Service Manual

Hemodialysis System 5008

Edition: 1/08.04
Part number: M35 179 1

CE 0123

Fresenius Medical Care

Table of Contents

7 Error Messages

8 Tools (Service Equipment)

9 Calibration / Adjustment

10 Repair

11 Functional Description

12 Service Program (Option)

1 Index

How to use the index: E.g., index entry 1-3 is to be interpreted as: Chapter 1, page 3

2 Important Information

2.1 Organization of the Technical Document

Page identification

Page number 1-3 is to be interpreted as: Chapter 1, page 3.

Document changes

Document changes will be released as new editions or supplements. In general: this manual is subject to change without notice.

Editorial information

The current edition of this technical document is:

1/08.04 = 1st edition, August 2004

2.2 How to Use the Technical Document

Intended use

This technical document is intended for service technicians and is to be used for first studies (to acquire a basic knowledge) and for reference purposes (for TSC, maintenance and repair). The study of this document, however, does not replace the training courses offered by the manufacturer.

Requirements

Knowledge of the current Operating Instructions of the respective system.
Background experience in mechanics, electrical and medical engineering.

Note and Caution symbols

Explanation of the Note and Caution symbols used:

Note

Informs the operator that in case of a failure to follow the steps as described, a specific function will be executed incorrectly or will not be executed at all, or will not produce the desired effect.

Caution

Advises the operator against certain procedures or actions that could cause damage to the equipment or may have adverse effects on operators and patients.

2.3 Precautions for Working on the System

Authorized persons

Assembly, extensions, adjustments, modifications or repairs may only be carried out by the manufacturer or persons authorized by him.

Measuring equipment and accessories

The activities described in this technical document require the availability of the necessary technical measuring equipment and accessories.

Precautions

Before turning power on, repair any visible damage.

Prior to opening the system and when working on the open system, the following precautions have to be taken:
– Protect the components against ingress of liquids.
– Do not touch live parts.
– All plugs, connections and components may only be disconnected or connected if de-energized.

ESD precautions

When repairing the system and replacing spare parts, observe applicable ESC precautions (e.g. EN 100 015-1).

Monitor support arm

If the 5008 hemodialysis system is to be placed in a horizontal position for servicing, the monitor support arm must be protected with the transport protection to prevent it from flipping over.

To be observed after working on the system

A disinfection and a T1 test must be performed after working on the system.

To be observed after aborting a disinfection program

After a disinfection program has been aborted or if the system is to be preserved, the hemodialysis system must be disconnected from the water supply after a maximum of 3 days. When the system is returned to use, check that the pressure of the water supply meets the prescribed minimum pressure.

2.4 Addresses

Please address any inquires to:

Fresenius Medical Care AG
61346 Bad Homburg
Germany
Phone: + 49 6172 609-0
www.fmc-ag.com

Service Central Europe

Fresenius Medical Care
Deutschland GmbH
Geschäftsbereich Zentraleuropa
Kundendienst / Servicecenter
Steinmühlstraße 24 I
61352 Bad Homburg
Germany
Phone: +49 6172 609-7100
Fax: +49 6172 609-7102
E-mail: ServicecenterD@fmc-ag.com

Service International

Fresenius Medical Care
Deutschland GmbH
Service Support International
Hafenstraße 9
97424 Schweinfurt
Germany
Phone: +49 9721 678-333 (hotline)
Fax: +49 9721 678-130

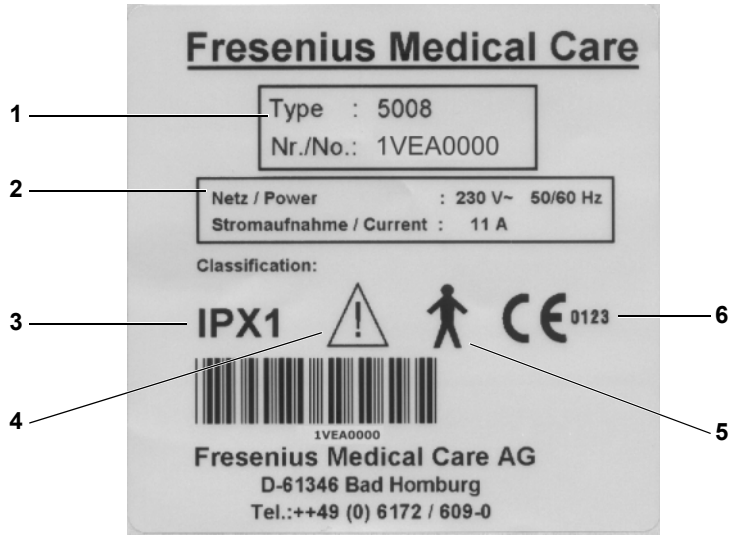
Local Service

3 Specifications

- **Dimensions, weight and housing material**

Dimensions	Height: approx. 162 cm (approx. 210 cm incl. IV pole) Width: approx. 48 cm (on base incl. brake) Depth: approx. 72 cm (approx. 86 cm with extended concentrate rack)
Weight	Approx. 135 kg (without options)
Housing material	PU vacuum cast resin

- **Type label**



1 Type identification, serial number

2 Power requirements

3 Protection against ingress of liquids: drip-proof

4 Caution, consult accompanying documents

5 Degree of protection against electric shock: Type B

6 CE mark

- **Electrical safety (classification according to EN 60601-1, IEC 601-1)**

Type of protection against electric shock	Safety class I
Degree of protection against electric shock	Type B, symbol: 

Applicable only to the BPM blood pressure cuff: Degree of protection against electric shock	Type CF, symbol: 
Degree of protection against ingress of liquids	Drip-proof, symbol: **IPX1**
Leakage currents	According to EN 60601-1
EMC specifications according to EN 60601-1-2 (IEC 601-1-2)	RFI emissions: Limit class A according to EN 55011, Group 1 Immunity: – Electrostatic discharge, atmospheric discharge: 8 kV – Electromagnetic fields: 27 MHz – 1000 MHz: 3 V/m – Bursts: Power line (alternating current): 1 kV – Surge voltages (alternating current): 2 kV

- **Electric supply**

Line voltage	100 to 230 V AC, ±10 %, 47 to 63 Hz (The decisive criterion is the line voltage and the operating current specified on the type label of the system)
Connection to power supply	16 A at 230 V, regulation according to VDE 0100 part 0107
Operating current dialysis	Approx. 6 A, (at 230 V) at a water inlet temperature of 17 °C Dialysate temperature 37 °C Dialysate flow: 500 ml/min
Power supply (internal)	+24 V ± 3 %, 20 A short-circuit proof +18 V ± 3 %, 14 A short-circuit proof 480 W total power output
Battery	Lead-acid battery (maintenance-free) 24 V, 7 Ah

- **Fuses**

Main power switch	2 x G 16 A (miniature circuit-breaker) rear of power supply unit

- **Operating conditions**

Water inlet pressure	1.5 to 6.0 bar
Water inlet temperature	5 °C to 30 °C with "Integrated hot rinse": 85 °C to 95 °C
Water inlet rate	1.5 l/min; at an inlet pressure of 1.5 bar

Water drain	0 to 100 cm above the floor, minimum 5 cm free fall. The water drain must be located at a lower level than the dialyzer position.
Concentrate supply	0 to -100 mbar; maximum suction height 1 m with Central Delivery System (option): 0.05 to 2.0 bar
Heat dissipation	Dialysis: approx. 400 Watt (at an ambient temperature of 20 °C)
Range of operating temperature	15 °C to 35 °C
Atmospheric pressure	700700 hPa to 1060 hPa
Relative humidity	30 % to 75 %, temporarily 95 %
Stability	5°
IV pole load capacity	Maximum: 5 kg Maximum load capacity of one hook: 5 kg

- **External connection options**

Caution

Any additional equipment connected to the analog and digital interfaces of the machine must comply with the applicable EN specifications (e.g. EN 60950 for data processing equipment and EN 60601 (IEC 601) for electro-medical equipment).
Apart from this requirement, all configurations must comply with the system standard EN 60601-1-1 (IEC 601-1-1), or their applicability with regard to safety has to be proven by a certificate issued by a testing agency authorized to test the ready-for-use machine.
The connection of additional equipment to the signal input or output component affects the system configuration and anyone connecting additional equipment is therefore responsible for compliance with the system standard EN 60601-1-1 (IEC 601-1-1).

Caution

The external alarm indicators do not relieve the operator of the obligation to observe the local alarms of the system.

LAN	Interface for the exchange of data. Electrically isolated by transformer. Port: RJ 45
RS232	Interface for the exchange of data. Electrically isolated by optocoupler. Port: DSUB 9-pin

Service/diagnostics	(Protected by cover!) For inhouse computer diagnostics. Port: DSUB 15-pin
24 V	(Protected by cover!) 24 V connection (2 A fuse) Port: Flanged socket, 4-pin
Alarm output	For the connection of an external alarm indicator (nurse call). (Potential-free alarm output. Alternating contact maximum 24 V/24 W). Port: 5-pin diode plug via a shielded line; shield grounded on either side.

- **Override conditions**

When overriding a safety system the responsibility for the patient's safety rests with the operator of the machine.

Audible alarm suppression	Mute alarm time: maximum 2 minutes (adjustable in the SETUP)
Alarm override	After confirmation of the error message and start of the blood systems: Arterial and venous pressure alarm for approx. 10 seconds (window inactive) Air detector alarm for approx. 2 seconds
Blood leak override	Override time: maximum 2 minutes
Override air-bubble detector	Override time: after starting removal of air: approx. 4 seconds

- **Operating programs**

T1 test	Automatic test for verification of the operating and safety systems. The T1 test is mandatory, – after power on (not following a power failure) – after a cleaning program
Preparation	Defined by the optical detector located below the venous bubble catcher. Preparation is terminated as soon as the optical detector senses opaque fluid in the blood lines.
Priming and rinsing the blood lines	Minimum rinse volume 500 ml; automatic switching to rinsing, if level in bubble catcher detected. Automatic raising of the fluid level during the rinse phase.
Reinfusion	Reinfusion volume adjustable in the SETUP. Return to dialysis still possible.
Dialysis	Bicarbonate dialysis
ISO-UF	Ultrafiltration without dialysate flow (Bergström method)

Cleaning programs

Rinse clear/rinse/mandatory rinse:
Time adjustable in the TECHNICIAN's SETUP,
Temperature: approx. 37 °C,
Flow: 600, 800 ml/min (adjustable in the SETUP)

Cold disinfection/degreasing, cold disinfection:
Time adjustable in the TECHNICIAN's SETUP,
Temperature: approx. 37 °C,
Flow: max. 900 ml/min

Heat disinfection:
Time adjustable in the TECHNICIAN's SETUP,
Flow: max. 900 ml/min

In all programs:
Blood pump stops, arterial and venous line occlusion clamp closed.
Progress of the program (time-counting) is interrupted in the event of a flow alarm.
The cleaning programs can be aborted.
The chemical disinfection program is followed by a mandatory rinse.

Flush

Rinsing of the water supply area

● **Dialysate circuit and safety systems**

Blood leak detector

Threshold of response ≤ 0.5 ml blood loss per minute into the dialysate at a hematocrit of 0.25.
(flow rate 100 ml/min to 1000 ml/min)

Transmembrane pressure

Display range: –100 to 400 mmHg
Resolution: 5 mmHg

Definition:

$$TMP = P_{bo} - (P_{di} + P_{do}) / 2 + Offset$$

TMP = Transmembrane pressure
P_{bo} = Blood pressure on the outlet side of the dialyzer
P_{di} = Dialysate pressure on the inlet side of the dialyzer
P_{do} = Dialysate pressure on the outlet side of the dialyzer
Offset = Flow-dependent pressure fluctuations

Ultrafiltration

Selectable UF rate: 0 ml/h to 4000 ml/h (in 10 ml increments)
Maximum rate internally adjustable to 1, 2, 3, or 4 l/h.
Pump volume accuracy: ±1 % (at P_{di} > –500 mbar)

The UF rate/effective blood flow ratio is being monitored during the treatment. If an incongruity occurs a warning will be displayed after approx. 10 seconds.

Pressure holding test

Event-controlled

Balancing

Accuracy: ±0.1 % related to the total dialysate volume

Maximum balancing error

$F = F_{UF} + F_{Bil}$

F = Maximum balancing error
F_{UF} = Ultrafiltration error
F_{bil} = Balancing error

Example:
Ultrafiltration error: with 1000 ml in 1 hour: ±1 % = ±10 ml/h
Balancing error: with 30 l fluid flow in 1 hour at a dialysate flow of 500 ml/min: ±0.1 %= ± 30 ml/h
Maximum balancing error:
$F = F_{UF} + F_{Bil}$ = (±10 ml/h) + (±30 ml/h) = ±40 ml/h

Degassing

Method: Negative pressure

Dialysate concentration (conductivity)

Display range: 12.8 to 15.7 mS/cm
Resolution: 0.1 mS/cm
Accuracy: 0.1 mS/cm
Method:
Temperature-compensated electronic conductivity meter with adjustable alarm limits.

Concentrates

Entering concentration types
Adjustment range: 125 to 151 mmol/l, depending on the concentrate used ±10 % of the base value.
Bicarbonate readjustment range: corresponds to ±8 mmol/l

bi*b*ag®

Bicarbonate concentrate preparation from the bi*b*ag®
Temperature range: 15 to 35 °C

Dialysate temperature

Adjustment range: (prescribed temperature) 34.0 °C to 39.0 °C
Resolution: 0.5 °C
Measuring accuracy: ±0.2 °C

Dialysate flow

Display range: 100 to 1000 ml/min
Resolution: 100 ml/min
Desired values: 100 to 1000 ml/min
Measurement by means of time pulse monitoring and balancing chamber volume

Auto flow: dialysate flow controlled in relation to the blood flow, determined by the dialyzer.

EcoFlow: dialysate flow automatically reduced to 100 ml/min in Preparation

Rinse and chemical disinfection temperature

Desired temperature: 37 °C
Resolution: 0.5 °C
Measuring accuracy: ±0.2 °C

Rinse and chemical disinfection flow

Desired value: 600 ml/min

Hot rinse and heat disinfection temperature	Desired temperature: 85 °C Resolution: 0.5 °C Measuring accuracy: ±2.0 °C
Hot rinse and heat disinfection flow	Desired value: 600 ml/min
Concentration of disinfectant	Dilution: Disinfectant is diluted with purified water in the dialysis system at a ratio of 1+24.
Flow alarm	Dependent on the programmed flow

- **Extracorporeal blood circuit and safety systems**

Arterial pressure measurement	Display range: –300 to +300 mmHg Resolution: 5 mmHg Accuracy: 7 mmHg (typical) OD senses non-opaque presence: Alarm window width: –300 to +300 mmHg OD senses opaque presence: Alarm window width: +40 to +200 mmHg Default value adjustable in the SETUP, factory setting 120 mmHg
Blood pump	Delivery rate: 30 to 600 ml/min Resolution: 10 ml/min (with a line diameter of 8 mm) Accuracy: < 5 % (without lines) Line diameter: 4.4 mm, 6.4 mm, 8.0 mm Blood pump stop alarm: 60 seconds Spring-loaded rollers, fully occluding, pressure-limited to 2 bar with 8 x 2.1 pump line segment (when using the prescribed tubing systems). (The blood pump design allows manual operation, hand crank in the rotor, in clockwise direction only.)
Venous pressure measurement	Display range: –100 to +500 mmHg Resolution: 5 mmHg Accuracy: 7 mmHg (typical) OD senses non-opaque presence: Alarm window width: –100 to +500 mmHg OD senses opaque presence: Alarm window width: 40 to 200 mmHg Default value adjustable in the SETUP, Factory setting 120 mmHg adjustable over a range of 20 to 500 mmHg (adjustable from -100 to 500 mmHg via SETUP.)
Fill level detector	Method: Capacitive measurement Switching point 13 mm, ±4 mm from upper edge
Optical detector	Method: Infrared transmission

Distinguishes between
OD light (saline or air in the tubing system)
OD dark (blood in the tubing system).

Air bubble detector

Method:
Ultrasonic transmission measurement on the line

Sensitivity:
– Air bubbles:
  Bubble volume ≥ 20 µl
– Blood foam (air-blood mixture)

Air alarm:
– BP rate < 100 ml/min:
  Air bubble: Volume ≥ 20 µl
  Blood foam
– BP rate ≥ 100 ml/min:
  10 air bubbles with an air bubble volume of < 50 µl each
  or 1 air bubble with an air bubble volume of ≥ 50 µl,
  Blood foam

The specified data refer to the most unfavorable case with a BP rate of 0 to 600 ml/min when using the blood lines specified in chapter Consumables.

Heparin pump

Delivery rate: 0.5 to 10 ml/h
Resolution: 0.1 ml/h
Accuracy: ±5 % for delivery rates of 0.5 to 10 ml/h and a measuring time of 2 hours up to 1.2 bar counter-pressure
(calibrated for 30 ml Fresenius heparin syringes)
With delivery rates of <1.0 ml/h the tolerance may exceed the specified ±5 %.

Stop time: 0 minutes up to 2 hours.
Resolution: 1 minute
Bolus injection: 1.0 up to 20.0 ml
Resolution: 0.1 ml

30 ml Fresenius heparin syringe

Audible alarm

Setting range of the loudness of the audible alarm:
Factory setting ≥ 65 db (adjustable)
Minimum setting: ≥ 65 db

● **DIASAFE®*plus* (option)**

Filter life: maximum 12 weeks.
Monitored by the dialysis system and a warning (Filter change) is displayed.

When using ONLINE*plus*™ (option):
Filter life: maximum 100 treatments.
Monitored by the dialysis system and a warning (Filter change) is displayed. If the warning is ignored, ONLINE*plus*™ will be disabled after the respective number has been exceeded.
After 90 treatments the number of the remaining treatments will be displayed in the cleaning programs.

- **OCM (option)**

Measuring accuracy of the clearance: ± 6 % standard deviation
Shortest measuring interval: 25 min
Time scale of the display: 10 s

- **ONLINE*plus*™ (option)**

Delivery rate: 25 to 600 ml/min (inside line diameter: 8.0 mm)
Resolution: 1 ml/min

Exchange volume: substituate goal 500 l adjustable in relation to treatment parameters

Accuracy: < 5 % (without lines)
(This specification only applies to the range from 30 to 350 ml/min. With delivery rates of < 30 ml/min the deviation may be greater.)

Volume counter display: 0.1 to 210 liters
Resolution: 0.1 liter

Spring-loaded rollers, fully occluding, pressure-limited to < 1.3 bar.
(The blood pump design allows manual operation, hand crank in the rotor, in clockwise direction only.)

Auto sub: The sub rate is determined as a function of:
– UF rate
– Blood flow
– Hematocrit (HCT)
– Total protein (TP)
– Filter performance

- **Single Needle (option)**

Blood pump stop alarm Single Needle pump	During Single Needle operation 180 seconds.
Stroke volume	10 to 50 ml in increments of 5 ml
External compliance chamber	50 ml or 60 ml stroke volume

Auto SN Delivery rate of the Single Needle pump	+20 % (programmable in the Operator setup.)

● **BPM (option)**

Blood pressure	Display Area – Systole: 30 mmHg to 280 mmHg – Diastole: 10 mmHg to 240 mmHg – MAP: 20 mmHg to 255 mmHg Resolution: 1 mmHg Accuracy of measured value ±3 mmHg
Pulse	Display range: 20 to 245 1/min Resolution: 1/min

● **BTM (option)**

Required blood flow for accurate BTM function	≥ 120 ml/min (The measuring and control functions of the BTM are deactivated if the blood flow is < 100 ml/min.)
Temperature measurement	Accuracy of the fistula temperatures (if correct ambient temperature is indicated): ± 0.5 °C Error in fistula temperatures per °C error of the set ambient temperature 0.08 °C (at a blood flow of 100 ml/min) 0.03 °C (at a blood flow of 300 ml/min) Body temperature change accuracy: ± 0.2 °C
Recirculation measurement	Accuracy of recirculation measurement (for 2.5 °C venous bolus amplitude): ± 2 % Maximum bolus amplitude: – 3 °C or + 3 °C Maximum duration of the bolus: up to 10 min Maximum dialysate temperature range used by the BTM: 33.5 °C to 39.5 °C
Body temperature control	Allowed range of desired values for body temperature change rate: – 0.5 °C/h to + 0.5 °C/h Maximum dialysate temperature range used by the BTM: 33.5 °C to 39.5 °C

- **Network (option)**

Caution

The responsible organization of the network is responsible for protecting the machine from excessive network load (e.g. by accumulation of broadcast messages or port scans). If necessary, the connection to the network must be established via a router or a firewall, for example.

The system configurator is responsible for the further secure data processing, e.g. in PC software applications.

The responsible organization of the network is responsible for the protection of the not encrypted, transferred data.

The data transfer of alarm states via the network must not be used as an external alarm alert (nurse call).

4 Installation

4.1 Preface

Instructions for all technicians who are authorized to commission our hemodialysis systems.

We, as manufacturers, permanently aim at delivering systems of highest quality.

To reach this aim, we need your support.

Please commission our hemodialysis systems by uniformly using the enclosed "initial start-up report" and enter the values determined in the columns provided.

The following is applicable:
Corrections are necessary only if the measured values are outside of the tolerances specified!

We will then evaluate the initial start-up reports, which will enable us to monitor the quality of our systems on their delivery.

After initial start-up, please asap send – by mail or by fax – the completed form (Initial Start-Up Report) back to the following address:

Fresenius Medical Care
Deutschland GmbH
Werk Schweinfurt
Herrn Alfred Laus, Abt. BM
Hafenstraße 9
97424 Schweinfurt
Fax: 09721/ 678450

Thank you very much for your help!

4.2 Important Information on Initial Start-Up

This technical document is intended for initial start-up only. It is not intended for restarting hemodialysis systems that have been shut down or have been put out of service temporarily.

The initial start-up must be performed by the Technical Service of Fresenius Medical Care or a person authorized by them!

Any information on initial start-up and the specifications in the Operating Instructions must be observed.

When bringing the hemodialysis system from a cooler to a warmer room, allow approx. 2 hours for the system to adjust to the ambient temperature before turning the unit on.

4.3 Initial Start-Up Report

5008	Initial Start-Up Report	Fresenius Medical Care

Technician's name:		**Service report number:**
Customer/Customer no.:		
Inventory no.:	**Device no.**	**Operating hours:**
Device type including option(s):		

No.	Description	Measure-ment value	✓
1	**Preparation**		
1.1	Hemodialysis system without visible shipping damage.		❑
1.2	Remove the transport protection for the monitor support arm.		❑
	Install the IV pole.		❑
1.3	Connect the water supply tubing.		❑
	Connect the drain and the flush tubings.		❑
	Protect the tubings from slipping out.		❑
	Standard: Length 3 m, internal diameter 6 mm Tubing dimensions, adjusted: Length _____ m, internal diameter_____ mm		❑
1.4	Connect the CDS tubings and protect them from slipping out.		
	Apply a shrink tube marking for the CDS tubings.		❑
	CDS 1		❑
	CDS 2		❑
	BIC		❑
1.5	Remove the shipping plugs from the overflows.		❑
1.6	When turning the hemodialysis system on, perform an audible check of the watchdog alarm.		❑
1.7	Rinse out the anti-freeze.		❑
1.8	Select the Filter change program. Connect the filter. DIASAFE®*plus*/ONLINE*plus*™ In the service mode, delete mandatory disinfection. Then completely run the rinse program.		❑
2	**SETUP settings** (Technician's SETUP/Operator SETUP)		
2.1	Check the SETUP on the hemodialysis system.		❑
3	**Check – water inlet flow / adjustment – degassing**		
3.1	Check MaxWaterFlow. Desired value: 1300 ml/min to 1550 ml/min	_____	Corr.: ❑ Yes ❑ No
3.2	Perform the degassing adjustment.		❑
4	**Check – dialysate flow**		
4.1	Check flow at 800 ml/min. Desired value: 770 ml/min to 830 ml/min	_____	❑

No.	Description	Measure-ment value	✓
5	**Check – temperature**		
5.1	Check PT07 (temperature) at 37 °C. (flow 500 ml/min) Desired value: 36.8 °C to 37.2 °C (display on hemodialysis system) Measure the reference temperature with an external measuring instrument. Difference = Reference temperature minus PT07 Desired value – difference: –0.5 °C to +0.2 °C	_____ _____	Corr.: ❑ Yes ❑ No
6	**Check – conductivity**		
6.1	Check CD7 (conductivity). Desired value: approx. 13.5 mS/cm to approx. 14.5 mS/cm Measure the reference conductivity with an external measuring instrument. Difference = Reference conductivity minus CD7 Desired value – difference: ±0.2 mS/cm	_____ _____	Corr.: ❑ Yes ❑ No
7	**Check – blood leak detector**		
7.1	Check the blood leak: Desired value: 4.8 V to 5.2 V	_____	Corr.: ❑ Yes ❑ No
7.2	Check the dimness: Desired value: 4.8 V to 5.2 V	_____	

No.	Description	Measure-ment value	✓
8	**Check – dialysate pressure**		
8.1	Zero point S03/S07		Corr.: ❑ Yes ❑ No
	Reference measuring instrument: 0 mbar	_____	
	Check S03. Desired value: +16 mbar to +76 mbar	_____	
	Check S07. Desired value: +16 mbar to +76 mbar	_____	
8.2	Slope S03/S07 (+)		
	Reference measuring instrument: +533 mbar (± 26 mbar)	_____	
	Check S03. Desired value: S03 = Display of reference measuring instrument + (+16 mbar to +76 mbar)	_____	
	Check S07. Desired value: S07 = Display of reference measuring instrument + (+16 mbar to +76 mbar)	_____	
8.3	Slope S03/S07 (–)		
	Reference measuring instrument: –533 mbar (± 26 mbar)	_____	
	Check S03. Desired value: S03 = Display of reference measuring instrument + (+16 mbar to +76 mbar)	_____	
	Check S07. Desired value: S07 = Display of reference measuring instrument + (+16 mbar to +76 mbar)	_____	

No.	Description	Measure-ment value	✓
9	**Check – electrical safety** In Germany according to DIN VDE 0751-1, edition 10/2001. In other countries, observe the local regulations!		
9.1	Visual inspection performed.		❑
9.2	Protective earth resistance maximum 0.3 ohms (with power cord)	_____ Ω	❑
9.3	Leakage current measurement (device leakage current) ❑ Differential current measurement according to figure C.6 ***or*** ❑ Direct measurement according to figure C.5 Nominal voltage of power supply: _____ V Device leakage current mains polarity 1 _____ µA with line voltage _____ V scaled to nominal voltage (maximum 500 µA, see Additional requirements) Device leakage current mains polarity 2 _____ µA with line voltage _____ V scaled to nominal voltage (maximum 500 µA, see Additional requirements) Test equipment used: _____	_____ µA _____ µA	❑
10	**Check – zero point arterial/venous pressure display and venous clamp**		
10.1	Zero point arterial pressure display Check the arterial pressure display (standby operation). Desired value: –5 mmHg to +5 mmHg	_____	Corr.: ❑ Yes ❑ No
10.2	Zero point venous pressure display Check the venous pressure display (standby operation). Desired value: –5 mmHg to +5 mmHg	_____	Corr.: ❑ Yes ❑ No
10.3	Check – venous clamp: A pressure change within 3 minutes must not exceed the following values: Arterial pressure display Maximum pressure change: ±5 mmHg Reference measuring instrument for pressure display Maximum pressure drop: –0.1 bar		❑

No.	Description	Measure-ment value	✓
11	**Final check**		
11.1	Check the error memory.		❑
11.2	Save calibration data and SETUP settings on a data disk.		❑
11.3	Perform the T1 test.		❑
11.4	Run the disinfection program (with Puristeril 340 or Puristeril plus or Diasteril or Citrosteril).		❑
11.5	Check the alarm function during the disinfection program. Open the shunt interlock. Audible alarm and traffic light		❑
11.6	Check absence of disinfectant by means of test strips (not with Citrosteril).		❑
11.7	Record entries in the medical device register and on the machine card.		❑
11.8	Operating Instructions and accessories package complete and appropriate for the system.		❑

Date:	Signature:	Stamp:

The system has been released for the intended use.	❑ Yes	❑ No

Test equipment used:

Temperature, conductivity, pressure
(type, serial number): _____

_____

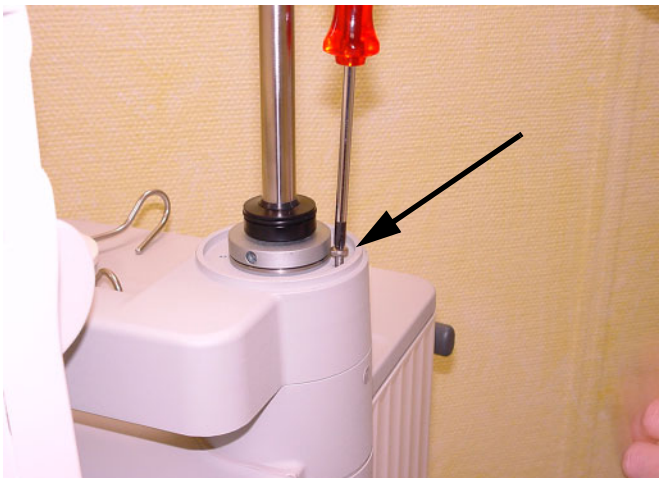
Protective earth resistance, leakage current
(type, serial number): _____

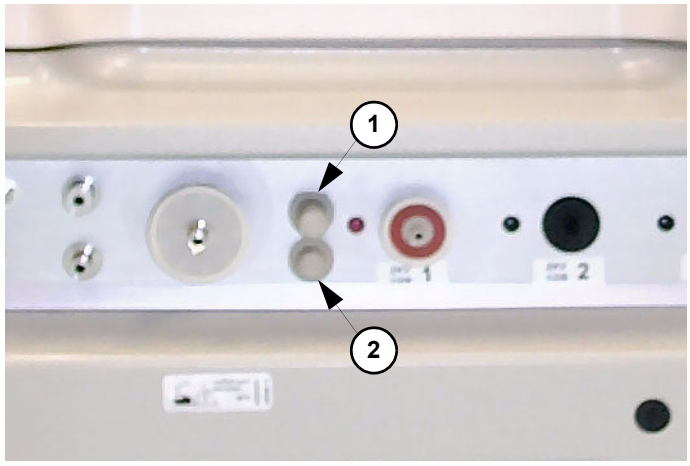
_____

Comments:

Date:	Signature:	Stamp:

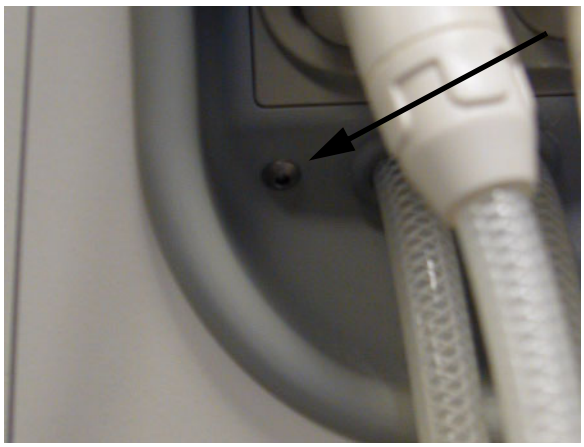
4.4 Explanations on the Initial Start-Up Report

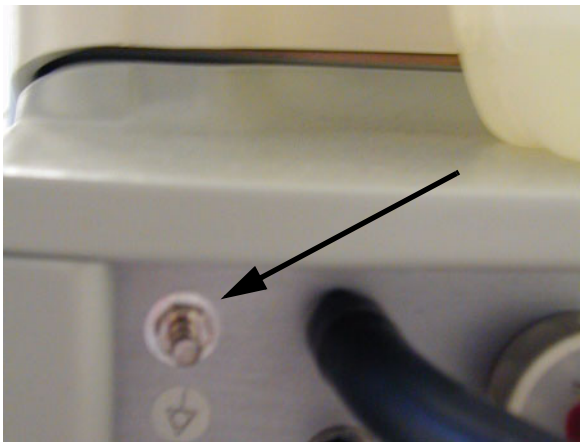
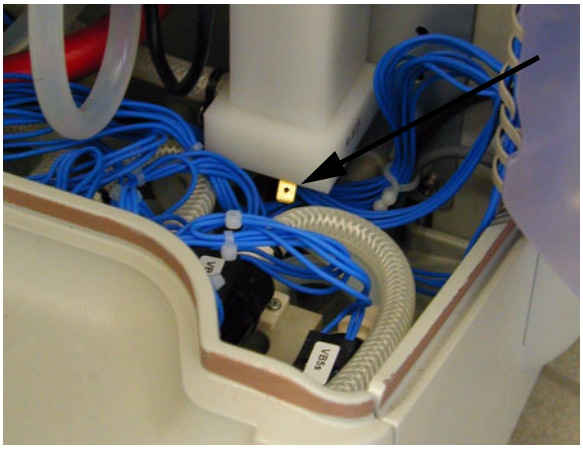
No.	Description
1	**Preparation**
1.1	Hemodialysis system without visible shipping damage.
1.2	Remove the transport protection for the monitor support arm.  Unscrew and remove the screw. (Keep the screw for subsequent transportation.) Install the IV pole. Insert the IV pole into the monitor support arm. Secure the IV pole with a threaded pin. Place the protective cover for the monitor support arm. Screw the IV pole hanger onto the IV pole.
1.3	Connect the water supply tubing. Connect the drain and the flush tubings. Protect the tubings from slipping out. (Standard: Length 3 m, internal diameter 6 mm) When using other tubing dimensions, adjust the tubing parameters in the technician's-SETUP. Tubing dimensions, adjusted: Length _____ m, internal diameter_____ mm
1.4	Connect the CDS tubings and protect them from slipping out. Apply a shrink tube marking for the CDS tubings.
	CDS 1
	CDS 2
	BIC

No.	Description
1.5	Remove the shipping plugs from the overflows.  1. Vent (water inlet chamber) 2. Vent (mixing chamber)
1.6	When turning the hemodialysis system on, perform an audible check of the watchdog alarm.
1.7	Rinse out the anti-freeze.
1.8	Select the Filter change program. Connect the filter. DIASAFE®*plus*/ONLINE*plus*™ In the service mode, delete mandatory disinfection. Then completely run the rinse program.
2	**SETUP settings** (Technician's SETUP/Operator SETUP)
2.1	Check the SETUP on the hemodialysis system. Make the appropriate settings for the respective hospital, if necessary.
3	**Check – water inlet flow / adjustment – degassing**
3.1	In the service mode, select FLOW DIAGRAM. Basic requirements: **The hemodialysis system must be closed.** Flow on. Check MaxWaterFlow. Desired value: 1300 ml/min to 1550 ml/min Use A04 for making corrections, if necessary. (If it is not possible to set a water inlet flow ≥ 1300ml/min, it will not always be possible to achieve the dialysate flow of 1000ml/min.)
3.2	In the service mode, select CALIBRATE. Basic requirements: Flow on. Perform the degassing adjustment. Touch the **Degassing (A01/P01)** button.

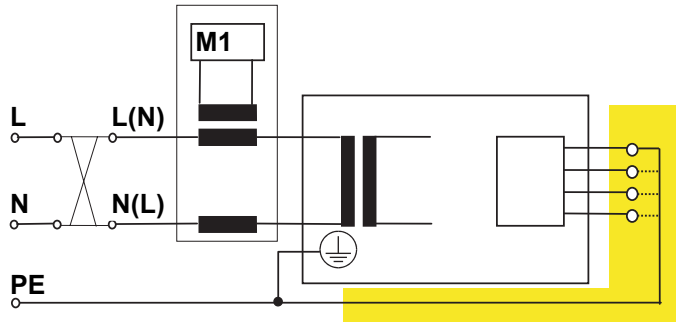
No.	Description
4	**Check – dialysate flow**
4.1	In the service mode, select CALIBRATE. Basic requirements: The hemodialysis system **must be closed.** Flow on, flow 800 ml/min Check flow. Desired value: 770 ml/min to 830 ml/min
5	**Check – temperature**
5.1	In the service mode, select CALIBRATE. Basic requirements: The hemodialysis system **must be closed.** Temperature 37 °C, flow on, flow 500 ml/min, Response time approx. 10 min. Check PT07 (temperature). Desired value: 36.8 °C to 37.2 °C (display on hemodialysis system) Measure the reference temperature with an external measuring instrument. Difference = Reference temperature minus PT07 Desired value – difference: –0.5 °C to +0.2 °C Example: PT07: 37 °C Desired value reference temperature: 36.5 °C to 37.2 °C
6	**Check – conductivity**
6.1	In the service mode, select CALIBRATE. Basic requirements: The hemodialysis system **must be closed.** External measuring instrument (e.g. UMED) connected for at least 5 minutes. Temperature 37 °C, flow on Check CD7 (conductivity). Desired value: approx. 13.5 mS/cm to approx. 14.5 mS/cm Measure the reference conductivity with an external measuring instrument. Difference = Reference conductivity minus CD7 Desired value – difference: ±0.2 mS/cm
7	**Check – blood leak detector**
	In the service mode, select CALIBRATE. Basic requirements: The hemodialysis system **must be closed. (Avoid external light.)** Temperature of approx. 37 °C achieved, flow on, flow 500 ml/min,
7.1	Check the blood leak: Desired value: 4.8 V to 5.2 V
7.3	Check the dimness: Desired value: 4.8 V to 5.2 V

No.	Description
8	**Check – dialysate pressure**
	In the service mode, select CALIBRATE. Basic requirements: The hemodialysis system **must be closed.** The reference measuring instrument must be placed at the bottommost position of the IV pole. Dialyzer couplings must be connected to the reference instrument. Flow on until dialysate lines and reference measuring instrument are free from air. Then flow off.
8.1	Zero point S03/S07 Reference measuring instrument: 0 bar Open the vent valve (UMED). Using a syringe (filled with fluid) set a value of 0 bar, via the vent valve. Check S03. Desired value: +16 mbar to +76 mbar Check S07. Desired value: +16 mbar to +76 mbar
8.2	Slope S03/S07 (+) Reference measuring instrument: +533 mbar (± 26 mbar) Using a syringe (filled with fluid) set a value of +533 bar, via the vent valve. Check S03. Desired value: S03 = Display of reference measuring instrument + (+16 mbar to +76 mbar) Check S07. Desired value: S07 = Display of reference measuring instrument + (+16 mbar to +76 mbar)
8.3	Slope S03/S07 (–) Reference measuring instrument: –533 mbar (± 26 mbar) Using a syringe (filled with fluid) set a value of –533 bar, via the vent valve. Check S03. Desired value: S03 = Display of reference measuring instrument + (+16 mbar to +76 mbar) Check S07. Desired value: S07 = Display of reference measuring instrument + (+16 mbar to +76 mbar)

No.	Description
9	**Check – electrical safety** In Germany according to DIN VDE 0751-1, edition 10/2001. In other countries, observe the local regulations!
9.1	Visual inspection performed. – Fuses accessible from the outside comply with the indicated values. – Labels and labelings are present and legible. – The mechanical condition permits further safe use. – There are no signs of damage or dirt. – No signs of damage on the power cord.
9.2	Protective earth resistance maximum 0.3 ohms (with power cord) The protective earth resistance must be checked on the following four measurement points.
	 1. Measurement point: power supply unit (power supply unit housing)
	 2. Measurement point: shunt door

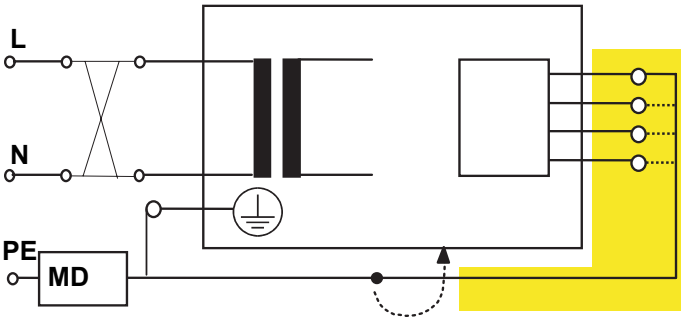
No.	Description
	 3. Measurement point: potential equalization
	 4. Measurement point: heater rod chamber

No.	Description
9.3	Leakage current measurement (device leakage current)



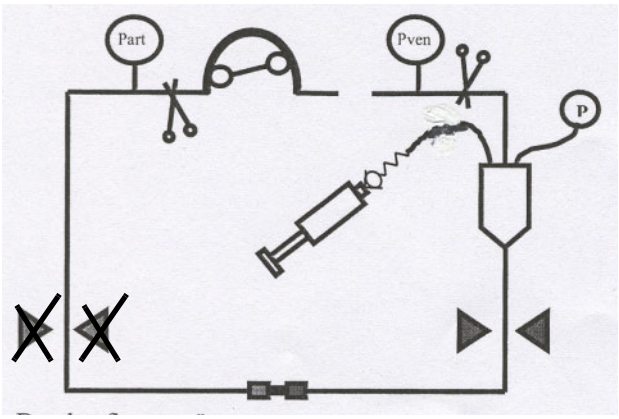
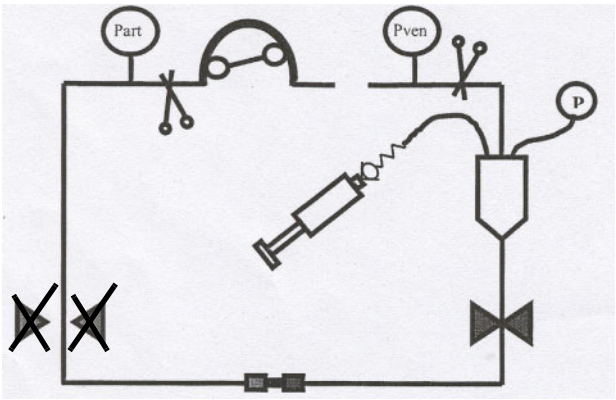
Differential current measurement according to figure C.6

or



Direct measurement according to figure C.5

No.	Description
	Basic requirements: – Measurement of the protective earth resistance performed. – Perform the measurement with the hemodialysis system being at operating temperature. – Dialysate: Dialysis temperature: ≥ 37 °C Dialysate flow: ≥ 300 ml/min Conductivity: ≥ 13 mS/cm – When performing a direct measurement, the following precautions also must be observed: The system must be insulated when installed. All external connections must have been removed from the system. The line voltage during the measurement will be recorded, as well as the maximum device leakage current of both mains polarities, scaled to the nominal voltage of the power supply. Maximum device leakage current: 500 µA Example: Line voltage during the measurement: 225 V Device leakage current for mains polarity 1: 180 µA for mains polarity 2: 120 µA Maximum value of both mains polarities: 180 µA Nominal voltage of power supply: 230 V Scaled to nominal voltage: 184 µA (180 µA: 225 V x 230 V = 184 µA Device leakage current < 500 µA: OK Additional requirements: If the device leakage current, scaled to the nominal voltage, is higher than 90 % of the admissible alarm limit (450 µA), the last measured value or the first measured value must additionally be considered for the rating. If the device leakage current has considerably increased since the last measurement or has continuously increased since the first measurement (creeping deterioration of the insulation), or if the sum composed of the current value plus the difference since the last measurement is >500 µA, the measurement has not been completed successfully. Example 1: Device leakage current: 470 µA Last measured value: 450 µA 470 + (470 – 450) = 470 + 20 = 490; is OK Example 2: Device leakage current: 470 µA Last measured value: 390 µA 470 + (470 – 390) = 470 + 80 = 550; not passed
10	**Check – zero point arterial/venous pressure display and venous clamp**
10.1	Zero point arterial pressure display Basic requirements: Blood lines inserted, pressure domes coupled, standby operation. Check the arterial pressure display. Desired value: –5 mmHg to +5 mmHg

No.	Description
10.2	Zero point venous pressure display Basic requirements: Blood lines inserted, pressure domes coupled, standby operation. Check the venous pressure display. Desired value: –5 mmHg to +5 mmHg
10.3	Check – venous clamp Basic requirements: – Blood lines inserted, standby operation. – Connect the arterial and the venous branch using the adapter fitting included. – Remove the line from the arterial clamp. – Clamp the blood line before the blood pump and on the venous drip chamber. – Connect the external pressure measuring instrument to the venous bubble catcher. – Connect the syringe and the one-way valve (if present) to the venous bubble catcher.  Pressure build-up – arterial side: Open the venous clamp. Using a syringe, build up an arterial pressure of 50 mmHg to 100 mmHg. Observe the arterial display on the hemodialysis system. Close the venous clamp.  Pressure build-up – venous side: Venous clamp closed. Using a syringe, build up a pressure of 2.5 bar to 2.7 bar. Observe the display on the external reference measuring instrument. Maximum pressure change within 3 minutes on the arterial pressure display of the hemodialysis system ±5 mmHg. Maximum pressure drop within 3 minutes on the display of the reference measuring instrument –0.1 bar.

No.	Description
11	**Final check**
11.1	Check the error memory. With service program: Erase error memory and service data recorder.
11.2	With service program: Save calibration data and SETUP settings on a data disk.
11.3	Perform the T1 test.
11.4	Run the disinfection program: (with Puristeril 340 or Puristeril plus or Diasteril or Citrosteril)
11.5	Check the alarm function during the disinfection program. Open the shunt interlock. Audible alarm and traffic light Alarm message Close the shunt interlock. The disinfection program will be continued.
11.6	Check absence of disinfectant by means of test strips (not with Citrosteril).
11.7	Record entries in the medical device register and on the machine card.
11.8	Operating Instructions and accessories package complete and appropriate for the system.

5 Setup

5.1 Operator Setup

Touch the **SYSTEM** menu button.

Insert the operator card.

Touch the **OPERATOR SETUP** button on the SYSTEM SCREEN.

Select the desired function from the Operator setup SCREEN.
Make changes, if required, and save.

How to use the Operator setup:
– Save with **OK**.
– Select default values with **Logo**.

● **Tubing system**

Submenu		Default value	Value range	Resolution	Selectable options
	Tubing system	AV Set 5008	–	–	–

● **Blood pump**

Submenu		Default value	Value range	Resolution	Selectable options
	Pump segment	8.0 mm	–	–	(4.4 mm) (6.4 mm) 8.0 mm
Delivery rates					
	Prime	100 ml/min	30–600 ml/min	10 ml/min	–
	Precirculation	100 ml/min	30–600 ml/min	10 ml/min	–
	Reinfusion	100 ml/min	30–300 ml/min	10 ml/min	–

- **Rinse/reinfusion volume**

Submenu		Default value	Value range	Resolution	Selectable options
Preparation (NaCl)					
	Rinse vol.	500 ml	500–5000 ml	100 ml	–
	(UF rinse vol.)	(0 ml)	(0–5000 ml)	(100 ml)	(–)
Reinfusion (NaCl)					
	Reinfusion volume	250 ml	0–480 ml	10 ml	–

- **Anticoagulation**

Submenu		Default value	Value range	Resolution	Selectable options
Heparin					
	Heparinization	Yes	–	–	Yes No
	Heparin unit	ml	–	–	ml I.U.
	Heparin start	Automatic	–	–	Automatic Manual
	Hep. rate	1.2 ml/h 10 I.U./h	0.5–10.0 ml/h 10–25 000 I.U./h	0.1 ml/h 10 I.U./h	– –
	Stop time	0:30	0:00–2:00	0:01	–
	Syringe	Fresenius 30 ml	–	–	Depending on Technician's Setup (define syringe types)
	Bolus	5.0 ml/h 1000 I.U./h	1.0–20.0 ml/h 0–15 000 I.U./h	0.1 ml/h 10 I.U./h	– –

- **Dialysate**

Submenu	Default value	Value range	Resolution	Selectable options
Dialyzer	FX series	–	–	FX series F series others
Auto flow factor	1.2 (depending on dialyzer)	–	–	not adjustable
Empty bibag	Automatic	–	–	Automatic Manual

- **Ultrafiltration**

Submenu	Default value	Value range	Resolution	Selectable options
Maximum UF rate	3000 ml/h	500–4000 ml/h	10 ml/h	–
Maximum profile rate	3500 ml/h	3010–4000 ml/h	10 ml/h	–
Program. UF profile	Closed	–	–	Closed Released
UF start	Automatic	–	–	Automatic Manual
UF goal	0 ml	0–9990 ml	10 ml	–
UF time	0 hrs 0 min	0–24 hrs.	1 min	–
UF rate	0 ml/min	0–4000 ml/min	10 ml/min	–

- **Alarm processing**

Submenu	Default value	Value range	Resolution	Selectable options
Tone Mute time	120 seconds	60–120 seconds	10 seconds	–
Warning times				
Flow off	10 min	–	–	10 min 20 min 30 min
UF off	5 min	5–15 min	1 min	–
Heparin off	1 min	1–5 min	1 min	–
Arterial/venous pressure settings				
Art. alarm limit	Centered	–	–	Centered Asymmetric
Art. window width	100 mmHg	40–200 mmHg	10 mmHg	–
Ven. alarm limit	Asymmetric	–	–	Asymmetric Centered
Ven. window width	100 mmHg	40–200 mmHg	10 mmHg	–
Ven. window position	Unlimited	–	–	Unlimited ≥ 20 mmHg

- **User interface**

Submenu		Default value	Value range	Resolution	Selectable options
Screen saver					
	Screen saver	Yes	–	–	Yes No
	Delay	5 min	1–60 min	1 min	–
Graphics		The diagram types listed under selectable options can be assigned to a group. Each group can contain a maximum of 4 graphics. Each diagram type can be contained in any group, but only once. Graphics can be assigned only if the particular option is available.			
	Group 1	UF Na diagram OCM diagram Pressure graphs BPM history	–	–	UF Na diagram Pressure graphs BTM BPM BPM (MAP) BVM OCM diagram BPM history
	Group 2	BPM BPM (MAP)	–	–	See group 1
	Group 3		–	–	See group 1
	Group 4		–	–	See group 1
Defining options		A maximum of 4 option buttons may be added The option buttons which have been added will appear on the lower right above the **SYSTEM** button. (If the BPM option is available, a maximum of 3 options may be created.) Options can be added only if the particular option is available.			
	Option	HEPARIN ONLINE	–	–	HEPARIN EMERGENCY CIRCULATE SINGLE NEEDLE ONLINE OCM BPM BVM BTM
Defining controls					
	–	–	–	–	–

- **Cleaning**

Submenu	Default value	Value range	Resolution	Selectable options
Mand. cleaning pgm. after treatment	Yes	–	–	Yes No

- **Auto On**

Submenu		Default value	Value range	Resolution	Selectable options
Weekly programs		The program and the power-up time may be preselected. Then turn programming on or off via Status. If various programming actions have been performed, it is possible to turn them all on or off via the **Auto On Programs I/O** button.			
	Program	No program	–	–	Rinse Heat disinfection T1 Test No program
	Power-up time	00:00	00:00–24:00	1 min	–
Single programs		The program and the power-up time may be preselected. Then turn programming on or off via Status. If various programming actions have been performed, it is possible to turn them all on or off via the **Auto On Programs I/O** button.			
	Program	No program	–	–	Rinse Heat disinfection T1 Test No program
	Power-up time	00:00	00:00–24:00	1 min	–

The bi*bag*® may be installed after completion of the last disinfection of the 5008 hemodialysis system (72 hours maximum before the treatment).
For profiting from this possibility, observe the following notes.

Requirements:
– Pre-program the T1 test under Auto On.
(Observe the time programming of the osmosis installation.)
– CDS for acid connected.

Caution

After removal of the foil, immediately connect the bi*bag*® using aseptic techniques. Then close the bicarbonate flap.

- **Emergency (response after touching the Emergency button)**

Submenu	Default value	Value range	Resolution	Selectable options
UF off	Yes	–	–	Yes No
Blood flow reduction	Yes	–	–	Yes No
Blood pressure measurement	No	–	–	Yes No
Online bolus	Yes	–	–	Yes No
Bolus	90 ml	90–240 ml	30 ml	–
Bolus rate	200 ml/min	50–250 ml/min	10 ml/min	–

- **Patient card**

Submenu	Default value	Value range	Resolution	Selectable options
Patient card	Writing to the patient card: – **Patient card** button In the Operator setup touched. – Remove the operator card. – Insert the patient card. – Message: *Patient card for ... date of birth...* – **OK**. – Touch the **OK** button. – Insert the desired patient data. (After touching the desired field, the patient data may be entered via the keypad.) – Touch the **OK** button to confirm the entered patient data. Visually check the confirmed patient data. – Touch the **Create patient card** button. – Message: *Saving data to card. Leave card inserted!* – Remove the patient card after the message disappeared.			
First name	–	–	–	–
Surname	–	–	–	–
Finesse ID	–	–	–	–
Date of birth	–	–	–	–

- **ONLINE (Can only be selected if the device option exists and if Filter 2 is set in the submenu Machine options in the Technician's Setup.)**

Submenu	Default value	Value range	Resolution	Selectable options
Treatment mode				
Treatment mode	HDF postdilution	–	–	HD HDF predilution HDF postdilution HF predilution HF postdilution
Bolus				
Bolus	150 ml	90–240 ml	30 ml	–
Bolus rate	200 ml/min	100–250 ml/min	10 ml/min	–
Preparation (Online)				
Onl. rinse vol.	800 ml	500–5000 ml	100 ml	–
Onl. UF rinse vol.	500 ml	0–5000 ml	100 ml	–
Reinfusion (online)				
Reinfusion volume	360 ml	60–480 ml	60 ml	–
Substitution				
Auto-sub	Yes	–	–	Yes No

- **OCM (Can only be selected if the device option exists.)**

Submenu	Default value	Value range	Resolution	Selectable options
OCM start	Automatic	–	–	Automatic Manual
Kt/V warning (see OCM description)	Yes	–	–	Yes No

- **Single Needle (Can only be selected if the device option exists.)**

Submenu	Default value	Value range	Resolution	Selectable options
Maximum stroke vol.	50 ml	–	–	–
Stroke volume	35 ml	10-50 ml	5 ml	–
Rate ratio (ratio blood pump speed to SN pump speed)	+20 %	–60 % to +60 %	5 %	–

- **Miscellaneous**

Submenu	Default value	Value range	Resolution	Selectable options
Installation place	Installation place of the 5008 hemodialysis system may be entered here (e.g. name of the clinic).			

- **BPM (Can only be selected if the device option exists.)**

Submenu	Default value	Value range	Resolution	Selectable options
SYS max	165 mmHg	100–280 mmHg	1 mmHg	–
DIA max	100 mmHg	100–240 mmHg	1 mmHg	–
MAP max	120 mmHg	80–255 mmHg	1 mmHg	–
PULSE max	150 1/min	50–245 1/min	1 1/min	–
SYS min	90 mmHg	30–140 mmHg	1 mmHg	–
DIA min	50 mmHg	10–90 mmHg	1 mmHg	–
MAP min	70 mmHg	20–120 mmHg	1 mmHg	–
PULSE min	40 1/min	20–140 1/min	1 1/min	–
Pressure preselection	160 mmHg	100–290 mmHg	1 mmHg	–

- **BTM (Can only be selected if the device option exists.)**

Submenu	Default value	Value range	Resolution	Selectable options
BTM				
BTM (Tubing detection after turning power on)	Active	–	–	Active Passive
Recirculation				
Recirculation measurement	Automatic	–	–	Automatic Manual
Body temperature				
Temp. control	Automatic	–	–	Automatic Manual
Temperature change	0.0 °C	–0.5 to +0.5 °C/h	0.1 °C/h	–
Room temperature				
Room temperature	20.0 °C	15.0–35.0 °C	1.0 °C	–

5.2 Technician's SETUP

Selecting the technician's SETUP

System turned power on.

Insert the technician's card.

Touch the **SYSTEM** button.

Touch the **SERVICE** button in the SYSTEM screen.

Touch the **SETUP** button on the SERVICE SCREEN.

How to use the OPERATOR SETUP

Save with OK.

Touch the logo to select default values.

- **Hydraulics settings**

Submenu		Default value	Value range	Resolution	Selectable options
Machine options					
	Machine options	DIASAFE®*plus* or ONLINE*plus*™ (not adjustable)	–	–	–
	Filter 1	–	–	–	Filter not present Present
	Filter 2	–	–	–	Filter not present Present
Water inlet tube					
	Length	3.0 m	1.0–5.0 m	0.1 m	–
	Internal diameter	6 mm	3–20 mm	1 mm	–

- **EBM settings**

Submenu		Default value	Value range	Resolution	Selectable options
Machine options					
	Motor type	Premotec	–	–	Premotec Papst others

- **Dialysate default values**

Submenu	Default value	Value range	Resolution	Selectable options
Concentrate	Depending on the setting in the technician's SETUP item "Define concentrates". SK-F 203	–	–	Depending on the setting in the technician's SETUP item "Define concentrates".
Prescr. Na	138 mmol/l	125–160 mmol/l	1 mmol/l	–
Prescr. Bic	32.0 mmol/l	0–40.0 mmol/l	1 mmol/l	–
Flow	500 ml/min	100–1000 ml/min	100 ml/min	–
Auto flow	Yes	–	–	Yes No
Auto flow factor	1.9	1.0–2.0	0.1	–
Temperature	36.5 °C	34 °C–39 °C	0.5 °C	–

- **Define concentrates**

Submenu	Default value	Value range	Resolution	Selectable options	
Operator list	AC-F 113 (10 l) AC-F 219/3 (6 l) AC-F 311 (6 l) AC-F 411 (6 l) AC-F 419 (6 l) SK-F 203 (6 l) SK-F 311 (10 l) AC-F 213 (6 l)	–	–	**SK-F 003** **SK-F 016** **SK-F 119** **SK-F 119/4** **SK-F 119/1** **SK-F 119/5** **SK-F 119/2** **SK-F 113/1** **SK-F 118** **SK-F 109** **SK-F 103** **SK-F 112** **SK-F 113** **SK-F 1/513** **SK-F 219/0** **SK-F 219/3** **SK-F 207** **SK-F 219/1** **SK-F 2129** **SK-F 21/56** **SK-F 213/4** **SK-F 212/1** **SK-F 216/1** **SK-F 219** **SK-F 21/53** **SK-F 209** **SK-F 218/1** **SK-F 218** **SK-F 202** **SK-F 203** **SK-F 212** **SK-F 216** **SK-F 213** **SK-F 223** **SK-F 212/2** **SK-F 2/513** **SK-F 318/1** **SK-F 313/2** **SK-F 301** **SK-F 309** **SK-F 311** **SK-F 312/1** **SK-F 316** **SK-F 313/1** **SK-F 318**	**SK-F 303** **SK-F 313** **SK-F 3/513** **SK-F 412/1** **SK-F 419** **SK-F 416** **SK-F 411/1** **SK-F 413/1** **SK-F 401** **SK-F 411** **SK-F 413** **AC-F 113** **AC-F 119** **AC-F 113/1** **AC-F 119/1** **AC-F 203** **AC-F 213** **AC-F 218** **AC-F 219** **AC-F 223** **AC-F 212/1** **AC-F 213/4** **AC-F 216/1** **AC-F 218/1** **AC-F 219/0** **AC-F 219/1** **AC-F 219/3** **AC-F 219/4** **AC-F 219/5** **AC-F 303** **AC-F 311** **AC-F 313** **AC-F 316** **AC-F 318** **AC-F 312/1** **AC-F 313/3** **AC-F 318/1** **AC-F 216** **AC-F 411** **AC-F 413** **AC-F 419** **AC-F 412/1** **AC-F 413/1** **AC-F 016**

- **Define syringe types**

Submenu	Default value	Value range	Resolution	Selectable options
Operator list	Fresenius 30 ml	–	–	B&D 10 ml Fresenius 10 ml Nipro 10 ml Terumo 10 ml Nipro 20 ml B&D 20 ml Terumo 20 ml JMS 20 ml B. Braun 30 ml B&D 30 ml Dispomed 30 ml Fresenius 30 ml Nipro 30 ml Terumo 30 ml

- **Define cleaning parameters**

Submenu	Default value	Value range	Resolution	Selectable options
PAGE 1				
Cleaning pgm combination	Heat disinfection	–	–	Rinse Heat disinfection Degreasing/cold disinfection
Disinfection port 1	Diasteril® (6 l)	–	–	Diasteril® (6000 ml) Citrosteril® (5000 ml) Puristeril® 340 (4400 ml)
Disinfection port 2	Sporotal® 100 (4. 3 l)	–	–	Sporotal® 100 (4300 ml)

Submenu	Minimum time (minutes : seconds)		Maximum time (minutes)	Resolution (minutes)
	Flow 600 ml/min	Flow 800 ml/min		
PAGE 2				
Rinse clear	Not programmable – see Rinse clear below			
Hot rinse				
with/without DIASAFE®*plus*	15:00	12:50	60	1
ONLINE*plus*™	17:30	14:50	60	1
Integrated hot rinse				
with/without DIASAFE®*plus*	05:00	05:00	60	1
ONLINE*plus*™	05:00	05:00	60	1
Cool down rinse				
with/without DIASAFE®*plus*	03:45	03:20	not adjustable	not adjustable
ONLINE*plus*™	04:30	03:55	not adjustable	not adjustable
Rinse				
with/without DIASAFE®*plus*	06:50	05:50	600	1
ONLINE*plus*™	07:45	06:35	600	1
Rinse clear				
with/without DIASAFE®*plus*	06:15	05:15	60	1
ONLINE*plus*™	07:10	06:00	60	1
Disinfection				
with/without DIASAFE®*plus*	08:40	08:40	60	1
ONLINE*plus*™	10:15	10:15	60	1
Heat disinfection				
with/without DIASAFE®*plus*	13:40	13:40	60	1
ONLINE*plus*™	15:40	15:40	60	1
Mandatory rinse				
with/without DIASAFE®*plus*	16:10	13:35	60	1
ONLINE*plus*™	18:10	15:05	60	1

Submenu		Default value	Value range	Resolution	Selectable options
PAGE 2					
	Cleaning flow	800 ml/min	–	–	800 ml/min 600 ml/min
	Heater rod power rating	2000 W (not adjustable)	–	–	–
	Audible info	No (not adjustable)	–	–	–
	Auto Off	10 min	–	–	Immediately 10 min 30 min 60 min No
	Mandatory disinfection after treatment	No (not adjustable)	–	–	–
	Disinfection note	No (not adjustable)	–	–	–

- **Define options (cannot be set yet)**

- **Define screen pages (cannot be set yet)**

- **Novram**

Submenu		Selectable options
	Novram	Delete mandatory disinfection
		Delete mandatory rinse

● Miscellaneous

Submenu	Default value	Value range	Resolution	Selectable options
Date (current date)				
Time (current time)				
Loudness	6	–	–	1–9
Sound	1	–	–	0–3
Sound check	Off	–	–	Off Audible alarm Audible warning Audible info Start-up sound
Skip T1 test	No	–	–	No Yes
Records	Yes	–	–	Yes No
Flash	Flash 1	–	–	Flash 1 Flash 2
Recording rate	Low	–	–	Low High

5.3 Information Regarding the Setting of Concentrates in the Technician's Setup

The following setting limits must be observed in the technician's menu for the specification of the concentrates:

- **Explanation of the terms used in the Settings menu**

Na^+ (sodium), K^+ (potassium), Ca^{2+} (calcium), Mg^{2+} (magnesium), C^- (chloride), $HCO3^-$ (bicarbonate)	Is the concentration of the respective ions in the ready-to-use dialysate.
NaB	Is the concentration of the sodium in the ready-to-use dialysate which originates from the bicarbonate concentrate. If the bicarbonate concentrate does not contain any additional saline, this value equals the total of the values for bicarbonate and acid (acid is most cases identical with the acetate) If the bicarbonate concentrate contains additional saline, the value for NaB equals the total of the final concentration of this saline in the ready-to-use dialysate, the bicarbonate and the acid. If the value set for NaB is zero it is assumed that the concentrate is pure bicarbonate concentrate, the software will set NaB = $HCO3^-$
CH_3COO^-	Acetate, is the concentrate of the acetate in the ready-to-use dialysate. **In case of bicarbonate dialysis**: If the value set here is zero, it is assumed that the prescription contains hydrochloric acid (HCl).
Acid	CH_3COOH or HCl, is the concentration of the acid which originates from the acidic or sodium concentrate (prior to the reaction with the bicarbonate component), in case of bicarbonate dialysis it is in most cases identical with the acetate. If the value set here is zero, it is assumed that it is identical with acetate, i.e. that the acetate of the ready-to-use dialysate is produced by the reaction of the acetic acid of the acid concentrate with the bicarbonate and that the concentrates did not contain any acetate prior to this reaction. This is the normal case. Acetic acid and hydrochloric acid are considered as acid.
Glucose	Is the concentration of the glucose in the ready-to-use dialysate. Caution: The unit of measure is g/L

- **Mixing ratio**

Acid proportion	Proportion of the acidic concentrate of the composition, is the reference quantity of the mixing ratio, constant = 1
Bic components	Proportion of the bicarbonate concentrate of the composition. In case of acetate dialysis the value is 0.

H_2O components Proportion of the RO water of the composition.

- **3mix dialysis**

Indi components Proportion of the individual concentrate of the composition. The value 0 stands for no individual concentrate dialysis.

NaI Is the concentration of the sodium (NaCl) in the ready-to-use dialysate which originates from the individual concentrate.

ConcI Is the concentration of the acid in the ready-to-use dialysate which originates from the individual concentrate. The Fresenius 3mix system currently uses hydrochloric acid. The use of acetic acid is possible if this is considered in the specification of the acetate proportion.

- **Setting limits for acetate dialysis**

Name	Unit	Min. value	Max. value	Condition
Na^+ sodium	1 mmol/L	125	150	
K^+ potassium	1/100 mmol/L	0.00	5.00	
Ca^{2+} calcium	1/1000 mmol/L	0.00	2.500	
Mg^{2+} magnesium	1/100 mmol/L	0.20	1.00	
Cl^- chloride	1/100 mmol/L	80.00	126	
$HCO3^-$ bicarbonate	1/10 mmol/L	0	0	
CH_3COO^- acetate		30.00	40.00	
Glucose	gm/L	0	3	
Acid proportion (here = acetate concentrate proportion)	non-dimensional	1 (= constant)		
Bic components	non-dimensional	0		
H_2O components	non-dimensional	19	40	
All others		0		

- **Setting limits for bicarbonate dialysis (3mix settings are not implemented)**

Name	Unit	Min. value	Max. value	Condition
Na^+ sodium	1 mmol/L	125	150	
Requirements: the NaCl (saline) concentration in the acidic concentrate must be ≥ 1800 mmol/l.				
K^+ potassium	1/100	0.00	5.00	
Ca^{2+} calcium	1/1000 mmol/l	0.00	2.500	
Mg^{2+} magnesium	1/100 mmol/l	0.20	1.00	
Cl^- chloride	1/100 mmol/l	80.00	126	
$HCO3^-$ bicarbonate	1/10 mmol/l	24.0	40.0	
Requirements: the concentration of bicarbonate in the bicarbonate concentrate must be ≥ 6 %.				
CH_3COO^- acetate	1/100 mmol	0.00	10.00	Acetate and acid input ≤ 10.00
Acid	1/100 mmol	1.50	4	in most cases = acetate
Glucose	gm/L	0	3	
Acid proportion	non-dimensional	1 (= constant)		
Bic components	non-dimensional	Bic components = H_2O components x 0.017	MixBic = H_2O components x 0.055	
H_2O components	non-dimensional	17 800 and additional 19 000 bic components	50.000	The following mixing ratio facilitates the calculation: Mix = 1+Bic components +H_2O components ≥ 20
Indi components	Not implemented.			
NaB	1/10 mmol/L	= bicarbonate	= bicarbonate + 30.0	

The table with possible settings offers optimum flexibility. It is, however, indispensable that all persons entering prescriptions are specially trained and instructed.
The input limits can**not** guarantee that the prescriptions entered will affect several setting limits and will not generate a conductivity alarm, are physiologic.

The allowed concentrate setting limits specified above also affect the limits which can be set by the operator. Some of the expected operator adjustments may then no longer be possible:

Operator setting limits:

Prescribed Na	Concentration of the prescription ± 10% (rounded off) and: 12.8 mS/cm ≤ expected conductivity ≤15.7 mS/cm and: 125 mmol/L ≤ prescribed Na ≤ 155 mmol/L
Prescribed bicarbonate	Concentration of the prescription ± 8 mmol/L and: 20 mmol/L ≤ prescribed bicarbonate ≤ 40 mmol/L and: 12.8 mS/cm ≤ expected conductivity ≤15.7 mS/cm Whichever condition is the most stringent applies.

6 TSC / TMC / Maintenance

6.1 Important Information

This chapter includes the Technical Safety Checks (TSC), the Technical Measurement Checks (TMC) and the Maintenance Procedures (MA) to be performed.
(Technical Measurement Checks are applicable only to Item 6.4 BPM.)

The Technical Safety Checks (TSC) and the Technical Measurement Checks (TMC) must be carried out every 2 years (24 months).

Performance of the Technical Safety Checks must be entered in the Medical Device Register.

The following applies to the technical measurement checks. After successful completion of the technical measurement checks, the respective parts of the hemodialysis system must be identified with a sign (label). This label must, in a unique and traceable manner, specify the year of the next Technical Measurement Check and the authority or person having performed the Technical Measurement Check.

Performance of the Maintenance Procedures (MA) is recommended by the manufacturer. The maintenance procedures must also be carried out every 2 years (24 months) and ensure smooth operation.

Precautions for working on the system

Assembly, extensions, adjustments, modifications or repairs may only be carried out by the manufacturer or persons authorized by him.
The activities described in the Technical Manual require the availability of the necessary technical measuring equipment and accessories.
Respect the following precautions when working on the open system:
Protect the components against ingress of fluids.
Do not touch live parts (e.g. connectors of the power cord or heater).
When repairing and when replacing spare parts, observe the applicable ESD precautions (e.g. EN 100 015-1).

6.2 Test Report – Technical Safety Checks, Technical Measurements Checks and Maintenance Procedures

	TSC / TMC / MA Test Report	
5008	**for the Technical Safety Checks and Technical Measurement Checks and Maintenance Procedures to be performed every 2 years (24 months)**	Fresenius Medical Care

The following inspections must be carried out by persons who are qualified to properly perform the Technical Safety Checks and Technical Measurement Checks owing to their educational background and training, their knowledge and experience gained in practice and who are not bound to any directions with regard to their inspection activity.

Technician's name:		**Service report number:**
Customer/Customer no.:		
Inventory no.:	**Serial no.:**	**Operating hours:**
Machine type: **including option(s):**		

TSC TMC	MA	No.	Description	Measure-ment value	✓
		1	**Visual inspections**		
TSC		1.1	Labels and labelings are present and legible.		❑
TSC		1.2	The mechanical condition permits further safe use. There are no signs of damage or safety-reducing dirt.		❑
TSC		1.3	No signs of damage on the power cord.		❑
TSC		1.4	Leakage sensors (S14, S35, EBM) inspected visually. Leakage sensors cleaned.		❑
TSC		1.5	Check valve for heat exchanger (A05) checked for proper function.		❑
TSC		1.6	Rotor position (blood pump) checked. Rotor cleaned.		❑
	MA	1.7	Dirty or shabby tubes replaced.		❑
	MA	1.8	Only applicable to CDS: Bicarbonate and concentrate flaps checked for proper functioning.		❑
	MA	1.9	Seal of rinse chamber replaced.		❑
	MA	1.10	Filters (F06, F08, F10, F11, F12, F13, F14, F15, F16) changed.		❑
	MA	1.11	Filters (F01, F07) checked and changed if necessary.		❑
	MA	1.12	O-rings in dialyzer couplings replaced.		❑
	MA	1.13	Disinfectant suction valves (V20, V34) replaced.		❑
	MA	1.14	Arterial and venous clamps checked.		❑
		2	**General checks**		
TSC		2.1	Power failure alarm checked. Permanent tone; alarm message: *Power failure – Machine is battery-operated*.		❑
	MA	2.2	Torque setting of monitor arm checked in all 3 axes.		❑
	MA	2.3	Every 4 years only: Battery replaced.		❑
		3	**Hydraulics unit**		
	MA	3.1	Loading pressure of balancing chamber checked.	_____	❑
	MA	3.2	Level sensor (S17, S19) checked. (Not applicable to bibag.)		❑
	MA	3.3	Leakage sensors (S14, S35) inspected.		❑

TSC TMC	MA	No.	Description	Measure-ment value	✓
		4	**Dialysis mode**		
TSC		4.1	PT7 (temperature) checked at 37 °C. (Flow 500 ml/min) Desired value: 36.8 °C to 37.2 °C (display on hemodialysis system) Measure the reference temperature with an external measuring instrument. Difference = Reference temperature minus PT7 Desired value – difference: –0.5 °C to +0.2 °C	_____ _____	❑
TSC		4.2	CD7 (conductivity) checked. Desired value: approx. 13.5 mS/cm to approx. 14.5 mS/cm Measure the reference conductivity with an external measuring instrument. Difference = Reference conductivity minus CD7 Desired value – difference: ±0.2 mS/cm	_____ _____	❑
	MA	4.3	Dialysate pressure checked.		❑
		4.3.1	Zero point S03/S07 Reference measuring instrument: 0 mbar Check S03. Desired value: +16 mbar to +76 mbar Check S07. Desired value: +16 mbar to +76 mbar	_____ _____ _____	
		4.3.2	Slope S03/S07 (+) Reference measuring instrument: +533 mbar (± 26 mbar) Check S03. Desired value: S03 = Display of reference measuring instrument + (+16 mbar to +76 mbar) Check S07. Desired value: S07 = Display of reference measuring instrument + (+16 mbar to +76 mbar)	_____ _____ _____	
		4.3.3	Slope S03/S07 (-) Reference measuring instrument: -533 mbar (± 26 mbar) Check S03. Desired value: S03 = Display of reference measuring instrument + (+16 mbar to +76 mbar) Check S07. Desired value: S07 = Display of reference measuring instrument + (+16 mbar to +76 mbar)	_____ _____ _____	

TSC TMC	MA	No.	Description	Measure-ment value	✓
		5	**Extracorporeal components**		
		5.1	Arterial pressure display checked.		
	MA	5.1.1	Zero point of arterial pressure display (standby operation) Desired value: –5 mmHg to +5 mmHg	_____	❑
	MA	5.1.2	Slope of arterial pressure display (standby operation) Desired value: –5 mmHg to +5 mmHg	_____	❑
		5.2	Venous pressure display checked.		
	MA	5.2.1	Zero point of venous pressure display (standby operation) Desired value: –5 mmHg to +5 mmHg	_____	❑
	MA	5.2.2	Slope of venous pressure display (standby operation) Desired value: –5 mmHg to +5 mmHg	_____	❑
TSC		5.3	Venous clamp checked. A pressure change within 3 minutes must not exceed the following values: Arterial pressure display, maximum pressure change: ±5 mmHg Pressure display of reference measuring instrument, desired maximum pressure drop: –0.1 bar		❑ ❑
	MA	5.4	Leakage sensor (EBM) cleaned.		❑

TSC TMC	MA	No.	Description	Measure-ment value	✓
		6	**Options**		
		6.1	biBag		
TSC	**MA**	6.1.1	O-ring at connector replaced.		❑
		6.2	Diasafe		
TSC	**MA**	6.2.1	Hydrophobic filter DIASAFEplus changed.		❑
		6.3	ONLINEplus		
TSC		6.3.1	Rotor position (ONLINEplus) checked. Rotor cleaned.		❑
	MA	6.3.2	Tube in tube squeeze valve replaced.		❑
TSC		6.3.3	Hydrophobic filter changed.		❑
TSC		6.3.4	O-rings at substituate port and rinse port replaced.		❑
		6.4	BPM		
	MA	6.4.1	Attachments of internal blood pressure module, printed circuit boards and cable connections checked.		❑
	MA	6.4.2	Tube connection properly fixed to hemodialysis system.		❑
	MA	6.4.3	Tubings and cuffs checked for damage. (damaged parts replaced)		❑
TMC		6.4.4	Leakage test performed. Pressure leakage rate: <6 mmHg/min	 _____	❑
TMC		6.4.5	Safety valve tested. System emptied at 320 mmHg, ±10 mmHg	 _____	❑
TMC		6.4.6	Blood pressure measurement performed. Measured values are plausible.		❑
TMC		6.4.7	Calibration performed. Pressure values / tolerance 250 mmHg / ±3 mmHg 200 mmHg / ±3 mmHg 150 mmHg / ±3 mmHg 100 mmHg / ±3 mmHg 50 mmHg / ±3 mmHg	 System / ref. System / ref. System / ref. System / ref. System / ref.	 ____/____ ____/____ ____/____ ____/____ ____/____	❑
		6.5	Single Needle		
TSC		6.3.1	Rotor position (Single Needle) checked. Rotor cleaned.		❑

TSC TMC	MA	No.	Description	Measure-ment value	✓
		7	**Check – electrical safety** In Germany according to DIN VDE 0751-1, edition 10/2001. In other countries, observe the local regulations!		
TSC		7.1	Visual inspections performed according to item 1.		❑
TSC		7.2	Protective earth resistance measured. max. 0.3Ω (with)	 _____ Ω	❑
TSC		7.3	Leakage current (device leakage current) measured. ❑ Differential current measurement according to figure C.6 ***or*** ❑ Direct measurement according to figure C.5 Nominal voltage of power supply: _____ V Device leakage current mains polarity 1 _____ µA with line voltage _____ V scaled to nominal voltage (maximum 500 µA, see Additional requirements) Device leakage current mains polarity 2 _____ µA with line voltage _____ V scaled to nominal voltage (maximum 500 µA, see Additional requirements) Test equipment used: _____	 _____ µA _____ µA	❑
		8	**Final inspection and testing**		
TSC	**MA**	8.1	T1 test performed with all options.		❑
TSC	**MA**	8.2	Disinfection performed.		❑

Date:	Signature:	Stamp:

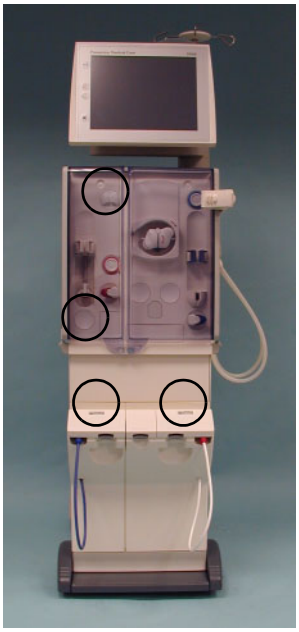
The system has been released for further use.	❑ Yes	❑ No

Comments:

Date:	Signature:	Stamp:

6.3 Explanations on Technical Safety Checks, Technical Measurement Checks and Maintenance Procedures

TSC TMC	MA	No.	Description
		1	**Visual inspections**
TSC		1.1	Labels and labelings are present and legible.



Front view:

Applicable to ONLINE*plus*™ (option):
Substituate and rinse ports; warning of scalding and cauterizing risks.

Bicarbonate and concentrate flaps; warning of scalding and cauterizing risks.

Under bicarbonate flap: reference to bi*b*ag®.

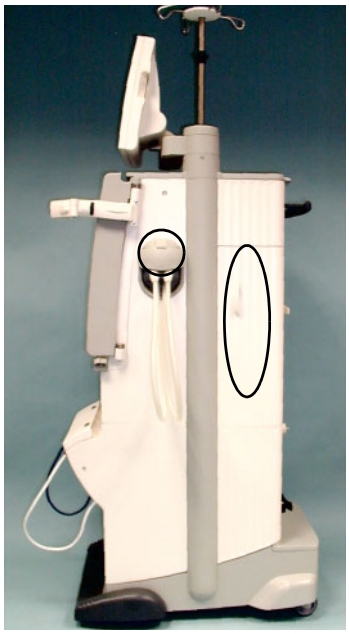
Rear view:

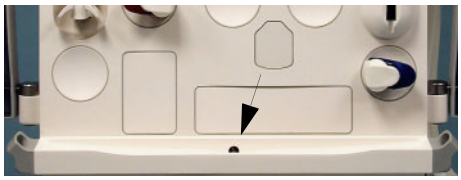
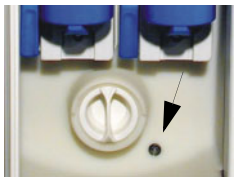
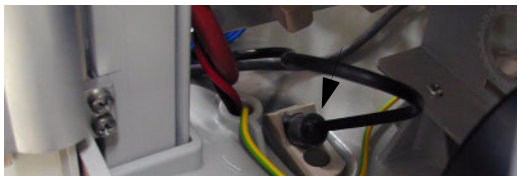
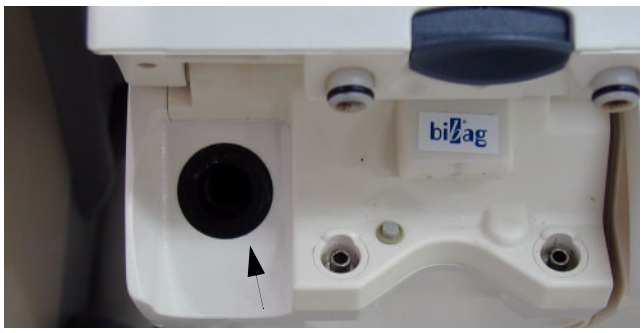
IV pole; maximum load warning

Upper door area; warning of tilting risk and
type label.

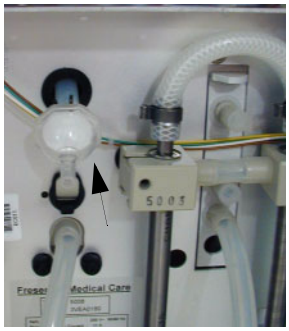
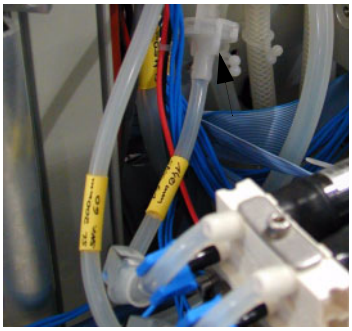
Disinfection connectors; warning of cauterizing risk.

Hydraulics connector
Potential equalization label
ZKV/CDS 1, ZKV/CDS 2 and BIC labels
Warning of scalding and cauterizing risks.
Accumulator label

TSC TMC	MA	No.	Description
			 To the right: Under shunt interlock: warning of scalding and cauterizing risks. Arrow labels on dialyzer connectors. On inside of door of dialysate filter chamber; Warning of scalding and cauterizing risks. On filter holders; filter 1 and filter 2 labels; warning of scalding and cauterizing risks.
TSC		1.2	The mechanical condition permits further safe use. There are no signs of damage or safety-reducing dirt. There must not be any damage or dirt affecting the electrical and mechanical properties. The following and other checks must be performed: The monitor can be swivelled and stays in the position desired. If its brakes are not locked, the carriage can be moved as desired. Check the brake. Check EBM, concentrate connectors, filter chamber, and complete hydraulics (e.g. leaks, corrosion, broken parts, loose parts).
TSC		1.3	No signs of damage on the power cord.

TSC TMC	MA	No.	Description
TSC		1.4	Leakage sensors (S14, S35, EBM) inspected visually. Leakage sensors cleaned. Visually check leakage sensors for cleanliness and mechanical damage. The lacquer coat of the sensors must not be damaged.  EBM (leakage sensor)  S 14 (leakage sensor of filter chamber)  S 35 (leakage sensor of hydraulics)
TSC		1.5	Check valve for heat exchanger (A05) checked for proper function. .
TSC		1.6	Rotor position (blood pump) checked. Rotor cleaned. Visually check the rotor position (blood pump); rotor in proper stator. Line rollers and guide pulleys are running smoothly.
	MA	1.7	Dirty or shabby tubes replaced. The following and other checks must be performed: Dialyzer supply and drain line
	MA	1.8	Only applicable to CDS: Bicarbonate and concentrate flaps checked for proper functioning. Check engagement and microswitch.
	MA	1.9	Seal of rinse chamber replaced.  Replace seal and iron ring.

TSC TMC	MA	No.	Description
	MA	1.10	Filters (F06, F08, F10, F11, F12, F13, F14, F15, F16) changed.

To the left:
F06
Hydrophobic filter compressor

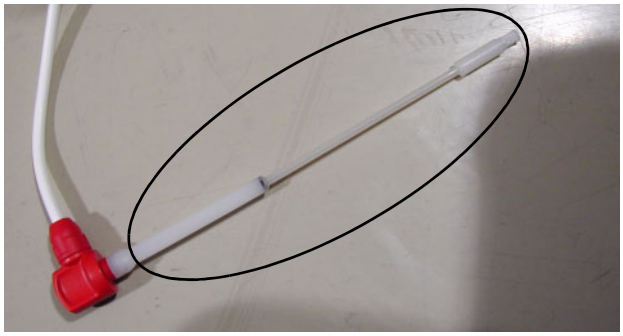
To the right:
F08
Filter of UF pump

To the left:
F10
Filter, disinfectant 1

To the right:
F16
Filter, disinfectant 2

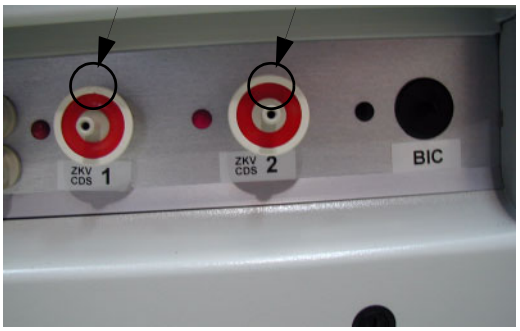
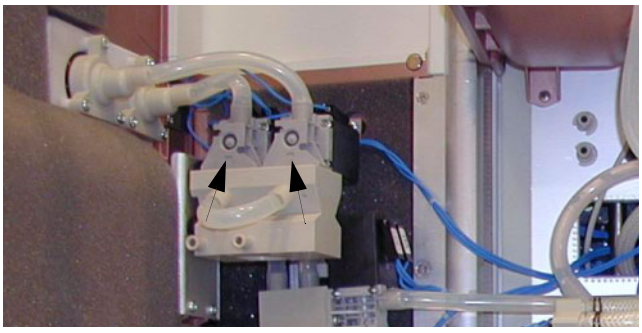
Change filter including O-ring. Grease O-rings before installing them.

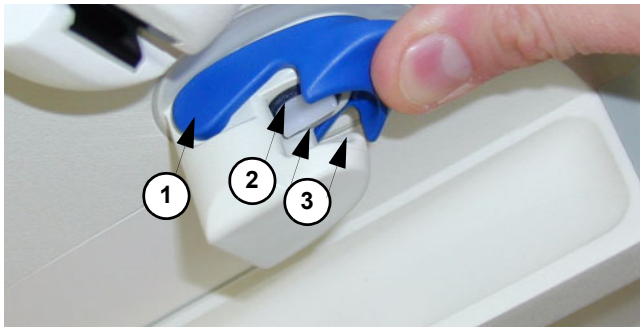
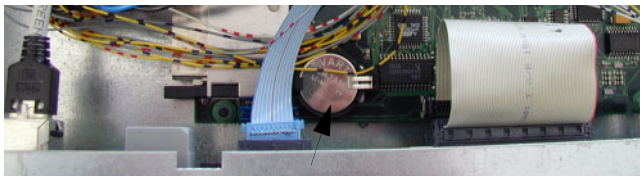
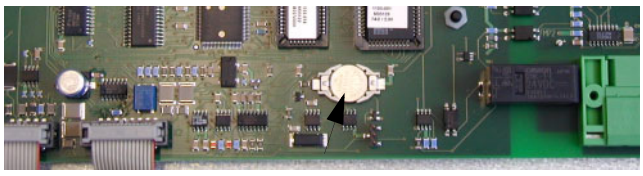
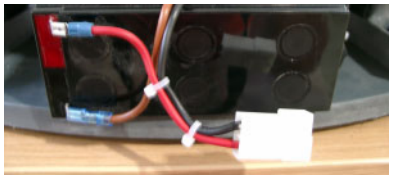
After installation, the mark must be at the top.

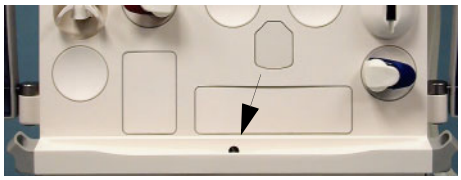
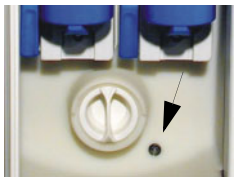


F11
Suction rod with acetate filter

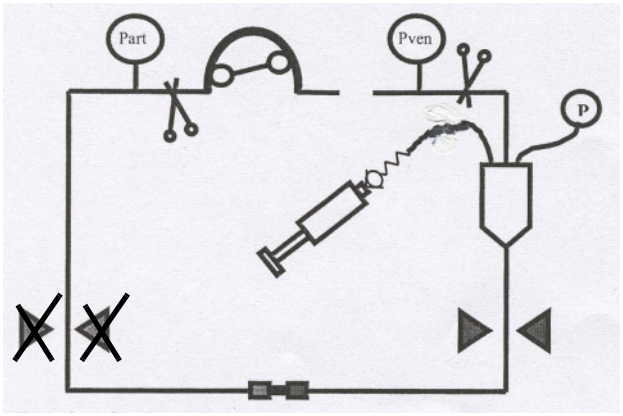
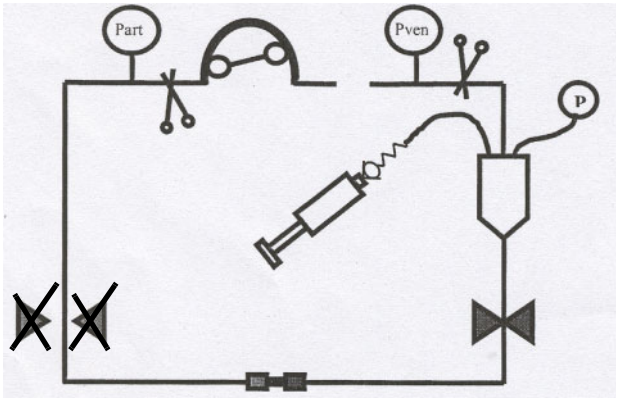
F12
Suction rod with bicarbonate filter

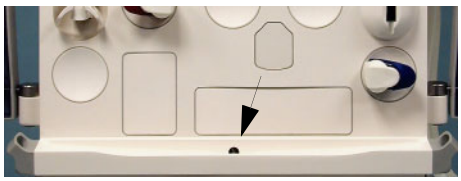
TSC TMC	MA	No.	Description
			 To the right: F15 Filter, CDS acid 1 Middle: F14 Filter, CDS acid 2 To the left: F15 Filter, CDS bicarbonate Change filter including O-ring. Grease O-rings before installing them. After installation, the mark must be at the top.
	MA	1.11	Filters (F01, F07) checked and changed if necessary.  To the right: F01 Water inlet filter To the left: F07 Dialysate filter If necessary, change filter including O-rings. Grease O-rings before installing them. After installation, the mark must be at the top.
	MA	1.12	O-rings in dialyzer couplings replaced. (Grease O-rings before installing them.)
	MA	1.13	Disinfectant suction valves (V20, V34) replaced.  To the left: V20 Disinfection valve 1 To the right: V34 Disinfection valve 2

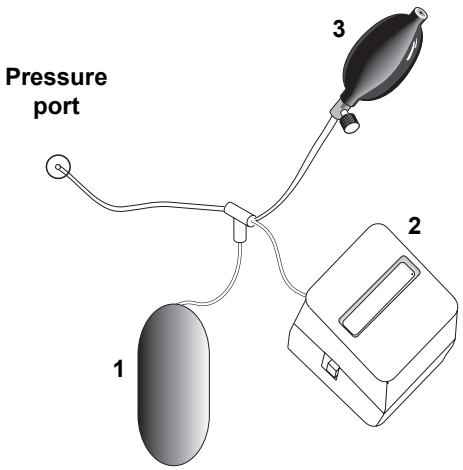
TSC TMC	MA	No.	Description
	MA	1.14	Arterial and venous clamps checked.  Integrity of: 1 Grip handle 2 Valve tappet 3 Clamping and tappet surfaces
		2	**General checks**
TSC		2.1	Power failure alarm checked. Permanent tone; alarm message: *Power failure – Machine is battery-operated*. Pull off power plug to check the power failure alarm.
	MA	2.2	Torque setting of monitor arm checked in all 3 axes.
	MA	2.3	Every 4 years only: Battery replaced.  Monitor battery Replace battery swiftly to prevent loss of data.  Power supply unit battery Turn on the hemodialysis system after having replaced the battery. The current time is applied after the next power-on.  Battery Place the battery connection cable in the appropriate guides.
		3	**Hydraulics unit**
	MA	3.1	Loading pressure of balancing chamber checked. This pressure should be measured in the course of maintenance procedures. Is done in the 5008 service program

TSC TMC	MA	No.	Description
	MA	3.2	Level sensor (S17, S19) checked. (Not applicable to biBag.)
	MA	3.3	Leakage sensors (S14, S35) inspected. Visually check leakage sensors for cleanliness and mechanical damage. The lacquer coat of the sensors must not be damaged.  EBM (leakage sensor)  S 14 (leakage sensor of filter chamber)
		4	**Dialysis mode**
TSC		4.1	PT7 (temperature) checked at 37 °C. (Flow 500 ml/min) Desired value: 36.8 °C to 37.2 °C (display on hemodialysis system) Measure the reference temperature with an external measuring instrument. Difference = Reference temperature minus PT7 Desired value – difference: –0.5 °C to +0.2 °C
TSC		4.2	CD7 (conductivity) checked. Desired value: approx. 13.5 mS/cm to approx. 14.5 mS/cm Measure the reference conductivity with an external measuring instrument. Difference = Reference conductivity minus CD7 Desired value – difference: ±0.2 mS/cm

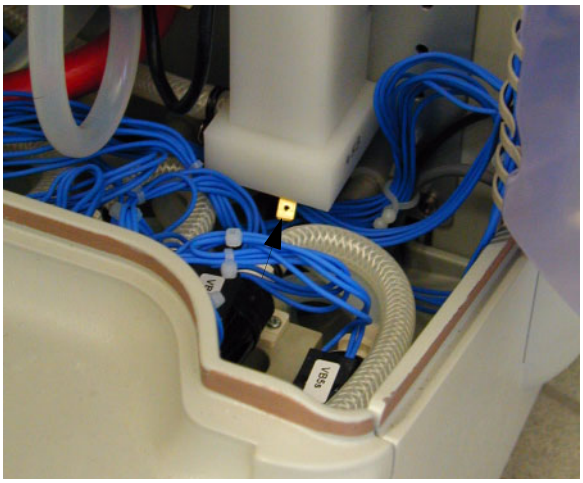
TSC TMC	MA	No.	Description
	MA	4.3	Dialysate pressure checked. In the service mode, select CALIBRATE. Basic requirements: The hemodialysis system **must be closed.** The reference measuring instrument must be placed at the bottommost position of the IV pole. Dialyzer couplings must be connected to the reference instrument. Flow on until dialysate lines and reference measuring instrument are free from air. Then flow off.
		4.3.1	Zero point S03/S07 Reference measuring instrument: 0 bar Open the vent valve (UMED). Using a syringe (filled with fluid) set a value of 0 bar, via the vent valve. Check S03. Desired value: +16 mbar to +76 mbar Check S07. Desired value: +16 mbar to +76 mbar
		4.3.2	Slope S03/S07 (+) Reference measuring instrument: +533 mbar (± 26 mbar) Using a syringe (filled with fluid) set a value of +533 bar, via the vent valve. Check S03. Desired value: S03 = Display of reference measuring instrument + (+16 mbar to +76 mbar) Check S07. Desired value: S07 = Display of reference measuring instrument + (+16 mbar to +76 mbar)
		4.3.3	Slope S03/S07 (–) Reference measuring instrument: –533 mbar (± 26 mbar) Using a syringe (filled with fluid) set a value of –533 bar, via the vent valve. Check S03. Desired value: S03 = Display of reference measuring instrument + (+16 mbar to +76 mbar) Check S07. Desired value: S07 = Display of reference measuring instrument + (+16 mbar to +76 mbar)
		5	**Extracorporeal components**
	MA	5.1	Zero point of arterial pressure display checked (standby operation) Desired value: –5 mmHg to +5 mmHg
	MA	5.2	Zero point of venous pressure display checked (standby operation) Desired value: –5 mmHg to +5 mmHg

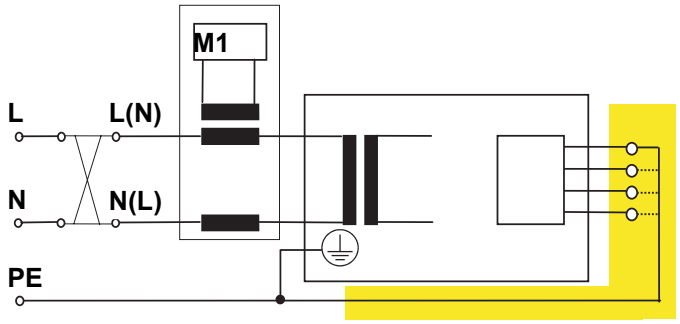
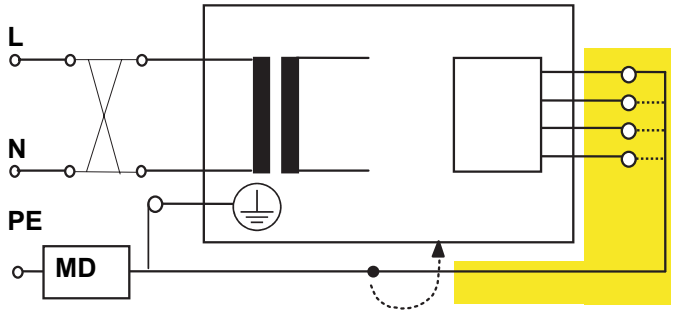
TSC TMC	MA	No.	Description
TSC		5.3	Venous clamp checked. Basic requirements: Blood lines inserted, standby operation. Connect the arterial and the venous branch using the adapter fitting included. Remove the line from the arterial clamp. Clamp the blood line before the blood pump and on the venous drip chamber. Connect the external pressure measuring instrument to the venous bubble catcher. Connect the syringe and the one-way valve (if present) to the venous bubble catcher.  Pressure build-up – arterial side: Open the venous clamp. Using a syringe, build up an arterial pressure of 50 mmHg to 100 mmHg. Observe the arterial display on the hemodialysis system. Close the venous clamp.  Pressure build-up – venous side: Venous clamp closed. Using a syringe, build up a pressure of 2.5 bar to 2.7 bar. Observe the display on the external reference measuring instrument. Maximum pressure change within 3 minutes on the arterial pressure display of the hemodialysis system ±5 mmHg. Maximum pressure drop within 3 minutes on the display of the reference measuring instrument –0.1 bar.

TSC TMC	MA	No.	Description
	MA	5.4	Leakage sensors (EBM) cleaned. Visually check leakage sensor for cleanliness and mechanical damage. The lacquer coat of the sensors must not be damaged.  EBM (leakage sensor)
		6	**Options**
		6.1	biBag
TSC	**MA**	6.1.1	O-ring at connector replaced.
		6.2	Diasafe
TSC	**MA**	6.2.1	Hydrophobic filter DIASAFEplus changed.
		6.3	ONLINEplus
TSC		6.3.1	Rotor position (ONLINEplus) checked. Rotor cleaned.
	MA	6.3.2	Tube in tube squeeze valve replaced.
TSC		6.3.3	Hydrophobic filter changed.
TSC		6.3.4	O-rings at substituate port and rinse port replaced.
		6.4	BPM
	MA	6.4.1	Attachments of internal blood pressure module, printed circuit boards and cable connections checked.
	MA	6.4.2	Tube connection properly fixed to hemodialysis system.
	MA	6.4.3	Tubings and cuffs checked for damage. (damaged parts replaced)
TMC		6.4.4	Leakage test performed. In the service mode, select DIAGNOSTICS. Select BPM from the DIAGNOSTICS menu. Basic requirements: Tube and blood pressure cuff connected. The blood pressure cuff must be placed on an artificial limb. Pressure preselection 250 mmHg Touch the **Leakage test I/O** button. (Test time approx. 4 minutes) Read off the leakage rate from Info BPM. The maximum pressure leakage rate must be ≤6 mmHg/min.

TSC TMC	MA	No.	Description
TMC		6.4.5	Safety valve tested. In the service mode, select DIAGNOSTICS. Select BPM from the DIAGNOSTICS menu. Basic requirements: Tube and blood pressure cuff connected. The blood pressure cuff must be placed on an artificial limb. Pressure preselection 290 mmHg Touch the **Calibration test I/O** button. Once the pressure has reached approx. 290 mmHg, increase the pressure by slowly pressing the blood pressure cuff. If 320 mmHg ±10 mmHg is exceeded, the cuff must deflate immediately. Touch the **Status** button in the Service menu. Touch the **Error memory** button. Touch the **BPM** button. Check the error memory. Turn the hemodialysis system off and back on again.
TMC		6.4.6	Blood pressure measurement performed. Touch the **SYSTEM** button. Touch the **Blood pressure** button. The blood pressure measurement starts. After the measurement, check whether the values are plausible.
TMC		6.4.7	Calibration performed. In the service mode, select DIAGNOSTICS. Select BPM from the DIAGNOSTICS menu. Remove tube and blood pressure cuff from the pressure connector.  Connect a rigid metal vessel (1), a pressure gauge (2), and an aspirator bulb with drain valve (3) to the pressure connector. Touch the **Calibration test I/O** button. Set the appropriate test pressure using the drain valve. Wait until the pressure has stabilized. Check the test pressure. 250 mmHg/ ±3 mmHg 200 mmHg / ±3 mmHg 150 mmHg / ±3 mmHg 100 mmHg / ±3 mmHg 50 mmHg / ±3 mmHg
		6.5	Single Needle
TSC		6.5.1	Rotor position (Single Needle) checked. Rotor cleaned.

TSC TMC	MA	No.	Description
		7	**Check – electrical safety** In Germany according to DIN VDE 0751-1, edition 10/2001. In other countries, observe the local regulations!
TSC		7.1	Visual inspections performed according to item 1. – Labels and labelings are present and legible. – The mechanical condition permits further safe use. There are no signs of damage or dirt. – No signs of damage on the power cord. – Fuses accessible from the outside comply with the indicated values. – Labels and labelings are present and legible.
TSC		7.2	Protective earth resistance measured. No more than 0.3 ohms (with power cord) The protective earth resistance must be checked on the following four measurement points.  1. Measurement point: power supply unit  2. Measurement point: shunt door

TSC TMC	MA	No.	Description	
				3. Measurement point: potential equalization
				4. Measurement point: heater

TSC TMC	MA	No.	Description
TSC		7.3	Leakage current (device leakage current) measured.  Differential current measurement according to figure C.6 *or*  Direct measurement according to figure C.5 Basic requirements: Measurement of the protective earth resistance performed. Perform the measurement in the dialysis or preparation mode with the system at operating temperature. Dialysate: Dialysis temperature: ≥ 37 °C Dialysate flow: ≥ 300 ml/min Conductivity: ≥ 13 mS/cm When performing a direct measurement, the following precautions also must be observed: The system must be insulated when installed. All external connections must have been removed from the system. The line voltage during the measurement will be recorded, as well as the maximum device leakage current of both mains polarities, scaled to the nominal voltage of the power supply. Maximum device leakage current: 500 µA Example: Line voltage during the measurement: 225 V Device leakage current for mains polarity 1: 180 µA for mains polarity 2: 120 µA Maximum value of both mains polarities: 180 µA Nominal voltage of power supply: 230 V Scaled to nominal voltage: 184 µA (180 µA: 225 V x 230 V = 184 µA Device leakage current < 500 µA: OK

TSC TMC	MA	No.	Description	
			Additional requirements: If the device leakage current, scaled to the nominal voltage, is higher than 90 % of the admissible alarm limit (450 µA), the last measured value or the first measured value must additionally be considered for the rating. If the device leakage current has considerably increased since the last measurement or has continuously increased since the first measurement (creeping deterioration of the insulation), or if the sum composed of the current value plus the difference since the last measurement is > 500 µA, the measurement has not been completed successfully. Example 1: Device leakage current: 470 µA Last measured value: 450 µA 470 + (470 – 450) = 470 + 20 = 490; is OK Example 2: Device leakage current: 470 µA Last measured value: 390 µA 470 + (470 – 390) = 470 + 80 = 550; not passed	
		8	**Final inspection and testing**	
TSC	**MA**	8.1	T1 test performed with all options.	
TSC	**MA**	8.2	Disinfection performed.	

6.4 TSC / TMC Report

5008	**TSC / TMC Report** for the Technical Safety Checks and Technical Measurement Checks to be performed every two years (24 months)	Fresenius Medical Care

The following inspections must be carried out by persons who are qualified to properly perform the Technical Safety Checks and Technical Measurement Checks owing to their educational background and training, their knowledge and experience gained in practice and who are not bound to any directions with regard to their inspection activity.

Technician's name:		**Service report number:**
Customer/Customer no.:		
Inventory no.:	**Serial no.:**	**Operating hours:**
Machine type: **including option(s):**		

No.	Description	Measurement value	✓
1	**Visual inspections**		
1.1	Labels and labelings are present and legible.		❑
1.2	The mechanical condition permits further safe use. There are no signs of damage or safety-reducing dirt.		❑
1.3	No signs of damage on the power cord.		❑
1.4	Leakage sensors checked visually. Leakage sensors cleaned.		❑
1.5	Check valve for heat exchanger (A05) checked for proper function.		❑
1.6	Rotor position (blood pump) checked. Rotor cleaned.		❑
2	**General checks**		
2.1	Power failure alarm – continuous sound – display message: Emergency operation		❑

No.	Description		Measurement value	✓
4	**Dialysis mode**			
4.1	Temperature tested with reference instrument. Desired temperature on temperature display Difference between system temp. / ref. temp.: –0.5 to +0.2 °C	System / ref.	____/____	❑
4.2	Conductivity tested with reference instrument. (The bi*b*ag® option requires connection of a bi*b*ag®.) Difference between system CD / ref. CD: ≤±0.2 mS/cm	System CD / ref. CD	____/____	❑
5	**Extracorporeal components**			
5.3	Check of venous clamp performed. A change in pressure must not exceed the following values within 3 minutes: Arterial pressure display, maximum change in pressure: ±5 mmHg Pressure display of reference measuring instrument, maximum pressure drop: –0.1 bar			❑
6	**Options**			
6.3	ONLINEplus			
6.3.1	Rotor position (ONLINEplus) checked. Rotor cleaned.			❑
6.4	BPM			
6.4.4 TMC	Leakage test performed. Pressure leakage rate: <6 mmHg/min		_____	❑
6.4.5 TMC	Calibration performed. Pressure values / tolerance 250 mmHg / ±3 mmHg 200 mmHg / ±3 mmHg 150 mmHg / ±3 mmHg 100 mmHg / ±3 mmHg 50 mmHg / ±3 mmHg	 System / ref. System / ref. System / ref. System / ref. System / ref.	 ____/____ ____/____ ____/____ ____/____ ____/____	❑
6.4.6	Safety valve tested. System emptied at 320 mmHg ±10 mmHg		_____	❑
6.4.7 TMC	Blood pressure measurement performed. Measured values are plausible.			❑
6.5	Single Needle			
6.5.1	Rotor position (Single Needle) checked. Rotor cleaned.			❑

No.	Description	Measurement value	✓
7	**Check – electrical safety** In Germany according to DIN VDE 0751-1, edition 10/2001. In other countries, observe the local regulations!		
7.1	Visual inspections performed according to item 1.		❑
7.2	Protective earth resistance maximum 0.3 ohms (with power cord)	_____ Ω	❑
7.3	Leakage current measurement (device leakage current) ❑ Differential current measurement according to figure C.6 ***or*** ❑ Direct measurement according to figure C.5 Nominal voltage of power supply: _____ V Device leakage current mains polarity 1 _____ µA with line voltage _____ V scaled to nominal voltage (maximum 500 µA, see Additional requirements) Device leakage current mains polarity 2 _____ µA with line voltage _____ V scaled to nominal voltage (maximum 500 µA, see Additional requirements) Test equipment used: _____	_____ µA _____ µA	❑
8	**Final inspection and testing**		
8.1	T1 test performed with all options.		❑
8.2	Disinfection performed.		❑

Date:	Signature:	Stamp:

The system has been released for further use.	❑ Yes	❑ No

Comments:

Date:	Signature:	Stamp:

7 Error Messages

The messages can be filed in the Message button.
Touch the **X** button to file the messages.
To retrieve the messages, touch the **Message button**.
If several messages are displayed, select the desired message.

The windows contain a brief description of the condition for the technician and the required instructions to correct the problem.
Help can be displayed directly by touching the **?** button in the window.
The associated Information window will be opened automatically.

Power failure and depleted battery
Screen failure

8 Tools (Service Equipment)

Caution

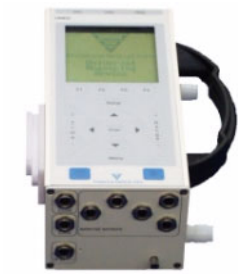
Only for OCM (option):
The accuracy of the measuring equipment used during the calibration is decisive for the accuracy of the OCM measurement.

The measuring equipment used for the calibration of the conductivity must have an accuracy of 0.05 mS/cm in the temperature range of 35 °C to 39 °C.

We recommend using the measuring device UMED (part no. M32 403 1) available from Fresenius Medical Care.

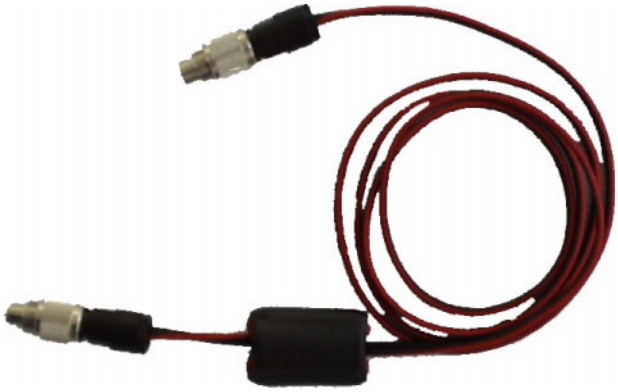
HMED pressure measuring device with case (set)

Part number: M30 770 1



UMED pressure measuring device with case (set)
(conductivity, pressure, temperature)

Part number: M32 403 1



Connection cable UMED - 5008

Part number: M35 152 1

Secutest VDE test device
(without printer module)

Part number: 631 064 1

Printer module (without illustration)

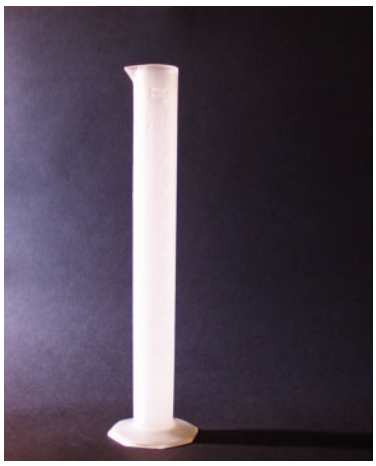
Part number: 630 652 1

Carrying bag (without illustration)

Part number: 630 648 1

PC Service Software

Part number: M35 016 1



Graduated cylinder 100 ml

Part number: 510 085 1

ESD Service Kit

Part number: 630 387 1

ESD Workshop Kit

Part number: 630 388 1

Toolcase 5008

Part number: M35 463 1

9 Calibration / Adjustment

- **Selecting calibration**

  Turn the system on.

  Insert the technician's card.

  Touch the **SYSTEM** button.

  Touch the **SERVICE** button in the SYSTEM screen.

  Message: *Please remove service card.*

  Touch the **CALIBRATE** button on the SERVICE SCREEN.

  If a red "K" is shown in one of the fields, this indicates that no valid calibration value is available.

- **Calibrating the touch screen**

  Select the **Calibrate touch screen** field. Touch the **Start calibration** button.

  The following message will be displayed on the upper left: *Please touch the target points*. Touch the "target points".

  The following message will be displayed on the lower right: *Please touch the target points*. Touch the "target points".

  When the touch screen has been calibrated, the CALIBRATE SCREEN will be displayed.

  INFO
  If the menu cannot be selected (touch screen decalibrated), use the following combination of buttons on the monitor. Consecutively press and hold the **Mute** key, the **Blood system Start** key and the **Blood system Stop** key.

- **Pressure transducer (S03/ S07/ S16)**

  Select the **Pressure transducer (S03/ S07/ S16)** field. Touch the **Start calibration** button.

  Automatic adjustment of the zero of the pressure transducers S03, S07 and S16.

  When the pressure transducers have been calibrated, the following message will be displayed: *Please check or recalibrate degassing (A01/P01) and loading pressure (A02/P02).*Touch the **Confirm** button.

The CALIBRATE SCREEN will be displayed.

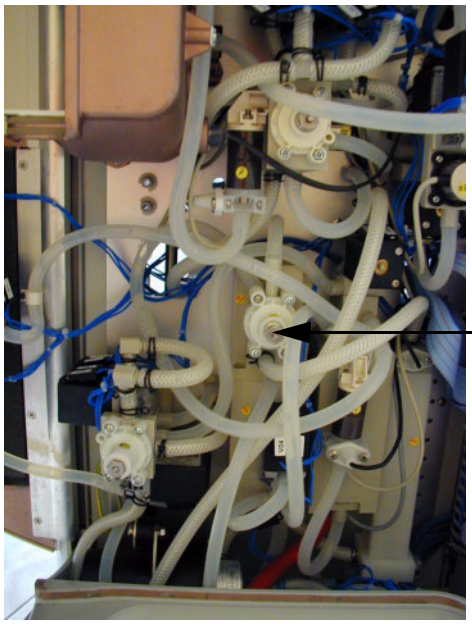
- **Degassing (A01 / P01)**

Select the **Degassing (A01/P01)** field. Touch the **Start calibration** button.

The following message will be displayed: *Adjustment of relief valve A01. between 1200 and 1300 mbar Pressure S16: XXXX mbar.* If the pressure is within the range, touch the **Confirm** button.

When the degassing (A01/P01) has been calibrated, the CALIBRATE SCREEN will be displayed.

If the pressure limitation is not within the desired range, it must be adjusted using A01.



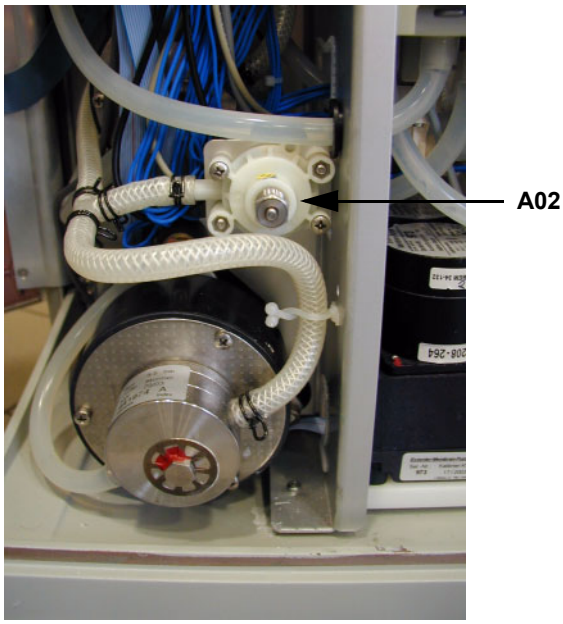
- **Loading pump (A02 / P02)**

Select the **Loading pump (A01/P01)** field. Touch the **Start calibration** button.

The following message will be displayed: *Adjustment of relief valve A02. between 1800 and 1900 mbar Pressure S03: XXXX mbar.* If the pressure is within the range, touch the **Confirm** button.

When the loading pump (A02/P02) has been calibrated, the CALIBRATE SCREEN will be displayed.

If the pressure limitation is not within the desired range, it must be adjusted using A02.



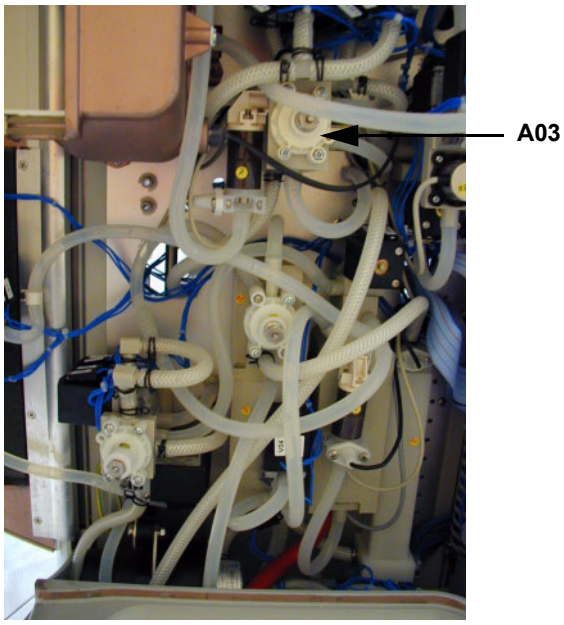
- **Flow pump (A03)**

Select the **Flow pump (A03)** field. Touch the **Start calibration** button.

The following message will be displayed: *Adjustment of relief valve A03. between 2550 and 2650 mbar Pressure S15: XXXX mbar.* If the pressure is within the range, touch the **Confirm** button.

The CALIBRATE SCREEN will be displayed. The flow pump (A03) is now calibrated.

If the pressure limitation is not within the desired range, it must be adjusted using A03.



- **Temperature (PT7/ PT8/ PT9)**

Select the **Temperature (PT7/ PT8/ PT9)** field. Touch the **Start calibration** button.

Measure the reference temperature with an external measuring instrument.

Basic requirements:
The hemodialysis system **must be closed.**
Flow on, response time approx. 10 minutes

Select the **Ref. temp.** field. Enter the reference temperature. Touch the **OK** button to confirm the value entered. Touch the **Accept value** button.

The CALIBRATE SCREEN will be displayed.

- **Conductivity (CD7/CD9)**

  Select the **Conductivity (CD7/CD9)** field. Touch the **Start calibration** button.

  Measure the reference conductivity with an external measuring instrument.

  Basic requirements:
  The hemodialysis system **must be closed.**
  Temperature 37 °C, flow on, response time approx. 10 minutes

  Adjust the prescribed Na to obtain a value of approx. 13.00 mS/cm. Select the **Ref. CD 13.00 mS/cm** field. Enter the reference conductivity. Touch the **OK** button to confirm the value entered. Touch the **Accept value** button.

  Adjust the prescribed Na to obtain a value of approx. 15.00 mS/cm. Select the **Ref. CD 15.00 mS/cm** field. Enter the reference conductivity. Touch the **OK** button to confirm the value entered. Touch the **Accept value** button.

  The CALIBRATE SCREEN will be displayed.

- **Volumes**

  Select the **Volumes** field. Touch the **Start calibration** button.

  The hydraulic volumes will be displayed.
  Balancing chamber
  Dosing chamber
  UF pump
  UF pump 2 (not yet active)

  The values displayed must match the values on the labels of the above components.

- **Blood leak**

  Select the **Blood leak** field. Touch the **Start calibration** button.

  The following message will be displayed: *Please confirm that the cuvette is clear and properly inserted into the blood leak detector! Calibration will then be performed automatically!* – **Confirm** – **Abort**. Touch the **Confirm** button.

  When the blood leak detector has been calibrated, the CALIBRATE SCREEN will be displayed.

- **OCM (option)**

  Before calibrating the OCM, the temperature must have been calibrated.

Select the **OCM** field. Touch the **Start calibration** button.

Automatic OCM adjustment.

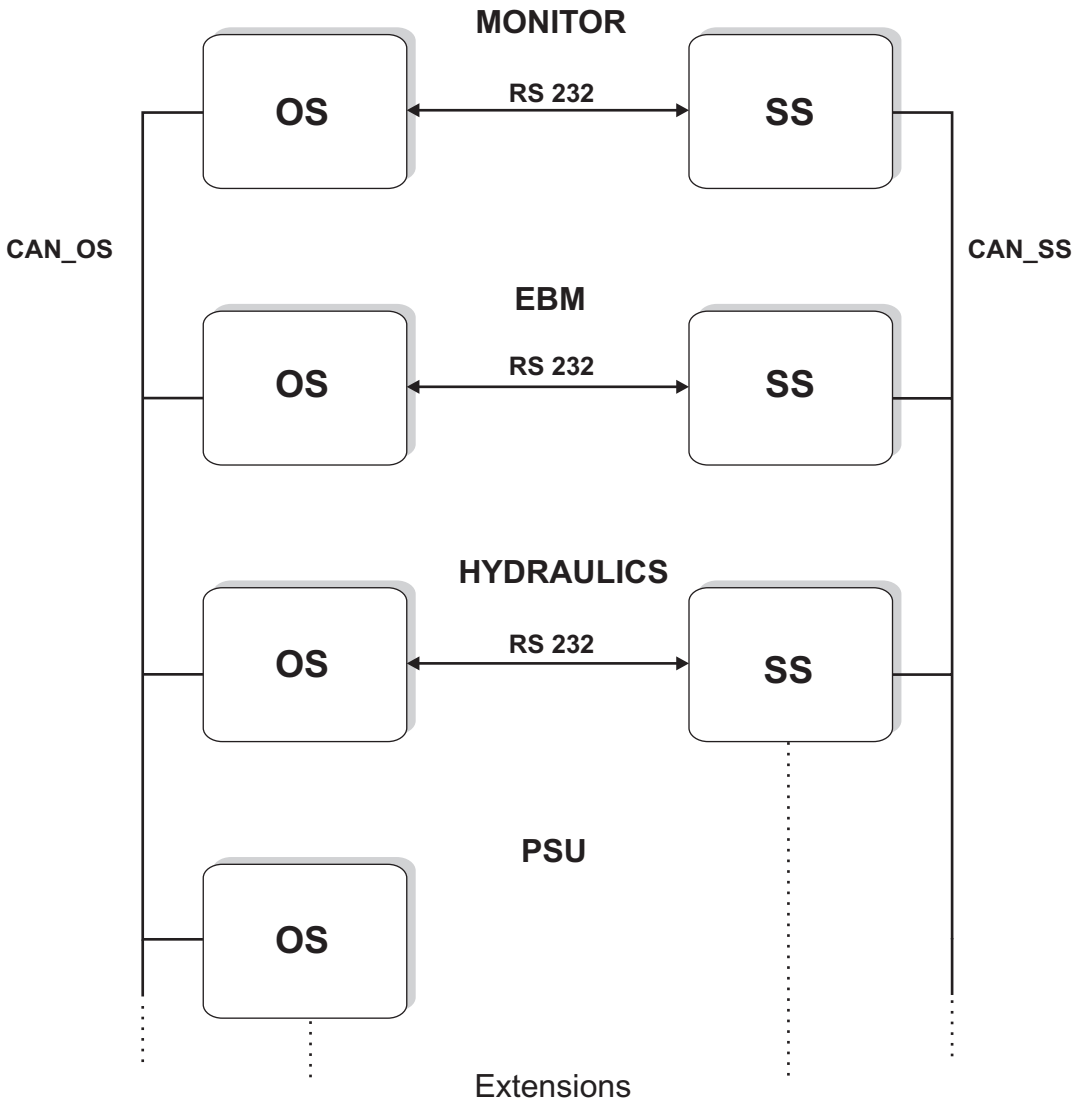
When the OCM detector has been calibrated, the CALIBRATE SCREEN will be displayed.

10 Repair

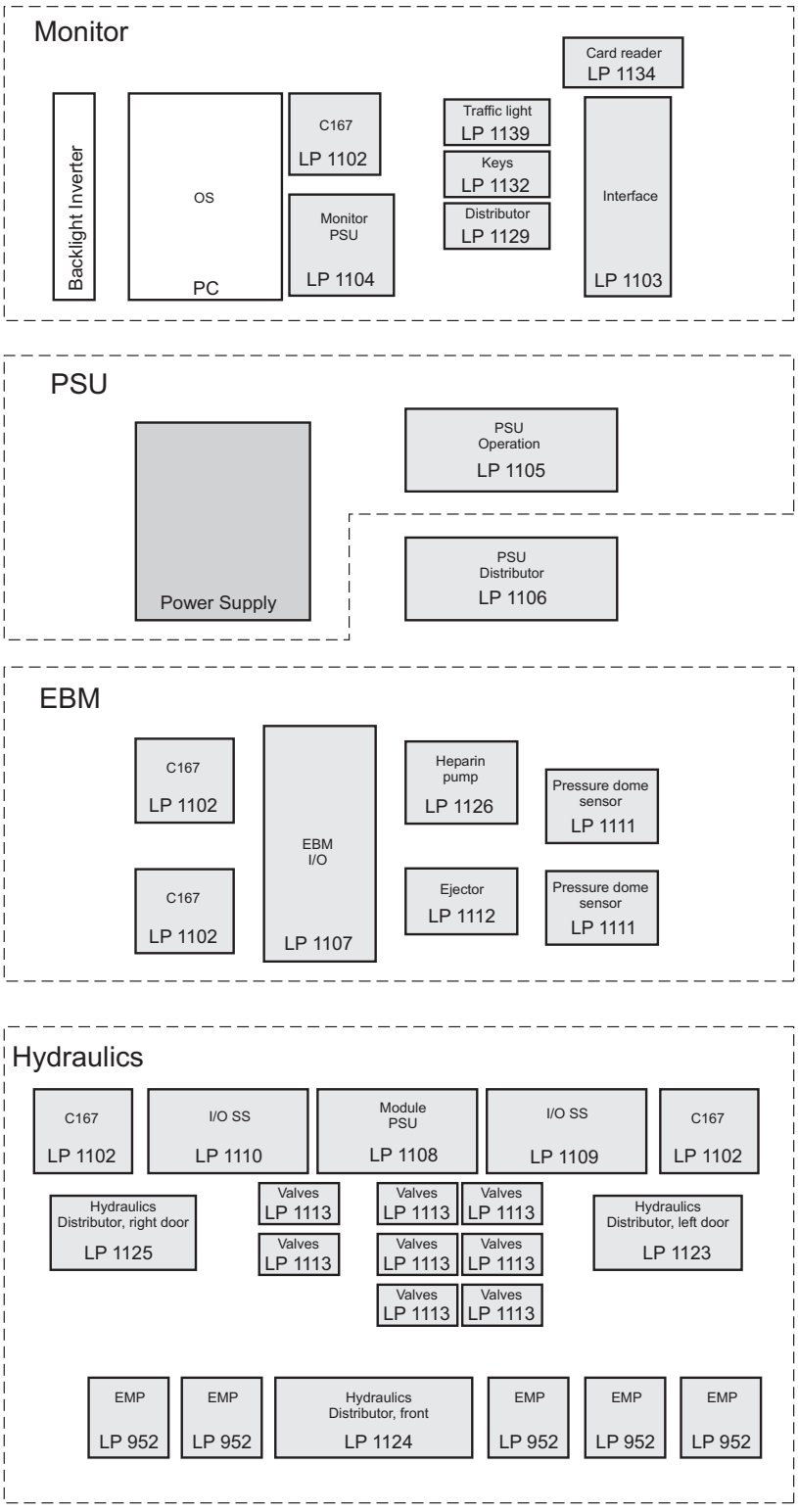
(no contents yet)

11 Functional Description

11.1 Overall System

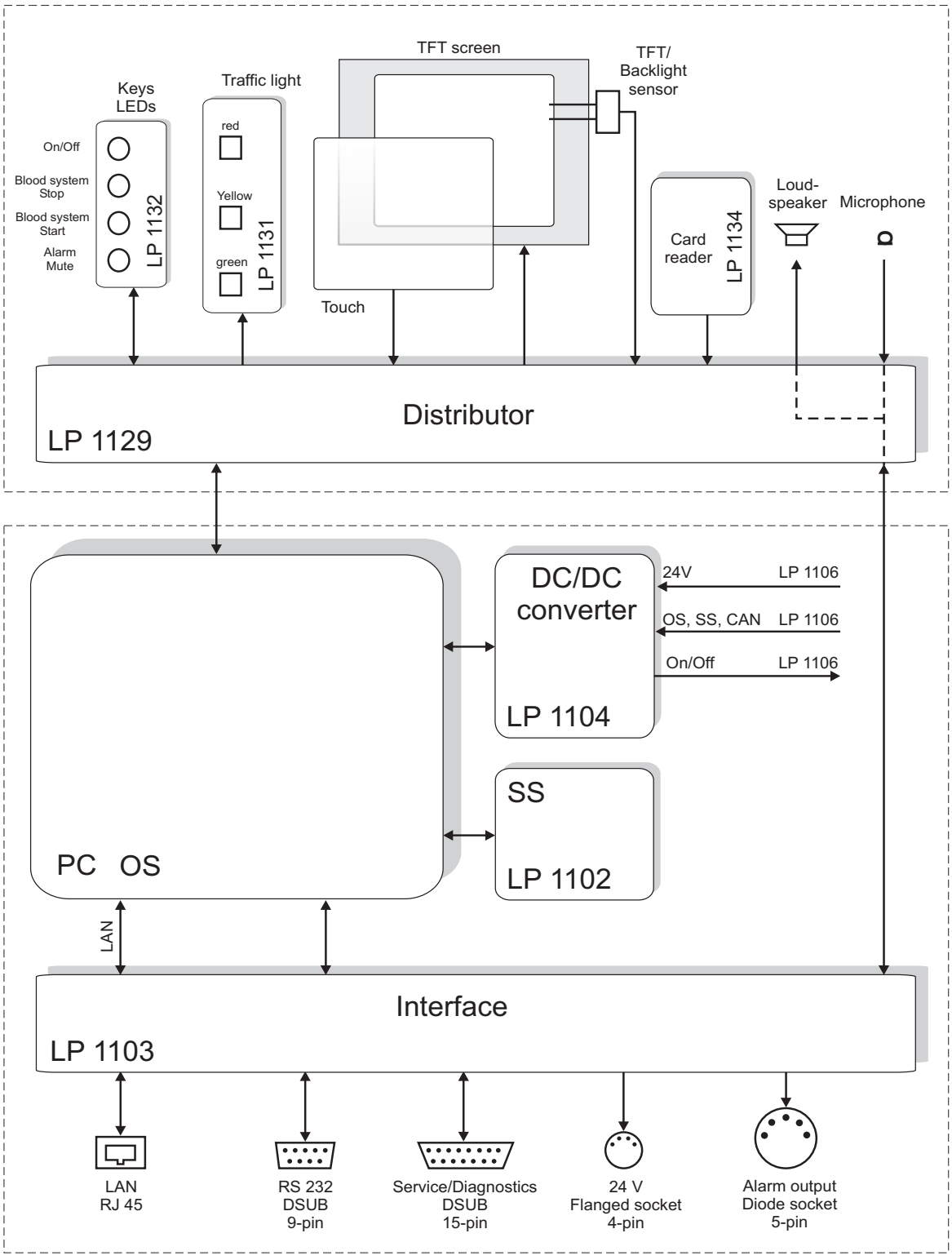


11.2 Overview of P.C.B.s



11.3 Monitor

- **Block diagram**



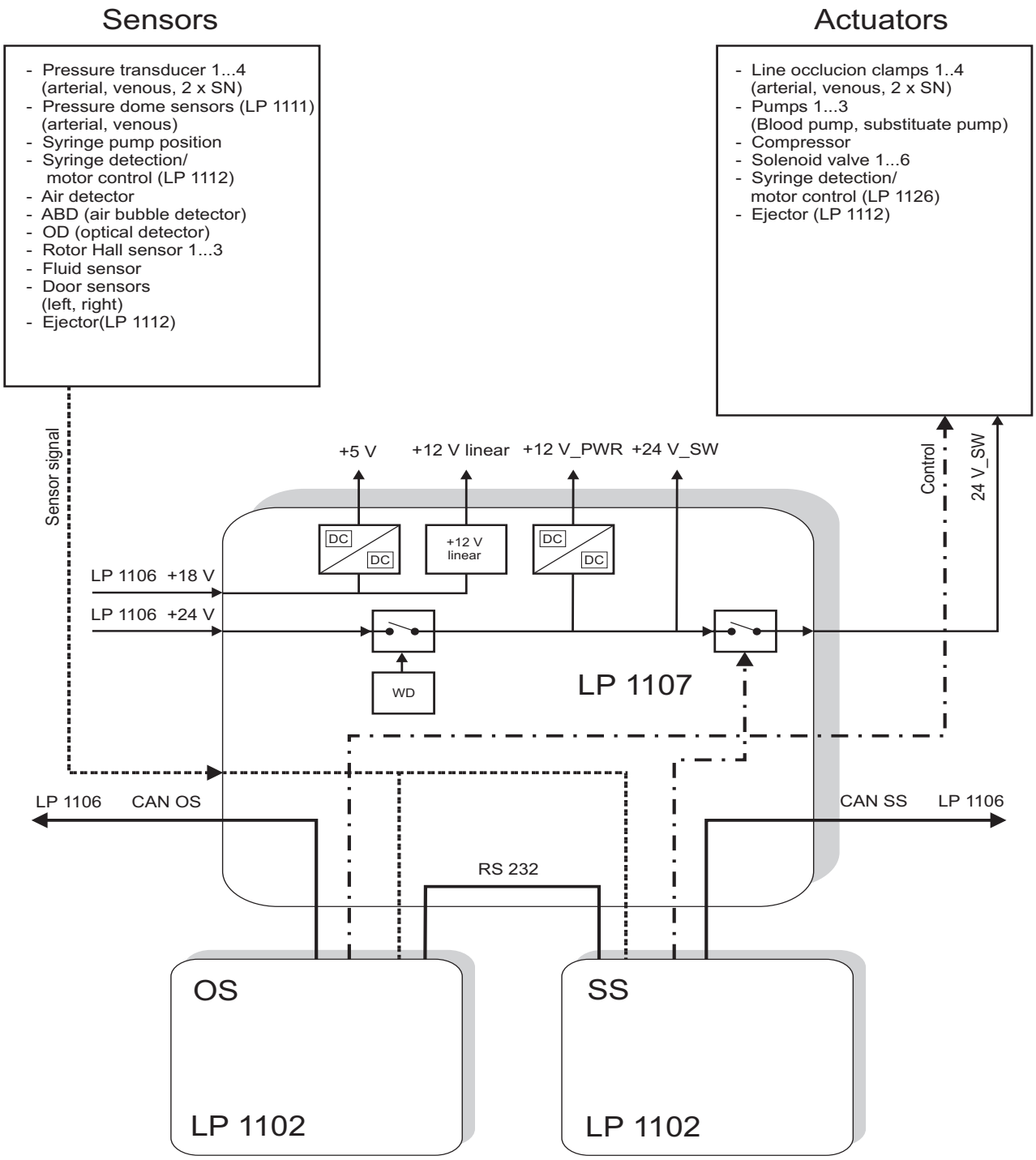
Description

P.C.B. LP 1104 houses the voltage supply for the entire monitor unit. Independent voltages are generated from the +24 V supplied by the power supply unit. +5 V for the OS/SS, +12 V or +5 V for the backlighting, +12 V/+5 V or 3.3 V for the TFT electronics.

P.C.B. LP 1103 provides the signal connections to the peripheral equipment. It has a LAN interface (Ethernet) and an opto-decoupled serial interface (RS 232). A Service/Diagnostics plug and a plug with 24 V connection (1 V) is available for the technician. An alarm output for the nurse call is also present.

11.4 EBM (Extracorporeal Blood Module)

- **Block diagram**



- **Description**

The power supply unit supplies the P.C.B. LP 1107 with +24 V and +18 V via P.C.B. LP 1106. The +5 V, +12 V linear and +12 V_PWR voltages are generated on P.C.B. LP1107. The +24 V_SW are enabled via the watchdog.

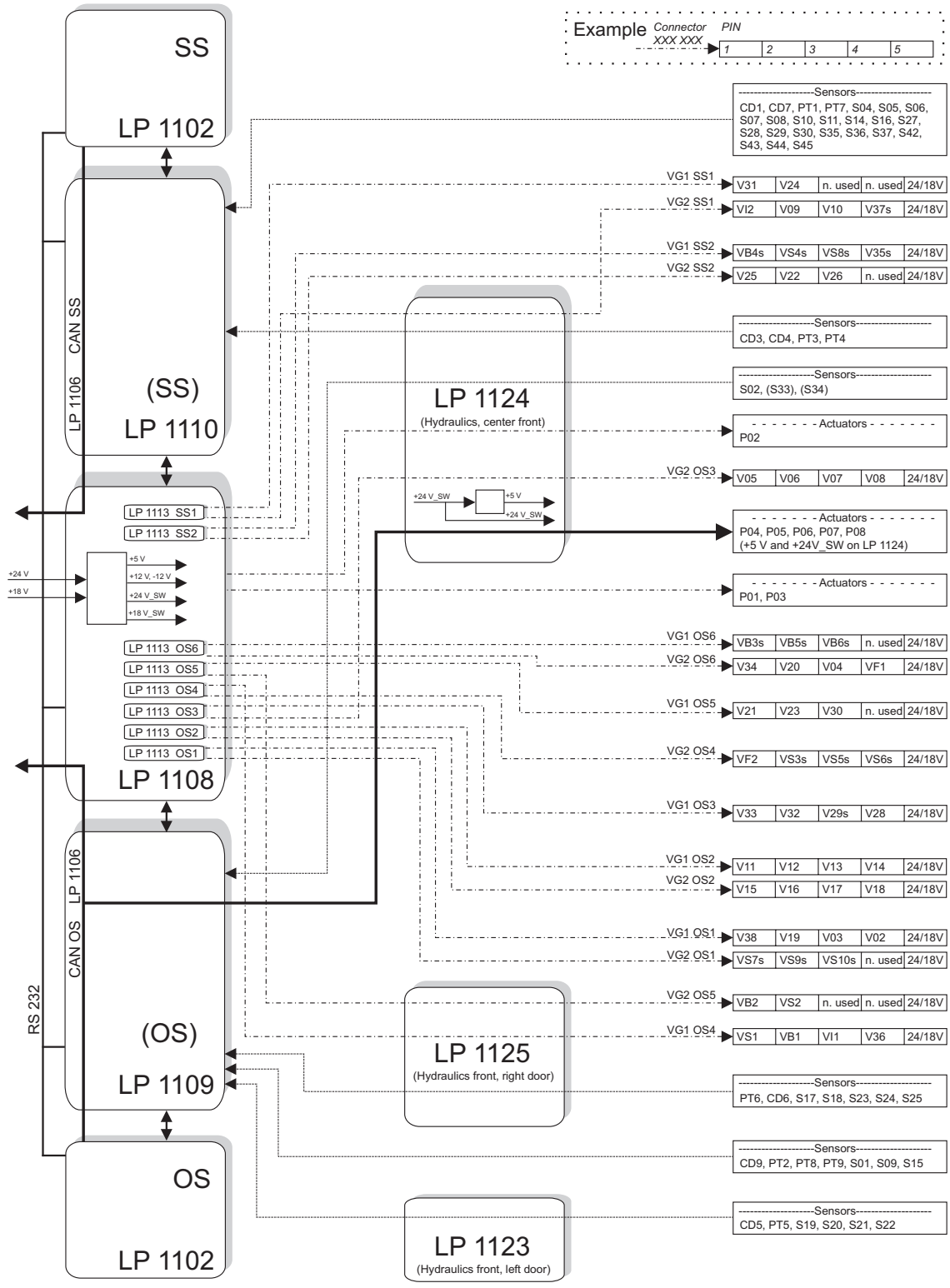
The sensor signals are routed via P.C.B. LP 1107 to the OS and the SS where they are evaluated. The OS controls the actuators via P.C.B. LP 1107. The 24_V_SW are controlled independently by the SS via P.C.B. LP 1107.

Distribution of the CAN bus of the OS and the SS is done via P.C.B. LP 1107. P.C.B. LP 1107 is connected to the OS (LP 1102) via the plug connector X1_OS, X2_OS and to the SS (LP1102) via the plug connector X1_SS, X2_SS.

The serial connection between the OS and the SS is also established via P.C.B. LP 1107.

11.5 Hydraulics Unit

● Block diagram



- **Description**

The power supply unit supplies the P.C.B. LP 1108 with +24 V and +18 V via P.C.B. LP 1106. The +5 V, ±12 V voltages are generated on P.C.B. LP1108. The +24 V_SW and the +18 V_SW are enabled via the watchdog. P.C.B. LP 1108 controls certain actuators and distributes the OS and SS CAN bus. P.C.B. LP 1108 is connected to the OS via P.C.B. LP 1109 and to the SS via the P.C.B. LP 1110.

P.C.B. LP 1109 includes the OS with the evaluation circuits for temperature, conductivity, pressure, optical sensors and switches, for example, and the gear pump motor control.

P.C.B. LP 1110 includes the SS with the evaluation circuits for temperature, conductivity, pressure, optical sensors, blood leak sensor, voltage monitoring and switches.

The P.C.B. LP 1102 houses the central processing unit with the CPU (C 167), a battery-buffered data memory, a CAN bus driver, an analog reference voltage source and a triple serial interface. P.C.B. LP 1102 requires the operating voltage +5 V, GND, +24 V and the Reset signal.

The valves are controlled by P.C.B. LP 1113. 8 valves, split in two valve groups with 4 valves each, are controlled. P.C.B. LP 1113 also provides for switching the valve groups between making and withstand voltage. The control states of the valves are read back to both the OS and the SS.

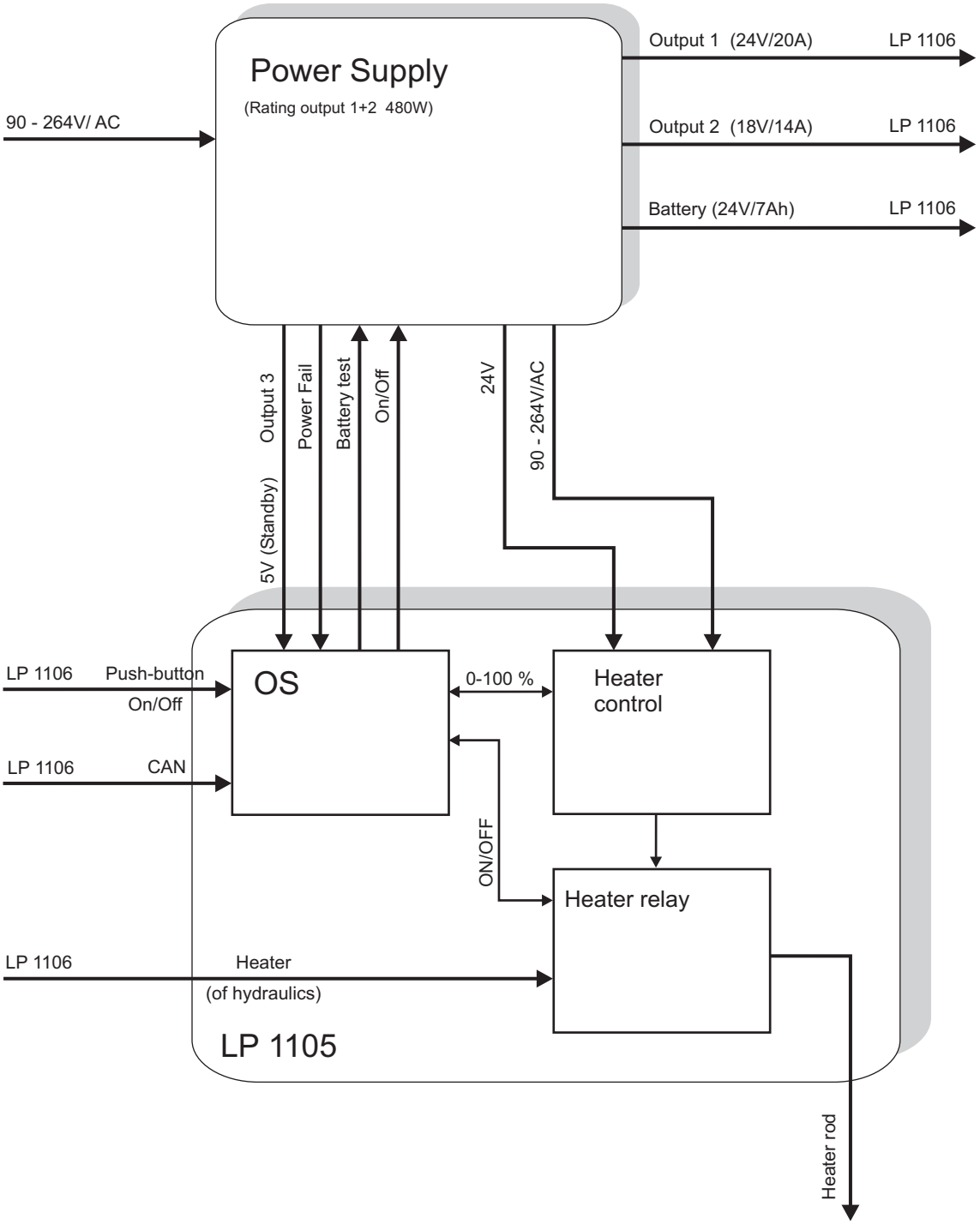
P.C.B. LP 1123 is used to distribute the electrical connections to the components installed on the front in the left door of the hydraulic unit. P.C.B. LP 1123 is connected to P.C.B. LP 1109.

P.C.B. LP 1124 is used to distribute the electrical connections to the components installed on the front in the center of the hydraulic unit. P.C.B. LP 1124 includes a 5 V switching power supply for the supply of the eccentric membrane pumps. P.C.B. LP 1124 is connected with P.C.B. LP 1109, LP 1110, the valve drivers LP 1113 and the +24 V_SW of P.C.B. LP 1108.

P.C.B. LP 1125 is used to distribute the electrical connections to the components installed on the front in the right door of the hydraulic unit. P.C.B. LP 1125 is connected with P.C.B. LP 1109 and the valve drivers LP 1113.

11.6 Power Supply Unit

- **Block diagram**



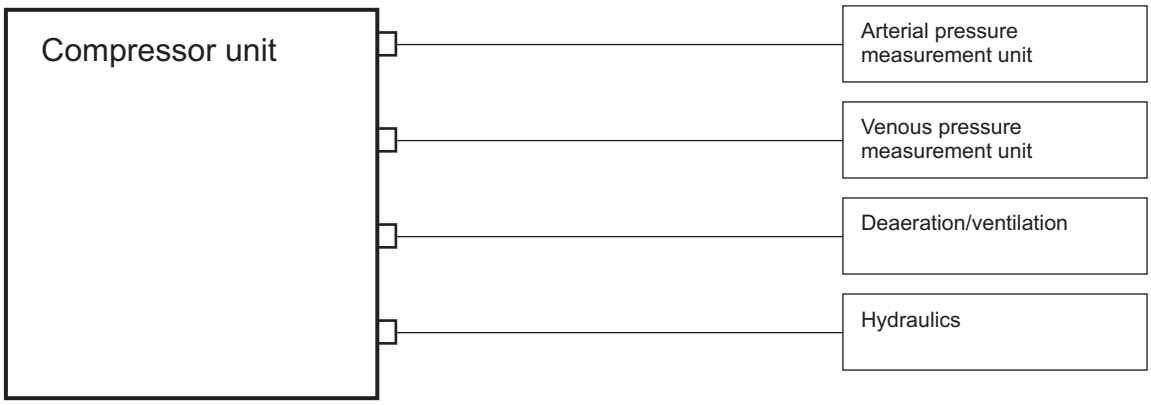
Description

The voltage is supplied by a primary-switched power supply unit. It does therefore not require a power transformer and can be connected to all common line voltages without switching. The charging circuit integrated in the power supply unit, charges the batteries to provide battery-backup in the event of a power failure. If a power failure occurs, the 24 V supply is buffered by the batteries.

P.C.B. LP 1105 includes a processor C515. This processor provides for the regulation and control of the heater and the On/Off logic for the entire system. A control chip with pulse-duration modulation controls the heater rod via two triacs. The data required for the control is sent via the CAN bus to the processors.

11.7 Pneumatic Unit

- **Block diagram**

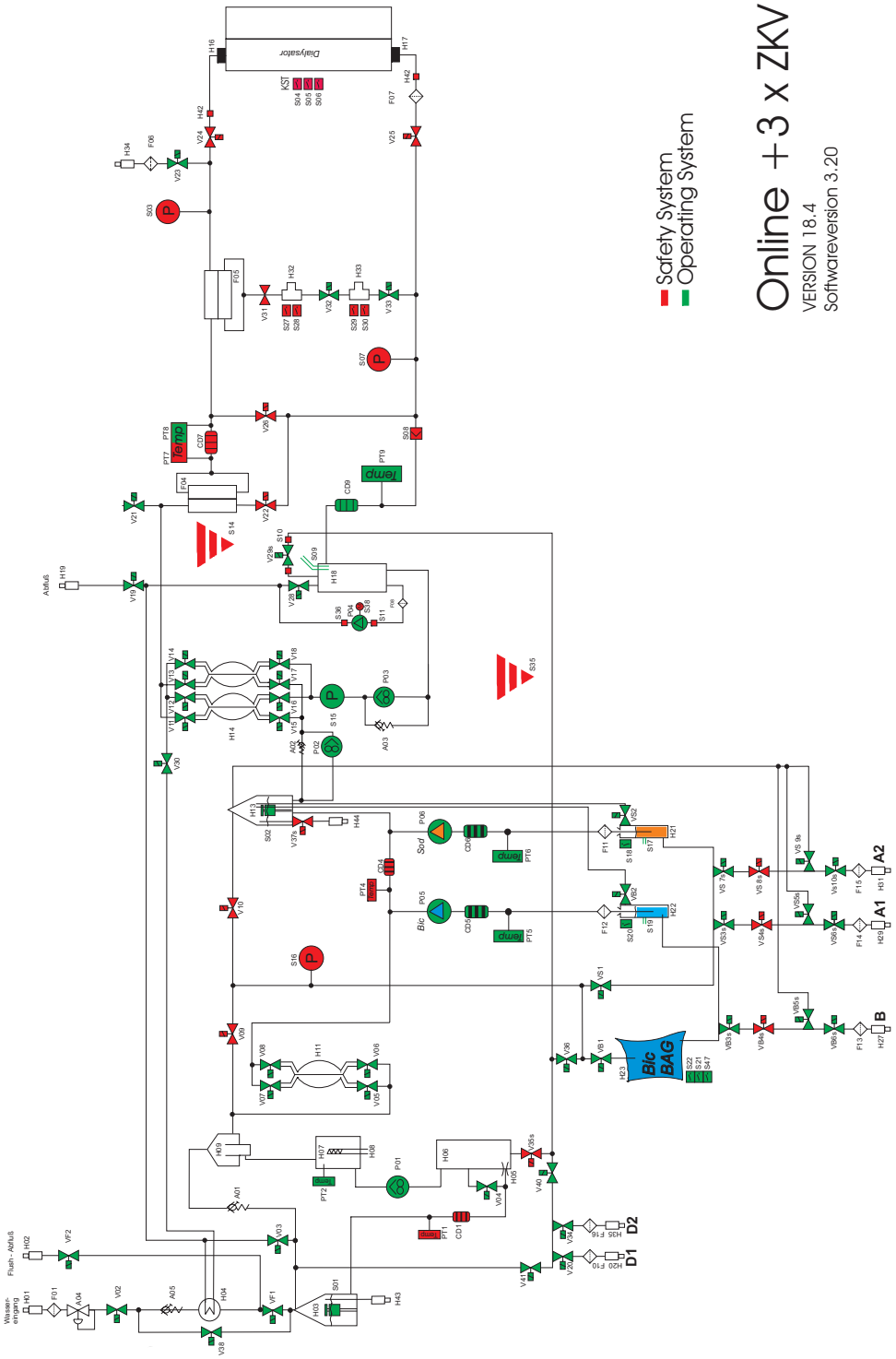


Description

The pneumatic unit is located in the EBM. In the EBM it is used to control the arterial and the venous pressure measurement unit. In the hydraulics unit, the pneumatic unit is required for the membrane integrity test and for the filter change program.

11.8 Hydraulics Unit

- **Flow diagram**



● Flow diagram – legend

Explanation of symbols

Axx	Elements for adjustment
CDx	Conductivity cells
Fxx	Filters
Hxx	Hydraulic components
Pxx	Pumps
PTx	Temperature sensors
Sxx	Other sensors
Vxx	Valves
Vxxs	Small valves (s)

Legend

A01	Loading pressure valve, dosing chamber
A02	Loading pressure valve, balancing chamber
A03	Relief valve
A04	Pressure reducing valve, water inlet
A05	Check valve for heat exchanger
CD1	Conductivity cell, permeate
CD4	Conductivity cell, mixed bicarbonate
CD5	Conductivity cell, bicarbonate
CD6	Conductivity cell, concentrate
CD7	Conductivity cell, overall conductivity
CD9	Conductivity cell, OCM
F01	Filter, water inlet
F04	DIASAFE® *plus*
F05	ONLINE*plus*™
F06	Hydrophobic filter, compressor EBM
F07	Particle filter
F08	Filter, UF pump
F10	Filter, disinfectant 1
F11	Suction tube with filter, concentrate
F12	Suction rod tube filter, bicarbonate
F13	Filter, CDS bicarbonate
F14	Filter, CDS concentrate 1
F15	Filter, CDS concentrate 2
F16	Filter, disinfectant 2
H01	Male connector, water inlet
H02	Male connector, Flush
H03	Water inlet chamber
H04	Heat exchanger
H05	Degassing orifice
H06	Degassing chamber
H07	Heater rod chamber
H08	Heater rod
H09	Primary air separator
H11	Dosing chamber
H13	Mixing chamber
H14	Balancing chamber
H16	Dialyzer coupling, to dialyzer
H17	Dialyzer coupling, from dialyzer
H18	Secondary air separator
H19	Male connector, drain
H20	Male connector, disinfectant 1
H21	Rinse chamber, concentrate
H22	Rinse chamber, bicarbonate
H23	Connector, bi*b*ag®
H27	Male connector, CDS bicarbonate
H29	Male connector, CDS concentrate 1
H31	Male connector, CDS concentrate 2
H32	Substituate port
H33	Rinse port
H34	Male connector, compressor EBM
H35	Male connector, disinfectant 2
H42	Male connectors, potential (2x)
H43	Male connector, vent water inlet chamber
H44	Male connector, vent mixing chamber
P01	Degassing pump
P02	Loading pump
P03	Flow pump
P04	UF pump
P05	Bicarbonate pump
P06	Concentrate pump
PT1	Temperature sensor, CD permeate
PT2	Temperature sensor, control
PT4	Temperature sensor, CD mixed bicarbonate
PT5	Temperature sensor, CD bicarbonate
PT6	Temperature sensor, CD concentrate
PT7	Temperature sensor, overall CD / CD and temperature display
PT8	Temperature sensor, re-adjustment
PT9	Temperature sensor, CD OCM
S01	Float switch, water inlet chamber
S02	Float switch, mixing chamber
S03	Pressure transducer, to dialyzer
S04	Sensor, shunt interlock in
S05	Sensor, shunt interlock open
S06	Sensor, shunt interlock out
S07	Pressure transducer, from dialyzer
S08	Blood leak detector
S09	Level sensor, secondary air separator
S10	Sensor, air separation valve
S11	UF pump, CD inlet
S14	Leakage sensor, filter chamber
S15	Pressure transducer, balancing chamber switching
S16	Pressure transducer, fill dry concentrate bag
S17	Level sensor, concentrate rinse chamber
S18	Sensor, concentrate rinse chamber lock
S19	Level sensor, bicarbonate rinse chamber
S20	Sensor, bicarbonate rinse chamber lock
S21	bi*b*ag® flap, bag operation position
S22	bi*b*ag® connected
S27	Sensor 1, substituate port
S28	Sensor 2, substituate port
S29	Sensor 1, rinse port
S30	Sensor 2, rinse port

(continued next page)

S35 Leakage sensor, hydraulics
S36 UF pump, CD outlet
S38 UF pump monitoring
S47 bi*b*ag® flap, cleaning position

V02 Water inlet valve
V03 Recirculation valve, cleaning
V04 Degassing orifice bypass valve
V05 Dosing chamber valve
V06 Dosing chamber valve
V07 Dosing chamber valve
V08 Dosing chamber valve
V09 Fill valve, dry concentrate bag
V10 Rinse valve, mixing chamber
V11 Balancing chamber valve
V12 Balancing chamber valve
V13 Balancing chamber valve
V14 Balancing chamber valve
V15 Balancing chamber valve
V16 Balancing chamber valve
V17 Balancing chamber valve
V18 Balancing chamber valve
V19 Drain valve
V20 Disinfection valve 1
V21 Vent valve, DIASAFE®*plus*
V22 Retentate valve
V23 Test valve/shutoff valve compressor EBM
V24 Dialyzer valve, to dialyzer
V25 Dialyzer valve, from dialyzer
V26 Bypass valve
V28 Fill valve, secondary air separator
V29s Air separation valve
V30 Outlet valve
V31 Substituate valve inlet
V32 Rinse valve 1, H(D)F
V33 Rinse valve 2, H(D)F
V34 Disinfection valve 2
V35s Negative pressure valve
V36 Rinse valve, dry concentrate path
V37s Vent valve, mixing chamber
V38 Bypass valve, heat exchanger
V40 Shutoff valve, disinfection
V41 Rinse valve, disinfection

VB1 Fill valve, bi*b*ag®
VB2 Vent valve, bicarbonate rinse chamber
VB3s CDS valve, bicarbonate shutoff valve OS
VB4s CDS valve, bicarbonate shutoff valve SS
VB5s CDS valve, bicarbonate test
VB6s CDS valve, bicarbonate in
VF1 Flush valve 1
VF2 Flush valve 2, drain
VS1 Fill valve, so*b*ag®
VS2 Vent valve, concentrate rinse chamber
VS3s CDS valve, concentrate 1 shutoff valve OS
VS4s CDS valve, concentrate 1 shutoff valve SS
VS5s CDS valve, concentrate 1 test
VS6s CDS valve, concentrate 1 in
VS7s CDS valve, concentrate 2 shutoff valve OS
VS8s CDS valve, concentrate 2 shutoff valve SS
VS9s CDS valve, concentrate 2 test
VS10s CDS valve, concentrate 2 in

Description

Turning power On

To ensure regular rinsing of the water inlet tubing, flushing is started after turning the machine on.

The flush is diverted between the measurement port (M01) and the water inlet valve (V02).

When the water inlet valve is closed (V02), a clocked circuit will open the flush valve (V01). The permeate is rinsed via the water inlet tubing, the flush valve (V01) and the water outlet tubing into the drain 1.

Degassing

Controlled by the float switch (S01) in the water inlet chamber (H03) the permeate flows into the degassing chamber (H06). A negative pressure is created due to the volumetric capacity of the degassing pump (P01) and the restriction of the degassing orifice (H05). This negative pressure is sufficient to force the air in the permeate to form air bubbles. These accumulate in the primary air separator (H09). The air bubbles are discharged via the loading pressure valve (A01) and the air outlet of the water inlet chamber (H03).

Heating

The permeate flowing through the heater rod chamber (H07) is heated to the regular dialysis temperature.

Mixing

A patient-specific dialysate is prepared by proportional and volumetric mixing of permeate with different dialysis concentrates.

The volume of the permeate is defined by means of the dosing chamber (H11). On its way to the mixing chamber (H13), a volume of bicarbonate and acid concentrate which matches the proportional mixing ratio is added (P05, P06) to the permeate at the dosing points (H12).

The concentrates can either be drawn in with the suction tubes (F11/F12) from canisters, via connectors (H23/H24) from bags or can be supplied by a central delivery system (H27/H29/H31).

Optional it is possible to add an individual concentrate which is electrolytically adapted to the patient. At the dosing point (H10) this concentrate is added to the permeate by the pump (P07) even before the dosing chamber.

The float switch (S02) in the mixing chamber (H13) controls the cyclic switching of the dosing chamber. It ensures that freshly prepared dialysate is permanently available to fill the balancing chambers.

Balancing and ultrafiltration

The design of the hydraulics of the dialysis system provides for a dialysate circuit which is closed against the atmosphere.

This presents the basis for volumetrically controlled ultrafiltration.

The balancing chambers (H14) are operated at inverse sequences to ensure that the volume of dialysate which enters the dialyzer equals the volume which flows back across the balancing chambers. An impermeable elastic membrane separates the used from the fresh dialysate.

Reduction of the weight is solely determined by the UF pump (P04). The UF pump removes a predefined volume (UF goal) from the closed system which it pumps to the drain 2, bypassing the balancing chambers. This volume is removed from the patient's blood as ultrafiltrate and is replaced by an equal volume flowing through the dialyzer membrane.

Dialysate circuit

Via the valves (V11, V13) fresh dialysate is fed in cycles by the balancing chambers via the filter (F04) and the dialyzer valve (V24) to the dialyzer.

The flow pump (P03) ensures that the dialysate discharged by the dialyzer is fed to the balancing chambers via the secondary air separator (H18).

If the level sensor (S09) detects air, the air separation valve (V29s) starts its activity. The air is discharged by the negative pressure in the degassing path and can therefore not enter the balancing chambers.

After the balancing process the dialysate is passed via the outlet valve (V30), the heat exchanger (H04) and the drain valve (V19) to the drain 2.

Correct mixing and the temperature of the fresh dialysate are monitored by the conductivity cells (CD3, CD4, CD7) and the temperature sensor (PT7). If the values are outside the predefined limits, the system will alert the operator and will switch to the bypass mode. The dialyzer valve (V24) closes, the bypass valve (V26) opens, which prevents the improper dialysate from being fed to the dialyzer.

The pressure transducer (S07) and the blood leak detector (S08) are further safety elements.

12 Service Program (Option)

Quick Guide
PC Service-Software 5008

4/29.04

Table of contents

General Information

Caution:
After each transfer of data from the Service program to the dialysis system, the operator of the Service program must check the data on the dialysis system for plausibility. The operator himself/herself is responsible that the data are correct.

Caution:
After each transfer of data from the Service program to the dialyis system, the dialysis system must be turned off and back on again before treating a patient.

Caution:
This Service program is intended for service purposes only. During patient treatment neither the interface cable to the PC nor the modem must be connected to a dialysis system.

Preparation

Preparation

System Requirements

Minimum system requirements:

- PC with at least 10 MByte of free hard disk space
- Microsoft Windows 98, ME, 2000 or XP
- 32 MByte RAM
- 1 CD-ROM drive
- 1 free USB port (for Service Card Reader)
- 1 free RS232 interface or
  1 network card or
  1 TAPI compatible modem
  (for communication with the 5008)

PC Service-Software 5008

Preparation

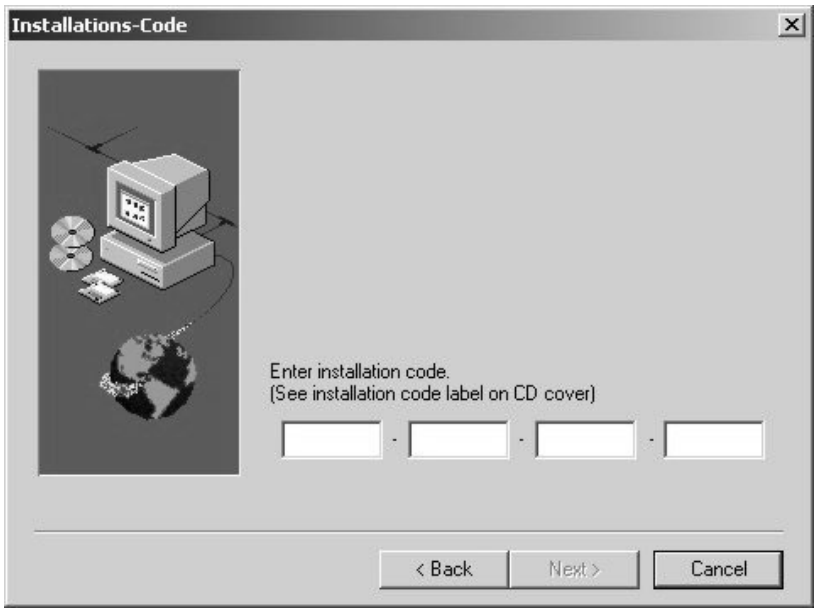
Software Installation

Caution:
Install the Towitoko Card Reader drivers before connecting the Service Card Reader to the PC!
These will be installed when the PC Service Software 5008 is installed.

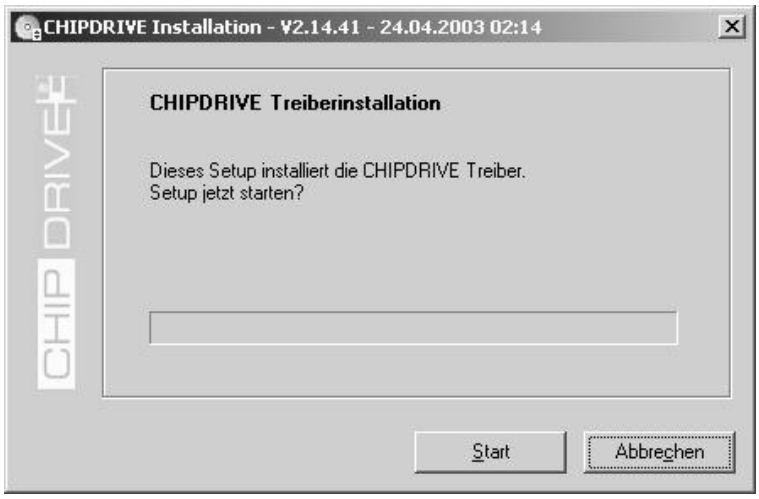
Caution:
If a previous version of the PC Service Software 5008 is already installed on the computer, this version must be uninstalled.
Make sure this version is completely uninstalled before installing the new software.

Caution:
Windows NT, 2000 or XP require administrator rights to install the PC Service Software 5008!

- Start Windows on your computer.
- Insert the installation CD in the CD-ROM drive.
- If the setup does not start automatically:
  - Start the Windows Explorer.
  - Then select the CD-ROM drive and start the setup.exe file.
- In the setup dialog box *Installations-Code (installation code)*, enter the installation code indicated on the CD cover.



When the setup is complete, the installation routine for the Service Card Reader driver will be started automatically.



Click Start to install the driver.

The software installation is complete.

PC Service-Software 5008

Preparation

Hardware Installation

Use the enclosed interface cable to connect the PC to the 5008 dialysis system.

Caution:
The interface cable for the *RS232 connection* is not a standard cable. It is therefore imperative to use the enclosed interface cable (M35111).

Caution:
In case of a direct network connection (PC <-> 5008) the included Cross-Over patch cable (M36433) must be used.

Caution:
Install the Towitoko Card Reader drivers before connecting the Service Card Reader to the PC!
These will be installed when the PC Service Software 5008 is installed.

Connect the Service Card Reader to a free USB port.

Preparation

Description of the Service Card

The use of the PC Service Software 5008 requires an appropriate authorization.
This is checked by the PC Service Software 5008 and the associated Service card.

The Service card is read out via:

1. the Service Card Reader on the PC.
   - Connect the Service Card Reader to a free USB port.
   - Insert the Service card into the Service Card Reader.
   - The Service card will be checked when starting the application and when using the software. If the card is not inserted or if it is removed, an error message will be displayed. The software will be exited after 10 seconds.

2. the Card Reader of the 5008.
   - Insert the Service card into the Card Reader of the 5008.
   - The authorizations will be set after establishing the communications.

The Service card is checked by a run-time monitoring function. The expiration date of the Service card is displayed in the About dialog.
30 days prior to expiration, an informational message is displayed when starting the application.
Once the expiration date is exceeded, the PC Service Software 5008 can no longer be accessed.

PC Service-Software 5008

Preparation

Starting the Software

After the hardware has been properly connected, the 5008 dialysis system can be turned on.

Caution:
For establishing a network connection with the 5008 via a Cross-Over patch cable, the following requirements must be met:

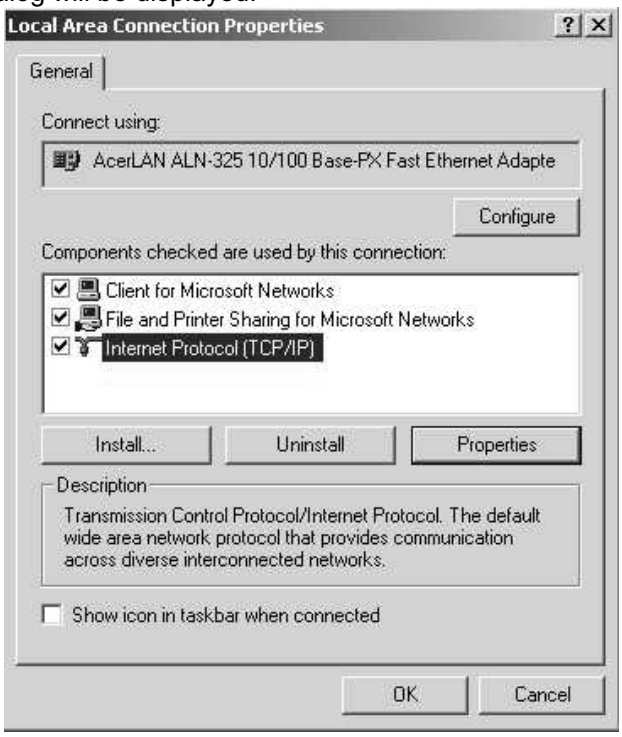
- before starting the application the IP Address of the Service PC must be set to *192.168.0.2*! (see Changing the IP Address)
- in the 5008 network setup *Service-PC active* must be checked, the selection must be confirmed with OK and the 5008 must be restarted!

The software can now be started on the PC by selecting
*Start->Programs->Fresenius->Service 5008->**Service 5008***
.

Changing the IP Address

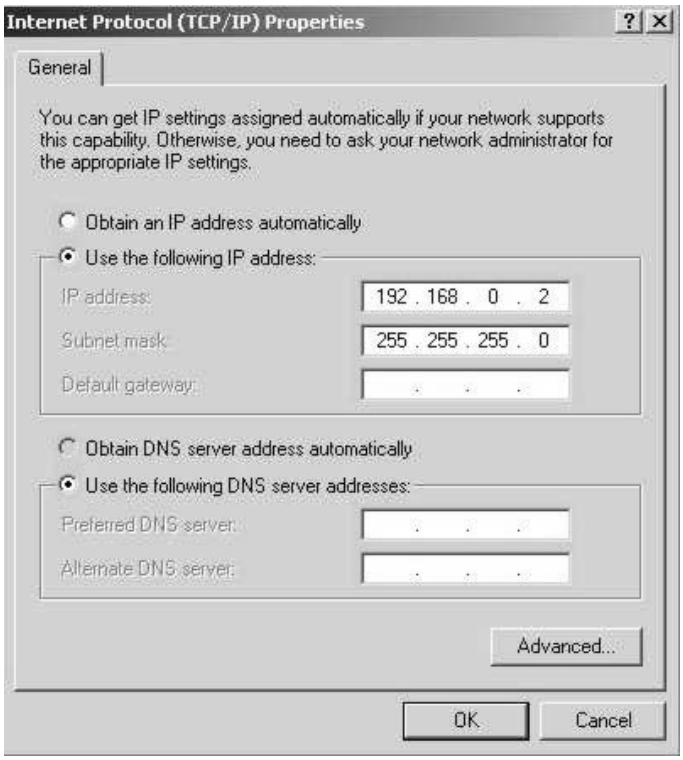
Step 1:
Windows:
Select *Start->Setting->Network- and Dial-up connections*

Step 2:
In this dialog, select the network card used. Then click the right mouse button to select the *Properties* pop-up menu.
The following dialog will be displayed:



Step 3:
Select *Internet Protocol (TCP/IP)* and click the *Properties* button.
The following dialog will be displayed:

PC Service-Software 5008



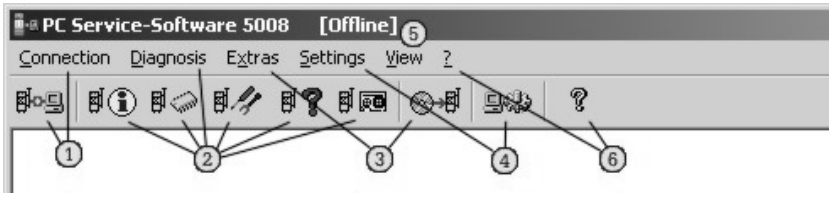
Step 4:
Adjust the settings as shown in the illustration above, then confirm the dialog with OK.

Step 5:
Restart the PC.

Menu/Toolbar

Menu Options/Toolbar:

Overview



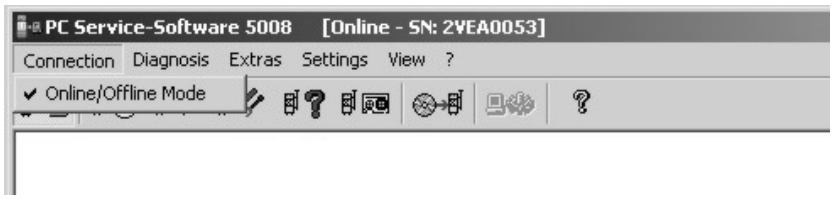
Brief explanation of the menu option/toolbar functions:

1 Connection
2 Diagnosis
3 Extras
4 Settings
5 View
6 Help/About

PC Service-Software 5008

Menu Options/Toolbar:

Connection

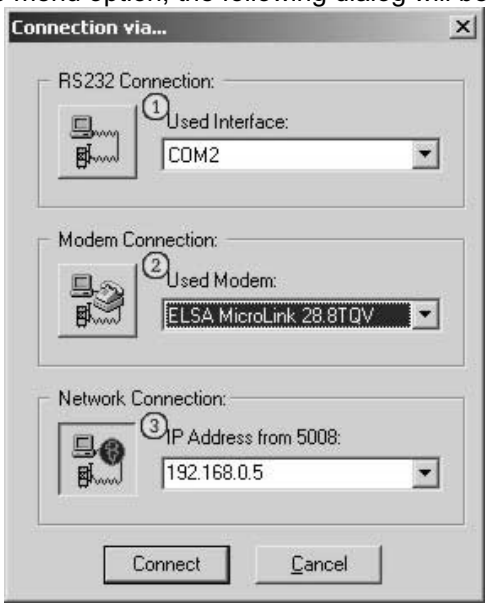


Online/Offline Mode (establishing/disconnecting communications):
This menu option is used to establish and disconnect communications with the 5008.

- **Online** (establishing communications):

Caution:
All windows within the Service software must be closed to establish communications.

After clicking the menu option, the following dialog will be displayed:

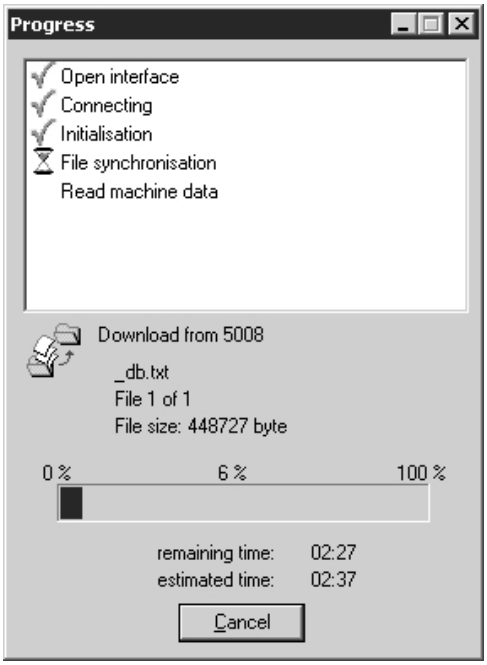


The operator here can select the desired connection:

1. RS232 connection, e.g. via COM1
2. modem connection, via a modem installed under Windows
3. network connection
   (see chapter Starting the Software)

Menu/Toolbar

After clicking the *Connect* button, the following dialog will be displayed:



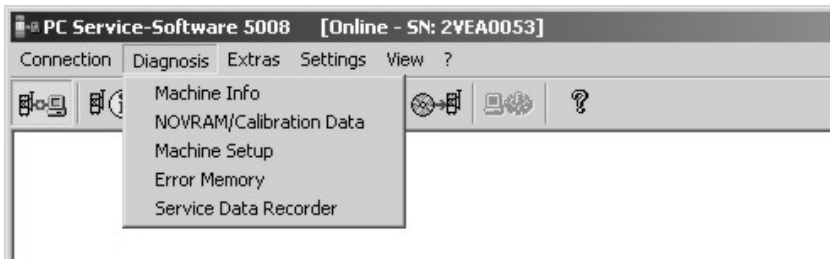
The PC Service Software 5008 establishes communications with the 5008 and synchronizes with the 5008.

- **Offline** (disconnecting communications):
  After clicking this menu option, communications with the 5008 will be disconnected.

PC Service-Software 5008

Menu Options/Toolbar:

Diagnosis



Machine Info
When clicking this menu option the *Machine Information* view will be displayed. Here the operator can view machine data such as

- Machine No.
- Date
- Time
- Machine options
- Filter1
- Filter2
- Operating Hours:
- ...

NOVRAM/Calibration Data
When clicking this menu option the *NOVRAM / Calibration data* view will be displayed.
Here the operator can

- read, display and save the NOVRAM data of the individual modules of the 5008.
- delete the NOVRAM data of individual modules.
- read and display the NOVRAM data from a file in order to upload the NOVRAM data, the calibration data or individual NOVRAM data to the 5008.

Machine Setup
When clicking this menu option the *Setup Data* view will be displayed.
Here the operator can

- read, partly display and save the setup data of the 5008.
- edit the setup data for the network settings.
- read and partly display the setup data from a file in order to upload them to the 5008.

Error Memory
When clicking this menu option the *Error Memory* view will be displayed.
Here the operator can

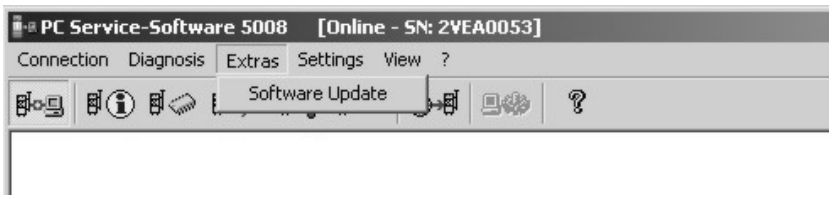
- read, display and save the error memory of the individual modules of the 5008.
- delete the error memory data of individual modules.

Service Data Recorder
When clicking this menu option the *Service Data Recorder* view will be displayed.
Here the operator can

- read which service data recorder files have been saved to the CompactFlash of the 5008.
- save selected service data recorder files.
- delete selected service data recorder files.

Menu Options/Toolbar:

Extras



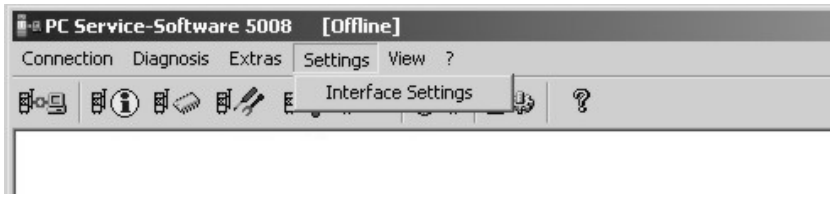
Software Update:
When clicking this menu option the *Software Update* view will be displayed.
Here the operator can

- download the Service report from the 5008.
  This report includes the software versions, the CRC, the creation date of the individual modules and information on missing files.
- select if files on the CompactFlash and/or modules are to be updated.
- upload the selected files to the 5008 and update the selected modules.

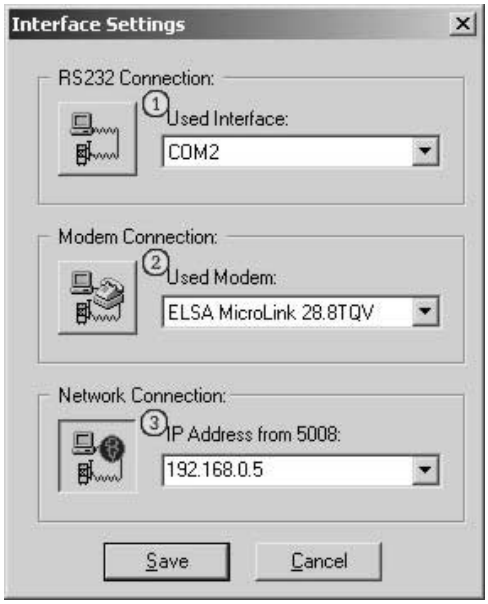
PC Service-Software 5008

Menu Options/Toolbar:

Settings



Interface Settings
When clicking this menu option, the dialog for the selection of the serial interface or for the selection of the modem for a modem connection will be displayed.



1 *RS232 Connection:*
Selection of the RS232 interface.

Caution:
For a direct connection via RS232 the serial interface cable (M35111) is required.

2 *Modem Connection:*
Selection of the modem.
The modem must be configured in the Window Control Panel.

Menu/Toolbar

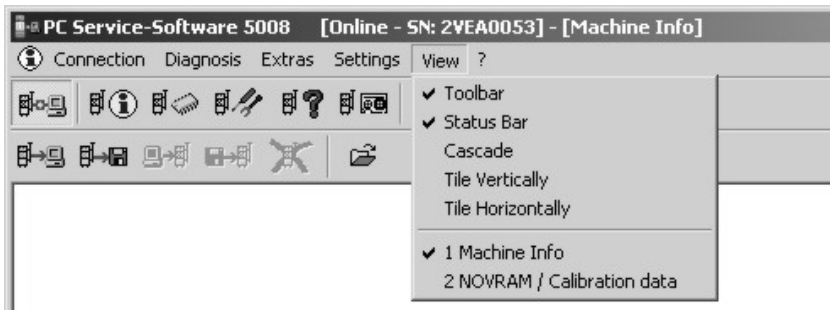
③ *Network Connection:*
Entry/selection of the 5008 IP address.
If the 5008 (network setup) is in the PC Service mode, IP address 192.168.0.5. must be set.

Caution:
For a direct connection via a network a Cross-Over patch cable (M36433) is required.

PC Service-Software 5008

Menu Options/Toolbar:

View



Toolbar:
When clicking this menu option the toolbar of the active window will be shown or hidden.

Status Bar:
When clicking this menu option the status bar of the active window will be shown or hidden.

Cascade:
When clicking this menu option all open windows will be displayed as cascading windows.

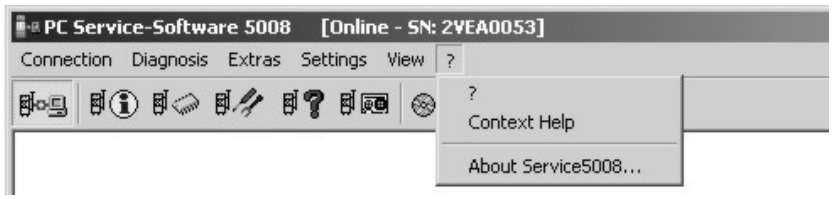
Tile Vertically:
When clicking this menu option all open windows will be displayed one next to the other.

Tile Horizontally:
When clicking this menu option all open windows will be displayed one above the other.

Open views:
In this field, the currently open views are listed. The active view is checked.

Menu Options/Toolbar:

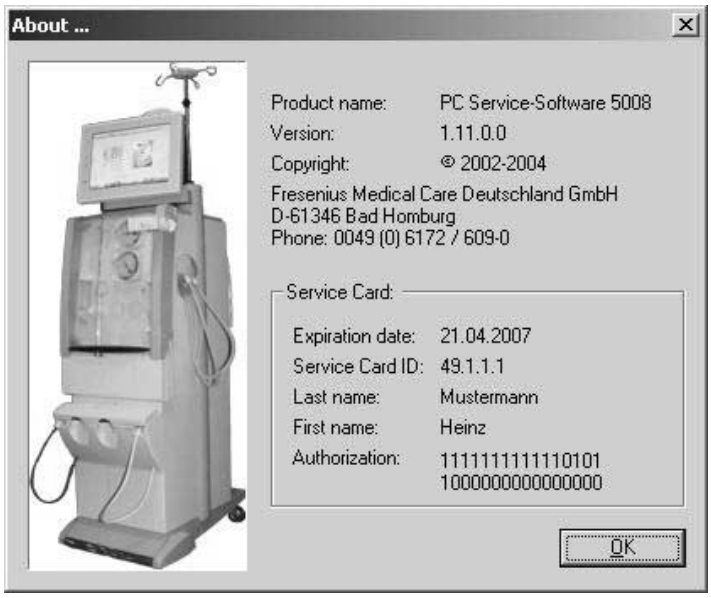
Help/About



?:
Clicking this menu option will open the help file.

Context Help
When clicking this menu option, the software will be set to the Context Help mode. In this mode the operator can click with the mouse on dialogs, views, to obtain context-sensitive on-screen help.

About Service5008 ..:.
When clicking this menu option, the *About ...* dialog will be opened.



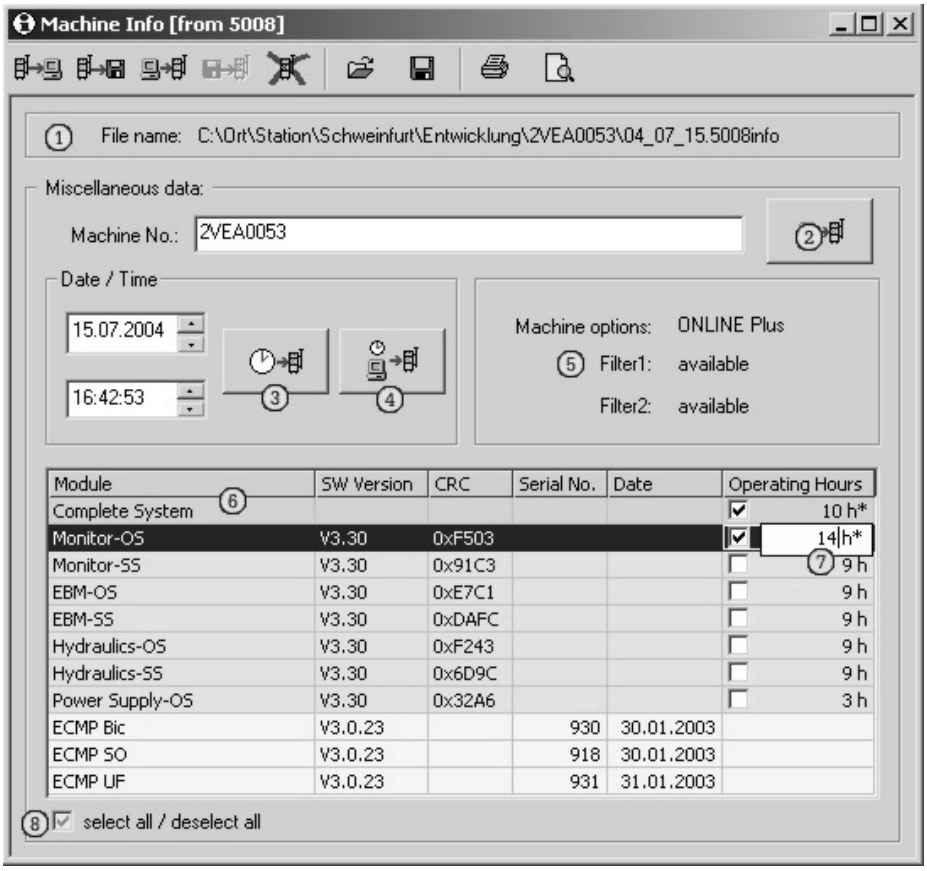
This dialog informs the operator of

- the software version
- the expiration date of the Service card
- his Service card ID
- his name
- his authorization.

Views

View

Machine Info



Downloads machine information from the 5008.

Downloads machine information from the 5008 and saves them to a file.

Uploads the selected operating hours (example above: complete system and monitor OS) to the 5008.

Deletes the selected operating hours (example above: complete system and monitor OS) of the 5008.

Opens machine information from a file.

Saves machine information to a file.

PC Service-Software 5008

Prints machine information.

Displays the Print Preview.

① Indicates the file name to which the machine information was saved or from which file the machine information was read.

② Indicates the machine number of the 5008.

Clicking the button will upload the machine number to the 5008.

③ Clicking the button will upload the time set by the operator to the 5008.

④ Clicking the button will upload the current time of the PC to the 5008.

⑤ Informs the operator of
- the machine options (Diasafe, ONLINE Plus)
- the status of filter1 (available, shunted)
- the status of filter2 (available, shunted)

⑥ Indicates module information.

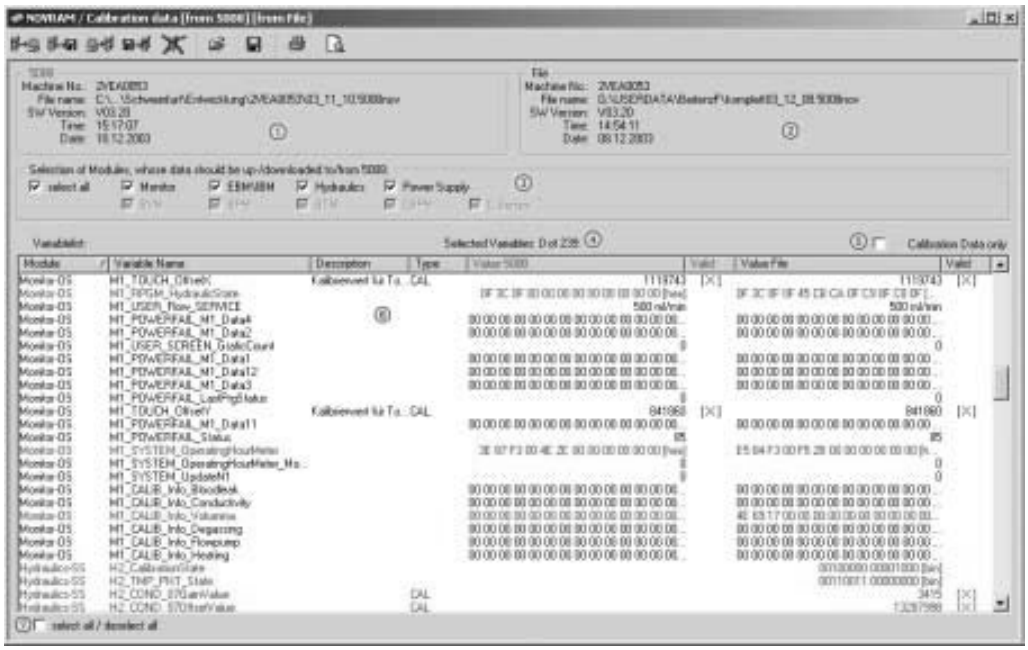
- Module: module name of the respective module
- SW Version: software version of the respective module
- CRC: cyclic redundancy check
- Serial No.: serial number of the respective module
- Date: Date when the respective module was created
- Operating Hours: Indicates the operating hours of the module.

⑦ The operator here can edit the operating hours of the complete system or of the individual modules.
For this purpose, click the appropriate field.
You must change to the Edit mode. It is sufficient to enter the value for the new operating hours.
Operating hours edited but not yet uploaded are identified by an asterisk (*).
Clicking the will upload the selected operating hours.

⑧ The operator may deselect the highlighted operating hours or select all of them.

View

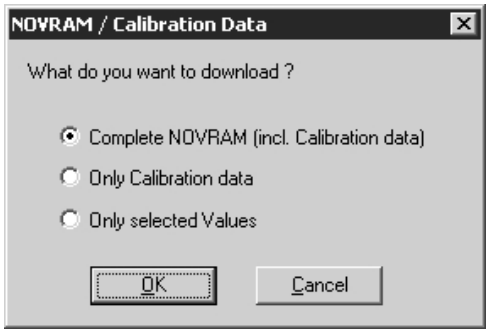
NOVRAM / Calibration data



Downloads NOVRAM data of the selected assembly ③ from the 5008.

Downloads NOVRAM data of the selected assembly ③ from the 5008 and saves them to a file.

Uploads, depending on the selection of the operator,



the entire NOVRAM data, only the calibration data or only the highlighted NOVRAM variables ⑥ to the 5008.

Opens a file and uploads, depending on the selection of the operator, the entire NOVRAM data or only the calibration data to the 5008.

Deletes the NOVRAM data of the selected assembly.

PC Service-Software 5008


Opens NOVRAM data from a file.
By default NOVRAM data (*.5008nov) will be opened.
Calibration data (*.5008cal) which have been recorded with software version V1.01 can be opened provided communications to the 5008 have been established.


Saves the NOVRAM data that was viewed to a file (*.5008nov).


Prints the NOVRAM data.


Displays the Print Preview.

① Shows general information (machine number, file name, software version of the 5008, download time and date) on the NOVRAM data downloaded from the 5008.

② Shows general information (machine number, file name, software version of the 5008, download time and date) on the NOVRAM data saved to the file.

③ Checkboxes where the operator can select for which assemblies the NOVRAM data are to be downloaded, to be deleted, to be displayed or which data are to be uploaded to the 5008.
Dimmed assemblies have been reported by the 5008 as not present.

④ Shows the operator the number selected by him and the total number of NOVRAM variables.

⑤ The operator can select if all NOVRAM data or only the calibration data are to be displayed.

⑥ Shows the NOVRAM data.

- Module: module name of the respective module
- Variable Name: internal name of the NOVRAM variable
- Description: brief description of the variable
- Type: calibration data are identified by CAL
- Value 5008: indicates the NOVRAM value of the 5008.
  - ... [hex]: hexadecimal representation
  - ... [bin]: binary representation
  - ... : value with associated unit (if available)
- Valid:
  - empty: NOVRAM variable without validity flag
  - [ ]: validity flag present
    NOVRAM variable identified as invalid
  - [X]: validity flag present
    NOVRAM variable identified as valid
- Value File: indicates the NOVRAM value from the file.
  - ... [hex]: hexadecimal representation
  - ... [bin]: binary representation
  - ... : value with associated unit (if available)
- Valid
  - empty: NOVRAM variable without validity flag
  - [ ]: validity flag present
    NOVRAM variable identified as invalid
  - [X]: validity flag present
    NOVRAM variable identified as valid

Explanation of colors:

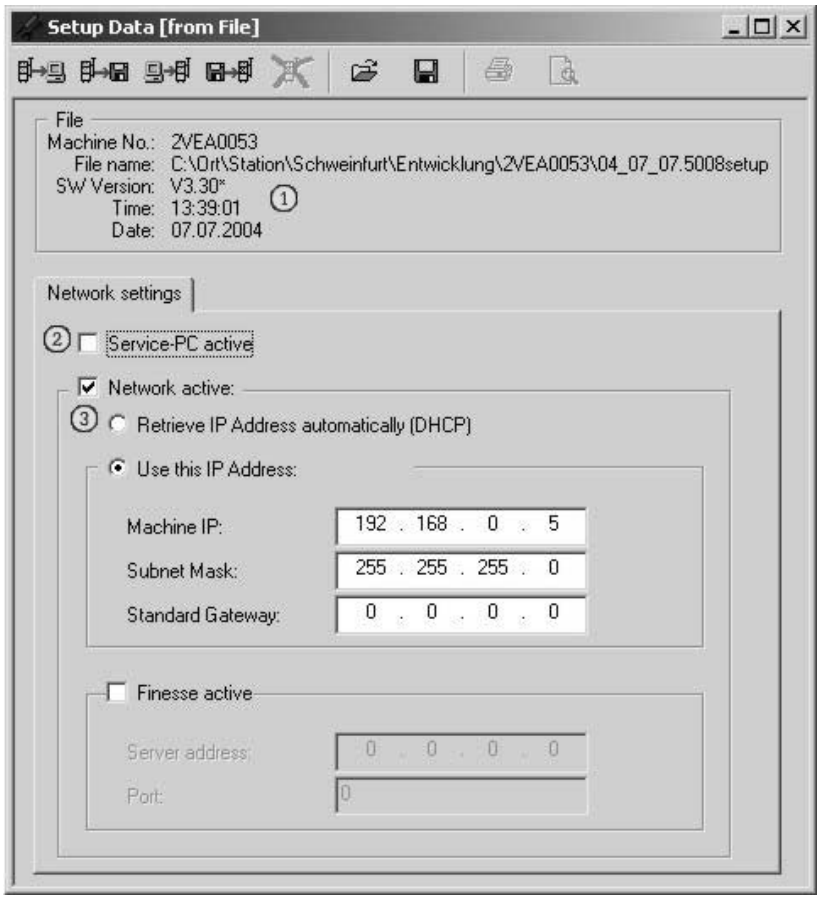
- **black:** everything ok.
- **red:** the NOVRAM value does not correspond with the value of the file.
- **blue:** the NOVRAM value of the file no longer exists in the software version of the 5008.

The **sort order** can be changed by clicking the column header.
The **width of the columns** can be changed with the mouse.
If the text inside the column is not shown completely, this will be indicated by "...".

⑦ The operator can undo the selection of the NOVRAM variables or select all NOVRAM variables.

View

Setup Data



PC Service-Software 5008

Caution:
The complete setup (operator and technician's) is always transferred from/to 5008.
In case of setup transmission to 5008 it might be necessary to verify the operator setup parameters!

 Uploads setup data from the 5008.

 Uploads setup data from the 5008 and saves them to a file

 Downloads setup data to the 5008.

 Loads setup data from a file and downloads them to the 5008.

 Loads setup data from a file.

 Saves the setup data displayed to a file (*.5008setup).

① Indicates general information
- Machine no.
- File name
- SW version of the 5008
  (in versions marked with an asterisk (*), the setup was modified)
- Download time
- Download date

on the error memory data downloaded from the 5008.

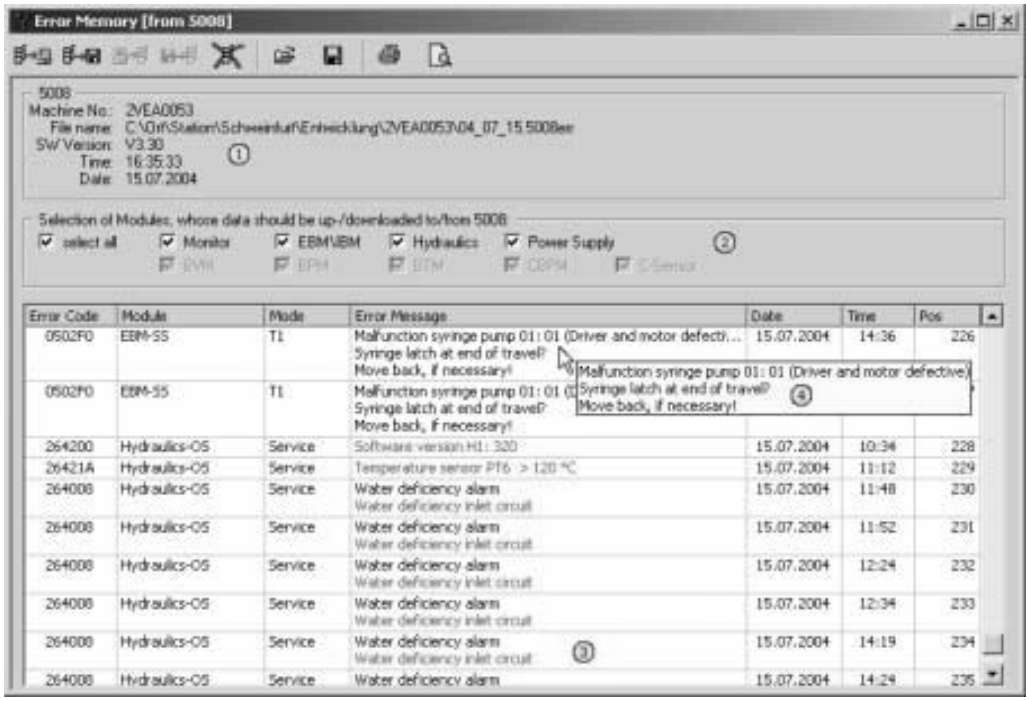
② Service-PC active must be selected if the PC Service Software 5008 is to be used for network communication with the 5008.

③ The operator can view, edit and save the network settings of the 5008 and upload them with all other setup data to the 5008.

Caution:
The network settings become active after restart of the 5008 only.

View

Error Memory



Downloads error memory data of the selected assembly ② from the 5008.

Downloads error memory data of the selected assembly ② from the 5008 and saves them to a file.

Deletes the error memory data of the selected assembly ②.
This should not be done before a backup of the error memory data has been created.

Opens the error memory data from a file (*.5008err).

Saves the error memory data to a file (*.5008err).

Prints the error memory data.

Displays the Print Preview.

① Indicates general information
- Machine no.
- File name
- Software version of the 5008
- Download time
- Download date

on the error memory data downloaded from the 5008.

② Checkboxes where the operator can select for which assemblies the error

PC Service-Software 5008

memory data are to be downloaded, displayed or to be deleted.
Dimmed assemblies have been reported by the 5008 as not present.

③ Shows the error memory data.

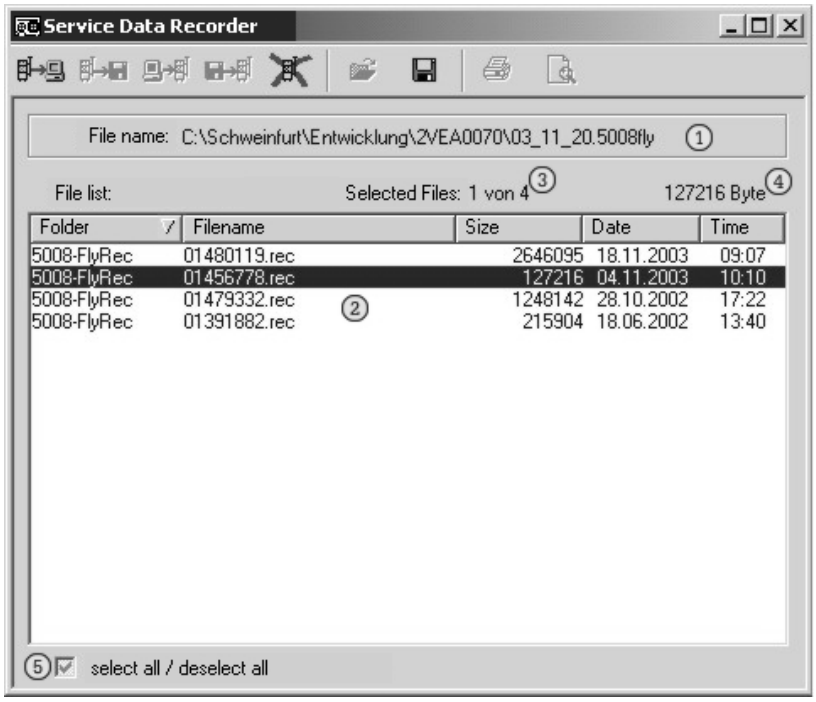
- Error Code: error code of the 5008
- Module: module name of the respective module
- Mode: current mode when the error occurred.
- Error message: error message in plain text.

  Explanation of colors (see section ③):
  - **black:** text for the operator is displayed in a message box on the 5008 and written into the error memory.
  - **red:** text is only written into the error memory.
- Date: date when the problem occurred.
  01.01.2001 means: the problem occurred prior to the initialization
- Time: time when the problem occurred.
- Pos: consecutive number as the data were downloaded from the 5008.

The **sort order** can be changed by clicking the column header.
The **width of the columns** can be changed with the mouse.
If the width of the column is too small for the text, this will be indicated by "...".
The complete text will be displayed in a tool tip ④ as soon as the mouse pointer is on the respective field.

View

Service Data Recorder



Downloads service data recorder file information from the 5008.

Caution:
The service data recorder files have not yet been downloaded from the 5008.

Deletes the service data recorder files selected under ② from the Compact-Flash.

Downloads the service data recorder files selected under ② from the 5008 and saves them to a compressed filed (*.5008fly).

① Indicates the file name to which the service data recorder files have been saved.

② Indicates information on the service data recorder file on the Compact-Flash.

- Folder: indicates where the service data recorder files are saved
- File name: indicates the file name of the service data recorder file.
- Size: indicates the size of the service data recorder file in bytes.

PC Service-Software 5008

- Date: indicates the date when the service data recorder file was saved.
- Time: indicates the time when the service data recorder file was saved.

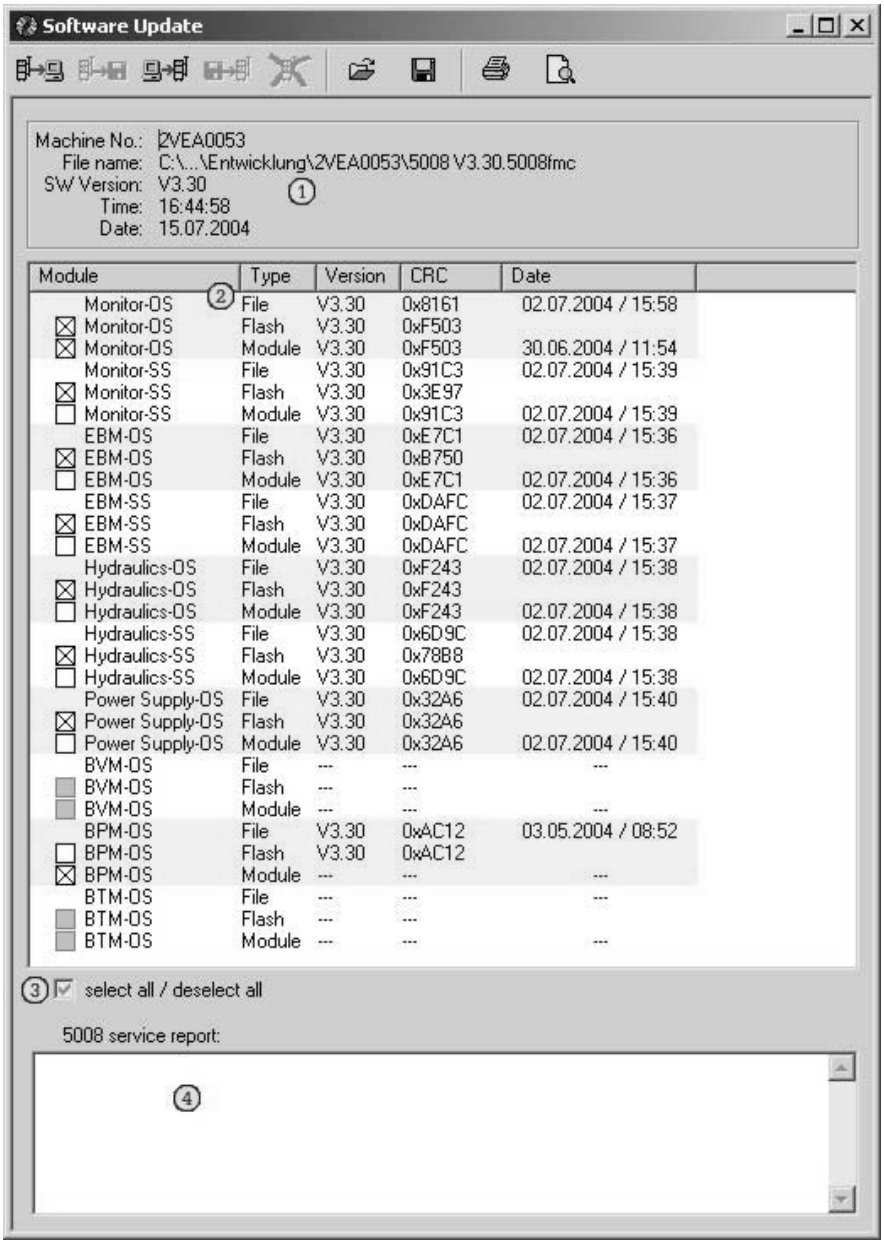
③ Number of the selected and total number of service data recorder files.

④ Current file size of the selected service data recorder files.

⑤ Deselects the selected service data recorder files or selects all.

View

Software Update



Downloads the service report from the 5008.
This report includes the software versions, revisions, the CRC, the creation date of the individual modules and information on missing files.

PC Service-Software 5008

Starts the software update of the 5008 in accordance with the operator's selection ②.

Opens the software update file.

Saves the software status to a file (*.5008sws).

Prints the software status.

Displays the Print Preview.

① Shows the file name of the software update file that has been opened.

② Shows information on the software versions of the individual modules.

- Module: Symbols:
  ☐ The module shall not be updated.
  ☒ The module shall be updated.
  ! ☒ The module shall be updated but with an older version!
  The update status can be changed by double-clicking the symbols.

  Module name of the respective module, e.g. Monitor-OS
- Type:
  - **File:** the information in this line refers to the version in the software update file for the respective module.
  - **Flash:** the information in this line refers to the version on the CompactFlash of the 5008 for the respective module.
  - **Module:** the information in this line refers to the version installed in the respective module.
- Version: version
- CRC: cyclic redundancy check
- Date: data and time of compilation

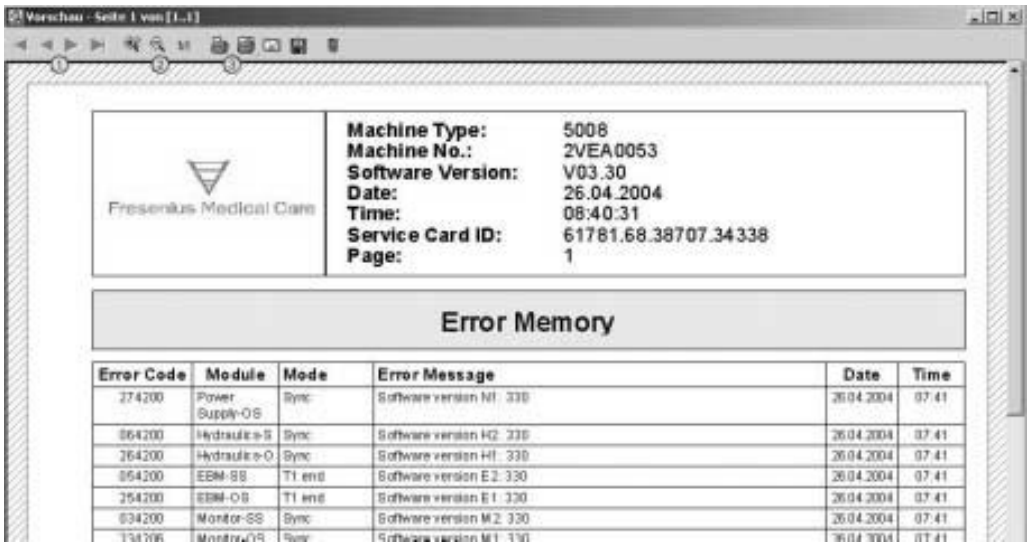
③ The operator can select if all modules are to be updated completely (check box checked) or if only the files listed in the service report which are missing or which are defective are to be updated (check box not checked).

④ More service report information for the operator:

- Files which are required by 5008 but which are missing or defective.

View

Print Preview



Click the *Print Preview* button  to view the print preview.

1. Selects individual pages
2. Zooms in
3. Prints the pages

Modification

List of Modifications

Quick Guide

Release	Modification
0/04.03	First edition
1/09.03	Help adapted to version V1.01 • Layout revised • Caution: Software for service purposes only, added on cover page • Table of contents added • Item 1 - Preparation - amended • Item 2.8 - Software Update - revised
2/49.03	Help adapted to version V1.10 • Screenshots updated • NOVRAM / Calibration data description adapted • Software Update description adapted
3/17.04	Help adapted to version V1.11 • Machine Info description (operating hours) adapted • List of Modifications: Software added
4/29.04	Help adapted to version V1.20 • System Requirements Network card added • Hardware Installation Part numbers of interface cables added • Starting the Software: Network access description added • Description of the Service Card (Access Protection) Note on ServiceCard expiration date added • Menu Options/Toolbar: Settings Network access description adapted • Menu/Toolbar: View added • View: Machine Info Setting/deleting operating hours added • View: Error Memory Error memory view description extended • View: Setup Data Note: Operator/Technician's setup added Description for *Service-PC active* added • View: Software Update Release number omitted

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Index