Important Information

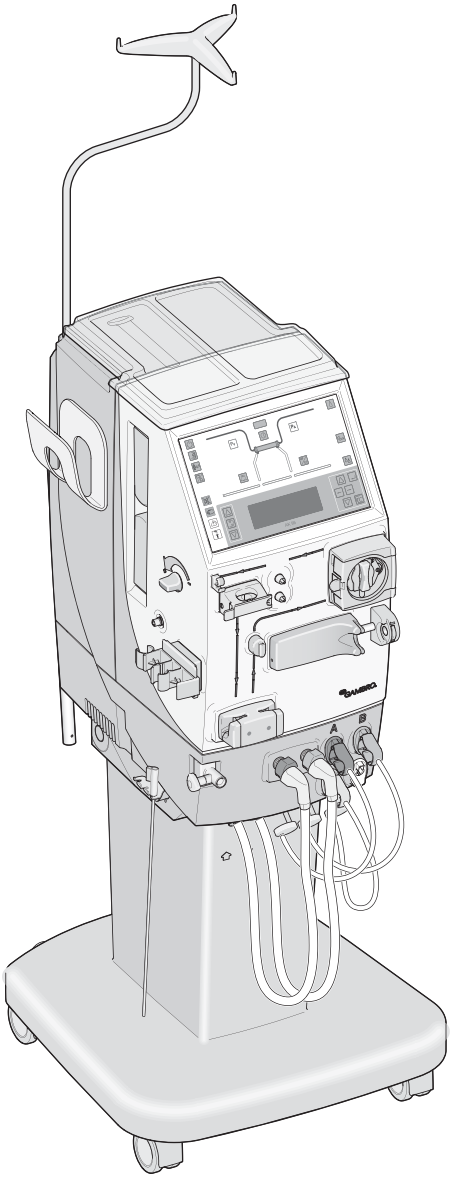
Concerning this manual; Operator's Manual, AK 96 Dialysis machine, Program version 3.xx, Rev 12.2010

Dear operator,

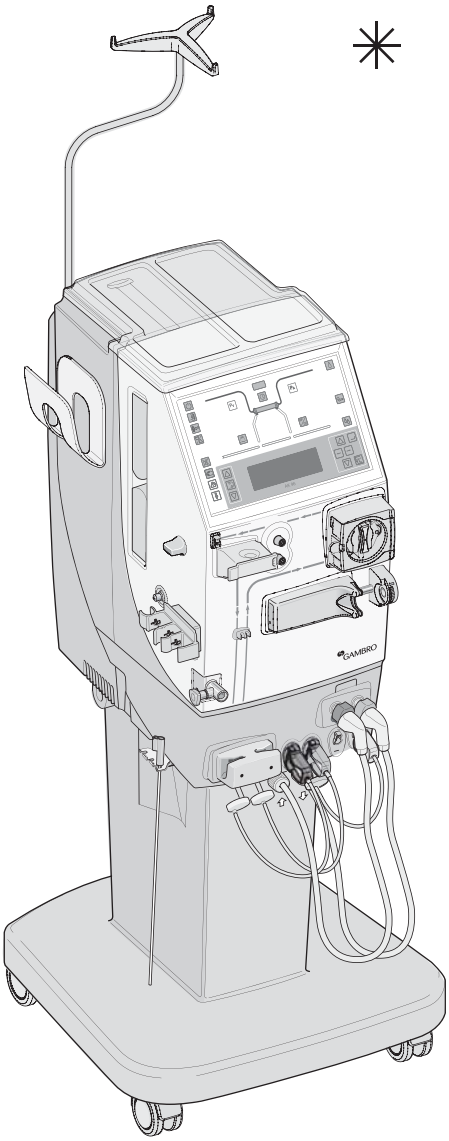
The exterior of the machine that you are using might be different in appearance from the exterior described in this manual. If there is a difference, this is because you are using a previous version of the machine.

Whenever this asterix symbol ✳ appears in the manual, it indicates that it is the previous version of the machine.
The differences are to be found in chapter 2 and 4.

Machine in this manual



Previous version of the machine ✳



AK 96® Dialysis Machine

Operator's Manual

For use with program version 3.xx

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Questions or comments about this publication can be directed to your local representative or to the manufacturer.

Order number:

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Patents:

The AK 96 dialysis machine is protected by one or more of the following patents:

US: 5173125, 5792367, 5567320, 7246530, 7435235

EP: 745213, 658352

CA: 1327022, 2138354

DE: 69528156T2, 69406253, 69406257

ES: 2109643

FR: 9403710

JP: 3183528, 3618352

KR: 94404

SE: 524229

The AK 96 dialysis machine is protected by one or more of the following designs:

WO: DM/070849

EU: 000747811–0001 – 000747811–0007

AL: 420833801

AU: 318776 – 318782

CA: 123590

IN: 213741, 213742

KR: 497613

AK 96® Dialysis Machine
Operator's Manual
Program version 3.xx

Note

- Please observe that this part of the Operator's manual for the AK 96 dialysis machine is one out of three. To assimilate these instructions the complete manual must be available. For information see “How To Use this Manual” on page 1:2 in part 1.

Note

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Chapter 1

Before you get started - General Information

Contents

How To Use this Manual

This Operator's Manual for the AK 96 dialysis machine is divided up into three parts according to their contents. The reason for this is ease of access for the operator of the machine. **It is important to observe that the parts should be considered as one document** in spite of the fact that it is printed in three separate parts. This means that things like references and index extend over the complete manual. Furthermore, note that **all** alarms and attention alarms are described in the third part, the “Alarm Handbook”.
The first part; “Base Manual for General Use” include instructions on how to generally use and run the machine.
The second part; “Instructions for Measurement Functions” include instructions on how to use the optional BPM (Blood Pressure Monitor) and Diascan function.
The third part; “Alarm Handbook” include all alarms and attention alarms originating from all functions of the machine.

The first part is printed in A 4 format, the second and third in A 5. The parts are put in a box which should be considered as cover of the complete manual. Conseqently, when the manual needs to be changed to a more recent version due to updating of the machine program version, the complete manual (all three parts) needs to be changed at the same time.

How to find what you are looking for

To be able to find what you are looking for in this manual, first read the brief explanation of how the chapters are structured and intended to be used further on in this section. Then use the table of contents either at the beginning of the complete manual or at the beginning of each chapter. There is also an index included last in each part extending over all three parts of the manual.

References to pages within the manual are shown with two figures, divided by a colon. The first figure is the chapter number and the second is the page number. For example; page 4:10 would be chapter 4, page 10. The first page in all three parts is the same, i.e. an overview of which chapter numbers are included in which part.

A small reference number beside the figures within the manual has been added to simplify manual production.

On the following pages is a brief explanation of how the parts and chapters in this manual are structured and are intended to be used.

Chapter Descriptions

Part 1; Base Manual for General Use

Chapter 1; Before you get started - General Information
This chapter contains information to be read before using the AK 96 dialysis machine.

Chapter 2; Description - The Machine and its Components
This chapter contains component descriptions (terms and details) of the blood part, the fluid part and the rear of the machine.

Chapter 3; Operating the Machine - Handling Guidelines
This chapter contains explanations of how the machine is to be controlled. For example, how to use the buttons and the keypad of the Operator's panel together with the menus on the Information Display. Furthermore in this chapter, the alarm functions are described and how parameters are to be set. How to use handling features of the machine are also explained here. The overview screens displayed on the Information Display are explained as well as the ultrafiltration control, and information is provided on what to do if a power failure occurs.

Chapter 4; Hemodialysis - Double Needle Treatment
This chapter contains instructions on how to perform hemodialysis with two needles, using the AK 96 dialysis machine. The chapter begins with how to start the machine and continues with how to attach the dialyzer and the blood lines, the priming procedure, starting the treatment and setting of parameters. It finishes with the discontinuing procedure.

Chapter 5; Hemodialysis - Single Needle Treatment (option)
This chapter contains instructions on how to perform hemodialysis with one needle. The chapter is based on chapter 4 "Hemodialysis - Double Needle Treatment" starting on page 4:1 in part 1, with added specific instructions for single needle treatment.

Chapter 6; Isolated Ultrafiltration
This chapter contains instructions on how to perform isolated ultrafiltration.

Chapter 7; Profiling
This chapter contains instructions on how to use the profiling function for ultrafiltration, as well as for the dialysis fluid concentration of sodium and bicarbonate.

Chapter 8; Hygiene and Maintenance
This chapter contains information and instructions concerning the hygiene and maintenance of the machine that should be carried out by the operator of the machine. The chapter begins with a general section where a schedule for hygiene and maintenance is included. The Hygiene sections contain general information and instructions on how to perform the disinfection programs. The Maintenance sections include instructions on the maintenance of the flow path and the exterior of the machine.

Chapter 9; Technical Data and Specifications

This chapter contains technical specifications of the control and supervisory systems of the machine. It also includes physical data, materials which come into contact with water, concentrates and dialysis fluid, environmental data and a list of standards which the machine complies with.

Chapter 10; Major changes in operator's manual

This chapter includes brief information about major changes between the current and previous program versions of the machine that have been made in the manual. The changes mentioned are mostly information concerning the operation of the machine and are specifically addressed to the operator.

Part 2; Instructions for Measurement Functions

Chapter 11; BPM – Blood Pressure Monitor (option)

This chapter contains instructions on how to use the BPM (if installed), which measures blood pressure and pulse rate. A particular blood pressure measurement cuff and a cuff hose are to be used. The chapter includes explanations of how the BPM is handled using the *BPM button* and the BPM screens, and also describes the alarm function. The BPM can be used manually if only one measurement check is to be done, or at set intervals during treatment.

Chapter 12; Diascan® function (option)

This chapter contains instructions on how to use the Diascan function, which measures clearance (K) and dialysis dose (Kt or Kt/V). The chapter is divided into two parts where the first section includes general information about the Diascan function, explanation of the Diascan screens and the alarm functions. The second section includes step-by-step instructions for measuring clearance and Kt/V, single or continuous measuring.

Part 3; Alarm Handbook

Chapter 13; Alarms

This chapter contains a list of alarms. The list includes additional information concerning possible causes and suggestions about measures to be taken for each alarm.

Chapter 14; Attention Alarms

This chapter contains a list of attention alarms. The list includes additional information concerning possible causes and suggestions about measures to be taken for each attention alarm. The attention alarms in the list is shown in alphabetical order.

Definitions of Expressions used in this Manual

Warning

WARNING

⚠ Is used to alert the user/operator **not to take** a certain action, which if taken can cause a potential hazard and result in a serious adverse reaction, injury or death. A warning may also be used to alert the user/operator **to take** a certain action to avoid the potential hazard as above.

WARNING

Caution

CAUTION

! Is used to alert the user/operator **to take** a certain action to protect against a possible hazard which, if ignored, could have an adverse effect on the patient or the equipment. A caution may also be used to alert the user/operator **not to take** a certain action to avoid the potential hazard as above.

CAUTION

Note

Note

- A reminder to the user/operator on normal treatment activity and on what is a suitable action in a particular situation.

Note

Other Keywords used in this Manual

User
A User in this manual, designates a person who has the comprehensive responsibility for how the AK 96 dialysis machine is being used. The user decides which clinic routines are applicable for the AK 96 dialysis machine.

Operator
An Operator in this manual, designates a person who has knowledge of and has been trained in hemodialysis and is in charge of the machine i.e. makes the machine settings which have to be done before, during and after the hemodialysis treatment. The operator is sometimes referred to as ”You”.

Authorized technician
The Authorized technician is a technician who has been through Gambro training on the AK 96 dialysis machine and has received a Gambro certificate or has gained equivalent knowledge in some other way.

Machine
Whenever the word Machine is used within this manual, machine always refers to the AK 96 dialysis machine if no other is written.

Manual
Whenever the word Manual is used within this manual, manual always refers to this Operator's Manual for the AK 96 dialysis machine if no other is written.

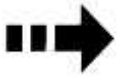
Option
Sometimes functions and machine components are marked Option, meaning that the machine may not be equipped with the described function/component. Sometimes the option is a function/component of which the machine has been manufactured with and sometimes the option can be implemented by an authorized technician afterwards upon request.

Figures

There are different type of figures included in this manual. Screens and menus shown on the Information Display are one type of figure. These figures are a direct "shot" of the Information Display of the machine and have not been revised afterwards in order for the operator to recognize current machine displays for the ongoing procedure. Some figures illustrate handling or point out components of the machine. To highlight certain items or illustrate movements arrows have been included in these figures.

This "straight arrow" in figures points out details described in the corresponding text. The arrow can also show a direction, i.e. if something is to be moved in a certain direction.

This "curved arrow" in figures shows a direction of a rotation. This can be the direction of something that is to be connected or opened/closed.



This "pressure arrow" appears in figures when something is to be pressed in or pulled out. The point where the arrow points to is the pressure/pulling point.

In addition, to highlight certain items, the details that the describing text in the instructions aims at, are highlighted in gray in the corresponding figure.

The buttons on the operator's panel light up in different situations to guide the operator or to inform of current status. If the button is lit or not is not normally illustrated in the handling instructions; the button figures are the same for lit, flashing and not lit buttons. This is valid for all instructions except for the alarm list (see "Alarm List" on page 13:9 in part 3) where the button figures also show status in order for the operator to apprehend the instructions fully.

This is an example of a lit button.

This is an example of a flashing button.

A small reference number beside the figure has sometimes been added to simplify manual production.

Symbols

Symbols within this Manual

When this symbol appears in the manual text, it indicates that it is possible to preset the value of a parameter. The preset can be done to adapt the settings of the machine to correspond with the routines of the user/clinic. It has to be done by an authorized technician.
All values mentioned in this manual are default values set in the machine when it was manufactured. It is important to check with the authorized technician if values have been changed, and if so, which ones.
For instance, it is possible to preset the machine for which mode to start up in, some alarm limits, some functions and options.

This symbol appears at the right hand side of a page when there is more important information to be read on the following page (there is not enough room for all assembled information on the same page). Please continue your reading to obtain the complete information.

In lists, different icons in front of the items show how the lists are to be used.

1. A numbered list is to be followed from the beginning to the end. This kind of list mostly appears in handling instructions.

- In a bullet list not all items may be valid and the items in the list are not presented in a particular order.

☑ A checkbox list is used when a number of items should be checked before a procedure is performed.

- In a dashed list all items are valid but are not presented in a particular order.

Symbols within the User Interface

See chapter 3, "Buttons" starting on page 3:8 in part 1.

Symbols fixed on to the Machine

All symbols in the list below may not be represented on this product. The symbols can be attached to the machine or attached to the original packaging.

Symbol	Description
	Alternating current
	Protective earth (ground)
	Warning, consult accompanying documents
	Off (power, disconnection from the mains)
	On (power, connection to the mains)
	Type B, applied part
	NIBP type BF applied part, defibrillator proof
	Do not stack
	Fragile – Handle with care

Symbol	Description
	This way up
	Keep dry
	Year of manufacturing
	Equipotentiality
	Separate collection for electrical and electronic equipment
IPX1	The AK 96 dialysis machine is protected against dripping water
	Warning, Dangerous voltage. Contact may cause electric shock or burn.
	The label is yellow with a black frame and icon. This symbol is a warning label not to tilt the machine through an angle of more than 5°.

WARNING

⚠ If a remote operator's panel has been installed, fluid bags must be removed from the infusion pole or placed on the top tray when transporting (moving) the machine.

WARNING

General Precautions before use

WARNING

⚠ Unauthorized modifications, alterations or repair and lack of maintenance or calibration of the AK 96 dialysis machine may result in malfunctioning or have other serious consequences for the safe operation of the equipment.

WARNING

CAUTION

- The AK 96 dialysis machine may only be operated by persons trained in hemodialysis and who have studied the instructions in this manual. The user/operator should draw special attention towards the text valid for the safety philosophy of the machine. See section "Safety Philosophy" on page 1:15 in part 1. Verify that the first digit of the program version of both the machine and the manual is the same. If the AK 96 dialysis machine does not perform as described in this manual, it should not be used until the condition is rectified.

- When unpacking, check the equipment for any signs of damage. If the equipment is in any way damaged, proper operation cannot be assured.

- Patients connected to the AK 96 dialysis machine should be monitored by competent personnel since life threatening situations can arise that may not activate alarms. The operator should pay attention to all appropriate alarms and follow the instructions, warnings, cautions, and notes given in this manual. It is imperative that the machine has passed the function check before connecting to a patient.

- During installation all calibration checks must be completed before the machine is used for dialysis treatment.

- The AK 96 dialysis machine needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in part 1and chapter 9, "Technical Data and Specifications".

- The use of mobile telephones or communication equipment in the vicinity of the AK 96 dialysis machine could adversely influence the performance of the machine. For further information, see part 1 and chapter 9, "Technical Data and Specifications".

- The AK 96 dialysis machine will perform as designed only if it is used and maintained in accordance with Gambro's instructions. Any warranties made by Gambro with respect to the AK 96 dialysis machine are void if the equipment is not used in accordance with the instructions provided. Gambro will not accept responsibility for any damage or injury resulting from improper use or maintenance or unauthorized repair.

CAUTION → → →

→ → → CAUTION

Preventive inspection, maintenance and calibration of the AK 96 dialysis machine shall be performed by a fully trained authorized service technician according to the Maintenance Manual in the AK 96 Service Manual which can be ordered from your Gambro representative. It is mandatory for preventive maintenance to be performed at least every other year. Yearly maintenance is recommended. The interval between preventive maintenance procedures might differ due to operating environment variations.

The AK 96 dialysis machine is in compliance with certain requirements concerning patient leakage current from the dialysis fluid in accordance with international standards and regulations. When a central venous catheter is used, and the tip of the catheter is close to the heart, it is however necessary to take extra precautions to minimize the risk of arrythmia due to leakage currents. For these treatments it is necessary to connect the potential equalization conductor between the AK 96 dialysis machine and the potential equalization bus bar in the electrical installation. Potential equalisation also has to be used when legal requirements of the installation place requires it.
To minimize the leakage currents from other electrical equipment it is recommended to place such equipment outside the patient area. Any equipment within the patient area shall fulfil the IEC 60601-1 and IEC 60601-1-1 standards and be a part of the potential equalization. One way to minimize the leakage currents from equipment within the patient area is to electrically isolate it. Make sure leakage current values are below respective limit required by CF type applied parts. Check with authorized technician.
If your clinic/hospital uses a central venous catheter during treatments please make sure your machine is equipped with a potential equalization connection. If not please contact your local Gambro Service Technician for further assistance.

The AK 96 dialysis machine is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

CAUTION

Note

- This Operator's Manual provides instructions necessary for the proper operation of the AK 96 dialysis machine. It is not a guide for the administration of hemodialysis.
- Machines are not disinfected before delivery. Always perform a chemical disinfection after installation, before initial use.
- When accuracy ranges are written as e.g. "(±1 ml/min or ±1%)" the widest range is valid.
- During transportation and storage the equipment has to be kept in its original packing. If transportation or storage time is more than 15 weeks the environmental data relating to the operation has to be followed.
- For the authorized technician the Service Manual for the AK 96 dialysis machine is available. The Service Manual provides all of the necessary information for installation and safe and required maintenance of the machine.
- It is important that the protective earth in the installation is of high quality.
- For the purpose of protecting the environment the AK 96 dialysis machine must not be disposed of with general domestic waste, but shall be separately collected for dismantling and recovery. Where applicable, national regulations shall be applied. Consult your local Gambro distributor for information.
- The AK 96 dialysis machine is intended for continuous operation.

Note

Intended Use

The Gambro AK 96 dialysis machine is designed to be used as a single patient machine to perform hemodialysis treatments upon prescription by a physician. Patient counselling and teaching of treatment techniques are directly under the supervision and discretion of the physician.

CAUTION

- Patient education, counselling, home care follow-up and medical maintenance must be performed under the direction and supervision of the physician prescribing the treatment. Gambro specifically denies any responsibility for patient education, counselling or home care and medical maintenance.

- When the AK 96 dialysis machine is used to produce bicarbonate containing dialysis fluid originating from non-liquid concentrates, the AK 96 dialysis machine is designed and validated for use with the Gambro BiCart cartridge. Gambro does not accept responsibility for use of other non-liquid concentrate containers.

CAUTION

Safety Philosophy

The AK 96 dialysis machine is designed according to the current standards for hemodialysis equipment, IEC 60601-2-16. This means that safety under so-called Single Fault Conditions is granted. In practice this means that controllable treatment parameters (i.e. conductivity, temperature and ultrafiltration) are controlled by one system, the **control system**, and monitored by another completely separate **protective system**, utilizing its own sensors, electrical circuits and microprocessors. The functionality of the protective system is checked by the AK 96 dialysis machine before each treatment. A fault detection during the pre-treatment tests will make it impossible to start the treatment.

In order to verify that the corresponding control and protective systems are operating with the correct input values, the user is instructed to compare the readings from these systems before connecting to the patient. Check that the calculated conductivity values (C/P) displayed in the conductivity menu are in agreement. If this comparison is not satisfactory, call an authorized technician.

The protective system will, when a parameter (measured by the protective system) is outside the alarm limits, put the AK 96 dialysis machine into a patient-safe condition. This means that the protective system can stop the blood pump, close the venous clamp, prevent the dialysis fluid from reaching the dialyzer and alert the operator with sound and light.

There is a risk that the blood of the patient may be contaminated with bacteria and endotoxins due to transport of undesired substances from the dialysis fluid compartment to the blood compartment of the dialyzer. This risk is reduced by using intact dialyzers, high inlet water quality, high quality of concentrates and by using the optional ultrafilter for dialysis fluid.

Ultrafiltration

For the ultrafiltration control system, the transmembrane pressure (TMP) is used as the protective system. Alarm limits for TMP related to the dialyzer UF coefficient and the expected UF rate, are to be set around the actual TMP value when starting treatment. The TMP alarm limit correspond to a UF-deviation limit described by $TMP_{Alarm\ limit}$ x $UF_{coefficient}$. Example: If the alarm window is set to ±50 mmHg and the UF-coefficient is 10 ml/mmHg x h the maximum weight deviations without any alarm is ±500 g/h. Default the alarm window is set to ±100 mmHg. It is essential to ensure that the alarm window is set as close as possible to the working TMP. As an additional precaution it is recommended that the blood pressure is checked regularly.

Venous pressure

To protect the patient against a hazardous blood loss to the environment AK 96 dialysis machine incorporates a venous pressure monitoring system. This system will react on a change in the venous pressure,

i.e. when the pressure falls below the low alarm limit. It must be observed that under certain pressure/flow conditions a blood loss to the environment may not be able to cause the venous pressure to fall below the low alarm limit. To avoid blood loss to the environment it is essential to ensure that all connections in the extracorporeal blood circuit are tight and secured, that the fistula needle is correctly positioned and secured and that the low alarm limit is set as close as possible to the working venous pressure.

The venous pressure measuring system is the protection against blood loss to the environment. This measuring system is automatically checked before each treatment. A failure will make it impossible to start the treatment.

Blood pump

The supervision of the stop time of the blood pump is the protection system against patient blood loss due to coagulation during treatment. The operator will be notified via an attention alarm that the blood pump stop time has been exceeded.

Blood leak detector

The blood leak detector system, which utilizes an optical sensor, is automatically tested before each treatment for being able to detect transparency (no blood) and non-transparency (blood) before each treatment. If the system cannot detect these states, it is impossible to start the treatment.

Air detector

The air detector utilizes an ultrasonic sound sensing system in which the transmitter is handled by one microprocessor and the receiver is handled by both microprocessors in the protective system. The system is tested pre-treatment for parameter deviation in terms of sensitivity change.

Any infusion/transfusion/medication given to the patient via the extracorporeal blood circuit of the AK 96 dialysis machine during treatment, must pass the venous drip chamber and the activated air detector. Instructions for infusions can be read in "Infusions during Treatment" on page 3:36 in part 1.

Chemical disinfectant intake

The AK 96 dialysis machine is designed to take in chemical disinfectants via a permanent connection. For this reason, the machine is equipped with an extra valve within the protective system. The machine automatically checks before each treatment if a chemical disinfection program has previously been performed and if so, the chemical intake valves are automatically checked during function check. A failure will make it impossible to start the treatment.

The Preparation of Dialysis Fluid

Inlet Water Requirements

The chemical and microbiological quality of the water used to prepare fluids for dialysis is an important factor for achieving and maintaining the proper quality of the dialysis fluid.

The quality of the water depends on the technical equipment for water treatment. Further, proper maintenance of the water treatment system and of the water distribution loop is essential.

The inlet water must comply with valid standards for water for dialysis; see "Water supply" on page 9:11 in part 1 for more details.

Preparation of the Dialysis Fluid

The AK 96 dialysis machine prepares dialysis fluid from inlet water and concentrates.

The dialysis fluid should be made from an acidic (A) concentrate and a dry bicarbonate concentrate (such as the BiCart cartridge). It can also be made from an acidic (A) concentrate and a liquid bicarbonate (B) concentrate or from an acetate concentrate. See "Concentrates" on page 1:19 in part 1.

UFD- Ultrafiltered Dialysis Fluid (option)

The AK 96 dialysis machine can be equipped with a holder in which an ultrafilter can be mounted. The ultrafilter purifies the dialysis fluid from possible contamination by bacteria and endotoxins.

Ultrafilter - Frequency of Change

The ultrafilter used when preparing Ultra Filtered Dialysis Fluid is to be changed regularly depending on the primary fluid quality and the desired final fluid quality. The results from microbiological controls have to determine the frequency of change. A frequency between once a month and once every three months can be expected.

For instructions on how to change the ultrafilter, see “Ultrafilter - How to change" on page 8:39 in part 1.

List of Concentrates, Accessories and Disposables

This manual contains a number of references to concentrates, accessories and disposables for use with the AK 96 dialysis machine. For ease of reference, set out below is a comprehensive listing of such concentrates, accessories and disposables as follows.

CAUTION

- The AK 96 dialysis machine has been tested and validated for use with the concentrates, accessories and disposables specified as follows.
- Gambro does not accept any responsibility or liability for use of concentrates, accessories or disposables other than those specified as follows. Depending on the circumstances, use of concentrates, accessories or disposables other than those specified may also reduce Gambro's warranties for the AK 96 dialysis machine.
- Observe the manufacturer's instructions for use regarding single use of blood lines and dialyzers.

CAUTION

Note

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

Note

Concentrates

CAUTION

Incorrect choice of dialysis fluid concentrate may cause incorrect composition of the dialysis fluid. Incorrect composition may lead to electrolytic imbalance in the patient's blood.

CAUTION

Liquid concentrates	**Area of use**
001-099 series	Liquid acetate concentrates for preparation of acetate dialysis fluid.
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.
Non-liquid concentrates	**Area of use**
BiCart® cartridge	Dry bicarbonate concentrate for preparation of bicarbonate dialysis fluid together with proper liquid A-concentrate.

Lines

Line number	Area of use
Gambro Medical Line (PVC+DOP/ EtO sterilized)	
BL 10 series	Arterial and venous blood line set
BL 100 series	Arterial and venous blood line set
AV 100 series	Arterial and venous blood line set
A 5000 series	Arterial blood lines Note especially the Warning text below concerning pediatric blood line set
V 5000 series	Venous blood lines Note especially the Warning text below concerning pediatric blood line set
Gambro Blood Tubing System (PVC+DOA/Beta sterilized)	
BL 200 series	Arterial and venous blood line set
Gambro Accessories	
C series	Hemodialysis accessories
C 705	A connection line with an expansion chamber. Used in single needle mode.

WARNING

⚠ Do not use the pediatric blood lines; A-5.128-B4 or V-5.127-X. The blood line clamps of the AK 96 dialysis machine cannot clamp these thin blood lines.

WARNING

Dialyzers/Ultrafilter

Dialyzer/Ultrafilter	Area of use
U9000®	Ultrafilter used when preparing Ultra Filtered Dialysis Fluid.
Dialyzers	Most types of dialyzers, except plate dialyzers, 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 AK 96 dialysis machine, with regards to e.g. the maximum UF coefficient and the recommended priming procedure. The connectors and the ports of the dialyzer must comply with ISO 8637 and EN 1283.

Blood Pressure Measurement Accessories

Gambro Cuff	Size
Adult	23 - 33 cm
Large Adult	31 - 40 cm
Small Adult	17- 25 cm
Child	12 - 19 cm
Gambro Cuff (single hand)	**Size**
Adult	28 - 37 cm
Large Adult	36 - 46 cm
Small Adult	21 - 29 cm
Gambro Cuff hose)	
3.0 m	Cuff hose used for measuring blood pressure together with the AK 96 dialysis machine.

Certification marks

CE 0086

CE-marking

The CE-conformity mark indicates that the AK 96 dialysis machine conforms to the requirements in the EC Council Directive 93/42/EEC of 14 June, 1993 concerning medical devices. It also indicates that the notified body British Standards Institution (BSI, No. 0086) has approved the Quality Management System. The CE conformity mark is only valid for the AK 96 dialysis machine. Disposables and any accessories specified for use with the AK 96 dialysis machine are marked with CE conformity marks in their own right.

CSA-marking

The CSA mark indicates that the AK 96 dialysis machine conforms to the requirements related to safety of medical devices for Canada and that the AK 96 dialysis machine has been evaluated to the applicable CSA standards for use in Canada.

CCC-marking

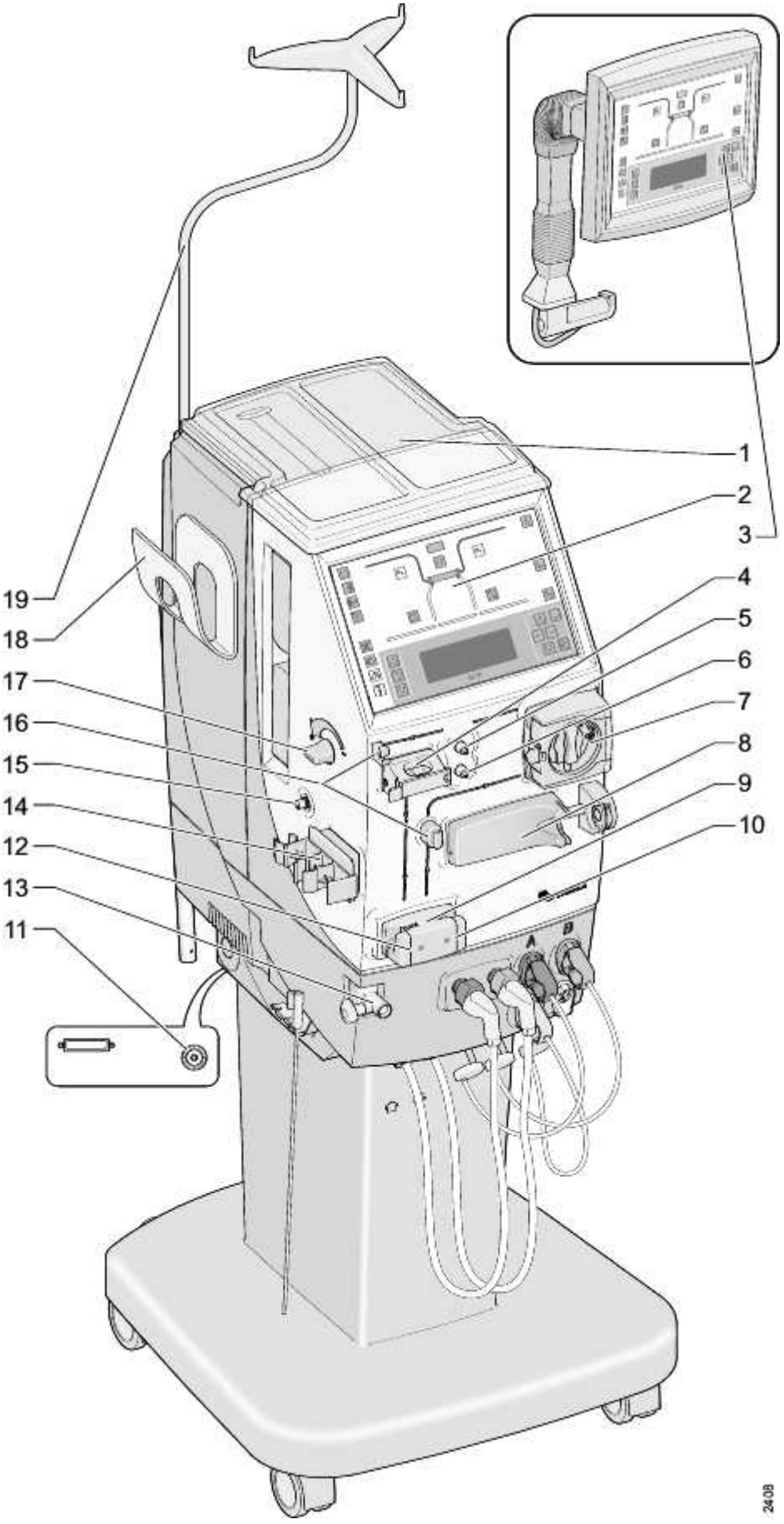
The CCC mark indicates that the AK 96 dialysis machine conforms to the safety requirements for China Compulsory Certification (CCC) as described by the competent authority Certification and Accreditation Administration of People's Republic of China (CNCA). The "S" adjacent to the CCC mark indicates that safety requirements are met.

Chapter 2

Description - The Machine and its Components

Contents

The Blood Part of the Machine



Blood Part Component Terms

The list below shows positions and terms, for the components pointed out in the overview picture of the blood part of the machine (see figure on the previous page). A detailed description where each component is described separately, sometimes with informative text included, follows next in this section.

1. Top Tray

2. Operator's Panel

3. Remote Operator's Panel (option)

4. Air Detector

5. Venous Pressure Transducer Connector

6. Arterial Pressure Transducer Connector

7. Blood Pump

8. Heparin Pump (option)

9. Priming Detector

10. Arterial Blood Line Clamp (option)

11. Potential Equalization Connection

12. Venous Blood Line Clamp

13. Arm for Dialyzer Holder

14. Expansion Chamber Holder

15. BPM Connector (option)

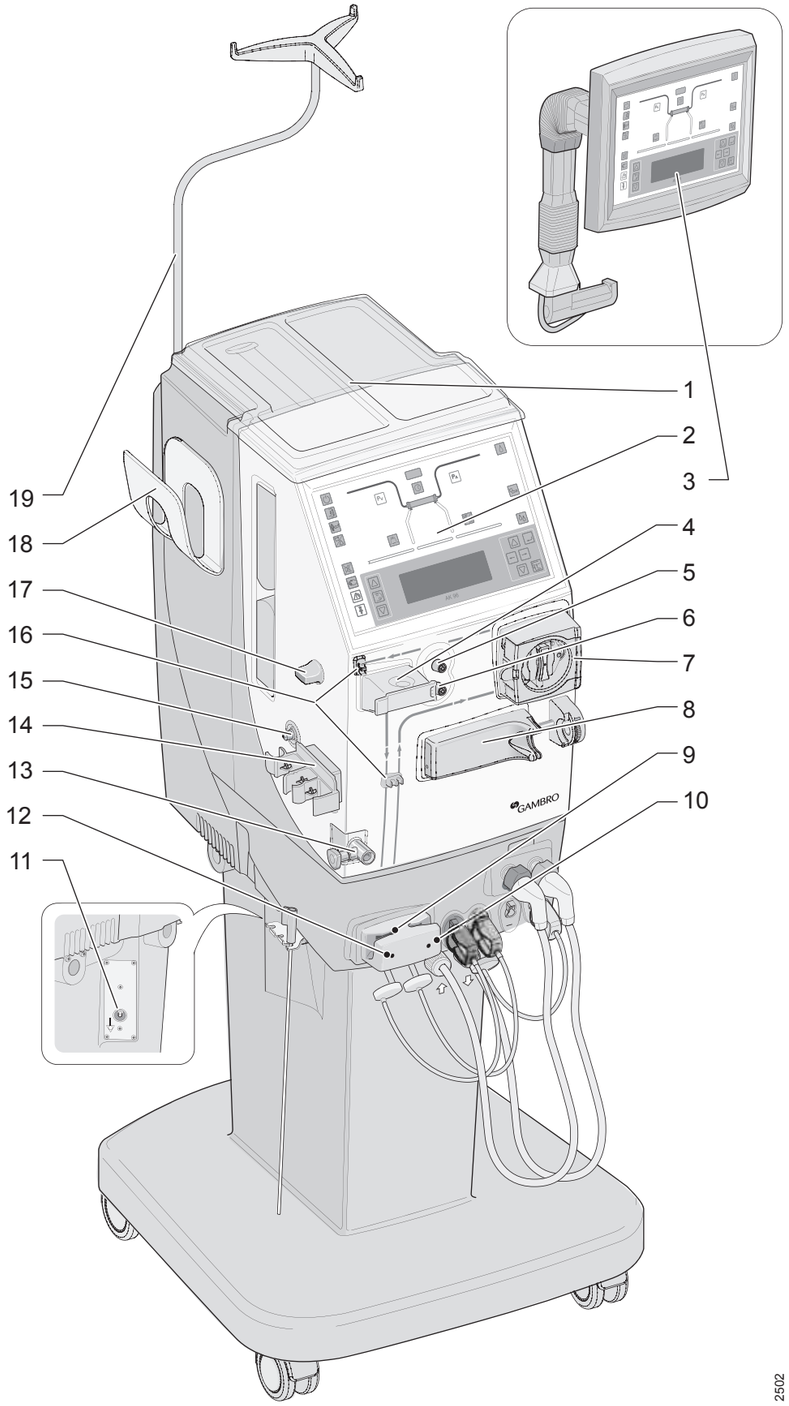
16. Blood Line Guides

17. Level Adjustment Knob

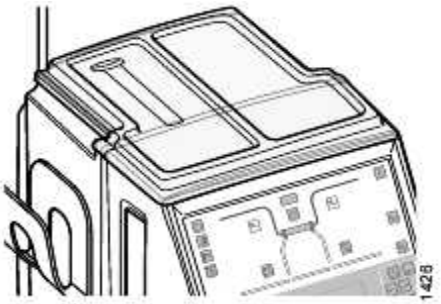
18. BPM Cuff Holder (option)

19. Infusion Pole

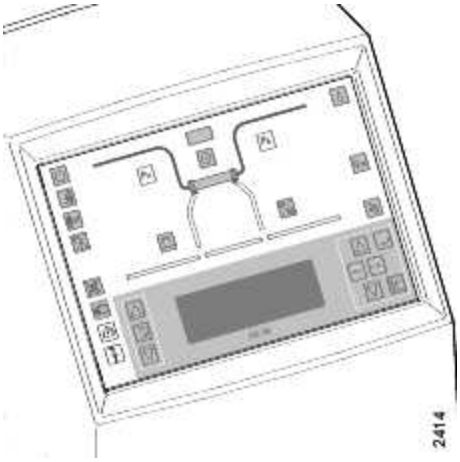
The Blood Part of the Machine



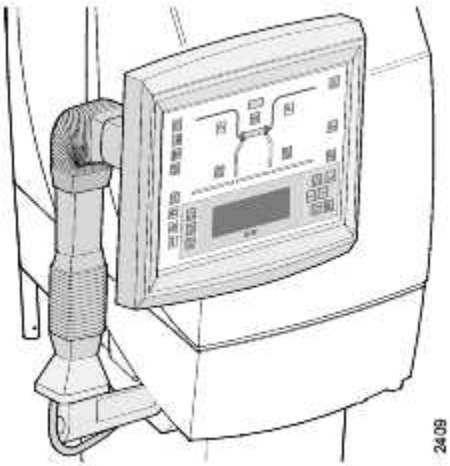
Blood Part Component Details



1. **Top Tray**
   To protect the machine against spillage, the top tray must always be correctly placed on top of the machine.



2. **Operator's Panel**
   The parts of the operator's panel are described in "The Operators Panel" on page 3:6 in part 1.

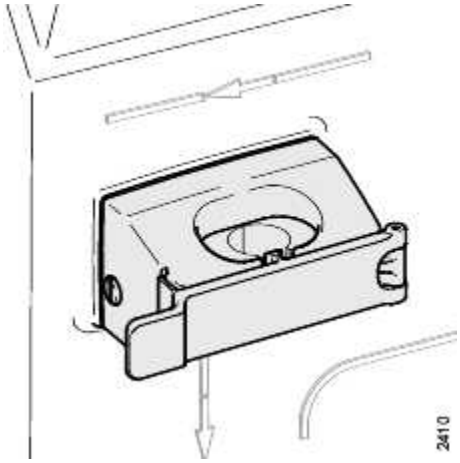


3. **Remote Operator's Panel** (option)
   The operator´s panel can be mounted in an external housing. This Remote Panel is easy to adjust in different positions. The handling procedures are the same as for the usual operator's panel.

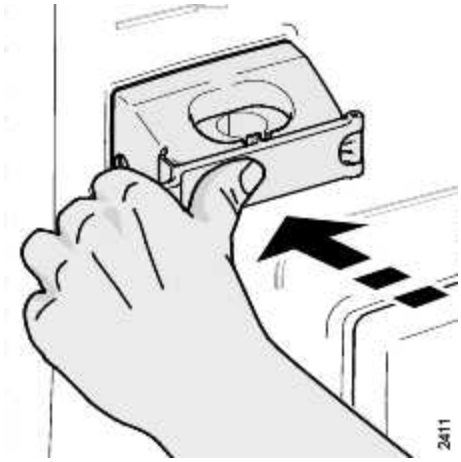
WARNING

⚠ If a remote operator's panel has been installed, fluid bags must be removed from the infusion pole or placed on the top tray when transporting (moving) the machine.

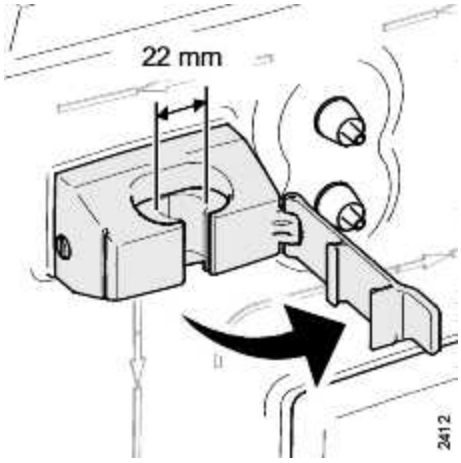
WARNING



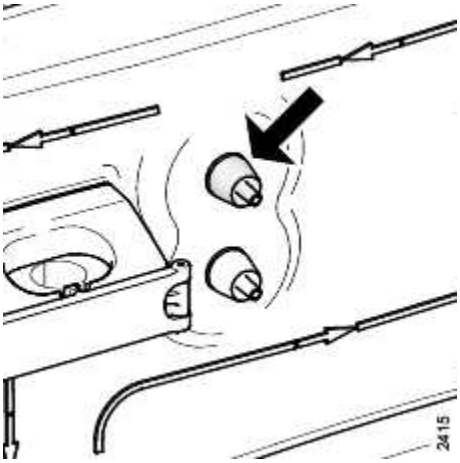
4. **Air Detector**
The ultrasonic air detector will detect air or foam in the venous drip chamber.



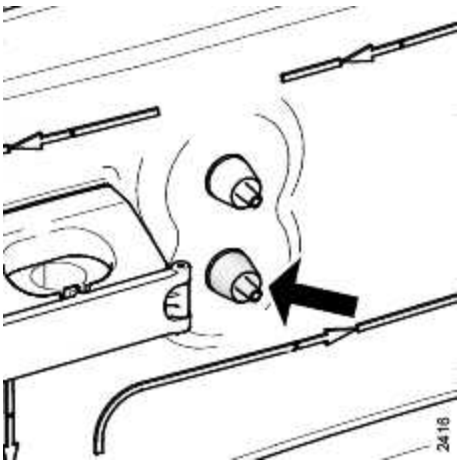
The air detector cover may be opened with ease by pressing the middle of the cover at the same time as the cover is being opened, as shown in the corresponding figure.



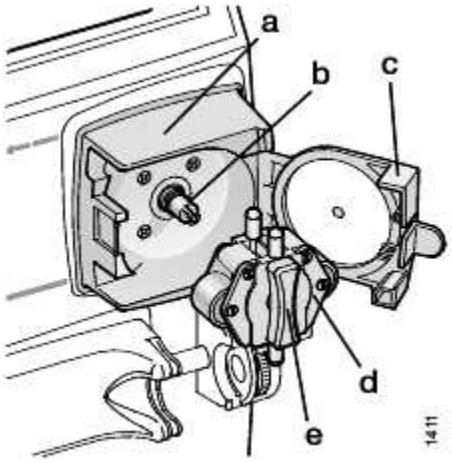
The air detector head is designed for a drip chamber with a diameter of 22 mm. Instructions on how to attach the venous drip chamber of the venous blood line in the air detector, can be read in "Venous Blood Line - Attach" on page 4:28 in part 1.



5. **Venous Pressure Transducer Connector**
The pressure in the venous drip chamber is measured when the venous pressure transducer of the venous blood line is attached properly to this connector. Instructions on this can be read in "Venous Blood Line - Attach" on page 4:28 in part 1.



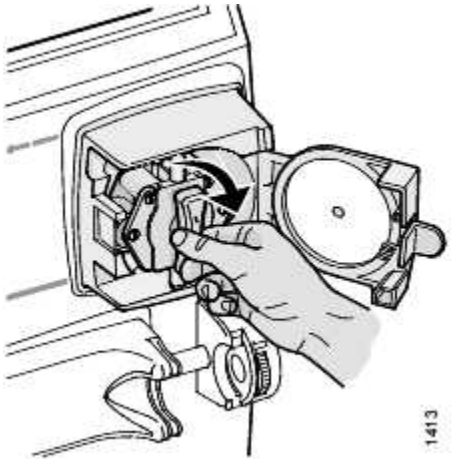
6. **Arterial Pressure Transducer Connector**
The pressure in the arterial blood line, just before the blood pump, is measured when the arterial pressure transducer of the arterial blood line is attached properly to this connector. Instructions on this can be read in "Arterial Blood Line - Attach" on page 4:16 in part 1.

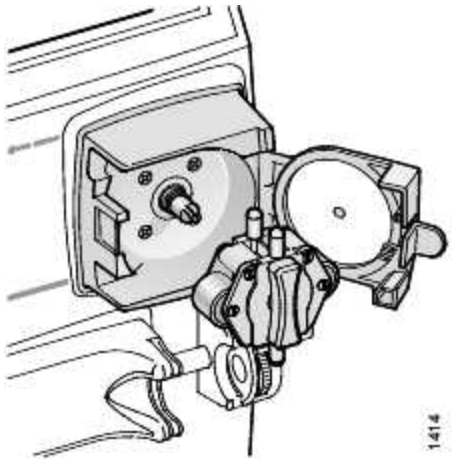


7. **Blood Pump**
The blood pump parts are:
a) the Pump Housing
b) the Pump Shaft
c) the Pump Cover
d) the Pump Rotor and
e) the Pump Handle
as shown in the corresponding figure.

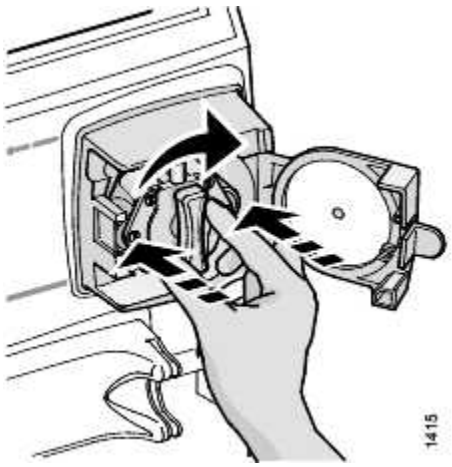
The blood flow measuring of the AK 96 dialysis machine is based on blood pump rotations (see also in "Blood Flow Control" on page 9:2 in part 1).
If the blood pump cover is opened whilst the blood pump is running, it will stop until the cover is closed again.
During a power failure the pump can be manually operated by turning the pump rotor in an anticlockwise direction, using the pump handle.

The pump cover may be opened with ease by pressing the middle of the cover at the same time as the cover is being opened, as shown in the corresponding figure.

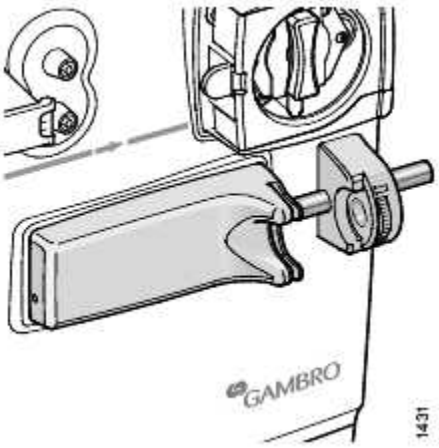




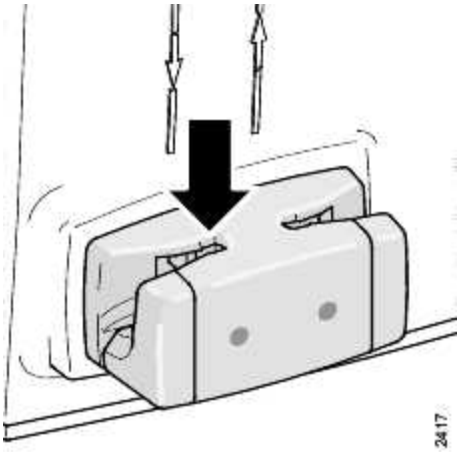
To remove the blood pump rotor; hold the handle and pull out. Then turn clockwise until the blood pump rotor loosens from the pump shaft.



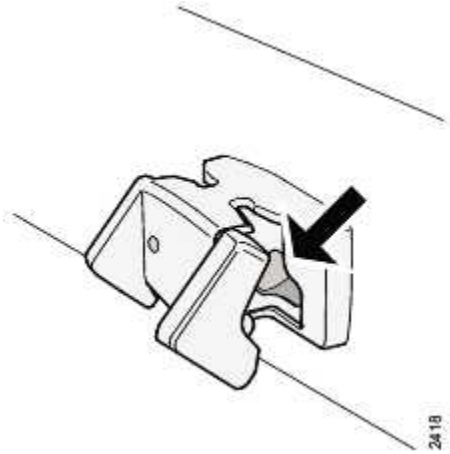
To attach the blood pump rotor; whilst holding the handle, place the rotor on the pump shaft. Then move your fingers from the handle and place them on the rotor as shown in the figure. Turn the rotor clockwise slowly, and at the same time push slightly, until it reaches the bottom position. Continue turning until the blood pump handle clicks in.



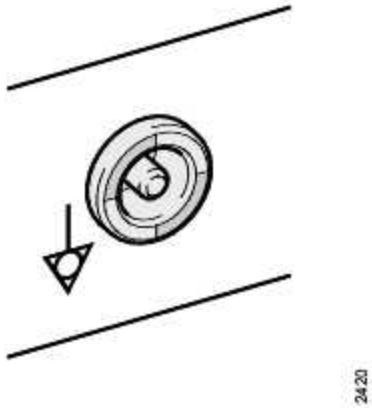
8. **Heparin Pump** (option)
The Heparin pump can be programmed for different syringe sizes. Syringes must comply with ISO 7886-2.
Instructions on how to attach the syringe to the pump, and how to do the heparin pump settings, can be read in "Arterial Blood Line - Attach" starting on page 4:16 in part 1, see point 8.



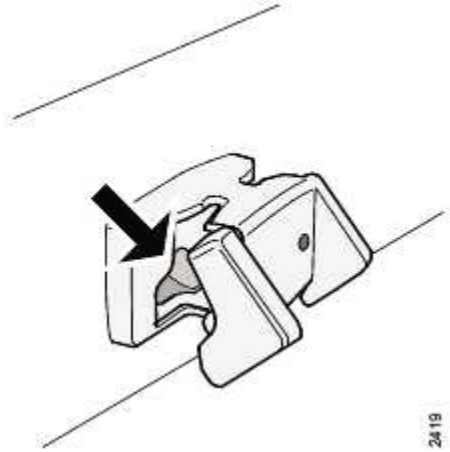
9. **Priming Detector**
The priming detector detects if there is blood in the venous blood line. When blood has been detected, treatment alarms are activated. Therefore, it is of the utmost importance that the venous blood line is correctly placed in the priming detector before treatment is started, see "Venous Blood Line - Attach" starting on page 4:28 in part 1, see point 5 for instructions on this.
Before the priming detector detects blood certain alarms are suppressed to facilitate the priming procedure. When blood has been detected, the treatment time starts to count down and accumulated treatment parameter values will start to be measured and displayed. The treatment time will continue to count down as long as blood is detected.



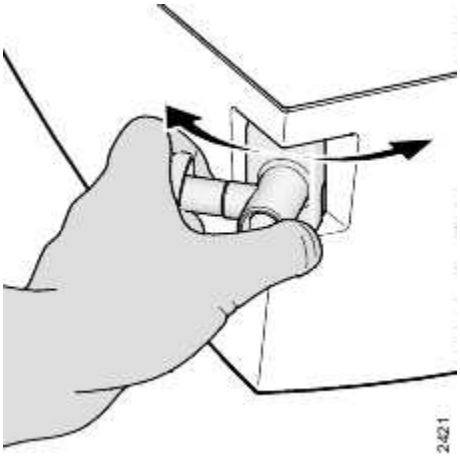
10. **Arterial Blood Line Clamp** (option)
    The arterial blood line clamp closes the arterial blood line in certain alarm situations during treatment. It is also of great importance when performing single needle treatment, as it is closed during the venous phase of the single needle cycle. This is to minimize recirculation. See "General" and "Glossary of single needle parameters and key terms" in the introductory parts of chapter 5 in part 1 for further information.



11. **Potential Equalization Connection**
    This connection is used for the potential equalization conductor. When a central venous catheter is used, the conductor must be connected to minimize the risk of electric shock. The connection is marked with the symbol for equipotentiality (see "Symbols fixed on to the Machine“ starting on page 1:9 in part 1).

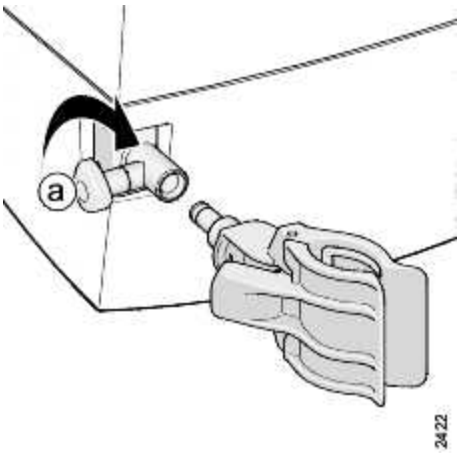


12. **Venous Blood Line Clamp**
    The venous blood line clamp closes the venous blood line in certain alarm situations during treatment. It is also of great importance when performing single needle treatment, as it is closed during the arterial phase of the single needle cycle. This is to minimize recirculation. See "General" and "Glossary of single needle parameters and key terms" in the introductory parts of chapter 5 in part 1 for further information.

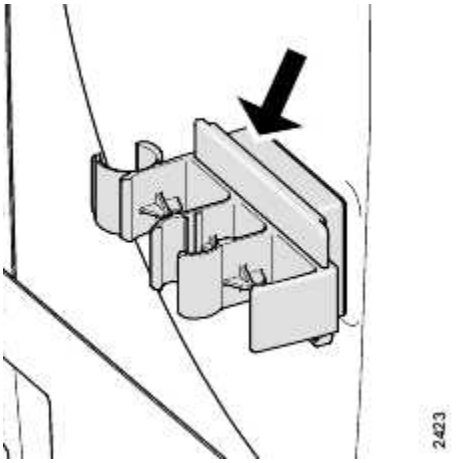


13. **Arm for Dialyzer Holder**
The dialyzer holder arm can be turned to two positions; pointing towards left or straight forward. The latter is recommended when the machine is to be moved around, especially when the dialyzer holder has been attached.

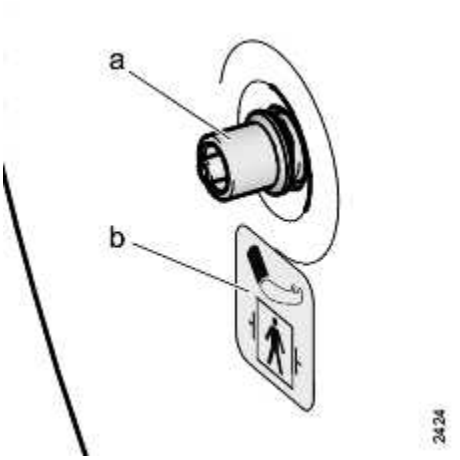
Turn the dialyzer holder arm by pushing it backwards or forwards, until it clicks into position as shown in the corresponding figure.



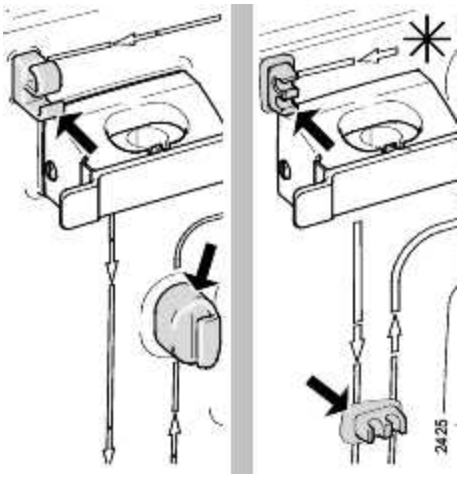
Attach the Dialyzer Holder to the holder arm and lock it into position using the locking screw (marked ⓐ in the corresponding figure) on the holder arm.



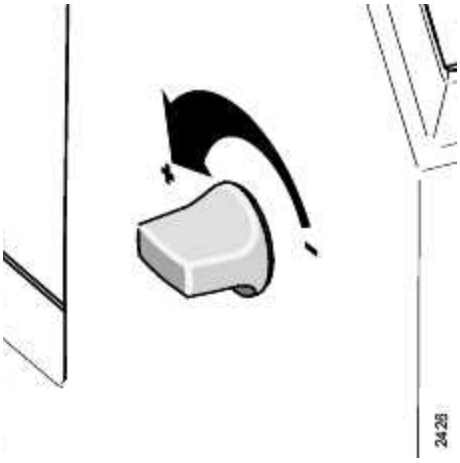
14. **Expansion Chamber Holder**
The holder is principally used for the expansion chamber included on the venous blood line when performing single needle treatment. See "Preparations" on page 5:3 in part 1 for instructions.



15. **BPM Connector** (option)
The line to the blood pressure cuff is to be connected to the BPM (Blood Pressure Monitor) nipple (marked ⓐ in the corresponding figure).
The BPM nipple is marked with a symbol fixed to the machine (ⓑ in the corresponding figure). For symbol information see "Symbols" in chapter 1 in part 1 and "General" in the introductory parts of chapter 11 "BPM – Blood Pressure Monitor (option)", on page 11:1 in part 2.

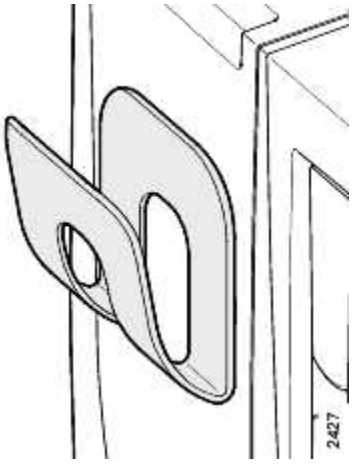


16. **Blood Line Guides**
The blood lines should always be placed in the guides during treatment for safety reasons.



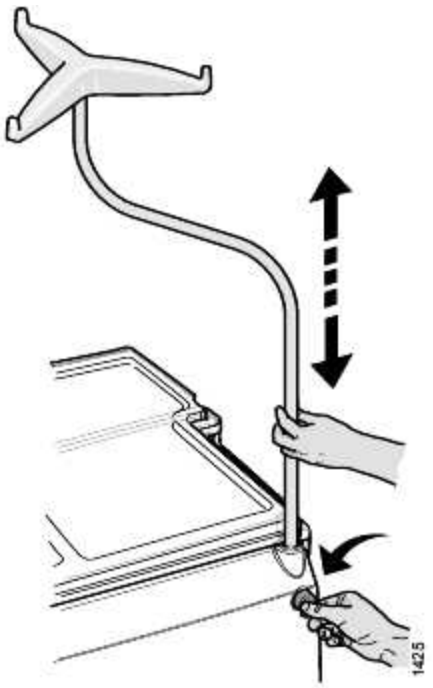
17. **Level Adjustment Knob**
The level in the venous drip chamber can be adjusted by turning the level adjustment knob. This is on condition that the venous pressure transducer has been connected to the venous pressure transducer connector.

Turn the level adjustment knob anticlockwise to raise the level and clockwise to lower it.



18. **BPM Cuff Holder** (option)
The holder has tape adhesive on both sides on the back which makes it possible to place it anywhere appropriate on the machine considered convenient.

The holder is in the main intended for the blood pressure cuff and line, but can also be used to hold paper documents.



19. **Infusion Pole**
The standard infusion pole is intended to be used for hanging up fluid bags. The maximum permitted load is 2 kg.

The height of the infusion pole can be adjusted by first loosening the infusion pole locking screw (on the machine) whilst holding the pole, and then moving the pole upwards or downwards as shown in the corresponding figure, before locking it into place.

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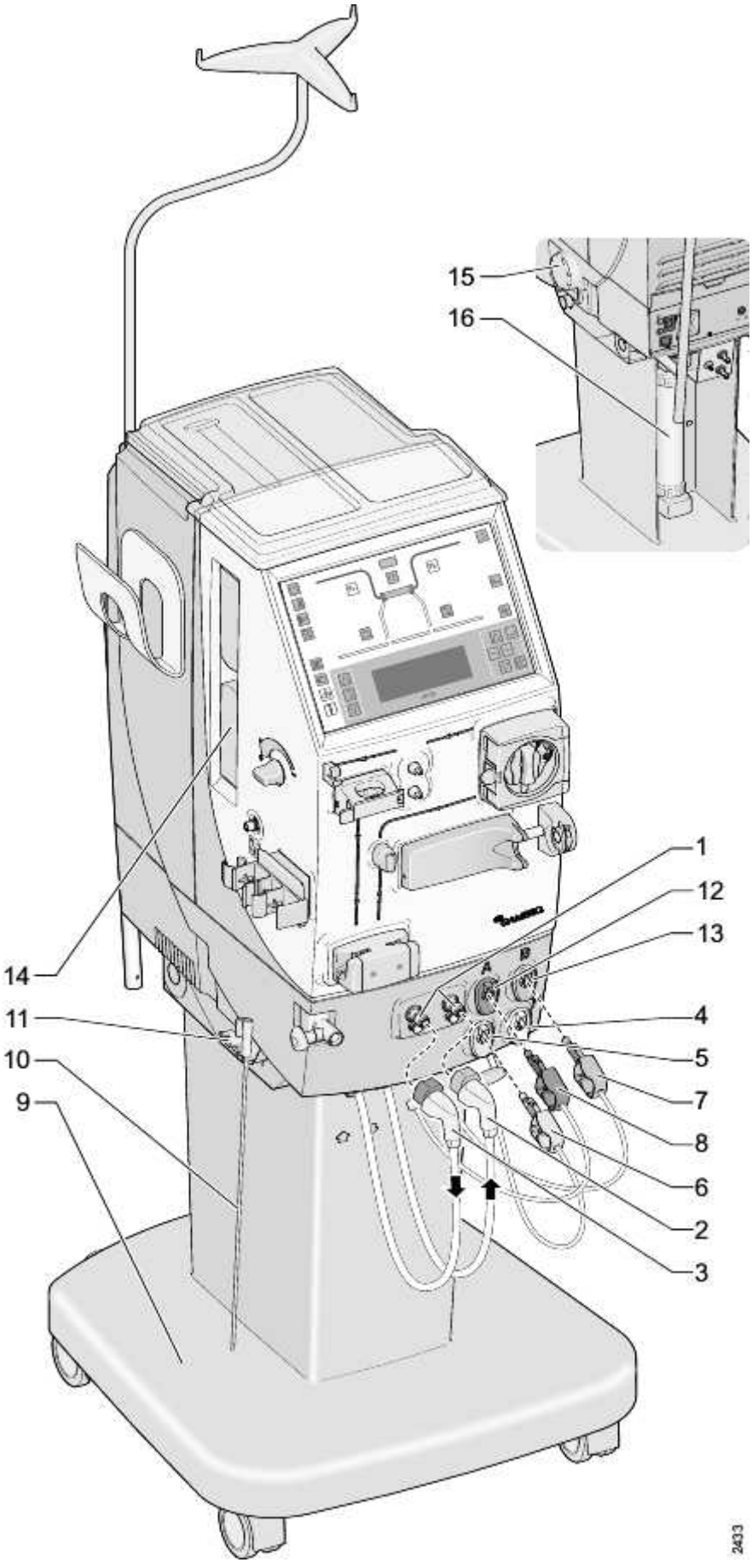
The Fluid Part of the Machine



Fluid Part Component Terms

The list below shows positions and terms, for the components pointed out in the overview picture of the fluid part of the machine (see figure on the previous page). A detailed description where each component is described separately, sometimes with informative text included, follows next in this section.

1. Safety Couplings for the Dialysis Fluid Tubes

2. Machine Outlet Dialysis Fluid Tube; from the machine to the dialyzer

3. Machine Inlet Dialysis Fluid Tube; to the machine from the dialyzer

4. Parking port (marked P) for Yellow Disinfectant Connector

5. Disinfection Port for Yellow Disinfectant Connector

6. Yellow Disinfectant Connector

7. Blue Concentrate Connector with White Tube Marking

8. Red Concentrate Connector

9. Base Plate

10. Pick-up Tube

11. Pick-up Tube Holder

12. Stand-by Port for Red Concentrate Connector

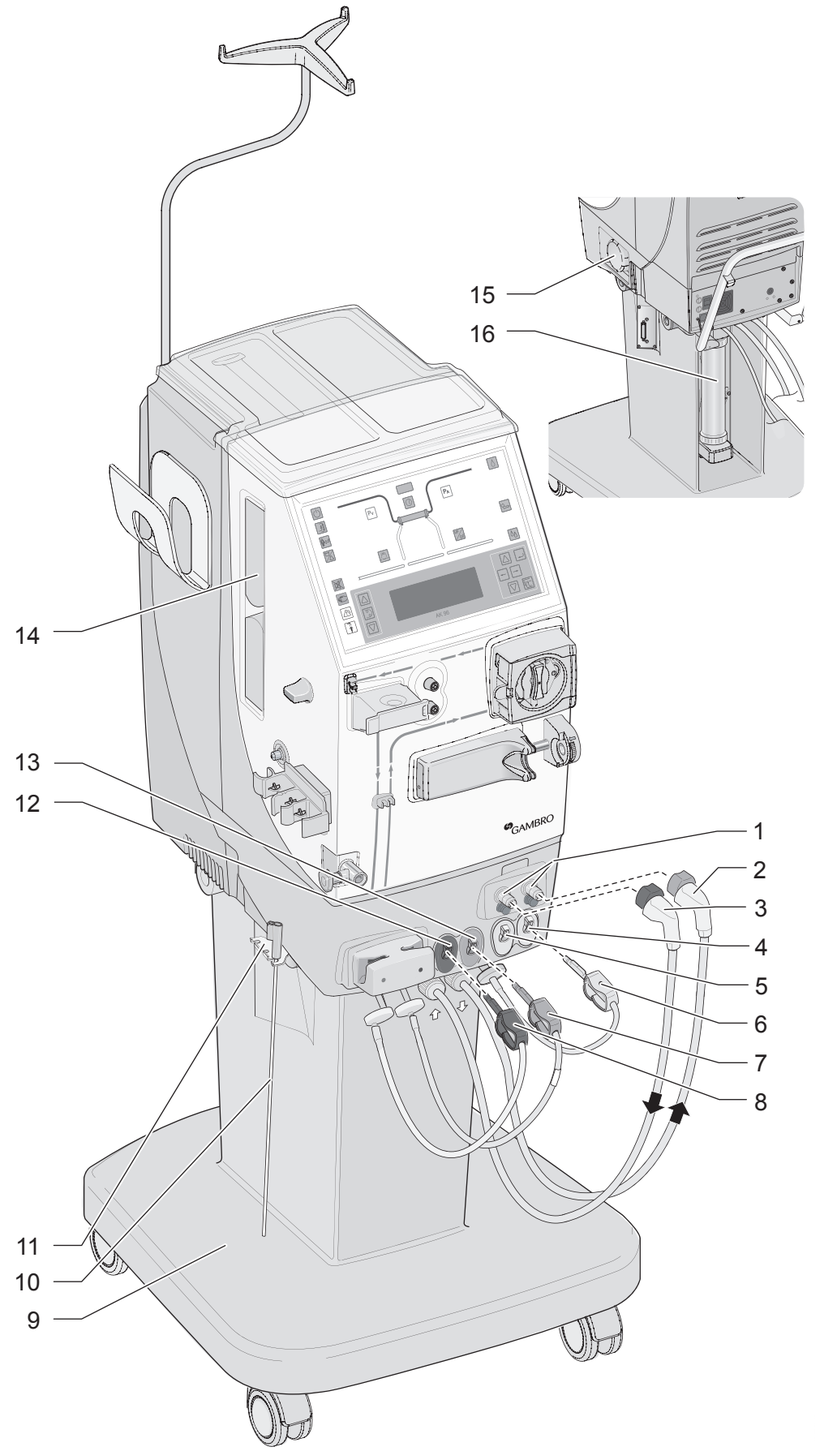
13. Stand-by Port for Blue Concentrate Connector

14. BiCart® Cartridge Holder (option)

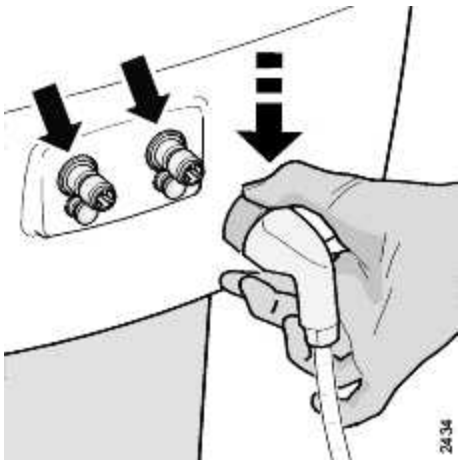
15. Blood Leak Detector

16. Dialysis Fluid Filter (option)

The Fluid Part of the Machine



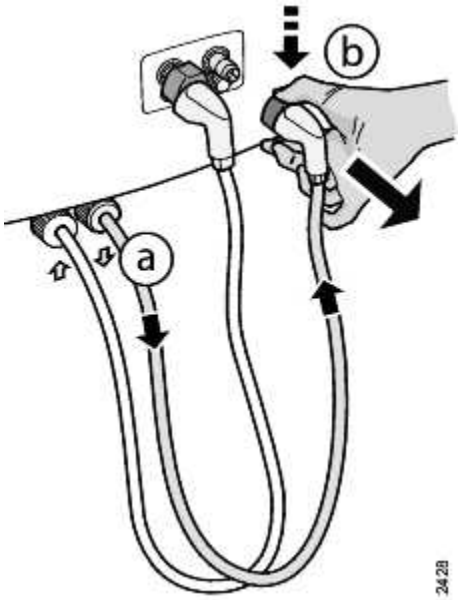
1. **Safety Couplings for the Dialysis Fluid Tubes**
The dialysis fluid tubes must be connected to the safety couplings during the initial part of the function check of the machine and when disinfection/rinse programs are running.



To correctly attach the dialysis fluid tube to the safety coupling; **press and hold the button on the dialysis fluid tube connector** while attaching it to the safety coupling.

Release the button and simultaneously **push the connector into place until it clicks in**. The small button positioned just below the safety coupling will now be depressed which means that the connector is correctly attached to the machine.

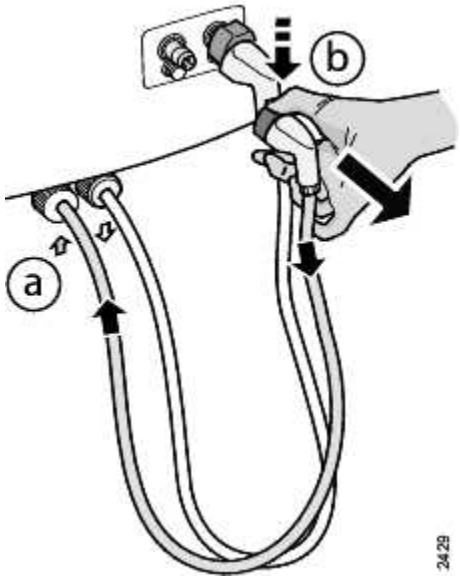
2. **Machine Outlet Dialysis Fluid Tube**
The newly prepared, **fresh** dialysis fluid, flows **from the machine to the dialyzer** via this tube. A small arrow, fixed just below where the tube comes out from the machine, shows the flow direction (marked ⓐ in the corresponding figure).



To remove the dialysis fluid tube from the safety coupling; **press and hold the button on the dialysis fluid tube** as shown in the corresponding figure (ⓑ), before removing it from the safety coupling.

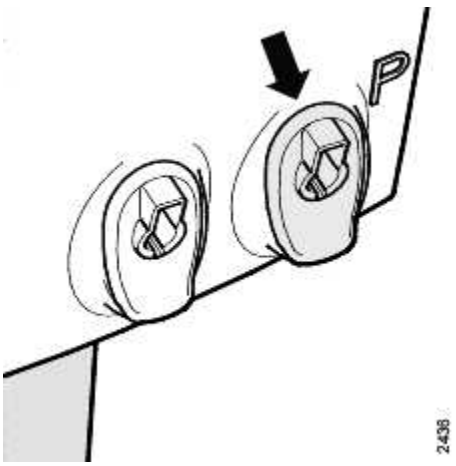
Instructions on how and when the tube can be attached to the dialyzer can be read in "Dialysis Fluid Tubes - Attach" on page 4:35 in part 1.

3. **Machine Inlet Dialysis Fluid Tube**
The **spent** dialysis fluid flows **to the machine from the dialyzer** via this tube. A small arrow, fixed just below where the tube comes out from the machine, shows the flow direction (marked ⓐ in the corresponding figure).

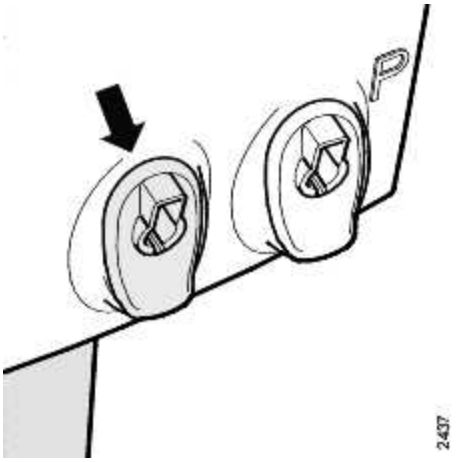


Remove the inlet dialysis fluid tube in the same way as the outlet dialysis fluid tube described in the previous point (2).

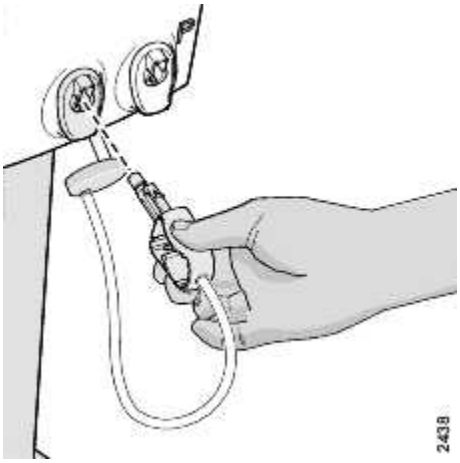
Instructions on how and when the tube can be attached to the dialyzer can be read in "Dialysis Fluid Tubes - Attach" on page 4:35 in part 1.



4. **Parking Port marked P, for Yellow Disinfectant Connector**
   The yellow disinfectant connector must be connected to this yellow port (marked P) at all times except when a chemical disinfection program is performed. See more information in point 6 further on in this list.

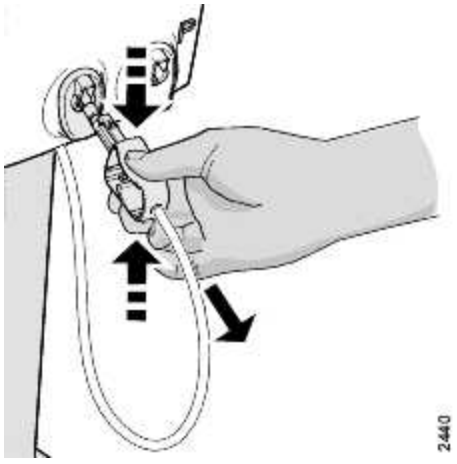


5. **Disinfection Port for Yellow Disinfectant Connector**
   The yellow disinfectant connector (point 6 in this list) is to be connected to this yellow port when a chemical disinfection program is performed. This is on condition that the disinfectant used for chemical disinfection program is permanently connected to the inlet line at the back of the machine (see "The Rear of the Machine" on page 2:28 in the next section).

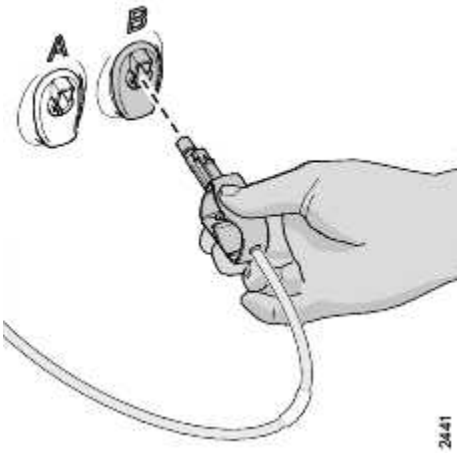


6. **Yellow Disinfectant Connector**
This connector must be placed in the parking port (point 4 in this list) at all times except when a chemical disinfection program is performed.
If the disinfectant used for chemical disinfection program is permanently connected to the inlet line at the back of the machine this connector is to be placed in the disinfection port (point 5 in this list) during the chemical disinfection program. If not, this connector is to be connected to the separately attached pick-up tube for intake of disinfectants and inserted into the disinfectant container. For further information concerning how to run a chemical disinfection program, see "Chemical Disinfection Program - Performing" on page 8:27 in part 1.

To correctly attach the connector to the port; insert the connector into the port and **push it into place until it clicks in**.

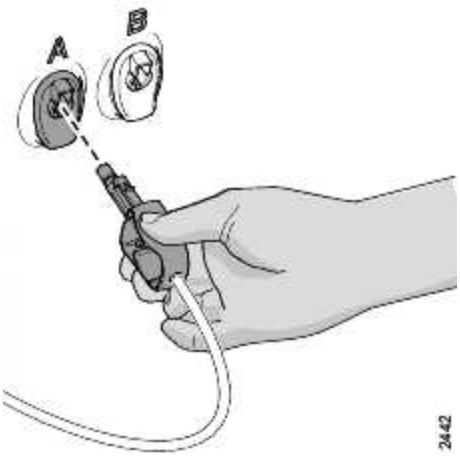


To remove the connector from the port; **compress the connector** as shown in the corresponding figure, **before pulling the connector out**.



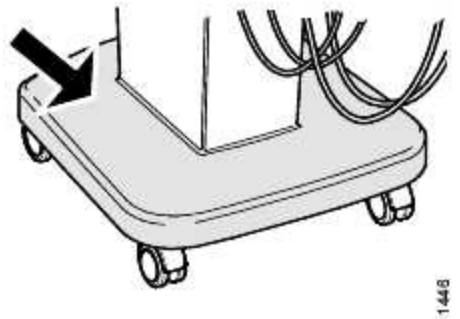
7. **Blue Concentrate Connector with White Tube Marking**
   This connector is used for the separately attached pick-up tube for liquid bicarbonate or acetate concentrate.

   The connector is attached and removed from the port in the same way as the yellow disinfectant connector (point 6 in this list).

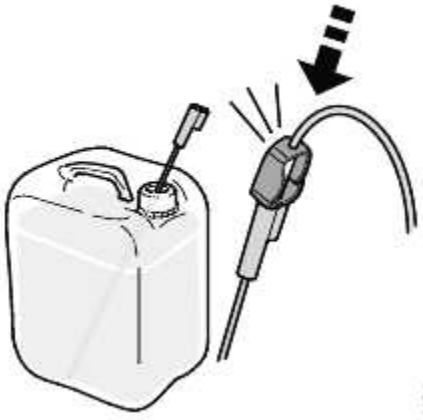


8. **Red Concentrate Connector**
   This connector is used for the separately attached pick-up tube for acidic concentrate.

   The connector is attached and removed from the port in the same way as the yellow disinfectant connector (point 6 in this list).

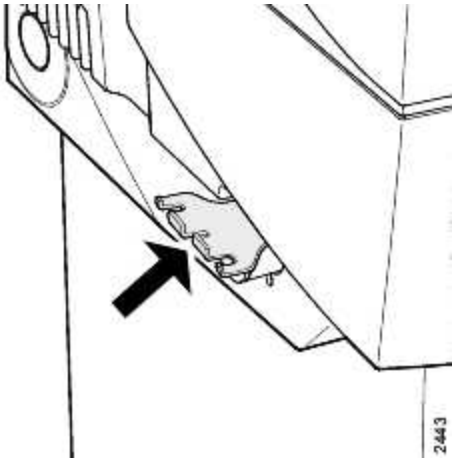


9. **Base Plate**
   The plate is designed for placement of concentrate containers during treatment.

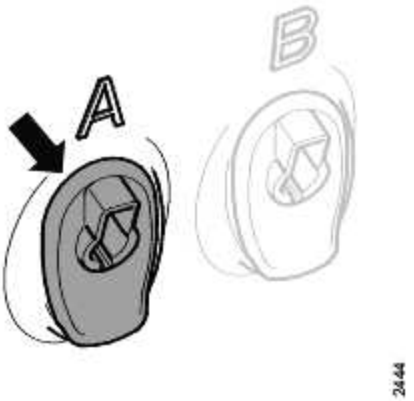


10. **Pick-up Tube**
The pick-up tubes are to be separately attached to the corresponding concentrate connector and then put into the proper concentrate container. (A separately attached pick-up tube can also be used for intake of disinfectants. For further information see "Chemical Disinfection Program - Performing" on page 8:27 in part 1.)

Attach the concentrate (or disinfectant) connector to the proper pick-up tube in the same way as when the connector is attached to the machine port (see point 6 in this list).

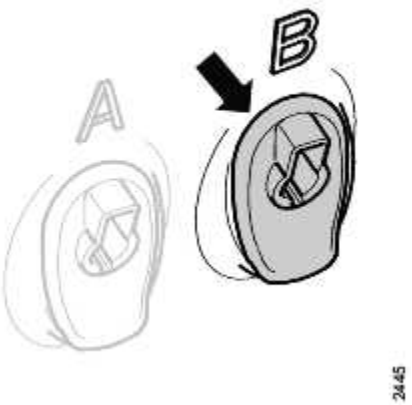


11. **Pick-up Tube Holder**
The clean pick-up tubes can be kept in this holder as shown in the corresponding figure. For pick-up tube rinsing/disinfection instructions, see "Pick-up Tubes" on page 8:41 in part 1 for instructions.

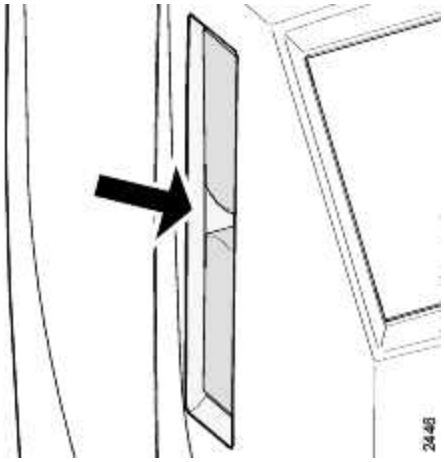


12. **Stand-by Port for Red Concentrate Connector**
The red concentrate connector (point 8 in this list) must be placed in this port at all times except when used for intake of acidic concentrate , during function check and treatment.

The connector is to be attached to the port in the same way as the yellow disinfectant connector, see point 6 in this list.

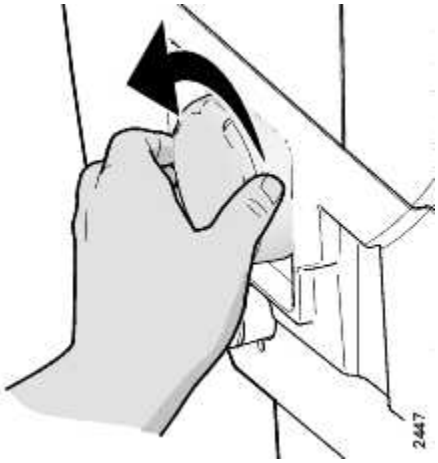


13. **Stand-by Port for Blue Concentrate Connector**
The blue concentrate connector with white tube marking (point 7 in this list) must be placed in this port at all times except when used for intake of liquid bicarbonate or acetate concentrate, during function check and treatment.
The connector is to be attached to the port in the same way as the yellow disinfectant connector, see point 6 in this list.

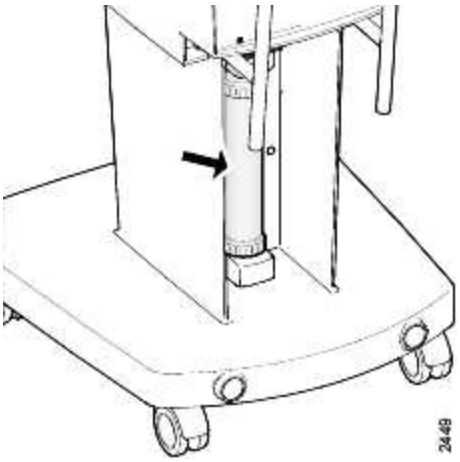


14. **BiCart® Cartridge Holder** (option)
This holder is used for the BiCart cartridge, a cartridge containing dry bicarbonate powder, for treatments. It is also used for the CleanCart A or C, cartridges containing cleaning (A) or decalcification (C), agents, for heat disinfection programs with CleanCart cartridge.

Instructions on how to attach the BiCart cartridge to the holder can be read in "Connect/Confirm Concentrates", page 4:7 in part 1, and how to change it during treatment on page 3:32 in part 1.
Instructions on how to attach the CleanCart cartridge to the holder can be read in "Heat Disinfection Program with CleanCart® cartridge - Performing", page 8:13 in part 1.



15. **Blood Leak Detector**
    If necessary (e.g. when cleaning, see in "Blood Leak Detector", page 8:41 in part 1), the blood leak detector cover can be opened as shown in the corresponding figure. Make sure that the sealing ring on the inside of the cover is securely in place when replacing the cover.



16. **Dialysis Fluid Filter** (option)
    See in "UFD- Ultrafiltered Dialysis Fluid (option)", page 1:17 in part 1 for information concerning this option.

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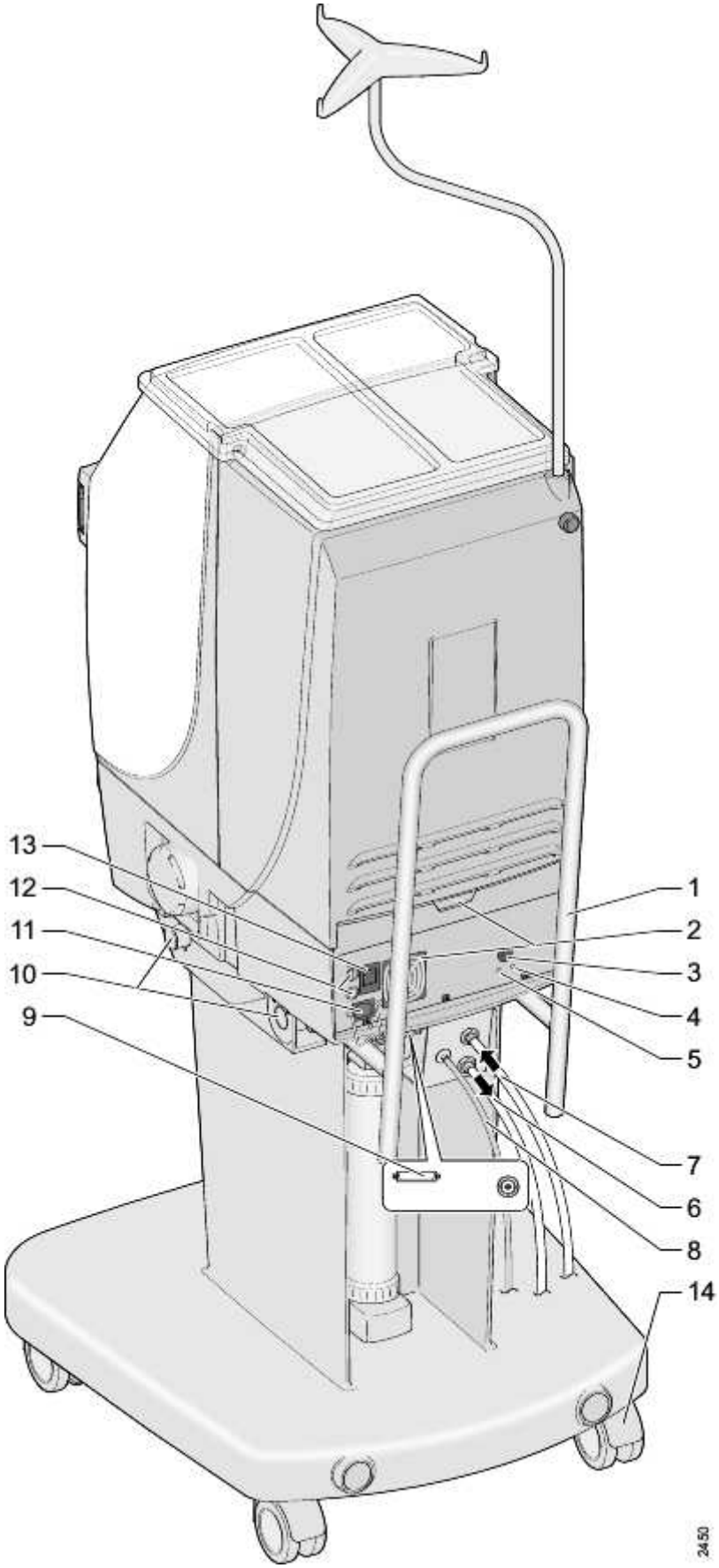
The Rear of the Machine



Rear Component Terms

The list below shows positions and terms, for the components pointed out in the overview picture of the rear of the machine (see figure on the previous page). A detailed description where each component is described separately, sometimes with informative text included, follows next in this section.

1. Transportation Handle

2. Air Filters

3. Halt Button

4. Battery Connect Indicator (green)

5. Battery Charge Indicator (yellow)

6. Outlet Tube

7. Inlet Water Tube

8. Disinfectant Inlet Tube

9. External Communication Port

10. Attachment for Service Table

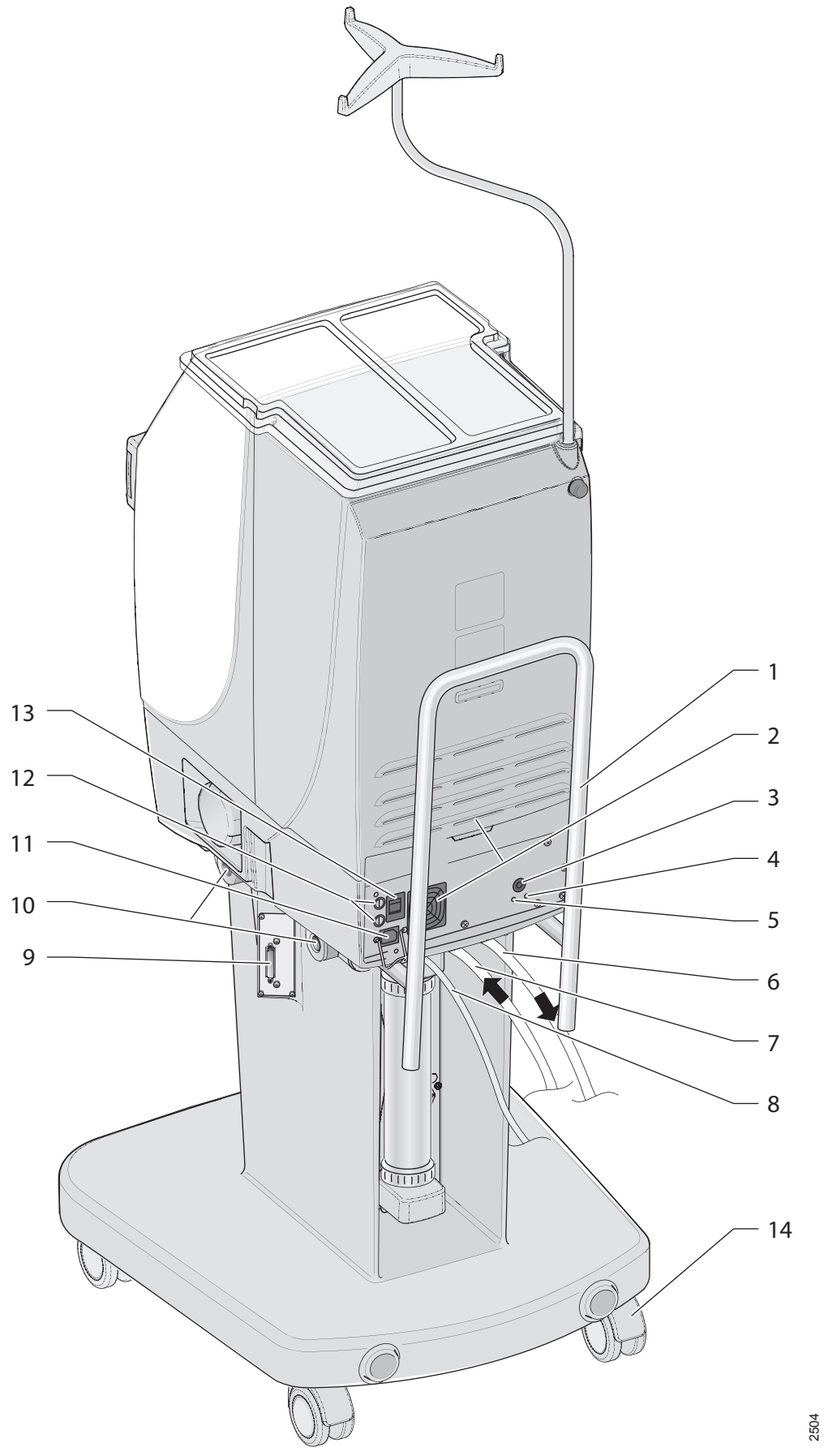
11. Mains Connection

12. Fuses

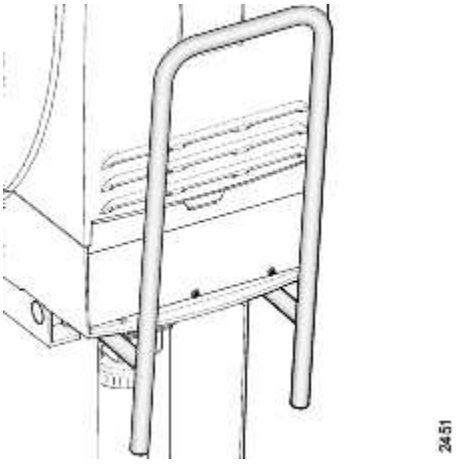
13. Main Switch

14. Wheels

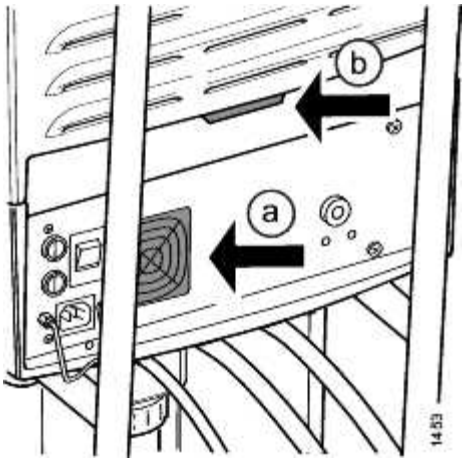
The Rear of the Machine



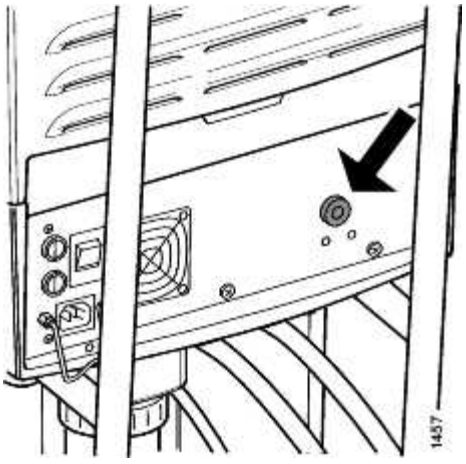
Rear Component Details



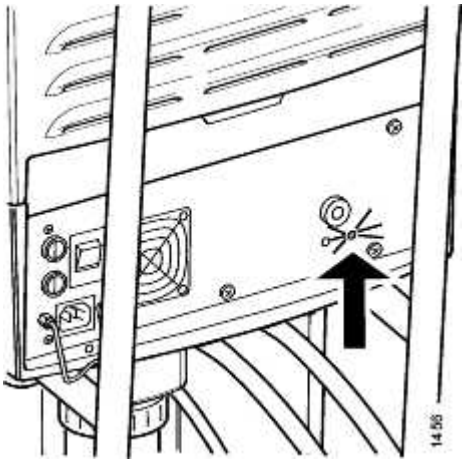
1. **Transportation Handle**
   This handle is to be used at all times when the machine is being moved around.



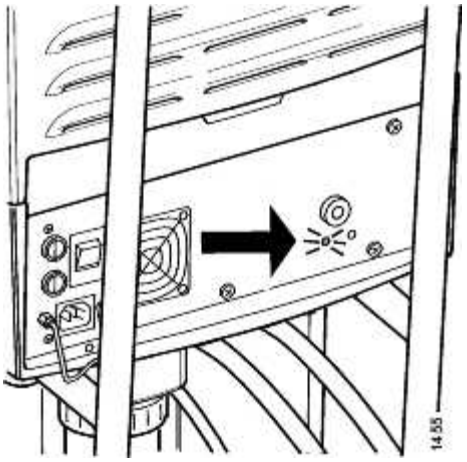
2. **Air Filters**
   There are two air filters. The filter marked ⓐ is used to protect the power supply unit. The filter marked ⓑ is used to protect the inside of the machine from dust.



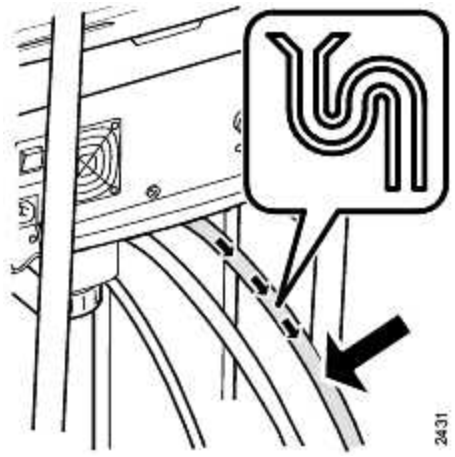
3. **Halt Button**
   When this button is pressed, the power supply to the machine is interrupted. As soon as the button is released the power returns and the machine performs a recovery. See "Recovery from Machine Shut Down" on page 3:29 in part 1.



4. **Battery Connect Indicator**
   If battery back-up has been installed, this green lamp will be lit (the lamp is marked BACO).

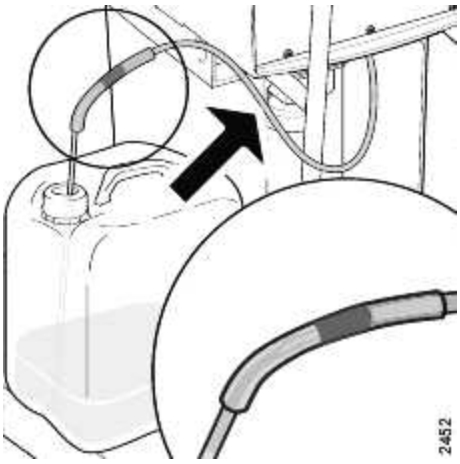


5. **Battery Charge Indicator**
   This yellow lamp (marked BACH) is lit when the mains cable is connected to the mains supply and the main switch is switched on (see point 13 further on in this list) indicating that the battery charge is ongoing.

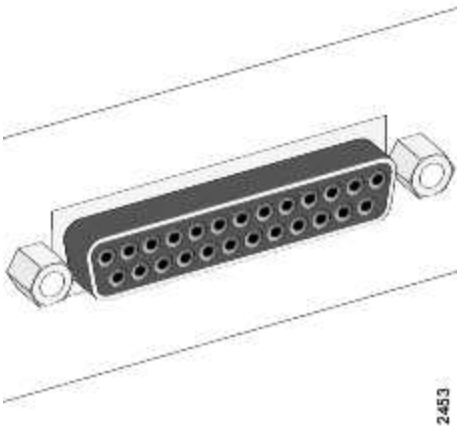


6. **Outlet Tube**
   The spent dialysis fluid flows out from the machine via this tube.

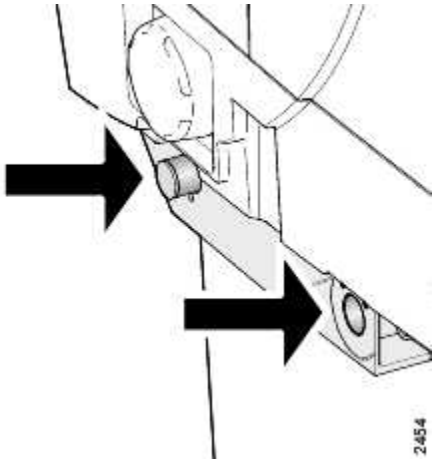
7. **Inlet Water Tube**
   The water used to prepare dialysis fluid flows into the machine via this tube. For more information see "Inlet Water Requirements" on page 1:17 in part 1.



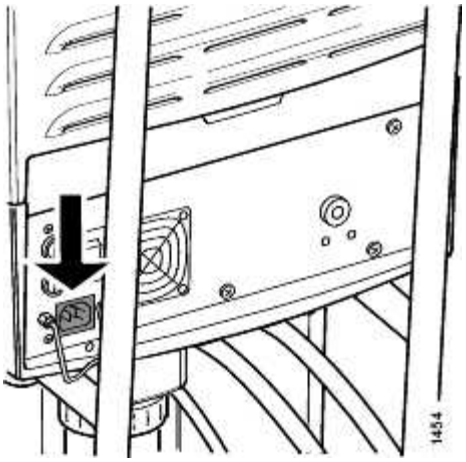
8. **Disinfectant Inlet Tube**
   The disinfectant used for the chemical disinfection program can be permanently connected to this inlet line.
   If this is the case, the yellow disinfectant connector is to be removed from the parking port (marked P) on the front of the machine and placed in the disinfection port when performing chemical disinfection program. For further information about how to run a chemical disinfection program, see "Chemical Disinfection Program - Performing" on page 8:27 in part 1.



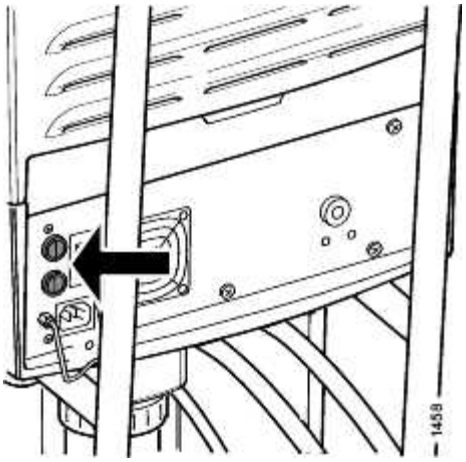
9. **External Communication Port**
   This port is to be used by the authorized technician. It can be used for service, connection to external computer systems and external alarms.



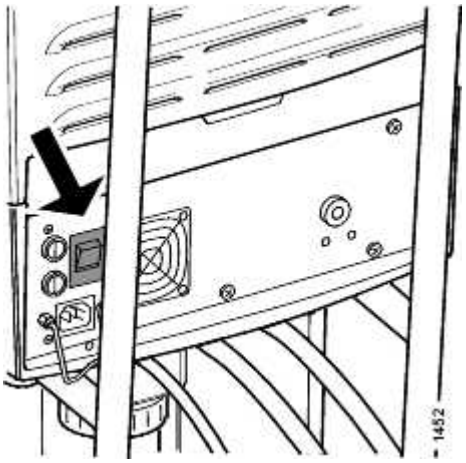
10. **Attachment for Service Table**
    These attachments, along with the 2 corresponding attachments on the opposite side of the machine, are to be used by the authorized technician when machine service is carried out.



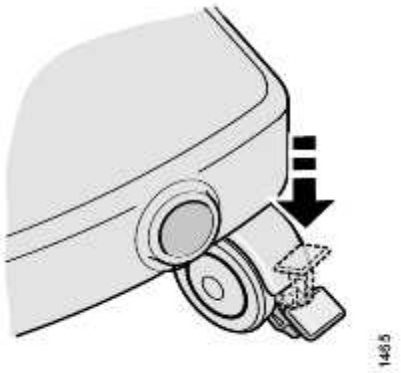
11. **Mains Connection**
    This connection is used for the mains cable which should always be connected, even when the machine is not in use in order for the batteries to be charged. Check that the cable locking spring, used to prevent the cable from loosening, is properly fixed.



12. **Fuses**
    When necessary, these fuses are to be changed by an authorized technician.



13. **Main Switch**
    The main switch should always be in the on position (indicated by a lit segment shown on the Time display) even when the machine is not in use. This is in order for the batteries to be charged.



14. **Wheels**
    It is recommended to lock the front wheels, especially during treatment, for safety reasons.

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Chapter 3

Operating the Machine - Handling Guidelines

Contents

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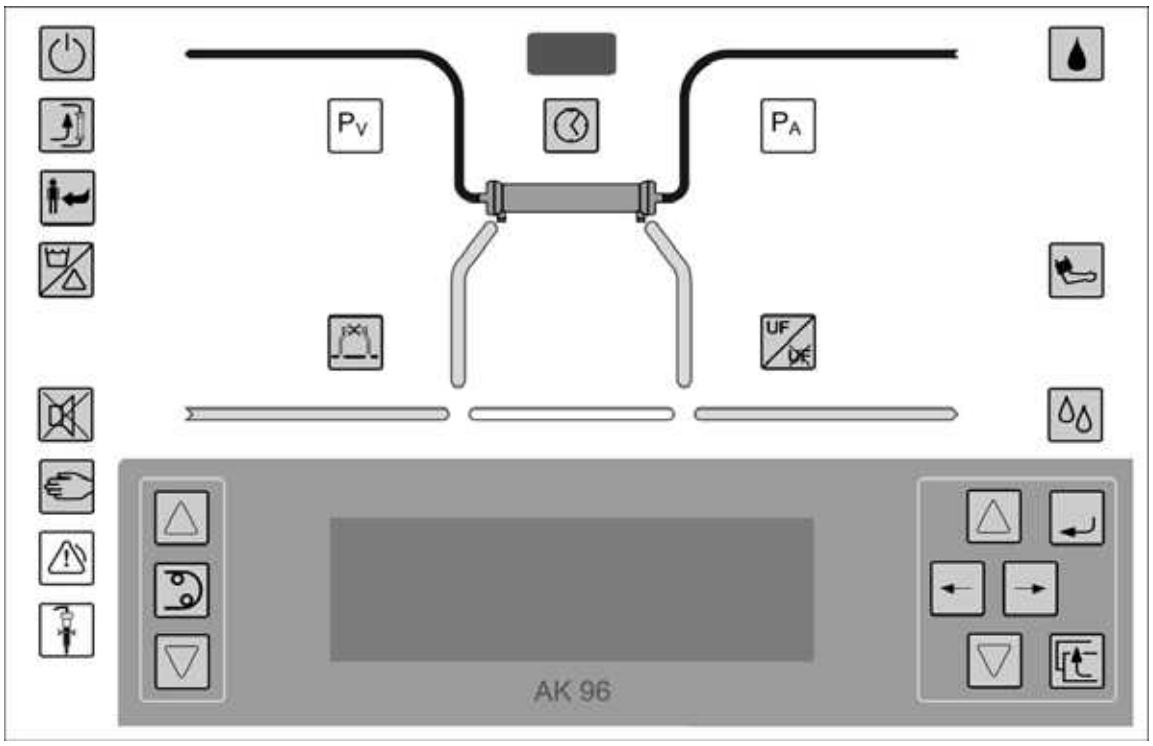
The Basics



The Operator's Panel of the AK 96 dialysis machine consists of; a time display at the top of the panel, a Flow Diagram below this, function buttons, a key pad (setting keys) and an Information Display. The purpose of these components is to inform the operator of status and parameter values and also to guide the operator through the various procedures.

The time display shows if the function check is ongoing. It also shows the time left for ongoing procedures.

The Flow Diagram is an essential part of the operators panel. It shows status and flow direction of the dialysis fluid. This is done by illuminating and changing the colours of the fluid path. The blood path on the Flow Diagram lights up red when blood has been detected in the venous blood line.

The buttons are either **function buttons** or **setting keys**. The function buttons give access to a variety of functions and parameters. Some function buttons only give access to one function. This applies when direct access to a function is necessary. Other buttons give access to several functions, each of which can be accessed by using the setting keys concurrently with text guidelines on the Information Display.

The Information Display is placed at the bottom of the Operator's Panel. It continuously shows information about ongoing procedures, alarms and activities. The keypad is placed immediately to the right of the Information Display.

The Handling Philosophy

The communication between the operator and the machine is principally done via the buttons and the Information Display. The operator selects options and gives the machine instructions by pressing buttons. The machine shows information on the Information Display, in the form of text, and on the buttons, which are either lit or not lit.

The Flow Diagram

The machine displays ongoing status during procedures by lighting up the flow paths on the Operator's Panel. There are two flow paths in the Flow Diagram, the fluid path and the blood path. The fluid path shows the status of the dialysis fluid in different colours of light, and the blood path lights up red when the machine has detected blood in the venous blood line.

The Flow Diagram also plays an important role in the handling of the machine as it constitutes the framework for the "flow path thinking". This means that the function buttons are placed according to where on the Flow Diagram they belong (the "blood buttons" are placed along the blood path and the "fluid buttons" along the fluid path). All operator actions should be preceded by the thought: "Is this action related to blood, or is it related to dialysis fluid?" By doing so the function or parameter that needs to be accessed can easily be found on the operators panel, as the function buttons are laid out principally according to this rule.

The Buttons

As well as the previously mentioned " flow path thinking", the function buttons are also placed according to how they are to be used. The setting keys are placed within the *Keypad* next to the Information Display or above and below the *Blood Pump button*. A lit function button means that the function behind the button has been activated. A flashing function button means a request to press it. Information will then be displayed on the Information Display. A lit setting key is a guide, meaning that it can be pressed to move further along on the Information Display.

The *On/Off button*, and buttons used for activating procedures, are placed in the upper left corner.

The "blood buttons" are placed along with the blood path of the Flow Diagram, and the "fluid buttons" are placed along with the fluid path.

The alarm buttons are situated together at the lower left on the Operator's Panel. These are the *Alarm button*, the *Attention button* and the *Air Detector button*. When alarms or attention alarms are generated, the alarm buttons will be activated. The *Mute button* at the top of the group is used to silence the buzzer.

The *Blood Pump button* is placed to the left, next to the Information Display. The setting keys used for increasing and decreasing the blood flow rate are placed above and below the button.

The *Keypad* is placed to the right, next to the Information Display. The *Keypad* consists of 6 setting keys which are to be used to do settings on the Information Display.

When a function button has been pressed, different displays and menus appear on the Information Display. The *Cursor keys* and the *Display Up/Down keys* are used to navigate within the menus on the Information Display. The *Select key* and the *Back key* are also connected to navigation and setting on the Information Display.

The *Blood pump button*, along with the *UF Start/Stop button* and the *Fluid Bypass button* are exceptions to those described above, as for these functions, the operator needs direct access. When the *Blood pump button* is pressed the blood pump will be switched on and off (no display). The blood flow rate is to be adjusted using the *Blood Pump Up/Down keys* connected to the button. When the *UF Start/Stop button* is pressed, the ultrafiltration starts and stops. When the *Fluid bypass button* is pressed, the dialysis fluid will enter or bypass the dialyzer.

The Operators Panel

On the following pages details concerning the parts of the Operator's panel are described.

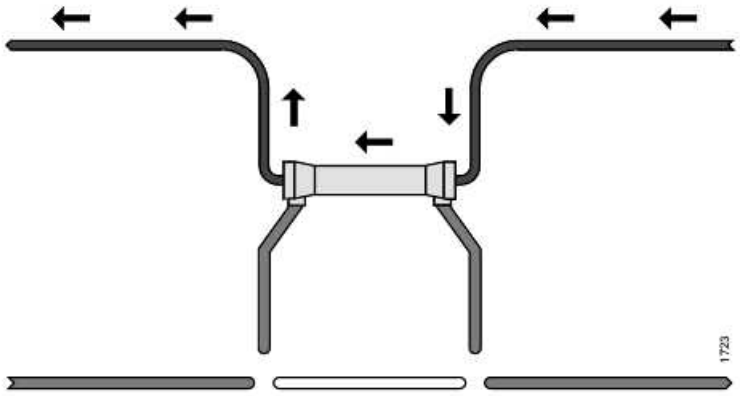
Time Display

During function check the time display shows FCh.
During treatment it shows the remaining treatment time.
During disinfection programs it shows estimated remaining time for the ongoing program.

Flow Diagram

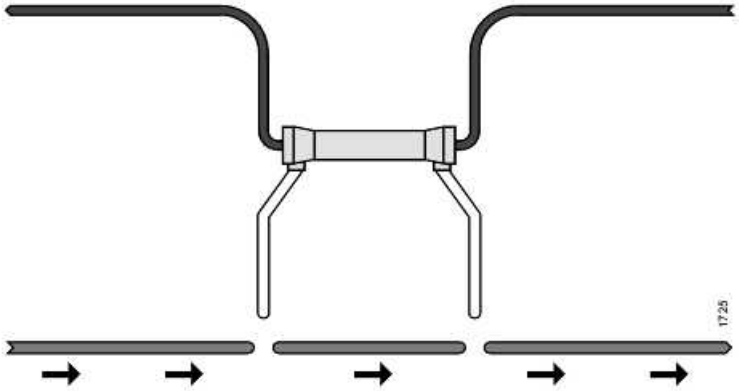
The Flow Diagram shows the status of the blood flow and the dialysis fluid flow.

The Blood Path



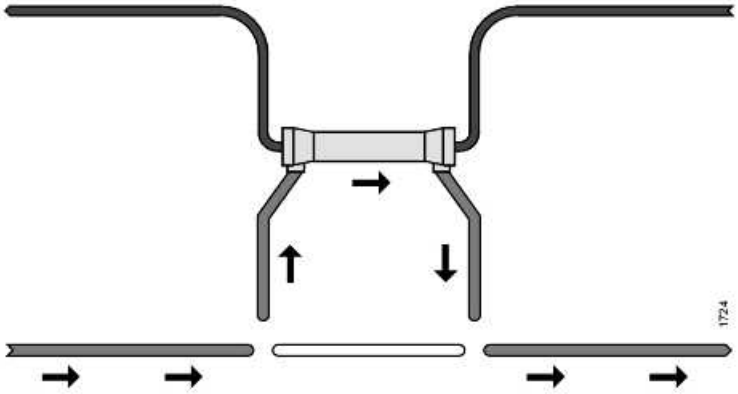
The blood path lights red when the priming detector detects blood.

The Bypass Path



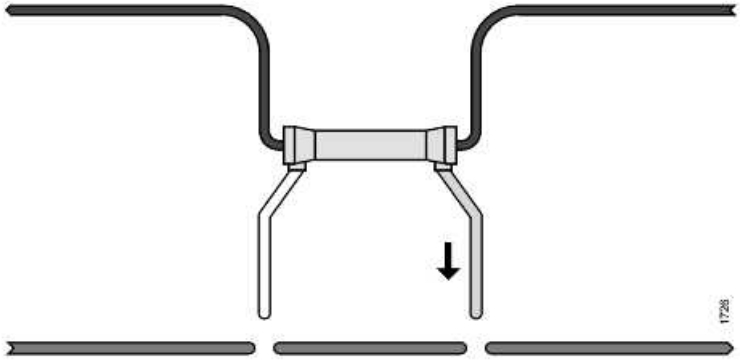
The bypass path lights green when the dialysis fluid preparation is ready (the conductivity level of the dialysis fluid is correct) for treatment. When the dialysis fluid is not correct the path is orange. The machine will automatically bypass the dialyzer during certain alarm conditions and during self-calibration.

The Dialyzer Path



The dialyzer path lights green when dialysis fluid is passing through the dialyzer.

The Ultrafiltration Path



The ultrafiltration path lights yellow during isolated ultrafiltration and in fluid bypass.

Buttons

Page References for the Buttons in this section

On/Off button, see page 3:10.

Priming button, see page 3:10.

Discontinuing button, see page 3:11.

Rinse/Disinfection button, see page 3:11.

Venous Pressure button, see page 3:11.

Time button, see page 3:12.
The Time Display, which is connected to this button, is described on page 3:6.

Arterial Pressure button, see page 3:12.

Blood Path button, see page 3:13.

BPM button, see page 3:15.

Fluid Bypass button, see page 3:15.

UF Start/Stop button, see page 3:15.

Fluid Path button, see page 3:15.

Mute button, see page 3:19.

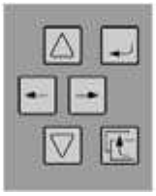
Attention button, see page 3:19.

Alarm button, see page 3:19.

Air Detector button, see page 3:19.

Blood Pump button, see page 3:20.

Blood Pump Up/Down keys, see page 3:20.



Keypad, see page 3:20.
The Information Display, which is connected to these buttons, is described on page 3:22.
The *Keypad* consists of the *Cursor keys*, the *Display Up/Down keys*, the *Select key* and the *Back key*. See below for page references for each key.

Right/Left Cursor keys, see page 3:21.

Display Up/Down keys, see page 3:21.

Select key, see page 3:20.

Back key, see page 3:21.

On/Off button

Press and hold the *On/Off button* for 3 seconds to switch the machine on and off.

At that moment, when the machine is switched on, the button lights up and a welcome display is shown on the Information Display for a few seconds. This display includes information on which program version is currently installed in the machine.

The *On/Off button* continues to be lit at all times when the machine is switched on.

It is not possible to switch the machine off, using the *On/Off button*, during treatment when blood is detected.

Note

- The main switch on the rear of the machine should always be in On position even when the machine is not in use. This is in order for the batteries to be charged. See "Rear Component Details"starting on page 2:31 in part 1, see point 13 for further information.

Note

Priming button

The *Priming button* automatically lights up when the machine has been switched on during the function check. This indicates that the machine is ready for blood line attachment and priming of the blood compartment of the dialyzer.

The *Priming button* continues to be lit, indicating that priming mode is active, until blood is detected.

Press the lit *Priming button* and the priming main menu opens on the Information Display.

Discontinuing button

The *Discontinuing button* is to be used to start the rinse-back procedure at treatment end. The discontinuing menus for patient disconnection and machine aftercare are also placed here. See "Discontinuing", page 4:59 in part 1 for further information.

Rinse/Disinfection button

The *Rinse/Disinfection button*, is used to activate rinse and disinfection programs. See chapter 8, "Hygiene and Maintenance" in part 1 for information.

Venous Pressure button

Press the *Venous Pressure button* to reach the venous pressure menu. In this menu, venous pressure values are displayed together with a bar graph for current value and current alarm limit settings.

The following will be shown on the Information Display:
`SET LOW`; low venous pressure alarm limit
`VEN PRESS`; current venous pressure
`SET HIGH`; high venous pressure alarm limit
`PA`; current arterial pressure
`QB`; blood flow rate

When the *Venous Pressure button* is pressed (in a non alarm situation), upper cursors will be placed on both the low and the high venous pressure alarm limits.
To move the complete alarm window (both low and high alarm limits will change simultaneously), first press the *Select key*. Then move the window on the scale using the *Up* and *Down Display keys*. Close using the *Select key*.
To adjust one alarm limit at a time, first press the *Left* or *Right Cursor key* to select alarm limit. Then press the *Select key* to open the position. Change the value using the *Up* and *Down Display keys*. Close using the *Select key*.

Time button

When the *Time button* is pressed the time menu is displayed.

The following will be shown on the Information Display:
SET; set treatment time
NON DIFF; passed treatment time without diffusion
PASSED; passed treatment time

Arterial Pressure button

Press the *Arterial Pressure button* to reach the arterial pressure menu. In this menu, arterial pressure values are displayed together with a bar graph for current value and current alarm limit settings.

The following will be shown on the Information Display:
SET LOW; low arterial pressure alarm limit
ART PRESS; current arterial pressure
SET HIGH[1]; high arterial pressure alarm limit
PV; current venous pressure
QB; blood flow rate

When the *Arterial Pressure button* is pressed (in a non alarm situation), upper cursors will be placed on both the low and the high arterial pressure alarm limits.
To move the complete alarm window (both low and high alarm limits will change simultaneously), first press the *Select key*. Then move the window on the scale using the *Up* and *Down Display keys*. Close using the *Select key*.
To adjust one alarm limit at a time, first press the *Left* or *Right Cursor key* to select alarm limit. Then press the *Select key* to open the position. Change the value using the *Up* and *Down Display keys*. Close using the *Select key*.

[1] this alarm limit can be preset to a fixed value by an authorized technician.

Blood Path button

Press the *Blood Path button* to reach the Blood Path main menu. In this menu, the BLOOD FLOW can be read/set/adjusted. Settings and activation of the HEPARIN pump are to be made and settings and activation for the SINGLE NEEDLE function can be made.

The following will be shown on the Information Display:
BLOOD FLOW; current blood flow rate
HEPARIN; sum of accumulated bolus volume during priming and total accumulated volume since treatment start
SINGLE NEEDLE; current stroke volume

Blood Flow

From the Blood Path main menu; select BLOOD FLOW by using the *Keypad* to reach the sub menu.

The following will be shown on the Information Display:
SET QB; set blood flow rate
SET LOW; set low alarm limit for blood flow rate
SEGMENT; blood pump segment diameter
ACTUAL QB; current blood flow rate
ACC; accumulated blood volume since treatment start

Heparin

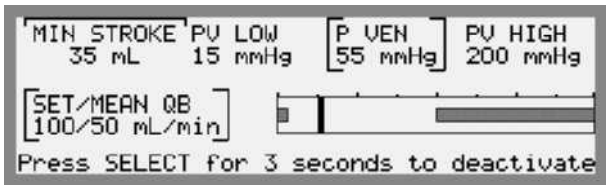
From the Blood Path main menu; select HEPARIN by using the *Keypad* to reach the sub menu.

The following will be shown on the Information Display:
Type of syringe (e.g. Terumo 30 mL).
BOLUS; set heparin solution bolus volume.
FLOW RATE; set heparin solution flow rate
STOP LIMIT; set stop time in minutes at which the heparin pump should stop before treatment end
ACC HEP; sum of accumulated bolus volume during priming and total accumulated volume since treatment start

The heparin pump will run concurrent to the blood pump in double needle treatment. In single needle treatment it will be running continuously irrespective of if the blood pump is running or not.

Single needle

From the Blood Path main menu; select SINGLE NEEDLE by using the *Keypad* to reach the sub menu.



The following will be shown on the Information Display:
MIN STROKE; displays the low alarm limit for the stroke volume
PV LOW; low venous pressure alarm limit
P VEN; current venous pressure
PV HIGH; high venous pressure alarm limit
SET/MEAN QB; displays set and mean blood flow rates. The set blood flow rate (arterial) is to be set/adjusted using the *Blood Pump Up/Down keys*. The mean blood flow rate is the effective blood flow rate displayed when performing single needle treatment

BPM button

Press the *BPM button* to reach the BPM main menu. On this menu blood pressure measuring can be activated. For instructions see chapter 11 in part 2.

Fluid Bypass button

The *Fluid Bypass button* is used to manually bypass the dialysis fluid from the dialyzer.

UF Start/Stop button

The *UF Start/Stop button* is used to start and stop the ultrafiltration.

Fluid Path button

Press the *Fluid Path button* to reach the Fluid Path main menu. In this menu parameter settings and functions related to dialysis fluid can be set/activated.

The following will be shown on the Information Display:
UF; calculated ultrafiltration rate and profiling type
CONC; selected concentrate
TEMP; current dialysis fluid temperature
COND; current conductivity value
DIA FLUID FLOW; current dialysis fluid flow rate
DIASCAN; function activated or not activated
TMP; current transmembrane pressure

Ultrafiltration

From the Fluid Path main menu; select UF by using the *Keypad* to reach the sub menu.

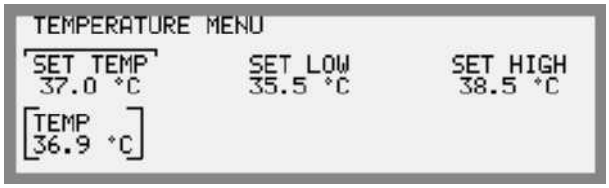
The following will be shown on the Information Display:
SET UF; set ultrafiltration volume (patient weight loss)
SET PRIMING UFR; set ultrafiltration rate during priming before blood is detected
SET MIN UFR; set minimum ultrafiltration rate during treatment
PROFILING; refer to chapter 7 "Profiling" in part 1
UF RATE; calculated ultrafiltration rate
ACC UF; accumulated ultrafiltration volume (patient weight loss)
ISOL UF; refer to chapter 6 "Isolated Ultrafiltration" in part 1

Concentrates

From the Fluid Path main menu; select CONC by using the *Keypad* to reach the sub menu. For instructions on connecting and selecting concentrates see "Connect/Confirm Concentrates", page 4:7 in part 1.

Temperature

From the Fluid Path main menu; select TEMP by using the *Keypad* to reach the sub menu.



The following will be shown on the Information Display:
SET TEMP; set dialysis fluid temperature
SET LOW; low alarm limit for temperature
SET HIGH; high alarm limit for temperature
TEMP; current dialysis fluid temperature

Conductivity

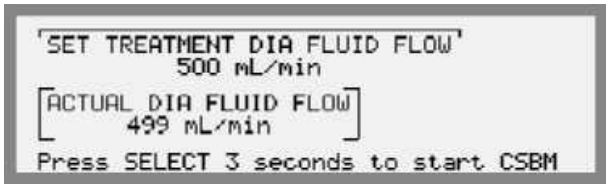
From the Fluid Path main menu; select COND by using the *Keypad* to reach the sub menu.

The following will be shown on the Information Display:
SET NA; set sodium value
SET HCO3; set bicarbonate value
PROFILING; see chapter 7 in part 1
COND (C/P); current dialysis fluid conductivity value, where C is the current conductivity value from the control system, and P is the current conductivity value from the protective system
SET COND (C/P); set dialysis fluid conductivity value, where C is the set conductivity value from the control system, and P is the set conductivity value from the protective system
PH; current dialysis fluid pH value

Dialysis fluid flow rate

From the Fluid Path main menu; select DIA FLUID FLOW by using the *Keypad* to reach the sub menu.

The dialysis fluid flow rate is a preset parameter value which cannot be adjusted by the operator during priming. The value can however be set in (SET TREATMENT DIA FLUID FLOW) during priming, but will not be effective until treatment start (when the priming detector detects blood in the venous blood line). In treatment the operator has access to adjust the value.



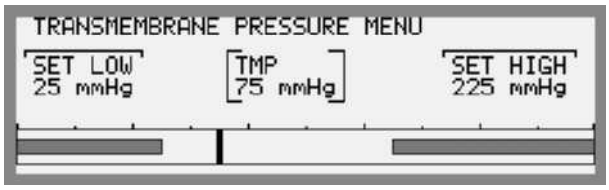
The following will be shown on the Information Display:
SET TREATMENT DIA FLUID FLOW; set dialysis fluid flow rate
ACTUAL DIA FLUID FLOW; current dialysis fluid flow rate
Press SELECT 3 seconds to start CSBM; this text is used when activating concentrate stand-by mode. See "Concentrate Stand-by Mode" page 3:30 in part 1 for instructions.

Diascan®

From the Fluid Path main menu; select DIASCAN by using the *Keypad* to reach the sub menu. For instructions on settings and activation of the Diascan function see chapter 12 in part 2.

Transmembrane Pressure

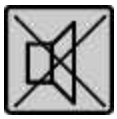
From the Fluid Path main menu; select TMP by using the *Keypad* to reach the sub menu.



The following will be shown on the Information Display:
SET LOW; low transmembrane pressure alarm limit
TMP; current transmembrane pressure
SET HIGH; high transmembrane pressure alarm limit

In this display, upper cursors will be placed on both the low and the high transmembrane pressure alarm limits.
To move the complete alarm window(both low and high alarm limits will change simultaneously), first press the *Select key*. Then move the window on the scale using the *Up* and *Down Display keys*. Close using the *Select key*.
To adjust one alarm limit at a time, first press the *Left* or *Right Cursor key* to select alarm limit. Then press the *Select key* to open the position. Change the value using the *Up* and *Down Display keys*. Close using the *Select key*.

Mute button



The *Mute button* is used to silence the buzzer and to activate the night light function.

Attention button

Attention button, see the initial parts of chapter 14 "Attention Alarms" in part 3.

Alarm button

Alarm button, see the initial parts of chapter 13 "Alarms" in part 3.

Air Detector button

Air Detector button, see "Air Detector Alarm" on page 13:19 in part 3.

Blood Pump button

The *Blood Pump button* is used to start and stop the blood pump at the set blood flow rate.

Blood Pump Up/Down keys

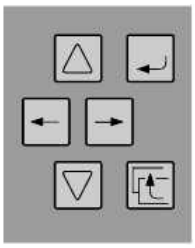
When pressed, this *Blood Pump Up key* will increase the blood flow rate.

When pressed, this *Blood Pump Down key* will decrease the blood flow rate.

When any of the *Blood Pump Up* or *Blood Pump Down key* is pressed, the `BLOOD FLOW MENU` will be displayed on the Information Display.

The following will be shown on the Information Display:
`SET QB`; set blood flow rate
`ACTUAL QB`; current blood flow rate
`VEN PRESS`; current venous pressure
`ART PRESS`; current arterial pressure

Keypad



The *Keypad* consists of *Cursor keys*, *Display Up/Down keys*, *Select key* and *Back key*.

Select key

The *Select key* is used to open and close settings of the menus on the Information Display. The operator is requested to use the *Select key* for instance when activating/deactivating functions and confirming attention alarms.

The *Select key* is also used to go into the positions of the menus; from the main menus and forwards between the menus of the subsections.

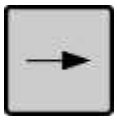
Back key

The *Back key* is used to step backwards. When pressed for 3 seconds from a sub menu the Treatment Overview Menu will resume.

Whenever the *Back key* is lit, it can be pressed to step backwards.

Cursor keys

The *Cursor keys* are used to step within the menus on the Information Display. The *Right Cursor key* moves the cursor in a clockwise direction and the *Left Cursor key* moves the cursor anticlockwise.



Right Cursor key

Left Cursor key

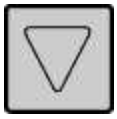
Display Up/Down keys

The Display Up/Down keys are used for setting and changing values of parameters shown on the Information Display. The Display Up key increases the value and the Display Down key decreases the value.

The keys can be used in two ways; by briefly pressing one of the keys repeatedly in small steps or, if the intension is a faster change of the value, by pressing the key pressed in until the proper value is shown.

The Display Up/Down keys are also to be used to scroll up and down when lists are displayed on the Information Display. For further information on how to use the keys in these lists, see either in "Alarms" on page 13:1 in part 3 or in "Disinfection History" on page 8:4 in part 1.

Display Up key



Display Down key

Information Display

Together with the *Keypad*, the Information Display is used for activating/deactivating functions, starting/stopping procedures and selecting options in addition to setting parameters and alarm limits. The Information Display also displays parameter values during priming and treatment procedures, it displays alarm and attention alarm messages and, if a function is currently active during treatment, this is also displayed here.

During priming and treatment procedures the Information Display will always be lit showing parameter values on the Priming and Treatment Overview Menus. These displays will immediately disappear when a function button on the Operator's Panel is pressed. The Priming or Treatment Overview Menus will automatically resume 20 seconds after the last time a button was pressed.

When an alarm is generated and the alarm button is pressed, an alarm list containing alarm messages will appear on the Information Display (besides other machine alarm actions). When an attention alarm is generated and attention button is pressed, the attention alarm text is to be read on the Information Display.

Viewing Angle Adjustment

Press the *Venous Pressure* and *Time button* simultaneously. Keep them pressed in, and the *Display Up/Down keys* will light up. While continuing to keep the *Venous Pressure* and the *Time button* pressed in, adjust the viewing angle of the Information Display using the *Display Up/Down keys*.

Cursors

When a menu is shown on the Information Display, each position of the menu can be pointed out by the use of a cursor. There are four different cursors, three of them can be manually moved by the operator using the *Cursor keys*. One has a fixed position on the menu.

Upper Cursor

This cursor indicates that the position has been selected and is possible to open by using the *Select key*. If the position holds a function, the subsection will be entered and a new menu will appear. If the position holds a parameter the cursor will move to the lower position. The Upper Cursor can be moved within the menu to select another position by using the *Cursor keys*.

Lower Cursor

This cursor indicates that the position has been opened and it is possible for the operator to change the value of the parameter using the *Display Up/Down keys*. After the proper value has been set, close the position using the *Select key* and the cursor will move to the next position of the menu.

Cursor Brace

This cursor indicates that the position has been pre selected. The cursor can be moved within the menu to select another position by using the *Cursor keys*.

Display Brace

This cursor has a fixed position and displays the value of a parameter. The position cannot be entered or moved by the operator.

Overview Displays

The Treatment Overview Menu will start to be displayed and continues to be displayed at all times during treatment when blood is detected. Current parameter values during treatment are displayed here. Activated functions are displayed at the bottom of the overview menus, in the activity field.

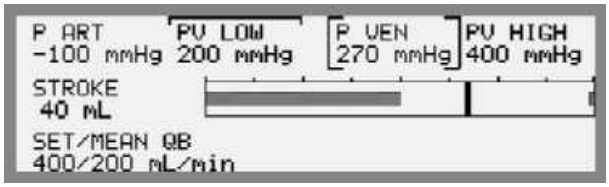
The Treatment Overview Menu is divided up in two parts, both showing current treatment parameters and which functions are activated at the moment. Switch between the two parts using the *Back key*. The first part containing current blood flow rate is always present when the treatment is ongoing but can easily be changed to the second part using the *Back key*. The second part will then be displayed for 20 seconds and after this the first part will automatically return.

When any other menu is displayed during treatment, the *Back key* can be pressed for 3 seconds if the Treatment Overview Menu is to be immediately displayed.

The following will be shown on the Information Display when the first part of The Treatment Overview Menu is displayed:
QB; current blood flow rate
P VEN; current venous pressure
P ART; current arterial pressure
UF RATE; current ultrafiltration rate
Activated functions are displayed at the bottom of the overview menu, in the activity field.

The second part of the overview shows the following on the Information Display:
ACC QB; accumulated blood volume since treatment start
ACC HEP; accumulated infusion volume since treatment start
ACC UFV; accumulated ultrafiltration volume (patient weight loss) since treatment start
UF RATE; current ultrafiltration rate
Activated functions are displayed at the bottom of the overview menu, in the activity field.

The first part of the Treatment Overview Menu for single needle treatment differs from the overview when performing double needle treatment, showing parameters of interest when single needle mode is active. Refer to chapter 5 in part 1.



The Ultrafiltration Control

During treatment the following equation is always applicable:

$$\frac{\text{Ultrafiltration volume}}{\text{Treatment time}} = \text{UF rate}$$

Treatment time and UF volume can be set within certain limits. The machine will automatically calculate and show the UF rate in litres/hour. When treatment time or UF volume is changed the UF rate will also change. The operator has to confirm the automatically set TMP alarm limits, set around the current TMP value, via the TMP confirm menu displayed on the Information Display.

An example on how a UF setting is to be done is shown as follows:

1. Press the *Time button* and set the treatment time (`SET`) using the *Keypad*.

2. Press the *Fluid Path button*, select `UF` and set the UF volume (`SET UF`). The calculated UF rate will be displayed in `UF RATE`.

3. When the flashing *UF Start/Stop button* is pressed (lights up), the ultrafiltration starts. The automatically set current TMP value, and the set (centralized) alarm limits, has to be confirmed by the operator via the TMP confirm menu displayed on the Information Display. Note that the alarm limits should be set in accordance with the UF rate and dialyzer UF coefficient.

CAUTION

When negative TMP alarm limits are set, the operator will **not** be notified via alarm or attention alarm that backfiltration may occur. However, it is possible for the authorized technician to preset the machine so that when negative TMP alarm limits have been set, such an attention alarm occurs.

CAUTION

An attention alarm may appear if an incorrect combination of settings have been made, e.g. the time is set to 0.00 and the UF volume is set. The alarm will disappear as soon as the time is sufficiently increased.

A high UF rate limit is automatically calculated and set as 120 % of the calculated UF rate. This limit is the highest UF rate during treatment.

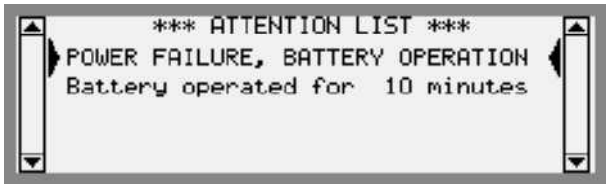
If, for any reason, the UF rate has been too low during a period of time, the machine will try to compensate for this by increasing the UF rate, but within the UF rate limits.

Power Failure

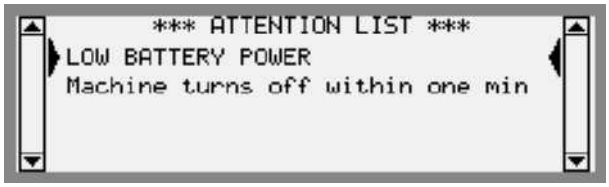
Battery Back-up Operation

The machine is equipped with a back-up battery. In case of a power failure, the battery will supply the machine with power. The settings and accumulated values are stored by the machine. The battery supplies the machine with power to all functions except for heating the dialysis fluid. This means that a low temperature alarm will occur after the power failure.

When a power failure occurs an attention alarm will be displayed indicating that the machine is using the battery back-up and also for how much time it will last:



When only one minute remains of battery power an attention alarm will be displayed:



Note

- If the machine has been used on battery back-up, note that the back-up battery will not have full capacity until it has been recharged by the machine.

Note

Override Battery Back-up Operation

If there is a need to override the battery back-up function during power failure, press and release the halt button at the rear of the machine. The machine will then shut down and will continue to be off until main power returns. When main power returns the machine will perform a recovery, see Recovery from Machine Shut Down on page 3:29.

Override of the battery back-up function can be used when there is a need to switch off or restart the machine for instance when it needs to be moved.

Machine Shut Down

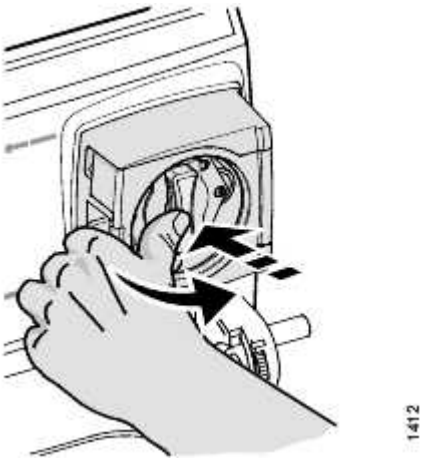
In case of a battery failure simultaneous with a power failure the machine will shut down and a segment on the Time Display will be flashing. The settings and accumulated values are stored by the machine. When the power returns the machine will perform a recovery, see Recovery from Machine Shut Down on page 3:29.

Return the Blood During Machine Shut Down

During a machine shut down, it is possible to manually return the blood to the patient.

1. Clamp the arterial blood line and disconnect it from the patient.

2. Connect the arterial blood line to the rinse-back solution and remove the clamp.



3. Open the cover of the blood pump and turn the blood pump manually.

4. When the required amount of blood has been returned to the patient, clamp the venous blood line and disconnect it from the patient.

WARNING

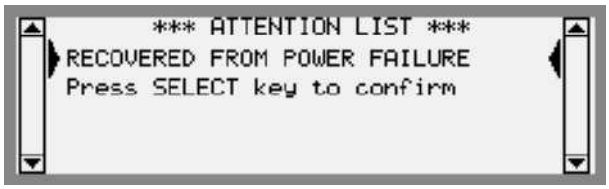
⚠ During manual procedure to return blood to patient in power failure, the operator assumes responsibility for visually monitoring all safety parameters which the machine cannot monitor in a power failure (e.g. air detection).

WARNING

Recovery from Machine Shut Down

In case of a short power failure, or a longer one where the machine shuts down, the settings and accumulated values are stored by the machine. If the machine has passed function check and time has appeared on the Time Display before power failure, the machine will perform a recovery when power returns. If the function check was not completed before the power failure occurred, a function check will be done when power returns.

When the machine performs a recovery an attention alarm will appear and the buzzer sounds. The text “reC” is shown on the Time Display.



The operator must confirm the recovery after restart by pressing the *Select key*. The machine will then continue the treatment from where it was interrupted.

CAUTION

Check treatment parameters after a recovery.

CAUTION

Note

- If the attention:

  appears, there will be no support for the buzzer and no flashing segment on the Time Display during power failure. However, the settings and accumulated values are stored by the machine. When it has been confirmed, the machine will not restart automatically.
  The *On/Off button* has to be pressed to recover function.

- The machine will still be able to operate since this is not the same battery as the back-up battery. Contact an authorized technician to change or recharge the battery.

- During power failures, when the buzzer is muted, the current consumption from the battery is high. In order to avoid this high consumption, switch the machine off by pressing the *On/Off button* for 3 seconds instead of pressing the *Mute button*. When the power returns, switch on again using the *On/Off button*. A normal recovery will now follow.

Note

Handling Features

Concentrate Stand-by Mode

When the machine has been switched on, has passed the function check with proper concentrates connected, and the bypass path on the Flow Diagram lights up green, it is possible for the machine to enter a stand-by mode where the consumption of concentrates will be stopped.

This stand-by mode, called concentrate stand-by mode, can be activated before or after the flashing *Fluid bypass button* has been pressed during priming i.e. before or after the priming of the fluid compartment of the dialyzer has been performed. (It cannot be activated if blood has been detected.)

Concentrate stand-by mode can be manually activated (default function) or automatically activated by preset.

On request from the clinic, an authorized technician can preset the type of presets for Concentrate stand-by mode that best suits the routine procedures of the specific clinic.
There are two presets that can be used, separately or in combination:

1. Automatic activation of concentrate stand-by mode when time is shown on the time display and the bypass path of the Flow Diagram lights up green. The time for activation may be straight away when the bypass path lights up green, or for a preset amount of time after.

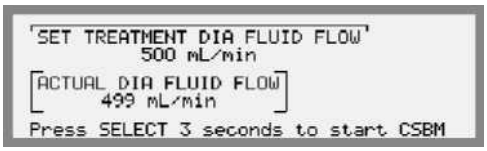
2. The time for automatic activation can also be preset to be when priming volume achieved menu is displayed during priming.

When the concentrate stand-by mode is active, the `CONCENTRATE STANDBY MODE` menu will be displayed at the Information Display. The bypass path of the Flow Diagram will be orange.

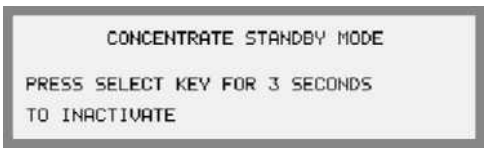
In addition to the above-mentioned presets, the machine can be preset to automatically turn off the water intake at the same time as Concentrate stand-by mode is active. In this case, the consumption of both water and concentrates will be stopped. The handling procedures will be the same.

Procedure for manual activation

1. Press the *Fluid path button*, select DIA FLUID FLOW using the *Keypad*.



2. Press the *Select key* for 3 seconds to activate concentrate stand-by mode.



3. The CONCENTRATE STANDBY MODE menu will now be displayed on the Information Display.

Resume fluid preparation

To resume the dialysis fluid preparation (Concentrate stand-by mode deactivated) press the *Select key* for 3 seconds when the CONCENTRATE STANDBY MODE is displayed. The dialysis fluid will be ready within approximately 2 minutes.

If dialysis fluid preparation has not been resumed during priming, it will automatically be resumed when blood is detected in the priming detector after treatment start. Dialysis fluid preparation will also automatically be resumed when concentrate stand-by mode has been active for more than one hour.

Miscellaneous

Change of BiCart® cartridge during Treatment

If the BiCart cartridge needs to be replaced by a new one during treatment, close the latches **for at least 2 seconds** before attaching the new cartridge. This is necessary in order for the machine to automatically prime the new BiCart cartridge. Instructions on how to remove the cartridge can be read in "Machine aftercare", page 4:63 in part 1. Instructions on how to attach the cartridge can be read in "Acidic concentrate and BiCart® cartridge", page 4:9 in part 1.

Change of Blood Pump Segments

If the blood lines being used need a specific blood pump segment diameter setting, the machine can be preset with 3 such variants. Check with authorized technician.

Change of blood pump segment setting should be done before the patient is connected.

CAUTION

Make sure a correct blood pump rotor is used. The blood pump rotor has to be properly adjusted in order to correctly occlude the blood pump segment being used. This is important in order to achieve the correct blood flow. Check with the authorized technician.

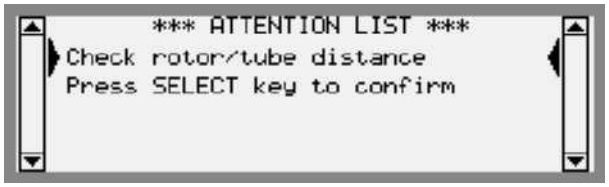
CAUTION

The machine has to be in priming mode and the blood pump has to be stopped in order for the diameter of the blood pump segment to be changed.

1. Press the *Blood Path button*.

2. Select `BLOOD FLOW` and `SEGMENT` using the Keypad.

3. Press the *Select key* to open the parameter, adjust using the *Display Up/Down Keys*.
4. Make sure to use a correct blood pump rotor. The blood pump rotor has to be properly adjusted in order to correctly occlude the blood pump segment being used.
5. Confirm the attention alarm:



by pressing the *Select key*.

Change of Dialyzer and Blood lines during Treatment

There may be a need of changing the blood lines and the dialyzer (i.e. the extracorporeal blood circuit) during the ongoing treatment due to, for example, clotting. Sometimes it is possible to return the blood to the patient, but it may also be necessary to immediately disconnect the complete blood circuit from the patient, without returning the blood.

1. Press the *Discontinuing button* to display the RINSE BACK MENU.

2. When NEW BLOOD CIRCUIT has been selected, press the *Select key* for 3 seconds to activate discontinuing mode.

At the moment when the *Select key* is pressed, the **blood pump will automatically be stopped** (flashing button). The *Discontinuing button* lights up. This will also automatically widen the venous pressure, the arterial pressure and the TMP alarm limits to their priming values without subsequent centralizing alarm. The UF rate will be reduced to minimum UF rate (unlit *UF Start/Stop button*).

The menu will change and it is possible to select either to **immediately disconnect the complete blood circuit** from the patient (DISCONNECT PATIENT) **or to return the blood to the patient before disconnecting the blood circuit** (RINSE BACK). Select the appropriate alternative and continue to the corresponding instructions as follows.

3. **If rinse-back**
   RINSE BACK, has been selected:

   3.a. Return the blood to the patient as usual procedure. For rinse-back instructions, see "Return The Blood", page 4:60 in part 1. Start on point 4 of the instructions and continue with all the instructions in "Return The Blood" (point 12 included) up until "Confirm Patient Disconnection", page Confirm Patient Disconnection in part 1.

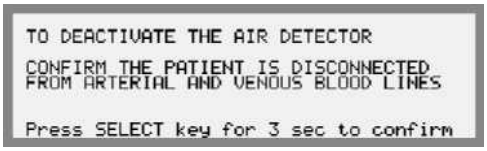
   3.b. Continue to point 5 in these instructions.

4. **If immediate patient disconnection**
   DISCONNECT PATIENT, has been selected:

   4.a. Check that the blood pump has been stopped.

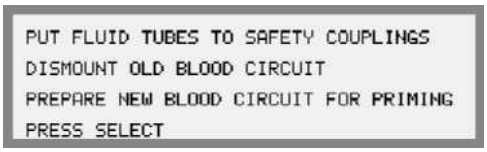
   4.b. Clamp the arterial and venous blood lines and disconnect the blood lines from the patient.

   4.c. Continue to point 5 in these instructions.



5. Check that the arterial and venous blood lines has been completely disconnected from the patient. Confirm this by pressing the *Select key* for 3 seconds and the menu will change to the `DISMOUNT OLD BLOOD CIRCUIT` menu.

When patient disconnection has been confirmed, the air detector will be deactivated and the dialysis fluid will automatically be bypassed from the dialyzer.



6. Disconnect the dialysis fluid tubes from the dialyzer and connect them to the safety couplings of the machine. Remove the dialyzer and the blood lines; follow the instructions in "Machine aftercare", page 4:63 in part 1, point 25 and additional warning.

7. Attach new dialyzer and blood lines; follow the corresponding instructions in "Attach Disposables", starting on page 4:13 in part 1.

8. Press the *Select key* when new disposables have been attached, the *Priming button* lights up indicating that priming mode has been activated.

9. Prime and de-air the new blood circuit as usual procedure. Follow the corresponding instructions starting on page 4:40 for "Manual Priming and Rinsing Procedure" and on page 4:46 for "Assisted Priming and Rinsing Procedure" in part 1.

Resume Treatment

10. Check/adjust the treatment parameters for the continuing treatment (see "Always Check/Adjust", page 4:52) in part 1.

11. Connect the blood lines and start the treatment as usual procedure. See corresponding instructions in "Connect the Patient", page 4:53 and "Start the Treatment", page 4:56 in part 1.

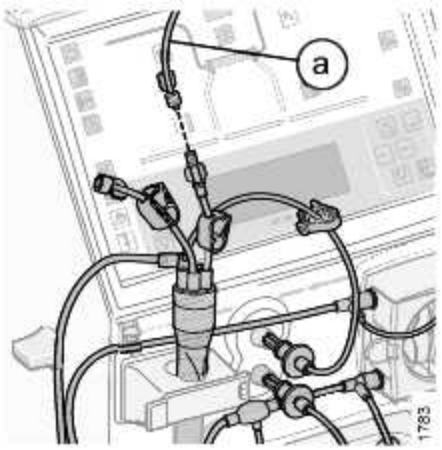
Especially note that **all treatment parameters**, set values as well as accumulated values, from treatment start up until where it was interrupted **have been saved** by the machine. If the Diascan or Profiling functions have been previously activated, attention alarms will be generated to give the operator instructions on how to set/adjust the values for the continuing treatment.

Infusions during Treatment

It is possible to give the patient infusions/transfusions/medications during treatment via the extracorporeal blood circuit. As a matter of principle, transfusions and medications are to be administered in the venous blood line after the dialyzer.

Infusions may be administered both in the arterial blood line or in the venous blood line, depending on type of infusion. Note especially that any infusion/transfusion/medication given to the patient via the extracorporeal blood circuit during treatment, must pass the venous drip chamber and the activated air detector.

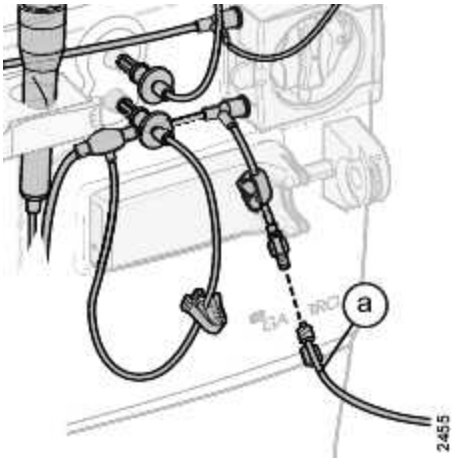
Post-blood pump infusions



Lines for infusions are first and foremost to be connected to the extracorporeal blood circuit post-blood pump, **i.e. after the blood pump**, preferably to the venous drip chamber. The corresponding figure shows post-blood pump connection of infusion. The infusion line is marked ⓐ.

Since there is a positive pressure in the blood lines post-blood pump (including the venous drip chamber), an overpressure must be established in the infusion line. Normally, this is done by using an infusion pump, an overpressure cuff or, if necessary, by manually creating an overpressure.

Pre-blood pump infusions



There is also the possibility of connecting the infusion line to the extracorporeal blood circuit pre-blood pump, **i.e. before the blood pump**. The corresponding figure shows pre-blood pump connection of infusion. The infusion line is marked ⓐ.

Since there is a negative pressure in the blood lines pre-blood pump, pay attention of the possibility of air entering the blood lines. Always carefully supervise pre-blood pump infusions. Do not use infusion pump or any other methods to create overpressure in the infusion line.

WARNING

⚠ When using a central venous catheter, and connecting the infusion line pre-blood pump, ensure that the arterial blood line towards the patient is properly clamped, before the infusion is started and during the ongoing infusion. This is to prevent air from entering the patient's blood stream since the pressure in the central venous catheter is sometimes negative.

WARNING

Chapter 4

Hemodialysis - Double Needle Treatment

Contents

Start the Machine

Check Before Switching the Machine On

- That the mains cable is connected to a mains supply with protective earth.
- That the main switch on the rear of the machine is in the on position (indicated by a lit segment shown on the Time display).
- That the water supply is connected to the machine (inlet water tube) and switched on.
- That the drain tube (outlet tube) is properly placed with an air gap between the machine and the drain/sewer system.
- That the dialysis fluid tubes are connected to the safety couplings of the machine.

Switch the Machine On

Note

- If the machine has been stored with chemical disinfectant, this solution must be rinsed out of the system before any treatment can be initiated.

Note

Switch the machine on by pressing the *On/Off button* for three seconds.

At this moment, the buzzer will sound shortly and the computer processor of the machine will count up (displayed on the Time display). The current program version installed on the machine will be displayed on the Information Display.

After a short while all the lamps on the operator's panel will light up simultaneously. The operator must look and check that the lamps are functioning. If any lamp does not light up, contact an authorized service technician. The machine will also test the buzzer sound.

Function Check

CAUTION

In order to protect the operator's fingers, do not attach the blood lines during the function check of the blood part, since the blood pump rotor and the blood line clamps will be moving during the check.

CAUTION

When the machine starts up it always carries out checks on internal safety and calibrations; the function check. "**F.Ch**" will appear on the Time Display and the Treatment Overview Menu will be shown on the Information Display. See "Overview Displays" on page 3:23 in part 1 for further information.

The *Back button* lights up. If pressed, the second part of the Treatment Overview Menu appears. Switch between the two parts using the *Back button*.

The Blood part will be checked first, it will only take a few minutes. During this time the blood pump cover must be closed and the pressure transducers of the blood lines cannot be connected.

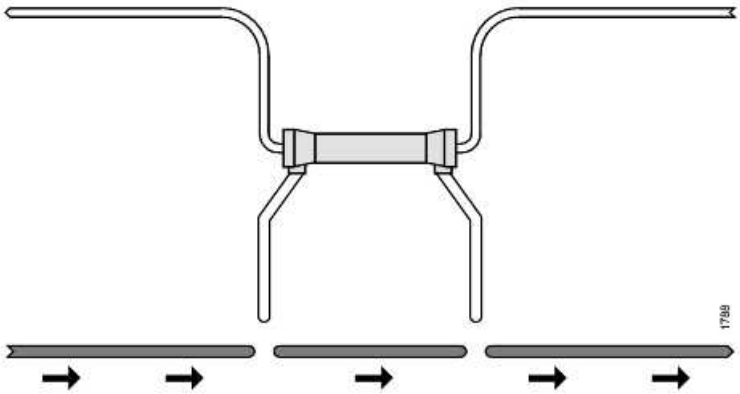
When the *Priming button* **lights up**, the *Blood Pump button* starts to flash, the *Air Detector button* lights up and it is now possible to attach the blood lines (if not done before switching the machine on). See "Attach Disposables" starting on page 4:13 in part 1. It is also possible to start the priming procedure of the blood part. See "Priming" starting on page 4:38 in part 1. Note that if a chemical disinfection program has been performed prior to the function check, the function check is prolonged. An attention alarm appears to guide the operator in this case.

To be able to finish the function check, the proper concentrates must be connected. See "Connect/Confirm Concentrates" starting on page 4:7 in part 1. Note that if BiCart cartridge is used, it can be attached after finalized function check. An attention alarm appears requesting the operator to attach the cartridge. The buzzer can be permanently muted. The BiCart cartridge must be attached to obtain green bypass path of the Flow Diagram.

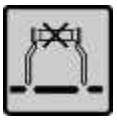
The dialysis fluid tubes must remain connected to the safety couplings of the machine until "F.Ch" disappears from the Time Display. Note that if the optional Dialysis Fluid Filter, see "UFD- Ultrafiltered Dialysis Fluid (option)" page 1:17 in part 1, has been installed, the

dialysis fluid tubes must remain connected to the safety couplings until the bypass path of the Flow Diagram lights up green.

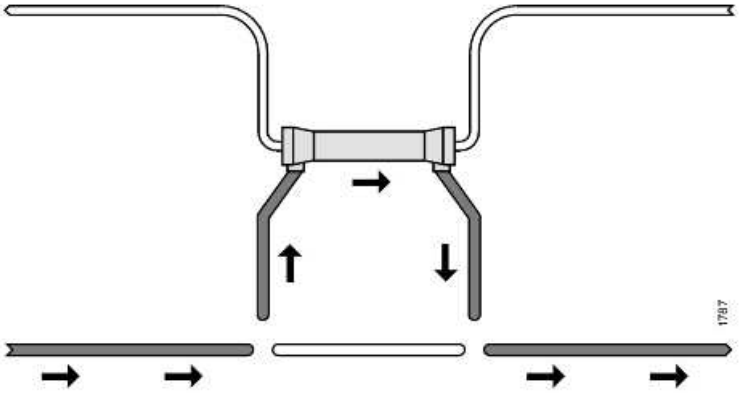
When "F.Ch" disappears from the Time Display the dialysis fluid tubes can be attached to the dialyzer.



The bypass path of the Flow Diagram also lights up. Before the correct conductivity level has been reached the bypass path will be orange. When the fluid preparation is finished **the bypass path turns green**.



At the same time the *Fluid bypass button* will be flashing. When pressed (and green path), the button lights up and the dialysis fluid will start to flow.



If the dialysis fluid tubes are connected to the safety couplings, the fluid will circulate within the machine. If they are connected to the dialyzer, the fluid will enter the dialyzer at that time. See "Dialysis Fluid Tubes - Attach" starting on page 4:35 in part 1 for instructions on how to properly attach the dialysis fluid tubes to the dialyzer.

If desired, the concentrates may be connected, and the blood lines may be attached, before the machine has been switched on. If so, do not connect the pressure transducers of the blood lines to the machine until the machine has been switched on and the *Priming button* lights up.

Priming may be started (the blood lines and the blood compartment of the dialyzer) during function check (after complete blood part checks).

It may also be performed during disinfection program. Bear in mind that the *Priming button* must be lit in both cases.

The set treatment time appears on the Time Display during priming when 70% of the priming volume has been achieved, the venous drip chamber has been filled, and the bypass path of the Flow Diagram lights up green.

CAUTION

! After chemical disinfection procedure a test for residues must have been performed prior to connecting to a patient.

CAUTION

Note

- After the machine has passed the function check and the bypass path on the Flow Diagram lights up green, it is possible to activate concentrate stand-by mode in order to save concentrates before patient connection. See information in "Concentrate Stand-by Mode" on page 3:30 in part 1.

Note

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Set-up the machine

Connect/Confirm Concentrates

CAUTION

- The operator must make sure that the chosen concentrates on the Information Display correspond with the connected concentrates during function check and during treatment.

- Verify that the prescribed concentrate(s) for the specific treatment is (are) used. Avoid changing type of concentrate containers during treatments.

CAUTION

Note

- In order to finalize the function check, the A-concentrate/acetate must be connected and the venous drip chamber filled to the correct level. The reason is, that the conductivity cells must be checked with conductivity and the air detector must be checked with fluid in the chamber. When the function check is finished, the treatment time appears on the time display.

- During the conductivity test in function check it is not possible to change between Bicarbonate and Acetate mode. If the conductivity check during function check was performed in Acetate mode it is not possible to switch to Bicarbonate mode during treatment. However, it is always possible to change from Bicarbonate to Acetate mode during treatment.

- Fixed conductivity alarm limits (±5 %) will be set automatically, centred around the conductivity set value.

Note

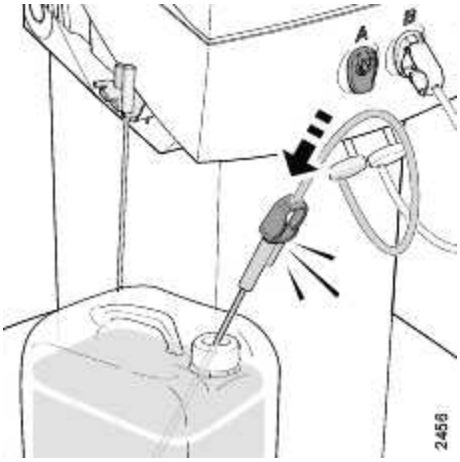
Concentrate Combinations

There are **three different alternatives** for concentrate combinations that can be used; acidic concentrate and bicarbonate concentrate in either dry (the BiCart cartridge) or in liquid form or acetate concentrate. Choose alternative, and follow the corresponding instructions:

- **Acidic concentrate and BiCart cartridge**, see next page for instructions.
- **Acidic concentrate and liquid bicarbonate concentrate**, see page 4:11 in part 1 for instructions.
- **Acetate concentrate**, see page 4:12 in part 1 for instructions.

For details about the following mentioned machine components, see corresponding information in "Fluid Part Component Details" starting on page 2:19 in part 1.

Acidic concentrate and BiCart® cartridge



1. **Attach Acidic concentrate**

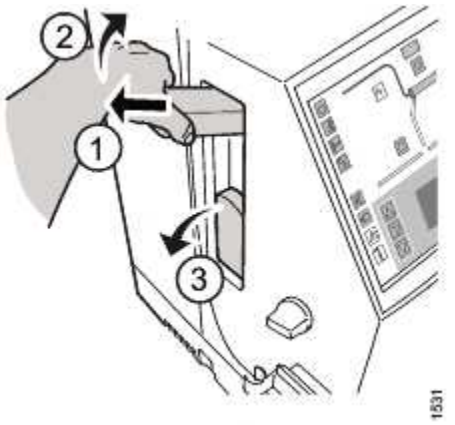
   1.a. Remove the red concentrate connector from the stand-by port of the machine (compress the connector before pulling the connector out).

   1.b. Attach the connector to a concentrate pick-up tube; insert the connector into the pick-up tube port and push it into place until it clicks in. Make sure that it clicks in properly to prevent air leakage during treatment.

   1.c. Put the pick-up tube into the proper acidic concentrate container (the blue concentrate connector must remain in the stand-by port).

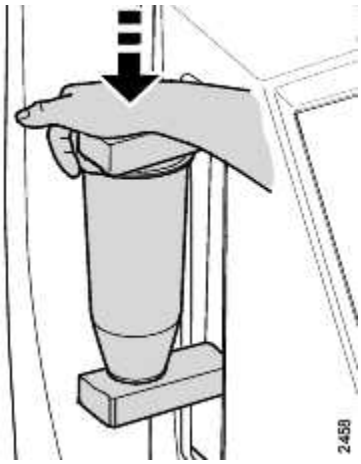
If SoftPac container for acidic concentrate is being used, connect the red concentrate connector to the particular connector used for SoftPac containers and insert it into the SoftPac container.

2. **Attach BiCart cartridge**



   2.a. Open the upper latch of the BiCart holder, pull out the latch ① and lift upwards to its uppermost position ② . Open the lower latch ③ .

   2.b. Place the bottom port of the BiCart cartridge into the hole of the lower latch as shown in the corresponding figure.



2.c. Bring down the upper latch and place the top port of the cartridge into the hole of the upper latch. Press down the upper latch to puncture the cartridge. The BiCart cartridge will be primed automatically.

Note

- Follow the instructions for use of the BiCart cartridge.
- The BiCart cartridge can be attached before, during or after the function check. This means that it can be attached after finalized function check but must be attached to obtain green bypass path of the Flow Diagram.

Note

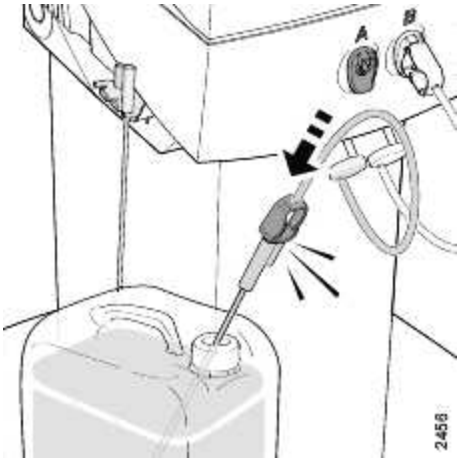
3. **Confirm concentrates**
   The confirm concentrate menus will automatically appear when the red concentrate connector is removed from the stand-by port.

3.a. Select BICARBONATE using the *Keypad*.

3.b. Confirm that the connected concentrates correspond with the displayed concentrate alternative on the Information Display, using the *Select key*.

Note that at any time after confirming the concentrates, it is possible to enter the concentrate menus to check/select concentrates. Press the *Fluid path button* and select CONC. Go into the sub menus and check/select the connected concentrates using the *Keypad*.

Acidic concentrate and liquid bicarbonate concentrate



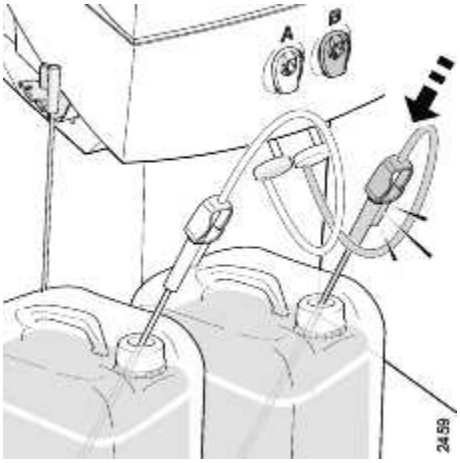
1. **Attach Acidic concentrate**

   1.a. Remove the red concentrate connector from the stand-by port of the machine (compress the connector before pulling the connector out).

   1.b. Attach the connector to a concentrate pick-up tube; insert the connector into the pick-up tube port and push it into place until it clicks in. Make sure that it clicks in properly to prevent air leakage during treatment.

   1.c. Put the pick-up tube into the proper acidic concentrate container (the blue concentrate connector must remain in the stand-by port).

If SoftPac container for acidic concentrate is being used, connect the red concentrate connector to the particular connector used for SoftPac containers and insert it into the SoftPac container.



2. **Attach Liquid Bicarbonate concentrate**

   2.a. Remove the blue concentrate connector from the stand-by port of the machine (compress the connector before pulling the connector out).

   2.b. Attach the connector to a concentrate pick-up tube; insert the connector into the pick-up tube port and push it into place until it clicks in. Make sure that it clicks in properly to prevent air leakage during treatment.

   2.c. Put the pick-up tube into the proper liquid bicarbonate concentrate container.

3. **Confirm concentrates**
   The confirm concentrate menus will automatically appear when the red or blue concentrate connector is removed from the stand-by port.

   3.a. Select `BICARBONATE` using the *Keypad*.

   3.b. Confirm that the connected concentrates correspond with the displayed concentrate alternative on the Information Display, using the *Select key*.

Note that at any time after confirming the concentrates, it is possible to enter the concentrate menus to check/select concentrates. Press the *Fluid path button* and select `CONC`. Go into the sub menus and check/select the connected concentrates using the *Keypad*.

Acetate concentrate

1. **Attach Acetate concentrate**

   1.a. Remove the blue concentrate connector from the stand-by port of the machine (compress the connector before pulling the connector out).

   1.b. Attach the connector to a concentrate pick-up tube; insert the connector into the pick-up tube port and push it into place until it clicks in. Make sure that it clicks in properly to prevent air leakage during treatment.

   1.c. Put the pick-up tube into the proper acetate concentrate container (the red concentrate connector must remain in the stand-by port).

2. **Confirm concentrates**
   The confirm concentrate menus will automatically appear when the blue concentrate connector is removed from the stand-by port.

   2.a. Select ACETATE using the *Keypad*

   2.b. Confirm that the connected concentrates correspond with the displayed concentrate alternative on the Information Display, using the *Select key*.

Note that at any time after confirming the concentrates, it is possible to enter the concentrate menus to check/select concentrates. Press the *Fluid path button* and select CONC. Go into the sub menus and check/select the connected concentrates using the *Keypad*.

Attach Disposables

WARNING

⚠ The operator must take proper precaution in order to prevent coagulation in the extracorporeal circuit.

Coagulation may lead to:

- inadequate delivery of dialysis
- risks associated with propagation of blood clots to the patient
- disabling of the air detector function if blood clots aggregate in the drip chamber

WARNING

CAUTION

To avoid patient blood loss and blood hemolysis, it is important to follow the manufacturer's instructions for use of the dialyzer and the blood lines. When attaching the blood lines always ensure that all connections are properly secured and that no part of the blood lines have been kinked. If the heparin pump is not to be used, especially ensure that the cap at the end of the thin line used for heparin solution, is properly closed.

CAUTION

Note

- Since tests of the blood pumps and the clamps are included in the function check, it is important that the blood lines are attached either before the function check or when the function check for the blood monitor has been completed (lit *Priming button*).

Note

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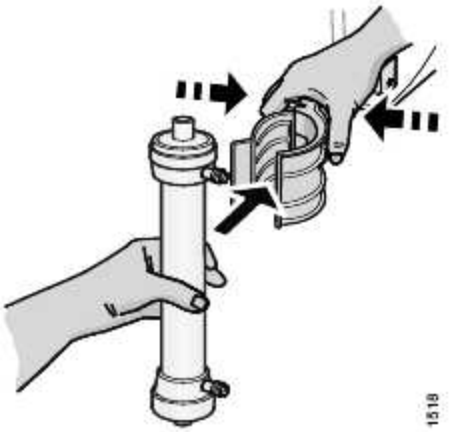
Dialyzer - Attach

Place the dialyzer in the holder by gently pushing it into the holder until it clicks in.



If necessary, squeeze the spring-clip as shown in the corresponding figure, to place the dialyzer in the holder.

Arterial Blood Line - Attach

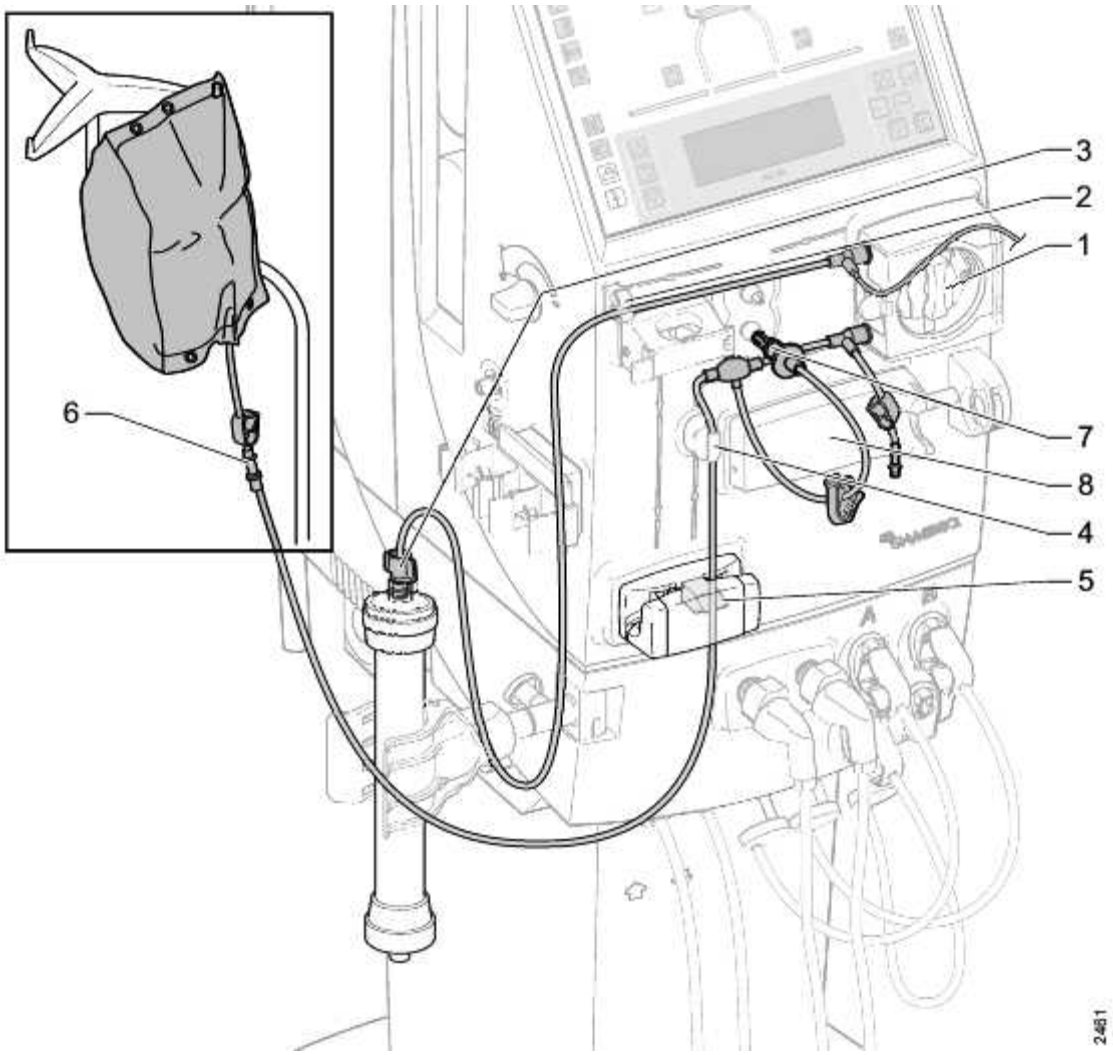
WARNING

⚠ Do not use the pediatric blood lines; A-5.128-B4 or V-5.127-X. The blood line clamps of the AK 96 dialysis machine cannot clamp these thin blood lines.

WARNING

Follow the Instructions For Use for the particular arterial blood line being used. In addition, especially observe the following items.

The items are pointed out in "set-up" order, starting with the blood pump.
A list of details on how to correctly attach the corresponding arterial blood line parts, follows on the pages directly after this.



1. Blood Pump

2. Blood Line Guide

3. Dialyzer Connection

4. Blood Line Guide

5. Arterial Line Clamp (option)

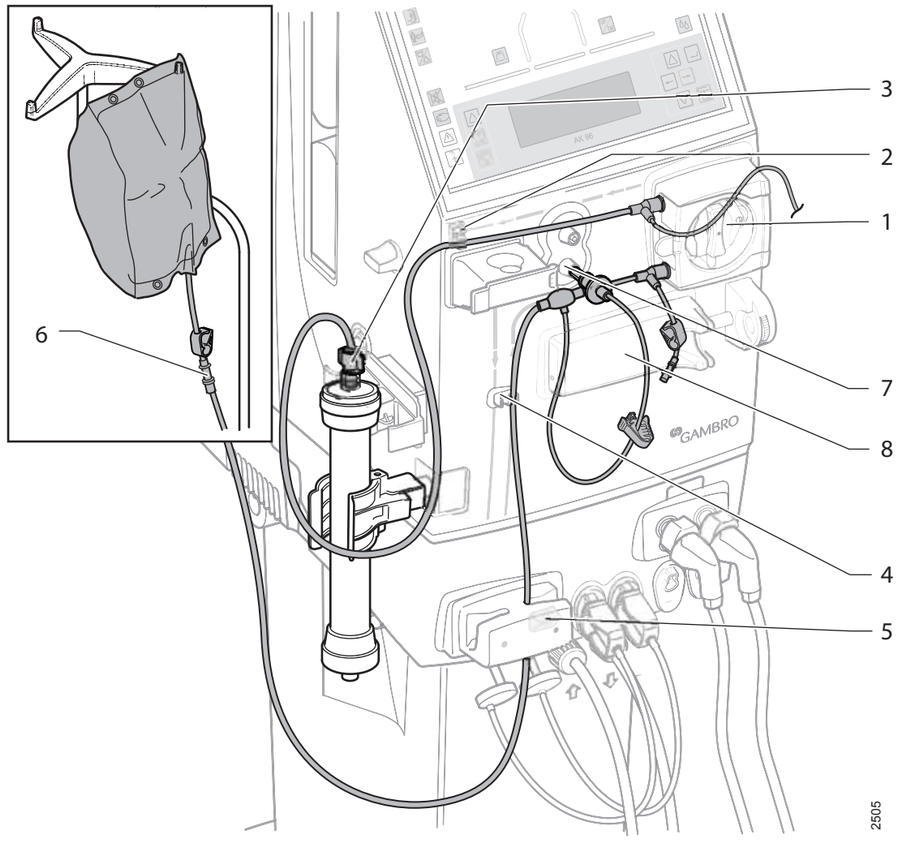
6. Arterial Patient Connector

7. Arterial Pressure Transducer Connector

8. Heparin Pump (option)

If desired, more information concerning the following mentioned components can be read in the list "Blood Part Component Details" on page 2:6 in part 1.

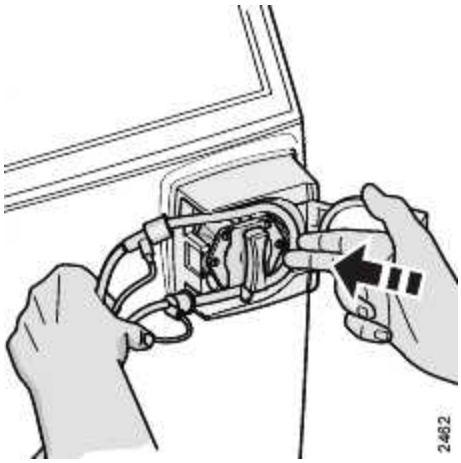
Arterial Blood Line - Attach



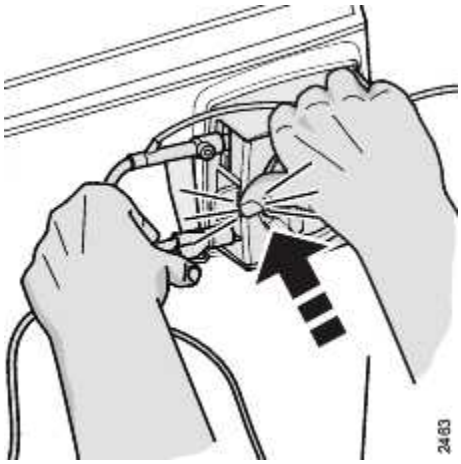
Details

1. **Blood Pump**
   Open the cover of the blood pump by pressing the middle of the cover at the same time as the cover is being opened. After this, the blood pump segment can be automatically or manually threaded.
   If the blood pump is automatically threaded, the machine will thread the blood pump segment over the blood pump rotor either during function check or when priming is started dependent on when the pump segment has been placed over the blood pump rotor.
   If it is manually threaded, the operator threads the segment through the blood pump during the arterial blood line set-up. Instructions on both alternatives follow after this.

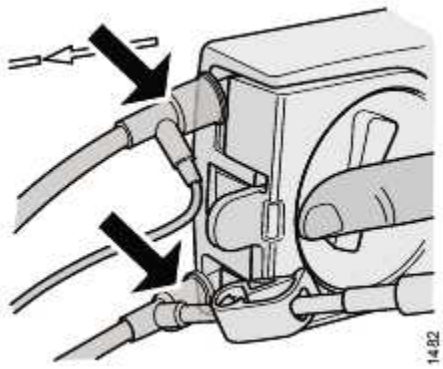
If automatically threaded



Place the blood pump segment over the blood pump rotor as shown in the corresponding figure.

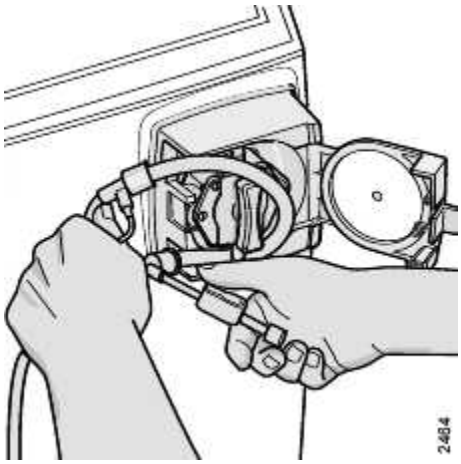


While keeping the segment in place, close the blood pump cover by pressing at the point shown in the corresponding figure.



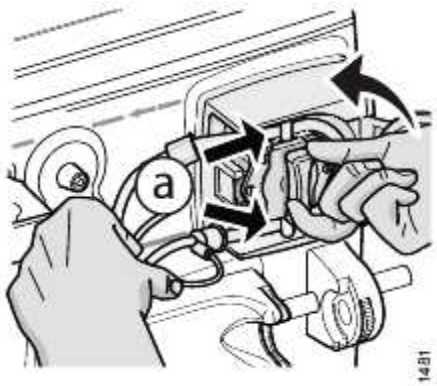
Make sure the blood pump segment collars are outside the pump housing.

If manually threaded

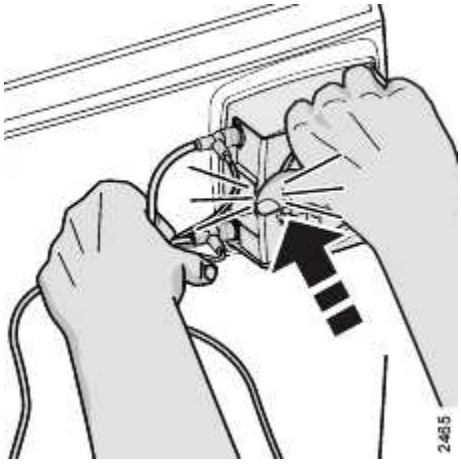


Place and hold the blood pump segment in the way shown in the corresponding figure.

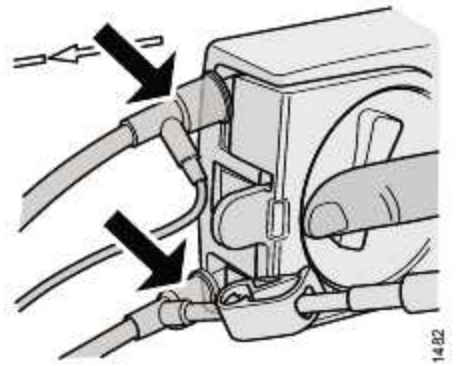
Press on the blood pump segment at the point shown in the figure before turning the blood pump rotor in an anti-clockwise direction. This is to hold the segment collar outside the pump housing while threading it.



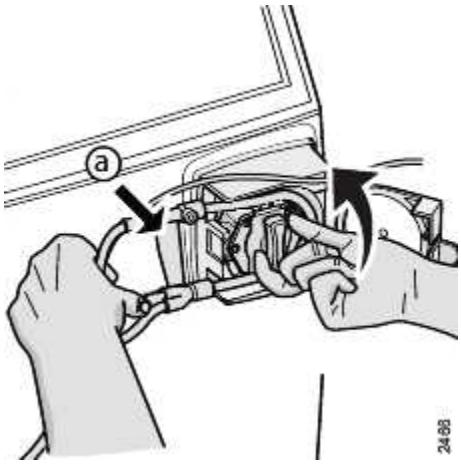
Continue turning the blood pump rotor in an anti-clockwise direction, while holding the segment, to thread the segment through the blood pump. The pins on the blood pump rotor, pointed out as ⓐ in the figure, hold the segment in place.



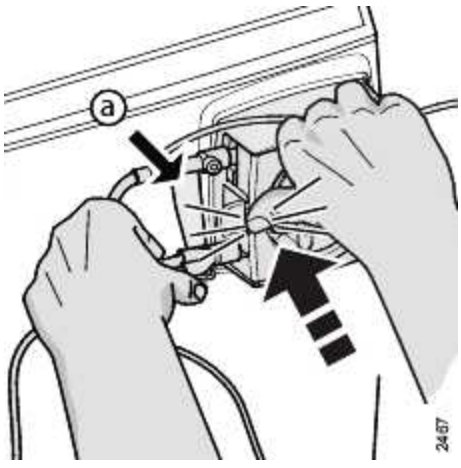
Close the blood pump cover by pressing at the point shown in the corresponding figure.

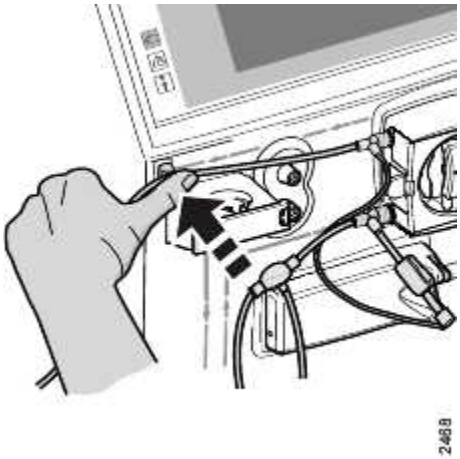


Make sure the blood pump segment collars are outside the pump housing.

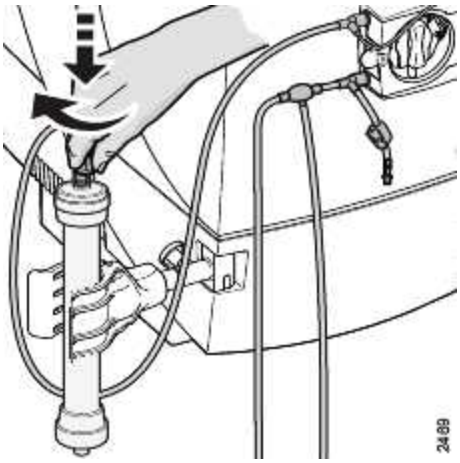


It is recommended to use a blood line with a plastic cross-bar between the segment collars, pointed out as ⓐ in the figure. The cross-bar holds the segment in place during treatment and it is also easier to thread the blood pump segment through the pump.

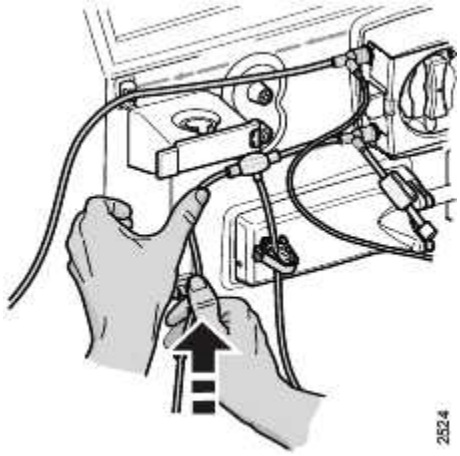




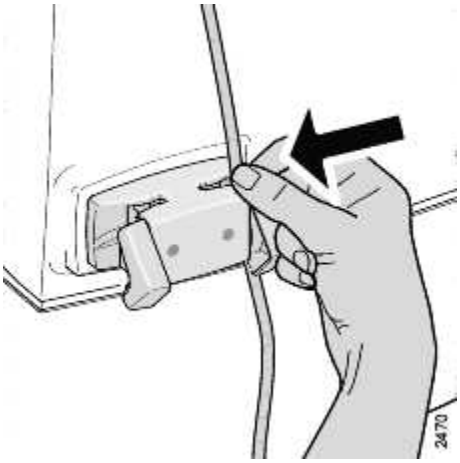
2. **Blood Line Guide**
Press lightly on the blood line to place it in one of the grooves of the guide.



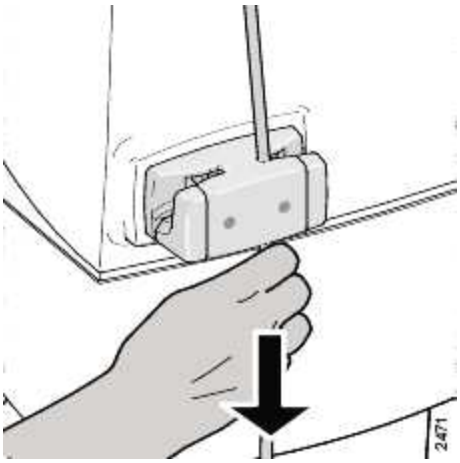
3. **Dialyzer Connection**
Attach the dialyzer end of the arterial blood line firmly to the dialyzer; press and simultaneously turn.



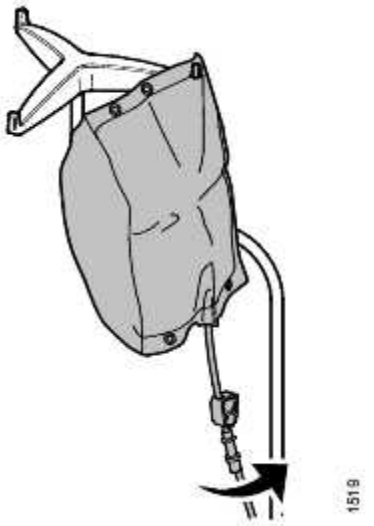
4. **Blood Line Guide**
Press lightly on the blood line to place it in one of the grooves of the guide.



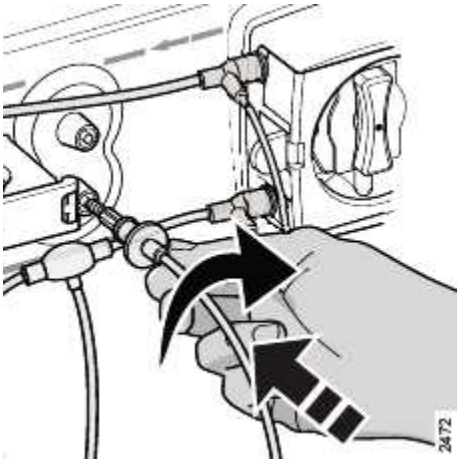
5. **Arterial Line Clamp**
   Introduce the blood line into the arterial clamp (marked with a red dot) by lightly pressing the line into the clamp.



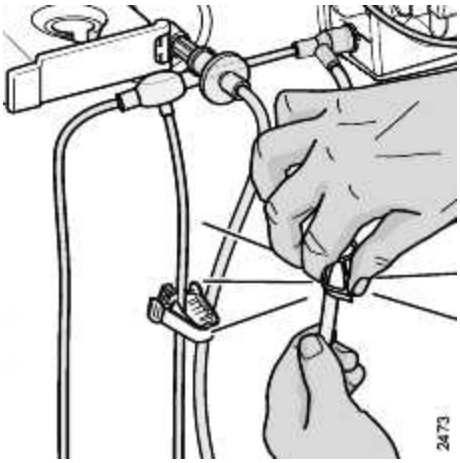
Then pull the blood line lightly downwards; the line goes into place when it is lightly pressed at the same time.



6. **Arterial Patient Connector**
   Connect the patient end of the arterial blood line to the priming fluid. Follow the manufacturer's instructions for use for type of priming fluid to be used for the particular dialyzer and blood lines.



7. **Arterial Pressure Connector**
   Attach the arterial pressure transducer protector of the blood line to the arterial pressure connector; press and simultaneously turn.



Check all necessary clamps
If the heparin pump is not to be used, especially ensure that the cap at the end of the thin line used for heparin solution, is properly closed.

8. **Heparin Pump**
   The heparin pump is used for continuous and/or bolus administration of heparin. Heparin is to be mixed (diluted) with the proper solution in a correct syringe used for the purpose. The Heparin pump can be programmed for different syringe sizes, syringes must comply with ISO 7886-2. Consult the authorized technician for information concerning heparin pump presets for the particular machine. Make sure that chosen syringe type matches displayed syringe type in the `HEPARIN MENU`, if not call authorized service technician.

See the following pages (continuing point 8) for instructions on how to attach the syringe to the heparin pump and how to set the heparin pump values in the machine.

CAUTION

To prevent the syringe from loosening from the heparin pump during treatment the syringe plunger has to be thoroughly secured. Check by lightly pulling on the plunger. When doing so, it must be impossible to pull the syringe out of the heparin pump.

CAUTION

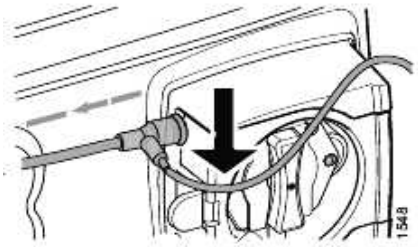
Note

- Make sure that chosen syringe type matches displayed syringe type in the HEPARIN MENU, if not call authorized service technician.

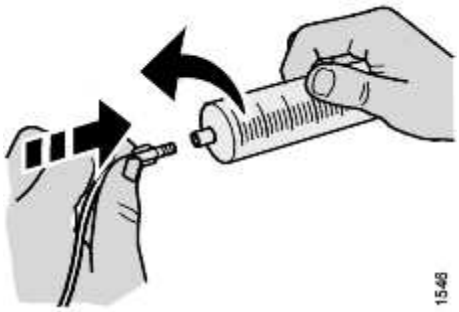
Note

Preparations if the heparin pump is to be used

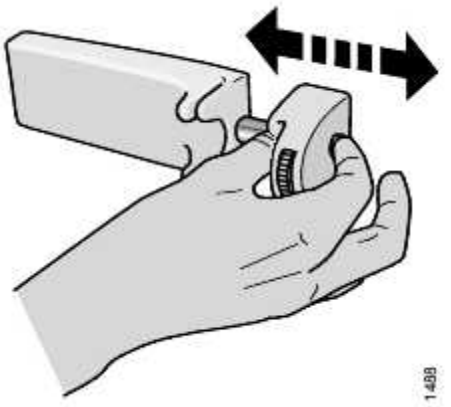
8.a. Prepare a syringe with the desired amount of heparin solution.



8.b. Attach the syringe to the connection at the end of the thin line coming out just after the blood pump segment (pointed out in corresponding figure) on the arterial blood line.



8.c. Prime the line with the heparin solution to the point where the line ends in the arterial blood line. The luer lock mounting ensures that the syringe is properly connected to the line, see corresponding figure.



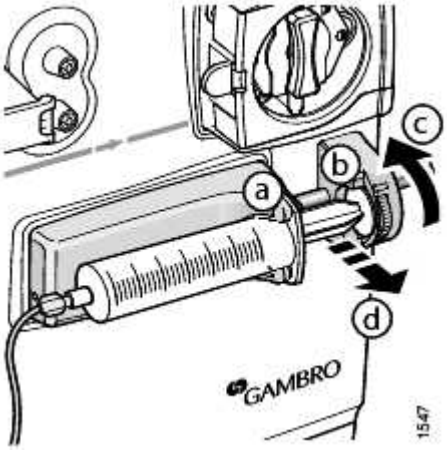
8.d. Pull out the piston on the heparin pump to end position. To change the position of the piston, press the end of the piston, hold it in and move the holder. When the piston is released the holder cannot move.

8.e. Make sure that chosen syringe type matches displayed syringe type in the HEPARIN MENU (press the *Blood Path button*, select HEPARIN) If not call authorized service technician.

8.f. Insert the syringe in the pump; the plastic collar at the end of the syringe must fit in the groove of the pump, ⓐ in the corresponding figure.

8.g. Push back the piston and insert the plastic plate on the plunger in the groove by the locking wheel, ⓑ in the figure.

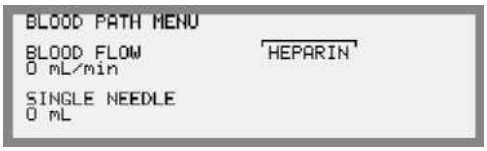
8.h. Turn the locking wheel upwards until resistance is felt. This is to lock the plastic plate of the plunger in the groove, ⓒ in the figure.



8.i. Check that the syringe is properly secured by lightly pulling on the plunger, ⓓ in the figure.

8.j. Press the *Blood Path button*, the BLOOD PATH MENU will be displayed on the Information Display.

8.k. Select HEPARIN using the *Keypad*, the HEPARIN MENU will be displayed.



8.l. If a bolus dose of heparin solution is to be administered at treatment start, set a bolus volume in ml (BOLUS) suitable for the patient using the *Keypad*.

8.m. Set a heparin solution flow rate in ml/hour (FLOW RATE) suitable for the patient. Note that during priming it is not possible to run the heparin pump with normal FLOW RATE.

8.n. If desired, set a heparin pump stop time `STOP LIMIT`. The stop time is the time in minutes at which the heparin pump should stop to run before treatment end.

When the heparin solution flow rate (`FLOW RATE`) and/or a bolus dose of heparin solution (`BOLUS`) has been set above zero, the heparin pump will automatically start to run at treatment start when blood is detected in the venous blood line. If a heparin solution bolus volume `BOLUS` has been set, this will be administered first. After this the heparin solution will automatically be administered at the set flow rate. Note that the sum of accumulated bolus volume during priming and total accumulated volume since treatment start will be shown below `ACC HEP`. To stop the heparin pump from running during treatment; set `FLOW RATE` to zero and bolus volume (`BOLUS`) to zero.

The heparin pump will run concurrent to the blood pump in double needle treatment. In single needle treatment it will be running continuously irrespective of if the blood pump is running or not.

During machine set-up and priming the heparin pump can be started at any time by pressing the *Select key* for three seconds until the text `Press SELECT 3 seconds to start bolus` disappears; the heparin pump immediately starts to run. (However, there is one exception, it is not possible to run the heparin pump when performing recirculation priming). Note that to stop the heparin pump from running during priming; set bolus volume (`BOLUS`) to zero.

Venous Blood Line - Attach

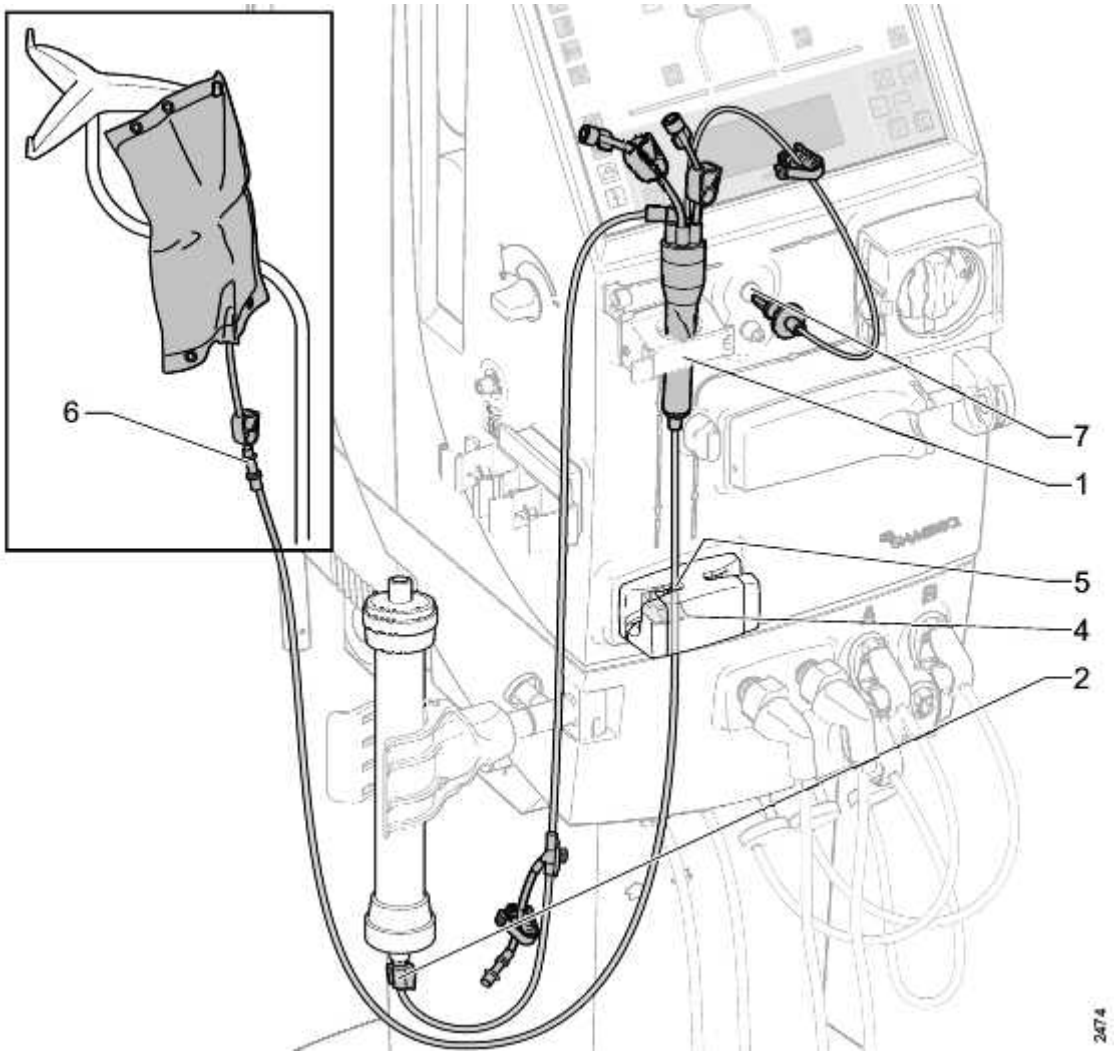
WARNING

⚠ Do not use the pediatric blood lines; A-5.128-B4 or V-5.127-X. The blood line clamps of the AK 96 dialysis machine cannot clamp these thin blood lines.

WARNING

Follow the Instructions For Use for the particular venous blood line being used. In addition, especially observe the following items.

The items are pointed out in "set-up" order, starting with the air detector.
A list of details on how to correctly attach the corresponding venous blood line parts, follows on the pages directly after this.



Venous Blood Line - Attach

1. Air detector

2. Dialyzer connection

3. Blood Line Guide ✳

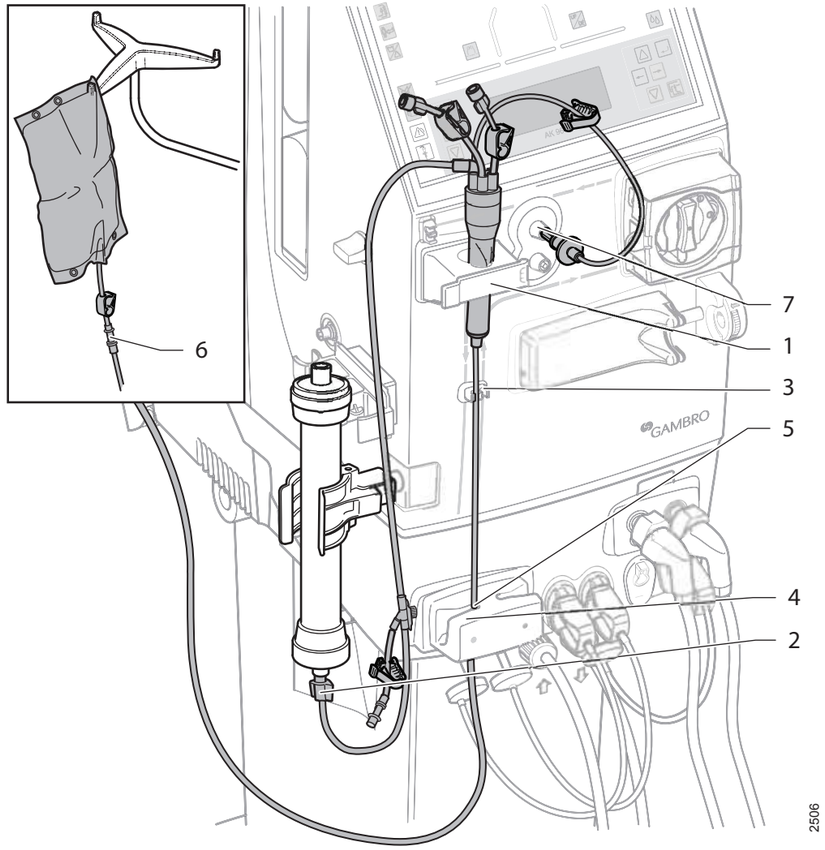
4. Venous Line Clamp

5. Priming Detector

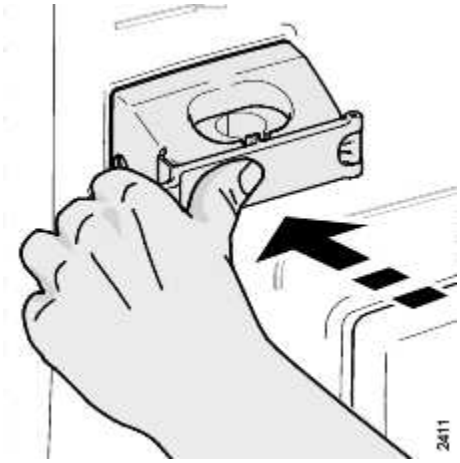
6. Venous Patient Connector

7. Venous Pressure Transducer Connector

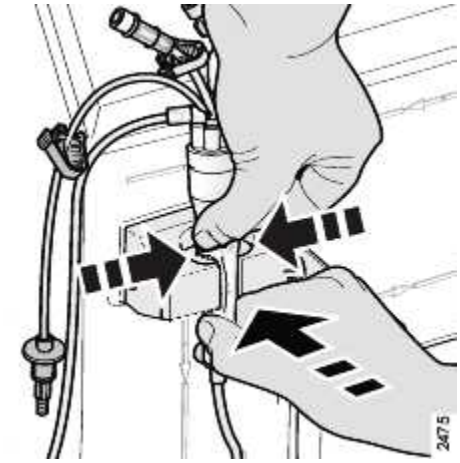
If desired, more information concerning the following mentioned components can be read in the list "Blood Part Component Details" on page 2:6 in part 1.



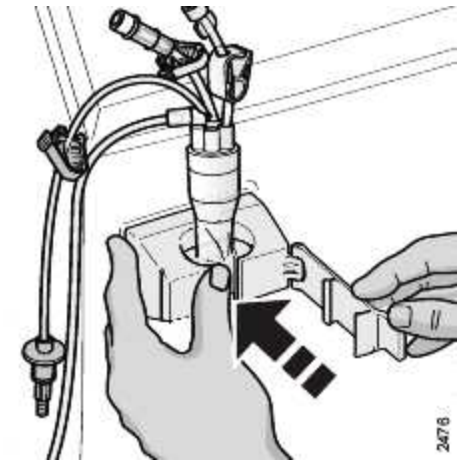
Details



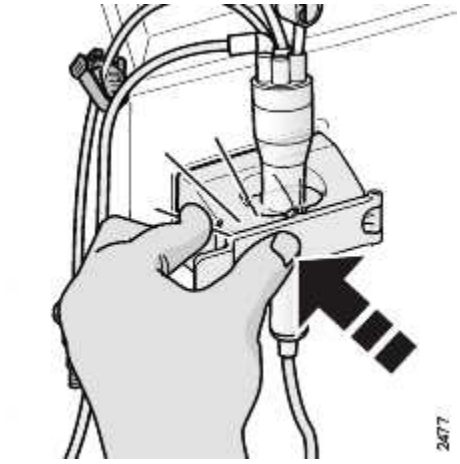
1. **Air detector**
   Open the cover of the air detector and place the venous drip chamber in it. It may be opened with ease by pressing the middle of the cover at the same time as the cover is being opened.



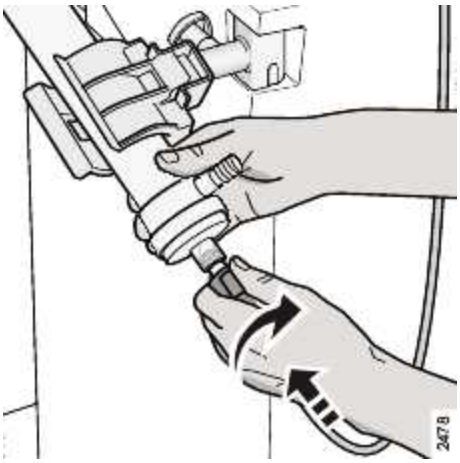
Compress the venous drip chamber as shown in corresponding figure and push it in to the air detector.



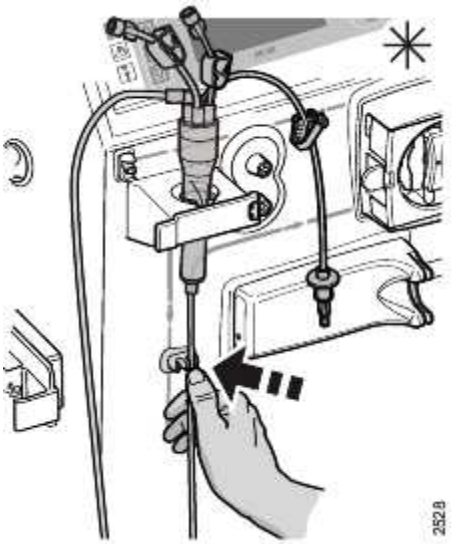
Press on the middle of the venous drip chamber, while closing the cover.



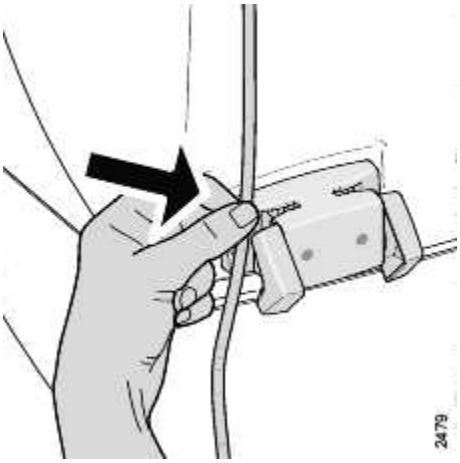
Close the cover until it clicks.
Adjust the position of the venous drip chamber to a proper position; as low as possible to prevent air from passing into the venous line. However, it should be possible to adjust the level well above the air detector head.



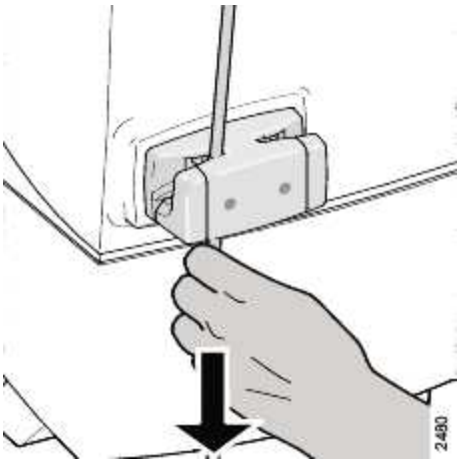
2. **Dialyzer connection**
   Attach the dialyzer end of the venous blood line firmly to the dialyzer; press and simultaneously turn.



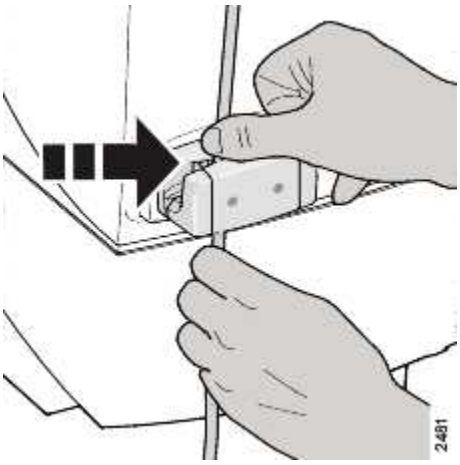
3. **Blood Line Guide**
   Press lightly on the blood line to place it in one of the grooves of the guide.



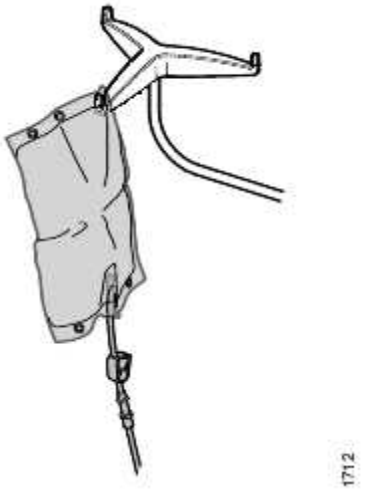
4. **Venous Line Clamp**
   Introduce the blood line into the venous clamp (marked with a blue dot) by lightly pressing the line into the clamp.



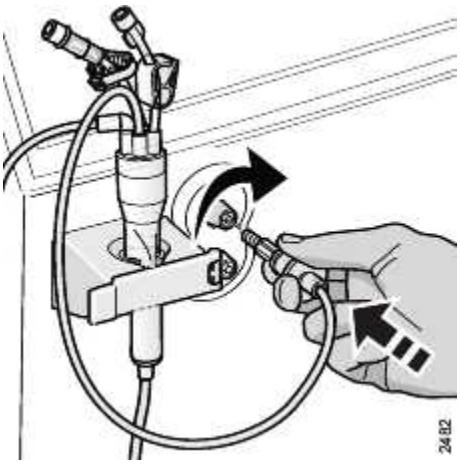
Then pull the blood line lightly downwards; the line goes into place when it is lightly pressed at the same time.



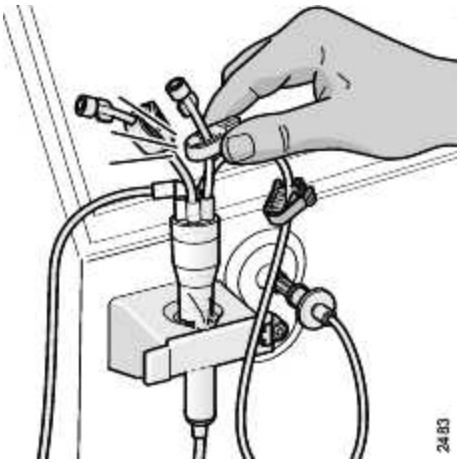
5. **Priming Detector**
   It is of the utmost importance that the venous blood line is correctly placed in the priming detector for the machine to be able to detect blood after treatment start.
   Check carefully that the venous blood line has reached end position in the venous line clamp as shown in the corresponding figure. For further information see point 9 "Priming Detector", in Blood Part Component Details" starting on page 2:5 in part 1.



6. **Venous Patient Connector**
   Hook the patient end of the venous blood line to a drain vessel or connect it to a waste bag. Bear in mind that the placement (as high as possible) of the drain vessel or waste bag is important to obtain a stable venous pressure above 50 mmHg during the priming procedure. This venous pressure is important for the machine to be able to test the venous pressure measurement function before treatment start.



7. **Venous Pressure Connector**
   Attach the venous pressure transducer protector of the blood line to the venous pressure connector; press and simultaneously turn.



Check all necessary clamps.

Dialysis Fluid Tubes - Attach

The dialysis fluid tubes may be attached to the dialyzer when the function check is complete, i.e. "F.Ch" disappears from the Time Display and the bypass path of the Flow Diagram lights up. The *Fluid bypass button* will start to flash and when pressed, the supply of dialysis fluid will be activated.

The dialysis fluid preparation is complete (correct conductivity level has been reached) when the bypass path on the Flow Diagram lights up green. If the dialysis fluid tubes are attached to the safety couplings of the machine at that moment, the dialysis fluid will start to circulate in the dialysis fluid tubes. If the dialysis fluid tubes have been attached to the dialyzer, the dialysis fluid will enter the dialyzer.

Note

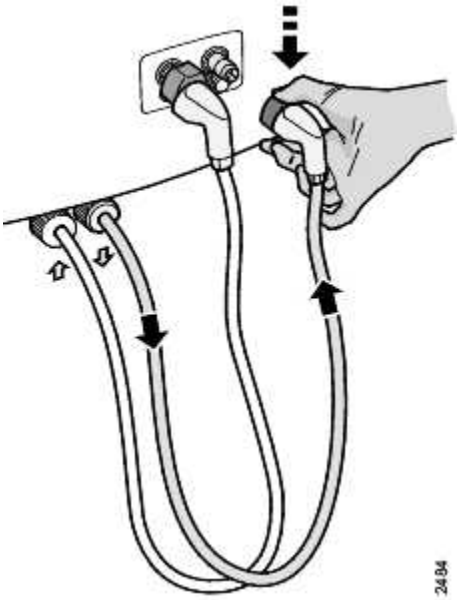
- **If the optional Dialysis Fluid Filter (UFD) has been installed,** the dialysis fluid tubes must remain connected to the safety couplings until the bypass path of the Flow Diagram lights up green. The machine performs a flush of the flow path where the ultrafilter is placed after “F.Ch” has disappeared from the Time Display. This is to ensure that correct conductivity is reached when the dialysis fluid enters the dialyzer. There is a large volume of fluid passing through the dialysis fluid tubes during the flush. An attention alarm text is simultaneously shown on the Information Display. Wait until the attention alarm text has disappeared and the bypass path of the Flow Diagram lights up green before disconnecting the dialysis fluid tubes[1].

Note

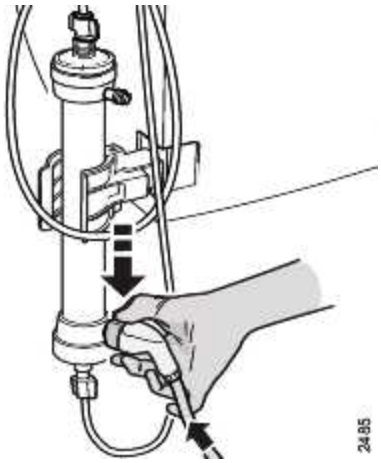
[1] If assisted priming is performed disregard note this note

Attaching procedure

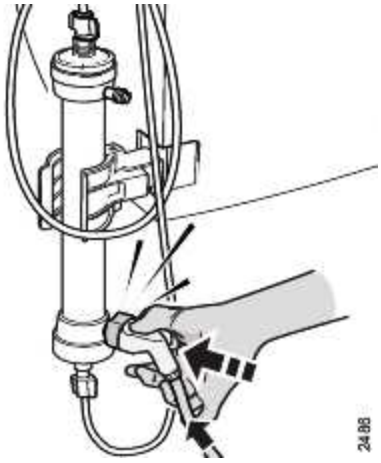
When the dialysis fluid preparation is complete (bypass path lights up green on the Flow Diagram) **first check** that the *Fluid bypass button* is flashing. If not, press the button to stop the dialysis fluid from circulating in the tubes, before starting the attaching procedure.



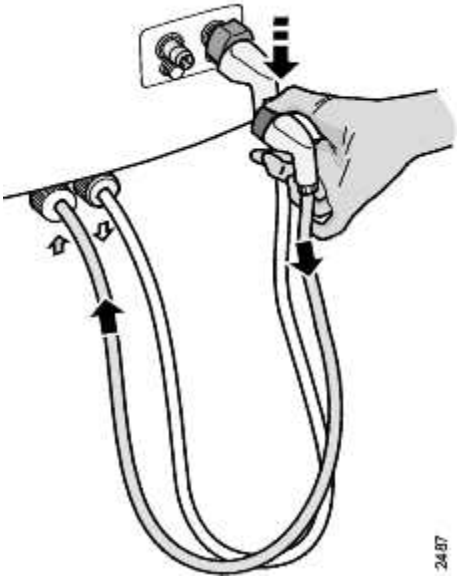
1. Disconnect the outlet dialysis fluid tube from the safety coupling of the machine; press and hold the button on the dialysis fluid tube before removing it from the safety coupling. The newly prepared, fresh dialysis fluid, flows **from the machine to the dialyzer** via this tube. A small arrow, fixed just below where the tube comes out from the machine, shows the flow direction.



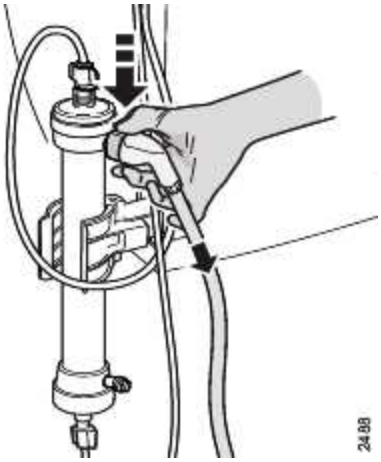
2. Keep the button on the dialysis fluid tube pressed and hold while attaching it to the dialyzer connector as shown in the corresponding figure.



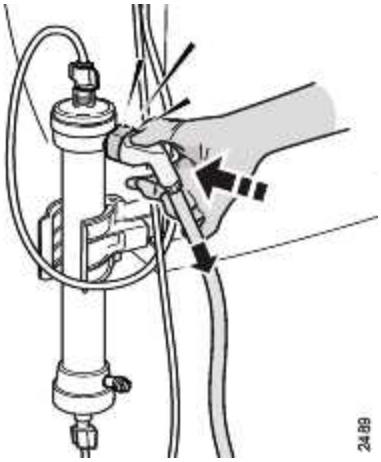
3. Release the button and simultaneously push the connector into place until it clicks in. Make sure that it clicks in properly to prevent leakage during treatment.



4. Disconnect the inlet dialysis fluid tube from the safety coupling of the machine; remove it in the same way as the outlet dialysis fluid tube described in the former point 1 in these instructions. The spent dialysis fluid flows **to the machine from the dialyzer** via this tube. A small arrow, fixed just below where the tube comes out from the machine, shows the flow direction.



5. Keep the button on the dialysis fluid tube pressed and hold while attaching it to the dialyzer connector as shown in the corresponding figure.



6. Release the button and simultaneously push the connector into place until it clicks in. Make sure that it clicks in properly to prevent leakage during treatment.

Priming

General

The priming and rinsing procedure of the extracorporeal circuit can be commenced as soon as the *Priming button* lights up during function check. For further information concerning what is happening and how it is indicated on the Operator's Panel, see "Function Check", starting on page 4:3 in part 1.

Make sure that the manufacturer's instructions for the specific dialyzer and the specific blood lines are being followed when the priming and rinsing procedure are performed.

Priming can be performed manually or with assistance from the machine. Instructions on handling procedures for both alternatives are described on the following pages. "Manual Priming and Rinsing Procedure" starts on page 4:40 and "Assisted Priming and Rinsing Procedure" starts on page 4:46. Both alternatives can be preset to be activated at start up by an authorized technician. The manual priming procedure is default active upon machine delivery.

Furthermore, the manual/assisted priming procedures can be divided up in 3 parts; priming, extra priming and recirculation priming. The priming part must always be performed in order to complete the priming procedure. The latter parts, where the handling procedures are the same for both manual and assisted priming, can be used if necessary or requested.

Priming Part

Manual Priming

When performing manual priming, the operator is in charge of the priming parameter settings, removing air from dialyzer and blood lines and generally monitoring the procedure. Some priming parameter values can however be preset by an authorized technician to facilitate the manual priming procedure; priming volume, blood pump speed, priming UF rate and dialysis fluid flow rate.

Assisted Priming

Assisted priming is a modular feature using preset settings to optimize and allow for consistent priming processes. To allow for different combinations of blood lines and dialyzers three different preset combinations of assisted priming can be programmed by an authorized technician and named according to local preference.

Assisted priming consists of several phases which can be adjusted, included or excluded.
During `ACTIVE PHASE:FILLUP`, the blood lines and the blood compartment of the dialyzer are filled with priming solution. The blood pump start can be preset to either not consider, or wait for correct dialysis fluid conductivity and temperature.

In ACTIVE PHASE:PRIMING, the air is removed from the dialyzer by opening and closing the venous clamp intermittently, while the blood pump runs.
During ACTIVE PHASE:FIRST FLUSH, the blood lines and dialyzer are rinsed with priming solution at the same flow rate as in the priming phase. When the blood pump stops automatically the operator is asked to connect the dialysis fluid tubes to the dialyzer and activate the dialysis fluid. The process stops after the first flush.
If the operator wants to continue, the blood pump is started so as to initiate ACTIVE PHASE:SECOND FLUSH. This makes it possible to do a final flush just before the treatment is initiated. The blood pump runs at the same speed as in the priming process.

Extra Priming Part

When priming is complete it can be continued by extra priming where an extra priming volume will be added. The extra priming procedure can be used if necessary, for instance just before treatment is initiated or when the extracorporeal circuit needs extra rinsing. Extra priming parameter values can be preset by an authorized technician to facilitate the procedure, similar to the ones for manual priming.

Recirculation Priming Part

If requested, priming can be extended by recirculation priming. During this procedure the same priming fluid will recirculate in a closed extracorporeal circuit for a preset period of time. The priming fluid in the circuit will be ultrafiltrated, and needs to be compensated for, by priming fluid connected to the circuit via an infusion line. The time for how long a period the procedure should last, as well as a recirculation priming UF volume is preset. Based on these two parameters, the machine calculates the recirculation priming UF rate. When recirculation priming UF volume and time have been achieved, the procedure is complete.
Recirculation priming can be used to adapt priming and rinsing to the routines of the clinic, or to a specific dialyzer or blood lines. Recirculation priming parameter values can be preset by an authorized technician to facilitate the procedure; time, recirculation priming UF volume, blood pump speed and dialysis fluid flow rate.

Before starting the procedure, the extracorporeal blood circuit must be prepared for recirculation priming in accordance with standard procedure used by the clinic. The patient ends of the arterial and venous blood lines must be connected together to make a closed extracorporeal circuit. Use a disposable blood line connection designed for this purpose, between the two blood lines. In addition, connect priming fluid via an infusion line in a similar way as when infusions are administered to the extracorporeal blood circuit during treatment. This is to compensate for the priming fluid being ultrafiltrated from the closed circuit. For information on how to connect the priming fluid, see “Infusions during Treatment”, page 3:36 in part 1 of this manual.

Manual Priming and Rinsing Procedure

Check Before Priming

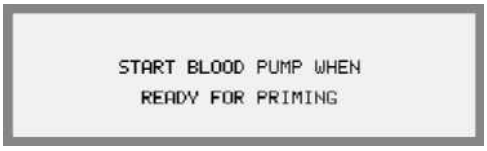
- ☑ Check that the priming fluid and waste bag are properly connected. Remove any obstructing clamps.
- ☑ Check that the venous blood line is correctly placed in the priming detector. See "Venous Blood Line - Attach", point 5, in previous instructions.
- ☑ Check that the pressure transducers of the blood lines have been properly attached to the pressure connectors of the machine.
- ☑ Check all connections.
- ☑ Check that the priming UF rate is correctly set; press the *Fluid Path button*, select `UF` and check/adjust `SET PRIMING UFR` using the *Keypad*. Follow the instruction for use of the dialyzer.

Note

- The `CONCENTRATE STANDBY MODE` menu, displayed on the Information Display, indicates that concentrate stand-by mode is active. Resume dialysis fluid preparation (deactivate concentrate stand-by mode) by pressing the *Select key* for three seconds, as the menu requests. The dialysis fluid will be ready within approximately 2 minutes.
- Always follow the manufacturer's recommendations for the minimum rinsing volume (for the blood lines and the dialyzer).

Note

Priming Procedure



This menu will be displayed on the Information Display when manual priming is active. If the `ASSISTED PRIMING SETUP MENU` is displayed, briefly press the lit *Priming button* and select `PRIMING` using the *Keypad*. Then press the *Select key* for three seconds to activate manual priming mode.

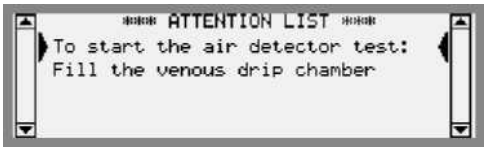
1. Check that the *Priming button* is lit.

Follow the manufacturer's instructions for use of the dialyzer and the blood lines.

2. Press the flashing *Blood pump button*. The pump speed (`PUMP SPEED`) will automatically start at 100 ml/min. Adjust as necessary using the *Blood Pump Up/Down keys*; the blood flow menu will be displayed, adjust `SET QB`. If the blood pump segment has been automatically threaded, check for possible kinks.

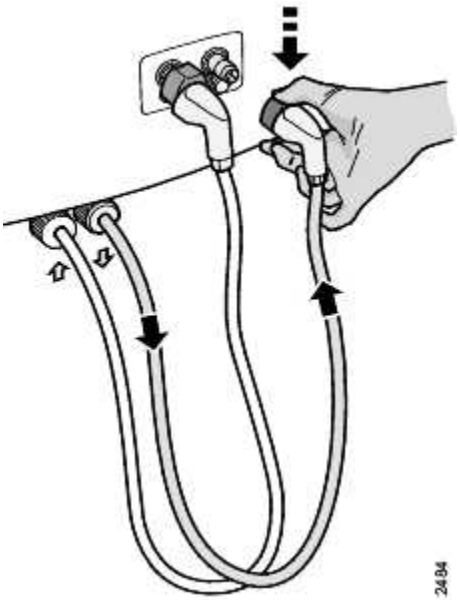
3. Prime and de-air the blood lines and the dialyzer. Especially note that the dialyzer should be filled from bottom to top to ensure proper de-airation.

The priming overview menu, which gives current information on the most important priming parameters, will be shown on the Information Display. The preset priming volume is shown below PRESET VOLUME. Below ACC VOLUME, to the left of the slash, the current priming volume obtained since priming start is shown. The total preset priming volume is displayed to the right of the slash.



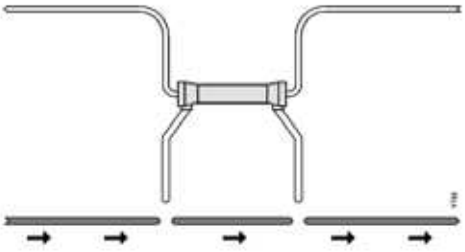
4. Fill up the level in the venous drip chamber (while the blood pump is running) using the level adjustment knob (anticlockwise direction). Adjust the level so it is well above the air detector head. Note that if the venous drip chamber is not being filled at the beginning of the priming procedure, an attention alarm without buzzer will appear to request the operator to do so.

5. The *Air detector button* will start to flash when the venous drip chamber has been filled. This is to request the operator to press it and by doing so, activate the air detector alarm function. It is not necessary to press the flashing button at this moment, the air detector activation may be moved forward until the extracorporeal circuit is completely de-aired. Additionally, if the air detector is not manually activated during priming, it will be automatically activated either when the priming volume is achieved, when CONNECT PATIENT is selected or when blood is detected. The activated air detector alarm function is indicated by an unlit button.



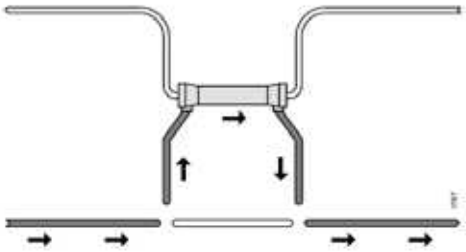
6. Attach the dialysis fluid tubes to the dialyzer when "F.Ch" disappears from the Time Display and the bypass path on the Flow Diagram lights up. See "Dialysis Fluid Tubes - Attach", page 4:35 in part 1 for instructions on how to attach the tubes.

Especially note that if UFD (dialysis fluid filter) is installed, the dialysis fluid tubes cannot be moved until the bypass path of the Flow Diagram lights up green.



Before the correct conductivity level has been reached the fluid flow path will be orange. When the fluid preparation is finished the bypass path on the Flow Diagram lights up green.

7. Press the flashing *Fluid bypass button*.



The dialysis fluid will now enter the dialyzer when the dialyzer path on the Flow Diagram lights up green. Especially note that the dialyzer should be filled from bottom to top to ensure proper de-airation.

8. If the attention alarm `HIGH VENOUS PRESS TEST NOT MADE` appears, the venous pressure has not exceeded 50 mmHg during the priming procedure, which means that the machine has not been able to test the venous pressure measurement function. Establish a stable venous pressure over 50 mmHg until the attention alarm disappears. If this attention alarm is left unattended, unnecessary alarms and technical error will be generated during initiating of treatment. See also “Venous Patient Connector” in “Venous Blood Line - Attach” previously in this chapter.

When the priming volume has been achieved, the blood pump automatically stops and the `PRIMING VOLUME ACHIEVED` menu is displayed. Check that the venous blood line is correctly placed in the priming detector. See "Venous Blood Line - Attach", point 5.

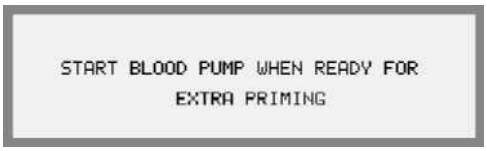
It is now possible to continue priming (`EXTRA PRIMING`) or if requested perform a recirculation procedure (`RECIRCULATION`). It is also possible to go directly to patient connection (`CONNECT PATIENT`).
Select desired alternative and continue to the corresponding instruction as follows.
If necessary, select a new priming procedure (`NEW PRIMING`) where priming will be repeated from the start and the set priming volume value be set to zero.

Note

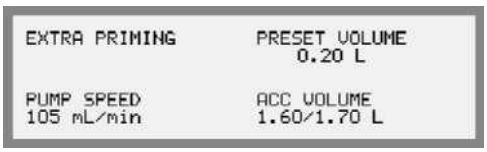
- Always follow the manufacturer's recommendations for the minimum rinsing volume (for the blood lines and the dialyzer).
- After the machine has passed the function check and the bypass path on the Flow Diagram lights up green, it is possible to activate concentrate stand-by mode in order to save concentrates before patient connection. See information in "Concentrate Stand-by Mode" on page 3:30 in part 1.

Note

Extra Priming Procedure



If necessary, continue priming by pressing the *Select key* when EXTRA PRIMING has been selected. The menu will change and request the operator to press the flashing *Blood pump button* when ready for extra priming. When the button is pressed, the pump speed will automatically start at 100 ml/min. Adjust as necessary using the *Blood Pump Up/Down keys*.



The extra priming overview menu, which gives current information on the most important extra priming parameters, will be shown on the Information Display. The preset extra priming volume is shown below PRESET VOLUME. Below ACC VOLUME, to the left of the slash, the current total priming volume obtained since priming start is shown. The total preset priming volume obtained since priming start is displayed to the right of the slash.
When the extra priming volume has been achieved, the blood pump automatically stops and an attention alarm appears. EXTRA PRIMING can be restarted as desired. Check priming fluid and waste bag.

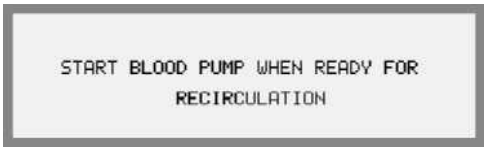
Select CONNECT PATIENT using the *Keypad* when the extra priming procedure is complete, and the menu will change. Continue by following the instructions in "Treatment", page 4:52 in part 1.
If requested, it is also possible to select RECIRCULATION at this moment, see the following instructions.

If the operator wishes to restart priming and at the same time set the priming volume value to zero, select NEW PRIMING when the priming volume achieved menu is displayed, using the *Keypad*. The machine will reactivate priming and it is possible to repeat the priming procedure from the start.

Recirculation Priming Procedure

If requested, extend priming by a recirculation priming procedure where the blood circuit is rinsed using the same priming fluid during the complete procedure.

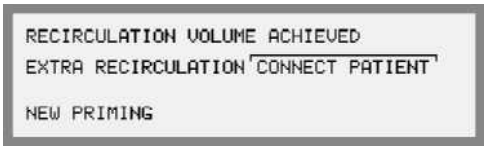
Before starting the procedure, the extracorporeal blood circuit must be prepared for recirculation priming in accordance with standard procedure used by the clinic. The patient ends of the arterial and venous blood lines must be connected together to make a closed extracorporeal circuit. Use a disposable blood line connection designed for this purpose, between the two blood lines. In addition, connect priming fluid via an infusion line in a similar way as when infusions are administered to the extracorporeal blood circuit during treatment. This is to compensate for the priming fluid being ultrafiltrated from the closed circuit. For information on how to connect the priming fluid, see “Infusions during Treatment”, page 3:36 in part 1 of this manual.



To enter recirculation priming procedure press the *Select key* when RECIRCULATION has been selected. The menu will change and request the operator to press the flashing *Blood pump button* when ready for recirculation priming. When the button is pressed, the pump speed will automatically start at 150 ml/min. Adjust as necessary using the *Blood Pump Up/Down keys*.

The recirculation priming overview menu, which gives current information on the most important recirculation priming parameters, will be shown on the Information Display. The preset recirculation priming UF volume is shown below PRESET UF VOLUME. Below ACC UF VOLUME, to the left of the slash, the current recirculation priming UF volume obtained since recirculation start is shown. The total preset recirculation priming UF volume is displayed to the right of the slash. When the recirculation priming UF volume and time have been achieved, the blood pump automatically stops.

EXTRA RECIRCULATION can be restarted as desired. Check the priming fluid connected via the infusion line. Note that the values below ACC UF VOLUME will be the accumulated ones since the first recirculating priming procedure.



Select CONNECT PATIENT using the *Keypad* when the recirculation priming procedure is complete, and the menu will change. Prepare the extracorporeal blood circuit for treatment in accordance with standard procedure used by the clinic. Continue by following the instructions in "Treatment", page 4:52 in part 1.

If the operator wishes to restart priming and at the same time set the priming volume value to zero, select NEW PRIMING when the priming volume achieved menu is displayed, using the *Keypad*. The machine will reactivate priming and it is possible to repeat the priming procedure from the start.

Assisted Priming and Rinsing Procedure

Check Before Priming

- ☑ Check that the priming fluid and waste bag are properly connected. Remove any obstructing clamps.
- ☑ Check that the venous blood line is correctly placed in the priming detector. See "Venous Blood Line - Attach", point 5, in previous instructions.
- ☑ Check that the pressure transducers of the blood lines have been properly attached to the pressure connectors of the machine.
- ☑ Check all connections.
- ☑ Check that the preset assisted priming parameters correspond with the manufacturer's instructions for use of the specific dialyzer being used.

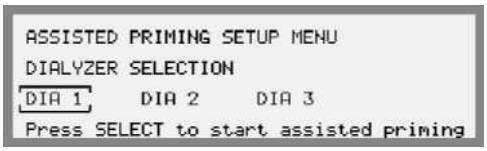
Note

- The CONCENTRATE STANDBY MODE menu, displayed on the Information Display, indicates that concentrate stand-by mode is active. Resume dialysis fluid preparation (deactivate concentrate stand-by mode) by pressing the *Select key* for three seconds, as the menu requests. The dialysis fluid will be ready within approximately 2 minutes.
- Always follow the manufacturer's recommendations for the minimum rinsing volume (for the blood lines and the dialyzer).

Note

Priming Procedure

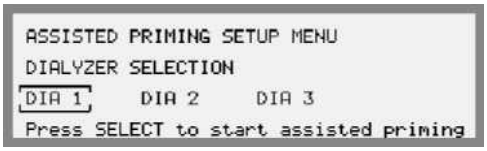
The procedure described below uses the default settings of assisted priming parameters. Make sure that the preset priming procedure is in accordance with the manufacturer's priming instructions for the specific dialyzer being used.



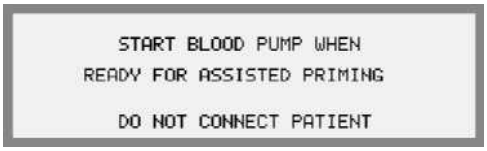
This menu will be displayed on the Information Display when assisted priming is active. If START BLOOD PUMP WHENREADY FOR PRIMING is displayed, briefly press the lit *Priming button* and select ASSISTED PRIMING using the *Keypad*. Then press the *Select key* for three seconds to activate assisted priming mode.

1. Check that the *Priming button* is lit.

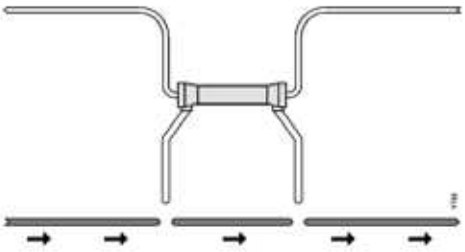
Follow the manufacturer's instructions for use of the dialyzer and the blood lines.



2. Select alternative in the ASSISTED PRIMING SETUP MENU using the *Keypad*.



3. Press the *Select key* and the menu will change.



If the dialysis fluid preparation is complete ("F.Ch" disappears from the Time Display and the bypass path on the Flow Diagram lights up) the dialysis fluid tubes can be connected to the dialyzer. See "Dialysis Fluid Tubes - Attach", page 4:35 in part 1 for instructions on how to attach the tubes. Especially note that if UFD (dialysis fluid filter) is installed, the dialysis fluid tubes cannot be moved until the bypass path of the Flow Diagram lights up green.

If the dialysis fluid preparation is not complete, the process can be started with the dialysis fluid tubes connected to the safety couplings.

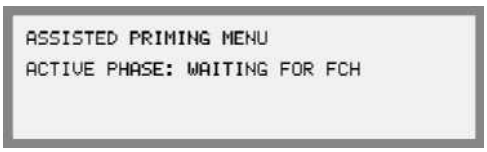
4. Press the flashing *Blood pump button* to start the blood pump and the procedure. If the blood pump segment has been automatically threaded, check for possible kinks. Note that the dialyzer should be filled from bottom to top to ensure proper de-airation.

The procedure starts with the fill up phase. ACTIVE PHASE:FILLUP will be displayed.

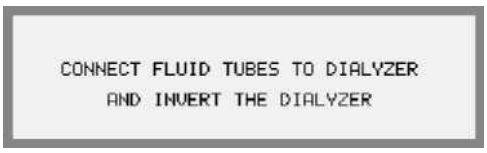
5. Fill up the level in the venous drip chamber (while the blood pump is running) using the level adjustment knob (anticlockwise direction). Adjust the level so it is well above the air detector head.

6. The *Air detector button* will start to flash when the venous drip chamber has been filled. This is to request the operator to press it and by doing so, activate the air detector alarm function. It is not necessary to press the flashing button at this moment, the air detector activation may be moved forward until the extracorporeal circuit is completely de-aired. Additionally, if the air detector is not manually activated during priming, it will be automatically activated either when the priming volume is achieved, when CONNECT PATIENT is selected or when blood is detected. The activated air detector alarm function is indicated by an unlit button.

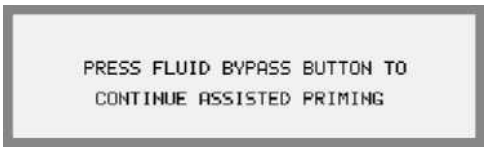
The procedure continues with the priming phase. The menu changes into ACTIVE PHASE:PRIMING.



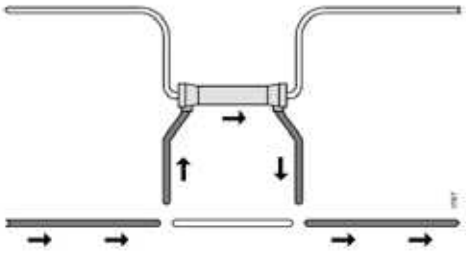
If the function check is still ongoing, WAITING FOR FCH will be displayed. Wait until the menu changes to CONNECT FLUID TUBES TO DIALYZER, then continue to the next point.



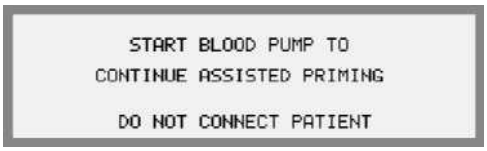
7. The blood pump automatically stops before the first flush phase starts and this menu is displayed on the Information Display. The operator is requested to attach the dialysis fluid tubes to the dialyzer if this has not previously been done. See "Dialysis Fluid Tubes - Attach", page 4:35 in part 1 for instructions on how to attach the tubes.
   Invert the dialyzer so that the dialyzer will be filled from bottom to top to ensure proper de-airation.



8. Press the flashing *Fluid bypass button*.



The dialysis fluid will now enter the dialyzer when the dialyzer path on the Flow Diagram lights up green. Especially note that the dialyzer should be filled from bottom to top to ensure proper de-airation.

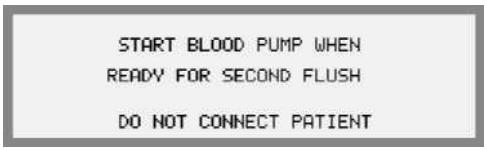


9. Press the flashing *Blood pump button* to restart the blood pump and to continue the procedure.

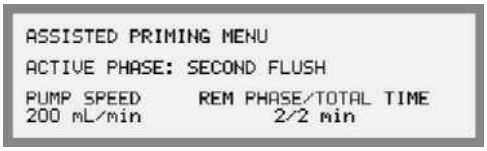
The procedure continues with the first flush phase, ACTIVE PHASE:FIRST FLUSH is displayed.

10. If the attention alarm HIGH VENOUS PRESS TEST NOT MADE appears, the venous pressure has not exceeded 50 mmHg during the priming procedure, which means that the machine has not been able to test the venous pressure measurement function. Establish a stable venous pressure over 50 mmHg until the attention alarm disappears. If this attention alarm is left unattended, unnecessary alarms and technical error will be generated during initiating of treatment. See also "Venous Patient Connector" in "Venous Blood Line - Attach" previously in this chapter.

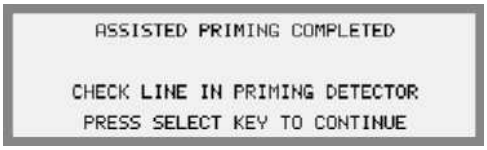
When the first flush is finished the blood pump automatically stops.



11. Press the flashing *Blood pump button* to restart the blood pump and to continue the procedure.



The procedure continues with the second flush phase, ACTIVE PHASE:SECOND FLUSH is displayed.



12. When the second flush is finished the assisted priming procedure is complete and the menu will change.

13. Check that the venous blood line is correctly placed in the priming detector. See "Venous Blood Line - Attach", point 5. Press the *Select key* to continue.

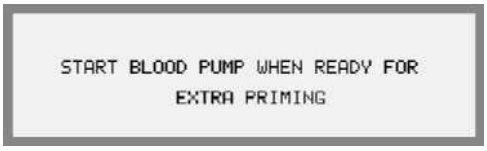
It is now possible to continue priming (EXTRA PRIMING) or if requested perform a recirculation procedure (RECIRCULATION). It is also possible to go directly to patient connection (CONNECT PATIENT).
Select desired alternative and continue to the corresponding instruction as follows.
If necessary, select a new priming procedure (NEW PRIMING) where priming will be repeated from the start and the set priming volume value be set to zero.

Note

- Always follow the manufacturer's recommendations for the minimum rinsing volume (for the blood lines and the dialyzer).
- After the machine has passed the function check and the bypass path on the Flow Diagram lights up green, it is possible to activate concentrate stand-by mode in order to save concentrates before patient connection. See information in "Concentrate Stand-by Mode" on page 3:30 in part 1.

Note

Extra Priming Procedure



If necessary, continue priming by pressing the *Select key* when EXTRA PRIMING has been selected. The menu will change and request the operator to press the flashing *Blood pump button* when ready for extra priming. When the button is pressed, the pump speed will automatically start at 100 ml/min. Adjust as necessary using the *Blood Pump Up/Down keys*.

The extra priming overview menu, which gives current information on the most important extra priming parameters, will be shown on the Information Display. The preset extra priming volume is shown below PRESET VOLUME. Below ACC VOLUME, to the left of the slash, the current total priming volume obtained since priming start is shown. The total preset priming volume obtained since priming start is displayed to the right of the slash.
When the extra priming volume has been achieved, the blood pump automatically stops and an attention alarm appears. EXTRA PRIMING can be restarted as desired. Check priming fluid and waste bag.

Select CONNECT PATIENT using the *Keypad* when the extra priming procedure is complete, and the menu will change. Continue by following the instructions in "Treatment", page 4:52 in part 1.
If requested, it is also possible to select RECIRCULATION at this moment, see the following instructions.

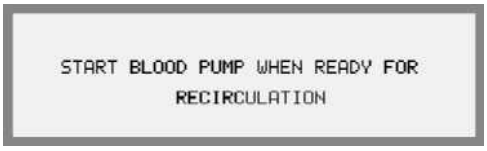
If the operator wishes to restart priming and at the same time set the priming volume value to zero, select NEW PRIMING when the priming volume achieved menu is displayed, using the *Keypad*. The machine will reactivate priming and it is possible to repeat the priming procedure from the start.

Recirculation Priming Procedure

If requested, extend priming by a recirculation priming procedure where the blood circuit is rinsed using the same priming fluid during the complete procedure.

Before starting the procedure, the extracorporeal blood circuit must be prepared for recirculation priming in accordance with

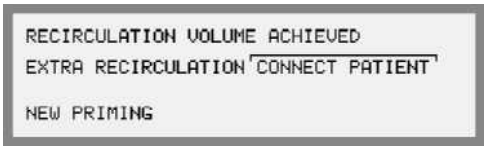
standard procedure used by the clinic. The patient ends of the arterial and venous blood lines must be connected together to make a closed extracorporeal circuit. Use a disposable blood line connection designed for this purpose, between the two blood lines. In addition, connect priming fluid via an infusion line in a similar way as when infusions are administered to the extracorporeal blood circuit during treatment. This is to compensate for the priming fluid being ultrafiltrated from the closed circuit. For information on how to connect the priming fluid, see “Infusions during Treatment”, page 3:36 in part 1 of this manual.



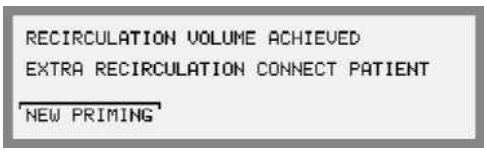
To enter recirculation priming procedure press the *Select key* when RECIRCULATION has been selected. The menu will change and request the operator to press the flashing *Blood pump button* when ready for recirculation priming. When the button is pressed, the pump speed will automatically start at 150 ml/min. Adjust as necessary using the *Blood Pump Up/Down keys*.

The recirculation priming overview menu, which gives current information on the most important recirculation priming parameters, will be shown on the Information Display. The preset recirculation priming UF volume is shown below PRESET UF VOLUME. Below ACC UF VOLUME, to the left of the slash, the current recirculation priming UF volume obtained since recirculation start is shown. The total preset recirculation priming UF volume is displayed to the right of the slash. When the recirculation priming UF volume and time have been achieved, the blood pump automatically stops.

EXTRA RECIRCULATION can be restarted as desired. Check the priming fluid connected via the infusion line. Note that the values below ACC UF VOLUME will be the accumulated ones since the first recirculating priming procedure.



Select CONNECT PATIENT using the *Keypad* when the recirculation priming procedure is complete, and the menu will change. Prepare the extracorporeal blood circuit for treatment in accordance with standard procedure used by the clinic. Continue by following the instructions in "Treatment", page 4:52 in part 1.



If the operator wishes to restart priming and at the same time set the priming volume value to zero, select NEW PRIMING when the priming volume achieved menu is displayed, using the *Keypad*. The machine will reactivate priming and it is possible to repeat the priming procedure from the start.

Treatment

Set Treatment Parameters

CAUTION

- To avoid hazardous side effects during the treatment, the parameters and the alarm limits must be suitable for the patient's needs and tolerance.
- Verify that the prescribed concentrate(s) for the specific treatment is (are) used. Avoid changing type of concentrate containers during treatments.
- The correct setting of the UF rate is important to avoid backfiltration. Set a minimum UF rate according to the instructions for the specific dialyzer.
- Once the treatment parameters have been set, the operator should verify that the control and protective systems for conductivity operate with the desired values and that they are in agreement. This verification is made by comparing the calculated set values in `SET COND (C/P)` in the conductivity menu.

CAUTION

Always Check/Adjust

- ☑ Check the preset treatment time on the Time Display, adjust if necessary. Press the *Time button*, adjust `SET TIME`.
- ☑ Set the UF volume (patient weight loss) to the required total ultrafiltration volume. Press the *Fluid Path button*, select `UF` and set the required value in `SET UF`.
- ☑ Check that the calculated UF rate (patient weight loss/h) is suitable. Press the *Fluid Path button*, select `UF` and check the value in `UF RATE`. Adjust treatment time or UF volume if necessary.
- ☑ Check that the dialysis fluid flow rate is set to the required value. Press the *Fluid Path button*, select `DIA FLUID FLOW` and check the value in `ACTUAL DIA FLUID FLOW`. Adjust if necessary in `SET TREATMENT DIA FLUID FLOW`.
- ☑ Check/adjust the set values for sodium `SET NA` and bicarbonate `SET HCO3` of the dialysis fluid. Press the *Fluid Path button*, select `COND` and adjust if necessary. Also check/adjust the set value for dialysis fluid temperature; press the *Fluid Path button*, select `TEMP` and adjust if necessary.

- ☑ If the heparin pump is going to be used, press the *Blood Path button* and select HEPARIN. Check/adjust the heparin solution flow rate (HEPARIN), the heparin solution bolus volume (BOLUS) and the pump stop limit STOP LIMIT. If not manually started, the heparin pump will automatically start when blood is detected in the venous blood line.

- ☑ If the functions for isolated ultrafiltration, profiling, Diascan or blood pressure measurement are going to be used, or if single needle treatment is going to be performed, see the corresponding chapter in this manual for instructions.

Connect the Patient

Note

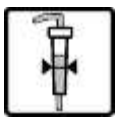
- The CONCENTRATE STANDBY MODE menu, displayed on the Information Display, indicates that concentrate stand-by mode is active. Resume dialysis fluid preparation (deactivate concentrate stand-by mode) by pressing the *Select key* for three seconds, as the menu requests. The dialysis fluid will be ready within approximately 2 minutes.

- Always follow the manufacturer's recommendations for the minimum rinsing volume (for the blood lines and the dialyzer).

Note

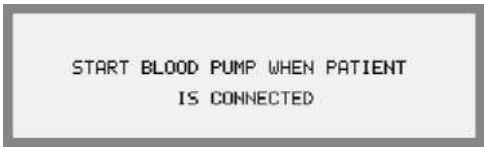
After CONNECT PATIENT has been selected a connect patient volume will be measured by the machine once the blood pump has been started. If blood has not been detected in the venous blood line when this connect patient volume has been achieved, an alarm will be generated; Blood is not detected. See “Connect Patient Alarm”Connect Patient Alarm, page 13:49 in part 3 for instructions.

1. Check that there is no air in the blood lines and that the level in the venous drip chamber is well above the air detector head. If expansion chambers are used, check that they are filled to the correct levels (refer to the instruction for use of the individual blood line).



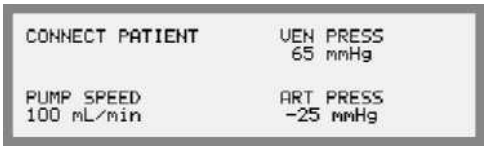
2. Manually activate the air detector alarm function by pressing the flashing *Air detector button* if it has not previously been activated during priming. If the air detector is not activated, it will automatically be activated when the priming detector detects blood. The activated air detector alarm function is indicated by an unlit button.

3. Check that the blood pump has been stopped, if not, press the *Blood pump button*. As CONNECT PATIENT has been previously selected, the blood pump will start at 100 ml/min when the flashing *Blood pump button* later is pressed. If desired, adjust the blood flow rate using the *Blood Pump Up/Down keys* to the proper value for treatment start.



4. Connect the blood lines to the patient as standard procedure. Remove any obstructing clamps.

5. Start the blood pump.

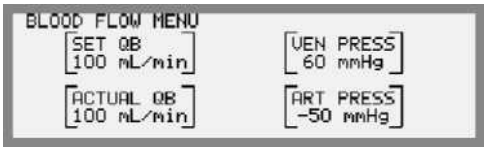


The connect patient overview menu, which gives current information on the most important parameters during patient connection, will be shown on the Information Display. To monitor the patient's blood access before blood has been detected in the venous blood line; read off current arterial pressure below `ART PRESS` and current venous pressure below `VEN PRESS`. The blood flow rate is displayed as `PUMP SPEED` until blood is detected in the venous blood line.

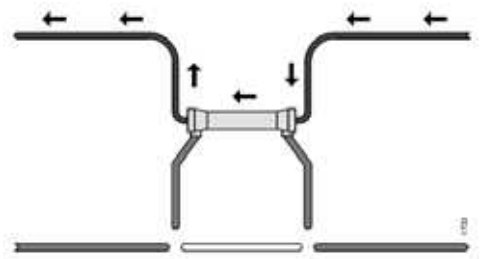
Note

- The blood pump can be automatically stopped when the priming detector detects blood in the venous blood line and the blood path in the Flow Diagram lights up.
- During patient connection, when blood has been detected in the venous blood line, the venous clamp can be open when the blood pump is stopped (manually, or automatically). This preset is to facilitate removal of air from the venous blood line after connecting the venous blood line to the patient. Bear in mind that when this preset is active, the operator is fully responsible for manually clamping the venous blood line and checking it from air whenever necessary during patient connection.

Note



6. Set the required blood flow rate suitable for the patient using the *Blood Pump Up/Down keys*; the blood flow menu will be displayed, adjust `SET QB`.



When the priming detector detects blood in the venous blood line, the blood path of the Flow Diagram lights up red and the treatment time starts to count down on the Time Display. When blood has been detected for 20 seconds the blood path of the Flow Diagram will remain lit until treatment end has been confirmed (by attention alarm) and the machine no longer detects blood in the venous blood line. This is valid even if the venous blood line is removed from the priming detector during treatment (i.e. the blood alarms will be kept).

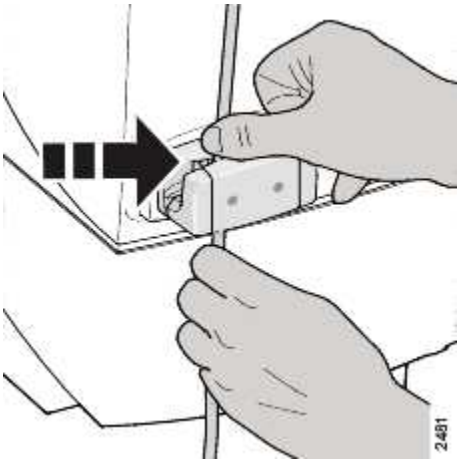
The Treatment Overview Menu will start to be displayed and continues to be displayed at all times during treatment when blood is detected. See in "Overview Displays", page 3:23 in part 1 for details.

The *Venous Pressure* and *Arterial Pressure button* will be flashing.

The *UF Start/Stop button* will be flashing.

See "Start the Treatment" in the next following section for information on how to continue.

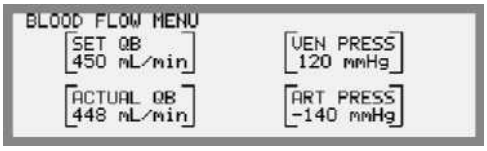
Start the Treatment



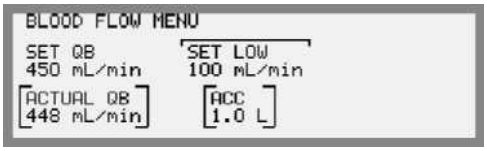
CAUTION

Make sure that the blood path of the Flow Diagram lights up, if it does not light up, check that the venous blood line is correctly placed in the priming detector. If the blood path does not light up, the machine considers the patient not connected and as a consequence the UF system is not controlling the patient ultrafiltration.
If the air detector has not been activated during priming it will not be automatically activated until the priming detector detects blood.

CAUTION



1. Check/adjust the blood flow rate (`SET QB`) to the required value suitable for the particular patient using the *Blood Pump Up/Down keys*.

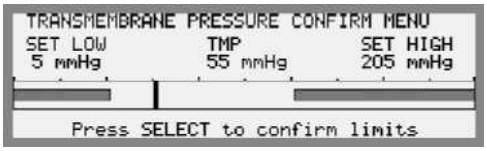


2. If desired, press the *Blood Path button* and open the `BLOOD FLOW MENU` using the *Keypad*. Check/adjust the low alarm limit for blood flow rate in `SET LOW` as necessary.

3. Press the flashing *Arterial Pressure button* to centralize the alarm limits around the current value. Or if desired, set the arterial pressure alarm limits manually using the *Keypad*.

4. Press the flashing *Venous Pressure button* to centralize the alarm limits around the current value. Or if desired, set the venous pressure alarm limits manually using the *Keypad*.

5. Press the flashing *UF Start/Stop button* (lights up) to start ultrafiltration. Note especially that at all times whenever necessary during treatment, the *UF Start/Stop button* can be pressed (flashing) in order to decrease the UF rate to minimum UF rate.
   Check that the minimum UF rate is set to the correct value. Press the *Fluid Path button*, select `UF` and check the value in `SET MIN UFR`. Adjust if necessary.



6. When the TRANSMEMBRANE PRESSURE CONFIRM MENU is displayed on the Information Display, press the *Select key* to confirm the settings i.e. that the current TMP value and the automatically set TMP alarm limits are set in accordance with the current UF rate and the UF coefficient of the dialyzer being used.

7. If the heparin pump is started, this will be running concurrent to the blood pump. If BOLUS has been set this will be administered first. After this the heparin solution will be administered at the set flow rate FLOW RATE. If the heparin solution flow rate is set to zero, an attention alarm appears requesting the operator to confirm that the heparin pump is not to be used.

8. If the functions for isolated ultrafiltration, profiling, Diascan, blood pressure measurement or single needle are going to be used, see the corresponding chapter in this manual for instructions on settings.

CAUTION

The correct setting of the UF rate is important to avoid backfiltration. Set a minimum UF rate according to the instruction for the specific dialyzer.

CAUTION

Pressure Alarm Limits Setting

Alarm Limit Centralizing Function

The machine is equipped with a centralizing function to simplify the correct setting of the alarm limits for arterial and venous pressure and for TMP.

The centralizing function means that when the *Arterial* or *Venous pressure buttons* are flashing, the buttons are to be pressed. When pressed, the alarm window will automatically be set around the current value. For TMP, the TRANSMEMBRANE PRESSURE CONFIRM MENU appears, where the operator confirms the automatically set TMP alarm limits.

The size of the alarm limit windows, and where on the pressure scale they are placed, vary for the different parameters and can be preset by an authorized technician. The default values which the machine is preset with upon delivery, can be read in chapter 9, "Technical Data and Specifications" in part 1. If the centralizing function is removed, or if wide alarm limits range are preset, it is the operator's responsibility to make sure that the alarm limits are properly set around the current values during treatment.

Arterial/Venous Pressure

Press the corresponding buttons (when flashing) to centralize the alarm limits around current values.
If necessary the alarm limits can be manually set/adjusted within the preset alarm window. Press the corresponding button and the pressure menu will be shown on the Information Display. Manually adjust the

alarm limits using the *Keypad*. See "Arterial Pressure Button" and "Venous Pressure Button" in chapter 3 for instructions on manual setting of the alarm limits.

The alarm windows will automatically be widened and the buttons start to flash when the blood flow rate is changed or when the *Blood Pump button* is pressed.

Upon request from the clinic, an authorized technician can preset the high arterial pressure alarm limit to a fixed value. This is to facilitate pre-blood pump infusions during treatment during certain conditions, see “Infusions during Treatment” page 3:36, part 1 for instructions. Note that the function of the high arterial pressure alarm limit is in this case deactivated implying that the operator is responsible for monitoring the arterial pressure during treatment.

WARNING

⚠ When the high arterial pressure alarm limit is preset to a fixed value or when the arterial pressure measurement function is not used, there is a risk for air-embolism if the arterial access is accidentally disconnected. This is especially so when using the machine in combination with a central venous catheter (due to possible negative pressure in the catheter).

WARNING

TMP

When the `TRANSMEMBRANE PRESSURE CONFIRM MENU` is displayed on the Information Display, press the *Select key* to confirm the settings i.e. that the current TMP value and the automatically set TMP alarm limits are set in accordance with the current UF rate and the UF coefficient of the dialyzer being used. If the TMP alarm limits have not been confirmed within two minutes, an attention appears where the operator is requested to confirm the current settings.

If necessary the TMP alarm limits can be manually set/adjusted within the preset alarm window by first pressing the *Fluid Path button*, selecting TMP, and adjusting the alarm limits using the *Keypad*. For instructions on manual setting of the alarm limits, see "Fluid Path button" in chapter 3. Go to "Transmembrane Pressure" last in the list.

The TMP alarm window will automatically be widened when the *UF Start/Stop button* is pressed.

CAUTION

! When negative TMP alarm limits are set, the operator will **not** be notified via alarm or attention alarm that backfiltration may occur. However, it is possible for the authorized technician to preset the machine so that when negative TMP alarm limits have been set, such an attention alarm occurs.

CAUTION

Discontinuing

Note

- **If the treatment is to be continued**, first press the flashing *Time button* to confirm treatment end. The TREATMENT TIME EXPIRED attention alarm will then be cleared and the treatment time confirm menu will be displayed on the Information Display. Then press the *Back key* and increase the treatment time (SET) using the *Keypad*. Increase the UF volume, or set the min UF rate to zero.

- **If the treatment is to be discontinued before the set treatment time is achieved**, the remaining time should be decreased to 0.00 (press *Time button*, change SET using the *Keypad*).

- If the treatment time is decreased to 0:00 (i.e. the set time is decreased in SET) and there is **still time left in isolated UF phase**, an attention alarm will appear. Deactivate isolated UF, press the *Select key* for 3 seconds when the isolated UF menu is displayed, or set ISOL UF time to zero.

Note

Confirm Treatment End

When the remaining treatment time shown on the Time Display equals 0:00 an attention alarm appears. Simultaneously, the *Time button* starts to flash.

At this moment the UF rate will be automatically reduced to minimum UF rate as the set UF volume is achieved; the *UF Start/Stop button* will be extinguished to indicate this. The TMP alarm limits will automatically be widened. The time shown on the Time Display will continue to count down but will show negative figures.

It is possible to **choose one the two following ways to continue:**

1.a. Confirm treatment end by pressing the *Select key*. The TREATMENT TIME EXPIRED attention alarm will be cleared and the RINSE BACK MENU will be displayed on the Information Display. Continue by following the instructions in the next section, “Return the Blood”, page , point 2.

1.b. Confirm treatment end by pressing the flashing *Time button*. The TREATMENT TIME EXPIRED attention alarm will be cleared and the menu will change (this menu will automatically disappear after 20 seconds or when the *Blood pump button* is being pressed). Press the *Select key* and the RINSE BACK MENU will be displayed on the Information Display. Continue by following the instructions in the next section, “Return the Blood”, page , point 2.
If the treatment is to be continued at this point, press the *Back key* and increase the treatment time (SET) using the *Keypad*. Increase the UF volume, or set the min UF rate to zero.

Return The Blood

CAUTION

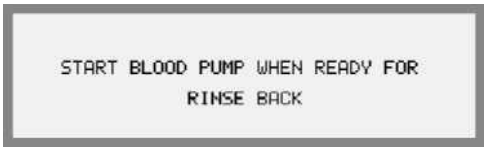
- During rinse-back procedure, when the blood is returned to the patient, the operator is responsible for monitoring the venous pressure since the supervision of venous needle dislocation is deactivated.
- The arterial clamp can be open during rinse-back procedure by preset. This is to facilitate returning all blood in the extracorporeal circuit to the patient. Bear in mind that if this preset is active, the operator is fully responsible for manually clamping the arterial blood line and checking it for air whenever necessary during rinse back procedure.

CAUTION

Procedure

As confirmation of treatment end has previously been confirmed (briefly pressed *Select key*), the RINSE BACK MENU is displayed on the Information Display.

2. When RINSE BACK has been selected, press the *Select key* for 3 seconds to activate discontinuing mode. The menu will change and request the operator to press the flashing *Blood pump button* when ready for rinse-back.

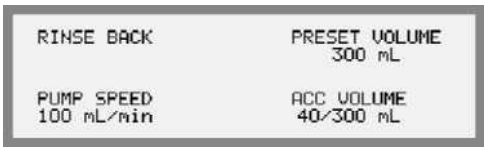


At the moment when the *Select key* is pressed, the **blood pump will automatically be stopped** (flashing button). The *Discontinuing button* lights up. This will also automatically widen the venous pressure, the arterial pressure and the TMP alarm limits to their priming values without subsequent centralizing alarm.

3. Clamp the arterial blood line and disconnect it from the patient.

4. Connect the arterial blood line to the rinse-back solution and remove the clamp.

5. Press the flashing *Blood pump button*. The rinse-back flow rate is set to 100 ml/min. If required, adjust the rinse-back flow rate using the *Blood Pump Up/Down keys* (blood flow rate `SET QB`).



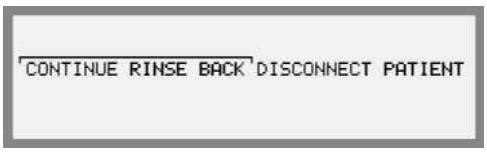
The rinse back overview menu, which gives current information on the most important rinse back parameters will be shown on the Information Display. The rinse-back volume, default preset to 300 ml, is shown below `PRESET VOLUME`. The current rinse-back volume used since rinse-back start is shown below `ACC VOLUME` to the left of the slash. If another rinse-back is started, this value will increase. The total preset rinse-back volume used since rinse-back start is displayed to the right of the slash.

During the rinse-back procedure, the venous clamp automatically opens and closes intermittently while the blood pump is running. The opening and closing rate of the venous clamp can be preset by an authorized technician (if the rate is set to zero, the clamping function will be bypassed).

6. When rinse-back is complete, the blood pump can be stopped in 3 different ways:

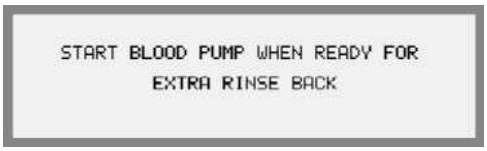
6.a. Automatically, when blood is no longer detected in the venous blood line.

6.b. Automatically, when the preset rinse-back volume has been achieved. The `RINSE BACK VOLUME ACHIEVED` menu appears together with an attention alarm.



6.c. Manually, when desired, by pressing the *Blood Pump button*.

7. If necessary, continue rinse-back by pressing the *Select key* when corresponding rinse-back type has been selected. The operator will be requested to press the flashing *Blood pump button* when ready for new, extra or continued rinse-back.



8. Press the flashing *Blood pump button* to start. If extra or continued rinse-back has been selected, the current rinse-back volume obtained since rinse-back start is shown below ACC VOLUME. If new rinse-back has been selected, the new rinse back volume will start from zero and the accumulated obtained since new rinse back start is shown below ACC VOLUME.

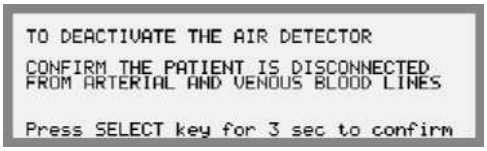
Extra, continued or new rinse-back can be repeated as necessary.

9. Stop the blood pump, if it has not automatically been stopped, when the required amount of blood has been returned to the patient. Clamp the venous blood line.

10. Disconnect the venous blood line from the patient.

11. Select patient disconnection (DISCONNECT PATIENT) using the *Keypad*.

Confirm Patient Disconnection



12. Check that the arterial and venous blood lines have been completely disconnected from the patient. Confirm this by pressing the *Select key* for 3 seconds and the menu will change to the DISCONNECT PATIENT MENU.

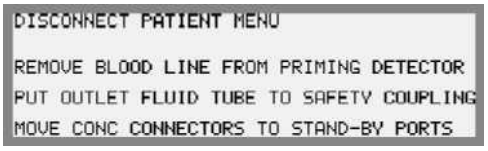
When patient disconnection has been confirmed, the air detector will be deactivated and the dialysis fluid will automatically be bypassed from the dialyzer.

Machine aftercare

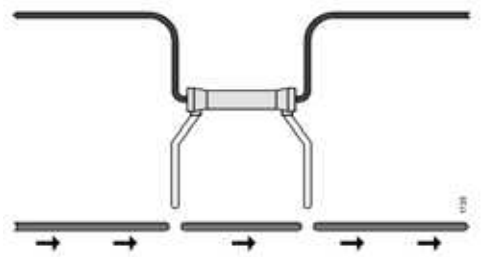
CAUTION

The venous line must be disconnected from the patient before emptying the fluid side of the dialyzer, i.e. connecting one of the fluid tubes to the safety coupling. Otherwise the negative pressure created by the machine in order to empty the dialyzer may cause a blood flow from the blood compartment to the fluid compartment of the dialyzer.

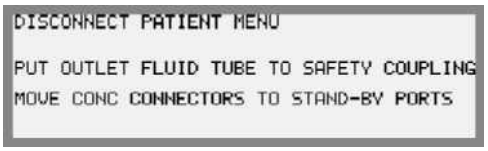
CAUTION



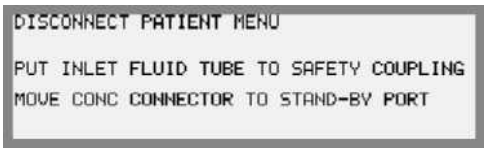
13. Check that the DISCONNECT PATIENT MENU is displayed on the Information Display.



14. If blood is still detected in the venous blood line (the light of the blood path of the Flow Diagram is still red), remove the venous blood line from the priming detector. The blood path light will then turn off.

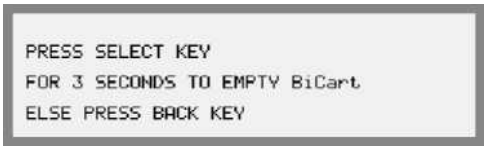


15. Invert the dialyzer. Remove the outlet dialysis fluid tube from the dialyzer and attach it to the safety coupling of the machine. The machine will now automatically create negative pressure in the fluid path, which empties the dialyzer of dialysis fluid.

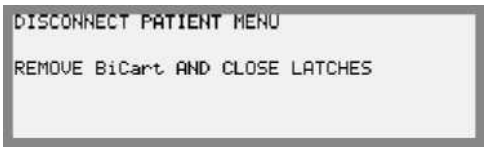


16. When the dialyzer has been emptied, remove the inlet dialysis fluid tube from the dialyzer and attach it to the safety coupling of the machine as well.

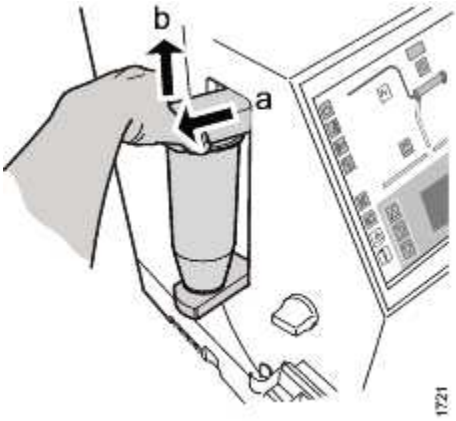
17. Connect the concentrate connector(s) to the stand-by ports.



18. If the BiCart cartridge has been used, select whether the machine should automatically empty the cartridge or not according to the instructions on the Information Display.

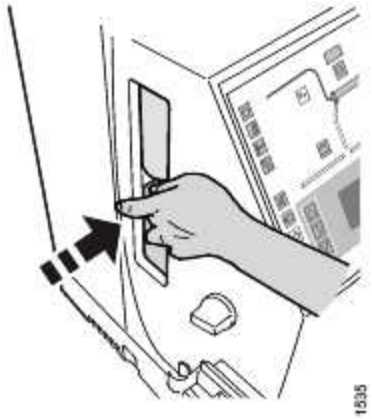


19. When the BiCart cartridge is empty (or directly if manual emptying has been chosen), continue by following the instructions on how to remove the cartridge from the holder.

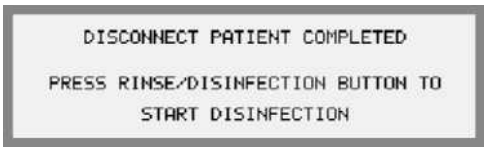


19.a. Open the upper latch of the BiCart holder; pull out the latch ⓐ and lift upwards to its uppermost position ⓑ. Remove the BiCart cartridge.

19.b. Close the upper latch by folding it in. Close the lower latch; pull out the latch and fold it in.



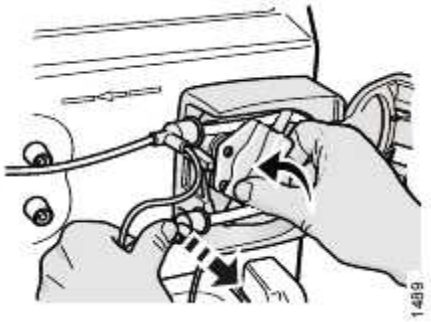
19.c. Check that both the latches of the BiCart holder have been properly closed.



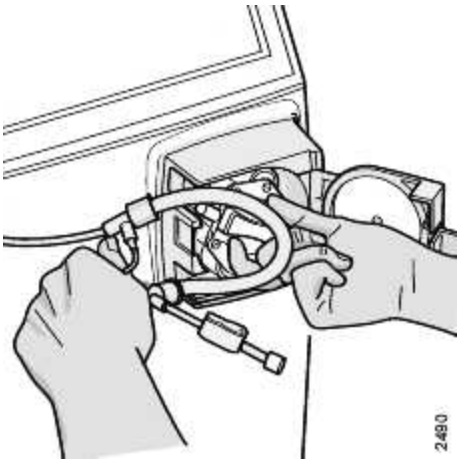
20. The *Rinse/Disinfection button* will now be flashing. Press the button and start a disinfection program, see handling instructions for each program in chapter 8 "Hygiene and Maintenance" in part 1.

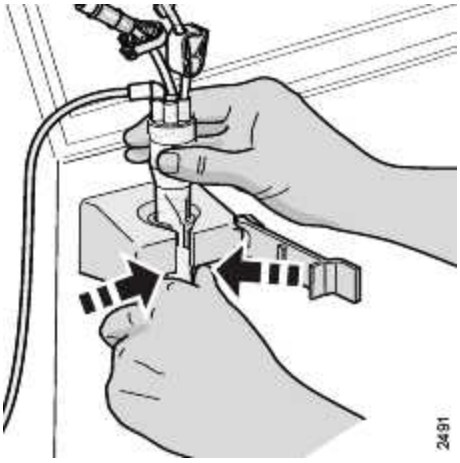
Follow the instructions for hygiene and maintenance of the AK 96 dialysis machine in chapter 8 in part 1.

21. Remove the dialyzer and the blood lines, dispose of according to local regulations.

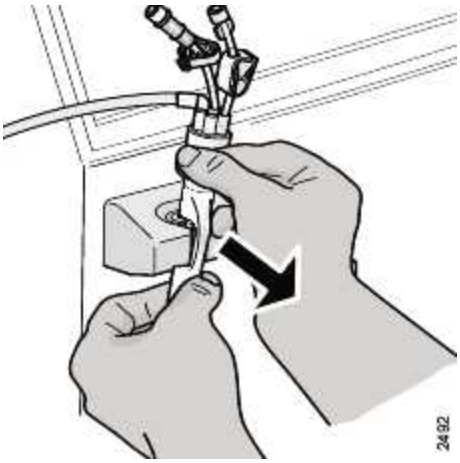


21.1. Clasp on the arterial blood line just before the pump segment. Pull it out while simultaneously turning the blood pump rotor in an anticlockwise direction. Make sure that the pins on the blood pump rotor are behind the pulled out segment while turning the rotor.





21.2. Open the cover of the air detector (press on the middle of the cover at the same time as the cover is being opened). Compress the venous drip chamber and then pull it out as shown in the corresponding figures.



WARNING

⚠ If any of the pressure transducer protectors on the blood lines have been filled with blood and show signs of damage, i.e. blood has penetrated the disc filter, there is a risk of contamination of the machine. It is necessary to call an authorized technician who must replace and clean machine components that may have been contaminated.

WARNING

Chapter 5

Hemodialysis - Single Needle Treatment (option)

General

Note

- When performing single needle treatment there is always a certain amount of recirculation.
  The AK 96 dialysis machine is equipped with a clamp on the arterial side in order to minimize recirculation.
  To further minimize recirculation the stroke volume should be maximized. To achieve this the following should be considered:
  - Make sure a correct blood pump rotor is used. There must be a correct adjustment of the occlusion of the blood pump segment being used. Check with the authorized technician.
  - The volume of the expansion chamber should be as big as possible.
  - The internal diameter of the needle should be as big as possible.

  Comments are available on request, concerning the expected recirculation of the blood flow in the extracorporeal circuit, contact your local Gambro representative.

Note

Glossary of single needle parameters and key terms

The Arterial phase is when the blood pump is running, the arterial line clamp is open and the venous line clamp is closed. The arterial phase can be controlled by pressure settings.

The Venous phase is when the blood pump is **not** running, the venous line clamp is open and the arterial line clamp is closed. The venous phase is controlled by pressure settings.

Cycle, together, an arterial phase and a venous phase are called a cycle.

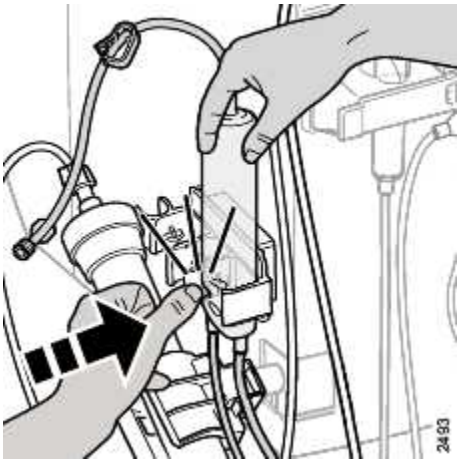
The Mean blood flow rate is the effective blood flow rate during the complete cycle, calculated from the arterial blood flow rate.

The Stroke volume is the blood volume that passes through the dialyzer during a cycle. The lower the stroke volume the greater the recirculation.

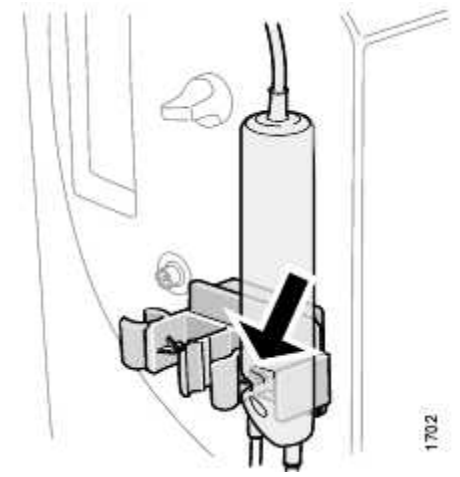
Preparations

Follow the instructions in chapter 4, "Hemodialysis - Double Needle Treatment" in part 1 from "Start the Machine", page 4:2 and forwards. Add the following below.

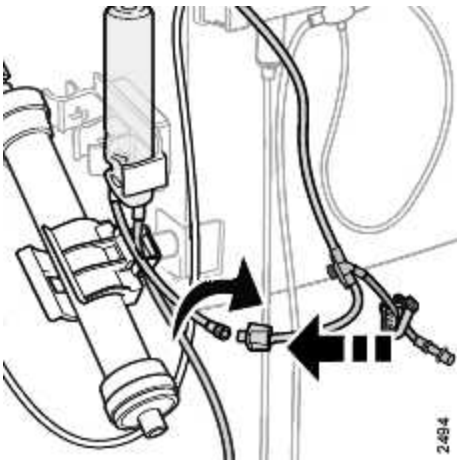
Attach an expansion chamber, connecting it between the dialyzer and the venous blood line. This is in order to reduce the amount of recirculation in the system (i.e. to achieve a greater stroke volume). Follow the instructions in "Venous Blood Line - Attach", page 4:28 in part 1. Add the following instructions on how to attach the expansion chamber.



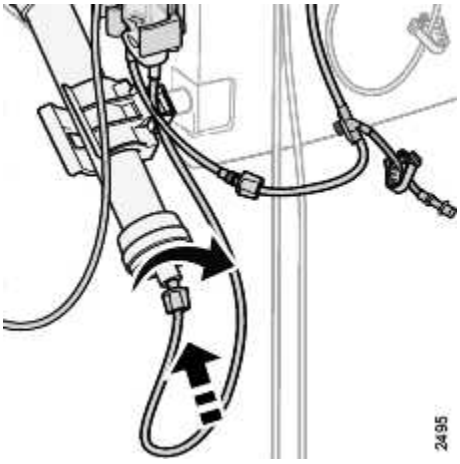
1. Place the venous expansion chamber in the holder in an upright position (inlet and outlet facing downwards). Make sure that it clicks in properly in the expansion holder.



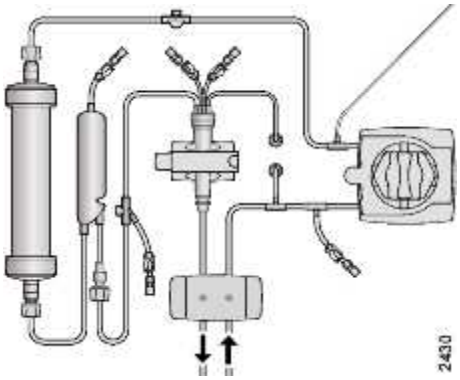
2. The edge inside the holder should fit into the groove of the expansion chamber as shown in the corresponding figure.



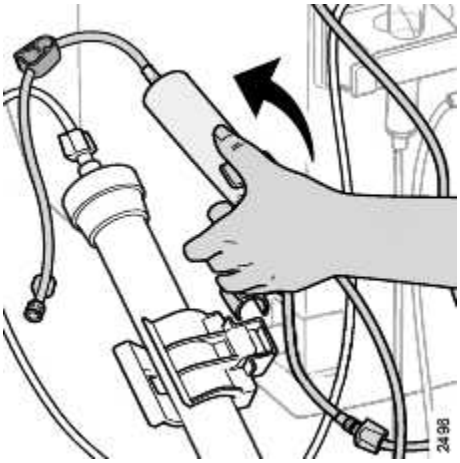
3. Connect the dialyzer end of the venous blood line to the blood line with the expansion chamber.



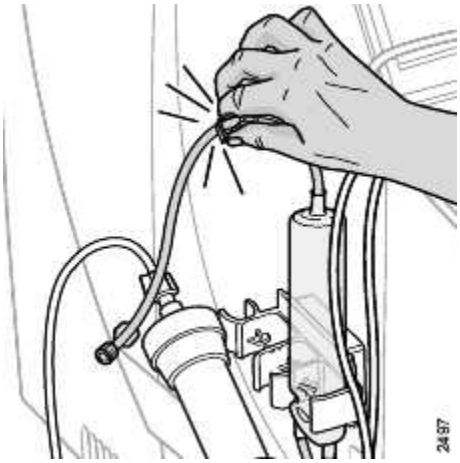
4. Connect the blood line with the expansion chamber to the dialyzer.



5. Prime and de-air the blood lines and the dialyzer as described in chapter 4 "Hemodialysis - Double Needle Treatment" in part 1.



5.a. Tilt the expansion chamber holder backwards until it clicks into position. By doing so the venous expansion chamber will be filled to a suitable level during priming.



5.b. Check that the venous expansion chamber has been filled to be level with the groove of the chamber. Make sure to close the clamp at the top of the expansion chamber.

Continue to follow the instructions in chapter 4, "Hemodialysis - Double Needle Treatment" starting on page 4:1 up to "Connect the Patient", page 4:53 in part 1.

Connect the Patient

Note

- The CONCENTRATE STANDBY MODE menu, displayed on the Information Display, indicates that concentrate stand-by mode is active. Resume dialysis fluid preparation (deactivate concentrate stand-by mode) by pressing the *Select key* for three seconds, as the menu requests. The dialysis fluid will be ready within approximately 2 minutes.
- Always follow the manufacturer's recommendations for the minimum rinsing volume (for the blood lines and the dialyzer).

Note

After CONNECT PATIENT has been selected a connect patient volume will be measured by the machine once the blood pump has been started. If blood has not been detected in the venous blood line when this connect patient volume has been achieved, an alarm will be generated; Blood is not detected. See “Connect Patient Alarm”Connect Patient Alarm, page 13:49 in part 3 for instructions.

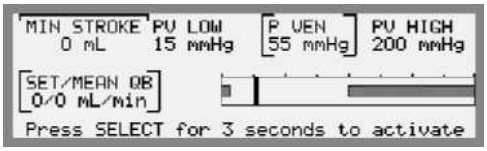
1. Check that the venous expansion chamber is in an upright position and is filled to a correct level (refer to the instructions for use of the individual blood line).
2. Check that there is no air in the blood lines and that the level in the venous drip chamber is well above the air detector head.

3. Manually activate the air detector alarm function by pressing the flashing *Air detector button* if it has not previously been activated during priming. If the air detector is not activated, it will automatically be activated when the priming detector detects blood. The activated air detector alarm function is indicated by an unlit button.

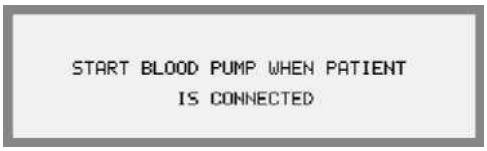
4. Check that the blood pump has been stopped, if not, press the *Blood pump button*. As CONNECT PATIENT has been previously selected, the blood pump will start at 100 ml/min when the flashing *Blood pump button* later is pressed. If desired, adjust the blood flow rate using the *Blood Pump Up/Down keys* to the proper value for treatment start.

5. Press the *Blood Path button*.

6. Select SINGLE NEEDLE using the *Keypad*.

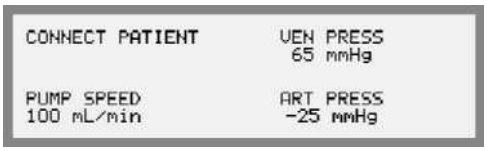


7. Activate the single needle function by pressing the *Select key* for 3 seconds. If desired adjust the alarm limit for minimum stroke volume MIN STROKE.



8. Connect the blood lines to the patient as standard procedure. Remove any obstructing clamps.

9. Start the blood pump.



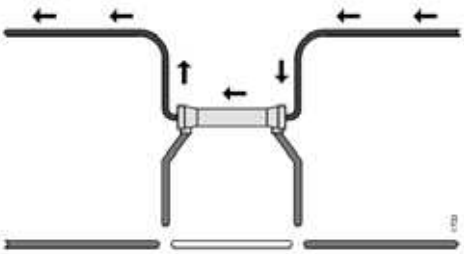
The connect patient overview menu, which gives current information on the most important parameters during patient connection, will be shown on the Information Display. To monitor the patient's blood access before blood has been detected in the venous blood line; read off current arterial pressure below ART PRESS and current venous pressure below VEN PRESS. The blood flow rate is displayed as PUMP SPEED until blood is detected in the venous blood line.

Note

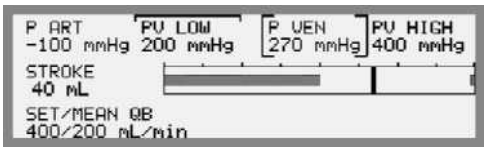
- The blood pump can be automatically stopped when the priming detector detects blood in the venous blood line and the blood path in the Flow Diagram lights up.
- During patient connection, when blood has been detected in the venous blood line, the venous clamp can be open when the blood pump is stopped (manually, or automatically). This preset is to facilitate removal of air from the venous blood line after connecting the venous blood line to the patient. Bear in mind that when this preset is active, the operator is fully responsible for manually clamping the venous blood line and checking it from air whenever necessary during patient connection.

Note

10. Set the required blood flow rate suitable for the patient using the *Blood Pump Up/Down keys*; the blood flow menu will be displayed, adjust SET QB. Especially note that the blood flow rate in SET QB and ACTUAL QB shown in the blood flow menu on the Information Display, is the blood flow rate when the blood pump is running in the arterial phase of the single needle cycle. It is **not** the mean blood flow rate for the single needle treatment.



When the priming detector detects blood in the venous blood line, the blood path of the Flow Diagram lights up red and the treatment time starts to count down on the Time Display. When blood has been detected for 20 seconds the blood path of the Flow Diagram will remain lit until treatment end has been confirmed (by attention alarm) and the machine no longer detects blood in the venous blood line. This is valid even if the venous blood line is removed from the priming detector during treatment (i.e. the blood alarms will be kept).



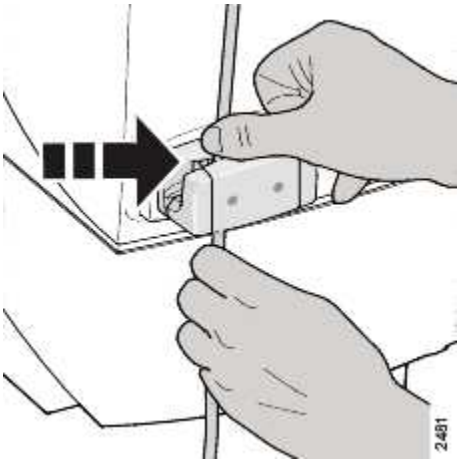
The Treatment Overview Menu for single needle treatment will start to be displayed and continues to be displayed at all times during treatment when blood is detected. The overview differs from the overview when performing double needle treatment, showing parameters of interest when single needle mode is active. See in "Overview Displays", page 3:23 in part 1 for details.

The *Venous Pressure* and *Arterial Pressure button* will be flashing.

The *UF Start/Stop button* will be flashing.

See "Start the Treatment" in the next following section for information on how to continue.

Start the Treatment

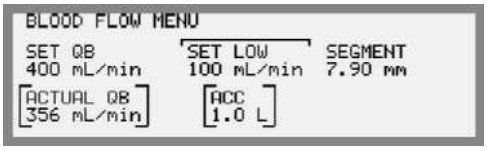


CAUTION

Make sure that the blood path of the Flow Diagram lights up, if it does not light up, check that the venous blood line is correctly placed in the priming detector. If the blood path does not light up, the machine considers the patient not connected and as a consequence the UF system is not controlling the patient ultrafiltration.
If the air detector has not been activated during priming it will not be automatically activated until the priming detector detects blood.

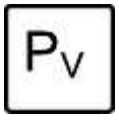
CAUTION

1. Check/adjust the blood flow rate to the required value suitable for the particular patient using the *Blood Pump Up/Down keys*. Note especially that the blood flow rate in `SET QB` and `ACTUAL QB`, is the blood flow rate when the blood pump is running in the arterial phase of the single needle cycle. It is **not** the mean blood flow rate for the single needle treatment. The mean blood flow rate is shown on the Treatment Overview Menu for single needle treatment "Overview Displays", see page 3:23 in part 1 for details.



2. If desired, press the *Blood Path button* and open the `BLOOD FLOW MENU` using the *Keypad*. Check/adjust the low alarm limit for the blood flow rate, when the blood pump is running in the arterial phase, in `SET LOW` as necessary.

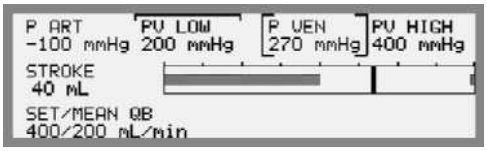
3. Press the flashing *Arterial Pressure button* to centralize the alarm limits around the current value. Or if desired, set the arterial pressure alarm limits manually using the *Keypad*.



4. Press the flashing *Venous pressure button*. At that moment, the high and low venous pressure alarm limits will automatically be set. The high alarm limit will be set to +350 mmHg and the low alarm limit will be set to +150 mmhg.

5. If desired, adjust the automatically set venous pressure alarm limits as necessary using the *Keypad*. Start by adjusting the high alarm limit. Then, during the arterial phase, gradually adjust the low venous pressure alarm limit as well. Make sure that the venous pressure alarm limits remain within the limits recommended by the clinic for that particular patient's blood access. See the next following Note for further information about this setting.

6. If necessary, adjust the level in the venous expansion chamber. The level should be as low as possible (i.e. without air passing into the blood lines at the end of the venous phase), in order to best achieve a proper stroke volume (`STROKE`).



7. Check that the current stroke volume (`STROKE`) shows a proper value. See "Glossary of single needle parameters and key terms" on page 5:2 in part 1 for further information.

8. Press the flashing *UF Start/Stop button* (lights up) to start ultrafiltration. Note especially that at all times whenever necessary during treatment, the *UF Start/Stop button* can be pressed (flashing) in order to decrease the UF rate to minimum UF rate.
   Check that the minimum UF rate is set to the correct value. Press the *Fluid Path button*, select `UF` and check the value in `SET MIN UFR`. Adjust if necessary.

Note

- The achieved stroke volume is determined by the size and position of the venous pressure alarm window. The wider the window, the greater the stroke volume. The higher the position of the window, the higher the venous flow. Set the venous pressure alarm limits in such a way that a proper stroke volume is being achieved. Bear in mind that as the venous pressure alarm limits are used to control the arterial and venous phases the extracorporeal circuit must continuously be monitored by visual inspection. A decreasing stroke volume and/or a decreasing mean blood flow rate may indicate clotting or a kinked venous blood line.
  To optimize the treatment:

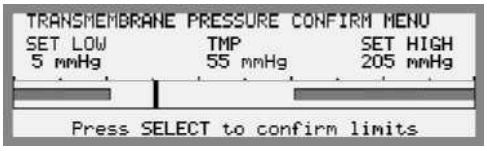
Note → → →

→ → → **Note**

- Check the stroke volume. If the Treatment Overview Menu for single needle is not currently displayed, press the *Back key*. Optimize by adjusting the venous pressure alarm window and keeping the level in the venous expansion chamber as low as possible.

- Maximize the arterial blood flow rate. Press the *Blood Pump Up/Down keys*, adjust SET QB. This will shorten the arterial phase, which results in more cycles[1] during the treatment i.e. increased mean blood flow rate (the value to the right displayed below SET/MEAN QB on Treatment Overview Menu) resulting in increased accumulated blood volume (ACC).

Note



7. When the TRANSMEMBRANE PRESSURE CONFIRM MENU is displayed on the Information Display, press the *Select key* to confirm the settings i.e. that the current TMP value and the automatically set TMP alarm limits are set in accordance with the current UF rate and the UF coefficient of the dialyzer being used.

8. If the heparin pump is started, this will be running continuously irrespective of if the blood pump is running or not. If BOLUS has been set this will be administered first. After this the heparin solution will be administered at the set flow rate FLOW RATE. If the heparin solution flow rate is set to zero, an attention alarm appears requesting the operator to confirm that the heparin pump is not to be used.

9. If the functions for isolated ultrafiltration, profiling, or blood pressure measurement are going to be used, see the corresponding chapter in this manual for instructions on settings.

CAUTION

The correct setting of the UF rate is important to avoid backfiltration. Set a minimum UF rate according to the instruction for the specific dialyzer.

CAUTION

[1] For further information, see "Glossary of single needle parameters and key terms", page 5:2 in part 1.

Pressure Alarm Limits Setting

Alarm Limit Centralizing Function

The machine is equipped with a centralizing function to simplify the correct setting of the alarm limits for arterial pressure and for TMP.

The centralizing function means that when the *Arterial button* is flashing, the button is to be pressed. When pressed, the alarm window will automatically be set around the current value. For TMP, the `TRANSMEMBRANE PRESSURE CONFIRM MENU` appears, where the operator confirms the automatically set TMP alarm limits.

The size of the alarm limit windows, and where on the pressure scale they are placed, vary for the two parameters and can be preset by an authorized technician. The default values which the machine is preset with upon delivery, can be read in chapter 9, "Technical Data and Specifications" in part 1. If the centralizing function is removed, or if wide alarm limits range are preset, it is the operator's responsibility the make sure that the alarm limits are properly set around the current values during treatment.

Arterial Pressure

Press the *Arterial Pressure button* (when flashing) to centralize the alarm limits around the current value.
If necessary the alarm limits can be manually set/adjusted within the preset alarm window. Press the *Arterial Pressure button* and the pressure menu will be shown on the Information Display. Manually adjust the alarm limits using the *Keypad*, see "Arterial Pressure button" in chapter 3 for instructions manual setting of the alarm limits.

The alarm window will automatically be widened and the button starts to flash when the blood flow rate is changed or when the *Blood Pump button* is pressed.

Upon request from the clinic, an authorized technician can preset the high arterial pressure alarm limit to a fixed value. This is to facilitate pre-blood pump infusions during treatment during certain conditions, see “Infusions during Treatment” page 3:36, part 1 for instructions. Note that the function of the high arterial pressure alarm limit is in this case deactivated implying that the operator is responsible for monitoring the arterial pressure during treatment.

WARNING

⚠ When the high arterial pressure alarm limit is preset to a fixed value or when the arterial pressure measurement function is not used, there is a risk for air-embolism if the arterial access is accidentally disconnected. This is especially so when using the machine in combination with a central venous catheter (due to possible negative pressure in the catheter).

WARNING

Venous Pressure

The alarm limits are to be manually adjusted. See in previous instructions, "Start the Treatment". point 5.

TMP

When the TRANSMEMBRANE PRESSURE CONFIRM MENU is displayed on the Information Display, press the *Select key* to confirm the settings i.e. that the current TMP value and the automatically set TMP alarm limits are set in accordance with the current UF rate and the UF coefficient of the dialyzer being used. If the TMP alarm limits have not been confirmed within two minutes, an attention appears where the operator is requested to confirm the current settings.

If necessary the TMP alarm limits can be manually set/adjusted within the preset alarm window by first pressing the *Fluid Path button*, selecting TMP, and adjusting the alarm limits using the *Keypad*. For instructions on manual setting of the alarm limits, see "Fluid Path button" in chapter 3. Go to "Transmembrane Pressure" last in the list.

The TMP alarm window will automatically be widened when the *UF Start/Stop button* is pressed.

CAUTION

! When negative TMP alarm limits are set, the operator will **not** be notified via alarm or attention alarm that backfiltration may occur. However, it is possible for the authorized technician to preset the machine so that when negative TMP alarm limits have been set, such an attention alarm occurs.

CAUTION

Discontinuing

Follow the instructions for discontinuing in "Discontinuing", page 4:59 in part 1, without deactivating the single needle function.

Chapter 6

Isolated Ultrafiltration

Contents

Isolated UF - General

Isolated UF (ultrafiltration) can be performed before, during or after the hemodialysis treatment. Instructions for each combination can be read further on in this chapter.

When performing isolated UF, there is no diffusion. This is because the dialysis fluid in this phase bypasses the dialyzer, and the machine therefore only performs ultrafiltration.

Note especially that due to the dialysis fluid bypass during isolated UF, the blood cannot maintain its temperature in the same way as it does during the diffusion phase.

As the UF rate is high during the isolated UF phase, it is recommended to optimize the blood flow rate, within the limits suitable for the patient, to avoid hemoconcentration in the dialyzer and the blood lines.

Isolated UF can be used if the amount of excessive fluid to be removed is too large for the specific patient to tolerate during hemodialysis (diffusion). It can also be used if the patient's condition requires immediate fluid removal.

The hemodialysis treatment is in this context referred to as "the diffusion phase" and the isolated UF is referred to as "the isolated UF phase".

The time and UF volume in isolated UF is automatically added to the diffusion phase and consequently increases the complete treatment time and the total UF volume. This is on condition that the machine's manufactured preset (the default preset) has not been changed. It is possible to change the preset so that time and UF volume will be included instead of added. The following instructions are based on the default preset.

Isolated UF - Performing

Before Treatment

Follow the instructions in chapter 4, "Start the Treatment" in part 1.

When the settings in "Set Treatment Parameters" on page 4:52 in part 1 are being made, set the time and UF volume for the diffusion phase only. Thereafter, make the settings for the isolated UF phase according to the following instructions.

Bear in mind that the time and UF volume in isolated UF are automatically added to the diffusion phase and consequently increase the complete treatment time and the total UF volume.

Procedure

Use the *Keypad* next to the Information Display to select options and to navigate within and between the menus. For details concerning the keys included in the *Key pad*, see "Keypad" in chapter 3. part 1

1. Press the *Fluid Path button*, select `UF`.
2. Select `ISOL UF` and enter the sub menu.

3. Set the ultrafiltration volume, `SET ISOL UF`, for the isolated UF phase.
4. Set the time, `SET TIME`, for the isolated UF phase.
5. Activate isolated UF by pressing the *Select Key* for 3 seconds. Isolated UF will automatically be activated when the *UF Start/Stop button* is being pressed at treatment start.

Start the treatment according to the instructions in "Connect the Patient" on page 4:53 and "Start the Treatment" on page 4:56 in part 1.

Note that if the heparin pump is used, it will run during the complete treatment (both diffusion and isolated UF phase) and keep the settings for `BOLUS`, `FLOW RATE` and `STOP LIMIT`.

Activated isolated UF is displayed at the activity field of the Treatment Overview Menu on the Information display. During the phase, the accumulated values for ultrafiltration `ACC UF` and time `ACC TIME` will be displayed on the isolated UF menu. Press the *Fluid Path button*, select `UF` and then `ISOL UF` to view the menu.

If necessary, isolated UF can be deactivated at any time during the phase, by pressing the *Select Key* for 3 seconds when the isolated UF menu is displayed.

When the time for the isolated UF phase is finished, the machine will automatically switch to diffusion phase. Check UF parameter settings.

During Treatment

Follow the instructions in chapter 4, "Start the Treatment" in part 1 to start the treatment.

When desired during the ongoing treatment, do the settings for the isolated UF phase and activate the function according to the following instructions.

Bear in mind that the time and UF volume in isolated UF are automatically added to the diffusion phase and consequently increase the complete treatment time and the total UF volume.

Procedure

Use the *Keypad* next to the Information Display to select options and to navigate within and between the menus. For details concerning the keys included in the *Key pad*, see "Keypad" in chapter 3. part 1

1. Press the *Fluid Path button*, select `UF`.
2. Select `ISOL UF` and enter the sub menu.

3. Set the ultrafiltration volume, `SET ISOL UF`, for the isolated UF phase.
4. Set the time, `SET TIME`, for the isolated UF phase.
5. Activate isolated UF by pressing the *Select Key* for 3 seconds. Isolated UF will now be activated.

Note that if the heparin pump is used, it will run during the complete treatment irrespective of the added isolated UF phase and keep the settings for `BOLUS`, `FLOW RATE` and `STOP LIMIT`.

Activated isolated UF is displayed at the activity field of the Treatment Overview Menu on the Information display. During the phase, the accumulated values for ultrafiltration `ACC UF` and time `ACC TIME` will be displayed on the isolated UF menu. Press the *Fluid Path button*, select `UF` and then `ISOL UF` to view the menu.

If necessary, isolated UF can be deactivated at any time during the phase, by pressing the *Select Key* for 3 seconds when the isolated UF menu is displayed.

When the time for the isolated UF phase is finished, the machine will automatically switch to diffusion phase. Check UF parameter settings.

After Treatment

Follow the instructions in chapter 4, "Start the Treatment" in part 1 to start the treatment. At any time during the ongoing treatment, do the settings for the isolated UF phase according to the following instructions.

Bear in mind that the time and UF volume in isolated UF are automatically added to the diffusion phase and consequently increase the complete treatment time and the total UF volume.

Procedure

Use the *Keypad* next to the Information Display to select options and to navigate within and between the menus. For details concerning the keys included in the *Key pad*, see "Keypad" in chapter 3. part 1

1. Press the *Fluid Path button*, select `UF`.
2. Select `ISOL UF` and enter the sub menu.

3. Set the ultrafiltration volume, `SET ISOL UF`, for the isolated UF phase.
4. Set the time, `SET TIME`, for the isolated UF phase.
5. Press the *Back key* for 3 seconds and the Treatment Overview Menu will resume. The Isolated UF settings will be kept.

When the diffusion phase is complete an attention alarm will appear:

6. Check that the previously set values are the correct ones and activate isolated UF by pressing the *Select Key* for 3 seconds. Isolated UF will now be activated.

Note that if the heparin pump is used, it will run during the complete treatment irrespective of the added isolated UF phase and keep the settings for `BOLUS`, `FLOW RATE` and `STOP LIMIT`. This means that the stop time will be adjusted in accordance with the time for the added isolated UF phase.

Activated isolated UF is displayed at the activity field of the Treatment Overview Menu on the Information display. During the phase, the accumulated values for ultrafiltration `ACC UF` and time `ACC TIME` will be displayed on the isolated UF menu. Press the *Fluid Path button*, select `UF` and then `ISOL UF` to view the menu.

If necessary, isolated UF can be deactivated at any time during the phase, by pressing the *Select Key* for 3 seconds when the isolated UF menu is displayed.

When the time for the isolated UF phase equals 0:00, the attention alarm `TREATMENT TIME EXPIRED` appears and the treatment is to be discontinued as usual procedure.

Chapter 7

Profiling

Contents

General

In order to optimize the dialysis treatment the concentrations of sodium and bicarbonate in the dialysis fluid and the ultrafiltration rate can automatically be changed following predetermined graphs.

Profiling of Na^+ and HCO_3^- dialysis fluid concentration

For sodium and/or bicarbonate concentrations, linear increasing or decreasing graphs can be set. The graph represents a constant change in the sodium and/or bicarbonate concentrations in the dialysis fluid throughout the treatment. The change is determined by the start and stop values set for each parameter. Based on these values, the machine will perform a smooth and constant adjustment of the concentrations during the treatment time when profiling has been activated. See the following figure.

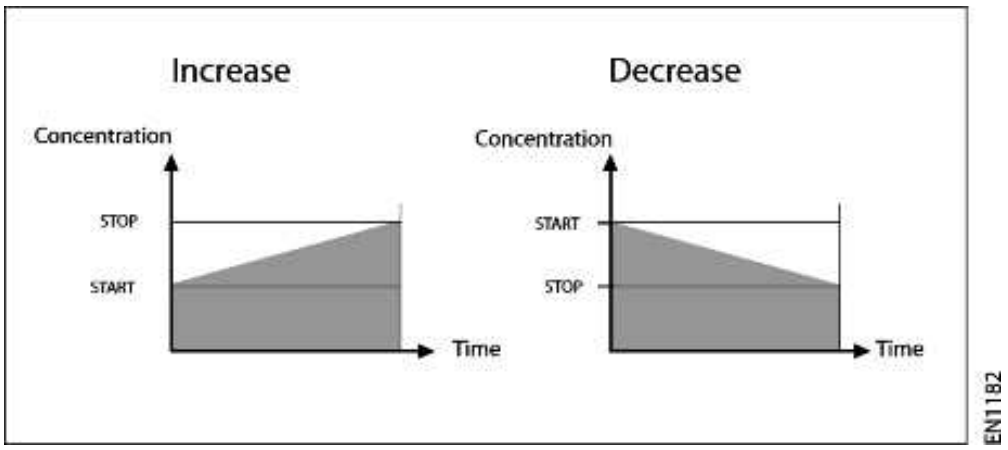


Figure 7:1 Linear graphs for sodium and bicarbonate profiling

Profiling of ultrafiltration rate

For ultrafiltration rate, 3 different graphs can be set. Linear increasing or decreasing graph, increasing or decreasing graph - in steps, or graph where the UF rate changes at intervals. All graphs represent changes of the UF rate throughout the treatment.

The change of UF rate for the linear graph is determined by the following settings; total UF volume, treatment time and start UF rate. Based on these parameters, the machine will perform a smooth and constant adjustment of the UF rate during the treatment time when profiling has been activated. See the following figure.

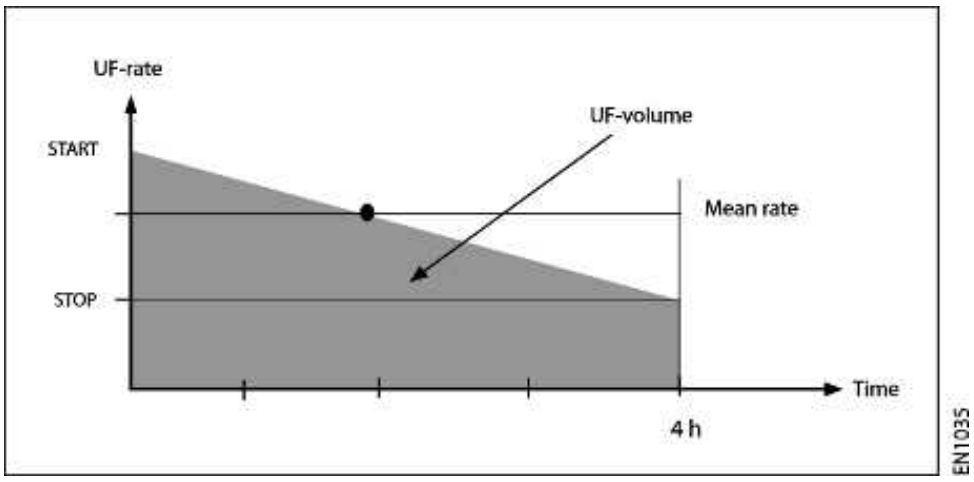


Figure 7:2 Decreasing linear graph for UF rate profiling

The change of UF rate for the graph in steps is determined by the following settings; total UF volume, treatment time, number of steps in the graph and start UF rate. Based on these parameters, the machine will perform adjustments of the UF rate in steps during the treatment time when profiling has been activated. See the following figure.

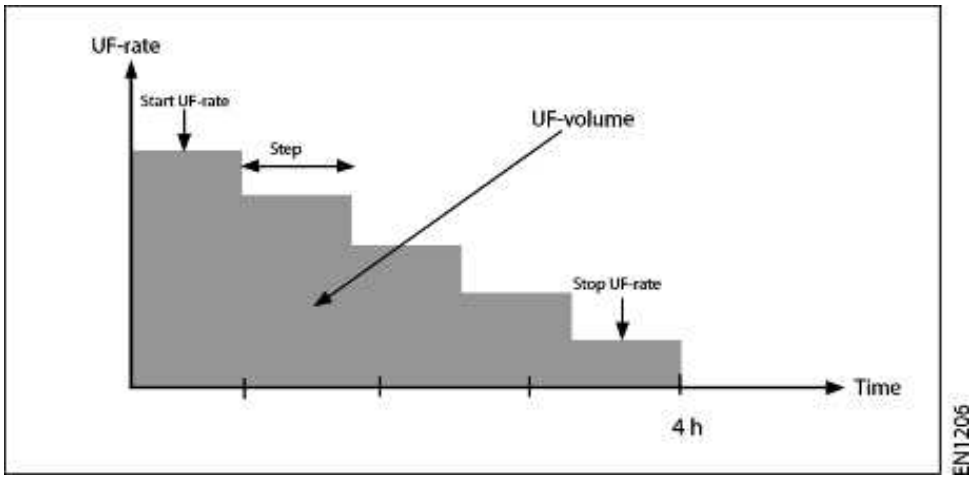


Figure 7:3 Decreasing graph in steps for UF rate profiling

The change of UF rate for the graph in intervals is determined by the following settings; total UF volume, treatment time, number of intervals in the graph and start UF rate. Based on these parameters, the machine will perform adjustments of the UF rate at intervals during the treatment time when profiling has been activated. See the following figure.

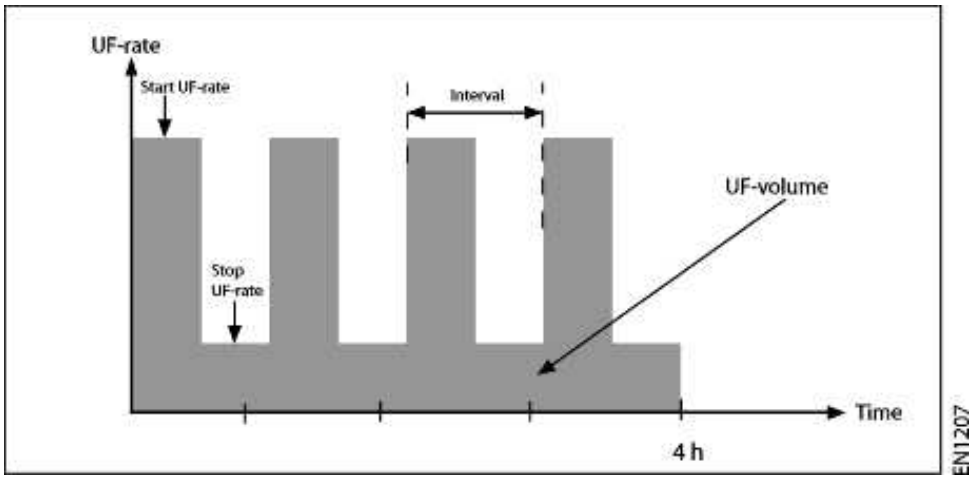


Figure 7:4 Graph in intervals for UF rate profiling

For all the UF rate graphs, the operator is requested to readjust the TMP alarm limits during treatment in accordance with the UF rate and the dialyzer UF coefficient.

If UF volume or treatment time is changed, after UF profiling has been activated, the profiling graph will automatically change as well. The UF rate change will if possible be kept and the graph will shift in parallel to the original graph.

Examples of UF rate linear graphs where time or UF volume has been changed are shown in the pictures below (changed graphs in gray, original graph in black). Note that if time is changed and the stop value of the new graph reaches the minimum UF rate, the slope of the graph will also change.

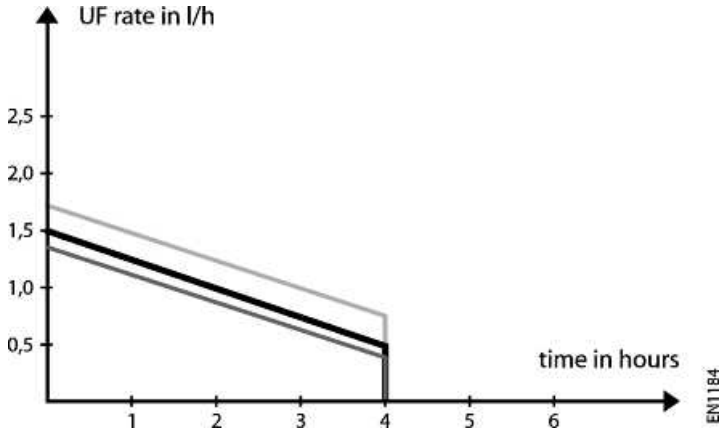


Figure 7:5 Change of UF rate linear graph when UF volume has been changed

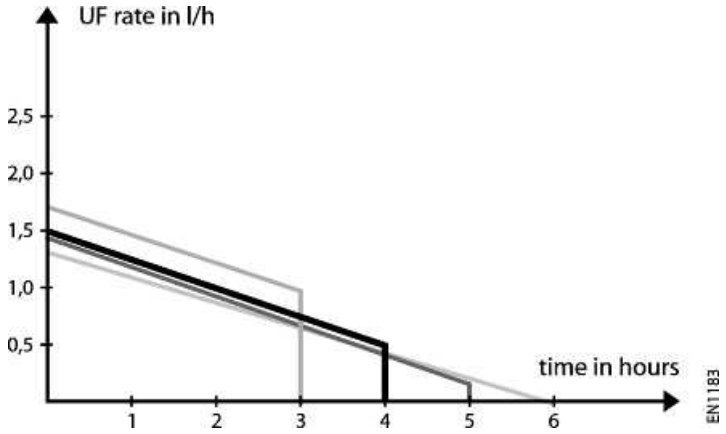


Figure 7:6 Change of UF rate linear graph when time has been changed

Note

- For any UF rate graph, always check the UF profiling settings if UF volume or treatment time is changed after UF profiling activation.

Note

Profiling Models

The profiling function of the AK 96 dialysis machine consists of three different models (memories). Profiles for sodium (NA), bicarbonate (HCO3) and ultrafiltration rate (UF) can be set for each model. It is possible to set profiles for all three parameters at the same time or just pick one or two parameters within the model. The models can be manually set or they can be preset by an authorized technician.

Profiling Setting/Activation

Profiling can be started at treatment start or at any time during treatment. The model that is to be used can be manually set or be preset by an authorised technician.
Step-by step instructions for the two alternatives are described further on in this section, in "Profiling without Preset Model", page 7:7 or in "Profiling with Preset Model", page 7:10 in part 1.

Profiling settings can be done as soon as the machine has been switched on and “FCh” is shown on the Time Display. It is possible to manually set a model or just select a preset model. Profiles for sodium (NA), bicarbonate (HCO3) and ultrafiltration rate (UF) can be set/adjusted for each model. If UF profiling (UF) is to be used, the UF volume for the following treatment has to be set before setting the UF profiling.

The profiling function for all three profiling parameters can be reached by first pressing the *Fluid Path button*, and then selecting UF or COND using the *Keypad*.

Activation The profiling function can be activated at the same time as when the setting is being done, or at any other time desired during treatment. When UF profiling has been activated it is possible to change the profiling settings without first deactivating profiling. However, changing sodium and/or bicarbonate profiling settings cannot be done without first deactivating profiling. The profiling function starts to be active when blood has been detected in the venous line and the *UF Start/Stop button* has been pressed.

Profiling without Preset Model

Setting and Activating the Model

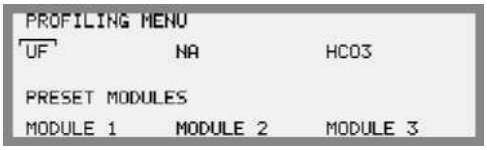
CAUTION

- The operator has to make sure that the profile chosen is suitable for the patient treated. The profiling parameters have to be checked prior to the treatment.
- Once the profiling values have been set, the operator should verify that the control and protective systems for sodium and bicarbonate profiling operate with the desired values and that they are in agreement. This verification is made in two steps. First by checking the set start (START) and stop (STOP) values for NA PROFILING (protective values), press the *Back key* and compare with the values NA displayed in the PROFILING MENU (control values). Secondly by checking the set start (START) and stop (STOP) values for HCO3 PROFILING (protective values), press the *Back key* and compare with the values HCO3 displayed in the PROFILING MENU (control values).
- During UF profiling, the operator must readjust the TMP alarm limits to follow the changing UF rate.

CAUTION

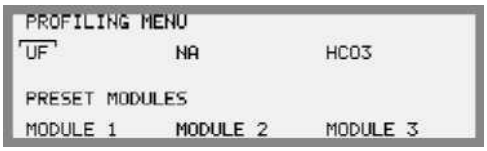
1. Press the *Fluid Path button* and select either UF or COND using the *Keypad*.

2. Select PROFILING.



3. Press the *Select key* and the PROFILING MENU will be displayed on the Information Display.
4. Select UF, NA, or HCO3 and continue by following the corresponding instructions for each parameter below.

Ultrafiltration



5. Press the *Select key* to go into the sub menu for UF.

6. Select LINEAR , INTERVAL or STEP profiling using the *Select key*. and continue by following the corresponding instructions below.

If linear graph

7. If linear graph (LINEAR) has been selected, set the start (START) value for UF rate. The stop value (STOP) will be automatically adjusted in proportion to the start value. This is to maintain the previously set UF volume for the following treatment.

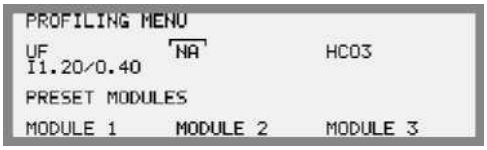
8. Activate the UF profiling function at this moment by pressing the *Select key* for 3 seconds. Or, if desired, it is possible to activate the UF profiling function at any time during priming or treatment.

If step or interval graph

7. If step or interval graph (INTERVAL or (STEP) has been selected, first set the number of intervals/steps at the first position, then continue with the start (START) value for UF rate. The stop value (STOP) value for UF rate will be automatically adjusted in proportion to the start value. This is to maintain the previously set UF volume for the following treatment.

8. Activate the UF profiling function at this moment by pressing the *Select key* for 3 seconds. Or, if desired, it is possible to activate the UF profiling function at any time during priming or treatment.

Sodium

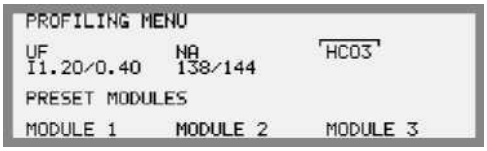


5. Press the *Select key* to go into the sub menu for NA and the NA PROFILING menu will be displayed.

6. Set the start (START) and/or stop (STOP) values for sodium.

7. Activate the sodium profiling function at this moment by pressing the *Select key* for 3 seconds. Or, if desired, it is possible to activate the sodium profiling function at any time during priming or treatment.

Bicarbonate



5. Press the *Select key* to go into the sub menu for HCO3 and the HCO3 PROFILING MENU will be displayed.

6. Set the start START and/or stop STOP values for bicarbonate.

7. Activate the bicarbonate profiling function at this moment by pressing the *Select key* for 3 seconds. Or, if desired, it is possible to activate the bicarbonate profiling function at any time during priming or treatment.

Note

- **If UF profiling has been activated**
  If UF volume or treatment time is changed, the profiling graph will automatically change as well. Always check the UF profiling settings if UF volume or treatment time is changed after UF profiling activation. For further details, see "Profiling of ultrafiltration rate", page 7:3.

- **If sodium or bicarbonate profiling has been activated**
  If treatment time is changed the profiling graphs will not change. As a consequence, the set stop values will not be reached if treatment time is decreased.

- **If isolated UF is to be used**, and profiling has been activated, the profiling will be bypassed during the isolated UF phase. PROFILING will still be displayed on the Information Display. When the isolated UF phase is complete, the profiling will automatically be reactivated starting where it was interrupted.

- **If sodium or bicarbonate profiling is deactivated during treatment**, the machine will continue running on the values from the point at which it was stopped. If profiling is reactivated without changed profiling parameters, the machine will continue running from the point where profiling was deactivated.

- **If UF profiling is deactivated during treatment**, the machine will recalculate the UF rate according to remaining UF volume and treatment time. If UF profiling is reactivated, without changed profiling parameters, the UF profiling graph will automatically change according to remaining UF volume and treatment time. Always check the UF profiling settings after deactivating and reactivating UF profiling.

Note

Profiling with Preset Model

Selecting and Activating the Model

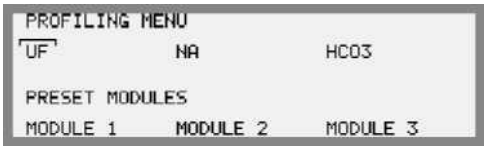
CAUTION

- The operator has to make sure that the profile chosen is suitable for the patient treated. The profiling parameters have to be checked prior to the treatment.
- Once the profiling values have been set, the operator should verify that the control and protective systems for sodium and bicarbonate profiling operate with the desired values and that they are in agreement. This verification is made in two steps. First by checking the set start (START) and stop (STOP) values for NA PROFILING (protective values), press the *Back key* and compare with the values NA displayed in the PROFILING MENU (control values). Secondly by checking the set start (START) and stop (STOP) values for HCO3 PROFILING (protective values), press the *Back key* and compare with the values HCO3 displayed in the PROFILING MENU (control values).
- During UF profiling, the operator must readjust the TMP alarm limits to follow the changing UF rate.

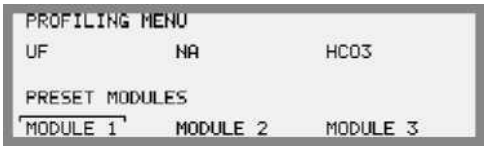
CAUTION

1. Press the *Fluid Path button* and select either UF or COND using the *Keypad*.

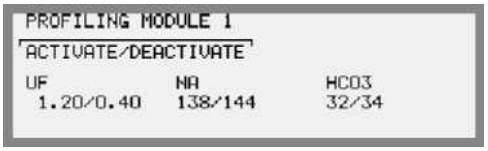
2. Select PROFILING.



3. Press the *Select key* and the PROFILING MENU will be displayed on the Information Display.



4. Below PRESET MODULES, select MODULE 1, MODULE 2 or MODULE 3 using the *Keypad*.



5. Check that the preset values in the model is correct. Activate the profiling model, by pressing the *Select key* for 3 seconds. Or, if desired, it is possible to activate the profiling function at any time during priming or treatment. Bear in mind, that the parameter settings of the complete model will be activated simultaneously. If necessary, it is possible to adjust the preset values of the parameters, refer to "Profiling without Preset Model", page 7:7.

Note

- **If UF profiling has been activated**
  If UF volume or treatment time is changed, the profiling graph will automatically change as well. Always check the UF profiling settings if UF volume or treatment time is changed after UF profiling activation. For further details, see "Profiling of ultrafiltration rate", page 7:3.

- **If sodium or bicarbonate profiling has been activated**
  If treatment time is changed the profiling graphs will not change. As a consequence, the set stop values will not be reached if treatment time is decreased.

- **If isolated UF is to be used**, and profiling has been activated, the profiling will be bypassed during the isolated UF phase. PROFILING will still be displayed on the Information Display. When the isolated UF phase is complete, the profiling will automatically be reactivated starting where it was interrupted.

- **If sodium or bicarbonate profiling is deactivated during treatment**, the machine will continue running on the values from the point at which it was stopped. If profiling is reactivated without changed profiling parameters, the machine will continue running from the point where profiling was deactivated.

- **If UF profiling is deactivated during treatment**, the machine will recalculate the UF rate according to remaining UF volume and treatment time. If UF profiling is reactivated, without changed profiling parameters, the UF profiling graph will automatically change according to remaining UF volume and treatment time. Always check the UF profiling settings after deactivating and reactivating UF profiling.

- **If profiling is activated (preset model) during treatment,** the profiling graph will still follow the preset parameters within the remaining treatment time.

Note

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Chapter 8

Hygiene and Maintenance

Contents

Hygiene and Maintenance - General

The contents of this chapter concerns the hygiene and maintenance of the AK 96 dialysis machine, which should be carried out by the operator of the machine.

CAUTION

- No further maintenance other than that mentioned in this chapter shall be performed by the operator/user of the machine. The casing must only be opened by an authorized technician, refer to the AK 96 Service Manual.

- Preventive maintenance shall be performed according to instructions in "General Precautions before use" in chapter 1 part 1 (page 1:11), of this manual.

CAUTION

In order to maintain a high microbiological quality of the dialysis fluid, it is important that the operator/user is attentive to the hygiene and maintenance of the machine. There are factors and procedures that affect the hygiene of the flow path, and consequently the quality of the prepared dialysis fluid. The following must be considered:

- The disinfection, decalcification and cleaning processes must be performed according to instructions in this chapter.
- The frequency of disinfection, decalcification and cleaning of the machine should be carried out according to recommendations in this chapter.
- The quality of the inlet water entering the machine.
- The quality of the concentrates being used.
- The inlet water tube, which preferably should be disinfected by using integrated heat disinfection.
- The arrangement of the drain connection from the machine, i.e. there must be a sufficient air-gap between the drain tube of the machine and the drainage system to avoid back contamination from the drainage system.

The AK 96 dialysis machine may be disinfected using heat where the fluid flow path is heated up. The AK 96 dialysis machine may also be disinfected by filling the fluid path with chemical disinfectants. For information concerning description and handling instructions of the different disinfection programs, see further on in this chapter.

The test procedure by which the effectiveness of disinfection has been verified is available on request, contact your local Gambro representative.

To prevent any cross-infection between patients the following precautions must be considered:

- Wipe down the outside of the machine with proper disinfectant.
- To protect the pressure connections on the machine, use blood lines where hydrofobic filters are integrated. Especially note that if any of the hydrofobic filters have been filled with blood and show signs of damage, the machine components for pressure measurements must be replaced and cleaned by an authorized technician.

Glossary of Disinfection Terms

Disinfection is removal or reduction of bacteria in the fluid path of the dialysis machine.

Decalcification is removal of calcium and magnesium-carbonate precipitates in the fluid path, originating from the bicarbonate dialysis fluid.

Cleaning is removal of fats, proteins and organic material, originating from the patient and located mainly in the fluid path of the machine downstream of the dialyzer.

Dwell Time is the time when the fluid path of the machine is filled with the correct concentration of disinfectant.

Disinfection History

The disinfection history list can not be shown during treatment.

At all other times when the machine does not detect blood, the *Rinse/Disinfection button* can be pressed for 3 seconds and a list of the 3 most recently performed disinfection programs (both heat and chemical disinfection programs) will be shown on the Information Display.

The last performed disinfection program is shown at the top of the list. The 20 most recently performed disinfection programs can be displayed by scrolling up and down using the *Display Up key* and the *Display Down key*.

If the disinfection program was **successfully** performed; `COMPL` is shown to the right on the Information Display. The time shown to the left is the time for when the disinfection program was **completed**.

If the disinfection program was **not successfully** performed; `INCOMP` is shown to the right on the Information Display. The time shown to the left is the time for when the disinfection program was **started**.

Go back from the disinfection history list by pressing the *Back key*.

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Schedule for Hygiene and Maintenance

The schedule below is recommended for use by the operator/user of the AK 96 dialysis machine. This recommendation is to keep a high level of performance of the machine. It is also a guideline for maintaining the hygiene of the fluid path and the exterior of the machine to ensure the safety of the patient.

Frequency	Measures	Cleaning	Decalcifi-cation	Disinfec-tion
After each treatment	1) Heat disinfection program. 2) Wipe down the outside of the machine with 70% ethanol or 60% isopropanol.			x
At least after every third treatment	Combine the heat disinfection program with CleanCart-C cartridge or liquid citric acid.	x	x	x
At least once every seventh treatment day	Heat disinfection program in combination with CleanCart-A cartridge or a chemical disinfection program with sodium hypochlorite. This should be performed directly after a heat disinfection program in combination with CleanCart-C cartridge or liquid citric acid.	x	x	x
When time after disinfection has exceeded seven days	Heat disinfection program before treatment.			x
Once every one to three months if UFD is installed[1]	Change of ultra filter followed by a heat disinfection program.			x

[1] For more information, see "Ultrafilter - Frequency of Change" in chapter 1 part 1.

Any heat disinfection program can be exchanged to a heat disinfection program in combination with CleanCart-C cartridge or liquid citric acid.

Heat disinfection can be replaced by chemical disinfection. But note that decalcification (CleanCart-C cartridge or liquid citric acid) cannot be replaced by chemical disinfection.

An integrated heat disinfection program is recommended when possible since it also includes the inlet water tube.

In order to enable the cleaning agents to remove fats, proteins etc. efficiently, cleaning (CleanCart-A cartridge or sodium hypochlorite) should be carried out after decalcification (CleanCart-C cartridge or liquid citric acid).

Note

- An attention alarm appears when the machine is switched on, if more than 5 days[2] have passed since the last complete disinfection program was carried out. It is still possible to perform a treatment, the attention alarm will disappear when the *Priming button* lights up during the function check. However, the attention alarm will reappear the next time the machine is switched on, if a disinfection program has still not been completely carried out.

Note

When the machine is planned not to be in use

If the machine is planned not to be in use for a period of time exceeding seven days, the microbiological standard of the flow path can be maintained with one of the following alternatives:

- Perform a heat disinfection program at least every seventh day and a heat disinfection program before treatment.
- Fill the machine with a proper chemical disinfectant in order to preserve it. See "Filling the machine with chemical disinfectant" on page 8:29 for instructions.

[2] The period of time can be preset

Disinfection, Decalcification and Cleaning Agents - Characteristics

The table below summarizes the characteristics of some generic substances used for internal disinfection, decalcification and cleaning of the AK 96 dialysis machine. For more specific information about a certain commercial product, see manufacturer's information.

Disinfection, decalcification and cleaning

	Efficiency on inorganic precipitates		**Efficiency on organic precipitates fats, proteins**	**Efficiency of disinfection**
	Calcium	**Iron oxide**		
CleanCart-C cartridge and heat	High	Low	Medium	High
CleanCart-A cartridge and heat	None	None	High	High
Peracetic acid 0.01 to 0.15 %	Low[3]	None	None	High
Citric acid liquid 2 % and heat	High	Low	Medium	High
Sodium hypochlorite 0.5 %	None	None	High	High
Formaldehyde 4 %	None	None	None	High
Glutardialdehyde 2 %	None	None	None	High
Oxalic acid 2 % and heat[4]	Low	High	None	High

[3] The manufacturers of disinfectants based on peracetic acid claim that these agents can also be used for decalcification. However, experience has shown that peracetic acid is not reliable alone, use CleanCart-C cartridge, citric acid or acetic acid regularly.

[4] Oxalic acid is recommended only when having problems with iron oxide precipitates (reddish-brown). Oxalic acid increases the wear of the machine.

Hygiene - Heat Disinfection

Heat Disinfection - General

During the heat disinfection program the inlet water is heated up and flushed through the fluid monitor. The program begins with a rinse in order to eradicate possible residues from concentrates used in the preceding treatment. After this, the program consists of three consecutive phases; the fillup phase, the circulation phase and the drain phase. The actual disinfection takes place in the circulation phase. The circulation phase consists of a number of cycles, where each cycle is a sequence in which heated water is passed through all parts of the fluid path. The standard heat disinfection program consists of 12 such cycles.

The AK 96 dialysis machine fluid path is constructed in a way that prevents possible contaminants in the post-dialyzer fluid path from reaching the patient. The construction principle is called *single pass*, which means no recirculation in the fluid path, and a separation between the pre-dialyzer circuit and the post-dialyzer circuit. This is to ensure that no fluid from the downstream (post) dialyzer circuit comes into contact with the pre-dialyzer circuit. The construction principle is an effective obstacle to transmission of blood-borne viruses like Hepatitis B, from the fluid path to the patient, if a blood leak in the dialyzer occurs. In addition the standard heat disinfection program has the capacity to make viruses inactive.

The combination of the standard heat disinfection program process (12 cycles) and the safe hygienic construction of the fluid path (single pass) described above provides high safety levels for the patient.

The standard heat disinfection program is validated by using microbiological challenge tests which gives a 5 log reduction of the following microorganisms; Pseudomonas aeruginosa (ATCC 9027), Staphylococcus aureus (ATCC 6538), Burkholderia cepacia (ATCC 17770) and Candida albicans (ATCC 10231).

The heat disinfection program can be extended for 22 cycles. The 22 cycles variant may be used in case of substantial contamination of the fluid path. This program provides different positions of the fluid path with at least 30% more heat. As a consequence, the duration of this heat disinfection program will be extended by approximately 10 minutes, compared to the standard program.

It is possible to run a heat disinfection program in combination with CleanCart cartridge:

- Decalcification program with CleanCart-C cartridge
- Cleaning program with CleanCart-A cartridge

If heat disinfection program with CleanCart cartridge is chosen, the contents of the CleanCart cartridge are dissolved and the solution is heated-up and flushed through the fluid monitor during the heat disinfection program as described above. This program is extended by a priming phase, a fill-up phase and a recirculation phase for the

CleanCart cartridge, which leads to a longer time to complete the program.

The CleanCart-C cartridge can be replaced by liquid citric acid in order to perform a decalcification program; heat disinfection program with liquid citric acid. The program is performed in a similar way as heat disinfection program with CleanCart cartridge.

Note

- In order to enable the cleaning agents to remove fats, proteins etc. efficiently, cleaning should be carried out after decalcification.

Note

For further details concerning the heat disinfection programs; see "Disinfection and Cleaning - Heat Disinfection" on page 9:9 in part 1.

Handling instructions of above mentioned heat disinfection programs are described on the following pages in this chapter.

Heat Disinfection Program - Performing

Note

- The program can be interrupted at any time when the program is running; press and hold the *Select key* for 3 seconds. The machine will then interrupt the procedure and finish off with a drain sequence.
- The pick-up tubes must be rinsed/disinfected separately. See "Pick-up Tubes" on page 8:41 for instructions.

Note

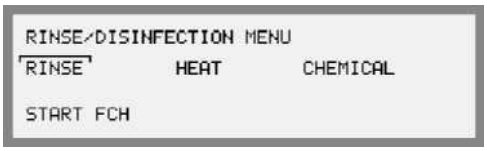
Check before starting the procedure

- ☑ That the dialysis fluid tubes are connected to the safety couplings and that the latches of the BiCart holder are closed.
- ☑ That the concentrate connectors are placed in the corresponding stand-by ports of the machine (blue and red), and that the yellow disinfectant connector is placed in the parking port (marked P).

Procedure

Use the *Keypad* next to the Information Display to select options and to navigate within and between the menus. For details concerning the keys included in the *Key pad*, see "Keypad" in chapter 3. part 1

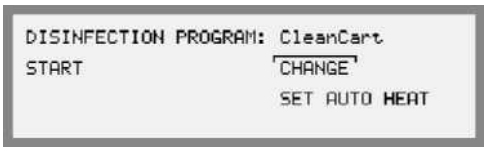
1. Press the *Rinse/Disinfection button* briefly.



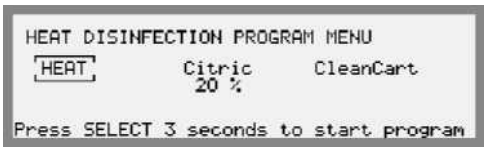
2. The `RINSE/DISINFECTION MENU` will be displayed on the Information Display.

3. Select `HEAT`.

4. Check that `HEAT` is displayed as the selected program.
   If `HEAT` is displayed, continue to point 5.
   If not, do point 4.a and 4.b before continuing to point 5.



4.a. Select CHANGE.



4.b. Select HEAT.

5. Start the program by pressing the *Select key* for 3 seconds, the *Rinse/Disinfection button* lights up. Note that if the automatic start of heat disinfection or rinse program has been activated, the *Rinse/Disinfection button* will already be lit.

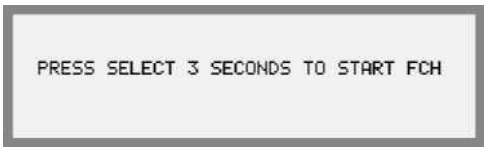
DISINFECTION IN PROGRESS: will be displayed and will remain throughout the program.

The *Rinse/Disinfection button* will continue to be lit throughout the program, indicating that the program is ongoing.

6. If an automatic switch off is required, press the *On/Off button* for 3 seconds.

When the program is complete, drain sequence included, the *Priming button* starts to flash (not if an automatic switch off has been done).

7. Switch the machine off by pressing the *On/Off button* for 3 seconds.



If a new treatment is to be started directly after the disinfection program, press the flashing *Priming button* briefly and PRESS SELECT 3 SECONDS TO START FCH will be displayed. Press the *Select key* for 3 seconds to start a new function check and simultaneously reset previous values to zero.

Heat Disinfection Program with CleanCart® cartridge - Performing

Note

- The program can be interrupted at any time when the program is running; press and hold the *Select key* for 3 seconds. The machine will then interrupt the procedure and finish off with a drain sequence.
- The pick-up tubes must be rinsed/disinfected separately. See "Pick-up Tubes" on page 8:41 for instructions.

Note

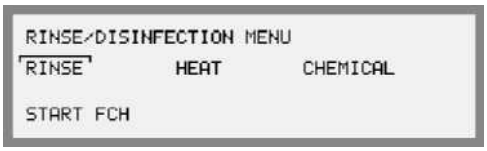
Check before starting the procedure

- ☑ That the dialysis fluid tubes are connected to the safety couplings and that the latches of the BiCart holder are closed.
- ☑ That the concentrate connectors are placed in the corresponding stand-by ports of the machine (blue and red), and that the yellow disinfectant connector is placed in the parking port (marked P).

Procedure

Use the *Keypad* next to the Information Display to select options and to navigate within and between the menus. For details concerning the keys included in the *Key pad*, see "Keypad" in chapter 3. part 1

1. Press the *Rinse/Disinfection button* briefly.



2. The `RINSE/DISINFECTION MENU` will be displayed on the Information Display.

3. Select `HEAT`.
4. Check that the key `CleanCart` is displayed as the selected program.
   If the key `CleanCart` is displayed, continue to point 5.
   If not, do point 4.a and 4.b before continuing to point 5.

4.a. Select `CHANGE`.

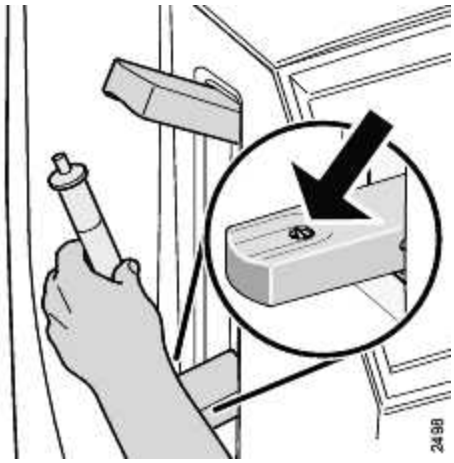
4.b. Select the key `CleanCart`.

5. Start the program by pressing the *Select key* for 3 seconds, the *Rinse/Disinfection button* lights up. Note that if the automatic start of heat disinfection or rinse program has been activated, the *Rinse/Disinfection button* will already be lit.

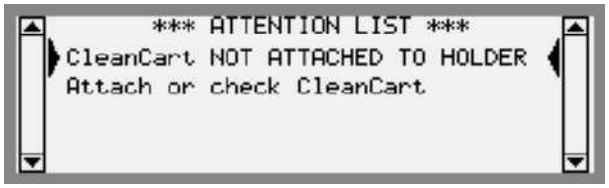
`DISINFECTION IN PROGRESS:` will be displayed and will remain throughout the program.

The *Rinse/Disinfection button* will continue to be lit throughout the program, indicating that the program is ongoing.

6. The program starts with a rinse phase, therefore wait for approximately 2-4 minutes before attaching the CleanCart cartridge to the holder. An attention alarm will be generated to notify you when, see next point.

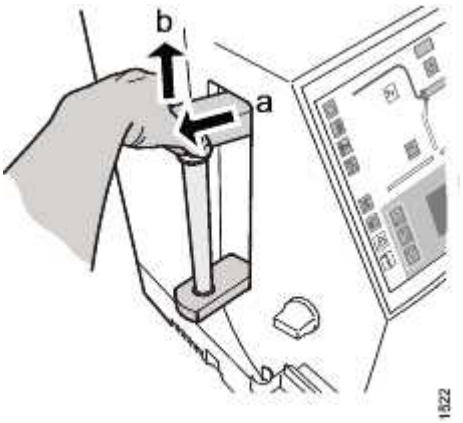


7. When the attention alarm:



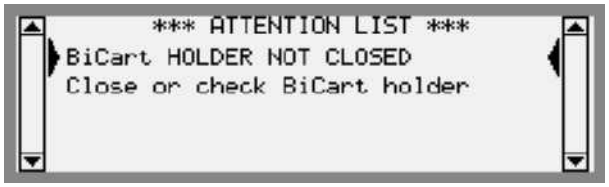
appears, open the latches of the BiCart holder and place the CleanCart cartridge to the holder in a similar way as when you place the BiCart cartridge to the holder.
Default, the cartridge can be left in the holder during the entire program (up until next function check is started) and will automatically be emptied. The program will now start, continue to point 9 in these instructions.

By preset, an attention alarm can appear to request the operator to empty the cartridge. In this case do point 8 before continuing to point 9.



8. If the attention alarm:

appears, open the upper latch of the BiCart holder (pull out, a in the corresponding figure and lift upwards, b). Press *Select key* briefly. When empty, the following attention will appear:

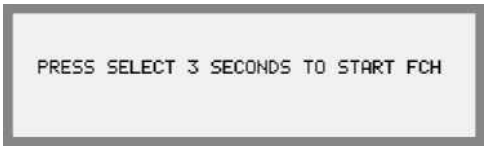


Remove the CleanCart cartridge, close the latches and the program will now start.

9. If an automatic switch off is required, press the *On/Off button* for 3 seconds.

When the program is complete, drain sequence included, the *Priming button* starts to flash (not if an automatic switch off has been done).

10. Switch the machine off by pressing the *On/Off button* for 3 seconds.



If a new treatment is to be started directly after the disinfection program, press the flashing *Priming button* briefly and PRESS SELECT 3 SECONDS TO START FCH will be displayed. Press the *Select key* for 3 seconds to start a new function check and simultaneously reset previous values to zero.

Heat Disinfection Program with Liquid Citric Acid - Performing

Note

- The program can be interrupted at any time when the program is running; press and hold the *Select key* for 3 seconds. The machine will then interrupt the procedure and finish off with a drain sequence.
- The pick-up tubes must be rinsed/disinfected separately. See "Pick-up Tubes" on page 8:41 for instructions.

Note

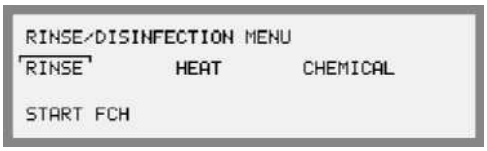
Check before starting the procedure

- ☑ That the dialysis fluid tubes are connected to the safety couplings and that the latches of the BiCart holder are closed.
- ☑ That the concentrate connectors are placed in the corresponding stand-by ports of the machine (blue and red), and that the yellow disinfectant connector is placed in the parking port (marked P).

Procedure

Use the *Keypad* next to the Information Display to select options and to navigate within and between the menus. For details concerning the keys included in the *Key pad*, see "Keypad" in chapter 3. part 1

1. Press the *Rinse/Disinfection button* briefly.



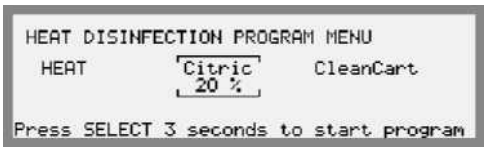
2. The RINSE/DISINFECTION MENU will be displayed on the Information Display.

3. Select HEAT.

4. Check that CITRIC 20% is displayed as selected program. If CITRIC 20% is displayed, continue to point 5. If not, do point 4.a and 4.b before continuing to point 5.

4.a. Select CHANGE.

4.b. Select CITRIC 20%.



5. Start the program by pressing the *Select key* for 3 seconds, the *Rinse/Disinfection button* lights up. Note that if the automatic start of heat disinfection or rinse program has been activated, the *Rinse/Disinfection button* will already be lit.

DISINFECTION IN PROGRESS: will be displayed and will remain throughout the program.

The *Rinse/Disinfection button* will continue to be lit throughout the program, indicating that the program is ongoing.

6. Connect the yellow disinfectant connector (see point 6 in "Fluid Part Component Details", starting on page 2:19 in part 1) to the pick-up tube and place it in the liquid citric acid container, alternatively move the disinfectant connector to the disinfectant port.

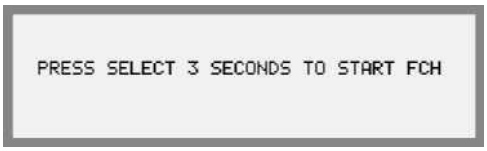
7. If the disinfectant connector is still connected to the parking port when the filling phase of the program starts, the following attention alarm will be generated:

Note especially that the disinfectant connector must remain in the disinfectant container/disinfectant port and not be moved to the parking port before the chemical disinfectant program is complete. This is due that the chemical disinfectant is pushed back to the disinfectant container to empty the connector/intake tube at the end of the program.

8. If an automatic switch off is required, press the *On/Off button* for 3 seconds.

When the program is complete, drain sequence included, the *Priming button* starts to flash (not if an automatic switch off has been done).

9. Switch the machine off by pressing the *On/Off button* for 3 seconds.



If a new treatment is to be started directly after the disinfection program, press the flashing *Priming button* briefly and `PRESS SELECT 3 SECONDS TO START FCH` will be displayed. Press the *Select key* for 3 seconds to start a new function check and simultaneously reset previous values to zero.

Integrated Heat Disinfection Program with WRO 300 H - Performing

By an authorized technician, the AK 96 dialysis machine can be preset to perform Integrated Heat disinfection program supported by the WRO 300 H water purification unit. This program is recommended when possible, since it includes heating of the inlet water tube.

The program starts with a heat disinfection program (or if selected, a heat disinfection program in combination with CleanCart cartridge or liquid citric acid) of the machine. When the circulation phase (for information, see "Heat Disinfection - General" on page 8:9) has finished a low flow heat phase starts. In this phase, the machine will receive hot water from the WRO 300 H, at a low flow rate, for 15 minutes. When this phase is complete, the machine finishes the program off as usual, with a drain phase. The low flow heat phase can be preset to be started automatically or manually, see following handling instructions in this section.

Note

- The program can be interrupted at any time when the program is running; press and hold the *Select key* for 3 seconds. The machine will then interrupt the procedure and finish off with a drain sequence.
- The pick-up tubes must be rinsed/disinfected separately. See "Pick-up Tubes" on page 8:41 for instructions.

Note

Check before starting the procedure

- ☑ That the concentrate connectors are placed in the corresponding stand-by ports of the machine (blue and red), and that the yellow disinfectant connector is placed in the parking port (marked P).
- ☑ Make sure that the WRO 300 H is switched on.
- ☑ That the dialysis fluid tubes are connected to the safety couplings and that the latches of the BiCart holder are closed.

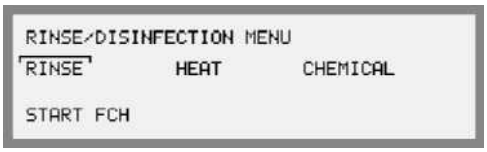
Procedure

Use the *Keypad* next to the Information Display to select options and to navigate within and between the menus. For details concerning the keys included in the *Key pad*, see "Keypad" in chapter 3. part 1

The low flow heat phase can be started automatically or manually. Automatic start is the default procedure described below, followed by the manual start procedure.

Automatic start of the Low Flow Heat phase

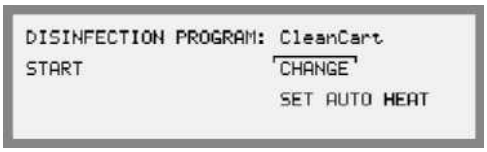
1. Press the *Rinse/Disinfection button* briefly.



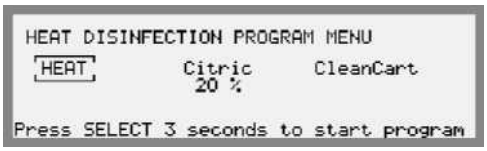
2. The RINSE/DISINFECTION MENU will be displayed on the Information Display.

3. Select HEAT.

4. Check that HEAT is displayed as selected program. If HEAT is displayed, continue to point 4. If not, do point 4.a and 4.b before continuing to point 5.



4.a. Select CHANGE.



4.b. Select HEAT.

5. Start the program by pressing the *Select key* for 3 seconds until the *Rinse/Disinfection button* lights up.

6. Respond to the text shown on the Information Display on whether to include the WRO or not. Use the alternative to include the WRO.

7. The process will continue automatically from here. When the heat disinfection of the AK 96 dialysis machine and the low flow heat are finished the *Priming button* will start to flash (not if an automatic switch off has been done). The WRO will perform a heat disinfection of its fluid path after the low flow heat.

Note that if a new function check is started during the WRO heat process an attention is generated during the function check due to

insufficient inlet pressure. The function check will wait for water from the WRO before continuing.

8. Switch the machine off by pressing the *On/Off button* for 3 seconds.

If a new treatment is to be started directly after the disinfection program, press the flashing *Priming button* briefly and PRESS SELECT 3 SECONDS TO START FCH will be displayed. Press the *Select key* for 3 seconds to start a new function check and simultaneously reset previous values to zero.

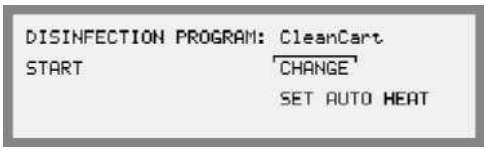
Manual start of the Low Flow Heat phase

1. Press the *Rinse/Disinfection button* briefly.

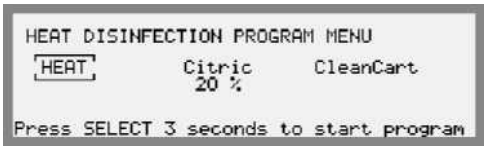
2. The RINSE/DISINFECTION MENU will be displayed on the Information Display.

3. Select HEAT.

4. Check that HEAT is displayed as selected program. If HEAT is displayed, continue to point 4. If not, do point 4.a and 4.b before continuing to point 5.

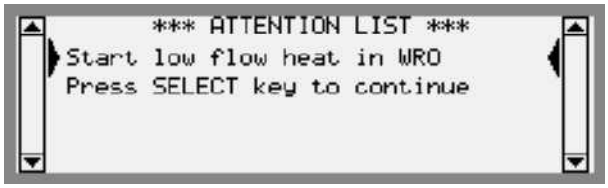


4.a. Select CHANGE.



4.b. Select HEAT.

5. When the circulation phase (for information, see in "General - Heat disinfection") of the heat disinfection program is finished, the program will be interrupted, and simultaneously an attention alarm appears:



6. When the low flow heat phase is finished, the machine enters drain phase, and simultaneously an attention alarm appears:

Follow the attention alarm request according to the instructions in the Operator's manual for WRO 300 H. Then press the *Select key* to confirm this.

Heat Disinfection Program - Automatic Start

Note

- The pick-up tubes must be rinsed/disinfected separately. See "Pick-up Tubes" on page 8:41 for instructions.

Note

The machine is equipped with an automatic start function for the heat disinfection program. This is a feature that enables the machine to automatically start a heat disinfection program at a predetermined time. The operator decides (programmes) which day of the week and at what time of the day the machine will be finished after having performed a heat disinfection program.

The machine can be programmed and the function activated, during any phase when the machine is switched on. Whenever this function is activated, and the machine has been switched off, the heat disinfection program will be started at the programmed time. See below for programming and activation instructions.

The machine must be connected to the water supply as well as to power, when performing a heat disinfection program with automatic start. The drain tube must be connected to the drain.

Check whenever activated

- That the dialysis fluid tubes are connected to the safety couplings and that the latches of the BiCart holder are closed.
- That the points in the list "Check Before Switching the Machine On" in chapter 4, part 1 on page 4:2 are fulfilled.
- That the concentrate connectors are placed in the corresponding stand-by ports of the machine (blue and red), and that the yellow disinfectant connector is placed in the parking port (marked P).

Programming and Activation Procedure

Use the *Keypad* next to the Information Display to select options and to navigate within and between the menus. For details concerning the keys included in the *Key pad*, see "Keypad" in chapter 3. part 1

1. Press the *Rinse/Disinfection button* briefly.

2. The `RINSE/DISINFECTION MENU` will be displayed on the Information Display.

3. Select HEAT.

4. Select SET AUTO HEAT .

5. AUTO HEAT MENU will be displayed.
6. Check that TIME NOW is correct. Change if required.
7. Set READY DAY i.e. the day when the program is to be finished.
8. Set READY TIME i.e. the time when the program is to be finished.
9. If the heat disinfection program should be performed other weekdays repeat point 7 to 9 for every day. The auto heat function can be switched off for the selected day by setting the ready time to OFF.
10. Press *Select key* 3 seconds to activate the auto heat function when all days are set.

11. The machine can now be switched off using the *On/Off button*. It will automatically start and initiate the set program to have it completed in due time.

The *Rinse/Disinfection button* will always be lit when the auto heat function has been activated and the machine is switched on.

If changes are to be made or the auto heat process shall be inactivated, enter the AUTO HEAT MENU as described above.

The *Select key* is used to activate and deactivate the auto heat function.

Should days in the schedule be deactivated the set “hours” in READY TIME for the intended day is set to OFF.

In combination with CleanCart® cartridge

If a heat disinfection program with CleanCart cartridge is desired, place a CleanCart cartridge into the BiCart holder before the automatic start of the heat disinfection program is due to start. Remove the empty CleanCart cartridge and close the latches of the BiCart holder when the program is finished before restarting the machine.

Heat Disinfection Program - Automatic Switch Off

The machine can be preset to switch off automatically after a complete heat disinfection program, i.e. when the *Priming button* is flashing, by an authorized technician.

It can also be switched off during the heat disinfection program, by manually pressing the *On/Off button* while the program is running. This will make all of the operator panel lights go out, except for the *Rinse/Disinfection button*, the Time Display and the Information Display. When the program is complete, the machine is automatically switched off.

Integrated Heat Disinfection

The AK 96 dialysis machine can be programmed to perform integrated heat disinfection.

In this mode, the machine receives hot water from the central water supply system when performing the heat disinfection program. The heat disinfection program can be started manually, or preferably be programmed to start automatically, during the heating of the central water supply system.

The advantage with integrated heat disinfection, is that the tube between the central water supply system (inlet water tube) and the machine is also disinfected.

Hygiene - Chemical Disinfection

Chemical Disinfection - General

CAUTION

- Disinfectants may be toxic. The user must therefore take note of necessary precautions before use. The manufacturer's instructions and recommendations have to be followed. Local regulations regarding the utilization of the different chemicals must be followed.
- Local regulations have to be followed regarding approved levels of disinfectant residues.
- After the Chemical disinfection procedure a test for residues must have been performed prior to connecting to a patient.

CAUTION

During the chemical disinfection program the machine is filled with disinfectant. The disinfectant could be concentrated or already diluted. If it is concentrated it is mixed with water to the correct concentration in the machine. The solution is then filled in all parts of the fluid path. After the dwell time (see "Glossary of Disinfection Terms" on page 8:3) the machine is rinsed and drained. If the machine is not to be used for a long period of time, it is possible to turn it off during the dwell time and then it stays filled until it is started again. See "Filling the machine with chemical disinfectant" on page 8:29 for instructions.

Chemical Disinfectants

Chemical disinfectants may be harmful to the materials used in the fluid path of dialysis machines. Disinfectants may also contain additives that cause foaming or are difficult to rinse out. Solutions based on peracetic acid (such as the Dialox and Dialox HP disinfectants), sodium hypochlorite and formaldehyde are compatible with the materials in the AK 96 dialysis machine, provided that they are used in accordance with the recommendations in "Disinfection and Cleaning - Chemical Disinfection" on page 9:8 in part 1. It is essential that the chemical disinfection program is adapted to the disinfectant used regarding dilution and dwell time. The machine has to be properly preset by an authorized technician.

After chemical disinfection procedure a test for residues must have been performed prior to connecting to a patient. On selecting the correct test for residues, follow the manufacturers instructions for the specific disinfectant.

If formaldehyde has been used, note especially that the ultrafilter used in UFD must be changed prior to the following treatment. Alternatively perform additional rinse/drain procedures according to "Residual Test after Chemical Disinfection" on page 8:31.

Note that it is important to wipe up any disinfectants spilled on the machine with a damp cloth.

For information about the disinfectants, such as dwell times, concentrations, consumption and mixing instructions, see “Disinfection and Cleaning - Chemical Disinfection”, on page 9:8 in part 1. For information concerning efficiency, see "Disinfection, Decalcification and Cleaning Agents - Characteristics", on page 8:8.

For further information concerning disinfectants, please contact your local Gambro representative.

Chemical Disinfection Program - Performing

Note

- The program can be interrupted at any time when the program is running; press and hold the *Select key* for 3 seconds. The machine will then interrupt the procedure and finish off with a drain sequence.
- The pick-up tubes must be rinsed/disinfected separately. See "Pick-up Tubes” on page 8:41 for instructions.

Note

Check before starting the procedure

- ☑ That the dialysis fluid tubes are connected to the safety couplings and that the latches of the BiCart holder are closed.
- ☑ That the concentrate connectors are placed in the corresponding stand-by ports of the machine (blue and red), and that the yellow disinfectant connector is placed in the parking port (marked P).

CAUTION

Before starting the chemical disinfection program, make sure that the content of the disinfectant container is enough for the program. If not, the machine will not be properly disinfected.

CAUTION

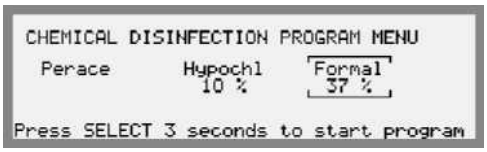
Procedure

Use the *Keypad* next to the Information Display to select options and to navigate within and between the menus. For details concerning the keys included in the *Key pad*, see "Keypad" in chapter 3. part 1

1. Press the *Rinse/Disinfection button* briefly.

2. The `RINSE/DISINFECTION MENU` will be displayed on the Information Display.

3. Select CHEMICAL.



4. Select the desired chemical disinfectant program .

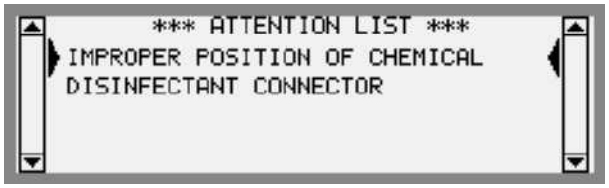
5. Start the program by pressing the *Select key* for 3seconds, *Rinse/Disinfection button* lights up.

DISINFECTION IN PROGRESS: will be displayed and will remain throughout the program.

The *Rinse/Disinfection button* will continue to be lit throughout the program, indicating that the program is ongoing.

6. Connect the yellow disinfectant connector (see point 6 in "Fluid Part Component Details", starting on page 2:19) to the pick-up tube and place it in the disinfectant container, alternatively move the disinfectant connector from the parking port to the disinfectant port.

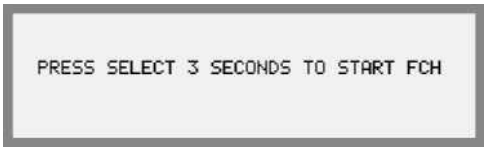
7. If the disinfectant connector is still connected to the parking port when the filling phase of the program starts, the following attention alarm will be generated:



Note especially that the disinfectant connector must remain in the disinfectant container/disinfectant port and not be moved to the parking port before the program is complete. This is due that the chemical disinfectant is pushed back to the disinfectant container to empty the connector/intake tube at the end of the program.

8. When the program is complete the *Priming button* starts to flash and DISINFECTION COMPLETED: is displayed.

9. Switch the machine off by pressing the *On/Off button* for 3 seconds.



If a new treatment is to be started directly after the disinfection program, press the flashing *Priming button* briefly and PRESS SELECT 3 SECONDS TO START FCH will be displayed. Press the *Select key* for 3 seconds to start a new function check and simultaneously reset previous values to zero.

Note especially that the chemical disinfectant connector cannot be moved to the parking port during the chemical disinfectant program.

Move the chemical disinfectant connector to the parking port before next function check.

CAUTION

After the Chemical disinfection procedure a test for residues must have been performed prior to connecting to a patient.

CAUTION

Filling the machine with chemical disinfectant

There may be a need to fill the machine with a chemical disinfectant during storage or when the AK 96 dialysis machine is planned to be left unused for a long period of time. This function has to be preset by an authorized technician, as well as the type of disinfectant. The chemical disinfectant should preferably be peracetic acid.

In order to perform a filling of the machine with chemical disinfectant follow the instructions in "Chemical Disinfection Program - Performing" on page 8:27 previously in this section from the beginning up to point 7. Continue as follows:

7. Press the *On/Off button* during the chemical disinfectant filling phase. The machine will continue to run the program for some minutes after the *On/Off button* has been pressed. This is to fill up all the tubes and to even out the concentration of the disinfectant. It will then be automatically switched off. Now the machine is filled with disinfectant.

Note especially that the disinfectant connector must remain in the disinfectant container/disinfectant port and not be moved to the parking port before the chemical disinfectant program is complete. This is due that the chemical disinfectant is pushed back to the disinfectant container to empty the connector/intake tube.

8. **When the machine is to be used again** and the *On/Off button* is pressed, the machine will start a rinse/disinfection program as soon as it is switched on. The *Rinse/Disinfection button* will be lit at this moment. The remaining time will be shown on the time display.

9. When the program is complete and the machine has been drained, the *Priming button* starts to flash.

10. If a new treatment is to be started, press the flashing *Priming button* to initiate a new function check instead of switching off the machine.

11. Switch off the machine by pressing the *On/Off button* for 3 seconds.

12. If `Formal 37%` program has been performed, the ultrafilter used in UFD must be changed prior to the following treatment. Alternatively perform additional rinse/drain procedures according to section “Residual Test after Chemical Disinfection", page 8:31.

The machine can be preset to automatically switch off after a complete chemical disinfection program, i.e. when the *Priming button* is flashing, by an authorized technician in the clinic.

CAUTION

After the Chemical disinfection procedure a test for residues must have been performed prior to connecting to a patient.

CAUTION

Note

- The pick-up tubes must be rinsed/disinfected separately. See "Pick-up Tubes” on page 8:41 for instructions.

Note

Residual Test after Chemical Disinfection

Before connecting to a patient, a residual test must be done on the prepared dialysis fluid. This is to make sure that the patient will not be exposed to chemical residuals after a chemical disinfection program.

The residual concentration in the dialysis fluid must be below levels specified by the clinic or by national standards. It is essential to use an appropriate test method, either with proven sensitivity for the chemical or recommended by the manufacturer of the chemical disinfectant.

CAUTION

After the Chemical disinfection procedure a test for residues must have been performed prior to connecting to a patient.

CAUTION

Note

- The pick-up tubes must be rinsed/disinfected separately. See "Pick-up Tubes" on page 8:41 for instructions.

Note

Procedure

1. Switch the machine on and let it pass function check with the proper concentrates attached.

2. When the green fluid path lights up, press the flashing *Fluid bypass button* in order to let fresh dialysis fluid flow through the dialysis fluid tubes.

3. Take the residual test sample from the flowing fluid on the dialysis fluid outlet tube (to dialyzer).

If the test shows disinfectant residues:

- DO NOT use connected BiCart cartridge.

- Press the *Rinse/Disinfection button* and start a new rinse/drain procedure (the button lights up). When this is finished, repeat the handling procedure described above.

If the machine still shows disinfectant residues, contact an authorized technician.

Central Chemical Disinfection - Performing

The AK 96 dialysis machine can be programmed to perform central chemical disinfection. This function, as well as the type of disinfectant, has to be preset (not default) by an authorized technician. In this mode, the machine receives disinfection solution through the central water supply system. The central disinfection program in AK 96 dialysis machine performs a continuous rinse through the fluid monitor until a preset time has passed or the operator has activated the rinse/drain function.

It is advisable to turn the AK 96 dialysis machine off if it is not supposed to be disinfected; this is to make sure that no disinfection solution will enter the machine when not desired.

Note

- The pick-up tubes must be rinsed/disinfected separately. See "Pick-up Tubes" on page 8:41 for instructions.

Note

Check before starting the procedure

- ☑ That the dialysis fluid tubes are connected to the safety couplings and that the latches of the BiCart holder are closed.
- ☑ That the concentrate connectors are placed in the corresponding stand-by ports of the machine (blue and red), and that the yellow disinfectant connector is placed in the parking port (marked P).

Procedure

Use the *Keypad* next to the Information Display to select options and to navigate within and between the menus. For details concerning the keys included in the *Key pad*, see "Keypad" in chapter 3. part 1

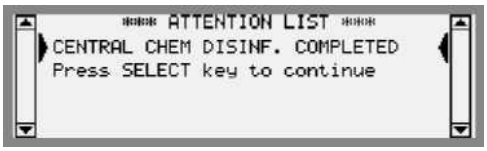
1. Press the *Rinse/Disinfection button* briefly.

2. The RINSE/DISINFECTION MENU will be displayed on the Information Display.

3. Select CHEMICAL.
4. Select the disinfectant that is set for CENTRAL administration.

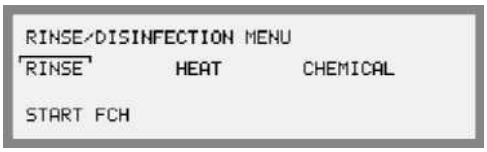
5. Start the program by pressing the *Select key* for 3 seconds, *Rinse/Disinfection button* lights up.

The machine now performs a continuous rinse through the flow path of the machine.



6. When the dwell time has passed, an attention is given to indicate that the Rinse/Drain sequence can be started.

Make sure that no more chemicals are left in the central water supply system:



7. Start the rinse/drain program by pressing the *Rinse/Disinfection button* and select `RINSE` (the button lights up).

8. When the rinse/drain program is complete and the machine has been drained, the *Priming button* starts to flash.

9. The machine can be preset to automatically switch off after a complete chemical disinfection program, i.e. when the *Priming button* is flashing, by an authorized technician.

CAUTION

After the Chemical disinfection procedure a test for residues must have been performed prior to connecting to a patient.

CAUTION

Hygiene - Rinse/Drain

Rinse/Drain - General

Rinse/Drain Program - Performing

Note

- The program can be interrupted at any time when the program is running; press and hold the *Select key* for 3 seconds. The machine will then interrupt the procedure and finish off with a drain sequence.
- The pick-up tubes must be rinsed/disinfected separately. See "Pick-up Tubes" on page 8:41 for instructions.

Note

Check before starting the procedure

- ☑ That the dialysis fluid tubes are connected to the safety couplings and that the latches of the BiCart holder are closed.
- ☑ That the concentrate connectors are placed in the corresponding stand-by ports of the machine (blue and red), and that the yellow disinfectant connector is placed in the parking port (marked P).

Procedure

Use the *Keypad* next to the Information Display to select options and to navigate within and between the menus. For details concerning the keys included in the *Key pad*, see "Keypad" in chapter 3. part 1

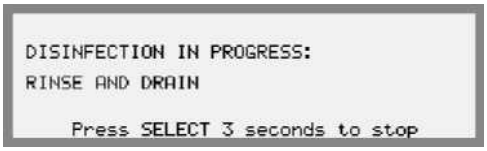
1. Press the *Rinse/Disinfection button* briefly.

2. The `RINSE/DISINFECTION MENU` will be displayed on the Information Display.

3. Select `RINSE`.

If only drain shall be performed: Select `CHANGE` and in the menu that appears select `DRAIN`.

4. Start the program by pressing the *Select key* for 3 seconds, *Rinse/Disinfection button* lights up.



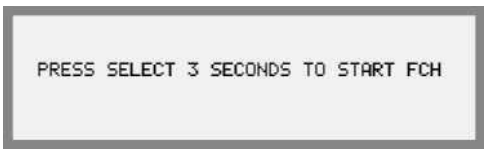
DISINFECTION IN PROGRESS: will be displayed and will remain throughout the program.

The *Rinse/Disinfection button* will continue to be lit throughout the program, indicating that the program is ongoing.

5. If an automatic switch off is required, press the *On/Off button* for 3 seconds.

When the program is complete, drain sequence included, the *Priming button* starts to flash (not if an automatic switch off has been done).

6. Switch the machine off by pressing the *On/Off button* for 3 seconds.



If a new treatment is to be started directly after the disinfection program, press the flashing *Priming button* briefly and PRESS SELECT 3 SECONDS TO START FCH will be displayed. Press the *Select key* for 3 seconds to start a new function check and simultaneously reset previous values to zero.

Rinse/Drain Program - Automatic Start

The machine is equipped with an automatic start function for the rinse/drain program. This is a feature that enables the machine to automatically start a rinse/drain program at a predetermined time. The operator decides (programmes) which day of the week and what time of the day the machine shall be finished, after having performed a rinse/drain program.

The machine can be programmed and the function activated, during any phase when the machine is switched on. Whenever this function is activated, and the machine has been switched off, the rinse/drain program will be started at the programmed time. See below for programming and activation instructions.

Note

- The pick-up tubes must be rinsed/disinfected separately. See "Pick-up Tubes" on page 8:41 for instructions.

Note

Check whenever activated

- ☑ That the dialysis fluid tubes are connected to the safety couplings and that the latches of the BiCart holder are closed.
- ☑ That the points in the list "Check Before Switching the Machine On" in chapter 4, part 1 on page 4:2 are fulfilled.
- ☑ That the concentrate connectors are placed in the corresponding stand-by ports of the machine (blue and red), and that the yellow disinfectant connector is placed in the parking port (marked P).

Programming and Activation Procedure

Use the *Keypad* next to the Information Display to select options and to navigate within and between the menus. For details concerning the keys included in the *Key pad*, see "Keypad" in chapter 3. part 1

1. Press the *Rinse/Disinfection button* briefly.

2. The `RINSE/DISINFECTION MENU` will be displayed on the Information Display.

3. Select `RINSE`.

4. Select `SET AUTO RINSE`.

5. Set the schedule for every weekday when a rinse should be completed. Press the *Select key* 3 seconds to activate. The *Rinse/Disinfection button* lights up.

Rinse/Drain Program - Automatic Switch Off

The machine can be preset to automatically switch off after a complete rinse/drain program, i.e. when the *Priming button* is flashing, by an authorized technician.

It can also be switched off during the rinse/drain program, by manually pressing the *On/Off button* while the program is running. This will make all of the operator panel lights go out, except for the *Rinse/Disinfection button* and the time display. When the program is complete, the machine automatically switches itself off.

Maintenance - The Flow Path

The Flow Path

The maintenance of the flow path with regard to cleaning and decalcification is important, in order to maintain the specified performance of the machine.

Cleaning

Fats, proteins and organic material originating from the patient may deposit down stream of the dialyzer. The number of treatments and the setting of parameters will influence the amount of deposits downstream of the dialyzer. A general guideline for the frequency of cleaning with CleanCart-C cartridge and sodium hypochlorite (alternatively CleanCart-A cartridge) is described in the introductory part of this chapter ("Schedule for Hygiene and Maintenance" on page 8:6). An increased level of cleaning may be necessary, depending on the conditions described above. It must be noted that a lower frequency may be sufficient to maintain the system.

Decalcification

Calcium-carbonate may deposit in the flow path. The requirements for decalcification vary depending on elements as water quality, type of concentrate and bicarbonate settings. A general guideline for the frequency of decalcification with CleanCart-C cartridge or liquid citric acid is described in the introductory part of this chapter ("Schedule for Hygiene and Maintenance" on page 8:6). An increased level of decalcification may be necessary, depending on the conditions described above. It must be noted that a lower frequency may be sufficient to maintain the system.

Note

- Incorrect cleaning of the UF cell may be a contributing factor for increased inaccuracy of the UF system. If any deviations in UF accuracy should occur, it is recommended to use sodium hypochlorite weekly.
- In order to enable the cleaning agents to remove fats, proteins etc. efficiently, cleaning should be carried out after decalcification.

Note

Ultrafilter - How to change

Note

- Make sure that the ultrafilter is changed in an aseptic way.

Note

Procedure

1. Release the lower part of the ultrafilter holder by pulling the handle and pressing the latch downwards.
2. Remove the ultrafilter by pulling it gently downwards.
3. Insert the new ultrafilter into the holder and push it gently upwards.
4. Close the holder by pushing the lower latch into position.
5. Confirm the change of ultrafilter (see Ultrafilter replacement reminder on page 8:39).
6. Label the ultrafilter with date for change.
7. Perform a Heat disinfection program before the AK 96 dialysis machine is used for treatment after the ultrafilter has been changed.

Ultrafilter replacement reminder

If UFD (Ultrafilter Dialysis Fluid) is installed the operator will be reminded to change ultrafilter. The operator will be notified by an attention alarm when a limit has been exceeded. There are three different limits: number of days since last change, number of heat disinfections since last change and number of hypochlorite disinfections since last change.

To confirm that the ultrafilter filter has been changed, select ULTRA FILTER in the RINSE/DISINFECTION MENU and press the *Select key*. Then press the *Select key* for 3 seconds to confirm. All three counters will now begin from zero again.

To change the limits call for a service technician.

Maintenance - the Exterior

The Exterior Surfaces

Wipe the exterior surfaces of the machine with a cloth moistened with ethanol (70 %) or isopropanol (60 %) in order to clean and disinfect it.

Note

- Do not use tenside-containing or iodine-based disinfectants. These solutions may crack or discolour most polymers.

Note

Top Tray

The top tray may be cleaned and disinfected with ethanol (70 %) or isopropanol (60 %).

CAUTION

In order to protect the internal parts of the AK 96 dialysis machine against spillage, the top tray must always be placed on top of the machine, except during technical service.

CAUTION

Pick-up Tubes

In order to dissolve salts and the remains of concentrates; rinse the outside and flush the inside of the pick-up tubes with water. This is to be done daily when they are being used. Let the pick-up tube dry naturally (do not wipe dry).
Disinfection of the pick-up tubes is recommended every to every other week. Wipe the outside with 70% ethanol. Flush the inside with 70% ethanol. Let the pick-up tube dry naturally (do not wipe dry).

Blood Pump

To remove the blood pump rotor; pull out the handle. Turn until the blood pump rotor loosens from the pump shaft. The blood pump rotor can be cleaned and disinfected in ethanol (70%) or isopropanol (60%). To attach the blood pump rotor; place it on the pump shaft. Move your fingers from the handle and place them on the rotor. Turn the rotor slowly and push slightly until it reaches the bottom position. Continue turning until the blood pump handle clicks in.

Blood Leak Detector

The blood leak detector should only be cleaned when a suspected false blood leak alarm has occurred and not as a preventive action. The risk of contaminating the blood leak detector and consequently the fluid path of the machine is large when opening it.

The AK 96 dialysis machine must be turned off before the blood leak detector is cleaned.
Unscrew the blood leak detector cover and clean the lenses with a soft non-fluffy cloth, moistened with disinfectant solution.

Note

- Make sure that the sealing ring on the inside of the cover is securely in place when replacing the cover.

Note

BPM Cuff

Cleaning instructions for the BPM cuff can be read in the "package insert" leaflet which is enclosed to the cuff upon delivery.

Chapter 9

Technical Data and Specifications

Contents

Performance and specification - Control System

Blood Flow Control

Values for the blood pump(s) are based on a pressure of -150 mmHg before the arterial blood pump with a pump segment of 7.9 mm and 2.0 mm wall thickness.

For 6.35 mm pump segment it is possible to set the blood flow to 15 ml/min.

For pediatric blood tubes with pump segment of 4.0 mm it is possible to set blood flow to 5, 10 or 15 ml/min. Accuracy is then ±5 ml/min.

Double Needle

Flow rate	0 and 20 to 500 ml/min (-150 mmHg pre pump pressure, 0 to 500 mmHg post pump pressure, pump segment diameter 7.9 mm)
Flow accuracy	±10 ml/min or ±10 %, whichever is largest
Accumulated blood volume	0 - 327 liters
Volume accuracy	±0.6 l * treatment time (h) or ±10 %

Single Needle

Single needle is only available if the optional arterial clamp is installed.

Arterial flow rate	0 and 20 to 500 ml/min (-150 mmHg pre pump pressure, 0 to 500 mmHg post pump pressure, pump segment diameter 7.9 mm)
Flow accuracy	±10 ml/min or ±10 %, whichever is largest
Pressure control	10 to 500 mmHg (±50 mmHg), venous pressure control
Accumulated blood volume	0 - 327 liters
Volume accuracy	±0.6 l * treatment time (h) or ±10 %

Heparin Pump

Automatically heparin administration is only available if the optional heparin pump is installed.

Heparin pump flow rate	0 - 10 ml/h (±1 ml/5h or ±5 %) The accuracy is based on tests with 20 ml and 30 ml syringes with diameter of 20 mm.
Heparin bolus flow rate	60 ml/h with 20 ml (diameter 20 mm) and 30 ml (diameter 22 mm) syringes.
Bolus volume	0 to 10ml (±0.2 ml or ±5% whichever is largest, with blood lines primed)
Size	Syringes shall comply with ISO 7886-2.
Stop time	The heparin pump stops before end of treatment 0.00 to 9.59 h
Counter pressure	Maximum 400 mmHg
Accumulated volume	0 - 999.9 ml

Blood pressure

Venous Pressure

Operating range	-700 to 750 mmHg
Alarm limits	10 to 500 mmHg in treatment mode -100 to 500 mmHg in priming mode
Accuracy	±10 % within range -700 to -500 mmHg. ±5 mmHg or ±3 %, whichever is largest within range -500 to 500 mmHg. ±10 % within range 500 to 750 mmHg.

At 300 ml/min dialysis fluid flow maximum venous pressure during treatment is approximately 250 mmHg.

Blood Pressure Monitor (BPM)

Blood pressure monitoring is only available if the optional BPM is installed.

The alarm limits below can be preset. The value put in brackets and in italics is the default value.

Systolic pressure range[1]	60 - 250 mmHg
Low alarm limit	60 - 250 mmHg *(100 mmHg)*
High alarm limit	60 - 250 mmHg *(150 mmHg)*
Diastolic pressure range[1]	40 - 200 mmHg
Low alarm limit	40 - 200 mmHg *(60 mmHg)*
High alarm limit	40 - 200 mmHg *(100 mmHg)*
Mean pressure range[1]	45 - 235 mmHg
Low alarm limit	45 - 235 mmHg *(75 mmHg)*
High alarm limit	45 - 235 mmHg *(115 mmHg)*
Pulse rate range	40 - 200 bpm (±3 bpm or ±2 % of reading)
Low alarm limit	40 - 200 bpm *(40 bpm)*
High alarm limit	40 - 200 bpm *(150 bpm)*

[1] Meets ANSI/AAMI SP-10 (1992). Mean error ±5 mmHg. Standard deviation 8 mmHg

Dialysis fluid preparation

Pressure regulators

After pressure regulator PR1 and the heat exchangers	80 kPa (0.8 ±0.1 bar)
After pressure regulator PR2	130 ±10 mmHg

Temperature

Temperature	Adjustable 33 to 40 °C. Accuracy is valid only if dialysis fluid temperature is greater or equal to ambient temperature.
Alarm limits	Adjustable 33 to 40 °C
Accuracy	+0.5/-1.5 °C (+1.0/-2.5 °C with UFD) at the dialysis fluid outlet from the machine.
Heater capacity	1300 W (+10 % / -5 %) at 115 V 3 X 580 W (+10 % / -5 %) at 230 V
Overheat protection	Reg-temp 80 °C or CondA-temp 70 °C in treatment, software Reg-temp 99 °C in disinfection, software The heater can only be on if there is a flow through the heater. The flow is detected by a flow switch.

Flow rate

Dialysis Fluid Flow Rate	300 to 700 ml/min in steps of 20 ml/min
Accuracy	±10 % or 50 ml/min whichever is largest

Degassing

By use of negative pressure, -610 mmHg.
Adjustable degassing pressure between -300 and -700 mmHg (-650 mmHg with 700 ml/min flow rate).

Accuracy	±40 mmHg

Dialysis fluid pressure

Dialysis fluid pressure	-400 to +300 mmHg
Accuracy	±10 mmHg or ±5 %

Proportioning of concentrates

The proportioning of concentrate is done through conductivity control. The concentrates are pumped into the system with one/two volumetrically supervised pumps. No minimum feeding pressure is necessary, the fluid is sucked in. Maximum feeding pressure, 150 kPa.

Acetate	Na^+, 130 to 160 mmol/l, (±3 mmol/l)
Bicarbonate	Na^+, 130 to 160 mmol/l, (±6 mmol/l) HCO_3^-, 20 to 40 mmol/l, (±6 mmol/l)
Measuring range	13 to 16 mS/cm
Accuracy	0.2 mS/cm
Alarm limits	±5 % of the calculated conductivity set value

Ultrafiltration control

Note

- Besides the ultrafiltration, patient weight change during treatment is also affected by other factors. These include factors such as fluid intake, food intake, perspiration, drug administration, infusion priming and rinse-back volumes amongst others. In addition, precise pre- and post-treatment weight is critical for adequate assessment of the ultrafiltration during the treatment. If these measurements are not accurate a discrepancy between the ultrafiltration achieved during the treatment and the changes in body weight will occur.

Note

Volume control	Direct electromagnetic measurement of dialysis fluid flow, before and after the dialyzer.
UF volume	Adjustable 0 to 10.00 l
Accuracy of measured volume	± 50 ml or ± 50 ml * passed treatment time (h) or ± 2.5 % whichever is greater.
UF coefficient	Maximum 85 ml/h/mmHg
UF-rate	0.0 to 4.0 l/h, given by the set values of UF volume and treatment time.
Time	Remaining treatment time control. 0.05 to 9.59 hour. minute (±1 minute)

Profiling

UF-rate	0.0 to 4.0 l/h
Na^+, Acetate/Bicarbonate mode	130 to 160 mmol/l
HCO_3^-, Bicarbonate mode	20 to 40 mmol/l

Diascan®

Clearance measurement is only available if the optional Diascan is installed. During UF STEP and INTERVAL profiling, Diascan system is not available. The specification is based on in vitro measurements with saline.

Clearance K typical precision	± 8% (± 1SD). Precision has been validated in HD double needle, for blood flows 200 to 400 ml/min and fluid flows 500 to 700 ml/min.
Cumulated water volume cleared of Kt	0 to 100 l (± 6% (± 1SD, based on 7 measurements)
Dialysis dose Kt/V	0 to 3
Measurement interval	15, 30 or 60 minutes

Note

- Total time for disinfection programs is estimated and may vary.

Note

Peracetic Acid Program (presetable)

Concentration of disinfectant	3.5 % peracetic acid
Concentration in machine	0.1 %; i.e. diluted 1 + 34 (1:35)
Volume	Approx. 87 ml (with UFD approx. 112 ml)
Contact time between treatments	10 minutes
Contact time overnight or when not in use (recommended with UFD)	Minimum 3h dwell time
Total time	30 minutes (230V and 115V) 59 minutes (230V) with UFD 65 minutes (115V) with UFD Time includes 10 min contact time

Hypochlorite Program (presetable)

Concentration of disinfectant	10 % available chlorine
Concentration in machine	0.5 %; i.e. diluted 1 + 19 (1:20)
Volume	Approx. 145 ml (with UFD approx. 153 ml)
Contact time between treatments	10 minutes
Contact time overnight or when not in use	Maximum 20 min, not intended for overnight disinfection!
Total time	30 minutes (with UFD 50 minutes) Time includes 10 min contact time

Formaldehyde Program (presetable)

Concentration of disinfectant	37 % formaldehyde
Concentration in machine	3.7 %; i.e. diluted 1 + 9 (1:10)
Volume	Approx. 275 ml (with UFD approx. 290 ml)
Contact time between treatments	20 minutes
Contact time overnight or when not in use (recommended with UFD)	Minimum 6h dwell time
Total time	119 minutes (230V and 115V) 150 minutes (230V) with UFD 165 minutes (115V) with UFD Time includes 20 min contact time

Disinfection and Cleaning - Heat Disinfection

Temperature: +93 °C (measured after heating rod)
≥80 °C (measured in the outlet before the heat exchanger)

Note

- The temperatures are verified at nominal values for the mains voltage and at 20 °C ambient temperature.
- Total time for disinfection programs is estimated and may vary.

Note

One of three alternatives for heat disinfection can be selected. The second alternative is presetable for a combined heating program and the third is a CleanCart / heating alternative.

The default settings are as follows:

Heat disinfection

AK 96	Disinfection programs	Total Time (min)	
		230 V	115 V
With UFD	Heat	36	40
	Heat Citric acid 20 %	52	57
	Heat CleanCart	50	55
Without UFD	Heat	33	37
	Heat Citric acid 20 %	49	54
	Heat CleanCart	46	51

Auto heat disinfection

Auto heat can be used with or without CleanCart. If the auto heat shall be performed with CleanCart must the cartridge be installed before the auto heat starts.

AK 96	Disinfection programs	Total Time (min)	
		230 V	115 V
With UFD	Heat	31	35
	Heat CleanCart	43	49
Without UFD	Heat	31	35
	Heat CleanCart	43	48

Heat disinfection program including WRO 300 H

	UFD not installed	UFD installed (option)
Temperature	93 °C	93 °C
Fill up phase	10	13
Circulation phase	15	15
Low flow heat phase	20	20
Drain phase	4	4
Total time	49	52

Note

- Drain phase follows after low heat phase. WRO 300 H will start heat disinfection simultaneously (if preset, see WRO 300 H Service Manual).

Note

Disinfection and Cleaning - Rinse/Drain

Note

- Total time for disinfection programs is estimated and may vary.

Note

Rinse/Drain	10 min.
Drain	4 min.

Disinfection and Cleaning - Exterior Cleaning

All outside parts of the machine can be cleaned with ethanol (70 %) or isopropanol (60 %).

Water supply

Flow rate	During treatment: maximum 770 ml/min During disinfection and rinse/drain: a maximum flow rate of 800 ml/min is required.
Minimum inlet pressure	0.12 MPa (1.2 bar)
Maximum inlet pressure	0.6 MPa (6 bar)
Inlet temperature	Treatment: +5 to +30 ºC Disinfection: +5 to +90 ºC
Connector in/outlet	Diameter 8 mm
Quality	Inlet water quality must comply with appropriate regulations and as a minimum requirement according to ISO 13959. Level for conductivity shall not exceed 0.1 mS/cm. It is possible to use water with higher conductivity if it consists mainly of sodium salts. This may however affect the accuracy of the fluid composition. **Note!** Local regulations may require the use of separation devices in the supply and special measures to protect against the possibility of back-syphonage from dialysis equipment into the water supply.
Drain	The drain tube outlet must be placed between floor level and maximum 1.2 m above the outlet connection from the fluid monitor. An air gap to atmospheric pressure must always be arranged at the tube outlet.
Length of drain tube	<=10 m
High pressure guard transducer	±500 mmHg, (±10 mmHg or ±5 %, whichever is largest)
Inlet pressure switch (INPS)	Increasing: +150 mmHg, ±20 mmHg Decreasing: +99 mmHg, ±20 mmHg
Safety guard switch (SAGS)	Increasing: -59 mmHg, ±7 mmHg Decreasing: -74 mmHg, ±7 mmHg

Power supply

Mains voltage	115 V (at 50 Hz or 60 Hz) or 230 V (at 50 Hz or 60 Hz) (~AC), (±12 %). The voltage has to be specified before installation. **Note!** The user must verify the quality of the protective earth in the installation.
Protection class	Machine: Class 1 type B BPM: Type BF
Power consumption	Max. 2025 W at 230 V Max. 1575 W at 115 V
Cable	3 conductor cable, Length max. 3.5 m Ratings: 230 - 250 V AC 13 -16A or 110 - 125 V AC 15 A
External fuses	For 115/230 V, 2 x 12AT for heater.
Mains plug	Earthed plug, 250 V AC / 10 -16 A, approved or Hospital grade, earthed plug, 125 V AC / 15 A, approved.
Earth leakage current	max 500 µA
Patient leakage current	max 100 µA AC max 10 µA DC

All leakage currents specified are without external equipment connected to the AK 96.

Connection of external equipment

External connector	25 pin D-Sub with RS-232C or RS-422/Current loop. Opto insulated fulfilling IEC 60601-1-1.

External equipment

Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g. IEC 60950 for data processing equipment).
Furthermore all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16 of the 3Ed. of IEC 60601-1, respectively).
Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local representative or the technical service department.

Extern alarm

Max voltage	24 V AC or DC
Max current	100 mA AC or DC

RS-232C

Max input voltage	± 15 V DC
High level min output voltage	5.0 V DC
Low level max output voltage	- 5.0 V DC
Max output current	± 5 mA DC

RS-422/Current loop

Typ current	20 mA DC
Max current	50 mA DC

Battery Back-up

Battery back-up of power supply	24 V, 7.0 Ah
Battery type	Sealed Lead Acid, 2 x 12 V
Running time	>30 minutes
Fuse	12 AT

Performance and specification - Supervisory system

Blood Pressure Supervision

Venous pressure

Operating range	-700 to +750 mmHg
Alarm limits, in treatment mode	10 to 500 mmHg
Alarm limits, in priming mode	-100 to 500 mmHg
Accuracy	±10 % within range -700 to -500 mmHg ±5 mmHg or ±3 %, whichever is largest within range -500 to 500 mmHg ±10 % within range 500 to 750 mmHg

Arterial pressure

Operating range	-700 to +750 mmHg
Alarm limits	-700 to +750 mmHg
Accuracy	±10 % within range -700 to -500 mmHg ±5 mmHg or ±3 %, whichever is largest within range -500 to 500 mmHg ±10 % within range 500 to 750 mmHg

Extracorporeal blood loss to the environment

Detection method	Venous pressure supervision

Air Detection

Detection method	Ultrasonic detector placed at the venous drip chamber. The detector has a two channel structure and the function of the detector is tested at the function test made by the microcomputers.
Drip chamber size	Diameter 22 mm
Sensitivity	Bubbles larger than 1 µl will be trapped by the drip chamber. An alarm will be issued if the blood level falls below the middle of the air detector.

Extracorporeal blood loss due to coagulation

Detection method	Supervision of the stop time of the blood pump
Alarm	The attention "`BLOOD PUMP STOP TIME EXPIRED, Start blood pump`"

Dialysis fluid preparation

Temperature

Temperature alarm (fixed)	40 °C (±0.5 °C)
Overheat protection	The heater can only be on if there is a flow through the heater. The flow is detected by a flow switch.

Conductivity

Alarm limits	±5 % of the calculated conductivity set value
Accuracy	0.2 mS/cm

Ultrafiltration Supervision

TMP	TMP is defined as the difference, $P_{b\ out}$ - $P_{d\ out}$, where $P_{b\ out}$ is the venous pressure and $P_{d\ out}$ is the pressure measured in the dialysis fluid, where it enters the machine after the dialyzer.
Alarm limits	-100 to 500 mmHg
Accuracy	±10 mmHg or ±5 %, whichever is largest (within range ±500 mmHg)

Blood leakage detection

Detection method	Infrared light detector.
Sensitivity	Alarm will be given for ≥0.3 ml blood, hematocrit 32 %, per minute at 300-700 ml/min dialysis fluid flow. Time delay for alarm, maximum 5 seconds (diffusion mode).

pH supervision

pH supervision is only available if the optional pH is installed.

pH measurement of	1 to 9.9 pH units
Dialysis Fluid	±0.2 pH units for pH 5 to 9 ±0.5 pH units for pH < 5 or pH > 9
Alarm limits	5.0 to 9.0 pH

Physical data

Dimensions and weight

Width; machine	Approx. 345 mm
Width; stand	Approx. 585 mm
Depth; machine	Approx. 600 mm
Depth; stand	Approx. 620 mm
Height	Approx. 1305 mm (without infusion stand).
Weight	Approx. 60 kg (without options)

Infusion stand

Maximum total load	2 kg

Materials in contact with dialysis fluid, concentrates and water

Polymers

Silicon rubber
PVC (Polyvinylchloride)
PEEK (Polyetherketone)
PEX (Polyethylene)
PP (Polypropylene)
PSU (Polysulphone)
PVDF (Polyvinylidene fluoride)
PTFE (Polytetrafluoro ethylene)

Metals

Stainless steel SS2343
Stainless steel SS2353
Stainless steel SS2562
Titanium
Platinum

Others

Carbon
Ceramic, Steatite 221
Ceramic, Aluminum oxide (Al_2O_3)
Glass

Environmental data

Operation

If condensation occur when moving the equipment between locations with different temperatures and high relative humidity (e.g. outdoor and indoor locations), the inside of the equipment shall be allowed to dry before switching on the equipment.

Ambient Temperature range	+18 to +35 °C
Relative Humidity range	15 to 85 % RH
Air Pressure range (atm. pressure)	700 to 1060 hPa

Transportation and storage

During transportation and storage the equipment has to be kept in its original packing. If transportation or storage time is more than 15 weeks, the environmental data relating to the operation has to be followed. The maximum ambient temperature for transportation and storage in 96 % Relative humidity is +40 °C.

Ambient Temperature range	-20 to +70 °C
Relative Humidity range	10 to 96 % RH
Air Pressure range (atm. pressure)	500 to 1060 hPa

Electromagnetic environment

The AK 96 is intended for use in the electromagnetic environment specified below. The customer or the user of the AK 96 should assure that it is used in such an environment.

Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The AK 96 dialysis machine 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 emissions CISPR 11	Class B	The AK 96 dialysis machine 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 (Not applicable for 115 V version)	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Complies (Not applicable for 115 V version)	

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic enviroment-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 lines	±2 kV for power lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV for differential mode ±2kV for common mode	±1kV for differential mode ±2kV for common mode	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 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the AK 96 dialysis machine requires continued operation during power mains interruptions, it is recommended that the AK 96 dialysis machine be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note

- U_T is the a.c. mains voltage prior to application of the test level.

Note

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic enviroment-guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the AK 96 dialysis machine, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
Radiated RF mobile phones	-	30V/m	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 meters (m).
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[2], should be less than the compliance level in each frequency range[3].
			Interference may occur in the vicinity of equipment marked with the following symbol: 

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.

Note

[2] 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 assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AK 96 dialysis machine is used exceeds the applicable RF compliance level above, the AK 96 dialysis machine should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the AK 96 dialysis machine.

[3] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the AK 96 dialysis machine

The AK 96 dialysis machine is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AK 96 dialysis machine can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AK 96 dialysis machine as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter (m)**		
	150kHz - 80MHz $d = \left[\frac{3,5}{3}\right]\sqrt{P}$	**80MHz - 800MHz** $d = \left[\frac{3,5}{3}\right]\sqrt{P}$	**800MHz - 2500MHz** $d = \left[\frac{7}{3}\right]\sqrt{P}$
0,01	0.11	0.11	0.23
0,1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23
Rated maximum output power of mobile phone	-	-	$d = \left[\frac{7}{30}\right]\sqrt{P}$
2W GSM/3G	-	-	0.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (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, objects and people.

Note

Standards

The machine complies with the following standards:

IEC 60601-1 General requirements for safety, Class I, type B

IEC 60601-2-16 Particular requirements for safety of haemodialysis, haemodiafiltration and haemofiltration equipment

IEC 60601-1-1 Safety requirements for medical electrical systems

IEC 60601-1-2 Electromagnetic compatibility, class B

IEC 60601-2-30 Particular requirements for the safety of automatic cycling indirect blood pressure monitoring equipment

EN 1060-1 Non-invasive sphygmomanometers Part 1: General requirements

EN 1060-3 Non-invasive sphygmomanometers Part 3: Supplementary requirements for electromechanical blood pressure measuring systems

References

Assembly Drawings K29000, K29001

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Chapter 10

Major Changes in Operator's Manual

Contents

Major Changes between Program Version 2.xx and 3.xx

Complete Manual

The paper version of the Operator's manual for the AK 96 dialysis machine has been divided up into three parts according to their contents and placed in a box. The first part is in A4 format, the second and third in A5. The parts should be considered as one document in spite of the fact that they are printed in three separate parts, meaning that the ordering procedure and so forth of the manual will be the same as before. Due to the partition the chapter numbers have been changed. For instructions on how the manual is intended to be used, see "How To Use this Manual",page 1:2 in part 1.

A preface has been included where Intellectual Property Rights can be found.

Chapter 2, part 1

The dialysis fluid flow rate is a preset parameter value which now cannot be adjusted by the operator during priming, yet, it is still possible to adjust it during treatment. See "Fluid Path button", page 3:15 in part 1.

Chapter 4, part 1

A heparin solution bolus volume can now be administrated using the heparin pump (previously called the syringe pump). For information of heparin pump setting possibilities, see in "Blood Part Component Details", page 2:5 point 8, in part 1.

It is now possible to extend the priming procedure (recirculation priming procedure) if requested. Comprehensive priming information can be read in "Priming", page 4:38 in part 1. Handling instructions on the different priming procedures are included on the following pages.

It is now possible to choose to confirm treatment end in two ways; by pressing either the *Select key* or the *Time button*. See "Discontinuing", page 4:59 in part 1 for information.

Chapter 13, Alarm Handbook

A new alarm has been implemented;

It appears when the CONNECT PATIENT procedure has been started, the connect patient volume is achieved and no blood has been detected in the venous blood line. See in “Alarms” for information.

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AK 96® Dialysis Machine Operator's Manual Program version 3.xx

Note

- Please observe that this part of the Operator's manual for the AK 96 dialysis machine is one out of three. To assimilate these instructions the complete manual must be available. For information see “How To Use this Manual” on page 1:2 in part 1.

Note

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Chapter 11

BPM – Blood Pressure Monitor (option)

Contents

General

The Blood Pressure Monitor (BPM) measures blood pressure and pulse rate. It is possible to use the BPM at any time whenever the machine is in its on position i.e. when the *On/Off button* is lit.

It is possible to use the BPM in three different ways.

Single measuring means that the blood pressure measurement checks will be performed one at a time. See "Single Measuring", page 11:7 for instructions.

Automatic - Interval Measuring means that the blood pressure measurement checks will be performed at set time intervals. These can be set between 5–60 minutes. See "Automatic - Interval Measuring", page 11:9 for instructions.

Automatic - Continuous Measuring means that the blood pressure measurement checks will be continuously performed during a time period of five minutes. See "Automatic - Continuous Measuring", page 11:13 for instructions.

The BPM cuff and cuff hose are protected against the discharge from a defibrillator (NIBP type BF applied part, defibrillator proof).

CAUTION

- Do not touch the BPM cuff or cuff hose when a defibrillator is being discharged, as doing so may cause electric shock.
- In the event of accidental wetting of the BPM cuff or cuff hose connections, wipe immediately to prevent moisture from entering the machine.
- No protective means for burn of the patient are provided when the BPM is used together with high frequency (HF) surgical equipment.

CAUTION

In addition to the BPM included in the machine, a blood pressure measurement cuff and a cuff hose are necessary.

The line from the cuff (cuff hose) is attached to the side of the AK 96 dialysis machine, see "Blood Part Component Details", page 2:5 in part 1, look for "BPM Connector" in the list. The cuff is available in different sizes, see “Blood Pressure Measurement Accessories", page 1:21 in part 1. The cuff and the cuff hose can be ordered from your Gambro representative.

It is important to use proper cuff size for accurate measurements. Use the circumference of the patient’s arm to determine cuff size. If the bladder is too wide, the blood pressure reading will be erroneously low; if it is too narrow, the reading will be erroneously high. Apply the cuff snugly so that one finger can fit between the cuff and the patient’s arm.

More information about how to choose the right cuff size, how to connect the cuff to the cuff hose and the cuff

hose to the machine can be read in the “package insert” leaflet which is enclosed with the cuff and cuff hose. The “package insert” leaflet also contains information about how to properly put the cuff on the patient's arm.

Patient factors which affect readings

Excess patient movement can interfere with readings. Ensure that the patient is not moving during readings, just as one would with manual readings.

Avoid applying external pressure to the cuff during readings.

Some arrhythmias may cause pressure fluctuations that make obtaining readings more difficult. If difficulty obtaining readings occurs in the presence of arrhythmia, blood pressure should periodically be verified by another method.

- Do not apply a blood pressure cuff to a limb with an access, e.g. fistula or graft.
- Do not apply a blood pressure cuff to a limb being monitored with a pulse oximetry sensor.
- Do not apply a cuff to a limb that has restricted blood flow.
- Avoid applying a cuff to a limb that has an intravenous line in place.

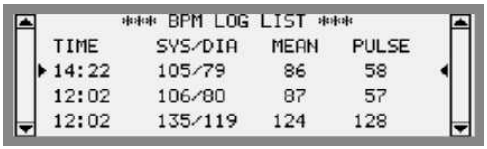
CAUTION

- Check that the blood circulation in the arm is not affected due to blood pressure measurement checks.
- The Blood Pressure Monitor must be used only for adult patients or for children with a pediatric cuff and not for infant or neonatal patients.
- The manufacturer advises the user that the information originating from the Blood Pressure Monitor cannot be used alone as unique source of information to induce any therapeutic or pharmacological actions.

CAUTION

BPM Log List

To read the BPM measuring results, first open the BPM menu using the *BPM button*. Then select LOG using the *Keypad* and a list of measurement results will be shown on the Information Display.



The *** BPM LOG LIST *** starts with the latest measurement at the top and has room for 20 measurement results. If there is need for more than 20 measurements during a treatment, the second result will be deleted, then the third and so on. The first result will be saved regardless of how many measurements are made.

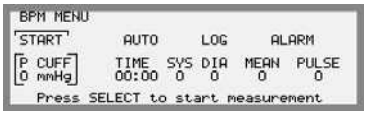
The values are shown as below:
TIME shows current time for when the blood pressure measurement check was completed.
SYS/DIA shows systolic/diastolic blood pressure.
MEAN shows mean blood pressure.
The value below PULSE shows pulse rate.

Single Measuring

The pressure in the blood pressure measurement cuff will be maximum 180 mmHg the first time the blood pressure is being measured when a blood pressure measurement check is carried out. If there are difficulties obtaining the correct values there will be two remeasurement checks with higher cuff pressure. If the measurement checks still fail there will be an attention alarm to guide the operator to take correct actions. If the measurement check was successfully performed, the cuff pressure will be maximum 30 mmHg above the latest measured systolic blood pressure for following measurement checks.

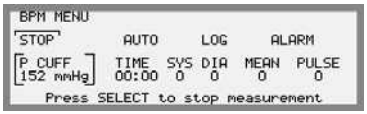
Procedure

1. Press the *BPM button*.



The BPM MENU will be shown on the Information Display.

2. When START has been selected, press the *Select key* to start the measurement check.



The BPM MENU will remain on the Information Display during the ongoing measurement check. The current pressure in the blood pressure measurement cuff is displayed in P CUFF.

If the measuring process needs to be interrupted, press the *Select key* to stop the procedure.

If desired, go back to the former menu using the *Back key*. BPM will be flashing at the activity field of the Treatment Overview Menu during the ongoing measurement check.

If desired, it is possible to preset an attention alarm that will advise the operator to check the result values in the *** BPM LOG LIST *** every time a measurement has been performed. This attention is optional and must be preset by a service technician. The list starts with the latest measurement at the top. See "BPM Log List", page 11:6.

The latest measurement result values will also be displayed on the BPM MENU.
TIME shows current time for when the blood pressure measurement check was completed.
SYS/DIA shows systolic/diastolic blood pressure.
MEAN shows mean blood pressure.
The value beside PULSE shows pulse rate.

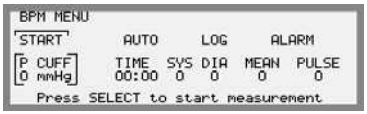
To read previous measuring results; select LOG using the *Keypad* to open the *** BPM LOG LIST ***. See "BPM Log List", page 11:6.

Automatic - Interval Measuring

The pressure in the blood pressure measurement cuff will be maximum 180 mmHg the first time the blood pressure is being measured when a blood pressure measurement check is carried out. If there are difficulties obtaining the correct values there will be two remeasurement checks with higher cuff pressure. If the measurement checks still fail there will be an attention alarm to guide the operator to take correct actions. If the measurement check was successfully performed, the cuff pressure will be maximum 30 mmHg above the latest measured systolic blood pressure for following measurement checks.

Procedure

1. Press the *BPM button*.

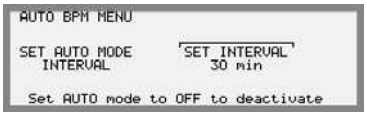


The BPM MENU will be shown on the Information Display.

2. Select AUTO using the *Keypad*.

The AUTO BPM MENU will be shown on the Information Display.

3. Select INTERVAL below SET AUTO MODE using the *Keypad* to activate automatic measuring.

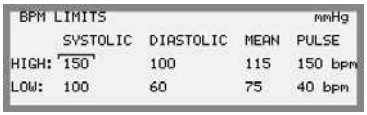


4. Check that the desired time intervals between the measurement checks, displayed below SET INTERVAL, correspond with the displayed ones, or change the time intervals using the *Keypad*. The time intervals can be set between 5–60 minutes.

5. If desired, set high and low alarm limits for systolic, diastolic and mean blood pressure as well as pulse rate by first pressing the *Back key* to go back to the BPM MENU. In this menu select ALARM using the *Keypad* to reach the BPM ALARM MENU.

5.a. First check or set ALARM to ON using the *Keypad*.

5.b. Then select SET LIMITS and the menu will change.



5.c. Set the proper alarm limits suitable for the patient using the *Keypad*. For further information, see "Blood Pressure Alarms", starting on page 13:26 in part 1.
Step back to the AUTO BPM MENU using the *Back key*.

The first measurement check in the sequence will be performed when the time for the first interval has ended, e.g. if the interval is set to 20 minutes the first check will be 20 minutes after activation. The current pressure in the blood pressure measurement cuff is displayed in P CUFF on the BPM MENU.

If the measuring process needs to be interrupted, when the BPM MENU is open, press the *Select key* to stop the procedure.

AUTO BPM will be shown at the activity field of the Treatment Overview Menu when automatic BPM measuring has been activated. During the ongoing blood pressure measurement check, this will be replaced by a flashing BPM label.

Note especially that it is possible to start a single measurement check at any time between the automatic measurement checks if necessary. When the Treatment Overview Menu is displayed; press the *BPM button* and

directly after the *Select key* to start (check that START/STOP has been selected).

The latest measurement result values will be displayed on the BPM MENU.
TIME shows current time for when the blood pressure measurement check was completed.
SYS/DIA shows systolic/diastolic blood pressure.
MEAN shows mean blood pressure.
The value beside PULSE shows pulse rate.

To read previous measuring results; select LOG using the *Keypad* to open the *** BPM LOG LIST ***. See "BPM Log List", page 11:6.

Note

- After treatment, when the cuff is removed from the patient, the blood pressure measurement will continue as set when automatic blood pressure measuring has been activated. Press the *Select key* for 3 seconds to deactivate the automatic measuring.

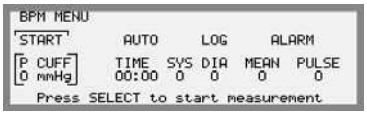
Note

Automatic - Continuous Measuring

The pressure in the blood pressure measurement cuff will be maximum 180 mmHg the first time the blood pressure is being measured when a blood pressure measurement check is carried out. If there are difficulties obtaining the correct values there will be two remeasurement checks with higher cuff pressure. If the measurement checks still fail there will be an attention alarm to guide the operator to take correct actions. If the measurement check was successfully performed, the cuff pressure will be maximum 30 mmHg above the latest measured systolic blood pressure for following measurement checks.

Procedure

1. Press the *BPM button*.



The BPM MENU will be shown on the Information Display.

2. Select AUTO using the *Keypad*.

The AUTO BPM MENU will be shown on the Information Display.

3. Select CONTINUOUS below SET AUTO MODE using the *Keypad* and press *Select key* to continue.

If desired, it is possible to set high and low alarm limits for systolic, diastolic and mean blood pressure as well as pulse rate in a similar way as when performing automatic measuring with set time intervals. See "Automatic - Interval Measuring" in the previous instructions, point 5. Note especially that alarms will **not** appear during the 5 minute period with continuous measurement checks. If alarms are generated, they will not appear until the 5-minute period has ended.

4. Press the *Select key* to activate continuous measuring for 5 minutes.

Blood pressure measurement checks will now be performed continuously for five minutes. The current pressure in the blood pressure measurement cuff is displayed in P CUFF on the BPM MENU.

BPM will be flashing at the activity field of the Treatment Overview Menu during the 5 minute period when the blood pressure measurement checks are being performed.

If the measuring process needs to be interrupted, when the BPM MENU is open, press the *Select key* to stop the procedure.

The latest measurement result values will be displayed on the BPM MENU.
TIME shows current time for when the blood pressure measurement check was completed.
SYS/DIA shows systolic/diastolic blood pressure.
MEAN shows mean blood pressure.
The value beside PULSE shows pulse rate.

To read previous measuring results; select LOG using the *Keypad* to open the *** BPM LOG LIST ***. See "BPM Log List", page 11:6.

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Chapter 12

Diascan® (option)

Contents

General

Application

The Diascan function can be used for:

- **Clearance measurement (K)** in order to read off the current dialysis efficiency for the ongoing treatment.
- **Dialysis dose measurement (Kt or Kt/V)** in order to check that the prescribed dialysis dose is being maintained, which provides quality assurance for the treatments.
- **Kt/V target supervision**, which means that the machine constantly calculates if the desired and minimum values for Kt/V, set by the operator for each individual patient, can be reached at treatment end. If not, the operator will be immediately notified during treatment.

The measurement checks can be performed one at a time when required, or continuously at set intervals during treatment.

If Kt/V measurement is required, distribution volume (VOLUME) has to be set before the measurement check takes place. The distribution volume is patient-related (based on the patient's dry weight) and has to be properly estimated and set by the machine operator in order to obtain a correct Kt/V value.

How the measuring process is performed by the machine

It is possible to measure clearance during treatment by using a conductivity sensor placed after the dialyzer in the fluid path.

A measurement check is performed in two phases.

During the first measurement phase (baseline phase) data from the sensor is collected for some minutes.

The second phase (step phase) begins with an increase or a decrease in the conductivity level. This is followed by data collection for some minutes. If there will be an increase or a decrease is dependent on the relation of the conductivity levels in the dialysis fluid before and after the dialyzer in the first phase. This is to ensure that the patient's sodium balance remains as neutral as possible.

When the second phase is complete the conductivity level is returned to the set value and the clearance calculation is performed. The calculation is based on the measured difference between the conductivity levels in the first and second phases.

Glossary of Diascan® parameters and key terms

Parameters:

K is clearance. Clearance tells the operator how much blood, in ml/min, is cleaned of urea after it has passed the dialyzer. This value can be compared with the current blood flow rate at that time.

Kt is clearance multiplied by elapsed treatment time. This value (in litres) can be compared with the accumulated blood volume (in litres) achieved since treatment start.

Kt/V is a calculation done by the machine depending on the set distribution volume entered by the operator of the machine.

Qb is blood flow rate in ml/min.

Key terms:

Diascan is the commercial name for a clearance sensor.

Distribution volume is the urea distribution volume in litres (water in the body), estimated for the individual patient, based on the patient's dry weight. The estimation is based on certain formulae used for this purpose, chosen by the prescribing physician responsible for the patient. The distribution volume has to be set by the machine operator in order for a correct Kt/V value to be obtained.

Forecast in this context is a machine-calculated prediction of the Kt or Kt/V value to be achieved at treatment end.

Target in this context is the desired Kt/V value set by the operator that is to be achieved at treatment end.

Precautions before use

CAUTION

Medical decisions must not only be based on information from The Diascan function, as there are many other factors which should be taken into account.

CAUTION

The Diascan function can be used in HD mode, double needle treatment. It can be used when performing single needle treatment but, the accuracy of machine measurement may be compromised. The same is valid for profiling of sodium and bicarbonate, whereas the measurement accuracy is not affected when using linear profiling of ultrafiltration rate. If profiling is active, the profiling values (conductivity and/or UF rate) will be frozen during the Diascan step.

The Diascan function cannot be used in combination with Isolated UF or in combination with UF profiling in steps or intervals. In any of these cases the machine will generate an attention alarm telling the operator that the Diascan function is not available.

During an ongoing Diascan measurement check, certain operator's actions will interrupt the measuring process and the machine will automatically reschedule measuring as soon as possible.

However, if two Diascan measurement checks in a row have been interrupted by the following actions, an attention alarm is generated. The operator is requested to confirm that the measurement check has been interrupted by pressing the *Select key*, and the machine will automatically reschedule measuring as soon as possible.

Actions that will interrupt the measurement check are:
- the blood flow rate is changed
- the *Blood Pump button* is pressed
- the *UF Start/Stop button* is pressed
- the *Fluid Bypass button* is pressed
- a treatment alarm which produces dialysis fluid bypass or blood pump stop is generated.
- sodium and bicarbonate (conductivity) of the dialysis fluid is changed
- temperature of the dialysis fluid is changed
- dialysis fluid flow rate is changed
- UF volume is changed
- linear UF profiling settings is changed
- linear UF profiling activation/deactivation is made
- sodium or bicarbonate profiling activation/deactivation is made
- isolated UF activation is made

In any of these cases the measurement check is interrupted. The attention alarm is to be confirmed by pressing the *Select key* and the machine will automatically reschedule measuring as soon as possible.

Note

- The blood flow rate and the dialysis fluid flow rate have to be set within certain ranges in order for correct Diascan measuring results to be obtained. See chapter 9 "Technical Data and Specifications" in part 1 for further details.

Note

Menus

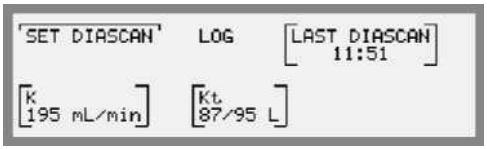
The Diascan function have 2 menus displayed on the Information Display; the Viewing Menu and the Setting Menu.

Diascan measurement result values are to be read in the viewing menu, which is displayed by first pressing the *Fluid Path button* and then selecting `DIASCAN` using the *Keypad*. In this menu, select `SET DIASCAN` to open the setting menu.

The Viewing Menu

When Diascan measurements have been performed, the measurement result values for K and accumulated Kt are displayed in this menu. A Kt forecast value is also displayed. If Kt/V measurement is desired, and a distribution volume has been set, the accumulated Kt and the Kt forecast value will be replaced by Kt/V values. Furthermore, if a Kt/V target value has been set, an estimation of the time needed to reach the target is also displayed in this menu. It is also possible to view the 20 last measurement results from this menu.

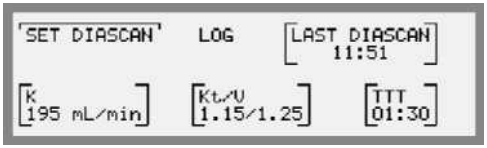
Measurement result values without Kt/V measurement



- `LAST DIASCAN` shows **current time** for when the Diascan measurement check was carried out.

- The value below K shows the last **measured clearance** value in ml/min.
- The value below Kt shows **accumulated Kt** achieved since treatment start.
- A **Kt forecast value** is displayed next to the accumulated Kt value. This value shows the Kt value estimated to be obtained when the treatment is complete. For further information, see "Forecast" in this section.
- LOG shows the 20 last measurement results. Scroll up and down in the list using the *Display Up/Down keys*.

Measurement result values, Kt/V measurement included



- LAST DIASCAN shows **current time** for when the Diascan measurement check was carried out.
- The value below K shows the last **measured clearance** value in ml/min.
- The value below Kt/V shows **accumulated Kt/V** achieved since treatment start.
- A **Kt/V forecast value** is displayed next to the accumulated Kt/V value. This value shows the Kt/V value estimated to be obtained when the treatment is complete. For further information, see "Forecast" in this section.
- TTT, **time to target**, shows an estimation of the treatment time needed to reach the desired Kt/V target value set by the operator. For further information, see "Time To Target" in this section.
- LOG shows the 20 last measurement results. Scroll up and down in the list using the *Display Up/Down keys*.

Forecast

Forecast is a calculation of the Kt or Kt/V value estimated to be obtained when the treatment is complete. If distribution volume (VOLUME) has been set, this Kt/V forecast value will be calculated by the machine and will automatically be shown as soon as the first Diascan measurement check has been performed. If distribution volume has not been set, the machine will only calculate and display the Kt forecast value. The calculated forecast

value (Kt or Kt/V) is adjusted after every successfully performed measurement check throughout the treatment.

Time To Target

If a target value for Kt/V (`Kt/V TARGET`) has been set, the machine will show an estimate of the treatment time needed to reach the desired Kt/V target value. Time to target will be calculated by the machine and will automatically be shown as soon as the first Diascan measurement check has been performed. This estimated time can be compared with the treatment time set but there will not be an attention alarm generated to make the operator attentive to any differences.

The Setting Menu

When DIASCAN has been selected in the viewing menu, the setting menu will be displayed on the Information Display. In this menu the Diascan function is to be activated, measurement mode is to be chosen and, if desired, an alarm limit for clearance can be set. If Kt/V measurement is desired, distribution volume is to be set in this menu. When this is done, it is possible to set a target value and an alarm limit for Kt/V; these settings are also entered here.

Activation/deactivation and measurement mode setting

Choose a single measurement check or continuous checks at intervals (the intervals are 15, 30 or 60 minutes).

Activate the Diascan function by selecting SINGLE, 15 MIN, 30 MIN or 60 MIN. Deactivate the function by selecting OFF.

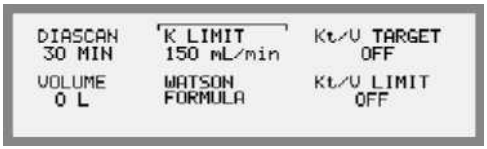
Note

If UFD is installed, the duration of the Diascan measurement check is extended. When 15 minute intervals have been set, the intervals may be automatically extended to around 30 minutes.

Note

Alarm limit for clearance

To set the alarm limit for minimum clearance, select `K LIMIT` and set a proper alarm limit value using the *Keypad*.



For further information; see "Clearance alarm limit", page 12:18.

Distribution volume

The operator is requested to set distribution volume in litres, estimated for the individual patient, in order to obtain a correct Kt/V value from the Diascan function. The distribution volume has to be properly estimated and set by the operator. The calculation of Kt/V done in the machine is entirely dependent on the value for the individual patient being the correct one. For further information; see "Glossary of Diascan® parameters and key terms", page 12:4.

If desired, it is possible for the machine to carry out a distribution volume calculation using the Watson formula, see further on in this section for instructions.

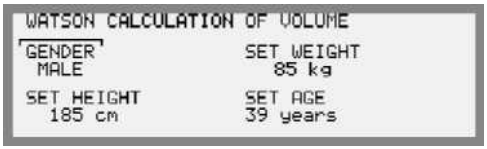
Distribution volume setting

To set a distribution volume, select VOLUME and set a proper value using the *Keypad*. 40 l is the default starting point value; adjust the value as necessary.

Distribution volume calculation and setting using the Watson formula

It is possible for the machine to carry out a distribution volume calculation, displayed in litres, using the Watson formula. In order for the machine to provide a value, the gender, weight, height and age (if male) of the particular patient must be entered into the machine. When the calculation has been done, a (W) will be displayed beside the distribution volume value provided, showing that the value has been calculated by the machine.

To set a distribution volume using the Watson formula, select WATSONFORMULA and the Watson calculation of volume menu will be displayed.



Select GENDER and choose FEMALE or MALE using the *Keypad*.

Select SET WEIGHT and enter patient weight using the *Keypad*.

Select SET HEIGHT and enter patient height in a similar way as weight.

If MALE has been selected, patient age (SET AGE) also needs to be entered in the same way.

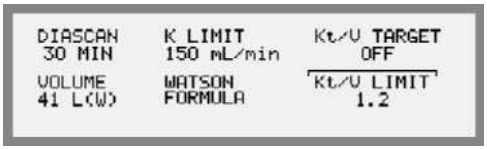
When all requested parameters have been entered, press the *Back key* and the machine performs the calculation. The setting menu will return.

The distribution volume value, in litres, calculated by the machine according to the Watson formula, will be shown below VOLUME. A (W) in brackets is shown beside the value indicating that the value has been calculated by the machine. Note that if the distribution volume value (VOLUME) is changed, the (W) beside the value will disappear.

If a new calculation is desired, select WATSONFORMULA and it will be possible to redo the procedure from the start.

Alarm limit for Kt/V

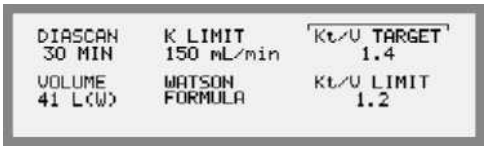
To set the alarm limit for minimum Kt/V, select Kt/V LIMIT and set a proper alarm limit value using the *Keypad*.



For further information; see "Kt/V alarm limit", page 12:19.

Target for Kt/V

To set a desired dialysis dose target value (Kt/V) which is to be achieved at treatment end, select Kt/V TARGET and set a proper value using the keypad. The target value for Kt/V can be set between OFF and 2.0.



When the Kt/V target value has been set, the machine calculates the time needed to reach the target. This time to target (TTT) will be displayed in the viewing menu as soon as the first Diascan measurement check has been performed.

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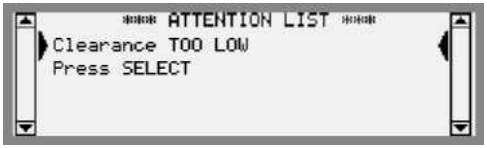
Alarms

Clearance alarm limit

The alarm limit for clearance is the lowest acceptable clearance value measured during treatment.
To set the alarm limit for minimum clearance, select `K LIMIT` and set a proper alarm limit value using the *Keypad*. The starting point value is 50% of the current blood flow rate at that time. Adjust the value as necessary. If the measured clearance value is below the alarm limit set, an attention alarm will be generated:



Check cause, adjust treatment parameters to increase clearance or adjust the alarm limit for clearance as above.

Kt/V alarm limit

The alarm limit for Kt/V is the lowest acceptable Kt/V forecast value (calculated by the machine) accepted when the treatment is complete. The value that is to be set is the minimum Kt/V value which has to be achieved when the treatment has finished. The alarm limit for Kt/V can be set between OFF and 1.95.
To set the alarm limit for minimum Kt/V, select `Kt/V LIMIT` and set a proper alarm limit value, after the distribution volume (`VOLUME`) has been set, using the *Keypad*. If the Kt/V forecast value, estimated at that time to be obtained when the treatment is complete, is below the Kt/V alarm limit set, an attention alarm will be generated:

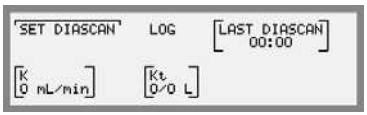
Check cause, adjust treatment parameters or adjust the alarm limit for Kt/V as above.

Step-by-step instructions for measuring clearance and Kt/V

Single clearance measurement check

Procedure

1. Press the *Fluid Path button*, select DIASCAN.



2. Select SET DIASCAN and the setting menu will be displayed.

3. When DIASCAN OFF has been selected, press the *Select key*.

4. Select SINGLE using the *Display Up key*. Single measurement is now activated.

The single clearance measurement check will be performed on an appropriate occasion chosen by the machine. The occasion chosen is dependent on when the self-calibrations of the machine are to be performed. DIASCAN will be shown at the activity field of the Treatment Overview Menu when the function has been activated.

During the period of time when the measurement check is being performed, DIASCAN, shown at the activity field of the Treatment Overview Menu, will be flashing.

When the measurement check has been performed, an attention alarm text without a buzzer will appear on the Information Display. Press the *Select key* to enter the LOG menu. The measurement result values are also displayed in the Diascan viewing menu.

When the measurement check has been performed Diascan will automatically be turned to OFF. It is possible to repeat the procedure at any time during treatment.

Note

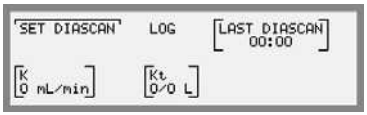
- To ensure a correct result a single clearance measurement check should be activated no later than 30 minutes before discontinuing treatment. This is to have enough time to obtain a measurement result.

Note

Continuous measuring of clearance

Procedure

1. Press the *Fluid Path button*, select DIASCAN.



2. Select SET DIASCAN and the setting menu will be displayed.

3. When DIASCAN OFF has been selected, press the *Select key*.

4. Select 15 MIN, 30 MIN, 60 MIN using the *Display Up key*. Continuous measurement of clearance is now activated.

5. If an alarm limit for clearance is required, select K LIMIT. Press the *Select key* and set a suitable alarm limit value using the *Display Up key*. For further information; see "Clearance alarm limit", page 12:18.

The first clearance measurement check in the sequence will be performed on an appropriate occasion chosen by the machine. The occasion chosen is dependent on when the self-calibrations of the machine are to be performed. DIASCAN will be shown at the activity field of the

Treatment Overview Menu when the function has been activated.

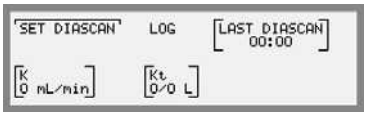
During the period of time when the measurement check is being performed, DIASCAN, shown at the activity field of the Treatment Overview Menu, will be flashing.

When a measurement check has been performed, an attention alarm text without a buzzer will appear on the Information Display  . Press the *Select key* to enter the LOG menu. The measurement result values are also displayed in the Diascan viewing menu.

Single Kt/V and clearance measurement check

Procedure

1. Press the *Fluid Path button*, select DIASCAN.



2. Select SET DIASCAN and the setting menu will be displayed.

3. When DIASCAN OFF has been selected, press the *Select key*.

4. Select SINGLE using the *Display Up key*. Single measurement is now activated.

5. Select VOLUME using the *Keypad*.
   The distribution volume is now to be set to a correct value for the individual patient. If desired, it is possible for the machine to carry out a distribution volume calculation using the Watson formula, see "Distribution volume", page 12:14.
   If the value is to be set manually, when VOLUME has been selected, set a proper value using the *Display Up key*. 40 l is the default starting point value. Adjust the value as necessary. Note that the distribution volume has to be properly estimated for the individual patient. The calculation of Kt/V done in the machine is entirely dependent on the value for the individual patient being the correct one. For further information; see "Glossary of Diascan® parameters and key terms", page 12:4.

The single clearance measurement check will be performed on an appropriate occasion chosen by the machine. The occasion chosen is dependent on when the self-calibrations of the machine are to be performed. DIASCAN will be shown at the activity field of the Treatment Overview Menu when the function has been activated.

During the period of time when the measurement check is being performed, DIASCAN, shown at the activity field of the Treatment Overview Menu, will be flashing.

When the measurement check has been performed, an attention alarm text without a buzzer will appear on the Information Display  . Press the *Select key* to enter the LOG menu. The measurement result values are also displayed in the Diascan viewing menu.

When the measurement check has been performed Diascan will automatically be turned to OFF. It is possible to repeat the procedure at any time during treatment.

Note

- Changes in treatment parameters (above all blood flow rate) affect measured clearance (K) values obtained during treatment and consequently, the calculated Kt/V result. If the Kt/V calculation at treatment end is based on few clearance results, or only one, check that these results are relevant for the complete treatment. This is in order to ensure that the Kt/V value is a relevant one.

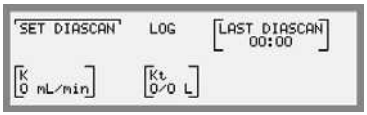
- To ensure a correct result a single clearance measurement check should be activated no later than 30 minutes before discontinuing treatment. This is to have enough time to obtain a measurement result.

Note

Continuous measuring of Kt/V and clearance

Procedure

1. Press the *Fluid Path button*, select DIASCAN.



2. Select SET DIASCAN and the setting menu will be displayed.

3. When DIASCAN OFF has been selected, press the *Select key*.

4. Select 15 MIN, 30 MIN, 60 MIN using the *Display Up key*. Continuous measurement of clearance is now activated.

5. If an alarm limit for clearance is required, select K LIMIT. Press the *Select key* and set a suitable alarm limit value using the *Display Up key*. For further information; see "Clearance alarm limit", page 12:18.

6. Select VOLUME using the *Keypad*.
   The distribution volume is now to be set to a correct value for the individual patient. If desired, it is possible for the machine to carry out a distribution volume calculation using the Watson formula, see "Distribution volume", page 12:14.
   If the value is to be set manually, when VOLUME has been selected, set a proper value using the *Display Up key*. 40 l is the default starting point value. Adjust the value as necessary. Note that the distribution volume has to be properly estimated for the individual patient. The calculation of Kt/V done in the machine is entirely dependent on the value for the individual patient being the correct one. For further information; see "Glossary of Diascan® parameters and key terms", page 12:4.

7. To set the alarm limit for minimum Kt/V, select Kt/V LIMIT and set a proper alarm limit value using the *Keypad.*.

8. When `Kt/V TARGET` has been selected set a desired dialysis dose target value (Kt/V) which is to be achieved at treatment end, using the *Display Up key*. The target value for Kt/V can be set between `OFF` and 2.0. When the Kt/V target value has been set, the machine calculates the time needed to reach the target. This time to target (`TTT`) will be displayed in the viewing menu as soon as the first Diascan measurement check has been performed.

The first Kt/V and clearance measurement check in the sequence will be performed on an appropriate occasion chosen by the machine. The occasion chosen is dependent on when the self-calibrations of the machine are to be performed. `DIASCAN` will be shown at the activity field of the Treatment Overview Menu when the function has been activated.

During the period of time when the measurement check is being performed, `DIASCAN`, shown at the activity field of the Treatment Overview Menu, will be flashing.

When a measurement check has been performed, an attention alarm text without a buzzer will appear on the Information Display. Press the *Select key* to enter the `LOG` menu. The measurement result values are also displayed in the Diascan viewing menu.

Note

- Changes in treatment parameters (above all blood flow rate) affect measured clearance (K) values obtained during treatment and consequently, the calculated Kt/V result. If the Kt/V calculation at treatment end is based on few clearance results, or only one, check that these results are relevant for the complete treatment. This is in order to ensure that the Kt/V value is a relevant one.

Note

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AK 96® Dialysis Machine Operator's Manual Program version 3.xx

Note

- Please observe that this part of the Operator's manual for the AK 96 dialysis machine is one out of three. To assimilate these instructions the complete manual must be available. For information see “How To Use this Manual” on page 1:2 in part 1.

Note

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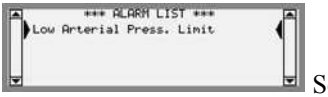
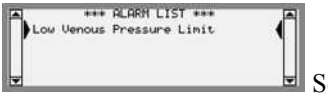
Chapter 13

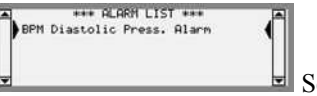
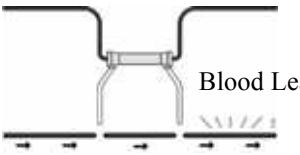
Alarms

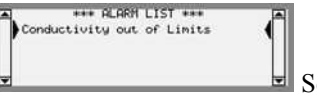
Contents

Alarms - Overview

Below is an overview of all alarms that can be generated by the AK 96 dialysis machine. It shows which button lights up, displayed alarm texts and page references to the Alarm List for each alarm.

Button	Function	Alarm
	Arterial Pressure Alarms	 See page 13:9.  See page 13:9.
	Venous Pressure Alarms	 See page 13:14.  See page 13:14.
	Air Detector Alarm	 See page 13:19.

Button	Function	Alarm
	Blood Pressure Alarms	 See page 13:26.  See page 13:26.  See page 13:26.  See page 13:26.
	Blood Path Alarms	 See page 13:22.  See page 13:24.
	Blood Leak Alarm	 See page 13:34.

Button	Function	Alarm
	Fluid Path Alarms	 See page 13:37.
		 See page 13:37.
		 See page 13:41.
		 See page 13:41.
		 See page 13:45.
		 See page 13:47.
	Connect Patient Alarm	 See page 13:49.
	Technical Alarm	 See page 13:51.

Alarms - General

Alarm Indication

When an alarm is generated, the machine indicates the alarm as follows:

- the *Alarm button* is flashing

- the *Mute button* is flashing
- the buzzer sounds continuously
- the button (not valid for Blood Leak alarm and Technical Alarm) of which the treatment parameter is connected to, and the alarm applies for, lights up. See the description for each alarm in the "Alarm List" page 13:9.

General Alarm Handling

Press the flashing *Alarm button*. The button lights up and the alarm text (which gives information on what has triggered the alarm) is displayed in the alarm list of the Information Display. At the same time as the *Alarm button* is being pressed, the buzzer will be simultaneously muted for 2 min.

If more than one alarm is triggered, the most recently generated alarm will be placed last in the list. The first alarm that was triggered is placed at the top of the list. The arrows on both sides of the text shows where you are in the list. Scroll up and down in the list using the *Display Up/Down keys* of the *Keypad*.

The menu connected to the treatment parameter of which the alarm applies for can be displayed in two different ways:

- by pressing the *Select key* when the alarm text is shown, and marked by arrows on both sides, on the Information Display

- by pressing the lit button connected to the treatment parameter of which the alarm applies for

In menus where it is possible to manually adjust the alarm limit, the value of which the alarm applies for will have an already opened position i.e. a lower cursor will be present.

The *Mute button* can be used to silence the buzzer for 2 minutes at a time. The buzzer sounds continuously for all alarms.

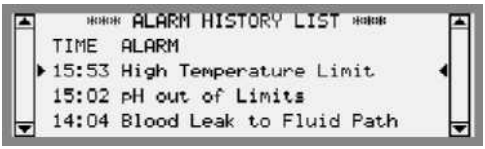
If a new alarm is issued (and the first alarm has not been reset) or if there are several alarms generated in succession, the *Alarm button* will start to flash again or continue to flash when the new alarm is issued. The alarm list will in this case be automatically updated.

When the *Back key* is pressed, and the alarm list is displayed on the Information Display, the menu that was previously opened will return.

It is possible to override (bypass) the machine alarm actions for low venous pressure, low arterial pressure, air detector and blood leak alarms for a limited amount of time. The purpose of the override option is to facilitate the handling of the machine in alarm situations. It is possible to override the alarm actions for more than one alarm at the same time, see instructions for each alarm in the Alarm List in this chapter. If the cause of the alarm has not been corrected within the override time, the alarm actions will automatically recur. The override time can be preset by authorized technician between 5-120 seconds except for the override of the air detector which can be preset 0-15 seconds.

Alarm History

When the *Alarm button* is pressed for 3 seconds, in a non-alarm situation, a list of the most recently generated alarms will be shown on the Information Display. The last generated alarm is shown at the top of the list. The arrows placed on both sides of the alarm text shows where you are in the list, scroll up and down by using the *Display Up/Down keys* of the *Keypad*.



The time for when the alarm was generated is shown to the left on the Information Display.

How to find the Alarm

The alarms in the Alarm List in this chapter are first and foremost arranged in accordance with where in the flow path of the Operator's panel the button which lights up (at the same time as the alarm is generated) is placed. The Alarm List starts with the "blood alarms" and finishes with the "fluid alarms". The Technical Error alarm is described last in the Alarm List.

You can also open page 13:2 to find alarm and page reference to the Alarm List in the "Alarms - Overview" list.

Alternatively, look for the alarm in the Table of Contents, first in this chapter.

Each alarm description in the Alarm List, is divided up into the following sections:

- **Appears:**
  Describes what conditions must be present for an alarm to appear; what triggers/generates the alarm.

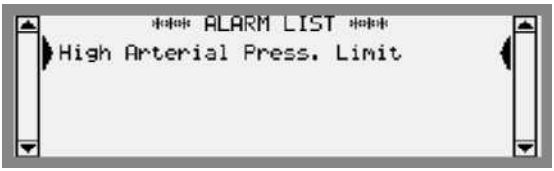
- **Possible cause:**
  Describes different imaginable reasons for the appearance of the alarm.

- **Machine actions:**
  Describes which actions that will automatically be taken by the machine due to the alarm.

- **Measures:**
  Describes which actions that are expected from the operator when an alarm appears.

Alarm List

Arterial Pressure Alarms



Appears:
The arterial pressure has reached the set arterial pressure high alarm limit.

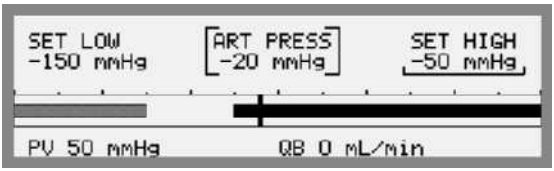
Machine actions:
- The blood pump stops.
- The venous blood line clamp closes.
- The ultrafiltration rate is set to zero and the dialysis fluid is bypassed from the dialyzer (when blood is detected).

When the arterial pressure is within the set alarm limits again, the blood pump automatically starts and the venous blood line clamp opens.

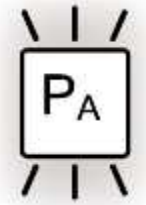
Possible cause:
- The arterial blood line has separated from the arterial needle.
- The position of the arterial needle has changed.
- Air or infusion fluid have entered the arterial blood line between the arterial needle and the blood pump e.g. when an infusion is connected to the arterial blood line prior to the blood pump.

Measures:

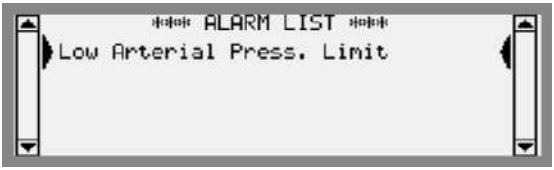
- Press the flashing *Alarm button* and the alarm text will be shown on the Information Display. Then press the *Select key* to open the arterial pressure menu. It is also possible to directly view the arterial pressure menu by pressing the lit *Arterial Pressure button*. The alarm limit setting of which the alarm applies for will be open.



- Check cause (the patient's blood access, the extracorporeal circuit) and do necessary actions in accordance with this. If the blood pump intermittently starts and stops, consider adjusting the blood flow rate or if necessary, manually stop the blood pump, using the *Blood Pump buttons*.
- If possible, adjust the arterial pressure high alarm limit using the *Key pad*.



After the arterial pressure alarm has been attended to, and if the arterial pressure alarm window is set to be wider than the preset value, the *Arterial Pressure button* will start to flash. Press the flashing button to centralize the alarm limits around the current value.



Appears:
The arterial pressure has passed the set arterial pressure low alarm limit.

Machine actions:
- The blood pump stops.
- The venous blood line clamp closes.
- The ultrafiltration rate is set to zero.

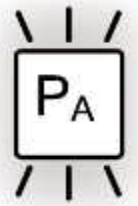
When the arterial pressure is within the set alarm limits again, the blood pump automatically starts and the venous blood line clamp opens.

Possible cause:
- The performance of the patient's vascular blood access is not in accordance with the set blood flow rate.
- The arterial blood line is kinked or clotted between the arterial needle and the arterial pressure measurement point.
- The position of the arterial needle has changed.

Measures:

- Press the flashing *Alarm button* and the alarm text will be shown on the Information Display. Then press the *Select key* to open the arterial pressure menu. It is also possible to directly view the arterial pressure menu by pressing the lit *Arterial Pressure button*. The alarm limit setting of which the alarm applies for will be open.

- Check cause (the patient's blood access, the extracorporeal circuit) and do necessary actions in accordance with this. If the blood pump intermittently starts and stops, consider adjusting the blood flow rate or if necessary, manually stop the blood pump, using the *Blood Pump buttons*.
- If possible, adjust the arterial pressure low alarm limit using the *Key pad*.
- If necessary, override (bypass) the machine alarm actions by pressing the lit *Arterial Pressure button* for 3 seconds. The blood pump will start up at the set blood flow rate, adjust if necessary. If the cause of the alarm has not been corrected within the override time, the machine alarm actions will automatically recur. If necessary, repeat the override procedure. See also "General Alarm Handling", page 13:5.



After the arterial pressure alarm has been attended to, and if the arterial pressure alarm window is set to be wider than the preset value, the *Arterial Pressure button* will start to flash. Press the flashing button to centralize the alarm limits around the current value.

WARNING

⚠ When entering override, it is essential to remember that the machine does not monitor that specific parameter. The operator is responsible for the monitoring during the override time.

WARNING

Venous Pressure Alarms

Appears:
The venous pressure has reached the set venous pressure high alarm limit.

Machine actions:
- The blood pump stops.
- The arterial blood line clamp closes in single needle mode.
- The ultrafiltration rate is set to zero.

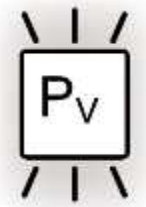
When the venous pressure is within the set alarm limits again, the blood pump automatically starts.

Possible cause:
- The venous blood line is kinked or clamped.
- The position of the venous needle has changed.
- Clotting has occurred in the venous blood line after the venous pressure measurement point; in the blood line, in the venous drip chamber, or in the needle.

Measures:

- Press the flashing *Alarm button* and the alarm text will be shown on the Information Display. Then press the *Select key* to open the venous pressure menu. It is also possible to directly view the venous pressure menu by pressing the lit *Venous Pressure button*. The alarm limit setting of which the alarm applies for will be open.

- Check cause (the patient's blood access, the extracorporeal circuit) and do necessary actions in accordance with this. If the blood pump intermittently starts and stops, consider adjusting the blood flow rate or if necessary, manually stop the blood pump, using the *Blood Pump buttons*.
- If possible, adjust the venous pressure high alarm limit using the *Key pad*.



After the venous pressure alarm has been attended to, and if the venous pressure alarm window is set to be wider than the preset value, the *Venous Pressure button* will start to flash. Press the flashing button to centralize the alarm limits around the current value.

Appears:
The venous pressure has passed the set venous pressure low alarm limit.

Machine actions:
- The blood pump stops.
- The venous blood line clamp closes.
- The ultrafiltration rate is set to zero and the dialysis fluid is bypassed from the dialyzer (when blood is detected).

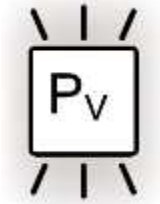
When the venous pressure is within the set alarm limits again, the blood pump automatically starts and the venous blood line clamp opens.

Possible cause:
- The venous blood line has separated from the dialyzer.
- The venous blood line has separated from the venous needle.
- The position of the venous needle has changed.
- Clotting before or in the dialyzer.

Measures:

- Press the flashing *Alarm button* and the alarm text will be shown on the Information Display. Then press the *Select key* to open the venous pressure menu. It is also possible to directly view the venous pressure menu by pressing the lit *Venous Pressure button*. The alarm limit setting of which the alarm applies for will be open.

- Check cause (the patient's blood access, the extracorporeal circuit) and do necessary actions in accordance with this. If the blood pump intermittently starts and stops, consider adjusting the blood flow rate or if necessary, manually stop the blood pump, using the *Blood Pump buttons*.
- If possible, adjust the venous pressure low alarm limit using the *Key pad*.
- If necessary, override (bypass) the machine alarm actions by pressing the lit *Venous Pressure button* for 3 seconds. The blood pump will start up at the set blood flow rate, adjust if necessary. If the cause of the alarm has not been corrected within the override time, the machine alarm actions will automatically recur. If necessary, repeat the override procedure. See also "General Alarm Handling", page 13:5.



After the venous pressure alarm has been attended to, and if the venous pressure alarm window is set to be wider than the preset value, the *Venous Pressure button* will start to flash. Press the flashing button to centralize the alarm limits around the current value.

WARNING

⚠ When entering override, it is essential to remember that the machine does not monitor that specific parameter. The operator is responsible for the monitoring during the override time.

WARNING

Air Detector Alarm

Appears:
Air has entered the venous drip chamber.

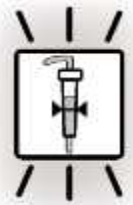
Machine actions:
- The blood pump stops.
- The venous and the arterial blood line clamps closes.
- The ultrafiltration rate is set to zero and the dialysis fluid is bypassed from the dialyzer (when blood is detected).

Possible cause:
- The blood line connections are not properly connected (at the arterial needle, at the dialyzer).
- The blood lines or the dialyzer has not been properly de-aired during priming.
- Air have entered the blood lines e.g. when an infusion is connected to the blood lines.
- The arterial needle is dislocated.

Measures:

- Press the flashing *Alarm button* and the alarm text will be shown on the Information Display.

- Check cause (the patient's blood access, the extracorporeal circuit, infusions) and do necessary actions in accordance with this.
- Adjust the level in the venous drip chamber by using the level adjustment knob. Turn the level adjustment knob anticlockwise to raise the level and clockwise to lower it.
- If necessary, override (bypass) the machine alarm actions by pressing the lit *Air Detector button* for 3 seconds. The blood pump will start up at 100 ml/min blood flow rate, adjust if necessary. If the cause of the alarm has not been corrected within the override time, the machine alarm actions will automatically recur. If necessary, repeat the override procedure. Especially note that the blood flow rate will remain at 100 ml/min after the override period and has to be manually adjusted. See also "General Alarm Handling", page 13:5.



- After the air in venous drip chamber alarm has been attended to, the *Air detector button* will start to flash. Press the flashing button to reset the alarm function.

WARNING

⚠ When entering override, it is essential to remember that the machine does not monitor that specific parameter. The operator is responsible for the monitoring during the override time.

WARNING

Low Blood Flow Rate Alarm

Appears:
The set blood flow rate has been lower than, or equal to, 100 ml/min for more than 5 minutes.

Machine actions:
None.

Possible cause:
- The blood flow rate has been decreased for any reason and not been adjusted afterwards.
- The blood pump has been automatically stopped too long due to machine alarm actions.
- The operator has left the blood pump in stop position too long.

Measures:

- Press the flashing *Alarm button* and the alarm text will be shown on the Information Display.

- Check cause for the low blood flow rate e.g. problems with the patient's blood access that has recently been taken care of, previously made air detector alarm override, previous technical alarm etc. If possible, increase the blood flow rate to the proper value and the alarm will automatically disappear when the blood flow rate is set above the alarm limit value.

- If necessary, adjust the alarm limit value by pressing the *Select key* to enter the `BLOOD FLOW MENU`. Adjust the alarm limit; `SET LOW`, as necessary.

Single Needle Stroke Volume Alarm

Appears:
In single needle treatment when the measured stroke volume STROKE is lower than the set stroke volume SET.

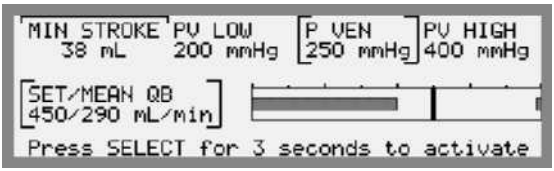
Machine actions:
None.

Possible cause:
- Decreased performance of the patient's blood access.
- Adjustments to optimize the single needle treatment may have been overlooked.

Measures:

- Press the flashing *Alarm button* and the alarm text will be shown on the Information Display.

- Check the level in the expansion chamber. It should be as low as possible but not so low that air passes into the blood lines at the end of the venous phase.
- If possible, adjust the venous pressure alarm window. The wider the window, the greater the stroke volume. The higher the position of the window (i.e. how high in the mmHg scale the window is placed), the higher the venous flow.
- When above mentioned measures have been made without expected result, adjust the set stroke volume as necessary. Press the *Select key* to open `SINGLE NEEDLE` and then adjust `MIN STROKE` using the *Keypad*. See in the chapter "Hemodialysis - Single Needle Treatment (option)" starting on page 5:1 in part 1 for further information.



Blood Pressure Alarms

Appears:
The patient's systolic blood pressure is outside the low or high alarm limits set.

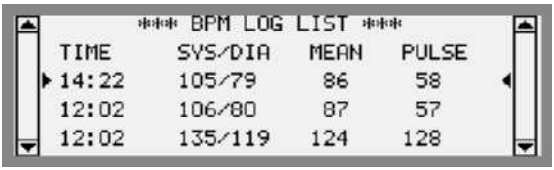
Machine actions:
None.

Possible cause:
- Circulatory disturbances in the patient.
- Inaccurate setting of alarm limits for the particular patient.

Measures:

- Press the flashing *Alarm button* and the alarm text will be shown on the Information Display.

- Press the *Select key* and the BPM log list will be displayed. Read off current and previous blood pressure measurement results. The most recent result is displayed at the top of the list.



- Check cause; do standard patient checks and take standard measures as whenever the patient has a circulatory disturbance.
- If desired, repeat the blood pressure measurement check manually (see "Single Measuring" on page 11:7 in part 2 for instructions).
- If possible, adjust the alarm limits in accordance with the status of the patient. When the BPM log list is displayed, press *Back button* and navigate to `ALARM` to adjust the limits, using the *Keypad*.

Appears:
The patient's diastolic blood pressure is outside the low or high alarm limits set.

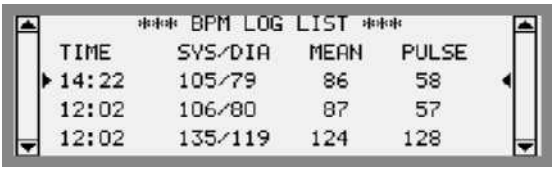
Machine actions:
None.

Possible cause:
- Circulatory disturbances in the patient.
- Inaccurate setting of alarm limits for the particular patient.

Measures:

- Press the flashing *Alarm button* and the alarm text will be shown on the Information Display.

- Press the *Select key* and the BPM log list will be displayed. Read off current and previous blood pressure measurement results. The most recent result is displayed at the top of the list.



- Check cause; do standard patient checks and take standard measures as whenever the patient has a circulatory disturbance.
- If desired, repeat the blood pressure measurement check manually (see "Single Measuring" on page 11:7 in part 2 for instructions).
- If possible, adjust the alarm limits in accordance with the status of the patient. When the BPM log list is displayed, press *Back button* and navigate to `ALARM` to adjust the limits, using the *Keypad*.

Appears:
The patient's mean blood pressure is outside the low or high alarm limits set.

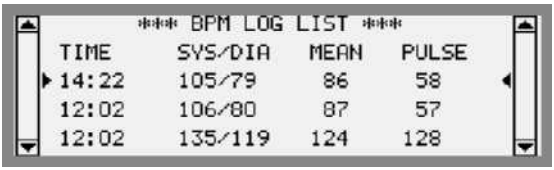
Machine actions:
None.

Possible cause:
- Circulatory disturbances in the patient.
- Inaccurate setting of alarm limits for the particular patient.

Measures:

- Press the flashing *Alarm button* and the alarm text will be shown on the Information Display.

- Press the *Select key* and the BPM log list will be displayed. Read off current and previous blood pressure measurement results. The most recent result is displayed at the top of the list.



- Check cause; do standard patient checks and take standard measures as whenever the patient has a circulatory disturbance.
- If desired, repeat the blood pressure measurement check manually (see "Single Measuring" on page 11:7 in part 2 for instructions).
- If possible, adjust the alarm limits in accordance with the status of the patient. When the BPM log list is displayed, press *Back button* and navigate to `ALARM` to adjust the limits, using the *Keypad*.

Appears:
The patient's puls rate is outside the low or high alarm limits set.

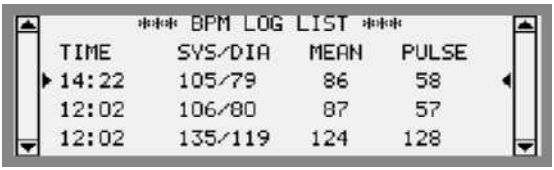
Machine actions:
None.

Possible cause:
- Circulatory disturbances in the patient.
- Inaccurate setting of alarm limits for the particular patient.

Measures:

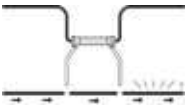
- Press the flashing *Alarm button* and the alarm text will be shown on the Information Display.

- Press the *Select key* and the BPM log list will be displayed. Read off current and previous blood pressure measurement results. The most recent result is displayed at the top of the list.



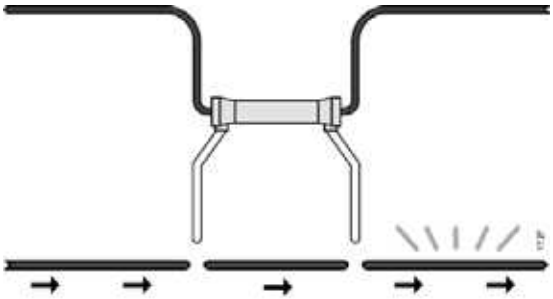
- Check cause; do standard patient checks and take standard measures as whenever the patient has a circulatory disturbance.
- If desired, repeat the blood pressure measurement check manually (see "Single Measuring" on page 11:7 in part 2 for instructions).
- If possible, adjust the alarm limits in accordance with the status of the patient. When the BPM log list is displayed, press *Back button* and navigate to `ALARM` to adjust the limits, using the *Keypad*.

Blood Leak Alarm



Appears:
Blood has entered the fluid path of the machine downstream the dialyzer.

Machine actions:
- The blood pump stops.
- The arterial blood line clamp closes.
- The ultrafiltration rate is set to zero and the dialysis fluid is bypassed from the dialyzer (when blood is detected).



- The machine indicates the alarm by a flashing part of the fluid flow path.

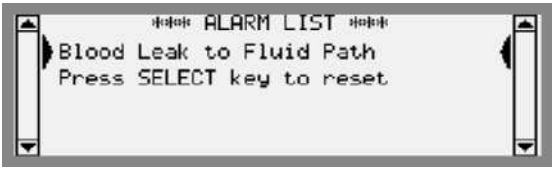
Possible cause:
- A dialyzer leakage, resulting in blood flowing from the blood compartment to the dialysis fluid compartment, has occurred.

- Air bubbles or particles in the fluid path of the machine, which can cause a false blood leak alarm, have entered the blood leak detector.

Measures:

- Press the flashing *Alarm button* and the alarm text will be shown on the Information Display.

- Check the machine inlet dialysis fluid tube (the tube to the machine from the dialyzer) for blood. Follow the routines of the clinic which may differ depending on the amount of blood has leaked to the fluid compartment and the status of the patient. The measures may vary between immediate discontinuing of the treatment without returning the blood to the patient, to continuing treatment without action.
- The blood leak machine alarm actions may be overridden (bypassed) by pressing the *Select key* . The blood pump will start up at 50 ml/min blood flow rate, adjust if necessary. The blood leak detector will automatically be rinsed with dialysis fluid during the override period. If the cause of the alarm has not been corrected within the override time, the machine alarm actions will automatically recur. If necessary, repeat the override procedure. Especially note that the blood flow rate will remain at 50 ml/min after the override period and has to be manually adjusted. See also "General Alarm Handling", page 13:5.



- After the blood leak alarm is over, the alarm text will change. Press the *Select key* to reset the alarm function.

WARNING

⚠ When entering override, it is essential to remember that the machine does not monitor that specific parameter. The operator is responsible for the monitoring during the override time.

WARNING

TMP Alarms

Appears:
The transmembrane pressure (TMP) has reached the set TMP high alarm limit.

Machine actions:
None.

Possible cause:
The TMP value during treatment depends mainly on the following parameters; the set treatment time, the set UF volume and the set blood flow rate. Changes of these three parameters affect the TMP value, as well as changed performance of the dialyzer as the treatment proceeds. Changes in the machine UF control system can also cause reduced accuracy in measuring the patient's weight loss. The following points may cause high TMP alarm:

- changes in the UF-control system of the machine
- the set treatment time has been decreased
- the set UF volume has been increased
- clogged dialyzer, partly or complete
- decreased blood flow rate

Measures:

- Press the flashing *Alarm button* and the alarm text will be shown on the Information Display. Then press the *Select key* to open the TMP menu.
  It is also possible to press the lit *Fluid Path button*, select `TMP` and go into the TMP menu, using the *Keypad*.
  The alarm limit setting of which the alarm applies for will be open.

- Check cause (the patient for unaccountable weight loss, the patient's blood access, the extracorporeal circuit, the dialyzer) and do necessary actions in accordance with this.
- Do standard patient checks for incorrect weight loss such as measuring blood pressure. If necessary, discontinue treatment and call an authorized technician.
- If possible, increase the set treatment time, decrease the set UF volume or increase the blood flow rate.
- If possible, adjust the high TMP alarm limit using the *Key pad.*.

When the Transmembrane pressure confirm menu is displayed on the Information Display, press the *Select key* to confirm the settings i.e. that the current TMP value and the automatically set TMP alarm limits are set in accordance with the current UF rate and the UF coefficient of the dialyzer being used.

Appears:
The transmembrane pressure (TMP) has passed the set TMP low alarm limit.

Machine actions:
None.

Possible cause:
The TMP value during treatment depends mainly on the following parameters; the set treatment time, the set UF volume and the set blood flow rate. Changes of these three parameters affect the TMP value, as well as changed performance of the dialyzer as the treatment proceeds. Changes in the machine UF control system can also cause reduced accuracy in measuring the patient's weight loss. The following points may cause low TMP alarm:

- changes in the UF-control system of the machine
- the set treatment time has been increased
- the set UF volume value has been decreased
- increased blood flow rate

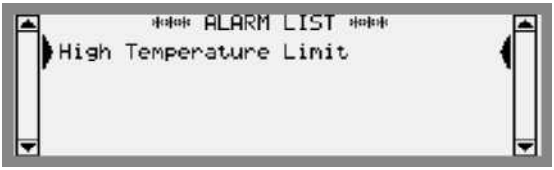
Measures:

- Press the flashing *Alarm button* and the alarm text will be shown on the Information Display. Then press the *Select key* to open the TMP menu.
  It is also possible to press the lit *Fluid Path button*, select `TMP` and go into the TMP menu, using the *Keypad*.
  The alarm limit setting of which the alarm applies for will be open.

- Check cause (the patient for unaccountable weight loss, the patient's blood access, the extracorporeal circuit, the dialyzer) and do necessary actions in accordance with this.
- Do standard patient checks for incorrect weight loss such as measuring blood pressure. If necessary, discontinue treatment and call an authorized technician.
- If possible, decrease the set treatment time or increase the set UF volume.
- If possible, adjust the low TMP alarm limit using the *Key pad*.

When the Transmembrane pressure confirm menu is displayed on the Information Display, press the *Select key* to confirm the settings i.e. that the current TMP value and the automatically set TMP alarm limits are set in accordance with the current UF rate and the UF coefficient of the dialyzer being used.

Temperature Alarms



Appears:
The dialysis fluid temperature has reached the set temperature high alarm limit.

Machine actions:
- The dialysis fluid is bypassed from the dialyzer.

When the dialysis fluid temperature is within the set alarm limits again, the dialysis fluid automatically enters the dialyzer.

Possible cause:
- The temperature of the inlet water to the machine is too high.
- The machine has not yet stabilized the dialysis fluid temperature after the function check.
- The machine has not yet stabilized the dialysis fluid temperature after an interruption of the water supply to the machine.

Measures:

- Press the flashing *Alarm button* and the alarm text will be shown on the Information Display. Then press the *Select key* to open the temperature menu.
  It is also possible to press the lit *Fluid Path button*, select TEMP and go into the temperature menu, using the *Keypad*.
  The alarm limit setting of which the alarm applies for will be open.

- Check cause (inlet water supply, power supply) and do necessary actions in accordance with this. Wait for correct dialysis fluid temperature to be resumed. If necessary, call for an authorized technician or discontinue treatment.

Appears:
The dialysis fluid temperature has passed the set temperature low alarm limit.

Machine actions:
- The dialysis fluid is bypassed from the dialyzer.

When the dialysis fluid temperature is within the set alarm limits again, the dialysis fluid automatically enters the dialyzer.

Possible cause:
- The machine has not yet stabilized the dialysis fluid temperature after an interruption of the water supply to the machine.
- The power supply to the heating rods in the machine has been interrupted.

Measures:

- Press the flashing *Alarm button* and the alarm text will be shown on the Information Display. Then press the *Select key* to open the temperature menu.
  It is also possible to press the lit *Fluid Path button*, select TEMP and go into the temperature menu, using the *Keypad*.
  The alarm limit setting of which the alarm applies for will be open.

- Check cause (inlet water supply, power supply) and do necessary actions in accordance with this. Wait for correct dialysis fluid temperature to be resumed. If necessary, call for an authorized technician or discontinue treatment.

Conductivity Alarm

Appears:
The dialysis fluid conductivity is outside the set alarm limits.

Machine actions:
- The dialysis fluid is bypassed from the dialyzer.
- If the dialysis fluid conductivity is below 9 mS/cm, the UF rate will automatically be set to zero.
- When the dialysis fluid conductivity is within the set alarm limits again, the dialysis fluid automatically enters the dialyzer.

Possible cause:
- The concentrate container/BiCart cartridge is empty.
- Air is drawn into the machine instead of concentrate.
- Incorrect concentrate has been connected e.g. the connected concentrate is not in accordance with the selected concentrate alternative.
- There is an interruption in the concentrate administration to the machine e.g. the concentrate connector is not properly connected to the pick-up tube, the BiCart cartridge is not properly attached (see "Acidic concentrate and BiCart® cartridge" on page 4:9 in part 1), the concentrate tube is kinked or occluded, the filter integrated on the concentrate tubes are clogged etc.

Measures:

- Press the flashing *Alarm button* and the alarm text will be shown on the Information Display. Then press the *Select key* to open the conductivity menu and to read off the conductivity values.
  It is also possible to press the lit *Fluid Path button*, select COND and go into the conductivity menu, using the *Keypad*.

- Check cause (concentrates, tubes, connectors) and do necessary actions in accordance with this. Wait for correct dialysis fluid conductivity to be resumed. If necessary, call for an authorized technician or discontinue treatment.

pH (option) Alarm

Appears:
The pH value of the dialysis fluid is outside the set alarm limits.

Machine actions:
- The dialysis fluid is bypassed from the dialyzer.
-

When the pH value of the dialysis fluid is within the set alarm limits again, the dialysis fluid automatically enters the dialyzer.

Possible cause:
- The content of the concentrate container does not correspond with the specifications given.
- Incorrect concentrate has been connected.
- Either the acidic container or the bicarbonate container/BiCart cartridge is empty (when using bicarbonate concentrates).

Measures:

- Press the flashing *Alarm button* and the alarm text will be shown on the Information Display. Then press the *Select key* to open the conductivity menu and to read off the pH value.
  It is also possible to press the lit *Fluid Path button*, select COND and go into the conductivity menu, using the *Keypad*.

- Check cause (concentrates, tubes, connectors) and do necessary actions in accordance with this. Wait for correct pH of the dialysis fluid to be resumed. If necessary, call for an authorized technician or discontinue treatment.

Connect Patient Alarm

Appears:
The CONNECT PATIENT procedure has been started, the connect patient volume is achieved and no blood has been detected in the venous blood line.

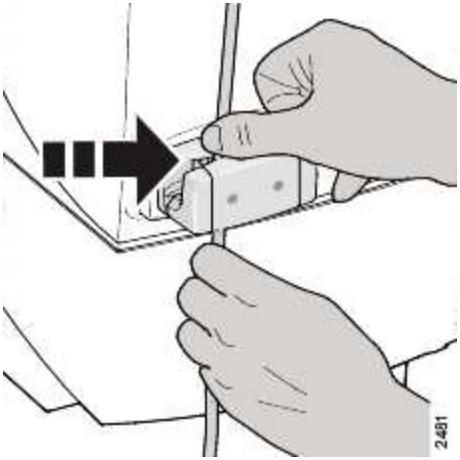
Machine actions:
- The blood pump stops.
- The venous blood line clamp closes.

Possible cause:
- The venous blood line is not properly inserted into the priming detector.

Measures:

- Press the flashing *Alarm button* and the alarm text will be shown on the Information Display.

- Check that the venous blood line is properly inserted into the priming detector.



When the priming detector detects blood in the venous blood line, the blood path of the Flow Diagram lights up red and the treatment time starts to count down on the Time Display.

- Press the *Select key* to confirm.
- When done select `CONTINUE CONNECT PATIENT` and press the *Select key*.

Technical Alarm

Appears:
There is a technical fault in the machine.

Machine actions:
The machine actions differ depending on the kind of technical error. The machine sometimes automatically enters a state which makes it impossible to continue the treatment.

Possible cause:
-

Measures:

- Press the lit *Alarm button* and the alarm text will be shown on the Information Display.

- Press the *Select key* and the Error Code List will be displayed. Read and note the error code text on the Information Display.
  If more than one technical error have been generated, the most recent is displayed at the top of the list. The arrows on both sides of the text shows where you are in the list. The display can show at most three technical errors at the same time. Use the *Display Down key* to view any further possible error codes.

- Technical error during treatment;**call the authorized technician**. If necessary during treatment, manually return the blood to the patient. See "Power Failure" on page 3:27 in part 1 for instructions.

- Technical error during function check; restart the machine using the *On/Off button* and the machine will perform a new function check. If the technical error reoccurs, call the authorized technician.

WARNING

⚠ A restart attempt after technical error during treatment may create a potential hazard for the patient.

WARNING

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Chapter 14

Attention Alarms

Contents

Attention Alarms - General

Attention Alarm Indication

When an attention alarm is generated, the machine indicates the attention alarm as follows:

- The *Attention button* flashes.

- The *Mute button* flashes.
- For most attention alarms the buzzer sounds.
  There are three kinds of buzzer sounds:
  - Soft - - - - - - - - - -
  - Supersoft - -(10 sec) - -(10 sec)
  - Continuous ----------

General Attention Alarm Handling

Press the flashing *Attention button*. The button lights up and the attention alarm text (which gives information on what has triggered the attention alarm) is displayed in the attention list on the Information Display.

At the same time as the *Attention button* is pressed, the *Mute button* lights up and the buzzer is muted for varying times depending on the attention alarm.

If more than one attention alarm is triggered, the current attention alarm text is marked by arrows on both sides of the text. The first attention alarm that was triggered is placed at the top of the list. Scroll up and down the list using the *Display Up/Down keys* of the *Keypad*.

The *Mute button* can be used to silence the buzzer for varying times depending on the attention alarm. The mute times for the different alarms are described below for each attention alarm.

If a new attention alarm is generated (and the first attention alarm has not been reset) or if there are several attention alarms generated in succession, the *Attention button* will start to flash again or continue to flash when the new attention alarm is generated. The flashing button is to be pressed until all attention alarms have been shown on the Information Display; i.e. when the *Attention button* lights up.

How to find the Attention Alarm

The attention alarms in the "Attention Alarm List" are arranged in alphabetical order.

Each attention alarm description in the "Attention Alarm List" is divided up into the following sections:

Appears: Describes what conditions must be present for an attention alarm to appear, what triggers/generates an alarm.

Machine actions: Describes actions that will automatically be taken by the machine due to the attention alarm.

Measures: Describes actions expected from the operator when an attention alarm appears.

Mutetime: When the *Mute button* is pressed, the buzzer sound will be muted during the specified period of time. Min. = minutes.

Buzzer sound: Describes which kind of buzzer sound is used for the attention alarm, see page 14:2.

Attention Alarm List

```
AIR DETECTOR NOT ACTIVATED
Press AIR DETECTOR button
```

Appears:
During priming 15 seconds after the venous drip chamber has been filled upon attention alarm request.

Machine actions:
The *Air detector button* will be flashing.

Measures:
Press the flashing *Air detector button* to activate the air detector alarm function.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
AIR LEAKAGE
Check fluid tube connections
```

Appears:
When the dialysis fluid tubes are not properly connected to the dialyzer.

Machine actions:
Buzzer is activated 2 min. after the attention alarm is generated.

Measures:
Check the dialysis fluid tubes connections. See instructions in "Dialysis Fluid Tubes - Attach" on page 4:35 in part 1.

Mute time:
2 min

Buzzer sound:
Soft buzzer

CAUTION

Incorrect weight loss may occur if the machine is left for a longer period with this attention alarm.

CAUTION

```
ART PRESS MENU HAS BEEN CLOSED
CHANGE HAS BEEN EXECUTED
```

Appears:
Parameter change has been made without confirming, using the *Select key*.
The appearance of the attention alarm can be preset.

Machine actions:
The machine has automatically confirmed the change.

Measures:
Check that the changed parameter is correct. The attention alarm will automatically disappear after it has been displayed.

Mute time:
2 min.

Mute time:
Soft buzzer

```
ART PRESSURE LIMITS TOO WIDE
Press ARTERIAL button to adjust
```

Appears:
The arterial pressure alarm window is wider than the preset value.

Machine actions:
None

Measures:
Press the flashing *Arterial Pressure button* to centralize the alarm limits around the current value.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
Attach tubes to safety bypass
Press SELECT to abort the test
```

Appears:
When it is not possible for the machine to detect that the dialysis fluid tubes are attached to the safety couplings. The corresponding machine test can not be made.

Machine actions:
The disinfection or rinse program has been interrupted.

Measures:
To be able to continue the activated disinfection or rinse program; check that the dialysis fluid tubes are properly attached to the safety couplings of the machine. Confirm this by pressing the *Select key* and the activated program will be resumed.
Alternately, consult an authorized technician.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
Attach tubes to safety bypass
Press SELECT to start disinf
```

Appears:
When it is not possible for the machine to detect that the dialysis fluid tubes are attached to the safety couplings. The corresponding machine test can not be made.

Machine actions:
The disinfection or rinse program has been interrupted.

Measures:
To be able to continue the activated disinfection or rinse program; check that the dialysis fluid tubes are properly attached to the safety couplings of the machine. Confirm this by pressing the *Select key* and the activated program will be resumed.
Alternately, consult an authorized technician.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
BATTERY FAILURE
Change battery or press SELECT
```

Appears:
When the battery that supplies the power failure buzzer is not properly charged. It is only displayed when blood is not detected.

Machine actions:
None.

Measures:
- The battery needs to be changed or recharged. Contact an authorized technician.
- Press the *Select key* to confirm the attention alarm and to be able to start the treatment.

If the attention alarm is confirmed without changing or recharging the battery, the machine will not be able to alarm or restart in case of power failure.

Mute time:
Permanently muted buzzer

Buzzer sound:
Soft buzzer (during function check)
No buzzer (during disinfectant program)

```
BiCart HOLDER NOT CLOSED
Close or check BiCart holder
```

Appears:
When the BiCart holder is not properly closed.

Machine actions:
Buzzer is activated 2 min. after the attention alarm is generated.

Measures:
Close the BiCart holder. See "Machine aftercare" on page 4:63 in part 1 for instructions.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
BiCart HOLDER NOT INSTALLED
Check concentrate selection
```

Appears:
BiCart concentrate has been selected, but the BiCart holder has not been installed.

Machine actions:
None.

Measures:
Check selected concentrate. See "Connect/Confirm Concentrates" on page 4:7 in part 1 for instructions.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
BiCart NOT ATTACHED TO HOLDER
Attach or check BiCart
```

Appears:
The BiCart cartridge has not been properly attached to the BiCart holder.

Machine actions:
Buzzer is activated 2 min. after the attention alarm is generated.

Measures:
Attach or check BiCart cartridge. See "Connect/Confirm Concentrates" on page 4:7 in part 1 for instructions.

Mute time:
Permanently muted buzzer

Buzzer sound:
Soft buzzer

BLOOD DETECTED IN ASSISTED PRIM

Appears:
When the priming detector detects blood during assisted priming procedure.

Machine actions:
The blood pump stops.

Measures:
First, make sure that the patient has not been connected to the blood lines. If this is not the case, clean the priming detector lens. Alternatively call the authorized technician.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
BLOOD IN PRIMING DETECTOR
Function check stopped
```

Appears:
When the priming detector detects blood during function check.

Machine actions:
The blood pump stops and the venous blood line clamp closes.

Measures:
First, make sure that the patient has not been connected to the blood lines. If this is not the case, clean the priming detector lens. Alternatively call the authorized technician.

Mute time:
2 min.

Buzzer sound:
Continuous buzzer

```
BLOOD LEAK DETECTOR FAILURE
Clean and press SELECT key
```

Appears:
During function check if the blood leak detector is dirty or out of function.

Machine actions:
None.

Measures:
Clean the blood leak detector, see "Blood Leak Detector" on page 8:41 in part 1 for instructions. Press the *Select key* when cleaned.
If the attention alarm appears again, call an authorized technician.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Soft buzzer

```
BLOOD PATH MENU HAS BEEN CLOSED
CHANGE HAS BEEN EXECUTED
```

Appears:
Parameter change has been made without confirming, using the *Select key*.
The appearance of the attention alarm can be preset.

Machine actions:
The machine has automatically confirmed the change.

Measures:
Check that the changed parameter is correct. The attention alarm will automatically disappear after it has been displayed.

Mute time:
2 min

Mute time:
Soft buzzer

```
BLOOD PATH PRESSURE TEST FAILED
Press SELECT key to continue
```

Appears:
May occur during assisted priming if the automatic pressure test/leakage test of the dialyzer fails.

Machine actions:
The blood pump stops.

Measures:
Press *Select key*. The priming phase will start automatically when the blood pump is started.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Soft buzzer

```
BLOOD PUMP DOOR NOT CLOSED
Close blood pump door
```

Appears:
When the blood pump cover has not been properly closed during treatment or priming.

Machine actions:
The blood pump stops.

Measures:
Close the blood pump cover. See "Blood Part Component Details" on page 2:5 in part 1 for instructions.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
BLOOD PUMP OVERLOAD
Check cause and start blood pump
```

Appears:
When it is hardly possible for the blood pump to run.

Machine actions:
The blood pump stops.

Measures:
Check that the blood pump segment is correctly positioned, see Arterial Blood Line - Attach on page 4:16 in part 1 for instructions. When properly positioned, press the *Select key*.
If the attention alarm appears again, call an authorized technician.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
BLOOD PUMP OVERLOAD IN FCH
Check blood pump, Press SELECT
```

Appears:
When it is hardly possible for the blood pump to run.

Machine actions:
The blood pump stops.

Measures:
Check that the blood pump segment is correctly positioned, see Arterial Blood Line - Attach on page 4:16 in part 1 for instructions. When properly positioned, press the *Select key*.
If the attention alarm appears again, call an authorized technician.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Soft buzzer

```
BLOOD PUMP STOP TIME EXPIRED
Start blood pump
```

Appears:
When the blood pump has been stopped for more than 1 min. .

Machine actions:
None

Measures:
Start the blood pump.

Mute time:
2 min.

Buzzer sound:
Continuous buzzer

```
BPM FAILURE
Turn off BPM
```

Appears:
When an error is detected by the BPM.

Machine actions:
None

Measures:
Press *BPM button* to clear the attention alarm. If the attention alarm recurs, call for an authorized technician.

Mute time:
Permanently muted buzzer

Buzzer sound:
Soft buzzer

```
BPM MENU HAS BEEN CLOSED
CHANGE HAS BEEN EXECUTED
```

Appears:
Parameter change has been made without confirming, using the *Select key*.
The appearance of the attention alarm can be preset.

Machine actions:
The machine has automatically confirmed the change.

Measures:
Check that the changed parameter is correct. The attention alarm will automatically disappear after it has been displayed.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
CENTRAL CHEM DISINF. COMPLETED
Press SELECT key to continue
```

Appears:
When the dwell time in central disinfection has passed.

Machine actions:
None

Measures:
Press the *Select key* to continue.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Supersoft buzzer

```
Check rotor/tube distance
Press SELECT key to confirm
```

Appears:
After a change of the blood pump segment has been made.

Machine actions:
None.

Measures:
See "Change of Blood Pump Segments" on page 3:33 in part 1 and confirm the attention alarm.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
CHEMICAL FILLUP NOT SUFFICIENT
Check supply of disinfectant
```

Appears:
During chemical disinfection program, in fill-up phase.

Machine actions:
The disinfection program is interrupted.

Measures:
Check the pick-up tube and the disinfectant container.
Machine retries the fill-up phase.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Supersoft buzzer

```
CleanCart FILL COMPLETED
Open upper latch, Press SELECT
```

Appears:
During heat disinfection program with CleanCart cartridge.

Machine actions:
None

Measures:
Open the upper latch of the BiCart holder and press the *Select key*. See also in the instructions for "Heat Disinfection Program with CleanCart® cartridge - Performing" on page8:13 in part 1. This attention alarm can be removed by preset.

Mute time:
Permanently muted buzzer

Buzzer sound:
Supersoft buzzer

```
CleanCart NOT ATTACHED TO HOLDER
Attach or check CleanCart
```

Appears:
During heat disinfection program with CleanCart cartridge. The CleanCart cartridge is not, or is not properly, attached to the Bicart holder.

Machine actions:
Buzzer is activated 1 min. after attention alarm is generated.

Measures:
Open the latches of the BiCart holder and place the CleanCart cartridge in the holder or check that it has been properly attached to the holder. See also in the instructions for "Heat Disinfection Program with CleanCart® cartridge - Performing" on page 8:13 in part 1.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Supersoft buzzer

```
CLEANING REQUIRED
hours since last cleaning   ###
```

Appears:
When a cleaning program is needed.

Machine actions:
None.

Measures:
If possible, run a cleaning program, i.e. a heat disinfection program with CleanCart-A cartridge or a chemical disinfection program with sodium hypochlorite. If not, the attention alarm can be cleared by pressing the *Select key*. If the machine is not disinfected after treatment, the attention alarm will reappear during the next treatment.
The period of time between the last performed cleaning and the appearance of the attention alarm can be preset.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Soft buzzer

```
Clearance TOO LOW
Press SELECT
```

Appears:
The measured clearance value is below the alarm limit set.

Machine actions:
None.

Measures:
Check cause, adjust treatment parameters to increase clearance or adjust the alarm limit for clearance.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Soft buzzer

```
Connect concentrate when time to
prepare machine for treatment
```

Appears:
During function check when the concentrates have not been connected to the machine.

Machine actions:
The function check is stopped. When the concentrates have been connected, the function check will automatically continue. See "Connect/Confirm Concentrates" on page 4:7 in part 1 for instructions.

Measures:
Connect the selected concentrate to the machine.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Soft buzzer

```
DECALCIFICATION REQUIRED
hours since last decalcific.###
```

Appears:
When a decalcification program is needed.

Machine actions:
None.

Measures:
If possible, run a decalcification program, i.e. a heat disinfection program with CleanCart-C cartridge or liquid citric acid. If not, the attention alarm can be cleared by pressing the *Select key*. If the machine is not disinfected after treatment, the attention alarm will reappear during the next treatment.
The period of time between the last performed decalcification and the appearance of the attention alarm can be preset.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Supersoft buzzer

DIALYSIS FLUID FLOW TOO LOW

Appears:
Appears during treatment when the dialysis fluid flow rate is too low. The dialysis fluid flow rate has been set below the low alarm limit or there is an obstruction in the dialysis fluid flow path.

Machine actions:
None.

Measures:
If possible, increase the dialysis fluid flow rate.
If this is not possible, consult an authorized technician.
It is possible to mute the buzzer by pressing the *Mute button*, but if the attention alarm is left without taking measures, it will reappear the next treatment.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Soft buzzer

```
DIALYSIS FLUID NOT READY FOR
TREATMENT. FLUID READY IN $## s
```

Appears:
When the dialysis fluid tubes are disconnected from the machine too soon after the function check has been finished.

Machine actions:
Automatic flush of the flow path where the ultrafilter is placed is performed.

Measures:
Wait until the attention alarm has disappeared and the bypass path of the Flow Diagram lights up green before disconnecting the dialysis fluid tubes, as there is a high fluid flow through the fluid tubes. The period of time for the appearance of the attention alarm is dependent on the dialysis fluid flow rate .

Mute time:
-

Buzzer sound:
No buzzer

```
DIALYSIS FLUID READY
Press FLUID BYPASS button
```

Appears:
When the function check is complete and the dialysis fluid is correct (the dialysis fluid path lights up green). The appearance of the attention alarm can be preset.

Machine actions:
None.

Measures:
Press the *Fluid bypass button* to flush the dialysis fluid tubes for 30 seconds.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
Diascan FAILURE
Turn OFF Diascan
```

Appears:
Appears when too many Diascan steps have been done during that particular treatment.

Machine actions:
None.

Measures:
Performing further Diascan steps may lead to an imbalance in the sodium level of the patient. The Diascan function is not permitted to perform any more measurement checks. Turn Diascan function off. Contact an authorized technician.
If this attention alarm appears frequently, discuss preset limits with an authorized technician.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Soft buzzer

```
DIASCAN IS NOT RESTARTED
Check settings and activate
```

Appears:
When treatment is resumed after the dialyzer and the blood lines have been changed during treatment.

Machine actions:
The Diascan function has been automatically deactivated.

Measures:
Press the *Fluid Path button*, select `DIASCAN` and then `SET DIASCAN` using the *Keypad*. Check that the set Diascan parameter values are the correct ones, adjust if necessary. Restart the Diascan function by pressing the *Select key* for 3 seconds.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
Diascan MEASUREMENT FAILED
Press SELECT key to confirm
```

Appears:
The machine was not able to perform the measurement check.

Machine actions:
If a single Diascan measurement check has been activated it will automatically be deactivated; the Diascan function is turned off.
If continuous Diascan measuring has been activated, the current Diascan measurement check will automatically be deactivated. The Diascan function will continue to be on and the following measurement checks will continue as set.

Measures:
Confirm the machine actions by pressing the *Select key*.
If desired, reactivate the single Diascan measurement check.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Soft buzzer

```
Diascan NOT POSSIBLE during
UF STEP/INTERVAL profiling
```

Appears:
During an attempt to activate the Diascan function when UF profiling in steps or intervals is active, or when an attempt to activate UF profiling in steps or intervals is made and Diascan measuring has previously been activated.

Machine actions:
The Diascan function is not available in combination with UF profiling in steps or intervals. The Diascan function will automatically be de-activated.

Measures:
- Note that the Diascan function is no longer active.
- The attention alarm automatically disappears after 30 seconds.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Soft buzzer.

```
Diascan PAUSED
during isolated UF
```

Appears:
During an attempt to activate the Diascan function during on-going isolated UF phase or, when an attempt to start a Diascan measurement check is made (single or continuous measuring) during on-going isolated UF phase.

Machine actions:
The Diascan measuring will automatically be paused during the Isolated UF phase as the Diascan function cannot perform measurement checks during the isolated UF phase. Diascan measurement will start automatically when the isolated UF phase is complete.

Measures:
- Note that the Diascan measuring will automatically be activated and rescheduled when the Isolated UF phase is complete, without further attention alarms.
- The attention alarm automatically disappears after 30 seconds.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Soft buzzer.

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```
Diascan RESCHEDULED TWICE
Press SELECT key to confirm
```

Appears:
Appears when two Diascan measurement checks in a row has been interrupted by any of the following actions:

- the blood flow rate is changed
- the *Blood pump button* is pressed
- the *Start UF Stop button* is pressed
- the *Fluid bypass button* is pressed
- a treatment alarm which produces dialysis fluid bypass or blood pump stop is generated
- sodium and bicarbonate (conductivity) of the dialysis fluid is changed
- temperature of the dialysis fluid is changed
- dialysis fluid flow rate is changed
- UF volume is changed
- linear UF profiling settings is changed
- linear UF profiling activation/deactivation is made
- sodium or bicarbonate profiling activation/deactivation is made
- isolated UF activation is made

The machine was not able to completely perform the measurement check as the measurement check has been interrupted.

Machine actions:
None.

Measures:
Confirm by pressing the *Select key* and the machine will automatically reschedule measuring as soon as possible.

Mute time:
No buzzer

```
DISCONNECT ARTERIAL PRESSURE
Press ARTERIAL button to confirm
```

Appears:
When the arterial pressure transducer of the arterial blood line has been attached too early in function check. See "Arterial Blood Line - Attach" on page 4:16 in part 1 for information.

Machine actions:
None.

Measures:
Disconnect the arterial pressure transducer and press *Arterial button* to confirm.
If the attention alarm is still generated, consult an authorized technician.

Mute time:
5 min.

Buzzer sound:
Soft buzzer

```
DISCONNECT VENOUS PRESSURE
Press VENOUS button to confirm
```

Appears:
When the venous pressure transducer of the venous blood line has been attached too early in function check. See "Venous Blood Line - Attach" on page 4:28 in part 1 for information.

Machine actions:
None.

Measures:
Disconnect the venous pressure transducer and press *Venous button* to confirm.
If the attention alarm is still generated, consult an authorized technician.

Mute time:
5 min.

Buzzer sound:
Soft buzzer

```
Disinfection IN PROGRESS
No change is possible
```

Appears:
When making an attempt to set treatment parameters during ongoing disinfection program.

Machine actions:
-

Measures:
Press the *Mute button*. The attention alarm disappears automatically when the attention alarm text has been selected in the `*** ATTENTION LIST ***` displayed on the Information Display.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Soft buzzer

```
DISINFECTION REQUIRED
days since last disinfection###
```

Appears:
When a heat disinfection program is needed.

Machine actions:
None.

Measures:
If possible, run a heat disinfection program. If not, the attention alarm can be cleared by pressing the *Select key*. If the machine is not disinfected after treatment, the attention alarm will reappear during the next treatment. The period of time between the last performed disinfection and the appearance of the attention alarm can be preset.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Supersoft buzzer

```
FCH IS WAITING
Attach conc connectors to ports
```

Appears:
During function check if a chemical disinfection program has previously been performed and the concentrate connectors (or disinfectant connector) are not properly connected to the machine.

Machine actions:
Function check is interrupted.

Measures:
Check that the concentrate connectors are properly connected to the stand-by ports. Check that the disinfectant connector is properly connected to the parking port. It is not possible to connect the concentrates yet.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
FCH IS WAITING
Close or check BiCart holder
```

Appears:
During function check if a chemical disinfection program has previously been performed and the latches of the BiCart holder are open.

Machine actions:
Function check is interrupted.

Measures:
Close the latches of the BiCart holder. It is not possible to connect the BiCart cartridge yet.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
FCH IS WAITING
INLET WATER TEMP IS TOO HIGH
```

Appears:
If inlet water temperature is too high during function check.

Machine actions:
Function check is interrupted. When inlet water temperature has decreased the function check will automatically continue.

Measures:
Check possible cause:
- Inlet water temperature has not decreased below 45 °C within 5 minutes after the high temperature test is started.
- Inlet water temperature has not decreased below 39 °C within 5 minutes after the high temperature test is finished.

If attention does not disappear, call for an authorized technician.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Super soft buzzer

```
FCH PROLONGED DUE TO CHEM TESTS
Do not connect conc. or BiCart
```

Appears:
In function check if a chemical disinfection program has previously been performed.

Machine actions:
Ongoing chemical valve leakage test.

Measures:
Wait for the machine test to be finished, to be able to connect the concentrates. It is possible when the attention alarm text has disappeared.

Mute time:
-

Buzzer sound:
No buzzer

```
FLUID BYPASS TIME EXPIRED
Press FLUID BYPASS button
```

Appears:
Appears 5 min. after the dialysis fluid has been bypassed; the *Fluid Bypass button* button has been pressed.

Machine actions:
None

Measures:
Press the *Fluid Bypass button*.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
FLUID PATH MENU HAS BEEN CLOSED
CHANGE HAS BEEN EXECUTED
```

Appears:
Parameter change has been made without confirming, using the *Select key*.
The appearance of the attention alarm can be preset.

Machine actions:
The machine has automatically confirmed the change.

Measures:
Check that the changed parameter is correct. The attention alarm will automatically disappear after it has been displayed.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
FLUID PATH OBSTRUCTION
Check fluid tubes and dialyzer
```

Appears:
The machine has detected an obstruction in the fluid path.

Machine actions:
None.

Measures:
Check if the obstruction is external i.e. if it involves the dialysis fluid tubes or the dialyzer. This is done by pressing the *Fluid bypass button*. If the attention alarm disappears, the obstruction is external. Check dialysis fluid tubes and dialyzer for possible obstruction.
If the attention alarm does not disappear, the obstruction is internal. Call an authorized technician.

Mute time:
2 min.

Buzzer sound:
Continuous buzzer

```
FLUID TUBE SENSOR TEST
Attach tubes to safety bypass
```

Appears:
When a disinfection or rinse program has been activated and the dialysis fluid tube sensor test has been interrupted.

Machine actions:
None.

Measures:
Remove and attach the dialysis fluid tubes from the safety couplings of the machine to restart the test.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
FLUID TUBE SENSOR TEST FAILED
Press SELECT key to confirm
```

Appears:
It was not possible for the machine to restart the dialysis fluid tube sensor test.

Machine actions:
None.

Measures:
To be able to continue the activated disinfection or rinse program; manually check that the dialysis fluid tubes are properly attached to the safety couplings of the machine. Confirm this by pressing the *Select key* and the dialysis fluid tube sensor test will be bypassed.
Alternately, consult the authorized technician responsible for the machine.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
FLUID TUBE SENSOR TEST
Remove tubes from safety bypass
```

Appears:
When a disinfection or rinse program has been activated and the dialysis fluid tube sensor test has been interrupted.

Machine actions:
None.

Measures:
Remove and attach the dialysis fluid tubes from the safety couplings of the machine to restart the test.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
FLUID TUBES IN SAFETY BYPASS
Connect fluid tubes to dialyzer
```

Appears:
This attention alarm can appear for three different reasons:

1. If the dialysis fluid tubes are still connected to the safety couplings and blood is detected by the priming detector.
2. If the dialysis fluid tubes are reconnected to the safety couplings during treatment. Buzzer is activated 5 min. after attention alarm is generated.
3. During assisted priming if the dialysis fluid tubes are still connected to the safety couplings and they are expected to be connected to the dialyzer.

Machine actions:
None

Measures:
Move the dialysis fluid tubes from the safety couplings to the dialyzer.

Mute time:
1. 2 min.

2. 2 min.

3. Permanently muted buzzer.

Buzzer sound:
1. Soft buzzer

2. Supersoft buzzer

3. Soft buzzer

```
FLUID TUBES NOT IN SAFETY BYPASS
Connect tubes to safety bypass
```

Appears:
When the dialysis fluid tubes have been removed from the safety couplings, during function check or during disinfection program.

Machine actions:
Function check is interrupted.

Measures:
Reconnect the dialysis fluid tubes to the safety couplings. If a disinfection or rinse program has been started, check that the dialysis fluid tubes are properly connected to the safety couplings.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
FLUID PATH OBSTRUCTION
DURING DISINFECTION
```

Appears:
If a obstruction in the fluid path has been detected during disinfection.

Machine actions:
Disinfection is aborted and the dialysis fluid pumps are stopped. Drain is automatically performed when pressure has decreased.

Measures:
Wait until drain is finished.
- Check if the obstruction is external, i.e. the fluid tubes is clamped.
- If equipped with UFD, check the UFD-filter.

Restart the disinfection. If the attention alarm recurs, call for an authorized technician.

Mute time:
5 min.

Buzzer sound:
Soft buzzer.

```
FUNCTION CHECK PROLONGED DUE TO
POWER FAILURE
```

Appears:
During power failure.

Machine actions:
Function check will be delayed until power returns.

Measures:
Please wait.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Supersoft buzzer

```
FUNCTION CHECK PROLONGED DUE TO
WRO
```

Appears:
During function check when the WRO is inaccessible.

Machine actions:
None.

Measures:
Please wait.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Supersoft buzzer

```
FUNCTION CHECK RESTARTED
Press SELECT key to confirm
```

Appears:
The function check has been prolonged due to internal tests.

Machine actions:
Function check is restarted and therefore prolonged.

Measures:
-

Mute time:
-

Buzzer sound:
No buzzer

```
HEATER EFFICIENCY NOT SUFFICIENT
Press SELECT key to confirm
```

Appears:
When it is not possible for the machine to reach the required temperature during the heat disinfection program.

Machine actions:
None

Measures:
Press *Select key* to confirm that the ongoing disinfection program is insufficient (too low temperature). Let the machine pass the ongoing program and thereafter start a new heat disinfection program.
If the attention alarm reappears, consult an authorized technician.

Mute time:
2 min.

Buzzer sound:
No buzzer

```
HEPARIN FLOW RATE SET TO ZERO
Press SELECT key to confirm
```

Appears:
When the heparin solution flow rate is set to zero.

Machine actions:
Buzzer is activated 2 min. after attention alarm is generated.

Measures:
Press the *Select key* to confirm that the heparin pump is not going to be used for the treatment.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
HEPARIN PUMP OVERLOAD
Check cause
```

Appears:
When the pressure in the syringe is too high.

Machine actions:
The heparin pump stops.

Measures:
Check the syringe and the thin line connected to the syringe for kinks. See Heparin Pump in "Arterial Blood Line - Attach" starting on page 4:16 in part 1 for instructions.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
HCO3- setting has been changed
Press SELECT key to confirm
```

Appears:
When treatment is resumed after the dialyzer and the blood lines have been changed during treatment.

Machine actions:
The machine has automatically reactivated the previously set bicarbonate profiling setting.

Measures:
Press the *Fluid Path button*, select `COND` and `PROFILING` using the *Keypad*. Check that the start and stop values for `HCO3` are the correct ones, press the *Select button* to confirm this. If not, select `HCO3` and deactivate profiling. Change the values and reactivate profiling as usual procedure. See corresponding instructions in chapter 7 "Profiling" in part 1.

Mute time:
2 min.

Buzzer sound:
No buzzer

```
HIGH CONDUCTIVITY NOT OBTAINED
Check concentrate
```

Appears:
During function check if incorrect conductivity is obtained.

Machine actions:
None

Measures:
Check that the red concentrate connector is properly connected to the pick-up tube and the concentrate container, see "Connect/Confirm Concentrates" on page 4:7 in part 1 for instructions. Check also that the correct concentrate has been connected.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Soft buzzer

```
HIGH INLET WATER COND.  #.#mS/cm
Check inlet water
```

Appears:
During function check if the inlet water conductivity is too high (higher than 2.5 mS/cm).
The appearance of the attention alarm can be preset.

Machine actions:
A technical alarm is generated.

Measures:
Consult an authorized technician.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Supersoft buzzer

```
HIGH INLET WATER COND.  #.#mS/cm
Confirm low K+, press SELECT key
```

Appears:
Appears during function check if the inlet water conductivity is between 0.5 and 2.5 mS/cm. The appearance of the attention alarm can be preset.

Machine actions:
Depending on the inlet water conductivity, minor electrolytes concentration (potassium, calcium, magnesium) will be reduced by 4 - 20% in the dialysis fluid.

Measures:
When this attention alarm appears, the operator must consult the attending physician before the attention alarm is confirmed and a treatment is started. It will not be possible to start a treatment until the attention alarm is confirmed.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
HIGH MONITOR TEMPERATURE ALARM
Turn off the monitor
```

Appears:
When internal monitor temperature exceeds 58 °C.

Machine actions:
None

Measures:
Consult an authorized technician. The air filter may be filled with dust.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Soft buzzer

```
HIGH VENOUS PRESS TEST NOT MADE
Apply ven press >50mmHg for test
```

Appears:
During priming or when treatment has been started and the machine has not been able to test the venous pressure measurement function.

Machine actions:
10 minutes after blood has been detected the treatment will stop if the attention alarm is left unattended.

Measures:
Establish a stable venous pressure over 50 mmHg until the attention alarm disappears.

Mute time:
2 min.

Buzzer sound:
Continuous buzzer 5 min after blood detection

```
IMPOSSIBLE AUTO START SETTING
Check auto heat/rinse ready time
```

Appears:
When the machine is switched off and the time for when the heat disinfection program or rinse program is set to be finished is too close to present time.

Machine actions:
The machine will not be switched off until the time setting has been changed.

Measures:
Change the time setting for when the rinse program or heat disinfection program is set to be finished.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
IMPOSSIBLE TIME OR UF SETTING
Adjust TIME or UFV
```

Appears:
When a too high UF volume has been set in combination with the set treatment time.

Machine actions:
Buzzer is activated 2 min. after attention alarm is generated.

Measures:
Adjust Time, `SET TIME`, or UF volume, `SET UF`, until the calculated UF rate is lower than the high limit for UF rate.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

IMPROPER POSITION OF CHEMICAL DISINFECTANT CONNECTOR

Appears:
When the chemical disinfectant connector is not in the correct position.

Machine actions:
Buzzer activated immediately. If the attention alarm is active during function check when the chemical valve leakage test is performed the function check will stop. If the attention alarm is active during priming or treatment the correct dialysis fluid can not be prepared.

Measures:
Check the placement of the yellow disinfectant connector.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
IMPROPER POSITION OF PICK UP
TUBE A
```

Appears:
When the red concentrate connector is not in the correct position.

Machine actions:
Buzzer is activated 2 min. after attention alarm is generated.

Measures:
Check the placement of the red concentrate connector.

Mute time:
5 min.

Buzzer sound:
Supersoft buzzer

```
IMPROPER POSITION OF PICK UP
TUBE B/ACETATE
```

Appears:
When the blue concentrate connector is not in the correct position.

Machine actions:
Buzzer is activated 2 min. after attention alarm is generated.

Measures:
Check the placement of the blue concentrate connector.

Mute time:
5 min.

Buzzer sound:
Supersoft buzzer

```
INCORRECT ACIDIC CONCENTRATE
Check concentrate
```

Appears:
When the selected concentrate does not match the concentrate connected to the machine.

Machine actions:
The dialysis fluid is bypassed from the dialyzer.

Measures:
Check concentrate selection and that the proper concentrate has been connected. See "Connect/Confirm Concentrates" on page 4:7 in part 1 for instructions.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
INCORRECT BICARB. CONCENTRATE
Check concentrate
```

Appears:
When the selected concentrate does not match the concentrate connected to the machine.

Machine actions:
The dialysis fluid bypasses the dialyzer.

Measures:
Check concentrate selection and that the proper concentrate has been connected. See "Connect/Confirm Concentrates" on page 4:7 in part 1 for instructions.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
INCORRECT CONCENTRATE
Check concentrate
```

Appears:
When the selected concentrate does not match the concentrate connected to the machine.

Machine actions:
The dialysis fluid bypasses the dialyzer.

Measures:
Check concentrate selection and that the proper concentrate has been connected. See "Connect/Confirm Concentrates" on page 4:7 in part 1 for instructions.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
INCORRECT DIA FLUID COMPOSITION
Check concentrates
```

Appears:
If the dialysis fluid composition deviation (the relation between the acidic and the bicarbonate concentrate) is too high.

Machine actions:
The dialysis fluid bypasses the dialyzer.

Measures:
Check concentrate selection and that the proper concentrate has been connected. See "Connect/Confirm Concentrates" on page 4:7 in part 1 for instructions.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
INCORRECT LANGUAGE SELECTION
Call service to correct language
```

Appears:
Selected language is not available as operator language.

Machine actions:
The machine uses English temporarily as operator language instead of the selected language.

Measures:
Contact an authorized technician.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Soft buzzer

```
INSUFFICIENT INLET PRESSURE
Check water supply
```

Appears:
When the water supply pressure is too low.

Machine actions:
Buzzer is activated 5 min. after attention alarm is generated in priming phase but immediately when attention alarm is generated in disinfection or treatment phase.

Measures:
Check water supply.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
Kt/V FORECAST TOO LOW
```

Appears:
Kt/V forecast value is below the Kt/V alarm limit set.

Machine actions:
None

Measures:
Check cause, adjust treatment parameters or adjust the alarm limit for Kt/V.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Soft buzzer

```
Kt/V TARGET REACHED
Press SELECT key to confirm
```

Appears:
The set target value for Kt/V has been reached.

Machine actions:
None.

Measures:
Confirm by pressing the *Select key*. It is also possible to increase the Kt/V target value, and the machine will recalculate time to target.

Mute time:
Permanently muted buzzer.

Buzzer sound:
No buzzer

```
LOW BATTERY POWER
Machine turns off within one min
```

Appears:
During power failure when the battery power is too low.

Machine actions:
The machine will automatically be stopped. Power failure buzzer will appear.

Measures:
Consider manually discontinuing the treatment, see "Power Failure" on page 3:27 in part 1 for instructions.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Soft buzzer

```
LOW FLOW HEAT ABORTED
Press SELECT key to confirm
```

Appears:
When the WRO 300 H cannot deliver hot water during integrated heat disinfection program with WRO 300 H. The low flow heat phase (where the machine receives hot water from the WRO 300 H) will not start.
It can also appear during manual start procedure of the low flow heat phase when the attention alarm `Start low flow heat in WRO`, `Press SELECT key to continue`, has not been confirmed within 5 minutes  .

Machine actions:
The low flow heat phase has automatically been cancelled.

Measures:
Press the *Select key* to confirm the attention alarm. The machine now enters drain phase as the circulation phase (for information, see in "Heat Disinfection - General" on page 8:9 in part 1) of the heat disinfection program is complete. Call for an authorized technician.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Supersoft buzzer

```
LOW FLOW HEAT NOT AVAIL. IN WRO
Press SELECT key to confirm
```

Appears:
When attempting to start integrated heat disinfection program with WRO 300 H, without a WRO model which supports low flow heat (where the machine receives hot water from the WRO 300 H).

Machine actions:
None.

Measures:
Press the *Select key*. to confirm.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Supersoft buzzer

```
Na+ setting has been changed
Press SELECT key to confirm
```

Appears:
When treatment is resumed after the dialyzer and the blood lines have been changed during treatment.

Machine actions:
The machine has automatically reactivated the previously set sodium profiling setting.

Measures:
Press the *Fluid Path button*, select COND and PROFILING using the *Keypad*. Check that the start and stop values for NA are the correct ones, press the *Select button* to confirm this. If not, select NA and deactivate profiling. Change the values and reactivate profiling as usual procedure. See corresponding instructions in chapter 7 "Profiling" in part 1.

Mute time:
2 min.

Buzzer sound:
No buzzer

```
NEGATIVE UF RATE
Check cause and press SELECT key
```

Appears:
When there is a backfiltration of 500 ml to the patient or a backfiltration rate >50 ml/min for 5 min.

Machine actions:
None.

Measures:
Check the outlet tube (the tube where the spent dialysis fluid flows out from the machine) for obstructions. If there are obstructions, remove them and press the *Select key* to confirm the removal. Check the UF rate is correct before leaving the machine, if not call an authorized technician.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

CAUTION

Incorrect weight loss may occur if the machine is left for a longer period with this attention.

CAUTION

```
NEW ULTRA FILTER REQUIRED
days since last change.     ###
```

Appears:
When the ultrafilter needs to be replaced because the limit for number of days since last change has been exceeded.

Machine actions:
None.

Measures:
Replace the ultrafilter and confirm that the ultrafilter has been replaced.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Supersoft buzzer.

```
NEW ULTRA FILTER REQUIRED
disinf. since last change   ###
```

Appears:
When the ultrafilter needs to be replaced because the limit for number of disinfections since last change has been exceeded.

Machine actions:
None.

Measures:
Replace the ultrafilter and confirm that the ultrafilter has been replaced.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Supersoft buzzer.

```
NEW ULTRA FILTER REQUIRED
hypochl. since last change  ###
```

Appears:
When the ultrafilter needs to be replaced because the limit for number of hypochlorite disinfections since last change has been exceeded.

Machine actions:
None.

Measures:
Replace the ultrafilter and confirm that the ultrafilter has been replaced.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Supersoft buzzer.

```
NO BACKFILTRATION WARNING
Press SELECT key to confirm
```

Appears:
When the low TMP alarm limit is set below zero.

Machine actions:
None.

Measures:
Since the TMP alarm limits have been set below zero there may be backfiltration to the patient without TMP alarm.
The appearance of the attention alarm can be preset.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
NO BPM VALUES
Check BPM cuff
```

Appears:
It was not possible to measure the patient's blood pressure.

Machine actions:
Buzzer delayed 2 min.

Measures:
Check that the cuff is correctly applied to the patient. It could also be that the patient is moving during the measurement check.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Soft buzzer

```
NO CHANGE IN BLOOD PRESSURE
Check cause, press BLOODPUMP btn
```

Appears:
The venous pressure is not fluctuating in accordance with the arterial and venous phases during single needle treatment.

Machine actions:
None.

Measures:
Check venous blood line for possible kinks or forgotten clamps.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
NO CUFF ATTACHED
Attach or check BPM cuff
```

Appears:
When the machine registers that no cuff is applied to the patient.

Machine actions:
Buzzer delayed 2 min.

Measures:
Check for kinks or leakage from the cuff and the cuff hose. Check also that the cuff hose is properly connected to the machine.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Soft buzzer

```
POWER FAILURE, BATTERY OPERATION
Battery operated for $# minutes
```

Appears:
During power failure when battery back-up is operating, the displayed minutes indicate the duration of the power failure.

Machine actions:
Only the blood unit will run after a power failure.

Measures:
-

Mute time:
Permanently muted buzzer.

Buzzer sound:
Soft buzzer

```
Press SELECT key to enter
BPM history list
```

Appears:
When a single blood pressure measurement check is finished.

Machine actions:
None

Measures:
Press *Select key* to display the BPM log list.

Mute time:
No buzzer

Buzzer sound:
No buzzer

```
Press SELECT to enter
Diascan log list
```

Appears:
When a Diascan measurement is finished.

Machine actions:
None.

Measures:
Press the *Select key* to display the Diascan log list.

Mute time:
Permanently muted buzzer.

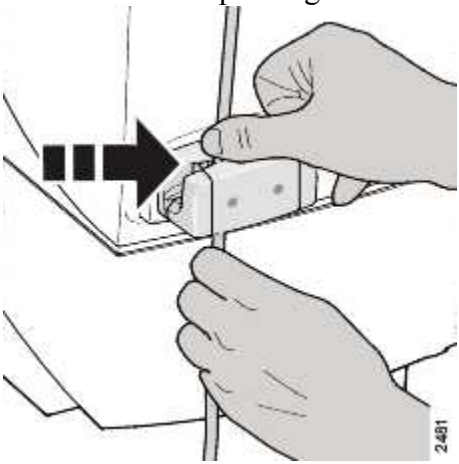
Buzzer sound:
No buzzer

```
PRIMING VOLUME LIMIT ACHIEVED
Check blood line. Press SELECT
```

Appears:
When the extra priming volume limit has been reached. This attention alarm can be removed by preset.

Machine actions:
None.

Measures:
If this attention alarm appears during initiation of the treatment, check that the venous blood line is properly inserted into the priming detector.



Press *Select key* to confirm.

Mute time:
2 min

Buzzer sound:
Soft buzzer

```
PROFILING IS NOT RESTARTED
Check settings and activate
```

Appears:
When treatment is resumed after the dialyzer and the blood lines have been changed during treatment.

Machine actions:
The machine runs with the conductivity and/or the UF rate settings present when `NEW BLOOD CIRCUIT` was selected and discontinuing mode was activated.

Measures:
Check current set values for the previously activated profiling. reactivate Press the *Fluid Path button*, select `COND` and/or `UF` using the *Keypad*. Check that the start and stop values for the profiling type are the correct ones, if not change the values. Reactivate the profiling function as usual procedure. See corresponding instructions in chapter 7 "Profiling" in part 1.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
RECOVERED FROM POWER FAILURE
Press SELECT key to confirm
```

Appears:
When the machine has recovered from power failure.

Machine actions:
None.

Measures:
Press the *Select key*. The Time Display shows “reC” until the *Select key* has been pressed. See Recovery from Machine Shut Down" on page 3:29 in part 1 for further information.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
PV AND QD SETTING IN CONFLICT
Increase Qd to 500 ml/min
```

Appears:
When the set UF rate cannot be obtained due to that the current venous pressure and the set dialysis fluid flow rate is in conflict.

Machine actions:
The dialysis fluid is bypassed from the dialyzer.

Measures:
If possible, increase dialysis fluid flow rate to at least 500 ml/min by pressing the *Fluid Path button* and selecting `DIA FLUID FLOW`. Adjust `SET TREATMENT DIA FLUID FLOW` using the *Keypad*.
If it is not possible to increase the dialysis fluid flow rate, if possible decrease the venous pressure and wait (maximum 5 minutes) until the dialysis fluid enters the dialyzer again.
If the attention alarm reappears consider discontinuing the treatment.

Mute time:
5 min.

Buzzer sound:
Soft buzzer

```
Remove tubes from safety bypass
Press SELECT to abort the test
```

Appears:
It was not possible for the machine to restart the dialysis fluid tube sensor test.

Machine actions:
None.

Measures:
To be able to continue the activated disinfection or rinse program; manually check that the dialysis fluid tubes are properly attached to the safety couplings of the machine. Confirm this by pressing the *Select key* and the dialysis fluid tube sensor test will be bypassed.
Alternately, consult the authorized technician responsible for the machine.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
RINSE/DIS MENU HAS BEEN CLOSED
CHANGE HAS BEEN EXECUTED
```

Appears:
Change has been made without confirming, using the *Select key*.
The appearance of the attention alarm can be preset.

Machine actions:
The machine has automatically confirmed the change.

Measures:
Check that the changed setting is correct. The attention alarm will automatically disappear after it has been displayed.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
SAGS TEST FAILED
Check water supply
```

Appears:
During disinfection program, when the machine cannot maintain the pressure required at the dialysis fluid tube connectors.

Machine actions:
The disinfection program stops.

Measures:
Check if the AK 96 dialysis machine is properly connected to the water supply.

Mute time:
Permanently muted buzzer.

Buzzer sound:
No buzzer

```
SET DIA FLUID FLOW NOT REACHED
Readjust flow or call service
```

Appears:
Current dialysis fluid flow rate (ACTUAL DIA FLUID FLOW) does not correspond with the set value (SET TREATMENT DIA FLUID FLOW). It is not possible for the machine to set the required dialysis fluid flow rate.

Machine actions:
None.

Measures:
If it is possible for the treatment to continue with a lower flow, adjust the set value to correspond with the current value; the attention alarm will disappear.
If this is not possible, consult an authorized technician.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Soft buzzer

```
Start heat in WRO
Press SELECT key to confirm
```

Appears:
When it is time to manually start the heat program in the WRO.

Machine actions:
None.

Measures:
Press the *Select key*.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Supersoft buzzer

```
Start low flow heat in WRO
Press SELECT key to continue
```

Appears:
When it is time to manually start the low flow heat program in the WRO.

Machine actions:
None.

Measures:
Press the *Select key*.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Supersoft buzzer

```
TIME MENU HAS BEEN CLOSED
CHANGE HAS BEEN EXECUTED
```

Appears:
Change has been made without confirming, using the *Select key*.
The appearance of the attention alarm can be preset.

Machine actions:
The machine has automatically confirmed the change.

Measures:
Check that the changed setting is correct. The attention alarm will automatically disappear after it has been displayed.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
TMP LIMITS TOO WIDE
Press SELECT key to confirm
```

Appears:
The TMP alarm window is wider than the preset value.

Machine actions:
None.

Measures:
Press the *Select key* to centralize the alarm limits around the current value. This text will appear at any time during treatment when the blood pump has been started or stopped, the ultrafiltration has been activated or deactivated, or when changes of treatment time and UF volume have been made.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

`To end treatment, zero time in isolated UF`

Appears:
Appears if the treatment time is turned down to zero and there is still time left in `ISOL UF`.

Machine actions:
None.

Measures:
Set `ISOL UF` time to zero or increase the treatment time.

Mute time:
-

Buzzer sound:
-

```
To obtain total UFV
ISOL UF must be started
```

Appears:
2 minutes before the diffusion phase is complete.

Machine actions:
None.

Measures:
Isolated UF must be started for the machine to be able to obtain the total UF volume within the set treatment time. Start isolated UF or adjust isolated UF time or treatment time.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Soft buzzer

```
To start the air detector test:
Fill the venous drip chamber
```

Appears:
During the beginning of the priming procedure when the venous drip chamber has not yet been filled.

Machine actions:
None.

Measures:
Fill up the level in the venous drip chamber (while the blood pump is running) using the level adjustment knob (anticlockwise direction). Adjust the level so it is well above the air detector head. When filled, the machine finalizes the function check and the set treatment time will appear on the Time Display (on condition that bypass path of the Flow Diagram is green). For information on the additional activation of the air detector alarm function, see in the instructions for the type of priming procedure being used in chapter 4.

Mute time:
-

Buzzer sound:
No buzzer

```
TOO HIGH TMP REQUIRED
Increase time or decrease UFV
```

Appears:
When the machine cannot maintain the required UF rate.

Machine actions:
Buzzer is activated 2 min. after attention alarm is generated.

Measures:
Check the dialyzer; too small/partly clotted, and do necessary actions in accordance with this. If possible, adjust set Time and/or set UF volume until TMP decreases.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
TREATMENT TIME EXPIRED
Press SELECT key to confirm
```

Appears:
When treatment is finished.

Machine actions:
None.

Measures:
Press the *Select key* to confirm end of treatment. See "Discontinuing" on page 4:59 in part 1 for discontinuing instructions.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Supersoft buzzer

```
TREATMENT WILL STOP IN 2 MINUTES
HIGH VENOUS PRESS TEST NOT MADE
```

Appears:
After 8 minutes in treatment, if the machine has not been able to test the venous pressure measurement function. This is due to that the venous pressure has not exceeded 50 mmHg during the priming procedure.

Machine actions:
The blood pump and the ultrafiltration will be automatically stopped 2 minutes after this attention alarm has been generated.

Measures:
Discontinue treatment. Contact authorized technician.

Mute time:
2 min.

Buzzer sound:
Continuous buzzer

```
UF RATE LIMIT REACHED
Re-adjust TIME or UFV
```

Appears:
When the current UF rate differs more than 20 % from the initially calculated UF rate.

Machine actions:
Buzzer is activated 2 min. after attention alarm is generated.

Measures:
Adjust Time and/or UF volume to allow the machine to calculate a new UF rate.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
UF VOLUME ACHIEVED TOO EARLY
Press SELECT key to confirm
```

Appears:
When the set UF volume (`SET UF`) has been achieved and the remaining treatment time is more than 20 minutes.

Machine actions:
The machine has automatically set the current UF rate to minimum UF rate.

Measures:
Press the *Fluid Path button*, select `UF` to reach the `UF MENU`. Check that the set minimum UF rate, `SET MIN UFR`, is a proper value for the paricular patient. If not, adjust the value using the *Keypad*. If necessary, consider adjusting the set treatment time or UF volume within the limits for the patient´s needs and tolerance.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
UF RATE LOWER THAN MINIMUM SET
Adjust TIME, UFV or MIN UF
```

Appears:
When the machine needs to decrease the UF rate below the set minimum UF rate in order to obtain the set UF volume at the end of treatment.

Machine actions:
Buzzer is activated 2 min. after attention alarm is generated.

Measures:
Decrease the set minimum UF rate or increase the UF rate by decreasing the treatment time, or by increasing the UF volume.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
UFR setting has been changed
Press SELECT key to confirm
```

Appears:
When treatment is resumed after the dialyzer and the blood lines have been changed during treatment.

Machine actions:
Press the *Fluid Path button*, select `UF` and `PROFILING` using the *Keypad*. Check that the start and stop values for `UF` are the correct ones, press the *Select button* to confirm this. If not, select `UF` and deactivate profiling. Change the values and reactivate profiling as usual procedure. See corresponding instructions in chapter 7 "Profiling" in part 1. Machine continues with set UF rate

Measures:

Mute time:
2 min.

Buzzer sound:
No buzzer

```
UF RATE STOPPED DUE TO HIGH PV
Lower PV
```

Appears:
When the set UF rate cannot be obtained due to too the current high venous pressure.

Machine actions:
The dialysis fluid is bypassed from the dialyzer.

Measures:
Check possible reason for the current high venous pressure, e.g. the patient´s blood access, dialyzer clotting, the functionality of the venous pressure transducer. Correct accordingly. Make sure that the venous pressure is decreased by at least 50 mmHg. The attention alarm will automatically disappear when the current venous pressure has been decreased.
If it is not possible to decrease the current venous pressure, wait (maximum 5 minutes) until the dialysis fluid enters the dialyzer again.
If the attention alarm reappears consider discontinuing the treatment.

Mute time:
5 min.

Buzzer sound:
Soft buzzer

```
UF STOP TIME EXPIRED
Press UF START/STOP button
```

Appears:
5 min after UF has manually been stopped.

Machine actions:
None.

Measures:
Press *UF Start/Stop button*.

Mute time:
5 min.

Buzzer sound:
Supersoft buzzer

```
UF VOLUME SET TO ZERO
Press SELECT key to confirm
```

Appears:
When the priming detector detects blood and the set UF volume is zero.

Machine actions:
Buzzer is activated 2 min. after attention alarm is generated.

Measures:
Press the *Select key* to confirm no ultrafiltration during treatment.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
VEN PRESS MENU HAS BEEN CLOSED
CHANGE HAS BEEN EXECUTED
```

Appears:
Parameter change has been made without confirming, using the *Select key*.
The appearance of the attention alarm can be preset.

Machine actions:
The machine has automatically confirmed the change.

Measures:
Check that the changed parameter is correct. The attention alarm will automatically disappear after it has been displayed.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
VENOUS LOW LIMIT BELOW +10 mmHg
Press VENOUS button to adjust
```

Appears:
10 minutes after the venous low alarm limit has been set below + 10 mmHg.

Machine actions:
None.

Measures:
Press *Venous Pressure button* and adjust the alarm limit to a proper value.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Continuous buzzer

```
VENOUS PRESSURE LIMITS TOO WIDE
Press VENOUS button to adjust
```

Appears:
The venous pressure alarm window is wider than the preset value.

Machine actions:
None.

Measures:
Press the flashing *Venous Pressure button* to centralize the alarm limits around the current value.

Mute time:
2 min.

Buzzer sound:
Soft buzzer

```
Wait 30 seconds to bypass
dialysis fluid
```

Appears:
If the *Fluid Bypass button* is pressed during the flushing of the dialysis fluid tubes.
This attention alarm can be removed by preset.

Machine actions:
Automatic flush of the flow path where the ultrafilter is placed is performed.

Measures:
Wait until the attention alarm has disappeared and the bypass path of the Flow Diagram lights up green before bypassing the dialysis fluid.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Soft buzzer

```
WRO COMMUNICATION FAILURE
Check WRO
```

Appears:
The communication between the machine and the WRO has stopped.

Machine actions:
None.

Measures:
Call an authorized technician.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Supersoft buzzer

```
WRO NOT READY
Please wait
```

Appears:
WRO inaccessible.

Machine actions:
None.

Measures:
Check information on WRO.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Supersoft buzzer

```
WRONG DISINFECTANT AGENT
Check agent, Press SELECT key
```

Appears:
A too high or too low disinfectant concentration has been detected.

Machine actions:
None.

Measures:
Check that the selected disinfectant matches the disinfectant connected to the machine, and press the *Select key* shortly to repeat fill-up phase.

Mute time:
Permanently muted buzzer.

Buzzer sound:
Supersoft buzzer

A

B

C

D

E

F

H

M

N

P

R

S

T

U

V

W