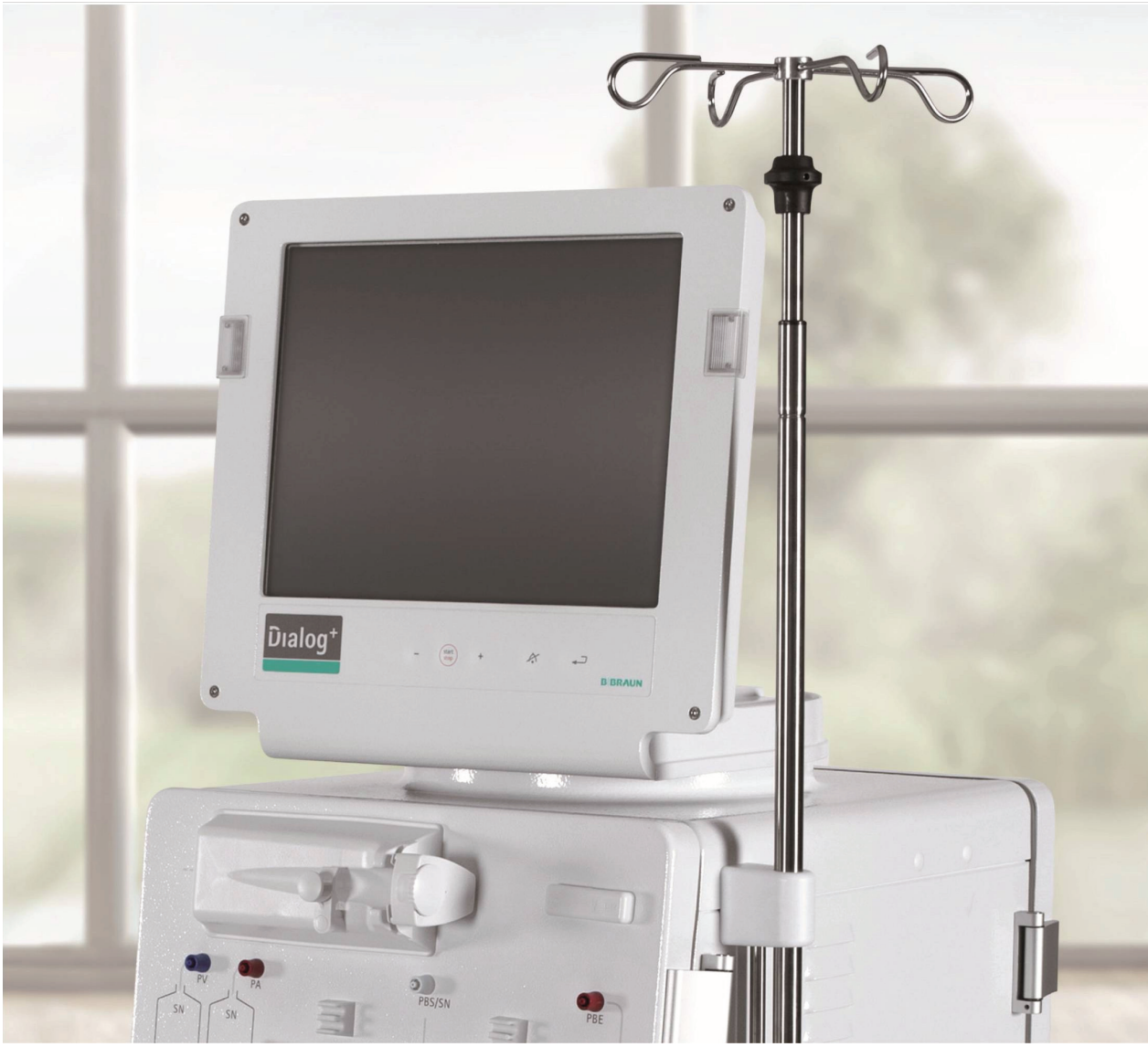
B BRAUN
SHARING EXPERTISE

Dialog+®

Dialysis Machine

Instructions for Use SW 9.1x EN



CE marking according to directive 93/42/EEC.

Technical alterations reserved.

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1 About these Instructions for Use

These instructions for use form an integral part of the machine. They describe the appropriate and safe use of the dialysis machine.

NOTICE!

The machine must always be used, cleaned and transported in accordance with these instructions for use. Only then the manufacturer will consider himself liable for any effect on safety, reliability and performance of the machine.
The instructions for use must always be available wherever the machine is in use.
Pass on the instructions for use to any future user of the machine.

Also observe instructions for use and product information of consumables.

Commissioning/decommissioning and servicing of the machine are only to be performed by service technicians authorized by the manufacturer. Therefore, this information is not part of these instructions for use but is contained in the service manual.

The instructions for use and the service manual contain important information on how to install, operate, maintain and dispose of the machine safely, properly and environmentally friendly. Observing these instructions helps to avoid danger, reduce repair costs and downtimes and
minimize environmental impact throughout the entire product life cycle.

1.1 Copyright

1.2 Validity

Article Numbers

These instructions for use apply to Dialog+ dialysis machines with the following article numbers (REF):

- 710200X
- 710201X
- 710207X

X = Combination of options at the time of delivery.

Software Version

These instructions for use apply to software version SW 9.1x (x = any).

Function of Home Hemodialysis

When using the machine for dialysis treatment in a home hemodialysis setup, ensure that the serial number of the machine is:

- higher than 256.719 but lower than 300.000 for Dialog+ standard machines
- higher than 316.860 but lower than 500.000 for Dialog+ HDF-Online machines
- higher than 515.940 for Dialog+ Light machines.

The serial number of your machine can be found on the type plate of the machine. For details, check Fig. 3-5 Type plate (36).

1.3 Target Group

The target group for these instructions for use are health professionals and persons trained by healthcare professionals.

The dialysis machine may only be used by persons instructed for its appropriate operation and for whom the responsible organization can prove that they have been instructed.

In limited care settings the target group includes patients/persons trained by healthcare professionals for operating the machine and all medical devices that the machine is used in combination with.

In home hemodialysis settings the target group includes patients/persons trained by healthcare professionals for operating the machine and all medical devices that the machine is used in combination with.

1.4 Warnings, Notices and Symbols

4 signal words are used in this document: DANGER, WARNING, CAUTION and NOTICE.

The signal words DANGER, WARNING and CAUTION point out particular hazardous situations for users and patients.

The signal word NOTICE points out information directly or indirectly related to prevention of damage and not to personal injury.

The signal word and the color of header indicate the degree or level of hazard:

⚠ DANGER!

Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

⚠ WARNING!

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

⚠ CAUTION!

Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.

NOTICE!

Used to address practices not related to personal injury, i.e. information directly or indirectly related to prevention of damage.

Warning messages also suggest measures that shall be taken in order to avoid the respective hazardous situation. Thus, warning messages related to personal injury have the following structure:

Header with signal word

Here, the type of hazard is indicated!

Here, the source of hazardous situation is indicated and possible consequences if measures are not followed.

- This is the list of measures to prevent the hazard.

1.5 Information and Activities

Information

This is additional useful information concerning procedures, background information and recommendations.

Activities

1. In this way instructions for an activity are listed.

   ↳ This symbol marks the result of an activity.

1.6 Abbreviations

ABPM	Automatic blood pressure measurement
BPA	Arterial blood pump
BPV	Venous blood pump
BSL	Bed Side Link
CO	Cross-Over
HD	Hemodialysis
HDF	Hemodiafiltration
HF	Hemofiltration
HP	Heparin pump
ISO UF	Isolated ultrafiltration
PA	Arterial pressure
PBE	Blood side entry pressure at dialysis machine

PBS	Blood pump control pressure for single-needle procedure
PDA	Dialysate outlet pressure sensor
PV	Venous pressure
RDV	Venous red detector
SAD	Safety air detector
SAKA	Arterial tube clamp
SAKV	Venous tube clamp
SN	Single-needle
SNCO	Single-Needle Cross-Over
SNV	Single-Needle Valve
TMP	Trans membrane pressure
TSM	Technical support and maintenance mode
UF	Ultrafiltration
ZKV	Central concentrate supply

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2 Safety

2.1 Intended Use and Indication

The machine is intended to be used for implementing and monitoring hemodialysis treatments for patients with acute or chronic kidney failure. It can be used for hospital, health center, limited-care or home hemodialysis.

Depending on the model, the following types of therapy can be carried out with the machine:

- Hemodialysis (HD)
- Isolated ultrafiltration (ISO UF): Sequential therapy (Bergstroem)
- Hemodiafiltration (HDF)
- Hemofiltration (HF)

2.2 Contraindication

There are no known contraindications for chronic hemodialysis.

2.3 Side Effects

Hypotonia, nausea, vomiting and cramps are possible side effects.

Oversensitive reactions caused by using the necessary tubing and filter materials have been observed in only a few cases. For this matter, please refer to the product information provided with the consumables.

2.4 Special Hazards and Precautions

2.4.1 Special Patient Conditions

The machine may only be operated on physician's instructions if patient suffers from one of the following conditions:

- Unstable circulation
- Hypokalemia

⚠ WARNING!

Fluid Balance deviations can exceed a level that can be tolerated by low weight patients, even if deviations are within the specified Dialog+ accuracy value, and in particular if the weight of the patients is equal or lower than 30 kg.

- The treatment of these patients shall be performed under the full supervision of the physician.
- In these cases, the use of an additional device to measure the weight loss is recommended.
- The appropriate dialyzer and blood line must be selected according to the patient’s size, weight and treatment type.

2.4.2 Electrical Hazards

The dialysis machine contains life-threatening electrical voltages.

⚠ WARNING!

Risk of electric shock and fire!

- Always insert mains plug completely into the mains socket.
- Always pull/push on the plug not on the mains cord to connect or disconnect the mains plug.
- Avoid damage of the mains cord for example by running over it with the machine.
- Complete disconnection from mains supply results only if the mains plug is removed completely from the mains socket. If the mains switch is switched off, the machine is not completely disconnected!

The machine shall not be used or connected to mains supply if the housing or the mains cord is damaged in any way. A damaged machine must be repaired or disposed of.

Switching off the mains switch will not isolate the mains voltage from all internal parts of the machine (e.g. mains filter, mains switch). To disconnect the complete machine from mains always remove the mains plug from the mains socket!

Grounding Reliability

The dialysis machine must be properly grounded.

Grounding reliability can only be achieved when equipment is connected to an equivalent receptacle marked "hospital only" or "hospital-grade". North American medical equipment cords and plugs have to be "hospital-grade" or "hospital only", meaning, they are subject to special requirements contained in relevant applied standards. It is imperative that the ground connection be reliably maintained to protect the patient and medical staff. Hospital-grade power cords and cordsets carry the "green dot" signifying that they have been designed and tested for grounding reliability, assembly integrity, strength and durability.

⚠ WARNING!

Risk of electric shock if machine is not properly grounded!

- The machine must be connected to a mains supply with protective earth.

2.4.3 Mains Connection

The machine shall be connected to a separate mains wall socket.
Do not connect customary consumer devices to the same mains socket as the machine and do not connect them in parallel.

The electrical installations of the premises must comply with these requirements.

2.4.4 Potential Equalization

When using the machine in combination with other therapeutic devices of protection class I, a connection line for electrical ground shall be used since the leakage currents from all connected devices are additive and an electrostatic discharge from the environment to the machine may occur. A special potential equalization cable is available that is to be connected to the corresponding terminal at the rear side of the machine.

⚠ WARNING!

Risk to patient due to leakage currents when using the machine in combination with other medical electrical equipment of protection class I.

- Connect potential equalization to the machine and to every other medical electrical equipment connected to or positioned within the reachable area of the patient (e.g. patient chairs).

Usage with Central Venous Catheter

⚠ WARNING!

Risk to patients with central venous catheter due to leakage currents!

- Establish potential equalization to ensure that patient leakage current complies with the limit values for type CF applied parts.

When using central venous catheters a higher degree of protection against electric shock is required. Electric currents can run through supply lines via dialysis fluid filter, dialyzer, central venous catheter, patient and every conducting object in the vicinity of the patient. Therefore, potential equalization must be provided. Patient leakage current must be below 10 µA in normal condition and below 50 µA in single fault condition which complies with the limit value of patient leakage current of type CF.

A special potential equalization cable is available that is to be connected to the corresponding terminal at the rear side of the machine.

The electrical installations of the premises must comply with these requirements.

2.4.5 Electromagnetic Interactions

The machine has been developed and tested in accordance with the valid standards for interference suppression and electromagnetic compatibility (EMC). However, it cannot be guaranteed that no electromagnetic interaction with other devices (e.g. mobile phones, computer tomograph (CT)) will occur.

In order to ensure the correct functioning of the machine, prevent electromagnetic interactions with other devices. For more information refer to the table Recommended Safe Distances in the 16.3 Recommended Safe Distances (340).

Use mobile phones and other devices emitting strong electromagnetic radiation with at least the minimum distance to the machine (according to IEC 60601-1-2, refer to the table Recommended Safe Distances in the 16.3 Recommended Safe Distances (340)).

⚠ WARNING!

Risk to the patient due to malfunction of the machine!
Increased electromagnetic emissions or decreased immunity of the machine may cause electromagnetic interactions.

- Establish potential equalization to ensure that patient leakage current complies with the limit values for type CF applied parts.
- When placing other medical electrical equipment (e. g. infusor) on or near by Dialog+ regularly observe the machine in order to ensure normal operation.
- Do not stack the Dialog+ with other machines to avoid electromagnetic disturbances.
- Only use accessories, transducers or cables specified to use with Dialog+.

In case of any questions contact your local distributor.

⚠ CAUTION!

Risk of therapy interruption!
If during the use of the medical device, functional restrictions occur due to increased stress on the medical device as a result of EMC interference. The medical device will turn to safe condition by stop of therapy and protect patients, users and third parties from harm.

- Continue the therapy.

NOTICE!

Placing other therapeutic or diagnostic medical devices on Dialog+ or near by or use of non-medical devices directly near the Dialog+ can influence electromagnetic interactions. In this case the user must observe the Dialog+ and all other machines to assure their correct operation.

2.4.6 IT Network

The machine provides a reinforced insulated interface for connection to an IT network, e.g. to a patient data management systems (PDMS).

The network system must comply with the following requirements:

- Network devices connected to the machine must comply with IEC 60601-1-2 (Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and test) or any other applicable national standard for electromagnetic compatibility.
- The network and devices of PDMS must comply with IEC 60601-1 (Medical electrical equipment - Part 1: General requirements for basic safety and essential performance), Chapter 16 (ME Systems) or any other applicable national standard concerning safety of information technology equipment and electrical separation.
- The network must have been installed according to the requirements of the European standard DIN EN 50173-1 (Information technology – Generic cabling systems - Part 1: General requirements) or any other applicable international standard, e.g. ISO/IEC 11801 (Information technology – Generic cabling for customer premises).

- The machine must be protected 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 not encrypted, transferred data must be protected using a protected, non-public network.
- The data transfer of alarm states via the network must not be used for external alarm signalling (e.g. staff call).

The risk can be kept acceptable with the measures implemented in the machine, if the requirements described above are complied with. However, failures in providing the required network connection may result in:

- Software-related problems
  Data corruptions in terms of accuracy, plausibility and completeness, caused by the network operator or server software, cannot be detected by the machine. Therefore, incorrect settings of therapy parameters might be possible.
- Hardware-related problems
  The electronic might be affected (e.g. electric shock, high voltage on the network line) due to a hardware failure of a PC, HUB or other component connected to the network.

The responsibility for integration of the machine into the specified network lies entirely with the responsible organization. It shall cover the following considerations:

- Connection to a network including other equipment could result in previously unidentified risks to patients, users or third parties.
- The responsible organization shall identify, analyze, evaluate and control these risks according to the guidance provided with IEC 80001-1:2010.
- Subsequent changes to the network could introduce new risks that require additional analysis. Changes to the network include:
  - Changes in network configuration
  - Connection of additional items
  - Disconnection of items
  - Update of equipment
  - Upgrade of equipment.

2.4.7 Special Hygienic Requirements

In order to protect patients against cross-contamination, pressure sensors for the blood line system are equipped with hydrophobic 0.2 µm filters. If, despite this protective measure, blood enters into the machine-side pressure sensors, the machine may only be used again after appropriate cleaning and disinfection was carried out by technical service.

Due to particularly stringent hygienic requirements, service of dialysis machines with dialysis fluid filters and of HDF Online machines shall be performed every 12 months. Dialysis fluid filters must be changed as specified in the respective instructions for use.

2.5 Information for the Responsible Organization

2.5.1 Conformity

The machine and options comply with requirements of following generally applicable standards in their respective valid national version:

- IEC 60601-1
- IEC 60601-2-16
- EN 80601-2-30 (for ABPM)
- IEC 60601-1-11

Additional equipment connected to analog or digital interfaces of the machine must demonstrably meet the relevant IEC specifications (e.g. IEC 60950 for data processing devices and IEC 60601-1 for medical electrical equipment). Also, all configurations must comply with the valid version of System Standard IEC 60601-1, chapter 17.

⚠ WARNING!

Risk to the patient or user!

Connection of the machine to the equipment other than described in the IFU could result in hazardous situations.

- Contact your local B. Braun Avitum AG representative or local distributor for detailed information.

Persons connecting additional devices to signal input or output components are configuring a system and are responsible for ensuring that the valid version of System Standard IEC 60601-1 is complied with. In case of any questions contact your local distributor or technical service.

The machine is distributed in countries where it is registered and classified according to local regulations.

2.5.2 Training by Manufacturer prior to Commissioning

The responsible organization must ensure that only trained personnel uses the machine. The training must be conducted by personnel authorized by the manufacturer. Contact your local B. Braun Avitum AG representative or distributor for detailed information concerning training courses.

2.5.3 Requirements on the User

The machine may only be used by skilled persons who are duly trained and instructed for its appropriate use according to these instructions for use and for whom the responsible organization can prove that they have been instructed.

The responsible organization must ensure that the instructions for use are read and understood by all persons entrusted with any kind of work on or with the machine. The instructions for use must be permanently available to the user.

Prior to using the dialysis machine, check for safe functioning and correct condition of the dialysis machine.

Based on the medical findings and the medical history of the patient, the physician in charge is responsible for the prescription of the suitable therapy and therapy parameters including dialysis dose and anticoagulation as well as the supervision of the therapy.

Limited-care centers

For treatment in limited-care centers, the patient/person becomes an intended user and must be trained comprehensively in order to be as competent for implementation of the own treatment as a qualified healthcare professionals.

Home Hemodialysis

For treatment in home hemodialysis, the patient/person becomes an intended user and must be trained comprehensively in order to be as competent for the implementation of the own treatment as a qualified healthcare professional.

The physician in charge of the home hemodialysis patient is responsible for careful selection of the patient's suitability to carry out home hemodialysis.

The responsible physician for the home hemodialysis patient and the responsible organization must qualify, supervise, ensure, document and prove that all home hemodialysis patients and persons involved in home hemodialysis are duly trained and instructed for the use of this machine according to these instructions for use and considering home hemodialysis training needs.

The training for the home hemodialysis patient must be conducted by healthcare professionals authorized by the manufacturer and experienced in home hemodialysis training.

Also check chapter 17 Appendix (345) for the training check list for the physician in charge.

⚠ WARNING!

Risk of strangling!

Tubings and other lines may cause strangulation.

- Be careful that tubings to the patient and lines from the patient are placed in a safe way.

⚠ WARNING!

Risk of suffocation!

Swallowable small parts can be part of the packaging, AV systems and accessories and may lead to suffocation.

- Store these parts to keep them out of the reach of children.
- Use the monitor storage of the machine.

NOTICE!

Take special care to keep children and pets away from the dialysis machine when performing home hemodialysis. Operate the machine in a clean environment.

2.5.4 Manufacturer's Responsibility

The manufacturer shall only be responsible for the effects on safety, reliability and performance of the machine, if

- the assembly, expansion, readjustments, changes or repairs were carried out by a person authorized by him and
- electrical installation of the affected room complies with valid national requirements on the equipment of medical treatment rooms (i. e. VDE 0100 part 710 and/or IEC60364-7-710).

The machine may only be used if

- the manufacturer or an authorized person acting on behalf of the manufacturer has carried out a functional check on site (initial commissioning),
- persons appointed by the responsible organization to use the machine have been trained in correct handling, use and operation of the medical product with aid of the instructions for use, enclosed information and maintenance information,
- the quality of water used with the machine corresponds to relevant standards,
- safe functioning and correct condition of the machine have been checked prior to its use.

2.5.5 Modifications of the Machine

⚠ WARNING!

Risk to the patient or risk to the user due to modifications of the machine!

- It is not allowed to modify the machine.

2.5.6 Preventive Maintenance and Technical Safety Inspection

The machine is not equipped with any user serviceable parts. Any maintenance, repair or exchange of components must be performed by technical service. All information required for installation and commissioning, calibration, service and repair is available from the manufacturer for service technicians.

Regular Preventive Maintenance (Service)

Regular preventive maintenance (service) shall be performed every 12 months according to the specified check list in the service manual and with reference to the instructions for use.

Regular preventive maintenance includes replacement of wear and tear parts to ensure fault-free operation of the machine. It may only be carried out by trained personnel.

If 5 % ≤ of lifetime remains an information window appears on the screen when changing from reinfusion to disinfection. If set maintenance interval is reached the above mentioned window appears everytime when selecting disinfection.

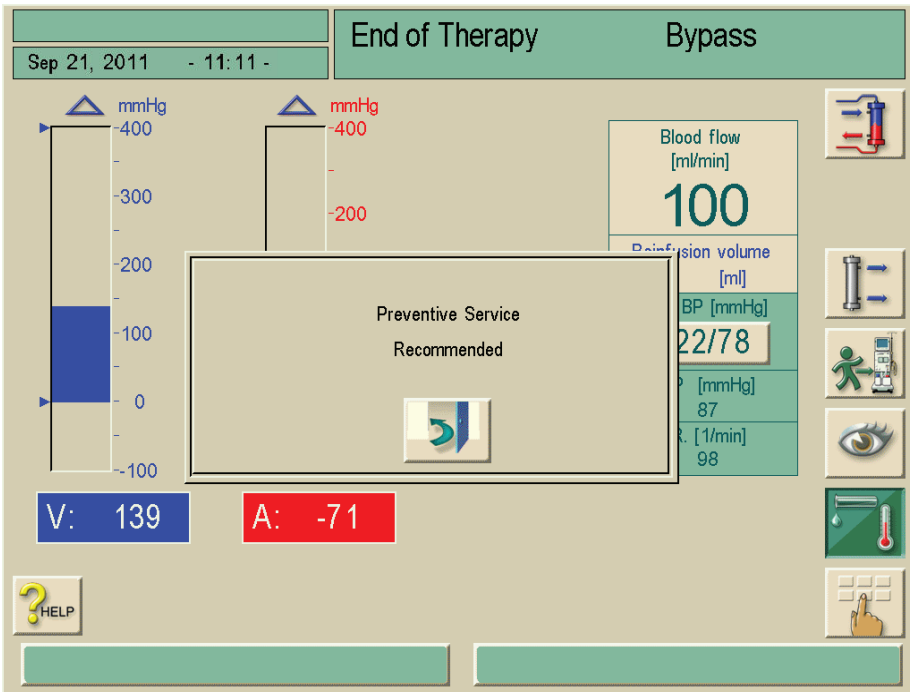

Fig. 2-1 Preventive Service Recommended

Technical Safety Inspection

Technical safety inspection shall be performed and documented every 12 months, according to the specified check list in the service manual and with reference to the instructions for use.

1. The machine shall be checked by persons who have been appropriately trained and do not need instructions for the check.
2. Results of technical safety inspection shall be documented, e.g. by applying an inspection label to the machine.
3. Evidence for execution of technical safety inspection must be kept by the responsible organization as part of their overall documentation.

Service Manual and Technical Training

A service manual can only be provided after participation at a technical training.

Battery (Emergency Power Supply)

The battery should be replaced at least every 5 years to maintain full battery functionality. Dispose of the battery according to local waste treatment regulations. For further information refer to service manual.

Blood Pump Roller

Blood pump roller should be replaced after unintended strong mechanical impact, for example if it dropped to the floor, or if structural alterations are detected.

2.5.7 Accessories, Spare Parts and Consumables

To ensure full functionality of the machine, only B. Braun products should be used.

Alternatively, only use consumables that

- comply with applicable legal requirements of your country and
- are released for use with this machine by their manufacturer.

Only use original accessories and spare parts manufactured by B. Braun Avitum AG and sold by B. Braun Avitum AG or authorized distributors.

2.5.8 Expected Service Life

For Dialog+, B. Braun specifies no limitation of service life. The actual working status of the machine should be evaluated according to:

- The machine performs a series of self tests before each treatment in order to ensure that all safety relevant functionalities are available.
- Only approved spare parts are used.
- Maintenance and service are performed by certified service technicians in accordance with the service manual.
- The technical safety inspection is performed regularly according to the service manual and related regulations.

The machine is fully operable while the above mentioned requirements are achieved accordingly

2.5.9 Disposal

After use, the disposables of a treatment, e.g. empty bags or containers, used blood lines and used filters, may potentially be contaminated with pathogens of transmissible diseases.The user is responsible for the correct disposal of these waste products.

Disposal must be carried out according to local regulations and internal procedures of the responsible organization. Do not dispose of in household waste disposal!

The machine contains substances that are hazardous to the environment when disposed of improperly.

Dispose of spare parts or machines according to the applicable laws and local regulations (e.g. directive 2012/19/EU). Do not dispose of in household waste disposal!

Spare parts or machines shall be cleaned and disinfected according to regulations before shipment and disposal. Batteries shall be removed before disposing of the machine (contact technical service).

B. Braun guarantees the taking back of spare parts and old machines.

2.5.10 Technical Changes

B. Braun Avitum AG reserves the right to change our products in line with further technical developments.

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3 Product Description

The basic model Dialog+ HDF Online is shown below. The legend highlights the components not installed in all basic models or that are available as an option.

Front View

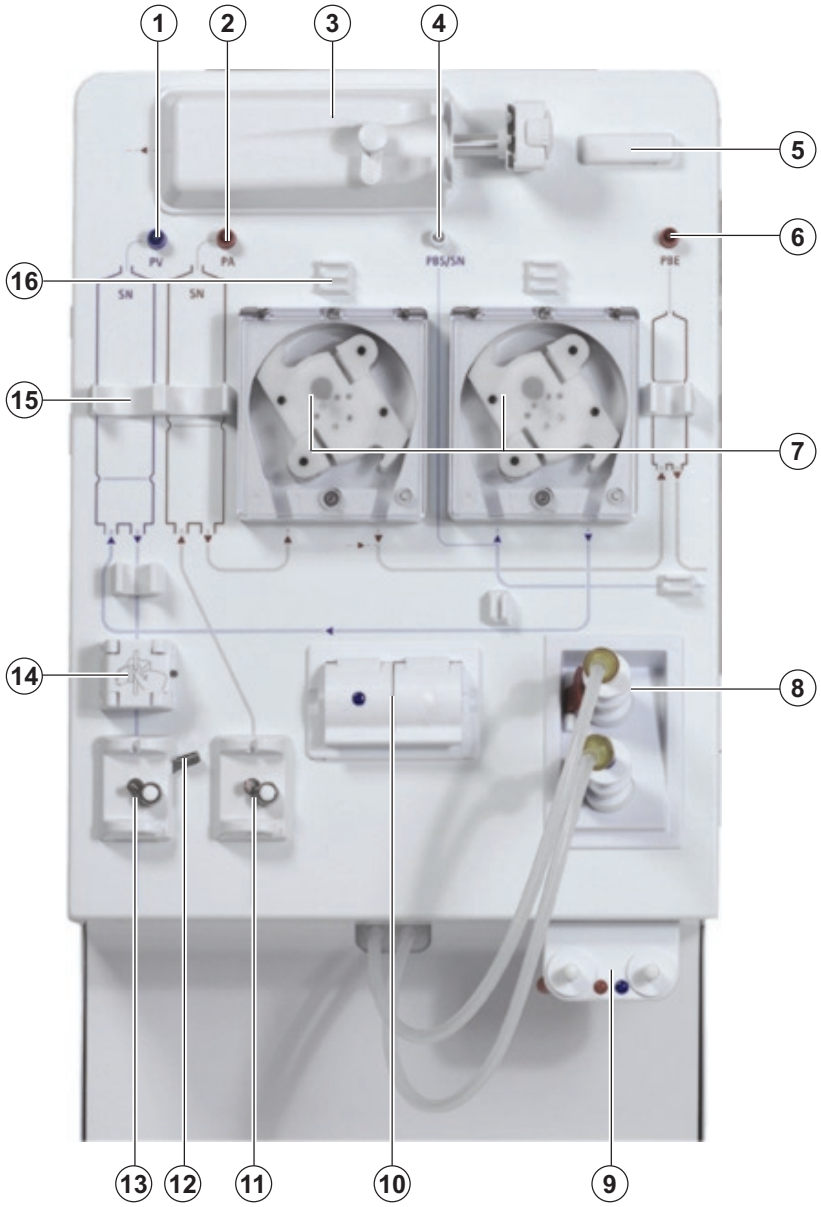


Fig. 3-1 Basic models, front view

1 Venous pressure sensor connection (blue)

2 Arterial pressure sensor connection (red)

3 Heparin pump

4 Pressure sensor connection for regulating the venous blood pump in Single-Needle Cross-Over operating mode (white)

5 Syringe stop

6 Pressure sensor connection for arterial inlet pressure to dialyzer (red)

7 Blood pump (one or two blood pumps depending on basic model)

8 Rinsing chambers for concentrate rods

9 Connection for central concentrate supply (option)

10 Connection for the supply and discharge of substitution solution (only for Dialog+ HDF-online)

11 Arterial tube clamp (for Dialog+ single-pump machine: only present with option ”Single-Needle Valve”)

12 Lever for manual opening of the venous tube clamp

13 Venous tube clamp

14 Safety air detector (SAD) and red sensor

15 Fixings for the chamber(s) of the SN blood line system

16 Fixing for blood line system

Side Views

1 Infusion pole (in some models, pole may not be adjustable)

2 Multi Functional Tray

3 Bicarbonate cartridge holder (standard for Dialog+ HDF Online, optional for Dialog+ Single Pump machine and Double Pump machine)

4 Connection for central concentrate supply (option)

5 Connection for disinfectant

6 Connection for dialyzer tubes and rinsing bridge

7 Card reader

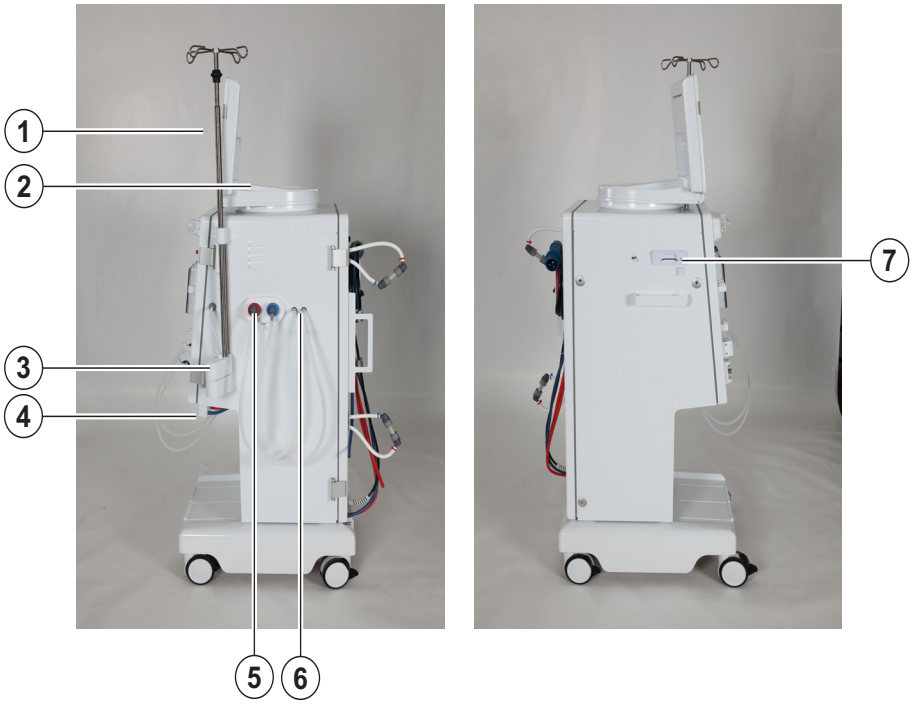


Fig. 3-2 Basic models, side views

Rear View

1 Mains switch
2 Nexadia (optional)
3 Staff call (optional)
4 Crank for manual blood return
5 Fixture for disinfectant container
6 Connection for potential equalization
7 Mains cord
8 Water inlet
9 Dialysate outlet

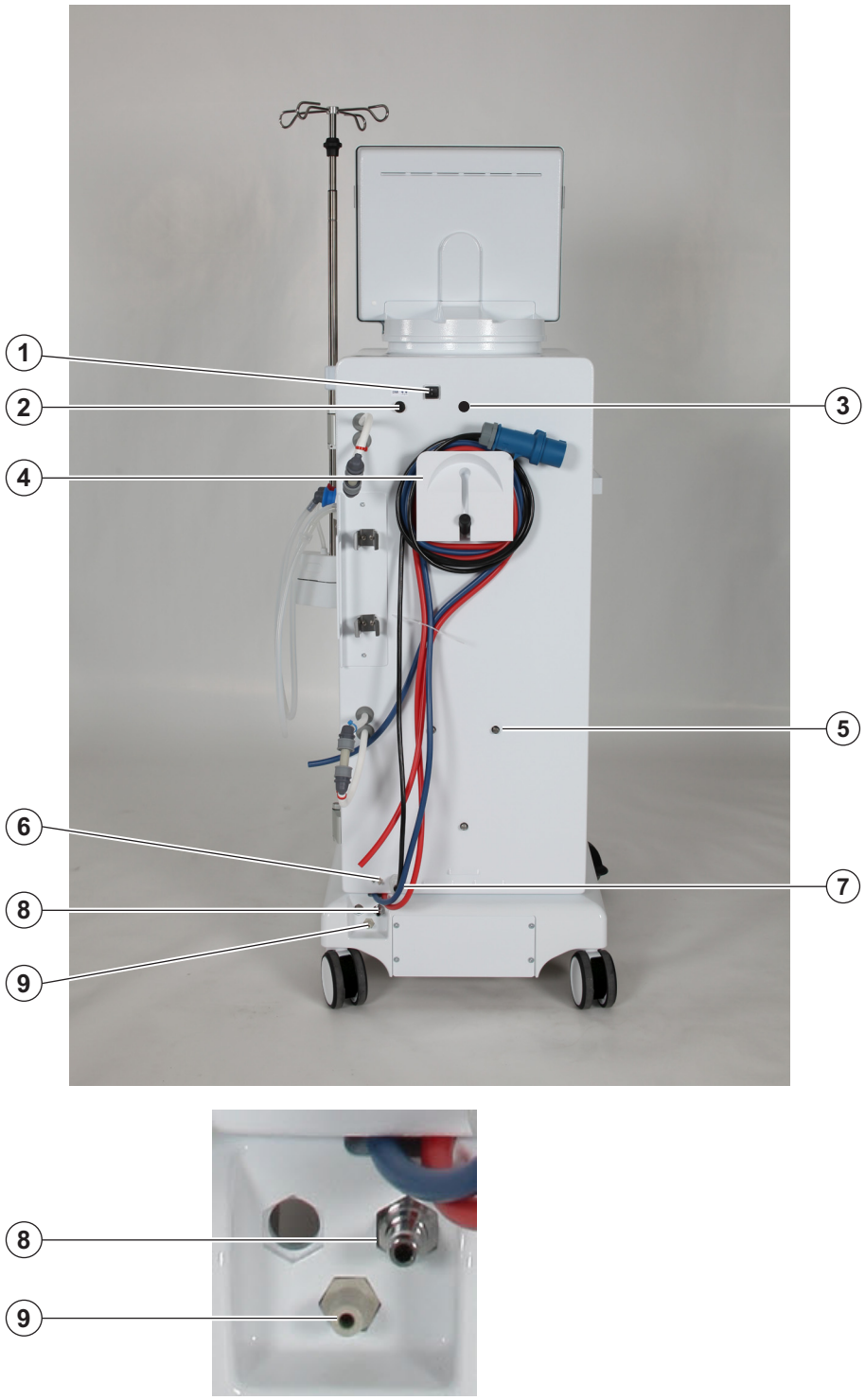


Fig. 3-3 Basic models, rear view

3.1 Brief Description

Fig. 3-4 Dialog+

The machine has a color touch screen on which most functions can be controlled directly by touch. The monitor has 5 hard keys.

The machine controls and monitors the dialysis fluid side as well as the extracorporeal blood side.

Dialysis fluid is prepared by the machine and transported to the dialyzer. Dialysis fluid (inflowing fluid) and dialysate (outflowing fluid) are balanced volumetrically. The composition of the dialysis fluid is constantly monitored.

The temperature can be set in a limited range. The pressure at the dialyzer is regulated depending on the UF rate and the used dialyzer. The UF rate can be set in a limited range.

Blood on the extracorporeal blood side is transported through the dialyzer. The heparin pump can be used to add anticoagulation to the blood in order to prevent clotting. The safety air detector (SAD) recognizes air in the blood line system. Loss of blood through the dialyzer membrane is monitored by the blood leak detector (BLD), which determines the amount of blood in dialysate.

The machine can be used for acetate or bicarbonate dialysis. Mixing ratio and concentrations may be set within certain limits. It is possible to set profiles.

Dialysis fluid flow (DF flow) can be set in a limited range.

Sequential ultrafiltration (SEQ UF) can be used for short-term extraction of higher amounts of fluid.

The machine is equipped with all required safety systems and complies with the standards IEC 60601-1 and IEC 60601-2. Operation can only be started if all self tests have successfully been passed. The alarm system itself is also part of the self tests.

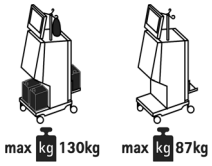
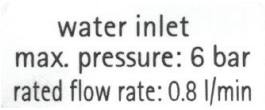
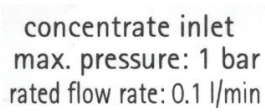
3.2 Therapy Types and Methods of Treatment

	Single Pump machine	Double Pump machine	HDF Online machine
Therapy types	HD ISO UF	HD ISO UF	HD ISO UF HF Online HDF Online
Methods of treatment	Double-Needle Single-Needle Valve	Double-Needle Single-Needle Valve Single-Needle Cross-Over	Double-Needle Single-Needle Single-Needle Cross-Over; only possible with therapy types HD and ISO UF

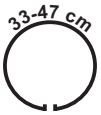
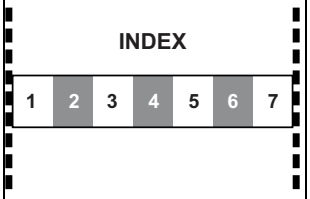
3.3 Symbols on the Dialysis Machine

Symbols on Machine

Symbol	Description
	Follow instructions for use Observe safety information
	Type B applied part Classification acc. to IEC 60601-1/IEC 60601-1
	Type BF applied part Classification acc. to DIN EN 60601-1/IEC 60601-1
	Connection for potential equalization line
	Dialysis machine OFF

Symbol	Description
	Dialysis machine ON
	Alternating current
	Schematic illustration on safety air detector (SAD) and air detector of the substitution line showing the correct way of installing the blood line
	Connection for optional staff call device
	Connection for optional automatic blood pressure measurement (ABPM)
	Corrosive material. Risk of chemical burns.
	Maximum machine weight of Dialog+ HDF Online including all options with (left) and without (right) all consumables (with all consumables = maximum working load)
	Maximum machine weight of Dialog+ Single Pump/Double Pump including all options with (left) and without (right) all consumables (with all consumables = maximum working load)
	Water inlet Maximum rated pressure Rated flow rate
	Concentrate inlet Maximum rated pressure Rated flow rate
	Warning for hot surface

Symbols on ABPM Cuff

Symbol	Description
	Consult instructions for use
	Type BF defibrillation proof applied part Classification acc. to IEC 60601-1
	Cuff is free of latex
	Cuff size: S (small), M (medium), L (large), XL (extra large). The respective size is indicated by the rectangle around the symbol.
	Upper arm diameter
	Marking for correct cuff size
	Marking for cuff placement

3.4 Type Plate

1 Product name
2 Reference number
3 Serial number
4 Manufacturing date
5 Country specific requirements that may vary
6 Manufacturer's address
7 Nominal power
8 Nominal voltage
9 Nominal frequency
10 Follow instructions for use
Observe safety information
11 Directives for disposal apply
12 Type B applied part
13 Housing protection class
14 CE mark and certified body indentifier

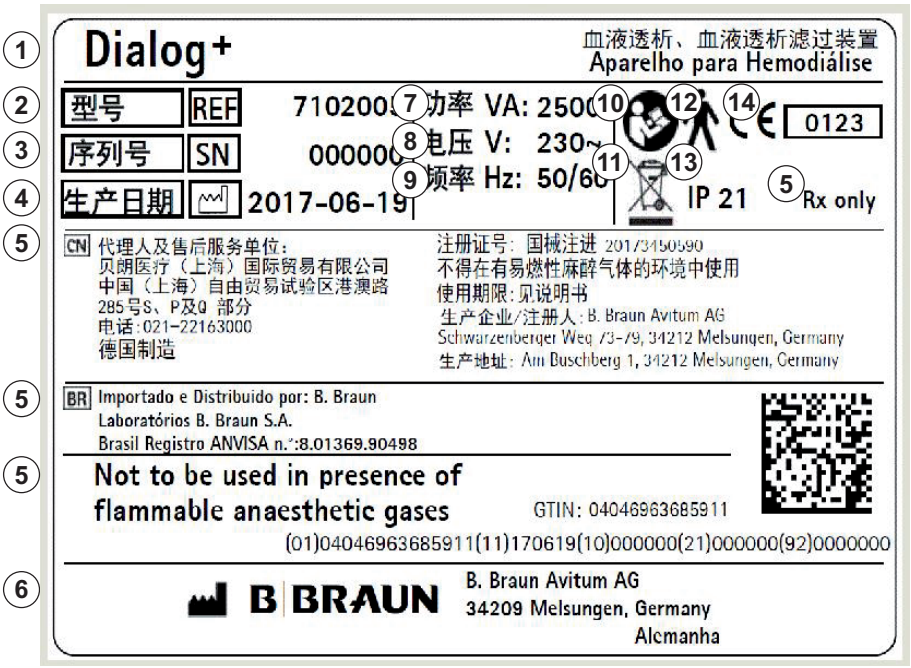


Fig. 3-5 Type plate

3.5 Controls and Indicators on Monitor

Signal Lamps

Signal lamps on the left and right of the monitor light up in three different colors to indicate the conditions "Operation", "Fault" and "Alarm".

1 Signal lamps:
Green = operation
Yellow = warning/note
Red = alarm
2 Keys on the monitor

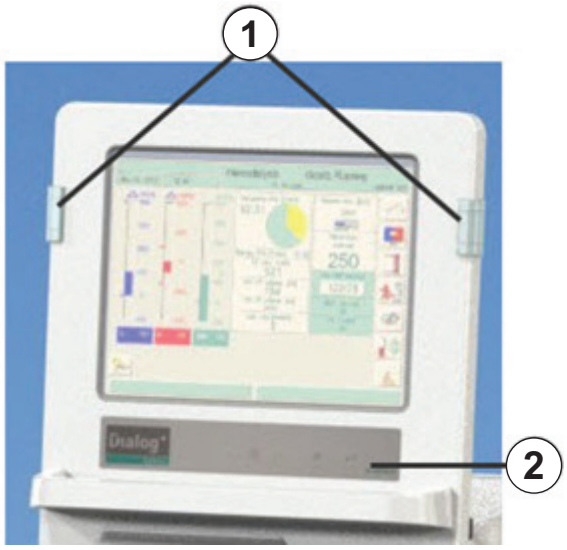


Fig. 3-6 Monitor

Keys on the monitor

Even with the screen switched off (e.g. during cleaning), the basic functions of the dialysis machine can be controlled via the keys on the monitor.

The “+” and “-“ keys (key 2 and 4) automatically count up or down by keeping the key pushed.

1 Battery symbol (display only:
Battery charging)

2 Reduce blood pump speed

3 Switch on/switch off blood pump

4 Increase blood pump speed

5 Confirm alarm (when key is illuminated); switches off the alarm mute key

6 Enter key: Confirm entered data and reset information (if key is illuminated)

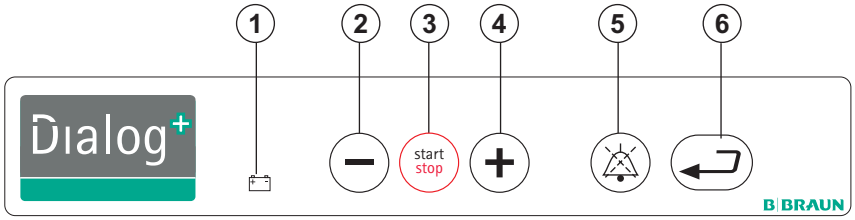


Fig. 3-7 Keys on the monitor

Touch Screen

Most functions of the dialysis machine are controlled via the touch screen. The screen **(1)** displays different contents (windows) depending on the activated program section. Different parts (fields and icons) **(4, 5 and 6)** of the screen react to touch. By touching one of these areas, another window is called up or a stored action is triggered.

Some windows show a lateral scroll bar. They could be scrolled by moving a finger on the scroll bar.

1 Screen
2 Patient name
3 Date line (date and time)
4 Fields
5 Call up help function for explaining the icons
6 Icons
7 Alarm field
8 Warning field

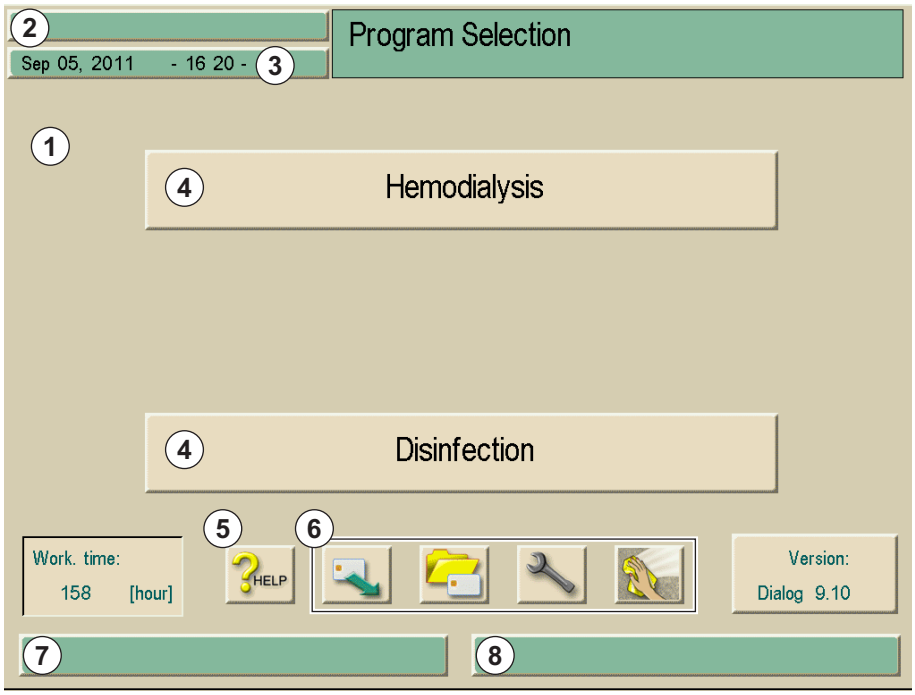


Fig. 3-8 Screen Display

The alarm field **(7)** on the left side displays safety relevant alarms in red. Alarms which are not safety relevant are displayed in yellow.

The warning field **(8)** on the right side displays warnings in yellow. Warnings do not require immediate interactions by the user.

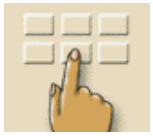
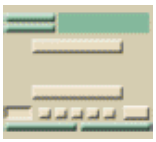
By clicking on an alarm/warning the alarm text with the alarm ID is displayed. By clicking again an alarm help text will open giving information about the alarm cause and remedial action.

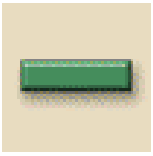
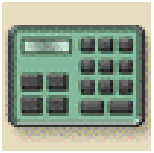
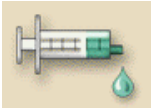
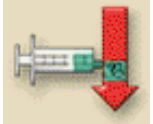
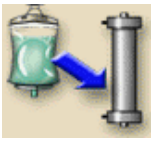
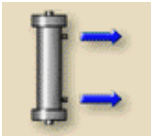
For more information refer to chapter 13 Alarms and Remedial Action (253).

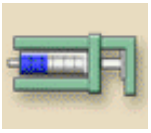
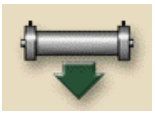
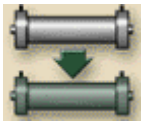
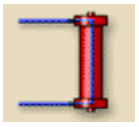
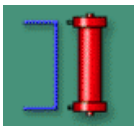
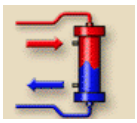
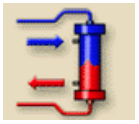
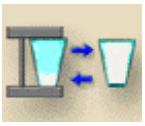
3.6 Overview of All Icons

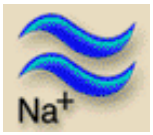
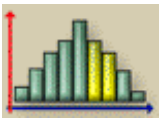
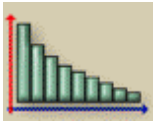
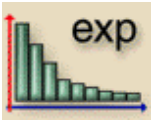
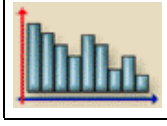
Icons are control buttons on the touch screen used for operating the dialysis machine. Depending on the displayed window, different icons are available, which all represent a specific action. By touching an icon, the respective action is carried out. A list of all icons is provided below.

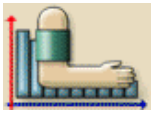
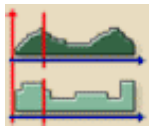
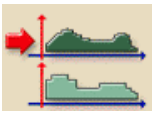
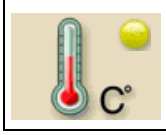
Icon	Description
	Leave window and accept data
	Leave window without accepting data
	Call up help function for explaining the icons

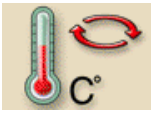
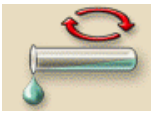
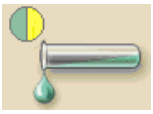
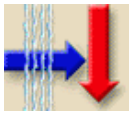
Icon	Description
	Call up history of current disinfection
	Call up service screen
	Switch off all icon functions for 10 sec to allow cleaning of monitor
	Set brightness of monitor
	Leave current window
	Call up overview
	Call up respective parameter window
	Set treatment parameters
	Return to program selection
	Erase therapy card
	Read patient data from therapy card
	Save patient data to therapy card

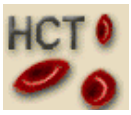
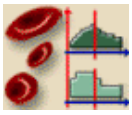
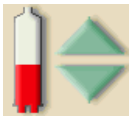
Icon	Description
	Select further setting options
	Reduce value
	Increase value
	Red symbol: error symbol during reading of patient data therapy card
	In profile window (except for UF profile): open numerical keypad for resetting the profile to a setting
	Call up keypad for entering numerical values
	Give heparin bolus
	Give arterial bolus
	Call up window for setting arterial bolus
	Call up dialyzer rinsing program with simultaneous ultrafiltration
	Empty dialyzer – dialysate is siphoned out of the dialyzer

Icon	Description
	Call up and set heparinization data
	Reset filter, empty (option DF filter)
	Filter data (only active if option DF filter has been installed or if the machine is equipped with HDF Online)
	Dialysis on main connection – dialysate flows through dialyzer
	Dialysis bypass – no dialysate in dialyzer
	Connect patient to online substitution
	Start reinfusion
	Empty bicarbonate cartridge: fluid is removed from the bicarbonate cartridge
	Change bicarbonate cartridge
	Change to therapy mode
	Change to "Therapy end" mode
	Disinfection from water supply inlet

Icon	Description
	Disinfection from water outlet
	Call up and set dialysate settings
	Activate stand-by
	Call up and set ultrafiltration data
	Call up minimum ultrafiltration
	Call up and set pressure limits
	Call up single-needle selection and settings
	Call up ultrafiltration profiles
	Call up profile settings for the respective parameter
	Call up linear profile in case of specified start and end values
	Call up exponential profile in case of specified start and end values
	Call up UF path bioLogic RR Comfort (option)

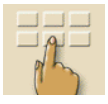
Icon	Description
	Select bioLogic RR Comfort (automatic blood pressure stabilization, option)
	Select bioLogic RR Comfort submenu
	Call up non-invasive blood pressure measurement (ABPM, option)
	Call up time setting (ABPM, option)
	Call up graphic representation of different parameters of therapy course
	Determine selection of graphically represented parameters
	Call up screen for entering laboratory values (urea) for Kt/V calculation
	Kt/V measurement (Option Adimea)
	Save dialysis efficacy and list of treatment values and Kt/V values
	Save disinfection data Call up weekly disinfection program
	Call up disinfection screen
	Start thermal disinfection

Icon	Description
	Start central thermal disinfection
	Start chemical disinfection from water supply
	Start brief disinfection/cleaning
	Start disinfection program
	Start central rinsing
	Activate automatic switch-on of dialysis machine at the programmed time
	Activate automatic switch-off of dialysis machine after disinfection
	Change settings for HDF/HF Online
	Call up disinfection history of last 150 disinfections
	Delete ABPM measured values list (option)
	Start ultrafiltration without dialysate (sequential therapy)
	Start ultrafiltration with dialysate
	Timer/stop watch

Icon	Description
	Suppressed warning sounds during preparation
	Select language of screen text
	Option Crit-Line Interface
	Crit-Line Table
	Crit-Line Trend
	Level regulation: enter to level regulation function
	Level regulation: decreasing chamber level
	Level regulation: increasing chamber level
	List of stored Adimea curves

3.7 Entering Numerical Values

The changing of values is based on the same principle for all parameters. We are, therefore, providing an example at this point. The example refers to the change of the parameter **UF quantity** on the ultrafiltration data window.



1. Touch icon on screen.
   - ↳ The selected icon lights up in green.
   - ↳ An icon appears for all parameter groups that can be changed.
   - ↳ If none of these icons is pressed within a preset time, the icons are switched off again. The preset time can be set by the service engineer in the service program.

2. Touch desired icon (here: icon for calling up ultrafiltration data window).
   - ↳ The preset values for the parameter are displayed.
   - ↳ The selected icon lights up in green.

3

3. Touch value to be changed on screen (here: value for UF quantity **2000 ml)**.

   ↳ A field of icons for changing the value is displayed.

   ↳ The desired value lights up in green.

1 Reduce value

2 Increase value

3 Call up keypad for entering values

4 Example: Calling up “Ultrafiltration data” screen

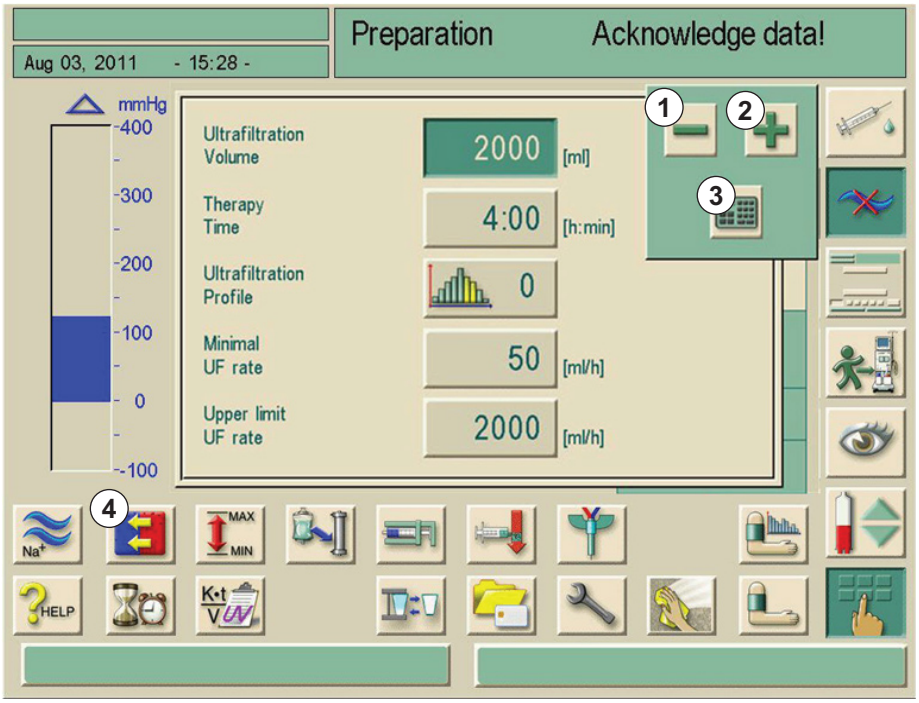
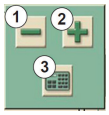


Fig. 3-9 Icons for changing the value

The dialysis machine can be set in the service program in such a way that a keypad appears immediately after the value to be changed has been touched. In this case, the keypad has no **O.K.** icon. To confirm entry, press Enter on the monitor.

1. Reduce value : Touch icon **1** until the desired value has been reached.



2. Increase the value: Touch icon **2** until the desired value has been reached.
3. Enter different value: Touch icon **3**.

A keypad is displayed. The permissible setting range is specified in square brackets below the numerical value (here: 100 ... 20000).

By pressing the icons **1** and **2** permanently, the setting could be adjusted up or down.

1 Numerical keys
2 Change sign of numerical value
3 Delete set numerical value
4 Leave window and accept data
5 Leave window without accepting data

Fig. 3-10 Numerical keypad

Delete the set numerical value: Touch key **3** on keypad.
Interrupt entry of numerical value and return to main window: Touch key **5**.

If a value outside the permissible range is entered, the message **Limits exceeded** is displayed below the entered value.

1. Enter value using keypad keys **1**.
2. If necessary, change sign via icon **2**.
3. Confirm entry with icon **4**.

To rush the access to the groups of parameters so-called “shortcuts” can be used.Therefore, touch the parameter which should be changed or a concerning graphic indicator on the main screen. The corresponding window of the group of parameters will open as shown in Fig. 3-11.

The following screen shows the available shortcut squares in frames.

1 Help icon, active

2 Shortcuts

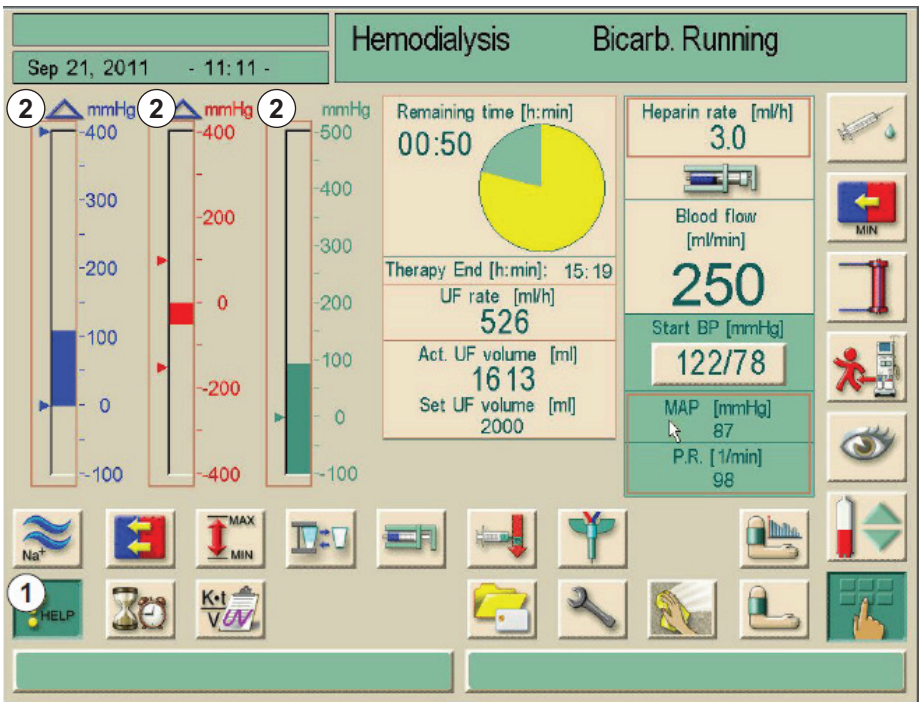


Fig. 3-11 Shortcut squares during activated help button

If a shortcut was touched inadvertently, or if no parameters are entered the parameter window will close automatically after 10 seconds.

The frames marking the shortcuts will only appear if the help function is activated.

1. Touch help button (1)
   - The shortcuts will be marked by brown frames.
2. Touch help button again
3. The frames disappear.

Shortcuts are only active if the corresponding parameters are relevant for the actual therapy. For example: The setting of the venous limit can only be done by shortcut within SN therapies.

Some shortcuts directly open the +/- window for changing the setting. For example: UF-quantity.

3.8 Therapy Types

3.8.1 Hemodialysis (HD)

Hemodialysis is the most common type of therapy used for cleaning blood. Depending on clinical requirements, treatment generally lasts between three and six hours (typically ca. 4 hours) and is carried out three times a week (in exceptional cases, twice a week).

Mode of Operation

The dialysis machine pumps blood through a patient's vascular access into the dialyzer.

Inside the dialyzer metabolic waste products are separated from the blood. The dialyzer operates as a filter that is divided into two parts by a semi-permeable membrane. On one side the patient's blood, on the other side the dialysate flows past.

During the therapy the dialysate is prepared by the dialysis machine. It consists of prepared water to which certain quantities of electrolyte and bicarbonate, depending on the individual patient's requirements, are added.

The concentrations of electrolyte and bicarbonate in the dialysate are adjusted in such a way that certain substances can be removed from the blood through convection, diffusion and osmosis, while other substances are added at the same time. This is mainly achieved by diffusive clearance through the semi-permeable membrane of the dialyzer. The dialysate transports the metabolic products from the dialyzer into the discharge line. The cleaned blood is then recycled into the patient.

During treatment the dialysis machine monitors the blood circulation outside of the body, pumps blood and dialysate in separate circulation systems through the dialyzer and monitors the composition and volume balance of the dialysate.

The heparin pump, which is also part of the dialysis machine, can be used to add anticoagulants to the blood in order to prevent the formation of blood clots in the extracorporeal circulation.

In addition to cleaning the blood, the dialysis machine removes water from the blood, which would be excreted through the kidney in healthy humans.

3.8.2 Isolated Ultrafiltration (ISO UF)

Isolated ultrafiltration (ISO UF, sequential therapy, Bergström therapy) is used for a short-term extraction of a higher amount of fluid from the patient.

For further information see chapter 12.5 UF Profiles (231).

Mode of operation

During isolated ultrafiltration no dialysate flows through the dialyzer. This therapy type serves only for extracting fluid from the patient.

3.8.3 Hemofiltration (HF/HF Online)

Hemofiltration (HF) is often used with patients suffering from blood circulation problems for whom this form of therapy is more comfortable. Middle-molecular substances such as ß-2 microglobulin are better eliminated from the blood by the HF therapy than by the HD therapy.

In HF Online therapy, the substitution fluid is prepared online. The machine produces highly purified dialysis fluid which can be used as substitution fluid. Unlimited substitution fluid is available, allowing higher infusion rates.

Mode of Operation

During Hemofiltration (HF) the blood is predominantly cleaned by convection on the dialyzer membrane.

In HF therapy, no dialysate is pumped through the dialyzer. Instead, a sterile substitution solution is infused into the blood cycle upstream or downstream of the dialyzer. Depending on whether the infusion takes place upstream or downstream of the dialyzer, the procedure is called predilution (upstream) or postdilution (downstream).

The filter membrane in the dialyzer has a higher water permeability than a HD filter. It contains a so-called high-flux membrane (hemofilter) and allows ultrafiltration of considerably more fluid than through HD therapy.

The electrolyte concentrations in the substitution solution and in the dialysate are identical. The infusion rate is 4-5 l/h. The same volume is ultrafiltered through the dialyzer. In this way the so-called convective clearance is increased so that the elimination results are the same as with HD therapy.

In HF Online therapy the substitution solution is prepared "online". Dialysate is sterile-filtered so that it can be used as substitution solution. Unlimited substitution solution is available, allowing higher infusion rates.

3.8.4 Hemodiafiltration (HDF/HDF Online)

Hemodiafiltration (HDF) is a combination of HD and HF. Both dialysate and substitution solution are used in this therapy.

This allows the combination of diffusive and convective clearance for small and medium molecular substances.

Mode of Operation

During Hemodiafiltration (HDF) the dialysis machine removes more water from the blood than necessary to replace the natural kidney function. The result is better cleaning of the blood, although the missing fluid has to be replaced. Therefore, substitution solution is simultaneously infused into the patient's body. Depending on whether the infusion takes place upstream or downstream of the dialyzer, the procedure is called predilution (upstream) or postdilution (downstream).

In HDF Online therapy a part of the dialysate is processed as substitution solution.

3.9 Methods of Treatment

3.9.1 Double-Needle Procedure

The double-needle procedure is the standard technique in hemodialysis. Blood is extracted from the patient through the arterial vascular access. The blood pump continuously pumps the blood through the arterial blood line system to the dialyzer. There, the exchange of metabolic waste products between the blood and the dialysis fluid proceeds across the semipermeable membrane of the dialyzer. After that, the blood is returned to the vein of the patient through the venous blood line system, the bubble catcher and a second vascular access to the vein. Used dialysis fluid is pumped to the dialysate outlet of the machine.

3.9.2 Single-Needle Procedure

The single-needle procedure is applied when patients had problems with the predominantly used double-needle dialysis. In the single-needle procedure, only one needle (single-needle cannula) or a single-lumen, single-needle catheter is applied to the patient. The arterial and venous ends of the blood line system are connected via a Y-piece. This procedure allows reducing the number of punctures by half compared to double-needle dialysis, thus, preserving the patient's shunt.

The following single-needle procedures are available:

- Single-Needle Cross-Over as an alternative to double-needle procedure,
- Single-Needle Valve as "emergency procedure" for terminating a dialysis in case of problems with a double-needle dialysis.

3.9.3 Single-Needle Cross-Over Procedure

The Single-Needle Cross-Over procedure with two blood pumps allows a continuous flow through the dialyzer with only one patient connection. During a Single-Needle Cross-Over procedure, the pressure and pulsation conditions within the dialyzer are roughly the same as in a double-needle dialysis.

Mode of Operation

1 Patient connection
2 Arterial tubing clamp
3 Arterial chamber
4 Arterial pressure sensor
5 Arterial blood pump
6 Heparin pump
7 Dialyzer with connection for dialysate
8 Control pressure for venous blood pump
9 Venous blood pump
10 Venous pressure sensor
11 Venous chamber
12 Air detector
13 Venous tubing clamp

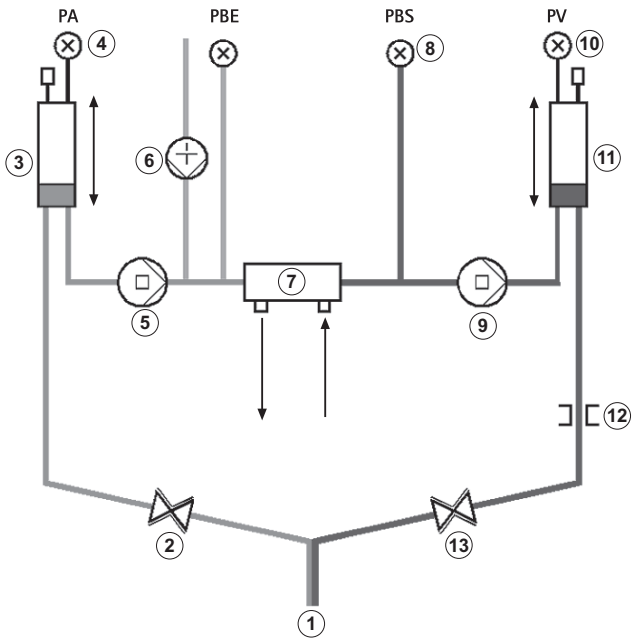


Fig. 3-12 Mode of operation - single-needle cross-over

With the arterial tubing clamp (2) open and the venous tubing clamp (13) closed, the arterial blood pumps (5) move, at the preset rate from the patient through the dialyzer (7) into the venous chamber (11). The level chamber rises. The pressure in the venous chamber (11) is monitored via the venous pressure sensor (10). Once the set venous switchover pressure has been reached, the arterial tubing clamp (2) closes. Shortly afterwards the venous tubing clamp (13) opens.

The blood from the venous chamber (11) flows back to the patient. The venous blood pump (9) pumps blood from the arterial chamber (3) through the dialyzer into the venous chamber (11). The pressure in the arterial chamber (3) is monitored via the arterial pressure sensor (10). Once the set arterial switching pressure has been reached, the venous tubing clamp (4) closes and the arterial tubing clamp (2) opens. Blood flows again into the arterial chamber and the process starts again with the withdrawal of blood from the patient.

Advantages of SNCO Compared to Conventional SN Procedures

Monitoring of the arterial entry pressure and venous return pressure allows a high blood flow without any gas formation in the blood and without the pump tube collapsing in the arterial blood pump.

As the second (venous) blood pump protects the dialyzer from the high pressure fluctuations of the venous side, the blood volume recirculating in the system and the load on the dialysis membrane in the dialyzer are low, and clotting can be avoided.

3

3.9.4 Single-Needle Valve Procedure

Single-Needle Valve procedure allows switching from a running double-needle dialysis in case of problems (e.g. at the shunt).
Single-Needle Valve procedure requires only one blood pump but can also be applied to a machine containing two pumps. The second blood pump remains switched off in this case.

Mode of Operation

1 Arterial tubing clamp (option)
2 Venous tubing clamp
3 Venous red sensor in the housing of the SAD
4 Safety air detector (SAD)
5 Venous chamber
6 Venous pressure sensor
7 Arterial pressure sensor
8 Arterial blood pump
9 Heparin pump
10 Arterial entry pressure at the dialyzer
11 Arterial chamber
12 Dialyzer

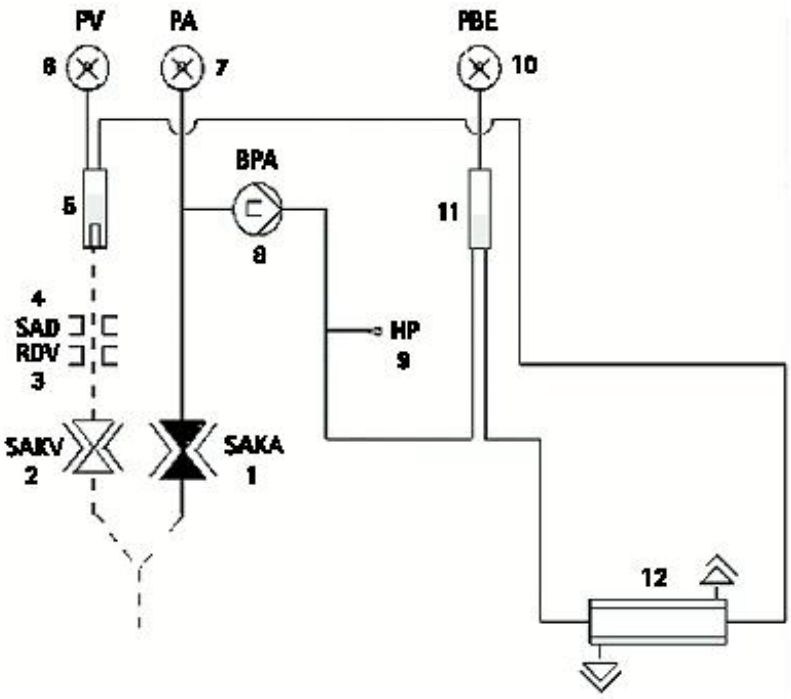


Fig. 3-13 Mode of operation - single-needle valve

The patient is connected through either a "standard AV set with 30 ml chamber" or an "AV set for Single-Needle Valve with a 100 ml chamber". The arterial and venous blood lines are connected through a Y-piece at the vascular access.

With the venous tubing clamp (2) closed and the arterial tubing clamp (1, if present) open, the blood pump (8) pumps blood from the patient through the dialyzer (12) into the venous chamber (5). The pressure in the venous chamber (5) is monitored via the venous pressure sensor (6). As soon as the preset upper switching pressure is reached, the blood pump (8) is switched off and the venous tubing clamp opens. If an arterial tubing clamp (1, if present) is installed, too, this clamp closes now and, thereby, blocks any recirculation of blood into the arterial tubing between Y-piece and blood pump.

Due to the pressure in the venous chamber (5), the blood flows through the dialyzer (12) back to the patient until the lower switching pressure is reached. Once the lower switching pressure has been reached in the venous chamber (5), or the preset return flow time has expired, the venous tubing clamp (2) closes. Shortly afterwards the arterial tubing clamp (1, if present) opens. The blood pump (8) is activated and the process starts again with the withdrawal of blood from the patient.

The return flow time is averaged over the first three cycles and automatically set between 3 and 10 s for the duration of the therapy. If the lower switching pressure was not reached, the machine switches to the arterial phase after 10 seconds.

3.10 Dialysis Efficacy (Kt/V)

If the theoretical calculation of the effectiveness is selected, the option Adimea as described in chapter 11 Use of Options (175) is not applicable.

The dialysis machine allows optimization of therapy over many treatments. For this purpose, the theoretical effectiveness is calculated by the dialysis machine. This theoretical figure can then be compared with the actual effectiveness determined from blood samples.

For the actual effectiveness, the urea values before and after dialysis have to be determined in the laboratory and entered into the dialysis machine.

Comparison of Theoretical and Actual Effectiveness over Many Treatments

The comparison of theoretical and actual effectiveness can be used as a decision aid for setting the therapy parameters and for selecting the dialyzer. Using the patient card, the dialysis machine can store and list the figures for the last 50 treatments.

⚠ WARNING!

Risk to the patient by the input of new treatment parameters.

- The treatment parameters may not be determined on the basis of the calculated Kt/V.
- A calculation of the Kt/V does not replace the therapy prescribed by the physician.

Monitoring the Effectiveness During the Current Treatment

During a treatment, the current effectiveness estimated by the dialysis machine can also be used as an indicator for the effectiveness that would be achieved if the treatment would be terminated at a specific time.

The warning during treatment that a certain target value for the effectiveness (Kt/V value), which was determined prior to treatment, cannot be reached, allows early corrective intervention into the running treatment.

NOTICE!

It cannot be guaranteed that the calculated Kt/V value will actually be reached.

Calculation During Particular Phases

The Kt/V value is **not** calculated during:

- Sequential phases of profiles
- Hemofiltration
- Infusion bolus, as the actual blood flow does not correspond to the blood pump speed

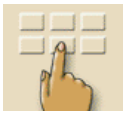
During a phase at a min. UF rate, the Kt/V value calculation is continued. During a single-needle dialysis, the Kt/V value calculation is based on the average blood flow.

3

3.11 Using the Timer/Stop Watch

The Dialog+ screen offers a timer or stop watch function for individual use. These functions are offered in the phases:

- Preparing
- Therapy
- End of Therapy
- Selection of disinfection and
- Disinfection.



1. Touch this icon.

2. Touch this icon

   ↳ The following screen appears:

1 Adjustment of an absolute time for a warning sound

2 Adjustment of an interval time for a warning sound

3 Displays rest or expired time

4 Starts/stops/resets timer or stop watch

5 Starts/stops the timer for recurring warnings after input in **1** or **2**

6 Switches off the warning sound after the chosen time interval

7 Opens an input window for reminder

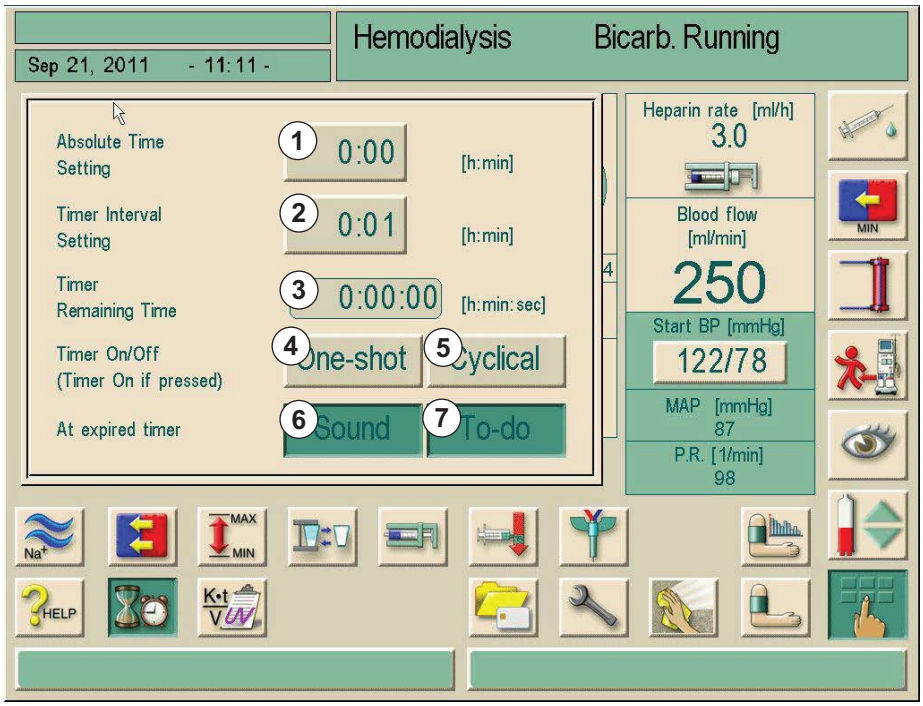


Fig. 3-14 Timer/stop watch function

If requested button **6** activates or inactivates the warning sound.

The user could choose between a single warning or a cyclic warning with fixed intervals.

For a Single Warning

- Requested adjustment with button **1** or **2**.
- Touch button **4** for single warning.

For Cyclic Warning

- Requested adjustment with button **2** (button **5** automatically activated).
- Touch button **5**.

The timer/stop watch function starts.

- To stop/reset touch respective button.

The timer function is counting the time shown in field **3** downwards; the stop watch is counting upwards.

- Touch button **7** for input of a reminder

At expiry of an adjusted time an advice appears in the message field “The set time interval expired” or an information window with the entered reminder-text appears. The signal lamps switch to yellow and an acoustic signal appears if it has been activated.

- Press the alarm mute key to acknowledge sound and message.

The timer/stop watch function is not interrupted by a possible power failure.

The running timer/stop watch function is shown with a symbol in the date line of the screen.

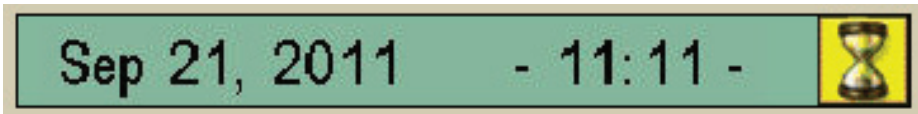


Fig. 3-15 Date line with timer symbol

Table of Contents

4 Installation and Commissioning

4.1 Scope of Supply

- Dialog+ dialysis machine
- Instructions for use
- Suction tube with screw lid for disinfectant
- Tube clamps for tubes
- One container lid each with coupling for inserting suction rods (white, red and blue)
- Storage box
- In case of option Central Concentrate Supply: Supply from wall connection coupling to dialysis machine

4.2 Goods-In Check

When delivered, unpacking must be performed by authorized personnel, for example a service technician.

1. Check packaging immediately for transport damages.
   - Check packaging for indications of brute force, water and signs of inappropriate handling for medical devices.
2. Document any damages.
3. In case of damages contact your local distributor immediately.

4.3 Initial Commissioning

Initial commissioning shall be performed by the responsible technical service only. Respective installation instructions can be found in the service documentation.

The responsible organization must confirm changes of default values in TSM mode performed by technical service during initial commissioning by signing a commissioning check list.

4.4 Storage

4.4.1 Storage in Originally Packed Condition

1. Store the dialysis machine in ambient conditions as specified in section 15.4 Dialysis Fluid Side (324).

4.4.2 Interim Storage of Machines Ready for Operation

1. Disinfect the dialysis machine.
2. Store the dialysis machine in ambient conditions as specified in section 15.3 Ambient Conditions (323).
3. Disinfect Dialog+ HDF Online at least once a week.

4.4.3 Decommissioning

1. Disinfect the dialysis machine.
2. Instruct technical service to empty the dialysis machine.
3. Store the dialysis machine in ambient conditions as specified in section 15.3 Ambient Conditions (323).

4.5 Transportation

4.5.1 Wheeling

⚠ CAUTION!

Cutting and crushing hazard!

The machine weighs up to 118 kg with all options, accessories and consumables installed and fluid circuit filled (maximum working load).

- Always move or carry the machine observing standard safety precautions and practices for transportation and handling of heavy equipment.

⚠ CAUTION!

Risk of electric shock if the machine is not disconnected from power supply!

- Ensure that the machine is disconnected from power supply before transportation.

⚠ CAUTION!

Risk of toppling over cables or tubes if those are not safely stored for transport!

- Ensure that cables and tubes are safely stored when moving or carrying the machine.
- Move the machine slowly.

NOTICE!

Always transport the machine in upright position. Horizontal transportation is only allowed after the machine has been emptied in TSM mode (contact technical service).

Storage of Cables, Tubes and Consumables

1. Before moving or carrying the machine, hang cables over handle on rear side of the machine as indicated in Fig. 4-1.

Fig. 4-1 Storage of cables and tubes

2. Store tubes safely in order to avoid toppling.
3. Fix or remove disinfectant container in order to avoid falling down.
4. Press dialyzer holder towards machine.

⚠ CAUTION!

Risk of damage if dialysis machine is tilted by > 10°!

- Have two or more persons at hand for transporting the machine on stairs and inclined areas.
- Do not tilt the dialysis machine by more than 10°.

Moving Machine Inside Buildings

1. Release the brakes from all casters.
2. Move the machine carefully.
3. On uneven surfaces (e. g. elevator entry), push the machine carefully and slowly or carry the machine, if required.
4. To move the machine up or down stairs or slopes, be 2 persons as shown in Fig. 4-2.
5. After moving, reapply brakes to all casters.

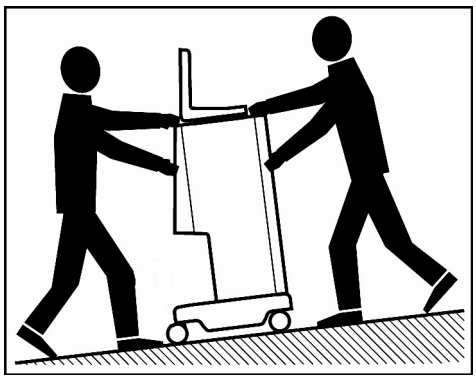


Fig. 4-2 Transport on stairs and slopes (2 persons)

Moving Machine Outside Buildings

1. Release the brakes from all casters.
2. Move the machine carefully.
3. On uneven surfaces, carry the machine.
4. After moving, reapply brakes to all casters.

4.5.2 Carrying

For carrying, the dialysis machine can be held at the base, at the rear panel and/or the protrusion at the front of the machine, as shown in the illustration below.

Fig. 4-3 Holding points for carrying the dialysis machine

⚠ CAUTION!

Risk of damage due to incorrect transportation (wrong holding points)!

- Do not hold machine on monitor, on bicarbonate cartridge holder or on infusion pole when transporting.

1. Use a belt to secure monitor to infusion pole.
2. Release caster brakes.
3. Tilt the dialysis machine.
4. Put down the dialysis machine.
5. Ensure that all brakes are applied when machine has reached treatment site.

4.6 Installation Site

The ambient conditions of the premises should be according to DIN VDE 0100 Part 710 and IEC 603647-7-10.

NOTICE!

When using the machine for home hemodialysis, it needs to be run as stationary medical device. Only personnel authorized by the manufacturer is allowed to change the connectors from/to the machine.
The machine shall be moved to the extent specified by the length of the connecting lines and cables.

NOTICE!

Observe information about ambient conditions, see 15.3 Ambient Conditions (323).

4.6.1 Connecting the Machine

After transportation, the machine must be reconnected to wall connections. When the machine is connected at treatment site, it becomes a stationary medical electrical equipment according to IEC 60601-1 that is not intended to be moved from one site to another.

⚠ WARNING!

Risk of contamination of the dialysis machine.

The contamination can be caused by connecting the dialysis machine to wall connectors or supply lines that are disinfected insufficiently.

- The organization shall monitor the hygienic quality of all supply connection according to their hygienic plan.

4.6.2 Electrical Connection

The existing mains voltage must correspond with the voltage specified on the rating plate.

The use of extension cables or adapters with the mains cord or the mains socket is NOT permitted. Modifications of the mains cord are forbidden! If the mains cord has to be changed, only the original mains cord listed in the spare parts list must be used.

Electrical installations in the room where the dialysis machine will be operated must conform with relevant regulations, e.g. VDE 0100 Part 710 and/or IEC-stipulations (like DIN EN 60309-1/-2 and VDE 0620-1 for example).

Using devices of protection class I the quality of the protective conductor is important. It is recommended to use a mains socket with additional PE-contact pin according to CEE 7/7 for cables with safety plug (Schuko). Alternatively, it is recommended to connect a potential equalization to the dialysis machine. Regulations and deviations specific to the individual country must also be observed. For further information, ask technical service.

4.6.3 Protection against Water Damage

We recommend the use of water detectors to protect against any unnoticed water leaks.

4.6.4 Potentially Explosive Areas

The dialysis machine may not be operated in areas at risk of explosion.

4.7 Water Supply

4.7.1 Quality of Water and Dialysis Fluid

The user must ensure that the water quality is continuously monitored.The following requirements must be fulfilled:

- The incoming water must be free from Mg^{++} and Ca^{++}.
- pH value between 5 and 7

Water and dialysis fluid must comply with the country-specific standards, i.e.:

- ISO 13959
  Water for haemodialysis and related therapies
- DIN VDE 0753-4
  Anwendungsregeln für Hämodialysegeräte
- ANSI/AAMI RD5-03
  Hemodialysis systems
- ANSI/AAMI RD61
  Concentrates for hemodialysis
- ANSI/AAMI RD62
  Water treatment equipment for hemodialysis applications
- AAMI WQD
  Water quality for dialysis
- American National Standard for Hemodialysis Systems (RD-5)
- European pharmacopoeia

4.7.2 Disposal of Used Fluids

⚠ WARNING!

Risk of infection due to backflow of contaminated fluids from the drain into the dialysis machine!

- Ensure air clearance between hemodialysis equipment waste connector and the drain (8 cm).

⚠ CAUTION!

Pipe system may be damaged by corrosive fluids!

- Use adequate drainage piping materials.

Ensure sufficient drainage capacity!

4.8 Setting Date and Time

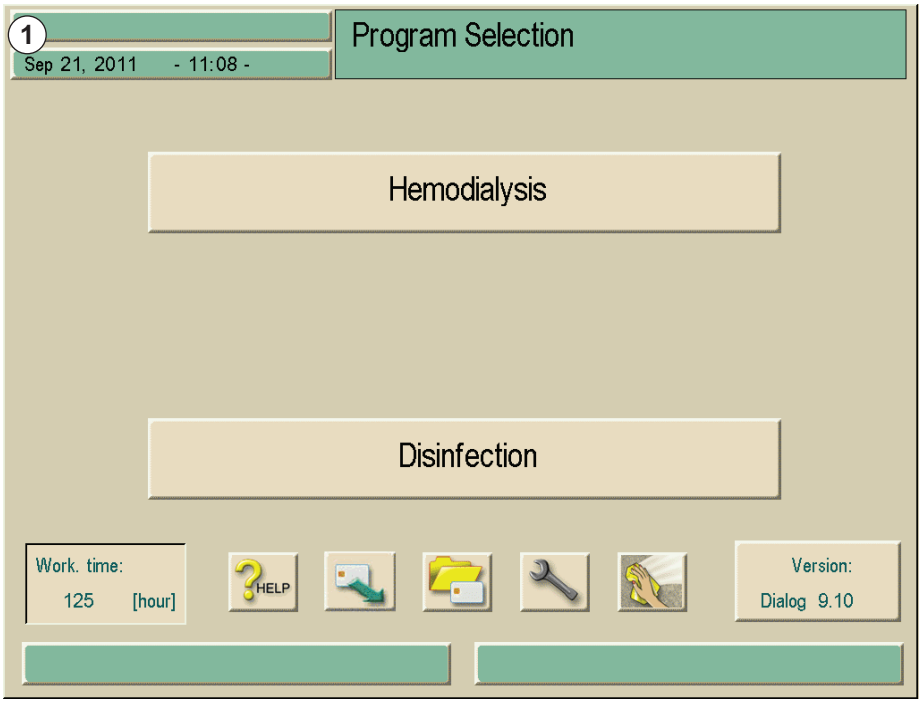


Fig. 4-4 Date and time

Setting Date

1. Touch field showing date and time **1**.
   - The field containing icons **2**, **3** and **4** appears.

There are two setting options:

1. To increase or decrease the date, change date with icons **2** and **3**.
2. To enter the date using the keypad, touch icon **4**.
   - The numeric keypad appears on the screen.
3. Enter date using keypad and confirm by selecting **OK**.

Setting Time

1. Touch field containing date and time **1**.

There are two setting options:

1. To increase or decrease time by minutes, change date with icons **2** and **3**
2. To enter the time using the keypad, touch icon **4**.
   - The numeric keypad appears on the screen.
3. Enter date using keypad and confirm by selecting **OK**.
4. Touch field containing date and time **1**.
   - The field containing **2**, **3** and **4** disappears.
   - The set date and time are displayed.

4.9 Switching On and Off

NOTICE!

- In case of any damage that may put into question the safe use of the machine, the dialysis machine may not be used. Inform the customer service in charge.
- Only switch on dialysis machine after it has reached room temperature.
- Observe requirements on installation site and water supply.

Switching On and Off

1. Press mains switch.
   - The dialysis machine switches from ON to OFF status or vice versa.

Accidental Pressing of the Mains Switch

In case of accidentally switching off the dialysis machine by actuating the mains switch **during a dialysis session**, proceed as follows:

1. Press mains switch again.
   - An alarm message is displayed on the screen: “System recovered”, for interruptions less than 15 minutes, and the therapy continues.
2. Confirm alarm by pressing ”Confirm alarm”.
   - In case of longer interruptions, the dialysis machine switches to the therapy selection window.

In case of accidentally switching off the dialysis machine by actuating the mains switch **during disinfection**, proceed as follows:

1. Press mains switch again.
   - The disinfection procress is continued.

In case of accidentally switching off the machine, a characteristic signal is activated three times.

Table of Contents

5 Preparing for Hemodialysis

⚠ WARNING!

Risk of strangling!

Tubings and other lines may cause strangulation.

- Be careful that tubings to the patient and lines from the patient are placed in a safe way.

⚠ WARNING!

Safety air detector (SAD) not active! Risk of air embolism!

- Do not connect the patient out of the “Therapy” phase, e. g. during “Preparation/Disinfection” phase!
- Out of the “Therapy” phase it is not allowed to use the blood pump for infusion (e. g. saline solution)!

Hemodialysis is the standard dialysis procedure for all system variants.The procedure is the same for all system variants.

⚠ WARNING!

Loss of blood or damage of blood by temperature, pressure or wrong composition of dialysis fluid!

- Ensure that the patient will only be connected in Therapy phase.

⚠ WARNING!

Risk of slipping and tumbling!

When handling dialysis components containing fluids (e.g. blood line system, dialyzer, canister, substitution port and waste port, etc.) fluids may flow on the floor.

- Ensure that floor is dry.
- If floor is wet, be careful not to slip out and dry floor.

NOTICE!

A connection of the patient in Preparing/Disinfection leads to an alarm by blood detection at the red detector. At the same time the blood pump will be stopped and SAKV will be closed.

5.1 Setting Up the Machine

Recommended Positions

The recommended positions of patient, user and machine are shown in the following figure:

1 Patient
2 Patient access
3 Blood lines
4 User
5 Machine
6 Rear connections

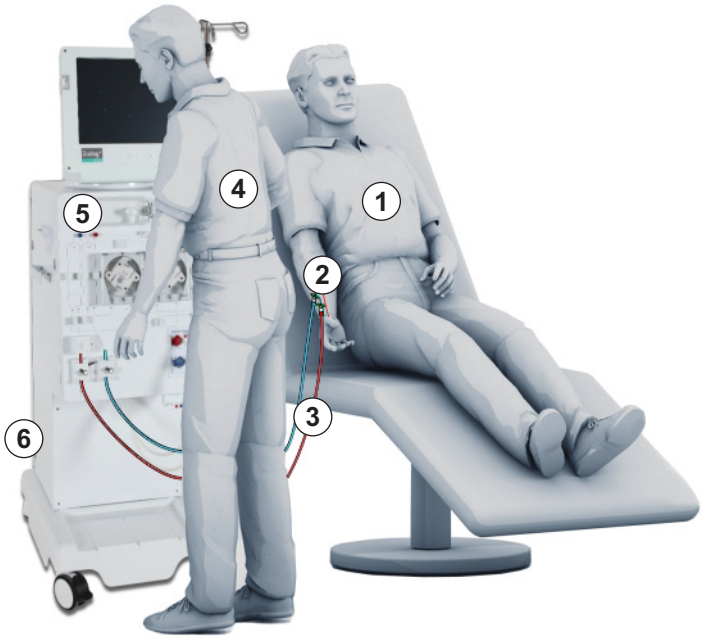


Fig. 5-1 Positions of patient, user and machine

During preparation and treatment, the user has to be able to get all acoustic and visual information and to react according to the instructions for use. Therefore, the user should stand in front of the machine, facing towards the monitor. The distance between user and monitor should be not more than 1 meter. This position allows an optimal view on the monitor and a comfortable handling of the keys and buttons.

A table for unpacking the consumables is recommended.

5.2 Calling up Hemodialysis

The physician in charge of the treatment is responsible for choosing the suitable therapy type, duration and frequency, based on medical and analytical findings and the general health and condition of the patient.

After switch-on, the following main screen is displayed on the dialysis machine:

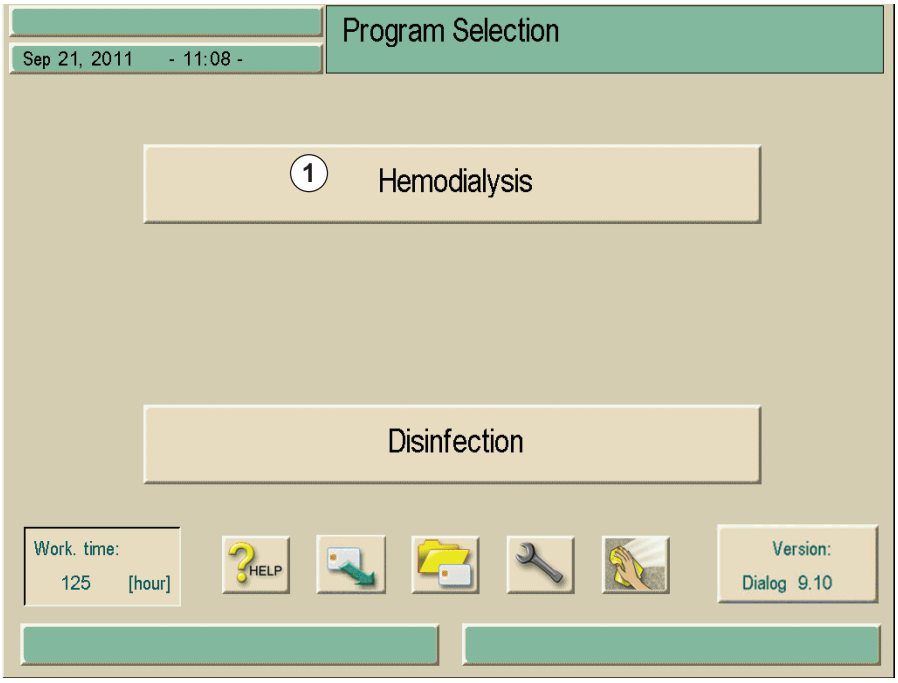


Fig. 5-2 "Hemodialysis" main screen

1. Touch field **1**.

   ↳ The first preparation screen for hemodialysis appears. The dialysis machine starts an automatic test sequence.

5.3 Automatic Test

At the automatic test stage, the dialysis machine automatically checks all control functions relevant to the safety of the machine.

While the dialysis machine is carrying out automatic tests you can begin entering the treatment parameters.

If the option *"Blood side pressure test with pressure compensation"* is activated in TSM, the excess pressure in the AV system will be removed via the dialyzer after the pressure test on the blood side.
Depending on the used type of dialyzer, this may take up to two minutes.

5.3.1 Operation During Automatic Test

1 Status field

2 Operating field

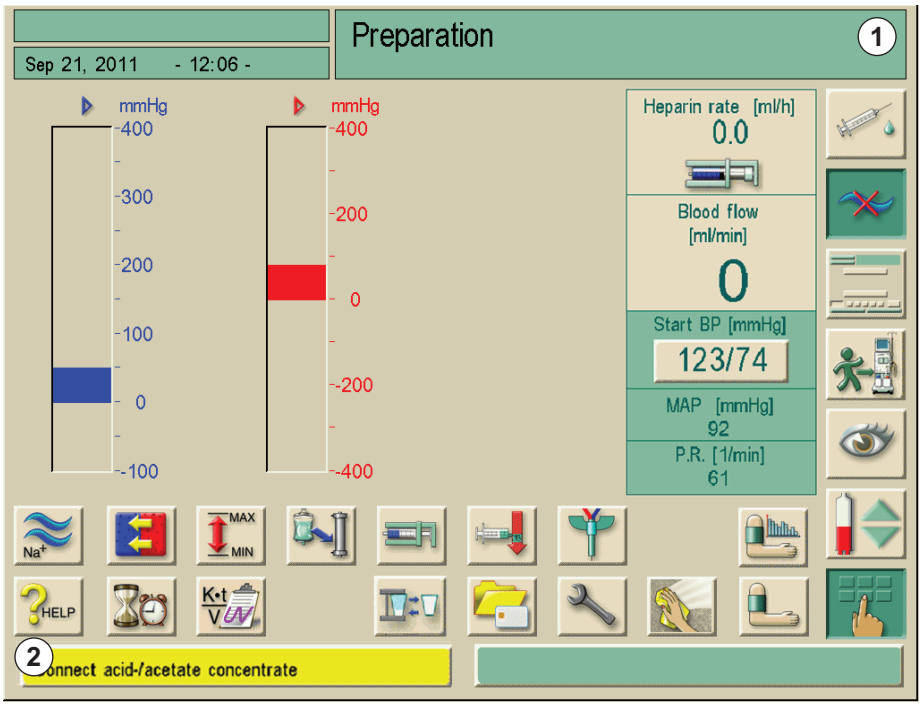


Fig. 5-3 First preparation screen “Hemodialysis”

While the dialysis machine goes through the automatic test sequence, messages on a yellow background appear in field **2** if the machine expects you to carry out actions such as connecting the concentrate. The test sequence is only continued once this action has been completed.

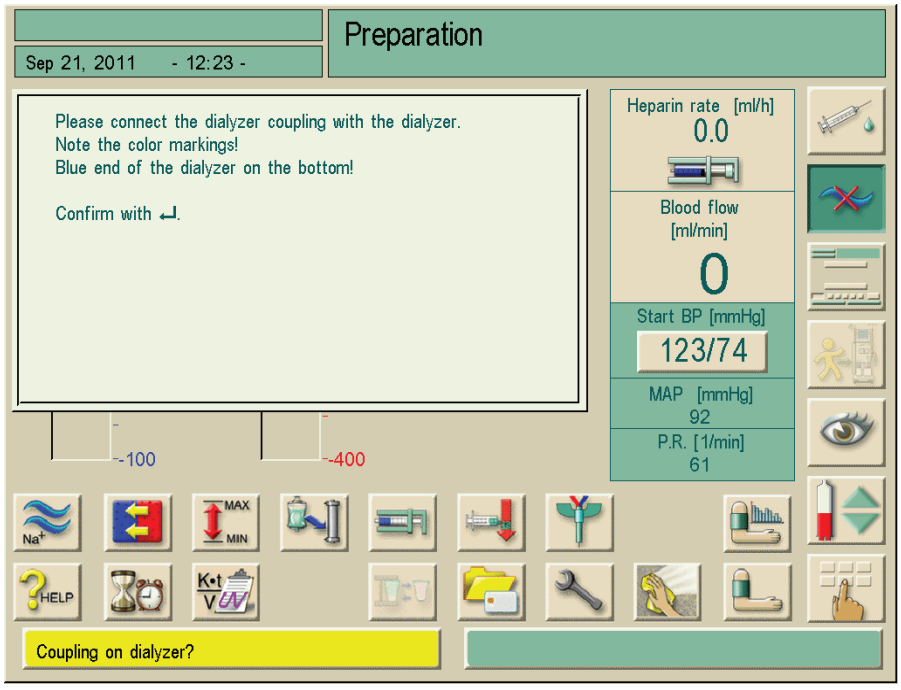
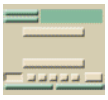


Fig. 5-4 Information window during automatic test

Information windows can be hidden, by a touch, for approx. 20 seconds while you use the screen for other actions, e.g. entering parameters. Upon completion of the entry, the information window will reappear. Taking over the data with the Enter button will only be possible after confirming the information window.



5.3.2 Terminating the Automatic Test Sequence

1. Touch icon.
   - ↳ The automatic test sequence is terminated.
   - ↳ The options “Return to therapy selection” and “Repeat blood-side tests” are displayed.
2. Touch the approriate field.

5.3.3 Completion of Automatic Test Sequence

This screen icon is enabled as soon as the dialysis machine has completed all automatic tests successfully. The patient can now be connected.

5.4 Reduction of Warning Sounds during Preparation

For the user there is a possibility to suppress some warning sounds during preparation, except only warning sounds which require interaction with the user. For example, fault removal or on demand for action. Optical alarms and the fault finding are not affected.

The function "Reduced warning sounds during preparation" can be used for the following warnings.

ID	Text
1927	Rinsing volume attained
1928	Filling volume is reached
1112	UF Rinse volume for dialyzer too high
1153	Repeat self test!
1033	Temperature too low
1034	Temperature too high
1038	Connect acid-/acetate concentrate
1040	Connect bicarbonate
1041	Connect blue concentrate coupling to rinse bridge
1045	Bicarbonate cartridge holder open

NOTICE!

Preparing the machine with reduced warning sounds could cause a delay of the following treatment. To schedule planned preparation time requires increased attention of the staff.

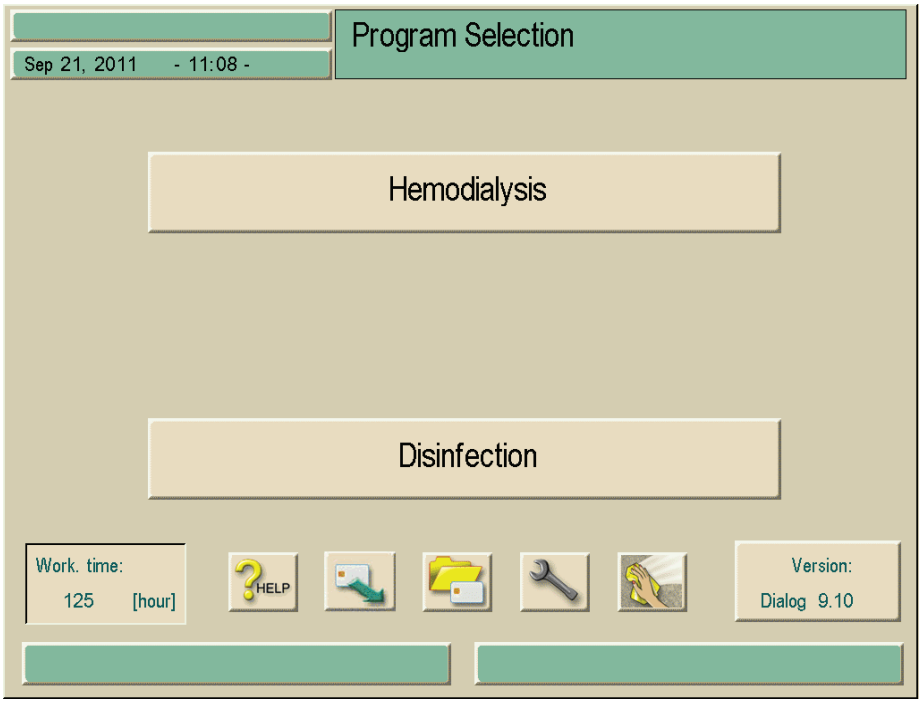


Fig. 5-5 "Hemodialysis" main screen

1. Touch icon at main screen.

   ↳ The following screen is displayed.

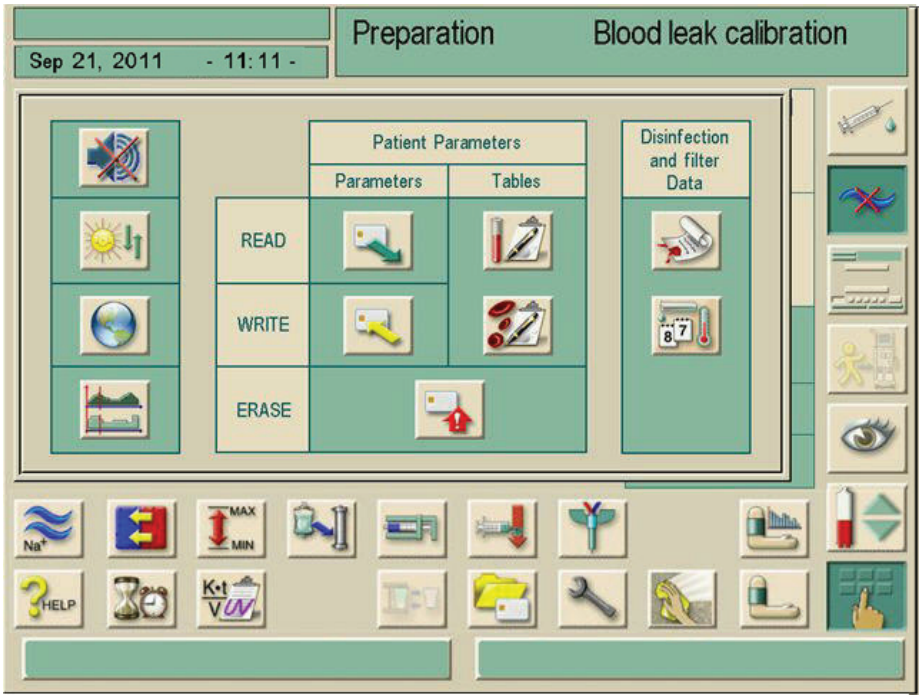
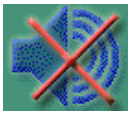


Fig. 5-6 Screen for suppression of acoustic signal

1. Touch icon.

If the function is not active (icon background not colored in green), it could be activated by touching the icon. The warning sounds listed in the table above are automatically suppressed. To indicate this, a crossed out speaker symbol appears at the date line of the screen.

Fig. 5-7 Date line with suppressed acoustic signal



Now the icon is shown as active (green colored background).

To touch the icon once more inactivates the function and turns on audible signals for the warning sounds listed above. The indicator at the date line disappears.

The function "Reduced warning sounds during preparation" could be preset in the TSM-mode by a technician.

The function "Reduced warning sounds during preparation" is only available during program selection and preparation and can be configured during selection of program and preparation. For all other phases of treatment this function is not available (icon appears gray). Changing into the next therapy the function automatically set resets to the TSM pre-adjustment.

5.5 Connecting Concentrate

After completion of the internal pressure test, the request **connect acetate/ acid concentrate** appears on a yellow background.

⚠ WARNING!

Risk to the patient due to incorrect composition of dialysis fluid!

- Ensure that the correct concentrates are provided for the intended therapy.
- Only use concentrates whose printed use-by date has not expired.
- Only use originally closed and intact concentrate containers.
- Observe storage information on concentrate containers.
- It is recommended to use concentrates produced by B. Braun Avitum AG.
- When concentrates are used that are not produced by B. Braun Avitum AG the correct mixing ratio and composition has to be checked on the concentrate label.

The physician in charge is responsible for determining the concentrates to be used.

For Bicarbonate Dialysis:

1. Insert red concentrate rod into the canister containing acidic bicarbonate concentrate, e.g. SW 325A.
2. Insert blue concentrate rod into the canister containing alkaline bicarbonate concentrate, e.g. bicarbonate-containing solution 8.4%.

   ↳ The dialysis machine continues the automatic test sequence.

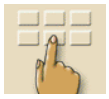
For Acetate Dialysis:

1. Place concentrate rod marked in red and white into container filled with acetate concentrate, e.g. SW 44.
2. Leave blue concentrate rod in blue concentrate rod holder.

   ↳ The dialysis machine continues the automatic test sequence.

5.6 Setting Rinsing Parameters

This option allows a rinsing of the dialyzer membrane with or without ultrafiltration.



1. Touch icons.
   - The rinsing parameters are displayed.

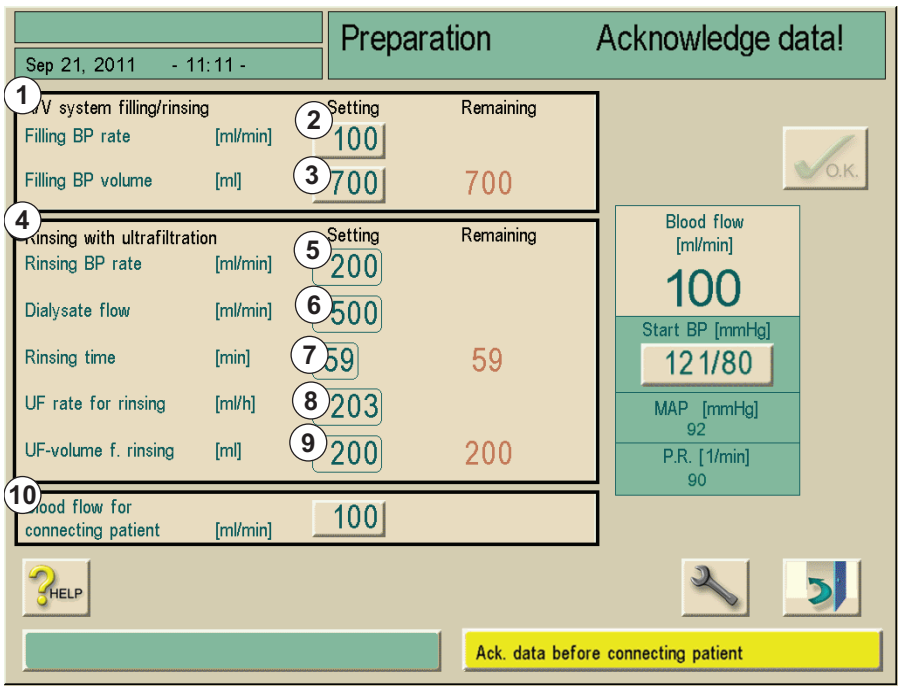


Fig. 5-8 "Rinsing parameters" screen

2. Set intended values for rinsing parameters according to the table below.

Item	Text	Range	Description
1	AV system filling/rinsing	-	Rinse blood side
2	Filling BP rate	50 - 600 ml/min	The rate with which the blood side is filled or rinsed
3	Filling BP volume	0 - 6000 ml	The blood pump stops after it has rinsed the blood side using the set volume
4	Rinsing with ultrafiltration	-	Rinsing of dialyzer membrane
5	Rinsing BP rate	50 - 300 ml/min	BP rate for rinsing program
6	Rinsing DF rate	300 - 800 ml/min	DF rate for rinsing program

Item	Text	Range	Description
7	Rinsing time	0 - 59 min	Duration of adjusted rinsing program
8	UF rate for rinsing	0 – 3000 ml/h when rinsing with a physiological saline solution	-
9	UF-volume for rinsing	0 – 2950 ml when rinsing with a physiological saline solution	-
10	Blood flow for connecting patient	50 - 600 ml/min	-

3. Confirm all settings by pressing the **O.K.** icon.
   - The initial preparation window reappears.
   - At the end of the chosen rinsing time the yellow signal lamp flashes.

⚠ CAUTION!

Risk of scalding or burning!
Machine disinfection is performed at high temperatures of up to 95 °C.

- Never connect/disconnect dialyzer couplings or substitution port during a running disinfection.

5.7 Inserting and Rinsing the Blood Line System

5.7.1 Inserting Blood Line System with Level Chambers

The blood pump tubing segment in the AV system must have the dimensions 8 x 12 mm or 7 x 10 mm (inner/outer dimension) for the standard machine. A roller rotor for pump segments 7 x 10 mm is available as an option.

⚠ WARNING!

Risk to patient due to incompatibility of blood line system and dialysis machine!

- Only use consumables produced by B. Braun Avitum AG.

⚠ WARNING!

Risk to patient due to hemolysis or blood loss when using a faulty blood line system!

- Check to ensure that the blood line system is not damaged.
- Check to ensure that no line is kinked.
- Make certain that all connections are tightly seated.

⚠ WARNING!

Risk to patient due to air in blood line system!

- Never connect a patient if the blood line system is filled with air.
- The patient shall only be connected if safety air detector (SAD) is active.

⚠ WARNING!

Risk to patient due to invisible ingress of micro air bubbles!

- Ensure that blood line is not kinked.
- Ensure that all connections are tightly seated.

⚠ WARNING!

Risk to patient due to infection as a result of contamination of the hydrophobic pressure sensor filter on the blood line system!

- Replace the machine-side hydrophobic pressure sensor filter if it was contaminated with blood and blood penetrates the machine.
- Instruct technical service to replace transducer protector.
- Only use the machine again when the filter has been changed.
- Execute disinfection after replacement.

⚠ WARNING!

Risk of contamination at the patient connectors on the blood line system per use of a rinsing bucket.

- Ensure hygienic handling of the blood lines.

1 Venous tube valve
2 Safety air detector with venous red detector
3 Venous chamber
4 Venous pressure sensor
5 Arterial pressure sensor
6 Arterial blood pump
7 Heparin pump
8 Pressure sensor for arterial entry pressure in front of the dialyzer (optional)
9 Arterial chamber
10 Dialyzer

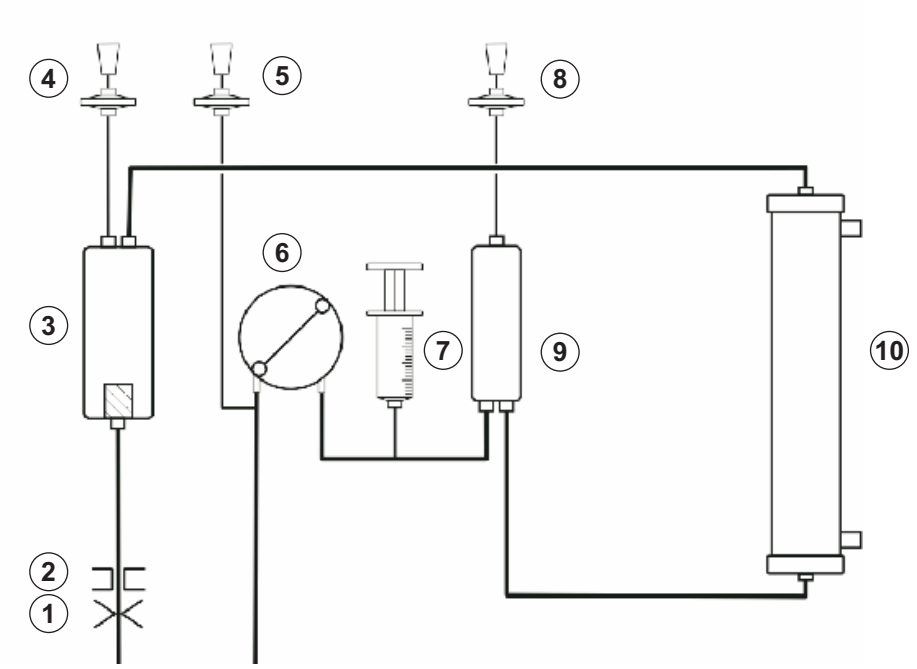


Fig. 5-9 Schematic view of extracorporeal circulation system used in hemodialysis

A dialyzer holder that can be attached to the infusion pole above the top fixing, is available as an accessory.

NOTICE!

To swivel or shift the dialysis holder, always undo the screw clamp on the infusion pole so that the latter will not be damaged.

1. Fix dialyzer in dialyzer holder.
2. Attach bag containing physiological saline solution (up to 2.5 kg) to infusion pole.
3. Connect arterial connection of blood line system to bag containing the physiological saline solution.
4. If present: Connect pressure measuring line for arterial pressure to the PA pressure sensor.
5. Open lid of (left) blood pump.
6. Insert tube end with patient supply into the matching opening of the rotor.
7. Turn rotor in direction of arrow.

⚠ WARNING!

Risk to the patient due to incorrect positioning of blood line!
When using ultrasound gel to ease inserting blood line, the safety air detector (SAD) is functioning improperly.

- Do not use ultrasound gel for positioning blood line in SAD.

⚠ CAUTION!

Risk to patient due to blood loss when using a faulty blood line system!

- Check to ensure that the blood line system and pump segments are not being damaged at the insertion.
- Check to ensure that the pump segment is placed in the backmost position of the pump housing.
- When inserting the pump segments do not rotate the rollers against a drag.
- If the blood line system has been damaged through the insertion, replace it by a new one.

8. Close lid of (left) blood pump.

The spacers on the inside of the lid do not serve to place the pump segment in the right position. They prevent the pump segment from moving out of the right position during operation, therefore, preventing only damage to the rollers.

9. Connect pressure sensor connector (if present) to PBE sensor connection.
10. Connect arterial and venous blood line system to dialyzer observing the color-coding. Do not yet remove the stops (if existent) on the lateral Hansen connectors.
11. Connect pressure measuring line for venous pressure to PV pressure sensor making certain the pressure measuring line is not kinked and the filter is screwed on securely.
12. Insert venous bubble catcher into fixing.
13. Open lid of air detector.
14. Insert tube into air detector and close lid.
15. Connect venous patient connection to the empty bag.
16. Insert blood line system into fixings.

⚠ WARNING!

Risk to patient due to blood loss by venous needle disconnection.

- Check patient access regularly.
- Check that pressure control system is active.

⚠ CAUTION!

Risk of damage to the blood line system due to prolonged clamping of the venous tube by the tube clamp!

- Only place the venous blood line into the tube clamp (SAK) on therapy day.

If a blood line system without PBE sensor is used, the message "No pressure measuring connection on PBE" is displayed during the pressure test.
The message automatically disappears after 60 seconds.

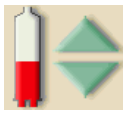
5.7.2 Rinsing and Testing the Blood Line System

1. Open the clamp in the line to the physiological saline bag.
2. Start blood pump by pressing the **+** button on the monitor.
   The blood line system will fill with physiological saline solution. The blood side of the dialysis circuit is rinsed and automatically tested for any leaks.

5.7.3 Level Regulation (if present)

The level regulation system allows the user to set saline levels in the blood line chambers for preparation by screen touch.

- During preparation the levels can only be set while the blood pump is running.
- The user is obligated to check for correct setting of the levels in the chambers.



1. Touch icon.
   ↳ The level regulation window opens.

1 PV - Venous chamber
2 PA - Arterial chamber
3 PBE - Arterial blood entry chamber

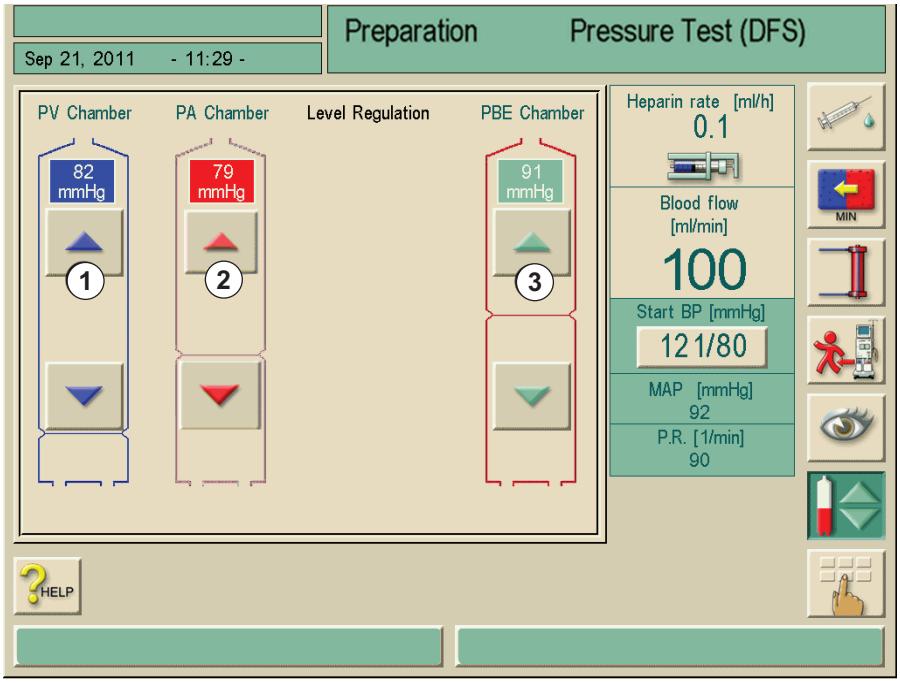


Fig. 5-10 Level regulation screen

The setting of the following chambers is possible:

- Venous chamber (PV) (1): the button is always active.
- Arterial chamber (PA) (2): the button is active from the beginning of preparation, but will be automatically deactivated if SN-CO is not selected or if the PBS is not connected after starting the therapy (if selected in TSM).
- Arterial blood entry chamber (PBE) (3): the button is always active (if selected in TSM).

5

The adjustment of the PBE chamber is only possible if an AV system with PBE line is used and the line is connected to the machine.

Level Increasing

1. Touch arrow up for respective chamber to increase level slightly
2. Observe level
3. Touch arrow up repeatedly for the correct setting, if necessary

Level Decreasing

1. Touch arrow down for respective chamber to decrease level slightly
2. Observe level
3. Touch arrow repeatedly again for the correct setting, if necessary

Deactivating Level Regulation

1. To leave the level regulation function, touch icon again

5.8 Preparing Heparin Pump

The heparin pump is suitable for blood line systems with heparinization downstream of the blood pump in the positive pressure region.

5.8.1 Inserting Heparin Syringe

1 Syringe bracket
2 Syringe gripping plate
3 Clip
4 Unlocking lever
5 Syringe stop

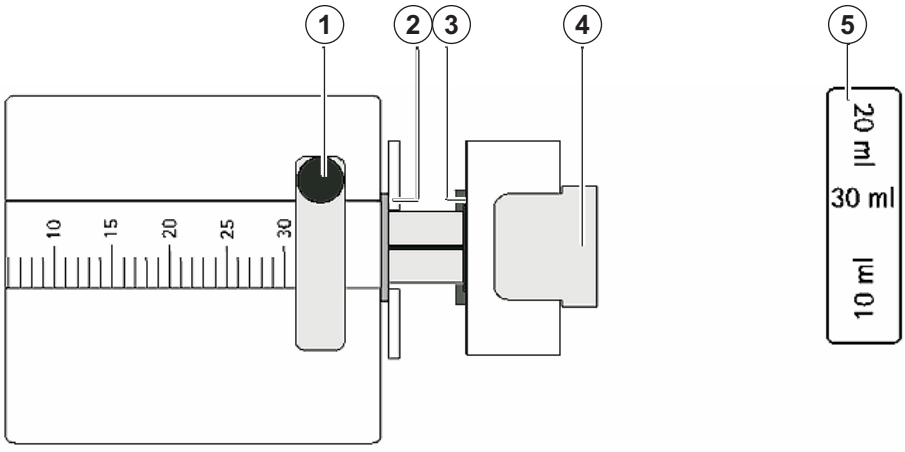


Fig. 5-11 Heparin syringe

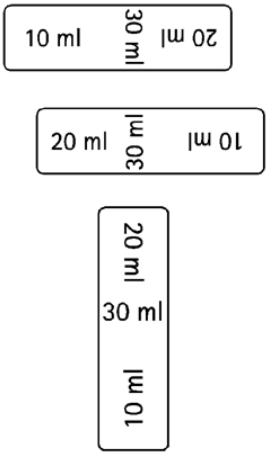


Fig. 5-12 Position of the syringe stop depending on syringe size

1. Set syringe stop **5** in such a way that the syringe size can be read.
2. Release unlocking lever **4** and pull out drive mechanism.
3. Lift and turn syringe bracket **1**.
4. Insert syringe in such a way that grip and pressure plate engage in the guide.
   - If the syringe was inserted correctly, the unlocking mechanism will jump back automatically. Do not close the unlocking mechanism manually.
5. Close syringe bracket.

⚠ WARNING!

Risk of coagulation!

- Ensure that heparin syringe is connected to heparin supply line.
- Ensure that clamp on heparin supply line is open.
- Ensure that heparin syringe and heparinization match in order to guarantee continuous heparinization due to pressure pulsation in the extracorporeal circuit: Avoid very low delivery rates with highly concentrated heparin in large syringes.
- Heparin syringe and heparin line should be completely deaerated in order to start heparinization directly from the beginning of therapy.

⚠ WARNING!

Risk to patient due to invisible ingress of micro air bubbles!

- Heparin syringe and heparin line should be completely deaerated in order to start heparinization directly from the beginning of therapy.

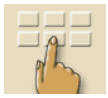
5.8.2 Venting Heparin Line

1. Before inserting the syringe, manually vent heparin line

or

1. Vent heparin line prior to starting the dialysis by providing a heparin bolus.

5.9 Setting Treatment Parameters



1. Touch icon in preparation window.
   ↳ A line of additional icons **1** is displayed.

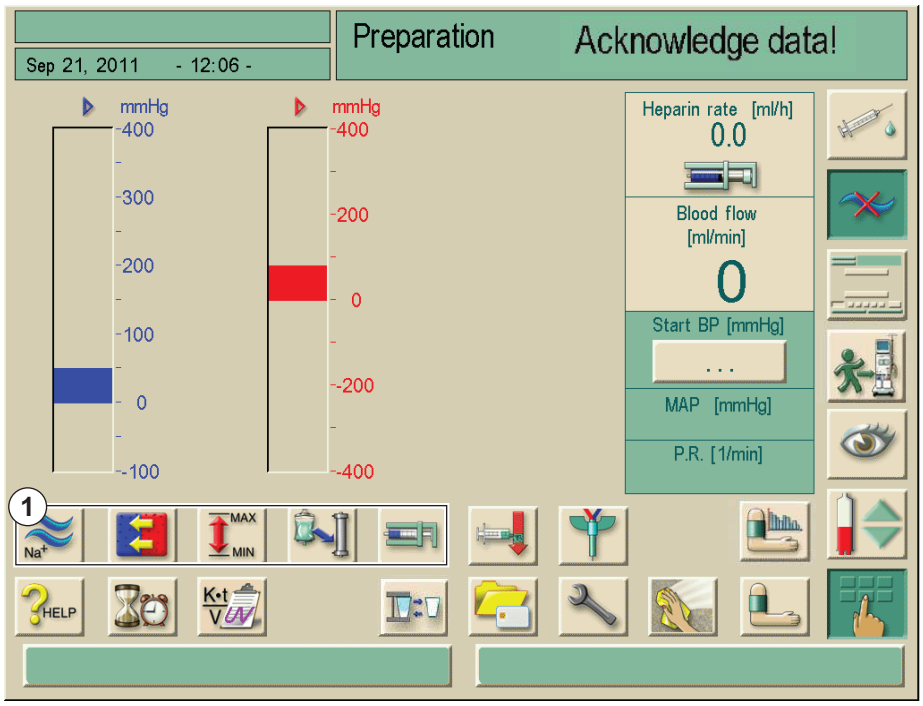
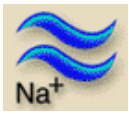
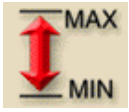
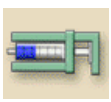
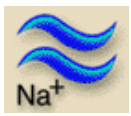


Fig. 5-13 Preparation window "Parameters"

With these icons, the following parameter groups can be called up:

Icon	Parameter group	Reference
	Dialysate parameters	5.9.1 Setting Dialysis Fluid Parameters (84)
	Ultrafiltration parameters	5.9.3 Setting Ultrafiltration Parameters (87)
	Pressure limit settings	5.9.4 Setting Pressure Limits (89)
	Heparinization data	5.9.5 Setting Heparin Parameters (92)

5.9.1 Setting Dialysis Fluid Parameters



1. Touch icon in preparation window.
   ↳ The dialysate parameters are displayed.

Fig. 5-14 "Dialysate parameters" screen

Set dialysate parameters according to the following table:

Item	Text	Range	Description
1	Conductivity	12.5 – 16.0 mS/cm in steps of 0.1 mS/cm (approx. 125 – 160 mmol/l)	-
2	Bicarbonate	-	Dialysis with an acidic bicarbonate hemodialysis concentrate and an alkaline bicarbonate hemodialysis concentrate formulation
3	Acetate	-	Dialysis with acetate concentrate
4	Bicarbonate Conductivity	2 – 4 mS/cm in steps of 0.1 mS/cm (approx. 20 - 40 mmol/l)	-
5	Dialysis fluid Temperature	33 - 40 °C in steps of 0.5 °C	-

Item	Text	Range	Description
6	Dialysate Flow	300 – 800 ml/min continuously adjustable	-
7	Profiles	-	Alternatively, profiles can be selected for the respective parameter, see section 11.4 Bicarbonate Cartridge (198).

The actual temperature at the dialyzer may differ marginally from the before adjusted temperature.

⚠ CAUTION!

Damage to the machine due to calcium depositions during bicarbonate dialysis!

- Decalcify the machine after each bicarbonate dialysis.

- The physician in charge is responsible for determining the concentrates to be used.
- The bicarbonate and acetate mode can be preset in the service program by technical service.
- Technical service can use the service program to set the limit value for mixing ratio monitoring in such a way that acetate dialysis cannot be performed.
- If the setting mmol has been selected in the service program, up to 10 acetate and bicarbonate concentrates can be preselected. An additional field with the name of the selected concentrate is displayed. Upon touching this field, a list of all available concentrates is displayed.
- If bicarbonate cartridges are used, see section 12.4 Configuring Profiles (228).

5.9.2 Monitoring Dialysis Fluid

It is possible to check the correct composition of the dialysate.

1. Once the conductivity of the dialysate has stabilized (after approx. 5 minutes), slowly take a sample from the sample port at the dialysis fluid DF tubing, using a small syringe, e.g. a 2 ml syringe.
2. Analyze the dialysate by, e.g. the following methods:

- pH measurement
- blood gas analysis
- chemical determination of bicarbonate concentration (titration)

Recommended Therapeutic Ranges

pH	7.2 – 7.5
pCO_2	40 – 60 mmHg
HCO_3^-	25 – 38 mmol/l

⚠ CAUTION!

Damage to the machine due to calcium depositions at pH value > 7.5 during bicarbonate dialysis!

- Observe the measured pH value.

pH values may be less accurate once the Dialog+ machine has initiated the stand-by mode as there is no dialysate flow to the dialyzer.

5.9.3 Setting Ultrafiltration Parameters

1. Touch icon in preparation window.

   ↳ The ultrafiltration parameters will be displayed.

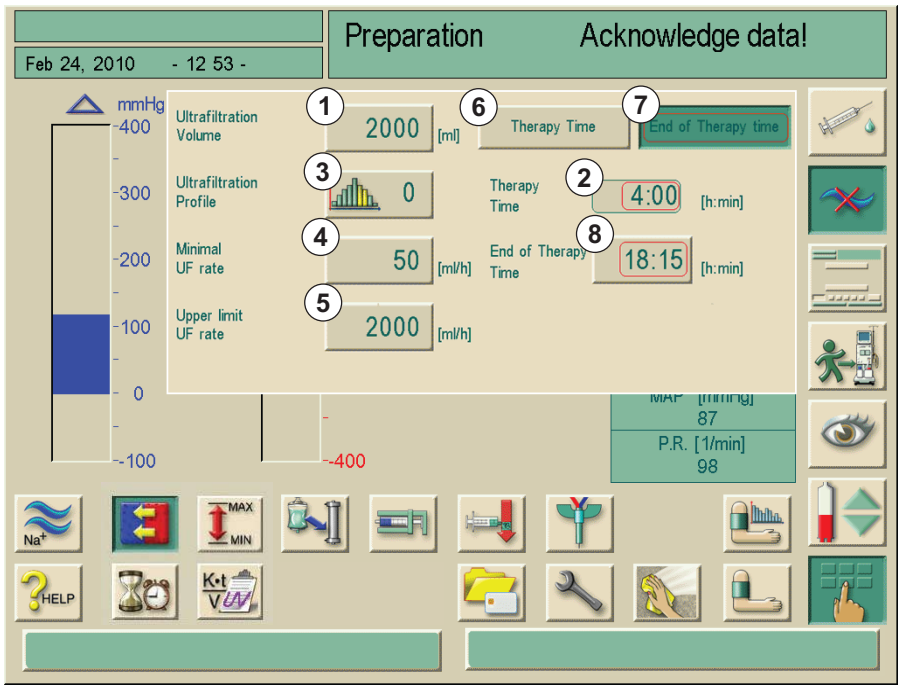


Fig. 5-15 "Ultrafiltration parameters" screen

1. Set ultrafiltration parameters according to the table below:

Item	Text	Range	Description
1	Ultrafiltration Volume	100 - 20000 ml	-
2	Therapy Time	10 min - 10 h	Therapy time

Item	Text	Range	Description
3	Ultrafiltration Profile	-	For selecting an ultrafiltration profile or choosing sequential therapy, see section 12.5 UF Profiles (231)
4	Minimal UF rate	0 - 500 ml/h	Min. ultrafiltration rate
5	Up. limit UF rate	0 - 4000 ml/h (must be set in TSM)	Max. ultrafiltration rate
6	Button to set therapy time	-	The therapy time can be set. The end of therapy time is calculated.
7	Button to set end of therapy time	-	The absolute time to end therapy can be set. The effective therapy time is calculated.
8	End of therapy time	-	The absolute end of therapy time is indicated.

Set the therapy time

1. Touch the buttons 6 and 2 in Fig. 5-15.
   - Set value by +/- or use the keypad to enter the value.

Set the absolute end of therapy time

1. Touch the buttons 7 and 8 in Fig. 5-15.

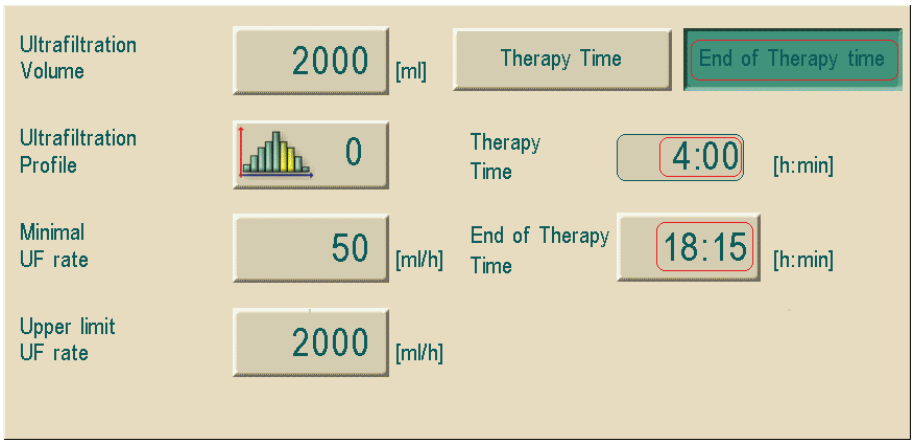


Fig. 5-16 Ultrafiltration parameters

A keypad will open. The end of therapy time can be set in a time range considering the ultrafiltration volume, the minimal UF rate and the upper limit UF rate.

Fig. 5-17 Set End of Therapy time

The effective therapy time is calculated as the difference between the set end of therapy time and the current time.

NOTICE!

The set end of therapy time will not be extended by Bypass phases.

NOTICE!

It is always possible to change back to set the therapy time.

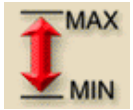
NOTICE!

To avoid alarms, adjust the upper limit for the ultrafiltration rate to value above the calculated actual ultrafiltration rate.

NOTICE!

Selecting low UF-rates with long UF-time can cause deviation between debit value and actual value. Corresponding warnings will appear on the screen. The deviation will be indicated and has to be confirmed by the user pressing the Enter button.

5.9.4 Setting Pressure Limits



1. Touch icon in preparation window.
   ↳ The pressure limit values will be displayed.

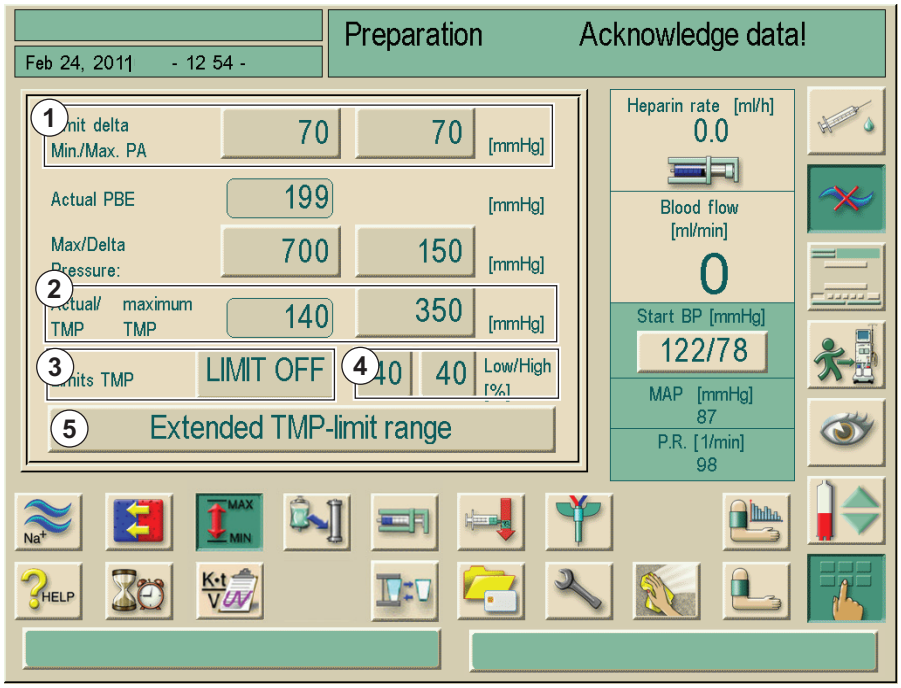


Fig. 5-18 "Pressure limits" screen

Set pressure limits according to the following table:

Item	Text	Range	Description
1	Limit delta Min./Max. PA	10 - 100 mmHg	Limits window for arterial entry pressure PA. Distance to min. and max. PA
2	Actual TMP/ maximum TMP	300 - 700 mmHg	Max. TMP: see information provided by dialyzer manufacturer
3	Limits TMP	ON/OFF	Monitoring the TMP at the dialyzer
4	Low/High	2 – 99 %	Limits window for TMP in % of actual value
5	Extended TMP-limit range	ON/OFF	The TMP limits enlarge to -100 mmHg if activated in TSM

Limits Window for Arterial Entry Pressure PA

The arterial entry pressure PA (pressure between patient and blood pump) is monitored by an automatically set limits window. This window is only active in the therapy phase and during final circulation.

A max. lower arterial limit is set in the service program (max. -400 mmHg). The automatically set lower limit cannot fall below this value.

The size of the arterial limits window is defined through the respective distance (delta) between the actual value and the lower and upper limits.

The total of the two distances to the actual value gives the width of the arterial limits window, i.e. in the above example 70 + 70 = 140 (mmHg).

⚠ WARNING!

Risk of injuring patients access by perforation per negative pressure!

- Ensure that max. PA is adapted to the actual shunt flow respectively follows the physicians order.

Limits Window for TMP Control

The TMP of the dialyzer is controlled by an automatically set limits window.

The size of the limits window is entered as a percentage of the actual value (Fig. 5-18). The limits window is, therefore, independent of the dialyzer in use.

When the limits window is switched off, the control of the dialyzer-dependant max. TMP is still active.

Activating the Bypass icon or changing the dialysate flow causes the limits window to be re-centred.

The lower TMP limit range can be enlarged for the use of highflux dialyzers (Fig. 5-18). This function has to be enabled in TSM.

Extended TMP-limit range

1. Touch icon.

   ↳ The lower TMP limit will be set to –100 mmHg. Through this the backfiltration warning when reaching -10 mmHg is not applicable.

⚠ WARNING!

Risk to the patient due to backfiltration.
When changing the TMP limit range, back filtration may occur

- Usage of dialysis fluid filter Diacap Ultra is recommended.
- In case of technical defect, contact technical service.

⚠ WARNING!

Risk of patient blood contamination by germs in dialysis fluid!

- Ensure that the dialysis fluid is clean.

⚠ WARNING!

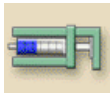
Risk of blood volume increase due to leakage in the hydraulic system (water cycle).
Risk of backfiltration.

- Check patient weight.
- In case of technical defect, contact technical service.

While using the function “Extended TMP-limit range” you will have to act on the assumption of back filtration.

For this reason we recommend the use of dialysis fluid filter (Diacap Ultra).

5.9.5 Setting Heparin Parameters



1. Touch icon in preparation window.

   ↳ The heparin parameters are displayed.

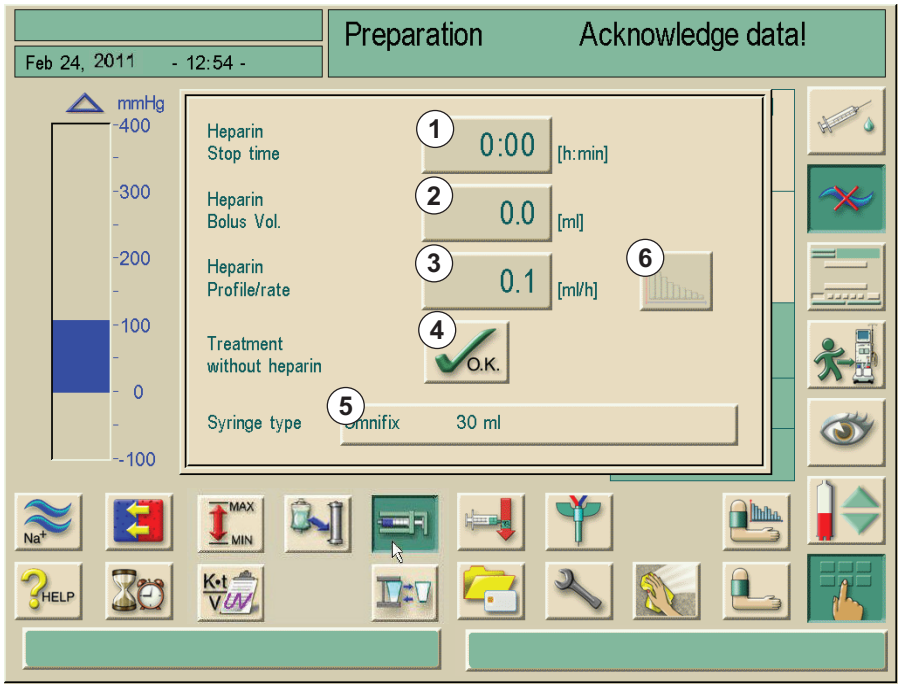


Fig. 5-19 "Heparin parameters" screen

2. Set heparin parameters according to the table below.

Item	Text	Range	Description
1	Heparin Stop time	0:00 – 10:00 h:min	The heparin pump is switched off by the set time prior to the end of the therapy
2	Heparin Bolus Vol.	0.1 - 10.0 ml	Bolus volume for a bolus administration during dialysis
3	Heparin Profile/ rate	0.1 – 10.0 ml/h	Continuous heparin rate over the entire duration of heparin administration
4	Treatment without heparin	not activated/ activated	Switching on/off the heparin monitoring function
5	Syringe type	10/20/30 ml	A list of permissible syringe types is stored in the service program
6	Profile	-	Setting a profile for heparin administration

⚠ WARNING!

Risk to the patient with high risk of internal bleeding (e. g. at recent surgery, gastro-intestinal abscess or similar diseases)!

- Check for indication of internal bleeding during therapy.
- Check the process of heparin application during therapy.

⚠ WARNING!

Blood clotting in the extracorporeal system!

- Ensure that the heparin pump is switched on after entering a delivery rate.
- Ensure that the heparin line clamp is open during therapy.

If in TSM presetting the heparin pump is set “off”, you’ll have to switch it on manually!

⚠ WARNING!

Risk to the patient due to wrong anticoagulant dosage caused by a mismatch between the heparin pump selected on the screen and the syringe actually inserted in the heparin pump!

- Always make certain the syringe selected on screen is the same as the type of syringe actually inserted.
- Only use syringes listed in the syringe table.
- If necessary, contact technical service.

5.10 Rinsing Dialyzer

⚠ WARNING!

Risk to patient due to invisible ingress of micro air bubbles!

- Check the upper cap of dialyzer for micro air bubbles after filling and rinsing the dialyzer.
- Repeat rinsing the dialyzer if micro air bubbles still exist.

After rinsing the blood side, an information window appears with the request to connect the dialyzer.

1. Take dialyzer tubes from rinsing bridge and connect to dialyzer. Observe color-coding.
2. Connect the dialyzer inlet coupling (blue) to the Luer Lock connection of the venous blood line.
3. Connect the dialyzer outlet coupling (red) to the Luer Lock connection of the arterial line.
4. Turn dialyzer so that the blue connection is facing downward.
5. Confirm correct connection of dialyzer by pressing the Enter key on the monitor.

6. Adjust level as follows:
   - Fill chamber in front of the dialyzer entry (PBE) nearly half full,
   - Fill venous drip chamber up to approx. 1 cm from the upper edge.

Once the set rinsing volume has passed the system the blood pump stops running. An information window appears.

1. Ensure that the blood line system and the dialyzer are filled and rinsed with physiological saline solution.
2. Ensure that all levels in the chambers have been set correctly.
3. Confirm correct settings by pressing Enter key on the monitor.
   - The dialysis machine is testing the blood line system.

This screen icon will be enabled as soon as the dialysis machine has successfully completed all automatic and blood side tests. The patient can now be connected.

5.11 Standby Mode

The dialysis machine features a standby mode for the dialysate side. This mode allows switching off the dialysate side in order to save on permeate and concentrate when the machine is being prepared and will not be used immediately.

⚠ WARNING!

Risk of germination in the dialysate during standby mode!
Infection risk to the patient!

- Do not use standby mode with dialyzers packed with germicide.
- Do not run the dialysis machine in standby mode over prolonged periods.
- The recommended duration of standby mode depends on the water quality and the environmental conditions (according to the hygiene plan of the dialysis center).

5.11.1 Activating the Standby Mode

Depending on the service program setting performed by technical service, there are the following ways in which the standby mode can be activated for an adjustable period:

- Automatic start after automatic test sequence
- Automatic start after rinsing program
- Manual start after automatic test sequence
- Manual start after rinsing program

Manual Activation of the Standby Mode

1. Touch icon.
   - The dialysis machine is in standby mode.
   - The pumps stop and no dialysate is produced in the machine.

5.11.2 Switching Off the Standby Mode

The max. duration of the standby mode is preset in the service program by technical service.
Depending on the setting entered by the technical service in the service program, there are the following options for switching off the standby mode:

- Manual switch-off
- Automatic switch-off after expired time
- Automatic switch-off during connection of patient

Manual Switch-Off the Standby Mode

1. Touch icon again.
   - ↳ The pumps are started and dialysate is circulated without passing through the dialyzer.
   - ↳ The machine is in bypass mode.
   - ↳ The machine will remain in bypass until the therapy is initiated.

5.12 Power Failure in Preparation

During a power failure in Preparation phase the status of this phase will be saved. If the power supply will be restored, only the interrupted work step must be repeated by the machine if necessary.

Already entered treatment parameters will remain unchanged.

The saved data will be stored up to 120 minutes. After that time the machine has to be prepared new.

This functionality allows a removing of a prepared machine to another treatment place.

5.13 Changing the Bicarbonate Cartridge During Preparation

It is possible to exchange a bic cartridge during preparation (see also chapter 12.4 Configuring Profiles (228)).

Table of Contents

6 Initiating Hemodialysis

6.1 Checking Patient Data

After completion of the preparation work, the icon for connecting the patient is enabled. The dialysis machine is in bypass mode. The signal lamps on the monitor change to yellow.

1. Touch icon in preparation screen.

   ↳ Two brief acoustic signals are sounded. The Enter key on the monitor is lit up. An overview of the entered patient data appears on the screen.

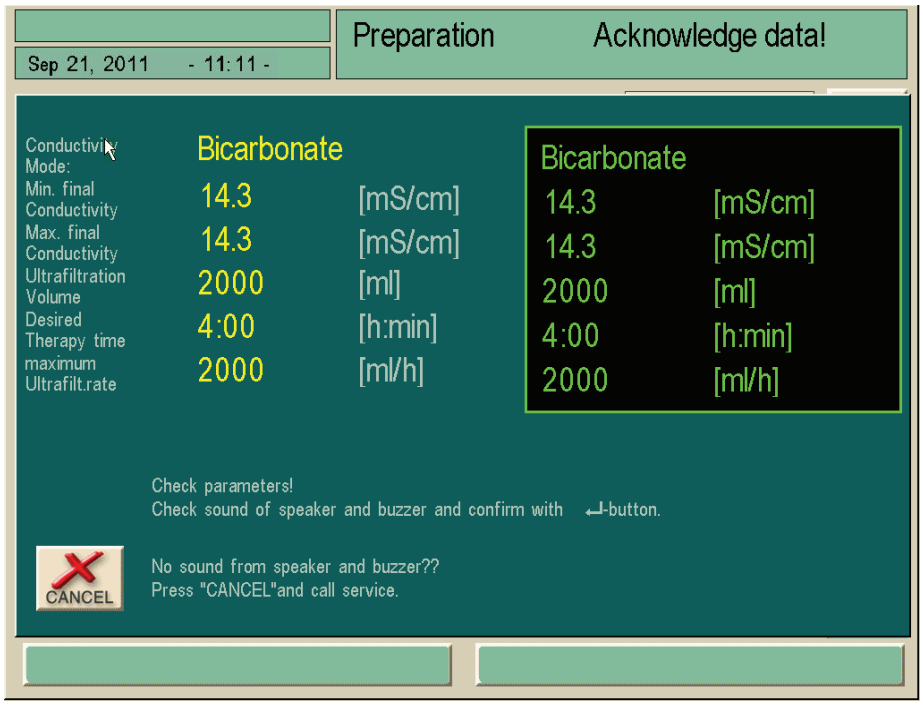


Fig. 6-1 "Patient data" screen

⚠ WARNING!

Risk to the patient due to inadequate monitoring of treatment parameters! If only one or no acoustic signal is sounded or Enter key flashes on the monitor, or if the displayed treatment parameters show discrepancies, the dialysis machine is defective and must not be used!

- Leave screen by pressing CANCEL.
- Contact technical service.

---

1. Check that patient data corresponds with what has been prescribed by the doctor and confirm by pressing the Enter key on the monitor.

   ↳ The treatment screen appears.

6.2 Connecting Patient and Starting Therapy

WARNING!

Risk to patients due to invisible ingress of micro air bubbles!
A high blood flow rate can increase the formation of micro air bubbles.

- Set blood flow rate according to therapy needs.

WARNING!

Risk to patients with central venous catheters due to excessive patient leak current!

- Connect electrical ground on the dialysis machine, see section 2.4.4 Potential Equalization (18).

NOTICE!

Before starting therapy after a disinfection the clamps SAKA and SAKV as well as the metallic parts of the substitution inlet/outlet ports may not exceed a temperature of 41°C.

1 Remaining therapy time, graphical and in numbers
2 Current UF rate
3 Current UF volume
4 Set UF volume
5 Heparin rate
6 Blood flow
7 Heparin bolus
8 Treatment with min. UF rate
9 Bypass
10 Information bar
11 Display of trans-membrane pressure (TMP), with limits
12 Display of arterial pressure, with limits
13 Display of venous pressure, with limits

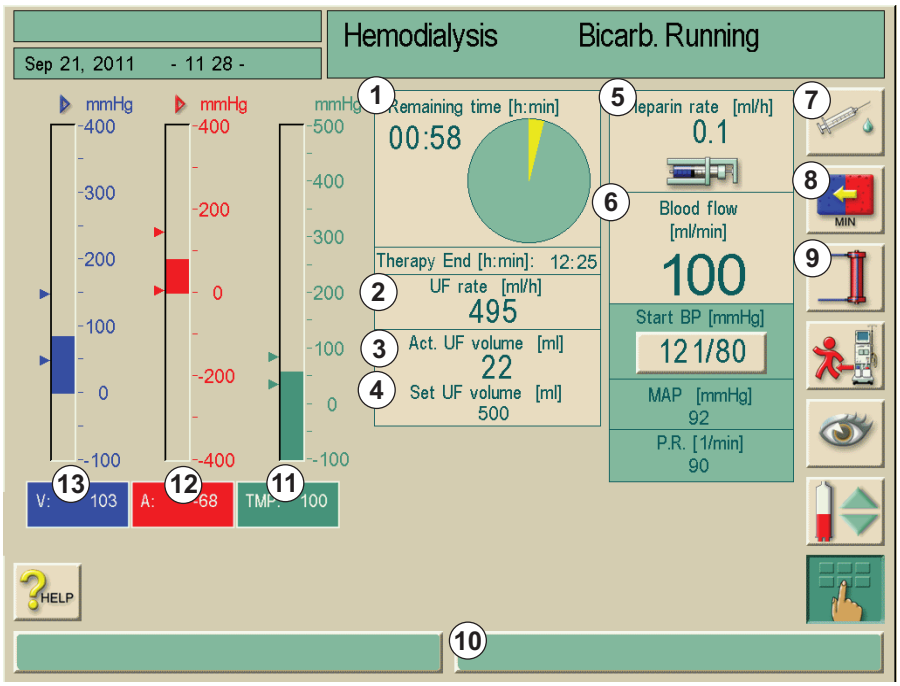
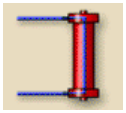


Fig. 6-2 "Hemodialysis" treatment screen

During the connection phase, the set limit values are not monitored. Therefore, particular care is required during the connection phase.

1. Connect arterial blood line to patient.
2. Start blood pump by pressing **START/STOP** button on the monitor.

3. Set blood flow.
4. Fill blood line system with blood.
   ↳ The blood pump stops automatically if blood is detected on the red sensor in the safety air detector (SAD).
5. Connect venous blood line to patient.
6. Start blood pump.
7. Touch icon.



   ↳ The dialysis machine switches to main connection and the therapy is running.

   ↳ The signal lamps on the monitor switch to green.

⚠ WARNING!

Risk to patient due to hemolysis if the blood flow setting is too high for the selected needle (PA pressure too low!)!

- Adapt blood flow taking into consideration the arterial pressure.

⚠ WARNING!

Risk to patient due to reduced dialysis efficacy since the actual blood flow is lower than the displayed flow rate if arterial pressures are highly negative!

- Correct the blood flow setting.
- Extend treatment time.

⚠ WARNING!

Risk to patient due to reduced dialysis efficacy since the blood flow is too low (for example wrong cross-section of the cannula)!

- Ensure that the blood flow is high enough.
- Ensure that the cross-section of the cannula is big enough.

⚠ WARNING!

Risk to patient due to air in blood line system!

- Never connect a patient if the blood line system is filled with air.
- The patient shall only be connected if safety air detector (SAD) is active.

⚠ WARNING!

Risk to patients due to invisible ingress of micro air bubbles!

- Make sure that the blood line is not kinked.
- Make sure that all connections are tightly seated.

WARNING!

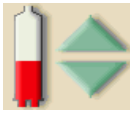
Risk to patient due to reduced dialysis efficacy!
At arterial pressures below -150 mmHg, the actual blood flow is lower than the displayed flow rate due to increased delivery rate deviations of the blood pump.

- Open clamp on arterial line.
- Correct blood flow setting.
- Extend therapy time.

6.2.1 Level Regulation (if present)

The level regulation system allows the user to set blood levels in the blood line chambers in treatment by screen touch.

- During treatment, the blood levels can only be set while the blood pump is running in double-needle mode. The active chambers depend on the used blood line system.
- The user has to check the correct setting of the levels in the chambers.



1. Touch icon.
   ↳ The level window opens.

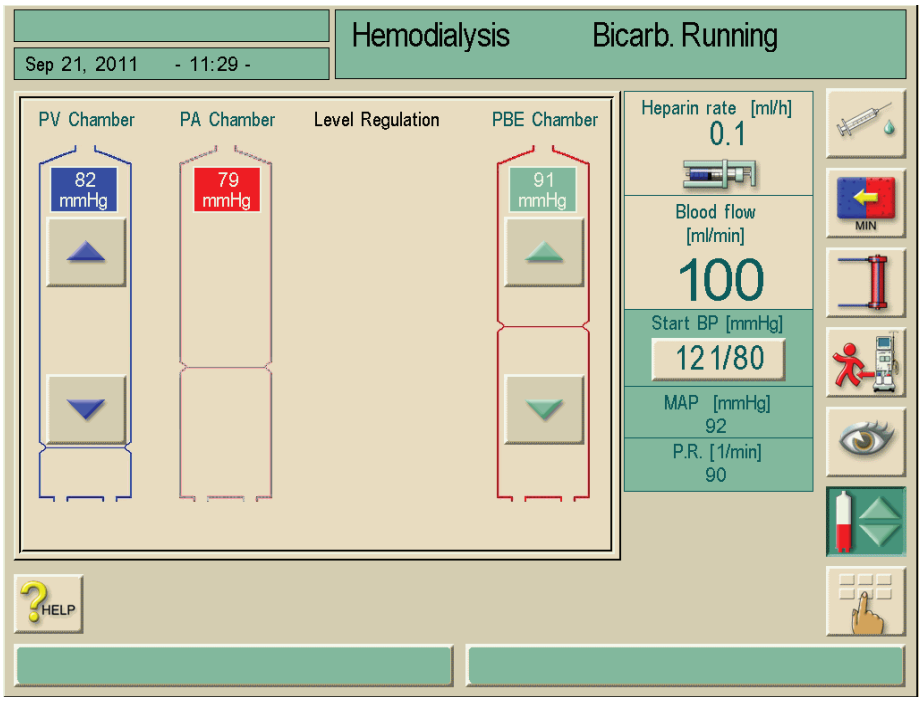


Fig. 6-3 Level regulation screen (if present)

Level Increasing

1. Touch arrow up for respective chamber to increase level slightly.
2. Observe level.
3. Touch arrow up again for the correct setting if necessary.

Level Decreasing

1. Touch arrow down for respective chamber to decrease level slightly.
2. Observe level.
3. Touch arrow down again for the correct setting if necessary.

Deactivating Level Regulation

1. To leave the level regulation function, touch icon again.

⚠ WARNING!

Risk to patients due to invisible ingress of micro air bubbles!

- Fill venous drip chamber to the highest possible position up to approx. 1 cm from the upper edge.

In case the blood pump is stopped, the level regulation system is not active. A message is displayed that a previous start of the blood pump is required.

In case of blood side alarms, level regulation is not possible. Alarms have to be cleared first.

⚠ WARNING!

Risk to patient due to infection as a result of contamination of the hydrophobic pressure sensor filter on the blood line system!

- Replace the hydrophobic pressure sensor filter if it was contaminated with blood and blood penetrates the machine.
- Instruct technical service to replace hydrophobic pressure sensor filter.
- Only use the machine again when the hydrophobic pressure sensor filter has been changed.
- Execute disinfection after replacement.

⚠ WARNING!

Risk of reduced dialysis efficacy!

- Ensure that no air enters into the dialyzer when decreasing the level in the PBE chamber.

6.3 During Therapy

⚠ WARNING!

Risk to patient due to blood loss if cannulas get disconnected or dislodged!
Standard monitoring function of the dialysis machine cannot safely detect that such a situation has arisen!

- Ensure that the patient access always remains fully visible during therapy.
- Ensure that cannulas are adequately fixed.
- Regularly check patient access.
- Venous lower limit should be set to ≥ 20 mmHg in TSM.

⚠ WARNING!

Risk to the patient due to incorrect treatment!
The heparin pump of the machine is not designed for administration of drugs.

- Use the heparin pump only for heparinization.

⚠ WARNING!

Risk of cross contamination if a blood leakage alarm occurs.

- If a blood leakage alarm occurs and tests positive for blood, the machine should be disinfected before using with a different patient to avoid the possibility of cross contamination.

ⓘ Safety devices for recognizing venous needle dislodgement are available. If intended to be used, the responsible organization is responsible to obtain these devices.

6.3.1 Monitoring Blood Side Pressure Limits

Venous Return Flow Pressure (PV)

ⓘ Venous pressure limits must be set as closely as possible to the currently measured value. For detailed information, refer to the service manual.
For single-needle procedure additional measures for phase volume are required.

The venous return flow pressure (PV) is monitored by an automatically set limits window. The limits window is set 10 seconds after the last activation of the blood pump and is identified by markings on the bar showing the venous return flow pressure.

The venous pressure alarm limits are set in the service program by technical service.

- The venous lower limit value is automatically adjusted during treatment. This means that the distance between the lower limit and the actual pressure decreases. This compensates for the hematocrit increase generally caused by ultrafiltration. The adjustment is carried out every 5 minutes and adds up to 2.5 mmHg at a time. The minimum distance of 22.5 mmHg is, however, always maintained.

1. Check venous lower pressure limit during dialysis.

   ↳ An optimal interval is approx. 35 mmHg between the lower pressure limit and the current value.

By changing the speed of the blood pump for a brief period it is possible to reposition the limits window. In this connection it is spread to the in TSM adjusted size. This means that an already adjusted lower limit value is put back to the in TSM adjusted interval.

Arterial Entry Pressure (PA)

The arterial entry pressure (PA, pressure between patient and blood pump) is automatically monitored within set limits. The limits window is set 10 second after the last activation of the blood pump.

An additional maximum lower limit value could be adjusted up to -400 mmHg in TSM. These limits are active in the therapy phase and during final circulation.

Blood Side Entry Pressure at the Dialyzer (PBE)

If a PBE pressure sensor is used, the blood side entry pressure **(1)** at the dialyzer is controlled by its upper limit. The PBE monitoring function warns or signals a possible blockage of the dialyzer due to a kinked tube or increased clotting within the dialyzer. The PBE measurement allows the user to monitor the formation of a secondary membrane layer in the dialyzer. A possible filter clotting might be avoided. The limits can only be set via the Alarm limits screen at the beginning of the therapy.

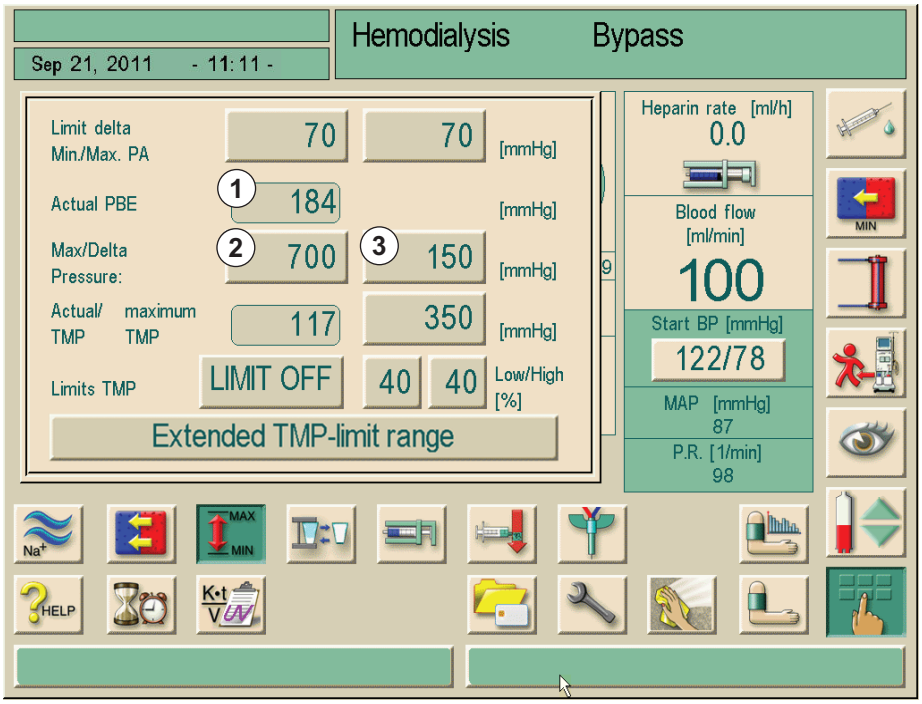


Fig. 6-4 "Alarm limits" screen during therapy

Additionally, to the maximum PBE value **(2)**, the Delta **(3)** can be adjusted. Delta represents a limiting value which lies above the average actual value of the PBE. The average value of the PBE is determined by the Dialog+ within the first five minutes after starting the therapy and stored as a reference value in the software. Changes of pressure by variations in blood flow are automatically considered (e. g.: average actual value of PBE at 155 mmHg plus Delta 150 mmHg. The result of this is a PBE limiting value of 305 mmHg.). Achieving this limiting value causes a yellow warning text appear.

Exceeding the limiting value a red alert text appears.
If the accumulation of a secondary membrane shall not be monitored, the Delta value could be adjusted to the maximum PBE limiting value.

It is possible to use a blood line system without PBE access. The machine realizes the absence of a pressure transducer during preparation. Monitoring PBE during therapy is omitted.

6.3.2 Treatment at Minimum UF Rate

Treatment at minimum UF rate can be activated to achieve, for instance, an immediate lowering of the set UF rate in case of falling blood pressure and unstable circulation.

The therapy time still continues during treatment at the minimum UF rate. Where necessary, adjust UF volume after a treatment at minimum UF rate.

Activate Minimum UF Rate

1. Touch icon.
   - The treatment continues with the set minimum UF rate.
   - The dialysis machine will sound an acoustic signal every 10 minutes.

Deactivate Minimum UF Rate

1. Touch icon again.
   - The treatment continues with or without UF compensation depending on the setting.

UF Compensation

UF compensation can be activated or deactivated in TSM.

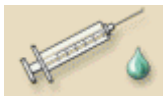
UF Compensation - YES

After temporary treatment with minimum UF rate, the preselected UF volume will be automatically achieved by increasing the UF rate in the set UF time.

UF Compensation - NO

After temporary treatment at minimum UF rate, the preselected UF quantity will not be automatically achieved in the preset UF time.

6.3.3 Heparin Bolus



1. Touch icon.
   - A safety message will be displayed.
2. Confirm heparin bolus by pressing Enter key on the monitor.
   - The heparin bolus preset in the heparin parameters is activated.

WARNING!

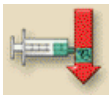
Risk of blood loss due to blood clotting in case of insufficient anticoagulation!

- In case of a heparin syringe pump failure, complete heparin bolus manually.

- The heparin bolus can be repeated.
- Technical service can program the dialysis machine in the service program in such a way that a heparin bolus is automatically administered whenever blood is detected at the red detector on the venous tube clamp. For this purpose, the extracorporeal circulation should be heparinized.

6.3.4 Arterial Bolus

Using the function “Arterial bolus” a defined volume of sodium chloride is infused from a NaCl bag.



1. Touch icon.
   - The set-up window for the arterial bolus is displayed.
2. Enter bolus volume.

1 Start bolus
2 Bolus volume
3 Infused bolus quantity
4 Arterial infused volume
5 Total volume infused

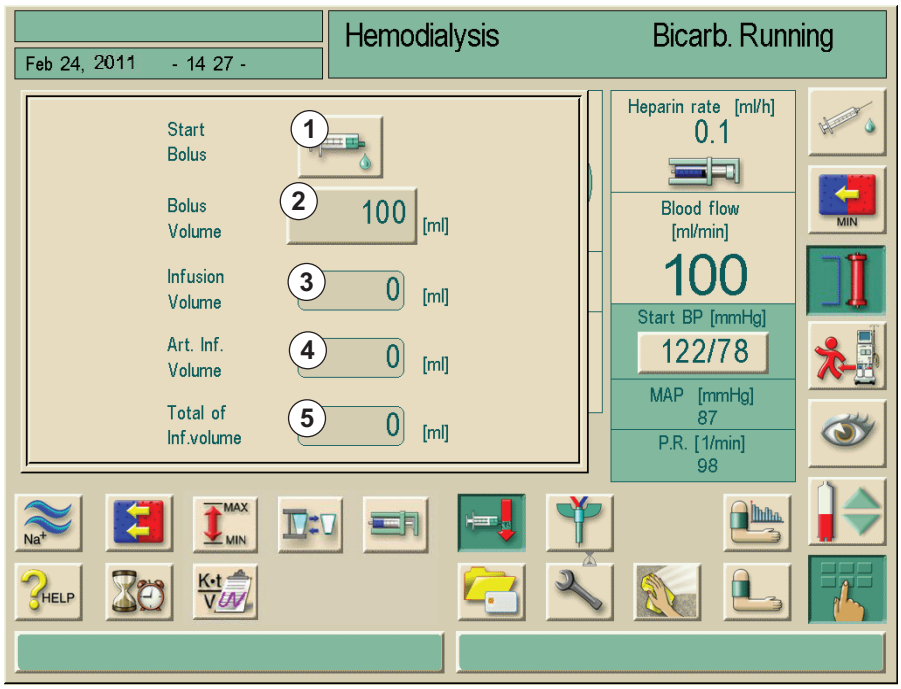


Fig. 6-5 Set-up window for arterial bolus

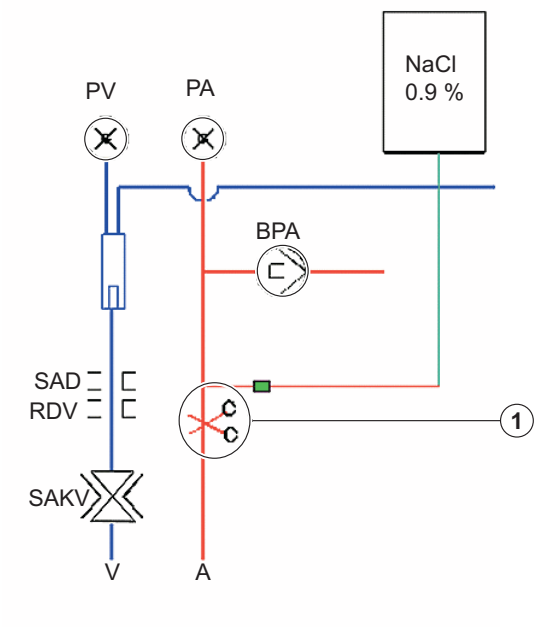
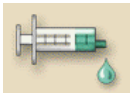


Fig. 6-6 Clamping off the arterial patient access



1. Touch icon.
   - The blood pump stops automatically and a safety message appears on the screen.
2. Connect bag with physiological saline solution to arterial infusion connector.
3. Clamp off arterial bolus **1** if necessary.
4. Confirm arterial bolus by pressing the Enter key on the monitor.
   - The arterial bolus is infused. The values can be monitored in the settings window.

Once the set quantity has been infused or the arterial bolus has been terminated by an alarm, a window appears to confirm **Bolus terminated.**

1. Remove clamp on patient access, clamp off infusion line and confirm by pressing the Enter key on the monitor.
   - The window for the arterial bolus is closed and replaced by the therapy screen.

⚠ WARNING!

Risk of sodium imbalance and patient overload!

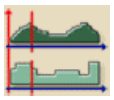
- In case of a blood pump failure during an arterial bolus or reinfusion, complete bolus manually.
- In case of a prematurely closed venous clamp, complete arterial bolus via hydrostatic infusion.

NOTICE!

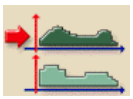
If the arterial bolus was terminated by an alarm, the entire bolus quantity will be infused upon reactivation of the arterial bolus.

6.3.5 Graphical Representation of Treatment Parameters (Trend)

1. Touch icon.
   ↳ A screen with the graphical representation icon appears.



2. Touch icon.



3. Touch icon.
   ↳ The following screen is displayed.

1 Trend group
2 Activate pre-adjustment from TSM
3 Edit a trend group
4 Safe and leave window
5 Leave window without saving

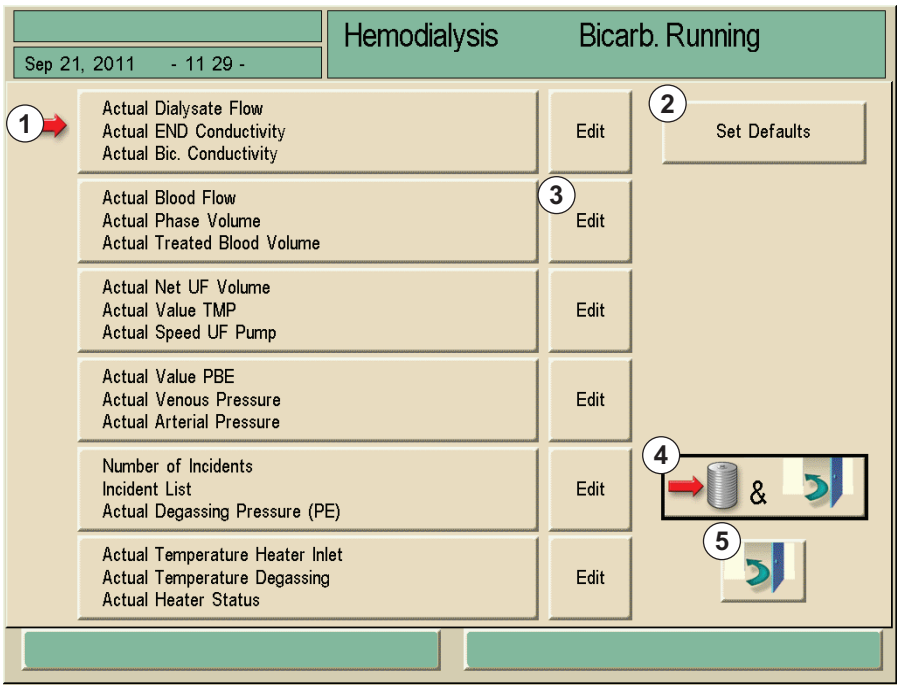


Fig. 6-7 Trend groups

A standard of six groups with three parameters each is preset in the TSM.

Instructions to edit individual trend groups is described in chapter 12.10 Edit Parameter of Trend Groups (248).

1. Touch field of selected trend group.
   ↳ The following screen is displayed.

1 Graphic representation of a treatment parameter

2 Move reference time period forwards

3 Move reference time period backwards

4 Set time for reference period

5 List of all trends

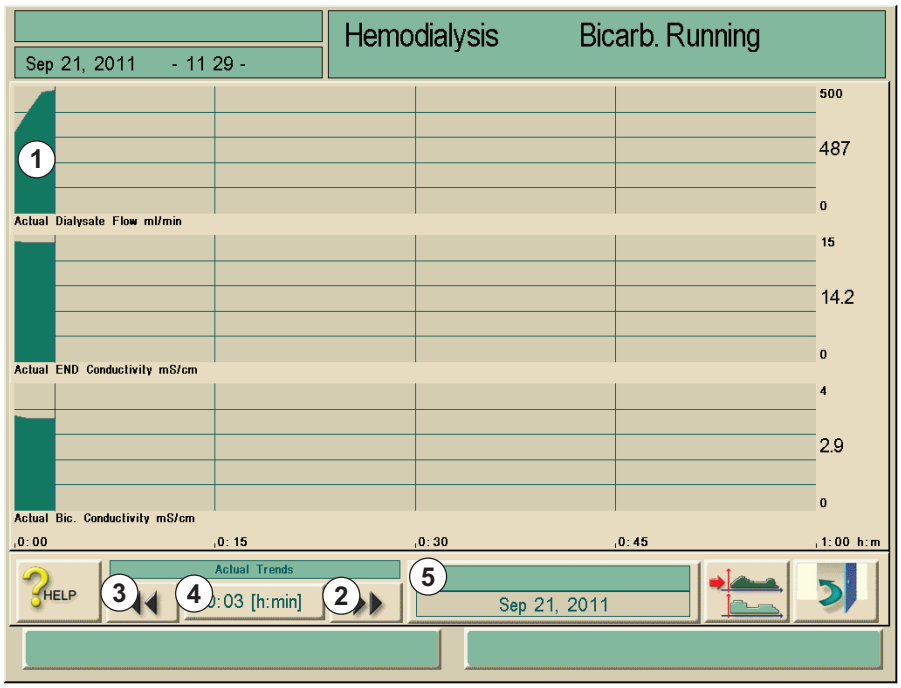


Fig. 6-8 Graphic representation of treatment parameters

Treatment Parameters at a Defined Point in Time

There are two ways by which the treatment parameters can be observed at a defined point in time:

1st Option:

1. Directly enter the time **(4)** in the Time window.

2nd Option:

1. Move the time reference line by using the icons **<< (2)** or **>> (3)**.

Call History of Trend Data

In addition to the current therapy the last 20 therapies carried out with the machine could be displayed.

1. Touch field **5**.

   ↳ The following screen is displayed.

1 Current therapy

2 All therapies, max. 20

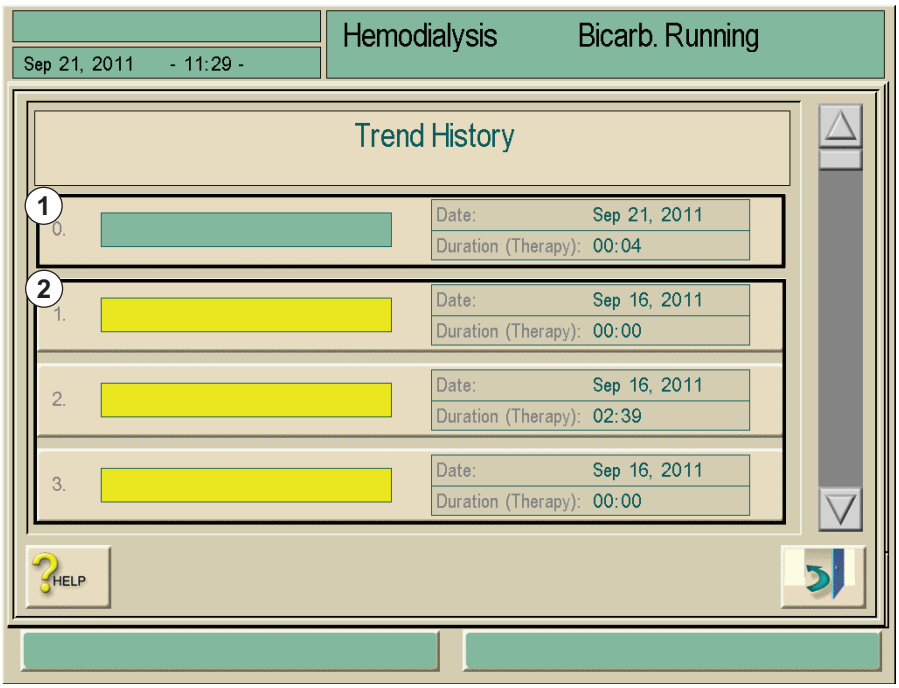


Fig. 6-9 "Trend-History" screen

1. To open the graphic representation touch respective field.

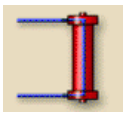
   ↳ The background of the Name field for the actual therapy is green, the background of the stored therapies is displayed in yellow.

Patient names only appear if they are manually entered before therapy or if a therapy card is used.

NOTICE!

Observe local data protection opening trend data which are marked with patient names.

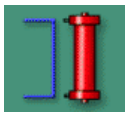
6.3.6 Interrupting Hemodialysis (Bypass)



1. Touch icon.

   ↳ The dialysis machine switches to the bypass mode. The hemodialysis is interrupted.

   ↳ The signal lamps on the monitor switch to yellow. The icon changes its display.



2. Touch icon again.

   ↳ The bypass mode is terminated, the treatment is continued.

⚠ WARNING!

Risk of low blood flow and thus reduced treatment efficacy!

If user fails to open clamp on arterial line after reconnecting patient, extremely negative pre-pressure at the pump occurs.

- Open clamp on arterial line after reconnecting the patient.

Depending on the settings in the service program, the change into the bypass mode must also be confirmed by pressing the Enter key on the monitor.

6.4 Completion of Treatment

On completion of the treatment, an acoustic signal can be heard and the message "Treatment time completed" is displayed, the signal lamps on the monitor switch to yellow.

- The UF rate is set to 50 ml/h.
- The blood pump is still running.
- The time beyond the treatment time is shown instead of the remaining time with a minus symbol in front. The graphics will be displayed in red.

6.4.1 Terminating Treatment

1. Touch icon.
   ↳ The message "Terminating treatment" is displayed.
2. Confirm termination of treatment by pressing the Enter key on the monitor.

6.4.2 Continuing Treatment

1. Touch icon.
   ↳ After entering new treatment parameters, the hemodialysis can be continued.

⚠ CAUTION!

Risk of blood pressure drop or cramps for the patient by continuous ultrafiltration!

- Ensure that ultrafiltration will be stopped in appropriate time.

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7 End of Therapy

7.1 Reinfusion

During the reinfusion phase the limits windows are set to their maximum values. The reinfusion phase, therefore, demands particular care.

After confirming End of Therapy, the following screen appears:

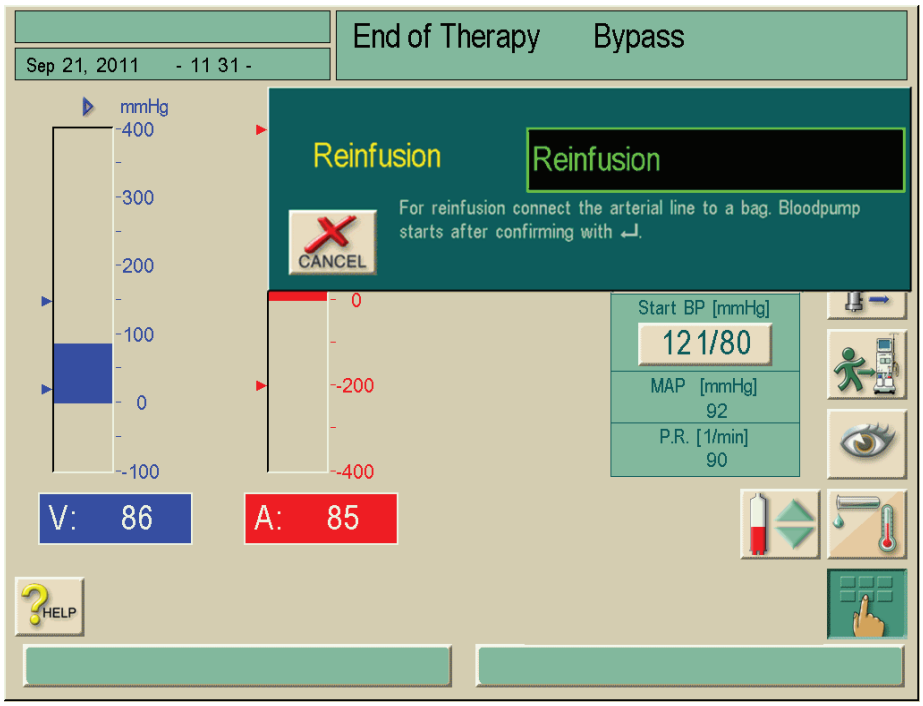


Fig. 7-1 "Confirm reinfusion" screen

WARNING!

Risk of air embolism in case of reinfusion with air!

- Only carry out reinfusion with fluids.

1. Remove arterial connection from patient.
2. Connect arterial line to infusion bag containing physiological saline solution.
3. Confirm arterial disconnection by pressing the Enter key on the monitor.
   - The blood pump starts the reinfusion.
   - The reinfusion screen appears.

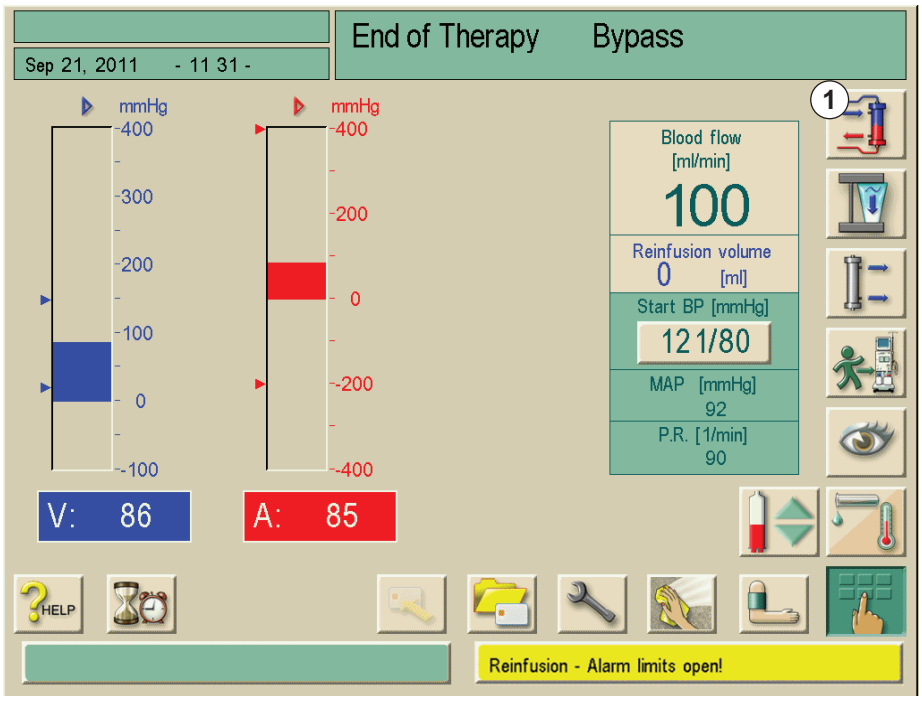


Fig. 7-2 "Reinfusion" screen

The dialysis machine monitors the reinfusion volume and reinfuses until the red detector (RDV) detects the physiological saline solution. The blood pump stops.

1. To continue reinfusion, start blood pump by pressing **START/STOP** button on the monitor.
   - The blood pump stops automatically after 400 ml have been reinfused or when a reinfusion time of 5 minutes has elapsed.
   - The query "Continue reinfusion?" appears on the screen.
2. To continue the reinfusion process, confirm by pressing the Enter key on the monitor.
   - The dialysis machine will carry out reinfusion of another 400 ml, or reinfusion for 5 minutes.
3. Disconnect venous patient connection.

The screen "Confirm reinfusion" (Fig. 7-1) appears only if configured accordingly in the service program. Otherwise, reinfusion must be called up by pressing icon **1** (Fig. 7-2).

The user is obliged to check for correct setting of the levels in the chambers.

7.2 Emptying Cartridge After Therapy

The cartridge can be emptied before or after emptying the dialyzer.

Emptying the Cartridge Before the Dialyzer is Emptied

1. Leave both couplings on the dialyzer.

2. Touch icon and confirm by pressing the Enter key on the monitor.
   ↳ The cartridge is emptied automatically.

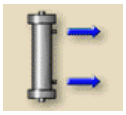
Emptying Cartridge After the Dialyzer is Emptied

1. Connect both couplings to the rinsing bridge.
2. Touch icon and confirm by pressing the Enter key on the monitor.
   ↳ The cartridge is emptied automatically.

NOTICE!

Once "Empty dialyzer" has been confirmed, the blood pump cannot be started anymore!

7.3 Emptying the Dialyzer



1. Touch icon.
   ↳ An information window describing the next steps appears.
2. Follow the instructions on screen and confirm by pressing the Enter key on the monitor.
   ↳ The dialyzer is emptied.
3. Once the dialyzer has been emptied, connect the second dialyzer coupling to the rinsing bridge.
4. Remove from the dialysis machine the dialyzer and blood line system and dispose of both.

The dialysis machine must be disinfected, see chapter 8 Disinfection (121).

The functions ”Empty dialyzer” and ”Empty cartridge” can be started simultaneously. However, they are carried out one after the other.The cartridge is emptied as long as both couplings are connected to the dialyzer or the rinsing bridge. If the blue coupling is connected to the rinsing bridge, the dialyzer is emptied.

7.4 Protocol - Overview of Therapy

1. Touch icon.
   ↳ An overview with the actual values appears for the following values:

- Treated blood volume
- UF volume of hemodialysis
- UF volume of sequential phases
- Heparin volume
- Substitution volume (only for HDF/HF online)
- Profile, if set

More parameters can be displayed by actuating the respective icons.

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8 Disinfection

8.1 Procedure and Disinfectants

For cleaning the housing and monitor, see section 8.11 External Cleaning (138).

In the disinfection mode, the following programs are available:

Disinfection program	Duration of disinfection	Notes
Chemical disinfection	approx. 35 – 55 min (depending on disinfectant)	—
Short chemical disinfection Also: decalcification with citric acid 50 %	approx. 25 – 45 min (depending on disinfectant)	Reduced disinfection effectiveness! Also for decalcification with citric acid 50 %, particularly following a bicarbonate dialysis.
Thermal disinfection	approx. 40 min	Use only in exceptional cases. Depending on water quality, carry out chemical disinfection at regular intervals. After a bicarbonate dialysis, first decalcify with citric acid 50 %.
Chemical disinfection with disinfection solution from central water supply manually or automatically	adjustable	Depending on the installed water treatment system. With the automatic method, the disinfection solution does not contact the optional DF filter.
Thermal disinfection with hot permeate from central water supply	approx. 30 min	Depending on the installed water treatment system.
Rinse permeate inlet	2 min up to 10:00 h adjustable	—

These procedures can be activated or deactivated to allow disinfection tailored to the individual situation.

Beyond that, the following options can be activated or deactivated:

- Disinfection necessary after every dialysis
- Termination of disinfection procedure possible/disabled
- Automatic disinfection

Settings in the service program such as intake volume, disinfection time, temperature or rinsing time can only be configurated by technical service!

Recommended Disinfectants

For disinfection we recommend citric acid 50 % or TIUTOL KF.

⚠ CAUTION!

The DF filter is damaged after the use of TIUTOL KF.

- An immediate filter exchange is required after the use of TIUTOL KF.

NOTICE!

Only use disinfection methods defined and validated by B. Braun. Suitable disinfectants are listed in the service manual.

8.2 Preparing for Disinfection

⚠ WARNING!

Scalding or chemical burns hazard for users if disinfectants escape from connection points!

- During disinfection:
  Do not remove dialyzer couplings.
  Do not pull out concentrate suction rods.

⚠ WARNING!

Chemical burns hazard when connecting or changing disinfectants!
Concentrated disinfectants may cause chemical skin burns when sprayed or spilled.

- Take appropriate measures, e.g. wear personal protective equipment (PPE), for example goggles and gloves.
- Rinse off splashes on skin and clothing with clear water.

⚠ CAUTION!

Risk of scalding or burning!
Machine disinfection is performed at high temperatures of up to 95 °C.

- Never connect/disconnect dialyzer couplings or substitution port during a running disinfection.
- Do not touch exposed parts of the machine's internal tubing system (rinsing bridge, dialyzer coupling/tubes, DF/HDF filter housing) during disinfection.

⚠ WARNING!

Potential machine damage by unknown ingredients of disinfectant!

- Ensure that the disinfectant is pure active chlorine (like TIUTOL KF).
- Ensure that the concentration of available chlorine in disinfectant is 3.9 g/100 g (like in TIUTOL KF).
- Otherwise, B. Braun won't assume any liability on the intactness of the machine.

⚠ CAUTION!

The DF filter is damaged after the use of TIUTOL KF.

- An immediate filter exchange is required after the use of TIUTOL KF.

1. Ensure that sufficient suitable disinfectant is connected.
   - ↳ If necessary, change disinfectant container.
   - ↳ Take into consideration that a disinfection cycle may be started automatically at a later time.

8.2.1 Positioning the Disinfectant Container

1. Insert disinfectant container into fixing at the rear of dialysis machine.
2. Connect disinfectant line to the disinfectant connection on the rinsing bridge.
3. Ensure that the disinfectant container is not positioned higher than the rinsing bridge.

8.2.2 Selecting Disinfection Program

Selecting the Disinfection Program Before the Dialysis

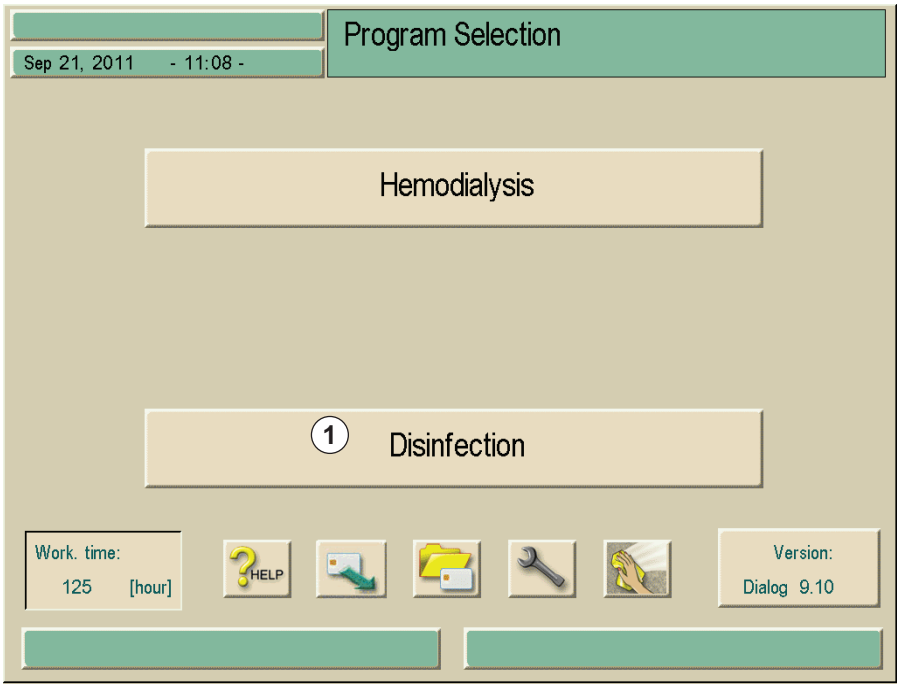


Fig. 8-1 Program selection

1. Touch field **1**.

   ↳ The screen listing the different disinfection programs appears.

1 Select disinfectant
2 Thermal disinfection
3 Chemical disinfection
4 Short chemical disinfection
5 Rinse permeate inlet
6 Chemical disinfection withdisinfection solution from central water supply
7 Thermal disinfection with hot permeate

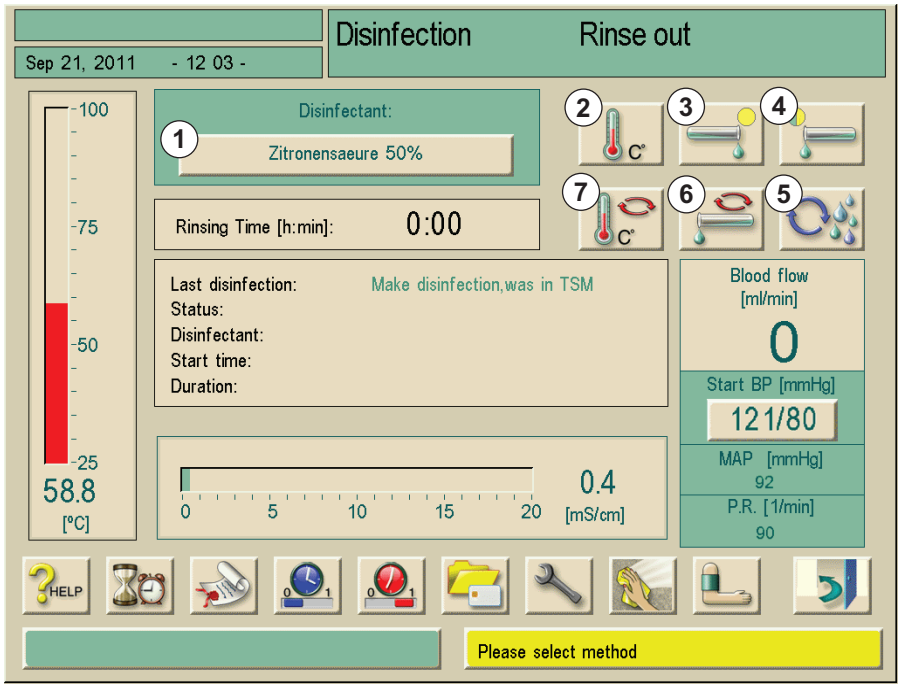


Fig. 8-2 Selection of disinfection program

1. Select disinfectant in field **1**.
2. Select disinfection program through icons **2** to **7**.

Selecting the Disinfection Program After Dialysis

1. Touch icon.

   ↳ The screen with the different disinfection programs is displayed, see Fig. 8-2.

2. Select disinfectant in field **1**.
3. Select disinfection program through icons **2** to **7**.

The study regarding the test procedure by which the efficacy of sanitization or disinfection has been verified is available on request.

8.3 Automatic Switch-off and Restarting

The following disinfection settings are available:

- Automatic switch-off after disinfection
- Automatic switch-off and restarting
- Weekly disinfection program, see section 12.2 Weekly Disinfection Program (224).

8.3.1 Automatic Switch-off After Disinfection

If the automatic switch-off function is activated, the machine will switch-off automatically after each manually started disinfection. A time-out can be set by the user. Please see chapter 12.1 Automatic Switch-Off (223) .

8.3.2 Automatic Switch-off and Restarting

The use of water detectors is recommended for detecting potential leaks during unsupervised operation.

This function allows switching off the dialysis machine automatically after disinfection. The dialysis machine is switched on automatically at the specified time and prepares the next dialysis.

1. Touch icon.

   ↳ The following window opens:

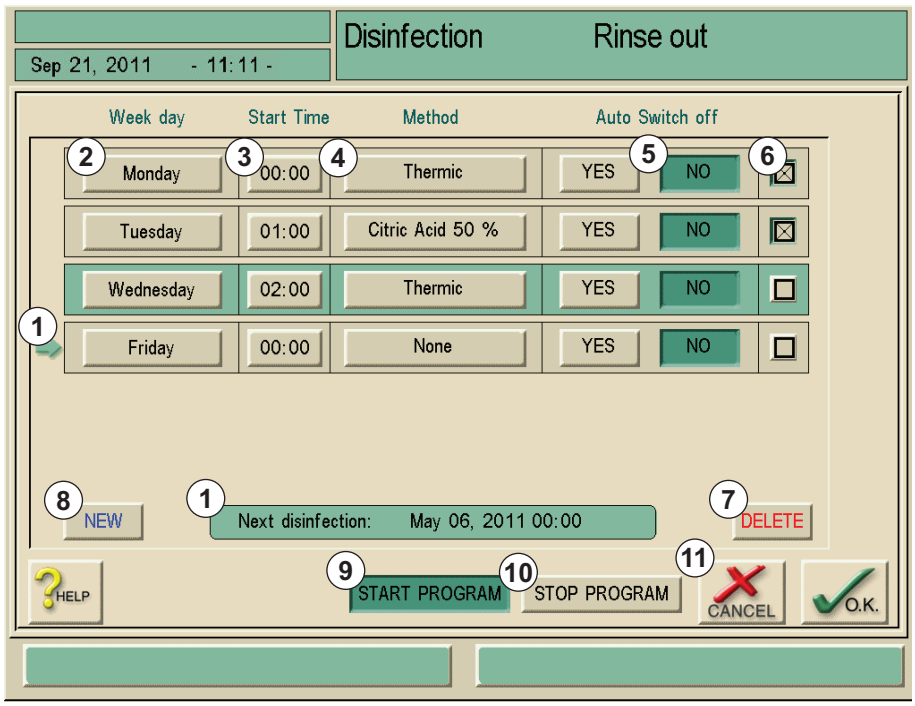


Fig. 8-3 Scheduled auto disinfection screen

Item	Text	Comment
1	Scheduled auto disinfection	The next programmed disinfection is indicated.
2	Week day	Any week day from Monday till Sunday can be entered, also several times, if more than one operation per day is required.
3	Start time	The start time of the operation can be entered.
4	Method	The following methods can be entered: • Rinsing • Thermal • Citric Acid 50 % • Central Thermal • None

Item	Text	Comment
5	Switch-Off	Enter whether the machine shall remain switched-on after the operation or shall switch-off. Yes: The dialysis machine will be switched-off right after the entered method. No: The dialysis machine will remain switched-on right after the entered method.
6	-	Marks row to delete.
7	Delete	Deletes all marked rows.
8	New	New rows can be added to the table (21 in total).
9	Start Program	The weekly disinfection program is started with this button. It runs until (10) is pressed.
10	Stop Program	The weekly disinfection program is stopped with this button. It is stopped until (9) is pressed.
11	Cancel	Leave window without saving setting.
	OK	Leave window with saving setting.

NOTICE!

Leave mains switch of dialysis machine switched on.
Ensure that sufficient disinfectant is connected.
Disinfection must in each case be reactivated for the following day.

NOTICE!

The auto switch-off and the weekly disinfection program have to be activated in TSM.

8.4 Chemical Disinfection

⚠ CAUTION!

Damage to dialysis fluid filter system!

- Where dialysis fluid filters are used, only use the disinfectants specified in the instructions for use of the dialysis fluid filter for disinfection.

1. Select disinfectant, e.g. “citric acid 50 %”.
2. Touch icon.
   ↳ The sequence of the disinfection program is displayed in field 1.

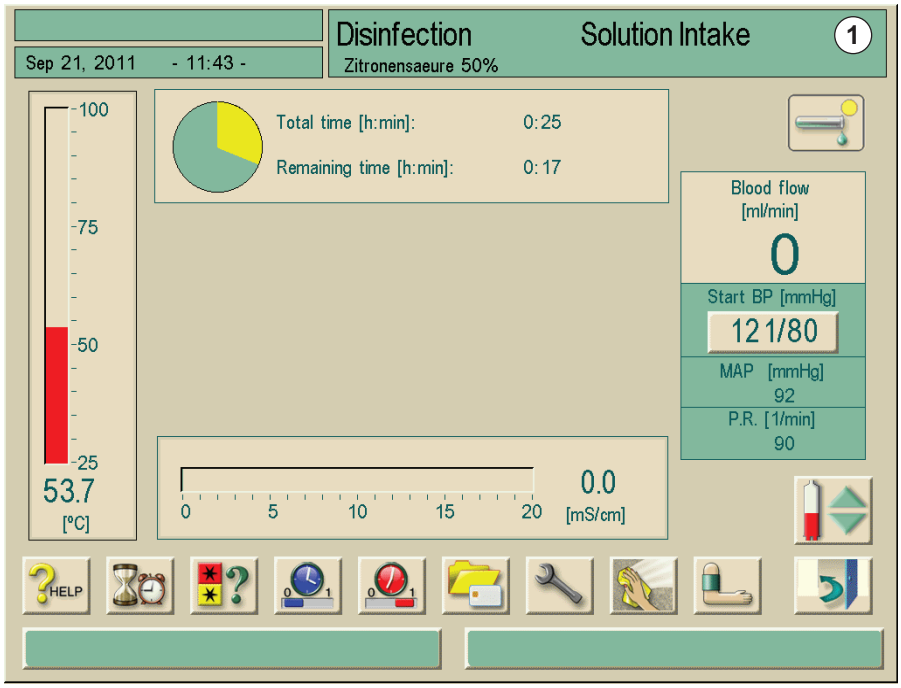


Fig. 8-4 "Chemical disinfection" screen

8

Sequence

After activation, the chemical disinfection is carried out automatically as follows:

- Automatic rinse-out
- Aspiration of disinfectant and start of heating cycle
- Disinfection phase: Exposure and circulation
- Rinse-out phase

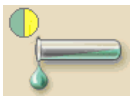
End of Disinfection

1. Check if system is free of disinfectant, see section 8.8 Checking for Disinfectant Residues (134).

8.5 Short Chemical Disinfection

NOTICE!

Short chemical disinfection is intended only for decalcification and can be carried out only with citric acid!



1. Activate icon.
   ↳ The short chemical disinfection is carried out.
2. Check if system is free of disinfectant, see section 8.8 Checking for Disinfectant Residues (134).

8.6 Thermal Disinfection

NOTICE!

Use thermal disinfection only in exceptional cases as its germ-reducing effect is not sufficient for regular application. Thermal disinfection is not suitable after bicarbonate dialysis as the dialysis machine needs to be decalcified. After a bicarbonate dialysis, chemical disinfection with citric acid 50 % is recommended.

1. Touch icon.
   - The thermal disinfection is started.
   - The progress of disinfection cycle is displayed on the screen.

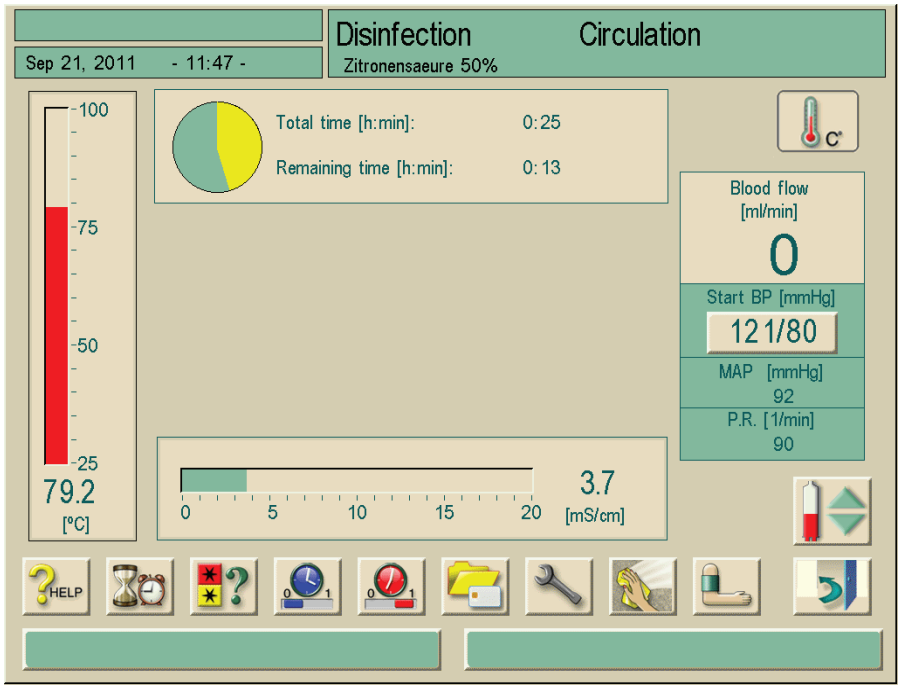


Fig. 8-5 "Thermal disinfection" screen

After activation, thermal disinfection is carried out as follows:

- Automatic rinse-out
- Heating to at least 85 °C
- Disinfection: Exposure and circulation
- Cooling down

8.7 Disinfection of Incoming Water from Water Supply

The dialysis machine offers the option of chemical or thermal disinfection of incoming water supplied through the water treatment system. The water treatment system must be suitable for this procedure.

Disinfectant	Machines without DF filter	Machine with DF filter
Heated Water	X	X
Paracetic Acid	X	X
Chlorine Based (bleach)	X	

The temperature monitoring during this disinfection program refers to the dialysis machine and **not** to the supply line.

Removal of fluid from the central water supply influences the temperature.

The use of water detectors is recommended for detecting potential leaks during unsupervised operation.

For information about the disinfection of the water treatment system, refer to the operating instructions for water treatment system.

⚠ WARNING!

Risk of poisoning the patient with disinfectants left in the water supply!

- During central disinfection install warning sign on dialysis machine, e.g. “Disinfectant in water inlet!”
- Reuse dialysis machine for dialysis operation only after the water inlet line has been adequately rinsed.
- Only connect inlet tubes to central water supply after they have been cleared of disinfectant

⚠ WARNING!

Contamination risk to patients if machine is not adequately disinfected. Disinfection of water inlet system is no substitute for disinfection of the machine.

- Disinfect the dialysis machine separately after disinfection of the water supply line.

⚠ WARNING!

Risk to the patient due to infection!
The central supply system may be contaminated with endotoxines and germs.

- The responsible organization is responsible for hygiene and therefore disinfection of central supply systems.

WARNING!

Risk to the patient due to excessive fluid removal in ultrafiltration (UF)!
Unknown ingredients of disinfectant or wrong disinfection method may damage the internal tubing system which may result in incorrect UF flow.

- Only use disinfectants and disinfection methods defines and validated by B. Braun.

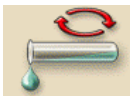
CAUTION!

Risk of damage to the machine due to material changes caused by unsuitable disinfectants!

- Only use agents suitable for Dialog+ for disinfecting the water inlet line.

8.7.1 Chemical Disinfection with Disinfecting Solution from Central Water Supply

During chemical disinfection of the water inlet, the disinfecting solution is taken from the central water supply and pumped into the dialysis machine.



1. Touch icon.
   - The following screen appears:

1 Set flow rate for inlet disinfection
2 Set duration for disinfection of the inlet line
3 Set flow rate for rinse-out
4 Set duration for disinfection of the inlet line

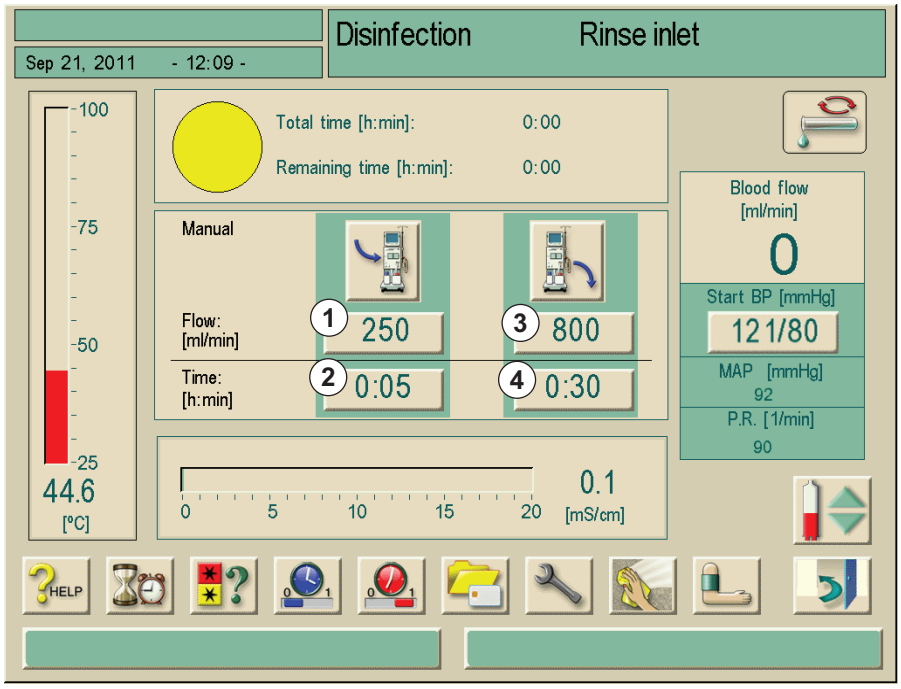


Fig. 8-6 "Disinfection" screen

1. Set the parameters
   - Inlet flow in field 1
   - Inlet time in field 2
   - Rinse-out flow in field 3
   - Rinse-out time in field 4

If the central water supply contains disinfectant:

1. Touch icon.
   - Inlet supply is started and stopped after the preset time.

Once all disinfectant has been rinsed out of the central water supply:

1. Touch icon.
   - Rinsing of the dialysis machine supply line is started and stopped after the preset time.
2. Check supply line and dialysis machine for disinfectants.

8.7.2 Automatic Chemical Disinfection with Disinfectant from Central Water Supply

This disinfection method should only be performed by staff who is also trained for RO equipment.

Due to technical defects, disinfectant or water from central water supply could leak over the dialysis machine. The use of humidity sensor is recommended.

During the automatic chemical disinfection of the water branch the disinfectant solution is removed from the central water supply into the dialysis machine. With this method certain valve positions prevent contact of the disinfectant with the DF-filter.

1. Select disinfection screen.
2. Touch icon.
   - The following screen appears.

1 Day disinfection
2 Set time
3 Night disinfection
4 Select disinfection program
5 Set date
6 Select disinfectant
7 Activate week progam

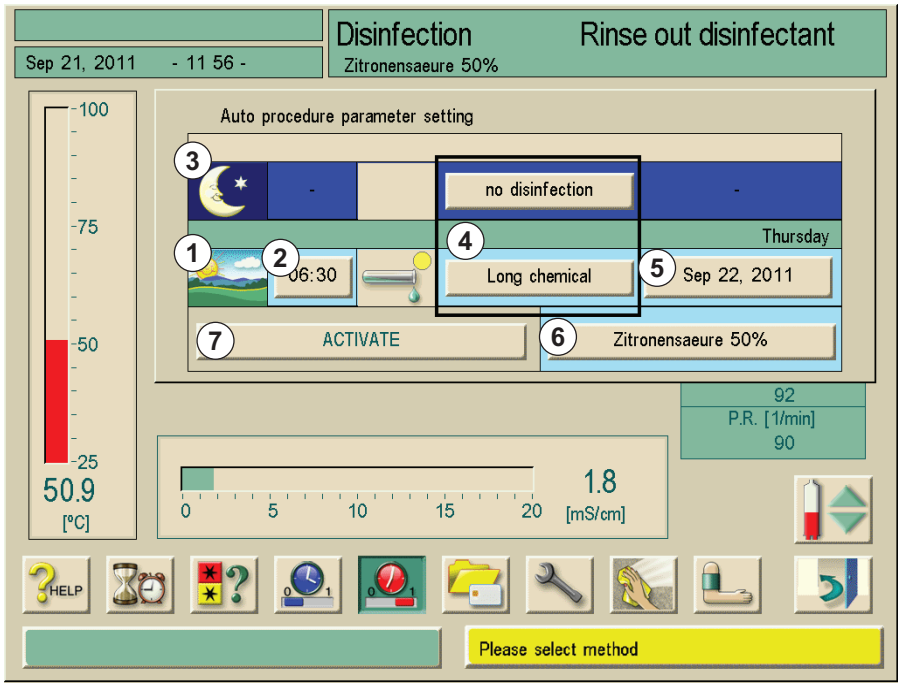


Fig. 8-7 "Disinfection" screen

1. Touch button for disinfection method (**4**, Fig. 8-7) .
2. Choose „Water inlet chemical“, confirm with **O.K.**
3. Set switch **ON** time (**2**, Fig. 8-7).
4. Touch button “Activate” (**7**, Fig. 8-7).

   ↳ A warning window for the automatically switching **OFF** appears. The dialysis machine switches **OFF** after disinfection. At the preset time the machine will switch **ON** again and execute the chosen disinfection.

NOTICE!

Keep mains switch **ON**.
Assure that there will be enough disinfectant with the right concentration available in central water supply. Otherwise, the disinfection effect might be reduced.

The following screen appears when switching **ON**:

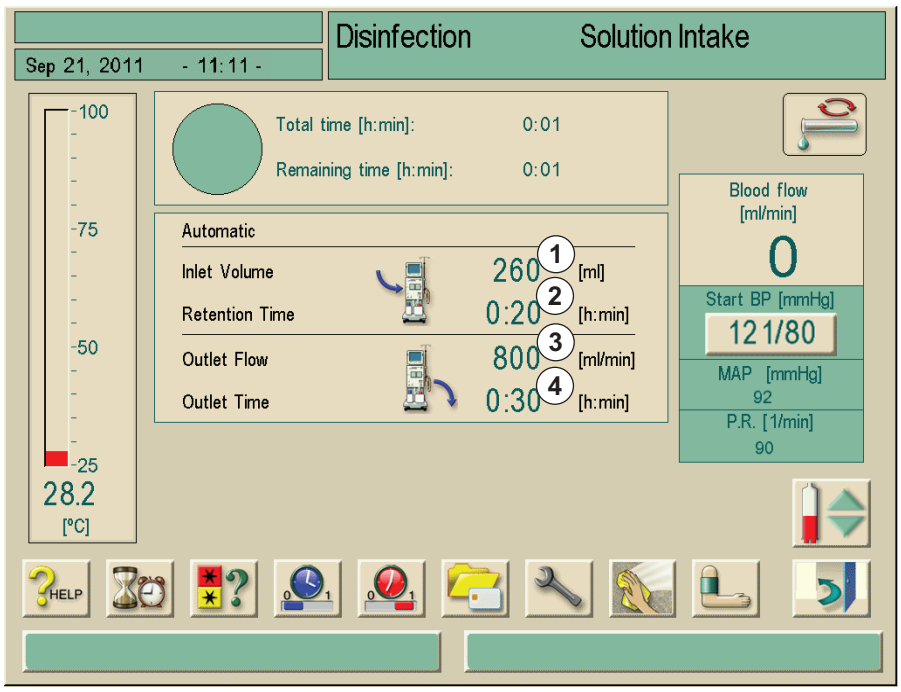


Fig. 8-8 Screen “Disinfection”

If the inlet volume **(1)** is reached, the dialysis machine deactivates itself. After end of the adjusted residence time **(2)**, the machine reactivates and starts rinse phase with adjusted parameters (**3** and **4**).

The service technician can preset the machine in TSM so that it will not reactivate itself. The dwell time ends and the rinse phase starts if the machine is switched **ON** manually.

If disinfection parameters are put in as night disinfection, the machine switches **OFF** after rinsing phase (see chapter 8.3 Automatic Switch-off and Restarting (124)).

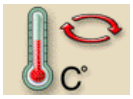
WARNING!

Risk of poisoning the patient with residual disinfectants in the dialysis machine!

- During central disinfection install warning sign on dialysis machine, e.g. “Disinfectant in dialysis machine!”
- Make sure that disinfectant-free water will be available at the beginning of rinse phase.
- Only use the machine for therapy after sufficient rinsing.
- Check if the dialysis machine is disinfectant-free.
- Only switch ON the machine if the RO equipment is switched ON. If the mains pressure is too low, disinfectant could reach from the inlet into the central water supply line.

8.7.3 Thermal Disinfection with Hot Permeate from Central Water Supply

During this disinfection program, hot permeate is taken from the central water supply into the dialysis machine. If necessary, the permeate is heated up to the temperature which is required for thermal disinfection of the dialysis machine.



1. Touch icon.

   ↳ The following screen appears and the program starts.

Fig. 8-9 Screen “central thermal disinfection“

8.7.4 Rinsing the Permeate Inlet

1. Ensure that the dialysis machine is switched on and connected to the central water supply.

2. Touch icon.

   ↳ The following screen appears and the program is started.

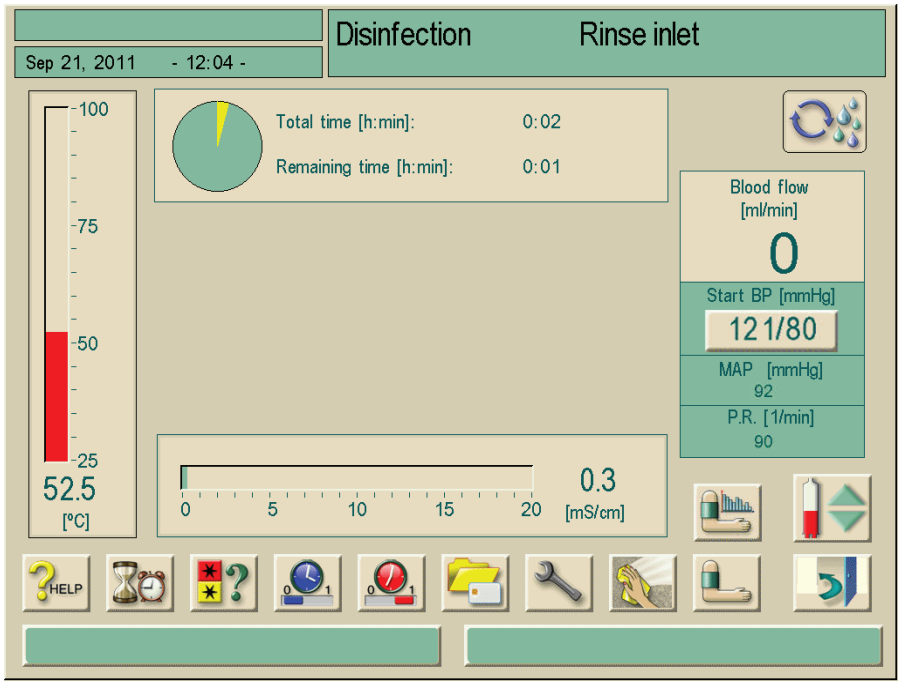


Fig. 8-10 "Rinse permeate inlet" screen

8.8 Checking for Disinfectant Residues

⚠ WARNING!

Risk of poisoning the patient with disinfectant residues left in the machine!

- After using disinfectants, check for any disinfectant residues on the dialyser couplings and on the discharge outlet!

NOTICE!

If citric acid 50 % was used as disinfectant, a check for disinfectant residues is not necessary.

The following information window appears on the screen after the set rinsing time:

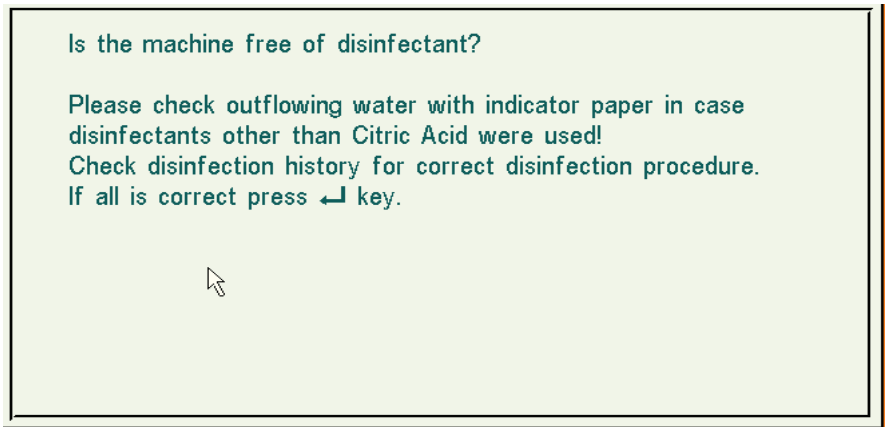


Fig. 8-11 Information window “Disinfectant residue check”

The following indicators can be used to check that the system is free from disinfectant:

Disinfectant	Disinfectant residue check
Citric acid 50 %	No check required
TIUTOL KF	Potassium iodide starch paper or pH determination with phenolphthalein as indicator
Paracetic Acid	Peroxide test stripe

⚠ CAUTION!

The DF filter is damaged after the use of TIUTOL KF.

- An immediate filter exchange is required after the use of TIUTOL KF.

If the dialysis machine still contains disinfectant:

1. Continue rinsing of dialysis machine and repeat indicator test.

If dialysis machine is free from disinfectant:

1. Press Enter key on monitor.

2. Touch icon.
   ↳ The dialysis machine moves to program selection.

Depending on configuration, the dialysis machine either switches to the Preparation screen or remains in the Rinse-out screen at the end of the rinse-out time. However, the window for confirming that the system is free from disinfectant remains active until it is confirmed by pressing the **Enter** key on monitor.

8.9 Decalcification

NOTICE!

When using citric acid 50 % for disinfection, decalcification of the dialysis machine is not required.
When using alkaline disinfectants, a decalcification with citric acid 50 % must first be carried out.

8.9.1 Automatic Descaling

Effective descaling of the DF filter is influenced by the preset contact time and the temperature used during the cleaning cycle that is set in the TSM. Dialysis therapies using higher concentrations of bicarbonate may require longer contact time and higher temperature.

WARNING!

There may be a risk of uncontrolled UF withdrawal from patient due to a calcified dialysis fluid filter.

- To prevent this, perform decalcification with citric acid 50 % after each treatment.
- Alternatively, the automatic descaling function can be performed after each treatment if activated in TSM.

WARNING!

Risk of blood contamination.

- Use the same type of acid concentrate as used in the previous treatment.

The automatic descaling function can be enabled in TSM. Instead of citric acid, acid concentrate used for treatment is drawn in from the machine in high concentration to decalcify the DF Filter between two bicarbonate therapies. It does not replace disinfection.

Automatic descaling is required if the machine is equipped with the option DF filter.

1. After the patient is disconnected from the machine, empty the dialyzer as usual.
2. Connect the dialyzer couplings to the rinsing bridge.

The bicarbonate cartridge may be left in the holder during the process. The bicarbonate concentrate coupling may be left connected to the concentrate source during the process.

1. Ensure connection of acid concentrate coupling to concentrate source.
2. The descaling process will start automatically after End of Therapy without any method selection if the user enters into Disinfection.

Automatic descaling only starts after a bicarbonate dialysis.
Automatic descaling cannot be started manually.

The following screen appears and the process is started:

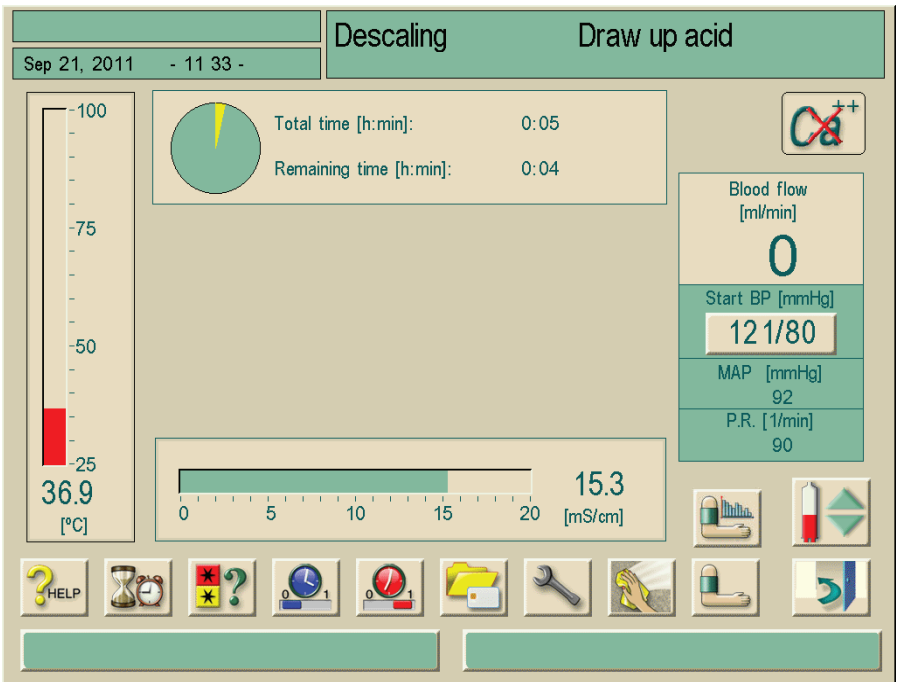


Fig. 8-12 "Descaling" screen – Acid drawing up

After acid is drawn up, the machine enters into acid rinse out.

The following screen appears:

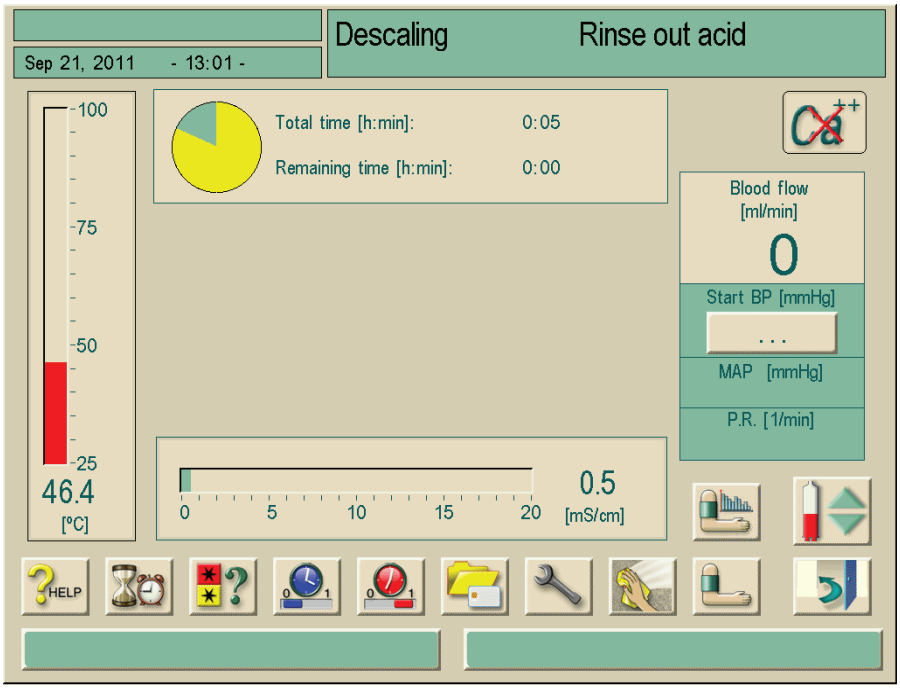


Fig. 8-13 "Descaling" screen – Acid rinse out

As soon as acid rinse out is completed, the machine enters into Preparation and starts the preparation process if the “Automatic Preparation Start after Disinfection” has been enabled in TSM.

If “Automatic Preparation Start after Disinfection” is disabled in TSM, the machine enters into Disinfection and starts disinfection rinsing automatically. In this case, all couplings must be on the rinsing bridges and the cartridge holder must be closed.

Automatic descaling can be interrupted in any phase of the process. The machine will go to Disinfection main screen and the acid rinse out will be carried out. Afterwards, disinfection rinsing will start automatically.

8.10 Terminating Disinfection

If the dialysis machine was configured in the service program in such a way that disinfection can be terminated, the disinfection program can be terminated at any time.

1. Touch icon.
   ↳ An information window appears.

If disinfectant has already been drawn in, the termination of the program is followed by a rinse-out phase (e.g. 5 minutes when using citric acid 50 %, or 20 minutes when using TIUTOL KF).
If the settings “Disinfection after every dialysis” and “Termination of disinfection” have been configured, a **full** disinfection must be carried out prior to the next dialysis.

⚠ CAUTION!

The DF filter is damaged after the use of TIUTOL KF.

- An immediate filter exchange is required after the use of TIUTOL KF.

1. To terminate the disinfection, press **Enter** key on the monitor.
   ↳ The “Select disinfection program” screen is displayed, see Fig. 8-2 Selection of disinfection program (124) . You can select a different disinfection program.

8.11 External Cleaning

Monitor and Surface

⚠ WARNING!

Electric shock and fire hazard!

- Ensure that no fluid enters the machine.
- Ensure that no fluid is on the mains plug or mains socket.

⚠ WARNING!

Risk of cross-infection because of contamination!

- It is recommended to clean the outer surface of the machine after each therapy by an appropriate disinfectant.
- In case of surface contamination with blood, disinfect and clean properly.
- In case of contamination of pressure connectors with blood, disinfect and clean properly.

1. Clean housing parts and monitor with ethanol (max. 70 %) or isopropanol (max. 70 %) based cleaning agents.
   Hypochlorite-based agents may not exceed a concentration of 0.1 % and may not be used on the touch foil.
2. Use cleaning and disinfection agents only in accordance with the respective instructions for use.

Wiping the Monitor During Operation

1. Touch icon.
   ↳ The touch foil will be deactivated for 10 seconds and can now be cleaned.

NOTICE!

Do not wipe the monitor too moistly. If necessary, dry with smooth cloth afterwards.

⚠ WARNING!

Risk to patient due to ultrafiltration deviation!

Non-alcohol-based agents (e.g. Clorox Bleach, any kind of Hexaquart) damage the housing of the Diacap Ultra dialysis fluid filter and may cause a fluid leakage.

- The housing of the dialysis fluid filter and online filter may only be cleaned with alcohol-based agents.
- Other disinfectants may only be used after contacting B. Braun.

Blood Pump Roller

NOTICE!

Do not repeatedly put the blood pump rollers into a disinfectant bath, otherwise the return safety device can be destroyed.

Solutions for External Disinfection

Product	Concentration	Manufacturer
Meliseptol	100 %	B. Braun
Melsitt	10 %	B. Braun
Melsept SF	10 %	B. Braun
Hexaquart plus	2 %	B. Braun
Clorox Bleach	0.8 %	Clorox Company, USA

8.12 Disposal of Old Dialysis Machines

The dialysis machine has to be disinfected according to regulations before disposal. For information about the disposal see chapter 2.5.9 Disposal (26).

Table of Contents

9 HDF Online/HF Online

In addition to hemodialysis, Dialog+ HDF Online also offers the therapy types hemodiafiltration and hemofiltration, in which the substitution solution is prepared online by the dialysis machine.

In this chapter, only those steps that differ from the hemodialysis procedure are described in detail.

The user is responsible for the surveillance of the hygienical soundness of the dialysis machine and the produced dialysis- and substitution fluid.

Pay regard to present regional regulations if necessary.

WARNING!

Risk to the patient due to contamination and pyrogenic reaction caused by unsuitable filter membranes!

- Only B. Braun Diacap Ultra filters may be used for HDF/HF therapy.
- Concerning the use of other filter types please contact B. Braun Avitum AG.
- Always observe the instructions for use provided with the filters.

WARNING!

Risk to the patient due to contamination and pyrogenic reaction caused by germ growth in the permeate or in the dialysis fluid!

- Execute regularly microbiological reviews of permeate and dialysis fluid/ substitution fluid.

9.1 Preparing for Hemodiafiltration/Hemofiltration

WARNING!

Risk to the patient due to contamination and pyrogenic reaction caused by germ growth during extended idle times for the system between treatments.

- Disinfect the dialysis machine before a new treatment especially after extended idle times.
- The responsible organization should develop a hygienic plan which defines disinfection programs.

9.1.1 Calling up Hemodiafiltration/Hemofiltration

Following switch-on and termination of disinfection the Dialog+ HDF Online dialysis machine displays the following main screen:

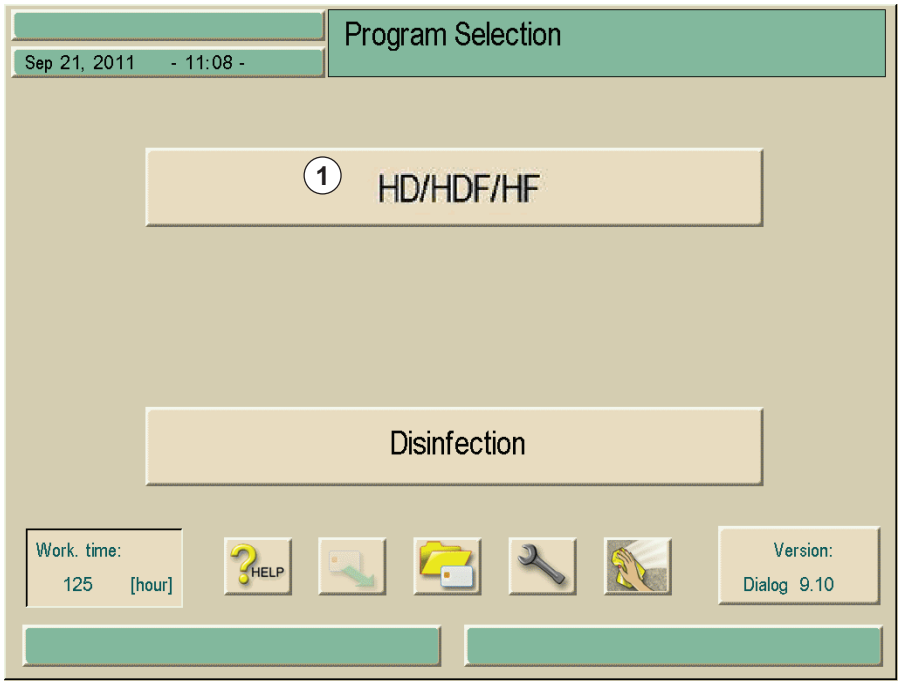


Fig. 9-1 Main screen " HD/HDF/HF"

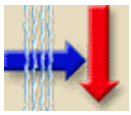
1. Touch field **1**.

   ↳ The first preparation screen for HD/HDF/HF is displayed. The dialysis machine starts an automatic test sequence.

9.1.2 Connecting Concentrate

See section 5.5 Connecting Concentrate (75).

9.1.3 Entering Substitution Parameters



1. Touch icon.

   ↳ A screen showing the substitution parameters is displayed.

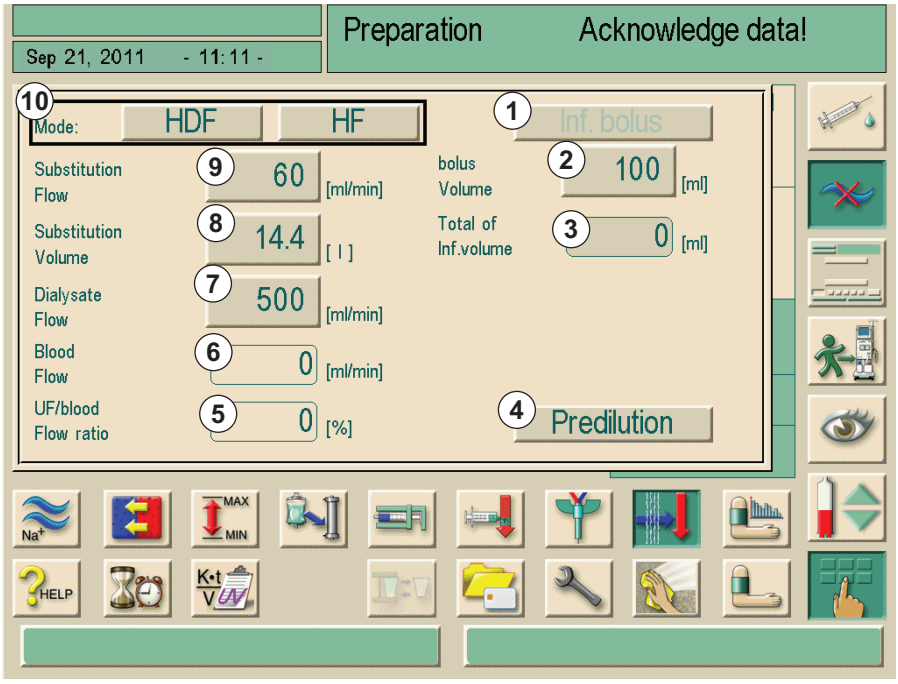


Fig. 9-2 "Substitution parameters HDF" screen

9

1. For hemodiafiltration touch field **HDF**,
   for hemofiltration touch field **HF**.

   ↳ The online system for substitution is activated now.

In this way the HDF/HF mode can be activated even during a running hemodialysis. However, in this case the substitution line will not be tested. Therefore, special care must be taken when connecting the line. Therefore, pay special attention to ensure that the direction of the pump operation corresponds with the desired flow direction of the substitution solution!

1. Set the treatment parameters for HDF/HF.

Item	Text	Value range	Description
1	Inf. bolus	-	Activates administration of an infusion bolus during therapy.
2	Nominal bolus volume	50 - 250 ml	-
3	Total of inf. volume	-	Total bolus volume administered, including arterial bolus if applicable.
4	Predilution	activated/deactivated	When activated, the UF/blood flow ratio monitoring function is turned off.

Item	Text	Value range	Description
5	UF/blood Flow ratio	-	Displays the ratio between blood flow (per minute) and total UF rate (per minute).
6	Blood flow	-	Displays the current blood flow rate.
7	Dialysate Flow	500 - 800 ml/min Preset to 600 ml/min for postdilution Preset to 700 ml/min for predilution	This field is displayed only if **HDF** was selected. For **HF**, the value is fixed to 500 ml/min.
8	Substitution Volume	max. 192 l	Substitution flow and substitution volume are interdependent. When one of the parameters is changed, the other is adjusted automatically.
9	Substitution Flow	20 - 400 ml/min	
10	Mode	HDF or HF	Activates HDF or HF mode.

The substitution fluid temperature corresponds to the dialysis fluid temperature (see chapter 5.9.1 Setting Dialysis Fluid Parameters (84)).

9.1.4 Inserting Blood Line System with Level Chambers

1 Venous pressure sensor
2 Arterial pressure sensor
3 Arterial blood pump
4 Heparin pump
5 Pressure sensor dialyzer input pressure
6 Dialyzer
7 Adapter predilution
8 Path of the substitution line with predilution
9 Path of the substitution line with postdilution
10 Online substitution pump
11 Substitution port outlet
12 Substitution port reflow
13 Venous tube clamp
14 Safety air detector/red sensor

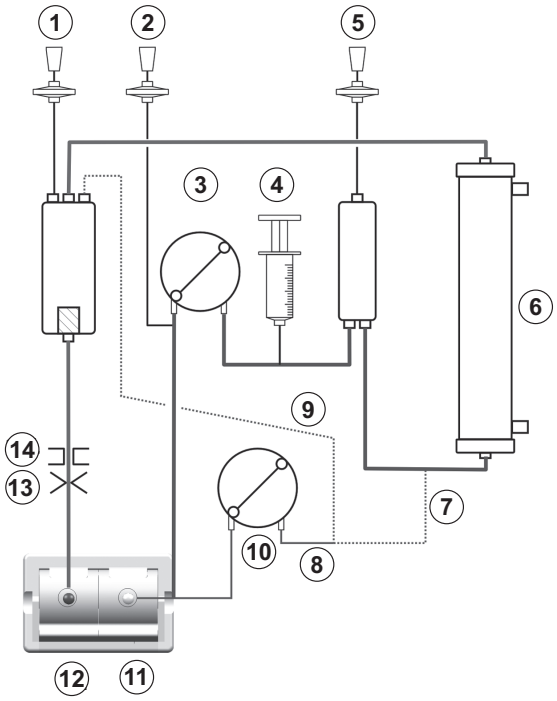


Fig. 9-3 Blood line system for HDF/HF therapy, connected for online rinsing

9.1.5 Priming Blood Line System with Fluid from Substitution Port

The Dialog+ HDF Online dialysis machine allows priming the blood line system and the dialyzer with substitution solution prepared by the machine. The rinsing liquid is taken from the machine and recycled back to it.

The dialysis solution is only available if all DF tests are passed and no DF alarm is due to be dealt with.

The following information window is displayed during the automatic test:

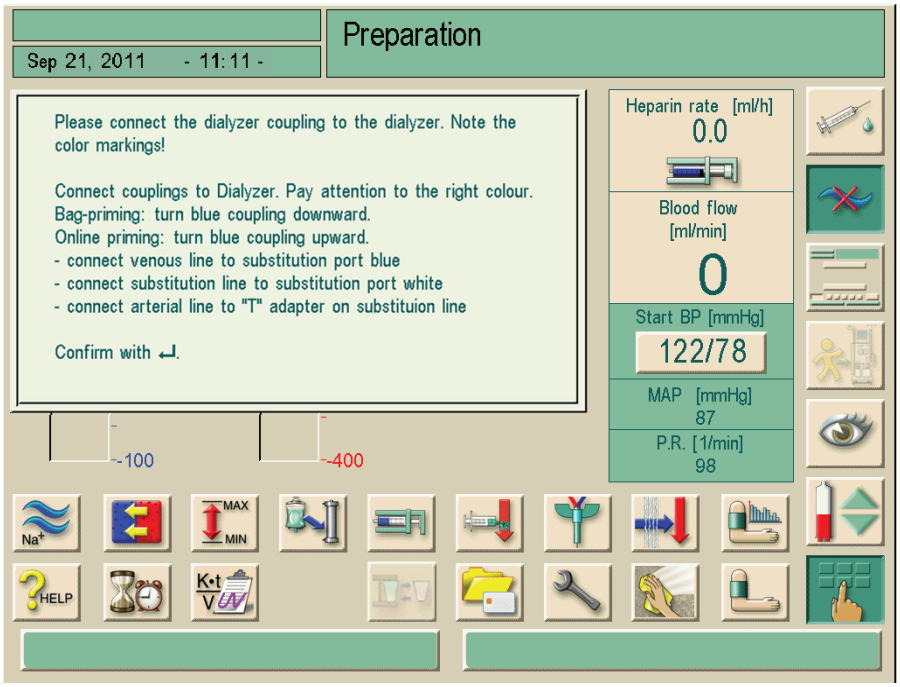


Fig. 9-4 Information window for connection

1. Take dialyzer connections from rinsing bridge and connect to dialyzer. Observe color-coding.
2. Turn dialyzer with blue connection facing **upward**.
3. Open substitution port outlet **2** and connect substitution line.
4. For **postdilution**, connect the other end of the substitution line to the venous bubble catcher. For **predilution**, connect the other end of the substitution line with the additional adapter upstream from the dialyzer.
5. Connect arterial patient connection to the Luer-lock connector of the substitution line between substitution port outlet and substitution pump.
6. Insert pump segment of the substitution line into the venous blood pump.
7. Connect venous patient connection to substitution port reflow **1**.
8. Confirm correct connection of dialyzer and substitution line by pressing Enter key on the monitor.

   ↳ The blood line system and the substitution line will be filled with substitution solution.

⚠ WARNING!

Risk to the patient due to air infusion!
Usage of ultrasound gel for insertion of blood line or a coagulum in the blood line will cause improper functioning of the safety air detector (SAD).

- Do not use ultrasound gel to ease inserting blood line into the SAD.
- Prevent clotting in blood lines and dialyzer during treatment.

↳ After approx. 10 seconds the following information window appears:

Fig. 9-5 Information window for level adjustment

9. Set level as follows:
   - Fill chamber in front of the blood side dialyzer inlet to about half full.
   - Fill venous drip chamber up to approx. 1 cm from the top.
10. Make sure the blood line and the dialyzer are completely filled with solution before confirming the window and turning the dialyzer.
11. Confirm correct settings by pressing the Enter key on the monitor.
    - The dialysis machine will test the blood line system and the substitution lines.
    - As soon as the automatic test is passed successfully, the rinsing program starts running with the set rinsing parameters.

The dialysis machine can also be conditioned with rinsing solution from bags, see section 5 Preparing for Hemodialysis (69).

9.1.6 Inspecting Blood Line System

⚠ DANGER!

Risk to patient due to uncontrolled ultrafiltration caused by leaks in the substitution line and at its connectors!

- Check substitution line and its connectors for external leaks prior to every treatment.
- Check substitution line and its connectors for leaks at regular intervals during complete therapy.

9.2 Preparing for Standard HD with Fluid from Substitution Port

It is possible to use the online fluid to prime for a standard HD treatment without using a substitution line.

1. Set-up standard double-needle blood line system as usual without connecting the arterial and venous patient Luer-Lock connectors.
2. In Program Selection, select "HD/HDF/HF".
   - ↳ The confirmation window (Fig. 9-4 Information window for connection (148)) appears.
3. Take dialyzer connections from rinsing bridge and connect to dialyzer. Observe color-coding.
4. Turn dialyzer with blue connection facing **downward**.
5. Connect the arterial line to the substitution port outlet (white).
6. Connect the venous line to the substitution port reflow (blue).
7. Confirm correct connection of dialyzer by pressing the Enter key on the monitor.

The blood line is filled with saline from the online port. Follow description in chapter 9.1.5 Priming Blood Line System with Fluid from Substitution Port (147).

1 Venous pressure sensor
2 Arterial pressure sensor
3 Arterial blood pump
4 Heparin pump
5 Pressure sensor dialyzer input pressure
6 Dialyzer
7 Online substitution pump (not used)
8 Substitution port outlet
9 Substitution port reflow
10 Venous tube clamp
11 Safety air detector/red sensor

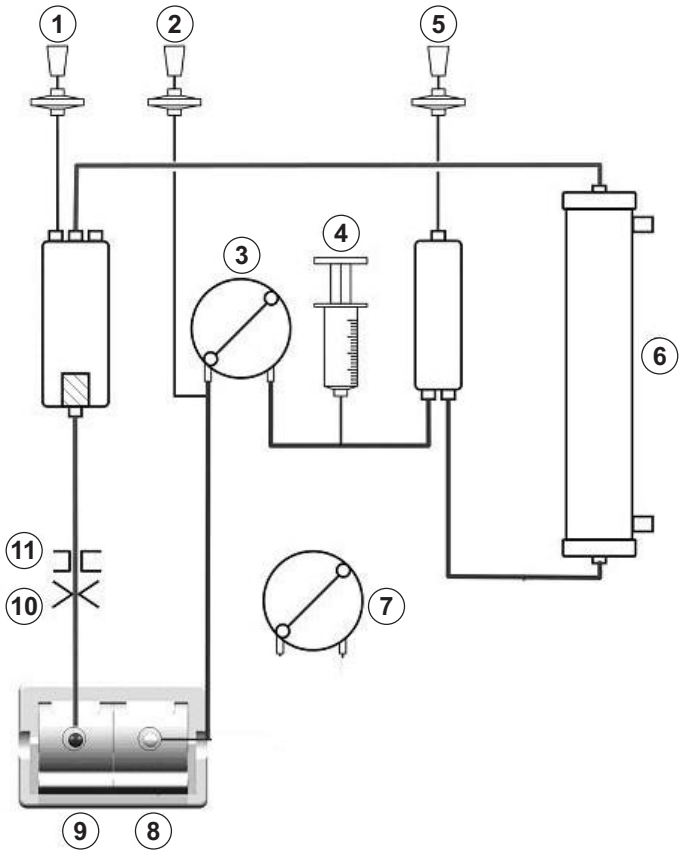


Fig. 9-6 Blood line system for HD with online fluid

9.3 Carry Out Hemodiafiltration/Hemofiltration

9.3.1 Connect Patient and Start Hemodiafiltration/Hemofiltration

⚠ DANGER!

Risk to patient due to blood loss caused by wrong positioning of the substitution line!

- Inspect the substitution line for its flow direction prior to every treatment.
- Position substitution line always prior to self test.
- It is recommended to use only substitution lines produced by B. Braun.

As soon as the patient data have been confirmed, the therapy screen is displayed with a window requesting "Connect patient".

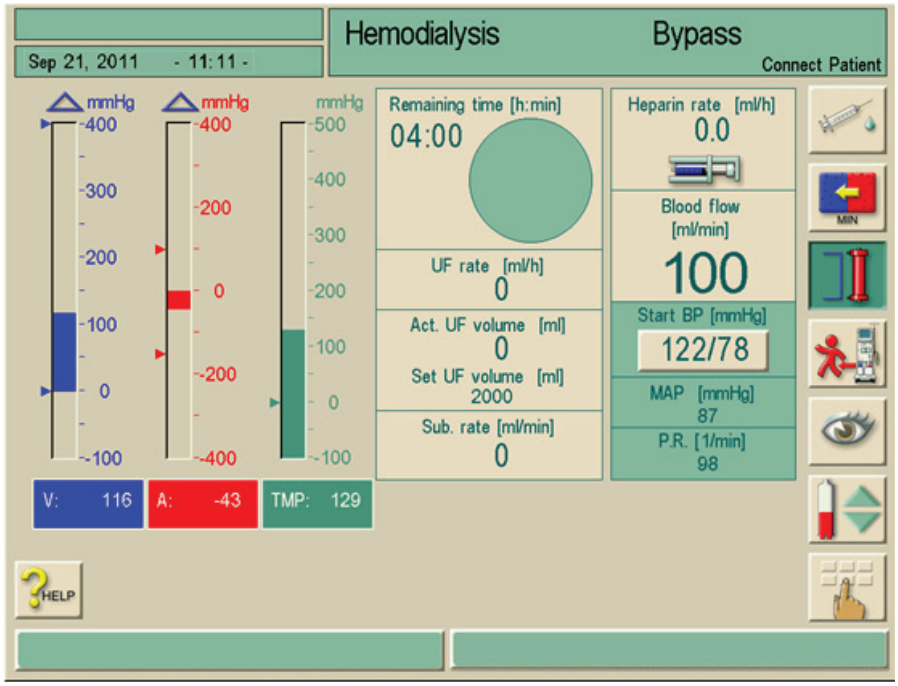


Fig. 9-7 Therapy screen "HDF/HF"

⚠ WARNING!

Risk of poisoning the patient if substitution port contains any disinfectant residue!

- After the use of disinfectants, check to make sure that the substitution port and the outlet are free from disinfectants!

⚠ WARNING!

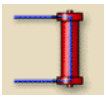
Risk of infection due to germ contamination of the substitution port!

- Observe hygiene aspects when connecting the arterial and venous blood lines.
- Do not touch the connectors with your bare hands.
- If necessary, disinfect with a suitable disinfectant.

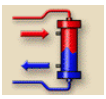
⚠ WARNING!

Risk of infection due to germ contamination of the connecting lines!

- Observe hygiene aspects when connecting the arterial and venous blood lines.
- Seal the connector on the substitution line with a suitable stopper.

1. Remove the arterial line from the substitution line and connect it to the patient.
2. Start blood pump by pressing **START/STOP** button on monitor.
   ↳ The blood pump operates automatically at the preset rate.
3. Fill blood line system with blood.
   ↳ The blood pump stops automatically if blood is detected at the red sensor downstream from the safety air detector.
4. Remove the venous blood line from substitution port reflow and connect it to the patient.
5. Close the substitution port.
6. Start blood pump by pressing **START/STOP** button on monitor.
7.  Touch icon.
   ↳ The dialysis machine switches to main connection and the hemodiafiltration/hemofiltration is started.
   ↳ The signal lamp on the monitor lights up green.

If the blood pumps are stopped manually or deactivated, the patient connection will be interrupted (venous pressure rises).

1.  Press the icon to continue patient connection after interruption.

9.3.2 During Hemodiafiltration/Hemofiltration

In the same way as during hemodialysis, the following additional functions are available during hemodiafiltration/hemofiltration:

- Treatment at minimum UF rate
- Administration of a heparin bolus
- Administration of an arterial bolus
- Halting the hemodiafiltration/hemofiltration

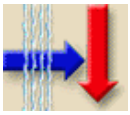
Administering an infusion bolus is also possible.

Infusion Bolus

⚠ CAUTION!

Loss of blood pressure because of missing volume for the stabilization of the circulation if the DF-flow is interrupted by a technical defect or by switching into bypass.

- Keep a NaCl-bag ready for infusion or reinfusion.



1. Touch icon.

   ↳ The substitution parameters and infusion bolus screen is displayed.

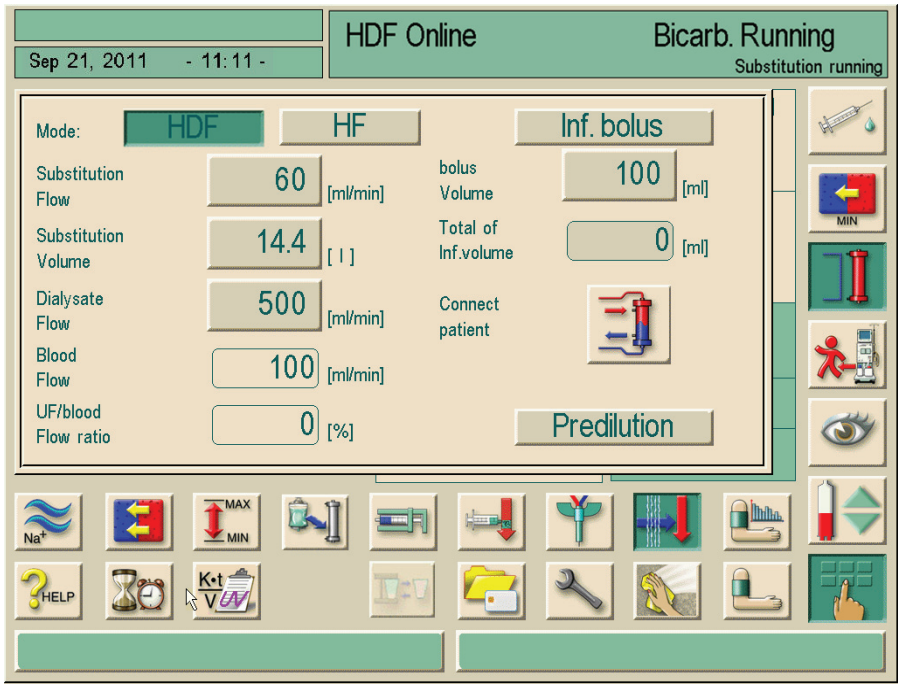


Fig. 9-8 "Substitution parameters HDF" screen

2. Adjust bolus volume if necessary. To end this, touch field **bolus Volume** and enter new setting.
3. Touch field **Inf. bolus** and acknowledge information by pressing Enter key on the monitor.

   ↳ The infusion of the bolus is started. The blood pump operates at 100 ml/min, the substitution pump at 200 ml/min. The infused volume is added up in the field **Total of Inf. volume.**

   ↳ As soon as the bolus has been administered completely, blood flow and substitution flow automatically reset to their original values.

Halting the Bolus Administration

1. Touch field **Inf. bolus** again during bolus administration.

   ↳ Bolus administration is stopped.

The bolus volume is not added to the ultrafiltration volume automatically so that it remains with the patient.

9.4 Finish Hemodiafiltration/Hemofiltration

At the end of the therapy an acoustic signal is sounded. The message *"Therapy time over"* is displayed. The dialysis machine reduces the UF rate to 50 ml/h.

1. Touch icon.

   ↳ A query window *"End of Therapy"* pops up

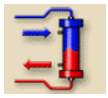
2. Confirm end of treatment by pressing Enter key on the monitor.

   ↳ The treatment is finished.

9.4.1 Reinfusion with Substitution Fluid

During the reinfusion phase, the limit windows are set to their maximum values. The reinfusion phase, therefore, demands particular care.

1. Touch icon.



   ↳ The following screen is displayed:

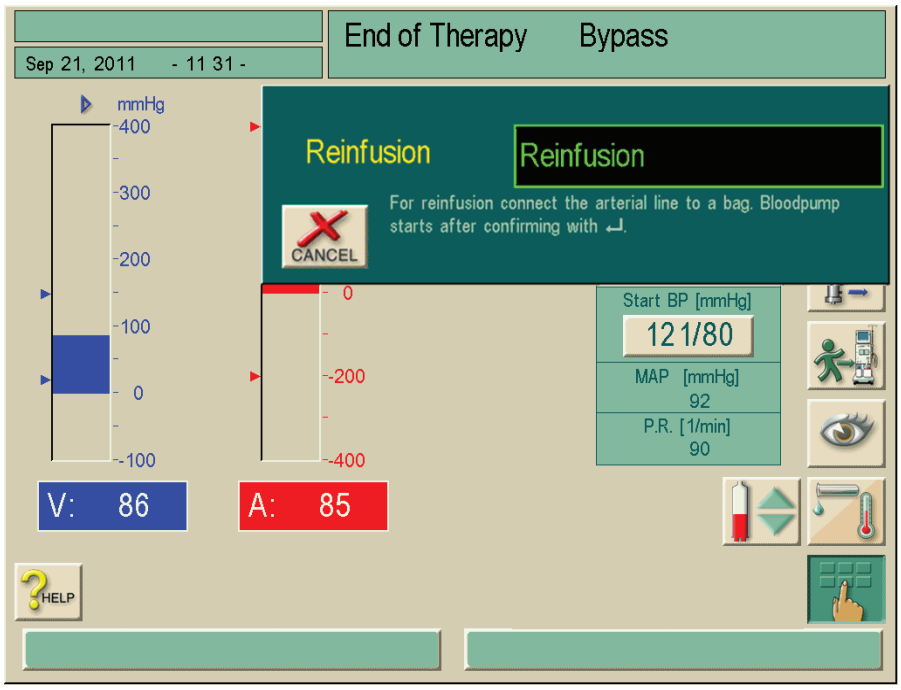


Fig. 9-9 "Confirm reinfusion" screen

The "Confirm reinfusion" screen (Fig. 9-9) appears only if configured accordingly in the service program. Otherwise, reinfusion must be called up by pressing icon **1** (Fig. 9-10).

⚠ WARNING!

Risk of infection due to germ contamination of the connecting lines!

- Observe hygienic aspects when connecting the arterial and venous lines.
- If necessary, disinfect with a suitable disinfectant.

In case a substitution line is used:

1. Remove arterial connection from patient.
2. Connect the arterial line to the rinsing connector of the substitution line between substitution port and substitution pump.
3. Open the clamp at the branch-off of the substitution line.

In case a standard HD treatment is completed and no substitution line is used:

1. Connect adapter to the substitution port outlet (see Fig. 9-3 Blood line system for HDF/HF therapy, connected for online rinsing (147)).
2. Connect arterial line to the adapter.
3. Confirm reinfusion phase by pressing Enter key on the monitor.
   ↳ The blood pump is started.

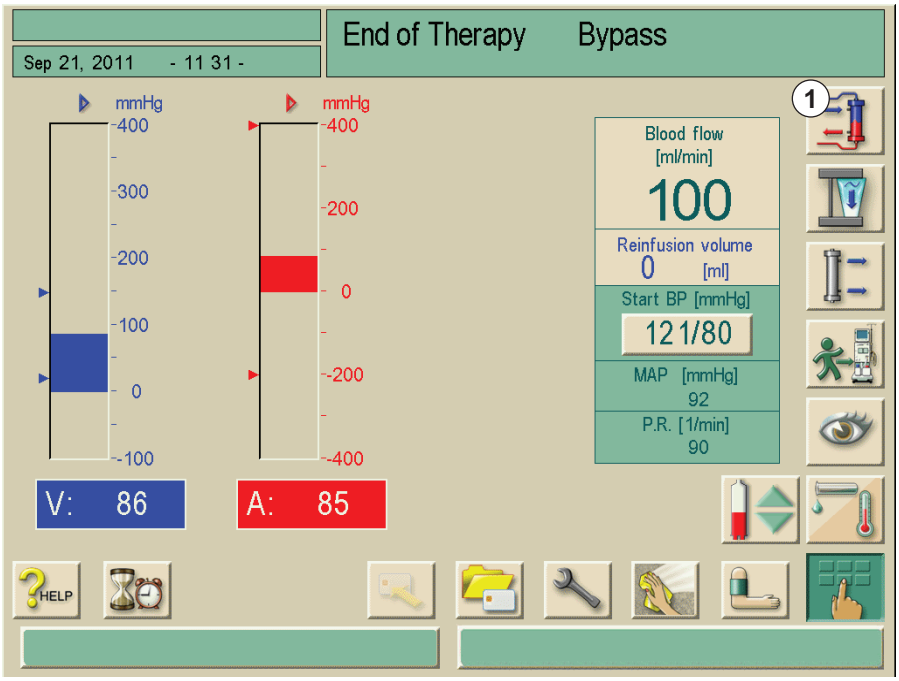


Fig. 9-10 "End of Therapy" screen with reinfusion activated

The dialysis machine monitors the reinfusion volume and reinfuses until the red detector recognizes a preset dilution level of the blood. The blood pump stops.

1. To continue reinfusion, press **START/STOP** button on the monitor.
   ↳ The blood pump also stops automatically after 400 ml have been reinfused or once a reinfusion time of 5 minutes has been achieved.
2. Disconnect venous patient connection.

It is also possible to connect the arterial line directly to the port outlet without an adapter. A long disinfection is mandatory directly after this procedure.

⚠ CAUTION!

Risk to patient due to cross contamination.

- Perform a long machine disinfection directly after End of Therapy in order to clean and disinfect the online ports correctly.

9.4.2 Emptying the Dialyzer

See section 7.3 Emptying the Dialyzer (117).

9.5 Disinfection

9.5.1 Regular Disinfection

The regular disinfection after a dialysis and in the morning prior to the first dialysis is described in chapter 8 Disinfection (121).

⚠ WARNING!

Changes to the material characteristics of the housing, encapsulation and capillaries of the filter due to unsuitable disinfectants!
Endangering of patient! Dialyzer is no longer safe to operate!

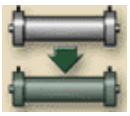
- Only use suitable disinfectants.
- Check information supplied with filter.

⚠ WARNING!

Scalding or alkali burn risk to users due to disinfectant solution escaping from the substitution port or the filter holders!
The substitution connection and the filter holder heat up during disinfection.

- Do not open the substitution port or the filter holder during disinfection.
- Make sure that the substitution port is closed correctly.

9.5.2 Displaying the Online Filter Data



1. Touch icon.
   ↳ The remaining operating time and the number of dialysis performed are displayed.

9.5.3 Changing the Online Filter

The online filters must be changed at the latest when the following information window pops up on the screen:

Fig. 9-11 Information window "Filter change"

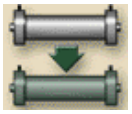
⚠ WARNING!

Contamination and pyrogenic reaction risk to patient due to infusion of contaminated fluid in case of a ruptured HDF/DF filter!

- The HDF/DF filters are designed for regular use. Avoid extended idle times without disinfection (according to the hygiene plan of the dialysis center).
- Do not use the filters after the filter service life has expired because, otherwise, the required quality of substitution solution cannot be ensured.

NOTICE!

We recommend disinfection with Tiutol KF prior to changing the dialysis fluid filters.



1. Touch icon.
   ↳ The selection menu appears.
2. Touch icon.
   ↳ The following window appears:

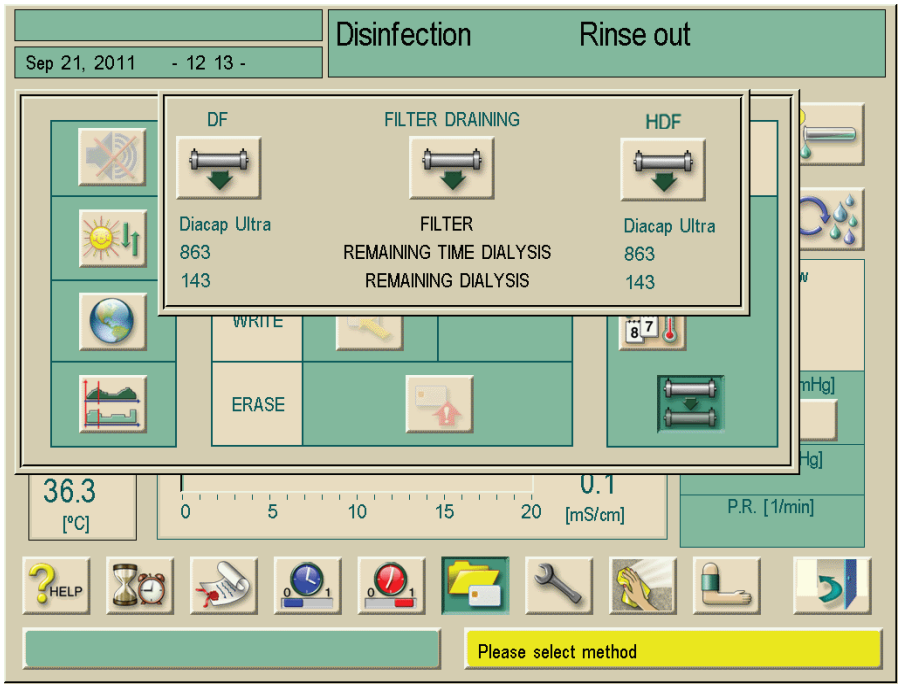
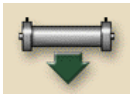


Fig. 9-12 Information window "Empty filters"



3. Touch middle icon "FILTER DRAINING".
   - A message asking you to open the substitution port is displayed.
4. Open the substitution port.
   - The filters are emptied and aerated. After approx. 90 s the message "HDF filter empty" is displayed.

For complete emptying, the emptying button should remain active for about 3 to 5 minutes. Minor residues remaining in the filters are unavoidable.

5. For the HDF filter, open filter cover **1**; for the DF filter, open filter cover **2**. Use a suitable screwdriver and open the cover.
6. Remove used-up filters and replace them with new ones.
7. Close the filter cover(s) and relock them with the screwdriver.

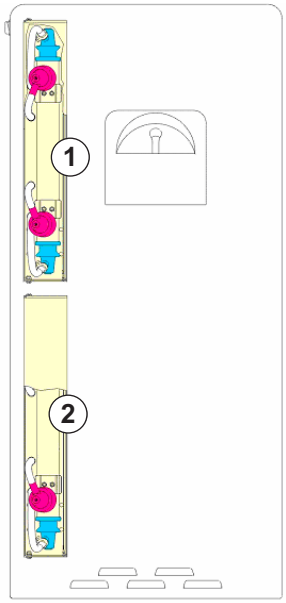


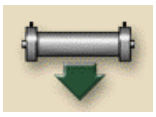
Fig. 9-13 Filter housing with cover

⚠ WARNING!

Risk to patient due to ultrafiltration deviation.

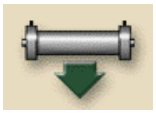
Kinked connection tubes can cause ultrafiltration deviations.

- Check that connections tubes to and from the DF filter and Online filter are not kinked or pinched.



8. To complete the filter change, touch the middle icon "EMPTY FILTERS" once more.

9. Close the substitution port.



10. Reset the filter data using the icons "DF" and "HDF".
11. Fill and rinse the filter.
12. Carry out disinfection with citric acid 50 %.

9.5.4 Sampling of Substitution Fluid

For hygienically faultless sampling of the above mentioned fluid proceed as follows.

1. Prepare the machine as usual.
2. Insert the substitution line.
3. Start therapy (without patient).
4. Adjust substitution rate to 200 ml/min.
5. Extract the required amount for your sample from the infusion connection of the substitution line.
6. End therapy.
7. Start disinfection.

Table of Contents

10 Single-Needle Procedures

⚠ WARNING!

Risk to patient due to single-needle procedure or to patients with central venous catheter!
Negative pressure can cause air in the blood line system.

- Connect the venous blood line tightly to patient access to avoid that air is infused to the patient.
- Observe pressure to be positive.

10.1 Single-Needle Cross-Over (SNCO)

In the following we describe the single-needle procedure only as far as it differs from double-needle dialysis. For detailed operating information see chapter 5 Preparing for Hemodialysis (69), 6 Initiating Hemodialysis (99) and 7 End of Therapy (115).

10.1.1 Preparing SNCO Therapy

Insert Blood Lines

⚠ WARNING!

Risk to the patient due to blood loss or hemolysis!
Using a faulty blood line system or leaks in blood line system upstream of tubing clamp result in blood loss. Any narrow passage in the extracorporeal circuit (e.g. kinks in the blood line or too thin cannulas) may cause hemolysis.

- Check that the blood line system is not damaged.
- Make sure that all connections are tight and leakproof.
- Check that no blood line is kinked.
- Choose a cannula size which provides the required mean blood flow.

The following is required:

- SNCO blood line system
- Dialog+ with two blood pumps

1. Insert arterial tube and chamber.
2. Push arterial tube through arterial tube clamp.
3. Insert venous tube and chamber.
4. Push venous tube through venous tube clamp.
5. Insert venous pump segment into venous blood pump just immediately before connecting the patient.
6. Connect pressure sensors PA, PBE, PBS and PV. Check for secure seat.

SNCO can also be activated or selected with a therapy in progress.

If the PBS pressure sensor is connected during an ongoing therapy, and the SNCO modus is selected, then, the dialysis machine checks the PBS pressure sensor and the plausibility of the action. The result must be confirmed by pressing the Enter key on the monitor.

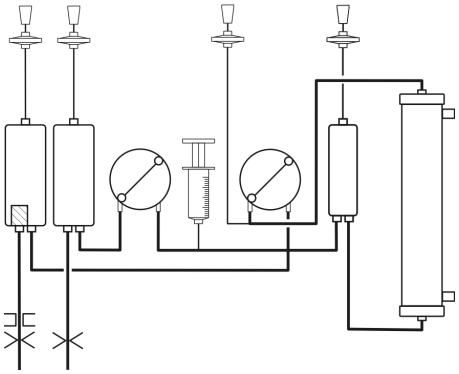


Fig. 10-1 Single-Needle Cross-Over (SNCO) blood line system

WARNING!

Risk of blood loss due to arterial line leakage upstream of the tube clamp!

- Ensure that there are no connection leaks and that the blood line system is fully intact.

WARNING!

Risk of low blood flow and thus reduced treatment efficacy!
If user fails to open clamp on arterial line after changing blood line system/ therapy mode an reconnecting patient, extremely negative prepump pressure occurs.

- Open clamp on arterial line after reconnecting patient.

Setting the SNCO Mode

1. Touch icon.

1 Set SNCO parameters
2 Activate SNCO parameters
3 Connect patient
4 Call up single-needle selection

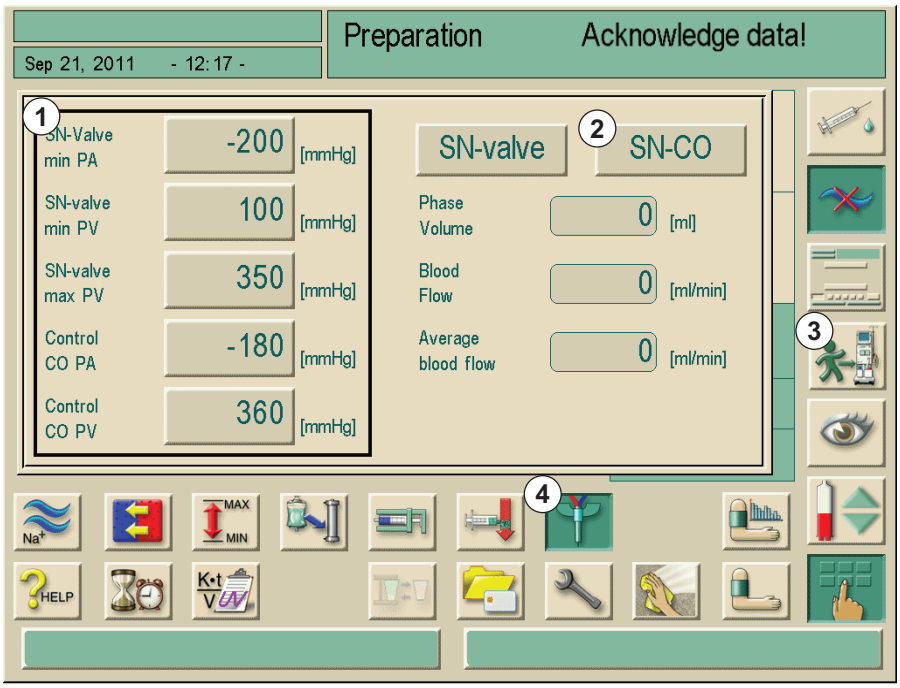


Fig. 10-2 Single-Needle Cross-Over (SNCO)

1. Touch SNCO field.
   - Fields not needed will be hidden.

1 Set Single-Needle Valve min PA
2 Set Single-Needle Valve parameters (min PV/ max PV)
3 Activate Single-Needle Cross- Over parameters

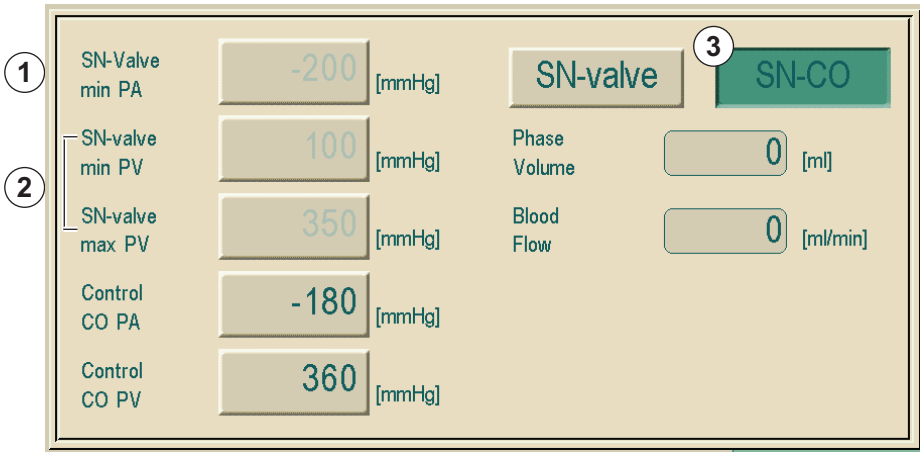


Fig. 10-3 Single-Needle Cross-Over parameters

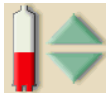
1. Fill and rinse blood line system, see section 5.7 Inserting and Rinsing the Blood Line System (77).
2. Set level in chambers as follows:
   - arterial approx. 50 % of chamber volume
   - venous approx. 35 % of chamber volume
   - After completion of preparations, icon **3** is enabled.

10.1.2 Level Regulation (if present) in Single-Needle Procedure

The level regulation system allows the user to set blood levels in the blood line chambers in single-needle cross-over mode by screen touch.

The user is obligated to check for correct setting of the levels in the chambers.

In SNCO mode, the blood level regulation requires a previous blood pump stop automatically performed by the machine.



1. Touch icon.
   - The level window opens. All chambers are paled (inactive).

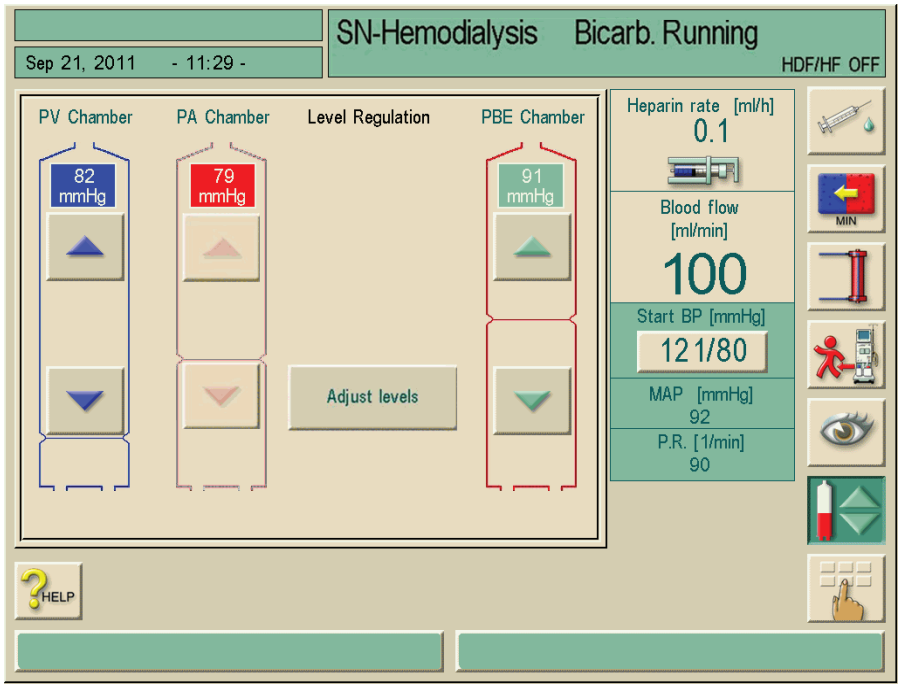


Fig. 10-4 Level regulation screen in single-needle

1. Touch button.
   - A supervisor window opens.

1. Confirm by pressing the Enter key.
   - Blood pump stops automatically. Pressure equalization is performed by opening the arterial and venous clamp.
   - The chambers are active and ready to adjust.

Level Increasing

1. Touch icon gently with one touch and observe level.
2. Touch again for the correct setting if necessary.

Level Decreasing

1. Touch icon gently with one touch and observe level.

The level regulation is performed with the preset blood flow speed, but with a maximum of 400 ml/min.

1. To determine the level regulation process, press button “Adjust levels”

or

1. press level regulation icon.
   ↳ Blood pump restarts automatically with preset values.

⚠ WARNING!

Risk to the patient due to infection by contamination of the manometer protection filter of the blood lines!

- Change manometer protection filter on the machine if the manometer protection filter of the blood lines has been in contact with blood.
- Contact technical service for manometer protection filter change.

⚠ WARNING!

Risk of reduced dialysis efficacy!

- Ensure that no air enters into the dialyzer when decreasing the level in the arterial and in the PBE chamber.

10.1.3 Running SNCO Therapy

1. Touch icon.
   ↳ The dialyzing machine switches to connection mode.
2. Confirm patient data, see section 6.1 Checking Patient Data (99).
3. Connect arterial tube.
4. Insert tube segment of venous blood pump. Ensure that the pressure gauge line for the blood pump control pressure is located upstream of blood pump inlet.
5. Start blood pumps.
6. Fill blood line system with blood.
7. Stop blood pumps.
8. Connect venous tube to patient.
9. Restart blood pumps.
   ↳ At 150 ml/min for central catheter
   ↳ At approx. 100 to 120 ml/min for fistula connection
   ↳ The dialysis is started.
10. Increase blood pumping rate, taking into account the phase volume.

Alternatively, the double-needle mode could be used. Therefore, the venous pump tube segment will be inserted after connecting the venous patient access.

- Then change into SN-mode.
- Confirm window on the screen.
- Start blood pump.

Dialysis starts.

⚠ WARNING!

Risk to patient due to reduced dialysis efficacy because of a high recirculation ratio with a small phase volume!

- Set phase volume between 30 and 35 ml.
- Use vascular accesses with flow rates as high as possible.

Changing the Phase Volume

For changing the phase volume, the control pressures can be set within certain limits depending on the patient's connection conditions.

For	Arteriel control pressure CO PA	Venous control pressure CO PV
Central catheter	up to -200 mmHg	360 to 390 mmHg
Good fistula		
Delicate fistula	up to -150 mmHg	300 mmHg
First puncture	-120 to -150 mmHg	250 to 300 mmJHg

1. If necessary, change phase volume through control pressures **CO PA** and **CO PV**:
   - To increase the phase volume: Increase interval between **CO PA** and **CO PV**.
   - To decrease the phase volume: Reduce interval between **CO PA** and **CO PV**.

During Dialysis

1. Observe levels in arterial and venous chamber. If necessary, change levels in field **SN chamber level**, see below.
2. Observe phase volume.

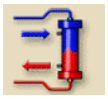
The phase volume reacts to:

- Changes in the blood flow
- Changes in the control pressures
- Blood levels in the chambers
- Pressure changes in shunt
- Blood pump stop in case of an alarm

1. In case of repeated alarms ”Phase volume to low”: Briefly reduce pump speed.
   ↳ The limits are reset.

10.1.4 Ending SNCO Therapy

The therapy ends automatically or after touching the respective icon. Also observe the following steps.



1. Leave tube segment of venous blood pump in venous blood pump.
2. Always start reinfusion by pressing the appropriate icon.
3. Disconnect patient, see chapter 7 End of Therapy (115)

Alternatively, it can be re-infused by double-needle mode.

- Touch field **2** in SNCO window (Fig. 10-2 Single-Needle Cross-Over (SNCO) (165)).
- Deactivate SNCO.
- Disconnect the patient (see chapter 8 Disinfection (121)).

10.2 Single-Needle Valve (SNV)

In the following we describe the single-needle valve procedure only as far as it differs from double-needle dialysis. For detailed operating information see 5 Preparing for Hemodialysis (69), 6 Initiating Hemodialysis (99) and 7 End of Therapy (115).

10.2.1 Preparing SNV Therapy

Inserting Tubes

The following is required:

- AV set for Single-Needle Valve (venous chamber 100 ml) or normal AV set for Dialog+ (venous chamber 30 ml)
- For Dialog+ single-pump machine: Option Single-Needle Valve with arterial tube clamp (without arterial tube clamp increased recirculation will occur)

⚠ WARNING!

Low effectiveness due to high recirculation ratio at small phase volumes when single-pump machines without Single-Needle Valve option are used!

- Set phase volume >12 ml.

1. Insert standard arterial tube.
2. Push arterial tube through arterial tube clamp (if present).
3. Insert venous tube.
4. Place venous tube through venous tube clamp.
5. Connect pressure sensors PA, PBE, PV. Check for secure seat.

Single-Needle Valve can also be selected during a running therapy.

Setting the Single-Needle Valve Mode

1. Touch icon.
   ↳ The following screen appears:

1 Set min. arterial control pressure
2 Set venous control pressure
3 Activate Single-Needle Valve parameters
4 Connect patient
5 Call-up Single-Needle selection

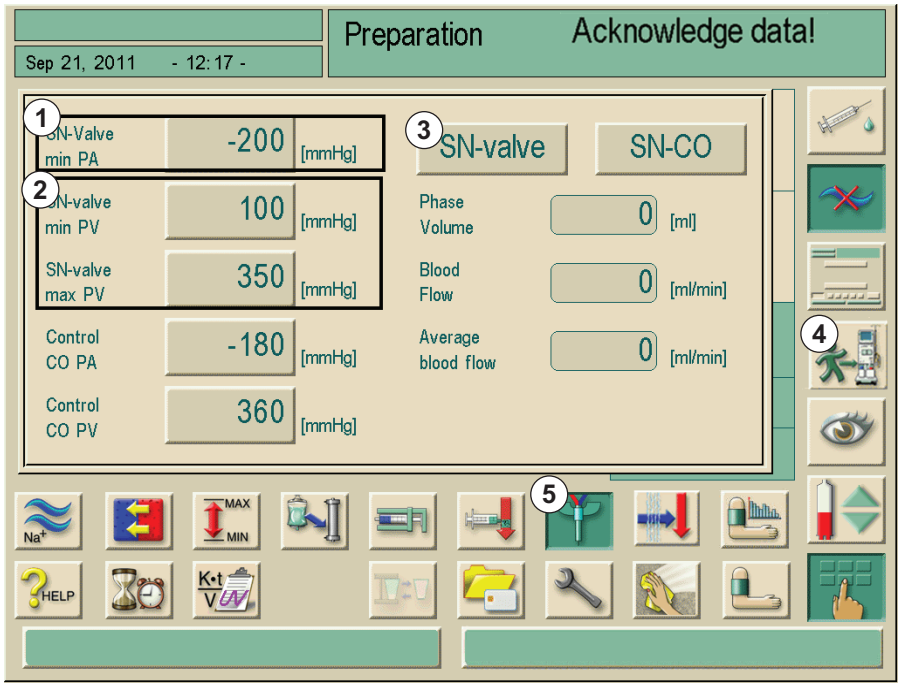


Fig. 10-5 Single-Needle Valve (SNV)

NOTICE!

It is possible to set a lower max. limit to protect the arterial pressure limit.

1. Touch field **Single-Needle Valve**.
   ↳ The field lights up in green.
   ↳ The preset control pressures **min. PV** and **max. PV** are displayed.

1 Set Single-Needle Valve min PA
2 Set Single-Needle Valve parameters (min PV/ max PV)
3 Activate Single-Needle Valve parameters

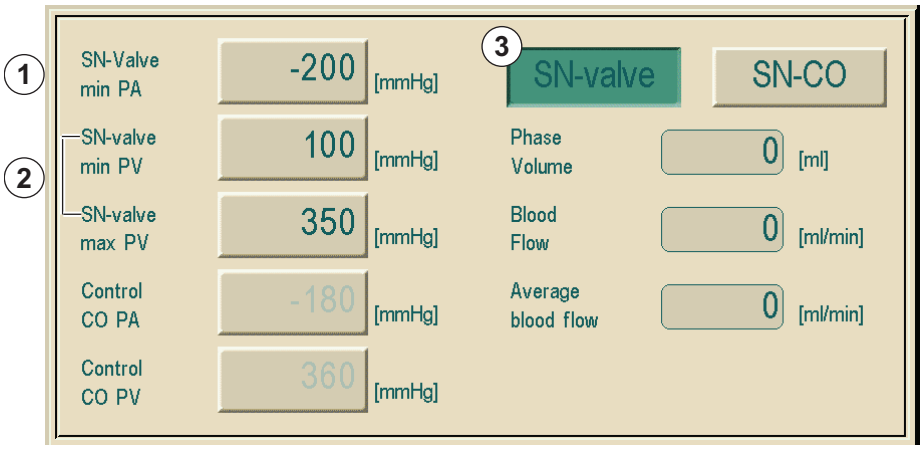


Fig. 10-6 Single-Needle Valve parameters

In order to achieve the highest effective blood flow at minimum recirculation, the control pressures must be set for an optimum phase volume.

10.2.2 Running SNV Therapy

1. Touch icon.
   ↳ The dialysis machine switches to therapy mode.
2. Confirm patient data, see section 6.1 Checking Patient Data (99).
3. Connect patient, see section 6.2 Connecting Patient and Starting Therapy (100).
4. Fill blood line system with blood. Fill level in venous chamber to only approx. 35 % in order to achieve a good phase volume.
5. Start blood pump and slowly increase speed depending on the vascular condition of the patient.
   ↳ The dialysis is started.

During dialysis, the following phase volume should be reached:

- For standard-AV set with 30 ml chamber: 12 – 18 ml
- For AV set for Single-Needle Valve with 100 ml chamber: 15 – 25 ml

In order to change the phase volume, the control pressures can be set within certain limits depending on the patient's connection conditions.

The level regulation system (if present) allows the user to set blood levels in the blood line chambers in Single-Needle Valve mode by screen touch. See section 10.1.2 Level Regulation (if present) in Single-Needle Procedure (165).

Effective blood flow in Single-Needle Valve is lower than blood flow displayed on the machine as the blood pump pumps in phases.

Recommendation

Lower venous control pressure min PV	Upper venous control pressure max PV
120 to 150 mmHg	up to 300 mmHg

1. If necessary, change phase volume through control pressures **min PV** and **max PV**:

- To increase the phase volume: Increase interval between **min PV** and **max PV**.
- To decrease the phase volume: Decrease interval between **min PV** and **max PV**.

1. Make certain the phase volume does not drop below 12 ml.

The phase volume reacts to:

- Changes in the blood flow
- Changes in the control pressures
- Blood levels in venous chambers
- Pressure changes in shunt

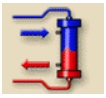
1. Observe level in venous chamber. If necessary, change level via field **SN chamber level**.
2. If necessary, adjust min. PV and max. PV, see section 6.3.1 Monitoring Blood Side Pressure Limits (104).

   ↳ The optimum return flow time is set automatically.

10.2.3 Ending SNV Therapy

The therapy ends automatically or after touching the respective icon, see section 6.4 Completion of Treatment (112). Also, observe the following steps.

1. Always start reinfusion by pressing the appropriate icon.



2. Disconnect patient, see chapter 7 End of Therapy (115).

Table of Contents

11 Use of Options

11.1 Automatic Blood Pressure Measurement (ABPM)

The option ABPM (automatic blood pressure measurement) allows non-invasive, oscillometric blood pressure measurements.

ABPM may only be operated by persons instructed for its appropriate use. Medical indication, patient population and operating conditions are the same as described for the machine.

ABPM works on the RR principle - the blood pressure measurement principle of the Italian physician Riva Rocci. The cuff is connected to a manometer. For blood pressure measurements, the ABPM automatically pumps up the cuff via an integrated pump and then deflates the cuff via an integrated deflating valve after blood pressure determination. ABPM controls the measurement limits. For more information refer to chapter Technical Data.

The blood pressure can be measured in the operating modes Preparation, Therapy and Disinfection.

ABPM blood pressure measurement offers the following functions:

- Simple immediate measuring prior, during and after the dialysis treatment.
- Clear display of blood pressure and pulse readings on the dialysis main screen
- Automatic, cyclic measuring
- Blood pressure based individual limits adjustment on the press of a button
- Optional color display of blood pressure and pulse curves
- Documentation of readings with time stamps
- Readings outside the limits are colored

⚠ WARNING!

Risk of hematoma formation caused by frequent blood pressure measurements of patients who take coumarins or other anticoagulant substances.

NOTICE!

The automatic blood pressure measurement function does not release users from the obligation to regularly monitor the patient.
The information transmitted and displayed by the option may not be used as only source of information for the medical indication.

ABPM must only be used with the ambient conditions specified in the chapter technical data, section Ambient conditions.

11.1.1 Handling of Old/New Cuff with ABPM

In order to improve therapy outcomes and patient comfort, B. Braun offers a new series of blood pressure cuffs for the option ABPM. To find out which module is assembled and cuff is needed, check the coupling in your machine and compare with the pictures below. Follow the appropriate instructions.

Fig. 11-1 Male coupling on the machine

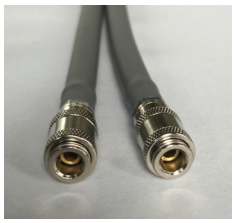


Fig. 11-2 Tubing female/female

1. Check if your Dialog+ contains the male coupling (Fig. 11-1).
2. Use tubing with two female couplings (Fig. 11-2).
3. Connect tubing with one female coupling to machine.
4. Connect same tubing with the other female coupling to cuff.
5. For further measurement, follow the instructions in chapter 11.1.2 Cuff (177).

Fig. 11-3 Female coupling on the machine

Fig. 11-4 Tubing female/male

1. Check if your Dialog+ contains the female coupling (Fig. 11-3).
2. Use tubing with one female coupling and one male coupling (Fig. 11-4).
3. Connect tubing with male ending to machine.

4. Connect tubing with female ending to cuff.
5. For further measurement, follow the instructions in chapter 11.1.2 Cuff (177)

11.1.2 Cuff

The cuffs delivered by B. Braunare latex free. This is also indicated by the symbol on the cuff.

⚠ WARNING!

Risk to the patient due to wrong measurements!
Using an unsuitable cuff will affect performance of the ABPM option.

- Only cuffs delivered by B. Braun should be used. Other cuffs must be qualified, e.g. by independent bodies.

The following cuffs are available for automatic blood pressure measurement ABPM:

- Small (upper arm size 18 – 26 cm)
- Medium (25 – 35 cm)
- Large (33 – 47 cm)
- Extra Large (42 - 54 cm)

A ”Medium” size cuff is supplied with every system delivered.

Applying the Cuff

⚠ WARNING!

Infection risk to the patient due to a contaminated cuff!

- When infectious (e.g. Hepatitis B) patients are treated, a separate cuff must be used for each patient.

1. Vent cuff prior to application. Compress cuff to let air escape.

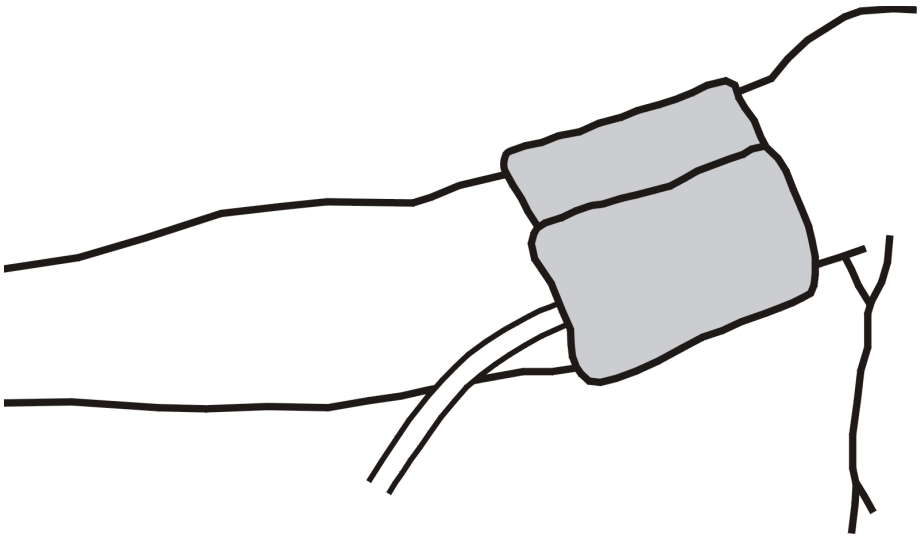


Fig. 11-5 Cuff

1. Apply cuff tightly in a suitable place around upper arm of the patient.
2. Place marking on inside of cuff over artery.
3. Ensure that cuff tube is not kinked.
4. If applicable, set measuring cycle to the desired time interval (1 - 60 min depending on the clinical situation).

Cuff should be positioned at heart level (middle of cuff at the level of the right atrium).

⚠ WARNING!

Risk to patient due to constrictions of body parts or interference of blood flow!
Continuous cuff pressure or too frequent measurements may result in constrictions of body parts or interference of blood flow.

- Avoid too frequent measurements.
- Regularly check body parts.
- Ensure that cuff tube is not kinked.

⚠ WARNING!

Risk to patient due to reduced dialysis efficacy!

- Do not apply cuff on the shunt arm.
- Do not apply cuff on limbs used for intravenous infusion or hemodialysis.

⚠ WARNING!

Risk to patient if cuff is placed over a wound!
Wound could burst open again.

- Never apply a cuff over a wound.

⚠ WARNING!

Risk to patients after mastectomy due to lymphostasis!

- Do not apply the cuff to the arm on the side of a mastectomy.
- Use other arm or leg for measurement.

NOTICE!

- Apply cuff tightly making certain that there is no venous flow-back or skin discoloration.
- Do not apply cuff in areas where blood circulation is impaired or where there is a risk of impairment to the blood circulation.
- Apply cuff as closely as possible to the forearm (approx. 2 cm above the elbow).
- Using the wrong cuff size can lead to wrong measurements.

Cleaning/Sterilizing the Cuff

NOTICE!

Never autoclave the cuff.

1. Ensure that no fluid enters the tube connections during cleaning.
2. Only clean cuff with soapy water or an alcohol solution (e. g. Meliseptol)

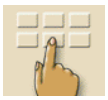
Sterilizing the Cuff

1. Only sterilize the cuff with ethylene oxide (ETO).

Connecting the Cuff Tube to the Dialysis Machine

1. Connect cuff tube to tube connection for blood pressure measurements at the dialysis machine. Ensure correct seat of connections.

11.1.3 Settings



1. Touch icon.
   ↳ The setting menu appears.

2. Touch icon.
   ↳ The ABPM main view appears:

1 Set the alarm limits
2 Set the cycle time, in minutes
3 Activate/deactivate cyclical measurement
4 Start/Stop ABPM

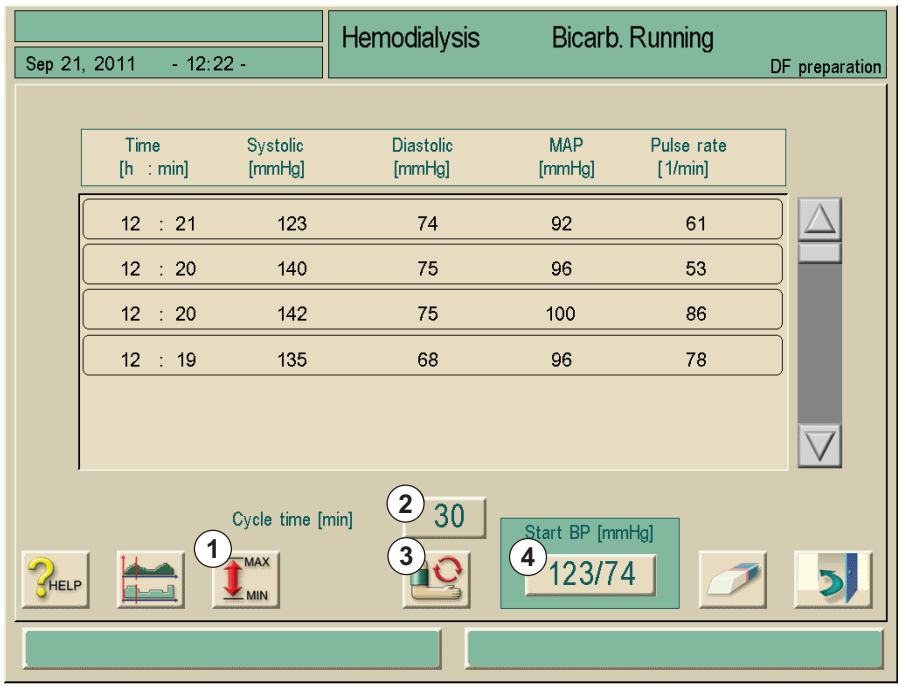


Fig. 11-6 "ABPM main view" screen

The window shows the data of the last two measurements:

- Time: Time (h:min)
- Systolic pressure: Systole (mmHg)
- Diastolic pressure: Diastole (mmHg)
- Mean pressure: MAP (mmHg)
- Pulse: Rate (1/min)

Setting for Cyclical Measurement

1. To set the measuring period (cycle time: 1 to 60 minutes), touch icon **2**.
2. To activate/deactivate the cyclic measurements within the set time interval, touch icon **3**.

The TSM allows a preset to determine whether the cyclic measurements are terminated by changing to Disinfection mode.

Setting the Alarm Limits

1. To view and set the alarm limits, touch icon **1**.
   ↳ The following screen appears:

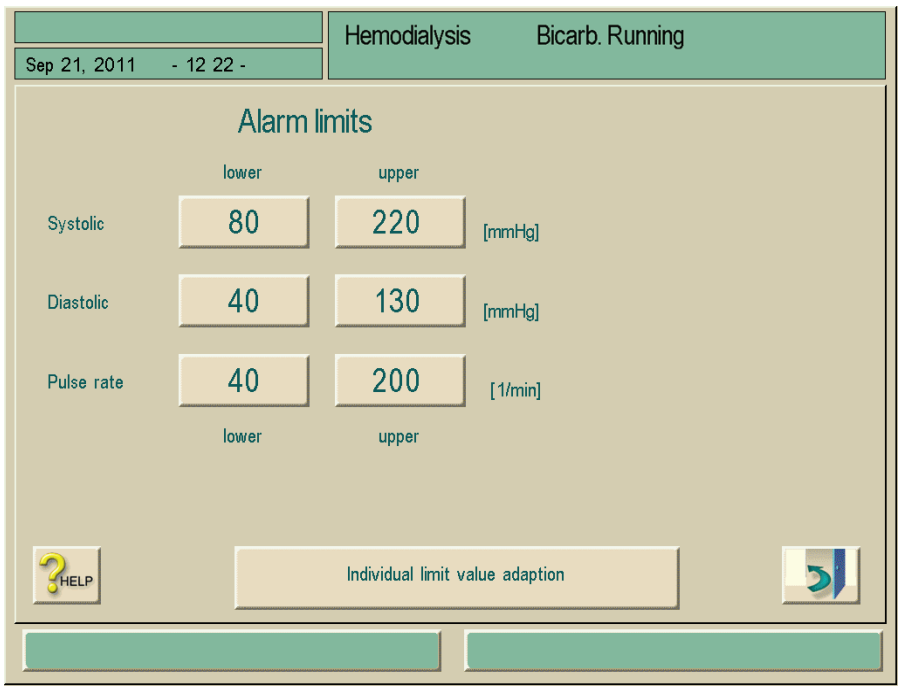


Fig. 11-7 "Alarm limits" screen

You can accept or adjust the alarm limits.

Option 1: Manual setting of alarm limits:

1. Touch the limit to be set.
2. Enter new setting via the keypad.

Option 2: To set the alarm limit based on the last measuring result:

1. Touch field Individual limit adaption.
   ↳ New limit settings are suggested on a colored background.
2. Confirm limit settings by pressing Enter key on the monitor.

Alarm limit values

Alarm limit	Lower	Upper
Lower limit systolic	50 mmHg	245 mmHg (but not higher than set upper limit systolic)
Upper systolic alarm limit	50 mmHg (but not lower than set lower limit systolic)	245 mmHg
Lower limit diastolic	40 mmHg	220 mmHg (but not higher than set upper limit diastolic)
Upper limit diastolic	40 mmHg (but not lower than set lower limit diastolic)	220 mmHg
Lower pulse rate	40 mmHg	200 mmHg (but not higher than set upper pulse rate)
Upper pulse rate	40 mmHg (but not lower than set lower pulse rate)	200 mmHg

NOTICE!

After an initial measurement, the alarm limits should be set closer around the current blood pressure values.
The suggested alarm limits normally range around ± 30 mmHg in critical areas at ± 10 mmHg around the last measured value.
To ensure best possible measurements, the cuff should be at heart level so that the measured blood pressure does not differ from the actual blood pressure due to the height difference.

11.1.4 Blood Pressure Measurement

Guidelines for Blood Pressure Measurement

In order to obtain accurate resting blood pressure measurements ensure following patient position:

- comfortable position,
- legs uncrossed,
- back and arm should be supported,
- patient should relax and not talk during measurement.

Blood pressure reading can be affected by

- measurement site,
- patient position (standing, sitting, lying down),
- exercise,
- patient's physiologic condition.

The following environmental or operational factors can affect the ABPM performance and/or blood pressure reading:

- common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation,
- arterial sclerosis,
- poor perfusion,
- diabetes,
- age,
- pregnancy,
- pre-eclampsia,
- renal diseases,
- patient motion, trembling, shivering.

In case of unexpected readings:

1. Check patient's position and measurement conditions.
2. Repeat measurement
3. Perform reference measurement, if required.

⚠ WARNING!

Risk to patient due to wrong measurements!
Pressurization of cuff can disturb or temporarily cause loss of function of other monitoring equipment. simultaneously used on the same limb of the patient.

- Regularly monitor the patient.
- Check monitoring results before changing treatment parameters.
- Never change treatment parameters on the basis of displayed values solely.
- The physician in charge is responsible for the medical indication.

Start/Stop Measurement

First measurement should be taken 5 minutes after therapy start at the earliest, according to IEC standard.

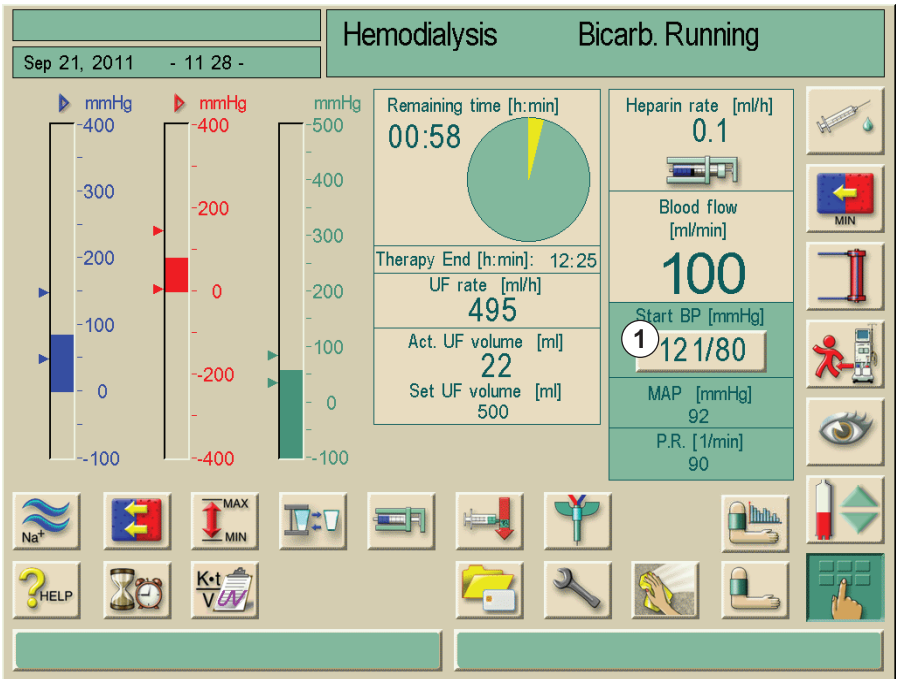


Fig. 11-8 "Therapy" screen

1. Touch field **1** on the "Therapy" screen (Fig. 11-8) and field **4** in the "ABPM main menu" window (Fig. 11-6 "ABPM main view" screen (179)).

   ↳ The last values measured for the systolic and diastolic pressure and the pulse rate are being displayed.

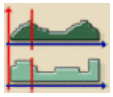
2. To stop an ongoing blood pressure measurement, touch the respective field again.

11.1.5 Showing and Graphically Displaying Measured Values

NOTICE!

Erroneous measurements are marked by an asterisk in the first position. By activating a line with an asterisk a window with the measuring results and an error description is called up.

When a measurement was canceled, the display field appears in yellow and shows"---/---".
The display field is also highlighted in yellow when the limits are exceeded.In the measurement overview, all results are displayed with the respective time information. Values shown in red indicate that limits have been exceeded.



1. Touch icon in ABPM main window (Fig. 11-6 "ABPM main view" screen (179)).

   ↳ The following screen appears:

1 Measured values at the time selected in field **4**.

2 Cursor

3 Arrow fields for moving the cursor

4 Selected time

5 Switch on/off graphic display

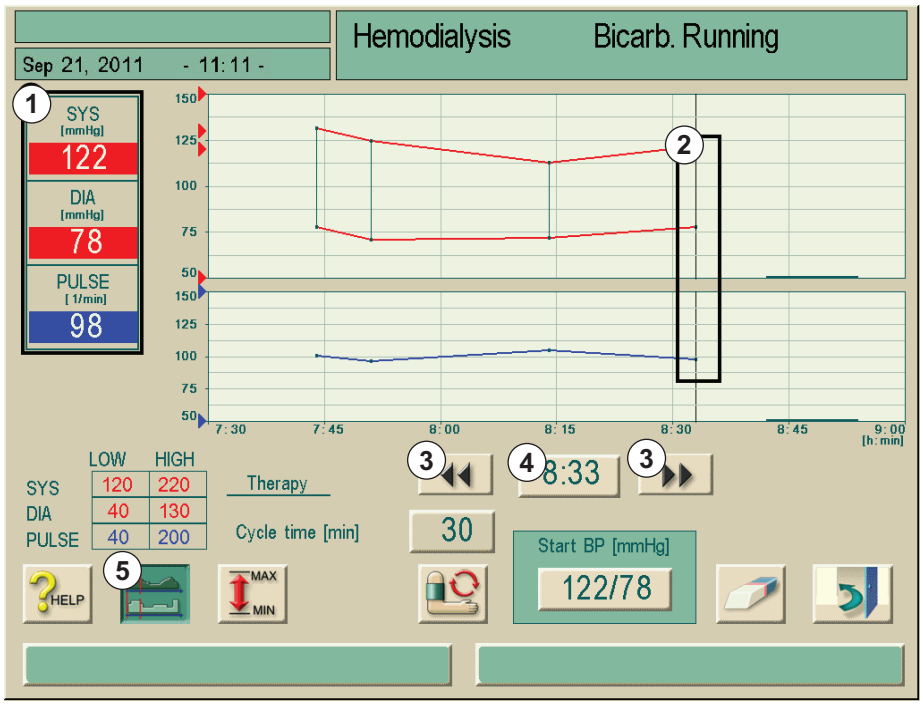


Fig. 11-9 Graphical representation of measured results

There are three different formats for graphic display.

1. To switch between display formats: Touch number field **1**.

11.2 bioLogic RR Comfort

bioLogic RR Comfort is an optional biofeedback system that is used to control the ultrafiltration (UF) rate during a complete dialysis therapy depending on patient's systolic blood pressure.

bioLogic RR Comfort may only be operated by persons instructed for its appropriate use. The medical indication, patient population and operating conditions are the same as described for the machine and automatic blood pressure measurement (ABPM).

11.2.1 Use and Mode of Operation

Basic Functioning

bioLogic RR Comfort option is based on the experience that patients have individual blood pressure progression patterns during a therapy. Instead of current blood pressure trends, typical blood pressure progressions from the past together with the currently measured value are used for ultrafiltration control with this system.

These blood pressure progressions are collected in a patient-related memory and evaluated after a "learning phase" of three therapies for the selection of a guideline. During the learning phase, blood pressure is measured in intervals of 5 minutes. The learning phase requires a therapy time of at least 3 hours.

Regular Blood Pressure Measurement

Normally, dialysis is performed with maximum ultrafiltration (UF) rate until a UF volume of 65 % is reached. The UF rate is then slowly decreased until 85 % of total UF volume is reached and remains constant at low UF rates until end of therapy (Fig. 11-10).

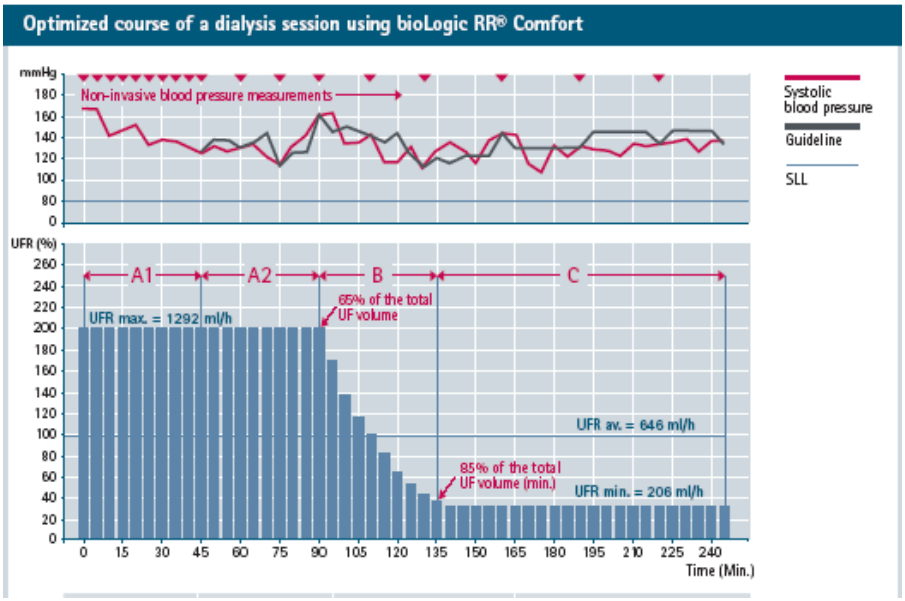


Fig. 11-10 Measuring intervals

Phase	Duration	Achieved UF volume	Regular measurement interval
A1	45 minutes	variable	5 minutes
A2	variable	up to 65 %	15 minutes
B	variable	up to 85 %	20 minutes
C	variable	from 85 %	30 minutes

From the beginning of therapy blood pressure is measured every 5 minutes by the option automatic blood pressure measurement (ABPM) (see chapter 11.1 Automatic Blood Pressure Measurement (ABPM) (175)) until a UF volume of 65 % is reached. Then the measuring interval is extended to 15 minutes in order to reduce the measuring stress for the patient. Then, the measuring interval is extended to 20 minutes until a UF volume of 85 % is reached. Last period starts when the 85 % of UF volume has been reach and from this moment until the end of treatment the blood pressure is measured every 30 minutes. Thus, e.g. with a maximum UF rate of 160 %, only 18 blood pressure measurements are performed during a 4 hours therapy without hypotensive event. This extension of time can be achieved thanks to the guideline method that searches in the saved curves of a patient for that with the best correlation with the current blood pressure curve and accepts it as the guideline. This guideline is then used together with the current blood pressure progression for UF control.

Additional manual blood pressure measurements can be performed, e.g. during the longer time intervals, and are taken into account by the algorithm. If the measured systolic blood pressure falls to a value of 1.25*SLL (systolic lower limit, see Fig. 11-11 “bioLogic RR Parameter” screen (187), 4), blood pressure measurement interval is increased to 5 minutes. If the measured systolic blood pressure falls below SLL, UF rate is reduced immediately until blood pressure increases above this lower limit. The option bioLogic RR Comfort is only available in combination with the option ABPM.

GuideLine Technique

The blood pressure progressions of up to 100 previous therapies are collected in a patient-related memory and stored on the patient card (see section 12.6 Patient Card (237)). Additional manual blood pressure measurements, e.g. during a longer interval, are taken into account by the system.

The GuideLine technique searches in the stored patient curves for that with the best correlation with currently measured blood pressures and accepts this curve as the patient guideline for UF rate adaption.

bioLogic RR Comfort Operating Modes

Depending on machine configuration, bioLogic RR Comfort has two operating modes:

- bioLogic RR: UF rate is controlled according to systolic blood pressure progression that is measures in intervals of 5 minutes.
- bioLogic RR Comfort: UF rate is controlled according to the systolic blood pressure progression using the guideline technique.

Fallback Modes

Treatment at minimum UF rate in case of

- current UF rate higher than maximum UF rate
- current UF rate lower than minimum UF rate
- current systolic blood pressure below lower limit (SLL) and current UF rate higher than minimum UF rate

Bypass mode in case of

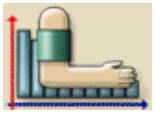
- three or more missing blood pressure readings
- no blood pressure reading request by bioLogic RR Comfort after maximum ABPM reading interval + 60 seconds

For bioLogic RR Comfort related alarm and warning messages, see section 13.2 Alarms and Troubleshooting (259).

Logging of bioLogic RR Comfort

Usage of bioLogic RR Comfort as well as values of relevant parameters are written once per second to the machine's log file during the whole treatment. The log file is always available, even after switching off the machine or after power supply interruption.

11.2.2 Setting Systolic Blood Pressure Lower Limit and Maximum UF Rate



1. Touch the icon in the "Preparation" or "Therapy" mode.
   ↳ The following screen is displayed:

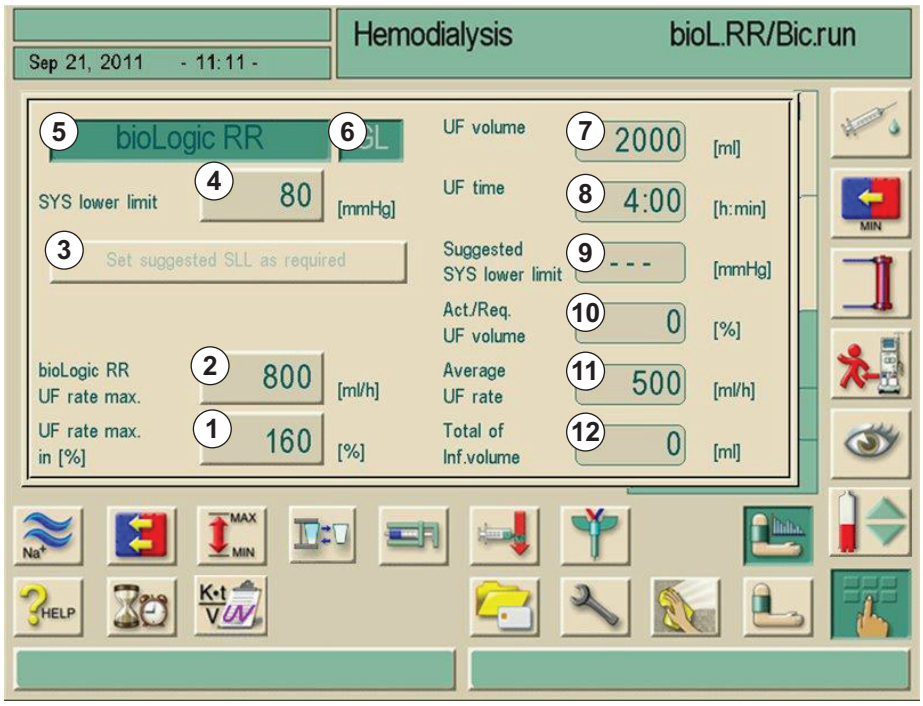


Fig. 11-11 "bioLogic RR Parameter" screen

2. Set the parameters for bioLogic RR Comfort according to the following table.

Item	Text	Range	Description
1	Max. UF rate	100 – 200 %	Enter max. UF rate for treatment with bioLogic RR either as absolute value or as percentage of the average UF rate. To guarantee an effective regulation of the UF rate and the optimal saving of blood pressure measurements, we recommend a max. UF rate of >160 %.
2	bioLogic RR max. UF rate	100 – 4000 ml/h	
3	Set suggested SLL as required	65 - 80 mmHg	Suggests an SLL which has been determined from previous therapies. The setting is performed by pressing this button. (Can be optionally set in TSM)

Item	Text	Range	Description
4	SYS lower limit	65 – 130 mmHg	Lower limit for systolic blood pressure Recommendation: To guarantee an effective regulation of the UF rate and the optimal saving of blood pressure measurements, we recommend the assumption of the suggestion value. If this function is deactivated, the value should be determined by the attending physician.
5	bioLogic RR	Activated/ deactivated	Activating/deactivating bioLogic RR (without guideline)
6	Comfort	Activated/ deactivated	Activating/deactivating bioLogic RR Comfort (with guideline)
7	UF volume	-	Display of the ultrafiltration volume, set under "UF-parameters"
8	UF time	-	Display of the treatment period set under "UF-parameters"
9	Suggested SYS lower limit	-	Display of the suggested SLL (Only when the function has been activated)
10	Act./Req. UF volume	-	Displays the UF volume reached in percent
11	Average UF rate	-	Display of the average UF rate set under "UF-parameters"
12	Total of inf. volume	-	Displays the accumulated infusion volume of the current therapy

NOTICE!

The SLL and max. UF rate/bioLogic RR Comfort max. UF rate parameters should be determined by the attending physician. The SLL should be set as low as possible in the range of the known tolerance of the patient.

NOTICE!

The reaching of the dry patient weight within the set therapy period can conflict with stable blood pressure behaviour.

The attending physician can decide to:

- Adapt the UF volume
- Extend the therapy period
- Accept that the UF target was not achieved.

For medical reasons, all values can also be adapted during the therapy

11.2.3 Setting Suggested Systolic Blood Pressure Lower Limit

1. Touch the "Set suggested SLL as required" field. The value shown on button **4**, Fig. 11-11 “bioLogic RR Parameter” screen (187), is accepted.
2. Optionally, set a value with button **4**.

NOTICE!

When accepting an SLL that was suggested by the system, the user should assure the plausibility of this value relative to the patient’s tolerance.

In the first five minutes after the therapy start the **bioLogic RR** and **Comfort** functions can be switched off again. As from the sixth minute a prompt must be additionally confirmed: Are you sure ...?. After confirmation of this prompt the functions cannot be activated again!

As from the sixth minute the text in the fields is displayed in blue to point out that the first five minutes have expired.

The "Set suggested SLL as..." function can be activated/deactivated in the TSM.

11.2.4 Activating/Deactivating bioLogic RR Comfort

⚠ CAUTION!

Drop in blood pressure due to increasing UF rate!
When the bioLogic RR Comfort option is switched off, an increase of the UF rate can occur due to a lower UF volume when the software of the Dialog+ attempts to compensate for the deficit!

- Pay attention to the UF rate after switching off.
- If necessary, reduce the UF volume.

1. To activate **bioLogic RR** and **Comfort** touch fields in the “biologic RR Parameter” screen
2. Touch button **6**, Fig. 11-11 “bioLogic RR Parameter” screen (187).
   ↳ Depending on the current status, automatic blood pressure stabilization is started or terminated.

Saving blood pressure curves requires the patient card or the option Nexadia. When the option is used for the first time, it must be activated manually. As from the second usage the guideline function is activated automatically.

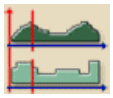
bioLogic RR can be operated without the Comfort function. The system then measures at intervals of five minutes and controls the ultrafiltration without the guideline.

Possibly activated UF profiles are deactivated after switching on bioLogic RR!

11.2.5 Graphic Representations

1. Touch the icon in the "ABPM Main Overview" screen (Fig. 11-6 ”ABPM main view” screen (179)).

   ↳ An overview with the icon for graphical representation is displayed.



2. Touch icon.

   ↳ The following screen is displayed:

1 Measured values for the systolic and diastolic blood pressures as well as for the pulse at the selected time; also functions as button for switching between different graphical representations

2 Graphical progression of systolic blood pressure and ultrafiltration rate

3 ON/OFF button for the screen with the graphic bioLogic RR Comfort representations

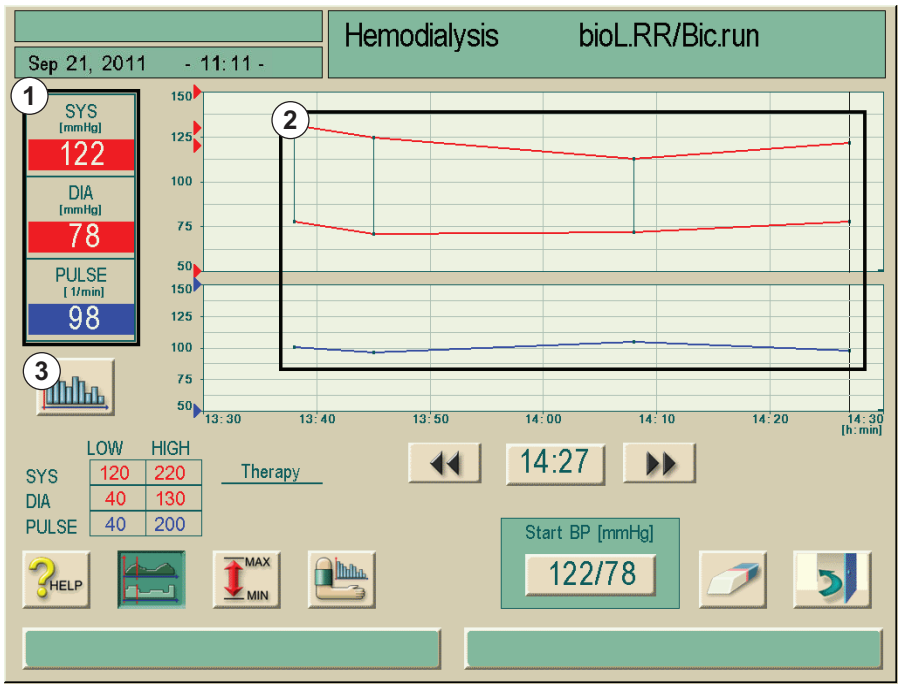


Fig. 11-12 Graphical representation of blood pressure and pulse

3. Touch icon.

   ↳ The following screen with the representation of the bioLogic RR parameters is displayed:

1 Graphical display of the bioLogic RR values

2 UF rate at the selected time

3 Reference value for the UF rate at the selected time

4 Systolic blood pressure at the selected time

5 Systolic blood pressure over the period of the treatment

6 Cursor

7 Reference line for the UF rate over the treatment period, probable progression

8 Arrow keys for selection of a point in time

9 Graphical display of delivered UF rate within an interval.

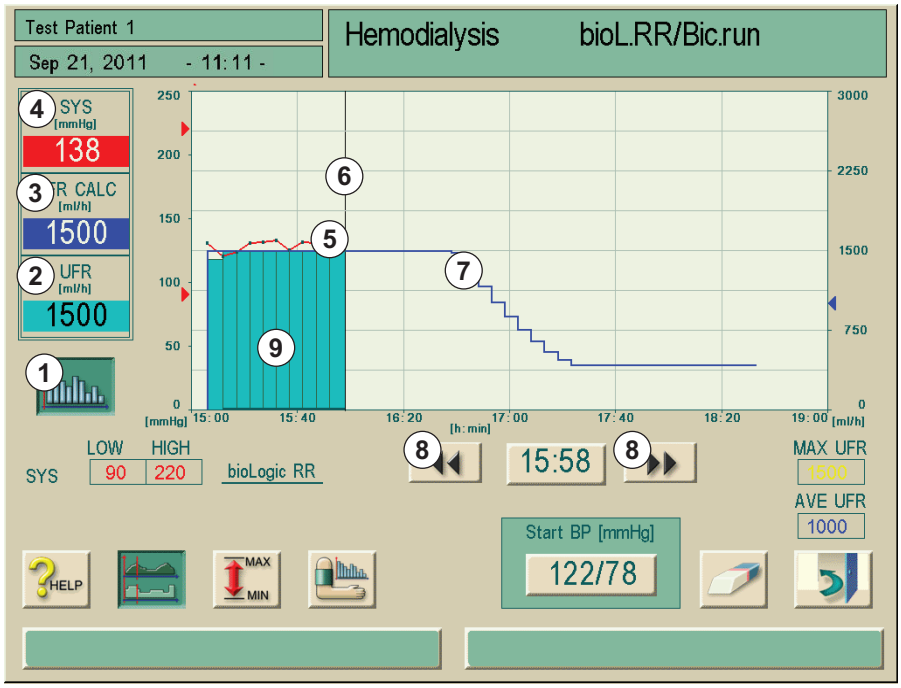


Fig. 11-13 Graphical representation, progression of ultrafiltration

11.3 Adimea

If the option Adimea is selected the theoretical calculation of the effectiveness as described in chapter 3.10 Dialysis Efficacy (Kt/V) (53) is not applicable.

The option Adimea is an exact measuring method for precise monitoring of the dialysis dose during a complete dialysis therapy.
The system works with spectroscopy (UV light) in order to measure the reduction of urinary waste products in the dialysate outlet of the dialysis machine. Due to continuously recorded measurements the Kt/V and the urea reduction ratio (URR) can be determined and displayed Besides the mentioned parameters, it is also possible to show the behavior of the UV light absorption allowing to evaluate the reduction of substances during the complete therapy.

Two calculation methods are available for calculation of Kt/V and URR:

- Single pool Kt/V (spKt/V)
- Equilibrated Kt/V (eKt/V)

The selection is performed once in TSM mode. The calculation method set is displayed on the screen.

11.3.1 Setting Adimea Parameters

1. Input of patient weight before dialysis (Fig. 11-14, 1).
   ↳ Setting the parameter enables the calculation and display of Kt/V, URR and UV absorption.
2. Input/adaptation of the target Kt/V value (Fig. 11-14, 2).

3. Enable/disable target warning (Fig. 11-14, 3).

   ↳ If the target warning is enabled, the system informs the user whether the target value will possibly not be reached at the end of therapy. In that case the user can adapt the parameters in order to reach the determined dialysis dose.

   ↳ The user can directly access three parameters which influence the Kt/V without changing the menu. Those are therapy time, blood flow and dialysate flow. Influences on curves and values will be displayed after a short processing time.

The introduction of the patient weight and, therefore, the activation of the Kt/V measuring function can be done at any time during therapy. The displayed Kt/V and URR and UV light absorption always consider the already achieved dialysis time.

1 Input of patient weight before dialysis

2 Input/adaptation of the target Kt/V value

3 Enable/disable target warning

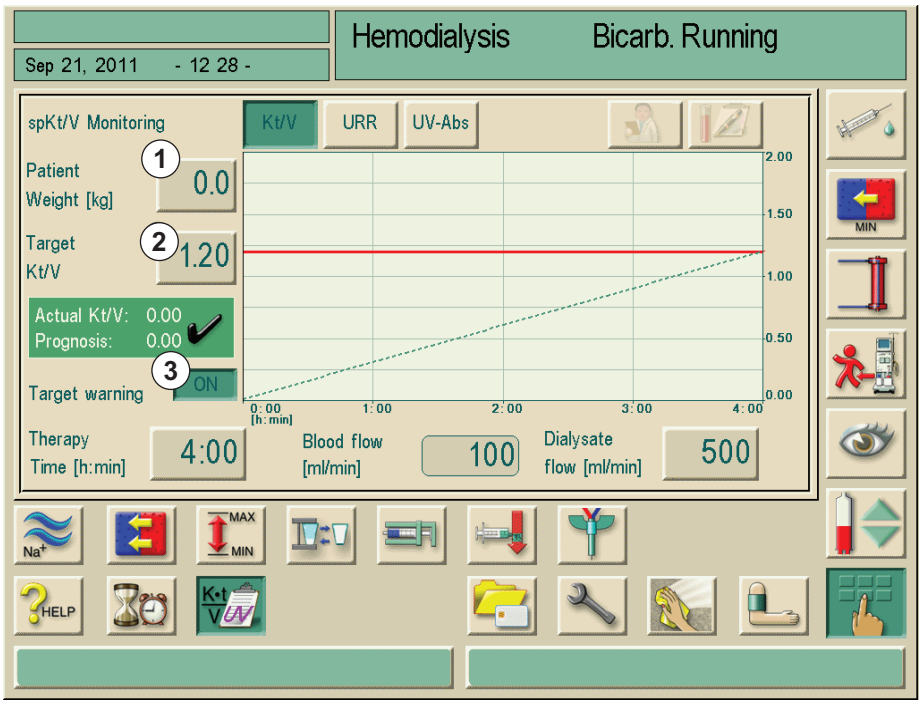


Fig. 11-14 Setting parameters

11.3.2 Graphical Presentations During Therapy

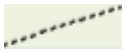
1. By touching the icons ”Kt/V“ and/or ”URR“ and/or ”UV absorption“ it is possible to change between the parameter display.

   ↳ A graphical and numerical overview of the current therapy is displayed on the respective screen.

   ↳ A blue line represents the actual progress of the respective parameter until the respective time of therapy.

   ↳ A green dashed line serves as orientation for the user to see whether the actual therapy progress will fulfill the target dialysis dose. If the blue curve is above the green dashed one, the target Kt/V will probably be reached at the end of therapy.

Explanation of Colored Lines

Red line		Target value at the end of therapy
Blue line		Actual progress line Kt/V, URR or UV absorption
Green dashed line		Orientation line of complete therapy
Black dashed line		Previous completed therapy (new feature)
Red dashed line (extension of blue line)		Prediction that target value will not be reached
Blue dashed line (extension of blue line)		Prognosis

1 Chose Kt/V and/or URR and/or UV absorption

2 Actual progress line of the Kt/V (graphical display) and actual Kt/V value (numerical display)

3 Orientation line of complete therapy

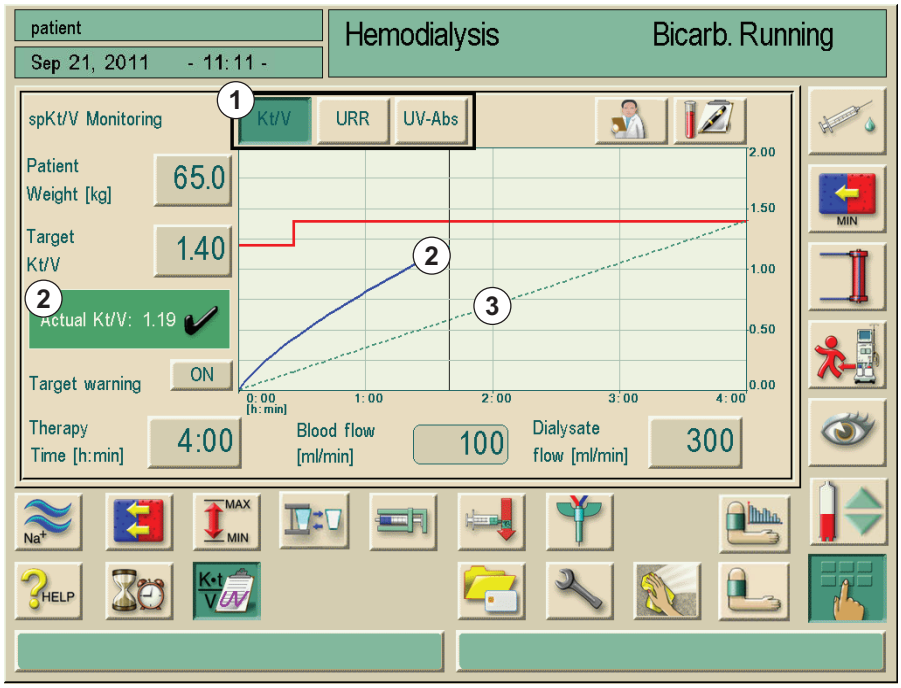


Fig. 11-15 Graphical display

In hemodialysis (HD) mode the user gets a “prognosis” of the estimated Kt/V value at the end of therapy. It is displayed numerically (Fig. 11-16, 1) and graphically (Fig. 11-16, 2). The blue actual progress line will be extended from the actual therapy status in order to predict the therapy progress.

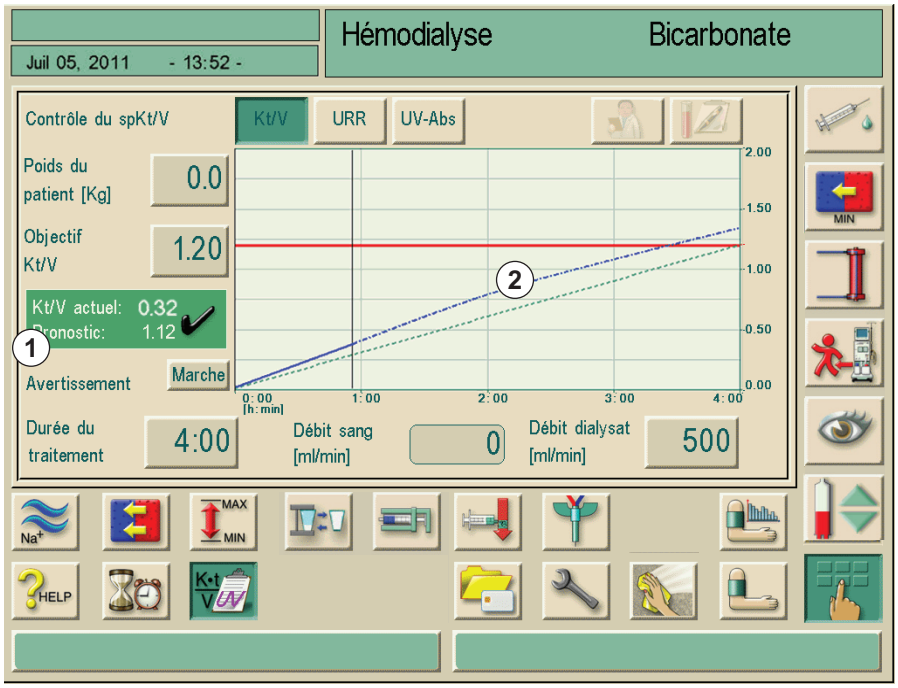


Fig. 11-16 Numerical and graphical display of the prognosis

11.3.3 Target Warning

If the “Target warning” is enabled, the machine will inform the user showing a yellow warning on the screen in case that either Kt/V resp. URR will not be reached at the end of therapy.

The warning is displayed if either the blue actual progress line (Fig. 11-17, 1) has already been below the green dashed orientation line (Fig. 11-17, 2) or if it could fall below it within the remaining therapy time (Fig. 11-18).

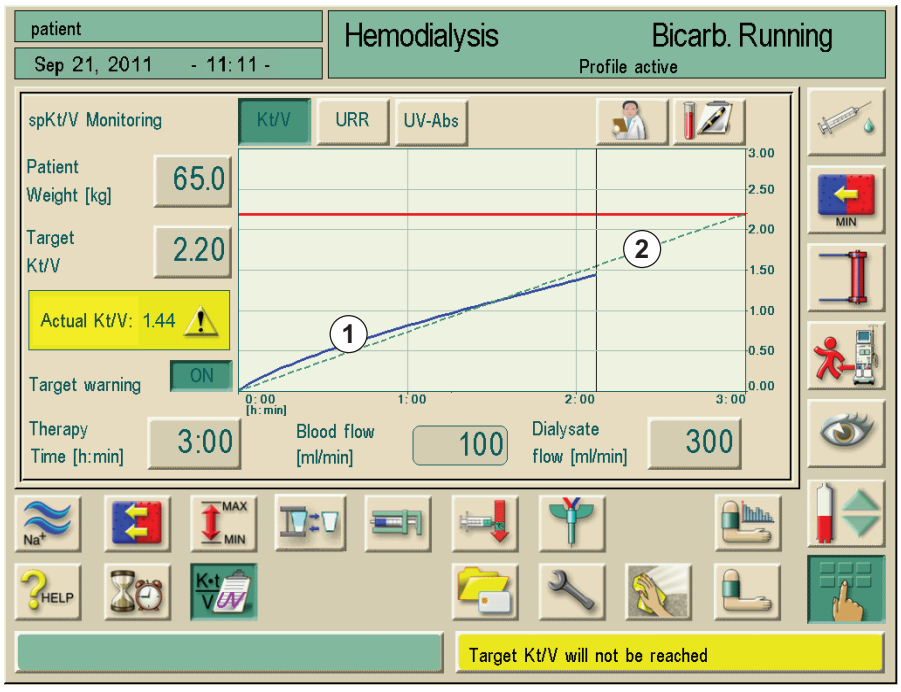


Fig. 11-17 Graphical display of blue actual progress line below green dashed orientation line

In the second case the blue line (Fig. 11-18, 1) will be extended by a red dashed line (Fig. 11-18, 2) predicting that the target value will not be reached.

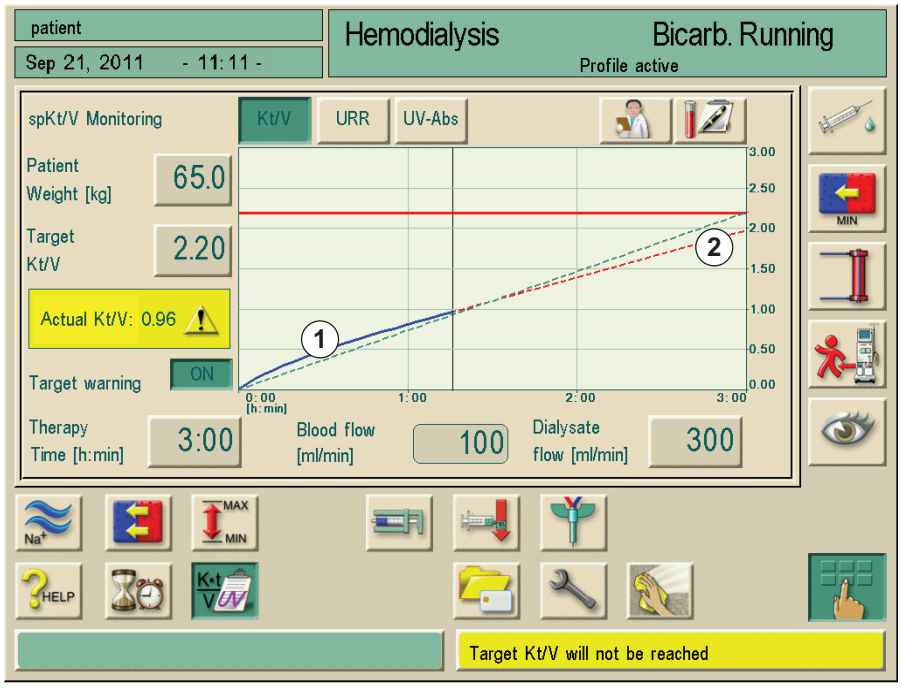


Fig. 11-18 Graphical display of parameters at the end of therapy

1. Adapt the parameters according to the following table:

Item	Text	Range	Description
1	Kt/V target value	0.00 - 3.00	Input of a Kt/V target value
2	Therapy time	1 h - 10 h	-
3	Dialysate flow	300 ml/min - 800 ml/min	-
4	Blood flow	50 ml/min - 600 ml/min	Adjustment via +/- keys on the monitor

⚠ WARNING!

Risk to the patient by the input of new treatment parameters.

- Ensure that the change of the treatment parameters corresponds with the prescription of the physician.

⚠ WARNING!

Risk to the patient by the input of new treatment parameters.

- The treatment parameters may not be determined on the basis of the measured Kt/V.
- A measurement of the Kt/V does not replace the therapy prescribed by the physician.

11.3.4 Extended Functionality When Using Patient Card

Using the patient card allows to store the patient's individual Kt/V parameters and graphic Kt/V or URR therapy progresses. Therefore, data are still available for the user after the end of therapy. It is possible to store up to 12 completed therapies and to compare them graphically or to evaluate Kt/V and URR values of up to 50 completed therapies. Trends or unusual therapies can be identified and analysed if necessary.

The graphical display will be shown by touching the respective icons.

1. Touch the icon.

   ↳ Up to 12 completed therapies are displayed:

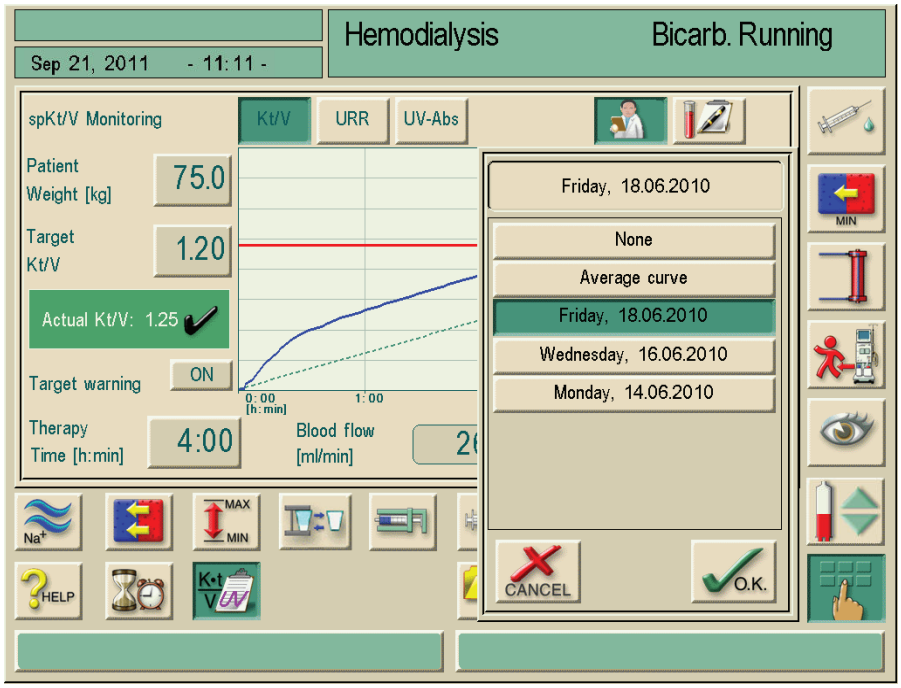


Fig. 11-19 Display of up to 12 stored therapies

1. By touching one of the displayed therapies the screen showing the black dashed progress line (Fig. 11-20, 1) opens:

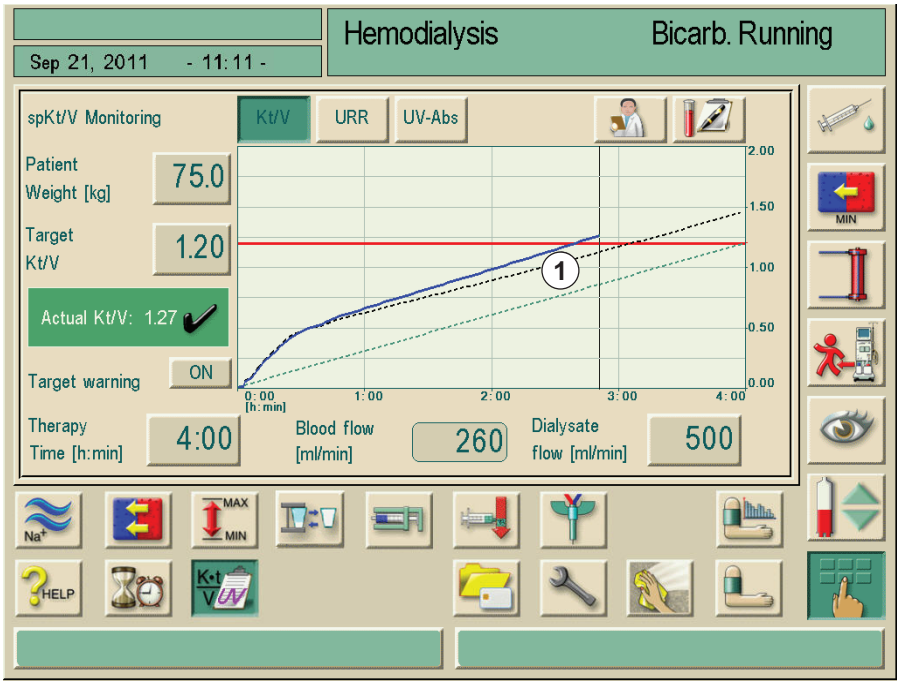


Fig. 11-20 Display of the black dashed progress line

11.3.5 Kt/V Table

1. Touch the icon.

   ↳ The data are read from the therapy card and displayed on the screen.

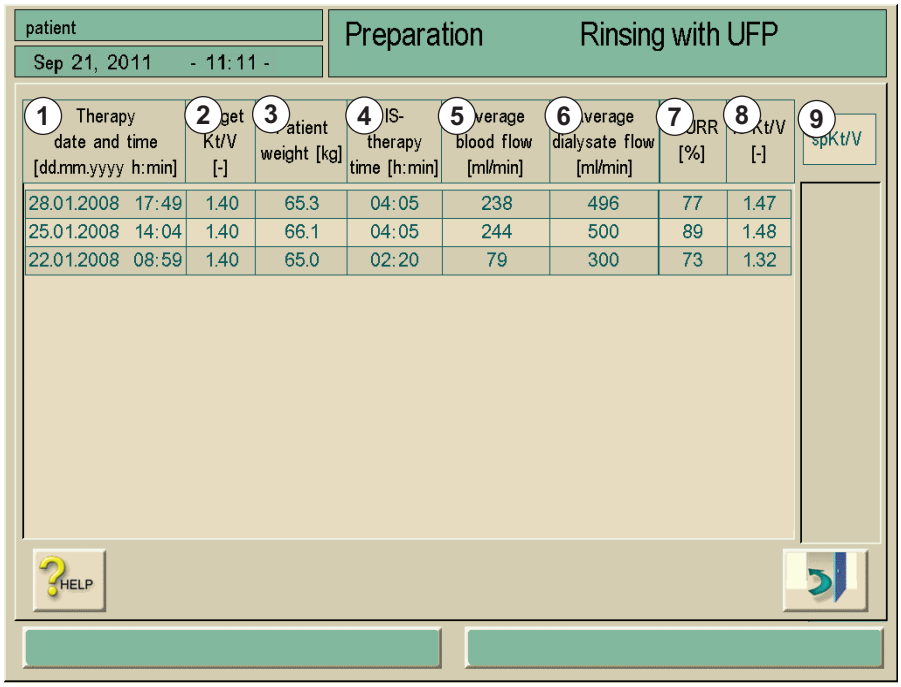


Fig. 11-21 "Kt/V Table" Screen

Item	Text	Description
1	Therapy date and time [dd.mm.yyyy, h:min]	Date and time of performed therapies
2	Target Kt/V [-]	Set Kt/V target value
3	Patient weight [kg]	Patient weight before dialysis
4	ACTUAL therapy time [h:min]	Actually performed therapy time
5	Average blood flow [ml/min]	Average blood flow over the therapy period
6	Average dialysate flow [ml/min]	Average dialysate flow over the therapy period
7	ACTUAL URR [%]	Achieved urea reduction ratio
8	ACTUAL Kt/V [-]	Reached Kt/V value
9	Calculation method (spKt/V, eKt/V)	Set calculation method

1. Touch the icon to exit the display.

11.4 Bicarbonate Cartridge

⚠ WARNING!

Risk to the patient!

- Only use bicarbonate cartridges Solcart B by B. Braun Avitum AG or bicarbonate cartridges that have been released for use with this dialysis machine.
- Never use cartridges containing substances other than bicarbonate.
- Never use bicarbonate cartridges containing acid concentrates for ”Bicarbonate with NaCl”.

- Observe datasheet of bicarbonate cartridge.
- Ambient temperatures of > 35 °C due to, e.g. direct exposure of the bicarbonate cartridge to sunlight, or large temperature differentials between, e.g. store and treatment room can lead to increased gas formation in the cartridge. This may trigger an alarm, or the bicarbonate content in the dialysate may deviate slightly from the specified value.
- When using a bicarbonate cartridge, the concentrate rod for the bicarbonate remains in the machine, and the coupling on the concentrate rod. As soon as the holder is opened, the dialysis machine detects that a cartridge is to be used.

11.4.1 Inserting Cartridge

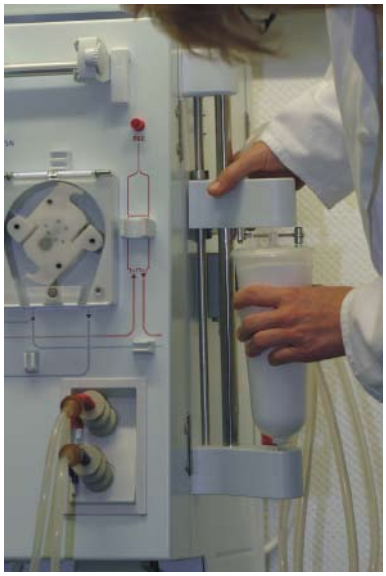


Fig. 11-22 Inserting a cartridge

1. Press in lateral button at top fixing and pull up top fixing as far as possible.
2. Using your left hand place cartridge between top and bottom fixings. At the same time, place inlet and outlet necks of cartridge into their respective recesses at the top and bottom fixings.

   ↳ The lever at the top fixing is automatically pushed back in the process.

⚠ CAUTION!

Crushing hazard!

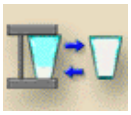
- When closing the cartridge holder do not bruise hands or fingers!

3. To close the cartridge holder, press top fixing centrally onto the cartridge.

   ↳ The cartridge is pierced, automatically vented and filled with permeate.

11.4.2 Changing Cartridge During Therapy

When the cartridge is empty, the bicarbonate conductivity alarm is triggered and an information window appears. An almost empty cartridge can be replaced before an alarm is activated.



With Draining

1. Touch icon.

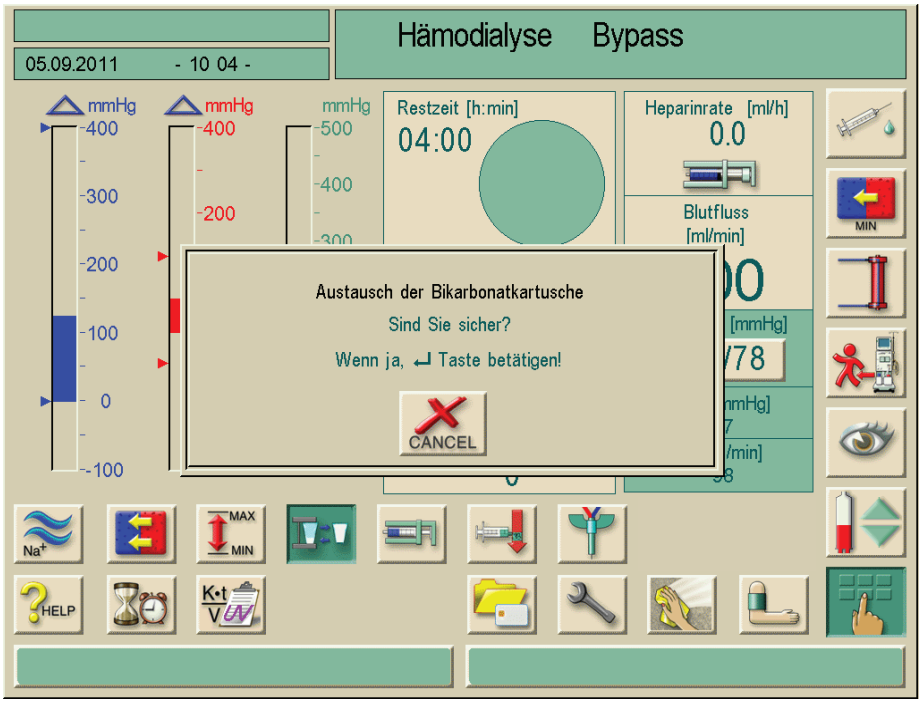


Fig. 11-23 Bicarbonate cartridge change

2. A confirmation window appears, confirm by pressing the Enter key.
   - The cartridge will not be drained, only the pressure will be released (if Bic cartridge **without** draining is selected in TSM service program).
   - An information window appears after some seconds.

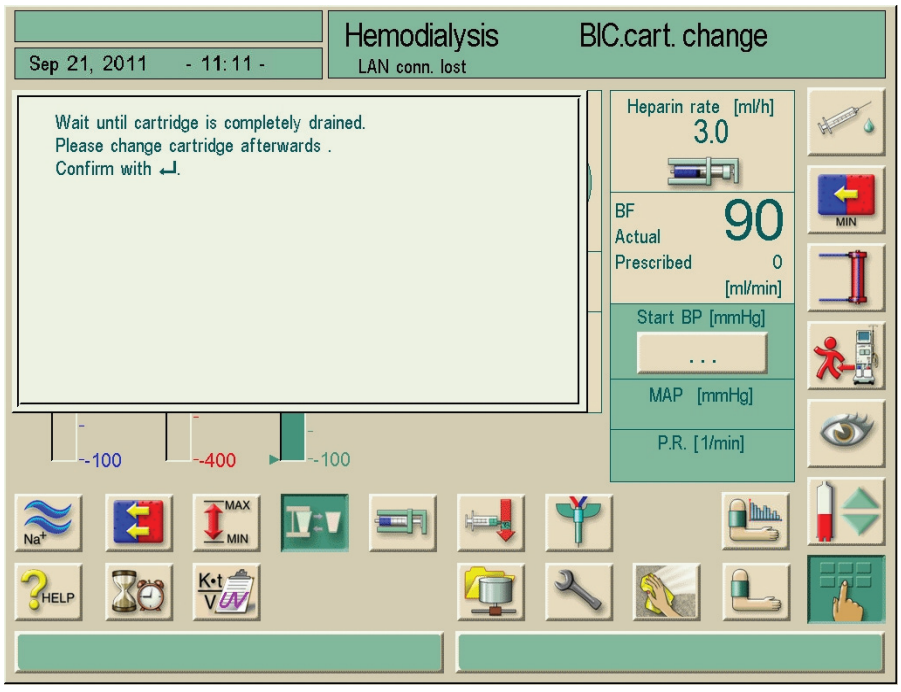
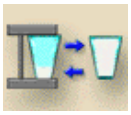


Fig. 11-24 Bicarbonate cartridge change with draining

3. Insert new cartridge.
4. After inserting the new cartridge, confirm by pressing the Enter key.
   - The machines prepares the new Bic cartridge.



Without Draining

1. Touch icon.

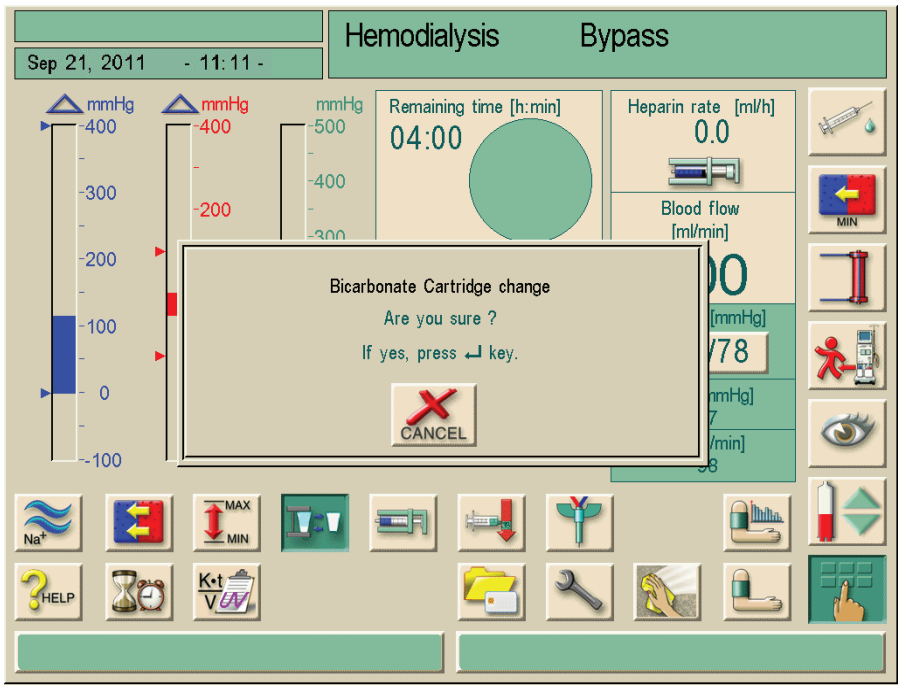


Fig. 11-25 Bicarbonate cartridge change

2. A confirmation window appears, confirm by pressing the Enter key.
   - The cartridge will not be drained, only the pressure will be released (if Bic cartridge without draining is selected in TSM).
   - An information window appears when the empty cartridge can be taken out.

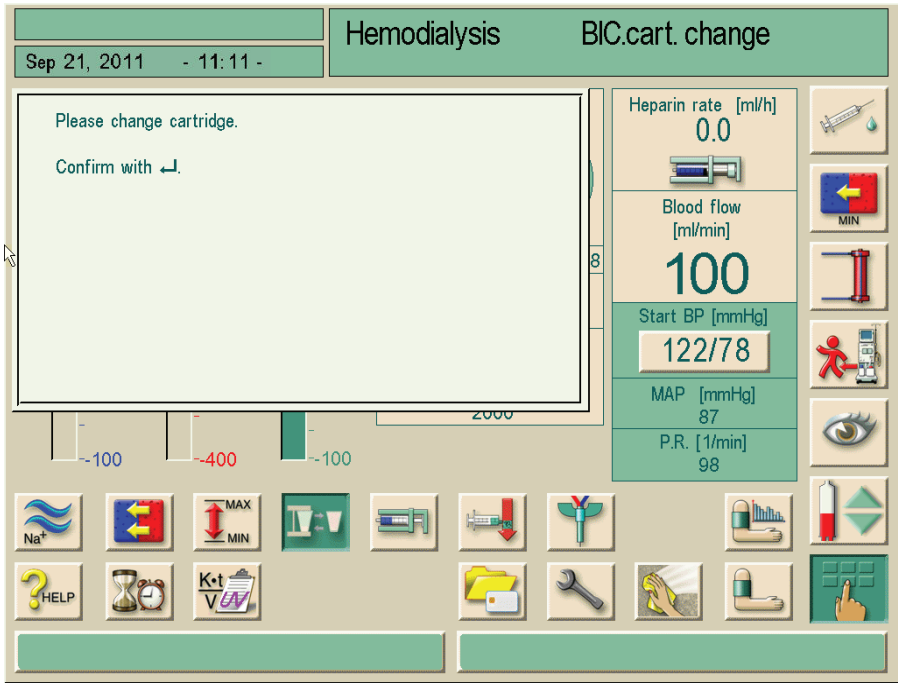


Fig. 11-26 Bicarbonate cartridge change without draining

11.4.3 Emptying Cartridge After Therapy

1. Touch icon and confirm by pressing the Enter keyƒ on the monitor.
   ↳ The cartridge is emptied automatically.

The functions ”Empty dialyzer” and ”Empty cartridge” can be started simultaneously, although, they are carried out successively.

The cartridge is emptied as long as both couplings are connected to the dialyzer or the rinsing bridge.

If the blue coupling is connected to the rinsing bridge, the dialyzer is emptied.

11.5 Central Concentrate Supply

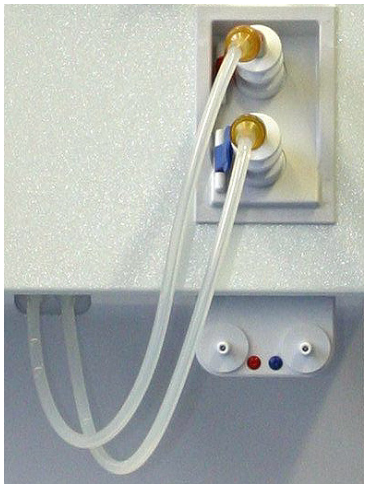


Fig. 11-27 ”Central concentrate supply” connections

When using a dialysis machine equipped with the "Central concentrate supply" option, the concentrate (acetate or bicarbonate components) does not have to be provided in containers but can be obtained from the central supply. Both components can be obtained centrally or individually from containers. Another option is combining a bicarbonate cartridge with acid components from central concentrate supplies.

1. To connect the concentrate, place couplings of suction rods onto connections of the central concentrate supply, which are located on the dialysis machine below the rinsing quivers. Observe color-coding!

The concentrate connections of the dialysis machine are, thus, directly connected to the wall connections of the central concentrate supply.

11.6 Dialysis Fluid Filter (DF Filter)

11.6.1 Use and Mode of Operation

The dialysis fluid filter is a hollow-fiber filter. It is used for performing hemodialysis therapy with ultra pure dialysate. Even if the machine has been correctly cleaned and disinfected, the permeate and the bicarbonate concentrate, which, unlike the acid-containing concentrate, is not autosterile, can be the source of possible contamination.

For additional information refer to the instructions for use for Diacap Ultra dialysis fluid filters.

⚠ WARNING!

Risk to patients due to uncontrolled fluid withdrawal!
External leaks on the filters (e.g. faulty tube connections) will affect the UF control system of the dialysis machine!

- Prior to each treatment, visually inspect filters for external leaks.

NOTICE!

Time of filter change

See relevant data sheet for the specified service life of the dialysis fluid filter in use.
The filter must be changed, when:

- the number of therapies set in the service program has been reached,
- the set number of operating hours has been reached,
- the test of the dialysate system during preparation is not passed and leaks are discovered at the filter.

NOTICE!

The dialysis fluid filter may only be operated with permeate or dialysate.

The following warning message appears when the DF filter has reached the preset setting in TSM:

Fig. 11-28 "Filter change" warning window

11.6.2 Changing Dialysis Fluid Filter

The dialysis machine supervises remaining operating hours of the filter as well as performed therapies. Operating hours are hours in Therapy as well as hours in Preparation and Disinfection.

When either the operating hours or the number of therapies are reached, a warning window will be displayed on the screen. It informs the user about the upcoming filter change. The warning window appears in case that 60 operating hours or 10 therapies remain. It is displayed when the user changes from Program Selection to Preparation and it lasts for 1 minute.

It is recommended to change the filter after 150 therapies or 900 operating hours.

DF filter and HDF filter should be changed according to their service life specified in the manufacturer's data sheet.

Preconditions

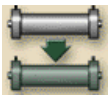
- No patient connected to dialysis machine
- Dialysis machine switched on
- Screen Disinfection selection is displayed, no disinfection program started (machine is in Rinse out (Fig. 11-29).

⚠ WARNING!

Risk to the patient!

- Only use dialysis fluid filter Diacap Ultra by B. Braun Avitum AG or dialysis fluid filters that have been released for this dialysis machine by the respective manufacturer.

1. Touch icon while in disinfection screen.
   ↳ A screen is displayed.



2. Touch icon.
   ↳ The following screen is displayed:

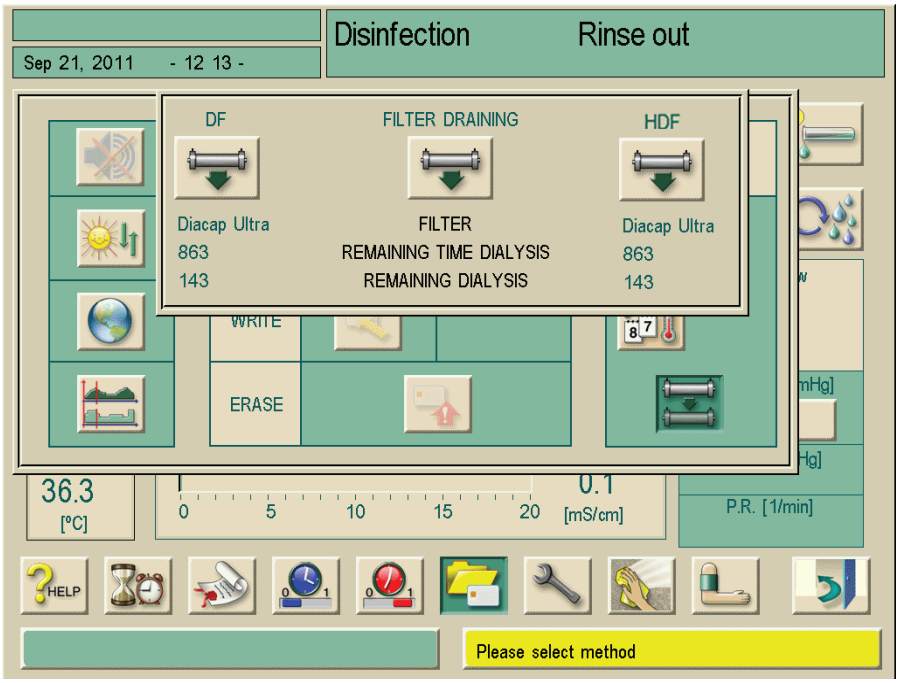
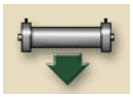


Fig. 11-29 "Filter draining" warning window

↳ The remaining dialysis time and the number of performed dialysis are displayed.



3. Touch the "FILTER DRAINING" icon.
   ↳ A prompt to remove the dialyzer feed connector is displayed.
4. Remove the dialyzer feed connector.
   ↳ The filter is drained and vented. After approx. 90 s, the message "DF filter drained" is displayed.

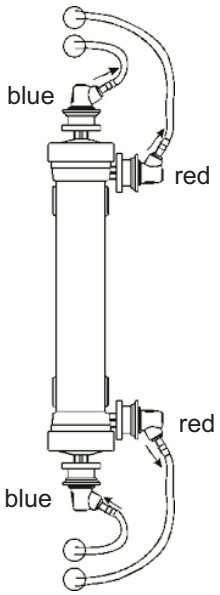


Fig. 11-30 Dialysis fluid filter change

5. Remove all couplings (red and blue) from the filter. Catch the fluid escaping in the process.
6. Hold old filter centrally and remove it from the clamping brackets of the filter holder.
7. Hold new filter centrally and press it into the clamping brackets of the filter holder.
8. Push blue couplings onto dialysate couplings on the filter caps.
9. Push red couplings onto lateral dialysate connections.
10. Reset data with the dialysis machine switched on.

NOTICE!

Perform a disinfection cycle after installation/change of the filter.

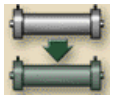
It is recommended to record the installation/change of the dialysis fluid filter in the machine logbook (date, batch number).
The Operating time and Number of dialysis data must be reset, see section 11.6.3 Resetting the Data (206).

11.6.3 Resetting the Data

Preconditions

- The dialysis machine is switched on.
- The disinfection selection screen is displayed.

1. Touch icon.
   ↳ A screen appears.



2. Touch icon.
   ↳ The following screen appears:

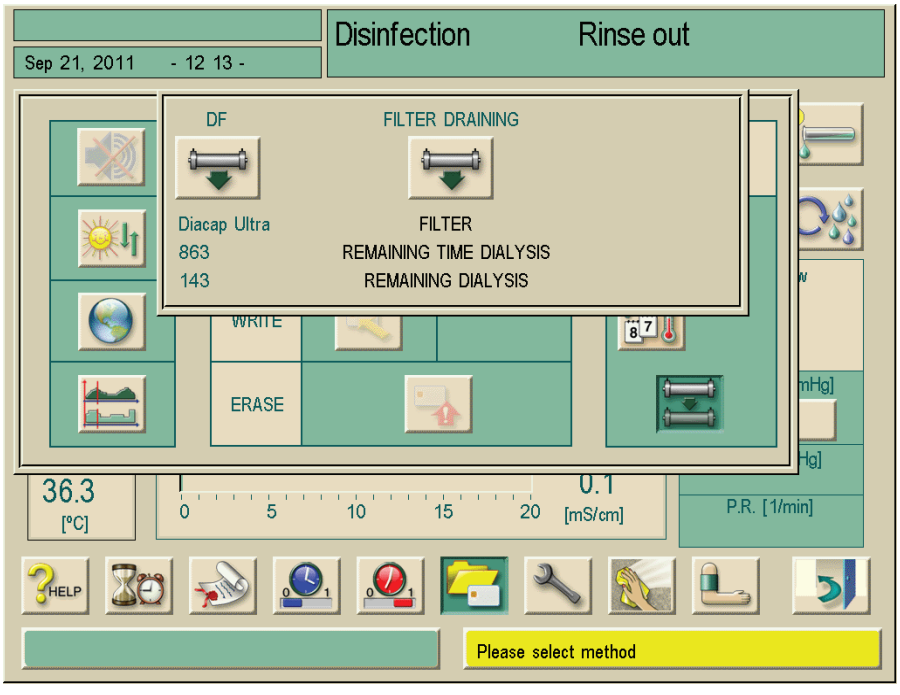
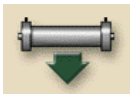


Fig. 11-31 "Select Disinfection" screen with active window "Filter change"



3. Touch icon to reset operating time and number of dialysis.
4. Confirm query by pressing the Enter key on the monitor.

11.6.4 Disinfection

The dialysis fluid filter is a fixed part of the dialysis machine for the entire duration of its use. It is cleaned and disinfected together with the dialysis machine.

Suitable disinfectants

The following agents are suitable for disinfecting the dialysis fluid filter Diacap Ultra:

- Citric acid 50 % (hot disinfection)
- TIUTOL KF (only immediately prior to a filter change)
- Paracetic Acid

⚠ WARNING!

Unsuitable disinfectants may cause changes to the material characteristics of the housing, encapsulation and capillaries of the filter!
Risk to the patient! The dialysis machine is no longer safe to operate!

- Only use suitable disinfectants.
- Essentially check information leaflet supplied with filter.
- Before using other disinfectants contact B. Braun service technician.

NOTICE!

Unsuitable disinfectants
The following substances may not be used for disinfecting the dialysis fluid filter:

Chlorine-containing fluids and organic solvents, e.g. chloroform, acetone, ethyl alcohol.

Watery solutions, e.g. sodium hypochlorite (bleaching lye) or soda lye.

The manufacturer will not accept any liability if unsuitable disinfectants are used.

⚠ WARNING!

There may be a risk of uncontrolled UF withdrawal from a patient due to a calcified dialysis fluid filter.

- To prevent this, perform decalcification with Citric Acid 50 % after each treatment.

11.6.5 Sampling of Dialysis Fluid

Sampling of Dialysate for Microbiologic Analysis

Samples of the dialysate can be taken regularly in order to perform hygienic inspections. Since quantities > 100 ml are frequently required, these should not be taken during treatment.

Proceed as follows to take such a sample:

1. Prepare the equipment.
2. Start therapy (without patient, no bypass).
3. Disinfect the injection socket in the sample port.
4. Connect the Luer syringe to the injection socket.
5. If required, switch off the TMP limiting value window.
6. Slowly withdraw the sample with a suitable syringe with a Luer connector.
7. Terminate the therapy.
8. Disinfect the equipment.

1 Sample port with injection socket

2 Dialyzer coupling with closed membrane port

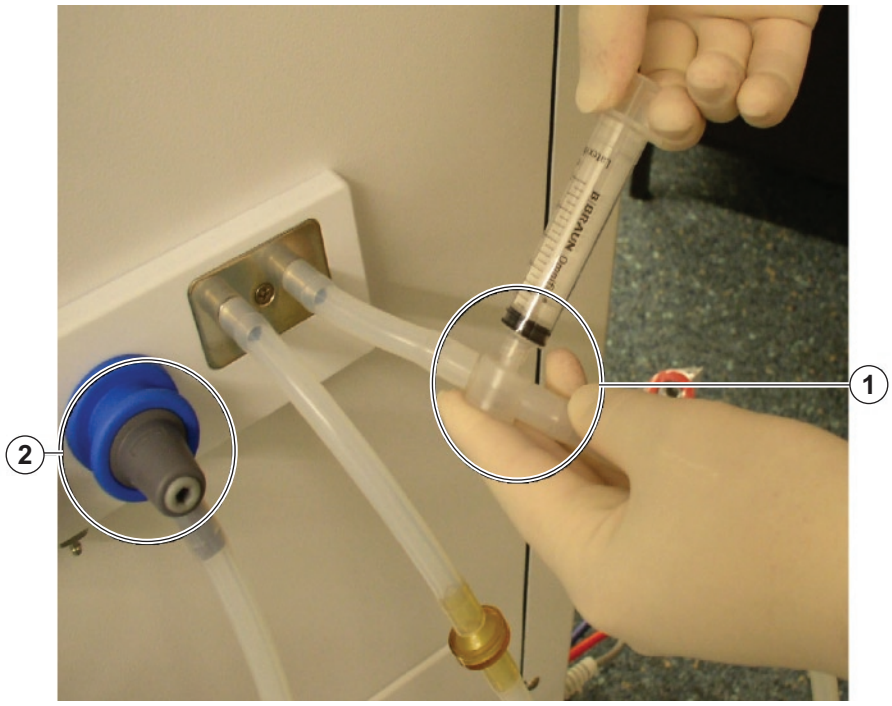


Fig. 11-32 Sample port

Sampling to Check the Composition of the Dialysis Fluid

Small quantities can be taken regularly to check the composition of the dialysate. Proceed as follows to take such a sample.

1. Once the conductivity of the dialysate has stabilized (after approx. 5 minutes), disinfect the sample port.
2. Slowly take a sample from the sample port at the dialysis fluid DF tubing, using a small syringe, e.g. a 2 ml syringe (Fig. 11-32).
3. Analyze the dialysate by, e.g. the following methods:
   - pH measurement
   - blood gas analysis
   - chemical determination of bicarbonate concentration (titration)

Recommended Therapeutic Ranges

pH	7,2 - 7,5
pCO_2	40 - 60 mmHg
HCO_3^-	25 - 38 mmol/l

⚠ WARNING!

Risk to patient due to UF deviations when the sample port leaks.

- Ensure that the sampling port does not leak after use.
- Install the sampling port according to the enclosed installation instructions.
- Fluid leaks from the sample port cause an increase in weight reduction.
- Check the sample port for air inlet.
  If necessary, remove the air.

⚠ WARNING!

Risk to the patient due to contamination

- Do not use the sample port for rinsing the extracorporeal circulation.
- Do not connect the arterial line for reinfusion to the sampling port.
- Only use sterile syringes.

⚠ WARNING!

Risk to the patient due to incorrect composition of dialysate.
When the dialysate flow is stopped, the samples taken could provide incorrect measuring results!

- Always perform sampling during therapy in the main connection, never in the bypass!
- Use only calibrated measuring equipment.
- Do not perform sampling during disinfection.

11.7 Emergency Power Supply/Battery

The battery operation mode serves for maintaining the extracorporeal blood circulation in case of a mains power failure.

In such even, the dialysis machine automatically switches to battery operation.

- *"Battery/bypass"* will be displayed in the status line.
- The remaining battery life is shown in the patient name field.
- This is followed by an acoustic signal.
- The alarm message "*Power failure – battery operation"* is displayed.

Active Functions During Battery Mode

The following functions and monitoring devices are active during battery operation:

- Screen and control elements
- All blood sided functions and alarms
- Blood pumps
- Tube clamps
- Air detector (SAD)
- Heparin pump
- Blood pressure measurement
- Single-needle operation
- Arterial bolus from bag

In the "end" mode, all blood side functions are active during battery operation as during mains operation. If necessary, the patient can be disconnected in the usual way.

Functions not Available During Battery Operation

The following functions are NOT available during battery operation:

- Dialysis treatment
- Ultrafiltration
- Substitution for HDF/HF Online
- Bolus administration for HDF/HF Online
- Emptying the dialyzer and cartridge
- Rinsing, disinfecting

Battery Operating Time

After a successful automatic battery test the battery has an operating time of at least 20 minutes. Switch off the machine after 20 minutes in order to guarantee the lifetime of the battery.

When mains power fails repeatedly, the battery will work for the residual operating time after each power failure.

Switching Off in Battery Operation

If the equipment is switched off in battery operation, it cannot be switched on again after a time span of 16 minutes unless it is connected to the mains.

11.7.1 Charging Indicator

An indicator light in the keyboard membrane of the screen indicates that the battery is being charged while the system is operating on mains power. Battery charging continues even when the machine is switched off. The indicator light goes dark as soon as the battery is fully charged.

11.7.2 Automatic Battery Test

During the automatic machine test performed at each call-up for dialysis, the battery function is tested, too. In case of an unsuccessful automatic test, an information message appears. The test could be unsuccessful for the following reasons:

Cause	Action
Battery not fully charged, e.g. because the machine has not been connected to mains power for some time.	Charge battery.
Faulty battery.	Inform technical service.
Fuse of battery has been triggered due to a technical defect.	Inform technical service.

Dialysis after an Unsuccessful Automatic Battery Test

Dialysis can be started although the battery self test was not passed. The battery is charged. Take into account that battery operation is not available or only for a limited time during a mains power failure.

Battery Change

To maintain the battery functionality, we recommend replacing the battery at least every 5 years. For correct disposal of the battery please refer to service manual.

⚠ WARNING!

Risk to the patient due to blood loss.
When the blood flow stops, because of blood pump failure during loss of mains power, blood clotting causes blood loss.

- Return blood to patient manually (see chapter 13.4 Manual Blood Return (308)).

11.7.3 End of Battery Operation

As soon as the mains power supply has been restored, the battery operation is automatically ended. The dialysate treatment is activated again. Once the unit has adjusted itself to the set values, dialysis is automatically continued. User intervention is not required.

11.8 Communication Interfaces

The dialysis machine has a RS232 communication interface for communicating with other information systems. Only one of the systems described below can be installed.

11.8.1 BSL (Bed Side Link)

With the BSL, the dialysis machine can be connected to the data management system Nexadia. For further information see Nexadia instructions for use.

11.8.2 Dialog+ Computer Interface (DCI)

The Dialog+ computer interface allows transferring various parameters to other EDP (Electronic Data Processing) systems installed on the ward. For further information see instructions for use of the Dialog+ computer interface.

11.8.3 Staff Call

The staff call is used for integrating the dialysis machine into an existing staff call system.

NOTICE!

The user may not solely rely on the function of the staff call option during the event of an alarm. Regular checking of the status of the patient is still required.

For further information see staff call system technical information.

11.9 Crit-Line Interface

11.9.1 Function

The Crit-Line unit from Hema Metrics ™ is an external measuring instrument which measures non-invasively various parameters in the blood via optical sensors. For this purpose, a suitable cuvette (disposable measuring chamber) must be placed on the dialyser inlet line.

The following parameters of the blood are measured or calculated:

- Hematocrit content of the blood (HCT) in %
- Oxygen saturation of the blood in %
- Flow in the vascular access in ml/min
- Recirculation in the vascular access in % (calculated)
- Change of the blood volume in % (calculated)

The serial interface of the Hema Metrics™ Crit-Line device is connected to the rear of the Dialog+ DSI(**D**ialog **S**erial **I**nterface) using its serial connection cable. The measured data of the Crit-Line unit are, thus, shown on the display of the Dialog+, saved on the Patient Card and can be recalled as trends.

B. Braun provides the serial DSI for the Dialog+ to the Crit-Line unit.B. Braun is neither responsible for the correct functioning of the Crit-Line unit or guaranteeing the correctness of the displayed values.

Dialog+ displays the data measured by Crit-Line on the monitor.

DANGER!

Hazard of leakage currents!

- When operating the Dialog+ with Crit-Line, use only the class II mains adapter supplied by Hema Metrics ™ .
- Do not position the mains adapter on the Dialog+.
- Do not connect the Crit-Line mains adapter to a different voltage phase than he Dialog+ is connected to.
- When operating the Crit-Line with the Dialog+ do not connect the serial data adapter to a different interface (for example a PC) than that of the Dialog+.
- Do not connect ANY other serial device to the DSI interface than the Hema Metrics ™ Crit-Line device or other devices released from B. Braun for operation with the DSI interface.

DANGER!

Hazard of short circuits!

- While cleaning the surface of the Dialog+ avoid water or disinfectant around the DSI interface. Wipe with a damp cloth only!

DANGER!

Hazard of electric shock!

- It is mandatory to use a potential equalization connecting the Crit-Line unit to an installed potential equalization pin in the dialysis center if catheter patients are treated.
- Place the Crit-Line mains adapter in a dry area.
- Do not connect the Crit-Line potential equalization cable to the Dialog+.
- Before Crit-Line mains adapter operation, carefully check connection of power cord and power receptacle.

WARNING!

Hazard of electromagnetic interferences!

- The Dialog+ with the DSI interface complies with IEC 60601-1-2 with respect to its EMC behavior.
- When several electrical devices are combined, the user has to ensure that no electromagnetic interferences occur in the existing working environment.

WARNING!

Risk to patient by the input of new treatment parameters!

- The Crit-Line monitoring of the relative blood volume, oxygen saturation and hematocrit does not relieve the user from the duty of performing regular patient checks.
- Treatment decisions should not be made on the basis of the displayed Crit-Line values alone.

⚠ WARNING!

Risk to patient due to missing alarms because of incorrect limit values settings!

- The reaching of alarm limits is indicated by Dialog+, however, this has no effect on the therapy.
- Set level carefully and follow the instructions of the physician.

⚠ WARNING!

Risk to patient due to inconsistent values!

- For setting the max. hematocrit limit and/or the min. saturation limit, please carefully follow the relevant clinical practices.
- Crit-Line alarms are displayed on the Dialog+ through single channel communication. A single fault condition with the Dialog+ software may result with alarms from the Crit-Line not being properly displayed.

⚠ CAUTION!

Risk of device incompatibility!

- The DSI is compatible with Crit-Line III TQA from Hema Metrics ™ only.
- Compatibility with older or future models of the Crit-Line cannot be guaranteed. Contact your Hema Metrics ™ customer service for more information.

⚠ CAUTION!

Risk of handling error!

- Please study and follow carefully the Reference Manual of Crit-Line unit and all the necessary user documentation of Crit-Line unit!

11.9.2 Set-Up and Connection With the Dialog+

1. Attach the cuvette between the arterial line and the dialyzer.
2. Place the Crit-Line unit on the Combi Shelf Holder (Art. No. 7102871) behind the monitor or on a safe, dry place.

In case catheter patients are treated:

1. Connect potential equalization cable (Art. No. 7106605) to potential equalization bolt on the back of the Crit-Line unit.
2. Connect other end of the potential equalization cable to the facility potential equalization connector.
3. Connect power plug of Crit-Line unit to wall or operate the unit on battery.
4. Plug in and tighten the Crit-Line unit serial adapter RS232 socket with the DSI interface RS232 plug of the Dialog+.
5. Connect the sensor clip with the cuvette.

It is recommended that the unit be switched on during therapy selection or preparation to enable initial communication between the Dialog+ and the Crit-Line. For further information on Crit-Line set-up please read carefully the Crit-Line operation manual.

After the blood pump starts in therapy mode, measurements on the Crit-Line unit should start immediately. For all other settings on the Crit-Line unit, follow the instructions in the associated instructions for use from Hema Metrics ™ .

⚠ WARNING!

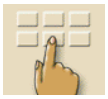
Hazard of incorrect Delta BV value during therapy!

- If the unit is switched on during therapy mode, the software calculates the relative blood volume based on the first valid hematocrit value which results in an incorrect Delta BV value.
- Start the measurement immediately after therapy start.

11.9.3 Setting

With the Crit-Line option enabled by the technician in TSM and the Crit-Line connected to the Dialog+ the message "CL enabled" is displayed in the upper part of the screen.

1. Touch the icon in the “Preparation“ or “Therapy“ mode.
   ↳ The settings overview is displayed.



2. Touch the icon.
   ↳ The Crit-Line main screen is displayed.

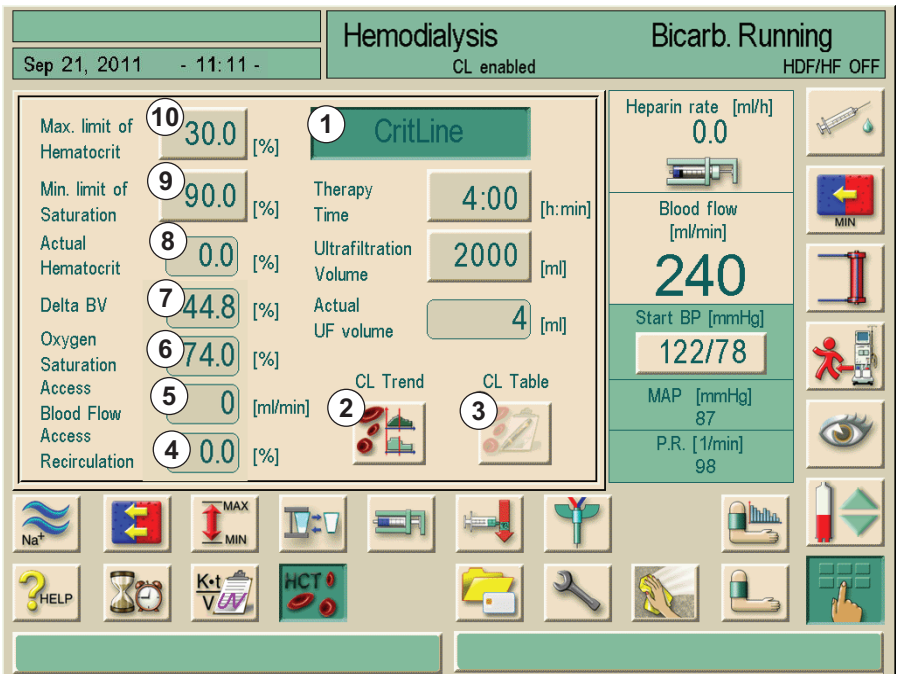


Fig. 11-33 Crit-Line Main Window

Item	Text	Range	Description
1	CL Start button	enabled/disabled	Starts the serial communication between Crit-Line and Dialog+
2	CL Trend	n/a	Shows the current and the last 20 graphical Crit-Line data trends
3	CL table	n/a	Reads the last 50 Crit-Line data of Patient Card
4	Access recirculation	-100 – 0 %	Display of calculated recirculation (in %)
5	Blood flow in access	50 – 2500 ml/min ± 15 %	Display of currently measured blood flow (in ml/min)
6	Oxygen saturation	55 – 100 %	Display of currently measured oxygen saturation (in %)
7	Delta BV	-100 – 0 %	Display of blood volume change (in %)
8	Actual hematocrit (HCT)	20 - 70 %	Display of currently measured hematocrit value (in %)
9	Min. limit of saturation	55 - 100 %	Display of lower oxygen saturation limit (in %)
10	Max. limit of hematocrit	20 - 70 %	Display of upper hematocrit value (in %)

Touching button 1 activates the function and the data transmission process from the Crit-Line unit to the Dialog+ begins. The transferred parameters are displayed in fields 4 to 8, exclusively in therapy mode. The oxygen saturation limit is set with button 9 and the hematocrit limit with button 10. The default values can be accepted or changed. An alarm is triggered when the values are exceeded.

The values are updated every 6 seconds. To obtain information concerning the portion of the recirculation of the vascular access, a saline bolus must be administered. See the relevant chapters in the Crit-Line instructions for use from Hema Metrics ™ .

The values are also displayed in the overview window.

1. Touch the icon.

2. Touch the icon.

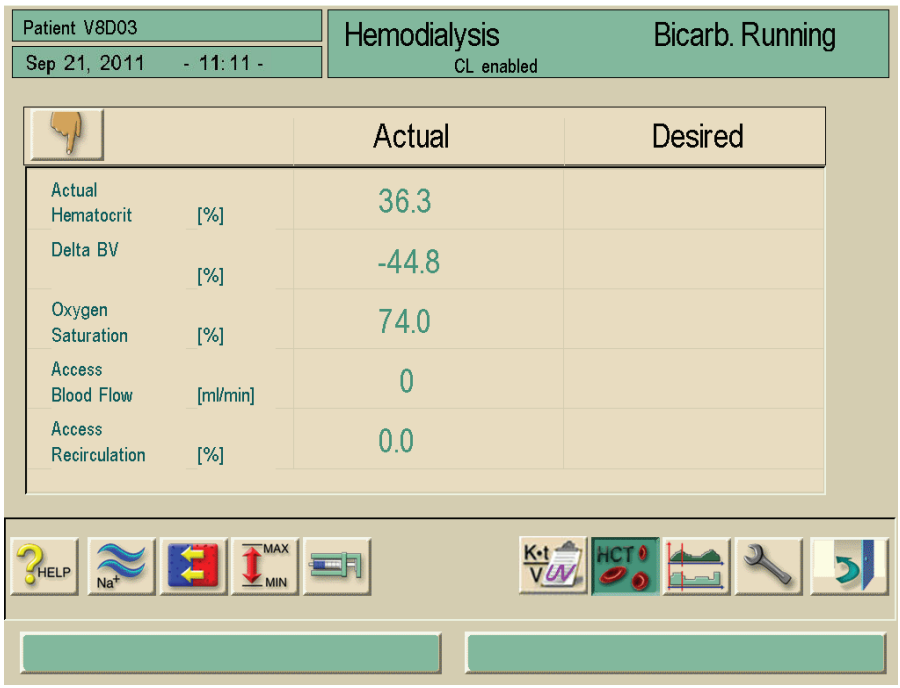


Fig. 11-34 Crit-Line Overview

11.9.4 Graphical Presentations of Trends

When button 2 in Fig. 11-33 Crit-Line Main Window (215) touched, the trends of hematocrit, blood volume change in percent, recirculation, access blood flow and oxygen saturation can be displayed. A trend group consisting of three trends is displayed on the screen. The trend groups can be edited by touching the trend button (5) (see chapter 12.10 Edit Parameter of Trend Groups (248)).

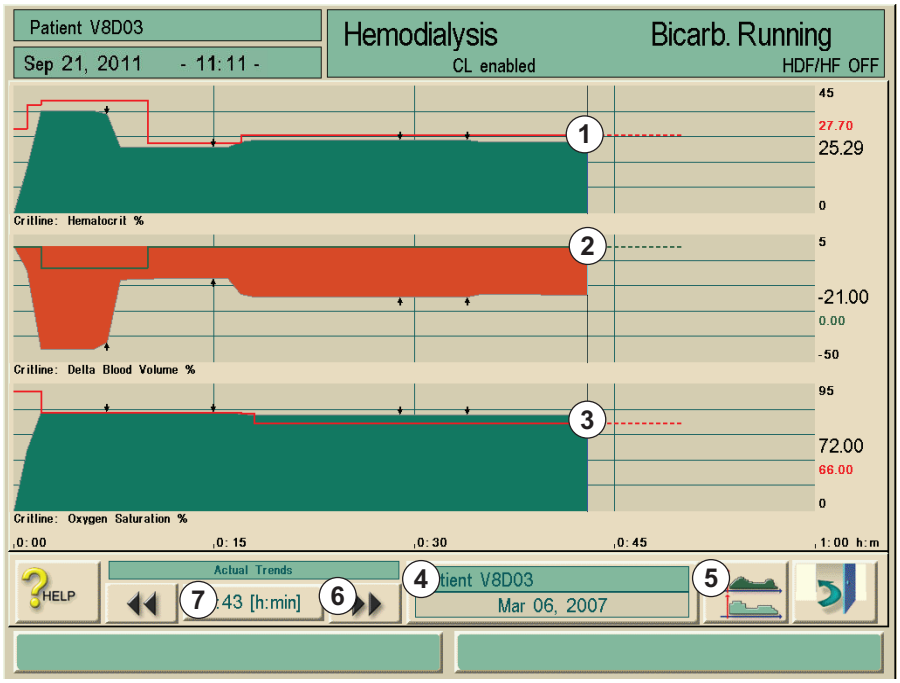


Fig. 11-35 Crit-Line Trends

The hematocrit and Delta BV limits are also displayed. The HCT limit (1) corresponds to the value set in Fig. 11-35 and the BV limit (2) is calculated from the HCT start value and the HCT limit. Line 3 shows the oxygen saturation limit.

The trend history (4) shows the actual progression as well as the last 20 saved trends.

Treatment parameters at a defined point in time:

There are two ways by which the treatment parameters can be determined at a defined point in time:

1st option:

1. Directly enter the time (7) in the Time window.

2nd option:

1. Move the time reference line by using the icons << or >> (6).

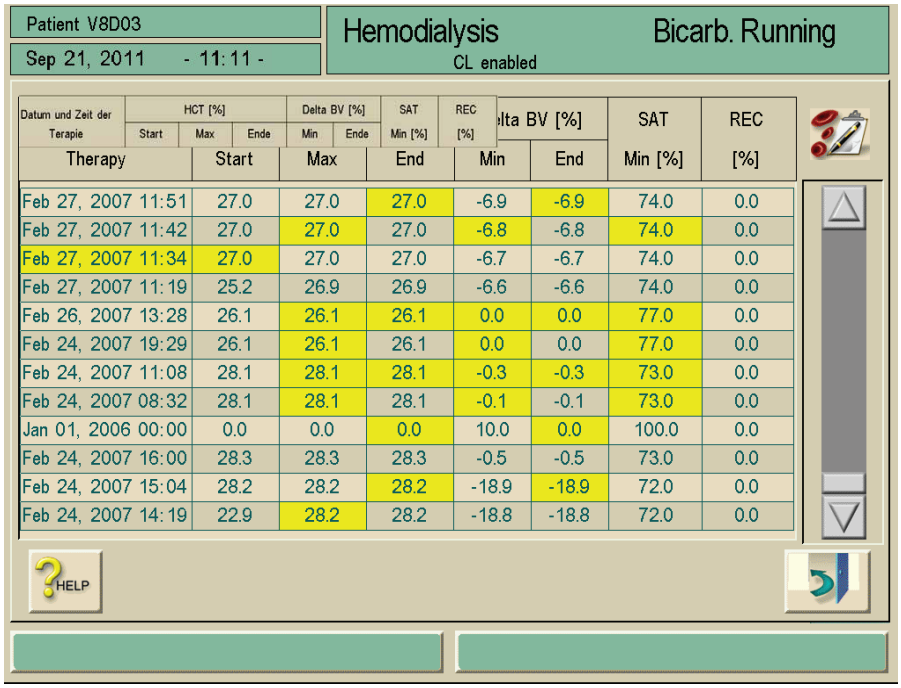
11.9.5 Reading Data from Patient Card

1. Touch button 3 in Fig. 11-33 Crit-Line Main Window (215).

   ↳ The saved data are read from the patient card and displayed.

The table saves up to 50 Crit-Line progressions and includes the following parameters:

- Date and time
- Hematocrit: Start value, maximum, end value
- Delta BV: Minimum and end value
- Oxygen saturation minimum
- Recirculation



Datum und Zeit der Therapie	HCT [%] Start	HCT [%] Max	HCT [%] Ende	Delta BV [%] Min	Delta BV [%] Ende	SAT Min [%]	REC [%]
Therapy	Start	Max	End	Min	End	Min [%]	[%]
Feb 27, 2007 11:51	27.0	27.0	27.0	-6.9	-6.9	74.0	0.0
Feb 27, 2007 11:42	27.0	27.0	27.0	-6.8	-6.8	74.0	0.0
Feb 27, 2007 11:34	27.0	27.0	27.0	-6.7	-6.7	74.0	0.0
Feb 27, 2007 11:19	25.2	26.9	26.9	-6.6	-6.6	74.0	0.0
Feb 26, 2007 13:28	26.1	26.1	26.1	0.0	0.0	77.0	0.0
Feb 24, 2007 19:29	26.1	26.1	26.1	0.0	0.0	77.0	0.0
Feb 24, 2007 11:08	28.1	28.1	28.1	-0.3	-0.3	73.0	0.0
Feb 24, 2007 08:32	28.1	28.1	28.1	-0.1	-0.1	73.0	0.0
Jan 01, 2006 00:00	0.0	0.0	0.0	10.0	0.0	100.0	0.0
Feb 24, 2007 16:00	28.3	28.3	28.3	-0.5	-0.5	73.0	0.0
Feb 24, 2007 15:04	28.2	28.2	28.2	-18.9	-18.9	72.0	0.0
Feb 24, 2007 14:19	22.9	28.2	28.2	-18.8	-18.8	72.0	0.0

Fig. 11-36 Crit-Line Table

A yellow background field states an abnormal deviation during the use of the Crit-Line device. This can be the case in particular when the unit is not used during the complete therapy.

Parameter	Condition for abnormal deviation
Date/Time	The first valid date/time information is not available until 5 minutes after the blood pump start.
HCT Start	The first valid HCT value is not available until 5 minutes after the blood pump start.
HCT Max.	At least 5 successive HCT values are missing or are incorrect.
HCT End	If the therapy will end in more than 5 minutes.
DeltaBV Min.	At least 5 successive DeltaBV values are missing or are incorrect.
DeltaBV End	If the therapy will end in more than 5 minutes.
Sat Min.	At least 5 successive saturation values are missing or are incorrect.

The table can also be called up in the End of Therapy phase by touching the "Parameter" and "Folder" icons.

- For all the set conditions of alarms/warnings the monitor must be enabled (Crit- Line button pressed in CL Parameter Window).
- If the monitor will be disabled (Crit-Line button released in CL Parameter Window) all the alarms/warnings are reset.
- The occurrence of “Crit-Line communication failed” warning resets all the other alarms and warnings.
- The “Set/check HCT Limit!” warning is immediately withdrawn if the HCT limit button is pressed – even if the value is not modified. The limit may also be set prior to the enabling: in this case the related warning does not occur at all.

Table of Contents

12 Configuration

12.1 Automatic Switch-Off

If the automatic switch-off function is activated, the machine will switch-off automatically after each manually started disinfection. A time-out can be set by the user.

Example:

Time-out 45 min → the machine will switch-off 45 min after the disinfection is completed, if there is no user action during the time out.

The automatic switch-off function is independent from the weekly disinfection program.

1 Select disinfectant
2 Thermal disinfection
3 Chemical disinfection
4 Short chemical disinfection
5 Rinse permeate inlet
6 Chemical disinfection with disinfection solution from central water supply
7 Thermal disinfection with hot permeate

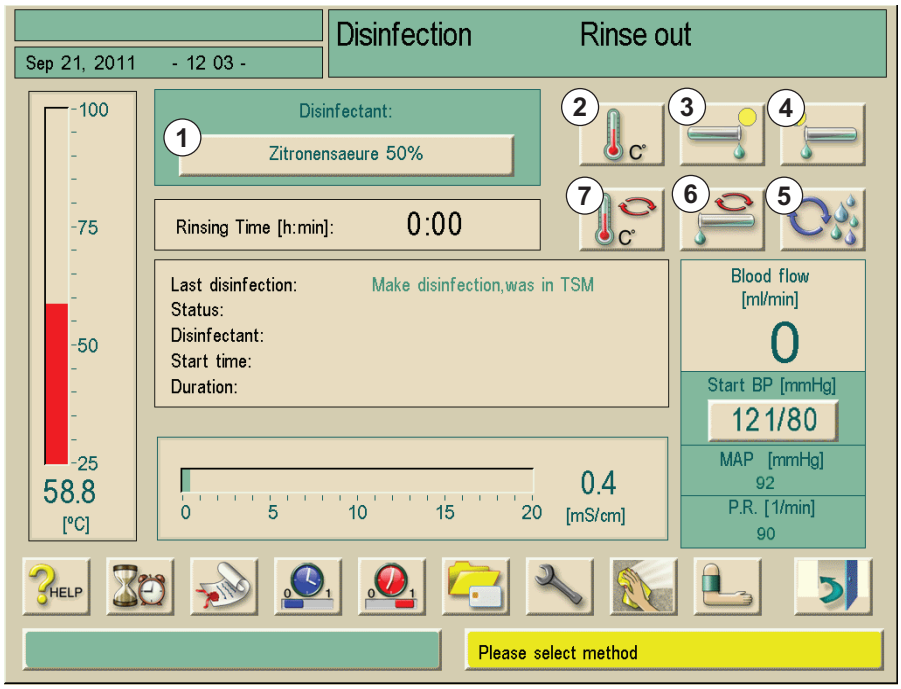


Fig. 12-1 Selection of disinfection program

1. Touch icon in Disinfection mode.
   ↳ A window will open.

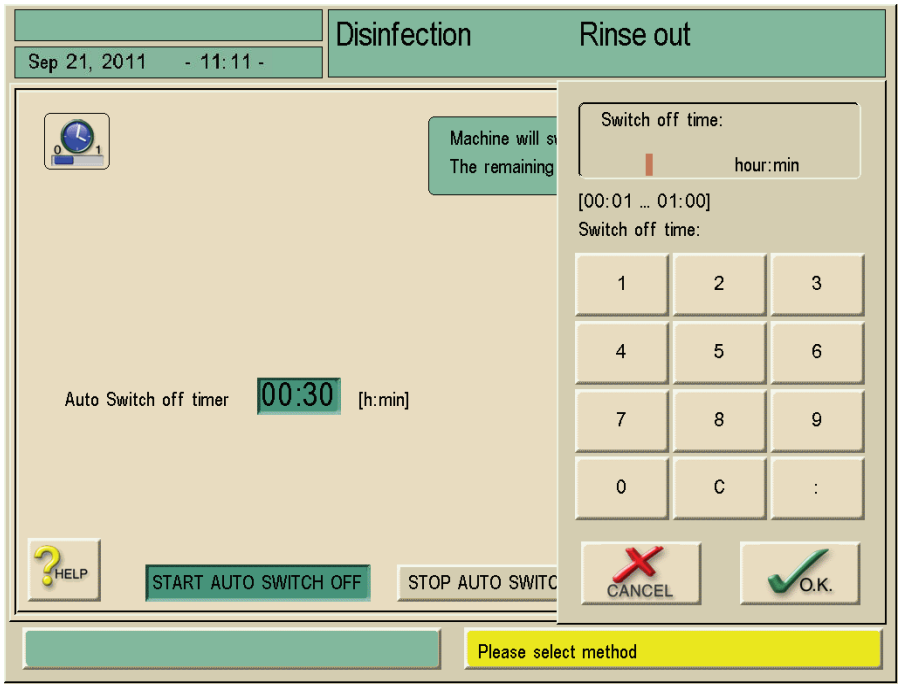


Fig. 12-2 "Auto Switch-Off" screen

2. Set time by using the number buttons.
3. Accept time by touching icon **O.K.**
4. To start program, press the **Start Auto switch off** button.
5. To change the time-out, enter anytime in Disinfection Selection or Disinfection.
6. To stop the program, press the **Stop Auto switch off** button.

12

NOTICE!

Leave mains switch of dialysis machine switched on.
Ensure that sufficient disinfectant is connected.

12.2 Weekly Disinfection Program

The weekly program "Weekly disinfection program" simplifies the configuration of the operations.

1. Touch icon in Disinfection mode (see Fig. 12-1 Selection of disinfection program (223))
   ↳ The following window opens:

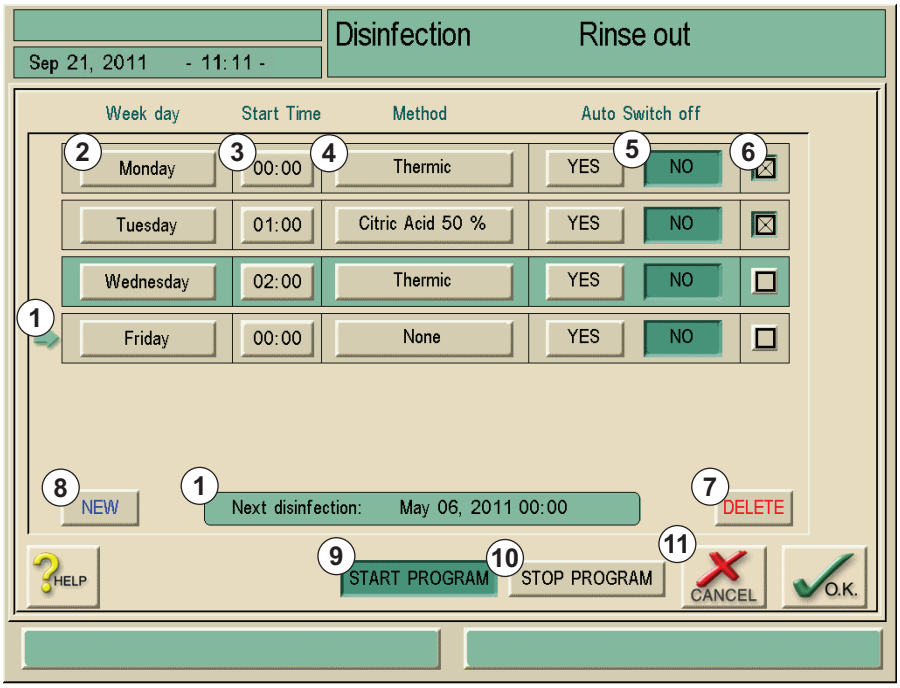


Fig. 12-3 Scheduled auto disinfection screen

Item	Text	Comment
1	Scheduled auto disinfections	The next programmed disinfection is indicated.
2	Week day	Any week day from Monday till Sunday can be entered, also several times, if more than one operation per day is required.
3	Start time	The start time of the operation can be entered.
4	Method	The following methods can be entered: • Rinsing • Thermal • Citric Acid 50 % • Central Thermal • None
5	Switch-off	Enter whether the machine shall remain switched-on after the operation or shall switch-off. Yes: The dialysis machine will be switched-off right after the entered method. No: The dialysis machine will remain switched-on right after the entered method.
6	-	Mark rows to delete
7	Delete	Deletes all marked rows

Item	Text	Comment
8	New	New rows can be added to the table (21 in total).
9	Start Program	The weekly disinfection program is started with this button. It runs until (10) is pressed.
10	Stop Program	The weekly disinfection program is stopped with this button. It is stopped until (9) is pressed.
11	Cancel	Leave window without saving setting
	OK	Leave window with saving setting

NOTICE!

Leave mains switch of dialysis machine switched on.Ensure that sufficient disinfectant is connected.

NOTICE!

The auto switch-off and the weekly disinfection program have to be activated in TSM.

12.3 Configuring Weekly Disinfection Program

The dialysis machine can be configured in such a way that it automatically switches on, carries out a disinfection and switches off again. The parameters of the automatic disinfection can be set for one week.

1. Touch icon on disinfection screen.
   ↳ The weekly disinfection program screen is displayed.

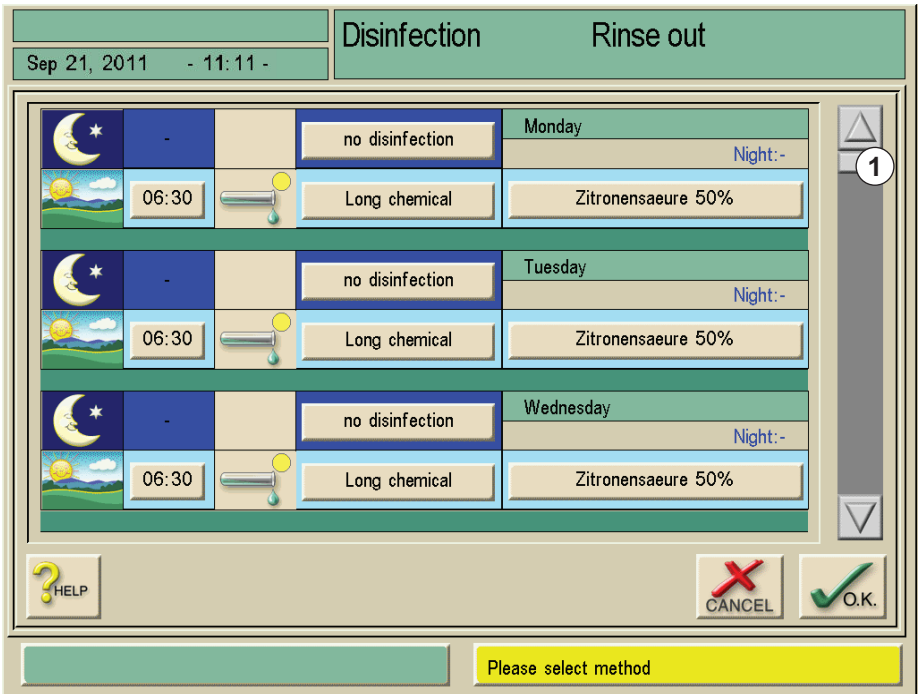


Fig. 12-4 Weekly disinfection program (Example)

Fig. 12-4 shows the set-up for the following disinfection modes:

Day/time	Description
Monday	
6.30 hrs.	A chemical disinfection with citric acid 50 % is carried out. The machine remains switched on after disinfection.
Tuesday	
6.30 hrs.	A chemical disinfection with citric acid 50 % is carried out.
Wednesday	
6.30 hrs.	A chemical disinfection with citric acid 50 % is carried out. The machine remains switched on after disinfection.

1. Use scroll bar **1** to move to other weekdays.
2. Touch respective field and change settings.
   ↳ The settings are automatically stored.

The following setting options are available:

- No disinfection
- Thermal disinfection
- Central thermal disinfection
- Central chemical disinfection
- Rinsing
- Long chemical disinfection (only daytime setting)
- Short chemical disinfection/cleaning (only daytime setting)

The automatic start of the preparation of the dialysis machine in the morning must be activated in the service program.

With the setting “Day/rinsing”, the dialysis machine changes to the ”Preparation/test” mode after switch-on.

Upon completion of an automatic night action, the dialysis machine switches itself off again.

Upon completion of an automatic day action, the dialysis machine remains in “Rinse-out” mode.

12.4 Configuring Profiles

12.4.1 Basic Principles

Parameters are set as absolute or constant values or as profiles with a time-adjusted progress.

The following parameters are available for profiles:

- Dialysate flow
- Dialysate temperature
- Conductivity (overall)
- Ultrafiltration
- Heparin
- Bicarbonate conductivity

For ultrafiltration, a selection of ten programmed or one individual profile is available.

12.4.2 Setting Profile Parameters

The setting of the parameters is explained using the conductivity (Na^+) profile as an example.

1 Profile settings
2 Enter therapy parameters
3 Heparinization data
4 Pressure limits
5 Ultrafiltration data
6 Dialysate parameters

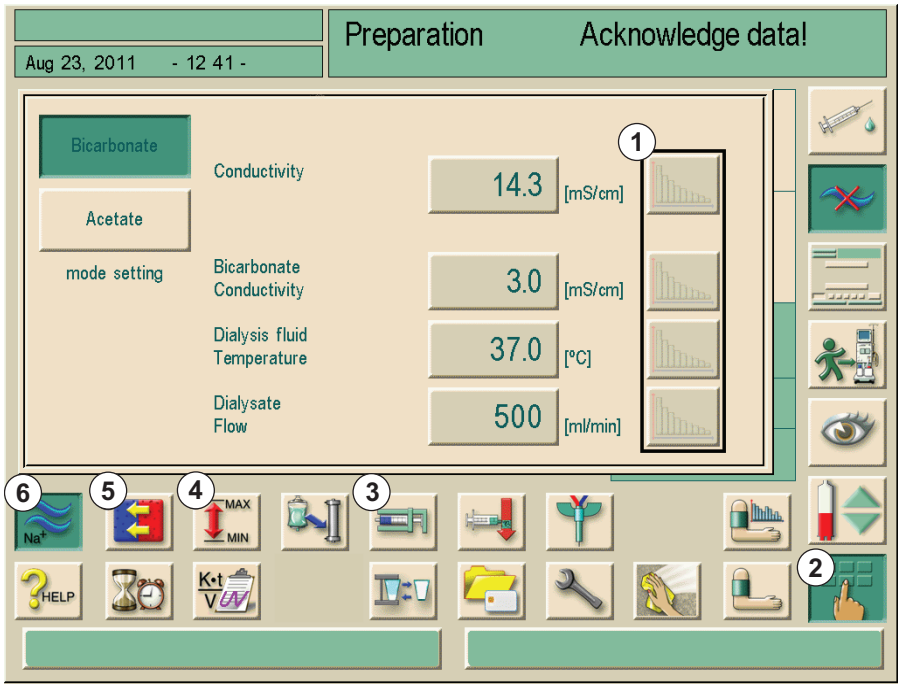


Fig. 12-5 "Conductivity" screen

1. Touch icon **2**.
2. Touch icon **6**.
3. Touch icon **1**.

   The following screen appears:

1 Linear profile
2 Exponential profile
3 Parameter bar
4 Duration of parameter bar
5 Therapy time setting
6 Manual input of the total value = resetting the profile to horizontal shape
7 Value for the selected parameter bar

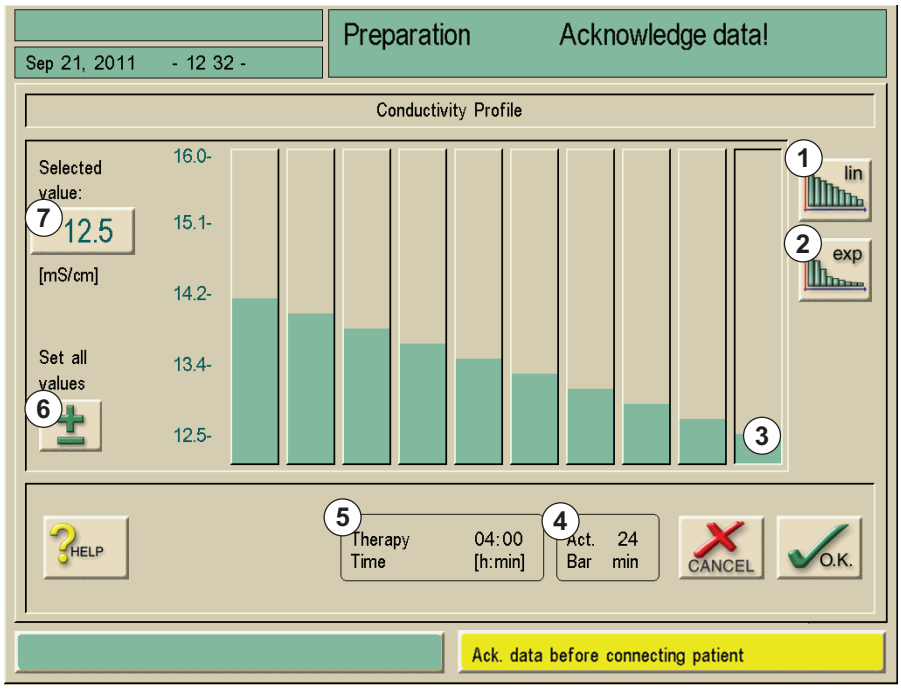


Fig. 12-6 "Profile parameters" screen

The “profile parameters” screen contains a graphic with ten parameter bars, representing the treatment time. In other words: Based on a 4 h (240 min) therapy time, one parameter bar covers 24 min.

Four options for adjusting the parameters are available.

Option 1: Manual adjustment of values

1. Adjust values by moving each parameter bar **3** on the touch screen, using your finger.

Option 2: Direct entry

1. Touch the parameter bar to be adjusted.
2. Touch icon **7**.
3. Enter value directly via the keypad or through icons +/-.
4. Accept value by touching icon **O.K**.

Option 3: Automatic (linear/exponential) distribution

1. Select first parameter bar.
2. Touch icon **7**.
3. Enter value via keypad and confirm with icon **O.K**.
4. Select last parameter bar.
5. Touch icon **7**.
6. Enter value via keypad and confirm with icon **O.K**.
7. Touch icon **1** or **2** to automatically distribute values linearly or exponentially.

Option 4: Create a developing profile by moving the finger over the diagram

1. Positioning the finger at the first or last bar.
2. Move the finger over all bars along the desired developing profile.

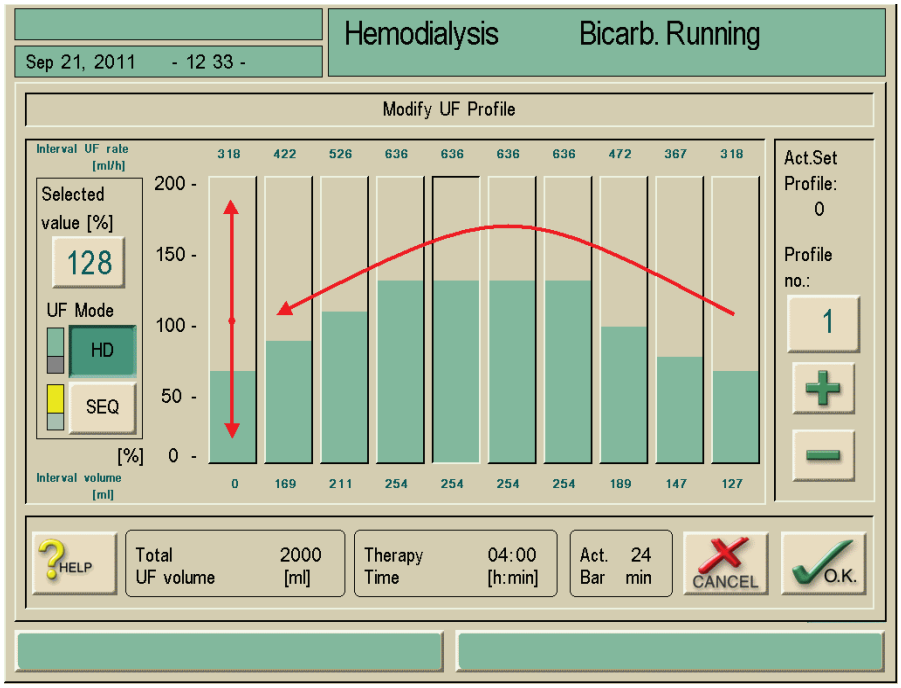


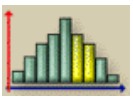
Fig. 12-7 Edit profile

12.5 UF Profiles

12.5.1 Select UF Profiles

Apart from the individual settings, the dialysis machine offers standardized ultrafiltration profiles. As another option, an individual UF profile can be preselected at any time and stored on the patient card or via BSL after the dialysis therapy. The profile table contains descriptions to the different profiles.

1. Touch icon.
   - ↳ The “UF parameters” screen appears.



2. Touch icon.
   - ↳ The “UF profile” screen appears.
   - ↳ The UF rate setting is specified above each parameter bar.

1 Profile number
2 Next profile number
3 Previous profile number
4 UF without dialysate (sequential therapy)
5 UF with dialysate

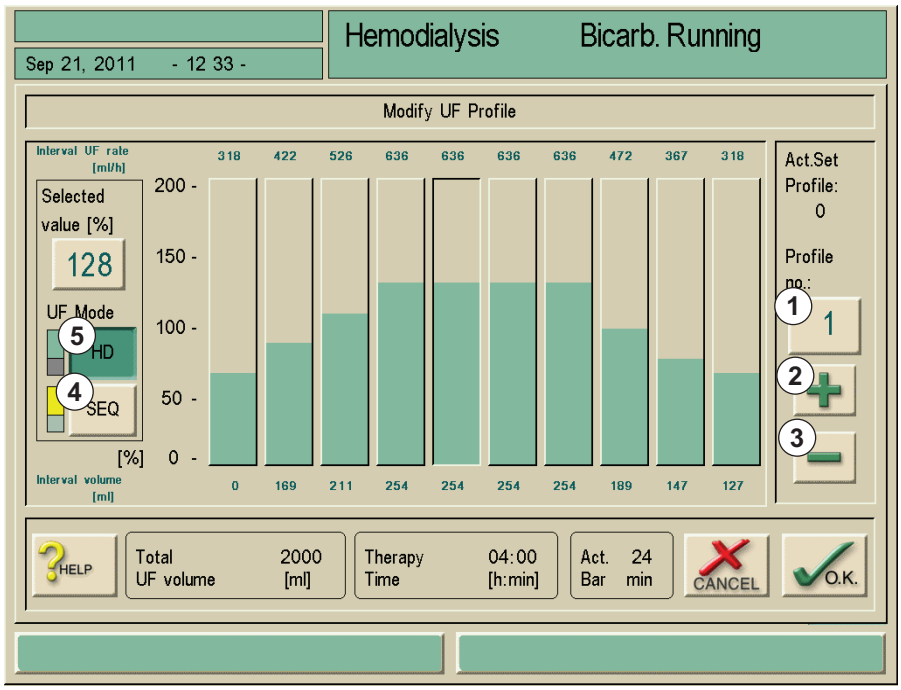


Fig. 12-8 ”UF profile” screen

3. Touch icon **2** or **3** to select other UF profiles.
   - ↳ Apart from the even ultrafiltration profile (profile 0), 9 other UF profiles are available.
4. Touch icon **4** or **5** to change from “Dialysate flow (HD)” mode to sequential therapy (SEQ).
   - ↳ The sequential phase is highlighted in yellow.

⚠ WARNING!

Risk of dehydration!

- A sequential therapy for a period of over 2 hours may only be set up on the instruction of a doctor.

WARNING!

Risk of hyperpotassemia/hypercalcaemia!

Carrying out a whole therapy in “sequential” mode may lead to increased blood values of the patient.

- A sequential therapy for a period of over 2 hours may only be set up on the instruction of a doctor.

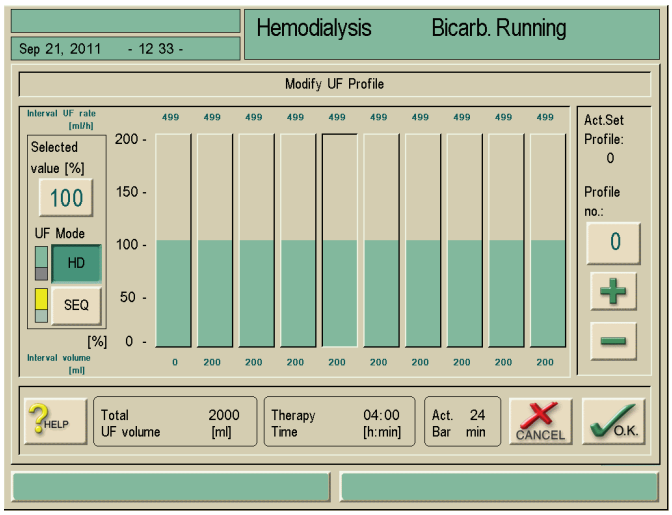
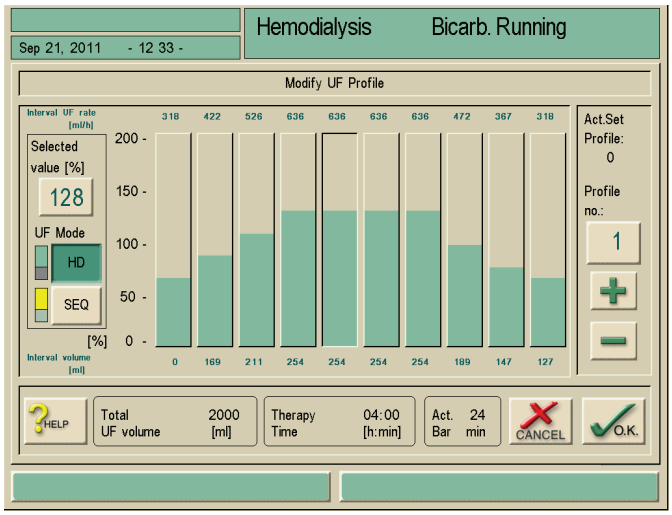
WARNING!

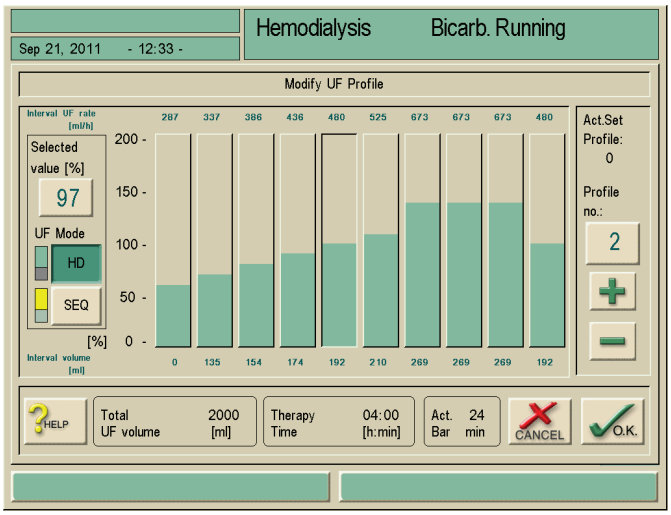
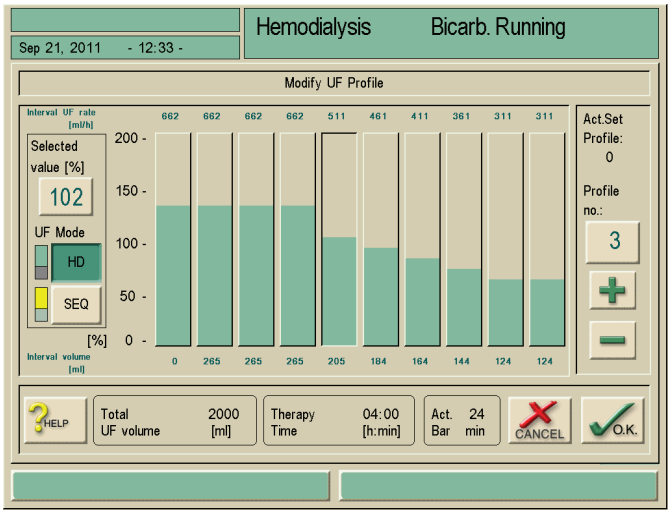
Risk of cardiovascular instability through high UF exposure!

- Regard to the patients individual constitution by adjusting the UF profile.
- The responsible physician should be informed.

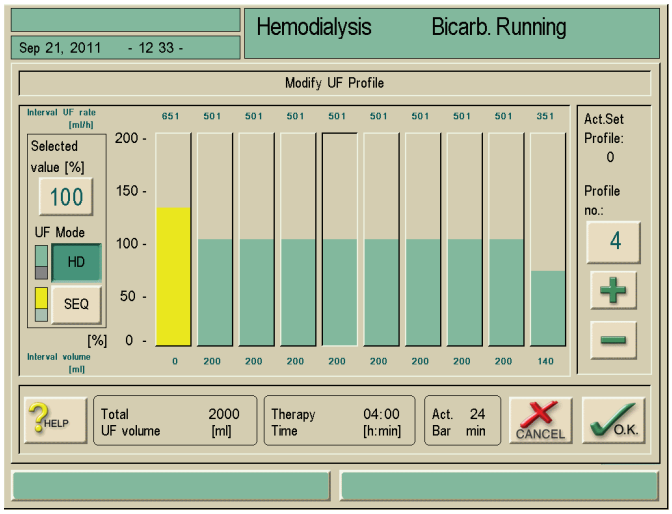
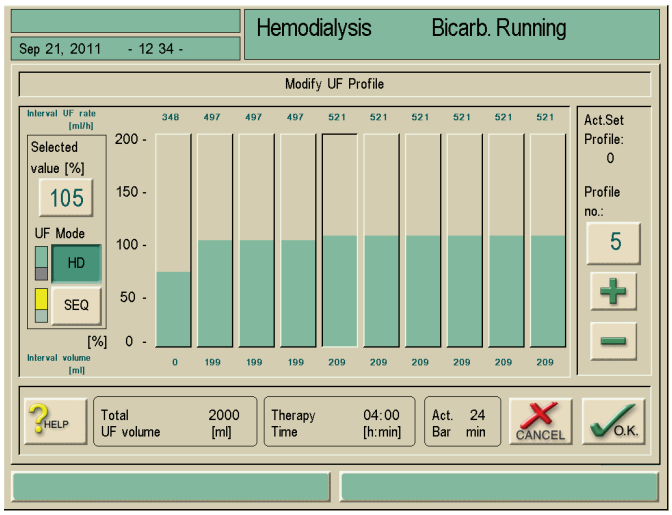
During automatic calculation, the last bar is adjusted depending on the total value.

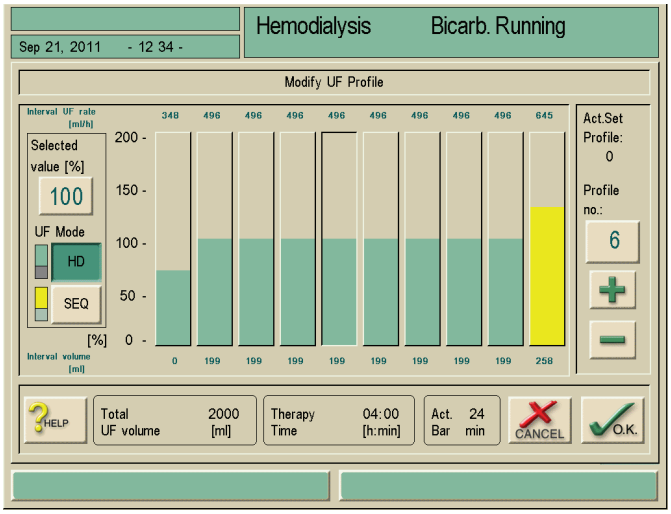
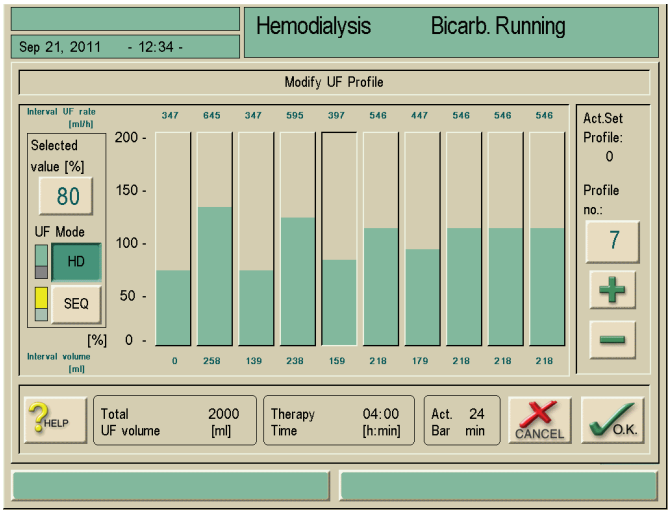
12.5.2 UF Profile Table

Profile no.	Description
0	Standard profile - Constant UF rate over entire therapy time. 
1	Particularly gentle therapy start and end phases, due to stepped UF rate increase/reduction. 

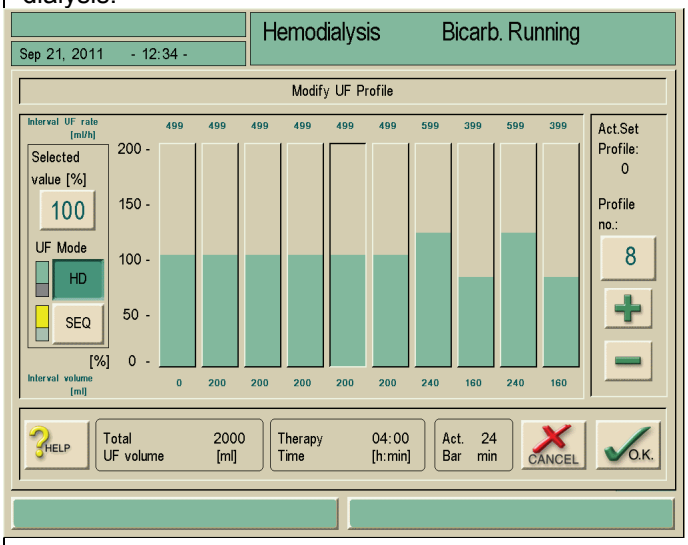
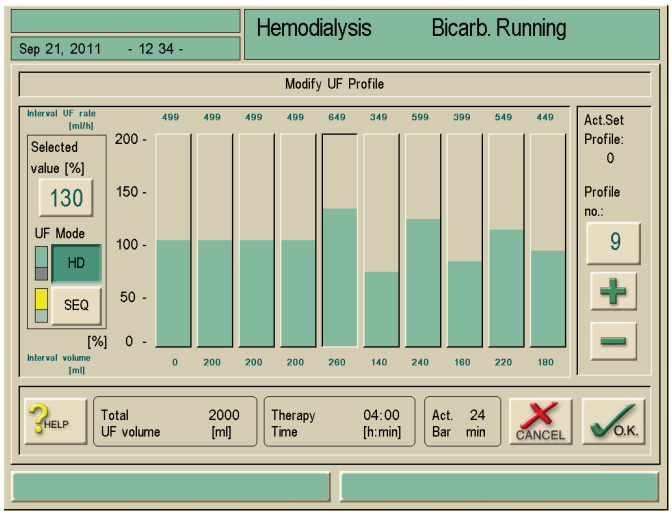
Profile no.	Description
2	Particularly gentle therapy start due to stepped UF rate increase. 
3	Particularly gentle therapy end due to stepped UF rate decrease. 

12

Profile no.	Description
4	In the first section, the sequential operating mode is set automatically. Suitable for patients from whom most of the fluid has to be extracted at the beginning of the treatment. 
5	Particularly suited for starting up parallel flow dialysers. 

Profile no.	Description
6	The sequential operating mode is automatically set in the last section. Suitable for patients from whom most of the fluid has to be extracted at the end of the treatment 
7	Alternating stressful and gentle phases during the initial treatment period, with constant fluid removal at the end of the treatment. 

12

Profile no.	Description
8	Alternating stressful and gentle phases at the end of the dialysis. 
9	Alternating stressful and gentle phases during the second treatment period, with constant fluid removal at the beginning of the treatment. 
10	Freely settable. When a given profile is changed, the machine assigns a name to it and stores it as profile 10. When the profile is changed again, the previous profile is overwritten.
11-30	Profiles no. 11 to 30 can be preset by the technical service according to customer requirements.

12.6 Patient Card

The Card reader can be installed as an option on Dialog+ machines.

The patient card offers the option of individually storing nearly all pre-settings for a therapy and calling them up again at the preparation stage.

Also, treatment results from up to 50 therapies can be stored after a therapy.

The patient card should be ordered from B. Braun to have a certified quality standard.

12.6.1 Erasing Data from Patient Card

1. Touch icon.
   - ↳ The selection menu appears.
2. Insert therapy card into drive.

3. Touch icon.
   - ↳ All data on the patient card will be erased!

12.6.2 Entering the Patient Name

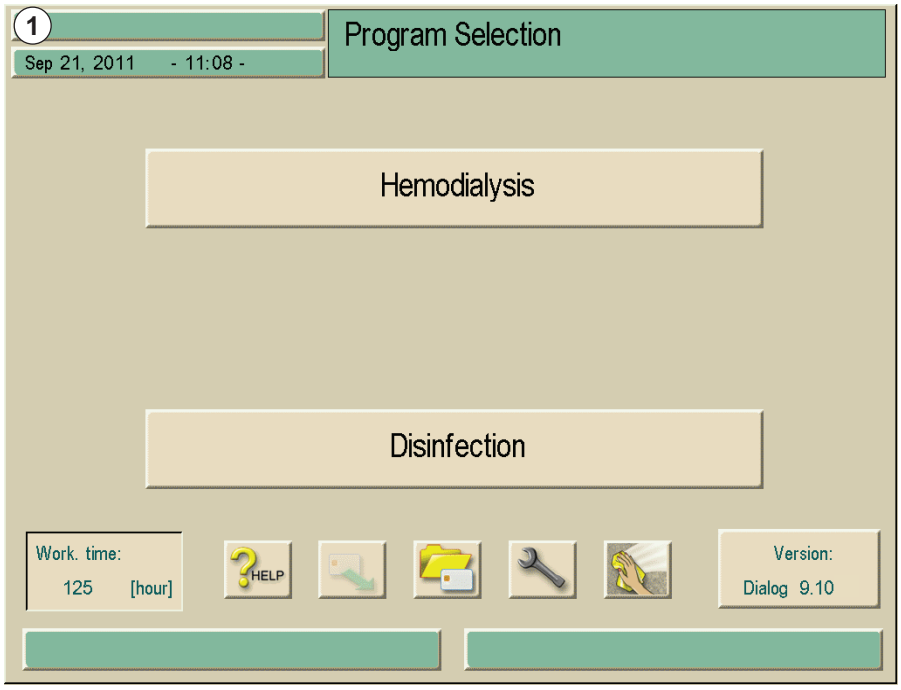


Fig. 12-9 Recording the patient name

The patient name can be entered in field **1** of the input screen.

1. Touch field **1**.
   - ↳ The keyboard appears on the screen.

1 Entry field
2 Delete all characters to the left of the cursor
3 Delete all characters
4 Delete all characters to the right of the cursor
5 Insertion mode
6 Shift key
7 Special characters on
8 Special characters off

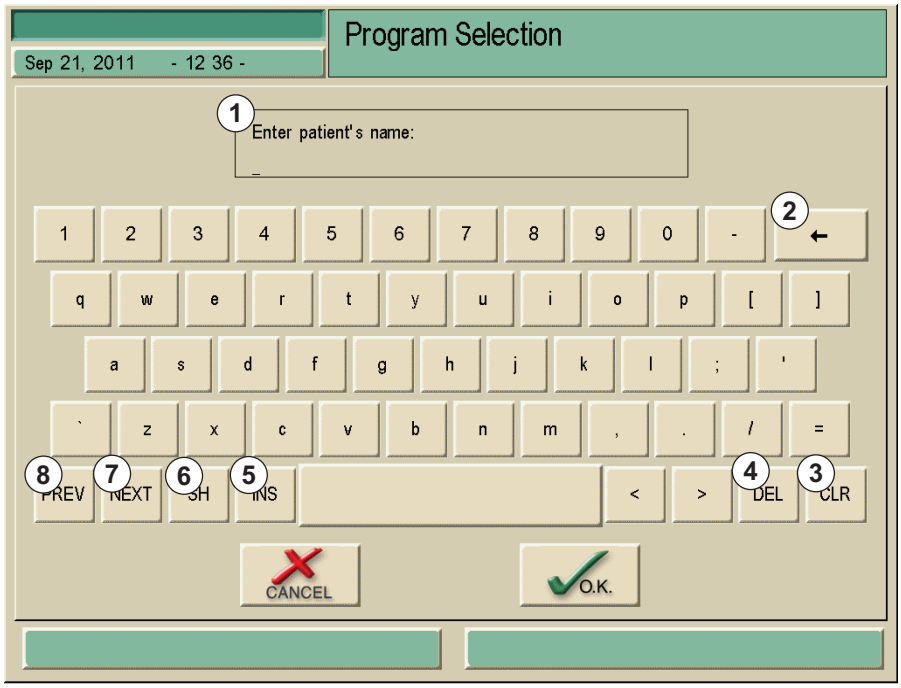


Fig. 12-10 Patient name keyboard

2. Enter patient name in field **1** using the keyboard, and confirm with icon **O.K**.

When working with the patient card, an additional field “Patient number” is displayed in the “Patient Overview” screen. This helps to differentiate between patients with the same name.

12

12.6.3 Reading Patient Data

Patient data can only be read in the Therapy selection and Preparation modes.

1. Insert patient card into card reader.
2. Touch icon.
   - The read-in operation is displayed on the screen.
3. Check data in overview. Change to second page, where applicable.
   - If the patient card contains data that for technical reasons cannot be read by the dialysis machine, this red icon appears.
4. Touch icon and confirm modification mask for the respective parameter with **O.K**.
   - The icon disappears once all faulty parameters have been changed.
   - Patient data can only be transferred from the card if there are no data left on the screen that are highlighted by a red background.
5. Accept all parameters by touching the **O.K**. icon appearing in the bottom right corner.

By inserting the patient card in Therapy selection or Preparation, data is read automatically.

12.6.4 Storing Patient Data (Parameter Settings)

1. Touch icon after changing the parameter settings.
   ↳ The patient data are stored on a patient card.
2. Save effectiveness data (Kt/V), see section 12.7 Entering Parameters for Computing the Effectiveness of the Dialysis (240).

NOTICE!

Machines operated with option Nexadia BSL have other saving options. These are described in the respective instructions for use.

12.7 Entering Parameters for Computing the Effectiveness of the Dialysis

1. Ensure that patient card has been inserted into the dialysis machine.
2. Touch icon.

   ↳ A screen for entering patient data for calculation of the theoretical effectiveness opens.

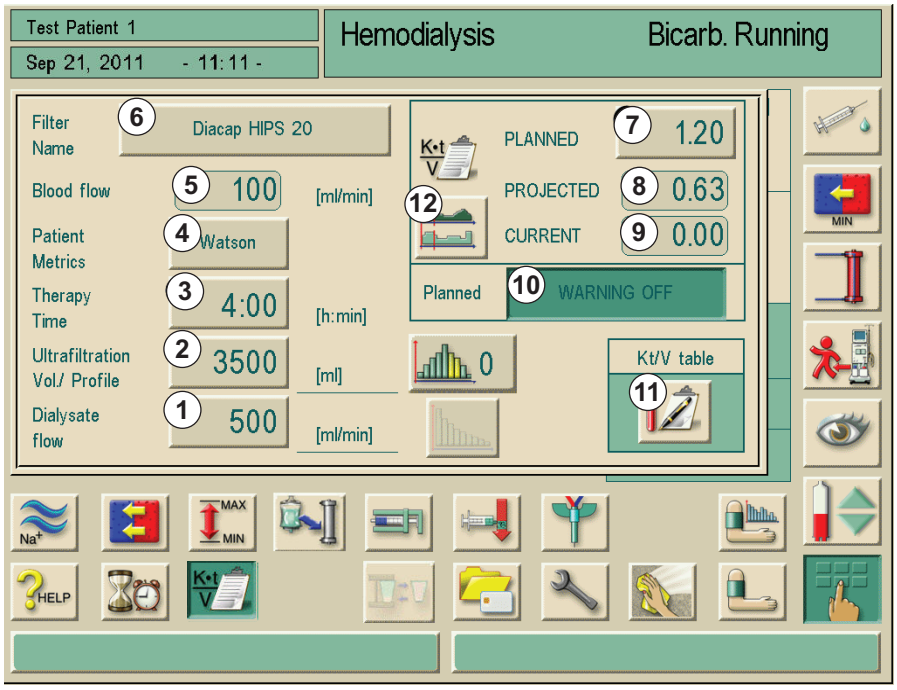


Fig. 12-11 Input window for calculating the effectiveness (Kt/V values)

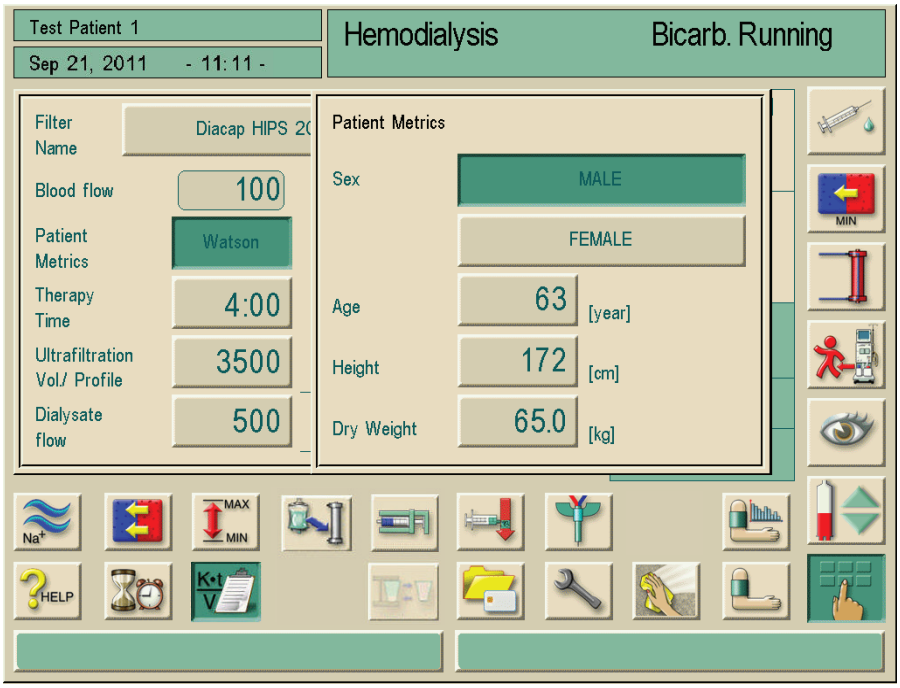


Fig. 12-12 Input window patient data after touching “Watson“ icon (Kt/UV)

Item	Text	Comment
1	Dialysate flow	Entry and display of dialysate flow in ml/min.
2	Ultrafiltration Vol./Profile	Entry and display of ultrafiltration volume in ml and profile of ultrafiltration.
3	Therapy Time	Entry and display of dialysis duration in hours and minutes.
4	Patient data	Entry of: • Sex • Age • Size • Dry weight for identification of urea distribution volume using the “Watson” formula.
5	Blood flow	Display of the measured value during dialysis.
6	Filter Name	Input and display of dialyzer in use. The data must be stored in a table in the service program.
7	PLANNED	Entry of intended Kt/V value.
8	PROJECTED	Computed probable Kt/V value at the end of the dialysis, calculated with the actual blood flow.

Item	Text	Comment
9	CURRENT	Current Kt/V value determined by the dialysis machine.
10	WARNING OFF Planned	If the intended Kt/V value (target value) will probably not be achieved, the dialysis machine automatically displays a warning. To switch off the warning function, activate field “Warning off”.
11	Kt/V table	Opens a screen with the table of the patient's Kt/V values from the patient card.
12	Kt/V graphics	Opens a graphical display of the planned and actual Kt/V progression.

1. Change the following parameters if necessary:

- Filter Name (**6**)
- Patient data (**4**)
- Therapy Time in hours and minutes (**3**)
- Ultrafiltration: Vol./Profile in ml (**2**)
- Dialysate flow in ml/min (**1**)
- Planned (**7**)

Show table

1. Touch icon (**11**).

   ↳ The Kt/V results are transferred from the patient card and shown in a screen:

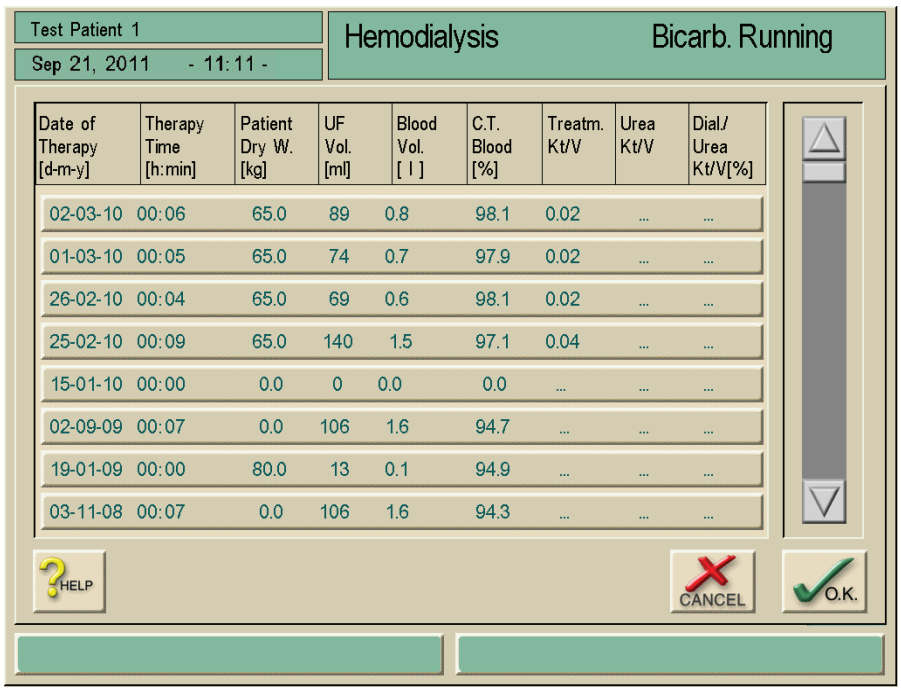


Fig. 12-13 ”Table Kt/V values” screen

Entering laboratory results

As the laboratory results before and after the dialysis are not available at that point, there is the option of entering these values into the table retrospectively.

1. Touch appropriate line.
   - A screen for entering the laboratory results appears:

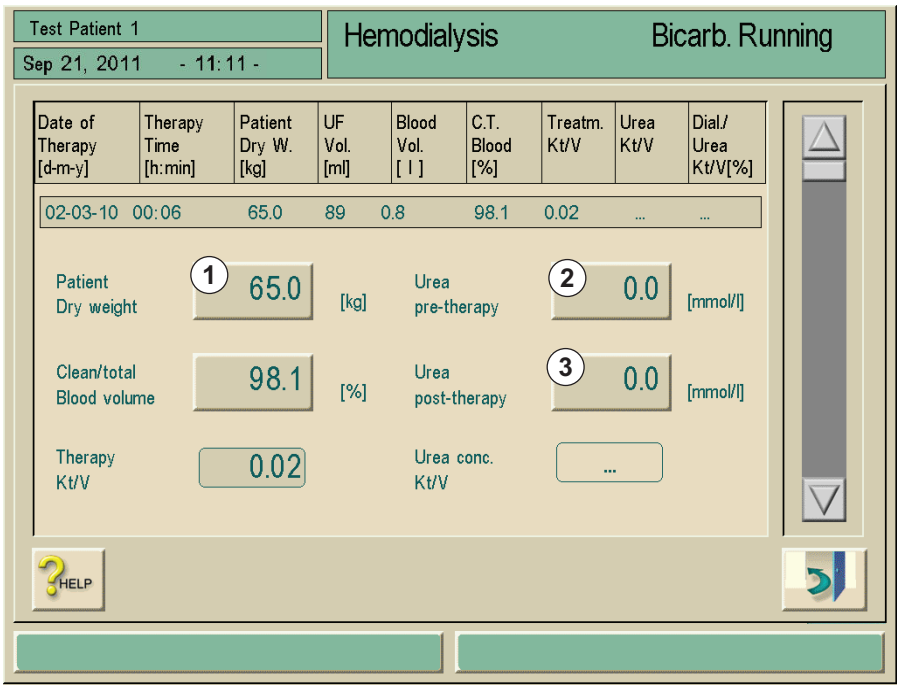


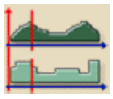
Fig. 12-14 Entering laboratory results

2. Enter the following laboratory results:
   - Dry weight of patient in kg (**1**)
   - Laboratory result for urea concentration prior to dialysis (mmol/l) (**2**)
   - Laboratory result for urea concentration after dialysis (mmol/l) (**3**)
3. Touch icon.

   - The table with the current Kt/V figures is displayed. Changed figures are automatically saved to the patient card.

Show Graphics

1. Touch icon



   - A graphical display of the projected and actual Kt/V progression is shown.

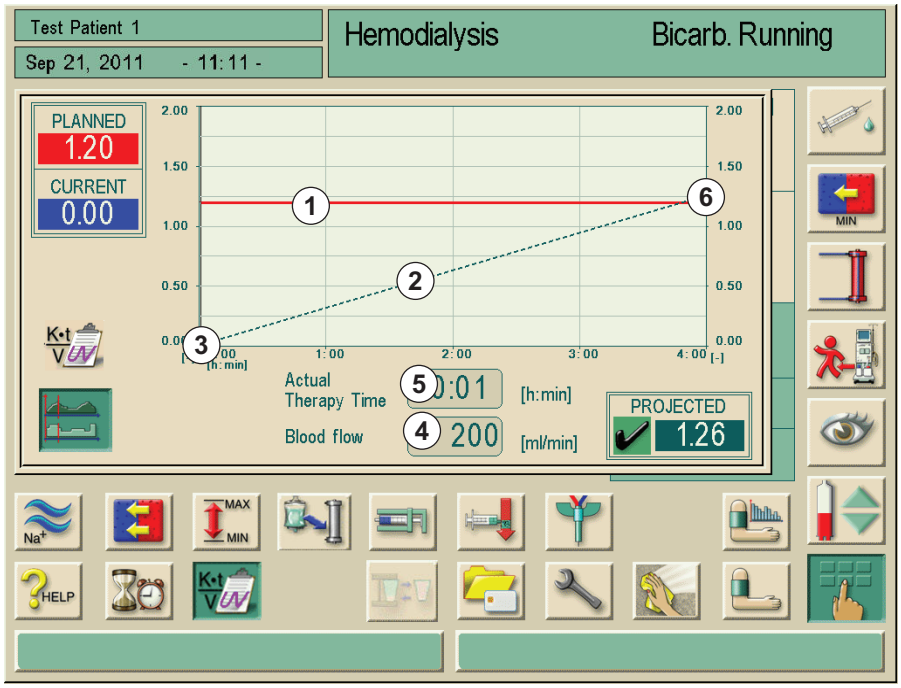


Fig. 12-15 Graphical display of Kt/V progression (Projected O.K.)

Item	Text	Comment
1	Aim Kt/V	Planned Kt/V aim
2	Projected Kt/V progression	Graphical display of the projected Kt/V progression
3	Actual and current Kt/V progression	Display of actual and current Kt/V progression
4	Current blood flow	Display of the momentary blood flow
5	Current Therapy time	Display of present Therapy time
6	Projected Kt/V aim	Display of projected Kt/V result (O.K., aim Kt/V will be reached, has been reached)
7	Projected Kt/V aim	Display of projected Kt/V result (not O.K., aim Kt/V won't be reached, hasn't been reached)
8	Cursor line	Cursor line shows the current therapy moment

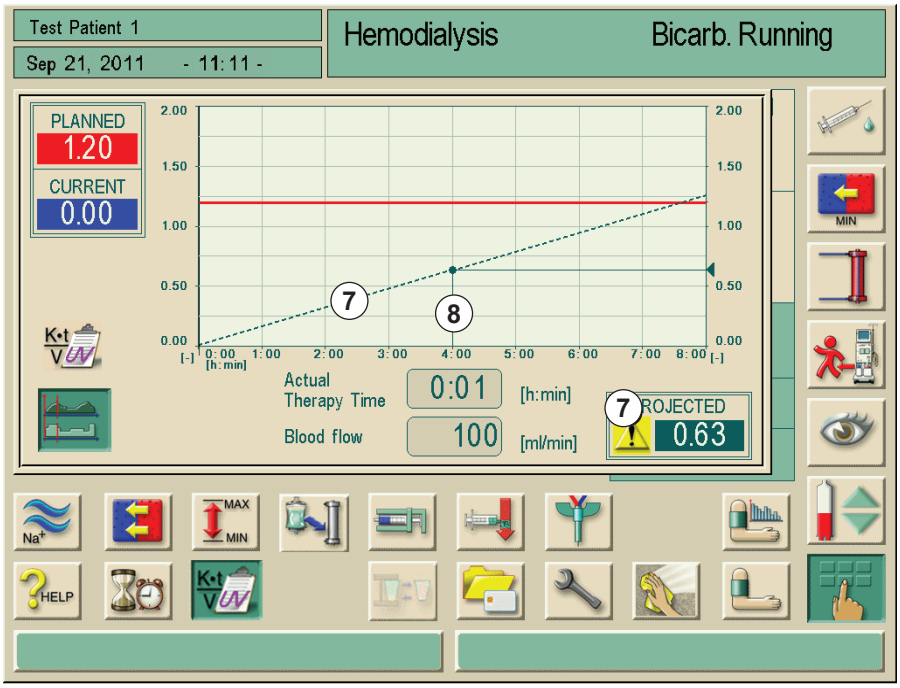


Fig. 12-16 Graphical display of Kt/V progression (Projected not O.K.)

Kt/V will not be calculated in the therapy mode “Seq.” and “HF”.

To arrange a correct blood withdrawal according to quality guidelines for a Kt/V calculation, the Dialog+ changes after the treatment on an UF rate of 50 ml/h.

The blood pump goes on with the selected speed.

A monitoring of the duration of this mode can be carried out by the use of the timer function.

End Kt/V

1. Touch icon on the “Table Kt/V value” screen.

   ↳ The screen is closed. All entered data are stored on the patient card. When closing the screen by touching the icon **CANCEL**, no data are stored.

12.8 Adjusting Monitor Brightness

The monitor brightness can be adjusted in the following way:

- Manually, continuously
- Manual switch between preset day/night brightness

This must be activated in the service program.

Procedure

1. Touch icon.

   ↳ The data management screen appears.

2. Touch icon.
   ↳ The screen for adjusting the brightness is displayed.

To set the brightness manually:

1. Adjust brightness using the slide displayed on the screen.
   ↳ ”Manual” is displayed at the center of the screen.

To set the brightness for daytime:

1. Activate field **Daytime settings**.
   ↳ ”Daytime” is displayed at the center of the screen.

To set the brightness for nighttime:

1. Activate the field **Nighttime settings**.
   ↳ ”Nighttime” is displayed at the center of the screen.

Screensaver

To activate the screensaver:

1. Touch the field **Yes** next to the field **Screensaver on**.

To deactivate the screensaver:

1. Touch field **No**.
2. To close the screen, touch the “Brightness adjustment” icon.

NOTICE!

It is recommended to activate the screensaver.

1. To close the screen, touch the “Data management” icon.

If **Screensaver on** has been activated with **Yes**, the screensaver will be activated after the time preset in the service program.

The screensaver shows 3 moving objects against a dark background:

- Pie chart of therapy time
- Mode
- Time
- If option ABPM is installed, last BP results are shown instead of time

Alarms or touching the screen switch off the screensaver and the active screen appears again.

12.9 Select Language of Screen Text

Depending on the languages available in the TSM, you can choose the language for the screen text.

Procedure

1. Touch icon.
   ↳ The data management screen appears.

2. Touch icon.
   ↳ The screen with all available languages appears.

Fig. 12-17 Screen “available languages“

3. Touch row with selected language.
4. Touch button for changing the language.
   ↳ Screen text appears in chosen language.

12.10 Edit Parameter of Trend Groups

You can edit the combination of parameters within the trend group.

1. Call screen “Overview trend groups” as described in chapter 6.3.5 Graphical Representation of Treatment Parameters (Trend) (109) .

1 Field trend group
2 Button “edit group”
3 Choose TSM presettings
4 Leave screen and save changes
5 Leave screen without saving

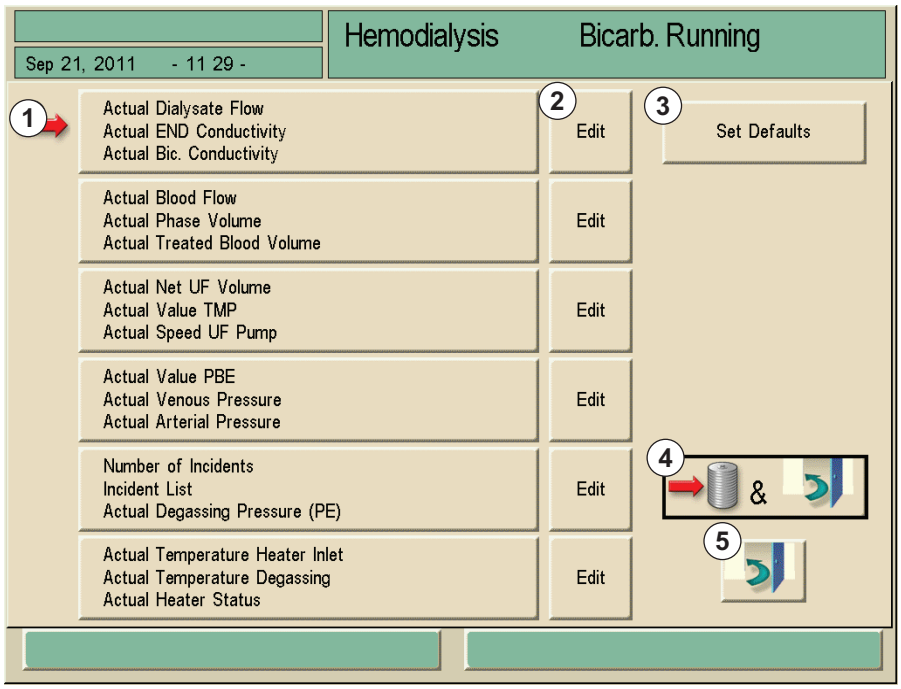


Fig. 12-18 Screen “Overview trend groups“

Single groups could be edited individually with parameters of your own choice.

1. Touch favoured button.

↳ The following screen appears.

1 Field “trend group parameters”
2 Field “list of parameters”
3 Scroll bar “trend groups”
4 Scroll bar “list of parameters 2”
5 Leave screen

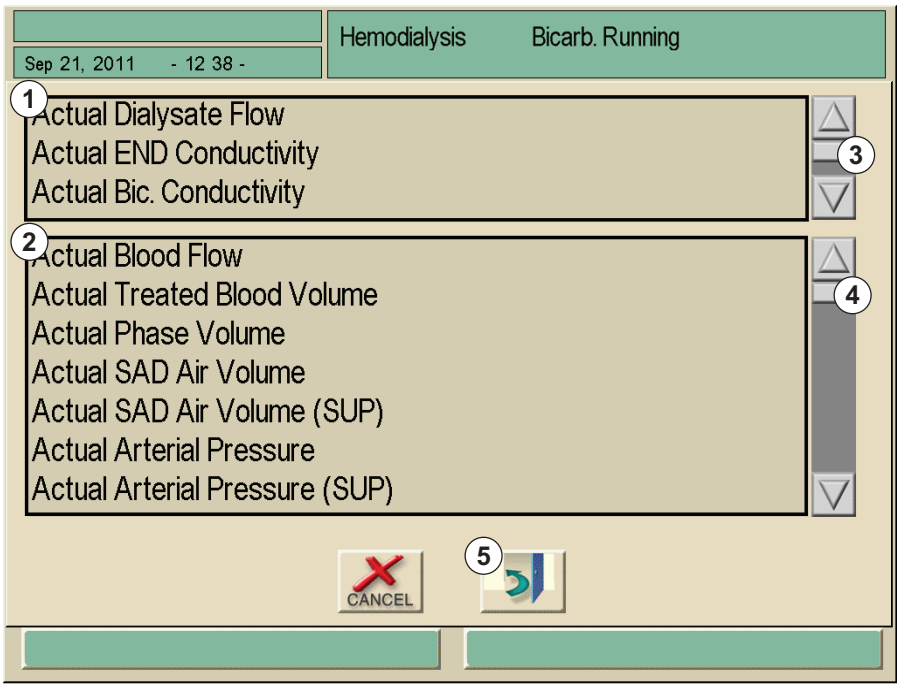


Fig. 12-19 Edit trend groups

2. Touch parameter which is to be replaced in field **1**.
   ↳ Parameter will be marked by a frame.
3. Search desired parameter in list **2** and touch it.
   ↳ The marked parameter will be replaced.
4. Choose next parameter and replace as described.
5. Touch icon to leave the screen.
   ↳ The screen “overview trend groups” appears.

6. Touch icon to save the new trend group.
   ↳ In the TSM preset trend groups could be set up again.

7. Touch icon.

Table of Contents

13 Alarms and Remedial Action

There are two types of alarm systems in the Dialog+.

The service technician can modify the alarm system between standard alarm system to intensive care unit (ICU) on demand in TSM.

13.1 Alarm System Overview

Dialog+ is provided with an alarm management system according to the standard IEC/EN 60601-1-8, which distinguished high, medium and low priority alarms.

During preparation and therapy, the user has to be able to get all acoustic and visual information and has to be able to react according to the instructions for use.

Therefore, the user should stand in front of the machine facing the monitor. The distance between user and monitor should not be more than 1 meter. This position allows an optimal view on the monitor and a comfortable handling of the keys on the monitor.

13.1.1 Alarm Handling

Each alarm has three states:

- **Condition:** Cause of the alarm system when it determined that a potential or actual hazard exists. The alarm system checks the alarm conditions periodically. If a condition exists, an alarm will be generated and the alarm handling will be performed (if necessary).
- **Reaction:** When an alarm is activated, the alarm system performs the necessary activities to keep the required safety state. All necessary activities which have to be performed when an alarm occurs are described in chapter 13.2 Alarms and Troubleshooting (259).
- **End condition:** The machine changes into normal operating condition after the alarm condition has been ended or the user solved the problem.

The alarm and its reactions can be removed, if the alarm condition is no longer valid according to alarm mute handling descriptions. The general alarm mute handling for each alarm and warning is described in chapter 13.1.2 Characteristics of Alarms (253).

13.1.2 Characteristics of Alarms

Alarm Priorities

The machine can generate different alarm levels:

- High priority alarms
- Medium priority alarms
- Low priority alarms

Alarms and warnings are shown in the alarm list in the order of their alarm ID. The triggering alarm or warning is shown in the alarm field.

Upon resetting the triggering alarm, all subsequent alarms or warnings are also deleted.

Message	Description
Alarm	• Alarm message is displayed in the alarm field. • Description of the alarm is displayed in the alarm field (if necessary).
Warning	Warning message is displayed in the warning field.

1 Help text
2 Warning field
3 Alarm field
4 Alarm list
5 Call up comments

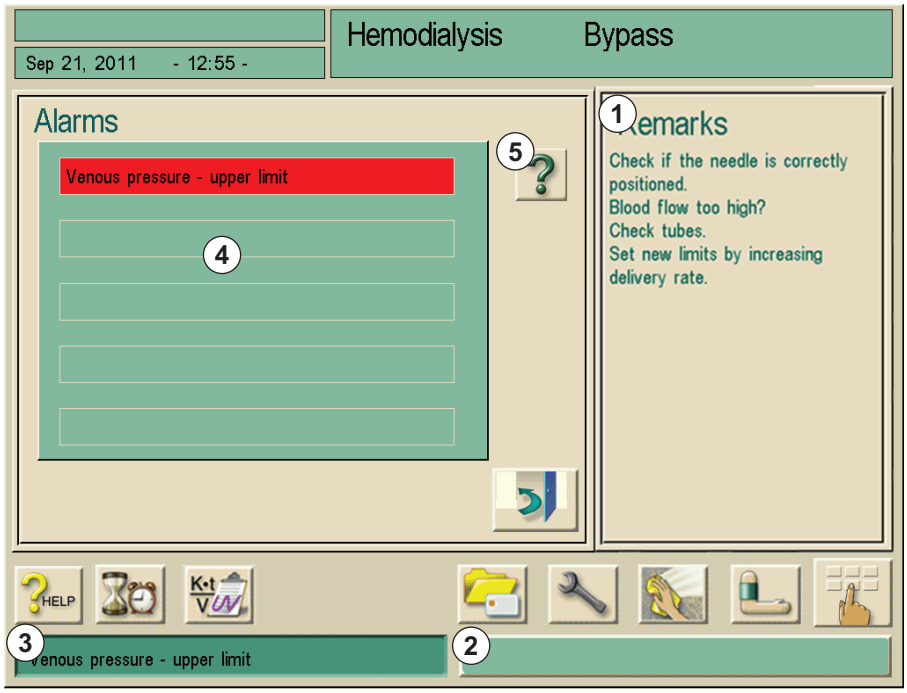


Fig. 13-1 Alarm display

- Alarms are displayed in alarm field **3**.
- The background of the alarm field changes from green to red.
- An acoustic signal is triggered.
- Signal lights on screen change to red.

The alarm with the highest priority is given acoustically, the alarm with lower priority is shown in the background with no separate alarm. The acoustic signal is emitted until either the cause of the alarm is remedied or the alarm mute key is pressed.

The Dialog+ machine assigns the appropriate priority to the alarm according to the table below:

Alarm Priority Optical and Acoustic Characteristics	Description
High Signal lamp: red flashing Sound: c f# c - c f# (repeated)*	Safety hazard, immediate user response is required.
High (Cardiac) Signal lamp: red flashing Sound: c e g - g C (repeated)*	Safety hazard, immediate user response is required.
Medium Signal lamp: yellow flashing Sound: c f# c (repeated)*	Safety hazard, prompt user response is required.
Medium (Cardiac) Signal lamp: yellow flashing Sound: c e g (repeated)*	Safety hazard, prompt user response is required.
Low (Hint + OSD) Signal lamp: solid yellow Sound: e c (repeated or only once)*	Safety hazard, user awareness is required.
Low (Hint) Signal lamp: solid yellow Sound: e c (repeated or only once)*	Safety hazard, user awareness is required.
Low Signal lamp: solid yellow Sound: no sound	Safety hazard, user awareness is required.

*Music Note	Tone Pitch
c	low
e	minor medium
f#	medium
g	major medium
C	high

NOTICE!

Technical service can activate an alternative alarm sound system in the TSM which differs from the continuing alarm sound in an alternating melody.

NOTICE!

The user is responsible for the reset of an alarm or warning and subsequently for the monitoring of the suppressed parameters of the dialysis machine.

The acoustic signal sound pressure of different priority alarms is at least 65 db (A) at a distance of 1 meter.

The alarm mute key mutes the acoustic alarm for the defined alarm mute time duration according to the alarm table in chapter 13.2 Alarms and Troubleshooting (259).

Alarm Handling

To reset a blood side alarm:

1. Press alarm mute key.
   - ↳ Acoustic signal is switched off.
2. Remedy the cause(s) of the alarm.
3. Press alarm mute key.
   - ↳ Machine is reset to its previous operating condition.

To reset a blood side alarm:

1. Press alarm mute key.
   - ↳ Acoustic signal is switched off.
   - ↳ Background color of the alarm field changes from red to yellow.Alarms on the dialysate-side are automatically reset once the cause of the alarm has been removed.

Warnings or information appear in warning field **2**. Warning field **2** flashes when more than one warning has been triggered.

The warning field **2** also contains the alarm ID. Note down the alarm ID, in case you need to contact technical service with possible queries.

1. Touch warning field **2**.
   - ↳ The alarm list **4** is displayed.

13.1.3 Alarm Limits and Presets

Dialog+ has a set of default alarm limits. Some of them can be modified during the therapy but their values cannot be saved. The preset values can not be overwritten by the user.

The alarm limits and settings prior to the power loss are restored automatically, if the power is lost for more than 15 minutes during therapy.

⚠ CAUTION!

Make sure that the alarm system is neither rendered useless by setting extreme values for the alarm limits nor deactivated by switching off the alarms.

- Do not set extreme high or extreme low alarm limits.
- Do not switch off alarms without remedying the alarm cause.

⚠ WARNING!

Risk to the patient due to blood loss, if PV lower delta is set too low! The machine controls a tracking algorithm for PV alarm limits of 2 mmHg per 2 minutes during therapy.

- Ensure that PV lower delta is not too low.

⚠ WARNING!

Risk to the patient due to unrecognized hazardous situations!

Alarm limits may be changed by authorized users.

- The authorized user must inform all other users about changed alarm limits.

13.1.4 Alarm Delay

The following blood leak alarms have an alarm delay of 30 seconds for the control system and 35 seconds for the protective system.

- Alarm code 1042: Blood leak >0.5 ml/min
- Alarm code 1955: Blood Leak (SUP)

For more details, see chapter 13.2 Alarms and Troubleshooting (259) Alarms and troubleshooting.

13.1.5 Verifying the Functionality of the Alarm System

The machine performs a series of self tests automatically after it is switched on at the beginning of each dialysis therapy. This allows a check of proper functionality of all machine components. The alarm system itself is also part of the self tests.

The machine can only start operating, if all self tests have successfully been passed.

NOTICE!

At failure or disturbance of the loudspeakers, the security system will activate the power supply buzzer to report an alarm acoustically.

- Contact technical service.

13.1.6 Operation in Case of Monitor Failure

In case of a monitor or touch screen function failure, all monitoring functions and the signal lamps on the monitor remain active. The blood pump can be controlled via the +/- keys and the START/STOP key.

NOTICE!

To prevent any disconcertion of user and patient, it is recommended to terminate therapy. This requires particular attention of the user.

NOTICE!

In case of alarms, special attention must be paid to the blood line system and the bubble catcher in front of the SAD. An alarm may only be reset when the user has verified that the venous patient line does not contain any air.

13.1.7 System Error Handling

When the safety system of the machine detects a system error, the machine will be set into patient-safe state. The machine stops the therapy by standstill of blood side and bypass of dialysate side, generates an acoustic alarm signal, and displays the following error message:

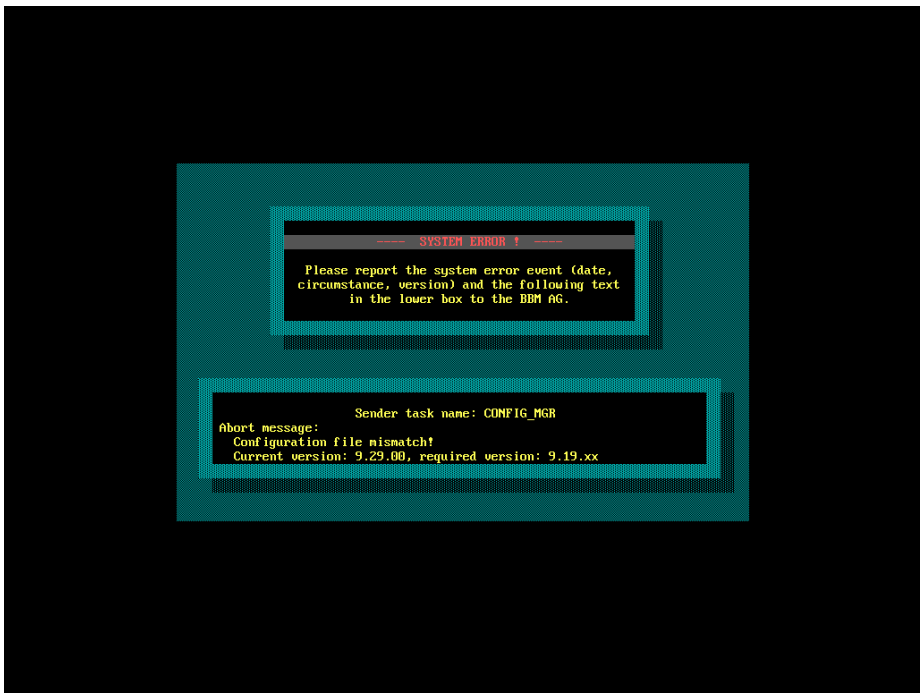


Fig. 13-2 System error message

The error message will always be displayed in English language.

The error message might be shown as raw text or as blank screen (see 13.1.6 Operation in Case of Monitor Failure (257)).

Required User Action

1. Switch machine off and on again. The machine will restore therapy parameters and the previous state.
2. After restart, press the *Alarm mute* key on the monitor twice to mute and confirm the alarm “System restored after power failure”.
3. Press the *Start/Stop* key on the monitor as soon as it is illuminated to start the blood flow.
4. Check the restored treatment parameters.

   ↳ Meanwhile, the machine will prepare the dialysis fluid and will leave the bypass mode automatically when ready. Therapy will be continued.

In the rare case that the error persists and therapy cannot be continued, return blood manually (see chapter 13.4 Manual Blood Return (308)) and disconnect the patient.

13.2 Alarms and Troubleshooting

All alarms and warnings are listed in following chapters. They are listed in ascending order of their code number.

13.2.1 Abbreviations in the Alarm Tables

Abbreviation	Definition
A	Alarm
W	Warning
Low	Safety hazard, user awareness is required
Low(Hint)	Safety hazard, user awareness is required
Low(Hint+OSD)	Safety hazard, user awareness is required
Medium	Safety hazard, prompt user response is required
Medium(Cardiac)	Safety hazard, prompt user response is required
High	Safety hazard, immediate user response is required
High(Cardiac)	Safety hazard, prompt user response is required
All	All phases
Sel	Select program
Pre	Preparation phase
The	Therapy phase
Eot	End of therapy phase
Dis	Disinfection phase

13.2.2 Dialysis Alarms

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
System restored after power failure (code 600) A/Low/All/0 s Power failure during Preparation/Treatment	Technical defect. The system was restored.	• Reestablish power supply.
Too long time of not using machine (code 620) W/Low(Hint)/All/0 s	Time of switched off state of machine was longer than maximum time configured in TSM.	• Disinfect machine before therapy.
UF Volume is reached (code 665) A/Low(Hint)/The/120 s	Therapy has ended.	• Disconnect patient.
UF Volume is overrun by 100 ml (code 666) A/Low(Hint)/The/120 s	Therapy has ended.	• Disconnect patient.
BP+ button stuck(code 672) A/Low(Hnt)/Sel/120 s A/Low(Hint)/Pre/120 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s A/Low(Hint)/Dis/120 s	The button BP+ is stuck.	• Release the button. • If stuck, contact technical service.
BP+ button stuck (code 672) W/Low(Hint)/All/120 s	The button BP+ is stuck.	• Release the button. • If stuck, contact technical service.
BP start/stopp button stuck (code 673) A/Low(Hint)/Sel/120 s A/Low(Hint)/Pre/120 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s A/Low(Hint)/Dis/120 s	The button BPS is stuck.	• Release the button. • If stuck, contact technical service.
BP start/stopp button stuck (code 673) W/Low(Hint)/All/120 s	The button BPS is stuck.	• Release the button. • If stuck, contact technical service.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
BP - button stuck (code 674) A/Low(Hint)/Sel/120 s A/Low(Hint)/Pre/120 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s A/Low(Hint)/Dis/120 s	The button BP - is stuck.	• Release the button. • If stuck, contact technical service.
BP - button stuck (code 674) W/Low(Hint)/All/120 s	The button BP - is stuck.	• Release the button. • If stuck, contact technical service.
↵ button stuck (code 675) A/Low(Hint)/Sel/120 s A/Low(Hint)/Pre/120 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s A/Low(Hint)/Dis/120 s	The ↵ button is stuck.	• Release the button. • If stuck, contact technical service.
↵ button stuck (code 675) W/Low(Hint)/Sel/120 s	The ↵ button is stuck.	• Press again. • If stuck, contact technical service.
↵ button stuck (code 676) W/Low(Hint)/All/120 s	The ↵ button is stuck.	• Press again. • Contact technical service.
UF Volume increased (code 677) W/Low/All/0 s	The UF volume was increased by the user.	• Take notice and observe patient.
The set time interval expired! (code 678) W/Low(Hint)/All/30 s W/Low/All/0 s	The set time interval of the timer has expired!	• Switch acoustic signal off and take required action.
Dialog time differs from the server time (code 679) W/Low(Hint)/All/0 s	The difference between the Dialog+ and server time is higher than 15 minutes.	• Deactivate the warning by going back to program selection or by pressing the 'Start Therapy' button.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
Timer expired before power return! (code 680) W/Low(Hint)/All/30 s W/Low/All/0 s	The set time interval of the Timer has expired during power failure!	• Switch acoustic signal off and take required action.
Patient Card is removed (code 682) W/Low(Hint)/All/0 s	The patient card has been removed.	• If you want to read or write additional data, insert the card again.
Card damaged, use a new/erased card (code 684) W/Low(Hint)/All/0 s	Reminder alarm to inform that the therapy has been started without self tests in preparation.	• Confirm this alarm to continue therapy.
Sound + LED test alarm (code 1002) A/Low(Hint)/Pre/120 s	Internal self test.	• No handling is necessary.
Blood side test failed (code 1003) A/Low(Hint)/Pre/120 s	Blood line not inserted in venous clamp.	• Insert line in venous clamp.
	Open cap or loose connection.	• Check tightness of connections and caps.
	Wet hydrophobic filter.	• Aerate pressure lines with syringe to remove fluid. If nothing helps, exchange blood line system.
	Wrong POD membrane position.	• Reposition POD membrane.
	Technical defect of pressure sensors or blood pump.	• In case of technical defect, contact technical service.
+/- 12 V Power Supply insufficient (code 1008) A/Low(Hint)/All/120 s Voltage level +12VAN or -12VAN is over the tolerance.	Technical defect.	• Contact technical service.
Mains failure - battery mode (code 1009) A/Low(Hint)/The/0 s A/Low(Hint)/Eot/0 s	The Dialog+ works with the accu.	• Check the mains power fuse.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
Water inlet disinf. - Intake disturbed (code 1013) A/Low/Dis/300 s	Reverse osmosis (RO) system switched off.	• Check RO device for supply.
	Water tube kinked or blocked.	• Make sure water inlet tube is connected to the wall socket and not kinked.
Water inlet disinf. - rinsing disturbed (code 1014) A/Low/Dis/300 s	The limit of the UF pump has been reached.	• Reduce the UF volume or increase the UF time. • If the problem persists, contact technical service.
TMP out of alarm limits (code 1015) A/Low(Hint)/The/300 s	TMP limits too low.	• Raise the TMP limit.
	UF coefficient of dialyzer too small.	• Careful: Take note of dialyzer limit value.
	Clotted dialyzer.	• Check dialyzer for clotting.
	UF rate too high.	• Reduce UF rate.
TMP too low (code 1016) A/Low(Hint)/Pre/300 s A/Low(Hint)/The/300 s	Technical defect.	• Increase UF volume. • Decrease UF time. • Contact technical service.
Dialyzer TMP limits exceeded (code 1017) A/Low(Hint)/Pre/120 s A/Low(Hint)/The/120 s The TMP (PV-PDA) is larger than the preset maximum TMP.	Excessive UF volume/time settings.	• Reduce UF volume/ increase UF time.
		• Reset TMP limits.
	Clotting.	• Check heparinization.
	Dialyzer factor too small.	• Use dialyzer with larger factor.
	Technical defect.	• Contact technical service.
Bicarbonate Cartridge not connected correctly (code 1018) A/Low(Hint)/Pre/0 s A/Low(Hint)/The/300 s A/Low(Hint)/Eot/0 s The cartridge could not be filled.	Bicarbonate cartridge probably not lanced correctly.	• Check if it fits the holder correctly.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
DF flow disturbed (membrane moving) (code 1019) A/Low/Pre/0 s A/Low/The/300 s A/Low/Eot/0 s	Malfunction of chamber system because of balance chamber membrane.	• Contact technical service.
DF pressure < -400 mmHg (code 1020) A/Low(Hint)/Pre/120 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s The dialysate pressure downstream of the dialyzer (PDA) is below -400 mmHg.	Dialyzer UF factor too small for set UF rate.	• Use dialyzer with larger UF factor.
	Too high UF volume set.	• Reduce UF volume/ increase UF time.
	Tube kinked.	• Check blood tubes.
	Technical defect.	• Contact technical service.
DF pressure > 400 mmHg (code 1021) A/Low(Hint)/Pre/120 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Pressure at the dialyzer is higher than 400 mmHg.	• Check PBE. • Check line system.
Water supply disturbed (code 1022) A/Low(Hint)/Pre/300 s A/Low(Hint)/The/300 s A/Low/Eot/0 s A/Low(Hint)/Dis/120 s 15 s after activation of the lower reed contact, the middle reed contact has not been reached again. The inlet valve is open during this time.	Water pressure too low.	• Check water inlet pressure (minimum pressure 0.5 bar).
	Water tap closed.	• Open shut-off valve.
	Water inlet tube kinked.	• Check inlet tube.
	Water inlet valve does not open or pressure reduction valve set incorrectly.	• Contact technical service.
	Technical defect.	
Malfunction of chamber system sensors (code 1023) A/Low/Pre/0 s A/Low/The/300 s A/Low/Eot/0 s The balance chamber sensors (MSBK1; MSBK2) have produced a reading outside the end values determined after switch-on of the voltage supply for over 1.5 min.	Technical defect.	• Preparation: Alarm will be cleared automatically. • Therapy: Press the “Reset alarm” (AQ) button twice in order to remove the alarm condition. • If alarm cannot be cleared, try to restart the machine. • Contact technical service.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
UF balance? Air leakage in dialyzer couplings (code 1026) A/Low(Hint)/The/120 s During the dialysis, the valve (VLA) had to be opened more than 10 times due to air (level below bottom electrode) in the bubble catcher.	Dialyzer not filled without air inclusions.	• Vent dialyzer (water side).
	Dialyzer connection leaking.	• Check dialyzer connections.
	Technical defect.	• Contact technical service.
Acetate- acid concentrate empty? (code 1027) A/Low(Hint)/Pre/300 s A/Low(Hint)/The/300 s A/Low(Hint)/Eot/300 s A/Low(Hint)/Dis/300 s The machine cannot suck in acetate or acid.	Empty canister.	• Exchange canister.
	Suction rod not correctly positioned in canister.	• Position suction rod correctly.
Bicarb. cond. limit (code 1028) A/Low/Pre/0 s A/Low/The/180 s A/Low/Eot/0 s The average value during a filling chamber cycle (250 ms sampling time) measured at BICLF deviates by more than +/-5 % from the preselected value.	Suction rod not correctly inserted in container.	• Check position of rod in container.
	Concentrate container empty.	• Replace container.
	Defective suction line.	• Replace suction line.
	Technical defect.	• Contact technical service.
Final conductivity limit (code 1029) A/Low/Pre/0 s A/Low/The/180 s A/Low/Eot/0 s The average value during a filling chamber cycle (250 ms sampling time) measured at ENDLF deviated by more than +/-5 % from the preset value.	Suction rods not correctly inserted in container.	• Check position of rods in container.
	Concentrate container empty.	• Connect new container.
	Suction line defective.	• Replace suction line.
	Technical defect.	• Contact technical service.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
Bicarbonate mixing ratio (code 1030) A/Low/Pre/0 s A/Low/The/120 s A/Low/Eot/0 s The mixing ratio H2O to bicarbonate concentrate is outside of the +/-7 tolerance around the preset ratio.	Incorrect concentrate used.	• Connect correct concentrate.
	Incorrect composition of concentrate.	• Where mix is produced on site, observe mixing ratio powder/water.
	Technical defect.	• Contact technical service.
Concentrate mixing ratio (code 1031) A/Low/Pre/0 s A/Low/The/120 s A/Low/Eot/0 s The mixing ratio H2O plus possibly BIC concentrate to acetate/acid concentrates was outside the permitted range over two filling chamber cycles.	Incorrect concentrate used.	• Connect correct concentrate.
	Concentrate container empty.	• Connect new container.
	Suction line defective.	• Replace suction line.
	Technical defect.	• Contact technical service.
Bicarbonate empty? (code 1032) A/Low(Hint)/Pre/300 s A/Low(Hint)/The/300 s A/Low(Hint)/Eot/300 s	The bicarbonate pump has stopped.	• Check concentrate supply and press **?** key.
Temperature too low (code 1033) A/Low/Pre/0 s A/Low/The/120 s A/Low/Eot/0 s The mean temperature (TSD) was 1 °C lower than the set value for more than 10 minutes.	Irregular dialysate flow.	• If alarm cannot be reset, contact technical service.
	Technical defect.	
Temperature too high (code 1034) A/Low/Pre/0 s A/Low/The/120 s A/Low/Eot/0 s The mean temperature (TSD) was 1 °C higher than the set value for more than 10 minutes.	Irregular dialysate flow.	• If alarm cannot be reset, contact technical service.
	Technical defect.	

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
Remove blue connector from Rinse-bridge (code 1035) A/Low/Dis/120 s	Filter change program for dialyzer filter.	• Remove blue connector from Rinse-bridge in order to let down the water.
Coupling on dialyzer? (code 1036) A/Low(Hint)/Pre/120 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	The dialyzer tubes are connected to the rinse bridge.	• Connect properly.
Coupling on rinse bridge? (code 1037) A/Low(Hint)/Pre/120 s A/Low(Hint)/Dis/120 s	The dialyzer tubes are not connected to the rinse bridge.	• Connect properly.
Connect acid-/acetate concentrate (code 1038) A/Low(Hint)/Pre/120 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s A/Low(Hint)/Dis/120 s	Acid or acetate container not connected.	• Connect acid-/acetate concentrate.
Connect red conc.coupling to rinse bridge (code 1039) A/Low(Hint)/Dis/120 s	Red concentrate coupling not connected to rinse bridge.	• Connect red concentrate coupling to rinse bridge.
Connect bicarbonate (code 1040) A/Low(Hint)/Pre/120 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Bicarbonate is not connected.	• Connect bicarbonate.
Conn. blue+ conc.coupling to rinse bridge (code 1041) A/Low(Hint)/Pre/120 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s A/Low(Hint)/Dis/120 s	Blue concentrate coupling not connected to rinse bridge.	• Connect blue concentrate coupling to rinse bridge.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
Blood leak >0,5 ml/min (code 1042) A/Low/Pre/0 s A/Low(Hint)/The/120 s	Blood in the tubes due to rupture in dialyzer.	• Exchange dialyzer.
	Sensor can also be dirty.	• Perform disinfection.
	Technical defect.	• Contact technical service.
Blood leak >0,35 ml/min (code 1043) A/Low/Pre/0 s A/Low(Hint)/The/120 s	Blood in the tubes due to rupture in dialyzer.	• Exchange dialyzer.
	Other cause: sensor is dirty.	• Perform disinfection.
	Technical defect.	• Contact technical service.
Blood leak: sensor dirty (code 1044) A/Low/Pre/0 s A/Low(Hint)/The/120 s The blood concentration measured at the sensor (BL) is negative.	Sensor dirty.	• Contact technical service.
	Air on dialysate-side.	• Reset alarm.
	Technical defect.	• Contact technical service.
Bicarbonate cartridge holder open (code 1045) A/Low(Hint)/Pre/120 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s A/Low(Hint)/Dis/120 s	Bicarbonate cartridge holder open.	• Close bicarbonate cartridge holder.
Bicarbonate Cartridge not allowed (code 1046) A/Low(Hint)/Pre/120 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s A/Low(Hint)/Dis/120 s	Bicarbonate cartridge function is not activated in TSM.	• Contact technical service.
	Technical defect.	
DF- or/and HDF-Filter holder open (code 1047) A/Low(Hint)/Pre/120 s A/Low/The/120 s A/Low/Eot/120 s A/Low(Hint)/Dis/120 s	Filter holder open at rear: • during Preparation • in Therapy or End of Therapy mode • during on-going disinfection	• Close filter holder. A filter change is only intended to happen in the disinfection phase.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
PBE upper limit (code 1048) A/Low/Sel/0 s A/Low/Pre/0 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s A/Low/Dis/0 s The blood sided dialyzer inlet pressure exceeds the set limit.	Excessive pump speed.	• Adjust blood flow to dialyzer and tube conditions. • Readjust limit.
	Blood side pressure increase in dialyzer (clotting).	• Check dialyzer for clotting.
	Tube kinked.	• Check blood line system.
	Technical defect.	• Contact technical service.
PBE lower limit (code 1049) A/Low/Sel/0 s A/Low/Pre/0 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s A/Low/Dis/0 s The blood side dialyzer inlet pressure dropped below 10 mmHg.	Tube leaking.	• Check blood line system.
	Tube kinked downstream of blood pump.	
	Technical defect.	• Contact technical service.
Arterial pressure - upper limit (code 1050) A/Low/Sel/0 s A/Low/Pre/0 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s A/Low/Dis/0 s The arterial suction pressure exceeds the preset arterial upper limit.	Patient access malfunction.	• Check patient access.
	Incorrect limits setting.	• Re-adjust limit.
	Incorrect position of cannula.	• Correct position of cannula.
	Technical defect.	• Contact technical service.
Arterial pressure - lower limit (code 1051) A/Low/Pre/0 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s A/Low/Dis/0 s The arterial suction pressure is lower than the preset arterial lower limit.	Excessive pump speed.	• Adjust blood flow to patient conditions.
	Incorrect limits setting.	• Re-adjust limit.
	Incorrect position of cannula.	• Correct position of cannula.
	Technical defect.	• Contact technical service.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
Venous pressure - upper limit (code 1052) A/Low/Sel/0 s A/Low/Pre/0 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s A/Low/Dis/0 s Venous pressure exceeds upper limit.	Pump speed too high.	• Adjust blood flow to patient conditions.
	Incorrect position of cannula.	• Correct position of cannula.
	Clotting in venous drip chamber.	• Check venous drip chamber.
	Technical defect.	• Contact technical service.
Venous pressure - lower limit - Check Access (code 1053) A/Low/Sel/0 s A/Low/Pre/0 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s A/Low/Dis/0 s The venous pressure is lower than the lower limit.	Pump speed too low.	• Adapt blood flow to patient conditions.
	Pressure measurement leaking, leading to blood level rise up to the hydrophobic filter.	• Produce leak-free connection, push back fluid column with syringe.
	Venous cannula pulled out from shunt.	• Restore connection.
	Technical defect.	• Contact technical service.
Preparation of new Bic Cartridge-bypass (code 1054) A/Low/Pre/0 s A/Low/The/0 s A/Low/Eot/0 s	A new bicarbonate cartridge is prepared.	• Wait until preparation of cartridge is completed.
SAD - Air! (code 1058) A/Low/Pre/0 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Air in blood line.	• Remove air from blood line. • Follow the instructions on the screen.
SAD - sensor error (code 1059) A/Low/Pre/0 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	S.A.D. is not functioning! Air monitoring is not possible!	• Disconnect patient and inform technician.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
Check heparin pump-put in syringe new (code 1060) A/Low/Pre/0 s A/Low(Hint)/The/300 s A/Low(Hint)/Eot/300 s A/Low/Dis/0 s	Syringe is not inserted or the inserted syringe has not been recognized or the delivery rate is set at 0.	• Insert syringe (again) • Set heparin rate >0 ml/h.
Do not remove the pump tube! (code 1061) A/Low(Hint)/Eot/120 s	Pump tube removed too early.	• Wait until End of Therapy is completed.
Pump cover open (arterial) (code 1062) A/Low/Sel/0 s A/Low/Pre/0 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s A/Low/Dis/0 s The reed contact in the blood pump housing has detected that the blood pump lid was opened with the pump running.	Blood pump cover opened.	• Close blood pump cover.
	Technical defect.	• Contact technical service.
Pump cover open (SN/Subst) (code 1063) A/Low/Sel/0 s A/Low/Pre/0 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s A/Low/Dis/0 s The reed contact in the blood pump housing has detected that the blood pump cover was opened with the pump running.	Blood pump cover open.	• Close blood pump cover.
	Technical defect.	• Contact technical service.
Phase volume too high (code 1064) A/High/The/120 s A/High/Eot/120 s Single-NeedleValve or SN-Cross Over: phase volume exceeds 80 ml.	Phase volume higher than 80 ml.	• Check for leaks in blood line system. • Check the blood pump speed. • If needed, set blood pump speed higher. • If needed, adapt the switch pressure.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
No heparin delivery - Syringe empty? (code 1065) A/Low(Hint)/Pre/120 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s A/Low/Dis/0 s	Syringe empty.	• Fill syringe.
	Connection line clamped off.	• Open clamp.
	Unsuitable syringe inserted.	• Insert suitable syringe.
	Syringe not inserted correctly.	• Insert syringe correctly.
	Technical defect.	• Contact technical service.
Heparin syringe holder open (code 1066) A/Low/Pre/0 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s A/Low/Dis/0 s	Wrong syringe or holder not correctly closed.	• Use correct syringe and close holder.
Phase volume too low-see HELP (code 1067) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s Pressure rise at venous pressure sensor too high during pump phase.	Phase volume significantly lower than average.	• Reduce blood flow. • If necessary, continue adjustment of control pressures. • Check for possible kinking in the bloodlines. • Check position of needle/ catheter.
	Alarm limits: Min. 12 ml	
Temporary communication problem (code 1069) A/Low/Sel/120 s A/Low/Pre/120 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s A/Low/Dis/120 s	Processor data transfer is malfunctioning.	• Contact technical service.
PBS too low (code 1070) A/Low/Sel/0 s A/Low/Pre/0 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s A/Low/Dis/0 s	Pressure disturbance in the dialyzer due to clotting or kinking.	• Short-term change of blood flow. • Check dialyzer and lines. • If necessary, end SNCO. • Contact technical service.
	Technical defect.	

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
PBS too high (code 1071) A/Low/Sel/0 s A/Low/Pre/0 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s A/Low/Dis/0 s	Pressure disturbance in the dialyzer due to clotting or kinking.	• Short-term change of blood flow. Check dialyzer and lines. If necessary, end SNCO.
	Technical defect.	• Contact technical service.
Can not draw in disinfectant (code 1082) A/Low/Dis/300 s	Too much air during suction of disinfectant.	• Check connections. • Disinfectant canister empty?
Emptying of upline-tank not possible (code 1083) A/Low/Dis/120 s	After chemical disinfection it is not possible to rinse out disinfectant from all flow parts - technical problem.	• Check the drain pipe. • Contact technical service.
Substitution disturbed - leakage? (code 1089) A/Low(Hint)/Pre/120 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Substitution volume on scales differs from the total substitution volume.	• Check tube system for leaks and kinks.
	Technical defect.	• Contact technical service.
Temperature for test not reached (code 1102) W/Low/All/0 s	The temperature for TSD test is not reached.	• If alarm persists, contact technical service.
Battery is not fully charged (code 1103) W/Low/All/0 s	The battery capacity does not suffice to operate the machine for at least 20 minutes or the battery is defective or the battery is not connected or the automatic circuit breaker in the battery drawer has been triggered.	• Restore power. • If battery fails, disconnect patient. • Contact technical service.
PBS test failure - see HELP text (code 1104) W/Low/All/0 s	The Single Needle Cross Over pressure test failed.	• Repeat test (restart Preparation). • Disconnect PBS line and switch-off SNCO. • If alarm persists, contact technical service.
Connect patient - Alarm limits open! (code 1105) W/Low/All/0 s	Reduced alarm functions for patient connection!	• Observe patient's access. • Increase blood flow slowly.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
Re-infusion - Alarm limits open! (code 1106) W/Low/All/0 s	Reinfusion, reduced safety.	• Observe patient's access. • Re infuse the blood with slow flow speed.
Preparation Dial. fluid System (code 1107) W/Low/All/0 s	The dialysate fluid system is prepared.	• Wait until preparation is completed.
UF rate too high (code 1108) W/Low/All/0 s	UF rate collides with time/volume or maximum UF rate limits.	• Decrease UF volume or increase time or increase UF max rate limits.
TMP limit exceeded (code 1109) W/Low/All/0 s	TMP delta limits too low.	• Raise the TMP delta limits.
	Blood pump speed too low.	• Increase blood pump speed if possible.
TMP alarm limit reached (code 1110) W/Low/All/0 s	TMP delta limits too low.	• Raise the TMP delta limits.
	Blood pump speed too low.	• Increase blood pump speed if possible.
Degassing insufficient (code 1111) W/Low/All/0 s The degasification pressure does not reach the set value.	Technical defect.	• If alarm cannot be reset, contact technical service.
UF Rinse volume for Dialyzer too high (code 1112) W/Low(Hint)/All/120 s	Too high rinse volume.	• Check blood line system for correct setup and close open connection.
	Dialyzer with too small UF coefficient.	• Contact technical service.
Level setting interrupted by alarm (code 1115) W/Low/All/0 s	An alarm interrupted the level setting.	• Reset alarm and take action to clear alarm. • Continue with level setting afterwards.
TMP too high (code 1116) W/Low/All/0 s	TMP limits too low.	• Raise the TMP limit.
	UF coefficient of dialyzer too small.	• Careful: Take note of dialyzer limit value.
	Clotted dialyzer.	• Check dialyzer for clotting.
	UF rate too high.	• Reduce UF rate.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
Degassing chamber - too much air (code 1117) W/Low/All/0 s	Poor or loose machine connections (water hoses, dialyzer couplings, dialysate filter couplings).	• Connect poor/loose coupling.
	Technical defect.	• Contact technical service.
Air in dialyzer - Leak? (code 1118) W/Low/All/0 s	Poor or loose connection of dialyzer couplings. Poor or loose connection of blood line system component.	• Connect couplings, tighten poor or loose connection in blood line system.
Dialyzing fluid disturbed (code 1119) W/Low/All/0 s	Blocked water hose.	• Check for blockage of water hose.
	Technical defect.	• Contact technical service.
Incorrect heparin rate (code 1120) W/Low(Hint)/All/600 s	Set heparin rate out of range.	• If warning remains, contact technical service.
Please start blood pump! (code 1140) W/Low(Hint)/All/120 s	The blood pump is stationary too long.	• Start blood pump.
PFV test failed (code 1141) W/Low(Hint)/All/0 s	PFV test failed.	• Repeat test (restart Preparation). • Contact technical service.
S.A.D alarm switched off (code 1142) W/Low/All/0 s	SAD alarm was switched off by the user.	• Take action to remove air, following the instructions.
LLS demands Bypass, LLC does not require Bypass (code 1143) W/Low(Hint)/All/120 s	Miscommunication between low level control system (LLC) and supervisor (LLS).	• Contact technical service.
No acoustic alarm at mains voltage loss (code 1144) W/Low/All/0 s	The power supply buzzer is defective. It is not possible to get an acoustic alarm in case of mains voltage loss.	• Contact technical service. • Replace the defective power supply.
Selftest error SMPS buzzer test (code 1145) W/Low/All/0 s	The test of the power supply buzzer must be repeated.	• If the test after several attempts was not passed, contact technical service.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
Phase volume too low-see HELP (code 1146) W/Low(Hint)/All/120 s	Wrong access position/clotted catheter.	• Check access for correct position.
	Too high blood flow.	• Reduce blood flow.
	Control pressure window too narrow.	• Extend control pressures.
PBE not connected! (code 1147) W/Low/All/0 s	PBE pressure line not or poorly connected.	• Connect PBE pressure line properly.
PBE too high (code 1148) W/Low(Hint)/All/120 s	The pressure at the blood side of the dialyzer is too high. Possible causes: the dialyzer is clogged because of clotting or bend in the AV System.	• Check blood line for kinking. • Check dialyzer for clotting. • Extend upper PBE limit. • If necessary, exchange dialyzer.
Battery is not fully charged (code 1149) W/Low/All/0 s	The battery capacity does not suffice to operate the machine for at least 20 minutes or the battery is defective or the battery is not connected or the automatic circuit breaker in the battery drawer has been triggered.	• Restore power. • If battery fails, disconnect patient. • Contact technical service.
Selftest error SMPS battery test (code 1150) W/Low/All/0 s	The test of the battery must be repeated.	• If test after several attempts was not passed, contact technical service.
HDF Online filter test failed! (code 1151) W/Low/All/0 s	Leakage.	• Repeat filter test. Automatic test for Online must be repeated by the machine and must be successful. • Check filter for leakage. • If there is no leakage, change filter.
Power supply service mode - no therapy (code 1152) W/Low/All/0 s	Technical defect.	• Contact technical service.
Repeat self test! (code 1153) W/Low(Hint)/All/120 s	Test fail due to wrong setup, open connection etc.	• Check blood line system for correct setup and close open connection.
	Technical defect.	• Contact technical service.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
SMPS-EEPROM defective (code 1154) W/Low/All/0 s	During the test of the power supply a defective EEPROM has been detected.	• Contact technical service.
+/-12 V test not ok (code 1155) W/Low/All/0 s	Test was not passed.	• Repeat test.
Blood leak test not ok (code 1156) W/Low/All/0 s	Test was not passed.	• Repeat test.
	Technical defect.	• If test cannot be passed, contact technical service.
DF pressure test will be repeated (code 1157) W/Low/All/0 s	The DF pressure test was not passed and will be repeated.	• Wait until test is completed. • If test fails again, contact technical service.
UF pump test will be repeated (code 1158) W/Low/All/0 s	The UF pump test was not passed and will be repeated.	• Wait until test is completed. • If test fails again, contact technical service.
Conductivity test not ok (code 1159) W/Low/All/0 s	Test was not passed.	• Repeat test.
	Technical defect.	• If test cannot be passed, contact technical service.
Temperature test not ok (code 1160) W/Low/All/0 s	Test was not passed. Technical defect.	• If test cannot be passed, contact technical service.
S.A.D. (Ref.) test not ok (code 1161) W/Low/All/0 s	Test level outside the range of calibration.	• Repeat test.
	Technical defect.	• If test cannot be passed, contact technical service.
S.A.D. (Freq.) test not ok (code 1162) W/Low/All/0 s	Test was not passed.	• If test cannot be passed, contact technical service.
Blood side pressure sensor test not ok (code 1163) W/Low/All/0 s	Technical defect.	• If test cannot be passed, contact technical service.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
VBICP test not ok (code 1164) W/Low(Hint)/All/120 s	Test was not passed.	• If test cannot be passed, contact technical service.
Self test VD failed (code 1165) W/Low/All/0 s	Technical defect.	• If test cannot be passed, contact technical service.
Self test subst. line failed (code 1166) W/Low/All/0 s	Test was not passed.	• If test cannot be passed, contact technical service.
Sound + LED Test failed (code 1167) W/Low/All/0 s	Technical defect.	• If test cannot be passed, contact technical service.
Blood side leakage test not ok (code 1169) W/Low/All/0 s	The pressure sensors are tested on equality and on the upper limits, but failed.	• Try again or contact technical service.
Timeout temp. not reached (code 1402) A/Low(Hint)/Dis/300 s	Technical defect.	• Contact technical service.
Power failure during disinfection (code 1403) A/Low(Hint)/Dis/300 s	Power failure during disinfection.	• Restore power.
Temperature too high (code 1420) W/Low(Hint)/All/300 s	The dialysis fluid temperature is temporarily too high.	• Wait until temperature is stable. • If warning persists, contact technical service.
Temperature too low (code 1421) W/Low(Hint)/All/300 s	The dialysis fluid temperature is temporarily too low.	• Wait until temperature is stable. • If warning persists, contact technical service.
BIC pump has stopped! (code 1426) W/Low(Hint)/All/300 s	Technical defect.	• Contact technical service.
Degassing circuit malfunction (code 1429) W/Low(Hint)/All/300 s	Too high degassing pressure during disinfection.	• Contact technical service.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
(SUP) Comm. malfunction-System error (code 1805) A/Low(Hint)/All/120 s	Technical defect.	• Contact technical service.
Actual UF volume deviation (code 1816) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s The UF volume calculated from the speed of the UF pump deviates significantly from the set value. The limits window can be extended up to threefold.	Technical defect.	• Contact technical service.
UF volume too high (code 1821) A/Low(Hint)/The/120 s	The measured UF volume is too high.	• Check patient weight and or contact technical service.
Patient connected? (code 1824) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	The red detector has detected blood.	• Start blood pump with the n button. Is the patient in Therapy mode?
High UF volume error-terminate dialysis (code 1826) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s The UF volume deviates more than 400ml.	Technical defect.	• Contact technical service.
Blood detected in Preparation/ Disinfection (code 1831) A/Low(Hint)/Pre/120 s A/Low(Hint)/Dis/120 s	Blood detected outside of Therapy. The Blood Pump with blood in A/V-System can be started only in Therapy.	• Make sure the patient is only connected in Therapy phase.
Mains failure - battery mode (code 1832) A/Low/The/0 s A/Low/Eot/0 s	Power failure.	• Restore power.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
Mains failure - battery mode (code 1833) A/Low(Hint)/The/0 s A/Low(Hint)/Eot/0 s	Power failure.	• Restore power.
Required UF Volume too high (code 1913) W/Low(Hint)/All/120 s	Set UF volume collides with time or max UF rate limit.	• Reduce the desired UF volume. • Extend time or max. UF rate.
Selected UF rate too low (code 1914) W/Low(Hint)/All/120 s	Set UF volume collides with time or min UF rate limit.	• Increase the desired UF volume. • Reduce time or min UF rate.
UF profile was modified (code 1915) W/Low(Hint)/All/120 s	The UF profile was changed in therapy.	• No action required.
Max. UF-rate too high (code 1916) W/Low/All/0 s	The max UF rate is set higher than allowed.	• Increase the max. UF rate. • If not possible, increase the UF time or reduce the UF volume.
Max. UF rate <min UF rate +100 ml/h (code 1917) W/Low(Hint)/All/0 s	Difference between max UF rate and min UF rate is lower than 100 ml/h.	• Reduce the UF time or increase the UF volume. • Increase max UF rate or reduce min UF rate.
Therapy time has elapsed (code 1923) W/Low(Hint)/All/300 s	The set UF time has expired.	• Terminate treatment and disconnect patient.
Rinsing volume attained (code 1927) W/Low(Hint)/All/300s	Selected rinsing volume reached.	• No action required.
Connect disposable to recirculation (code 1928) W/Low(Hint)/All/120 s	Priming volume has been reached before circulation.	• Connect arterial and venous connection of blood line system to priming bag for circulation.
Bypass >2 min. (code 1943) W/Low(Hint+OSD)/All/300 s	Machine is in bypass longer than two minutes.	• Switch-off bypass.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
Longer than 5 minutes in termination (code 1944) W/Low(Hint)/All/300 s	Treatment time has elapsed since more than 5 minutes.	• Terminate treatment and disconnect patient.
Bicarbonate mixing ratio (SUP) (code 1950) A/Low/Pre/0 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s The mixing ratio H2O to bicarbonate concentrate is outside of the +/-7 tolerance around the preset ratio.	Incorrect concentrate used.	• Connect correct concentrate.
	Incorrect composition of concentrate.	• Where mix is produced on site, observe mixing ratio powder/water.
	Technical defect.	• Contact technical service.
Final conductivity limit (SUP) (code 1951) A/Low/Pre/0 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s The average value during a filling chamber cycle (250 msec. sampling time) measured at ENDLF deviates by more than +5 % from end conductivity confirmed as “maximum”, or by more than -5 % from the level confirmed as “minimum”.	Suction rods not correctly inserted in container.	• Check position of rods in container.
	Concentrate container empty.	• Connect new container.
	Suction line defective.	• Replace suction line.
	Technical defect.	• Contact technical service.
Temperature too high (SUP) (code 1952) A/Low/Pre/0 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Data transfer to the Low Level System is malfunctioning.	• Turn off the machine and begin again. • If not possible, contact technical service.
Max. UF rate exceeded (SUP) (code 1953) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s The required UFR is 20 ml/h higher than the specified max. UFR.	UF volume too high.	• Decrease UF volume, increase UF time.
	Dialyzer factor too small.	• Use dialyzer with higher factor.
	Technical defect.	• Contact technical service.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
Blood Leak (SUP) (code 1955) A/Low/Pre/0 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Rupture in dialyzer.	• Change dialyzer.
	Technical defect.	• Contact technical service.
Venous pressure upper limit (SUP) (code 1956) A/Low/Pre/0 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Wrong needle position.	• Check the correct position of the needle.
	Too high blood flow.	• Reduce blood flow. Set new limit window by shortly changing the delivery rate.
	Kinked/clamped line.	• Check blood line tubing.
	Obstruction in the dialyzer.	• Check dialyzer for clotting.
Blood pump is stationary (SUP) (code 1957) A/Medium/The/120 s A/Medium/Eot/120 s	Supervisor Alarm: Blood pump has been stationary for more than 1 minute. Possible damage to blood!	• Start blood pump.
SAD (SUP) (code 1958) A/Low/Pre/0 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Air in SAD region.	• Remove air, see text on screen.
	Level drop in bubble catcher. Blood pressure too high (foam formation).	• Correct level in bubble catcher.
SAD - Air! (code 1058) A/Low/Pre/0 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Tube system not an authentic replacement part.	• Use original tube system.
	Tube system deformed/scratched or damaged otherwise.	• Ensure during insertion that system is not deformed/scratched or damaged in any other way. • Do not leave SAD tube inserted overnight.
	Technical defect.	• Contact technical service.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
Venous pressure lower limit (SUP) (code 1959) A/Low/Pre/0 s A/High/The/120 s A/High/Eot/120 s	Venous needle disconnection!	• Check the correct position of the needle.
	Open connection.	• Check tubing.
	Too low blood flow.	• If needed, increase blood flow. Set new limit window by shortly changing the delivery rate.
System error in the Supervisor (code 1960) A/High/All/120 s	Supervisor Alarm: No data received from the controller.	• Contact technical service.
SAD: sensor error (SUP) (code 1961) A/Low/Pre/0 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s SAD - sensor error (code 1059) A/Low/Pre/0 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	External sound pulses.	• Disconnect patient.
	Measurement frequency smaller than 600 Hz.	
	Technical defect.	• Contact technical service.
S.A.D. Function Ref. (SUP) (code 1962) A/Low/Pre/0 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s The alarm level is outside the calibration value +/-50 mV.	Technical defect.	• Contact technical service.
PV lower limit (SUP) (code 1963) A/Low/Pre/0 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Delta PV is too low for phase volume monitoring for single needle mode.	• Increase Delta PV.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
SN-pump control pres. fail. (PBS)(SUP) (code 1964) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Technical defect.	• Contact technical service.
UF time exceeded (SUP) (code 1965) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Therapy time has elapsed.	• Start reinfusion or extend therapy time.
UF volume exceeded (SUP) (code 1966) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s The actual volume calculated on the basis of rev counter readings (UFP_S) exceeds the preselected UF volume by 200 ml.	Technical defect.	• Contact technical service.
Disinfectant valve open! (SUP) (code 1967) A/Low(Hint)/Sel/120 s A/Low(Hint)/Pre/120 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s A/Low/Dis/0 s	Technical defect.	• Contact technical service.
Safety data not confirmed! (SUP) (code 1968) A/Low(Hint)/Pre/120 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Safety data was not confirmed.	• Repeat the check by modifying one parameter. Contact technical service.
Internal memory failure (SUP) (code 1970) A/Low(Hint)/All/120 s	Sensor data are faulty. The unit is not ready for operation.	• Contact technical service.
Hardware error RAM/ROM (SUP) (code 1971) A/Low(Hint)/All/120 s	The RAM/ROM test has detected a fault. The unit is not ready for operation.	• Contact technical service.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
SN phase volumes > 100 ml (SUP) (code 1972) A/High/The/120 s A/High/Eot/120 s	Phase volume is > 100 ml.	• Correct blood pump delivery rate.Check blood line system for leaks.
Main phase change error (SUP) (code 1973) A/Low(Hint)/All/120 s	Technical defect.	• Contact technical service.
Venous pump speed deviation (SUP) (code 1974) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Technical defect.	• Contact technical service.
Wrong direction of valves DFS (SUP) (code 1975) A/Low(Hint)/The/120 s	Technical defect.	• Contact technical service.
Arterial pressure - lower limit (SUP) (code 1976) A/Low/Pre/0 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Wrong needle position.	• Check patient access and lines.
	Kinked arterial line.	• Check arterial blood line.
	Too high blood flow.	• Reduce blood flow.
	Arterial lower limit too high.	• Reduce lower limit if needed.
Checked data crashed (SUP) (code 1978) A/Low(Hint)/The/120 s	Technical defect.	• Contact technical service.
Check AV-Line for PA monitoring (SUP) (code 1980) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	A connection of the arterial line was not detected at PA.	• If an AV line for pressure measurement is present, connect it to the PA pressure sensor.
Blood leak (SUP) (code 1981) A/Low/Pre/0 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Blood in the tubes due to rupture in dialyzer.	• Exchange dialyzer.
	Other cause: sensor is dirty.	• Perform disinfection.
	Technical defect.	• Contact technical service.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
Actual UF volume too high (SUP) (code 1995) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Actual UF volume too high.	• Reduce UF volume or extend time.
Infusion bolus volume too high (SUP) (code 1998) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Infusion bolus volume is too high.	• Reduce bolus volume. • Terminate bolus. • If alarm repeats, contact technical service.
BPA volume too high (SUP) (code 1999) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Actual blood pump volume is too high.	• Reduce blood pump speed. • If needed, contact technical service.
S.A.D. flow too high (SUP) (code 2000) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	The supervisor has detected a too high SAD flow.	• Connect patient. • If needed, contact technical service.
Connect Patient: delivered blood vol. >450 ml (code 2014) A/Low(Hint)/The/120 s	The supervisor has detected a deviation of blood pump rotation.	• Connect patient. • If needed, contact technical service.
Reinfusion: delivered blood vol. >450 ml (code 2015) A/Low(Hint)/Eot/120 s	The supervisor has detected a deviation of blood pump rotation.	• The reinfusion volume should be checked. • If needed, contact technical service.
SAD flow too high (>700ml/min) (SUP) (code 2019) A/Low/Pre/0 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	The supervisor has detected a too high SAD flow.	• Reduce the blood flow or the bolus volume. • To reset: press n button. • If reset is not possible - contact technical service.
art. bolus vol. > 300 ml (SUP) (code 2026) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Arterial bolus volume exceeded 300 ml.	• Contact technical service.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
Mainflow/bypass valves failure (SUP) (code 2027) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Technical defect.	• Contact technical service.
SUP: data out of range (code 2029) A/Low(Hint)/Pre/120 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Entered data is out of range.	• Correct data.
S.A.D. flow too high (SUP) (code 2032) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	The supervisor has detected a too high SAD flow.	• Reduce blood pump speed. • If needed, contact technical service.
System error - see HELP! (code 2033) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	System error.	• Switch machine off and on. • If alarm repeats, contact technical service.
SUP: Test of alarm system (code 2034) A/Low(Hint)/Pre/120 s	The supervisor is testing the alarm system.	• Wait until test is completed.
SUP: OSD red test failed (code 2035) A/Low(Hint)/Pre/120 s	The test for the red signal of the status indicator failed.	• Repeat test. • If alarm repeats, contact technical service.
↵ button sticks (code 2036) A/Low(Hint)/Sel/120 s A/Low(Hint)/Pre/120 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s A/Low(Hint)/Dis/120 s	The ↵ button is stuck.	• Press ↵ button. • If it cannot be released, contact technical service.
SUP: input data invalid (code 2037) A/Low(Hint)/Pre/120 s A/Low(Hint)/The/120 s	Supervisor has detected invalid data.	• Correct data if possible.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
SUP:OSD red check failed (code 2038) A/Low(Hint)/Pre/120 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	The test for the red signal of the status indicator failed (Supervisor).	• Repeat test. • If alarm repeats, contact technical service.
Faulty air separator valve VLA (SUP) (code 2040) A/Low(Hint)/The/120 s	Technical defect of valve VLA.	• In case of recurrence end therapy and inform service. Technical defect of valve VLA.
Minimum UF active (code 2057) W/Low(OSD)/All/600 s	The selected min UF volume is active!	• If possible, switch-off minimum UF to continue treatment with normal UF rate.
UF removal too low (code 2064) W/Low/All/0 s	Actual UF volume is more than 200 ml below requested UF volume.	• Check patient weight. • If alarm reappears, disconnect patient and contact technical service.
Please start the blood pump! (code 2067) W/Low(Hint)/All/120 s	Blood pump is stationary.	• Start blood pump.
Continued with expired filter(s) (code 2078) W/Low/All/0 s	The DF filter(s) have reached the set life time.	• Exchange DF filter(s).
Filter(s) will be soon expired (code 2079) W/Low/All/0 s	The DF filter(s) will expire after 60 working hours or 10 treatments.	• Check filter lifetime.
Please, start the blood pump! (code 2080) W/Low(Hint)/All/0 s	Blood pump is stationary.	• Start blood pump.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
Delta PBE is limited by maximum (code 2085) W/Low/All/0 s	Possible blockage of dialyzer due to kinked blood line or increased clotting within the dialyzer.	• Check dialyzer for clotting and blood line system for kinking. • Spread PBE delta limits if needed. • If situation does not improve, flush blood lines and dialyzer with saline. • If needed, terminate therapy and change blood line system and dialyzer.
A-bolus finished/interrupted (code 2086) W/Low/All/120 s	Arterial bolus finished / interrupted.	• Restart arterial bolus if needed. • Increase max UF rate or reduce min UF rate.
Min. UF Rate >Max UF Rate - 100 ml/h (code 2087) W/Low(Hint)/All/0 s	Difference between max UF rate and min UF rate is lower than 100 ml/h.	• Reduce UF time or increase UF volume.
Dialysate flow is changed by therapy (code 2095) W/Low/All/0 s	Automatic dialysate flow change initiated by changing to HDF online mode.	• No action required.
Heparin stop time decreased (code 2099) W/Low/All/0 s	Heparin stop time longer than therapy time.	• Decrease heparin stop time.
SN active! Ven. level correct? (code 2100) W/Low/All/0 s	SN mode is activated.	• Ensure that the venous chamber has a correct level.
Erasing card successful (code 2103) W/Low/All/0 s	Erasing of the card has been finished successfully.	• No action required.
Erasing card failed (code 2104) W/Low/All/0 s	Erasing of the card has not been finished successfully.	• Try again or use another card.
Battery mode (code 2105) W/Low/All/0 s	Machine runs on battery.	• Restore power after maximum 20 minutes.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
Filter-Blocking is possible (code 2106) W/Low(Hint)/All/300 s	The analysis of the measured pressures at the dialyzer indicate a filter blocking.	• Check blood lines for kinking. • Increase heparin. • Flush with saline or decrease UF rate.
Filter-Blocking is likely (code 2107) W/Low/All/0 s	The analysis of the measured pressures at the dialyzer indicate a filter blocking.	• Check blood lines for kinking. • Increase heparin. • Flush with saline or decrease UF rate.
Therapy interruption >10 min. (code 2108) W/Low(Hint)/All/120 s	The therapy is interrupted for more than 10 minutes.	• If problem remains for additional 5-10 minutes, switch the machine off and on. • Otherwise contact technical service.
Heparin infusion completed (code 2127) W/Low(Hint)/All/0 s	The heparin bolus is completed.	• No action required.

13.2.3 ABPM Alarms

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
ABPM: SYS press. is too high (code 9100) A/Low(Hint)/All/120 s	Systolic pressure exceeds the set upper limit.	• Repeat measurement. • Select individual limit adjustment. • Manually change individual limits. • Inform doctor.
ABPM: SYS press. is too low (code 9101) A/High(Cardiac)/All/120 s	Systolic pressure is below the set limit.	• Repeat measurement. • Select individual limit adjustment. • Manually change individual limits. • Inform doctor.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
ABPM: DIA press. is too high (code 9103) A/Low(Hint)/All/120 s	Diastolic pressure exceeds a set upper limit.	• Repeat measurement. • Select individual limit adjustment. • Manually change individual limits. • Inform doctor.
ABPM: DIA press. is too low (code 9104) A/High(Cardiac)/All/120 s	Diastolic pressure drops below a set lower limit.	• Repeat measurement. • Select individual limit adjustment. • Manually change individual limits. • Inform doctor.
ABPM: body movement (code 9119) W/Low(Hint)/All/0 s	Measurement was disturbed by movement.	• Repeat measurement.
ABPM: Internal communication disturbed. (code 9138) A/Low(Hint)/All/0 s	ABPM not operational; no further measurements possible.	• Carry out pulse measurement with separate RR device, or manually.
ABPM: Service (S/04) (code 9154) A/Low/All/120 s	Technical defect.	• Contact technical service.
ABPM: Self-test error (code 9157) A/Low(Hint)/All/0 s	Technical defect.	• Contact technical service.
ABPM: wait... (code 9162) W/Low(Hint)/All/0 s	The ABPM module is processing.	• Wait until processing is completed.
	Cycle intervals could be too small.	• Check the cycle interval and increase it.
ABPM: Pulse rate too high (code 9169) A/Low(Hint)/All/120 s	Pulse frequency exceeds upper limit.	• Repeat measurement. • Select individual limit adjustment. • Manually change individual limits. • Inform doctor.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
ABPM: Pulse rate too low (code 9170) A/High(Cardiac)/All/120 s	Pulse frequency lower than lower limit.	• Repeat measurement. • Select individual limit adjustment. • Manually change individual limits. • Inform doctor.
ABPM: Reading interrupted (code 9171) W/Low(Hint)/All/0 s	Measurement stopped.	• Repeat measurement.
ABPM: Module failure please switch off/on (code 9172) W/Low(Hint)/All/0 s	Is displayed after confirmation of alarm 9301. Blood pressure module has performed a safety switch-off.	• Switch dialysis machine off and on again; all data remain stored.
ABPM: Check alarm limits (code 9173) W/Low(Hint)/All/0 s	Loaded ABPM alarm limits do not match to the first ABPM reading.	• Set alarm limits more closely around blood pressure values.Use 'individual limit adaption' or change a value individual.
ABPM: Air leak - check cuff connection (code 9300) A/Low/All/120 s	Blood pressure module has performed a safety switch-off.	• Check connections to ABPM and cuff. • Switch dialysis machine off and on again; all data remain stored.
ABPM: Module failure please switch off/on (code 9301) A/Low/All/120 s	Blood pressure module has performed a safety switch-off. Message remains on the display after 9172 confirmation.	• Switch dialysis machine off and on again; all data remain stored.
ABPM: Inflation pressure not reached (code 9302) A/Low/All/120 s	–	• Check cuff for correct position. • Re-apply cuff if necessary. • Repeat measurement.
ABPM: Pulsation not detected (code 9303) A/Low/All/120 s	–	• Check connections to ABPM and cuff. • Measure pulse manually.
ABPM: Excessive arm movement (code 9304) W/Low(Hint)/All/0 s	Strong patient arm movement.	• Repeat measurement.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
ABPM: systol. BP >max. cuff pressure (code 9305) A/Low/All/120 s	Considerable increase in blood pressure since last measurement.	• Carry out pulse measurement with separate RR device, or manually.
ABPM: Pulse measurement disturbed (code 9306) A/Low/All/120 s	–	• Check cuff for correct position. • Carry out pulse measurement with separate RR device, or manually.
ABPM: Irregular pulse (code 9307) A/Low/All/120 s	–	• Check cuff for correct position. • Carry out pulse measurement with separate RR device, or manually.
ABPM: Reading took too long (code 9308) A/Low/All/120 s	The max. measurement time of 110 seconds is exceeded.	• Carry out pulse measurement with separate RR device, or manually.
ABPM: Pulse over 100 beats (code 9309) A/Low/All/120 s	The max. measurement time of 110 seconds is exceeded.	• Carry out pulse measurement with separate RR device, or manually.
ABPM: Cuff pressure >320 mmHg (code 9310) A/Low/All/120 s	Cuff pressure has exceeded the cuff pressure limit.	• Check patient's arm position. • Carry out pulse measurement with separate RR device, or manually.
ABPM: Pulse signal very low (code 9311) A/Low/All/120 s	–	• Check cuff for correct position. • Carry out pulse measurement with separate RR device, or manually.
ABPM: Large pressure transient (code 9312) A/Low/All/120 s	Large pressure transient detected.	• Check blood pressure of the patient manually. • Repeat ABPM reading.
ABPM: Not defined error code (code 9313) A/Low/All/120 s	Not defined error code received from the blood pressure module.	• If the problem occurs again, contact technical service.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
ABPM: BP reading failed (code 9314) A/Low(Hint)/All/120 s	Wrong cuff position.	• Reposition cuff.
	No/missing cuff tubing connection.	• Connect tube correctly.
	Patient arm movement.	• Repeat reading without movement.
	Vital signs out of limits.	• Check patients vital signs.
	Technical defect.	• Contact technical service.

13.2.4 Crit-Line Alarms

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
HCT is over limit (Dialog) (code 930) A/low(Hint)/The/120 s	UF rate or volume too high.	• Reduce UF rate or volume. • Adapt limit at the Dialog+.
	Limit at the Dialog too low.	
HCT reading failed! (code 931) A/low(Hint)/The/120 s	Crit-Line device is switched off.	• Check Crit-Line device and connection to Dialog+ • Contact technical service, if necessary.
	Connection disturbed.	
	Technical defect.	
No blood detected in Crit-Line (code 932) W/low/All/0 s	Sensor not placed correctly at blood chamber.	• Check sensor and blood chamber. • Contact technical service, if necessary.
Sensor obstruction in Crit-Line (code 933) W/low/All/0 s	Foreign material/dirt between sensor and blood chamber.	• Check/clean sensor or remove material. • Contact technical service, if necessary.
SAT is under limit (code 935) A/low(Hint)/The/120 s	Patient O2 under-supply limit is too high.	• Call doctor. • Adapt limit.
HCT is over limit (Dialog) (code 940) W/low(Hint)/All/0 s	UF rate or volume too high.	• Reduce UF rate or volume. • Adapt limit at the Dialog+.
	Limit at the Dialog+ too low.	
HCT reading failed! (code 941) W/low(Hint)/all/0 s	Crit-Line not switched off.	• Check Crit-Line device and connection to Dialog+. • Contact technical service.
	Connection disturbed.	
	Technical defect.	

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
Crit-Line communication failed (code 942) W/low(Hint)/all/0 s	Crit-Line not switched on. Connection disturbed. Technical defect.	• Check Crit-Line device and connection to Dialog+. • Contact technical service.
Please initiate Crit-Line monitor! (code 943) W/low(Hint)/all/0 s	Crit-Line measurement not started.	• Start Crit-Line measurement.
HCT is over limit (Crit-Line) (code 944) W/low(Hint)/all/0 s	UF rate or volume too high. Limit at the Crit-Line monitor too low.	• Reduce UF rate or volume. • Adapt limit at Crit-Line monitor.
Set/check HCT limit! (code 945) W/low(Hint)/all/0 s	HCT limit not set or default not confirmed.	• Set value or confirm.
SAT is under limit (code 946) W/low(Hint)/all/0 s	Patient O2 under-supply limit is too high.	• Call doctor. • Adapt limit.

13.2.5 Level Regulation Alarms

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
Volume limit level regulation (code 1011) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Max. blood volume exceeds 190 ml.	• Check blood line system for leakage.
Timeout level regulation (code 1024) A/Low(Hint)/Pre/120 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s A//Low(Hint)/Dis/120 s	Level regulation period is limited to 3 minutes.	• Set level in less than 3 minutes.
Arterial pressure too low (code 1171) W/Low/All/0 s	Arterial pressure is too low to increase PA chamber level.	• Check arterial access.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
Blood pump is running (code 2028) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Blood pump must not run in Emptying Dialyzer or when SAD-alarm-resolving is active.	• Stop blood pump.
Volume limit level regulation (SUP) (code 2039) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Max. blood volume exceeds 220 ml.	• Check blood line system for leakage.
Arterial pressure monitoring error (code 2041) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Insufficient arterial pressure pulsation.	• Set levels correctly. • Ensure that hydrophobic filters are fluid free.
Valve position level regulation (SUP) (code 2042) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Wrong valve position.	• Contact technical service.
Venous pressure monitoring error (code 2043) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Insufficient venous pressure pulsation.	• Set levels correctly.
PBE pressure monitoring error (SUP) (code 2044) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Insufficient PBE pressure pulsation.	• Set levels correctly. • Ensure that hydrophobic filters are fluid-free.
PBS pressure monitoring error (SUP) (code 2045) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Insufficient PBS pressure pulsation.	• Ensure that hydrophobic filters are fluid-free.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
Level adjustment requires blood pump running (code 5310) W/Low/All/0 s	The user tries to set levels while the blood pump is stationary.	• Start blood pump before setting levels.
Level adjustment requires blood pump running (code 5311) W/Low/All/0 s	The user tries to set levels while the blood pump is stationary.	• Start blood pump before setting levels.

13.2.6 Adimea Alarms

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
Adimea: Target Kt/V will not be reached (code 1550) W/Low(Hint)/All/0 s	The planned Kt/V value will not be reached until the end of the treatment.	• Adapt treatment parameters (time, blood flow, dialysate flow) to reach target value or switch of target warning on main screen.
Adimea: Sensor not calibrated (code 1551) W/Low/All/0 s	This message is shown in Therapy when: Sensor calibration has not been successful during Preparation.	• The sensor will work properly after machine switch off/on. • If the condition repeats more than two or three times contact technical service.
	Unstable signal at therapy start most probably due to patient related factors, i.e. problems on vascular access.	
	Communication failure between machine and sensor during Therapy.	
	Successive failures during measurement most probably because of air bubbles in the dialysate fluid.	
Adimea: Sensor not connected (code 1552) W/Low/All/0 s	Sensor is not present.	• Contact technical service.
	Physical interruption or electromagnetic disturbances on the USB communication interface.	

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
Adimea: Calibration failure (code 1553) A/Low(Hint)/Pre/120 s	The Adimea calibration was interrupted. Most probably due to micro-bubbles on the dialysate during preparation.	• The therapy can proceed without Adimea or the calibration may be repeated by pressing ↵. • If Adimea can not be used, contact technical service.
Adimea: Calibration failure (code 1553) W/Low/All/0 s	Problems during self calibration stage, most probably due to air bubbles in dialysate fluid.	• The machine offers the option to repeat the calibration procedure in case of failure.
Adimea: Sensor can not warm up (code 1554) W/Low/All/0 s	The photo-diodes of the sensor are defective.	• Contact technical service.
	Sensor cannot warm up during calibration, full accuracy is not achieved.	
	Sensor cannot warm up at least 10 times when actively measuring during therapy. In this case, the sensor is disabled because measurement accuracy cannot be guaranteed.	
Adimea: Sensor is disabled (code 1555) W/Low/All/0 s	Accuracy of sensor is not fully reached.	• Contact technical service.
	Sensor was disabled during therapy because of warming up problems.	
Entered target Kt/V will not be reached (code 1556) W/Low/All/0 s	Kt/V target not reached because: • Therapy time is too short. • Blood flow too slow. • Access recirculation. • Remaining air in dialyzer. • Clotted or too small dialyzer. • DF flow too low.	• Check therapy time, dialyzer, vascular access, blood and DF flow. • Consult physician about further measures for next treatments.
Adimea: Patient weight missing (code 1558) W/Low/All/0 s	Pre-dialytic patient weight was not entered in the Adimea screen.	• Enter patient weight.

13.2.7 bioLogic RR Comfort Alarms

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
bioL. RR UF volume can not be reached (code 3000) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	80 % weight loss was not achieved at 80 % of treatment time with 50 ml tolerance.	• Acknowledge at any time unconditionally. • Press bioLogic RR button. Alarm disappears automatically.
bioL. RR 3 or more missing readings (code 3001) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	13 minutes without successful blood pressure measurement since the request of bioLogic RR algorithm.	• Acknowledge the alarm twice in order to trigger a new blood pressure measurement. Alarm disappears automatically if a successful measurement is performed. • Press bioLogic RR button. Alarm disappears automatically.
bioL. RR Internal error (code 3002) A/Low(Hint)/Pre/120 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Internal error occurred in bioLogic RR.	• Press bioLogic RR button. Alarm disappears automatically.
bioL. RR No reading request (code 3003) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	The time between two blood pressure reading requests is more than the time limit.	• Press bioLogic RR button. Alarm disappears automatically.
bioL. RR UF volume may not be reached (code 3100) W/Low(Hint)/All/120 s	70 % weight loss was not achieved at 70 % of treatment time with 50 ml tolerance.	• Press bioLogic RR button. Alarm disappears automatically.
bioL. RR UF profile canceled (code 3101) W/Low(Hint)/All/60 s	UF profile was set before bioLogic RR button was pressed. Set UF profile is canceled.	• Press bioLogic RR button. Alarm disappears automatically. bioLogic RR sets the profile.
bioL. RR SYS Lower Limit reduced (code 3102) W/Low(Hint)/All/60 s	Max. SYS Lower Limit of 130 mmHg exceeded (value 130 mmHg is valid for bioLogic RR).	• Press bioLogic RR button. • Reduce SYS Lower Limit to max. 130 mmHg.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
bioL. RR Missing reading (code 3103) W/Low(Hint)/All/0 s	3 minutes without successful blood pressure reading since the request of bioLogic RR algorithm.	• Press bioLogic RR button. Alarm disappears automatically.
bioL. RR 2 missing readings (code 3104) W/Low(Hint)/All/0 s	8 minutes without successful blood pressure measurement reading since the request of biologic RR Comfort.	• Press biologic RR button. Alarm disappears automatically.

13.2.8 HDF Online Alarms

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
Open Subst-port (white) (code 1056) A/Low/Dis/120 s	Substitution port(s) is/are closed.	• Open substitution port(s) outlet for filter draining in order to aerate the filter.
Substitutions-port outlet open (code 1078) A/Low/Sel/0 s A/Low(Hint)/Pre/120 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s A/Low(Hint)/Dis/120 s	Substitution port outlet is open.	• Close outlet port. • If the port is closed and the alarm is still displayed, contact technical service.
Substitutions-port outlet closed (code 1079) A/Low/Sel/0 s A/Low(Hint)/Pre/120 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s A/Low(Hint)/Dis/120 s	Substitution port outlet is closed.	• Open outlet port. • If the port is opened and the alarm is still displayed, contact technical service.
Substitutions-port inlet open (code 1080) A/Low/Sel/0 s A/Low(Hint)/Pre/120 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s A/Low(Hint)/Dis/120 s	Substitution inlet port open.	• Close inlet port. • If the port is closed and the alarm is still displayed, contact technical service.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
Substitutions-port inlet closed (code 1081) A/Low/Sel/0 s A/Low(Hint)/Pre/120 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s A/Low(Hint)/Dis/120 s	Substitution inlet port closed.	• Open inlet port. • If the port is opened and the alarm is still displayed, contact technical service.
Pump cover open (substitution) (code 1093) A/Low/Pre/0 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Pump cover is open.	• Close cover.
HDFO: Reinf not possible by DFS error (code 1100) W/Low(Hint)/All/120 s	A reinfusion with online fluid is not possible due to a conductivity or temperature error of the dialysate fluid.	• Wait until dialysate fluid is available. • Disconnect patient with saline bag.
HDFO: Con.Pat not possible by DFS error (code 1101) W/Low(Hint)/All/120 s	A patient connection with online fluid is not possible due to a conductivity or temperature error of the dialysate fluid.	• Wait until dialysate fluid is available. • Connect patient with saline or waste bag.
HDF online - bolus stopped (code 1113) W/Low(Hint)/All/120 s	The HDF online bolus was interrupted due to a conductivity or temperature error of dialysis fluid.	• Stop bolus function. • Wait until conductivity or temperature error of dialysis fluid. • If urgent, apply arterial bolus by external saline bag.
HDF test not ok (code 1170) W/low/All/0 s	Test HDF Online blood line system was not successfully passed.	• Check connections of the blood line system to the A/V Set and wait until the machine repeats the test. • If the test is not passed, contact technical service.
Substitution line connection test failed (code 1430) W/Low/All/0 s	Substitution line is not or poorly connected. Substitution line is clamped.	• Connect substitution line properly, open clamp.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
Start without self test! (SUP) (code 1969) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Self tests have not been done.	• Press AQ button twice. • Switch off/on machine. • If alarm persists, contact technical service.
HDF alarm has blood pump stopped (SUP) (code 1979) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	LLS detected that the UFP pump rotates in wrong direction.	• If the alarm reappears after acknowledge, contact technical service.
Leakage in the Subst. system (SUP) (code 1993) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Leakage in the substitution system.	• Check the substitution system. • If necessary, switch off HDF.
UF volume too high (SUP) (code 1994) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Deviation of HDF too high.	• The limit values can be extended with the Enter button. • If necessary switch off HDF.
UF rate too high (SUP) (code 1996) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	It is no longer possible to increase limit value extension.	• Switch off HDF. • Check patient weight.
UF rate too low (SUP) (code 1997) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	UF rate too low.	• Switch off HDF. • Check patient weight.
HDFO: Bolus volume too high (SUP) (code 2016) A/Low(Hint)/Pre/0 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Supervisor detected too high bolus volume.	• Press “Reset alarm” button to reset. If not possible contact technical service. • Disconnect patient.
Subst.: Check flow direction and tightness (code 2017) A/Low(Hint)/The/120 s	Substitution line not properly connected.	• Check substitution line correct connection.
	Leakage.	• Check substitution line for leakage.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
HDF test failed (SUP) (code 2018) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Supervisor detected too high bolus rate.	• Press “Reset alarm” button to reset. • If not possible, contact technical service.
HDFO: OSP activated (SUP) (code 2020) A/Low/Pre/0 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Technical defect. Online substitution pump (OSP) rotates when dialyzer inlet valve (VDE)/dialyzer outlet valve (VDA) is closed.	• Press “Reset alarm” button to reset. If not possible, contact technical service. • Disconnect patient.
HDFO: VSB or VSAA opened (SUP) (code 2021) A/Low/Pre/0 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Technical defect. Substitution connection outlet valve (VSAA) is open.	• Press “Reset alarm” button to reset. If not possible, contact technical service. • Disconnect patient. • Make a disinfection.
HDFO: VBE opened (SUP) (code 2022) A/Low(Hint)/Sel/120 s A/Low(Hint)/Pre/120 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s A/Low(Hint)/Dis/120 s	Technical defect. Filter vent valve (VBE) is open. Online dialysis not possible.	• Press “Reset alarm” button to reset. If not possible, contact technical service. • Disconnect patient.
HDFO: DF system not rinsed (SUP) (code 2023) A/Low/Pre/0 s A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Technical defect. Water part not rinsed after disinfection.	• Press “Reset alarm” button to reset. If not possible, contact technical service. • Disconnect patient.
HDFO: delivered blood volume >450 ml (code 2025) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Online infusion bolus volume has exceeded the maximum of 450 ml.	• Terminate bolus. • If alarm repeats, contact technical service.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
HDF Inf. bolus volume too high (SUP) (code 2030) A/Low(Hint)/The/120 s A/Low(Hint)/Eot/120 s	Supervisor detected too high bolus rate.	• Press “Reset alarm” button to reset. If not possible, contact technical service. • Disconnect patient.
(HDF/UF) alarm limits expanded (code 2070) W/Low/All/0 s	Any of the UF TLC or LLS alarm limits have been expanded.	• Leave Therapy or End of Therapy.
No bolus in bypass! (code 2081) W/Low(Hint)/All/0 s	No online bolus possible in bypass.	• If possible deactivate bypass and wait. • In emergency cases, apply an infusion bolus via saline bag.
Bolus interrupted! (code 2082) W/Low(Hint)/All/0 s	Blood pump stopped or set to 0 ml/min, online bolus button released or end of therapy confirmed.	• Restart blood pump reset to more than 0 ml/min. • Reactivate bolus or re-enter therapy.
HDFO bolus not possible in Battery/bypass (code 2084) W/Low/All/0 s	Battery operation! No online bolus during battery operation, machine is in bypass.	• If needed apply saline bag infusion and/or wait for power recovering.
HDF/HF is not possible - failed Selftest (code 2090) W/Low(Hint)/All/60 s	HDF/HF not possible, self test failed.	• Check blood and substitution line for correct setup and connection. • Repeat self test. • If warning persists, contact technical service.
Bolus is not possible - failed Selftest (code 2091) W/Low(Hint)/All/60 s	HDF online bolus not possible, self test failed.	• If needed, apply bolus by saline bag.
No bolus in sequential mode! (code 2092) W/Low(Hint)/All/60 s	During sequential mode (Bergström) HDF online bolus is not possible.	• If needed, apply bolus by saline bag.
No bolus while connecting patient! (code 2093) W/Low(Hint)/All/60 s	HDF online bolus not possible during connecting patient.	• If needed, apply bolus by saline bag.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
No bolus while filter rinsing active! (code 2094) W/Low(Hint)/All/60 s	HDF online bolus not possible during dialysis fluid filter rinsing.	• If needed, apply bolus by saline bag
HDF-Online: DF less than BF + 100 ml/min (code 2101) W/Low/All/0 s	Hemodiafiltration (HDF): Dialysate flow is below blood flow.	• Increase dialysate flow and/or decrease blood flow. • Ratio DF to blood should be 2:1.
HDF-Online: DF less than BF + 100 ml/min (code 2102) W/Low/All/0 s	Hemodiafiltration (HDF): Dialysate flow is below blood flow.	• Increase dialysate flow and/or decrease blood flow. • Ratio DF to blood should be 2:1.
Conductivity alarm possible (code 2128) W/Low(Hint)/All/0 s	Using fluid from the substitution port with dialysate flow lower than 300 ml/min might cause conductivity alarms.	• Increase the dialysate flow. • Use bag instead of substitution fluid.

13.2.9 Disinfection Alarms

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
Disinfection temperature too low (code 1125) W/Low/All/0 s	Too low temperature during disinfection.	• Contact technical service.
Disinfection temperature too high (code 1126) W/Low/All/0 s	Too high temperature during disinfection.	• Contact technical service.
Solution Intake Failed (code 1401) A/Low(Hint)/Dis/300 s	Empty disinfection canister or dislocation of disinfection canister tube.	• Connect a new canister of disinfectant and/or insert the suction hose into the disinfectant canister.
LF too low (check disinfectant) (code 1422) W/Low(Hint)/All/300 s	The conductivity during disinfection is too low. Wrong disinfectant?	• Check correct disinfectant.
	Technical defect.	• If warning persists, contact technical service.

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
Last disinfection with disturbance? (code 1423) W/Low(Hint)/All/300 s	The last disinfection has not been finished successfully.	• Check in the disinfection history the cause. • Repeat disinfection if necessary.
Please select method (code 1424) W/Low(Hint)/All/0 s	A disinfection method has not been selected yet.	• Select a method.
It is disinfectant in the device (code 1425) W/Low(Hint)/All/300 s	Disinfection is in progress/not completed.	• Wait until disinfection is completed.
DISINF Warning #7 (code 1427) W/Low/All/0 s	Error during disinfection.	• If warning persist, contact technical service.
Device rinsing finished (code 1428) W/Low/All/0 s	Disinfection almost completed.	• Wait until disinfection is fully completed.

13.2.10 Nexadia Alarms

Alarm message (code) Type/Priority/Alarm phase/Alarm repetition time	Cause	Remedial action
New message! (code 670) W/Low/All/0 s	A new message arrived from Nexadia.	• Read the message and take action.
New medication! (code 671) W/Low/All/0 s	A new message for medication arrived from Nexadia.	• Read the message for medication and take action.
New checklist item! (code 683) W/Low/All/0 s	New checklist message.	• Read checklist item and take action.

13.3 Remedying SAD Alarms

In case of air in the area of the SAD, the tube clamp (SAKV) is closed due to the alarm action. Due to the reaction time of the system, a small amount of air could be below the SAD, too, in case of SAD alarms.

NOTICE!

For removing the air, a note is displayed on the screen.
Check that all connections are tight.

If the alarm was triggered by micro foam, it is sufficient to reset the alarm. The reset deletes the alarm not before 2 s after switching off the alarm tone. The measuring region of the SAD must now be free of air bubbles.

Removing Air Bubbles (If Level Regulation System is Present)

If air bubbles in the venous line have triggered the alarm, these bubbles must be removed as follows:

1. Clamp tube between venous bubble catcher and dialyzer.
2. Press **Enter** key on the monitor to open the window “increase venous level”.
3. To increase the venous level press the “increase venous level” icon.
4. When the air has been removed, open clamp between venous bubble catcher and dialyzer and press the key “Reset alarm”.

Removing Air Bubbles (If Level Regulation System is not Present)

If air bubbles in the venous line have triggered the alarm, these bubbles must be removed as follows:

1. Clamp tube between venous bubble catcher and dialyzer.
   - This prevents blood from being sucked from the dialyzer.
2. Using a syringe, create a vacuum of at least -75 mmHg at the venous air bubble catcher, see venous pressure display.
   - As the air is located in the region of the patient access, it must be moved back to the venous bubble catcher by this vacuum action.
3. Press **Enter** key on monitor.
   - Venous clamp opens briefly.
   - Blood flows back from the patient access and the air is moved into the venous bubble catcher.
4. Remove clamp between venous bubble catcher and dialyzer.
5. Once the air has been removed, press “Reset alarm (AQ)” button on monitor. Repeat procedure if necessary.
   - Once all air has been removed from the SAD, the alarm is deleted. If some air remains in that region, the process must be repeated.

13.4 Manual Blood Return

In case of a power failure during dialysis and where no emergency power supply is available, the blood must be returned manually to the patient. immediately in order to avoid coagulation

If blood line system is filled with blood, manual blood flow using the crank must be started 2 minutes after blood pump stop at the latest in order to avoid coagulation.

In case of power failure, a contact audible alarm sounds for 1 minute with a delay time of less than 1 second. The alarm can be reset by pressing mains switch on the monitor.

⚠ WARNING!

Risk to the patient due to blood loss to the environment!

- In case that treatment is to be continued, insert arterial line into arterial tubing clamp SAKA and venous line into venous tubing clamp SAKV before restarting therapy.

⚠ WARNING!

Risk to the patient!

- During manual blood return, no air infusion monitoring functions are active in the dialysis machine. Staff have to monitor both the patient and the dialysis machine.
- Always carry out the manual blood return by two persons and with the utmost care.
- Always turn blood pump clockwise indicated by arrows on the roller rotor.

1. Remove crank from rear of dialysis machine.
2. Open (left) blood pump lid and insert crank into the roller rotor.

The crank for manual blood return may be one of two alternatives (see following pictures).

Fig. 13-3 Use of crank (alternative 1)

Observe, using the crank on the picture above, to insert it in the external hole to ease the manual rotation.

Fig. 13-4 Use of crank (alternative 2)

3. Disconnect arterial side from patient, see section 7.2 Emptying Cartridge After Therapy (116).
4. Remove venous blood line from the SAKV.
5. Evenly operate the blood pump using the crank. Observe appropriate speed and maintain an adequate blood level in the venous bubble catcher.

6. Continue to monitor venous patient access, which may not contain any air.
7. When the physiological saline solution reaches the venous tube clamp, close the clamp.
8. Disconnect the patient on the venous side.

13.5 Omission of Acoustic Signals

13.5.1 Omission of Acoustic Signals for Alarm

The sounds are omitted for the following alarms:

ID	Text
600	System restored

13.5.2 Omission of Acoustic Signals for Advice

The sounds are omitted for the following advices:

ID	Text
1900	The selected interval is over
1903	Selected UF volume too high
1904	Selected UF volume too low
1905	Selected UF time too high
1906	Selected UF time too low
1907	Interval cannot be modified
1908	Max. UF ratio has profile modified
1911	Selected heparin rate too high
1912	Selected heparin rate too low
1922	UF volume has been decreased
1934	Rinsing time too long
1935	Rinsing time too short
1936	UF rinsing volume too high
1937	UF rinsing volume too low
1942	Acknowledge data before connecting patient
2056	No Heparin bolus
2060	Please press longer EQ button again
2066	UF + HDF rate >5500 ml/h please reduce!

ID	Text
2073	Rinsing rate too low
2074	Rinsing rate too high
1093	Pump cover open (substitution)
1054	Preparation of new Bic Cartridge-bypass

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14 Accessories

This chapter lists the mechanical accessories, options and consumables intended to be used with the machine. The accessories are listed as product groups, but may be available in different types or sizes. For detailed information and article numbers for ordering refer to the product information for extracorporeal blood treatment on your local B. Braun Internet page (country specific domain) / Products &Therapies or contact your local distributor.

14.1 Options

Name	Article no. (REF)
Nexadia - BSL: Card reader and networking device*	7102230
ABPM: Automatic blood pressure measurement	7102226
bioLogic RR Comfort for card reader: Automatic blood pressure stabilization with template method (only with option ABPM)	7105324
Bicarbonate cartridge holder	7105171
Emergency power supply (Accu)	7102244
Central concentrate supply (ZKV)	7105196
DF filter	7102102
Staff call*	7102315
Roller rotor for pump segment 7x10	7102340
DCI* (Dialog+ Communication Interface)	7107218
Connection line for electrical ground	8701628
Adimea	7102233
Crit-Line Interface	7106604
Crit-Line Potential Equalization Kit	7106605
Card reader incl. 5 cards	7105230

NOTICE!

*Because of defined cable length the marked items are only allowed to be used in order to meet the standard according to EMC (electromagnetic compatibility) directive.

14.2 Mechanical Accessories

Name	Article no.
Dialyzer holder	7107426
Multi Functional Tray	7105238
Universal Front Tray	7105239
Box Comfort	7107322
Box	7107320
Plain universal storage	7102890
Monitor storage	7102872
Protocol storage	7102873
ABPM: Small cuff, latex-free	7102372
ABPM: Medium cuff, latex-free	7102771
ABPM: Large cuff, latex-free	7102380
ABPM: Extra large cuff, latex free	7102390
Tubing female/male	7102698
Tubing female/female	7102699
Universal Storage Tray	7105500
Disinfection Canister Holder	7102277
Dialog+ patient therapy card (set with 5 pieces)	7105232
Cuff basket	7102865
Cuff holder	7102781
Rinse bucket	7105237

14.3 Consumables

The consumables listed in the following are an extract of B. Braun product range. Further consumables and their technical data are available on request.

The Dialog+ has been tested and validated for use with consumables listed in the following tables. B. Braun does not take any responsibility or liability when consumables other than those listed are used.

Dialyzers

- xevonta
- Diacap
- Diacap Pro

Blood Line Systems

- HD Double-Needle lines
- HDF Double-Needle lines
- Single-Needle lines
- ECOPRIME Concept lines
- Universal lines
- Individual lines

Concentrates

- Acid concentrates SW xxx
- Acid concentrate bag (different sized; not available in all countries)
- Bicarbonate concentrate 8.4 %
- Bicarbonate cartridge Sol-Cart B
- Renosol set, for central concentrate supply
- Natrium hydrogen carbonate, in bag

Dialysis Fluid Filters

- Diacap Ultra DF Online Filter

Infusion and Rinsing Solution

- NaCl in Ecoflac plus container

Disinfectants for Internal Disinfection

- Citric acid 50 %

Cleaning Agents for Surface Disinfection

- Meliseptol
- Melsitt
- Hexaquart plus

14.4 Other Accessories

B. Braun currently offers accessories from the following product areas:

- Accessories for A/V blood line system
- Cannulas
- Dialysis catheters
- Luer-Lock connectors
- Syringes

For further information please contact your B. Braun representative.

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15 Technical Data

This chapter lists the technical data of the machine. Unless otherwise stated, the following standard conditions apply for machine operating data:

Parameter	Values
Ambient temperature	23 °C ± 2 °C
Temperature of osmosis water and concentrate	20 °C
Blood flow	300 ml/min
DF flow	500 ml/min
DF temperature	37 °C

15.1 General Technical Data

Description	Values
Nominal voltage	120 V~ ± 10 % 230 V~ ± 10 %
Nominal frequency	50 Hz / 60 Hz ± 5 %
Nominal current	Max. 16 A at 120 V~ Max. 10 A at 230 V~
Nominal power	2500 VA
Medical devices class[a]	II b
Medical electrical equipment classification [b]	Class I
Applied part classification [b]	Type B
Housing protection class[c]	IP21[d]
Dimensions (W x H x D)	Approx. 51 x 168 x 64 cm
Empty (dry) weight	Approx. 85 kg without options
Maximum weight [e]	118 kg
Packaging weight	< 30 kg

Description	Values
Water inlet pressure	0.5 - 6 bar
Water inlet temperature for dialysate preparation	10 - 30 °C
Water inlet temperature for disinfection	Max. inlet temperature: 95 °C
Water inlet flow	Max. peak 2.6 l/min
Water consumption in therapy	at standard flow rate 0.5 /min at max. flow rate 0.8 l/min
Drain temperature	Max. 95 °C
Concentrate supply	From container Central supply 0 - 1 bar
Alarm system	
Muting duration of audible alarms	See alarm repetition time in section 13.2 Alarms and troubleshooting
Sound pressure level of audible alarms	≥ 65db(A)
Therapy time	Set range from 10 min to 10 h Resolution 1 min

a. risk level according to EC Directive for Medical Devices (93/42/EEC)
b. type of protection against electric shock according to IEC 60601-1
c. according to IEC 60529
d. protection against foreign bodies > 12 mm and vertically falling drip water
e. maximum weight of Double Pump machine with all options

For detailed technical description as well as for information regarding fuse ratings and battery specifications, refer to the service manual.

15.2 Energy and Environment

Description	Values
Environmental influence	
Average energy (heat) emission in treatment and disinfection	0.4 kW
Average water emission per treatment	130 l
Energy	
Average energy consumption • 10 °C • 20 °C	 max. 5.0 kWh max. 4.0 KWh
Energy emission	Approx. 230 W

15.3 Ambient Conditions

Description	Values
Operation	
Temperature	+15 to +35 °C
Relative humidity	15 % – 70 % (without condensation)
Atmospheric pressure	700 – 1060 mbar
Altitude [a]	Max. 3000 m AMSL
Energy emission to drain [b] at water inlet temperature of	
• 10 °C	max. 3.9 kWh
• 20 °C	max. 2.5 kWh
Transportation and storage (dry)	
Temperature	-20 to +60 °C 5 °C to +60 °C if filled with fluid
Relative humidity	15 % – 80 % (without condensation)
Atmospheric pressure	700 – 1060 mbar

a. if the machine shall operate in > 3000 m AMSL, contact manufacturer.
b. incl. preparation, treatment and disinfection (citric acid 50 % at 83 °C)

15.4 Dialysis Fluid Side

Description	Values
Temperature setting range	33 – 40 °C
DF temperature accuracy	±0.5 °C
Alarm Limits	± 1 °C deviation from set value
Excessive-temperature protection	41 °C
Protection system	Independent temperature sensor
Conditioning	Conductivity controlled, temperature compensated
Operating regime	Conductivity bicarbonate 2 – 4 mS/cm, 4 – 7 mS/cm Overall conductivity 12.5 – 16.0 mS/cm
Protective system	Monitoring by second conductivity sensor with different geometry; monitoring of mixing ratio
Measurement tolerance	±0.2 mS/cm
Total conductivity alarm limit	±5 % deviation from set value from 11.875 mS/cm to 16.800 mS/cm (Na)
Relation between conductivity and concentration	Overall conductivity = {[Overall concentration (mmol(l) - Bic concentration (mmol/l) x Conv. Factor(acid)} + [Bic concentration (mmol/l) x Conv. Factor (bic)] Bic conductivity = Bic concentration (mmol/l) x Conv.Factor (bic)
Working range Bicarbonate without NaCl	0.06 - 0.14 mmol * cm/mS Conversion factor to Na concentration in Acid: 0.07 - 0.14 mmol * cm/mS
Working range Bicarbonate with NaCl	0.05 - 1.000 mmol * cm/mS Conversion factor to Na concentration in Acid: 0.05 - 0.142 mmol * cm/mS
Worst case composition of dialysis fluid at single fault condition for BIC dialysis	Under single fault condition in the dialysis fluid preparation the composition of the concentration of ions/electrolytes of all components in the dialysis fluid will shift due to the tolerance factors of BIC component and acidic component.

Description	Values
Deviation of ions from BIC component in single fault condition (protective system stops any treatment)	max. ±25 % deviation from set value of BIC
Resulting deviation of ion concentration of acidic component (except sodium) caused by BIC deviation	max. ±12 % deviation of ion concentrations (e.g. Mg, Ka, Ca, ...)
Sample calculation for deviation of ions in dialysis fluid under single fault condition	Use this formula to calculate the deviation for acidic component: X = tolerance factor for acidic component svtx = set value for total conductivity svb = set value for BIC X = ±(100 -(svtc-1.25*svb)*100/(svtc-svb)) Example: svb = 3 mS/cm svtc = 14.3 mS/cm X = ±6.6 % Example: Potassium = 2 mmol/l Deviation: 2 mmol/l ± 6.6 % = 1.868 ... 2.132 mmol/l
DF Flow	300 to 800 ml/min
DF Flow in HDF	500 to 800 ml/min
DF flow accuracy at dialyzer inlet	±5 %
Dialysate pressure value range	-450 to +400 mmHg
Tolerance (PDA)	±10 mmHg
Blood leak detector	Red sensitive
Alarm threshold	> 0.35 ml/min blood at HCT 25 %
Ultrafiltration	Volume-controlled via balance chambers, ultrafiltration through ultrafiltration pump Sequential ultrafiltration (Bergström)
Working range	0 ml/min at min UF: setting range 50 - 4000 ml/h
Overall tolerance*	$F = F_{bal} + F_{UF}$

Description	Values
F_{bal}	Min. 35 ml/h or ±0.2 % related to the total dialysate volume
F_{uF}	Ultrafiltration pump tolerance < 1 %
Protective system	Independent monitoring of accumulated UF volume for max. 200 ml deviation
Optional conversion factor (conductivity mS/cm to concentration mmol/L)	0.05 - 1,000 mmol*m/mS
Trans membrane pressure	
Limit range (max. TMP)	300 – 700 mmHg
Absolute alarm limit	-100 mmHg
Window to current TMP	10 - 100 mmHg
Limit window	Adjustable (2 - 99 %)
Calculation method	TMP = [(PBE + PV) / 2] - PDA + Offset or TMP = PV - PDA + Offset
Degassing system	Negative pressure by degassing pump, controlled by PE
Tolerance	± 50 mmHg

* The overall accuracy F is the sum of 2 different errors:

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

F_{bal} = balance chamber deviation (measures per chamber cycles and depends on the dialysate flow)

F_{UF} = UF pump error

15.5 Extracorporeal Circulation

Description	Data
Pumping rate	50 - 600 ml/min (8/12 mm) 50 - 400 ml/min (7/10 mm) Adjustable in 10 ml steps.
Tolerance interval	±10 % (arterial pressure 0 ... -150 mmHg, total treated blood volume ≤ 120 liters) ±25 % for arterial pressure from -150 mmHg down to -200 mmHg
Working pressure range	Intake pressure: up to -390 mmHg Pumping pressure: 0 - 1725 mmHg
Heparin pump	Suitable for 10 - 30 ml syringes
Pumping rate	0.1 - 10.0 ml/h (0.1 ml/h resolution)
Bolus rate	600 ml/h
Tolerance interval	±10 % or 0.1 ml/h
Pressure range	0 to +480 mmHg
Bolus volume range	0 to 10 ml (in steps of 0.1 ml)
Safety air detector	Method: Ultrasonic transmission measurement, automatic cyclical checks during entire operating phase Sensitivity: Air bubbles: Bubble volume ≥ 50 µl Blood foam Single bubbles: 0.2 ml at 50 - 200 ml/min SAD flow 0.3 ml at 201 - 400 ml/min SAD flow 0.5 ml at 401 - 600 ml/min SAD flow or Single-Needle therapy 0.7 ml at 601 - 1,200 ml/min SAD flow (during Single-Needle therapy)
Red sensor	In SAD housing, optically detects blood in tubing system.
Pressure measurement at arterial inlet of dialyzer (PBE)	Electronic pressure sensor

Description	Data
Working range	0 to 700 mmHg
Tolerance	±10 mmHg
Upper limit	Set range 100 to 700 mmHg
Arterial inlet pressure (PA) measurement	Electronic pressure sensor
Working range	-400 to +400 mmHg
Tolerance	±10 mmHg
Absolute low limit	Default -200 mmHg Set range -400 to 0 mmHg
Venous return pressure (PV) measurement	Electronic pressure sensor
Working range	-50 to +400 mmHg
Tolerance	±10 mmHg
Absolute low limit	Default 20 mmHg Set range -50 to 100 mmHg
Dynamic alarm window	Dynamic, configurable alarm value range Default lower alarm limit 35 mmHg below PV (set range 0 to 100 mmHg). Default upper alarm limit 100 mmHg over lower alarm limit (set range 40 to 200 mmHg). After blood pump adjustment, the alarm window is re-centered.

15.6 Materials Coming Into Contact With Water, Dialysate, Dialysis Concentrates and/or Disinfectants

Material name	Abbreviation if existent
Ceramics	-
Ethylene Propylene Diene Monomer	EPDM
Glass	-
Graphite	-
Polyester	-
Polyetheretherketone	PEEK
Polyetherimid	PEI
Polyethylene	PE
Polyisoprene	-
Polymethylmethacrylate	PMMA
Polyoxymethylene	POM
Polyphenylsulfone	PPSU
Polypropylene	PP
Polypropylene Oxide	PPO
Polytetrafluoroethylene	PTFE
Polyvenyl Chloride	PVC
Polyvinylidene difluoride	PVDF
Silicone	-
Stainless steel	-
Thermoplastic Urethane	TPU
Polycarbonate/Acrylnitril Butadien Styrol	PC/ABS

15.7 Packaging Materials

Part	Material
Base plate	Plywood AW 100
Shell (folding box and lid)	Corrugated cardboard
Padding	Polyethylene foam (Stratocell S, Ethafoam 400) Corrugated cardboard Solid cardboard
Gusseted bag	PE 50µ
Abrasion protection	PE foil

15.8 Technical Data HDF/HF Online

Description	Values
HDF (Haemodiafiltration) / HF Hemofiltration	
Substitution rate	20 – 400 ml/min ± 10 %
Substitution temperature	Equal to dialysis fluid temperature
Substitution temperature	Accuracy: ± 0.5 °C at substitution flow ≥ 100 ml/min Accuracy: + 1/- 2.2 °C at substitution flow < 100 ml/min
Protective system	See dialysis fluid temperature
Infusion bolus	50 – 250 ml ± 10 %
Online filter / Dialysis fluid filter	
Operating time	See instructions for use of filter manufacturer

15.9 Automatic Blood Pressure Measurement (ABPM)

Description	Values
Cuff pressure range	0 – 320 mmHg
Cuff	Protected applied part
Inflation pressure during first cuff inflation	200 mmHg
Inflation pressure during subsequent measurements	Last SYS pressure +30 mmHg
Blood pressure measurement range	Systole 45 - 280 mmHg MAP [a] 25 - 240 mmHg Diastole 15 - 220 mmHg
Tolerance	±5 mmHg or ±2 %
Pulse rate determination	30 – 240 BPM
Pulse rate tolerance	±2 % or 2 BPM
Defibrillation	Not protected applied part
Safety classification [b]	Class I, type BF
Overpressure cut-off	300 mmHg +10 %

a. mean arterial pressure
b. type of protection against electric chock according to IEC 60601-1

15.10 Disinfection

Program	Description
Thermal disinfection temperature	83 °C Setting range: 0 to 95 °C
Disinfection/cleaning	Automatic program with enforced rinse-out. The parameters for the disinfectant used can be set in the service program. HDF Online and dialysis fluid filter option: Only disinfectants cleared for the dialysis fluid filter can be used.
Thermal disinfection	Automatic program cycle.

During disinfection processes, dialysis is blocked. Reports on the efficacy or the individual disinfection program can be obtained from the manufacturer.

Disinfectant parameters can be set in TSM mode by technical service.

HDF Online and dialysis fluid filter are to be used.

15.11 Technical Data of Crit-Line Interface

The intended use of the DSI interface is to connect the Crit-Line III TQA device of Hema Metrics ™ to the Dialog+ or other devices released by B. Braun for operation.

It is prohibited to connect any other device.

The DSI interface is galvanically isolated from the Dialog+ /staff/patient according to the standard IEC 60601-1.

Description	Values
Maximum specific transfer rate	115.2 KBaud
Maximum voltage level (all pins in relation to GND (ground)-level)	±25 V DC
Maximum ohmic impedance of external serial connection cable	7 KΩ
Maximum capacitive impedance of external serial connection cable	2500 pF

15.12 Formula of Kt/V

Kt/V is, beside urea reduction ratio (URR), a characteristic value for dialysis efficacy. It is based on the following parameters:

- Dialyzer clearance of urea
- Effective dialysis time
- Volume of distribution or urea (approx. equal to patient’s total body water)

The following abbreviations are used:

Abbreviation	Description
K	Clearance [ml/min]
t	Dialysis time [min]
V	Urea distribution volume [ml]

The dimensionless parameter Kt/V is calculated as:

$$\frac{K \times t}{V}$$

The human body water content can roughly be estimated to approx. 60 % of body mass, i.e. a patient with a body mass of 80 kg has a total urea distribution volume of approx. 48,000 ml (V = 80 kg x 0.6 l/kg = 48 l).

Dialyzer clearance (K) multiplied by dialysis time (t) corresponds to the cleared blood volume during treatment. Thus, Kt/V represents the ratio of cleared blood volume to urea distribution volume. A value of 1.0 would indicate that a blood volume equal to the distribution volume of urea has been completely cleared

Kt/V may vary considerably from treatment to treatment due to measurement errors and other factors. Therefore, the Kt/V target value for hemodialysis should be ≥ 1.2 in order to ensure an adequate dialysis dose of at least 1.0.

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16 Electromagnetic Compatibility (EMC)

Electromagnetic compatibility (EMC) means that medical electrical equipment has the capability to work satisfactory in an electromagnetic environment, without causing electromagnetic emissions, which would be unacceptable for all other medical electrical equipment in this environment.

⚠ WARNING!

The Dialog+ machine needs special precautions regarding EMC. Observe the following information:

- The machine must be set up, powered on and serviced in accordance with the EMC information in this section. The safe distances and ambient/ operation conditions specified must be ensured and complied with. Portable and mobile RF communications equipment can affect medical electrical equipment. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Dialog+, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by B. Braun Avitum AG as replacement parts for internal components, may result in increased emissions or decreased immunity of the machine.
- Functional reliability is only guaranteed if accessories that have been approved, and therefore are recommended by B. Braun Avitum AG, are used. Accessories are listed in chapter 14 Accessories (315).
- If the equipment is operated in the vicinity of other equipment which may cause high levels of interference (e.g. HF surgical equipment, nuclear spin tomography units, mobile telephones, etc.) this equipment may be disturbed. Maintain the protective distances recommended by the manufacturers of these machines.
- In order to meet with the compliance levels, only original accessories and replacement parts may be used. Otherwise, there may be increased emissions or reduced machine immunity. If the machine is used in a system involving other devices (e.g. electro surgery), this system should be checked to ensure correct operation of the system.

⚠ CAUTION!

The device is unsafe to use in proximity to Magnetic Resonance Imaging (MRI) equipment!

- The device must not be used near a Magnetic Resonance Imaging unit without protection.

The following guidelines may not be applicable in all situations. Electromagnetic wave propagation is affected by the absorptive and reflective qualities of the surrounding structures, objects and people.

16.1 Electromagnetic Interference Emissions

Guidance and Manufacturer's Declaration – Electromagnetic Interference Emissions		
The dialysis machine is designed to be used in the electromagnetic environmental conditions described below. Customers or users of the machine should ensure that it is being operated in such an environment.		
Interference Emission Measurements	**Compliance**	**Electromagnetic Environmental Guidelines**
RF emissions acc. to CISPR 11	Group 1/ Class B (see Note 1)	The machine uses RF energy for its internal functions only. As such, its RF emissions rate is very low and it us unlikely to interfere with nearby electronic equipment.
Voltage fluctuation/ emissions according to IEC 61000-3-3	Complies	The machine is intended for use in all establishments (including residential areas and similar) directly connected to a public power grid that also supplies buildings used for residential purposes.
Harmonic emissions according to IEC 61000-3-2	Complies	
Note: The limits for interference emissions are measured with the maximum set-up (fully equipped Dialog+ dialysis machine).		

16.2 Electromagnetic Immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The dialysis machine is designed to be used in the electromagnetic environmental conditions described below. Customers or users of the machine should ensure that it is being operated in such an environment.			
Immunity Tests	**Test Level EN 60601-1-2 EN 60601-2-16**	**Compliance Level**	**Electromagnetic Environmental Guidelines**
Electrostatic discharge (ESD) acc. to IEC 61000-4-2	Contact discharge: IEC 60601-1-2	±8 kV outage with alarm permitted	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	Air discharge: IEC 60601-1-2	±15 kV outage with alarm permitted	
Electrical fast transient/ bursts acc. to IEC 61000-4-4	For power supply lines: ±2 kV	±2 kV	Mains power quality should be that of a typical commercial or hospital environment. [a]
	For input and output lines: ±1 kV	±1 kV	
Surges acc. to IEC 61000-4-5	Differential mode voltage: ±1 kV	±1 kV	Mains power quality should be that of a typical commercial or hospital environment. [a]
	Common mode voltage: ±2 kV	±2 kV	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
Voltage dips, brief supply voltage interruptions and fluctuations acc. to IEC 61000-4-11	<5 % U_T [b] for ½ period (>95 % dip)	Complies through the use of an internal energy source	The supply voltage quality should be the same as that of a typical commercial of hospital environment. [a] The machine is designed for continuous operation if mains power interruption occurs. The machine will temporarily lose function, which ceases after the disturbance, and will recover its normal performance without user intervention.
	40 % U_T [b] for 5 periods (60 % dip)		
	70 % U_T [b] for 25 periods (30 % dip)		
	<5 % U_T [b] for 5 seconds (>95 %)		
Magnetic field at supply frequency (50/ 60 Hz) acc. to IEC 61000-4-8	3 A/m	100 A/m	Magnetic fields at the supply frequency should correspond to those typically found in commercial and hospital environments. [a]
Conducted RF interference acc. to IEC 61000-4-6	IEC 60601-1-2: 150 kHz to 80 MHz 3 V_{RMS} in ISM bands	150 kHz to 80 MHz 10 V_{RMS} in all frequency bands	Do not use portable radio communications equipment closer to the machine (including connection cables) than the recommended safe distance calculated using the appropriate equation for that frequency. Recommended safe distance: $d = 1.2 \sqrt{P}$ [b, c]
Radiated RF interference acc. to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m 80 MHz to 6 GHz	The field strength should be lower than 10 V/m Recommended safe distances: $d = 1.2 \sqrt{P}$ [c] (for 80 MHz to 800 MHz) $d = 2.3 \sqrt{P}$ [c] (for 800 MHz to 6 GHz) Field strengths from stationary RF transmitters should be below the compliance level for all frequencies, based on an on-site test. Interference is possible in the vicinity of equipment that has the following symbol 

a. The machine is intended for use under the listed conditions and under keeping its essential performance, basic safety and its tolerance.

b. U_T is the AC mains voltage prior to test level application.

c. With P as the maximum rated power of the transmitter in watts (W) according to the transmitter manufacturer specifications and d as the recommended safe distance in meters (m).

NOTICE!

The deviating test values derived from IEC 60601-2-16 are labeled in the table. However, these test values allow one outage with an alarm while the test values according to DIN EN 60601-1-2 do not allow any outage.
The compliance levels for ISM frequency bands between 150 kHz and 80 MHz and in the 80 MHz to 2.5 GHz frequency range are designed to minimize the likelihood of mobile/portable communications equipment causing interference if accidentally brought into the patient area. For this reason, the additional factor 10/3 is used when calculating the safe distances in these frequency ranges.
Field strengths emitted from stationary transmitters (such as base stations for cordless telephones and land mobile radio devices, amateur radio stations, or AM and FM radio and television broadcasts) theoretically cannot be predicted exactly. Consider conducting a study of the site to determine electromagnetic environmental conditions as regards stationary transmitters. If the measured field strength in the area, the Dialog+ dialysis machine is being used in exceeds compliance levels, monitor the Dialog+ dialysis machine to ensure that it is functioning properly. If abnormal performance is observed, additional measures may be necessary, e.g., changing the device's location or facing it in a different direction.

16.3 Recommended Safe Distances

Recommended safe distances between portable and mobile RF telecommunications devices and the Dialog+ machine

The Dialog+ machine is designed to be used in an electromagnetic environment in which emitted RF disturbances are controlled. Users of the machine can help to prevent electromagnetic interference by complying with the minimum distances between portable and mobile RF telecommunications devices (transmitters) and the Dialog+ as recommended below, in accordance with the maximum output power of the communication device.

Nominal output power (P) of transmitter in Watt [W]	Safe distance (d) in Meter [m], according to transmitting frequency		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 6 GHz $d = 2.3 \sqrt{P}$
< 0.1 W	0.30 m	0.30 m	0.30 m
0.1 W	0.38 m	0.38 m	0.73 m
1 W	1.20 m	1.20 m	2.3 m
10 W	3.80 m	3.80 m	7.27 m

Recommended safe distances between portable and mobile RF telecommunications devices and the Dialog+ machine			
100 W	12.0 m	12.0 m	23.0 m

Note 1: The higher value applies at 80 MHz and 800 MHz.

Note 2: For transmitters with other output power ratings than specified in the table above, the separation distance (d) can be determined using the equation for the relevant column. P is the transmitter's rated power in W according to the manufacturer's specification.

Note 3: An additional factor of 10/3 is used to calculate the recommended separation distance of transmitters in the frequency range between 80 MHz and 2.5 GHz, in order to reduce the probability of a mobile communication device used unintentionally in the patient area causing a fault.

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17 Appendix

Training Check List

For home hemodialysis patient and users according to the Dialog+ Instructions for Use.

User Name	
Responsible Organization	
Physician in Charge	
Training Period	

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Initiating the Treatment	6 Initiating Hemodialysis (99)
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Handling the Dialog+ Options	11 Use of Options (175)
Cleaning and Disinfection of the Machine	8 Disinfection (121)
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Alarms and how to react	13 Alarms and Remedial Action (253)

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Electromagnetic Compatibility	16 Electromagnetic Compatibility (EMC) (337)
Environmental	15 Technical Data (321) 15.3 Ambient Conditions (323)

Individual Training Concept	
Content	Notes

Responsible Organization	*Date, Name of Responsible Organization*
Duly trained and instructed	*Date, Signature of Trainer / Instructor*
Training received and understood	*Date, Signature of User / Patient*