(see Note 1)*	Enables/disables the Dynamic Host Configuration Protocol, used to assign the IP address.	No	/
Dialyzer	Presets the default dialyzer type to be used in AFB K Treatments.	Evodial 1.6, Evodial 2.2 Default: Evodial 1.6	/
Diascan (AFB K)	Activates/deactivates the use of the Diascan function during AFB K Treatment.	No/Yes Default: No	/

PARAMETER	DESCRIPTION	VALUE/RANGE	UNIT
Diascan (HD-DN)	Activates/deactivates the use of the Diascan function during HD-DN Treatment.	No/Yes Default: No	/
Diascan (HDF Post)	Activates/deactivates the use of the Diascan function during HDF Post Treatment.	No/Yes Default: No	/
Diascan (HD-SN)	Activates/deactivates the use of the Diascan function during HD-SN Treatment.	No/Yes Default: No	/
Diascan Use	Enables/disables the Diascan function in Treatment Environment and accordingly updates the "Default Settings" parameter list.	No/Yes Default: No	/
Diastolic Lower	Presets the minimum diastolic alarm limit.	30 to 100 Default: 50	mmHg
Diastolic Upper	Presets the maximum diastolic alarm limit.	50 to 195 Default: 100	mmHg
Dilution Ratio *(See Note 1)*	Displays the dilution ratio during: Peracetic, Low Peracetic, Bacteriostatic Peracetic, Bacteriostatic Low Peracetic and Hypochlorite disinfection programs.	Default: 35	/
Disinf. from *(See Note 1)*	Displays the inlet port location for the disinfectant used during the following chemical disinfection programs: Peracetic, Low Peracetic, Bacteriostatic Peracetic and Bacteriostatic Low Peracetic.	Default: Grey Rear Connector	/
Disinf. from *(for hypochlorite)* *(See Note 1)*	Displays the inlet port location for the disinfectant, used during the Chemical Disinfection program with Hypochlorite.	Default: Yellow Rear Connector	/
Dose Rate	Presets the heparin administration rate during the treatment (Linear Mode).	• 30 mL syringes: 1.5 to 10.0 Default: 1.5 • 10 mL syringes: 0.5 to 4.0 Default: 1.5	mL/h

PARAMETER	DESCRIPTION	VALUE/RANGE	UNIT
Dose Size	Presets the amount of the automatically administrated heparin dose (Intermittent Mode).	• 30 mL syringes: 0.5 to 12.0 Default: 1.0 • 10 mL syringes: 0.5 to 4.0 Default: 1.0	mL
Duration	Presets the duration of the Rinse process.	16/27/38 Default: 16	minutes
Dwell Time	Presets the duration of the Dwell phase during chemical disinfection (the time the hydraulic circuit is filled with disinfectant solution).	5/10 Default: 5	minutes
Exalis	Enables/disables the Exalis function in Treatment Environment and accordingly updates the “Default Settings” parameter list	No/Yes Default: No	/
Foxalis	Enables/disables the Foxalis function in Treatment Environment and accordingly updates the “Default Settings” parameter list.	No/Yes Default: Yes	/
Gateway (IP Address fields 1st, 2nd, 3rd and 4th)	Presets the host address that permits the routing of the package towards a subnet different in respect to the one of the machine. If the Netroute and Subnet Mask are preset to 0, all the packages with different destination of the subnet, whom the machine belongs to, will be addressed to the Gateway.	0 to 255 Default: 192.168.111.31	/
Gl	Presets the amount of glucose in an added solution and indicates the amount of glucose in a preinserted one.	0.00-655.35	mmol/L
HCO3-	Presets the amount of sodium bicarbonate in an added solution and indicates the amount of sodium bicarbonate in a preinserted one.	0.0-6553.5	mmol/L
HD Dialysis Fluid Flow	Presets the dialysis fluid flow in HD-DN Treatment.	300-800 Default: 500	mL/min

PARAMETER	DESCRIPTION	VALUE/RANGE	UNIT
Heat Temperature	Presets the temperature of the Heat disinfection	Heat A/Heat B Default: Heat A	/
Heat A	Presets the temperature of the Heat disinfection to 95°C	/	/
Heat B	Presets the temperature of the Heat disinfection to 99°C	/	/
Hemocontrol Use *(See Note 3)*	Enables/disables the Hemocontrol function in Treatment Environment and accordingly updates the "Default Settings" parameter list.	No/Yes Default: No	/
Hemoscan (AFB K)	Activates/deactivates the use of the Hemoscan function during AFB K treatments.	No/Yes Default: No	/
Hemoscan (HD-DN)	Activates/deactivates the use of the Hemoscan function during HD-DN Treatments.	No/Yes Default: No	/
Hemoscan (HDF Post)	Activates/deactivates the use of the Hemoscan function during HDF Post Treatment.	No/Yes Default: No	/
Hemoscan (HD-SN)	Activates/deactivates the use of the Hemoscan function during HD-SN Treatment.	No/Yes Default: No	/
Hemoscan Use *(See Note 4)*	Enables/disables the Hemoscan function in Treatment Environment and accordingly updates the "Default Settings" parameter list.	No/Yes Default: No	/
Heparin	Enables/disables the Heparin function in Treatment Environment and accordingly updates the "Default Settings" parameter list.	No/Yes Default: Yes	/
High Na	Enables/disables High Na Smartscan message	No/Yes Default: Yes	/
High QD	Enables/disables the smartscan option for detection of high value of the ratio Dialysis fluid flow rate/Blood flow rate.	No/Yes Default: Yes	/
High Volume Priming Volume	Presets the default priming volume for high priming mode.	1100 to 4000 Default: 1100	mL
Hours *(see Note 9)*	Presets the current hour of the time displayed in treatment environment.	0 to 23 Default: 0	/

PARAMETER	DESCRIPTION	VALUE/RANGE	UNIT
Id Card Only	When Exalis/Foxalis are disabled, allows to download from the Patient Card only the patient's name, surname and ID and to show them on the *Prescription* screen.	No/Yes Default: No	/
Infusion bag	Preset the infusion bag type to be used in AFB K Treatment.	Hospasol 145, Hospasol 167 Default: Hospasol 145	/
Infusion Flow	Presets the infusion flow rate during AFB K Treatment.	1.0 to 4.0 Default: 1.0	L/h
Infusion Rate During Bolus *(See Note 2)*	Presets the substitution fluid flow rate during bolus infusion in HDF Post Treatment.	20 to 330 Default: 150	mL/min
Initial Dose	Initial heparin dose (Linear and Intermittent Mode).	• 30 mL syringes: 0.0 to 12.0 Default: 0.0 • 10 mL syringes: 0.0 to 4.0 Default: 0.0	mL
Interval (DiaScan)	Presets the time between two consecutive diascan measurements.	15/30 Default: 15	minutes
IP Address (fields 1st, 2nd, 3rd and 4th)	Presets the machine Internet Protocol address (HostID), identifying the univocal machine configuration within the network.	0 to 255 for the 1st, 2nd and 3rd field 1 to 254 for the 4th field Default: 192.168.111.50	/
IP Address (fields 1st, 2nd, 3rd and 4th) (Print Me/Screenshot)	Presets the machine Internet Protocol address (HostID) univocally identifying the machine where the Print Me Manager software application has been installed.	0 to 255 for the 1st, 2nd and 3rd field 1 to 254 for the 4th field Default: 10.21.4.251	/
Isolated UF Use	Enables/disables the Isolated UF function in Treatment Environment.	No/Yes Default: No	/
K+	Presets the amount of potassium in an added solution and indicates the amount of potassium in a preinserted one.	0.00-655.35	mmol/L

PARAMETER	DESCRIPTION	VALUE/RANGE	UNIT
K	Presets the value of potassium concentration in the dialysis fluid during AFB K Treatment.	1.5 to 3.5 Default: 2.0	mmol/L
K Final *(See Note 7)*	Presets the value of potassium concentration in the dialysate at the end of AFB K Treatment in K Profile mode.	1.0 to 3.0 Default: 1.5	mmol/L
K Initial *(See Note 7)*	Presets the value of potassium concentration in the dialysate at the beginning of AFB K Treatment in K Profile mode.	3.1 to 5.5 Default: 4.0	mmol/L
K Profile	Enables/disables the K Profile function during the AFB K Treatment.	No/Yes Default: No	/
Language	Presets the language of the Graphical User Interface.	DAN/DEU/ENG/ FIN/FRA/ITA/ NED/NOR/POR/ RUS/SLO/SPA/ SWE Default: ENG	/
Length (30ml syringe size)	Displays the default length of the 30ml syringe size.	71.6/66.9/80.7/ 68.7/81.6 Default: 71.6	mm
Length (10ml syringe size)	Displays the default length of the 10ml syringe size.	50.7/60.8 Default: 50.7	mm
Low Consumption Use	Enables/disables the Low Consumption function in Treatment Environment.	No/Yes Default: No	/
Low Power	Presets the time interval between the end of the rinse process and the beginning of the Low Power Mode.	0:10 to 24:00 Default: 0.30	h:min
Low QB	Enables/disables the smartscan option for detection of low blood flow rate value.	No/Yes Default: Yes	/
Low QD	Enables/disables the smartscan option for detection of low value of the ratio dialysis fluid flow rate/ blood flow rate.	No/Yes Default: Yes	/
Low Real QB	Enables/disables the smartscan option for detection of low real blood flow rate value.	No/Yes Default: Yes	/
Low Volume Priming Volume (*See Note 5*)	Presets the default priming volume for low priming mode	850-4000 Default: 850	mL

PARAMETER	DESCRIPTION	VALUE/RANGE	UNIT
Lower Interval (Arterial Pressure)	The interval between the current arterial pressure and the minimum safe pressure set.	-10 to -80 Default: -60	mmHg
Lower Interval (Venous Pressure)	The interval between the current venous pressure and the minimum safe pressure set.	-10 to -40 Default: -40	mmHg
Manuf. Log	Enables/disables the Manuf. Log function in Treatment Environment.	No/Yes Default: No	/
Max Heart Rate	Presets the maximum value allowed for the heart rate alarm limit	40 to 200 Default: 120	pulse
Measure Interval	Presets the time interval between the start of an automatic blood pressure measurement and the start of the subsequent one.	0:05 to 1:00 (in steps of 5 min) Default: 0.30	h:min
Mg++	Presets the amount of magnesium in an added solution and indicates the amount of magnesium in a preinserted one.	0.00-655.35	mmol/L
Min Heart Rate	Presets the minimum value allowed for the heart rate alarm limit	30 to 120 Default: 40	pulse
Minutes *(see Note 9)*	Presets the current minutes of the time displayed in treatment environment.	0 to 59 Default: 0	/
Month	Presets the current month.	1 to 12 Default: 1	/
Na+	Presets the amount of sodium in an added solution and indicates the amount of sodium in a preinserted one.	10.0-6553.5	mmol/L
Netroute (IP Address fields 1st, 2nd, 3rd and 4th)	TCP/IP Configuration Address of the machine. Each Artis Dialysis System must have a unique identifier.	0 to 255 Default: 0.0.0.0	/
Next Installation of Rear Ultrafilter	Presets the time interval between two subsequent Ultrafilter replacement reminders.	30 to 90 Default: 90	d
New Password	Allows to insert the new service password for the password change procedure.	/	/

PARAMETER	DESCRIPTION	VALUE/RANGE	UNIT
New Sound Unit	Enables/disenables the use of the New Sound Unit.	No/Yes Default: No	/
Old Password	Allows to insert the old service password for the password change procedure.	/	/
Online Bolus Volume	Presets the bolus volume of the online substitution fluid during HDF Post Treatment.	50 to 1000 (in steps of 10mL) Default: 150	mL
Online Substitution Rate	Presets the substitution fluid flow rate during HDF Post Treatment.	20 to 330 Default: 30	mL/min
Patient Position	Presets the patient position during the blood pressure measurement.	Lying/Sitting/ Standing Default: Lying	/
Ph Maximum (available if the Ph Monitor is preset as "Yes")	Presets the pH value maximum limit during chemical disinfection (Peracetic, Low Peracetic, Bacteriostatic Peracetic and Bacteriostatic Low Peracetic).	7.5-13.0 Default: 7.5	/
Ph Minimum (available if the Ph Monitor is preset as "Yes")	Presets the pH value minimum limit during chemical disinfection (Peracetic, Low Peracetic, Bacteriostatic Peracetic and Bacteriostatic Low Peracetic).	1.0-7.5 Default: 1.0	/
Ph Monitor (available if the PH Probe is preset as "Yes")	Enables/disable the pH monitoring during Peracetic, Low Peracetic, Bacteriostatic Peracetic and Bacteriostatic Low Peracetic disinfection programs	No/Yes Default: No	/
PH Probe	Activates/deactivates the pH sensor and enables/disables pH Monitor button in the *Preset: Disinfection/Rinse* sub-screen for the Peracetic, Low Peracetic, Bacteriostatic Peracetic, Bacteriostatic Low Peracetic disinfection programs.	No/Yes Default: No	/
Pre-Dialyzer Limit TMP Preset	Presets the upper system's pressure limit in Pressure Control mode.	0 to 800 Default: 750	mmHg
Pre-Dialyzer Limit VC Preset	Presets the upper system's pressure limit in Volume Control mode.	0 to 800 Default: 500	mmHg

PARAMETER	DESCRIPTION	VALUE/RANGE	UNIT
Pre-Dialyzer P Threshold	Presets a percentage of the Pre-Dialyzer Pressure Upper Limit that, when reached during an Ultra Scan, should generate a warning.	70-100 Default: 80	%
Print Me	Enables/disables the printing function (displays/hides the Print Me action button) in the Report screen and accordingly updates the “Default Settings” parameter list.	No/Yes Default: No	/
PT Connect PS	Presets the blood flow rate after patient connection.	10 to 150 Default: 100	mL/min
Pump Speed Rate of Change	Presets the default rate of the Arterial Pump speed.	25/50/100 Default: 50	mL/min/s
QF/QB	Presets the ratio between the UF Rate and the Blood Flow Rate Value in Post dilution mode (in AFB K Treatment).	30 to 50 Default: 35	%
QF/QB (Pressure Control)	Presets the ratio between the UF Rate and the Blood Flow Rate Value in Post dilution mode (Pressure Control Mode).	30 to 60 Default: 40	%
QF/QB (Volume Control)	Presets the ratio between the UF Rate and the Blood Flow Rate Value in Post dilution mode (Volume Control Mode).	30 to 50 Default: 40	%
QVen/QArt Ratio	Presets the ratio between the speed of the venous pump and the speed of the Arterial Pump in HD-SN Treatment.	0.5 to 2 Default: 1.33	
Remaining Disinfections	Presets the total number of disinfection programs after which the Ultrafilter replacement reminder is activated.	50 to 150 Default: 150	/
Remaining Hypchlrt Disinfs	Presets the number of Hypochlorite disinfection programs after which the Ultrafilter replacement reminder is activated.	4 to 12 Default: 12	/
Remote Control Use	Enables/disables the Remote Control function in Treatment Environment.	No/Yes Default: Yes	/
Re New Password	Allows to confirm the new service password for the password change procedure.	/	/

PARAMETER	DESCRIPTION	VALUE/RANGE	UNIT
Rinse Time	Displays the duration of the rinse process during chemical disinfection with Peracetic and Bacteriostatic Peracetic.	38:00	min:s
Rinse Time	Displays the duration of the rinse process during chemical disinfection with Low Peracetic and Bacteriostatic Low Peracetic.	27:00	min:s
Rinse Time	Displays the duration of the rinse process during chemical disinfection with Hypochlorite.	94:00	min:s
Rinseback PS	Presets the flow rate of treated blood during rinseback process.	10 to 300 Default: 100	mL/min
Rinseback Volume	Presets the volume of treated blood during rinseback process.	50 to 500 Default: 250	mL
RS 232	Enables/disables the RS 232 serial port (used for communication with external devices) in Treatment Environment.	No/Yes Default: No	/
Safebag	Presets the default Safebag KV concentrate solution type to be used for dialysis fluid preparation in AFB K Treatment.	KV95G/KV93G Default: KV93G	/
Scale Tare Infusion	Presets the alarm limit value for the Hospasol infusion bag end.	30 to 1000 Default: 50	g
Screenshot *(Not currently available)*	Enables/disables the screenshot function in Treatment Environment and accordingly updates the "Default Settings" parameter list.	No/Yes Default: No	/
Secure Levels (ADDR Allowed fields fields 1st, 2nd, 3rd and 4th)	Presets the HostIDs or groups of HostIDs that can communicate with the machine. All the other traffics coming from not authorized HostIDs (that does not belong to those specified) will be rejected.	0 to 255 Default: 0.0.0.0	/
SelectBag Citrate	Presets the default SelectBag Citrate type to be used for dialysis fluid preparation.	Default: CX250G	/
SelectBag One	Presets the default SelectBag One type to be used for dialysis fluid preparation.	Default: AX250G	/

PARAMETER	DESCRIPTION	VALUE/RANGE	UNIT
SelectCart	Presets the default SelectCart type to be used for dialysis fluid preparation.	Default: SelectCart	/
Service Log	Enables/disables the *Service Log* function in Treatment Environment.	No/Yes Default: Yes	/
Skip Optional T1 Tests	Allows to skip some Function Checks after the first treatment of the day, if all the other conditions are satisfied.	No/Yes Default: Yes	/
Sodium	Presets the sodium concentration in the Bicarbonate dialysis fluid.	130 to 160 Default: 140	mmol/L
Srv Port	Presets the number of the Server Port configured in the PC where the Print Me Manager software application has been installed.	1 to 65535 Default: 3030	/
Station ID	Presets the communication code that identifies the location of the Artis Dialysis System in the Exalis room overview window.	1 to 255 Default:50	/
Stop Time	Presets the time interval between the end of the heparin administration and the end of the Dialysis treatment (Linear and Intermittent Mode).	0:00 to 8:00 Default: 0.30	h:min
Stroke Volume (HD-SN Treatment)	Presets the volume of blood taken in by the pump at each stroke in HD-SN Treatment.	20-60 Default: 30	mL
Subnet Mask	Presets a separate subdivision of the network system completing the machine ID Address, identifying the network (NetworkID) and the host identifiers (HostID).	Default: 255.255.255.0	/
Syringes	Presets the default syringe type for heparin administration during dialysis.	Terumo 30ml/Ico 30ml/Pic 30ml/BD 30ml/Penta 30ml/ Terumo 10ml/BD 10ml Default: Terumo 30ml	/
Systolic Lower	Presets the minimum systolic pressure alarm limit.	60 to 200 Default: 90	mmHg

PARAMETER	DESCRIPTION	VALUE/RANGE	UNIT
Systolic Upper	Presets the maximum systolic pressure alarm limit.	90 to 255 Default: 200	mmHg
Target Kt/V	Presets the ionic Kt/V value to be achieved at the end of treatment.	0.10-3.00 Default: 1.20	/
Temperature	Presets the dialysis fluid temperature.	35.5 to 39.5 Default: 37.0	°C
Time *(See Note 1)*	Displays the duration of the heat disinfection process.	34:00	min:s
Time *(See Note 1)*	Displays the duration of the heat disinfection programs (Heat/ Integrated Heat)	34:00	min:s
Time *(See Note 1)*	Displays the duration of the heat disinfection programs (Heat+CleanCart C/ Heat+CleanCart A).	44:00	min:s
Time Display Mode	Presets the mode the current time is displayed.	AM/PM / 24h Default: 24h	/
Time Interval	Presets the time interval between the automatically delivered heparin doses (Intermittent Mode).	0:05 to 2:00 Default: 2.00	h:min
TMP	Presets the Transmembrane Pressure during HDF Post Treatment.	0 to 350 Default: 100	mmHg
TMP Dialysis Fluid Flow	Presets the dialysis fluid flow in Pressure Control mode.	300 to 800 Default: 600	mL/min
Tmp Step Down Resolution	Presets the decreasing quantity of TMP Set Value to be performed in case that, during the Ultra Scan, the TMP reaches the TMP Upper Limit or the Pre-Dialyzer Pressure Upper Limit	20 to 50 Default: 20	mmHg
TMP Upper Limit (AFB K)	Presets the upper alarm limit of the Transmembrane Pressure during AFB K Treatment.	0 to 500 Default: 300	mmHg
TMP Upper Limit (HD-DN)	Presets the upper alarm limit of the Transmembrane Pressure during HD-DN Treatment.	0 to 500 Default: 300	mmHg
TMP Upper Limit (Pressure Control)	Presets the upper alarm limit of the Transmembrane Pressure during HDF Post Treatment.	0 to 450 Default: 350	mmHg
TMP Upper Limit (Volume Control)	Presets the upper alarm limit of the Transmembrane Pressure during HDF Post Treatment.	0 to 500 Default: 300	mmHg

PARAMETER	DESCRIPTION	VALUE/RANGE	UNIT
Treatment Mode	Presets the treatment mode.	HD-DN/HDF Post/HD-SN/AFB K Default: HD-DN	/
Treatment Time	Presets the total treatment time.	0:10 to 8:00 Default: 4.00	h:min
UC Auto Preset Enable	Enables/disables the Ultra Control function autopreset.	No/Yes Default: Yes	/
UC Scan Completed Alarm	Enables/disables the alarm for completed Ultra Control function.	No/Yes Default: No	/
UC Scan Interrupted Alarm	Enables/disables the alarm for interrupted Ultra Control function.	No/Yes Default: No	/
Ultra Control Use	Enables/Disables the Ultra Control function in Treatment Environment.	No/Yes Default: No	/
Ultrafilter Use	Enables/Disables the Ultrafilter function in Treatment Environment.	No/Yes Default: No	/
Unlock Rinse	Unlocks the mandatory rinse following the software installation on the machine.		
Upper Interval (Arterial Pressure)	The interval between the current arterial pressure and the maximum safe pressure set.	+10 to +100 Default: +60	mmHg
Upper Interval (Venous Pressure)	The interval between the current venous pressure and the maximum safe pressure set.	+10 to +70 Default: +70	mmHg
VC Dialysis Fluid Flow	Presets the dialysis fluid flow in Volume Control Treatment Mode.	300 to 800 Default: 600	mL/min
Ven Treatment Max Limit	Presets the maximum venous pressure limit default.	150 to 400 Default: 300	mmHg
Ven Treatment Min Limit	Presets the minimum venous pressure limit default.	10 to 100 Default: 10	mmHg
Volume (30ml syringe size) *(See Note 1)*	Displays the default capacity of the 30ml syringe size.	30	mL
Volume (10ml syringe size) (See Note 1)	Displays the default capacity of the 10ml syringe size.	10	mL
Year	Presets the current year.	2000 to 2036 Default: 2000	/

NOTE 1

This is a default parameter value that cannot be preset or modified.

NOTE 2

This parameter value should be left as default value (150 mL/min) or it can be decreased (below 150mL/min); it must NOT be increased.

NOTE 3

The "Hemocontrol Use" parameter can be enabled only if the "Hemoscan Use" parameter has been previously enabled.

NOTE 4

The "Hemoscan Use" parameter can be disabled only if the "Hemocontrol Use" parameter has been previously disabled.

NOTE 5

This parameter is available only if the "Autopriming Mode" is preset to "Low Volume".

NOTE 6

The "BiCart Select" and "BiCart Citrate" parameters can be enabled only if the "BiCart Select Use" and "BiCart Citrate Use" parameters have been previously enabled.

NOTE 7

This parameter is available only if the "K Profile" parameter has been previously enabled.

NOTE 8

For a complete description of the Service 2 menu, refer to the "Artis Service Preset Manual" for service technician.

NOTE 9

The default value related to this parameter is automatically updated by the Artis Dialysis System.