5008
Hemodialysis System

Operating Instructions

Software version: 3.52
Edition: 5/09.06
Part no.: M38 816 1
CE 0123

Caution!
These Operating Instructions in pdf-format are for information only.
They are not a replacement for the Operating Instructions supplied with the machine/device and options.

Fresenius Medical Care

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2 Important Information

2.1 Important Information on the Operating Instructions

2.1.1 How to Use the Operating Instructions

Identification

The document can be identified by the following information on the title page and on the labels, if any:
- Software version of the system
- Edition of the technical document
- Part number of the technical document

Page identification

The page identification 1-3, for example, refers to Chapter 1, page 3.

Editorial information

The editorial information 1/01.05, for example, refers to: 1. edition, January 2005.

Changes

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

Importance of the instructions

These Operating Instructions are part of the accompanying documents and an integral part of the system. They contain information necessary for the use of the system.
The Operating Instructions must be carefully studied before attempting to operate the system.

Before the responsible organization may start operating the system, the person responsible for the operation must have been instructed by the manufacturer on how to use the system and must be thoroughly familiar with the contents of the Operating Instructions.

The system may only be operated by persons certificated to have been instructed on the proper operation and handling of the unit.

Description of the options

Chapters 15 to 28 describe the operation of the options. For further information please refer to the appropriate chapters. (e.g. The SN Specifications are listed in chapter 11 System Description.)

2.1.2 Signification of the Safety Precautions

Explanation of the Caution and Note symbols used:

Caution

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

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.

2.1.3 Signification of the Highlight Symbol

Explanation on the following symbol:

Here you will find hints on easy handling.

2.2 Important Information on the System

2.2.1 Brief Description

Dialysis treatments with the hemodialysis system 5008 can be performed without any additional equipment. The hemodialysis system controls and monitors the dialysate circuit and the extracorporeal blood circuit.

The monitor comprises of four keys. All entries are made via a high-resolution color monitor (touch screen). The current treatment data are shown on the display.

In the dialysate circuit, product water is heated, degassed, mixed with hemodialysis concentrate, and delivered to the dialyzer. Inflowing and outflowing quantities are balanced volumetrically. The pressure at the dialyzer is adjusted depending on the ultrafiltration rate selected and the type of dialyzer used.

The blood in the extracorporeal blood circuit is transported through the dialyzer. The blood can be continuously heparinized. An air bubble detector prevents infusion of air. Any dangerous loss of blood is prevented by a blood leak detector, a fluid detector and by monitoring the venous return pressure. The arterial pressure monitoring unit detects an aspiration of the needle in the vessel.

The hemodialysis system 5008 is designed for both acetate dialysis and bicarbonate dialysis. The mixing ratio, the Na^+ concentration and the bicarbonate concentration may be programmed within certain limits. The hemodialysis system allows programming of Na and UF profiles.

ISO-UF (ultrafiltration without dialysate flow) may be performed.

The dialysate flow can be adjusted from 100 to 1000 ml/min, in increments of 100 ml/min. The AutoFlow function automatically regulates the dialysate flow, depending on the dialyzer type and blood flow.

The 5008 hemodialysis system reflects the latest state of technology. It is equipped with all safety systems required for its function and for patient safety. It complies with the requirements of EN 60601-1 (IEC 601-1). The BPM (optional) complies with the EN 1060-1 standard for non-invasive sphygmomanometers, Part 1 General Requirements.

The 5008 hemodialysis system is classified as Class II b (MDD) equipment.

2.2.2 Intended Use

- **Fields of application**

The 5008 hemodialysis system is designed for performing chronic and acute hemodialysis. It can be used in home dialysis, hemodialysis and limited care centers and clinical hemodialysis.

- **Side effects**

Hemodialysis therapies occasionally cause hypotension, nausea, vomiting and cramps in some patients. In addition, the package inserts enclosed with the consumables (e.g. hemodialysis concentrates, dialyzers) must be observed.

- **Contraindications**

– Hyperkalemia (only with potassium-containing hemodialysis concentrates)
– Hypokalemia (only with potassium-free hemodialysis concentrates)
– Uncontrollable coagulation anomalies

A different method of extracorporeal treatment may be indicated in hemodynamically unstable patients.

- **Restrictions**

None

2.2.3 Target Group

The system may only be installed, operated and used by persons with the appropriate training, knowledge and experience.

2.2.4 Duties of the Responsible Organization

The responsible organization assumes the following responsibilities:

– Compliance with the national or local installation, operation, use and maintenance regulations
– Respect of the accident prevention regulations
– Correct and safe state of the system
– Permanent availability of the Operating Instructions

2.2.5 Disclaimer of Liability

The system has been approved for use with the consumables and accessories listed in the Operating Instructions.

Should the responsible organization wish to use other consumables and accessories than those listed in the Operating Instructions, the responsibility to ensure the correct function of the system lies exclusively with the responsible organization. The applicable legal regulations must be complied with (e.g. in Germany the Medical Device Directive, MDD and the MPBetreibV = German regulation for the operation of medical products).

The manufacturer does not assume any responsibility or liability for personal injury or other damage and excludes any warranty for damage to the system resulting from the use of non-approved or unsuitable consumables or accessories.

2.2.6 Guarantee / Warranty

- **Guarantee**

For guarantee refer to the respective sales contracts.

- **Warranty**

The customer's rights of warranty depend on the applicable legal regulations.

2.2.7 Safety Precautions

- **Basic safety precautions**

Caution

When using a RO unit or CDS the following must be observed:

Operating Instructions of the RO unit or CDS used.

When cleaning the RO unit and its supply lines, the hemodialysis system must be disconnected from the RO unit at the water supply.

During cleaning of the CDS distribution tubings, the hemodialysis system must be separated from the CDS.

- **Electric hazards**

Caution

The use of additional extension cables or multiway sockets / connectors is prohibited.

2.2.8 Additional Optional Equipment Supplied by Fresenius Medical Care

– DIASAFE®*plus*

– AquaUNO (single station ´reverse osmosis unit)
For connecting the AquaUNO to the 5008 hemodialysis system, the two following cables must be used:
Control cable connection set: 3 meters (part no.: M37 525 1) or 11 meters (part no.: M37 510 1)
Adapter cable AquaUNO - 5008 (part no.: M36 940 1)

2.2.9 Initial Start-Up

Prior to the initial start-up thoroughly study the information given in chapter 11.

2.2.10 Start-Up Requirements

The 5008 hemodialysis system must be in a perfect state. If the 5008 hemodialysis system shows signs of mechanical damage preventing safe operation, stop using the machine. Applied parts that are damaged must be replaced.

2.2.11 Operation

The following must be observed when entering parameters:
The parameters entered must be verified by the operator, i.e. the operator must check that the values entered are correct. If the verification reveals a deviation between the desired parameters and the parameters displayed on the system, the setting must be corrected before activating the function.
The actual values displayed must be compared with the desired values specified.

2.2.12 Technical Safety Checks (TSC), Technical Measurement Checks (TMC)

The technical safety checks and technical measurement checks required must be performed every 2 years.

2.2.13 Repair

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

2.2.14 Technical Documentation

Upon request the manufacturer will provide circuit diagrams, descriptions, spare parts lists and other documents. These are intended to support trained personnel in servicing and repairing the machine.

The following is also available on request:
– Test procedure by which the effectiveness of sterilization or disinfection has been verified.
– Comments, concerning the expected recirculation of the blood flow in the extracorporeal circuit in Single-Needle treatments, if the recommended administration sets, dialyzers, fistula needles and catheters are used.

2.3 Addresses

Please address any inquiries to:

Manufacturer

Fresenius Medical Care AG & Co. KGaA
D-61346 Bad Homburg
+49 (0)6172/609-0
www.fmc-ag.com

Service Central Europe

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

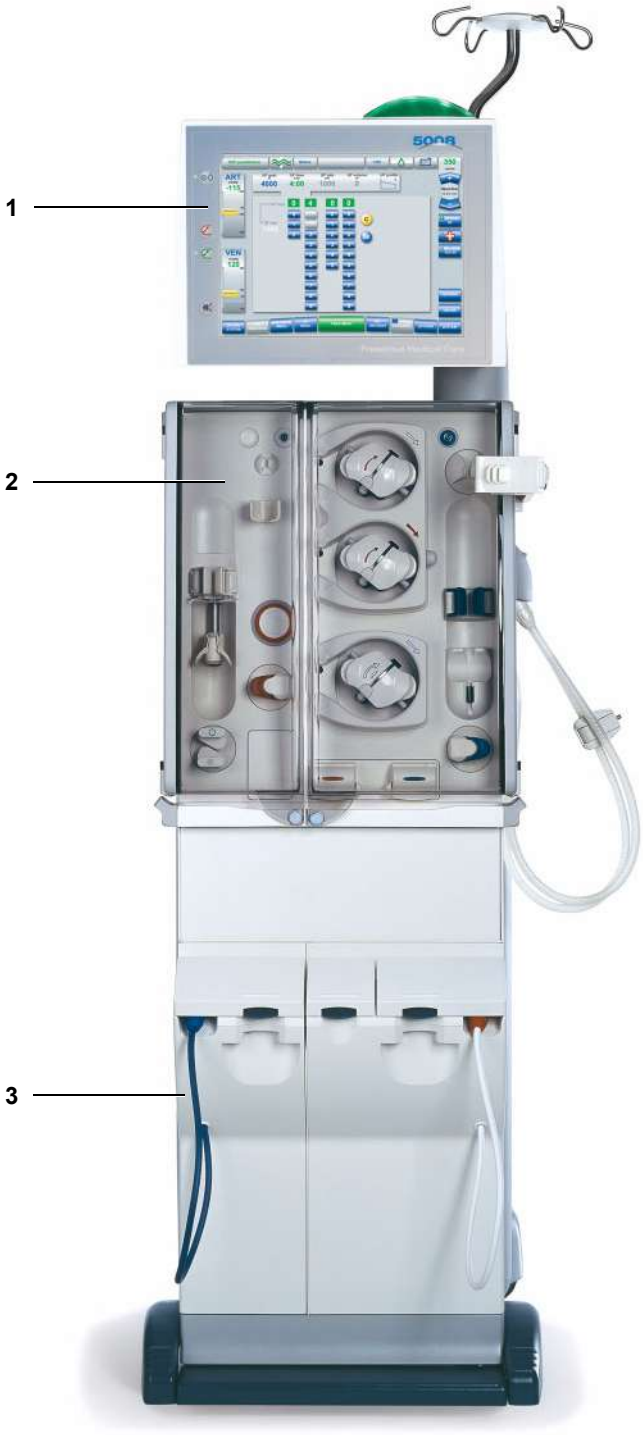
International Service

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

Local Service

3 Design

3.1 Front View

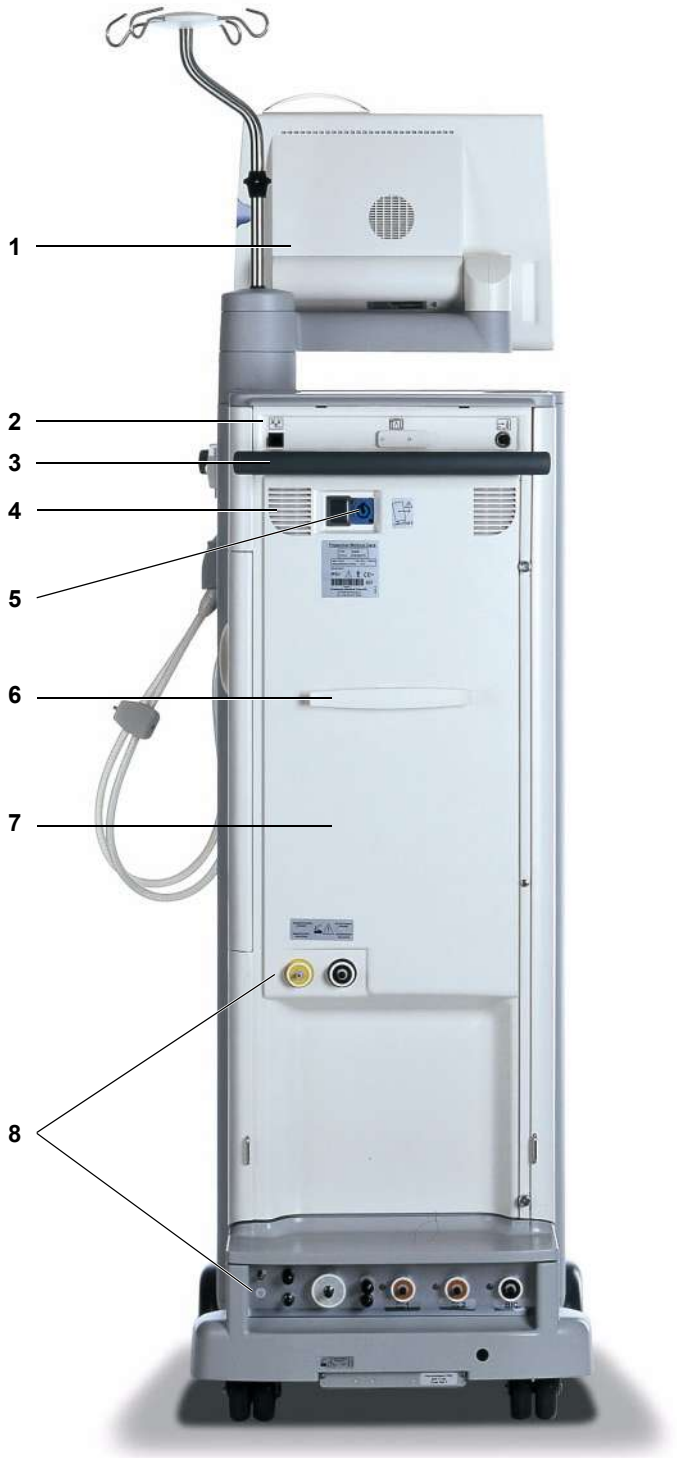


1 Monitor

2 Extracorporeal blood module

3 Hydraulics

3.2 Rear View



1 Monitor
2 External connection options
3 Push handle
4 Fan filter (service door)
5 Power connection (supply point)
6 Line holder (for transport)
7 Service door
8 Hydraulic connectors

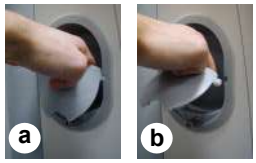
3.3 Lateral View, Left Side

1 Cover, tray, cuff holder or shunt interlock

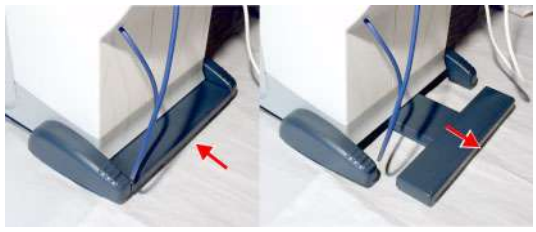
2 Concentrate rack (extractable)

3 Brake

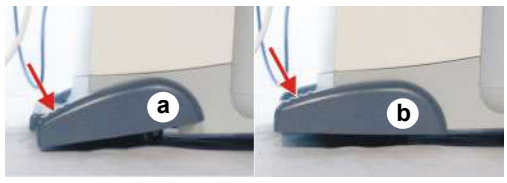
Remove the cover from the tray:
(**a**) Push the cover down and turn it.
(**b**) Pull the cover out.



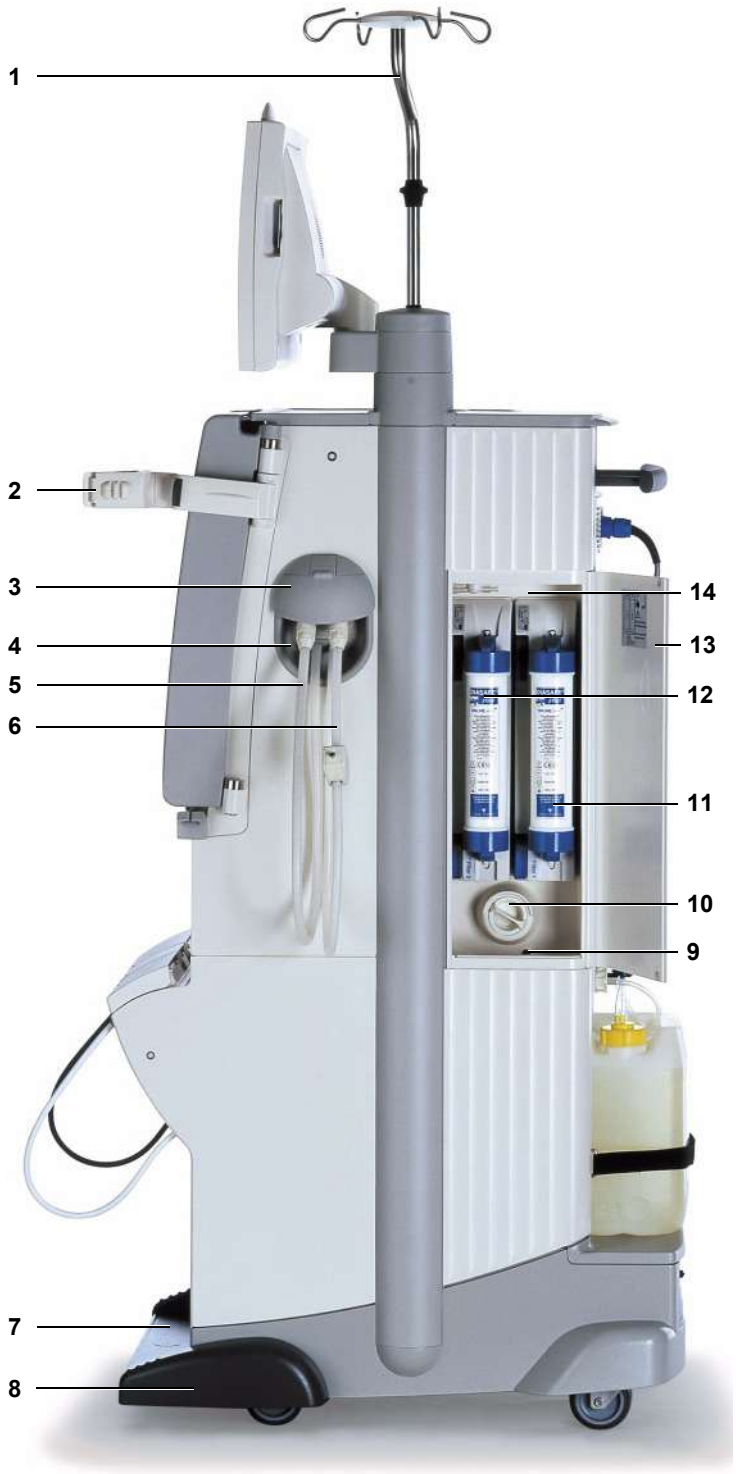
To extract the concentrate rack:
Push with your foot from the front against the rack.
To retract the concentrate rack:
Push with your foot from the front against the rack until it clicks into place.



To apply or release the brake:
(**a**) Push the lever down to apply the brake.
(**b**) Push the lever down to release the brake.



3.4 Lateral View, Right Side



1 IV pole

2 Dialyzer holder

3 Shunt door for dialysate lines

4 Shunt interlock

5 Dialysate return line (dialyzer coupling blue)

6 Dialysate supply line (dialyzer coupling red)

7 Concentrate rack (extractable)

8 Brake

9 Leakage sensor, filter chamber

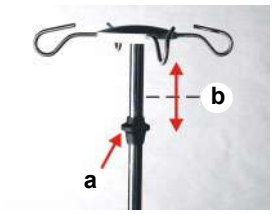
10 Particle filter, dialysate

11 Filter 1 – DIASAFE®*plus*, right

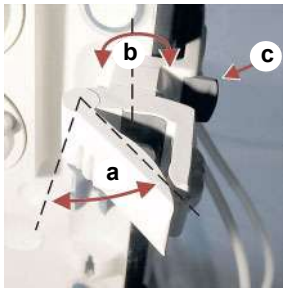
12 Filter 2 – ONLINE*plus*™, left

13 Door, filter chamber

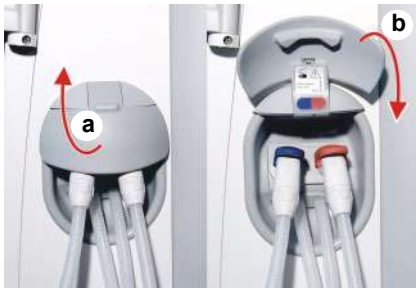
14 Filter chamber



To adjust the IV pole:
Push the knob (**a**) upwards and simultaneously extract or retract the IV pole (**b**).

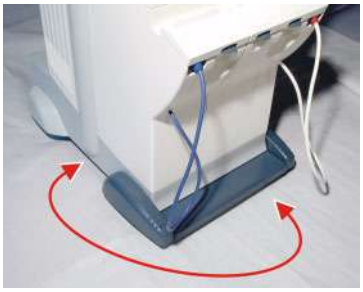


Dialyzer holder:
Push the lever (**a**) to the left to insert the dialyzer. The dialyzer can be moved to any desired position (**b**). Press or pull the lever (**c**) to swivel the dialyzer holder to the right. (When the right-hand door is opened, the dialyzer holder will automatically move to the right.)



To open or close the shunt door:
Open the shunt door by flipping it to the top (**a**). Close the shunt door by flipping it down (**b**).

To remove the dialysate couplings:
Push the lever down and hold it, and remove the dialysate coupling.



To move the hemodialysis system:
The hemodialysis system can be moved in all directions.

3.5 Monitor Front

1 Display failure sensor (hidden)

2 **On/Off** LED/key (green)
(LED is illuminated – system in operation. LED is flashing – system is connected to power supply, standby.)

3 **Blood system Stop** LED/key (red)

4 **Blood system Start** LED/key (green)

5 **Mute** LED/key (red)
(LED is illuminated – audible alarm suppressed. LED is flashing – audible alarm active.)

6 Screen

7 Operating mode indicator (green, yellow, red)
LED is green to indicate correct operation.
LED is yellow in case of a warning or an info.
LED is yellow and flashing in Emergency mode.
LED is red in case of an alarm.
LED is not illuminated during the cleaning programs.

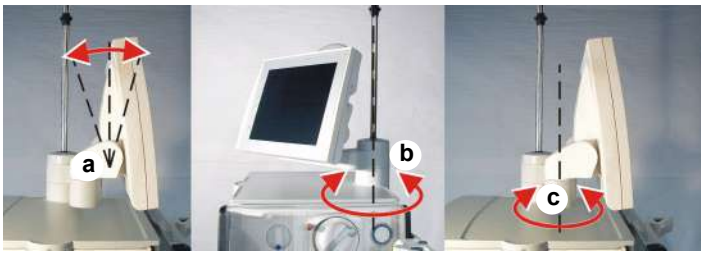
3.6 Monitor Rear

1 Card receptacle
(for PatientCard/UserCard/ServiceCard)

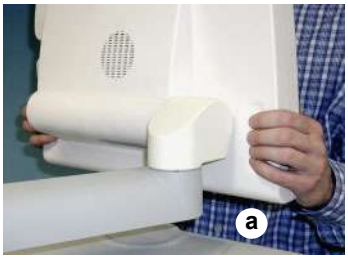
2 Loudspeaker

3 Recessed handle

4 Monitor arm



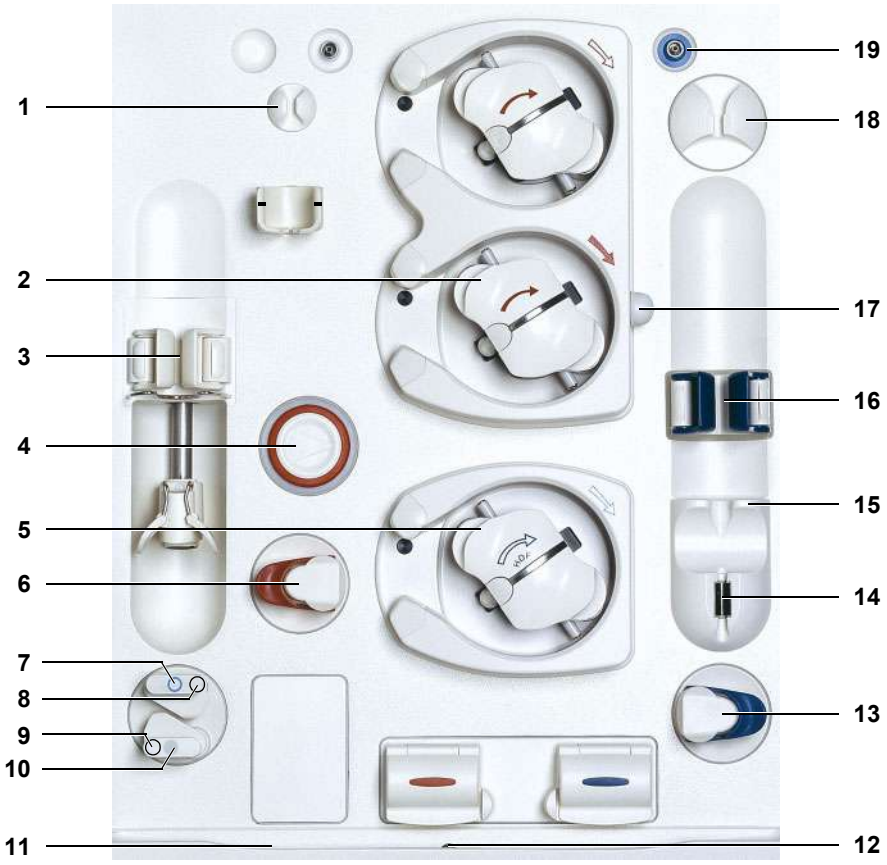
To move the monitor:
To bring the monitor into the desired position, it can be swiveled about three axes (**a**), (**b**), (**c**).



(**a**) To move it, hold the monitor at the points shown.

(**b**) Insert card.

3.7 Extracorporeal Blood Module



1 Line holder
2 Blood pump
3 Heparin pump (if present)
4 Arterial pressure measurement unit
5 Substituate pump
6 Arterial occlusion clamp
7 Substituate catch/lock (blue)
8 Substituate port, hidden by the substituate catch (blue)
9 Rinse port, hidden by the rinse port catch (grey)
10 Rinse port catch (grey)
11 Groove
12 Leakage sensor, extracorporeal blood module
13 Venous occlusion clamp
14 Venous monitoring function (optical detector, air bubble detector)
15 Locator for venous bubble catcher
16 Venous monitoring function (level detector)

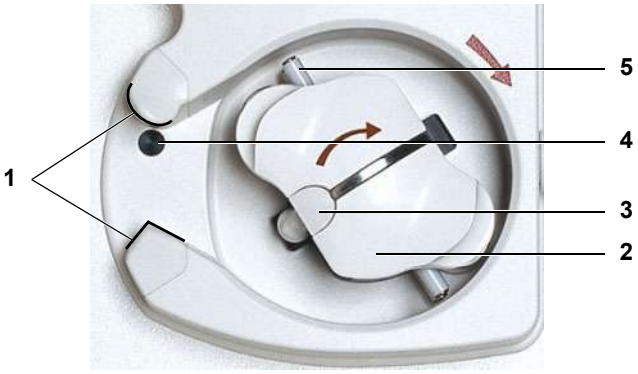
17 Line holder for SafeLine™

18 Line holder

19 Venous pressure port

Open or close the doors on the upper side as shown in the illustration.

- **Blood pump**



1 Holder (shape-coded) for line guide

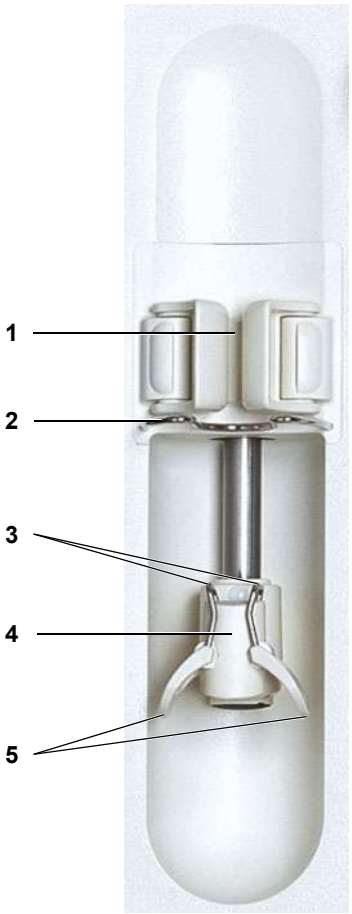
2 Rotor

3 Handle for an emergency operation

4 Key/ejector (for inserting and removing the line segment)

5 Line pulleys

- **Heparin pump**



1 Barrel holder with syringe detector

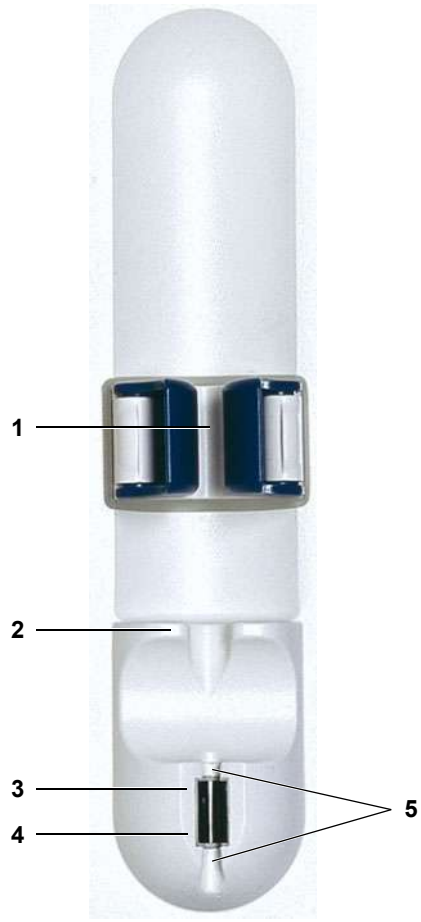
2 Bracket

3 Fixation for the plunger

4 Grip handle

5 Clamping brackets

- **Venous fill level and air monitoring function**



1 Tension lever with level detector (for the venous bubble catcher)

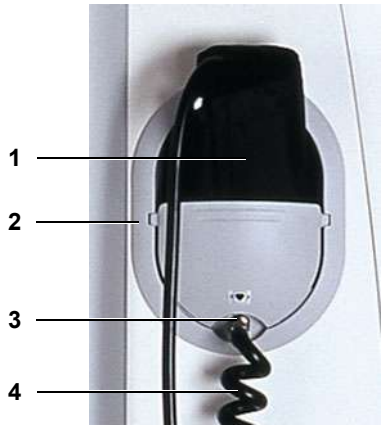
2 Locator for venous bubble catcher

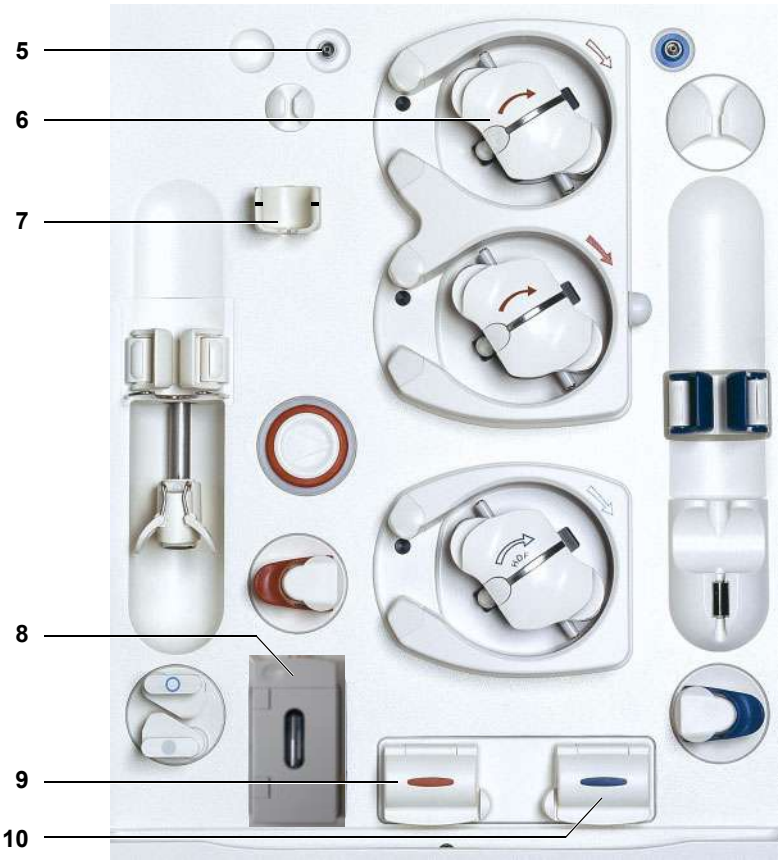
3 Optical detector

4 Air bubble detector (ABD)

5 Line housing

3.8 Extracorporeal Blood Module with Additional Functions





BPM (option)	**1**	Blood pressure cuff
	2	Cuff holder
	3	Pressure port (BPM)
	4	Pressure tubing
SN (option)	**5**	Single-Needle pressure port
	6	Single-Needle pump
	7	Holder for SN chamber (with mark)
BVM (option)	**8**	BVM measuring head
BTM (option)	**9**	Arterial measuring head (BTM)
	10	Venous measuring head (BTM)

3.9 Hydraulics

1 Bicarbonate flap

2 Bicarbonate suction tube (blue)

3 bi*b*ag® port

4 Indibag flap

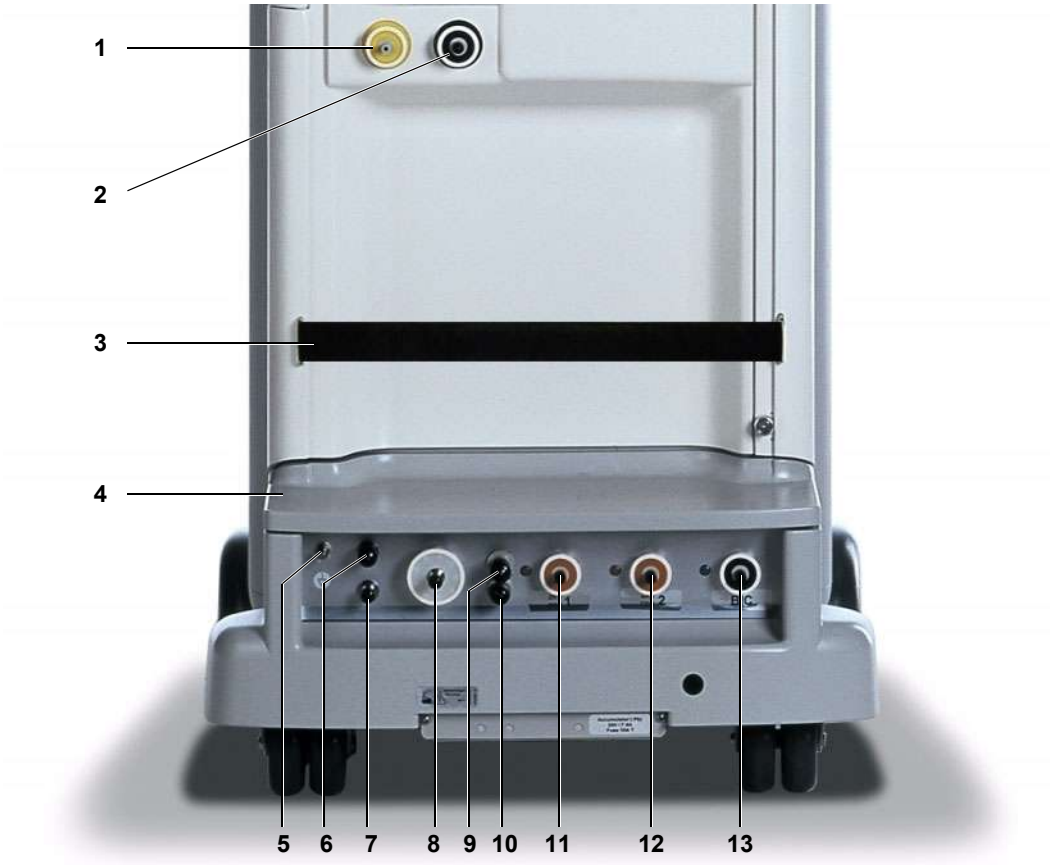
5 indi*b*ag® port

6 Concentrate flap

7 so*b*ag® port

8 Concentrate suction tube (red)

3.10 Hydraulics Connectors



1 Disinfectant connector (left – colored coding, yellow)

2 Disinfectant connector (right – colored coding, black)

3 Holder for disinfectant container

4 Tray for disinfectant container

5 Potential equalization

6 Drain

7 Flush drain (option)

8 Water supply (permeate)

9 Vent (water inlet chamber)

10 Vent (mixing chamber)

11 Connector for CDS 1, red (Central Delivery System) acid 1

12 Connector for CDS 2, red (Central Delivery System) acid 2 (option)

13 Connector for BIC, blue (central bicarbonate supply) (option)

3.11 External Connection Options/Connection to Power Supply

Caution

Before connecting any optional equipment, observe the notes under Specifications.

1 LAN (local area network) network connection

2 Service/diagnostics, RS232, 24 V
Connector for AquaUNO (single station reverse osmosis unit)

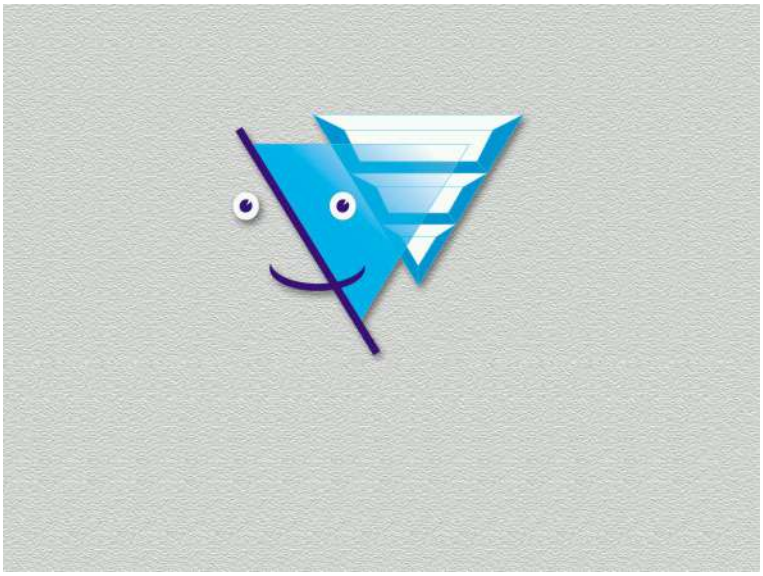
3 Alarm output (staff call)

4 Power connection (supply point)

5 Power switch

4 Graphical User Interface

4.1 After Turning Power on to the System



START-UP SCREEN

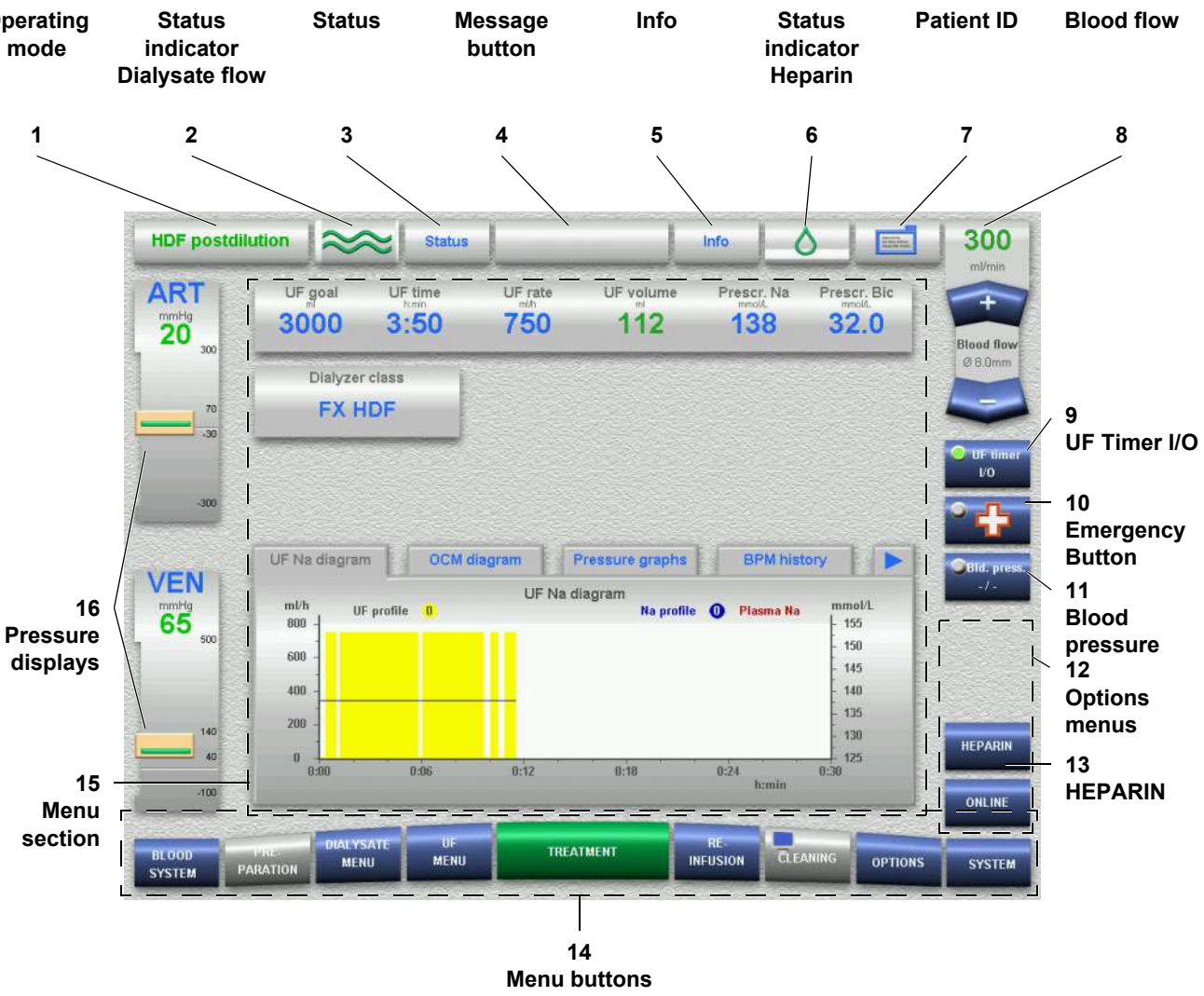
The display shows the machine type, the current software version and the clinical data (on request) for approx. 15 seconds.

SELECTION SCREEN

The following selections are possible:
– Treatment
– Cleaning program (e.g. Rinse)

Touch the desired button to make your selection.

4.2 Overview (Screen)



1 Operating mode
Displays the operating mode of the system (e.g. Dialysis). In addition, a progress bar is displayed, depending on the operating mode, e.g. in the Rinse mode.

2 Dialysate flow status indicator
- Flow turned on – waves green (grey bar is moving.)
- Bypass – waves green (grey bar is not moving.)
- Flow turned off – waves grey

3 Status
Displays data on the system condition. (Software, error memory, cleaning status, system info)

4 Message button
Allows retrieval of information, warnings and alarms (3 maximum)

5 Info
Displays information on the current procedure.

6 Heparin status indicator
– Pump switched on – drop green
(Grey bar is moving.)
– Pump switched off – drop grey

7 Patient ID (patient identification)
Treatment data sheet will be displayed.
Combined with the use of the patient card, it is possible to retrieve current treatment data. Storage of 3 previous treatments.

8 Blood flow
Displays the effective blood flow.
Rocker switch for increasing **+** / reducing **–** the effective blood flow.

9 UF Timer I/O
Button for starting/stopping ultrafiltration and the timer function.

10 Emergency button

11 Blood pressure
(Displayed only, if BPM option is available.)

12 Options menus
Via the **OPTIONS** menu button, it is possible to program up to four option menus with direct access.

13 HEPARIN
(displayed only, if selected in the Operator Setup)

14 Menu buttons
Corresponding menu opens automatically during operation
OR
touch button for opening the respective menu.

15 Menu section
In the center of the screen, the appropriate data for each menu is displayed.
Indicators/buttons/diagrams/graphics are displayed depending on the Setup settings.

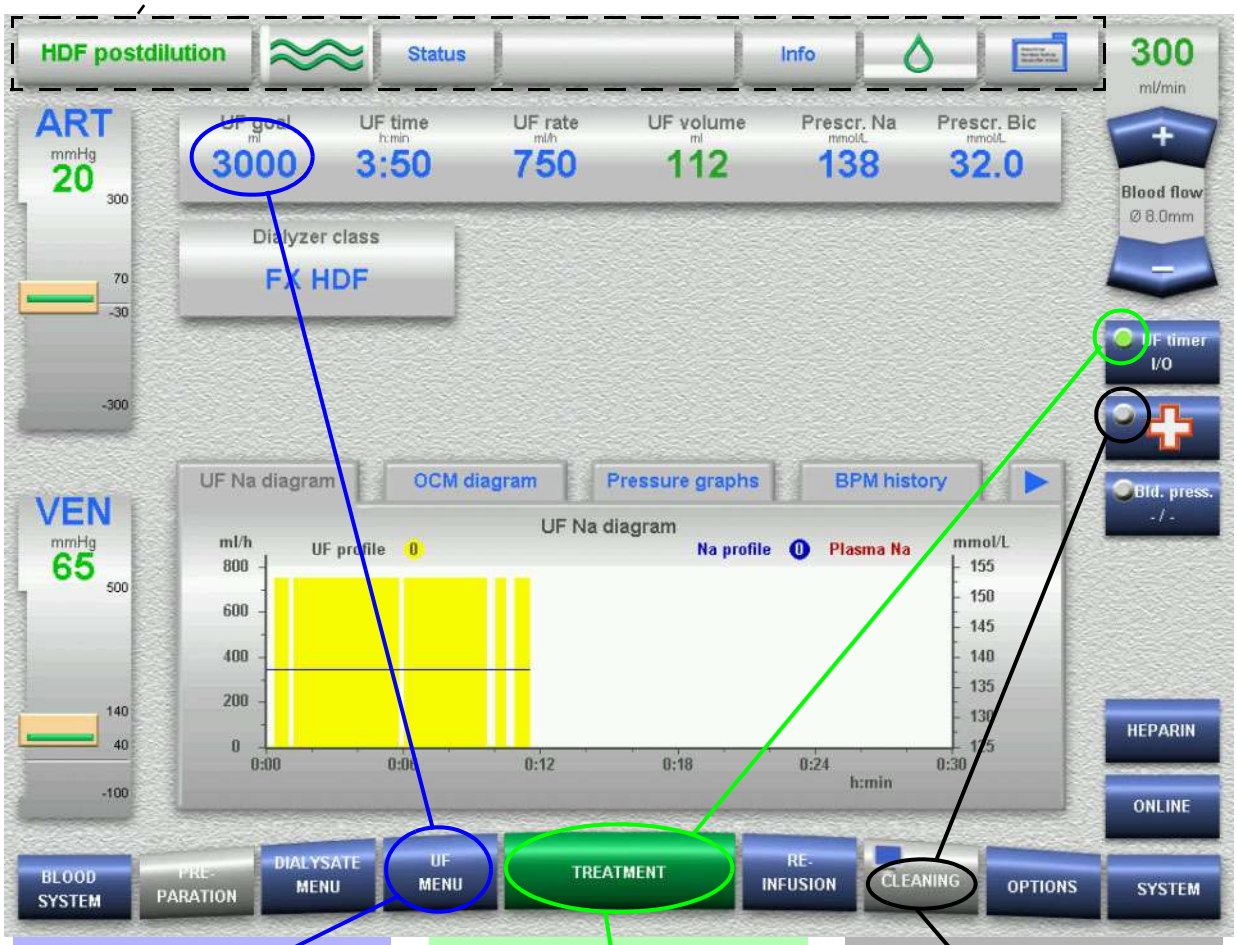
16 Pressure displays
ART (arterial pressure)
VEN (venous pressure)
The actual value is displayed as a numerical value and as a bar.
The alarm window is displayed in block representation, according to the window size.
Touch the **ART** or **VEN** field for setting the alarm limits.

4.3 General Operation Philosophy

It is possible to control all treatment sections via the screen menu.

- **Screen colors**

The fields in the header bar are:
Grey in the normal operating mode
Orange during the functional test (T1 test)
Orange during rinse procedure of the extracorporeal blood circuit, until the minimum rinse volume has been reached.
Yellow during the cleaning programs



BLUE
Selection possible

Examples
UF goal value field
UF MENU button

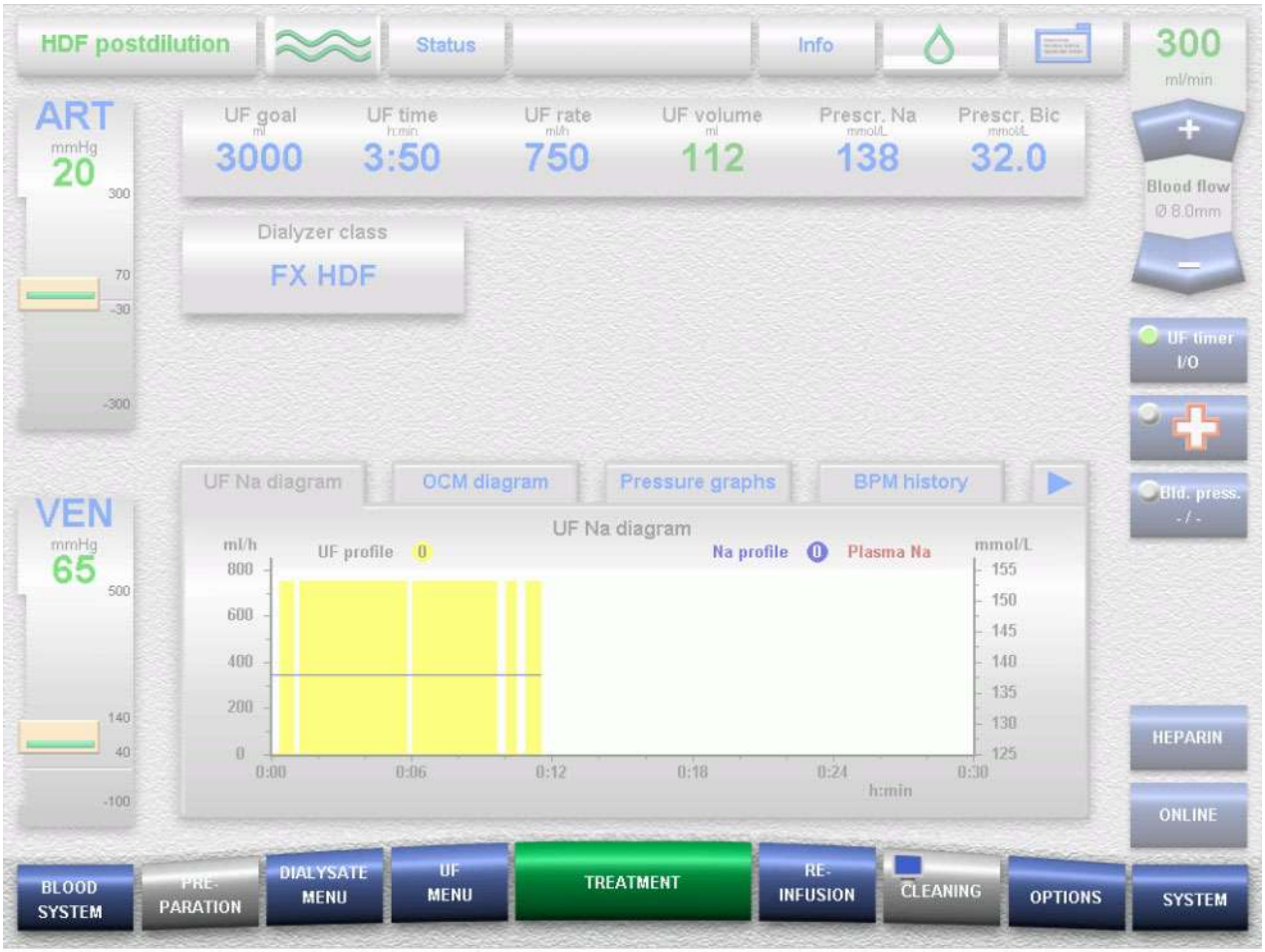
GREEN
Active

Examples
UF Timer I/O indicator
TREATMENT button

GREY
Not active
Example
Emergency menu I/O indicator

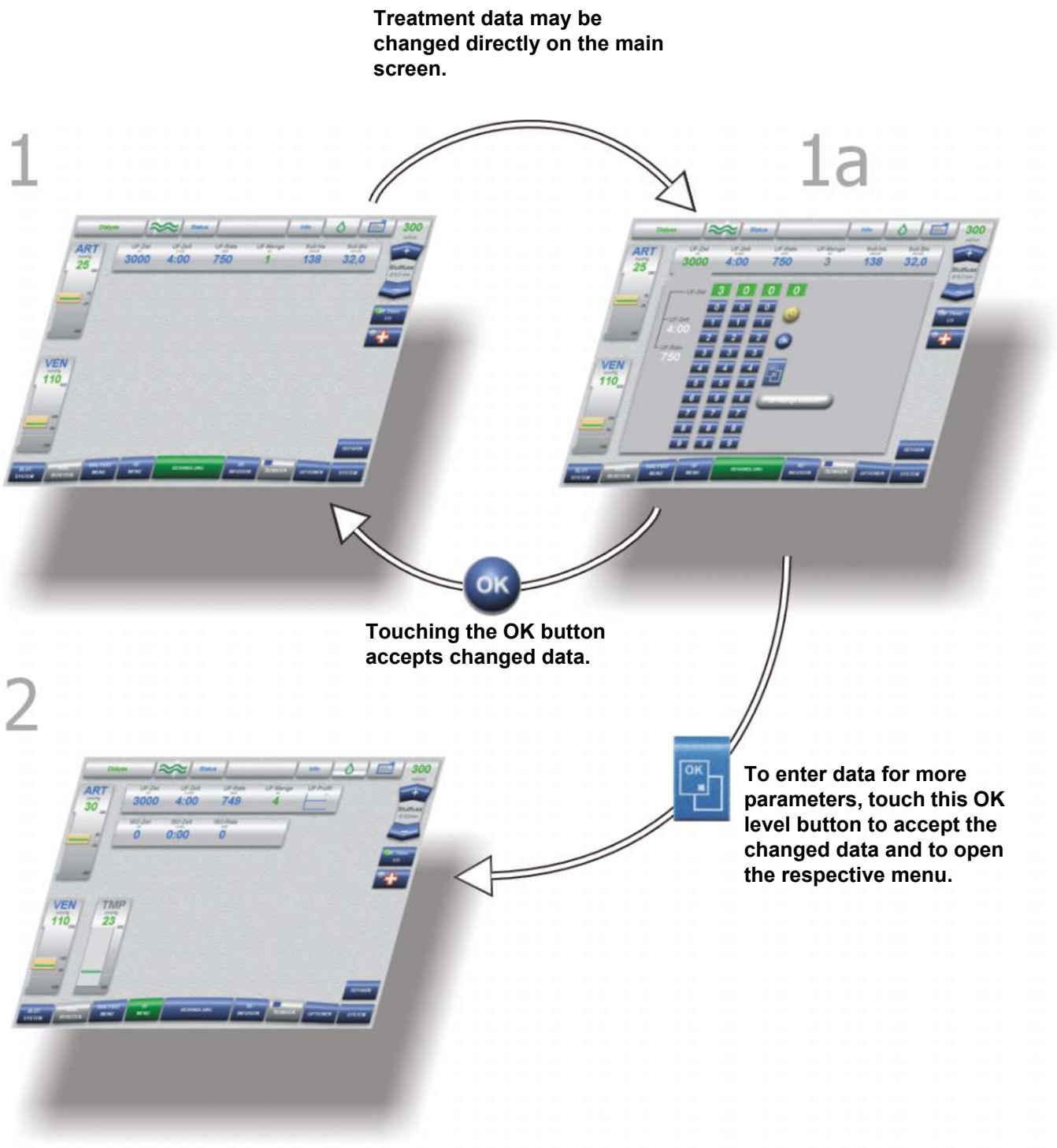
Selection not possible
Example
CLEANING button

- **Course of the treatment**



9 menu buttons in 3-D-design are placed at the bottom screen bar, representing the chronological course of operation. The change to the corresponding menus is performed automatically when the respective conditions have been fulfilled. (Exception: **DIALYSATE MENU**, **UF MENU**, **OPTIONS** and **SYSTEM**)

- **Design of the menu structure**

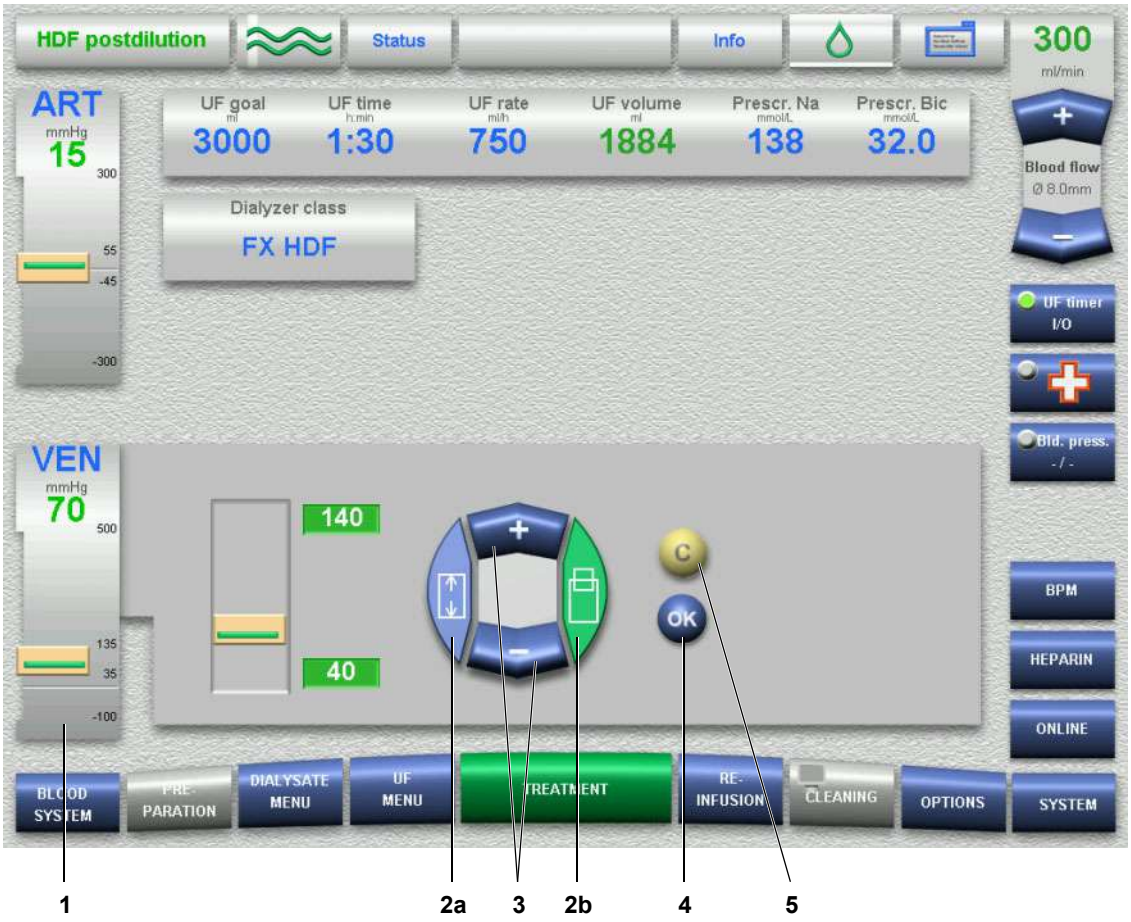


4.4 Examples for Data Entry (Treatment Data)

- **Setting via the numeric keypad (for example setting the prescribed Na)**

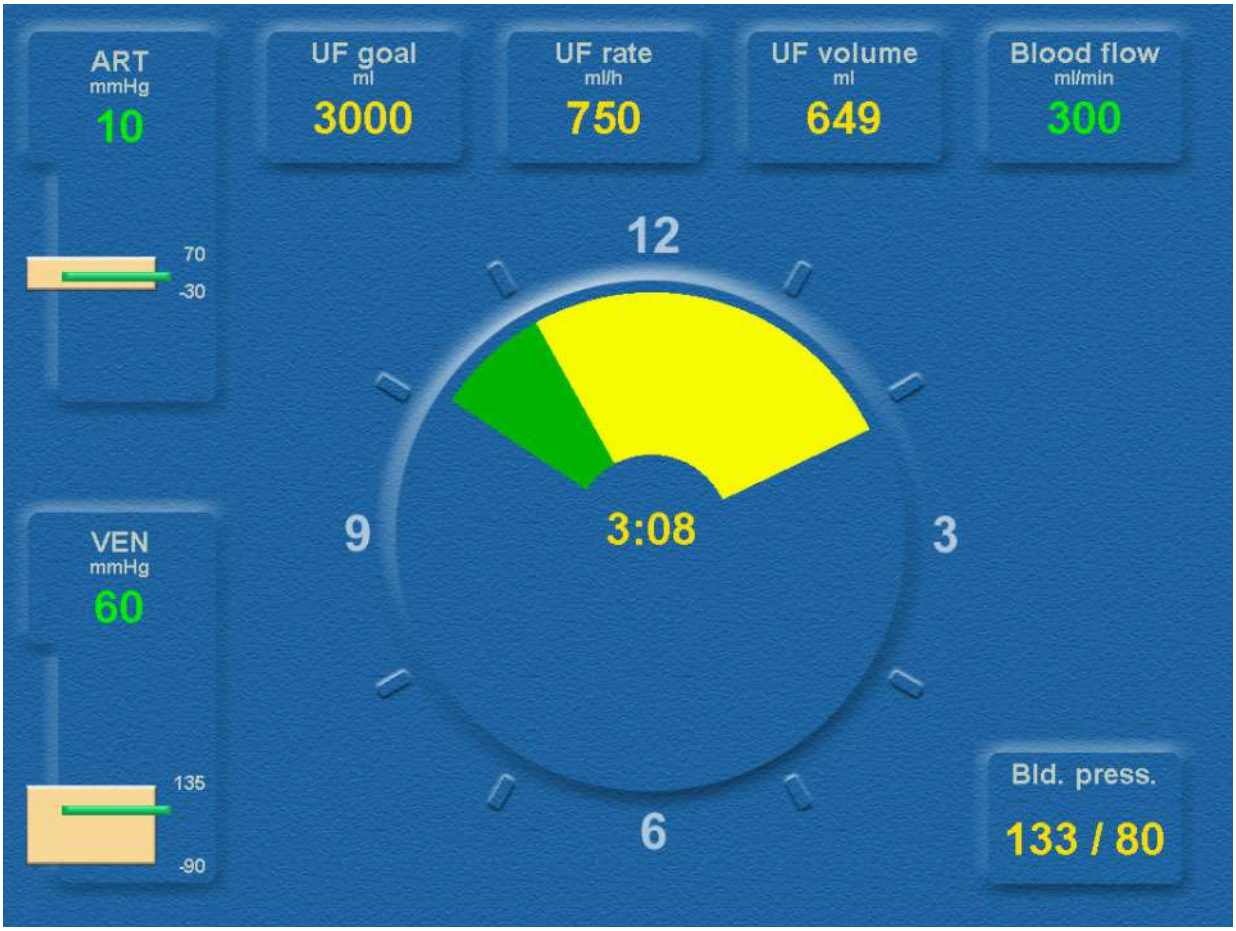
1. Touch the **Prescr. Na** field.
2. Enter the desired prescribed Na via the keypad.
   Check the entered value (prescribed value).
   (Grey keys prevent implausible entries.)
3. Touch the **OK** button to accept the entered value.
   Visually check the accepted value.
4. Touch the **C** button for making corrections.

- **Setting via the rocker switch (for example changing the venous alarm limits)**



1. Touch the **VEN** field.
2. a, Adjustment of window width – left
   b, Adjustment of window position – right
3. Adjust the desired alarm window via the **+/–** rocker switch.
   Check the entered alarm window value in the venous pressure display (prescribed value).
4. Touch the **OK** button to accept the selected alarm window.
   Visually check the accepted alarm window.
5. Touch the **C** button for making corrections.

4.5 Screen Saver



SCREEN SAVER

Displays the following data:
- the arterial and the venous pressures
- the UF parameters goal, rate and volume
- the effective blood flow
- the remaining treatment time in the center
- the last measured blood pressure
  (Only if the BPM system option exists.)
- the BVM rate and - under UF goal - the maximum UF goal = “+“ as well as the minimum UF goal = “-“
  (Only if the BVM system option exists.)

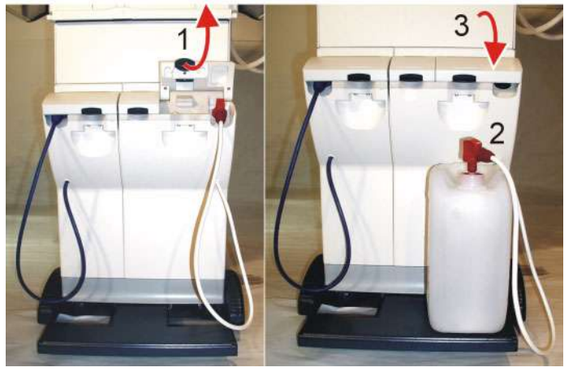
It is only displayed during the treatment, following a certain timed delay after the last screen action. (Timed delay adjustable in the Operator setup.)

The SCREEN SAVER disappears when any part of the screen is touched.

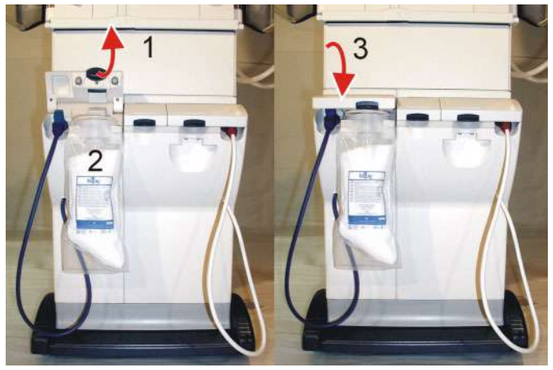
The SCREEN SAVER disappears immediately:
- when a message is given (info, warning or alarm),
- when the BPM (optional) starts a measurement.

Fold-Out Sheet
5 Preparation

Connecting the concentrate container (e.g. acid)

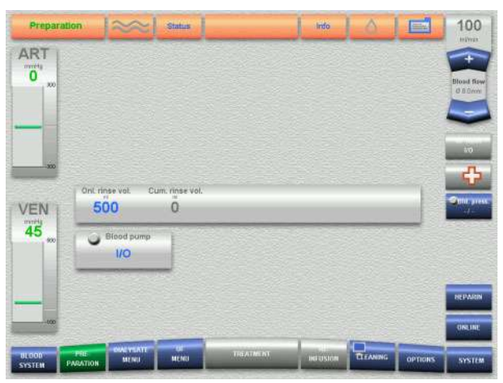


Connecting the bag (e.g. bi*bag*®)



BLOOD SYSTEM SCREEN

PREPARATION SCREEN



PREPARATION SCREEN

DIALYSATE SCREEN

UF SCREEN

HEPARIN SCREEN

5 Preparation

5.1 Preparation using ONLINE*plus*™

Irrespective of the treatment mode, all 5008 ONLINE*plus*™ hemodialysis systems can be operated without rinse or infusion solutions provided in NaCl bags. The fluid volumes required for preparation, bolus administration or during reinfusion will then be produced ONLINE by the 5008 hemodialysis system according to the actual requirements, thus saving both cost and time.

5.1.1 Turning the Hemodialysis System On

Caution

The stability of the 5008 hemodialysis system must be ensured.

Establish the water and power supply.

Press the **On/Off** key. (Turn the hemodialysis system on!)
The **On/Off** LED is illuminated.

START-UP SCREEN

The display shows the machine type, the current software version and the clinical data (on request) for approx. 15 seconds.

Caution

After a downtime of more than 72 hours, a cleaning program must be performed completely before starting the treatment.

If necessary, check the hemodialysis system for presence of residual disinfectant. (see chapter 8 Cleaning).

Note

If the message: *Defective battery* is acknowledged by pressing the **Skip** key, it might be that the audible alarm will not be generated, if a power failure occurs.

5.1.2 The Following Must be Observed when Using Consumables

Caution

The system has been approved for use with the consumables and accessories listed in the Operating Instructions.

Should the responsible organization wish to use other consumables and accessories than those listed in the Operating Instructions, the responsibility to ensure the correct function of the system lies exclusively with the responsible organization. The applicable legal regulations must be complied with (e.g. in Germany the Medical Device Directive, MDD and the MPBetreibV = German regulation for the operation of medical products).

The manufacturer does not assume any responsibility or liability for personal injury or other damage and excludes any warranty for damage to the system resulting from the use of non-approved or unsuitable consumables or accessories.

Caution

The symbols printed on the packaging of the consumables have to be observed. The symbols are described in the chapter System Description (consumables symbols).

When using consumables, it is important to take note of the following symbols:

Do not reuse

Use by

Caution

The consumables may only be used if the packaging and the respective consumable including the protective caps used are not damaged. The protective caps must not have fallen off.

The plastics used for the consumables may not be compatible with components of drugs or disinfectants. If they are planned to be used, the compatibility of the consumables' components must be ensured before the treatment. If connectors made of polycarbonate are for example exposed to aqueous solutions with the pH value > 10 or to aliphatic solutions this will cause tension cracks.

5.1.3 Selecting the Concentrate Supply

● **Connecting the concentrates**

Caution

Concentrate:
The concentrate displayed on the screen must comply with the specifications mentioned on the acid or the acetate container or on the bag. This also applies to the concentrate composition in CDS operation.

Concentrate packages:
– Assure that the packages used contain sufficient concentrate to complete the treatment.
– Use only the dedicated coded containers or the bi*b*ag® for bicarbonate dialysis.

Bicarbonate dry concentrate bi*b*ag®:
Only the bi*b*ag® manufactured by Fresenius Medical Care may be used.

The bi*b*ag® must only be used for one treatment.

Only use the bi*b*ag® in combination with acid bicarbonate hemodialysis concentrate according to the prescribed dilution. Other mixing ratios may lead to a hazard for the patient.

Acid and basic bicarbonate hemodialysis concentrate have to be diluted immediately prior to application only. The bag's content must be used up within 12 hours after dilution. Discard residual volumes. The powder is non-pyrogenic.

Conductivity limits:
The alarm limits are automatically set around the expected value. The actual value of the conductivity display must have attained the expected desired value after a maximum of 10 minutes.
Should this not be the case, the actual value must first be checked in the laboratory. Change or check the concentrate, if necessary, or call service.

Note

The bicarbonate suction tube must be inserted into the rinse chamber during the bi*b*ag® treatment.

Extract the concentrate rack.

Bicarbonate dialysis

To connect the (acid) concentrate container:
Push the latch (1) upwards. Open the concentrate flap. Place the red concentrate suction tube (2) into the acid container. Close the concentrate flap (3) until it clicks into place.

To connect the bi*b*ag®:
Push the latch (1) upwards. Open the bicarbonate flap. Remove the bi*b*ag® from its packaging. Remove the foil from the bi*b*ag®. Attach the bi*b*ag® (2). Close the bicarbonate flap (3) until it clicks into place.
OR
To connect the bicarbonate container:
Insert the bicarbonate suction tube (blue) into the bicarbonate container.
Close the bicarbonate flap.

CDS, Central Delivery System (option)

Note

The responsible organization is responsible for the proper installation and function of the CDS.

Acetate dialysis

Connect the concentrate container.
Insert the concentrate suction tube (red) into the acetate container.
The bicarbonate suction tube (blue) remains in the rinse chamber.

Selecting a treatment

SELECTION SCREEN

Touch the **Treatment** field.

If there is no tubing system inserted, the system automatically moves to the BLOOD SYSTEM screen.

BLOOD SYSTEM SCREEN

The T1 test is now running in parallel with the preparation of the hemodialysis system. The color of the header bar is orange for the duration of the T1 test.
The operating mode display shows the progress of the T1 test.

Message: *T1 test completed* is displayed for a moment after successful completion of the T1 test.

5.1.4 Important Items to be Considered Before and During the Treatment

Caution

Aseptic technique:
Use aseptic technique for all bloodside connections and all connections in the area where sterile solutions are to be used.

Caution

Preventing contamination:
Use tubing systems with hydrophobic filters at the pressure lines to prevent cross-contamination.
Connect the hydrophobic filters so that an ingress or loss of air is not possible and that any wetting by fluid is reliably avoided, also in case of pressure fluctuations.
If a hydrophobic filter has become wet, the tubing system must be replaced.

On tubing systems with additional connection sites, a replacement pressure line may be connected (accessory available from Fresenius Medical Care).

The blood in the pressure line must not be forced back by means of a syringe. This could damage the hydrophobic membrane and thus lead to a contamination.

If fluid may have passed the hydrophobic filter, the system must be checked for contamination after completion of the treatment. If the system is contaminated, it has to be taken out of service. All affected components have to be disinfected or replaced in accordance with the manufacturer's specifications before the system is put into operation again.

Caution

When inserting the tubing systems, the following precautions must be respected:

– The tubing systems have to be free of kinks, tension and twists and must not be jammed (risk of hemolysis). Use the line holders provided.
– Ensure the correct position of the screwed connections, especially of the connection sites to the patient, the dialyzer and the system and check or correct them during the treatment if necessary. Take the appropriate measures if required (e.g. retightening of the Luer Lock connection or replacement of the tubing system).
– Check the protective caps for tight fit and tighten them if necessary.
– The lines for the supply of infusions should always be clamped, except if they are needed.
– During long-term operation, the blood lines must be changed after 24 hours at the latest.
– Do not use cannulas with a diameter of > 20 gauge to pierce the septum of the injection sites. Insert the cannula vertically and in the center of the septum. Disinfect the injection sites with 70% alcohol before use.
– The blood pump must be set to the diameter of the pump segment, refer also to the product label of the blood lines. If a wrong line diameter is set, this may cause significant deviations in the blood flow and thus in the dialysis dose.
– Materials which come directly or indirectly into contact with blood are: Plasticized PVC, unplasticized PVC, polyethylene, polycarbonate, latex-free rubber, ABS.
– The minimum temperature of the tubing systems during use is 18 °C.

Caution

Delivery operation of the pump(s) with open doors (blood pump, substituate pump, optional Single-Needle pump):
When the doors are open and the rotor of the pump(s) is running, make sure that **no objects**, such as fingers, hair or ball point pens, come into contact with the rotor (risk of injury).

Arterial pressure measurement unit:
Prevent foreign objects from coming into contact with the arterial pressure measurement unit.

Heparin pump:
If heparin syringes of third party suppliers are used, the operator is responsible and has to ensure that the syringe data displayed match the actual data.
Heparin syringes without Luer lock are not recommended as the connection between the heparin syringe and the blood lines may come loose. If heparin syringes without Luer lock are used it is the operator's responsibility to ensure that the connection between the heparin syringe and the blood lines does not loosen inadvertently.

IV pole:
Securely fix bags or other objects to be hung from the IV pole.

Caution

Before the treatment, check:
- The safe connection of all connection sites of the tubing system.
- The tightness of the tubing system during and after priming.
- Retighten the connections and replace the tubing system, if necessary.
- The absence of air in the tubing system and the correct position of all fluid levels.

To be observed when working on the tubing system during the treatment:
If the position of the tubing system or of one of its components is changed, the correct position of the entire tubing system must be restored afterwards, above all the correct position of the line guides.

During the treatment check at appropriate intervals:
- The condition of the patient.
- The function of the hemodialysis system and the extracorporeal blood circuit. Pay particular attention to the venous insertion site, as a possible dislocation of the venous cannula may not always be detected by the pressure monitoring system.
- The tubing system for leakages or possible loosening of connections as well as entry of air.
- The fluid level in the venous bubble catcher. Correct it, if required (desired level: approx. 1 cm below the upper edge of the cover)

Caution

Venous alarm limit:
The lower venous alarm limit must be set as close as possible to the actual venous pressure value.

Note

The dialyzer holder is not suitable for rectangular plate dialyzers.

Note

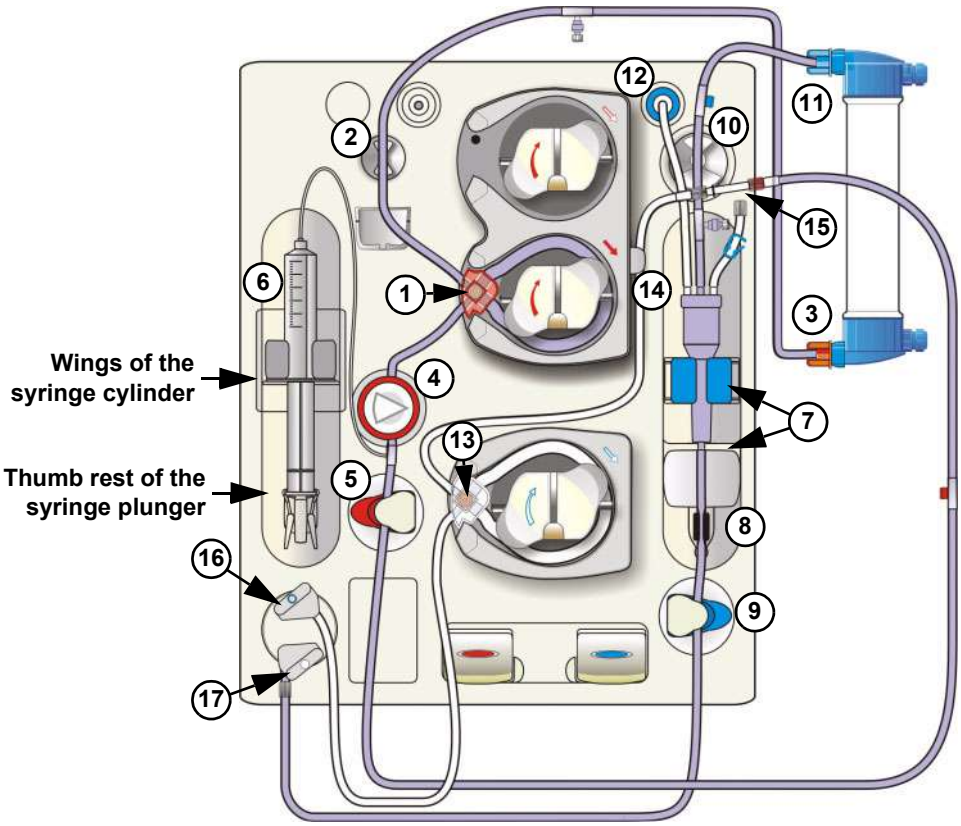
For hygienic reasons, the blood lines should be inserted immediately prior to the treatment only.

If the blood lines were inserted more than 8 hours before the treatment, malfunctions may occur. Correcting these malfunctions may require removing the present blood lines and inserting new blood lines.

5.1.5 Preparing the Extracorporeal Blood Circuit with ONLINE*plus*™

- **Inserting the arterial and the venous tubing system**

When inserting the tubing system, follow the description of the menu displayed.



Open the doors of the Extracorporeal Blood Module.

1 Insert the line guide into the blood pump until a signal is sounded. The arterial pressure measurement unit is opened. (After closing the doors the pump segment will be automatically inserted into the blood pump.)

2 Insert the arterial blood line into the line holder.

3 Connect the arterial blood line to the lower port of the dialyzer.

4 Insert the arterial pressure dome into the arterial pressure measurement unit.

5 Insert the arterial blood line into the arterial occlusion clamp.

Caution

If no heparin syringe is used, retighten the cap of the heparin line and close the clamp.

6 Connect the heparin syringe to the arterial tubing system.
To place the heparin syringe in the holder:
Press on the clamping brackets to move the grip handle to its lower position.
Place the heparin syringe between the barrel holders.
The syringe wings must be positioned between the barrel holders and the bracket.
The thumb rest of the syringe plunger now must be positioned between the clamps of the grip handle.
Press on the clamping brackets to move the grip handle to its starting position.

Caution

When inserting the heparin syringe, the following precautions must be respected:
– Only use heparin syringes with a volume of up and equal to 30 ml.
– Ensure that the heparin syringe is correctly inserted into the heparin pump and locked. Follow the description and the illustration.

7 Insert the venous bubble catcher into the level detector. Mind the locator for the venous bubble catcher.

8 Insert the venous line into the optical detector/air bubble detector.
The line must be positioned completely inside the line housing.

Caution

The following must be observed for the air bubble detector:
– No ultrasound-conducting objects and agents may be used.
– The line housing must be clean and dry.

9 Insert the venous blood line into the venous occlusion clamp.

10 Insert the venous blood line into the line holder.

11 Connect the venous blood line to the upper port of the dialyzer.

12 Connect the venous pressure line to the venous pressure connector.

Caution

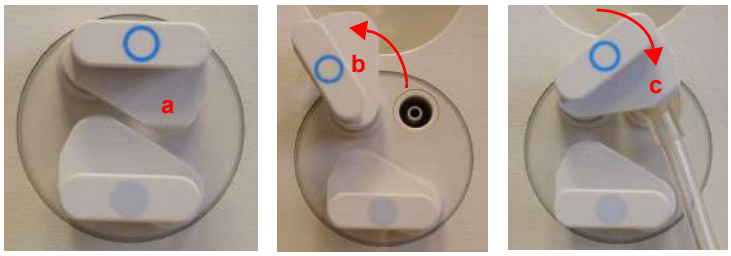
Tightly connect the hydrophobic filter of the venous pressure line to the venous pressure connector in order to avoid an ingress or loss of air.

Inserting the lines may be continued only after successful completion of the T1 test.

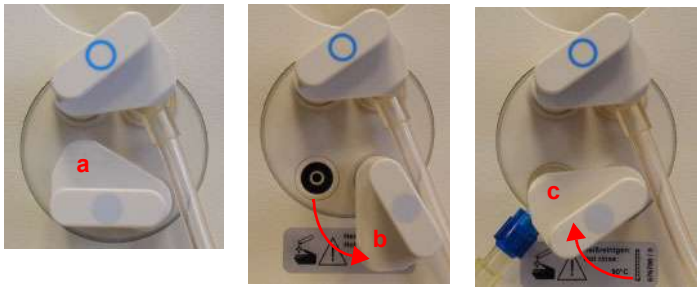
13 Insert the SafeLine™ line guide into the substituate pump until a signal is sounded.
(After closing the doors the SafeLine™ pump segment will be automatically inserted into the substituate pump.)

14 Insert the SafeLine™ into the line holder.

15 Connect the arterial patient access line to the SafeLine™.



16 To connect the substituate connector to the substituate port:
The catch for the substituate port (blue) is in initial position (a).
Pull and turn the substituate catch (blue) counterclockwise into position (b).
Push the substituate connector firmly into the substituate port.
Pull and turn the substituate catch (blue) clockwise until it clicks into place at position (c). If necessary to make sure of a tight closure push in the substituate catch (blue).



17 To insert the rinse connector (connected onto the venous patient line) into the rinse port:
The catch for the rinse port (grey) is in initial position (a).
Pull and turn the rinse port catch (grey) counterclockwise into position (b).
Push the rinse connector firmly into the rinse port.
Pull and turn the rinse port catch (grey) clockwise until it clicks into place at position (c). If necessary to make sure of a tight closure push in the rinse port catch (grey).

Close the doors.
(The line segment(s) are automatically inserted, the arterial pressure measurement unit closes.)

The system automatically switches to the PREPARATION SCREEN.

Message: *Connect dialyzer couplings!*

5.1.6 Connecting the Dialysate Lines

Note

The dialysate lines may only be connected after the T1 test has been completely terminated.

Message: *Connect dialyzer couplings!*

Open the shunt door.

Connect the dialysate supply line (dialyzer coupling red) to the dialyzer (on the side of the venous blood outlet port).

Connect the dialysate return line (dialyzer coupling blue) to the dialyzer (on the side of the arterial blood inlet port).

Close the shunt door.

5.1.7 Priming the Extracorporeal Blood Circuit with ONLINE*plus*™

- **Starting the Rinse procedure**

PREPARATION SCREEN

Check/set the rinse volume.
Check/set the delivery rate of the blood pump.

The rinse volume and the delivery rate are automatically set to the value preselected in the Operator Setup. Change the rinse volume and the delivery rate if necessary.

Touch the **Blood pump I/O** button. (**Blood pump I/O** indicator green.)

If not yet done, the parameters for dialysate, UF and the heparin pump now may be checked/set.

- **Interrupting the Rinse procedure**

PREPARATION SCREEN

Touch the **Blood pump I/O** button. (**Blood pump I/O** indicator grey.)

Message: *Do not connect patient! Minimum rinse volume not reached. – Rinse* **Continue**

Touch the **Continue** button to continue rinsing. (**Blood pump I/O** indicator green.)

- **Rinse procedure completed**

  Endless rinse will start when the Online rinse volume and the Online UF rinse volume have been reached.
  The delivery rate of the blood pump is automatically reduced to 50 ml/min, and the dialysate flow is reduced to EcoFlow (100 ml/min).
  In case of ONLINE*plus*™, the total flow is composed of EcoFlow (100 ml/min) and the respective substituate rate.

5.1.8 Checking/Setting the Dialysate Parameters

Note

Calcium carbonate precipitations may occur in the bicarbonate dialysis, depending on the use and the dose of the concentrates and the duration of the treatment. Detailed information will be provided by the manufacturer on request.

The Prescr. Bic can be reduced to 25.0 mmol/l during preparation (adjustable in the Technician's Setup). If the Bic reduction is selected, 25.0 mmol/l appears below the value Prescr. Bic. The Bic reduction is de-activated when the treatment starts.

After completion of the T1 test, the EcoFlow (100 ml/min) is automatically selected. The flow can be changed as desired.

On the PREPARATION SCREEN you can directly check, select and change the Prescr. Na and Prescr. Bic parameters.

In the **DIALYSATE MENU**

Check the dialysate parameters.
Set the desired parameters. Touch the **OK** button to confirm the values entered.
Visually check the confirmed values.

Touch the **PREPARATION** menu button to return to the PREPARATION SCREEN.

5.1.9 Checking/Setting the UF Parameters

On the PREPARATION SCREEN you can directly check, select and change the UF goal, UF time and UF rate parameters.

Note

If only the UF rate is entered for ultrafiltration (instead of volume and time), check the UF rate displayed in the Dialysis menu for plausibility after saving the data.

In the **UF MENU**

Possible setting variants:
– UF goal/UF time (UF rate is calculated)
– UF goal/UF rate (UF time is calculated)
– UF rate/UF time
– UF rate
– Time
– UF profiles
– ISO goal/ISO time (ISO rate is calculated)
– ISO goal/ISO rate (ISO time is calculated)

The following must be observed in case of ISO-UF:

The ISO-UF treatment type can be started at any time and can be repeated as often as necessary.
The parameters entered at the beginning of the treatment (UF goal and UF time) must be taken into consideration.

In case of a combination with UF and Na profiles, first enter the ISO UF parameters. Then set the respective profiles.

The total volume to be removed (UF goal), the total treatment time (UF time) or the UF goal and the UF rate must always be programmed. The ISO data goal and time cannot be higher than the UF goal/time.

The UF goal/UF time or UF goal/UF rate parameters must first be entered.

Set the desired parameters.
Touch the **OK** button to confirm the entered values.
Visually check the confirmed values.

Touch the **PREPARATION** menu button to return to the PREPARATION SCREEN.

5.1.10 Checking/Setting the Sodium and UF Profiles

Caution

When using Na profiles, the following precautions must be observed: The balancing neutrality of the profiles was computed for a dialysis dose of KT/V = 1.2. In case of higher deviations (KT/V > 1.4; KT/V < 1.0) the balancing neutrality may not always be achieved.

Basic requirements for setting the profiles:
the UF parameters must have been set.

- **Na profiles**

In the **DIALYSATE MENU**

Check the dialysate parameters.
Minimum value that can be set for Start Na: 3 mmol higher than the prescribed Na

Set the desired profile.

Check/set Start Na (maximum value).
(The minimum Na value is automatically adjusted.)

The following must be observed:
– The treatment may also be started with the Na profile only.
– It is only possible to select matching profile groups.
  (E.g. if UF profile 1 has been selected, only Na profile 1 is available.)
– After having started the profiles, it is no longer possible to alter the Concentrate, Prescr. Na and Prescr. Bic parameters.
– The minimum UF time must be set:
  Profiles 1, 2: UF time 2:00 hrs
  Profile 3: UF time 3:30 hrs

Set the desired parameters.
Touch the **OK** button to confirm the entered values.
Visually check the confirmed values.

Touch the **PREPARATION** menu button to return to the PREPARATION SCREEN.

- **UF profiles**

In the **UF MENU**

Check the UF parameters.
Minimum UF parameters that can be set:
Profiles 1, 2: UF goal 200 ml, UF time 2:00 hrs, UF rate 10 ml
Profile 3: UF goal 200 ml, UF time 3:30 hrs, UF rate 10 ml

Set the desired profile.

Check/set the start rate.
(The minimum profile rate is automatically adjusted.)

The following must be observed:
– The treatment may also be started with the UF profile only.
– It is only possible to select matching profile groups.
  (E.g. if Na profile 1 has been selected, only UF profile 1 is available.)
– After having started the profiles, it is no longer possible to alter the UF time and UF rate parameters.
– ISO UF parameters and Na parameters may be selected only before starting or after ending a profile.

Set the desired parameters.
Touch the **OK** button to confirm the entered values.
Visually check the confirmed values.

Touch the **PREPARATION** menu button to return to the PREPARATION SCREEN.

5.1.11 Checking/Setting the Heparin Pump Parameters

Caution

Administer the heparin dose according to the physician's instructions.

In the **HEPARIN** menu

Check the heparin pump parameters.
Set the desired parameters. Touch the **OK** button to confirm the values entered.
Visually check the confirmed values.

Touch the **PREPARATION** menu button to return to the PREPARATION SCREEN.

5.2 Preparation with Rinse Solution Bag

If the 5008 ONLINE*plus*™ hemodialysis system cannot be operated without rinse solution bags, rinse or infusion solutions provided in NaCl bags may be used instead.

5.2.1 Turning the Hemodialysis System On

Caution

The stability of the 5008 hemodialysis system must be ensured.

Establish the water and power supply.

Press the **On/Off** key. (Turn the hemodialysis system on!)
The **On/Off** LED is illuminated.

START-UP SCREEN

The display shows the machine type, the current software version and the clinical data (on request) for approx. 15 seconds.

Caution

After a downtime of more than 72 hours, a cleaning program must be performed completely before starting the treatment.

If necessary, check the hemodialysis system for presence of residual disinfectant. (see chapter 8 Cleaning).

Note

If the message: *Defective battery* is acknowledged by pressing the **Skip** key, it might be that the audible alarm will not be generated, if a power failure occurs.

5.2.2 The Following Must be Observed when Using Consumables

Caution

The system has been approved for use with the consumables and accessories listed in the Operating Instructions.

Should the responsible organization wish to use other consumables and accessories than those listed in the Operating Instructions, the responsibility to ensure the correct function of the system lies exclusively with the responsible organization. The applicable legal regulations must be complied with (e.g. in Germany the Medical Device Directive, MDD and the MPBetreibV = German regulation for the operation of medical products).

The manufacturer does not assume any responsibility or liability for personal injury or other damage and excludes any warranty for damage to the system resulting from the use of non-approved or unsuitable consumables or accessories.

Caution

The symbols printed on the packaging of the consumables have to be observed. The symbols are described in the chapter System Description (consumables symbols).

When using consumables, it is important to take note of the following symbols:

Do not reuse

Use by

Caution

The consumables may only be used if the packaging and the respective consumable including the protective caps used are not damaged. The protective caps must not have fallen off.

The plastics used for the consumables may not be compatible with components of drugs or disinfectants. If they are planned to be used, the compatibility of the consumables' components must be ensured before the treatment. If connectors made of polycarbonate are for example exposed to aqueous solutions with the pH value > 10 or to aliphatic solutions this will cause tension cracks.

5.2.3 Selecting the Concentrate Supply

● **Connecting the concentrates**

Caution

Concentrate:
The concentrate displayed on the screen must comply with the specifications mentioned on the acid or the acetate container or on the bag. This also applies to the concentrate composition in CDS operation.

Concentrate packages:
– Assure that the packages used contain sufficient concentrate to complete the treatment.
– Use only the dedicated coded containers or the bi*b*ag® for bicarbonate dialysis.

Bicarbonate dry concentrate bi*b*ag®:
Only the bi*b*ag® manufactured by Fresenius Medical Care may be used.

The bi*b*ag® must only be used for one treatment.

Only use the bi*b*ag® in combination with acid bicarbonate hemodialysis concentrate according to the prescribed dilution. Other mixing ratios may lead to a hazard for the patient.

Acid and basic bicarbonate hemodialysis concentrate have to be diluted immediately prior to application only. The bag's content must be used up within 12 hours after dilution. Discard residual volumes. The powder is non-pyrogenic.

Conductivity limits:
The alarm limits are automatically set around the expected value. The actual value of the conductivity display must have attained the expected desired value after a maximum of 10 minutes.
Should this not be the case, the actual value must first be checked in the laboratory. Change or check the concentrate, if necessary, or call service.

Note

The bicarbonate suction tube must be inserted into the rinse chamber during the bi*b*ag® treatment.

Extract the concentrate rack.

Bicarbonate dialysis

To connect the (acid) concentrate container:
Push the latch (1) upwards. Open the concentrate flap. Place the red concentrate suction tube (2) into the acid container. Close the concentrate flap (3) until it clicks into place.

To connect the bi*b*ag®:
Push the latch (1) upwards. Open the bicarbonate flap. Remove the bi*b*ag® from its packaging. Remove the foil from the bi*b*ag®. Attach the bi*b*ag® (2). Close the bicarbonate flap (3) until it clicks into place.
OR
To connect the bicarbonate container:
Insert the bicarbonate suction tube (blue) into the bicarbonate container.
Close the bicarbonate flap.

CDS, Central Delivery System (option)

Note

The responsible organization is responsible for the proper installation and function of the CDS.

Acetate dialysis

Connect the concentrate container.
Insert the concentrate suction tube (red) into the acetate container.
The bicarbonate suction tube (blue) remains in the rinse chamber.

Selecting a treatment

SELECTION SCREEN

Touch the **Treatment** field.

If there is no tubing system inserted, the system automatically moves to the BLOOD SYSTEM screen.

BLOOD SYSTEM SCREEN

The T1 test is now running in parallel with the preparation of the hemodialysis system. The color of the header bar is orange for the duration of the T1 test.
The operating mode display shows the progress of the T1 test.

Message: *T1 test completed* is displayed for a moment after successful completion of the T1 test.

5.2.4 Important Items to be Considered Before and During the Treatment

Caution

Aseptic technique:
Use aseptic technique for all bloodside connections and all connections in the area where sterile solutions are to be used.

Caution

Preventing contamination:
Use tubing systems with hydrophobic filters at the pressure lines to prevent cross-contamination.
Connect the hydrophobic filters so that an ingress or loss of air is not possible and that any wetting by fluid is reliably avoided, also in case of pressure fluctuations.
If a hydrophobic filter has become wet, the tubing system must be replaced.

On tubing systems with additional connection sites, a replacement pressure line may be connected (accessory available from Fresenius Medical Care).

The blood in the pressure line must not be forced back by means of a syringe. This could damage the hydrophobic membrane and thus lead to a contamination.

If fluid may have passed the hydrophobic filter, the system must be checked for contamination after completion of the treatment. If the system is contaminated, it has to be taken out of service. All affected components have to be disinfected or replaced in accordance with the manufacturer's specifications before the system is put into operation again.

Caution

When inserting the tubing systems, the following precautions must be respected:

– The tubing systems have to be free of kinks, tension and twists and must not be jammed (risk of hemolysis). Use the line holders provided.
– Ensure the correct position of the screwed connections, especially of the connection sites to the patient, the dialyzer and the system and check or correct them during the treatment if necessary. Take the appropriate measures if required (e.g. retightening of the Luer Lock connection or replacement of the tubing system).
– Check the protective caps for tight fit and tighten them if necessary.
– The lines for the supply of infusions should always be clamped, except if they are needed.
– During long-term operation, the blood lines must be changed after 24 hours at the latest.
– Do not use cannulas with a diameter of > 20 gauge to pierce the septum of the injection sites. Insert the cannula vertically and in the center of the septum. Disinfect the injection sites with 70% alcohol before use.
– The blood pump must be set to the diameter of the pump segment, refer also to the product label of the blood lines. If a wrong line diameter is set, this may cause significant deviations in the blood flow and thus in the dialysis dose.
– Materials which come directly or indirectly into contact with blood are: Plasticized PVC, unplasticized PVC, polyethylene, polycarbonate, latex-free rubber, ABS.
– The minimum temperature of the tubing systems during use is 18 °C.

Caution

Delivery operation of the pump(s) with open doors (blood pump, substituate pump, optional Single-Needle pump):
When the doors are open and the rotor of the pump(s) is running, make sure that **no objects**, such as fingers, hair or ball point pens, come into contact with the rotor (risk of injury).

Arterial pressure measurement unit:
Prevent foreign objects from coming into contact with the arterial pressure measurement unit.

Heparin pump:
If heparin syringes of third party suppliers are used, the operator is responsible and has to ensure that the syringe data displayed match the actual data.
Heparin syringes without Luer lock are not recommended as the connection between the heparin syringe and the blood lines may come loose. If heparin syringes without Luer lock are used it is the operator's responsibility to ensure that the connection between the heparin syringe and the blood lines does not loosen inadvertently.

IV pole:
Securely fix bags or other objects to be hung from the IV pole.

Caution

Before the treatment, check:
- The safe connection of all connection sites of the tubing system.
- The tightness of the tubing system during and after priming.
- Retighten the connections and replace the tubing system, if necessary.
- The absence of air in the tubing system and the correct position of all fluid levels.

To be observed when working on the tubing system during the treatment:
If the position of the tubing system or of one of its components is changed, the correct position of the entire tubing system must be restored afterwards, above all the correct position of the line guides.

During the treatment check at appropriate intervals:
- The condition of the patient.
- The function of the hemodialysis system and the extracorporeal blood circuit. Pay particular attention to the venous insertion site, as a possible dislocation of the venous cannula may not always be detected by the pressure monitoring system.
- The tubing system for leakages or possible loosening of connections as well as entry of air.
- The fluid level in the venous bubble catcher. Correct it, if required (desired level: approx. 1 cm below the upper edge of the cover)

Caution

Venous alarm limit:
The lower venous alarm limit must be set as close as possible to the actual venous pressure value.

Note

The dialyzer holder is not suitable for rectangular plate dialyzers.

Note

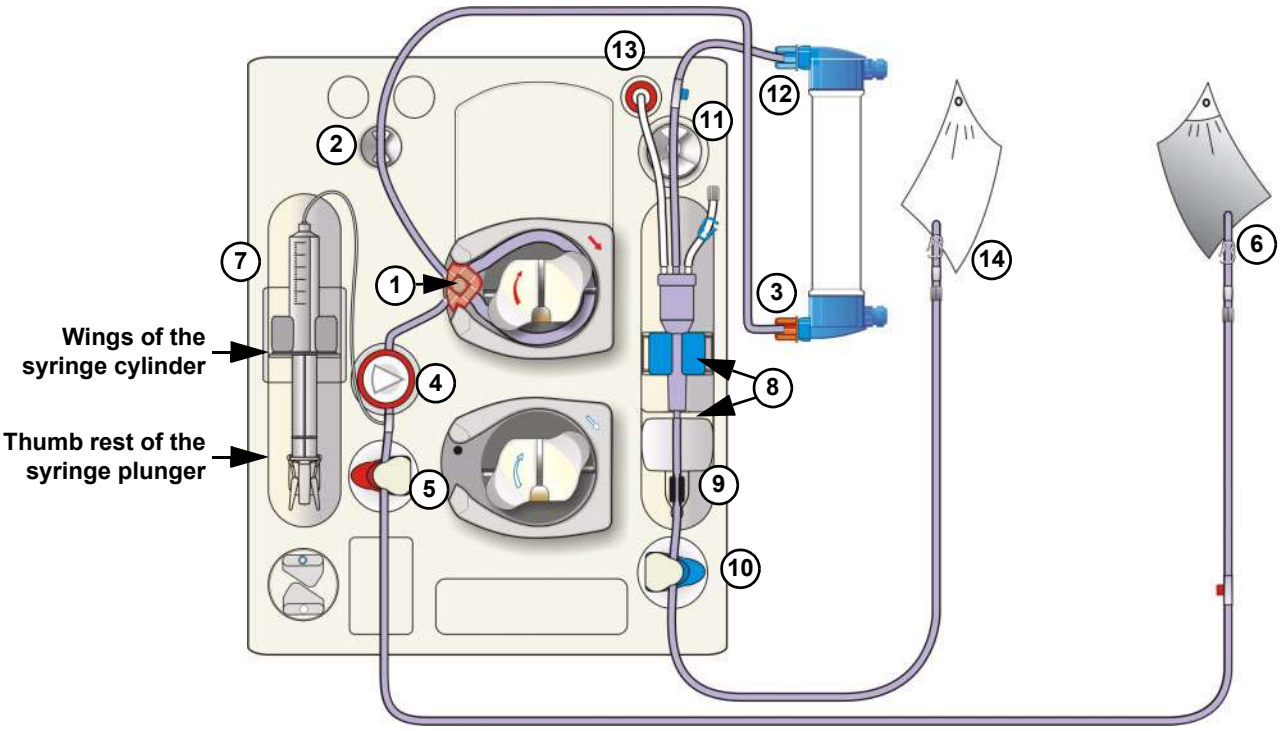
For hygienic reasons, the blood lines should be inserted immediately prior to the treatment only.

If the blood lines were inserted more than 8 hours before the treatment, malfunctions may occur. Correcting these malfunctions may require removing the present blood lines and inserting new blood lines.

5.2.5 Preparing the Extracorporeal Blood Circuit with Rinse Solution Bag

- **Inserting the arterial and the venous tubing system**

When inserting the tubing system, follow the description of the menu displayed.



Open the doors of the Extracorporeal Blood Module.

1 Insert the line guide into the blood pump until a signal is sounded. The arterial pressure measurement unit is opened. (After closing the doors the pump segment will be automatically inserted into the blood pump.)

2 Insert the arterial blood line into the line holder.

3 Connect the arterial blood line to the lower port of the dialyzer.

4 Insert the arterial pressure dome into the arterial pressure measurement unit.

5 Insert the arterial blood line into the arterial occlusion clamp.

6 Connect the arterial patient connection of the tubing system to the rinse solution bag.

Caution

If no heparin syringe is used, retighten the cap of the heparin line and close the clamp.

7 Connect the heparin syringe to the arterial tubing system.
To place the heparin syringe in the holder:
Press on the clamping brackets to move the grip handle to its lower position.
Place the heparin syringe between the barrel holders.
The syringe wings must be positioned between the barrel holders and the bracket.
The thumb rest of the syringe plunger now must be positioned between the clamps of the grip handle.
Press on the clamping brackets to move the grip handle to its starting position.

Caution

When inserting the heparin syringe, the following precautions must be respected:
– Only use heparin syringes with a volume of up and equal to 30 ml.
– Ensure that the heparin syringe is correctly inserted into the heparin pump and locked. Follow the description and the illustration.

8 Insert the venous bubble catcher into the level detector. Mind the locator for the venous bubble catcher.

9 Insert the venous line into the optical detector/air bubble detector. The line must be positioned completely inside the line housing.

Caution

The following must be observed for the air bubble detector:
– No ultrasound-conducting objects and agents may be used.
– The line housing must be clean and dry.

10 Insert the venous blood line into the venous occlusion clamp.

11 Insert the venous blood line into the line holder.

12 Connect the venous blood line to the upper port of the dialyzer.

13 Connect the venous pressure line to the venous pressure connector.

Caution

Tightly connect the hydrophobic filter of the venous pressure line to the venous pressure connector in order to avoid an ingress or loss of air.

14 Connect the venous patient connection of the tubing system to the prime collection bag. (Prime collection bag not included in scope of delivery of the tubing system.)

Close the doors.
(The line segment(s) are automatically inserted, the arterial pressure measurement unit closes.)

Break the cone on the rinse solution bag.

The system automatically switches to the PREPARATION SCREEN.

Message: *Connect dialyzer couplings!*

5.2.6 Connecting the Dialysate Lines

Note

The dialysate lines may only be connected after the T1 test has been completely terminated.

Message: *Connect dialyzer couplings!*

Open the shunt door.

Connect the dialysate supply line (dialyzer coupling red) to the dialyzer (on the side of the venous blood outlet port).

Connect the dialysate return line (dialyzer coupling blue) to the dialyzer (on the side of the arterial blood inlet port).

Close the shunt door.

5.2.7 Priming the Extracorporeal Blood Circuit with Rinse Solution Bag

- **Starting the Rinse procedure**

PREPARATION SCREEN

Check/set the rinse volume.
Check/set the delivery rate of the blood pump.

The rinse volume and the delivery rate are automatically set to the value preselected in the Operator Setup. Change the rinse volume and the delivery rate if necessary.

Touch the **Blood pump I/O** button. (**Blood pump I/O** indicator green.)

If not yet done, the parameters for dialysate, UF and the heparin pump now may be checked/set.

- **Interrupting the Rinse procedure**

PREPARATION SCREEN

Touch the **Blood pump I/O** button. (**Blood pump I/O** indicator grey.)

Message: *Do not connect patient! Minimum rinse volume not reached. – Rinse* **Continue**

Do not connect a patient if rinsing is interrupted during the T1 test or during a cleaning program.

Touch the **Blood pump I/O** button to continue the Rinse procedure. (**Blood pump I/O** indicator green.)

- **Rinse procedure completed**

Message: *Rinse volume reached.* – *Rinse* **Continue** – *Circulation* **Start** **Mute** LED is flashing. Audible signal
Connect the venous tubing system to the rinse solution bag.
Touch the **Start** button to launch precirculation. (**Blood pump I/O** indicator green.)

- **Interrupting the Circulation procedure**

PREPARATION SCREEN

Touch the **Blood pump I/O** button. (**Blood pump I/O** indicator grey.)

If T1 test active:
Message: *CAUTION! T1 test still in progress! Patient cannot be connected!*

Touch the **Blood pump I/O** button to continue the circulation procedure. (**Blood pump I/O** indicator green.)

5.2.8 Checking/Setting the Dialysate Parameters

Note

Calcium carbonate precipitations may occur in the bicarbonate dialysis, depending on the use and the dose of the concentrates and the duration of the treatment. Detailed information will be provided by the manufacturer on request.

The Prescr. Bic can be reduced to 25.0 mmol/l during preparation (adjustable in the Technician's Setup). If the Bic reduction is selected, 25.0 mmol/l appears below the value Prescr. Bic. The Bic reduction is de-activated when the treatment starts.

After completion of the T1 test, the EcoFlow (100 ml/min) is automatically selected. The flow can be changed as desired.

On the PREPARATION SCREEN you can directly check, select and change the Prescr. Na and Prescr. Bic parameters.

In the **DIALYSATE MENU**

Check the dialysate parameters.
Set the desired parameters. Touch the **OK** button to confirm the values entered.
Visually check the confirmed values.

Touch the **PREPARATION** menu button to return to the PREPARATION SCREEN.

5.2.9 Checking/Setting the UF Parameters

On the PREPARATION SCREEN you can directly check, select and change the UF goal, UF time and UF rate parameters.

Note

If only the UF rate is entered for ultrafiltration (instead of volume and time), check the UF rate displayed in the Dialysis menu for plausibility after saving the data.

In the **UF MENU**

Possible setting variants:
– UF goal/UF time (UF rate is calculated)
– UF goal/UF rate (UF time is calculated)
– UF rate/UF time
– UF rate
– Time
– UF profiles
– ISO goal/ISO time (ISO rate is calculated)
– ISO goal/ISO rate (ISO time is calculated)

The following must be observed in case of ISO-UF:

The ISO-UF treatment type can be started at any time and can be repeated as often as necessary.
The parameters entered at the beginning of the treatment (UF goal and UF time) must be taken into consideration.

In case of a combination with UF and Na profiles, first enter the ISO UF parameters. Then set the respective profiles.

The total volume to be removed (UF goal), the total treatment time (UF time) or the UF goal and the UF rate must always be programmed. The ISO data goal and time cannot be higher than the UF goal/time.

The UF goal/UF time or UF goal/UF rate parameters must first be entered.

Set the desired parameters.
Touch the **OK** button to confirm the entered values.
Visually check the confirmed values.

Touch the **PREPARATION** menu button to return to the PREPARATION SCREEN.

5.2.10 Checking/Setting the Sodium and UF Profiles

Caution

When using Na profiles, the following precautions must be observed:
The balancing neutrality of the profiles was computed for a dialysis dose of KT/V = 1.2. In case of higher deviations (KT/V > 1.4; KT/V < 1.0) the balancing neutrality may not always be achieved.

Basic requirements for setting the profiles:
the UF parameters must have been set.

- **Na profiles**

In the **DIALYSATE MENU**

Check the dialysate parameters.
Minimum value that can be set for Start Na: 3 mmol higher than the prescribed Na

Set the desired profile.

Check/set Start Na (maximum value).
(The minimum Na value is automatically adjusted.)

The following must be observed:
– The treatment may also be started with the Na profile only.
– It is only possible to select matching profile groups.
(E.g. if UF profile 1 has been selected, only Na profile 1 is available.)
– After having started the profiles, it is no longer possible to alter the Concentrate, Prescr. Na and Prescr. Bic parameters.
– The minimum UF time must be set:
Profiles 1, 2: UF time 2:00 hrs
Profile 3: UF time 3:30 hrs

Set the desired parameters.
Touch the **OK** button to confirm the entered values.
Visually check the confirmed values.

Touch the **PREPARATION** menu button to return to the PREPARATION SCREEN.

- **UF profiles**

In the **UF MENU**

Check the UF parameters.
Minimum UF parameters that can be set:
Profiles 1, 2: UF goal 200 ml, UF time 2:00 hrs, UF rate 10 ml
Profile 3: UF goal 200 ml, UF time 3:30 hrs, UF rate 10 ml

Set the desired profile.

Check/set the start rate.
(The minimum profile rate is automatically adjusted.)

The following must be observed:
– The treatment may also be started with the UF profile only.
– It is only possible to select matching profile groups.
(E.g. if Na profile 1 has been selected, only UF profile 1 is available.)
– After having started the profiles, it is no longer possible to alter the UF time and UF rate parameters.
– ISO UF parameters and Na parameters may be selected only before starting or after ending a profile.

Set the desired parameters.
Touch the **OK** button to confirm the entered values.
Visually check the confirmed values.

Touch the **PREPARATION** menu button to return to the PREPARATION SCREEN.

5.2.11 Checking/Setting the Heparin Pump Parameters

Caution

Administer the heparin dose according to the physician's instructions.

In the **HEPARIN** menu

Check the heparin pump parameters.
Set the desired parameters. Touch the **OK** button to confirm the values entered.
Visually check the confirmed values.

Touch the **PREPARATION** menu button to return to the PREPARATION SCREEN.

5.3 Single-Needle (Option) Preparation Using ONLINE*plus*™

Irrespective of the treatment mode, all 5008 ONLINE*plus*™ hemodialysis systems can be operated without rinse or infusion solutions provided in NaCl bags. The fluid volumes required for preparation, bolus administration or during reinfusion will then be produced ONLINE by the 5008 hemodialysis system according to the actual requirements, thus saving both cost and time.

5.3.1 Turning the Hemodialysis System On

Caution

The stability of the 5008 hemodialysis system must be ensured.

Establish the water and power supply.

Press the **On/Off** key. (Turn the hemodialysis system on!)
The **On/Off** LED is illuminated.

START-UP SCREEN

The display shows the machine type, the current software version and the clinical data (on request) for approx. 15 seconds.

Caution

After a downtime of more than 72 hours, a cleaning program must be performed completely before starting the treatment.

If necessary, check the hemodialysis system for presence of residual disinfectant. (see chapter 8 Cleaning).

Note

If the message: *Defective battery* is acknowledged by pressing the **Skip** key, it might be that the audible alarm will not be generated, if a power failure occurs.

5.3.2 The Following Must be Observed when Using Consumables

Caution

The system has been approved for use with the consumables and accessories listed in the Operating Instructions.

Should the responsible organization wish to use other consumables and accessories than those listed in the Operating Instructions, the responsibility to ensure the correct function of the system lies exclusively with the responsible organization. The applicable legal regulations must be complied with (e.g. in Germany the Medical Device Directive, MDD and the MPBetreibV = German regulation for the operation of medical products).

The manufacturer does not assume any responsibility or liability for personal injury or other damage and excludes any warranty for damage to the system resulting from the use of non-approved or unsuitable consumables or accessories.

Caution

The symbols printed on the packaging of the consumables have to be observed. The symbols are described in the chapter System Description (consumables symbols).

When using consumables, it is important to take note of the following symbols:

Do not reuse

Use by

Caution

The consumables may only be used if the packaging and the respective consumable including the protective caps used are not damaged. The protective caps must not have fallen off.

The plastics used for the consumables may not be compatible with components of drugs or disinfectants. If they are planned to be used, the compatibility of the consumables' components must be ensured before the treatment. If connectors made of polycarbonate are for example exposed to aqueous solutions with the pH value > 10 or to aliphatic solutions this will cause tension cracks.

5.3.3 Selecting the Concentrate Supply

● **Connecting the concentrates**

Caution

Concentrate:
The concentrate displayed on the screen must comply with the specifications mentioned on the acid or the acetate container or on the bag. This also applies to the concentrate composition in CDS operation.

Concentrate packages:
– Assure that the packages used contain sufficient concentrate to complete the treatment.
– Use only the dedicated coded containers or the bi*b*ag® for bicarbonate dialysis.

Bicarbonate dry concentrate bi*b*ag®:
Only the bi*b*ag® manufactured by Fresenius Medical Care may be used.

The bi*b*ag® must only be used for one treatment.

Only use the bi*b*ag® in combination with acid bicarbonate hemodialysis concentrate according to the prescribed dilution. Other mixing ratios may lead to a hazard for the patient.

Acid and basic bicarbonate hemodialysis concentrate have to be diluted immediately prior to application only. The bag's content must be used up within 12 hours after dilution. Discard residual volumes. The powder is non-pyrogenic.

Conductivity limits:
The alarm limits are automatically set around the expected value. The actual value of the conductivity display must have attained the expected desired value after a maximum of 10 minutes.
Should this not be the case, the actual value must first be checked in the laboratory. Change or check the concentrate, if necessary, or call service.

Note

The bicarbonate suction tube must be inserted into the rinse chamber during the bi*b*ag® treatment.

Extract the concentrate rack.

Bicarbonate dialysis

To connect the (acid) concentrate container:
Push the latch (1) upwards. Open the concentrate flap. Place the red concentrate suction tube (2) into the acid container. Close the concentrate flap (3) until it clicks into place.

To connect the bi*b*ag®:
Push the latch (1) upwards. Open the bicarbonate flap. Remove the bi*b*ag® from its packaging. Remove the foil from the bi*b*ag®. Attach the bi*b*ag® (2). Close the bicarbonate flap (3) until it clicks into place.
OR
To connect the bicarbonate container:
Insert the bicarbonate suction tube (blue) into the bicarbonate container.
Close the bicarbonate flap.

CDS, Central Delivery System (option)

Note

The responsible organization is responsible for the proper installation and function of the CDS.

Acetate dialysis

Connect the concentrate container.
Insert the concentrate suction tube (red) into the acetate container.
The bicarbonate suction tube (blue) remains in the rinse chamber.

Selecting a treatment

SELECTION SCREEN

Touch the **Treatment** field.

If there is no tubing system inserted, the system automatically moves to the BLOOD SYSTEM screen.

BLOOD SYSTEM SCREEN

The T1 test is now running in parallel with the preparation of the hemodialysis system. The color of the header bar is orange for the duration of the T1 test.
The operating mode display shows the progress of the T1 test.

Message: *T1 test completed* is displayed for a moment after successful completion of the T1 test.

5.3.4 Important Items to be Considered Before and During the Treatment

Caution

Aseptic technique:
Use aseptic technique for all bloodside connections and all connections in the area where sterile solutions are to be used.

Caution

Preventing contamination:
Use tubing systems with hydrophobic filters at the pressure lines to prevent cross-contamination.
Connect the hydrophobic filters so that an ingress or loss of air is not possible and that any wetting by fluid is reliably avoided, also in case of pressure fluctuations.
If a hydrophobic filter has become wet, the tubing system must be replaced.

On tubing systems with additional connection sites, a replacement pressure line may be connected (accessory available from Fresenius Medical Care).

The blood in the pressure line must not be forced back by means of a syringe. This could damage the hydrophobic membrane and thus lead to a contamination.

If fluid may have passed the hydrophobic filter, the system must be checked for contamination after completion of the treatment. If the system is contaminated, it has to be taken out of service. All affected components have to be disinfected or replaced in accordance with the manufacturer's specifications before the system is put into operation again.

Caution

When inserting the tubing systems, the following precautions must be respected:

– The tubing systems have to be free of kinks, tension and twists and must not be jammed (risk of hemolysis). Use the line holders provided.
– Ensure the correct position of the screwed connections, especially of the connection sites to the patient, the dialyzer and the system and check or correct them during the treatment if necessary. Take the appropriate measures if required (e.g. retightening of the Luer Lock connection or replacement of the tubing system).
– Check the protective caps for tight fit and tighten them if necessary.
– The lines for the supply of infusions should always be clamped, except if they are needed.
– During long-term operation, the blood lines must be changed after 24 hours at the latest.
– Do not use cannulas with a diameter of > 20 gauge to pierce the septum of the injection sites. Insert the cannula vertically and in the center of the septum. Disinfect the injection sites with 70% alcohol before use.
– The blood pump must be set to the diameter of the pump segment, refer also to the product label of the blood lines. If a wrong line diameter is set, this may cause significant deviations in the blood flow and thus in the dialysis dose.
– Materials which come directly or indirectly into contact with blood are: Plasticized PVC, unplasticized PVC, polyethylene, polycarbonate, latex-free rubber, ABS.
– The minimum temperature of the tubing systems during use is 18 °C.

Caution

Delivery operation of the pump(s) with open doors (blood pump, substituate pump, optional Single-Needle pump):
When the doors are open and the rotor of the pump(s) is running, make sure that **no objects**, such as fingers, hair or ball point pens, come into contact with the rotor (risk of injury).

Arterial pressure measurement unit:
Prevent foreign objects from coming into contact with the arterial pressure measurement unit.

Heparin pump:
If heparin syringes of third party suppliers are used, the operator is responsible and has to ensure that the syringe data displayed match the actual data.
Heparin syringes without Luer lock are not recommended as the connection between the heparin syringe and the blood lines may come loose. If heparin syringes without Luer lock are used it is the operator's responsibility to ensure that the connection between the heparin syringe and the blood lines does not loosen inadvertently.

IV pole:
Securely fix bags or other objects to be hung from the IV pole.

Caution

Before the treatment, check:
- The safe connection of all connection sites of the tubing system.
- The tightness of the tubing system during and after priming.
- Retighten the connections and replace the tubing system, if necessary.
- The absence of air in the tubing system and the correct position of all fluid levels.

To be observed when working on the tubing system during the treatment:
If the position of the tubing system or of one of its components is changed, the correct position of the entire tubing system must be restored afterwards, above all the correct position of the line guides.

During the treatment check at appropriate intervals:
- The condition of the patient.
- The function of the hemodialysis system and the extracorporeal blood circuit. Pay particular attention to the venous insertion site, as a possible dislocation of the venous cannula may not always be detected by the pressure monitoring system.
- The tubing system for leakages or possible loosening of connections as well as entry of air.
- The fluid level in the venous bubble catcher. Correct it, if required (desired level: approx. 1 cm below the upper edge of the cover)

Caution

Venous alarm limit:
The lower venous alarm limit must be set as close as possible to the actual venous pressure value.

Note

The dialyzer holder is not suitable for rectangular plate dialyzers.

Note

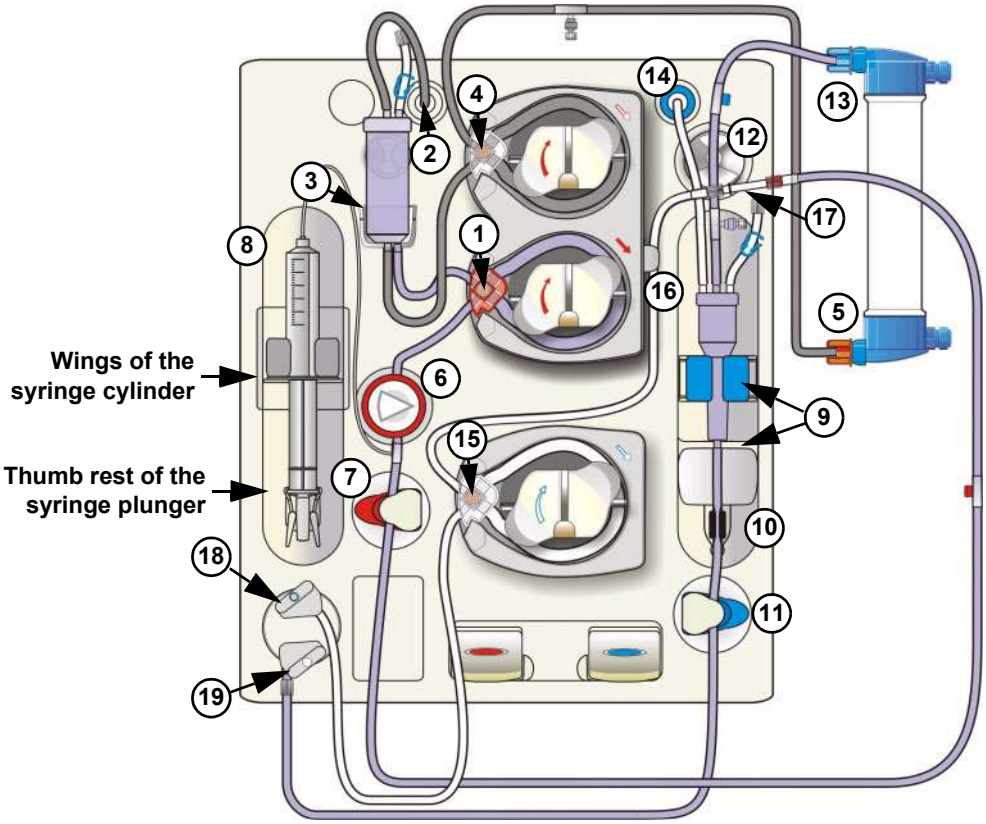
For hygienic reasons, the blood lines should be inserted immediately prior to the treatment only.

If the blood lines were inserted more than 8 hours before the treatment, malfunctions may occur. Correcting these malfunctions may require removing the present blood lines and inserting new blood lines.

5.3.5 Preparing the Extracorporeal Blood Circuit with ONLINE*plus*™

- **Inserting the arterial and the venous tubing system**

When inserting the tubing system, follow the description of the menu displayed.



Open the doors of the Extracorporeal Blood Module.

1 Insert the line guide into the blood pump until a signal is sounded. The arterial pressure measurement unit is opened. (After closing the doors the pump segment will be automatically inserted into the blood pump.)

2 Connect the SN pressure line to the Single-Needle pressure port.

3 Insert the SN chamber in its holder.

4 Insert the SN line guide into the Single-Needle pump until a signal is sounded. (After closing the doors the SN pump segment is automatically inserted in the Single-Needle pump, if the level detector detected fluid.)

5 Connect the arterial blood line to the lower port of the dialyzer.

6 Insert the arterial pressure dome into the arterial pressure measurement unit.

7 Insert the arterial blood line into the arterial occlusion clamp.

Caution

If no heparin syringe is used, retighten the cap of the heparin line and close the clamp.

8 Connect the heparin syringe to the arterial tubing system.
To place the heparin syringe in the holder:
Press on the clamping brackets to move the grip handle to its lower position.
Place the heparin syringe between the barrel holders.
The syringe wings must be positioned between the barrel holders and the bracket.
The thumb rest of the syringe plunger now must be positioned between the clamps of the grip handle.
Press on the clamping brackets to move the grip handle to its starting position.

Caution

When inserting the heparin syringe, the following precautions must be respected:
– Only use heparin syringes with a volume of up and equal to 30 ml.
– Ensure that the heparin syringe is correctly inserted into the heparin pump and locked. Follow the description and the illustration.

9 Insert the venous bubble catcher into the level detector. Mind the locator for the venous bubble catcher.

10 Insert the venous line into the optical detector/air bubble detector.
The line must be positioned completely inside the line housing.

Caution

The following must be observed for the air bubble detector:
– No ultrasound-conducting objects and agents may be used.
– The line housing must be clean and dry.

11 Insert the venous blood line into the venous occlusion clamp.

12 Insert the venous blood line into the line holder.

13 Connect the venous blood line to the upper port of the dialyzer.

14 Connect the venous pressure line to the venous pressure connector.

Caution

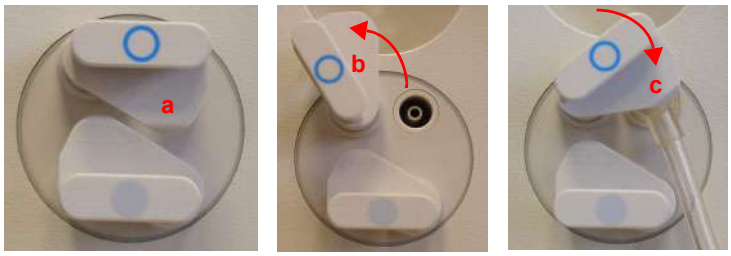
Tightly connect the hydrophobic filter of the venous pressure line to the venous pressure connector in order to avoid an ingress or loss of air.

Inserting the lines may be continued only after successful completion of the T1 test.

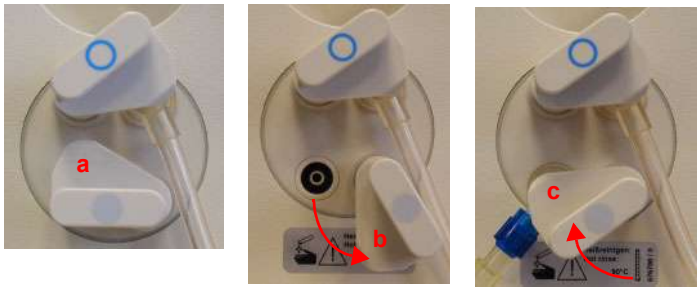
15 Insert the SafeLine™ line guide into the substituate pump until a signal is sounded.
(After closing the doors the SafeLine™ pump segment will be automatically inserted into the substituate pump.)

16 Insert the SafeLine™ into the line holder.

17 Connect the arterial patient access line to the SafeLine™.



18 To connect the substituate connector to the substituate port:
The catch for the substituate port (blue) is in initial position (a).
Pull and turn the substituate catch (blue) counterclockwise into position (b).
Push the substituate connector firmly into the substituate port.
Pull and turn the substituate catch (blue) clockwise until it clicks into place at position (c). If necessary to make sure of a tight closure push in the substituate catch (blue).



19 To insert the rinse connector (connected onto the venous patient line) into the rinse port:
The catch for the rinse port (grey) is in initial position (a).
Pull and turn the rinse port catch (grey) counterclockwise into position (b).
Push the rinse connector firmly into the rinse port.
Pull and turn the rinse port catch (grey) clockwise until it clicks into place at position (c). If necessary to make sure of a tight closure push in the rinse port catch (grey).

Close the doors.
(The line segment(s) are automatically inserted, the arterial pressure measurement unit closes.)

The system automatically switches to the PREPARATION SCREEN.

Message: *Connect dialyzer couplings!*

5.3.6 Connecting the Dialysate Lines

Note

The dialysate lines may only be connected after the T1 test has been completely terminated.

Message: *Connect dialyzer couplings!*

Open the shunt door.

Connect the dialysate supply line (dialyzer coupling red) to the dialyzer (on the side of the venous blood outlet port).

Connect the dialysate return line (dialyzer coupling blue) to the dialyzer (on the side of the arterial blood inlet port).

Close the shunt door.

5.3.7 Priming the Extracorporeal Blood Circuit with ONLINE*plus*™

- **Starting the Rinse procedure**

PREPARATION SCREEN

Check/set the rinse volume.
Check/set the delivery rate of the blood pump.

The rinse volume and the delivery rate are automatically set to the value preselected in the Operator Setup. Change the rinse volume and the delivery rate if necessary.

Touch the **Blood pump I/O** button. (**Blood pump I/O** indicator green.)

If not yet done, the parameters for dialysate, UF and the heparin pump now may be checked/set.

- **Interrupting the Rinse procedure**

PREPARATION SCREEN

Touch the **Blood pump I/O** button. (**Blood pump I/O** indicator grey.)

Message: *Do not connect patient! Minimum rinse volume not reached. – Rinse* **Continue**

Touch the **Continue** button to continue rinsing. (**Blood pump I/O** indicator green.)

- **Rinse procedure completed**

  Endless rinse will start when the Online rinse volume and the Online UF rinse volume have been reached.
  The delivery rate of the blood pump is automatically reduced to 50 ml/min, and the dialysate flow is reduced to EcoFlow (100 ml/min).
  In case of ONLINE*plus*™, the total flow is composed of EcoFlow (100 ml/min) and the respective substituate rate.

5.3.8 Checking/Setting the Dialysate Parameters

Note

Calcium carbonate precipitations may occur in the bicarbonate dialysis, depending on the use and the dose of the concentrates and the duration of the treatment. Detailed information will be provided by the manufacturer on request.

The Prescr. Bic can be reduced to 25.0 mmol/l during preparation (adjustable in the Technician's Setup). If the Bic reduction is selected, 25.0 mmol/l appears below the value Prescr. Bic. The Bic reduction is de-activated when the treatment starts.

After completion of the T1 test, the EcoFlow (100 ml/min) is automatically selected. The flow can be changed as desired.

On the PREPARATION SCREEN you can directly check, select and change the Prescr. Na and Prescr. Bic parameters.

In the **DIALYSATE MENU**

Check the dialysate parameters.
Set the desired parameters. Touch the **OK** button to confirm the values entered.
Visually check the confirmed values.

Touch the **PREPARATION** menu button to return to the PREPARATION SCREEN.

5.3.9 Checking/Setting the UF Parameters

On the PREPARATION SCREEN you can directly check, select and change the UF goal, UF time and UF rate parameters.

Note

If only the UF rate is entered for ultrafiltration (instead of volume and time), check the UF rate displayed in the Dialysis menu for plausibility after saving the data.

In the **UF MENU**

Possible setting variants:
– UF goal/UF time (UF rate is calculated)
– UF goal/UF rate (UF time is calculated)
– UF rate/UF time
– UF rate
– Time
– UF profiles
– ISO goal/ISO time (ISO rate is calculated)
– ISO goal/ISO rate (ISO time is calculated)

The following must be observed in case of ISO-UF:

The ISO-UF treatment type can be started at any time and can be repeated as often as necessary.
The parameters entered at the beginning of the treatment (UF goal and UF time) must be taken into consideration.

In case of a combination with UF and Na profiles, first enter the ISO UF parameters. Then set the respective profiles.

The total volume to be removed (UF goal), the total treatment time (UF time) or the UF goal and the UF rate must always be programmed. The ISO data goal and time cannot be higher than the UF goal/time.

The UF goal/UF time or UF goal/UF rate parameters must first be entered.

Set the desired parameters.
Touch the **OK** button to confirm the entered values.
Visually check the confirmed values.

Touch the **PREPARATION** menu button to return to the PREPARATION SCREEN.

5.3.10 Checking/Setting the Sodium and UF Profiles

Caution

When using Na profiles, the following precautions must be observed: The balancing neutrality of the profiles was computed for a dialysis dose of KT/V = 1.2. In case of higher deviations (KT/V > 1.4; KT/V < 1.0) the balancing neutrality may not always be achieved.

Basic requirements for setting the profiles:
the UF parameters must have been set.

- **Na profiles**

In the **DIALYSATE MENU**

Check the dialysate parameters.
Minimum value that can be set for Start Na: 3 mmol higher than the prescribed Na

Set the desired profile.

Check/set Start Na (maximum value).
(The minimum Na value is automatically adjusted.)

The following must be observed:
– The treatment may also be started with the Na profile only.
– It is only possible to select matching profile groups.
  (E.g. if UF profile 1 has been selected, only Na profile 1 is available.)
– After having started the profiles, it is no longer possible to alter the Concentrate, Prescr. Na and Prescr. Bic parameters.
– The minimum UF time must be set:
  Profiles 1, 2: UF time 2:00 hrs
  Profile 3: UF time 3:30 hrs

Set the desired parameters.
Touch the **OK** button to confirm the entered values.
Visually check the confirmed values.

Touch the **PREPARATION** menu button to return to the PREPARATION SCREEN.

- **UF profiles**

In the **UF MENU**

Check the UF parameters.
Minimum UF parameters that can be set:
Profiles 1, 2: UF goal 200 ml, UF time 2:00 hrs, UF rate 10 ml
Profile 3: UF goal 200 ml, UF time 3:30 hrs, UF rate 10 ml

Set the desired profile.

Check/set the start rate.
(The minimum profile rate is automatically adjusted.)

The following must be observed:
– The treatment may also be started with the UF profile only.
– It is only possible to select matching profile groups.
  (E.g. if Na profile 1 has been selected, only UF profile 1 is available.)
– After having started the profiles, it is no longer possible to alter the UF time and UF rate parameters.
– ISO UF parameters and Na parameters may be selected only before starting or after ending a profile.

Set the desired parameters.
Touch the **OK** button to confirm the entered values.
Visually check the confirmed values.

Touch the **PREPARATION** menu button to return to the PREPARATION SCREEN.

5.3.11 Checking/Setting the Heparin Pump Parameters

Caution

Administer the heparin dose according to the physician's instructions.

In the **HEPARIN** menu

Check the heparin pump parameters.
Set the desired parameters. Touch the **OK** button to confirm the values entered.
Visually check the confirmed values.

Touch the **PREPARATION** menu button to return to the PREPARATION SCREEN.

5.3.12 Checking/Setting the Single-Needle Parameters

In the **SINGLE-NEEDLE** menu

Check the Single-Needle parameters.
Set the desired parameters. Touch the **OK** button to confirm the values entered.
Visually check the confirmed values.

Touch the **PREPARATION** menu button to return to the PREPARATION SCREEN.

5.4 Single-Needle (Option) Preparation with Rinse Solution Bag

If the 5008 ONLINE*plus*™ hemodialysis system cannot be operated without rinse solution bags, rinse or infusion solutions provided in NaCl bags may be used instead.

5.4.1 Turning the Hemodialysis System On

Caution

The stability of the 5008 hemodialysis system must be ensured.

Establish the water and power supply.

Press the **On/Off** key. (Turn the hemodialysis system on!)
The **On/Off** LED is illuminated.

START-UP SCREEN

The display shows the machine type, the current software version and the clinical data (on request) for approx. 15 seconds.

Caution

After a downtime of more than 72 hours, a cleaning program must be performed completely before starting the treatment.

If necessary, check the hemodialysis system for presence of residual disinfectant. (see chapter 8 Cleaning).

Note

If the message: *Defective battery* is acknowledged by pressing the **Skip** key, it might be that the audible alarm will not be generated, if a power failure occurs.

5.4.2 The Following Must be Observed when Using Consumables

Caution

The system has been approved for use with the consumables and accessories listed in the Operating Instructions.

Should the responsible organization wish to use other consumables and accessories than those listed in the Operating Instructions, the responsibility to ensure the correct function of the system lies exclusively with the responsible organization. The applicable legal regulations must be complied with (e.g. in Germany the Medical Device Directive, MDD and the MPBetreibV = German regulation for the operation of medical products).

The manufacturer does not assume any responsibility or liability for personal injury or other damage and excludes any warranty for damage to the system resulting from the use of non-approved or unsuitable consumables or accessories.

Caution

The symbols printed on the packaging of the consumables have to be observed. The symbols are described in the chapter System Description (consumables symbols).

When using consumables, it is important to take note of the following symbols:

Do not reuse

Use by

Caution

The consumables may only be used if the packaging and the respective consumable including the protective caps used are not damaged. The protective caps must not have fallen off.

The plastics used for the consumables may not be compatible with components of drugs or disinfectants. If they are planned to be used, the compatibility of the consumables' components must be ensured before the treatment. If connectors made of polycarbonate are for example exposed to aqueous solutions with the pH value > 10 or to aliphatic solutions this will cause tension cracks.

5.4.3 Selecting the Concentrate Supply

● **Connecting the concentrates**

Caution

Concentrate:
The concentrate displayed on the screen must comply with the specifications mentioned on the acid or the acetate container or on the bag. This also applies to the concentrate composition in CDS operation.

Concentrate packages:
– Assure that the packages used contain sufficient concentrate to complete the treatment.
– Use only the dedicated coded containers or the bi*b*ag® for bicarbonate dialysis.

Bicarbonate dry concentrate bi*b*ag®:
Only the bi*b*ag® manufactured by Fresenius Medical Care may be used.

The bi*b*ag® must only be used for one treatment.

Only use the bi*b*ag® in combination with acid bicarbonate hemodialysis concentrate according to the prescribed dilution. Other mixing ratios may lead to a hazard for the patient.

Acid and basic bicarbonate hemodialysis concentrate have to be diluted immediately prior to application only. The bag's content must be used up within 12 hours after dilution. Discard residual volumes. The powder is non-pyrogenic.

Conductivity limits:
The alarm limits are automatically set around the expected value. The actual value of the conductivity display must have attained the expected desired value after a maximum of 10 minutes.
Should this not be the case, the actual value must first be checked in the laboratory. Change or check the concentrate, if necessary, or call service.

Note

The bicarbonate suction tube must be inserted into the rinse chamber during the bi*b*ag® treatment.

Extract the concentrate rack.

Bicarbonate dialysis

To connect the (acid) concentrate container:
Push the latch (1) upwards. Open the concentrate flap. Place the red concentrate suction tube (2) into the acid container. Close the concentrate flap (3) until it clicks into place.

To connect the bi*b*ag®:
Push the latch (1) upwards. Open the bicarbonate flap. Remove the bi*b*ag® from its packaging. Remove the foil from the bi*b*ag®. Attach the bi*b*ag® (2). Close the bicarbonate flap (3) until it clicks into place.
OR
To connect the bicarbonate container:
Insert the bicarbonate suction tube (blue) into the bicarbonate container.
Close the bicarbonate flap.

CDS, Central Delivery System (option)

Note

The responsible organization is responsible for the proper installation and function of the CDS.

Acetate dialysis

Connect the concentrate container.
Insert the concentrate suction tube (red) into the acetate container.
The bicarbonate suction tube (blue) remains in the rinse chamber.

Selecting a treatment

SELECTION SCREEN

Touch the **Treatment** field.

If there is no tubing system inserted, the system automatically moves to the BLOOD SYSTEM screen.

BLOOD SYSTEM SCREEN

The T1 test is now running in parallel with the preparation of the hemodialysis system. The color of the header bar is orange for the duration of the T1 test.
The operating mode display shows the progress of the T1 test.

Message: *T1 test completed* is displayed for a moment after successful completion of the T1 test.

5.4.4 Important Items to be Considered Before and During the Treatment

Caution

Aseptic technique:
Use aseptic technique for all bloodside connections and all connections in the area where sterile solutions are to be used.

Caution

Preventing contamination:
Use tubing systems with hydrophobic filters at the pressure lines to prevent cross-contamination.
Connect the hydrophobic filters so that an ingress or loss of air is not possible and that any wetting by fluid is reliably avoided, also in case of pressure fluctuations.
If a hydrophobic filter has become wet, the tubing system must be replaced.

On tubing systems with additional connection sites, a replacement pressure line may be connected (accessory available from Fresenius Medical Care).

The blood in the pressure line must not be forced back by means of a syringe. This could damage the hydrophobic membrane and thus lead to a contamination.

If fluid may have passed the hydrophobic filter, the system must be checked for contamination after completion of the treatment. If the system is contaminated, it has to be taken out of service. All affected components have to be disinfected or replaced in accordance with the manufacturer's specifications before the system is put into operation again.

Caution

When inserting the tubing systems, the following precautions must be respected:

– The tubing systems have to be free of kinks, tension and twists and must not be jammed (risk of hemolysis). Use the line holders provided.
– Ensure the correct position of the screwed connections, especially of the connection sites to the patient, the dialyzer and the system and check or correct them during the treatment if necessary. Take the appropriate measures if required (e.g. retightening of the Luer Lock connection or replacement of the tubing system).
– Check the protective caps for tight fit and tighten them if necessary.
– The lines for the supply of infusions should always be clamped, except if they are needed.
– During long-term operation, the blood lines must be changed after 24 hours at the latest.
– Do not use cannulas with a diameter of > 20 gauge to pierce the septum of the injection sites. Insert the cannula vertically and in the center of the septum. Disinfect the injection sites with 70% alcohol before use.
– The blood pump must be set to the diameter of the pump segment, refer also to the product label of the blood lines. If a wrong line diameter is set, this may cause significant deviations in the blood flow and thus in the dialysis dose.
– Materials which come directly or indirectly into contact with blood are: Plasticized PVC, unplasticized PVC, polyethylene, polycarbonate, latex-free rubber, ABS.
– The minimum temperature of the tubing systems during use is 18 °C.

Caution

Delivery operation of the pump(s) with open doors (blood pump, substituate pump, optional Single-Needle pump):
When the doors are open and the rotor of the pump(s) is running, make sure that **no objects**, such as fingers, hair or ball point pens, come into contact with the rotor (risk of injury).

Arterial pressure measurement unit:
Prevent foreign objects from coming into contact with the arterial pressure measurement unit.

Heparin pump:
If heparin syringes of third party suppliers are used, the operator is responsible and has to ensure that the syringe data displayed match the actual data.
Heparin syringes without Luer lock are not recommended as the connection between the heparin syringe and the blood lines may come loose. If heparin syringes without Luer lock are used it is the operator's responsibility to ensure that the connection between the heparin syringe and the blood lines does not loosen inadvertently.

IV pole:
Securely fix bags or other objects to be hung from the IV pole.

Caution

Before the treatment, check:
- The safe connection of all connection sites of the tubing system.
- The tightness of the tubing system during and after priming.
- Retighten the connections and replace the tubing system, if necessary.
- The absence of air in the tubing system and the correct position of all fluid levels.

To be observed when working on the tubing system during the treatment:
If the position of the tubing system or of one of its components is changed, the correct position of the entire tubing system must be restored afterwards, above all the correct position of the line guides.

During the treatment check at appropriate intervals:
- The condition of the patient.
- The function of the hemodialysis system and the extracorporeal blood circuit. Pay particular attention to the venous insertion site, as a possible dislocation of the venous cannula may not always be detected by the pressure monitoring system.
- The tubing system for leakages or possible loosening of connections as well as entry of air.
- The fluid level in the venous bubble catcher. Correct it, if required (desired level: approx. 1 cm below the upper edge of the cover)

Caution

Venous alarm limit:
The lower venous alarm limit must be set as close as possible to the actual venous pressure value.

Note

The dialyzer holder is not suitable for rectangular plate dialyzers.

Note

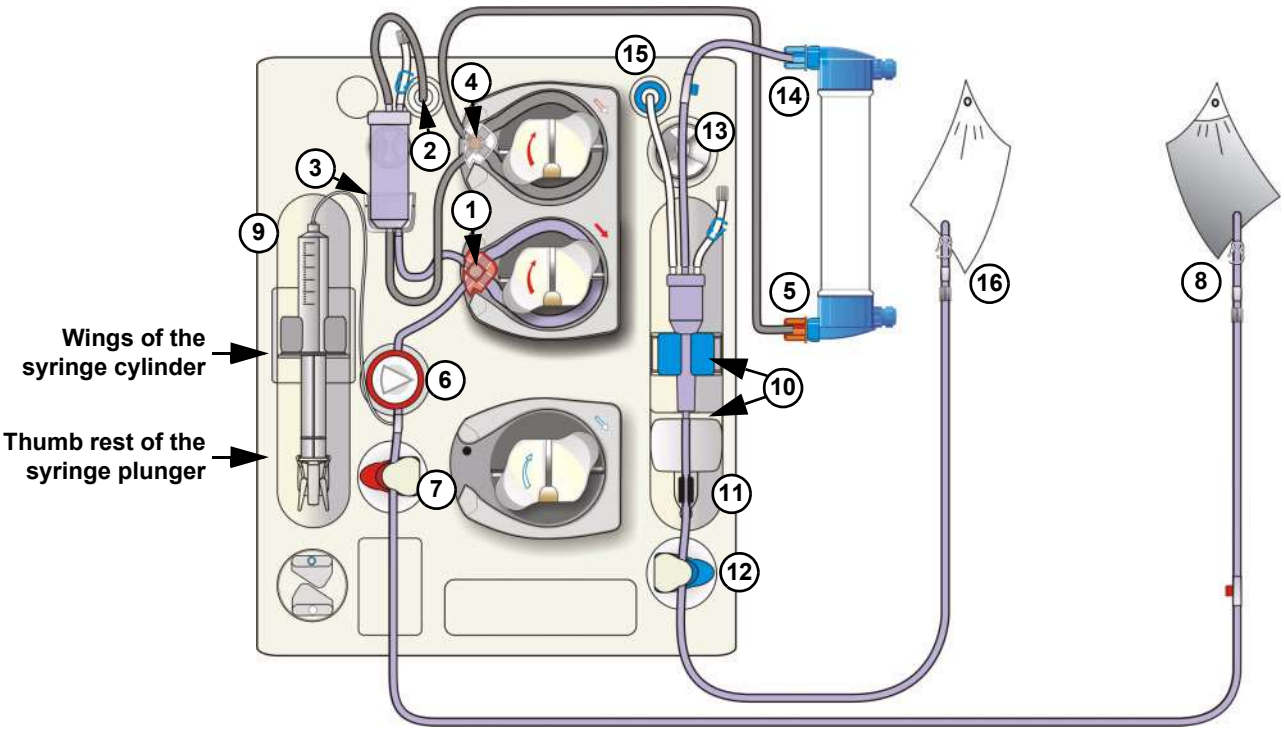
For hygienic reasons, the blood lines should be inserted immediately prior to the treatment only.

If the blood lines were inserted more than 8 hours before the treatment, malfunctions may occur. Correcting these malfunctions may require removing the present blood lines and inserting new blood lines.

5.4.5 Preparing the Extracorporeal Blood Circuit with Rinse Solution Bag

- **Inserting the arterial and the venous tubing system**

When inserting the tubing system, follow the description of the menu displayed.



Open the doors of the Extracorporeal Blood Module.

1 Insert the line guide into the blood pump until a signal is sounded. The arterial pressure measurement unit is opened.
(After closing the doors the pump segment will be automatically inserted into the blood pump.)

2 Connect the SN pressure line to the Single-Needle pressure port.

3 Insert the SN chamber in its holder.

4 Insert the SN line guide into the Single-Needle pump until a signal is sounded.
(After closing the doors the SN pump segment is automatically inserted in the Single-Needle pump, if the level detector detected fluid.)

5 Connect the arterial blood line to the lower port of the dialyzer.

6 Insert the arterial pressure dome into the arterial pressure measurement unit.

7 Insert the arterial blood line into the arterial occlusion clamp.

8 Connect the arterial patient connection of the tubing system to the rinse solution bag.

Caution

If no heparin syringe is used, retighten the cap of the heparin line and close the clamp.

9 Connect the heparin syringe to the arterial tubing system.
To place the heparin syringe in the holder:
Press on the clamping brackets to move the grip handle to its lower position.
Place the heparin syringe between the barrel holders.
The syringe wings must be positioned between the barrel holders and the bracket.
The thumb rest of the syringe plunger now must be positioned between the clamps of the grip handle.
Press on the clamping brackets to move the grip handle to its starting position.

Caution

When inserting the heparin syringe, the following precautions must be respected:
– Only use heparin syringes with a volume of up and equal to 30 ml.
– Ensure that the heparin syringe is correctly inserted into the heparin pump and locked. Follow the description and the illustration.

10 Insert the venous bubble catcher into the level detector. Mind the locator for the venous bubble catcher.

11 Insert the venous line into the optical detector/air bubble detector. The line must be positioned completely inside the line housing.

Caution

The following must be observed for the air bubble detector:
– No ultrasound-conducting objects and agents may be used.
– The line housing must be clean and dry.

12 Insert the venous blood line into the venous occlusion clamp.

13 Insert the venous blood line into the line holder.

14 Connect the venous blood line to the upper port of the dialyzer.

15 Connect the venous pressure line to the venous pressure connector.

Caution

Tightly connect the hydrophobic filter of the venous pressure line to the venous pressure connector in order to avoid an ingress or loss of air.

16 Connect the venous patient connection of the tubing system to the prime collection bag. (Prime collection bag not included in scope of delivery of the tubing system.)

Close the doors.
(The line segment(s) are automatically inserted, the arterial pressure measurement unit closes.)

Break the cone on the rinse solution bag.

The system automatically switches to the PREPARATION SCREEN.

Message: *Connect dialyzer couplings!*

5.4.6 Connecting the Dialysate Lines

Note

The dialysate lines may only be connected after the T1 test has been completely terminated.

Message: *Connect dialyzer couplings!*

Open the shunt door.

Connect the dialysate supply line (dialyzer coupling red) to the dialyzer (on the side of the venous blood outlet port).

Connect the dialysate return line (dialyzer coupling blue) to the dialyzer (on the side of the arterial blood inlet port).

Close the shunt door.

5.4.7 Priming the Extracorporeal Blood Circuit with Rinse Solution Bag

- **Starting the Rinse procedure**

PREPARATION SCREEN

Check/set the rinse volume.
Check/set the delivery rate of the blood pump.

The rinse volume and the delivery rate are automatically set to the value preselected in the Operator Setup. Change the rinse volume and the delivery rate if necessary.

Touch the **Blood pump I/O** button. (**Blood pump I/O** indicator green.)

If not yet done, the parameters for dialysate, UF and the heparin pump now may be checked/set.

- **Interrupting the Rinse procedure**

PREPARATION SCREEN

Touch the **Blood pump I/O** button. (**Blood pump I/O** indicator grey.)

Message: *Do not connect patient! Minimum rinse volume not reached. – Rinse* **Continue**

Do not connect a patient if rinsing is interrupted during the T1 test or during a cleaning program.

Touch the **Blood pump I/O** button to continue the Rinse procedure. (**Blood pump I/O** indicator green.)

- **Rinse procedure completed**

Message: *Rinse volume reached.* – *Rinse* **Continue** – *Circulation* **Start** **Mute** LED is flashing. Audible signal
Connect the venous tubing system to the rinse solution bag.
Touch the **Start** button to launch precirculation. (**Blood pump I/O** indicator green.)

- **Interrupting the Circulation procedure**

PREPARATION SCREEN

Touch the **Blood pump I/O** button. (**Blood pump I/O** indicator grey.)

If T1 test active:
Message: *CAUTION! T1 test still in progress! Patient cannot be connected!*

Touch the **Blood pump I/O** button to continue the circulation procedure. (**Blood pump I/O** indicator green.)

5.4.8 Checking/Setting the Dialysate Parameters

Note

Calcium carbonate precipitations may occur in the bicarbonate dialysis, depending on the use and the dose of the concentrates and the duration of the treatment. Detailed information will be provided by the manufacturer on request.

The Prescr. Bic can be reduced to 25.0 mmol/l during preparation (adjustable in the Technician's Setup). If the Bic reduction is selected, 25.0 mmol/l appears below the value Prescr. Bic. The Bic reduction is de-activated when the treatment starts.

After completion of the T1 test, the EcoFlow (100 ml/min) is automatically selected. The flow can be changed as desired.

On the PREPARATION SCREEN you can directly check, select and change the Prescr. Na and Prescr. Bic parameters.

In the **DIALYSATE MENU**

Check the dialysate parameters.
Set the desired parameters. Touch the **OK** button to confirm the values entered.
Visually check the confirmed values.

Touch the **PREPARATION** menu button to return to the PREPARATION SCREEN.

5.4.9 Checking/Setting the UF Parameters

On the PREPARATION SCREEN you can directly check, select and change the UF goal, UF time and UF rate parameters.

Note

If only the UF rate is entered for ultrafiltration (instead of volume and time), check the UF rate displayed in the Dialysis menu for plausibility after saving the data.

In the **UF MENU**

Possible setting variants:
– UF goal/UF time (UF rate is calculated)
– UF goal/UF rate (UF time is calculated)
– UF rate/UF time
– UF rate
– Time
– UF profiles
– ISO goal/ISO time (ISO rate is calculated)
– ISO goal/ISO rate (ISO time is calculated)

The following must be observed in case of ISO-UF:

The ISO-UF treatment type can be started at any time and can be repeated as often as necessary.
The parameters entered at the beginning of the treatment (UF goal and UF time) must be taken into consideration.

In case of a combination with UF and Na profiles, first enter the ISO UF parameters. Then set the respective profiles.

The total volume to be removed (UF goal), the total treatment time (UF time) or the UF goal and the UF rate must always be programmed. The ISO data goal and time cannot be higher than the UF goal/time.

The UF goal/UF time or UF goal/UF rate parameters must first be entered.

Set the desired parameters.
Touch the **OK** button to confirm the entered values.
Visually check the confirmed values.

Touch the **PREPARATION** menu button to return to the PREPARATION SCREEN.

5.4.10 Checking/Setting the Sodium and UF Profiles

Caution

When using Na profiles, the following precautions must be observed:
The balancing neutrality of the profiles was computed for a dialysis dose of KT/V = 1.2. In case of higher deviations (KT/V > 1.4; KT/V < 1.0) the balancing neutrality may not always be achieved.

Basic requirements for setting the profiles:
the UF parameters must have been set.

- **Na profiles**

In the **DIALYSATE MENU**

Check the dialysate parameters.
Minimum value that can be set for Start Na: 3 mmol higher than the prescribed Na

Set the desired profile.

Check/set Start Na (maximum value).
(The minimum Na value is automatically adjusted.)

The following must be observed:
– The treatment may also be started with the Na profile only.
– It is only possible to select matching profile groups.
(E.g. if UF profile 1 has been selected, only Na profile 1 is available.)
– After having started the profiles, it is no longer possible to alter the Concentrate, Prescr. Na and Prescr. Bic parameters.
– The minimum UF time must be set:
Profiles 1, 2: UF time 2:00 hrs
Profile 3: UF time 3:30 hrs

Set the desired parameters.
Touch the **OK** button to confirm the entered values.
Visually check the confirmed values.

Touch the **PREPARATION** menu button to return to the PREPARATION SCREEN.

- **UF profiles**

In the **UF MENU**

Check the UF parameters.
Minimum UF parameters that can be set:
Profiles 1, 2: UF goal 200 ml, UF time 2:00 hrs, UF rate 10 ml
Profile 3: UF goal 200 ml, UF time 3:30 hrs, UF rate 10 ml

Set the desired profile.

Check/set the start rate.
(The minimum profile rate is automatically adjusted.)

The following must be observed:
– The treatment may also be started with the UF profile only.
– It is only possible to select matching profile groups.
(E.g. if Na profile 1 has been selected, only UF profile 1 is available.)
– After having started the profiles, it is no longer possible to alter the UF time and UF rate parameters.
– ISO UF parameters and Na parameters may be selected only before starting or after ending a profile.

Set the desired parameters.
Touch the **OK** button to confirm the entered values.
Visually check the confirmed values.

Touch the **PREPARATION** menu button to return to the PREPARATION SCREEN.

5.4.11 Checking/Setting the Heparin Pump Parameters

Caution

Administer the heparin dose according to the physician's instructions.

In the **HEPARIN** menu

Check the heparin pump parameters.
Set the desired parameters. Touch the **OK** button to confirm the values entered.
Visually check the confirmed values.

Touch the **PREPARATION** menu button to return to the PREPARATION SCREEN.

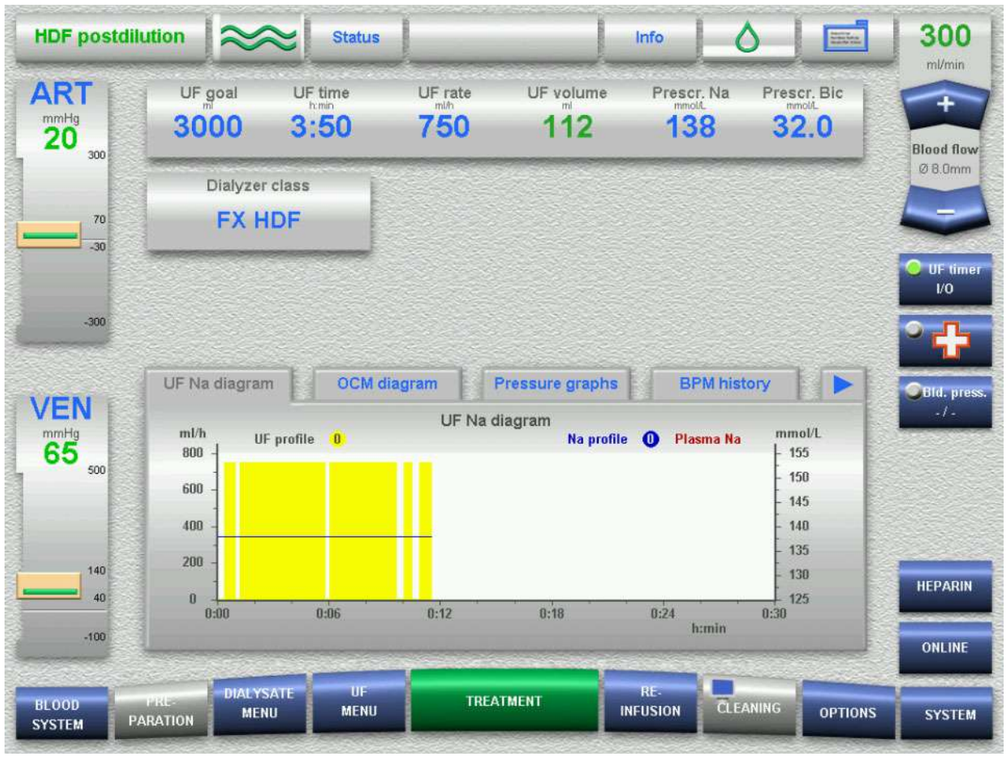
5.4.12 Checking/Setting the Single-Needle Parameters

In the **SINGLE-NEEDLE** menu

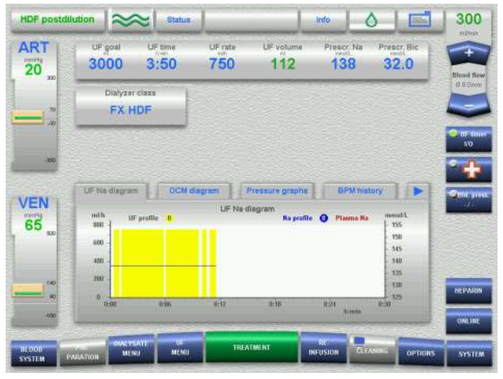
Check the Single-Needle parameters.
Set the desired parameters. Touch the **OK** button to confirm the values entered.
Visually check the confirmed values.

Touch the **PREPARATION** menu button to return to the PREPARATION SCREEN.

Fold-Out Sheet
6 Treatment



TREATMENT SCREEN



SN, setting the level in the SN chamber

6 Treatment

6.1 TreatmentusingONLINE*plus*™

Irrespective of the treatment mode, all 5008 ONLINE*plus*™ hemodialysis systems can be operated without rinse or infusion solutions provided in NaCl bags. The fluid volumes required for preparation, bolus administration or during reinfusion will then be produced ONLINE by the 5008 hemodialysis system according to the actual requirements, thus saving both cost and time.

6.1.1 Connecting the Patient — Double-Needle Dialysis Using ONLINE*plus*™

Caution

The patient may only be connected if the following conditions are fulfilled:
The header bar of the screen has to be grey (normal operating mode).
The hemodialysis system must be alarm-free.
Air-free priming of the extracorporeal circuit has been completed.

PREPARATION SCREEN

Touch the **Blood pump I/O** button. (**Blood pump I/O** indicator grey.)
The blood pump stops.

Message: *Priming / Rinsing* – **Continue** – **Exit**
Touch the **Exit** button.

Disconnect the arterial tubing system from the SafeLine™.

Connect the SafeLine™ before (predilution) or below the dialyzer (postdilution).

Connect the arterial line to the patient.

Remove the rinse connector.
Disconnect the venous tubing system from the rinse connector and connect it to the patient or, if desired, to a separate prime collection bag.

Close the rinse port.

Message: *Start the blood pump* – **Confirm**

Touch the **Confirm** button.

Optical detector sensed blood.

Message: *Blood detected - Dialysis* **Start**
The blood pump stops. The arterial/venous occlusion clamp closes.
Mute LED is flashing.

Connect the venous connector of the tubing system to the patient (provided this has not been done yet).

Caution

When using high-flux dialyzers and selecting low UF rates there is a possibility of local backfiltration.
Backfiltration depends on:
– the type of high-flux dialyzer
– the different flow resistances on the dialysate and the blood side
– the viscosity of the blood

Touch the **Start** button.

The system automatically changes to the TREATMENT SCREEN. Heparin pump and ultrafiltration are started automatically, if preset in the Operator Setup. Set the blood flow to the desired delivery rate. The alarm limits will be set automatically.

The substituate pump will start automatically after approx. 3 minutes. The substituate pump may also be started in advance by touching the **Sub pump I/O** button.
(The substituate pump will be stopped in the event of a blood or a dialysate alarm.)

6.1.2 Changing the ONLINE*plus*™ Parameters

In the **ONLINE** menu

Touch the **Sub pump I/O** button to turn the substituate pump on or off.

If Online parameters are to be changed:
Set the desired Online parameters. Touch the **OK** button to confirm the values entered.
Visually check the confirmed values.

Touch the **TREATMENT** menu button to return to the TREATMENT SCREEN.

6.1.3 ONLINE*plus*™ Bolus Administration

Touch the **ONLINE** menu button.

Check the bolus parameters.
Set the desired bolus parameters. Touch the **OK** button to confirm the values entered. Visually check the confirmed values.

Touch the **Bolus I/O** button to turn the bolus function on or off. (The cumulated bolus amount is displayed in increments of 30 ml.)

Touch the **TREATMENT** menu button to return to the TREATMENT SCREEN.

Note

When administering larger volumes of substitution fluid, the blood may be diluted to an extent which causes the optical detector to sense light.

Message: *No blood detected.* – *Dialysis* **Continue** – *Reinfusion* **Start** – *Machine* **Remove lines**
The blood pump stops. The arterial/venous occlusion clamp closes. **Mute** LED is flashing. Audible signal

Touch the **Continue** button to go on with the dialysis treatment.

6.1.4 Changing the Dialysate Parameters

The TREATMENT SCREEN permits direct setting of the prescribed Na and prescribed Bic parameters.

The DIALYSATE MENU is used to set the flow through the dialyzer. (In case of ONLINE*plus*™, the total flow consists of the set flow and the respective substituate rate.)

In the **DIALYSATE MENU**

Touch the **Flow I/O** button to turn the dialysate flow on or off.

How to change dialysate parameters:
Set the desired dialysate parameters. Touch the **OK** button to confirm the values entered.
Visually check the confirmed values.

Touch the **TREATMENT** menu button to return to the TREATMENT SCREEN.

6.1.5 Changing the UF Parameters

The TREATMENT SCREEN permits direct setting of the UF parameters.

It is not necessary to touch the **UF Timer I/O** button before or after changing the UF parameters.

In the **UF MENU**

How to change UF parameters:
Set the desired UF parameters. Touch the **OK** button to confirm the values entered.
Visually check the confirmed values.

Touch the **TREATMENT** menu button to return to the TREATMENT SCREEN.

During the treatment, it is possible to increase the maximum possible UF rate in the Operator setup.

6.1.6 Sodium and UF Profiles

If sodium or UF profiles are programmed during the treatment, they will start with a delay time of 20 seconds.

- **Starting**

Automatically, if OD dark (adjustable in the Operator setup).
Touch the **UF timer I/O** button.

- **Stopping/aborting**

Touch the **UF timer I/O** button.

Message: *UF profile and Na profile were stopped*. – *Both profiles* **Abort** – *UF profile* **Abort** – *Treatment* **Continue**

Touch the desired button.

If no button is touched, the profiles will be stopped for a certain time (adjustable in the Operator setup).

6.1.7 Changing the Heparin Pump Parameters

In the **HEPARIN** menu

Touch the **Heparin I/O** button to turn the heparin pump on or off.

How to change heparin pump parameters:
Set the desired heparin pump parameters. Touch the **OK** button to confirm the values entered.
Visually check the confirmed values.

Touch the **TREATMENT** menu button to return to the TREATMENT SCREEN.

6.2 Treatment (Prepared with Rinse Solution Bag)

If the 5008 ONLINE*plus*™ hemodialysis system cannot be operated without rinse solution bags, rinse or infusion solutions provided in NaCl bags may be used instead.

6.2.1 Connecting the Patient — Double-Needle Dialysis (Prepared with Rinse Solution Bag)

Caution

The patient may only be connected if the following conditions are fulfilled:
The header bar of the screen has to be grey (normal operating mode).
The hemodialysis system must be alarm-free.
Air-free priming of the extracorporeal circuit has been completed.

PREPARATION SCREEN

Touch the **Blood pump I/O** button. (**Blood pump I/O** indicator grey.)
The blood pump stops.

Connect the arterial line to the patient.
If infusion of the rinse solution contained in the line is desired, now connect the venous line.

Touch the **Blood pump I/O** button. (**Blood pump I/O** indicator green.)
The blood pump is delivering.
Set the delivery rate of the blood pump to the desired value.

Optical detector sensed blood.

Message: *Blood detected - Dialysis* **Start**
The blood pump stops. The arterial/venous occlusion clamp closes.
Mute LED is flashing.

Connect the venous connector of the tubing system to the patient (provided this has not been done yet).

Caution

When using high-flux dialyzers and selecting low UF rates there is a possibility of local backfiltration.
Backfiltration depends on:
– the type of high-flux dialyzer
– the different flow resistances on the dialysate and the blood side
– the viscosity of the blood

Touch the **Start** button.

The system automatically changes to the TREATMENT SCREEN. Heparin pump and ultrafiltration are started automatically, if preset in the Operator Setup. Set the blood flow to the desired delivery rate. The alarm limits will be set automatically.

6.2.2 Changing the Dialysate Parameters

The TREATMENT SCREEN permits direct setting of the prescribed Na and prescribed Bic parameters.

In the **DIALYSATE MENU**

Touch the **Flow I/O** button to turn the dialysate flow on or off.

How to change dialysate parameters:
Set the desired dialysate parameters. Touch the **OK** button to confirm the values entered.
Visually check the confirmed values.

Touch the **TREATMENT** menu button to return to the TREATMENT SCREEN.

6.2.3 Changing the UF Parameters

The TREATMENT SCREEN permits direct setting of the UF parameters.

It is not necessary to touch the **UF Timer I/O** button before or after changing the UF parameters.

In the **UF MENU**

How to change UF parameters:
Set the desired UF parameters. Touch the **OK** button to confirm the values entered.
Visually check the confirmed values.

Touch the **TREATMENT** menu button to return to the TREATMENT SCREEN.

During the treatment, it is possible to increase the maximum possible UF rate in the Operator setup.

6.2.4 Sodium and UF Profiles

If sodium or UF profiles are programmed during the treatment, they will start with a delay time of 20 seconds.

- **Starting**

Automatically, if OD dark (adjustable in the Operator setup).
Touch the **UF timer I/O** button.

- **Stopping/aborting**

  Touch the **UF timer I/O** button.

  Message: *UF profile and Na profile were stopped. – Both profiles* **Abort** *– UF profile* **Abort** *– Treatment* **Continue**

  Touch the desired button.

  If no button is touched, the profiles will be stopped for a certain time (adjustable in the Operator setup).

6.2.5 Changing the Heparin Pump Parameters

In the **HEPARIN** menu

Touch the **Heparin I/O** button to turn the heparin pump on or off.

How to change heparin pump parameters:
Set the desired heparin pump parameters. Touch the **OK** button to confirm the values entered.
Visually check the confirmed values.

Touch the **TREATMENT** menu button to return to the TREATMENT SCREEN.

6.2.6 Administering Infusion Solutions

Note

When administering infusion solutions (e.g. saline), the blood may be diluted, causing the optical detector to sense light.

Message: *No blood detected. – Dialysis* **Continue** *– Reinfusion* **Start** *– Machine* **Remove lines**
The blood pump stops. The arterial/venous occlusion clamp closes. **Mute** LED is flashing. Audible signal

Touch the **Continue** button to go on with the dialysis treatment.

6.3 Single-Needle (Option) Treatment Using ONLINE*plus*™

Irrespective of the treatment mode, all 5008 ONLINE*plus*™ hemodialysis systems can be operated without rinse or infusion solutions provided in NaCl bags. The fluid volumes required for preparation, bolus administration or during reinfusion will then be produced ONLINE by the 5008 hemodialysis system according to the actual requirements, thus saving both cost and time.

6.3.1 Connecting the Patient — Single-Needle Dialysis Using ONLINE*plus*™

Caution

The patient may only be connected if the following conditions are fulfilled:
The header bar of the screen has to be grey (normal operating mode).
The hemodialysis system must be alarm-free.
Air-free priming of the extracorporeal circuit has been completed.

PREPARATION SCREEN

Touch the **Blood pump I/O** button. (**Blood pump I/O** indicator grey.)
The blood pump stops.

Message: *Connect patient?* – *Standard* **Connect** – *Single-Needle* **Connect** – **Continue**

The following describes the procedures used for Continue, Single-Needle Connect and Standard Connect.

Continue

Touching the **Continue** button will continue the previously activated procedure.

Single-Needle Connect

Touch the *Single-Needle* **Connect** button.

Disconnect the arterial tubing system from the SafeLine™.

Connect the SafeLine™ before (predilution) or below the dialyzer (postdilution).

Connect the arterial line to the patient.

Remove the rinse connector.
Disconnect the venous tubing system from the rinse connector and connect it to the patient or, if desired, to a separate prime collection bag.

Close the rinse port.

Message: *Start the blood pump* – **Confirm**

Touch the **Confirm** button.

Message: *Set the level in the SN chamber to the mark.* ▲ *Level* ▼ – *Level set* **OK** – **Abort**

Touch the ▲ *or* ▼ button to set the level to the mark of the SN chamber holder.
(The doors must be closed.)

Touch the **OK** button.

The blood pump is delivering.
Set the delivery rate of the blood pump to the desired value.

Single-Needle pump is delivering.
If Auto SN has not been activated, set the delivery rate of the Single-Needle pump to the desired value.

Optical detector sensed blood.

Message: *Blood detected - Dialysis* **Start**
The blood pump stops. The arterial/venous occlusion clamp closes.
Mute LED is flashing.

Caution

When using high-flux dialyzers and selecting low UF rates there is a possibility of local backfiltration.
Backfiltration depends on:
– the type of high-flux dialyzer
– the different flow resistances on the dialysate and the blood side
– the viscosity of the blood

Touch the **Start** button.

Note

If the level in the SN chamber rises too high during the treatment it has to be reduced (see chapter 6.3.5 , page 6-12)

The system automatically changes to the TREATMENT SCREEN. Heparin pump and ultrafiltration are started automatically, if preset in the Operator Setup. Set the blood flow to the desired delivery rate. The alarm limits will be set automatically.

The substituate pump will start automatically after approx. 3 minutes. The substituate pump may also be started in advance by touching the **Sub pump I/O** button.
(The substituate pump will be stopped in the event of a blood or a dialysate alarm.)

Standard Connect

Touch the *Standard* **Connect** button.

Disconnect the arterial tubing system from the SafeLine™.

Connect the SafeLine™ before (predilution) or below the dialyzer (postdilution).

Connect the arterial line to the patient.

Remove the rinse connector.
Disconnect the venous tubing system from the rinse connector and connect it to the patient or, if desired, to a separate prime collection bag.

Close the rinse port.

Message: *Start the blood pump* – **Confirm**

Touch the **Confirm** button.

The blood pump is delivering.
Set the delivery rate of the blood pump to the desired value.

Optical detector sensed blood.

Message: *Blood detected - Double-Needle dialysis* **Start** – *Single-Needle dialysis* **Start**
The blood pump stops. The arterial/venous occlusion clamp closes.
Mute LED is flashing.

Caution

When using high-flux dialyzers and selecting low UF rates there is a possibility of local backfiltration.
Backfiltration depends on:
– the type of high-flux dialyzer
– the different flow resistances on the dialysate and the blood side
– the viscosity of the blood

Touch the *Double-Needle dialysis* **Start** button.

The Single-Needle line segment is removed.

Message: *To continue:* - Open the door - Remove the SN pump segment - Press the SN line guide again into the Single-Needle pump until a signal is sounded - Close the door.

The system automatically changes to the TREATMENT SCREEN. Heparin pump and ultrafiltration are started automatically, if preset in the Operator Setup. Set the blood flow to the desired delivery rate. The alarm limits will be set automatically.

The substituate pump will start automatically after approx. 3 minutes. The substituate pump may also be started in advance by touching the **Sub pump I/O** button.
(The substituate pump will be stopped in the event of a blood or a dialysate alarm.)

6.3.2 Changing the ONLINE*plus*™ Parameters

In the **ONLINE** menu

Touch the **Sub pump I/O** button to turn the substituate pump on or off.

If Online parameters are to be changed:
Set the desired Online parameters. Touch the **OK** button to confirm the values entered.
Visually check the confirmed values.

Touch the **TREATMENT** menu button to return to the TREATMENT SCREEN.

6.3.3 ONLINE*plus*™ Bolus Administration

Touch the **ONLINE** menu button.

Check the bolus parameters.
Set the desired bolus parameters. Touch the **OK** button to confirm the values entered. Visually check the confirmed values.

Touch the **Bolus I/O** button to turn the bolus function on or off. (The cumulated bolus amount is displayed in increments of 30 ml.)

Touch the **TREATMENT** menu button to return to the TREATMENT SCREEN.

Note

When administering larger volumes of substitution fluid, the blood may be diluted to an extent which causes the optical detector to sense light.

Message: *No blood detected.* – *Dialysis* **Continue** – *Reinfusion* **Start** – *Machine* **Remove lines**
The blood pump stops. The arterial/venous occlusion clamp closes. **Mute** LED is flashing. Audible signal

Touch the **Continue** button to go on with the dialysis treatment.

6.3.4 Changing the Single-Needle Parameters

In the **SINGLE-NEEDLE** menu

If you wish to alter Single-Needle parameters:
Set the desired Single-Needle parameters. Touch the **OK** button to confirm the values entered.
Visually check the confirmed values.

Touch the **TREATMENT** menu button to return to the TREATMENT SCREEN.

6.3.5 Setting the Level in the SN Chamber

Note

Do not lower the level in the SN chamber manually, but only as described below.

In the **BLOOD SYSTEM** menu

Touch the ▲▼ button on the Single-Needle chamber displayed on the screen.

Message: *Set the level in the SN chamber to the mark.* ▲ *Level* ▼ – *Level set* **OK** – **Abort**

Touch the ▲ *or* ▼ button to set the level to the mark of the SN chamber holder.
(The doors must be closed.)

Touch the **OK** button.

Touch the **TREATMENT** menu button to return to the TREATMENT SCREEN.

6.3.6 Aborting SN during the Treatment

In the **SINGLE-NEEDLE** menu

Touch the **Single-Needle I/O** button. (**Single-Needle I/O** indicator grey.)

Message: *Connect the arterial and the venous patient line to the respective vascular access. – Double-Needle* **Start** – **Abort**

Touch the **Start** button.

The Single-Needle line segment is removed.

Message: *To continue:* - Open the door - Remove the SN pump segment - Press the SN line guide again into the Single-Needle pump until a signal is sounded - Close the door.

Thereafter, the treatment is continued without Single-Needle mode.

6.3.7 Starting SN during the Treatment

In the **SINGLE-NEEDLE** menu

Touch the **Single-Needle I/O** button. (**Blood pump I/O** indicator green.)

Message: *Connect both the arterial and the venous patient line to the same vascular access. – Single-Needle* **Start** – **Abort**

Touch the **Start** button.

The Single-Needle line segment is automatically inserted in the Single-Needle pump.

Message: *Set the level in the SN chamber to the mark.* ▲ *Level* ▼ – *Level set* **OK** – **Abort**

Touch the ▲ *or* ▼ button to set the level to the mark of the SN chamber holder.
(The doors must be closed.)

Touch the **OK** button.

6.3.8 Changing the Dialysate Parameters

The TREATMENT SCREEN permits direct setting of the prescribed Na and prescribed Bic parameters.

The DIALYSATE MENU is used to set the flow through the dialyzer. (In case of ONLINE*plus*™, the total flow consists of the set flow and the respective substituate rate.)

In the **DIALYSATE MENU**

Touch the **Flow I/O** button to turn the dialysate flow on or off.

How to change dialysate parameters:
Set the desired dialysate parameters. Touch the **OK** button to confirm the values entered.
Visually check the confirmed values.

Touch the **TREATMENT** menu button to return to the TREATMENT SCREEN.

6.3.9 Changing the UF Parameters

The TREATMENT SCREEN permits direct setting of the UF parameters.

It is not necessary to touch the **UF Timer I/O** button before or after changing the UF parameters.

In the **UF MENU**

How to change UF parameters:
Set the desired UF parameters. Touch the **OK** button to confirm the values entered.
Visually check the confirmed values.

Touch the **TREATMENT** menu button to return to the TREATMENT SCREEN.

During the treatment, it is possible to increase the maximum possible UF rate in the Operator setup.

6.3.10 Sodium and UF Profiles

If sodium or UF profiles are programmed during the treatment, they will start with a delay time of 20 seconds.

- **Starting**

Automatically, if OD dark (adjustable in the Operator setup).
Touch the **UF timer I/O** button.

- **Stopping/aborting**

Touch the **UF timer I/O** button.

Message: *UF profile and Na profile were stopped.* – *Both profiles* **Abort** – *UF profile* **Abort** – *Treatment* **Continue**

Touch the desired button.

If no button is touched, the profiles will be stopped for a certain time (adjustable in the Operator setup).

6.3.11 Changing the Heparin Pump Parameters

In the **HEPARIN** menu

Touch the **Heparin I/O** button to turn the heparin pump on or off.

How to change heparin pump parameters:
Set the desired heparin pump parameters. Touch the **OK** button to confirm the values entered.
Visually check the confirmed values.

Touch the **TREATMENT** menu button to return to the TREATMENT SCREEN.

6.4 Single-Needle (Option) Treatment (Prepared with Rinse Solution Bag)

If the 5008 ONLINE*plus*™ hemodialysis system cannot be operated without rinse solution bags, rinse or infusion solutions provided in NaCl bags may be used instead.

6.4.1 Connecting the Patient — Single-Needle Dialysis (Prepared with Rinse Solution Bag)

Caution

The patient may only be connected if the following conditions are fulfilled:
The header bar of the screen has to be grey (normal operating mode).
The hemodialysis system must be alarm-free.
Air-free priming of the extracorporeal circuit has been completed.

PREPARATION SCREEN

Touch the **Blood pump I/O** button. (**Blood pump I/O** indicator grey.)
The blood pump stops.

Message: *Connect patient?* – *Standard* **Connect** – *Single-Needle* **Connect** – **Continue**

The following describes the procedures used for Continue, Single-Needle Connect and Standard Connect.

Continue

Touching the **Continue** button will continue the previously activated procedure.

Single-Needle Connect

Connect the arterial and venous lines to the patient.

Touch the *Single-Needle* **Connect** button.

Message: *Start the blood pump* – **Confirm**

Touch the **Confirm** button.

Message: *Set the level in the SN chamber to the mark.* ▲ *Level* ▼ – *Level set* **OK** – **Abort**

Touch the ▲ *or* ▼ button to set the level to the mark of the SN chamber holder.
(The doors must be closed.)

Touch the **OK** button.

The blood pump is delivering.
Set the delivery rate of the blood pump to the desired value.

Single-Needle pump is delivering.
If Auto SN has not been activated, set the delivery rate of the Single-Needle pump to the desired value.

Optical detector sensed blood.

Message: *Blood detected - Dialysis* **Start**
The blood pump stops. The arterial/venous occlusion clamp closes.
Mute LED is flashing.

Caution

When using high-flux dialyzers and selecting low UF rates there is a possibility of local backfiltration.
Backfiltration depends on:
– the type of high-flux dialyzer
– the different flow resistances on the dialysate and the blood side
– the viscosity of the blood

Touch the **Start** button.

Note

If the level in the SN chamber rises too high during the treatment it has to be reduced (see chapter 6.4.3 , page 6-19)

The system automatically changes to the TREATMENT SCREEN.
Heparin pump and ultrafiltration are started automatically, if preset in the Operator Setup. Set the blood flow to the desired delivery rate. The alarm limits will be set automatically.

Standard Connect

Connect the arterial line to the patient.
If infusion of the rinse solution contained in the line is desired, now connect the venous line.

Touch the *Standard* **Connect** button.

Message: *Start the blood pump* – **Confirm**

Touch the **Confirm** button.

The blood pump is delivering.
Set the delivery rate of the blood pump to the desired value.

Optical detector sensed blood.

Message: *Blood detected - Double-Needle dialysis* **Start** – *Single-Needle dialysis* **Start**
The blood pump stops. The arterial/venous occlusion clamp closes.
Mute LED is flashing.

Connect the venous connector of the tubing system to the patient (provided this has not been done yet).

Caution

When using high-flux dialyzers and selecting low UF rates there is a possibility of local backfiltration.
Backfiltration depends on:
– the type of high-flux dialyzer
– the different flow resistances on the dialysate and the blood side
– the viscosity of the blood

Touch the *Double-Needle dialysis* **Start** button.

The Single-Needle line segment is removed.

Message: *To continue:* - Open the door - Remove the SN pump segment - Press the SN line guide again into the Single-Needle pump until a signal is sounded - Close the door.

The system automatically changes to the TREATMENT SCREEN. Heparin pump and ultrafiltration are started automatically, if preset in the Operator Setup. Set the blood flow to the desired delivery rate. The alarm limits will be set automatically.

6.4.2 Changing the Single-Needle Parameters

In the **SINGLE-NEEDLE** menu

If you wish to alter Single-Needle parameters:
Set the desired Single-Needle parameters. Touch the **OK** button to confirm the values entered.
Visually check the confirmed values.

Touch the **TREATMENT** menu button to return to the TREATMENT SCREEN.

6.4.3 Setting the Level in the SN Chamber

Note

Do not lower the level in the SN chamber manually, but only as described below.

In the **BLOOD SYSTEM** menu

Touch the ▲▼ button on the Single-Needle chamber displayed on the screen.

Message: *Set the level in the SN chamber to the mark.* ▲ *Level* ▼ – *Level set* **OK** – **Abort**

Touch the ▲ *or* ▼ button to set the level to the mark of the SN chamber holder.
(The doors must be closed.)

Touch the **OK** button.

Touch the **TREATMENT** menu button to return to the TREATMENT SCREEN.

6.4.4 Aborting SN during the Treatment

In the **SINGLE-NEEDLE** menu

Touch the **Single-Needle I/O** button. (**Single-Needle I/O** indicator grey.)

Message: *Connect the arterial and the venous patient line to the respective vascular access.* – *Double-Needle* **Start** – **Abort**

Touch the **Start** button.

The Single-Needle line segment is removed.

Message: *To continue:* - Open the door - Remove the SN pump segment - Press the SN line guide again into the Single-Needle pump until a signal is sounded - Close the door.

Thereafter, the treatment is continued without Single-Needle mode.

6.4.5 Starting SN during the Treatment

In the **SINGLE-NEEDLE** menu

Touch the **Single-Needle I/O** button. (**Blood pump I/O** indicator green.)

Message: *Connect both the arterial and the venous patient line to the same vascular access. – Single-Needle* **Start** – **Abort**

Touch the **Start** button.

The Single-Needle line segment is automatically inserted in the Single-Needle pump.

Message: *Set the level in the SN chamber to the mark. ▲ Level ▼ – Level set* **OK** – **Abort**

Touch the ▲ *or* ▼ button to set the level to the mark of the SN chamber holder.
(The doors must be closed.)

Touch the **OK** button.

6.4.6 Changing the Dialysate Parameters

The TREATMENT SCREEN permits direct setting of the prescribed Na and prescribed Bic parameters.

In the **DIALYSATE MENU**

Touch the **FIow I/O** button to turn the dialysate flow on or off.

How to change dialysate parameters:
Set the desired dialysate parameters. Touch the **OK** button to confirm the values entered.
Visually check the confirmed values.

Touch the **TREATMENT** menu button to return to the TREATMENT SCREEN.

6.4.7 Changing the UF Parameters

The TREATMENT SCREEN permits direct setting of the UF parameters.

It is not necessary to touch the **UF Timer I/O** button before or after changing the UF parameters.

In the **UF MENU**

How to change UF parameters:
Set the desired UF parameters. Touch the **OK** button to confirm the values entered.
Visually check the confirmed values.

Touch the **TREATMENT** menu button to return to the TREATMENT SCREEN.

During the treatment, it is possible to increase the maximum possible UF rate in the Operator setup.

6.4.8 Sodium and UF Profiles

If sodium or UF profiles are programmed during the treatment, they will start with a delay time of 20 seconds.

- **Starting**

Automatically, if OD dark (adjustable in the Operator setup).
Touch the **UF timer I/O** button.

- **Stopping/aborting**

Touch the **UF timer I/O** button.

Message: *UF profile and Na profile were stopped. – Both profiles* **Abort** *– UF profile* **Abort** *– Treatment* **Continue**

Touch the desired button.

If no button is touched, the profiles will be stopped for a certain time (adjustable in the Operator setup).

6.4.9 Changing the Heparin Pump Parameters

In the **HEPARIN** menu

Touch the **Heparin I/O** button to turn the heparin pump on or off.

How to change heparin pump parameters:
Set the desired heparin pump parameters. Touch the **OK** button to confirm the values entered.
Visually check the confirmed values.

Touch the **TREATMENT** menu button to return to the TREATMENT SCREEN.

6.4.10 Administering Infusion Solutions

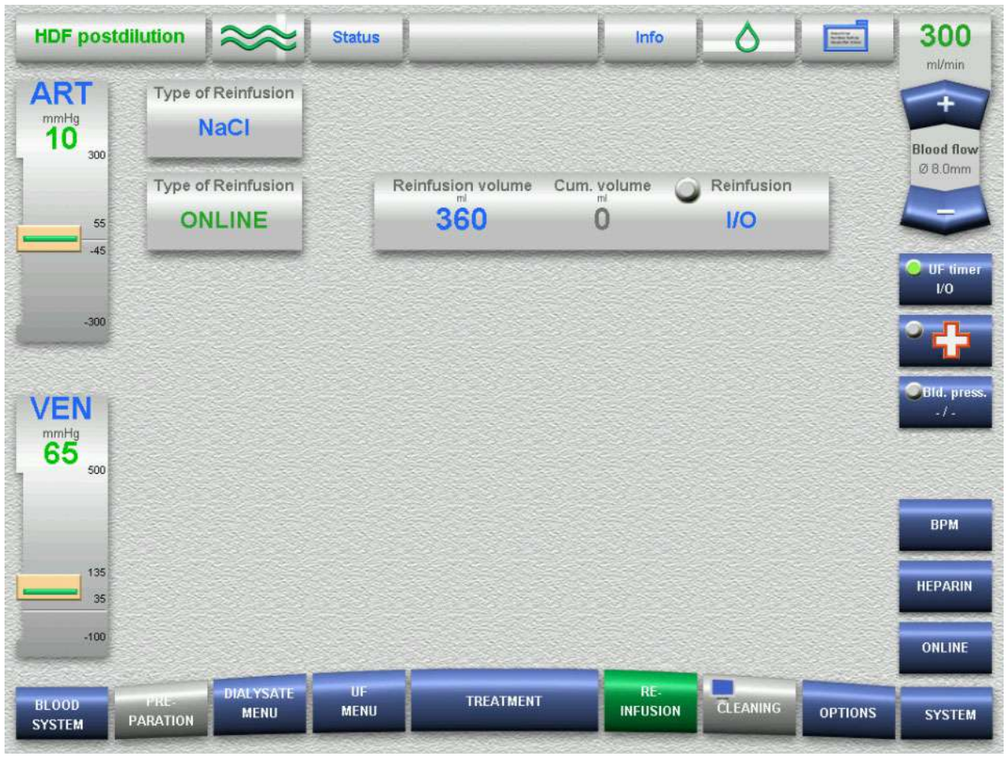
Note

When administering infusion solutions (e.g. saline), the blood may be diluted, causing the optical detector to sense light.

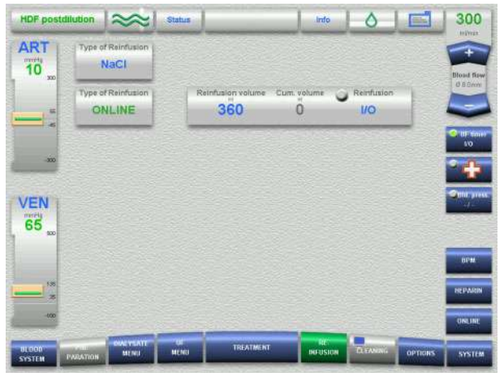
Message: *No blood detected.* – *Dialysis* **Continue** – *Reinfusion* **Start** – *Machine* **Remove lines**
The blood pump stops. The arterial/venous occlusion clamp closes. **Mute** LED is flashing. Audible signal

Touch the **Continue** button to go on with the dialysis treatment.

7 Fold-Out Sheet Reinfusion



REINFUSION SCREEN



7 Reinfusion

7.1 Reinfusion using ONLINE*plus*™

Irrespective of the treatment mode, all 5008 ONLINE*plus*™ hemodialysis systems can be operated without rinse or infusion solutions provided in NaCl bags. The fluid volumes required for preparation, bolus administration or during reinfusion will then be produced ONLINE by the 5008 hemodialysis system according to the actual requirements, thus saving both cost and time.

7.1.1 Disconnecting the Patient — Double-Needle Dialysis Using ONLINE*plus*™

- **End of treatment**

  End of treatment after achieving UF goal
  OR
  Aborting treatment with Reinfusion program

  End of treatment after achieving UF goal

  Message: *Treatment goal achieved* – *Dialysis* **Continue** – *Reinfusion* **Start**
  Mute LED is flashing. Audible signal

  Touch the **Start** button.
  The system switches automatically to the REINFUSION SCREEN.
  Perform a reinfusion

  Aborting treatment with Reinfusion program

  Touch the **REINFUSION** menu button.

  REINFUSION SCREEN

  Touch the **Reinfusion I/O** button.
  Perform a reinfusion

- **Performing reinfusion**

  REINFUSION SCREEN

  Message: *ONLINE reinfusion: Connect SafeLine to arterial patient line* – **OK** – *Reinfusion* **NaCl** – **Treatment**
  The blood pump stops. The arterial/venous occlusion clamp closes.
  Mute LED is illuminated. Audible signal

  Disconnect the SafeLine™ from the blood line and attach a recirculating adapter to the SafeLine™. Then disconnect the arterial line from the patient and connect it to the SafeLine™ via the recirculating adapter.

  Touch the **OK** button. (**Reinfusion I/O** indicator green.)
  (A change to NaCl reinfusion is possible at any time.)

The blood pump rate is returned automatically to 100 ml/min (Operator Setup setting), it can be changed at any time.

Check/set the reinfusion volume.

The reinfusion volume can be changed at any time. The reinfusion volume is automatically set to the value preselected in the Operator Setup menu.

Optical detector does not sense blood.

Message: *Blood reinfused – Reinfusion* **Continue** – *Machine* **Remove lines**
The blood pump stops. The arterial/venous occlusion clamp closes. **Mute** LED is flashing.

Touch the **Continue** button to reinfuse the residual patient blood. (**Reinfusion I/O** indicator green.)

Reinfusion volume achieved.

Message: *Reinfusion volume achieved! Reinfusion* **Continue** – *Machine* **Remove lines**
The blood pump stops. The arterial/venous occlusion clamp closes. **Mute** LED is illuminated. Audible signal

Caution

When performing a reinfusion with rinse solution (e.g.saline), remove the substituate connector on the SafeLine™ from the substituate port before selecting Remove lines.

Touch the **Remove lines** button.

Message: *Blood lines will be removed automatically. Please wait, the doors must be closed!*

The line segment is removed. Then the arterial pressure measurement unit will be opened.

Message: *Please open the doors to continue.*

Open the doors.

Message: *Please remove the blood lines completely and close the doors!*

7.1.2 Emptying the Dialyzer

Message: *Please insert the dialyzer coupling into the shunt interlock to empty the dialyzer.*

Turn the dialyzer. The dialysate inlet port must be at the upper end.
Open the shunt door.
Place the dialysate supply line (red) on the red color-coded position.
Close the shunt door.

The drain program is in progress.

Message: *The dialyzer is being emptied*.

The drain program is terminated.

Message: *The dialyzer is now empty. Please insert both dialysate couplings into the shunt interlock!*

Open the shunt door.
Place the dialysate return line (blue) on the blue color-coded position.
Close the shunt door.

7.1.3 bi*b*ag® Emptying the

Emptying of the bi*b*ag® is started automatically after emptying of the dialyzer. (Operator Setup setting)

Touch the **DIALYSATE MENU** menu button.

Touch the **Empty bags** field.

Touch the **bibag** field and accept with the **OK** button.

The drain program is in progress.

Message: *The bibag is empty and it can now be removed or – Empty bibag* **Repeat**

Remove the bi*b*ag®.

Note

Always clean the sealing area of the connector after dialysis to remove bicarbonate precipitate.

Close the bicarbonate flap.

7.1.4 Removing the Blood Lines

Caution

Discard the extracorporeal blood circuit after the treatment.

Observe the regulations for the handling of potentially contaminated materials.

Remove the blood lines. Close the doors.

Caution

It is imperative to disinfect the system after each treatment.

7.2 Reinfusion with Rinse Solution Bag

If the 5008 ONLINE*plus*™ hemodialysis system cannot be operated without rinse solution, rinse or infusion solutions provided in NaCl bags may be used instead.

7.2.1 Disconnecting the Patient — Double-Needle Dialysis with Rinse Solution Bag

- **End of treatment**

End of treatment after achieving UF goal
OR
Aborting treatment with Reinfusion program

End of treatment after achieving UF goal

Message: *Treatment goal achieved* – *Dialysis* **Continue** – *Reinfusion* **Start**
Mute LED is flashing. Audible signal

Touch the **Start** button.
The system switches automatically to the REINFUSION SCREEN.
Perform a reinfusion

Aborting treatment with Reinfusion program

Touch the **REINFUSION** menu button.

REINFUSION SCREEN

Touch the **Reinfusion I/O** button.
Perform a reinfusion

- **Performing reinfusion**

REINFUSION SCREEN

Message: *Connect a bag of NaCl. Start reinfusion* - **OK** - **Treatment**
The blood pump stops. The arterial/venous occlusion clamp closes.
Mute LED is illuminated. Audible signal

Disconnect the arterial patient access line and connect it to the reinfusion solution. Break the cone of the reinfusion bag.

Touch the **OK** button. (**Reinfusion I/O** indicator green.)

The blood pump rate is returned automatically to 100 ml/min (Operator Setup setting), it can be changed at any time.

Check/set the reinfusion volume.

The reinfusion volume can be changed at any time. The reinfusion volume is automatically set to the value preselected in the Operator Setup menu.

Optical detector does not sense blood.

Message: *Blood reinfused – Reinfusion* **Continue** – *Machine* **Remove lines**
The blood pump stops. The arterial/venous occlusion clamp closes. **Mute** LED is flashing.

Touch the **Continue** button to reinfuse the residual patient blood. (**Reinfusion I/O** indicator green.)

Reinfusion volume achieved.

Message: *Reinfusion volume achieved! Reinfusion* **Continue** – *Machine* **Remove lines**
The blood pump stops. The arterial/venous occlusion clamp closes. **Mute** LED is illuminated. Audible signal

Touch the **Remove lines** button.

Message: *Blood lines will be removed automatically. Please wait, the doors must be closed!*

The line segment is removed. Then the arterial pressure measurement unit will be opened.

Message: *Please open the doors to continue.*

Open the doors.

Message: *Please remove the blood lines completely and close the doors!*

7.2.2 Emptying the Dialyzer

Message: *Please insert the dialyzer coupling into the shunt interlock to empty the dialyzer.*

Turn the dialyzer. The dialysate inlet port must be at the upper end.
Open the shunt door.
Place the dialysate supply line (red) on the red color-coded position.
Close the shunt door.

The drain program is in progress.

Message: *The dialyzer is being emptied*.

The drain program is terminated.

Message: *The dialyzer is now empty. Please insert both dialysate couplings into the shunt interlock!*

Open the shunt door.
Place the dialysate return line (blue) on the blue color-coded position.
Close the shunt door.

7.2.3 bi*b*ag® Emptying the

Emptying of the bi*b*ag® is started automatically after emptying of the dialyzer. (Operator Setup setting)

Touch the **DIALYSATE MENU** menu button.

Touch the **Empty bags** field.

Touch the **bibag** field and accept with the **OK** button.

The drain program is in progress.

Message: *The bibag is empty and it can now be removed or – Empty bibag* **Repeat**

Remove the bi*b*ag®.

Note

Always clean the sealing area of the connector after dialysis to remove bicarbonate precipitate.

Close the bicarbonate flap.

7.2.4 Removing the Blood Lines

Caution

Discard the extracorporeal blood circuit after the treatment.

Observe the regulations for the handling of potentially contaminated materials.

Remove the blood lines. Close the doors.

Caution

It is imperative to disinfect the system after each treatment.

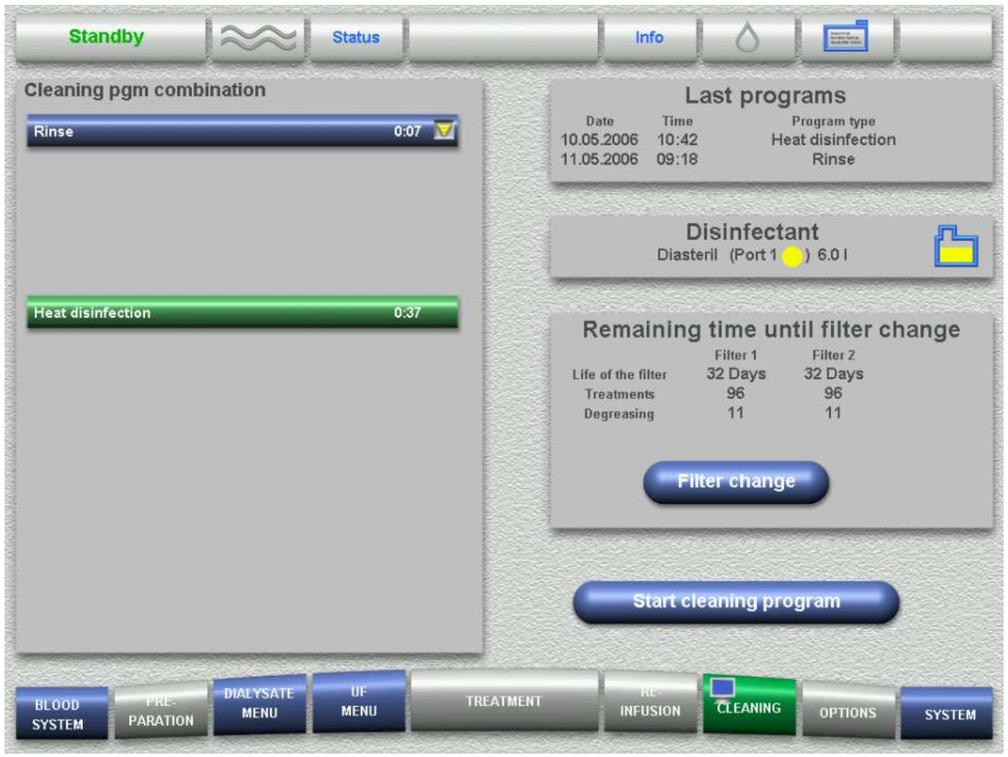
7.3 Single-Needle (Option) Reinfusion Using ONLINE*plus*™

The procedures for end of treatment after achieving the UF goal or aborting treatment with reinfusion program are described in the chapters mentioned below (see chapter 7.1 , page 7-1).

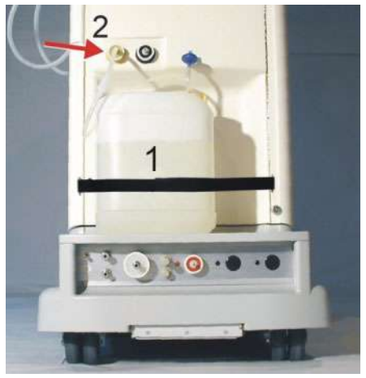
7.4 Single-Needle (Option) Reinfusion with Rinse Solution Bag

The procedures for end of treatment after achieving the UF goal or aborting treatment with reinfusion program are described in the chapters mentioned below (see chapter 7.2 , page 7-5).

8 Fold-Out Sheet Cleaning

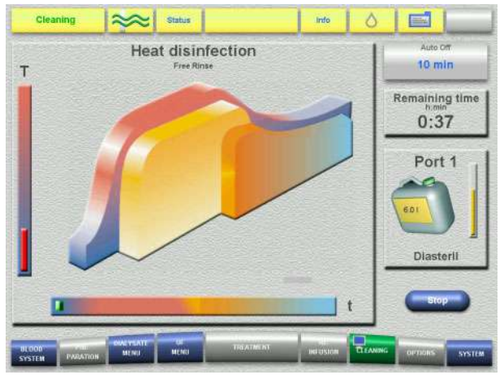


Connecting the disinfectant container



CLEANING SCREEN

Program run graphic (e.g. Diasteril)



8 Cleaning

8.1 Basic Requirements

The following basic requirements must be fulfilled before the start of a cleaning program:
- The dialysate supply line (red) is in the shunt interlock.
- The dialysate return line (blue) is in the shunt interlock.
- The shunt door is closed.
- The concentrate suction tube (red) is connected to the rinse chamber.
- The concentrate flap is closed.
- The bicarbonate suction tube (blue) is connected to the rinse chamber.
- The bicarbonate flap is closed.
- The indi*b*ag® flap must be closed.
- The optical detector does not sense blood.
- Only with ONLINE*plus*™. The substituate port and the rinse port must be closed.

Any failure to comply with the basic requirements will be indicated by a message on the display.

Caution

Contact of the DIASAFE®*plus* with organic solvents can affect the properties of the housing material, potting compound and the capillaries. Safe function can therefore not be ensured and the manufacturer shall no longer have any liability. (see DIASAFE®*plus* package insert.)

8.2 Connecting the Disinfectant Container

Caution

When using disinfectants, observe the manufacturer's instructions for use.

When connecting the disinfectant container also observe the following criteria:
– The containers must be provided with a ventilation opening.
– The coding of the disinfection connectors.
– The disinfectant must match the respective disinfection program.
– Different disinfectants may not be mixed with each other.

Prior to the use of disinfectants other than those listed in chapter 12 "Consumables", make sure these are efficient and are compatible with the materials affected in the hemodialysis system.
Improper use of disinfectants (concentration, temperature range, dwell time) may cause damage to the hemodialysis system.

The disinfection connectors are coded. The following lists show the coding of the disinfection connectors, the disinfectants to be used and the appropriate disinfection programs.

Left disinfection connector, yellow:

Disinfectant	Disinfection program	Temperature
Citrosteril®	Heat disinfection	85 °C
Diasteril®	Heat disinfection	85 °C
Puristeril® 340	Cold disinfection	37 °C
Puristeril*plus*	Cold disinfection	37 °C

Right disinfection connector, black:

Disinfectant	Disinfection program	Temperature
Sporotal® 100	Degreasing/ Cold disinfection	37 °C

Place the appropriate disinfectant container in its position on the rear of the machine and connect the container.

Connect the disinfectant container (e.g.: Citrosteril® container).
Place the Citrosteril® container (1) on the rack. Connect the Citrosteril® container to the yellow port (2) on the left.

8.3 Starting a Cleaning / Disinfection Program

Caution

Cleaning programs in progress involve the following risks:
– Heat disinfection (risk of scalding)
– Heat disinfection (risk of scalding and caustic burning)
– Disinfection (risk of caustic burning)

These risks are particularly present on the following accessible machine parts:
– Concentrate and bicarbonate flap
– Dialysate lines and dialysate connectors
– Vent tubing (rear of system)
– Water drain
– Filter 1,
  Filter 2 (only with ONLINE*plus*™)
  if the door of the dialysate filter chamber is open
– Substituate port and rinse port (only with ONLINE*plus*™)

These risks can be present as long as the respective cleaning program is not yet completed.

Note

Flow alarms during cleaning programs will increase the length of the cleaning program at least by the time of the alarm.

The count-down times shown during the cleaning programs are calculated values. This time may vary depending on the ambient conditions.

Note

The DIASAFE®*plus* may be cleaned a maximum of 11 times with Sporotal® 100 within its filter life. The cleaning procedures with Sporotal® 100 are monitored and indicated by the hemodialysis system.

CLEANING SCREEN

Select the desired cleaning program.

Touch the **Start cleaning program** button.

The color of the header bar is yellow for the duration of the cleaning program.

Caution

While the cleaning programs are in progress, it is not permitted to connect the dialysate lines to the dialyzer.

Depending on the settings in the Operator setup, it is also possible to start the cleaning programs automatically.

8.4 Aborting a Cleaning / Disinfection Program

Caution

Do not turn the hemodialysis system off with the **On/Off** monitor key while a cleaning program is in progress.

If the hemodialysis system has to be turned off during a cleaning program due to a technical defect, press the **On/Off** monitor key for approx. 5 seconds.

Caution

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.

Note

If a disinfection program is aborted during the disinfection phase, the complete disinfection program must be performed again.

If a disinfection program is aborted during the mandatory rinse phase, the mandatory rinse time will start again.

In both cases it is, however, possible to restart a different disinfection program.

CLEANING SCREEN

Touch the **Stop** button.

Message: *Abort cleaning program?* – **Yes** – **No**

Touch the **Yes** button to abort the program.

Touch the **No** button to continue the program.

If no button is touched within approx. 10 seconds, the cleaning program will be continued automatically.

8.5 Cleaning / Disinfection Program Complete

SELECTION SCREEN

If, in the Operator setup, in the "Cleaning" submenu, "Audible info" is set to "Yes", the system will signal the end of a cleaning program or a disinfection program for approx. 30 seconds as follows:
Message: *Cleaning program successfully completed!* – **OK**
Audible info
The SELECTION SCREEN will then be displayed.

8.6 Checking for Residual Disinfectant

Caution

Following a disinfection the system must be checked for presence of residual disinfectant, e.g. for
– Puristeril® 340, Puristeril® *plus*: potassium-iodide-starch paper,
– Sporotal® 100: potassium-iodide-starch paper,
– Diasteril®: determination of the pH

Observe the "use by" date of the indicator paper.

If the test shows a residual concentration, or in the event of a positive pH reaction (yellow color pH ≤ 4.1), restart a rinse program. After completion of the rinse program the system once more must be checked for presence of residual disinfectant.

8.7 Surface Cleaning / Disinfection

● **Cleaning / disinfecting the hemodialysis system**

After the treatment, the exterior of the hemodialysis system and the options used must be cleaned and disinfected with a cleaning and disinfecting agent. The active substance concentration must not exceed <5% for amphoteric surfactants and <48% for alcohol. (See Consumables.) Do not use any sharp objects for cleaning.

Caution

Only for ONLINE*plus*™:
Do not open the substituate port and the rinse port when cleaning the surface. If this instruction is not complied with, a disinfection program must be performed after cleaning the surface.

Applies to the venous pressure ports and SN (option):
Do not spray into the venous pressure ports and SN (option).

Only for BTM (option) and BVM (option):
The surface may only be cleaned with a damp cloth. Do not spray into the opened measuring heads.

● **Cleaning the screen**

Before cleaning the screen:
Touch the **Monitor Symbol** button for approx. 3 seconds. (The screen will be "frozen".)

After cleaning the screen:
Touch the **Monitor Symbol** button for approx. 1 second. (Normal screen operation is restored.)

The screen will be "unfrozen" if a warning or an alarm occurs.

8.8 Turning the Hemodialysis System Off

Press the **On/Off** key for approx. 3 seconds.

Turn the hemodialysis system off!

The **On/Off** LED is flashing (standby indicator).

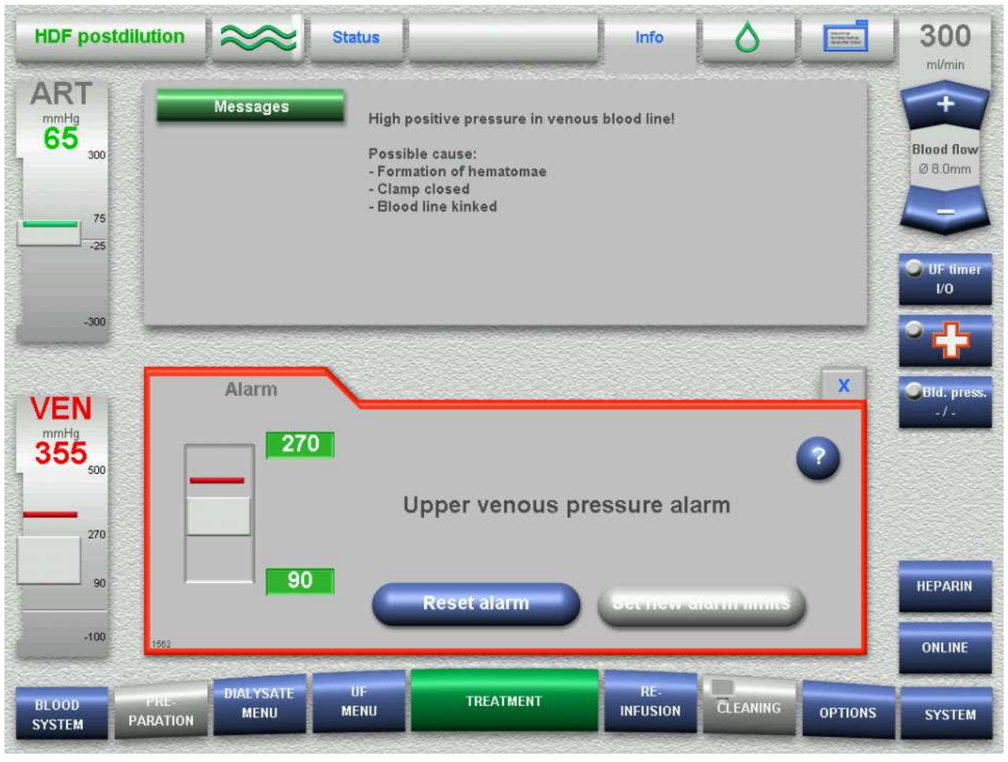
Close the water supply.

Automatic turn-off of the hemodialysis system on completion of the cleaning program:
While a cleaning program is performed the Auto Off field is displayed.
The Auto Off field is a toggle field:

– Auto Off toggled off
– Auto Off Time after which the machine will turn itself off (programmable in the Technician's Setup).

If a time has been defined for Auto Off, the hemodialysis system will turn itself off automatically after the programmed time.

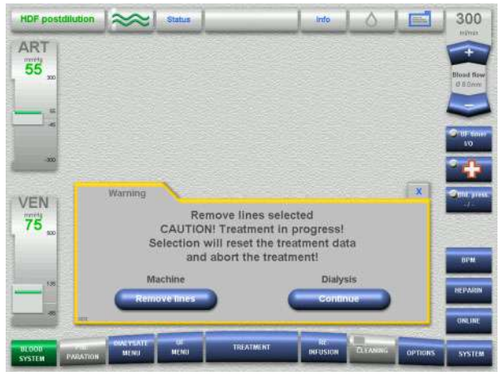
Fold-Out Sheet
9 Alarm processing



Informational message

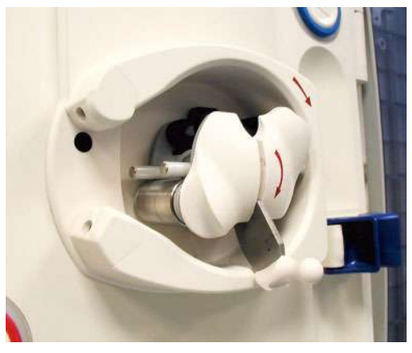
Manually opening the arterial pressure measurement unit

Warning message



Alarm message (Info window at the top opened)

Flipping the handle outward



9 Alarm Processing

9.1 Messages (Information/Warning/Alarm)

The alarm messages are organized in three categories.
– Info (window with grey frame)
– Warning (window with yellow frame)
– Alarm (window with red frame)

Different tones are assigned to the messages (information/warning/alarm). These can be changed in the technician's Setup menu.
For identification purposes, the BPM option is provided with a separate audible warning tone.

Up to 3 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 operator 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.

If the problem cannot be corrected, call the service.

9.2 Air Detected Below the Venous Bubble Catcher

- **To be observed before removing air**

Presence of air below the venous bubble catcher is indicated by an audible alarm. The following message will be displayed: *Air detected below the venous bubble catcher!*

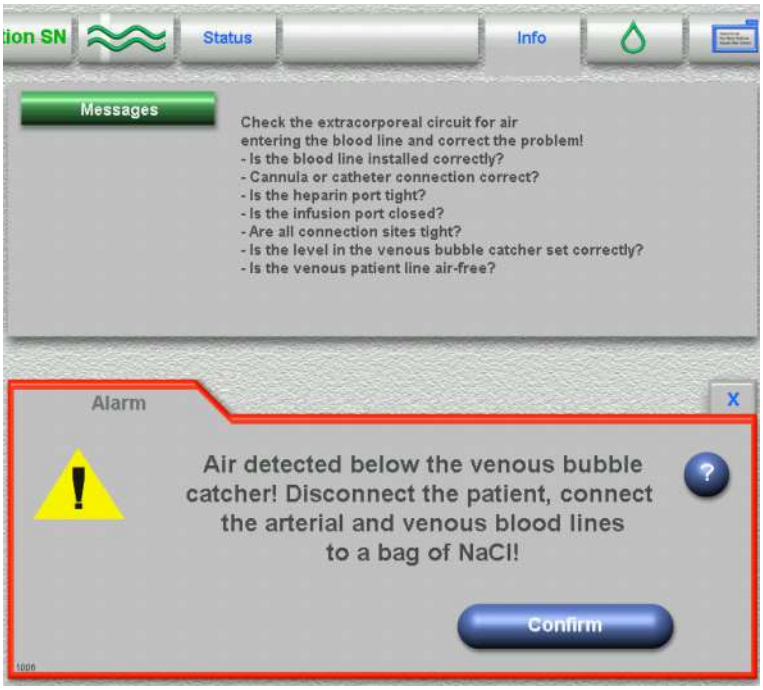
Caution

To prevent infusion of air which presents a hazard for the patient, the following instructions must be observed:
When removing air, the instructions displayed by the hemodialysis system must be strictly followed. The operator is responsible that the instructions are carried out correctly.
In addition, detailed descriptions can be displayed in the associated Info window by touching the **?** button.

If the venous pressure is > 100 mmHg, it must be reduced on the venous bubble catcher using a syringe until the system displays the next instruction.

During the air removal procedure the blood pump delivery rate is automatically reduced to 50 ml/min. The blood pump delivery rate can be increased as required to improve the separation of air and micro bubbles.

● Air removal procedure

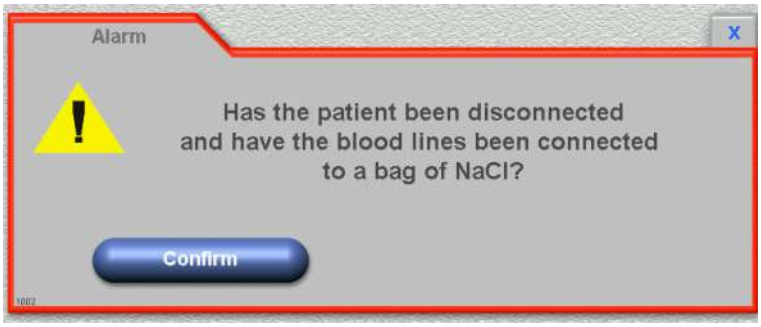


Alarm message

Info window (can be displayed by touching the **?** button)

Follow the instructions.

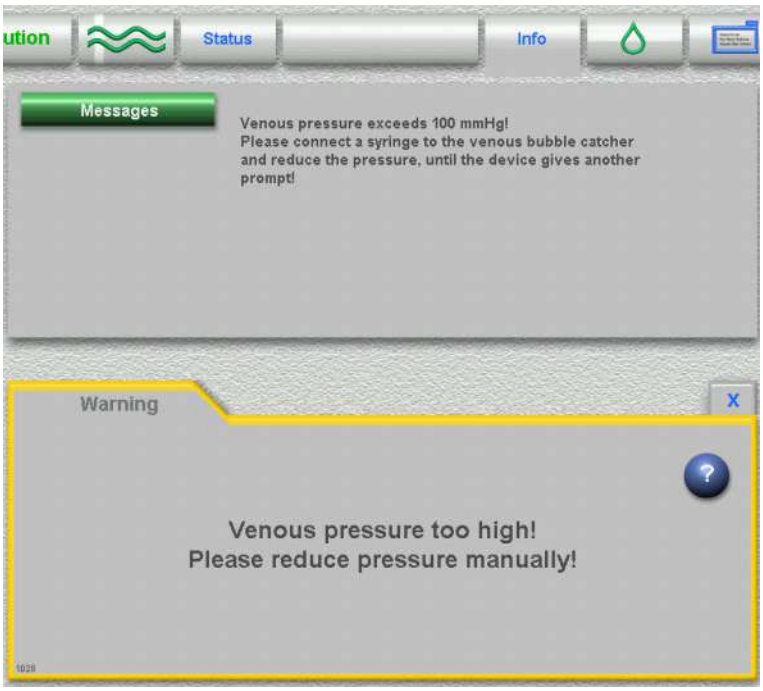
Touch the **Confirm** button.



Alarm message

Safety prompt

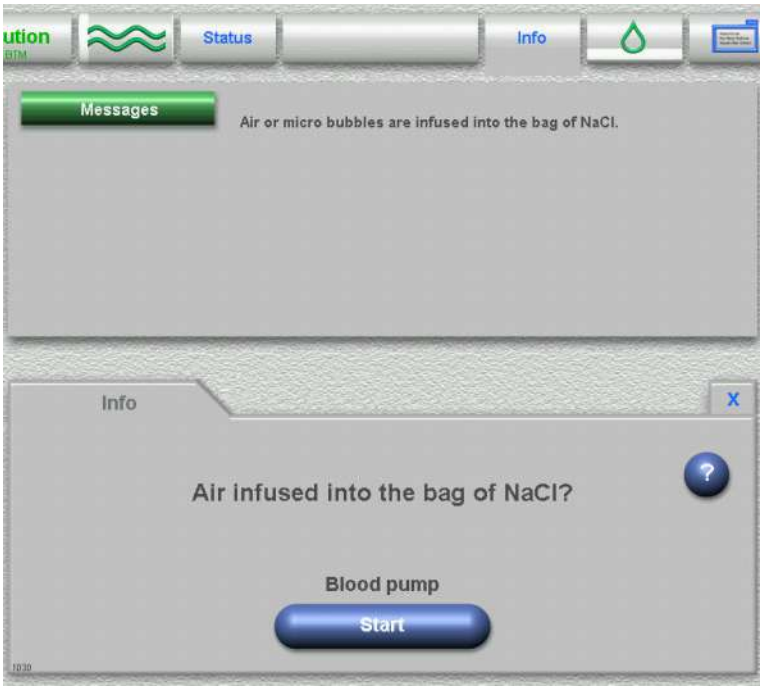
After the instructions have been carried out, Touch the **Confirm** button.



Informational message
(Will only be displayed if the venous pressure is > 100 mmHg.)

Info window (can be displayed by touching the **?** button)

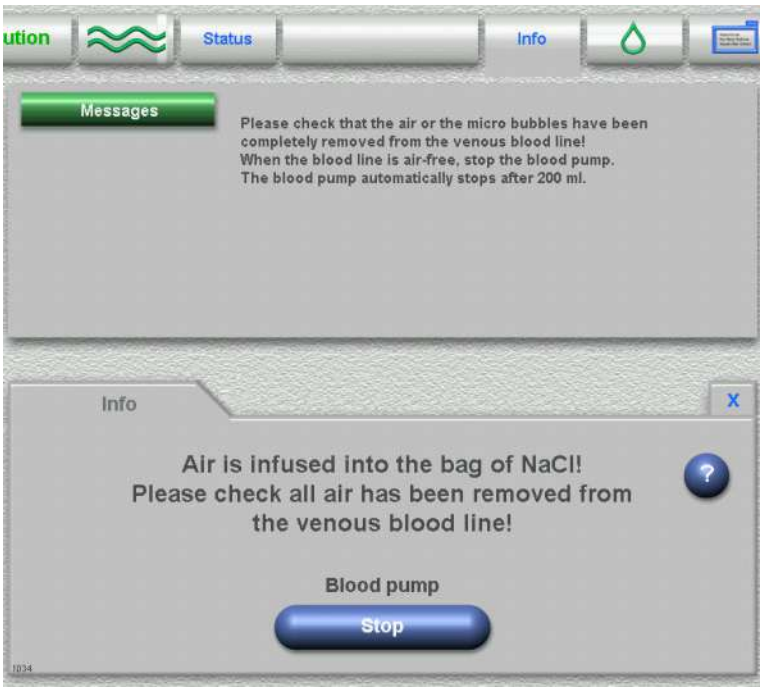
The next message will automatically be displayed if the venous pressure is < 100 mmHg.



Informational message

Info window (can be displayed by touching the **?** button)

Touch the **Start** button.

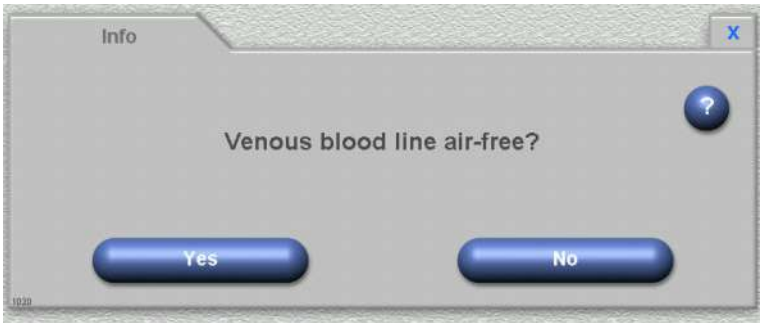


Informational message

Info window (can be displayed by touching the **?** button)

The blood pump will automatically stop after 200 ml.

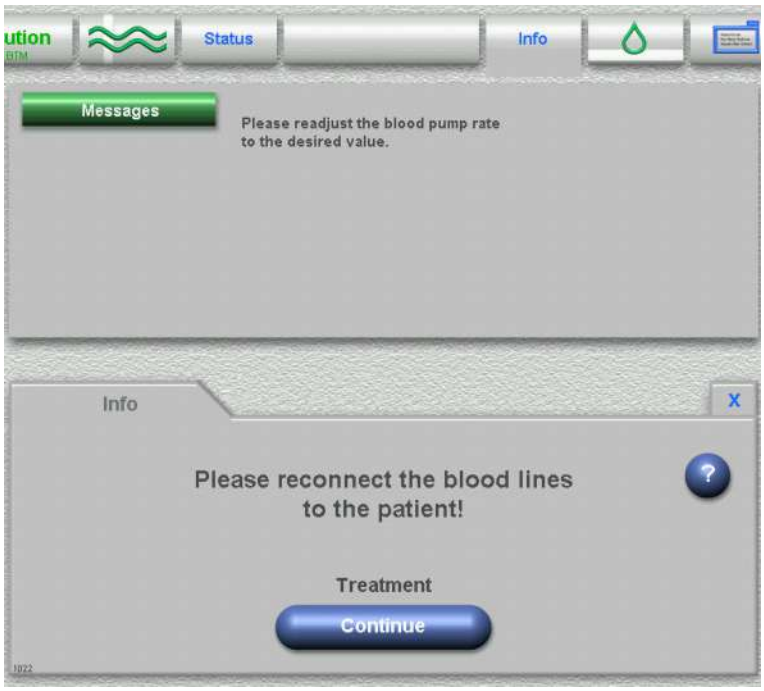
If no air is present in the system, the blood pump can also be stopped before this volume is reached by touching the **Stop** button.



Informational message

Touch the **Yes** button if all air has been removed from the venous tubing system.

Touch the **No** button if air is still present in the venous tubing system.
Automatically the previous info message is then displayed.



Informational message

Info window (can be displayed by touching the **?** button)

Follow the instructions.

Touch the **Continue** button.

The blood pump will start with the delivery rate displayed. Check the delivery rate and change, if necessary.

9.3 Micro Bubbles Detected Below the Venous Bubble Catcher

- **To be observed before removing micro bubbles**

Presence of micro bubbles below the venous bubble catcher is indicated by an audible alarm. The following message will be displayed: *Micro bubbles detected below the venous bubble catcher!*

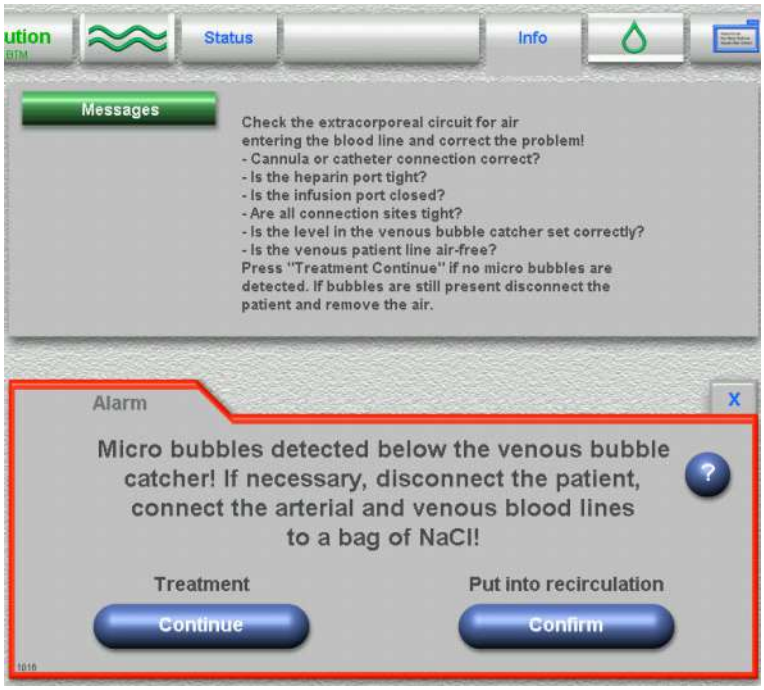
Caution

To prevent infusion of air which presents a hazard for the patient, the following instructions must be observed:
When removing air, the instructions displayed by the hemodialysis system must be strictly followed. The operator is responsible that the instructions are carried out correctly.
In addition, detailed descriptions can be displayed in the associated Info window by touching the **?** button.

If the venous pressure is > 100 mmHg, it must be reduced on the venous bubble catcher using a syringe until the system displays the next instruction.

During the air removal procedure the blood pump delivery rate is automatically reduced to 50 ml/min. The blood pump delivery rate can be increased as required to improve the separation of air and micro bubbles.

- **Alarm message Micro bubbles detected below the venous bubble catcher!**



Alarm message

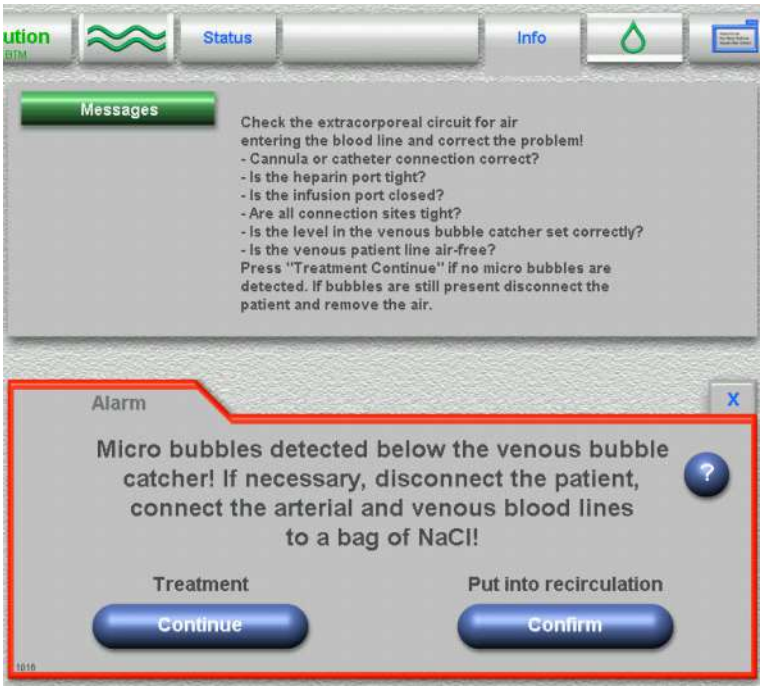
Info window (can be displayed by touching the **?** button)

Touch the **Continue** button and observe the following section "Overriding the Micro bubbles alarm message".

OR

Touch the **Confirm** button and observe the following section "Micro bubbles removal procedure".

● Overriding the Micro bubbles alarm message



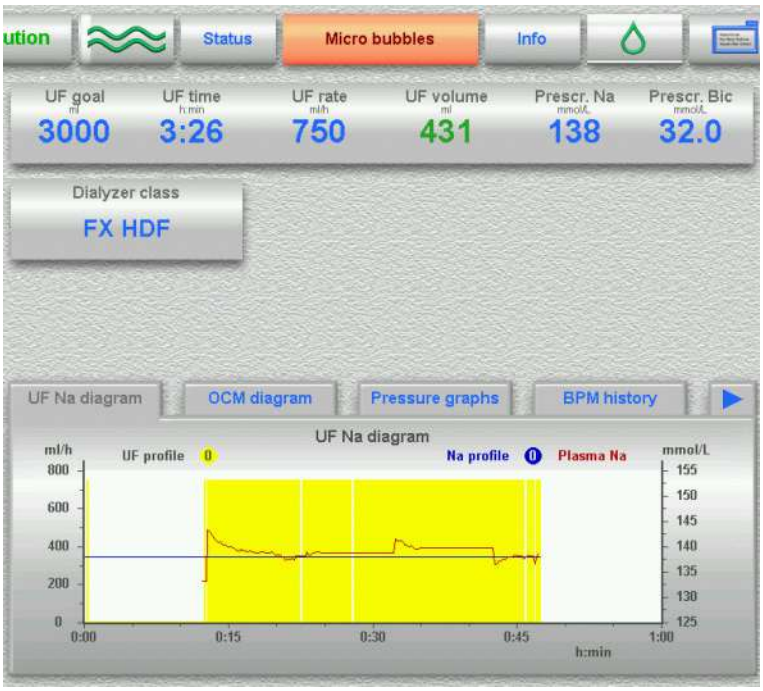
Alarm message

Info window (can be displayed by touching the **?** button)

Follow the instructions.

Touch the **Continue** button if no micro bubbles are detected.

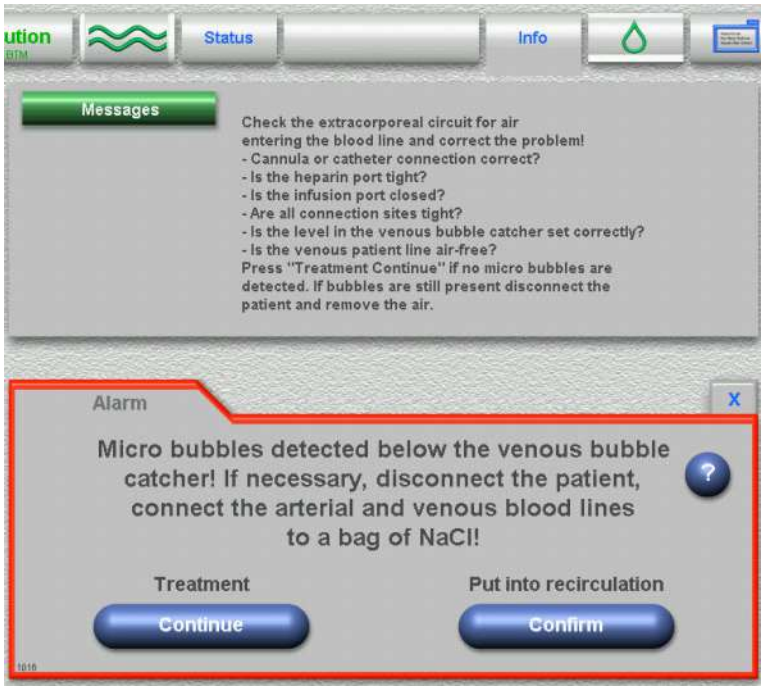
It is possible to override the alarm messages 5 times only during a treatment, using the **Continue** button. If micro bubbles continue to be detected, remove the air as described in the chapter mentioned below (see chapter 9.2 , page 9-2).



Micro bubbles will be displayed in the Message button field.

The alarm message will be overridden for the time set in the Technician's Setup.

- **Micro bubbles removal procedure**

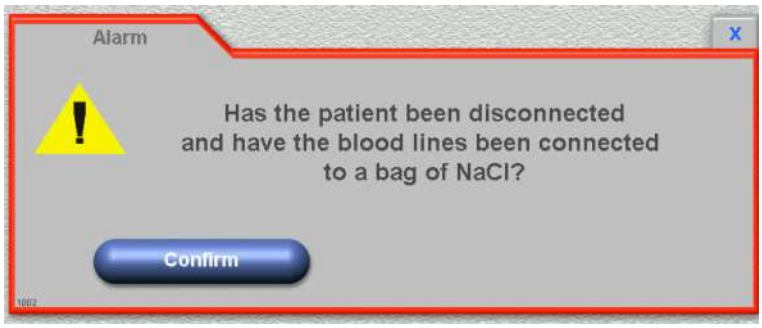


Alarm message

Info window (can be displayed by touching the **?** button)

Follow the instructions.

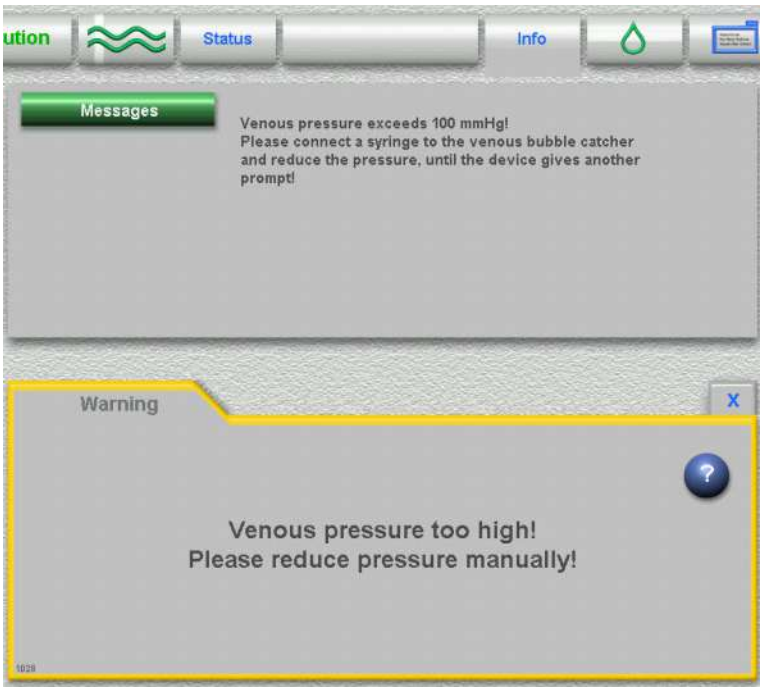
Touch the **Confirm** button.
Then follow the further instructions.



Alarm message

Safety prompt

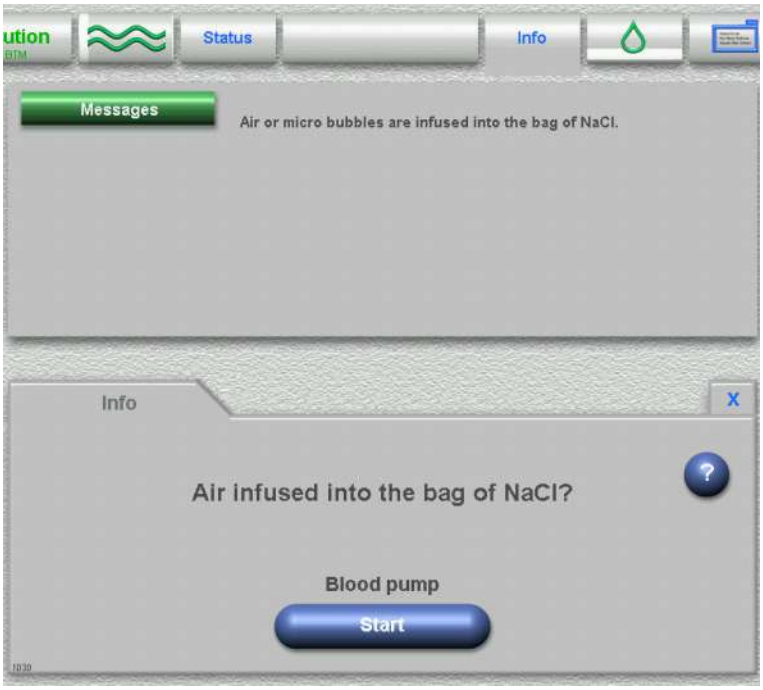
After the instructions have been carried out,
Touch the **Confirm** button.



Informational message
(Will only be displayed if the venous pressure is > 100 mmHg.)

Info window (can be displayed by touching the **?** button)

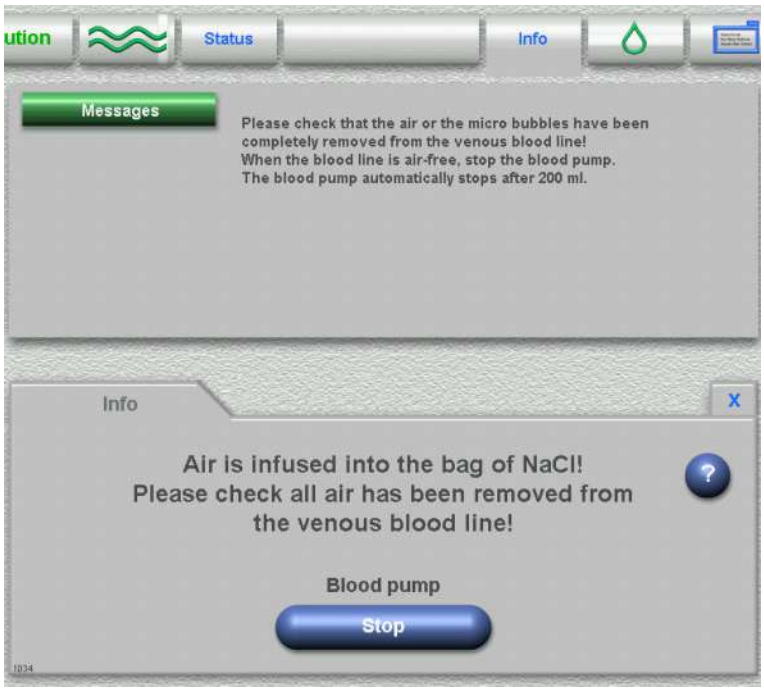
The next message will automatically be displayed if the venous pressure is < 100 mmHg.



Informational message

Info window (can be displayed by touching the **?** button)

Touch the **Start** button.

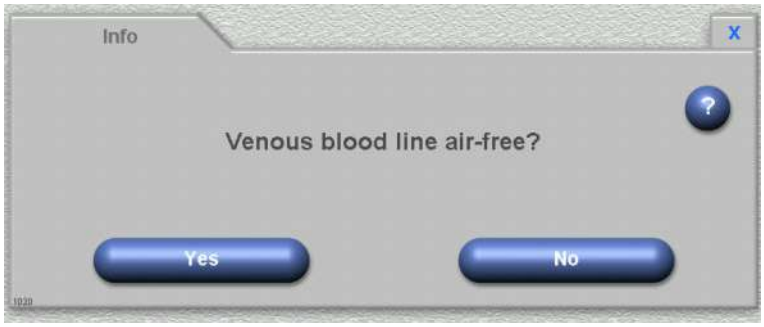


Informational message

Info window (can be displayed by touching the **?** button)

The blood pump will automatically stop after 200 ml.

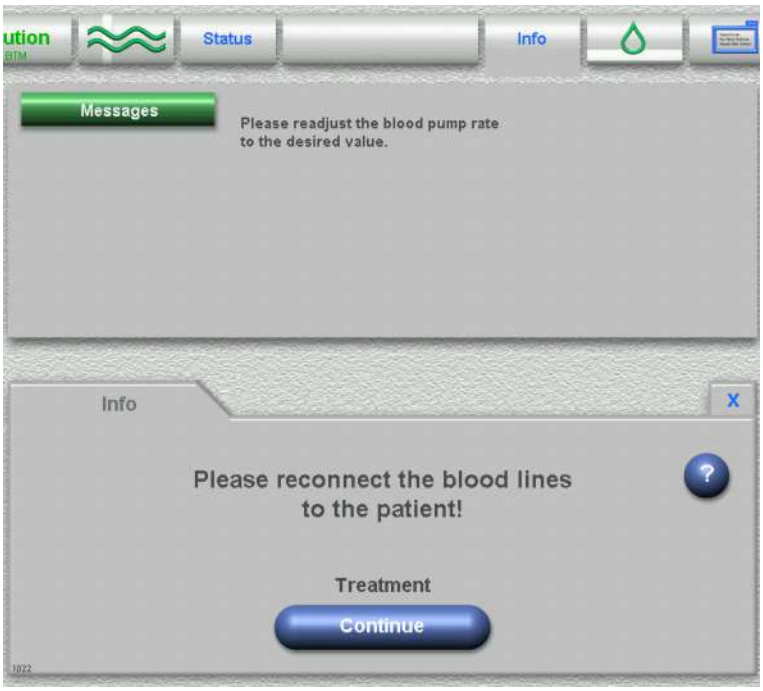
If no air is present in the system, the blood pump can also be stopped before this volume is reached by touching the **Stop** button.



Informational message

Touch the **Yes** button if all air has been removed from the venous tubing system.

Touch the **No** button if air is still present in the venous tubing system.
Automatically the previous info message is then displayed.



Informational message

Info window (can be displayed by touching the **?** button)

Follow the instructions.

Touch the **Continue** button.

The blood pump will start with the delivery rate displayed. Check the delivery rate and change, if necessary.

9.4 Management of Alarm Limits

The 5008 hemodialysis system is provided with an automatic management of alarm limits. It allows avoiding false alarms, which might for example be caused by a movement of the patient.
The preset asymmetric venous standard alarm limits lead to a sensitive reaction in case of a venous pressure alarm.
The pressure monitoring sensitivity can additionally be individually adjusted by taking the following steps:

– Setting the alarm window width to a range from min. 40 mmHg to max. 200 mmHg.
– Setting the alarm window so that it is asymmetric or centered to the current pressure value.

9.5 Blood Leak

● **Dimness warning**

Message: *Blood leak detector: dimness warning – Desired: > 2000 mV – Actual XXXX mV* – **Confirm**

Cause:
Blood leak detector detects dimness.
Dialysate side primed in dialysis mode.
High deaeration caused by high ultrafiltration rate.
Dialysate drain line not tightly connected.
Grease or calcium deposits.

Touch the **Confirm** button. The dialysis treatment may be terminated in the usual manner.

If the dimness warning was caused by calcium and/or grease deposits, perform the usual disinfection program after the treatment.

● **Blood leak**

Message: *Blood leak!* – **Override**

Cause:
Dialyzer membrane rupture.

Touch the **Override** button.
Blood leak override will be displayed in the Message button field.

Override time: 2 minutes each time the button is touched.
The alarm indicator will stop lighting if the leak is closed.
If not, replace the dialyzer.

● **Severe blood leak**

Message: *Severe blood leak!* – **Override**

Cause:
Severe dialyzer membrane rupture.

Touch the **Override** button.
Blood leak override will be displayed in the Message button field.

Override time: 1.5 minutes each time the button is touched.
The alarm indicator will stop lighting if the leak is closed.
If not, replace the dialyzer.

9.6 Conductivity

- **Conductivity alarm**

Message: *Conductivity alarm*

Cause:
The dialysate conductivity value is out of range.

Remedy:
Verify the concentrate side.
Correct the problem causing the alarm.

9.7 Manually Opening the Arterial Pressure Measurement Unit

Relieve the pressure in the blood lines.

Connect a syringe to the upper left port in the dialysate filter chamber.
Use a syringe to open the arterial pressure measurement unit.

9.8 Power Failure (Outage)

- **Power failure and battery operation**

In case of a power failure, the following message will be displayed: *Power failure – System is battery-operated.* Acknowledge the audible alarm. (UF pump stops, substituate pump stops, dialysate flow off.)

After power return, the message disappears.
(Dialysate alarms will be suppressed for further 2 minutes approximately.)

- **Power failure and depleted battery**

Caution

Emergency operation:
Perform a manual reinfusion
To return the blood to the patient, use the handle integrated in the pump rotor. For manual reinfusion, remove the venous patient access line from the venous occlusion clamp. Visually check the line for air (emergency operation)!

Direction of rotor rotation:
When using the handle, please observe which way the rotor rotates. Only rotate clockwise as shown on the pump housing.

Short-term power failure and depleted battery

Maintain the extracorporeal blood circuit.

Flip the handle outwards. Pull out the knob on the handle tray. Only rotate the handle clockwise.

Remove the venous patient connection line from the venous occlusion clamp. Visually check the line for air.

After power return:
Flip the handle inwards. Re-insert the venous patient connection line into the venous occlusion clamp.

Long-term power failure and depleted battery

If power supply is not available for a prolonged period of time, initiate reinfusion with rinse solution.

Disconnect the arterial patient connection and connect it to the rinse solution bag.

Flip the handle outwards. Pull out the knob on the handle tray. Only rotate the handle clockwise.

Remove the venous patient connection line from the venous occlusion clamp. Visually check the line for air.

Manually return the blood.

Remove the venous patient connection after manual blood return.

Close the clamps on the blood lines.

Manually remove the blood lines. Manually open the arterial pressure measurement unit.

9.9 Screen Failure

- **Screen failure, no screen reaction**

Caution

Touch the **Blood system Stop** button (red).
The pumps will be stopped.
(blood pump, substituate pump, optionally Single-Needle pump)

Emergency operation:
Perform a manual reinfusion
To return the blood to the patient, use the handle integrated in the pump rotor. For manual reinfusion, remove the venous patient access line from the venous occlusion clamp. Visually check the line for air (emergency operation)!

Direction of rotor rotation:
When using the handle, please observe which way the rotor rotates. Only rotate clockwise as shown on the pump housing.

Reinfusion with rinse solution.

Disconnect the arterial patient connection and connect it to the rinse solution bag.

Flip the handle outwards. Pull out the knob on the handle tray. Only rotate the handle clockwise.

Remove the venous patient connection line from the venous occlusion clamp. Visually check the line for air.

Manually return the blood.

Remove the venous patient connection after manual blood return.

Close the clamps on the blood lines.

Manually remove the blood lines. Manually open the arterial pressure measurement unit.

- **Screen failure, screen dark or display distorted**

Caution

Touch the **Blood system Stop** button (red).
The pumps will be stopped.
(blood pump, substituate pump, optionally Single-Needle pump)

Reinfusion with rinse solution.

All monitoring systems are active.

Disconnect the arterial patient connection and connect it to the rinse solution bag.

Touch the **Blood system Start** button (green).

The blood pump delivery rate will be limited to the reinfusion rate. The alarm limits will be set around the actual values.

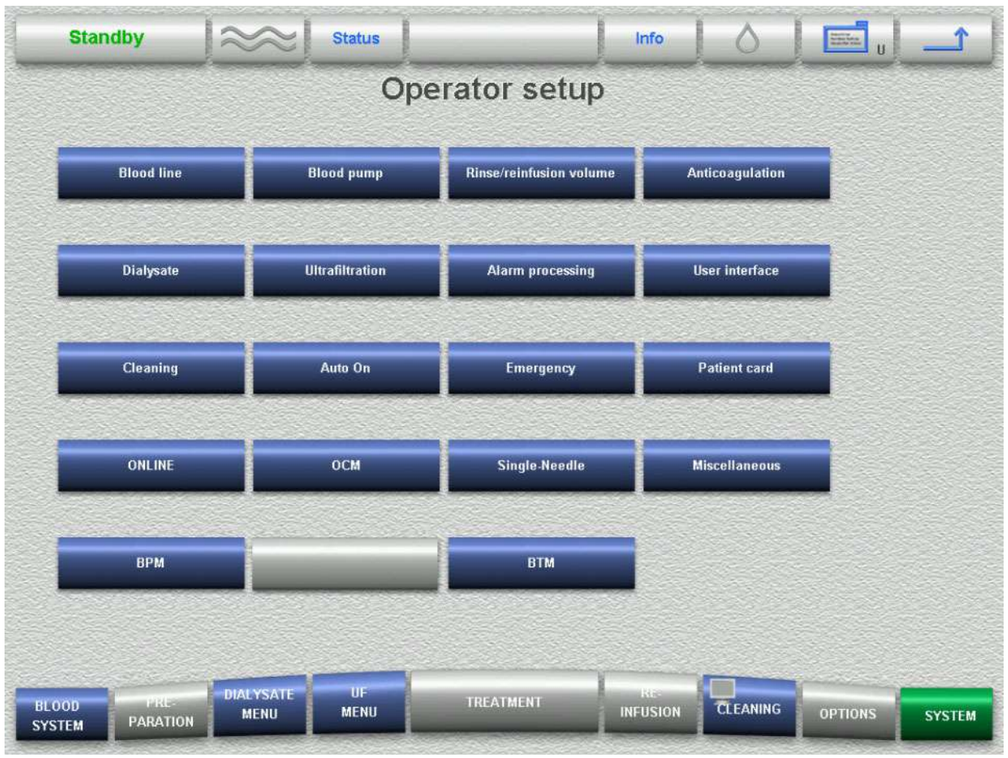
Perform a reinfusion.

Remove the venous patient connection after blood return.

Close the clamps on the blood lines.

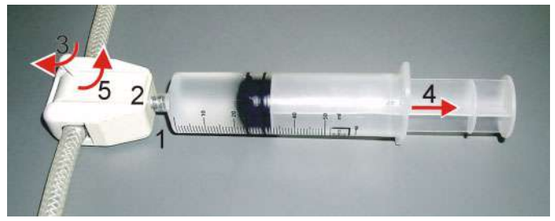
Manually remove the blood lines. Manually open the arterial pressure measurement unit.

Fold-Out Sheet
10 Other Functions

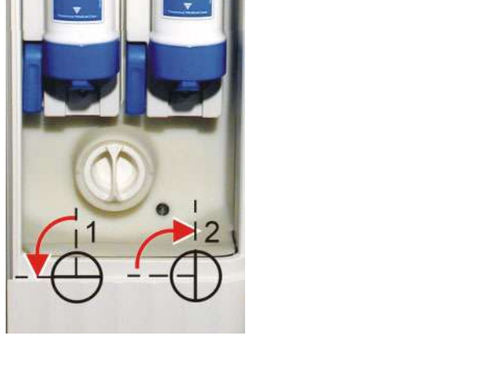


SYSTEM SCREEN

Collecting a sample

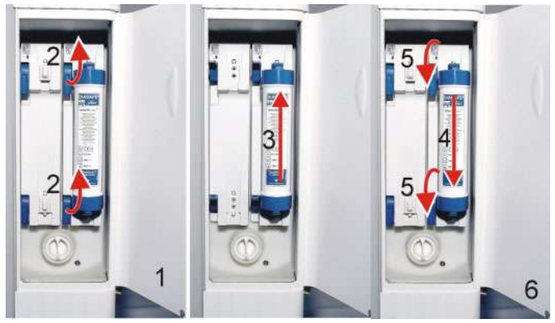


SETUP SCREEN (Operator setup)



BLOOD SYSTEM SCREEN

Changing the DIASAFE®*plus*



Cleaning the dialysate particle filter

10 Other Functions

10.1 SYSTEM SCREEN Settings

- **Selecting the SYSTEM SCREEN settings**

  The system is turned on.

  Touch the **SYSTEM** menu button.
  Select the settings in the **SYSTEM** menu.

- **Adjusting the SYSTEM SCREEN settings**

  Select the desired function.
  Make changes, if required. Save with **OK**.
  Select default values with **FMC Logo**.

- **SYSTEM SCREEN settings – overview**

Sub-item		Default value	Value range	Resolution	Selectable options
	Date	Day, month, year (Adjustable only with ServiceCard)	–	–	–
	Time	–	00:00 to 23:59	0:01	–
	Brightness	0 (not adjustable)	–	–	–
	Loudness	6	1 to 9	1	–
	Graphic time scale	Auto (The last time segments of the respective treatment will be displayed.)	–	–	Auto 10 min 20 min 30 min 1 h 2 h 4 h 6 h 10 h

10.2 Operator Setup

- **Selecting the Operator setup**

  The system is turned on.
  Insert the UserCard.

  Touch the **SYSTEM** menu button.
  In the **SYSTEM** menu touch the **OPERATOR SETUP** button.

- **Adjusting the settings in the Operator setup**

  In the **OPERATOR SETUP** menu

  Select the desired function.
  Make changes, if required. Save with **OK**.
  Select default values with **FMC Logo**.

- **Blood line**

Sub-item		Default value	Value range	Resolution	Selectable options
	Blood line	AV Set 5008	–	–	–

- **Blood pump**

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

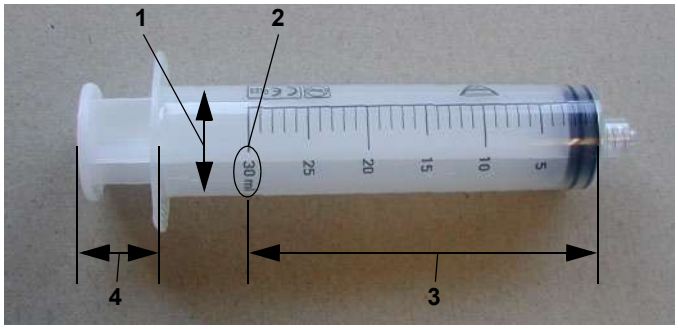
- **Rinse/reinfusion volume (only in case of preparation with NaCl bags.)**

Sub-item		Default value	Value range	Resolution	Selectable options
Preparation (NaCl)					
	Rinse vol.	500 ml	500 to 5000 ml	100 ml	–
	UF rinse vol. (Currently not adjustable.)	(0 ml)	(0 to 5000 ml)	(100 ml)	(–)
Reinfusion (NaCl)					
	Reinfusion volume	250 ml	0 to 480 ml	10 ml	–

- **Anticoagulation**

Sub-item		Default value	Value range	Resolution	Selectable options
Heparin					
	Heparinization	Yes	–	–	Yes No
	Heparin unit (I.U. currently not adjustable)	ml	–	–	ml (I.U.)
	Heparin start	Automatic	–	–	Automatic Manual
	Hep. rate (I.U. currently not adjustable)	1.2 ml/h (10 I.U./h)	0.5 to 10.0 ml/h (10 to 25 000 I.U./h)	0.1 ml/h (10 I.U./h)	– (–)
	Stop time	0:30	0:00 to 2:00	0:01	–
	Syringe	Fresenius 30 ml	–	–	Depending on Operator setup (Define syringe types)
	Bolus	5.0 ml/h 1000 I.U./h	1.0 to 20.0 ml/h 0 to 15 000 I.U./h	0.1 ml/h 10 I.U./h	– –
	Auto bolus (Currently not adjustable.)	(No)	(–)	(–)	(No) (Yes)

Define syringe types					
	Sub-item	**Default value**	**Value range**	**Resolution**	**Selectable options**
Remove syringe types from the operator list by touching the **Remove syringe** button. Remove own syringe types by touching the **Delete syringe** button.					
	Operator list	Fresenius 30 ml	–	–	–
	Syringe types	–	–	–	Fresenius 30 ml B. Braun 20 ml B. Braun 30 ml B&D 20 ml B&D 30 ml JMS 20 ml Nipro 20 ml Safti 20 ml Terumo 20 ml Terumo 30 ml
	Parameter Displays the parameters of the selected syringe.	–	–	–	–
Currently not active: By means of the following list, define own syringe types in the Syringe types list by touching the **New syringe** button (see the following heparin pump illustration).					
	Syringe name	–	–	–	–
	Diameter **(1)** (Internal diameter)	–	10.00 to 30.00 mm	5 mm	–
	Volume **(2)**	–	10.00 to 30.00 ml	5 ml	–
	Syringe total length **(3)**	–	30.00 to 95.00 mm	5 mm	–
	Total length (i.e. rem. length) **(4)**	–	5.00 to 30.00 mm	5 mm	–



- **Dialysate**

Sub-item		Default value	Value range	Resolution	Selectable options
Default values Dialysate					
	Concentrate	Depending on Operator Setup "Define concentrates". SK-F 203	–	–	Depending on Operator Setup "Define concentrates".
	Prescr. Na	138 mmol/l	125 to 160 mmol/l	1 mmol/l	–
	Prescr. Bic	32.0 mmol/l	0 to 40.0 mmol/l	1 mmol/l	–
	Flow	500 ml/min	100 to 1000 ml/min	100 ml/min	–
	Auto flow	Yes	–	–	Yes No
	Factor	1.5	1.0 to 2.0	0.1	–
	Temperature	36.5 °C	34 °C to 39 °C	0.5 °C	–
Bags					
	Empty bibag	Automatic	–	–	Automatic, (If optical detector does not sense blood.) Manual

Define concentrates					
Sub-item		**Default value**	**Selectable options**		
Remove concentrates from the operator list by touching the **Remove concentrate** button. Remove own concentrates by touching the **Delete concentrate** button. Add own concentrates to the Concentrates list by touching the **New concentrate** button (adjustable only with ServiceCard). The composition of the concentrate selected under "Dialysate", "Default values, dialysate" cannot be changed and the concentrate cannot be deleted.					
	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)	–	–	–
	Concentrate list	–	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 113/1, AC-F 119, AC-F 119/1, AC-F 119/4, AC-F 119/5 AC-F 203, AC-F 212/1, AC-F 213, AC-F 213/4, AC-F 216/1, AC-F 218, AC-F 218/1, AC-F 219, AC-F 219/0, AC-F 219/1, AC-F 219/3, AC-F 219/4, AC-F 219/5, AC-F 223 AC-F 303, AC-F 311, AC-F 312/1, AC-F 313, AC-F 313/1, AC-F 313/2, AC-F 313/3, AC-F 316, AC-F 318, AC-F 318/1, AC-F 319 AC-F 216, AC-F 411, AC-F 412/1, AC-F 413, AC-F 413/1, AC-F 419, AC-F 419/2, AC-F 016 AF 10, AF 11, AF 12, AF 13, AF 14, AF 15, AF 70, AF 71, AF 72, AF 73, AF 74		

Explanation of the terms used in the Settings menu

Name	Description
Concentrate name	Abbreviation used by the manufacturer, usually name of the A concentrate.
Proportions of the components	
A concentrate, Parts	Proportion of the acidic concentrate of the composition, is the reference quantity of the mixing ratio, constant = 1.
B concentrate, Parts	Proportion of the bicarbonate concentrate of the composition. In case of acetate dialysis the value is 0.
Water, Parts	Proportion of the RO water of the composition.
Electrolytes	
Na^+ (sodium)	Is the concentration of the respective ions in the ready-to-use dialysate.
K^+ (potassium)	
Ca^{++} (calcium)	
Mg^{++} (magnesium)	
Cl^- (chloride)	
HCO_3^- (bicarbonate)	
CH_3COO^- (acetate)	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).
Other ingredients	
Glucose	Is the concentration of the glucose in the ready-to-use dialysate. Caution: The unit of measure is g/l.
Component ingredients	
Acid (A)	CH_3COOH (acetic acid) or HCl (hydrochloric acid), is the concentration of the acid which originates from the acidic or A 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.
Na(B)	Is the concentration of the sodium in the ready-to-use dialysate which originates from the B concentrate (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 in most cases identical with the acetate). If the B concentrate contains additional saline, the value for Na(B) equals the total of the final concentration of this saline in the ready-to-use dialysate, the HCO_3^- (bicarbonate) and the acid (A). If a zero figures under Na(B), it is assumed to be pure bicarbonate concentrate.

Explanation of the tables of the Settings menu

The input limits cannot prevent that the prescriptions entered
– will affect several setting limits and will generate a conductivity alarm,
– are not physiologic.

The concentrate setting limits for acetate dialysis and bicarbonate dialysis specified hereafter 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:
(Whichever condition is the most stringent applies.)

Prescr. 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

Prescr. Bic:
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

Setting limits for acetate dialysis

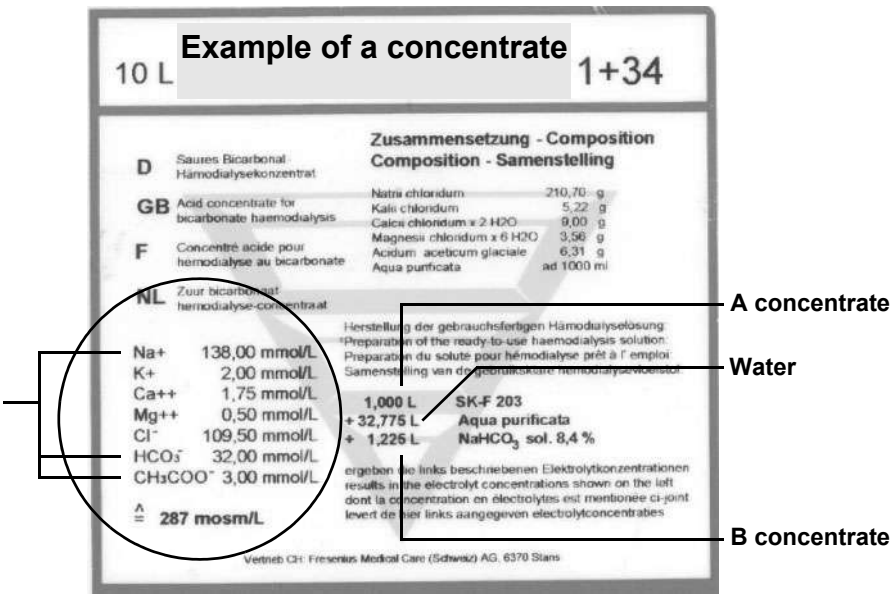
Name	Unit	Min. value	Max. value	Requirement
Concentrate name				
Proportions of the components				
A concentrate	non-dimensional	1 (= constant)		
B concentrate	non-dimensional	0		
Water	non-dimensional	19	40	
Electrolytes				
Na^+	1 mmol/l	125	150	
K^+	1/100 mmol/l	0.00	5.00	
Ca^{++}	1/1000 mmol/l	0.00	2.500	
Mg^{++}	1/100 mmol/l	0.20	1.00	
Cl^-	1/100 mmol/l	80.00	126	
HCO_3^-	1/10 mmol/l	0	0	
CH_3COO^-	1/100 mmol/l	30.00	40.00	
Other ingredients				
Glucose	g/l	0	3	
Component ingredients				
Acid (A)		0		
Na(B)		0		

Setting limits for bicarbonate dialysis

Name	Unit	Min. value	Max. value	Requirement
Concentrate name				
Proportions of the components				
A concentrate	non-dimensional	1 (= constant)		
B concentrate	non-dimensional	H_2O components x 0.017	H_2O components x 0.055	
Water	non-dimensional	17.800, and additionally 19.000 B concentrate parts	50.000	The following mixing ratio facilitates the calculation Mix = 1 + B concentrate parts + H_2O parts ≥ 20
Electrolytes				
Na^+	1 mmol/l	125	150	Requirement: the NaCl (saline) concentration in the acidic concentrate must be ≥ 1800 mmol/l.
K^+	1/100 mmol/l	0.00	5.00	
Ca^{++}	1/1000 mmol/l	0.00	2.500	
Mg^{++}	1/100 mmol/l	0.20	1.00	
Cl^-	1/100 mmol/l	80.00	126	
HCO_3^-	1/10 mmol/l	24.0	40.0	Requirement: the concentration of bicarbonate in the bicarbonate concentrate must be ≥ 6 %.
CH_3COO^-	1/100 mmol/l	0.00	10.00	Acetate and acid input ≤ 10.00
Other ingredients				
Glucose	g/l	0	3	
Component ingredients				
Acid (A)	1/100 mmol/l	1.50	4	in most cases = acetate
Na(B)	1/10 mmol/l	= bicarbonate HCO_3^- + acid (A)	= bicarbonate + 30.0	

Example for parameter entry in case of bicarbonate dialysis

The canister label of the concentrate used as an example shows the electrolyte proportions in the bicarbonate. (On products from other manufacturers, this information may be listed separately.)



Name	Value	Unit	INFO
Concentrate name			Example of a concentrate, (1+34)
Proportions of the components			
A concentrate, parts	1.000	l	
B concentrate, parts	1.225	l	
Water	32.775	l	
Electrolytes			
Na^+ (sodium)	138.00	mmol/l	
K^+ (potassium)	2.00	mmol/l	
Ca^{++} (calcium)	1.75	mmol/l	
Mg^{++} (magnesium)	0.50	mmol/l	
Cl^- (chloride)	109.50	mmol/l	
HCO_3^- (bicarbonate)	32.00	mmol/l	
CH_3COO^- (acetate)	3.00	mmol/l	
Other ingredients			
Glucose	2.00	g/l	
Component ingredients			
Acid (A)	3	mmol/l	CH_3COO^- (acetate)
Na(B)	35	mmol/l	HCO_3^- (bicarbonate) Na^+ in the bicarbonate

It is possible to verify data entry as follows:

The balance resulting from the sum of all electrolytes with a positive charge and of all electrolytes with a negative charge must be equal to 0. The maximum deviation resulting from rounding errors is 0.04. (When adding the electrolytes, it must be observed that some of them may have a double charge. These electrolytes must be counted twice.)

Electrolytes with a positive charge (+)			**Electrolytes with a negative charge (–)**		
Positive electrolytes	**Value**	**Total**	**Negative electrolytes**	**Value**	**Total**
Na^+ (sodium)	138.00	138.00	Cl^- (chloride)	109.50	109.50
K^+ (potassium)	2.00	2.00	HCO_3^- (bicarbonate)	32.00	32.00
Ca^{++} (calcium)	1.75	3.50	CH_3COO^- (acetate)	3.00	3.00
Mg^{++} (magnesium)	0.50	1.00			
TOTAL		144.50	TOTAL		144.50

Calculation example for concentrates indicated in g/l

Some manufacturers indicate the amount of the individual concentrate components in g/l. For these concentrates, the unit mmol/l of the ready-to-use dialysate must be calculated based on the atomic weights.

Canister labeling 1:35, NaCl 210.68 g/l

Atomic weight NaCl:
Atomic weight Na 22.990 + atomic weight Cl 35.453 = atomic weight NaCl 58.443

Conversion NaCl from g/l to mmol/l:
NaCl 210.68 g/l / 35 (mixing ratio) = 6.019 g/l
6.019 g/l / 58.443 (atomic weight NaCl) = 0.103 mol/l = 103 mmol/l

Entry Na^+:
Na^+ = 103 mmol/l (Na^+ of NaCl) + 35 mmol/l (Na^+ of bicarbonate) = 138 mmol/l (entry Na+)

- **Ultrafiltration**

Sub-item		Default value	Value range	Resolution	Selectable options
	UF start	Automatic	–	–	Automatic (If optical detector senses blood.) Manual
	UF with time/rate only (rate preset, no time)	Blocked	–	–	Blocked Released
	Free UF profile (Currently not adjustable)	Blocked	–	–	Blocked Released
	Max. UF rate	3000 ml/h	500 to 4000 ml/h	10 ml/h	–
	Max. profile rate	3500 ml/h	3010 to 4000 ml/h	10 ml/h	–
Current treatment data (Displays the current treatment data during the treatment.)					
	Max. UF rate	–	–	–	–
	Max. profile rate	–	–	–	–

- **Alarm processing**

Sub-item		Default value	Value range	Resolution	Selectable options
	Tone Mute time	120 seconds	60 to 120 seconds	10 seconds	–
Warning times					
	Flow Off	10 min	–	–	10 min 20 min 30 min
	UF Off	5 min	5 to 15 min	1 min	–
	Heparin Off	1 min	1 to 5 min	1 min	–
Arterial/venous pressure settings					
	Art. alarm limit	Centred	–	–	Centred Asymmetric
	Art. window width	100 mmHg	40 to 200 mmHg	10 mmHg	–
	Ven. alarm limit	Asymmetric	–	–	Asymmetric Centred
	Ven. window width	100 mmHg	40 to 200 mmHg	10 mmHg	–
	Ven. window position	Unlimited	–	–	Unlimited ≥ 20 mmHg (Lower value of the alarm limit window not adjustable below 20 mmHg.)
	Kinking warning (= BLK on/off)	Yes	–	–	Yes No
	Venous transducer (= WET on/off)	Yes	–	–	Yes No

- **User interface**

Sub-item		Default value	Value range	Resolution	Selectable options
Screen saver (= SCREEN SAVER)					
	Screen saver	Yes	–	–	Yes No
	Delay	0:05 h:min	0:01 to 1:00 h:min	0:01 h:min	–

Graphics					
	Sub-item	**Default value**	**Value range**	**Resolution**	**Selectable options**
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 only be selected if the particular option is available.					
	Group 1	UF Na diagram OCM diagram Pressure graphs BPM history	–	–	UF Na diagram Pressure graphs OCM diagram BTM T control BTM rec. BTM events BPM BPM (MAP) BPM history BVM
	Group 2	BPM BPM (MAP)	–	–	See group 1
	Group 3		–	–	See group 1
	Group 4		–	–	See group 1

Define options					
	Sub-item	**Default value**	**Value range**	**Resolution**	**Selectable 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 CIRCULATE SINGLE-NEEDLE menu ONLINE OCM BPM BTM BVM

Define controls					
	Sub-item	**Default value**	**Value range**	**Resolution**	**Selectable options**
On the TREATMENT SCREEN 6 fields are displayed in one row by default. In addition, 2 further rows with a maximum of 12 fields, depending on the field size, may be created. Option fields can be added only if the particular option is available.					
	From the DIALYSATE MENU	–	–	–	Concentrate Na profile Temperature Flow Auto flow Dialyzer
	From the UF MENU	–	–	–	UF profile
	From the HEPARIN menu	–	–	–	Hep. rate Stop time Bolus Cum. vol. Bolus I/O
	From the ONLINE menu	–	–	–	Treatment mode Auto-sub Sub goal Sub rate Sub pump I/O HCT TP
	From the SINGLE-NEEDLE menu	–	–	–	Effective blood flow Stroke vol. Lower SN pressure Upper SN pressure Ratio (approx.)
	From the BTM menu	–	–	–	Recirculation I/O

- **Cleaning**

Sub-item		Default value	Value range	Resolution	Selectable options
	Autom. cleaning pgm. after treatment	Yes	–	–	Yes No
	Audible info	No	–	–	No Yes
	Auto Off	10 min	–	–	10 min 30 min 60 min No Immediately
	Disinfection note Message: *The last disinfection was performed XX hours/days ago.*)	Yes	–	–	Yes No

● Auto On

Following completion of the last disinfection of the 5008 hemodialysis system of the day it is possible to connect a bi*b*ag® (72 hours is the maximum time allowed prior to the treatment).
If you wish to use this possibility, the following actions must be performed.

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

Caution

After removal of the foil, immediately connect the bi*b*ag® using aseptic technique. Then close the bicarbonate flap.

Sub-item	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 several programming actions have been performed, it is possible to turn them all on or off via the **Auto On Programs I/O** button.			
Programs +	No program	–	–	Rinse Heat disinfection Standby T1 test No program
power-up time	00:00	00:00 to 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 several programming actions have been performed, it is possible to turn them all on or off via the **Auto On Programs I/O** button.			
Programs +	No program	–	–	Rinse Heat disinfection Standby T1 test No program
power-up time	00:00	00:00 to 24:00	1 min.	–

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

Sub-item		Default value	Value range	Resolution	Selectable options
	UF Off	Yes	–	–	Yes No
	Blood flow reduction (to 100 ml/min)	Yes	–	–	Yes No
	Blood pressure measurement	No	–	–	No Yes
	Standard bolus (activation of the bolus and bolus rate values set hereafter)	Yes	–	–	Yes No
	Bolus	90 ml	90 to 240 ml	30 ml	–
	Bolus rate	200 ml/min	50 to 250 ml/min	10 ml/min	–
	Emergency bolus (Preset: bolus = 240 ml, bolus rate = blood flow before emergency – 50 ml/min)	No	–	–	No Yes

- **Patient card**

Sub-item	Default value	Value range	Resolution	Selectable options
Patient card (PatientCard) Part number: M35 765 1	Writing to the patient card: – In the Operator setup select **Patient card**. – Remove the operator card. – Insert the patient card. – Message: *Patient card for ... date of birth ...* – Touch the **OK** button. – Enter the desired data for the patient. (After pressing the desired field enter the data using the keypad.) – To confirm each entry of the patient data touch the **OK** button. Visually check the confirmed patient data. – Touch the **Create patient card** button. – Message: *Saving data to card. Leave card inserted!* – Remove the patient card following the message.			
First name	–	–	–	–
Surname	–	–	–	–
Database ID	–	–	–	–
Date of birth	–	–	–	–

- **ONLINE (can only be selected if the ONLINE option exists and if Filter 2 is set in the System options submenu in the Technician's setup.)**

Sub-item	Default value	Value range	Resolution	Selectable options
Treatment mode				
Treatment mode	HDF postdilution	–	–	HDF postdilution HF predilution HF postdilution HD HDF predilution
Bolus				
Bolus	150 ml	90 to 240 ml	30 ml	–
Bolus rate	200 ml/min	100 to 250 ml/min	10 ml/min	–
Preparation (ONLINE)				
Onl. rinse vol.	800 ml	500 to 5000 ml	100 ml	–
Onl. UF rinse vol. (If Onl. UF rinse vol. = 0, UF rinse will not be displayed during Preparation.)	500 ml	0 to 5000 ml	100 ml	–
Reinfusion (ONLINE)				
Reinfusion volume	360 ml	60 to 480 ml	60 ml	–
Substitution				
Auto-sub	Yes	–	–	Yes No
Hemoconcentration				
Monitoring (Intended to avoid excessive hemoconcentration in the dialyzer due to a too high ultrafiltration.)	Yes	–	–	Yes No
–				
Dialyzer class	FX HighFlux	–	–	FX HighFlux F HighFlux

Define dialyzer classes					
Sub-item		**Default value**	**Value range**	**Resolution**	**Selectable options**
Remove dialyzer classes from the operator list by touching the **Remove class** button. Remove own dialyzer classes by touching the **Delete class** button.					
	Operator list	–	–	–	–
	Dialyzer classes	–	–	–	FX HighFlux F HighFlux
	Parameter Displays the parameters of the selected dialyzer class.	–	–	–	–
By means of the following list, define own dialyzer classes in the Dialyzer classes list by touching the **New class** button.					
	Name of dialyzer class	–	–	–	–
AutoSub factor					
	Predilution	1.00	0.50 to 1.50	0.05	–
	Postdilution	1.00	0.60 to 1.40	0.05	–

- **OCM (can only be selected if OCM exists.)**

Sub-item		**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 system option exists.)**

Sub-item		Default value	Value range	Resolution	Selectable options
	Maximum stroke vol.	50 ml	–	–	–
	Stroke vol.	35 ml	10 to 50 ml	5 ml	–
	Rate ratio (ratio blood pump speed to SN pump speed)	+20 %	–60 % to +60 %	5 %	–
Single-Needle Click-Clack SN pressure window, venous pressure: Width: 80 to 480 mmHg; maximum SN pressure: 480 mmHg, minimum SN pressure: 20 mmHg;					
	Lower SN pressure	50 mmHg	–	10 mmHg	–
	Upper SN pressure	400 mmHg	–	10 mmHg	–

- **Miscellaneous**

Sub-item		Default value	Value range	Resolution	Selectable options
	Installation place (Displayed in submenu "Status", "Device info")	Installation place of the 5008 hemodialysis system may be entered here (e.g. name of the hospital).			
	Pressure holding test, dialyzer couplings	Yes	–	–	Yes No

- **BPM (can only be selected if the system option exists.)**

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

- **BVM (can only be selected if the system option exists.)**

Sub-item	Default value	Value range	Resolution	Selectable options
BVM (Cuvette detection after turning power on)	Passive	–	–	Passive Active
Max. BVM rate	2800 ml/h	0 to 2800 ml/h	50 ml/h	–
Hemoglobin - unit	g/dl	–	–	g/dl mmol/l
Use OCM/ONLINE measurement data (Presetting of the button in the BVM menu)	Yes	–	–	Yes No
Initial target volume deviation				
Positive deviation (Limitation to the value set in the Technician's setup)	0 ml	0 to xxxx ml	50 ml	–
Negative deviation (Limitation to the value set in the Technician's setup)	0 ml	0 to xxxx ml	50 ml	–

- **BTM (can only be selected if the system option exists.)**

Sub-item	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
Change rate	0.0 °C/h	–0.5 to +0.5 °C/h	0.1 °C/h	–
Max. dialysate temperature	38.0 °C	37.0 to 38.0 °C	0.5 °C	–
Room temperature				
Room temperature (Is not measured, but has to be set.)	20.0 °C	15.0 to 35.0 °C	1.0 °C	–

10.3 Emergency Button

The functions customized in the Operator setup will be activated after touching the **Emergency button**.

- **Setting the Emergency button functions**

  In the Operator setup, "Emergency" submenu, it is possible to set several functions which will be activated after touching the **Emergency button**.

  In the "OPTIONS" submenu, under "EMERGENCY", it is possible to set ONLINE bolus functions which will be activated after touching the **Emergency button**.

- **Activating the Emergency button function**

  Only touch the **Emergency button**, e.g., if a drop in the patient's blood pressure occurs.

  Touch the **Emergency button**.

  Operating mode indicator is flashing yellow

  EMERGENCY MENU displays the preselected ONLINE bolus functions.

- **Deactivating the Emergency button function**

  Touch the **Emergency button**.

  Operating mode indicator green, in alarm-free condition.

  The status before activating the emergency function will be restored.

10.4 Emptying / Changing the bi*bag*®

Touch the **DIALYSATE MENU** menu button.

Touch the **Empty bags** field.

Touch the **bibag** field and accept with the **OK** button.

The drain program is in progress.

Message: *The bibag is empty and it can now be removed or – Empty bibag* **Repeat**

Remove the bi*bag*®.

If a new bi*bag*® is to be used:

Connect the new bi*b*ag®.

Close the bicarbonate flap until it clicks into place.

10.5 Changing the DIASAFE®*plus*

Caution

Use only the original Fresenius DIASAFE®*plus*.

Caution

Observe the following rules of hygiene when inserting the DIASAFE®*plus*:
- Only use filters with undamaged packaging.
- Remove the packaging and the protective straps only immediately before installing the filter
- Only touch the connectors if required.

Note

The CLEANING SCREEN shows when the next filter change is necessary.

If a cleaning program is selected, a message will be displayed in time, informing about an imminent filter change.

- **Filter change criteria**

  - The maximum filter life (12 weeks) has been reached
  - The filter is defective (T1 test failed).
  - Applicable to ONLINE*plus*™: The maximum number of treatments (100) has been reached.

- **Changing the DIASAFE®*plus***

Caution

To change the filter it is imperative to use the filter change program.

Note

The change of the DIASAFE®*plus* must be entered in the Medical Device Register (date, batch number).

Make sure that no patient is connected to the system.

CLEANING SCREEN

Touch the **Filter change** button.

Message: *Filter change, Filter 1, Filter 2, Both filters*

Select the desired filter(s).
Touch the **Start** button.

Message: *Filter change in progress.....*

Message: *Emptying of filter completed. Please confirm filter change!*

Change the filter.
(e.g. filter 1)
Open the door of the dialysate filter chamber (1). Open the locking levers (2). Slide the used filter (3) upwards and out of the guide slot. Remove the protective straps from the new filter. Slide the new filter (4) from the top into the guide slot. Close the locking levers (5). Close the door of the dialysate filter chamber (6).

Touch the **Confirm** button.

Message: *Filter change in progress.....*

After the filter(s) has/have been primed:
Message: *Disinfection required.*

Touch the **Cleaning menu** button.

Caution

Disinfect the system after each filter change.

10.6 Cleaning the Dialysate Particle Filter

Turn the particle filter holder to the left (1). Pull it out slightly towards you and turn it to the right (2). Clean the dialysate particle filter. Re-insert the filter holder and turn it to the left, then push it lightly in and turn it again to the right. In this last position the filter holder must click into place.

10.7 Collecting a Sample

Connect a syringe (1) (e.g. 10 10 ml Luer-lock) to the Luer-lock of the sampling valve. Press the key (2) and keep it pressed. Lock the key with the locking pin (3). Draw up the syringe (4) (discard the first specimen). Release the locking pin (5). The key will automatically close the valve.

10.8 Removing Lines During Preparation

During Preparation, it is possible to remove the desired blood line part via the **BLOOD SYSTEM** MENU.

10.9 Removing Lines During Treatment

10.9.1 Removing the Arterial Line

In the **BLOOD SYSTEM** menu

Touch the **Remove arterial line** button.

Message: *Remove arterial blood line with blood in the blood line?* – **OK** – **Abort**

Touch the **OK** button.

Keep the doors closed until the arterial line segment has been removed and the arterial pressure measurement unit has been opened.

Message: *If necessary, remove arterial blood line and insert a new one. Connect a bag of NaCl to the arterial blood line, but do not yet connect to the dialyzer. Close the doors.*

Open the doors. Insert a new arterial blood line. Close the doors.

Message: *Prime the arterial blood line. Press and hold the "Prime" button, until the arterial line has been completely primed.* – **Prime** – *Treatment* **Continue**

Press and hold the **Prime** button, until the arterial line has been primed.

Connect the arterial line to the patient and to the dialyzer.

Touch the **Continue** button.

10.9.2 Removing the Venous Line

In the **BLOOD SYSTEM** menu

Touch the **Remove venous line** button.

Message: *Remove venous blood line with blood in the blood line?* – **OK** – **Abort**

Touch the **OK** button.

Message: *Remove the venous line and replace it by a new blood line filled by gravity, then close the doors.*

The treatment will be continued automatically.

10.9.3 Removing the SafeLine™

In the **BLOOD SYSTEM** menu

Touch the **Remove SafeLine** button.

Message: *When changing the* SafeLine *1.* Disconnect the SafeLine from *the blood line 2. Remove the connector from the substituate port. 3. Close the port 4. Close the doors* – **OK** – **Abort**

Touch the **OK** button.

Message: *SafeLine will be removed automatically. Please keep the doors closed whilst waiting!*

Message: *Please remove the SafeLine™ and then close the doors!*

Message: *The substituate connector was removed. ONLINE treatment was aborted.* – **OK**

Touch the **OK** button.

Message: *Treatment mode changed!* – **OK**

Touch the **OK** button.

10.9.4 Connecting/Retrofitting the SafeLine™

Open door. Place the SafeLine™ line guide in the substituate pump. Connecting the substituate connector to the substituate port. Close the substituate port. Close door.

Message: *SafeLine being filled. Disconnect the SafeLine from the blood line!* – **Confirm**

Touch the **Confirm** button.

Message: *Please wait. Substituate for priming the* SafeLine *is being made available.*

Message: *Prime the SafeLine. Press and hold the "Prime" button, until the* SafeLine *has been sufficiently primed.* – **Prime** – **Exit**

Press and hold the **Prime** button until the SafeLine™ has been primed.

Touch the **Exit** button.

Depending on the selected substitution mode, connect the SafeLine™ before or after the dialyzer and follow the corresponding message prompts.

10.9.5 Removing All Lines

In the **BLOOD SYSTEM** menu

Touch the **Remove all lines** button.

Message: *Remove lines selected / CAUTION! Treatment in progress! Selection will reset the treatment data and abort the treatment!* – Machine **Remove lines** – Dialysis **Continue**

Touch the **Remove lines** button.
For a description of the further procedure refer to chapter 7 Reinfusion.

The treatment must be restarted as described in chapter 5.

10.10 Circulation

The Circulation function allows to disconnect the patient from the 5008 hemodialysis system for a short time during the treatment.

The circulation time is 10 minutes. During circulation time, the temperature of the blood in the blood line changes. The Circulation function can be repeated as often as desired and can be aborted at any time.

In the **OPTIONS** MENU (or directly, if defined as an options button)

Touch the **CIRCULATION** button.

Touch the Circulation **Start** button.

Message: *Extracorporeal circuit will be recirculated!* – **Circulation** – *Dialysis* **Continue**

Use an adapter to interconnect the arterial and the venous patient access lines.

Touch the **Circulation** button.
Blood flow 100 ml/min

Message: *Stop circulation?* – **OK**

If the patient has to be reconnected, touch the **OK** button.

Message: *Has the patient been reconnected?* **Circulation** – *Dialysis* **Continue**

Reconnect the patient.

Touch the **Continue** button.

Check the blood flow.

10.11 Setting the Level in the Venous Bubble Catcher

The venous bubble catcher must be correctly inserted into the level detector. Mind the locator for the venous bubble catcher.

In the **BLOOD SYSTEM** menu

Setting the level with the ▲ or ▼ button

Press and hold the ▲ or ▼ button until the level has reached the desired position.

Setting the level with the Level Set button

Touch the **Level Set** button.
(The function is available only if the rinse procedure using the rinse volume has been completed.)
The level is automatically lowered and then raised to the correct position.

10.12 Single-Needle Click-Clack

- **To be observed before using the Single-Needle Click-Clack option**

  This procedure should be used in exceptional cases only, since the stroke volumes and, thus, the corresponding recirculation shares can be very unfavorable. For displaying the effective blood flow, a recirculation volume of 2 ml per Single-Needle Click-Clack cycle (standard DN dialysis cannula) will be considered. The actual recirculation, however, may differ, depending on the dialysis cannula used.
  The arterial and the venous blood line are connected with a Y-piece to the vascular access.

  If a Single-Needle blood line has been inserted, it is not possible to select Single-Needle Click-Clack.

  Single-Needle Click-Clack may be selected only after the minimum rinse volume has been reached in Preparation mode.

  During a Double-Needle treatment, Single-Needle Click-Clack may be started or aborted at any time.

  When reinfusion is started, Single-Needle Click-Clack will be switched off.

  An ONLINE-HDF(HF) treatment currently in progress will be aborted, and treatment will be continued with HD. An ONLINE bolus can be administered at any time. Reinfusion may be performed using the ONLINE option.

- **Starting Single-Needle Click-Clack**

  In the **SINGLE-NEEDLE** menu

  If you wish to alter Single-Needle Click-Clack parameters:
  Set the desired parameters. Touch the **OK** button to confirm the values entered.
  Visually check the confirmed values.

  Touch the **Click-Clack I/O** button.

  Message: *Connect both the arterial and the venous patient line to the same vascular access. – Single-Needle* **Start** – **Abort**

  Connect both the arterial and the venous patient line to the same vascular access.

  Touch the **Start** button.

  Touch the **TREATMENT** menu button to return to the TREATMENT SCREEN.

- **Aborting Single-Needle Click-Clack**

  In the **SINGLE-NEEDLE** menu

  Touch the **Click-Clack I/O** button.

Message: *Connect the arterial and the venous patient line to the respective vascular access.* – *Double-Needle* **Start** – **Abort**

Connect the arterial and the venous patient line to the respective vascular access.

Touch the **Start** button.

11 System Description

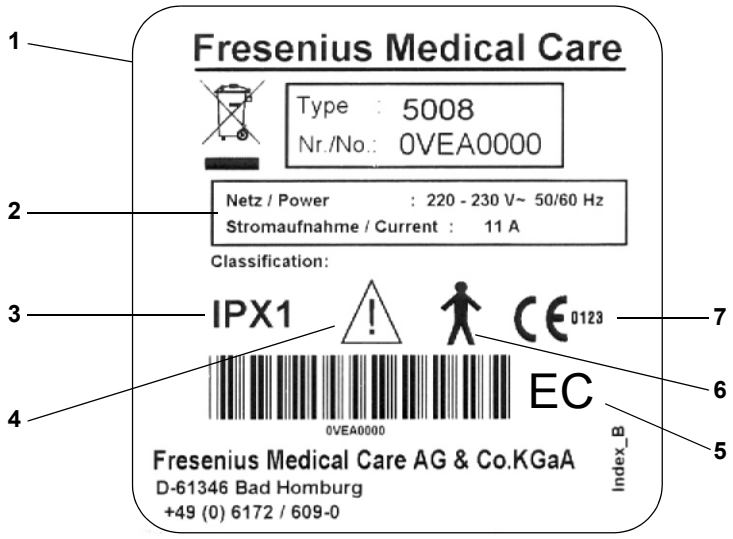
11.1 Specifications

11.1.1 Dimensions and Weight

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. 125 kg (without options)

11.1.2 Type Label (System Identification)

The type label shown is a sample only. The decisive criterion is the data specified on the type label of the system.



1 Type identification, serial number

2 Power requirements

3 Protection against ingress of liquids: drip-proof

4 Caution, consult accompanying documents

5 Equipment code (EC: Equipment Code)

6 Degree of protection against electric shock: Type B

7 CE mark

11.1.3 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	Defibrillator-protected applied part of the type CF, Symbol: 
Degree of protection against ingress of liquids	Drip-proof, symbol: **IPX1**
Leakage currents	According to EN 60601-1

11.1.4 Electrical Supply

Line voltage	100 to 240 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, regulation according to VDE 0100 part 710
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

11.1.5 Fuses

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

11.1.6 Guidance and Manufacturer's Declaration on EMC (IEC 60601-1-2:2001)

- **Electromagnetic emissions**

Guidance and manufacturer's declaration – electromagnetic emissions		
The 5008 hemodialysis system is intended for use in the electromagnetic environment specified below. The customer or the user of the 5008 hemodialysis system should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The 5008 hemodialysis system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The 5008 hemodialysis system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

- **Electromagnetic immunity**

Guidance and manufacturer's declaration – electromagnetic immunity			
The 5008 hemodialysis system is intended for use in the electromagnetic environment specified below. The customer or the user of the 5008 hemodialysis system should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial and/or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	After power supply interruptions, the 5008 hemodialysis system battery takes over the supply without delay.

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			
			Portable and mobile RF communications equipment should be used no closer to any part of the 5008 hemodialysis system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V	$d = 1.17 \sqrt{P}$ 150 kHz to <80 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m	$d = 0.35 \sqrt{P}$ 80 MHz to <800 MHz $d = 0.7 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range [b].  Interference may occur in the vicinity of equipment marked with the following symbol:
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the 5008 hemodialysis system is used exceeds the applicable RF compliance level above, the 5008 hemodialysis system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the 5008 hemodialysis system.			
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

- **Recommended separation distances between portable and mobile RF communications equipment and the hemodialysis system 5008**

Recommended separation distances between portable and mobile RF communications equipment and the hemodialysis system 5008

The 5008 hemodialysis system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the 5008 hemodialysis system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 5008 hemodialysis system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to < 80 MHz $d = 1.17 \sqrt{P}$	80 MHz to < 800 MHz $d = 0.35 \sqrt{P}$	800 MHz to 2.5 GHz $d = 0.7 \sqrt{P}$
0.01	0.11	0.035	0.07
0.1	0.37	0.11	0.22
1	1.17	0.35	0.7
10	3.7	1.10	2.21
100	11.7	3.5	7.0

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

11.1.7 Operating Conditions

Water inlet pressure 1.5 to 6.0 bar

Water inlet temperature 5 °C to 30 °C
for "Integrated hot rinse": 85 °C to 95 °C

In case of line voltages between 100 V and 120 V and low water inlet temperatures, a restriction of the dialysate flow is possible due to the available mains voltage.
Example:
Line voltage 110 V, heater output 1200 W, water inlet temperature 10 °C, dialysate temperature (desired value) 37 °C,
= flow ≤ 800 ml/min

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)

Operating temperature range 15 °C to 35 °C

Atmospheric pressure 700 hPa to 1060 hPa

Relative humidity 30 % to 75 %, temporarily 95 %

Stability	5° Admissible inclination during operation: ≤ 3°
IV pole load capacity	Maximum: 5 kg Maximum load capacity of one hook: 5 kg

11.1.8 External Connection Options

Caution

Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g. IEC 60950 for data processing equipment). Furthermore all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16 of the 3Ed. of IEC 60601-1, respectively). Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local representative or the technical service department.

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
Service/diagnostics	(Protected by cover!) For inhouse computer diagnostics. Interface for the exchange of data (RS232). 24 V (1 A fuse) Port: DSUB 15-pin Connector for AquaUNO (single station reverse osmosis unit)
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.

11.1.9 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 Operator setup)

Alarm override	After confirmation of the error message and start of the blood systems: The arterial and venous pressure alarms will be overridden for approx. 10 seconds. (window inactive)
Blood leak override	Override time: maximum 2 minutes
Override air-bubble detector	Override time: – After starting active removal of air: approx. 4 seconds – Micro bubbles alarm: 120 seconds

11.1.10 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 dark in the blood lines.
Priming and rinsing the blood lines	Minimum rinse volume 500 ml; automatic switching to Rinse mode, if fluid level detected in the level detector. Automatic raising of the fluid level during the rinse phase.
Reinfusion	Reinfusion volume adjustable in the Operator setup. Return to dialysis still possible
Dialysis	Bicarbonate dialysis
ISO-UF (sequential therapy)	Ultrafiltration without dialysate flow (Bergström method)
Single-Needle Click-Clack	With blood pump, arterial and venous occlusion clamp. Pressure-pressure-controlled with adjustable pressure reverse values. Exceptional procedure in case of problems with the vascular access during Double-Needle treatment.
Circulation (during the treatment)	The Circulation function allows to disconnect the patient from the 5008 hemodialysis system for a short time during the treatment. During circulation the hemodialysis system 5008 shows the following behavior: – the blood flow is set to 100 ml/min – the heparin pump rate is set to 1 ml/h – the alarm limits for the arterial and the venous pressure are monitored for not exceeding the respective end of scale – Ultrafiltration, ONLINE*plus*™ and OCM are inactive – the BTM, BVM control options are inactive – the interval mode of the BPM option is turned off

Cleaning programs

Free rinse/Rinse/Mandatory rinse:
Time adjustable in the Technician's setup,
Temperature: approx. 37 °C,
Flow: 600, 800 ml/min (adjustable in the Technician's setup)

Degreasing/cold disinfection, 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,
Temperature: approx. 85 °C,
Flow: max. 900 ml/min

In all programs:
Progress of the program (time-counting) is interrupted in the event of a flow alarm.
The cleaning programs can be aborted.
A mandatory rinse is performed after the following programs:
– Chemical disinfection
– Heat disinfection

Flush (option)

Rinsing of the water supply area

11.1.11 Dialysate Circuit and Safety Systems

Blood leak detector

Response threshold ≤ 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 = Correction of flow-dependent pressure drops

Ultrafiltration

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

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

Pressure holding test

Event-controlled

UFC measurement

At the beginning of the treatment, a measurement of the ultrafiltration coefficient (UFC) of the dialyzer connected is performed. This value is taken as initial value for different parameters (e.g. TMP monitoring).

If this measurement can not be performed successfully 3 times because of malfunctions, a message will be displayed: *3rd invalid UFC measurement* with the appropriate information about possible causes. As long as no current value is measured, a default value is used for the calculation instead of the measured value.

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 / – 0.5 °C
(measuring accuracy under calibration conditions for a dialysate flow of 500 ml/min.)

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

AutoFlow: The AutoFlow function automatically regulates the dialysate flow, depending on the dialyzer type and blood flow.

Entering the factor (AutoFlow) will modify the ratio of selected blood flow to dialysate flow. The default value of the factor (AutoFlow) in the Operator setup is 1.5.

Example:

Blood flow: 300 ml/min, factor: 1.5

Dialysate flow = 450 ml/min

The factor (AutoFlow) may be modified in the Operator setup and in the DIALYSATE SCREEN.
Values above 1.5 may result in a minor increase of the dialysis dose. At the same time, the water, concentrate and energy consumption increases.
The contrary applies to values below 1.5, i.e., the dialysis dose may decrease, while the water, concentrate and energy consumption may be reduced.

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

The following has to be observed regarding the dialysate flow:
If the water inlet rate is not sufficient for achieving the maximum dialysate flow of 1000 ml/min, the admissible adjustment range will be delimited accordingly.

Rinse temperature

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

Hot rinse:
Desired temperature: 85 °C
Resolution: 0.5 °C
Measuring accuracy: ±2.0 °C

Disinfection temperature

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

Degreasing/cold disinfection:
Desired temperature: 37 °C
Resolution: 0.5 °C
Measuring accuracy: ±0.2 °C

Heat disinfection:
Desired temperature: 85 °C
Resolution: 0.5 °C
Measuring accuracy: ±2.0 °C

Rinse and disinfection flow

Desired value: 600 ml/min or 800 ml/min (depending on the settings in the Technician's setup)

Concentration of disinfectant

Dilution:
The disinfectants (Citrosteril®, Diasteril®, Puristeril® 340, Puristeril® *plus*) are diluted with purified water in the dialysis system at a ratio of 1+24.
The disinfectant (Sporotal® 100) is diluted with purified water in the dialysis system at a ratio of 1+34.

Flow alarm	Dependent on the programmed flow

11.1.12 Extracorporeal Blood Circuit and Safety Systems

Arterial pressure measurement	Display range: –300 to +300 mmHg Resolution: 5 mmHg Accuracy: 7 mmHg (typical) OD senses light: Alarm window width: –300 to +300 mmHg OD senses dark: Alarm window width: +40 to +200 mmHg Default value adjustable in the Operator 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: ±10 % Line diameter: 4.4 mm, 6.4 mm, 8.0 mm Blood pump stop alarm: 60 seconds (During Single-Needle operation - option - 180 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).
Venous pressure measurement	Display range: –100 to +500 mmHg Resolution: 5 mmHg Accuracy: 7 mmHg (typical) OD senses light: Alarm window width: –100 to +500 mmHg OD senses dark: Alarm window width: 40 to 200 mmHg Default value adjustable in the Operator setup, Factory setting 120 mmHg adjustable over a range of 20 to 500 mmHg (adjustable in the Operator setup from -100 to 500 mmHg.)
Level detector	Method: Capacitive measurement Switching point 13 mm, ±4 mm from upper edge
Optical detector	Method: Infrared transmission Distinguishes between OD light (rinse solution 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) – Micro bubbles

Air alarm:
– BP rate < 100 ml/min:
  Air bubble: Volume ≥ 20 µl
  Blood foam
  Micro bubbles
– 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
  Micro bubbles

The specified data refer to the most unfavorable case with a BP rate of 0 to 600 ml/min when using the blood lines approved for the 5008 hemodialysis system.

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 for a pressure range from –0.4 to +0.4 bar
(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 min
Bolus administration: 1.0 to 20.0 ml
Resolution: 0.1 ml

30 ml Fresenius heparin syringe

Single-Needle Click-Clack

Stroke volume: depending on the blood lines used

Cycle monitoring:
Arterial phase: 50 ml
Venous phase: 15 s

Width of SN pressure window, venous pressure: 80 to 480 mmHg
Maximum SN pressure: 480 mmHg
Minimum SN pressure: 20 mmHg

Audible alarm

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

11.1.13 DIASAFE®*plus*

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

When using ONLINE*plus*™:
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 and under "Status", "Device info".

11.1.14 OCM

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

11.1.15 ONLINE*plus*™

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

Sub goal: depending on the treatment parameters

Accuracy: ±10 %
(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.)

Sub volume:
Resolution: 0.1 liters

Spring-loaded rollers, fully occluding, pressure-limited to < 1.3 bar.

Auto-sub: Automatic control of the substitution rate, considering the following factors:
– Procedure (pre/postdilution)
– Dialyzer class (filter capacity)
– Effective blood flow
– Hematocrit (Hct)
– Total protein (TP)
– UF rate

If one of the above-mentioned factors is altered, the substitution rate will be adapted automatically.

11.1.16 Single-Needle (Option)

Stop alarm Blood pump Single-Needle pump
During Single-Needle operation 180 seconds.

Stroke volume
10 to 50 ml in increments of 5 ml

SN chamber
50 ml stroke volume

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

11.1.17 BPM (Option)

Blood pressure
Display range
– Systole: 30 mmHg to 280 mmHg
– Diastole: 10 mmHg to 240 mmHg
– MAP: 20 mmHg to 255 mmHg

	Resolution: 1 mmHg
Accuracy of blood pressure measurement	Maximum systematic deviation in measurement: Systolic blood pressure –0.9 mmHg Diastolic blood pressure –3.2 mmHg
	Standard deviation according to clinical tests: Systolic blood pressure 6.4 mmHg Diastolic blood pressure 7.1 mmHg
	BHS grading: Systolic: A Diastolic: B
	Maximum deviation in measurement of the cuff pressure: ±3 mmHg
Pulse	Display range: 20 to 245 1/min
	Resolution: 1/min

11.1.18 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
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: (adjustable in the Operator setup) 35.0 °C to 37.0 °C, 37.5 °C or 38.0 °C

11.1.19 BVM (Option)

The following accuracy information is valid after successful calibration of the cuvette during Preparation.

Rel. blood volume	55 to 115 % Accuracy within the range 70 to 105 %, 1.7 % absolute (The accuracy of blood volume measurement may be impaired in case of extremely high lipid concentrations (e.g. triglycerides > 400 mg/dl).)
Hemoglobin	7 to 17 g/dl Accuracy: ±0.8 g/dl (The accuracy of hemoglobin measurement is valid only for plasma protein concentrations ranging between 60 and 85 g/l.)
Hematocrit	20 to 55 % Accuracy: ±2.9 Hct % (The accuracy of hematocrit measurement is valid only for plasma protein concentrations ranging between 60 and 85 g/l.)

11.1.20 Network

Caution

The responsible organization of the network is responsible for protecting the system 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 (staff call).

11.2 Storage

The hemodialysis system must be stored vertically in a well-ventilated room with low variations in temperature.

Temperature

Without antifreeze: +5 °C to +60 °C
With antifreeze: –20 °C to +60 °C

Relative humidity

30 % to 75 %, temporarily 95 %

Atmospheric pressure

500 hPa to 1060 hPa

Antifreeze

When storing the hemodialysis system with antifreeze, make sure to use antifreeze of the following composition:
– 49.875 % water
– 49.875 % glycerine
– 0.25 % ClearSurf™

Maintenance of the integrated battery

Upon receipt of the system, charge the battery as follows:
– Use the power cable to connect the system to the electrical power source.
– Actuate the power switch to turn the system on.
– Leave the system on for 10 hours.

If the system is not used, repeat this procedure every six months.

11.3 Transportation

● **Inside buildings**

Release the brake

The hemodialysis system can be swiveled, turned or pushed in any direction.

To get over uneven surfaces (e.g. elevator entry):
To avoid damage or prevent the machine from toppling over always push the hemodialysis system slowly over uneven surfaces.

To go up and down steps/stairs:
To go up and down steps/stairs at least two persons are required.

Procedure:
Transport protection for the monitor support arm. (Tighten the screw.)
Apply the brake
Close the vent tubing.
Lift the machine for transportation. When lifting the system never hold it by the IV pole, the handle or one of the system components (e.g. EBM doors).

- **Outside buildings**

  – Never push the hemodialysis system across an uneven paving (e.g. cobblestone pavement). Always lift it.

  – When transporting the hemodialysis system in a vehicle, always protect it with the appropriate packing materials and place it either vertically or horizontally.

  – When transporting the machine outside buildings for a prolonged period of time, the storage temperature range must be observed. (If necessary, fill the machine with an antifreeze.)

11.4 Environmental Compatibility and Recycling

- **Preface**

  Only environmentally compatible and recyclable materials have been used for the manufacture of the system and the consumables.

  Within the EC member states the system is taken back in accordance with directive 2002/96/EG (WEEE). Please also observe the applicable local legal regulations.

  The system and the consumables are generally considered to be contaminated and must therefore be sufficiently disinfected by the responsible organization as specified by the manufacturer.

  The respective regulations for the disposal of electronic scrap should be followed for the disposal of electronic boards.

  Disposal of batteries should always conform to applicable regulations.

  Further information regarding disposal is available on request.

- **Materials used – system**

  Materials shown on a grey background color come into contact with purified water, dialysate and dialysate concentrate.

  Plastics and cast resins

Abbreviation	Material
EPDM	Ethylene-propylene terpolymer
FPM (FKM)	Fluoro rubber
PFA	Perfluoroalkox copolymer
PAEK	Polyaryletherketone
PPSU	Polyphenylene sulphone
PVDF	Polyvinylidenefluoride
PTFE	Polytetrafluor ethylene

Abbreviation	Material
PP	Polypropylene
PP-GF20	Polypropylene 20 % glass fiber
PES	Polyethersulfone
PPO	Polyphenylene oxide
PPO-GF20	Polyphenylene oxide 20 % glass fiber
SI	Silicone
TPE	Thermoplastic elastomere
PBT/ABS GF 20	Polybutylenterephthalate/acrylonitrite-butadiene-styrene 20 % glass fiber
ABS	Acrylonitrite-butadiene-styrene
PA 6.6	Polyamide
PC/ABS	Polycarbonate/acrylonitrite-butadiene-styrene
POM	Polyoxymethylene
EPDM+PP	Ethylene-propylene terpolymer/polypropylene
PC	Polycarbonate
PU foam	Polyurethane foam
PS	polystyrene

Metals/glass/graphite/ ceramic

Abbreviation	Material
Glass	Glass
Graphite	Graphite
Ceramics	Ceramics
V4A	Special steel
VA	Special steel
Ti	Titanium
St	Steel
Fe	Iron
Al	Aluminium and aluminum alloys
CuZn39	Brass
Magnet	Samarium-cobalt magnet
Magnet	NdFe magnet

Electrical equipment

Abbreviation	Material
Motors	Copper
	Plug connectors
	Tin
Plug connectors	Copper and tin
	Glassfiber enforced thermoplast
Transformers	Potting compound PU
	Polyester, polyurethane
	Copper
	UP resin
	Iron cores
Microswitches	Polyacetal
	Glassfiber enforced polyamide
	Silicone
	Silver, gold
	Brass
	Copper beryllium
Cables	Copper
	PVC
	Teflon
Electronics	P.C.B. base material
	Epoxy fiberglass
	Ferrite cores
	Lithium batteries
	Lead-acid batteries

Auxiliary materials

Abbreviation	Material
Adhesives	Loctite 3321
	UHU Plus Endfest
	Scotchweld DP 499
Insulating material	Polyethylene

Abbreviation	Material
Lacquers	Acrylic enamel
	Screening lacquer – copper conductive lacquer
	PUR structural lacquer
Grease	Unisilicone

- **Materials used – consumables**

Blood lines

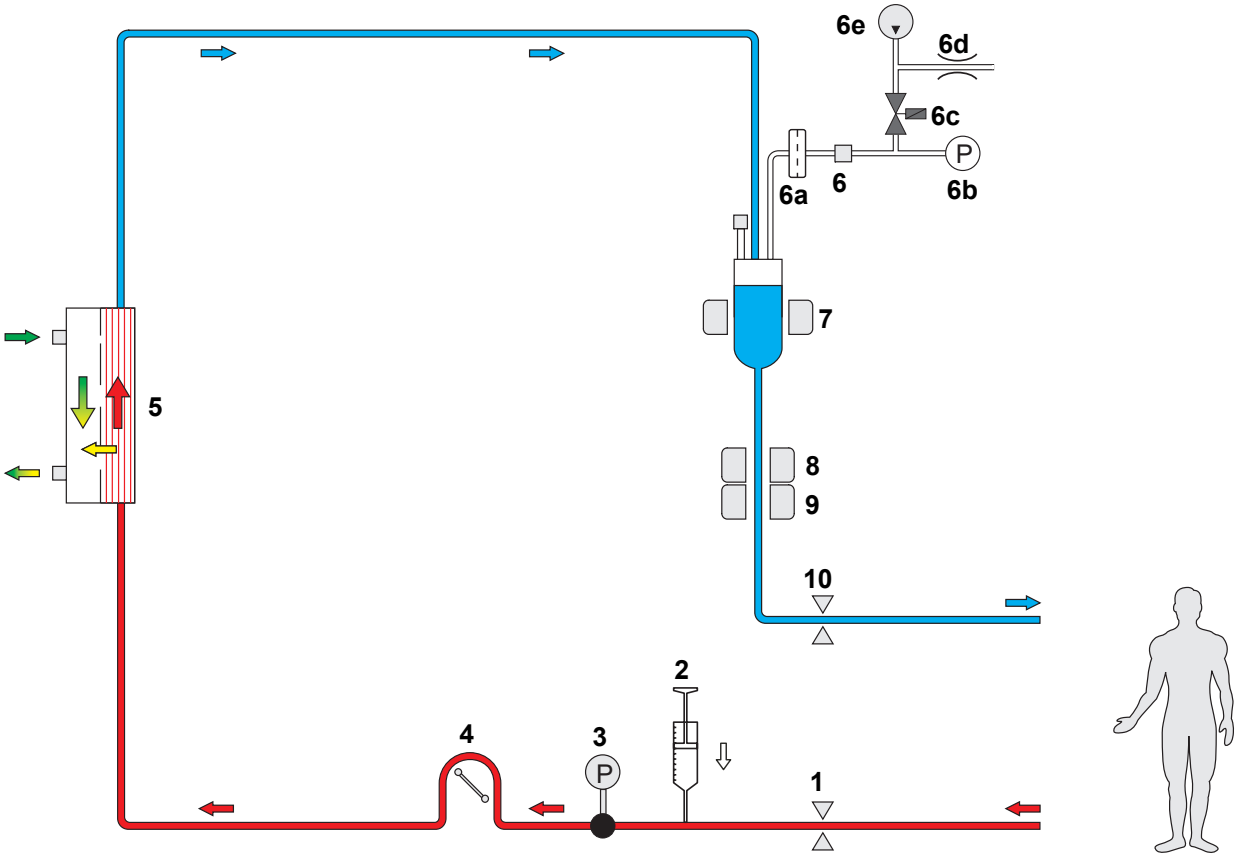
Abbreviation	Material
PVC	Medical plasticized PVC
PC	Polycarbonate
PVC	Medical unplasticized polyvinyl chloride
ABS	Acrylonitrite-butadiene-styrene
PA	Polyamide
PE	Polyethylene

bibag

Abbreviation	Material
PA	Polyamide
PE	Polyethylene

11.5 System Description

11.5.1 Extracorporeal Blood Circuit



1 Arterial occlusion clamp
2 Heparin pump
3 Arterial pressure measurement unit
4 Blood pump
5 Dialyzer
6 Venous pressure port
6a External hydrophobic filter
6b Venous pressure sensor
6c Valve
6d Orifice
6e Compressor
7 Level detector
8 Optical detector
9 Air bubble detector (ABD)
10 Venous occlusion clamp

Arterial path

The blood passes from the patient's vascular access to the arterial occlusion clamp. The heparin pump is located between the arterial line clamp and the arterial pressure measurement unit, before the blood pump. The heparin pump is used to administer heparin doses to the blood at an adjustable rate. The arterial pressure measurement unit measures and monitors the pressure caused by the blood pump on the access. The pressure is transferred by a pressure dome which is located in the tubing system and which is forced against the membrane of the pressure measurement unit. After it has passed the arterial pressure measurement unit, the blood reaches the blood pump. The blood pump pumps the blood to the dialyzer.

Venous path

The venous pressure port is situated next to the dialyzer. where the venous return pressure is measured and monitored within tight limits. The venous bubble catcher is placed into the level detector. If the level in the venous bubble catcher falls it will be detected by the level detector. Below the venous bubble catcher the blood passes through the optical detector (OD). This detector differentiates between OD light (rinse solution or air in the tubing system) or OD dark (blood in the tubing system). The OD is followed by the air bubble detector, which prevents infusion of air. The blood then flows from the air bubble detector via the venous occlusion clamp back to the patient.

Single-Needle Click-Clack

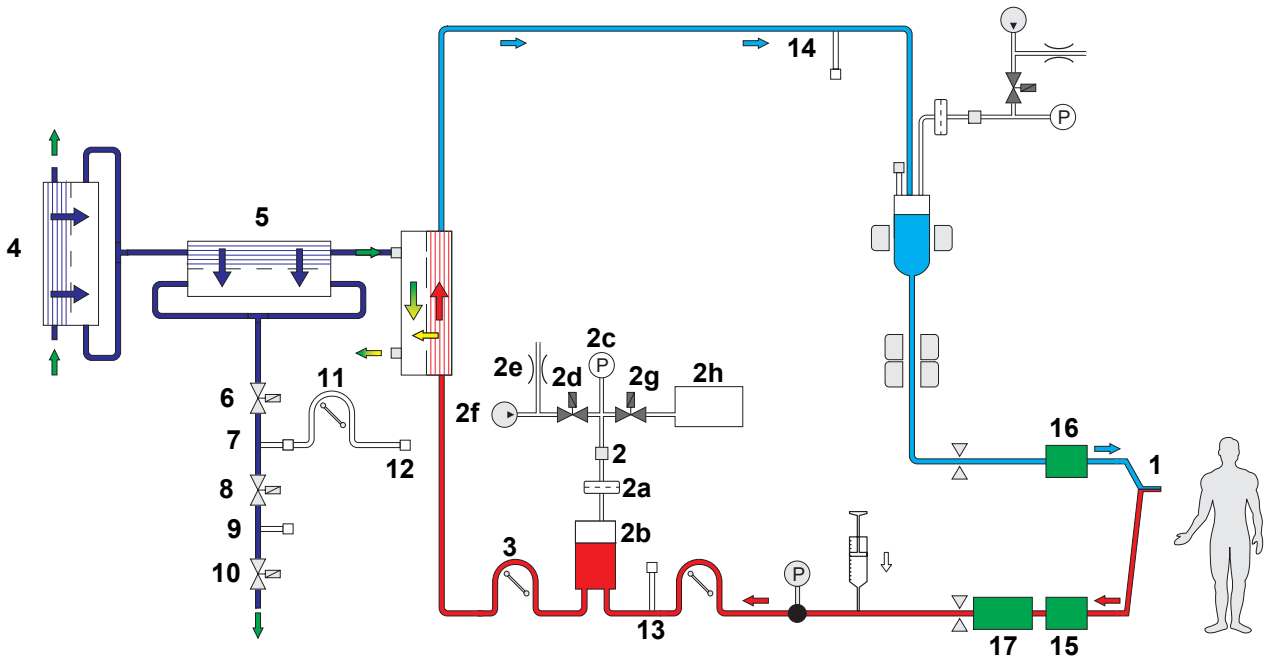
The blood is transported through the extracorporeal blood circuit in a recurrent cycle. The cycle consists of the arterial and the venous phases.
During the arterial phase, the arterial occlusion clamp is open, and the venous occlusion clamp is closed. The blood pump is delivering. This causes a pressure to be built up in the blood lines. When the venous pressure has reached the upper SN pressure, the system switches to the venous phase.
During the venous phase, the arterial occlusion clamp is closed, and the venous occlusion clamp is open. The blood pump is not delivering. The pressure built-up in the blood lines will be reduced. When the venous pressure has reached the lower SN pressure, the system switches to the arterial phase.

Blood alarms

A blood alarm occurs:
- If the arterial pressure is above or below the preset limits.
- If the venous pressure is above or below the preset limits.
- If the TMP is above or below the alarm limits.
- If the air bubble detector detects air.
- If the blood pump stops for ≥ 60 seconds.
- In the event of a blood leak of the dialyzer.
- Level monitored in the venous bubble catcher (warning).
- During Single-Needle Click-Clack: cycle exceeded

If a blood alarm is initiated:
- The blood pump will stop.
- The substituate pump will stop (only with ONLINE*plus*™).
- the venous occlusion clamp is closed.
- A visual and an audible alarm will be given.
- Ultrafiltration will be stopped.
- The heparin pump is stopped.

11.5.2 Extracorporeal Blood Circuit with Additional Functions



SN (option)

1 Single-Needle patient line
2 Single-Needle pressure port
2a External hydrophobic filter
2b SN chamber
2c Single-Needle pressure sensor
2d Valve SN 1
2e Orifice
2f Compressor
2g Valve SN 2
2h Internal compliance chamber
3 Single-Needle pump

ONLINE*plus*™

4 Filter 1
5 Filter 2
6 Substituate valve
7 Substituate port
8 Rinse valve 1
9 Rinse port
10 Rinse valve 2
11 Substituate pump
12 SafeLine™Connector (to 13 Predilution or to 14 Postdilution)
13 Connector predilution
14 Connector postdilution

BTM (option)

15 Arterial measuring head
16 Venous measuring head

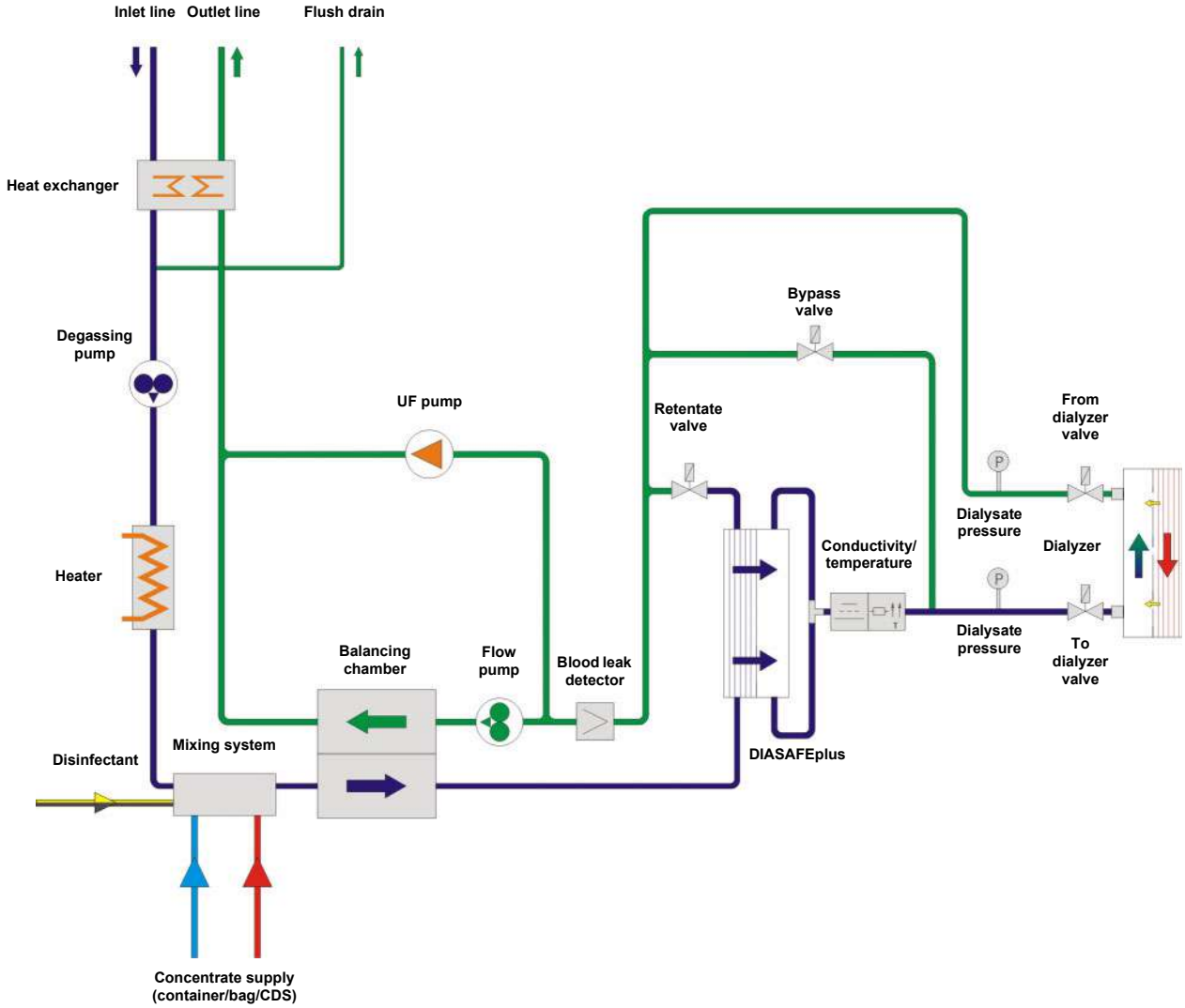
BVM (option)

17 BVM measuring head

SN (option)	During Single-Needle dialysis, blood is alternately removed from and returned to the patient through one needle.
ONLINE*plus*™	With the ONLINE*plus*™ option the substituate is derived from the dialysate by means of two filter stages and a substituate pump and is supplied to the extracorporeal blood circuit (predilution or postdilution).
BTM (option)	The BTM arterial and venous measuring heads are designed to measure the temperature of the arterial and venous blood temperature at this position.
BVM (option)	The BVM measuring head is designed to measure the relative blood volume of the patient.

11.5.3 Hydraulics

● Flow diagram



● Basic description

Product water enters the hydraulics of the hemodialysis system via the water inlet. It is then preheated by the out-flowing dialysate by means of the heat exchanger. The Flush is activated after switching on the system and water is flushed from the water inlet to the Flush outlet. The product water is then degassed and heated before passing to the mixing system where it is mixed with the appropriate concentrates to produce dialysate.

In the balancing chamber, the volumes to and from the dialyzer are volumetrically balanced. The fresh dialysate then enters the dialyzer having passed through the DIASAFE®*plus* and the dialyzer valve.

Conductivity and temperature sensors check the dialysate for the correct mixing ratio and temperature. If these are not within the set alarm limits, the dialyzer supply valve closes and the bypass valve opens, therefore discharging any incorrect dialysate directly to the drain.

Transmembrane pressure is calculated from the values of the dialysate pressure transducers. The blood leak detector generates an alarm if any blood loss is detected in the dialysate. The preset correct fluid removal from the patient is achieved by the UF pump whilst the flow pump controls the dialysate flow from the dialyzer to the balancing chamber. The used dialysate is then passed via the heat exchanger to the drain to be removed.

When the disinfection programs are in progress, disinfectant is supplied via the mixing system and the hydraulics to clean and disinfect the unit.

11.5.4 Description bi*b*ag®

When using the bi*b*ag®, a bag containing sodium bicarbonate powder ($NaHCO_3$) is used instead of a canister containing a liquid bicarbonate solution.

The powder is prepared in the hemodialysis system to produce ready-to-use bicarbonate.

For recommended values for the maximum treatment times in relation to the package size used and the dialysate flow refer to the table below.

Package size	Maximum treatment times
bi*b*ag® 650 g ($NaHCO_3$)	300 ml/min approx. 10 hours 500 ml/min approx. 6 hours 800 ml/min approx. 4 hours
bi*b*ag® 900 g ($NaHCO_3$)	300 ml/min approx. 15 hours 500 ml/min approx. 9 hours 800 ml/min approx. 6 hours

11.5.5 OCM Description

- **Information regarding OCM**

OCM logo

OCM® is a registered trademark.

Intended use

Fields of application

The OCM allows determination of the average effective urea clearance (K), the dialysis dose Kt/V and the plasma sodium concentration during dialysis.

- **Description**

Description of the procedure

OCM measurement technique

An Online Clearance Measurement is performed at different times during a dialysis treatment to determine the clearance over time and to detect a reduction in efficiency that occurred during the treatment. The measurement can be started by the operator on the dialysis system or can be programmed in the SETUP to start with each dialysis treatment.

During an Online Clearance Measurement the conductivity of the dialysate flowing into the dialyzer is adjusted in accordance with a fixed time schedule. If the base conductivity is within 13.9 to 14.6 mS/cm, the measurement direction will alternate, otherwise the variations will always be performed in the same direction.

A pre- and post-dialyzer measurement of the conductivity is performed by two mutually independent temperature-compensated conductivity cells.

Sequence of measuring cycles during treatment
The interval between two measurements can be freely selected in increments of 1 minute. The minimum interval is 25 minutes. No measurement will be started if only 12 minutes are left until completion of the UF time.

If an OCM measurement is aborted, e.g. by changing one of the dialysis parameters, the measurement will be repeated at the next possible occasion.

Conductivity limits during a measurement
To prevent a conductivity alarm, the CD window will automatically and temporarily be spread while a measurement is in progress.

Note

It must always be ensured that the CD limits are set symmetrically.

Changing the concentrate settings during a CD variation
The current desired conductivity should not be changed during the CD variation as this would cause the measurement to be aborted and to be repeated later.

11.5.6 ONLINE*plus*™ Description

The term "ONLINE" means that the substitution fluid is produced from the dialysate during the treatment. Both procedures (HDF and HF) can be performed as predilution (pre-dialyzer addition of the substituate) and postdilution (post-dialyzer addition of the substituate).

With the ONLINE*plus*™ option the substituate for the treatment modes HDF and HF "ONLINE" is derived from the dialysate by means of two filter stages and a substituate pump and is infused into the patient. As the patient is connected via the dialyzer (High-Flux) to the closed dialysate circuit of the dialysis system, the volume balance remains neutral. Fluid is therefore removed from the patient by the UF pump only.

The ONLINE*plus*™ option consists primarily of a substituate pump, the substituate port (to connect the SafeLine™ disposable as substituate line), a rinse port (to rinse the dialyzer) and two DIASAFE®*plus* filters.

Apart from the preparation of the substituate from the dialysate, the ONLINE*plus*™ also provides the following functions:
– Priming/rinsing the extracorporeal blood circuit with substituate
– Infinite rinsing of the EBC and the dialyzer
– Bolus with substituate; a bolus can also be given in HD, provided the SafeLine™ is connected (the bolus will NOT be balanced!)
– Reinfusion (blood return) with substituate

● **Intended use**

Fields of application

In addition to hemodialysis (HD) the ONLINE*plus*™ option also supports the following procedures (the treatment mode can be changed during the treatment):
– Hemofiltration (HF) pre-/postdilution
– Hemodiafiltration (HDF) pre-/postdilution
– ONLINE priming and rinsing of the extracorporeal blood circuit
– Bolus administration in case of hypotension

Chemical composition of the substitution fluid produced online

The chemical composition of the fluid produced with the ONLINE*plus*™ is identical to the composition of the fresh dialysate selected by the operator. This applies to all electrolytes contained in the dialysate and especially the bicarbonate content of the fluid.

The amount of bicarbonate to be considered is determined by:

Quantity bicarbonate [mmol]	=	volume infused [l]	X	bicarbonate concentration of the dialysate [mmol/l]

Restrictions

An HF treatment may not be performed with a dialyzer with one filtrate connector (HF filter without dialysate couplings).

11.5.7 SN Description (Option)

During SN dialysis, blood is alternately collected from and returned to the patient through one needle. (2-pump procedure).

When the arterial clamp is open the arterial blood pump rotates and delivers blood into the SN chamber. The volume delivered depends on the stroke volume set (10 to 50 ml). The Single-Needle pump is stopped and the venous occlusion clamp is closed. The external compliance chamber is connected to the Single-Needle pressure transducer. The internal compliance chamber located within the EBM is filled with air. The arterial blood pump stops and the arterial clamp closes as soon as the stroke volume and pressure is achieved. The SN blood pump rotates and pumps the blood through the dialyzer, the venous bubble catcher and the venous occlusion clamp into the patient. As soon as the pressure in the internal compliance chamber reduces below the lower set limit, the process described above restarts.

The therapeutical result (clearance) depends on the effective blood flow and the stroke volume. The higher the stroke volume, the lower the proportionate recirculation. For this reason, the largest possible blood flow and the largest possible stroke volume should be set. These settings differ from patient to patient and, owing to the individual vascular accesses, have different limits.

Approximation formula for the average blood flow (Q_{SN}):
$Q_{SN} = (BPR_{art} + BPR_{SN}) / 4$

11.5.8 BPM Description (Option)

Theory of operation

The module utilizes the oscillometric principle. The blood pressure cuff is inflated by an electric pump. Thereafter, the pressure in the blood pressure cuff is gradually reduced via the relief valve. The pulse-related changes in the cuff pressure are superimposed on the cuff pressure generated by the pump and controlled by the relief valve.

The BPM control limits the maximum pressure in the blood pressure cuff to 300 mmHg. An additional monitoring unit ensures immediate deflation of the pressure if the pressure in the blood pressure cuff exceeds 320 mmHg.

Fields of application

The BPM can be used to make the following blood pressure measurements:
– Single measurement
– Interval (long-term interval measurement)
– Quick (short-term interval measurement)

All values of the blood pressure measurements of one treatment are saved. They can be represented in graphical diagrams or in a protocol.

The BPM is provided with a safety unit (insulated pressure line) to protect the patient against burns when high-frequency (HF) surgical devices are used at the same time.

The patient symbol to the left of the pressure connector indicates that the BPM can be used simultaneously with a defibrillator (defibrillator-protected applied part of the BF type). Proper functioning of the BPM is not affected by the defibrillator discharging.

Restrictions

The following lists comprises a selection of generally applicable contraindications:
– Use of a heart lung machine
– Complications in the peripheral circuit
– Convulsions
– Spasms
– Tremors
– Tachycardia

The attending physician is responsible for deciding on whether or not the BPM should be used.

11.5.9 BTM Description (Option)

- **Recirculation**

In order to ensure a sufficient dialysis efficiency, continuous monitoring of the vascular access function is necessary. This can be achieved by recirculation measurement.

With the BTM option, the thermo dilution method is used for recirculation measurement.

For performing the measurement, a temperature bolus is generated by temporarily altering the dialysate temperature. Inside the dialyzer, the bolus is transferred to the blood side and recorded by the venous measuring head of the BTM. Now the bolus flows along the recirculation paths for the fistula and the cardiopulmonary recirculation. The arterial measuring head will finally record a reduced bolus. The quotient of the measurement values for the arterial and the venous bolus heights finally determines the recirculation value.

- **Body temperature control**

The BTM module is designed for controlling the patient's body temperature according to the concept of "physiological dialysis".

The importance of the blood temperature for cardiovascular stability has already been demonstrated by several studies. Low dialysate temperatures proved to be favorable to circulation stability, while higher temperatures resulted in an increase in the patient's core temperature and hypotension occurring more frequently.

According to that a noticeable improvement of circulation stability can be achieved if thermal conditions during dialysis are not left to chance, as before, but are monitored and controlled individually by the BTM.

In order to control the body temperature of the patient, the BTM continuously measures this temperature, attempting to achieve the curve defined by the operator by controlling the dialysate temperature. The curve is determined by specifying the time-related change of the body temperature (in °C/h).

The body temperature is determined by the measurement values of the two (art./ven.) temperature-compensated measuring heads and the measurement values resulting from the recirculation measurements.

11.5.10 BVM Description (Option)

- **Measuring principle**

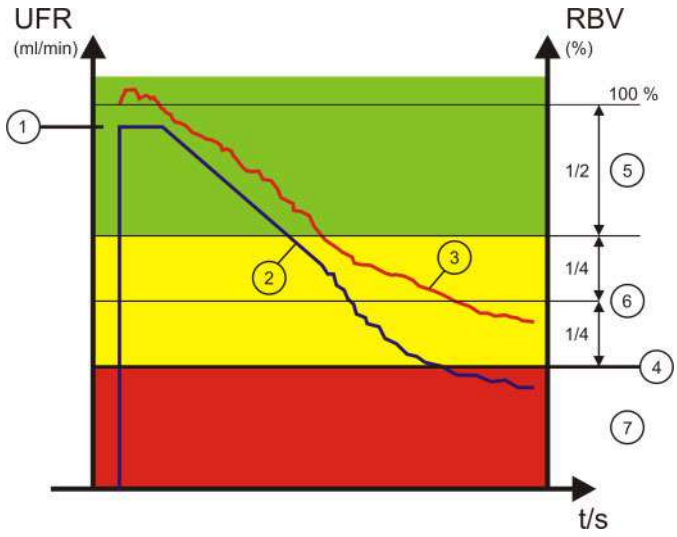
The BVM is designed for non-invasive online determination of the relative change of the blood volume (RBV), of the hematocrit (Hct) and the hemoglobin (Hb) during the treatment. During the treatment, fluid is removed from the patient's body by means of ultrafiltration. This procedure reduces the plasma water volume, whereas certain blood components (cells, hemoglobin, plasma proteins) are not able to leave the intravasal space. The intravascular mass of the proteins remains almost constant in case of blood volume changes due to ultrafiltration or following fluid. As a result, the mass proportion and the protein concentration, and thus the density of the examined blood will change.

Density changes of a medium may be determined by measuring the acoustic velocity. Based on these criteria, the BVM measures the density of the blood and the resulting parameters RBV, Hct and Hb.

The blood volume is measured in a special measuring cuvette in the arterial blood line. The temperature also influences the velocity and is therefore also determined and taken into consideration.

- **UF control**

Influence of the RBV on the UF rate



1 Max. BVM rate

2 BVM rate (UF rate preset by the BVM)

3 RBV

4 Crit. RBV

5 BVM-Rate = 2 x remaining UF volume / remaining treatment time, limited by max. BVM rate

6 Control range, UFR depending on current RBV

7 UFR = 0

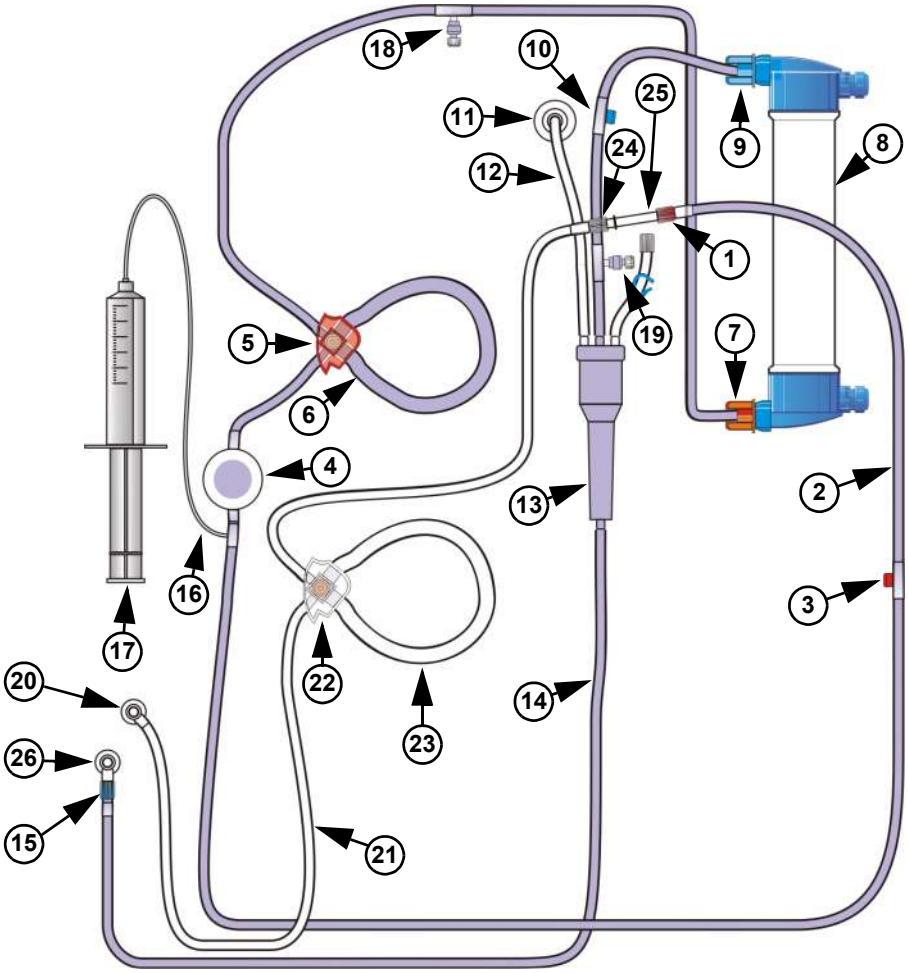
The illustration (Influence of the RBV on the UF rate) shows an example of a treatment performed with UF rate control depending on the blood volume.
The BVM rate is initially higher than during a treatment performed without control.
In the later phase of the treatment, the BVM rate then will be continuously reduced, preventing the blood volume from falling below a predefined value which is individually critical for each patient (crit. RBV).

Whereas the blood volume is not monitored during a treatment with a constant UF rate or with a UF profile - representing a permanent risk of a blood pressure drop due to insufficient refilling - this treatment mode is characterized by continuous monitoring of the RBV. Each event and each measure having an effect on the blood volume will be detected. As a countermeasure, the BVM rate may be reduced immediately in case of unfavorable changes of the blood volume. Continuous monitoring and control therefore result in a significant improvement of the patients' stability and well-being, especially for patients suffering from blood circuit instability.

The BVM rate may be limited depending on the blood pump rate and the measured hematocrit, to avoid a too important hemoconcentration in the dialyzer.

11.6 Blood Lines (Description)

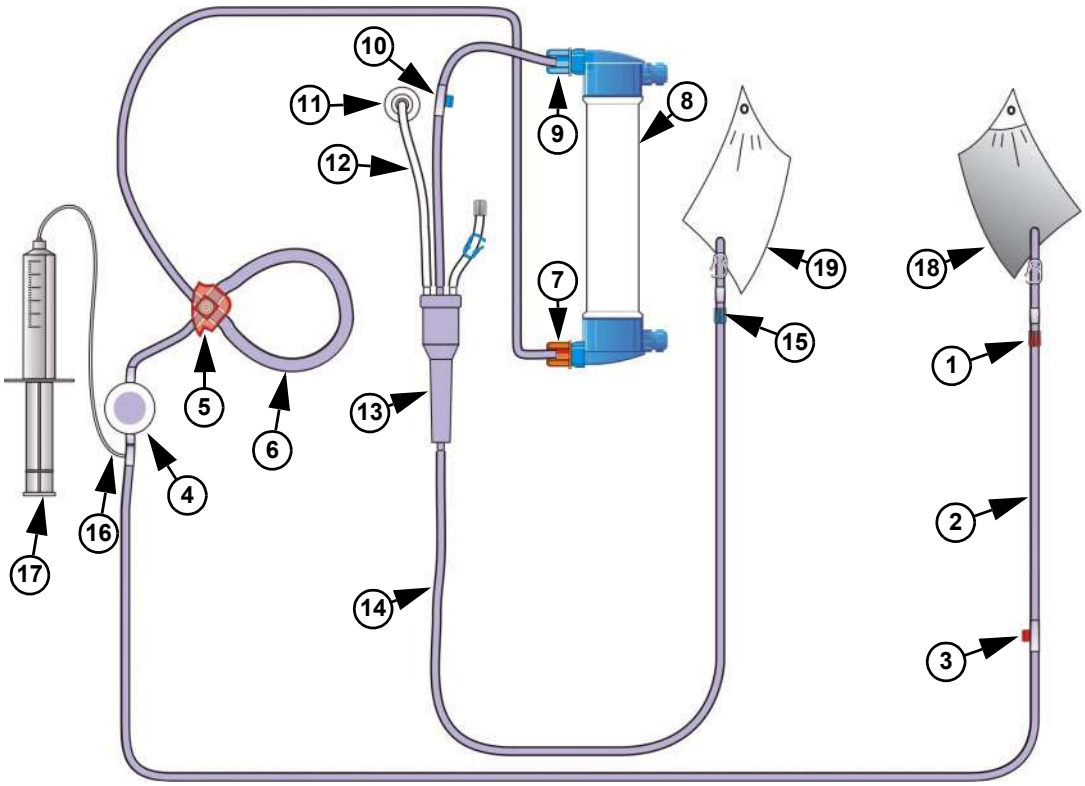
11.6.1 Blood lines with ONLINE*plus*™



1 Arterial patient connection
2 Arterial blood line
3 Arterial injection site/collection site
4 Arterial pressure dome
5 Line guide
6 Pump segment
7 Dialyzer connector (arterial blood line)
8 Dialyzer
9 Dialyzer connector (venous blood line)
10 Venous injection site/collection site
11 Connection, venous pressure line
12 Venous pressure line

13 Venous bubble catcher
14 Venous blood line
15 Venous patient connection
16 Heparin line
17 Heparin syringe
18 Connector predilution
19 Connector postdilution
20 Substituate connector (SafeLine™)
21 SafeLine™
22 SafeLine™ line guide
23 SafeLine™ pump segment
24 Connector pre/postdilution (SafeLine™)
25 Recirculating adapter (SafeLine™)
26 Rinse connector

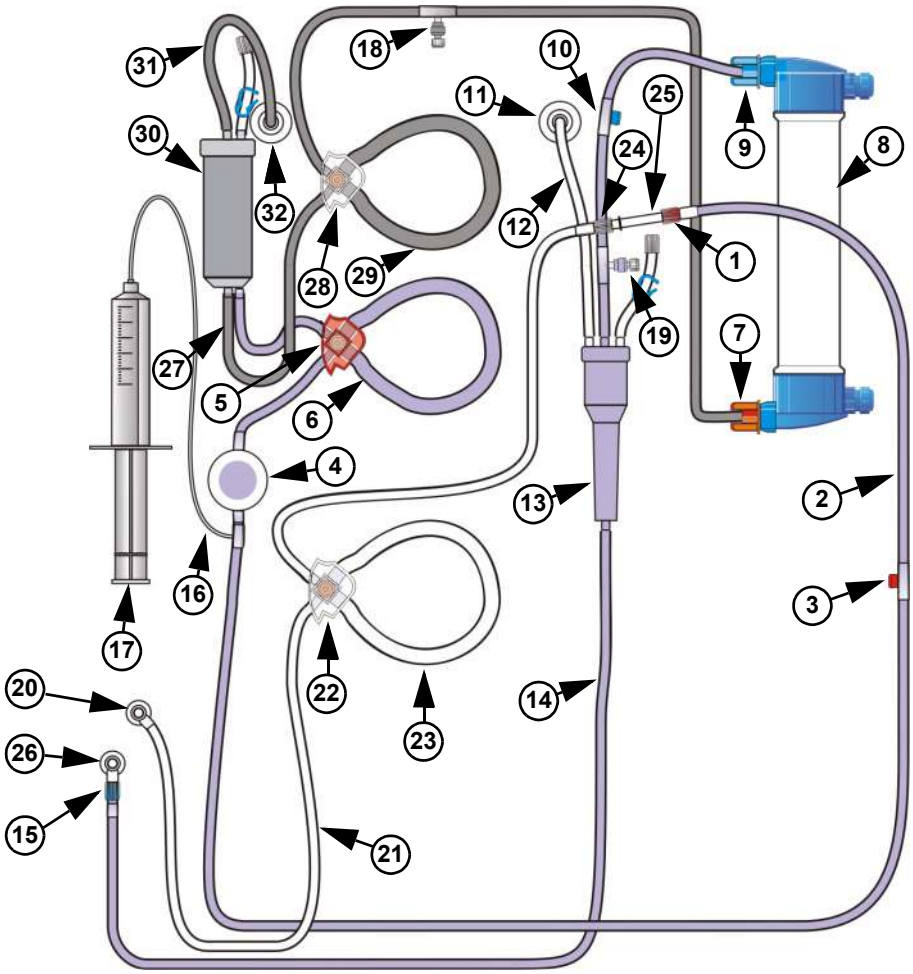
11.6.2 Blood lines with rinse solution bag



1 Arterial patient connection
2 Arterial blood line
3 Arterial injection site/collection site
4 Arterial pressure dome
5 Line guide
6 Pump segment
7 Dialyzer connector (arterial blood line)
8 Dialyzer
9 Dialyzer connector (venous blood line)
10 Venous injection site/collection site
11 Connection, venous pressure line
12 Venous pressure line
13 Venous bubble catcher
14 Venous blood line
15 Venous patient connection
16 Heparin line
17 Heparin syringe
18 Rinse solution bag

19 Prime collection bag

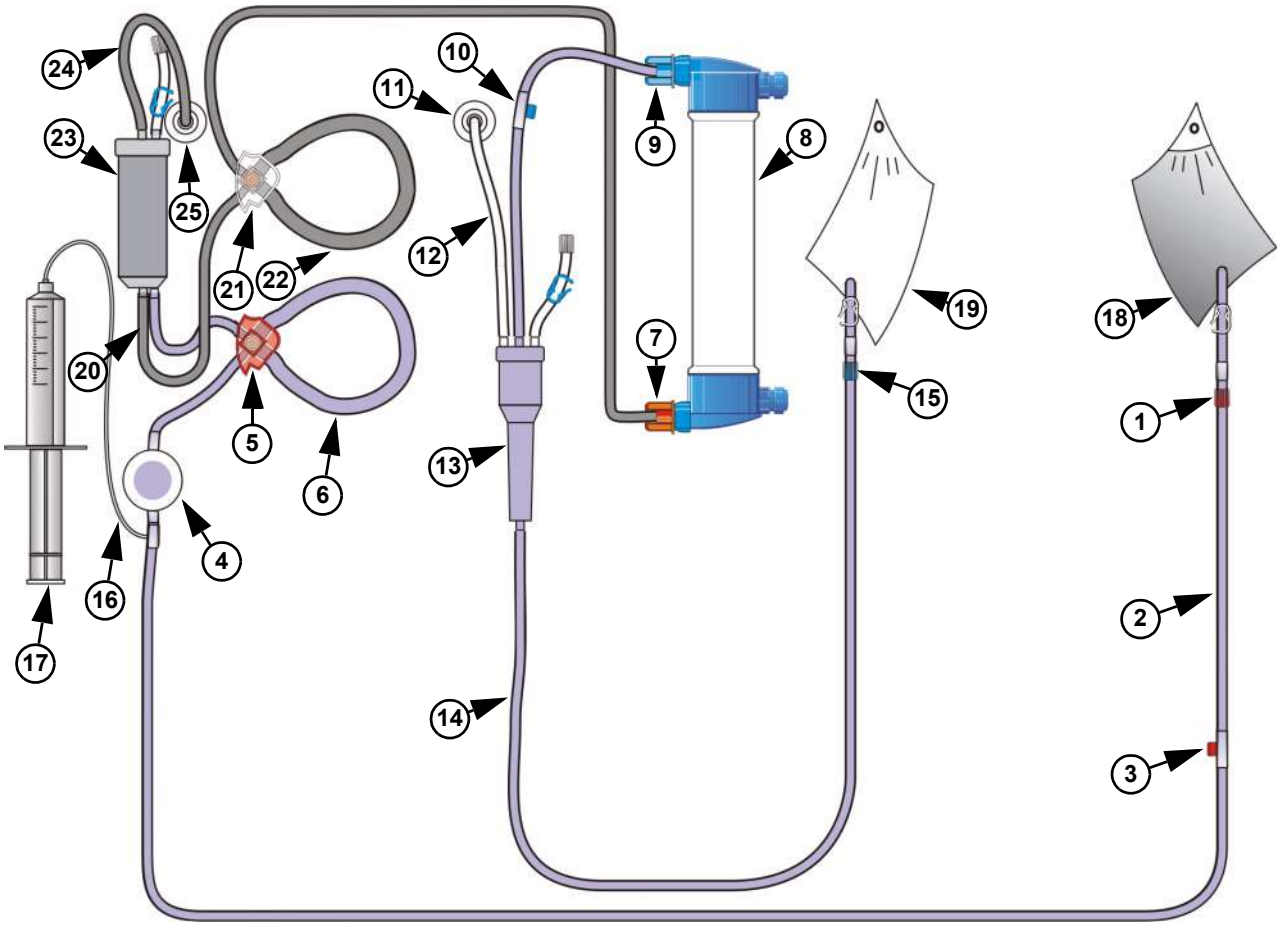
11.6.3 Blood Lines with ONLINE*plus*™ Single-Needle



1 Arterial patient connection
2 Arterial blood line
3 Arterial injection site/collection site
4 Arterial pressure dome
5 Line guide
6 Pump segment
7 Dialyzer connector (arterial blood line)
8 Dialyzer
9 Dialyzer connector (venous blood line)
10 Venous injection site/collection site
11 Connection, venous pressure line
12 Venous pressure line
13 Venous bubble catcher
14 Venous blood line

15 Venous patient connection
16 Heparin line
17 Heparin syringe
18 Connector predilution
19 Connector postdilution
20 Substituate connector (SafeLine™)
21 SafeLine™
22 SafeLine™ line guide
23 SafeLine™ pump segment
24 Connector pre/postdilution (SafeLine™)
25 Recirculating adapter (SafeLine™)
26 Rinse connector
27 Arterial blood line (Single-Needle part)
28 SN line guide
29 SN pump segment
30 SN chamber
31 SN pressure line
32 Connector, SN pressure line

11.6.4 Blood Lines with Single Needle with Rinse Solution Bags



1 Arterial patient connection
2 Arterial blood line
3 Arterial injection site/collection site
4 Arterial pressure dome
5 Line guide
6 Pump segment
7 Dialyzer connector (arterial blood line)
8 Dialyzer
9 Dialyzer connector (venous blood line)
10 Venous injection site/collection site
11 Connection, venous pressure line
12 Venous pressure line
13 Venous bubble catcher
14 Venous blood line
15 Venous patient connection

16 Heparin line

17 Heparin syringe

18 Rinse solution bag

19 Prime collection bag

20 Arterial blood line (Single-Needle part)

21 SN line guide

22 SN pump segment

23 SN chamber

24 SN pressure line

25 Connector, SN pressure line

11.7 Initial Start-Up

11.7.1 Relevant Instructions Before Initial Start-Up

Caution

The system may only be used in accordance with the accompanying documents.
Only then will the manufacturer consider himself liable for any effects on safety, reliability and performance of the system.

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

In case of a first installation of the dialysis system, observe the Specifications.

When bringing the dialysis 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.

Caution

If the hemodialysis system is taken out of service after the initial start-up, the following instructions have to be observed. When the machine is returned to use, check that the pressure of the water supply meets the prescribed minimum pressure.

11.7.2 Electrical Installation

Connection to the power supply system

The national standards and regulations (e.g. in Germany VDE 0100-107) must be observed when connecting the machine to the power supply system.

Protective earth

When using safety class I devices, the quality of the protective conductor of the installation is of particular importance. It must be taken into consideration that in many countries regulations have been enacted by the national authorities.

Potential equalization

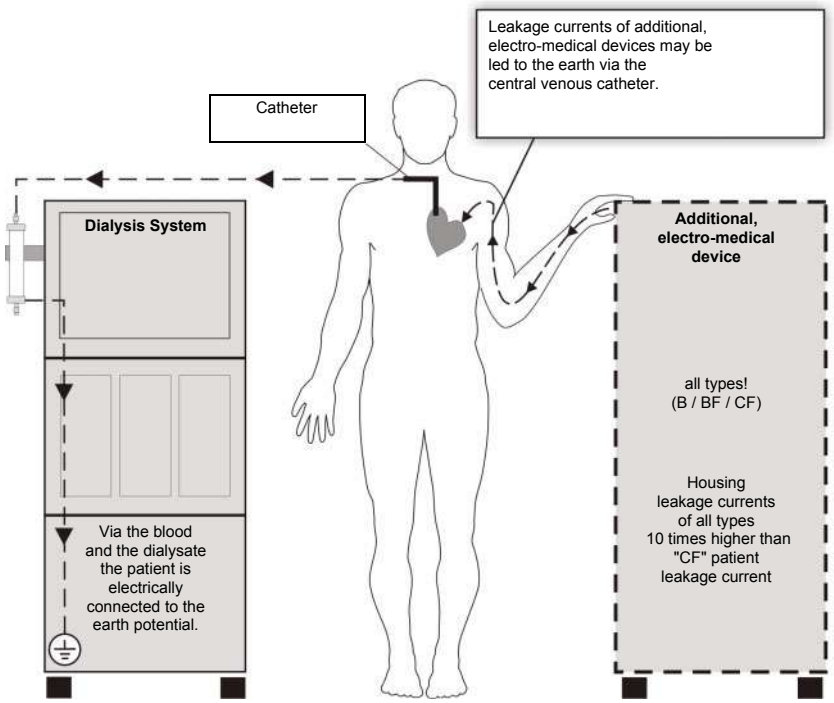
Connect the potential equalization to the rear of the machine if this is required by the legal regulations at the place of installation (e.g. according to VDE 0100-107 in rooms of application group 2).

If additional equipment, which is not included in the accessories, is connected to the dialysis system, there is a danger that the permissible leakage currents will be exceeded.

Caution

When using central venous catheters, the following precautions must be observed:

1. The dialysis system must be connected to a potential equalization.
2. If additional electro-medical devices are connected to the patient or they are positioned within the reachable area of the patient, it must be ensured that all leakage currents of these devices (device leakage currents, housing leakage currents, earth leakage currents and patient leakage currents) are below the respective limit for CF applied parts.
   This means:
   10 µA maximum in normal conditions, and 50 µA in "single fault conditions".
   This also applies to patient positioning devices (e.g. patient chairs).
   Devices with leakage currents within these limits, but with an application current exceeding the specified leakage currents (e.g. on electro stimulators) must not be used. This also applies to defibrillators, which have no applied part type CF.
   If all requirements have been fulfilled, these devices may be operated on the patient or within the reachable area of the patient, provided they are, like the dialysis system, integrated into the potential equalization.
   If these conditions are not fulfilled, no other additional electro-medical device must be connected to the patient or positioned within the reachable area of the patient.
   In case of doubt, ask your local technician.



3. When determining the room design, a group 1 room is sufficient, i.e., the power may be turned off in case of a single fault condition, and the treatment may be aborted or repeated.
   Additionally, the room must comprise a potential equalization. For further information refer to the national regulations (e.g. in Germany DIN VDE 0100-710).

Power cable

If the power cable needs to be replaced, use only the original power cable listed in the spare parts catalog.

Electromagnetic radiation

Do not use devices emitting electromagnetic radiation, e.g. walkie-talkies, portable phones, radio transmitters, in the vicinity of dialysis systems in operation. This may cause a malfunction of the dialysis system.

Batteries

Maintenance of the built-in batteries:

Upon receipt of the system, charge the battery as follows:
– Use the power cable to connect the system to the electrical power source.
– Actuate the power switch to turn the system on.
– Leave the system on for 10 hours.

If the system is not used, repeat this procedure every six months.

11.7.3 Water Supply

Purified water quality

Only water which is suitable for dialysis should be used for operating the dialysis system. The quality of the water should comply with the local regulations (e.g. European Pharmacopoeia - 4th Edition – ISO 13959:2002).

Specifications

The ranges of the water inlet pressure, the supply pressure of the dialysate concentrate, the temperature, and the flow rates, which are required for operating the hemodialysis system, are listed in the chapter Specifications.

Installation

The national regulations with regard to the prevention of backflow into the water supply system and the air gap between drain connection and sewage connection must be observed when installing and operating the machine (e.g. in Germany VDE 0753, part 4). For further information refer to the Specifications.
Each system must be provided with its own free fall air gap.

11.7.4 Water Supply – Additional Instructions to be Observed When Using the DIASAFE®*plus* and the ONLINE*plus*™

Caution

When using the DIASAFE®*plus* the following criteria must be observed with regard to the quality of purified water, concentrate and dialysate:
– Use only reverse osmosis water.
– Always ensure that both purified water and dialysate meet the applicable standard (see below).

For microbiologic quality standards / recommendations refer to the table below.

Dialysate quality

The DIASAFE®*plus* removes bacteria and endotoxins from the dialysate thus enabling the preparation of high-purity dialysate.

Microbiological quality standards / recommendations

	Purified water	**Concen-trate**	**Dialysate (not filtered)**	**High-purity dialysate**
Microbial counts (in CFU/ml)	<100	<1000	<1000	<1
Endotoxins (in I.U./ml)	<0.25	<1	<1	<0.03
CFU: Colony-Forming Units I.U.: International Units				

General notes

The microbiological purity of dialysate prepared in the dialysis center is of critical importance.

Purified water quality

The European Pharmacopoeia – 4th Edition lists maximum limits for chemical and microbiological quality.

Modern reverse osmosis units and the appropriate design of water storage and delivery systems (e.g. short distribution loops avoiding stagnant flow zones) ensure compliance with this standard.

Concentrate quality

Bicarbonate concentrate is an ideal nutrient medium for microorganisms. The use of sterile or microorganism-poor concentrates is recommended. Online dry concentrates (bi*b*ag®) assist in the preparation of dialysate with high microbiological quality. The use of concentrate residues from open containers and the preparation of bicarbonate concentrate in the dialysis center are *not* recommended. Central delivery systems for concentrate or dialysate must meet high hygienic standards and demand regular inspection.

11.7.5 Performing the Initial Start-Up

For initial start-up it is imperative to follow the start-up report. A current start-up report is supplied with each hemodialysis system.

11.8 Technical Safety Checks and Technical Measurement Checks

11.8.1 To be Observed Before Starting the Checks

This chapter includes the Technical Safety Checks (TSC) and the Technical Measurement Checks (TMC) to be performed. (Technical Measurement Checks are applicable only to Item 6.1 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.

Numbers not listed are not part of the TSC/TMC. These are part of the maintenance procedures.

Please refer to the Service Manual for further explanatory information on the Technical Safety Checks, the Technical Measurement Checks and the Maintenance Procedures.

11.8.2 TSC / TMC Report

Technician's name:	System type including option(s) / software version:	
Customer/customer no.:	Device no.:	Inventory no.:
Service report no.:	Operating hours:	Equipment code:

No.	Description	Correct.	Meas. value	✓
1	**Visual inspections**			
1.1	Labels and labeling 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	The power cable shows no signs of damage.	–		❑
1.4	Leakage sensors (S14, S35, EBM) inspected 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. ---Only with ONLINE*plus*™: Rotor position (substituate pump) checked. Rotor cleaned. ---Only with Single-Needle: Rotor position (Single-Needle pump) checked. Rotor cleaned.	–		❑
1.10	Filter (F06) replaced.	–		❑
1.18	---Only with ONLINE*plus*™: O-rings at substituate port and rinse port replaced.	–		❑
2	**General checks**			
2.1	Power failure alarm checked. Permanent tone; alarm message: *Power failure – System is battery-operated*.	–		❑
4	**Dialysis mode**			
4.1	Temperature tested with reference instrument. Desired temperature on temperature display Difference between system temp. / ref. temp.: –0.5 °C to +0.2 °C	–	System / ref. ____/____	❑
4.2	Conductivity tested with reference instrument. (If the bi*bag*® option is used, the test has to be performed in conjunction with a bi*bag*®.) Difference between system CD / ref. CD: ≤±0.2 mS/cm	–	System / ref. ____/____	❑

No.	Description	Correct.	Meas. value	✓
4.3	OCM calibration performed.	–		❑
5	**Extracorporeal components**			
5.1	Arterial pressure display			
5.1.1	Zero point of arterial pressure display checked (standby operation) Desired value: 0 mmHg; –5 mmHg to +5 mmHg	–	_____	❑
5.1.2	Slope of arterial pressure display tested. (standby operation) Desired value: 300 mmHg; –5 mmHg to +5 mmHg	–	_____	❑
5.2	Venous pressure display			
5.2.1	Zero point of venous pressure display checked (standby operation) Desired value: 0 mmHg; –5 mmHg to +5 mmHg	–	_____	❑
5.2.2	Slope of venous pressure display tested. (standby operation) Desired value: 300 mmHg; –5 mmHg to +5 mmHg	–	_____	❑
5.3	Venous clamp checked. 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**			
6.1	BPM			
6.1.4 TMC	Leakage test performed. Pressure leakage rate: <6 mmHg/min.	–	_____	❑
6.1.5 TMC	Safety valve tested. System emptied at 320 mmHg, ±10 mmHg	–	_____	❑
6.1.6 TMC	Blood pressure measurement performed. Measured values are plausible.	–		❑
6.1.7 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. ____/____ ____/____ ____/____ ____/____ ____/____	❑
7	**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 measured. Max. 0.3 Ω (with power cable)		_____ Ω	❑

No.	Description	Correct.	Meas. value	✓
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)		_____ µA _____ µA	❑
8	**Final inspection and testing**			
8.1	T1 test performed with all options.			❑
8.2	Disinfection performed.			❑

Test equipment used:

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

_____

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

_____

Comments:

Date:	Signature:	Stamp:

The system has been released for its intended use. **(Attach test badge.)**		❑ Yes ❑ No
Next **inspection date:**		
Comments:		
Date:	**Signature:**	**Stamp:**

11.9 Definitions and Terms

Terms used in these Operating Instructions are explained in the following.

Arterial pressure — Pressure in the extracorporeal circuit between arterial cannula and blood pump.

Purified water — Water suitable for hemodialysis (e.g. water purified by reverse osmosis).

Bubble catcher — Device integrated in the blood line for the separation of gases which are not dissolved in the blood.

Blood alarms — Group of alarms which cause the blood systems to stop:
- Arterial pressure
- Venous return pressure
- Transmembrane pressure
- Blood leak
- Air
- BP stop alarm

Blood systems — Systems which maintain and control the function of the extracorporeal circuit.

Bypass — Process during which the dialysate is diverted away from the dialyzer.

Dialyzer blood port — Arterial or venous blood port on the dialyzer.

Dialysate — The exchange fluid used in dialysis.

Dialysate pressure — The pressure present in a defined section of the system carrying the dialysate, e.g. at the dialyzer outlet.

Pressure line connection — Connector for the pressure line, e.g. Luer-lock.

Pressure line — Line connecting the tubing system to the pressure monitoring unit.

Compliance chamber — Receptacle for leveling variations in pressure and volume, e.g. in Single-Needle dialysis.

Extracorporeal circuit — A section of the blood circulation which takes place outside of the body.

ISO-UF (sequential therapy) — Separation of the hemodialysis procedure into two successive treatment phases each including either ultrafiltration only or diffusion and ultrafiltration (procedure according to the Bergström method).

Conductivity — Reciprocal specific electrical resistance, e.g. of the dialysate.

Pump head — The pump head consists of the pump rotor and the pump stator.

Pump rotor — Driven part of the pump head.

Pump line segment — Line segment which is inserted in the pump head.

Pump line holder	Device for fixing the blood pump line segment.
Pump stator	Stationary support for the pressure rollers of the pump rotor.
Occlusion clamp	Device for automatic clamping of the blood lines, e.g. in the event of alarms or in Single-Needle dialysis.
Single-Needle dialysis	Treatment procedure using a fistula needle or a one-lumen catheter.
Transmembrane pressure	Difference between the pressures acting upon the dialyzer membrane (pressure on blood-side, dialysate pressure).
Venous return pressure	Pressure in the extracorporeal circuit before the venous cannula (e.g. in the venous bubble catcher).
Water alarms	Group of alarms which do not cause the blood systems to be turned off: conductivity (bypass operation), temperature (bypass operation), flow.

11.10 Abbreviations

AC	Alternating current
BC	Balancing chamber
BIC	Bicarbonate
BP	Blood pump
BPM	Blood Pressure Monitor
BTM	Blood Temperature Monitor
BVM	Blood Volume Monitor
CD	Conductivity
CDS	Central delivery system
DC	Direct current
EBM	Extracorporeal Blood Module
EMC	Electromagnetic compatibility
Fig.	Figure (diagram)
HD	Hemodialysis
HDF	Hemodiafiltration
HF	Hemofiltration
LD	Air Detector

LED	Light-emitting diode
MV	Solenoid valve
OCM	Online Clearance Monitoring
OD	Optical detector
SIL	Shunt interlock
SN	Single-Needle
TMC	Technical Measurement Checks
TMP	Transmembrane pressure
TSC	Technical Safety Checks (TSC)
UF	Ultrafiltration

11.11 Symbols

Caution, consult accompanying documents; General danger

IPX1

Protection against ingress of liquids:
Drip-proof (IPX1)

Degree of protection against electric shock:
Type B

Degree of protection against electric shock:
Defibrillator-protected applied part of type CF,

Alternating current

Protective conductor terminal

Ground terminal

Equipotentiality

Dangerous electrical voltage

Risk of caustic burning

Elevated surface temperature

Risk of tilting when inclined by more than 5°

I/O

ON / OFF

On / Off

Blood pump

Mute

Transmitter

Identification of electric and electronic devices

11.12 Consumables Symbols

Refer to the Operating Instructions

Do not re-use

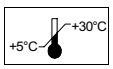
Use by

Batch code

Date of manufacture

Quantity

Catalogue number



Temperature limitation

Pump segment diameter

Sterile. Sterilised using ethylene oxide

Sterile. Sterilised using irradiation

Sterile. Sterilised using steam or dry heat

12 Consumables

12.1 To be Observed in Chapter Consumables

Caution

The system has been approved for use with the consumables and accessories listed in the Operating Instructions.

Should the responsible organization wish to use other consumables and accessories than those listed in the Operating Instructions, the responsibility to ensure the correct function of the system lies exclusively with the responsible organization. The applicable legal regulations must be complied with (e.g. in Germany the Medical Device Directive, MDD and the MPBetreibV = German regulation for the operation of medical products).

The manufacturer does not assume any responsibility or liability for personal injury or other damage and excludes any warranty for damage to the system resulting from the use of non-approved or unsuitable consumables or accessories.

The items listed in this chapter are an extract from our extensive product range. Further products and information are available on request.

12.2 Dialyzers

- **Fresenius Medical Care Polysulfone® dialyzers of the F series (low-flux and high-flux) e.g.: F6 / F6HPS / F60S**

- **Fresenius Medical Care Helixone® dialyzers of the FX class (low-flux and high flux) e.g.: FX8 / FX80**

12.3 Blood Lines

- **Fresenius Medical Care ONLINE Priming/HDF blood lines for the 5008 hemodialysis system**

12.4 Disposable Syringes

Product	Part number	Information
30 ml heparin syringe	503 032 1	Luer lock connector, latex-free plug

12.5 Hemodialysis Concentrates

- **Fresenius Medical Care solutions for bicarbonate dialysis**

  Acid bicarbonate hemodialysis concentrate 1+44 AC-F (45-fold)
  Acid bicarbonate hemodialysis concentrate 1+34 SK-F (35-fold)
  for mixing with basic sodium hydrogen carbonate concentrate 8.4 %

- **Bicarbonate dry concentrate for bi*b*ag®**

Product	Part number	Information
bi*b*ag® 650 g ($NaHCO_3$)	506 078 1	16 bags per box
bi*b*ag® 900 g ($NaHCO_3$)	506 080 1	12 bags per box

12.6 Dialysate Filter DIASAFE®*plus*

Product	Part number	Information
DIASAFE®*plus*	500 820 1	10 filters per carton

12.7 Surface Disinfection / Surface Cleaning

- **Agents for surface disinfection and surface cleaning**

Product	Part number	Information
Fresenius Medical Care ClearSurf™ D, F, NL, I GB, E, P, SLO RUS, PL, RO, BG S, DK, CZ, SK GR, H, HR, TK	 508 569 1 508 573 1 508 579 1 508 577 1 508 578 1	(6 x 2 liters) Type of disinfection: scrub / wipe disinfection Active substance base: cationic tensides Active substance concentration: see product description 0.5 % – 1 hour 1.0 % – 15 minutes
50 ml beaker	603 062 1	
20 ml dosing pump	603 063 1	

12.8 Disinfectants for the Hydraulics

- **Disinfection and decalcification**

Product	Part number	Information
Fresenius Medical Care Diasteril®	508 564 1	6 liters Active substance base: hydroxyacetic acid Active substance concentration: approx. 0.8 % (diluted)
Fresenius Citrosteril®	508 535 1	5 kg container Active substance base: citric acid hydrate Active substance concentration: approx. 0.8 % (diluted)
Fresenius Puristeril® 340	508 551 1	5 kg container Active substance base: peracetic acid Active substance concentration: approx. 0.15 % (diluted)

Product	Part number	Information
Fresenius Medical Care Puristeril *plus* (D, NL, F, GB, S, DK) (E, P, I, H, HR, GR) (RUS, SK, RO, PL, SLO, GB)	 508 570 1 508 571 1 508 572 1	5 kg container Active substance base: peracetic acid Active substance concentration: < 0.1 % (diluted)

- **Disinfection and degreasing**

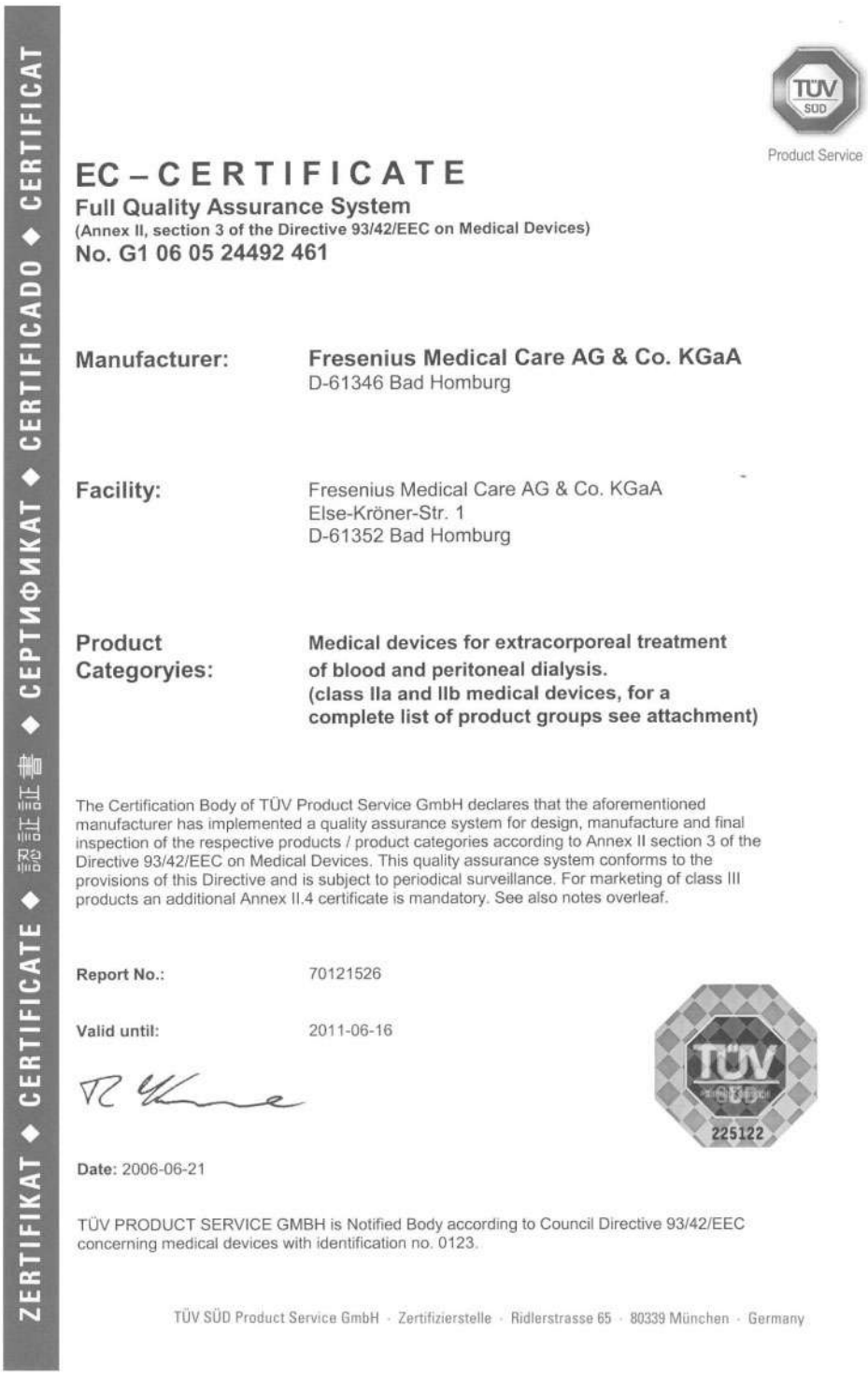
Product	Part number	Information
Fresenius Sporotal® 100	508 542 1	5 kg container Active substance base: sodium hypochlorite Active substance concentration: approx. 0.1 % (diluted)

12.9 Disinfectant Indicators

Product	Part number	Information
pH test strips	628 816 3	Indicator for Diasteril®
Potassium-iodide-starch paper	508 521 3	6 x 100 strips Indicator for Sporotal® 100 Indicator for Puristeril® 340 and Puristeril® *plus*

13 Certificates

13.1 EC Certificate



ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Product Service

EC – CERTIFICATE

Full Quality Assurance System

(Annex II, section 3 of the Directive 93/42/EEC on Medical Devices)

No. G1 06 05 24492 461

Manufacturer: **Fresenius Medical Care AG & Co. KGaA**
D-61346 Bad Homburg

Facility: Fresenius Medical Care AG & Co. KGaA
Else-Kröner-Str. 1
D-61352 Bad Homburg

Product Categoryies: **Medical devices for extracorporeal treatment of blood and peritoneal dialysis. (class IIa and IIb medical devices, for a complete list of product groups see attachment)**

The Certification Body of TÜV Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective products / product categories according to Annex II section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system conforms to the provisions of this Directive and is subject to periodical surveillance. For marketing of class III products an additional Annex II.4 certificate is mandatory. See also notes overleaf.

Report No.: 70121526

Valid until: 2011-06-16

TÜV SÜD 225122

Date: 2006-06-21

TÜV PRODUCT SERVICE GMBH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstrasse 65 · 80339 München · Germany

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Product Service

Attachment to
EC Certificate
No. G1 06 05 24492 461
dated June 21st, 2006

Non-active medical devices

(AT = Adsorption Treatment / HD = Hemodialysis / PD = Peritoneal Dialysis)

No.	Product group / Product name	Classification in accordance with 93/42/EEC	Rule
1.1	**Disinfectants** e.g. *Diasteril®, Clearsurfe®*	IIa	15
1.2	**Bloodlines and accessories** e.g. NaturalLine, AdvancedLine, BasicLine, Filter (Blood return line)	IIa	2
1.3	**Tubing systems for AT, HD, PD Plasmapherese and accessories** e.g. Safeline, cycler systems, closure caps, disinfection caps, adaptors, catheters extensions	IIa	2
1.4	**Fistula needles and sets**	IIa	7
1.5	**Catheters for HD**	IIa	7
1.6	**Dialysis fluid filter** e.g. DIASAFE®, DIASAFE®*plus*	IIa	3
1.7	**ph electrode for AT**	IIa	2
1.8	**Solution for conservation**	IIa	15
1.9	**Fittings and tubes for water treatment systems** e.g. distribution ring	IIa	2

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Product Service

Attachment to
EC Certificate
No. G1 06 05 24492 461
dated June 21st, 2006

Non-active medical devices

(AT = Adsorption Treatment / HD = Hemodialysis / PD = Peritoneal Dialysis)

No.	Product group/Product name	Classification in accordance with 93/42/EEC	Rule
2.1	**Hemodialysis concentrates** e.g. SMARTCART®, *bi*bag®, *indi*bag®, *so*bag®, Flexicart, Granudial®, GENIUS®-concentrates, Renalyte acid, Renalyte acetate, Renacarb, SKF, BCF, SMARTbag®	IIb	3
2.2	**Hemodialyser / Hemofilter** e.g. HPS-serie, F-serie, FS-serie, HdF-serie, FX-class®, Ultraflux	IIb	3
2.3	**Plasmafilter** e.g. Plasmaflux®, AlbuFlow®	IIb	3
2.4	**Catheters for PD and accessories** e.g. Tenckhoff catheter, Swan-Neck catheter, silicone glue	IIb	8
2.5	**Adsorber** e.g. prometh®, DALI®, PROSORBA®, Immunosorba®	IIb	3

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Product Service

Attachment to
EC-Certificate
No. G1 06 05 24492 461
dated June 21st, 2006

Non-active medical devices
(AT = Adsorption Treatment / HD = Hemodialysis / PD = Peritoneal Dialysis)

No.	Product group/Product name	Classification in accordance with 93/42/EEC	Rule
3.1	**Heating plates for PD treatment** e.g. PD-THERMOSAFE *plus*	IIa	9
3.2	**Bioimpendance device** e.g. BCM	IIa	10
3.3	**Central delivery systems** e.g. CDS	IIa	11
4.1	**Machines for peritoneal dialysis and accessories** e.g. sleep•safe, PD-*NIGHT*®	IIb	11
4.2	**Machines for hemodialysis and accessories** e.g. 4008, 5008, GENIUS®	IIb	11
4.3	**Machines for adsorption treatment and accessories** e.g. 4008 ADS, Prometheus®, Art	IIb	11
4.4	**Machines for acute dialysis and extracorporeal blood treatment and accessories** e.g. multiFiltrate, 4008S ARrT*plus*®	IIb	11
4.5	**Water treatment systems** e.g. Aquasafe, AquaHWCS, AquaWTU, AquaB, AquaUNO, JPM	IIb	11

Munich, CRT2

Reiner Krumme

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14 Appendix

14.1 Bibliography

- **Dialysis in general**

  Franz, H.E.: “Blutreinigungsverfahren”, Technik und Klinik; Hemodialysis; peritoneal dialysis, CAPD, hemofiltration, hemodiafiltration, hemoperfusion, membrane plasma separation; 2nd, revised edition / 1991 Georg Thieme Verlag Stuttgart, New York; 1st edition 1973 under the title: "Praxis der Dialysebehandlung“; ISBN 3 13 497702 8.

- **Dialysate filter system and ON-LINE HDF**

  Publications, investigating report on polysulfone membranes, with the enclosed literature references.

  “No evidence for endotoxin transfer across high flux polysulfone membranes”, among others by Professor Dr. med. Jürgen Bommer from the Ludolf-Krehl-Klinik in Heidelberg.

  “Filtration of dialysate using an ON-LINE dialysate filter”, dated June 5, 1990, among others by Francise Dumler MD, Division of Nephrology & Hypertension, Henry Ford Hospital, 2799 West Grand Blvd., Detroit, MI, 48202, USA as well as Fresenius brochures on DIASAFE and polysulfone high-flux with literature.

  “Hemodiafiltration with ON-LINE Production of Bicarbonate Infusate: a new standard for high efficiency, low-cost dialysis in elderly and uncompliant patients” among other by Dr. B. Canaud, Division of Nephrology, Lapeyronie University Hospital, 555, Route de Ganges, 34059 Montpellier, France.

- **Blood Temperature Monitor (BTM)**

  “Fresenius Publikation” (EDTNA-Journal 1992) with further literature.

- **Blood Volume Monitor (BVM)**

  “Fresenius Publikation” (BVM-Blutvolumenmonitor) with further literature.

Fold-Out Sheet
15 OCM

OCM SCREEN

OCM diagram

15 Option OCM (Online Clearance Monitoring)

15.1 To Be Observed Before Using the OCM

Caution

The treatment parameters may not be determined on the basis of the measured parameters (Clearance, Kt/V, Plasma Na).

A measurement of the clearance and the plasma Na does not replace the therapy prescribed by the physician.

The measurement will not be started if the following treatment procedures have been selected:
– ONLINE*plus*™ HF treatment
– Single-Needle
– ISO-UF
– Single-Needle Click-Clack

● **Definitions of Terms**

Kt/V

The Kt/V is the dialysis dose of the dialysis treatment in progress.

K = Blood flow completely cleared of urea per unit of time (Clearance)

t = effective dialysis time

V = volume of distribution of urea

The quality of the Kt/V information content depends on the accuracy of the individual parameters, i.e. primarily on the accuracy of the volume of urea distribution V that was entered. The accuracy of V is the responsibility of the attending physician.
If no valid value for V is available (neither entered directly nor calculated from the patient data), Kt instead of Kt/V will be calculated and displayed.

Interval

Time between two measuring cycles

Hct

Percentage of the volume of the red blood cells in the total blood.

Clearance

The clearance (K) (in ml/min) is the average effective urea clearance. which describes the blood flow volume that is completely cleared of urea.

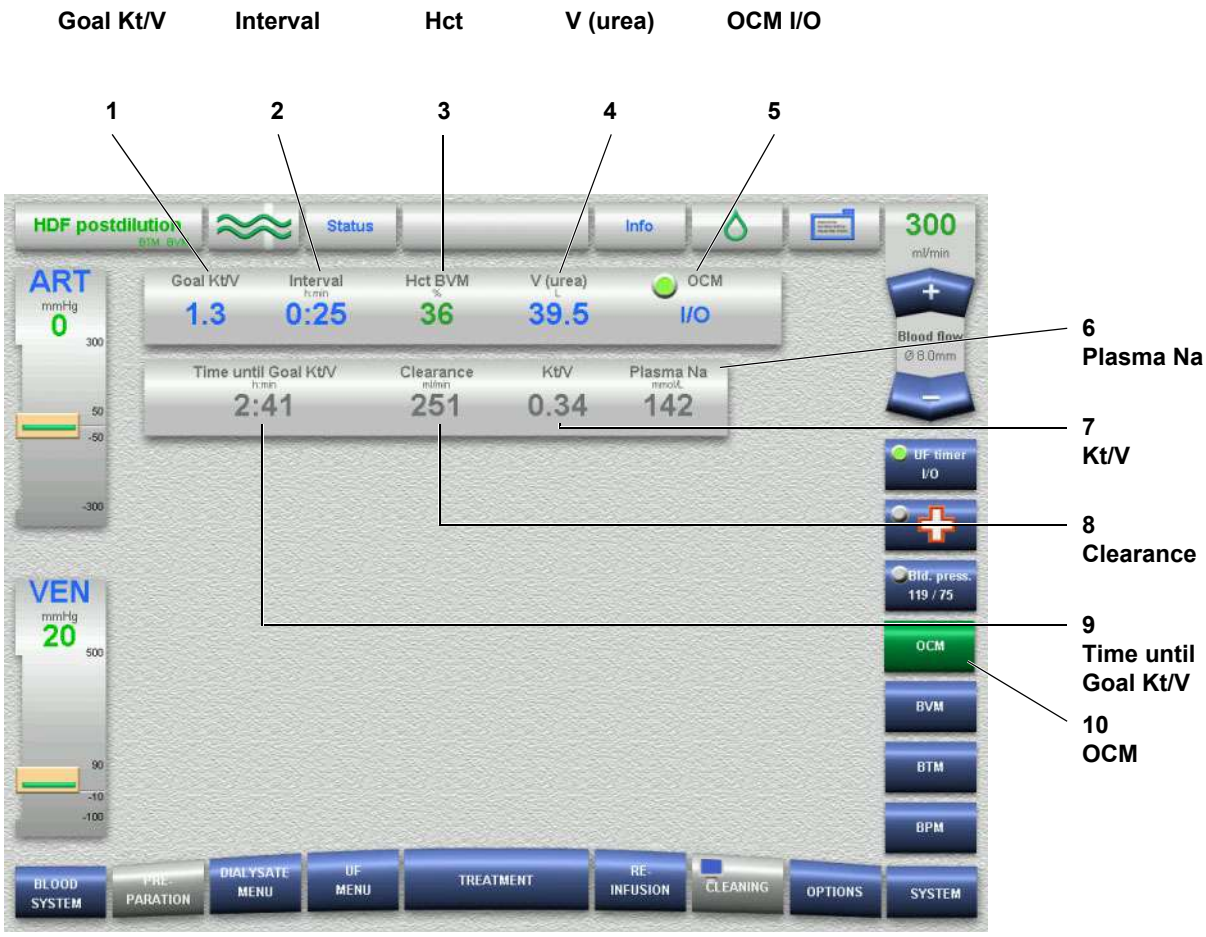
Plasma Na

The plasma Na (in mmol/l) corresponds to the sodium concentration in the patient's plasma.
If the blood flow is ≤ 80 ml/min, the plasma Na value will not be displayed.

Note

The accuracy of the plasma Na value depends on the recirculation.

15.2 Menu Overview



1 Goal Kt/V
Displays the Goal Kt/V.
Touch the **Goal Kt/V** field or entering the Goal Kt/V.

2 Interval
Displays the measurement interval.
Touch the **Interval** field for entering the measurement interval.

3 Hct
Displays the hematocrit.
Touch the **Hct** field for entering the hematocrit.

4 **V (urea)**
Displays the V (urea).
Touch the **V (urea)** field for entering V (urea).

5 **OCM I/O**
Button for starting/stopping the OCM.

6 **Plasma Na**
Displays the Plasma Na.

7 **Kt/V**
Displays the Kt/V.

8 **Clearance**
Displays the clearance.

9 **Time until Goal Kt/V**
Displays the time remaining until achieving the dialysis dose entered for Goal Kt/V.

10 **OCM**
OCM menu button

15.3 Checking/Setting the OCM Parameters

In the **OCM** menu

The following parameters can be checked/set.

Goal Kt/V	Dialysis dose prescribed by the physician
Interval	Time between two measuring cycles
Hct	For the calculation of K and Plasma-Na $^{+}$
V (urea)	Volume of urea distribution of the patient; to be entered in liters

For the calculation of V (urea)

Weight	For the calculation of V (urea)
Height	For the calculation of V (urea)
Age	For the calculation of V (urea)
Sex	For the calculation of V (urea)

Note

We recommend entering V (urea). If V (urea) is not known, it will be calculated by the system from the weight, height, age and sex using the formula developed by Watson. Alternatively V (urea) can be determined in the laboratory from blood samples. The PC program DC-Tool distributed by Fresenius Medical Care is available for this purpose. The Hct value determined from a blood sample prior to the treatment must be entered in the Hct field.

If V (urea) is not known, either **Not known** or **Calculate** can be selected under V (urea).

If **Not known** is selected, **----** appears under V (urea).

If **Calculate** is selected, the corresponding parameters weicht, height, age and sex can be entered.

15.4 Stability Criteria

The following dialysis parameters are checked for stability before the OCM measurement is started. The OCM bolus is only started if all parameters are sufficiently stable.

Stability criteria:
– Stable conductivity
– Not change of the blood flow by more than 10 ml/min
– Not change of the substituate flow by more than 10 ml/min
– Blood flow > 80 ml/min
– Dialysate flow > 270 ml/min

15.5 Starting the OCM

In the **OCM** menu

Touch the **OCM I/O** button or automatic start, depending on the setting in the Operator setup).

The measurement starts approximately 10 to 15 minutes after the start of the treatment (optical detector senses blood).

15.6 Aborting the OCM

In the **OCM** menu

Touch the **OCM I/O** button.

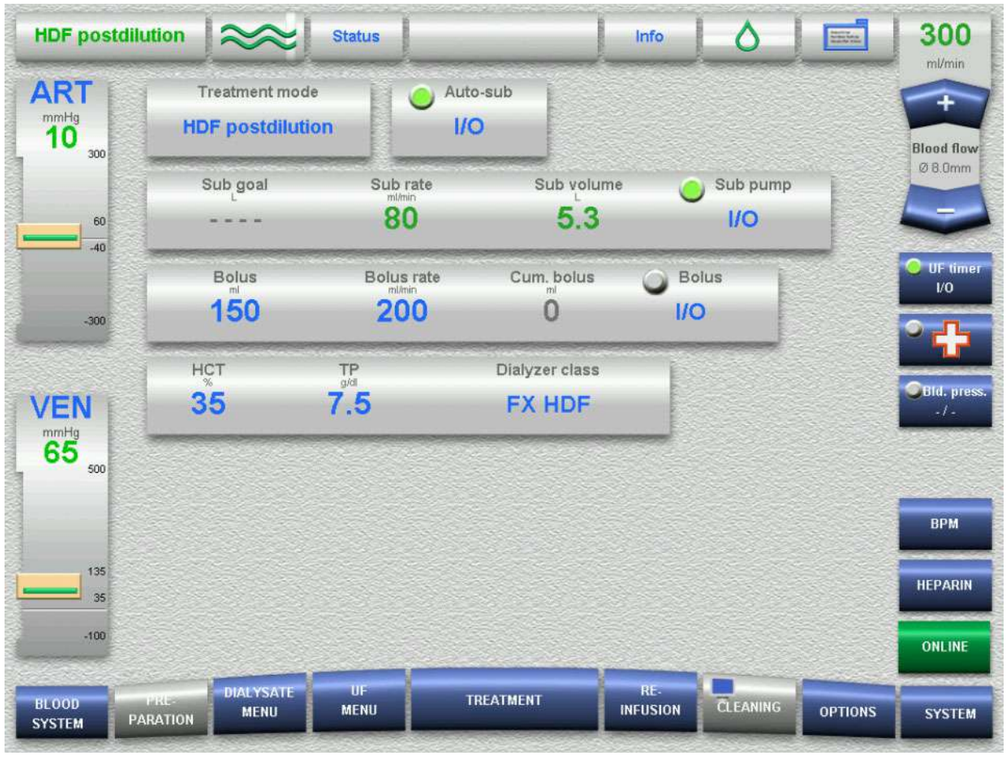
The OCM can be turned off at any time.

The OCM will also be turned off if the stability criteria are not fulfilled anymore.

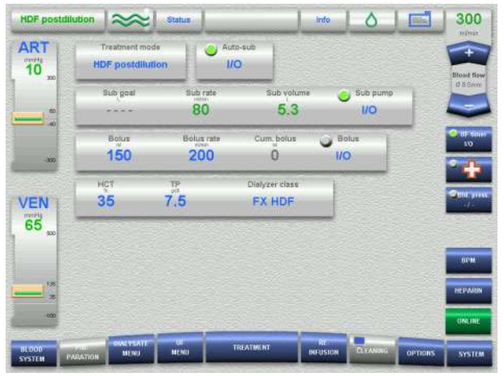
15.7 Alarm Processing

Message	**Kt/V warning**
	A warning will be displayed if the OCM detects after approx. 90 minutes of treatment that the Kt/V goal is expected to be more than 15 % below the Kt/V goal which has been entered. This warning can be deactivated in the Operator setup.

Fold-Out Sheet
16 ONLINE*plus*™

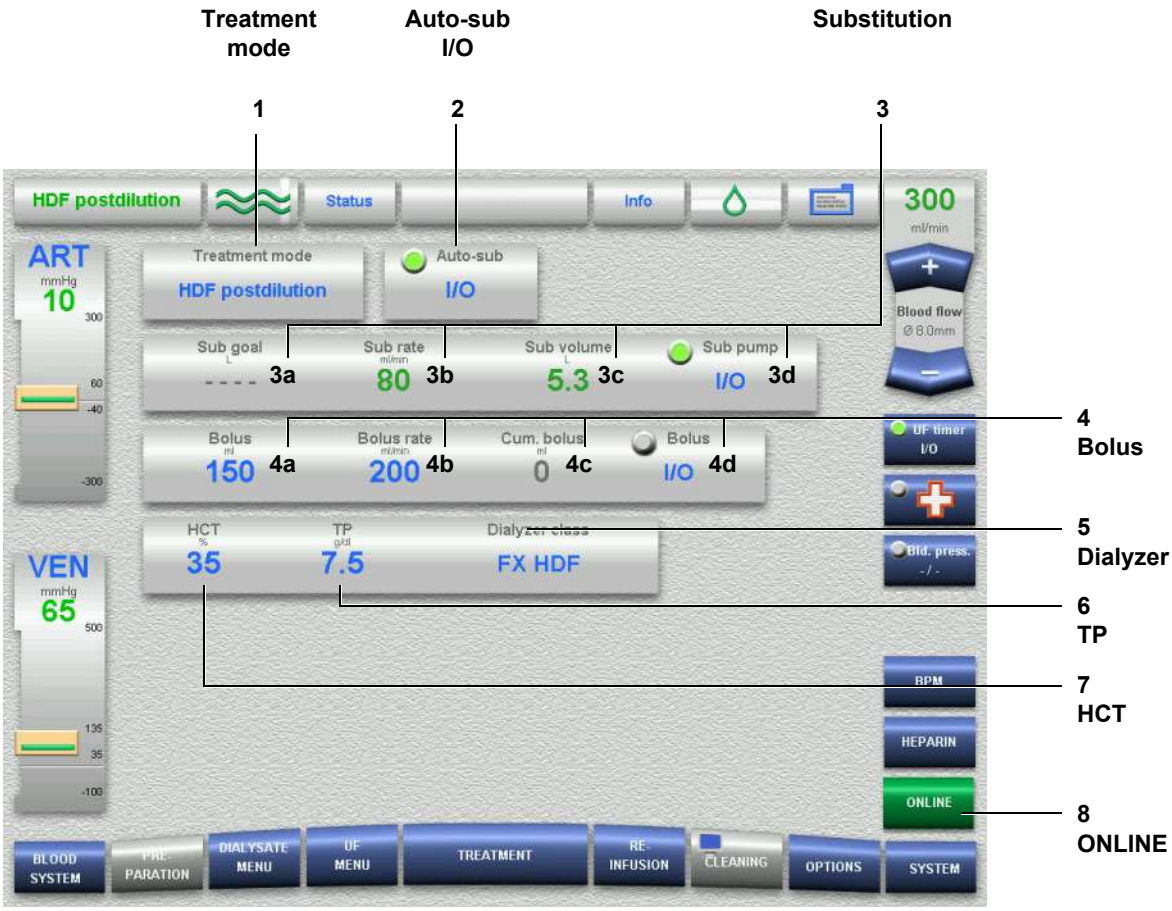


ONLINE SCREEN



16 ONLINE*plus*™

16.1 Menu Overview



1 Treatment mode
Permits selection of the treatment mode.

2 Auto-sub I/O
Button for starting/stopping auto-substitution.

3a Sub goal
Displays the substitution goal.

3b Sub rate
Displays the substitution rate.

3c Sub volume
Displays the substitution volume.

3d Sub pump I/O
Button for starting/stopping the substituate pump.

4a Bolus
Displays the bolus volume.

4b Bolus rate
Displays the bolus rate.

4c Cum. Bolus
Displays the cumulated bolus volume.

4d **Bolus I/O**
Button for starting/stopping the bolus function.

5 **Dialyzer**
Displays the selected dialyzer type.

6 **TP**
Displays the total protein.

7 **HCT**
Displays the hematocrit.

8 **ONLINE**
ONLINE menu button

16.2 Preparation/Treatment/Reinfusion

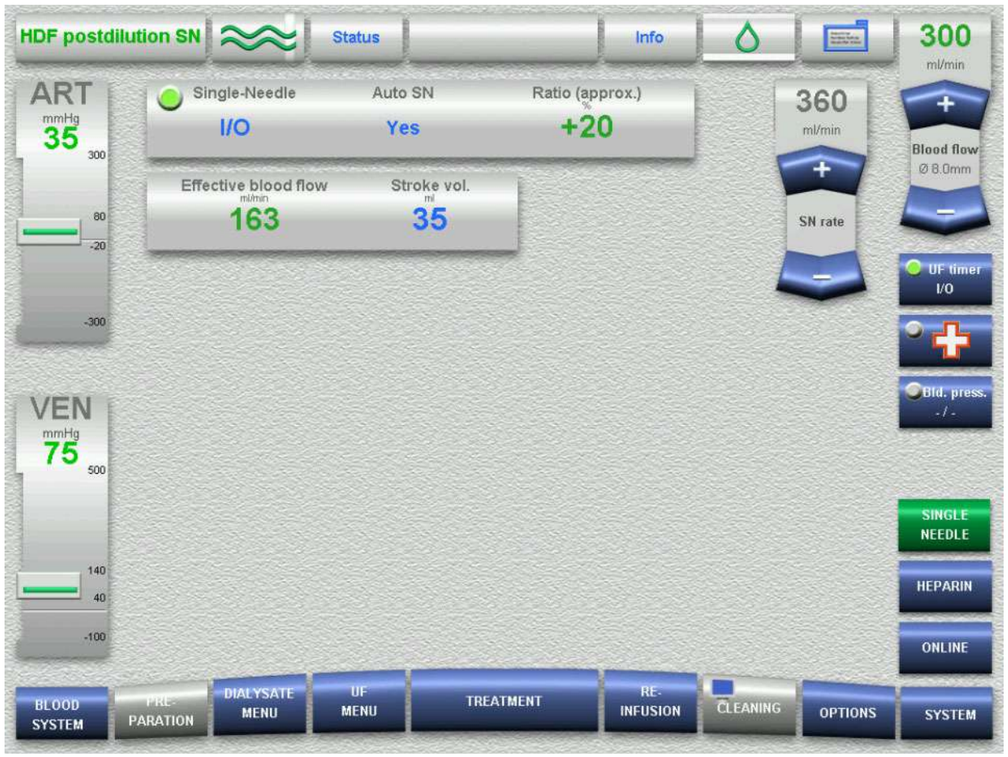
The treatment using the ONLINE*plus*™ module is described in the following chapters:

– Preparation using ONLINE*plus*™ (see chapter 5.1 , page 5-1)

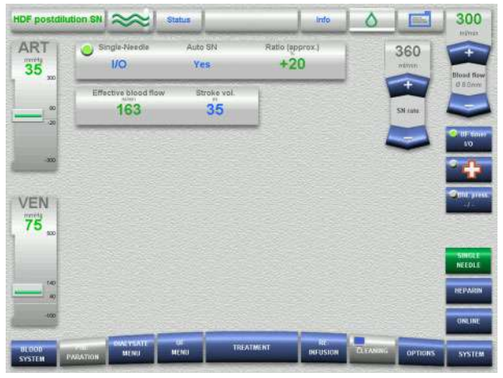
– Preparation using ONLINE*plus*™ (see chapter 6.1 , page 6-1)

– Reinfusion using ONLINE*plus*™ (see chapter 7.1 , page 7-1)

Fold-Out Sheet
17 Option SN

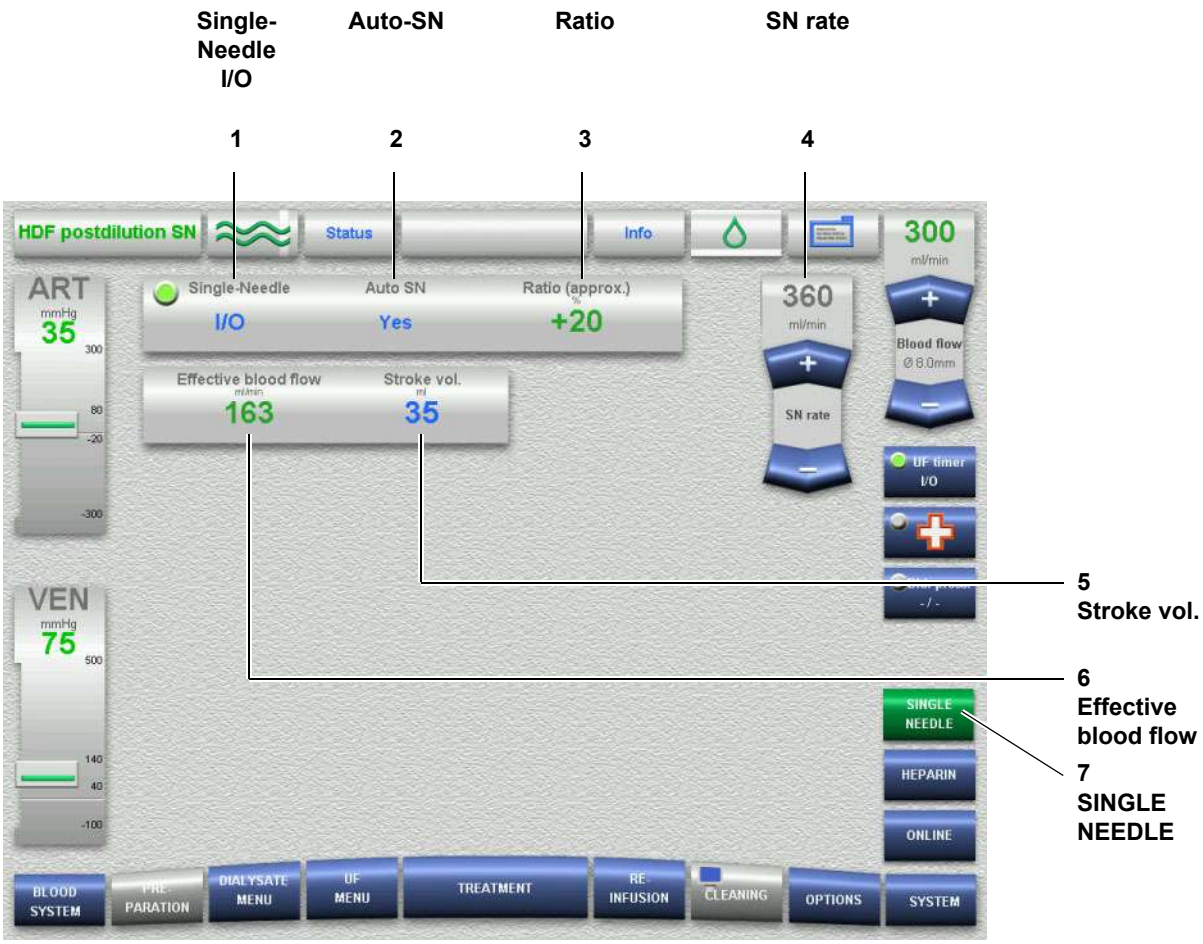


SINGLE-NEEDLE SCREEN



17 Option SN (Single-Needle)

17.1 Menu Overview



1 **Single-Needle I/O**
Button for starting/stopping the Single-Needle treatment mode.

2 **Auto SN**
Button for preselecting Auto SN.
(In the Auto SN mode, the ratio of the blood pump rate to the Single-Needle pump rate is defined automatically.)

3 **Ratio**
Displays the ratio of the blood pump rate to the Single-Needle pump rate.

4 **SN rate**
Displays the SN rate.
Rocker switch for increasing **+** / reducing **–** the Single-Needle flow.

5 **Stroke vol.**
Displays the effective blood flow.

6 **Effective blood flow**
Displays the Single-Needle stroke volume.

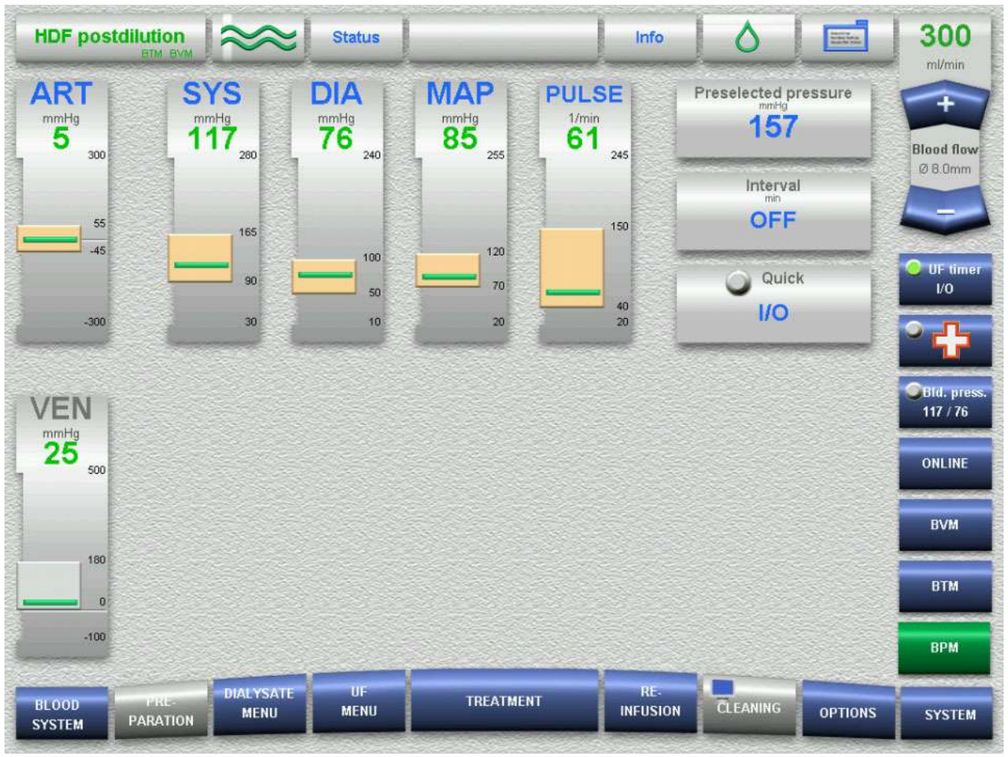
7 **SINGLE-NEEDLE**
SINGLE-NEEDLE menu button

17.2 Preparation/Treatment/Reinfusion

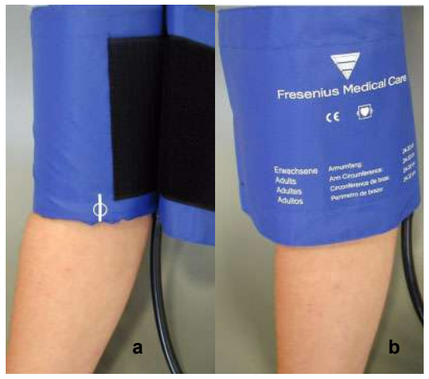
The Single-Needle treatment is described in the following chapters:

- Single-Needle (option) preparation using ONLINE*plus*™ (see chapter 5.3 , page 5-31)
- Single-Needle (option) preparation with rinse solution bag (see chapter 5.4 , page 5-47)
- Single-Needle (option) treatment using ONLINE*plus*™ (see chapter 6.3 , page 6-9)
- Single-Needle (Option) treatment (prepared with rinse solution bag) (see chapter 6.4 , page 6-17)
- Single-Needle (option) reinfusion using ONLINE*plus*™ (see chapter 7.3 , page 7-9)
- Single-Needle (option) reinfusion with rinse solution bag (see chapter 7.4 , page 7-9)

Fold-Out Sheet
18 Option BPM

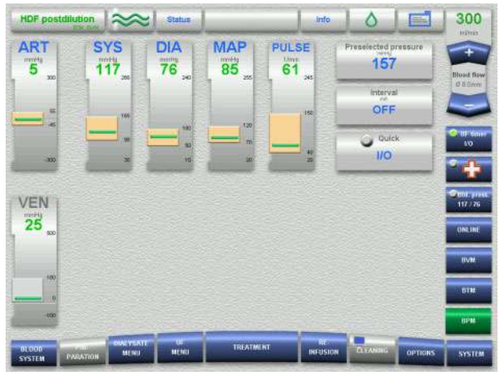


Applying the blood pressure cuff



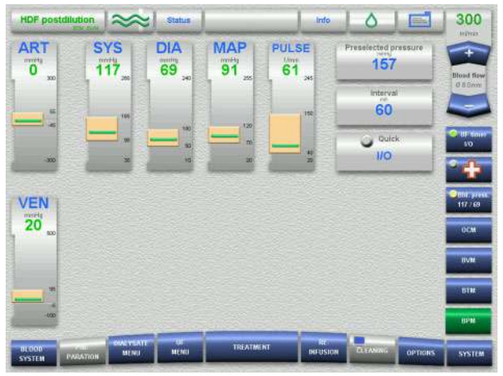
BPM, graphic (SYS/DIA/PULSE)

BPM SCREEN



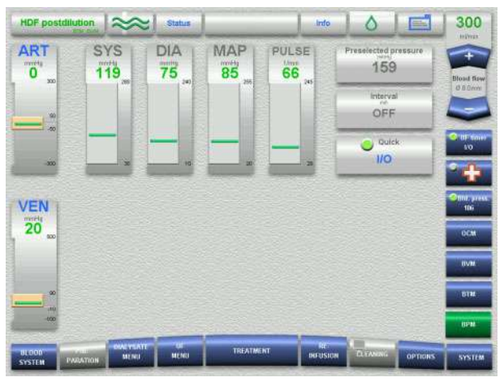
BPM (MAP), graphic (MAP/PULSE)

BPM SCREEN (Interval)



BPM history

BPM SCREEN (Quick)



18 Option BPM (Blood Pressure Monitoring)

18.1 To Be Observed Before Using the BPM Option

Caution

Only the approved accessories may be used.
Ensure you select the proper blood pressure cuff when using the BPM to achieve the best possible measurement results. For an overview of blood pressure cuffs, please refer to chapter 12 Consumables.

The blood pressure cuff may only be connected to the 5008 hemodialysis system.

It is not permitted to use the BPM for measurements on neonates or infants.

The pressure tubing must neither be kinked nor squeezed.

While using the BPM make sure that the patient's blood circulation is not affected by the continuous presence of blood pressure cuff over a prolonged treatment time, especially when repeatedly using the automatic short-term mode.

18.2 Blood Pressure Cuffs / Pressure Tubing

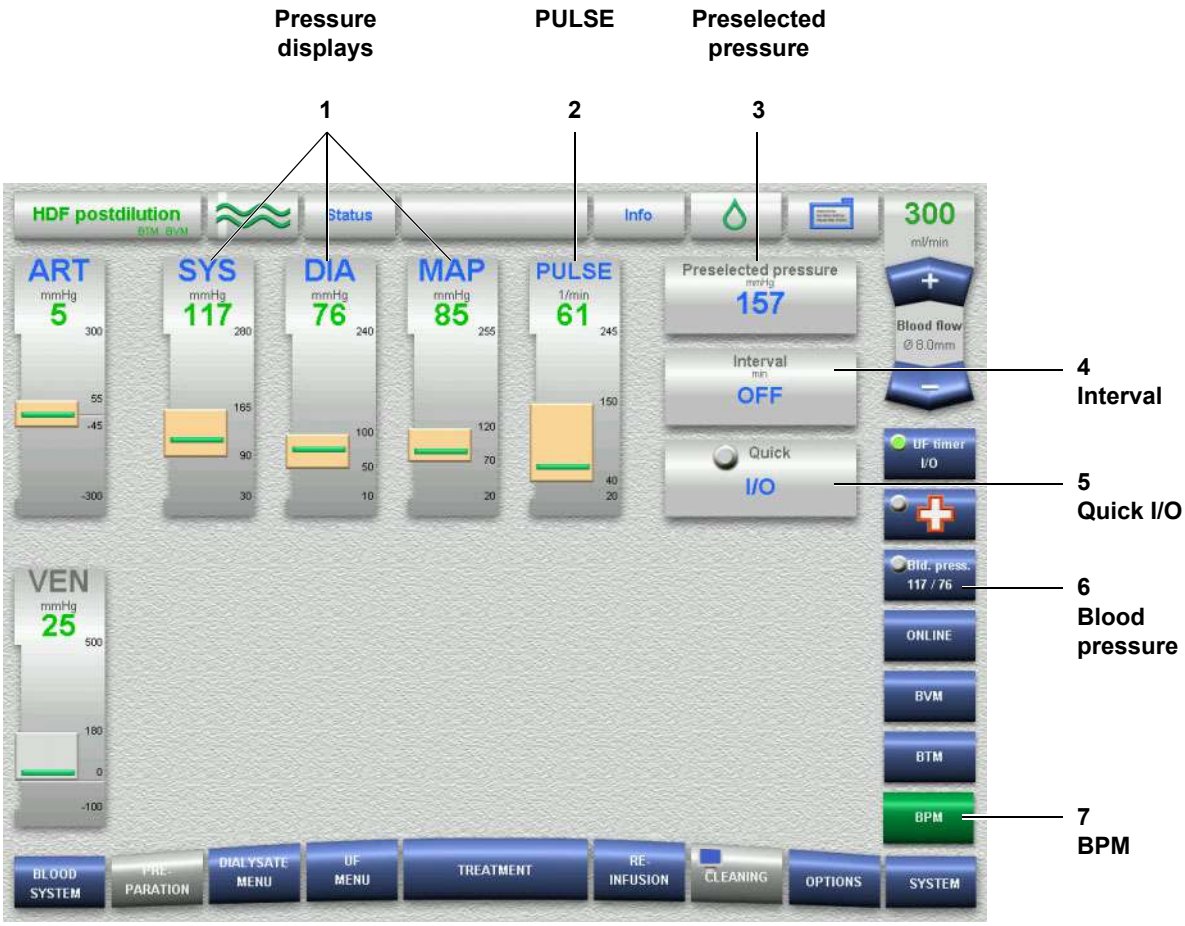
- **Blood pressure cuffs**

Product	Part number	Information
Blood pressure cuff (Velcro)	M35 972 1	Adults – small arm, arm circumference 17 cm to 26 cm
Blood pressure cuff (Velcro)	M35 969 1	Adults – standard, arm circumference 24 cm to 32 cm
Blood pressure cuff (D-ring and Velcro)	M35 617 1	Adults – standard, arm circumference 24 cm to 32 cm
Blood pressure cuff (Velcro)	M35 974 1	Adults – large arm, arm circumference 32 cm to 42 cm
Blood pressure cuff (Velcro)	M35 975 1	Adults – thigh, circumference 42 cm to 50 cm
Blood pressure cuff (Velcro)	M35 973 1	Children, arm circumference 13 cm to 20 cm

- **Pressure tubing**

Product	Part number	Information
Pressure tubing	M35 618 1	Non-conductive spiral tube

18.3 Menu Overview



1 Pressure displays
SYS (systolic pressure)
DIA (diastolic pressure)
MAP (mean arterial pressure)
The actual value is displayed as a numerical value and as a bar.
The alarm window is displayed in block representation, according to the window size.
Touch the **SYS**, **DIA** or **MAP** field for setting the alarm limits.

2 PULSE
The actual value is displayed as a numerical value and as a bar.
The alarm window is displayed in block representation, according to the window size.
Touch the **PULSE** field for setting the alarm limits.

3 **Preselected pressure**
Displays the inflation pressure.
Setting of the inflation pressure.

4 **Interval**
Button for selecting the Interval function.
(Possible settings: OFF or 5, 10, 15, 30, 45, 60 minutes)

5 **Quick I/O**
Button for turning the Quick function on and off.
(Measurement time approx. 5 minutes)

6 **Blood pressure**
Button for starting or aborting a measurement.
Displays the inflation pressure during the blood pressure measurement and the pressure values (SYS/DIA) after the blood pressure measurement.
Blood pressure display:
– No blood pressure measurement – grey
– Blood pressure measurement in progress – green
– Interval (long-term interval) selected, measurement pause – yellow

7 **BPM**
BPM menu button

18.4 Applying the Blood Pressure Cuff

Caution

It is not permitted to apply the blood pressure cuff to limbs that are connected to a vascular access (e.g. fistula).

When applying the blood pressure cuff, the following precautions must be respected:
The Velcro tape of the cuff must close exactly, so that the cuff will not get out of place while being inflated.

Place the blood pressure cuff tightly and correctly around the selected limb, e.g. the upper arm. Observe the illustrations shown on the fold-up page. The blood pressure cuff must be correctly aligned and must have a good contact to the skin. The marking must be positioned directly over the artery.

18.5 Checking/Setting the Inflation Pressure/Alarm Limits

Caution

Do not select an inflation pressure that is unnecessarily high.

When the first measurement is taken, the set inflation pressure is used. For all further measurements, the BPM automatically determines the inflation pressure on the basis of the previous systolic pressure.

In the **BPM** menu

Check the **SYS**, **DIA**, **MAP**, and **PULSE** alarm limits.

If necessary, set the desired parameters. Touch the **OK** button to confirm the values entered.
Visually check the confirmed values.

18.6 Starting the Blood Pressure Measurement

The patient should never be left unattended during a measurement, so that the measurement can be stopped immediately, if unpredictable operating conditions occur.

The following applies to all measurements:
The maximum duration of a measurement is 3 minutes.
A measurement is repeated no more than 3 times.

Single measurement

Touch the **Blood pressure** button. (**Blood pressure** display green.)

Interval (long-term interval measurement)

In the **BPM** menu

Touch the **Interval** field. Select the desired interval. Touch the **OK** button to confirm the value entered.
Visually check the confirmed value.

Caution

In the interval mode, pay particular attention to avoid unintended further measurements from being started automatically.

Touch the **Blood pressure** button. (**Blood pressure** display green.
The **Blood pressure** display is yellow in measurement pauses.

Quick (short-term interval measurement)

In the **BPM** menu

Touch the **Quick I/O** button. (**Quick I/O** display green. **Blood pressure** display green.)

18.7 Blood Pressure Measurement Completed

Blood pressure display grey. (Yellow in case of interval.)
The pressure values (SYS/DIA) are displayed.
(Partial results will also be displayed.)

Check the blood pressure parameters for plausibility and patient allocation.

18.8 Aborting the Blood Pressure Measurement

Touch the **Blood pressure** button.
Blood pressure display grey. (Yellow in case of interval.)

Caution

If it is not possible to abort the blood pressure measurement with the **Blood pressure** button, the pressure tubing must be immediately disconnected from the pressure connector.

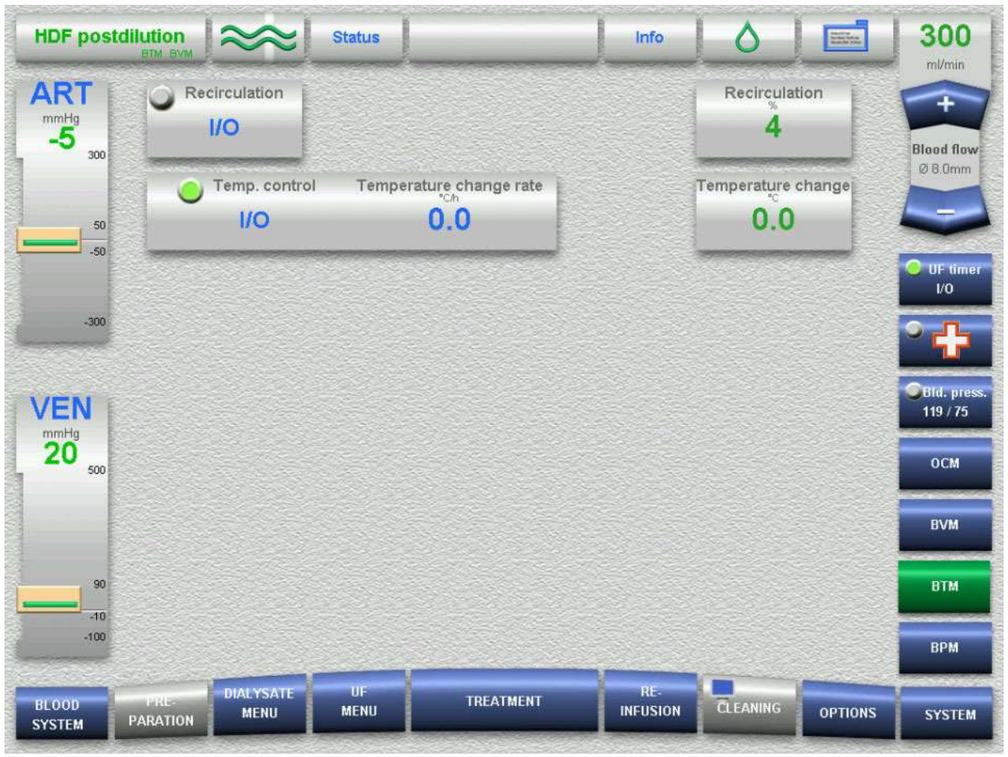
18.9 Displaying Graphics and Blood Pressure History

Depending on the settings in the Operator setup, the following items can be displayed in the respective treatment menu:
– BPM, graphic (contains SYS, DIA and PULSE)
– BPM (MAP), graphic (contains MAP and PULSE)
– BPM history for up to 60 measurements (contains SYS, DIA, MAP, and PULSE) Use the ▲ or ▼ button to scroll through the BPM history, if required.

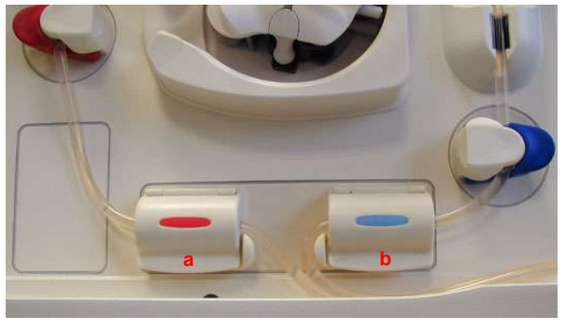
19 Option CBPM

(not yet available)

Fold-Out Sheet
20 BTM Option

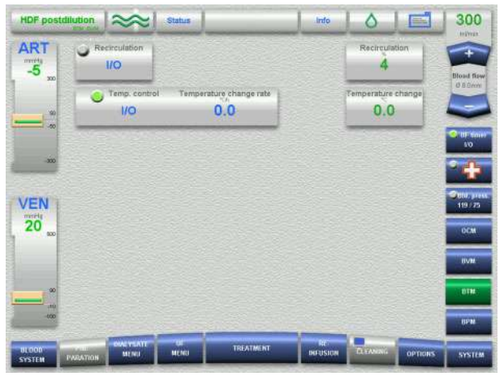


Inserting the tubing system into the measuring heads



BTM events

BTM SCREEN



BTM T control, graphic

BTM rec., graphic

20 Option BTM (Blood Temperature Monitor)

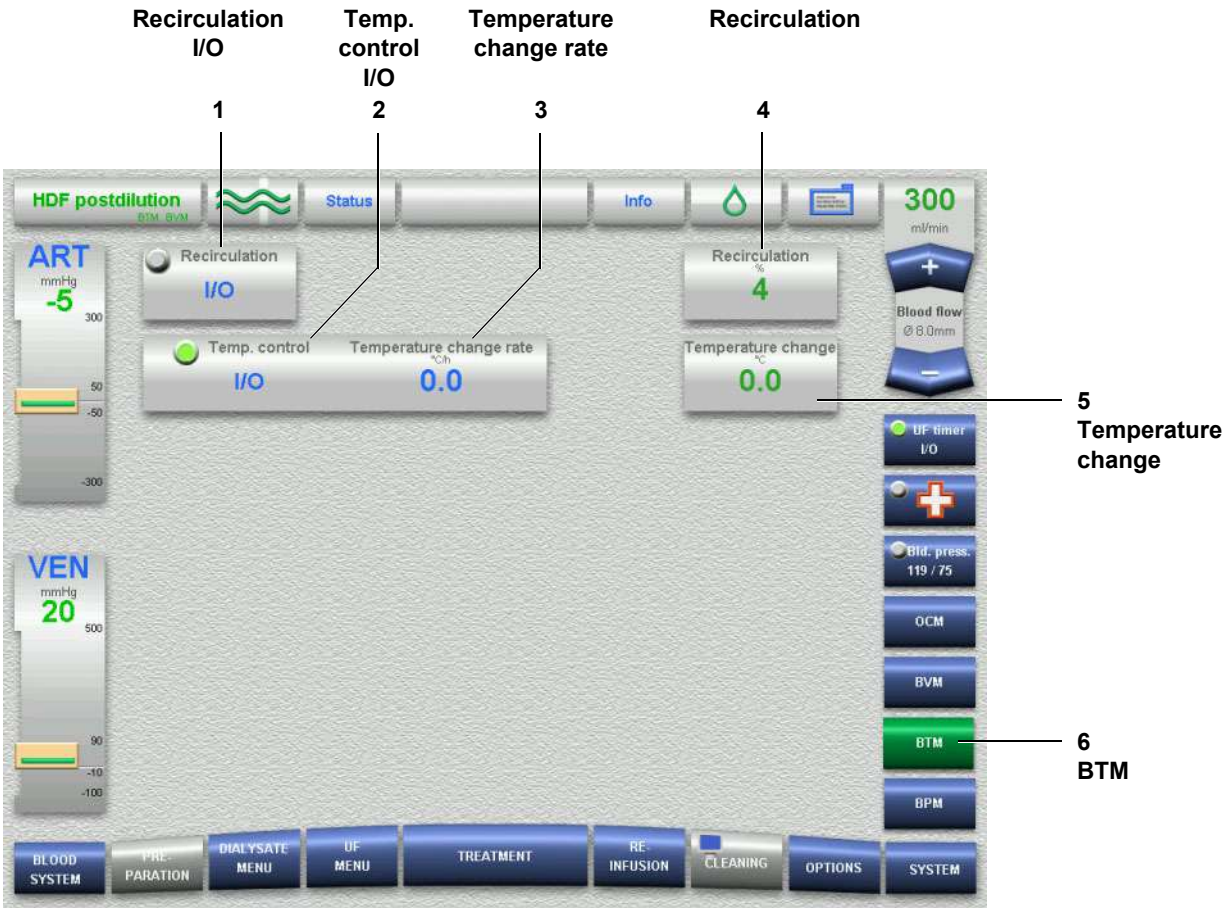
20.1 To Be Observed Before Using the BTM Option

Note

The ambient temperature must match the ambient temperature set in the Operator setup, BTM submenu.

Do not cover the blood lines, as this would result in a deterioration of the measuring accuracy.

20.2 Menu Overview



1 **Recirculation I/O**
Button for starting/stopping recirculation measurement.
Single recirculation measurement.

2 **Temp. control I/O**
Button for starting/stopping the body temperature control.

3 **Temperature change rate**
Entry of the body temperature change rate.

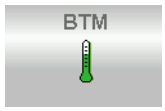
4 **Recirculation**
Display of the complete recirculation fraction.

5 **Temperature change**
Display of the body temperature change since beginning of the treatment.

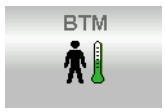
6 **BTM**
BTM menu button

In the **DIALYSATE MENU** the following additional information is displayed:

BTM inactive



BTM measuring fistula temperature



BTM body temperature control active

BTM recirculation measurement active

20.3 Preparation

Insert the arterial tubing system into the arterial measuring head (a).

Insert the venous tubing system into the venous measuring head (b).

20.4 Recirculation

Caution

If the measured recirculation value does not make sense for the patient, the recirculation value must be checked by means of an independent method before deciding about further therapies.

- **Starting**

Touch the **Recirculation I/O** button. (**Recirculation I/O** indicator green.)
(Automatic, depending on the settings in the Operator setup.)

After completion of the recirculation measurement, the result is displayed in the **BTM** menu under Recirculation.

- **Aborting**

Touch the **Recirculation I/O** button. (**Recirculation I/O** indicator grey.)

20.5 Temperature Control

- **Checking/setting the temperature change rate**

  In the **BTM** menu

  Check the temperature change rate.

  If necessary, set the desired parameter. Touch the **OK** button to confirm the value entered.
  Visually check the confirmed value.

- **Starting**

  Touch the **Temp. control I/O** button. (**Temp. control I/O** indicator green.) (Automatic, depending on the settings in the Operator setup.)

  After completion of the recirculation measurement, the result is displayed in the **BTM** menu under Recirculation.

  The temperature control then starts automatically.

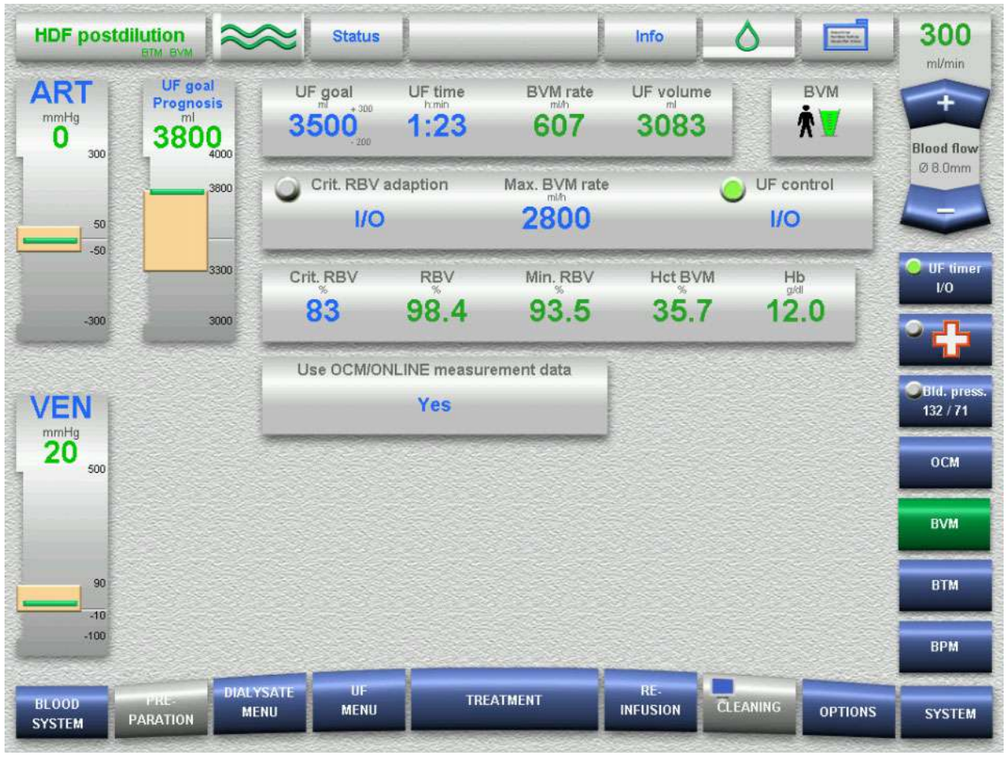
- **Aborting**

  Touch the **Temp. control I/O** button. (**Temp. control I/O** indicator grey.)

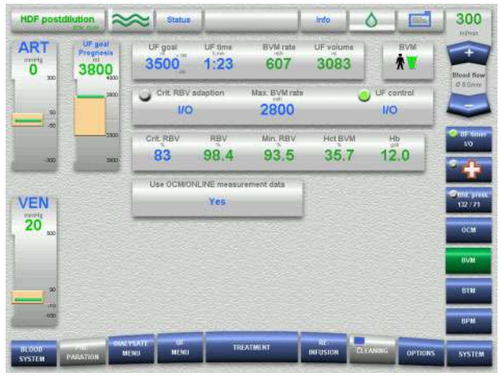
20.6 Displaying Graphics and BTM Events

Depending on the settings in the Operator setup, the following items can be displayed in the respective treatment menu:
– BTM T control (comprises the body temperature change and the dialysate temperature)
– BTM rec. (comprises the arterial and the venous fistula temperature as well as the dialysate temperature)
– BTM events (records up to 9 events)

Fold-Out Sheet
21 BVM Option



BVM SCREEN



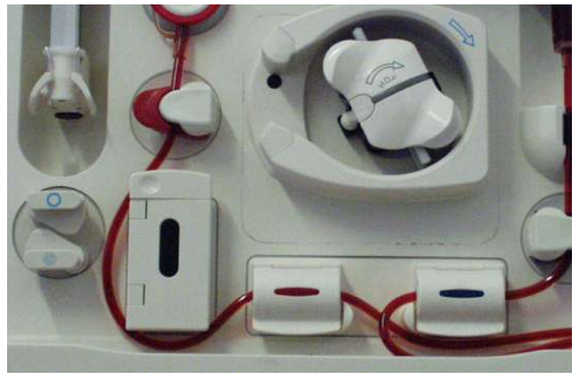
BVM (Rel. blood volume, graphic)

BVM, BPM

BVM, events

Inserting the tubing system into the measuring head

Inserting the tubing system without cuvette



21 Option BVM (Blood Volume Monitor)

21.1 To Be Observed Before Using the BVM Option

Note

The BVM may be operated with special blood lines only. (See chapter 12 Consumables.)

The area around the BVM measuring head must not be wet by fluid, as this will alter the measurement.

Do not open the door of the BVM measuring head during the treatment.

If using the ONLINE*plus*™ option, the SafeLine™ must not be kinked.

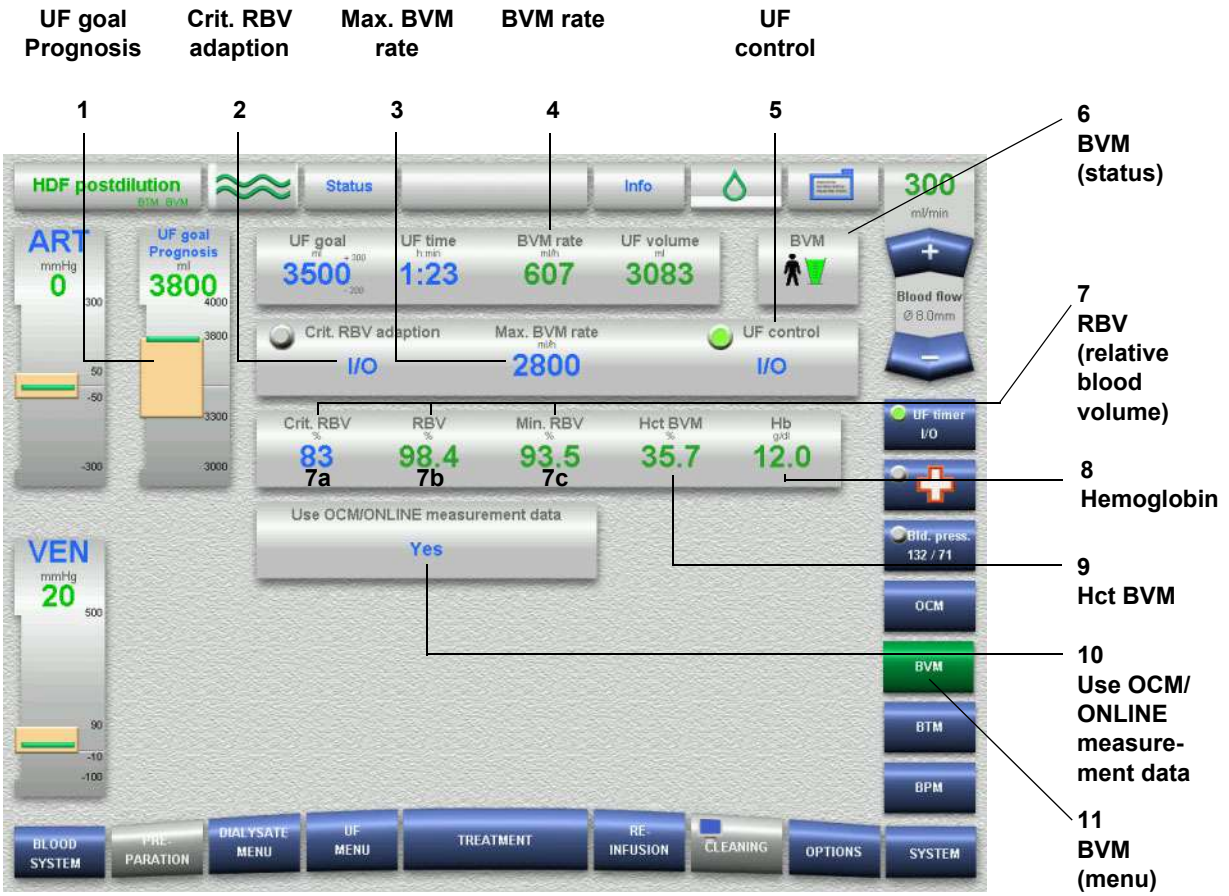
The BVM measuring head must not be exposed to intensive, direct sunlight.

Caution

The following must be observed when inserting the tubing system without cuvette on hemodialysis system with BVM option:

– Do not insert the tubing without cuvette into the measuring head.
– Place the tubing along the left side of the BVM measuring head. (See also fold-out sheet, figure "Inserting the tubing system without cuvette".)

21.2 Menu Overview



1 UF goal prognosis

The prognosis for the obtainable UF volume is represented as a numerical value and as a bar graph.
(The value is displayed only when half of the UF goal has been achieved.)
How to enter the admissible UF goal range:
Maximum UF goal = UF goal + positive UF goal deviation
Minimum UF goal = UF goal - negative UF goal deviation
The admissible UF goal range is displayed in block representation, according to the window size.

2 Crit. RBV adaption

Button for starting/stopping the special mode supporting the determination of the critical RBV which can be set individually for every patient..
Function while the BVM is measuring:
At the end of the treatment, the lowest measured RBV (min. RBV) will be transferred to the PatientCard as the new crit. RBV.
If, during the treatment, one or several blood pressure measurement(s) occurred with a "lower" - systolically, MAP or diastolically based - blood pressure alarm, the respective RBV will be determined and saved. At the end of the treatment, the highest of these values will be transferred to the PatientCard as the new

crit. RBV.
Function while the BVM is controlling:
During the treatment and depending on the situation, the operator can reduce the crit. RBV during the first half of the volume to be removed. Depending on the current RBV, this step may be repeated several times.

3 Max. BVM rate
The maximum UF rate performed by UF control may be entered and will be displayed here.

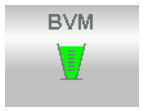
4 BVM rate
Display of the BVM rate. The BVM rate is the UF rate specified by the BVM.

5 UF control
Button for starting/stopping the UF control.

6 BVM (status)
Displays the BVM status.
The **BVM** display is available in the **BVM** menu, but also in the **UF MENU** and on the PREPARATION SCREEN. If the **BVM** field is touched, the system switches to the **BVM** menu.
In the **BVM** display, the following symbols may appear:

Cuvette not detected

Cuvette detected (Cuvette not yet calibrated, measuring accuracy possibly outside the specification.)



Cuvette calibrated (ready for measurement)

Control switched on

7 RBV (relative blood volume)

7a Crit. RBV
Displays the critical relative blood volume of the respective treatment (percentage). Must be set prior to each treatment or is transferred automatically, e.g. from the PatientCard.

7b RBV
Displays the current, measured relative blood volume (percentage).

7c Min. RBV
Displays the lowest relative blood volume of the respective treatment (percentage).

8 Hb
Displays the current hemoglobin concentration in mmol/l or g/dl.

9 Hct BVM
Displays the current hematocrit (percentage).

10 Use OCM/ONLINE measurement data
Button for transferring the measurement data (Hct BVM) into the respective edit fields on the OCM/ONLINE screen. If the measurement value of the BVM is invalid, the default value will be used on the respective screens.

11 BVM (menu)
BVM menu button

21.3 Preparation

Insert the BVM cuvette into the BVM measuring head.

21.4 Calibration

Calibration requirements:
– The BVM cuvette must be filled with a rinse solution.
– The temperature of the rinse solution exceeds 18 °C.

Cuvette calibration for increasing the measuring accuracy is performed automatically. After successful calibration, the BVM symbol "Cuvette calibrated" will be displayed.

21.5 Measuring the RBV (Relative Blood Volume), Hemoglobin and Hematocrit

Caution

If the measured RBV (relative blood volume), hemoglobin and hematocrit values do not make sense for the patient, the measurement results must be checked by means of an independent method before deciding about further therapies.

When detecting blood inside the cuvette, the BVM automatically starts the measurement and determines its reference of RBV = 100 %.

21.6 Displaying Graphics

Depending on the settings in the Operator setup, the following items can be displayed in the respective treatment menu:
– BVM UFR, displays the UF rate, the RBV and the control ranges depending on the crit. RBV.
– BVM BPM, displays the RBV and the blood pressure measurement values (Systolic and Diastolic).
– BVM events, displays the events occurred during UF control.
(e.g. Operator: operator changed parameters.)
(e.g. Warning: operator made a selection after a warning message displayed by the 5008.)

21.7 Alarm Processing

Message

Message: *BVM adaption mode: Achieving UF goal is uncertain. Reduce critical RBV by 1 % or continue UF control. – Crit. RBV* **Reduce** – *Control* **Continue**

This message is displayed only during the first half of the volume to be removed. Depending on the current RBV, this step may be repeated several times.

Touch the **Reduce** button, if the patient's condition is good. The new crit. RBV will be set.
(If a PatientCard is used, this new crit. RBV will also be used for the next treatment.)

Touch the **Continue** button, if the patient's condition is not good. The control continues in the usual manner.

Message

Message: *BVM: Achieving UF goal is uncertain. Continue UF control or set a minimum BVM rate of XXX ml/h. – Control* **Continue** – *Minimum rate* **Set**

This message is displayed only during the first half of the volume to be removed.
If the patient's condition is good, this may be because the crit. RBV is too high.

Touch the **Continue** button for the control to continue without any modification. The message will be repeated if the RBV does not increase again.

Touch the **Set** button to set the minimum BVM rate. The message is displayed only once during the first half of the volume to be removed. Until the end of the treatment, at least the minimum BVM rate will be used (lower limitation of the BVM rate), even if the RBV continues to decrease. If the patient recovers, treatment will be performed with a higher BVM rate, according to the RBV.
The minimum UF goal prescribed will imperatively be respected.

After the UF control parameter (e.g. UF goal) was changed, the BVM minimum rate is automatically cleared.

Message

Message: *BVM: Achieving UF goal is uncertain. Reduce minimum UF goal by XXX ml or set a minimum BVM rate of XXXX ml/h. – Minimum goal* **Reduce** – *Minimum rate* **Set**

This message is displayed only during the second half of the volume to be removed.

Touch the **Reduce** button to modify the prescription. The control continues in the usual manner.
(If a PatientCard is used, this new minimum UF goal will also be used for the next treatment.)

Touch the **Set** button to set the minimum BVM rate. The message is displayed only once during the second half of the volume to be removed. Until the end of the treatment, at least the minimum BVM rate will be used (lower limitation of the BVM rate), even if the RBV continues to decrease. If the patient recovers, treatment will be performed with a higher BVM rate, according to the RBV.
The minimum UF goal prescribed will imperatively be respected.

After the UF control parameter (e.g. UF goal) was changed, the BVM minimum rate is automatically cleared.

Message

Message: *BVM: Clotting in dialyzer possible. Blood flow too low compared to the minimum BVM rate. Increase the blood flow to a minimum of XXX ml/min.* – **Confirm**

Touch the **Confirm** button.

If possible, increase the blood flow at least up to the indicated value. If not, reduce the UF goal or prolong the UF time.

22 Network

22.1 To Be Observed Before Using the Network

Caution

Before being applied, the treatment parameters which the 5008 hemodialysis system receives via the network or the patient card must be checked by the operator for plausibility and compliance with the medical prescription.

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

Note

For reasons of data protection, the operator is responsible for safely keeping the patient card.

The data on the patient card is stored with less time resolution than displayed during the treatment.

22.2 DataXchange Panel

22.2.1 To Be Observed Before Using the DataXchange Panel

Caution

There are special requirements for further processing of the data.

The responsible organization operating the network is responsible for ensuring that the network is available for the necessary data transfer.

Any data falsifications regarding the correctness, plausibility and completeness of the data which are caused by the network and the server software are not detected by the 5008.

The DataXchange Panel provides an area of the 5008 monitor which can be controlled entirely from outside.

The data shown is transmitted by a server and is displayed on the 5008 monitor. The data is entered to the server via the 5008 monitor.

The operation philosophy of the DataXchange Panel is the same as that of the 5008.

22.2.2 Operation

- **Opening the DataXchange Panel**

  Insert the patient card.

  The patient name will be shown in the **Patient ID** display.

  Touch the **Patient ID** button in the header. The Treatment page and further pages which can be selected from a table of contents (tabs) are transferred to the DataXchange Panel.

- **Closing the DataXchange Panel**

  To close the DataXchange Panel:
  – touch the **Patient ID** button in the header; or
  – pull out the patient card outside of treatment; or
  – select other screens, e.g. the UF SCREEN.

- **DataXchange Panel data transfer**

  If the indicator in the **Patient ID** display is flashing, new information for the DataXchange Panel is available.

23 Options BLK, WET

23.1 To be Observed Before Using the BLK, WET Options

23.1.1 Definitions of Terms

- **BLK**

  Bloodline kinking and filter clotting monitoring

  Detection of whether there are kinks in the blood lines between the blood pump and the dialyzer.
  Detection of whether there are clots in the dialyzer.

- **WET**

  Wet transductor protector

  Detection of whether the venous hydrophobic filter is wet.

23.2 BLK

- **Task**

  If there are kinks in the blood lines or if clots are beginning to develop in the dialyzer, this might result in a mechanically generated hemolysis.

  The BLK option detects kinked blood lines between the blood pump and the dialyzer or clots beginning to develop in the dialyzer, and emits a warning.

- **Description**

  The BLK checks the extracorporeal tubing system between the blood pump and the venous bubble catcher for changes in the flow resistance.

  The BLK principle is based on monitoring the signals at the venous pressure sensor.
  The blood pump generates periodic pressure pulses. Starting at the blood pump, these pressure pulses migrate along the tubing system through the dialyzer and to the venous bubble catcher and are detected in the venous pressure sensor of the dialysis system. Any change in the pressure pulses is caused by a change in the blood flow properties in the extracorporeal blood circuit. This, in turn, may be caused by a kink in the tubing system or by clots developing in the dialyzer.

- **Treatment**

The BLK is activated in the HD, HDF and HF treatment modes, with the optical detector sensing blood.
In the Single-Needle or in the Single-Needle Click-Clack treatment mode, the BLK is not activated.

- **Alarm processing**

If the following HDF/HF message is displayed: *Kinking between blood pump and dialyzer detected! Please check the blood line for possible kinking!* – Device adaptation – **Accept** – *Problem corrected* **Confirm**.

If the following HD message is displayed: *Pressure is increasing on the blood-side dialyzer inlet port!* – Device adaptation – **Accept** – *Problem corrected* **Confirm**.

Touch the **Confirm** button after you have detected and eliminated an obvious problem in the tubing system.
The threshold values for triggering a BLK warning remain unchanged.

Touch the **Accept** button if you do not detect any kinks in the tubing system nor any clots developing in the dialyzer.

The threshold values for triggering a BLK warning will be adjusted accordingly, in order to avoid following messages.

23.3 WET

Caution

Preventing contamination:
Use tubing systems with hydrophobic filters at the pressure lines to prevent cross-contamination.
Connect the hydrophobic filters so that an ingress or loss of air is not possible and that any wetting by fluid is reliably avoided, also in case of pressure fluctuations.
If a hydrophobic filter has become wet, the tubing system must be replaced.

On tubing systems with additional connection sites, a replacement pressure line may be connected (accessory available from Fresenius Medical Care).

The blood in the pressure line must not be forced back by means of a syringe. This could damage the hydrophobic membrane and thus lead to a contamination.

If fluid may have passed the hydrophobic filter, the system must be checked for contamination after completion of the treatment. If the system is contaminated, it has to be taken out of service. All affected components have to be disinfected or replaced in accordance with the manufacturer's specifications before the system is put into operation again.

- **Task**

A wet hydrophobic filter may result in incorrect pressure values.

The WET detects when the venous hydrophobic filter is wet and emits a warning.

- **Description**

During the treatment, the WET continuously checks whether the pressure pulses generated by the blood pump arrive at the venous pressure sensor. If the hydrophobic filter is wet, the transmission of the pressure pulses to the venous pressure sensor is interrupted.

- **Treatment**

The WET is activated in the HD, HDF and HF treatment modes, with the optical detector sensing blood.
In the Single-Needle or in the Single-Needle Click-Clack treatment mode, the WET is not activated.

- **Alarm processing**

Message: *Please check if the hydrophobic filter on the venous pressure transducer is wet!* – Device adaptation – **Accept** – *Problem corrected* **Confirm**.

Touch the **Confirm** button after you have detected and eliminated an obvious problem in the tubing system.
The threshold values for triggering a WET warning remain unchanged.

Touch the **Accept** button if you do not detect any wetting of the hydrophobic filter.
The threshold values for triggering a WET warning will be adjusted accordingly, in order to avoid following messages.

If the **Accept** button is touched for the second time after a repeated warning, the WET will be deactivated for the rest of the treatment.

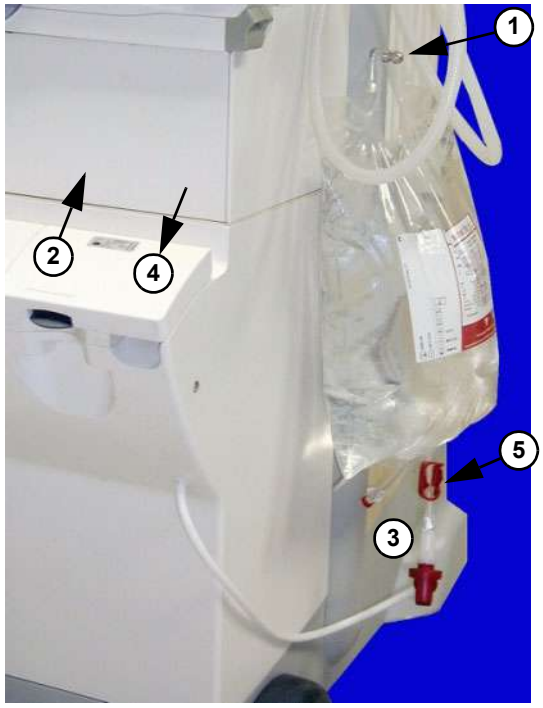
24 Option smart*b*ag

24.1 To Be Observed Before Using the smart*b*ag Option

The smart*b*ag supplies the 5008 hemodialysis system with concentrate provided in a 5-liter bag. For this purpose, the concentrate suction tube (red) has been modified appropriately for connection with the smart*b*ag.

Bicarbonate continues to be supplied via a bi*b*ag®, a bicarbonate container or a central bicarbonate supply.

24.2 Connecting the smart*b*ag



In Preparation mode:

From the **Dialysate menu**, select Concentrate.

1 Install the smart*b*ag in the holder.

2 Open the concentrate flap.

3 Remove the protective cap from the smart*b*ag.
Tightly screw the concentrate connector (red) to the smart*b*ag.

4 Close the concentrate flap.

5 Open the clamp on the smart*b*ag.

24.3 Removing the smart*b*ag

After the end of the treatment:

1 Close the clamp on the smart*b*ag.

2 Open the concentrate flap.

3 Remove the concentrate connector (red) from the smart*b*ag and connect it to the rinse chamber.

4 Close the concentrate flap.

5 Remove the smart*b*ag.