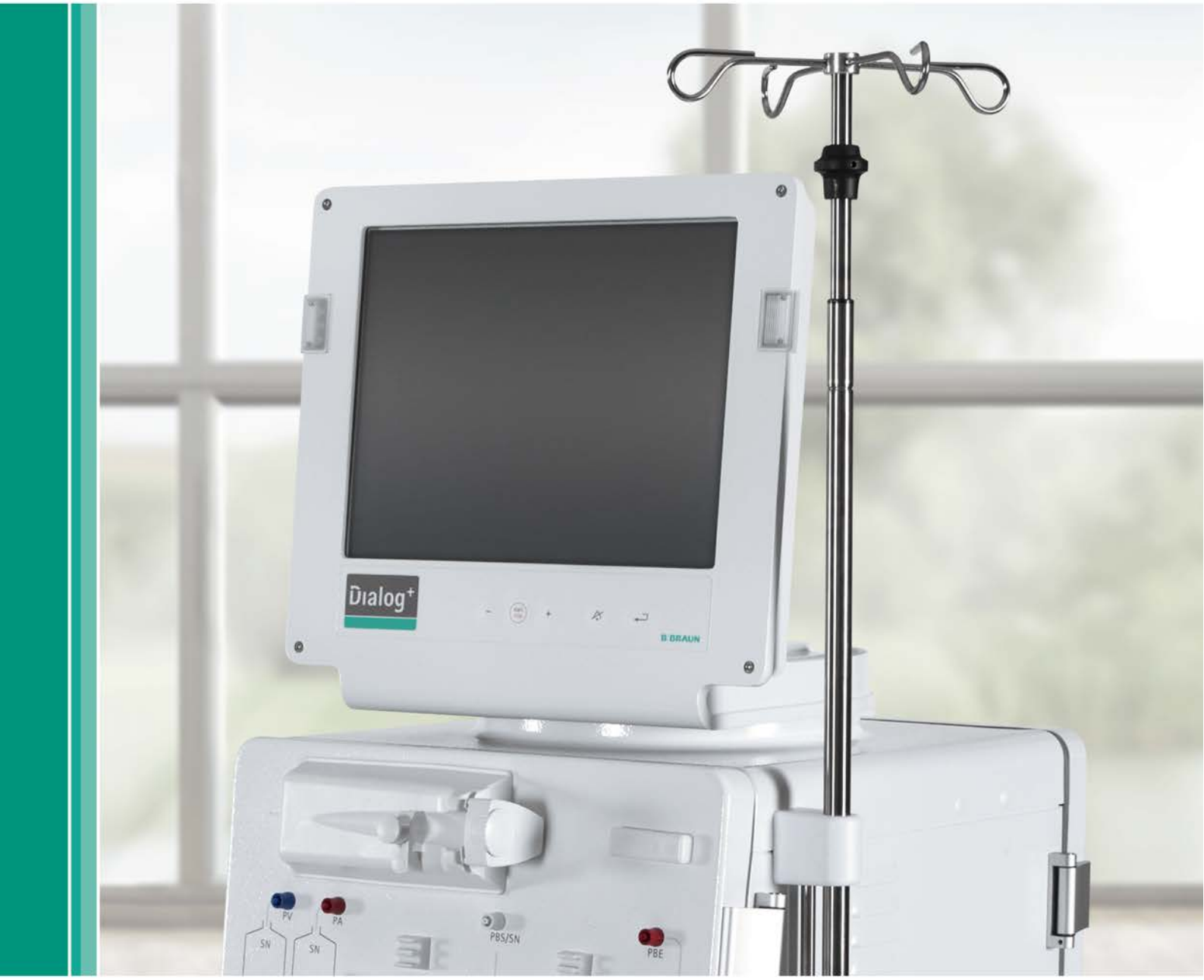
Dialog+® Dialysis Machine

Instructions for Use SW 9.1x



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SHARING EXPERTISE

CE 0123

CE marking according to directive 93/42/EEC
Technical alterations reserved

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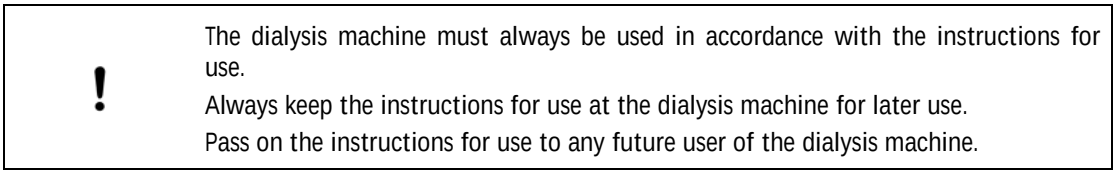
1 Safe handling

1.1 About these instructions for use

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



The dialysis machine must always be used in accordance with the instructions for use.

Always keep the instructions for use at the dialysis machine for later use.

Pass on the instructions for use to any future user of the dialysis machine.

1.1.1 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 9.1x (x = any).

1.1.2 Target group

The target group for these instructions for use is specialist medical staff.

The dialysis machine may only be used by persons instructed for its appropiate operation.

1.1.3 Warnings, notices and symbols in these instructions for use

Warnings in these instructions for use point out particular hazards for users, patients, third parties and the dialysis machine. They also suggest measures that can be taken to avoid the respective hazard.

There are three levels of warning notices:

Warning term	Meaning
DANGER	Imminent danger that can lead to death or serious injury if not avoided.
WARNING	Potentially imminent danger that can lead to death or serious injury if not avoided.
CAUTION	Potentially imminent danger that can lead to minor injuries or damage to equipment if not avoided.

The warning notices are highlighted in the following manner (see below example for a CAUTION warning):

CAUTION

Here, the type and source of the danger are listed and possible consequences if measures are not followed!

➢ **This is the list of measures to prevent the hazard.**

! This is the list of important information, directly or indirectly relating to safety and the prevention of damage.

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

➢ This symbol marks the instructions for action.

1.1.4 Abbreviations

ABPM	Automatic blood pressure monitoring
BPA	Arterial blood pump
BPV	Venous blood pump
BSL	Bed Side Link
CO	Cross-over
HD	Haemodialysis
HDF	Haemodiafiltration
HF	Haemofiltration
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
SN-CO	Single-needle cross-over
TMP	Trans membrane pressure
TSM	Technical support and maintenance mode
UF	Ultrafiltration
ZKV	Central concentrate supply

1.2 Intended use and indication

The dialysis machine can be used for implementing and monitoring haemodialysis treatments for patients with acute or chronic kidney failure. The system can be used for hospital, health centre, limited-care or home dialysis.

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

- Haemodialysis (HD)
- Isolated ultrafiltration (ISO UF): Sequential therapy (Bergström)
- Haemodiafiltration (HDF)
- Haemofiltration (HF)

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1.3 Contraindication

There are no known contraindications for chronic haemodialysis.

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

1.4 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 few cases. For this matter, please refer to the product information provided with the consumables.

1.5 Special hazards and precautions

1.5.1 Special patient conditions

The dialysis system may only be operated on doctor´s instructions if the 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 dialyser and blood line must be selected according to the patient's size, weight and treatment type.**

1.5.2 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.**

It must not be used or connected to mains voltage if the housing or the mains cord is damaged in any way. A damaged dialysis machine must be submitted for repairs or disposed of.

Interaction with other devices

When using the dialysis machine in combination with other therapeutic devices of protection class I, a potential equalisation device must be connected, since the leakage currents from all connected devices are additive and the electrostatic discharge from the environment to Dialog+ may occur.

Do not connect customary consumer devices to the same power socket as the dialysis machine or to connect them in parallel.

Use with central-venous catheter

For cardiac application, a higher degree of protection against electric shock is required. Electric currents can run through supply lines via the dialysis fluid filter, the dialyser, the catheter, the patient and every conducting object in the vicinity of the patient. That is why electrical potential equalisation must be provided. As soon as earth potential equalisation is connected to the machine the patient leakage current has to be below 10 µA, which complies with the limit value for patient leakage current of type CF. A special potential equalisation cable is available. It can be connected to the bolt at the rear side of the machine. The ambient conditions of the premises must be in accordance to the local requirements (see chapter 1.6.4).

1.5.3 Electromagnetic interactions

The dialysis 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 will occur (examples: mobile phones, computer tomograph (CT)).

CAUTION

Risk of electrostatic discharge from other devices.

- **It is recommended that mobile phones and other devices emitting strong electromagnetic radiation only be used at a minimum distance, according to IEC 60601-1-2 (see also chapter 15.3).**

!

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.

1.5.4 Maintenance and filter change

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

Due to the particularly stringent hygienic requirements, we recommend annual servicing of dialysis machines with dialysis fluid filters and of Dialog+ HDF-online. The dialysis fluid filters must be changed as specified in the respective instructions for use.

1.6 Information for the operator

1.6.1 Training by manufacturer prior to commissioning

The operator may only use the device after the manufacturer has trained the responsible staff based on these instructions for use.

1.6.2 Requirements on the user

The dialysis machine may only be used by persons instructed for its appropriate operation.

The operator must ensure that the instructions for use are read and understood by all operators of the dialysis machine.

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

1.6.3 Conformity

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

- IEC 60601-1
- IEC 60601-2-30
- DIN EN 1060-1
- DIN EN 1060-3

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

Persons connecting additional devices to signal input or output components are performing a system configuration and are, thus, responsible for ensuring that the valid version of System Standard IEC 60601-1-1 is complied with. In case of queries, please contact your local specialist dealer or technical service.

In each country the distribution of the machine is carried out provided that the device is registered and classified according to the local regulations.

1.6.4 Manufacturer's responsibility

The manufacturer, assembler, installer or implementer shall only be responsible for the effects on the safety, reliability and performance of the device, if

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

The device may only be operated if the manufacturer or an authorised person acting on behalf of the manufacturer

- has carried out a functional check on site (initial commissioning),
- if the persons appointed by the operator to use the device have been trained in the correct handling, use and operation of the medical product with the aid of the instructions for use, enclosed information and maintenance information and
- if the quality of the water used with the device corresponds to the relevant standards.

1.6.5 Technical changes

We reserve the right to change our products in line with further technical developments.

1.7 Disposal and taking back of old dialysis machines

Dialysis machines may be returned to the manufacturer for disposal in accordance with the applicable disposal guidelines (EC directive 2002/96).

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The company B. Braun Avitum AG guarantees the taking back of old B. Braun dialysis machines.

The dialysis machine has to be disinfected according to regulations before disposal.

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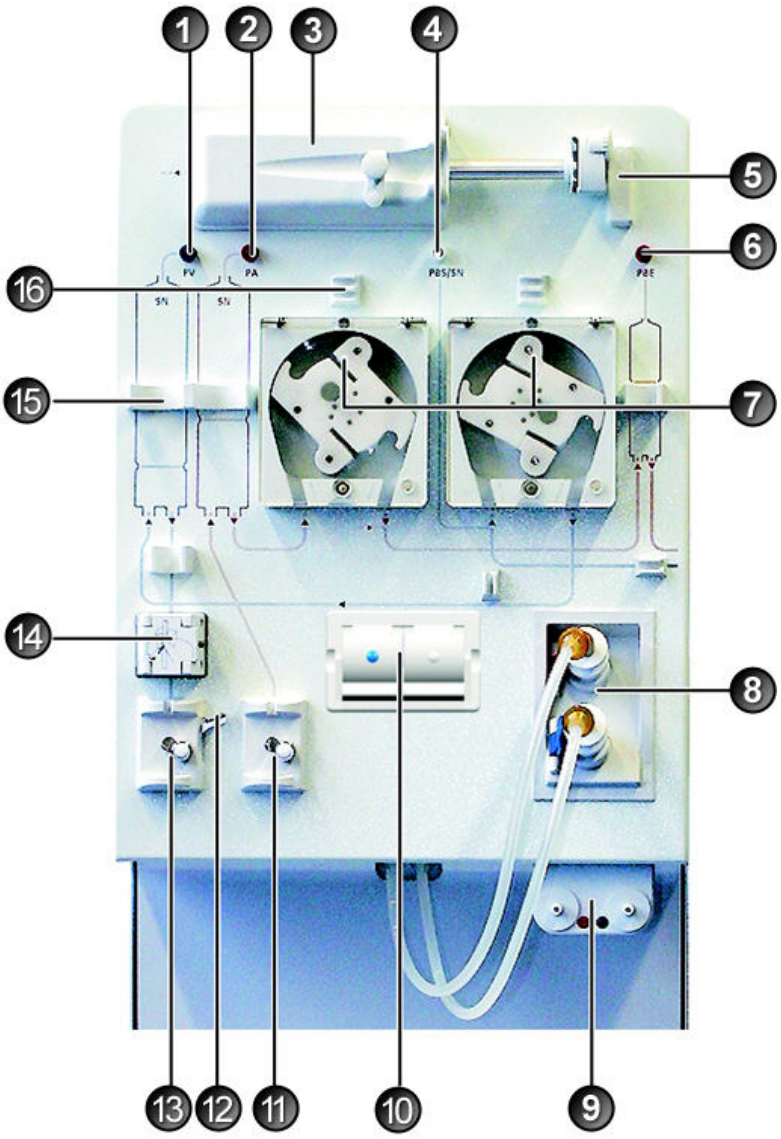
2 Product description

2.1 Basic models

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



Legend

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 dialyser (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 "SN-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 tube system
16 Fixings for blood tube system

Fig. 2-1 Basic models, front view

2

Side views

Legend

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 dialyser tubes and rinsing bridge
7 Card reader

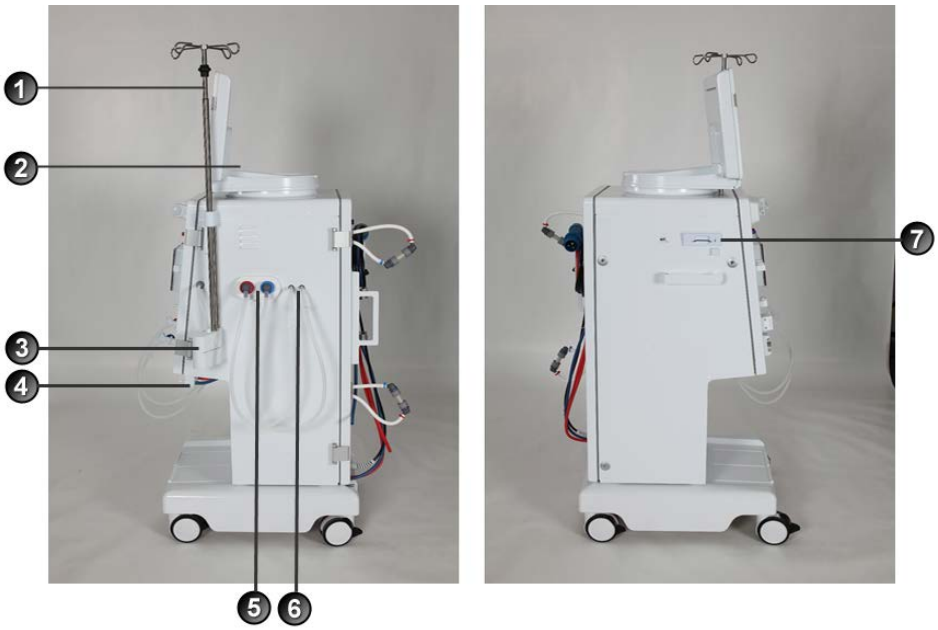
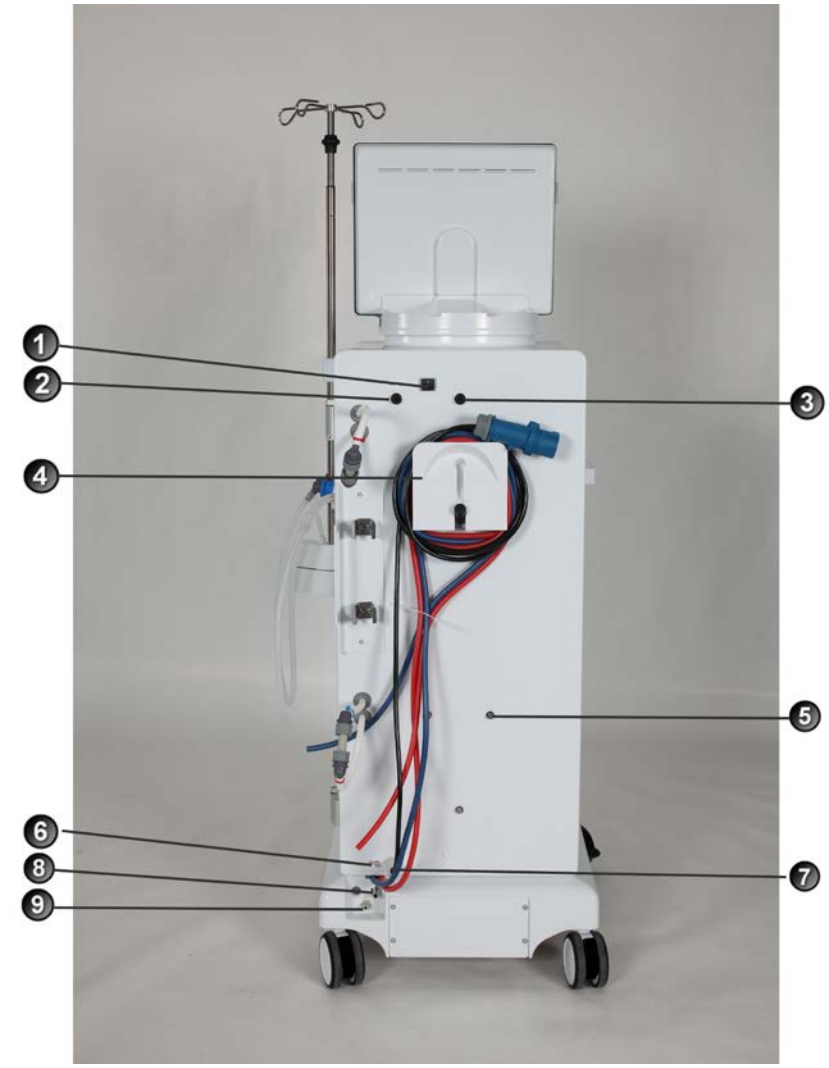


Fig. 2-2 Basic models, side views

Rear view

Legend

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



8 Water inlet
9 Dialysate outlet

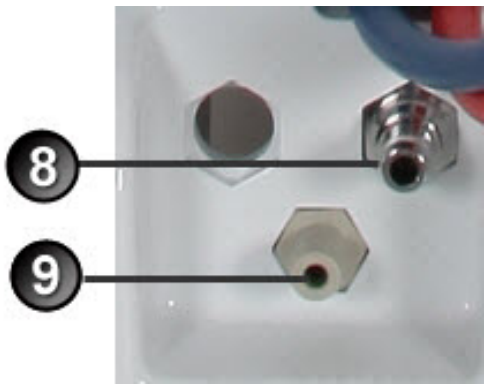


Fig. 2-3 Basic models, rear view

2.1.1 Dialog+ single-pump machine

The Dialog+ single-pump dialysis machine is suitable for hospitals, health centres, limited-care and home dialysis. It offers the following features as standard:

- Colour screen and on-screen operation (colour touch screen)
- Acetate/bicarbonate operation
- Volumetric ultrafiltration device
- Heparin syringe pump
- Fixed or freely selectable profile controls for dialysate composition, temperature and flow rate, for heparin supply and for ultrafiltration
- Heat exchanger

The following features are available as additional options:

- Automatic blood pressure monitoring (ABPM)
- bioLogic RR Comfort (Automatic blood pressure stabilisation, only in combination with ABPM)
- Bicarbonate cartridge holder
- Central concentrate supply (ZKV)
- Dialysis fluid filter
- Emergency power supply
- Data interface (also available for other use):
  - Dialog+-computer interface
  - Staff call
  - BSL (Bed Side Link): Card reader and interface to Nexadia data management system
- SN-valve with additional tube clamp
- Rollers 7 x 10 mm
- Adimea
- Crit-Line Interface
- Card reader

Therapy types

The Dialog+ dialysis machine with a single blood pump can be used for the following therapy procedures:

- Haemodialysis (HD)
- Isolated ultrafiltration (ISO UF)

Methods of treatment

The Dialog+ dialysis machine with a single blood pump can be used for the following therapy methods:

- Double-needle procedure
- Single-needle valve procedure

2.1.2 Dialog+ double-pump machine

The Dialog+ double-pump dialysis machine is suitable for hospital, health centre, limited-care and home dialysis and offers the following features as standard:

- Colour screen and on-screen operation (colour touch screen)
- Double-pump single-needle equipment
- Acetate/bicarbonate operation
- Volumetric ultrafiltration device
- Heparin syringe pump
- Fixed or freely selectable profile controls for dialysate composition, temperature and flow rate, for heparin supply and for ultrafiltration
- Heat exchanger

The following features are available as additional options:

- Automatic blood pressure monitoring (ABPM)
- bioLogic RR Comfort (Automatic blood pressure stabilisation, only in combination with ABPM)
- Bicarbonate cartridge holder
- Central concentrate supply (ZKV)
- Dialysais fluid filter
- Emergency power supply
- Data interface (also available for other use):
  - Dialog+-computer interface
  - Staff call
  - BSL (Bed Side Link): Card reader and interface to Nexadia data management system
- Rollers 7 x 10 mm
- Adimea
- Crit-Line Interface
- Card reader

Therapy types

The Dialog+ double-pump dialysis machine can be used for the following therapy types:

- Haemodialysis (HD)
- Isolated ultrafiltration (ISO UF)

Methods of treatment

The Dialog+ double-pump dialysis machine can be used for the following therapy methods:

- Double-needle procedure
- Single-needle cross-over procedure
- Single-needle procedure

2.1.3 Dialog+ HDF-online

The Dialog+ HDF-online dialysis machine is suitable for hospital, health centre, limited-care and home dialysis and offers the following features as standard:

- Colour screen and on-screen operation (colour touch screen)
- Double-pump single-needle equipment
- Acetate/bicarbonate operation
- Volumetric ultrafiltration device
- Heparin needle pump
- Fixed or freely selectable profile controls for dialysate composition, temperature and flow rate, for heparin supply and for ultrafiltration
- Online production of ultra-clean dialysate for haemodialysis with two-stage dialysis fluid filter system to ensure the cleanness of the substitution solution
- Online production of substitution solutions free from bacteria and pyrogenes as used for haemofiltration and haemodiafiltration
- Option of adding substitution solutions by pre- or post-dilution
- Bicarbonate cartridge holder
- Heat exchanger

The following features are available as additional options:

- Automatic blood pressure monitoring (ABPM)
- bioLogic RR Comfort (Automatic blood pressure stabilisation, only in combination with ABPM)
- Central concentrate supply (ZKV)
- Emergency power supply
- Data interface (also available for other use):
  - Dialog+-computer interface
  - Staff call
  - BSL (Bed Side Link): Card reader and interface to Nexadia data management system
- Rollers 7 x 10 mm
- Adimea
- Crit-Line Interface
- Card reader

Therapy types

The Dialog+ HDF-online dialysis machine can be used for the following therapy types:

- Haemodialysis (HD)
- Isolated ultrafiltration (ISO UF)
- Haemofiltration (HF-online)
- Haemodiafiltration (HDF-online)

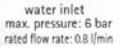
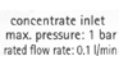
Methods of treatment

The Dialog+ HDF-online dialysis machine can be used for the following therapy methods:

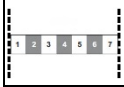
- Double-needle procedure
- Single-needle cross-over procedure; only possible with therapy types HD and ISO UF
- Single-needle procedure

2.2 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
	Connection for potential equalization line
	Dialysis machine OFF
	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 monitoring (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
	Upper arm diameter
	Cuff size: S (small), M (medium), L (large), XL (extra large). The respective size is indicated by the rectangle around the symbol.
	Marking for cuff placement
	Marking for correct cuff size
	Reference number
	Patient name
	Medical device
	Cuff side to be applied to the patient
	CE marking
	Manufacturer

2.3 Control elements and information on the monitor

Signal lamps

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

Legend

1 Signal lamps:
Green = operation
Yellow = warning/note
Red = alarm

2 Buttons on the monitor

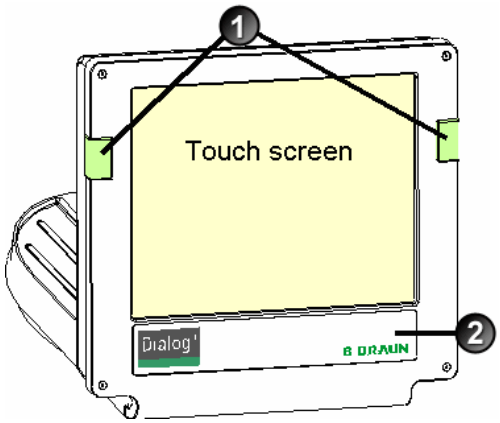


Fig. 2-4 Monitor

Buttons 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 buttons on the monitor.

The "**+**" and "**-**" buttons (button **2** and **4**) automatically count up or down by keeping the button pushed.

Legend

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 button is illuminated); switches of the alarm buzzer

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

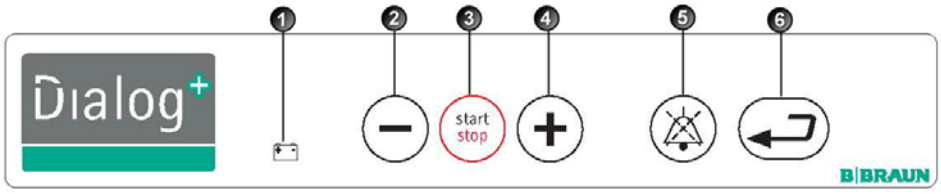


Fig. 2-5 Buttons on the monitor

Touch screen

Most functions of the dialysis machine are controlled via the touch screen. The screen displays different contents (windows) depending on the activated program section. Different parts (fields and icons) 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.

Legend

1. Screen
2. Fields
3. Icons
4. Call up help function for explaining the icons

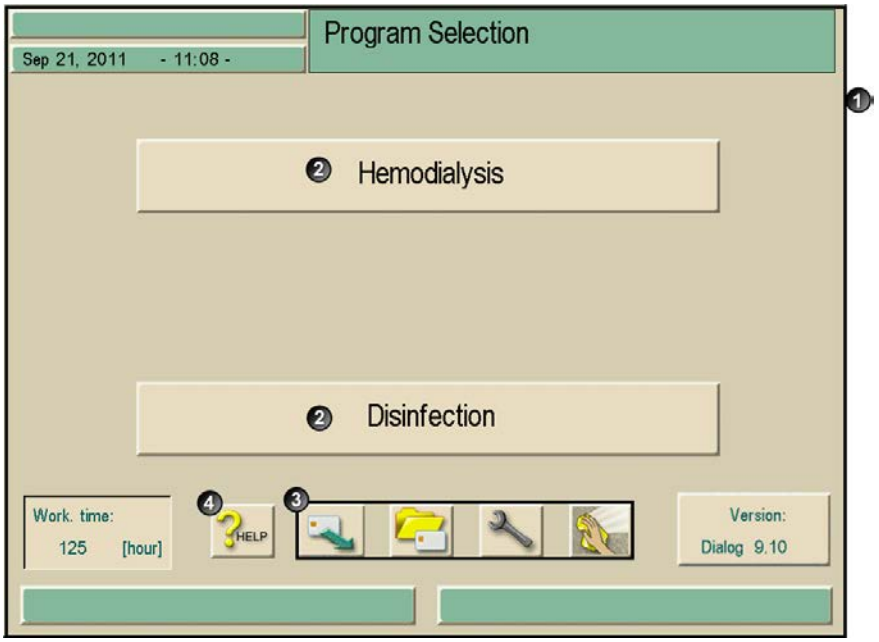
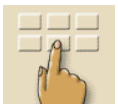
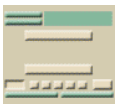
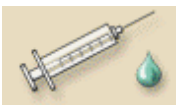


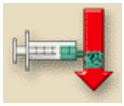
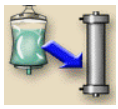
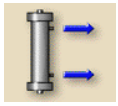
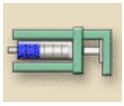
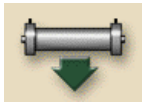
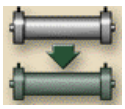
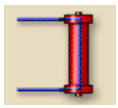
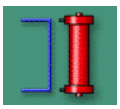
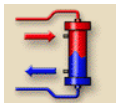
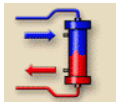
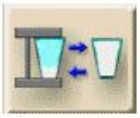
Fig. 2-6 Screen display

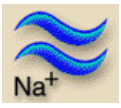
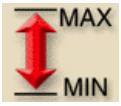
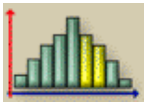
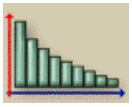
2.4 Overview of all icons

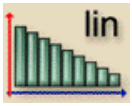
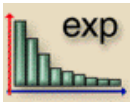
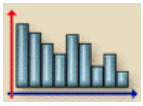
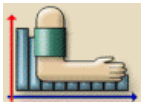
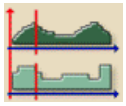
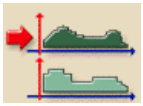
Icons are control buttons on the touch screen used for operating the dialysis machine. Depending on the displayed window, different icons are available, which all represent a specific action. By touching an icon, the respective action is carried out. A list of all icons is provided below.

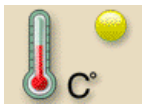
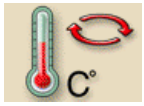
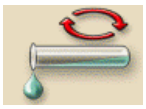
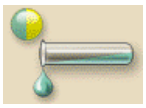
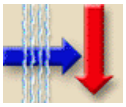
	Leave window and accept data
	Leave window without accepting data
	Call up help function for explaining the icons
	Call up history of current disinfection
	Call up service screen
	Switch off all icon functions for 10 sec to allow cleaning of monitor
	Set brightness of monitor
	Leave current window
	Call up overview
	Call up respective parameter window

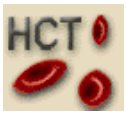
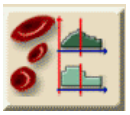
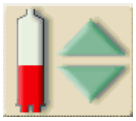
	Set treatment parameters
	Return to program selection
	Erase therapy card
	Read patient data from therapy card
	Save patient data to therapy card
	Select further setting options
	Reduce value
	Increase value
	Red symbol: error symbol during reading of patient data therapy card
	In profile window (except 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 dialyser rinsing program with simultaneous ultrafiltration
	Empty dialyser – dialysate is siphoned out of the dialyser
	Call up and set heparinisation 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 dialyser
	Dialysis bypass – no dialysate in dialyser
	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
	Disinfection from water supply – discharge
	Call up and set dialysate data
	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

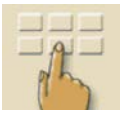
	Call up linear profile in case of specified start and end values
	Call up exponential profile in case of specified start and end values
	Call up UF path bioLogic RR Comfort (option)
	Select bioLogic RR Comfort (automatic blood pressure stabilisation, option)
	Select bioLogic RR Comfort submenu
	Call up non-invasive blood pressure monitoring (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 effectiveness and list of treatment values and Kt/V values
	Save disinfection data Call up weekly disinfection program
	Call up disinfection screen

	Start thermal disinfection
	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

	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

2.5 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.



➢ 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.

➢ 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.

➢ 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.

Legend

1 Reduce value

2 Increase value

3 Call up keypad for entering values

4 Example: Calling up "Ultrafiltration data" screen

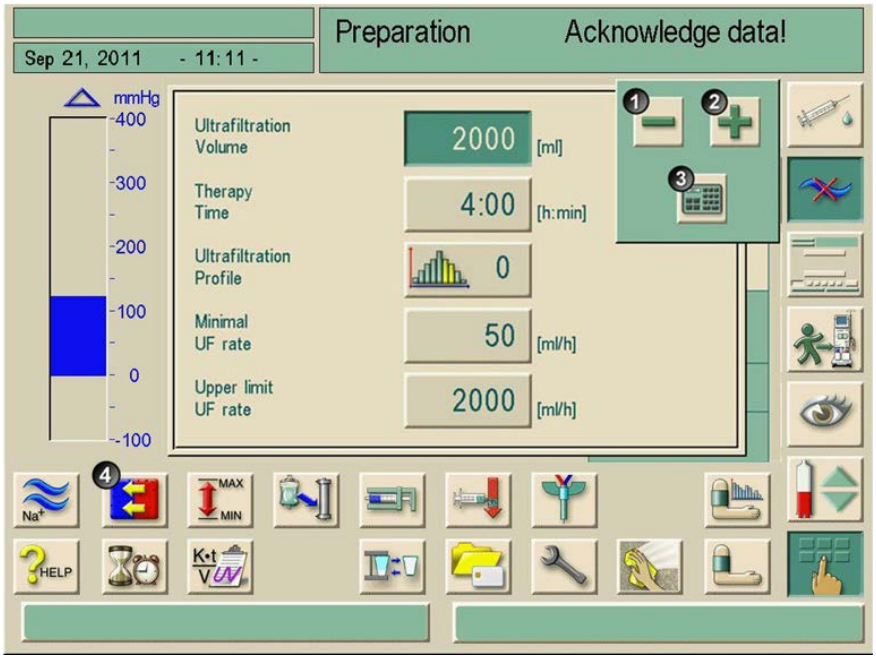
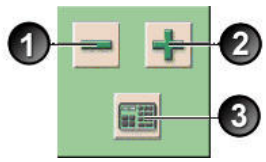


Fig. 2-7 Icons for changing the value

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 ↵ on monitor.



➢ Reduce value: Touch icon **1** until the desired value has been reached.
➢ Increase value: Touch icon **2** until the desired value has been reached.
➢ 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.

Legend

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. 2-8 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.

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

2

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. 2-9.

The following screen shows the available shortcut squares in frames.

Legend

1 Help icon, active

☐ Shortcuts

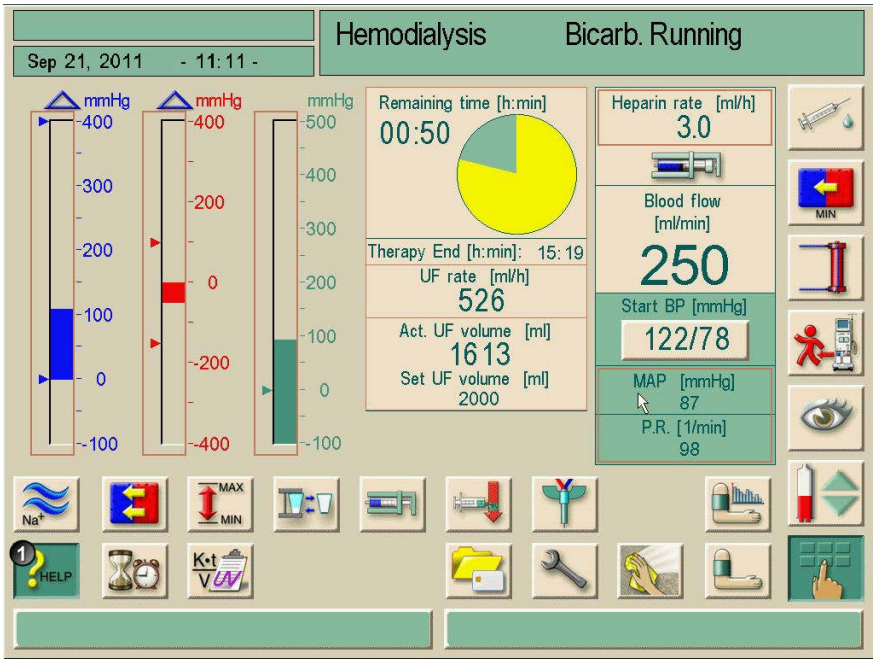


Fig. 2-9 Shortcut squares during activated help button

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.

➢ Touch help button (**1**)

The shortcuts will be marked by brown frames.

➢ Touch help button again

➢ The frames disappear.

i

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.

2.6 Therapy types

2.6.1 Haemodialysis (HD)

Haemodialysis 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 dialyser.

Inside the dialyser metabolic waste products are separated from the blood. The dialyser 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 dialyser. The dialysate transports the metabolic products from the dialyser 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 dialyser 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.

2.6.2 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 section 11.3.

Mode of operation

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

2.6.3 Haemofiltration (HF/HF-online)

Haemofiltration (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.

Mode of operation

During Haemofiltration (HF) the blood is predominantly cleaned by convection on the dialyser membrane.

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

The filter membrane in the dialyser has a higher water permeability than a HD filter. It contains a so-called high-flux membrane (haemofilter) 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 dialyser. 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.

2.6.4 Haemodiafiltration (HDF/HDF-online)

Haemodiafiltration (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 haemodiafiltration (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 dialyser, the procedure is called predilution (upstream) or postdilution (downstream).

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

2.7 Methods of treatment

2.7.1 Double-needle procedure

The double-needle procedure is the standard technique in haemodialysis. Blood is extracted from the patient through the arterial vascular access. The blood pump continuously pumps the blood through the arterial tube system to the dialyser. There, the exchange of metabolic waste products between the blood and the dialysate proceeds through the semipermeable membrane of the dialyser. After that, the blood is taken back through the venous tube system, the bubble catcher and a second vascular access to the vein.

2.7.2 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 tube 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 dialysis
- Single-needle valve as "emergency procedure" for terminating a dialysis in case of problems with a double-needle dialysis.

2.7.3 Single-needle cross-over procedure

The single-needle cross-over procedure with two blood pumps allows a continuous flow through the dialyser with only one patient connection. During a single-needle cross-over procedure, the pressure and pulsation conditions within the dialyser are roughly the same as in a double-needle dialysis.

Mode of operation

Legend

1 Patient connection
2 Arterial tube clamp
3 Arterial chamber
4 Arterial pressure sensor
5 Arterial blood pump
6 Heparin pump
7 Dialyser 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 tube clamp

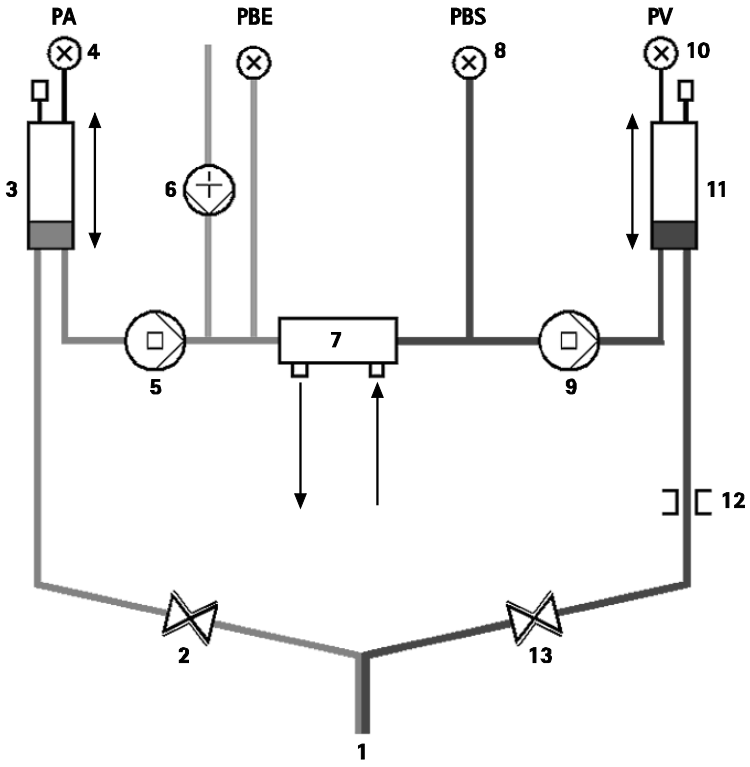


Fig. 2-10 Mode of operation – single-needle cross-over

With the arterial tube clamp open and the venous tube clamp closed, the blood pumps move, at the preset rate, blood from the patient through the dialyser into the venous chamber. The blood level in the venous chamber rises. The pressure in the venous chamber is monitored via the venous pressure sensor. Once the set venous switchover pressure has been reached, the arterial tube clamp closes. Shortly afterwards the venous tube clamp opens.

The blood from the venous chamber flows back to the patient. The blood pumps operate simultanously and pump blood from the arterial chamber through the dialyser into the venous chamber. The pressure in the arterial chamber is monitored via the arterial pressure sensor. Once the set arterial switchover pressure has been reached, the venous tube clamp closes and the arterial tube clamp opens. Blood flows again into the arterial chamber and the process starts again with the withdrawal of blood from the patient.

Advantages compared to conventional single-needle procedures

The 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 dialyser 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 dialyser are low, and clotting can be avoided.

2.7.4 Single-needle valve procedure

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

Mode of operation

Legend

1 Arterial tube clamp (option)
2 Venous tube 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 dialyser
11 Arterial chamber
12 Dialyser

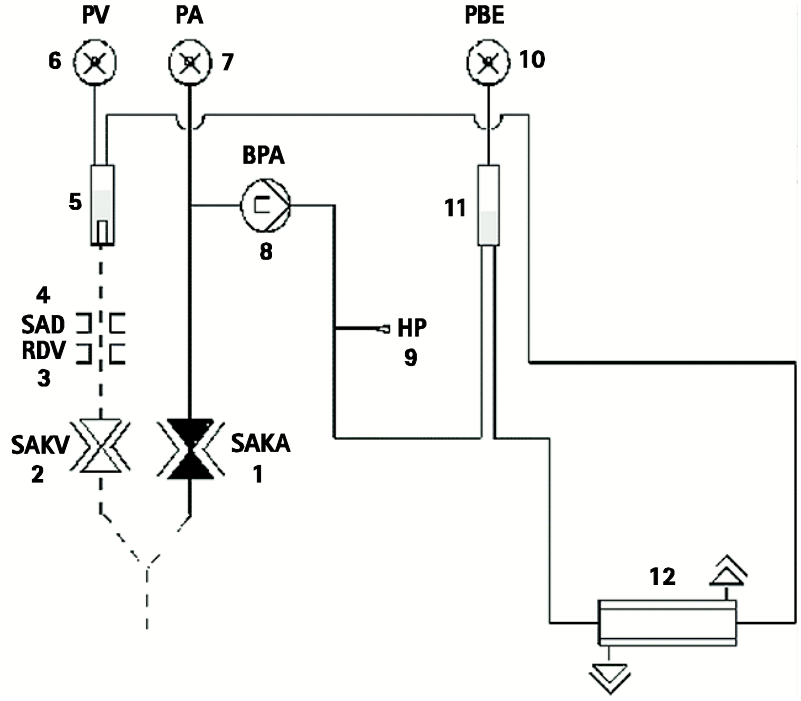


Fig. 2-11 Mode of operation – single-needle valve

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

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

Due to the pressure in the venous chamber, the blood flows through the dialyser back to the patient until the lower switching pressure is reached. Once the lower switching pressure has been reached in the venous chamber, or the preset return flow time has expired, the venous tube clamp closes. Shortly afterwards the arterial tube clamp (if present) opens. The blood pump 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.

2.8 Effectiveness of dialysis (Kt/V)

i If the theoretical calculation of the effectiveness is selected, the option Adimea as described in chapter 10 is not applicable.

The dialysis machine allows optimisation 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 dialyser. Using the patient therapy 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.

! 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:

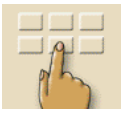
- Sequential phases of profiles
- Haemofiltration
- Infusionbolus, as the actual blood flow does not correspond to the blood pump speed

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.

2.9 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.



➢ Touch this icon.

➢ Touch this icon.
The following screen appears

Legend

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

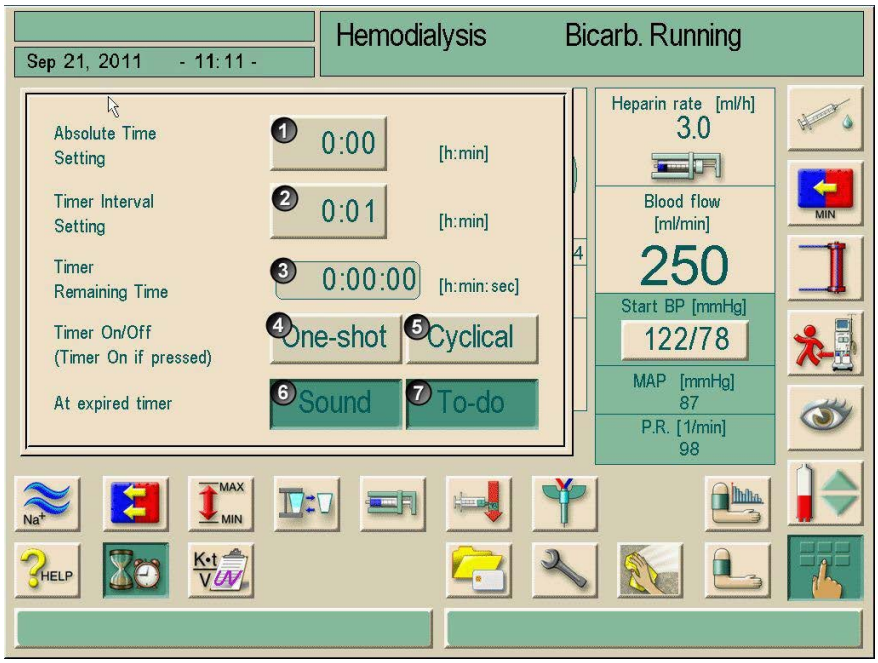


Fig. 2-12 Timer/stop watch function

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 🔔 button to acknowledge sound and message.

---

i 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. 2-13 Date line with timer symbol

Table of contents

3 Installation and commissioning

3.1 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

Goods-in check

➢ Unpack dialysis machine and check for completeness and damage.
➢ In case of damage, call technical service.

3.2 Storage

3.2.1 Storage in originally packed condition

➢ Store the dialysis machine in ambient conditions as specified in section 15.2.

3.2.2 Interim storage of devices ready for operation

➢ Disinfect the dialysis machine.
➢ Store the dialysis machine in ambient conditions as specified in section 15.2.
➢ Disinfect Dialog+ HDF-online at least once a week.

3.2.3 Decommissioning

➢ Disinfect the dialysis machine.
➢ Instruct technical service to empty the dialysis machine.
➢ Store the dialysis machine in ambient conditions as specified in section 15.2.

3.3 Transportation

3.3.1 Wheeling

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°.**

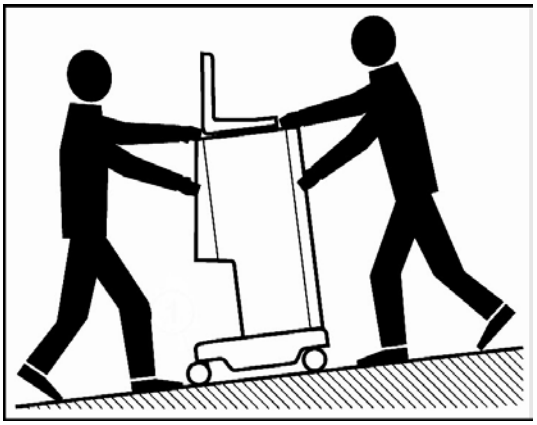


Fig. 3-1 Transport on stairs and slopes (2 persons)

- Release the brakes from all casters.
- Wheel the dialysis machine.
- Reapply the brakes to all casters.

3.3.2 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. 3-2 Holding points for carrying the dialysis machine

CAUTION

Danger 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.**

- Use a belt to secure monitor to infusion pole.
- Release caster brakes.
- Tilt the dialysis machine.
- Put down the dialysis machine.
- Apply caster brakes.

3.4 Installation site

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

> **!** **Ambient conditions**
> Observe information about ambient conditions, see section 15.2.

3.4.1 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 equalisation to the dialysis machine. Regulations and deviations specific to the individual country must also be observed. For further information, ask technical service.

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.

3.4.2 Protection against water damage

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

3.4.3 Potentially explosive areas

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

3.5 Water supply

3.5.1 Quality of water and dialysate

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 of between 5 and 7

Water and dialysate 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

3.5.2 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 haemodialysis 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!

3.6 Initial commissioning

Initial commissioning should be carried out by the responsible technical service.

3.7 Setting date and time

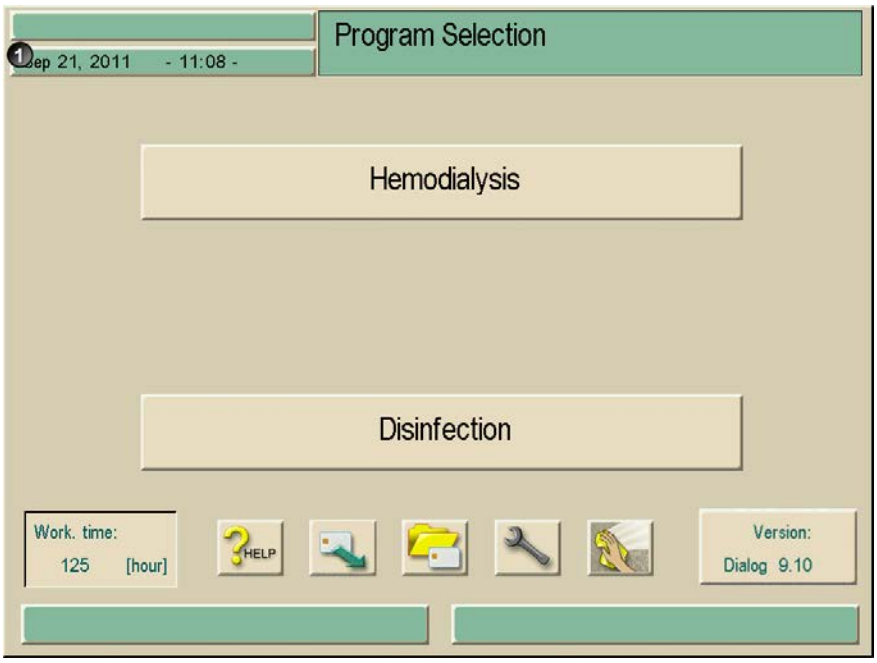
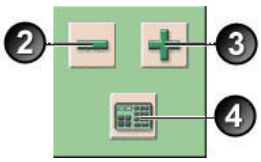


Fig. 3-3 Date and time



Setting date

➢ Touch field showing date and time **1**.

The field containing icons **2**, **3** and **4** appears.

There are two setting options:

➢ To increase or decrease the date, change date with icons **2** and **3**.

➢ To enter the date using the keypad, touch icon **4**.

The numeric keypad appears on the screen.

➢ Enter date using keypad and confirm by selecting **OK**.

Setting time

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

There are two setting options.

➢ To increase or decrease time by minutes, change date with icons **2** and **3**.

➢ To enter the time using the keypad, touch icon **4**.

The numeric keypad appears on the screen.

➢ Enter date using keypad and confirm by selecting **OK**.

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

The field containing **2**, **3** and **4** disappears.

The set date and time are displayed.

3.8 Switching on and off

- 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

➢ 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:

➢ Press mains switch again.

An alarm message is displayed on the screen: “System recovered”, for interruptions less than 15 minutes, and the therapy continues.

➢ 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:

➢ Press mains switch again.

The disinfection process is continued.

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

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4 Preparing for haemodialysis

WARNING

Safety air detector (SAD) not active! Danger 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)!**

Haemodialysis 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, dialyser, canisters, 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.**

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.

4.1 Calling up haemodialysis

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

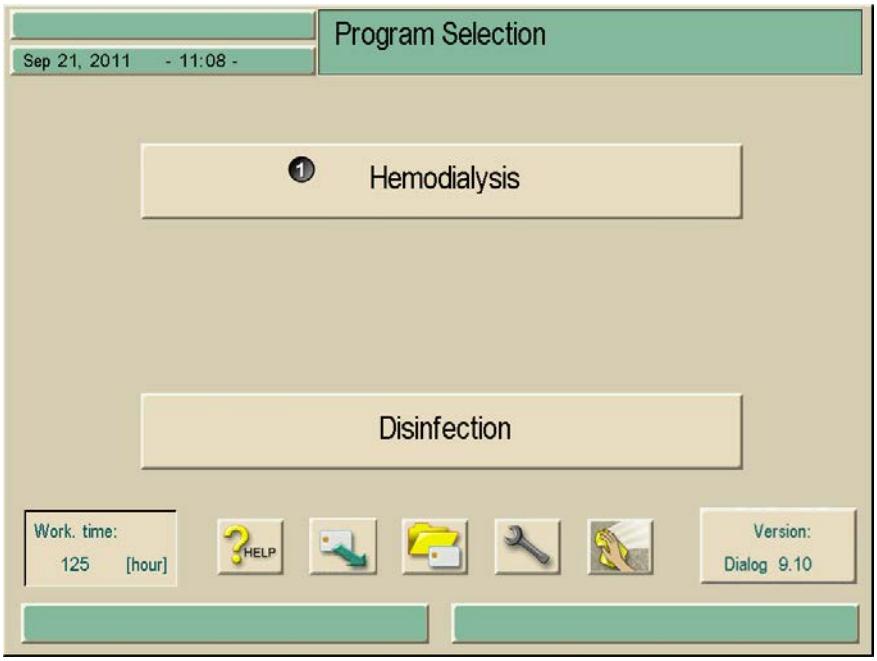


Fig. 4-1 "Haemodialysis" main screen

➢ Touch field **1**.

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

4.2 Automatic test

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

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

i 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 dialyser after the pressure test on the blood side.

Depending on the used type of dialyser, this may take up to two minutes.

4.2.1 Operation during automatic test

Legend

1 Status field

2 Operating field

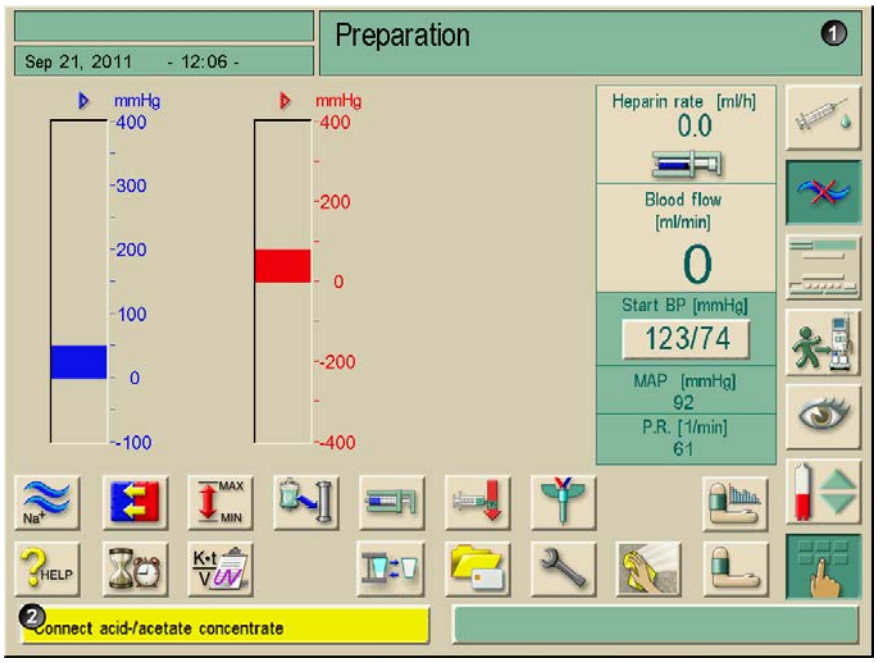


Fig. 4–2 First preparation screen "Haemodialysis"

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.

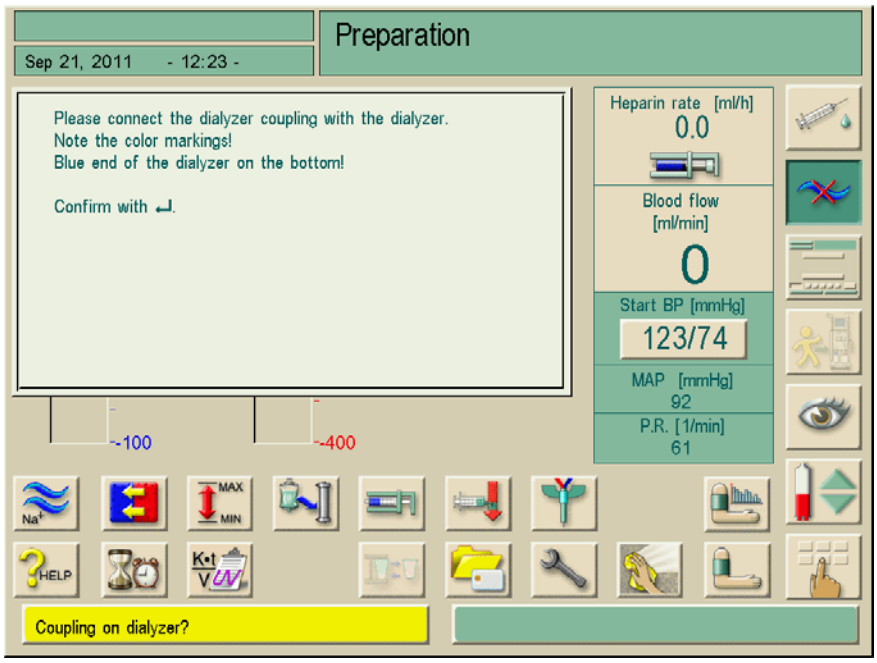
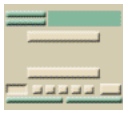


Fig. 4–3 Information window during automatic test

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.

4.2.2 Terminating the automatic test sequence



➢ Touch icon.

The automatic test sequence is terminated.

The options "Return to therapy selection" and "Repeat blood-side tests" are displayed.

➢ Touch the appropriate field.

4.2.3 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.

4.3 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 dialyser 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

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

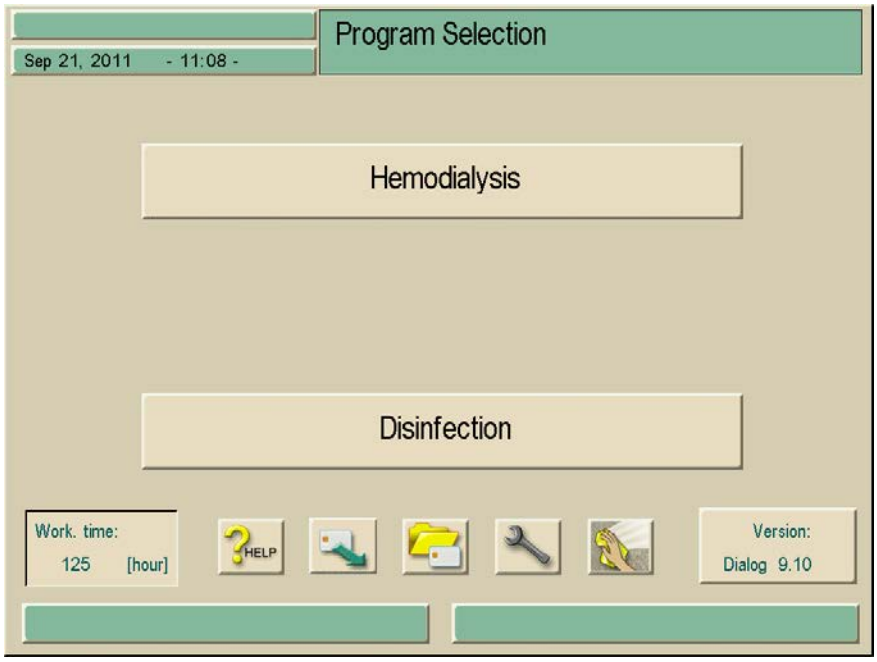


Fig. 4–4 "Haemodialysis" main screen

➢ Touch icon at main screen.
The following screen is displayed

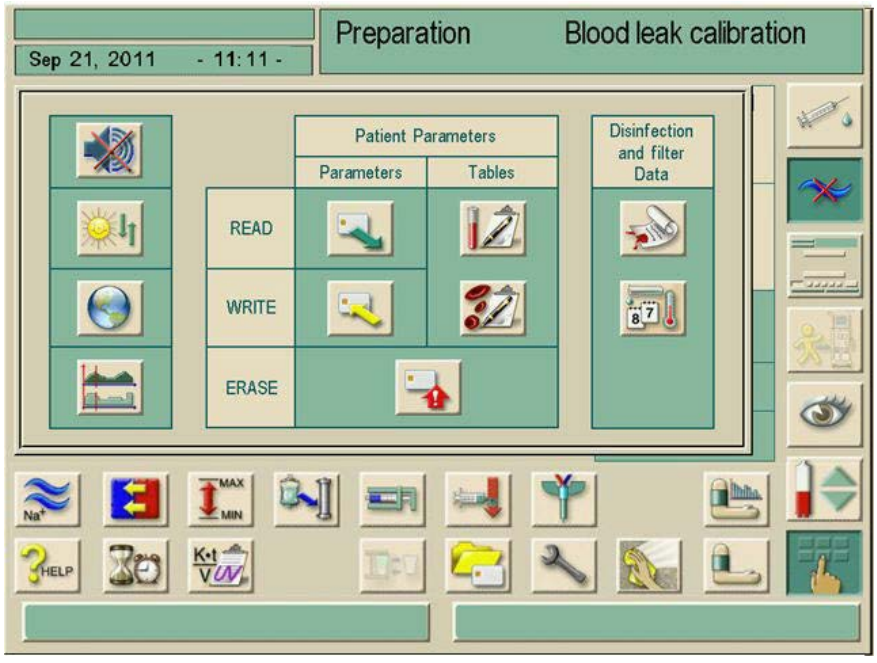


Fig. 4–5 Screen for suppression of acoustic signals

➢ Touch icon

If the function is not active (icon background not coloured 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. 4-6 Date line with suppressed acoustic signal

Now the icon is shown as active (green coloured 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 grey). Changing into the next therapy the function automatically set resets to the TSM pre-adjustment.

4.4 Connecting the 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 dialysate!

- **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:

- ➢ Insert red concentrate rod into the canister containing acidic bicarbonate concentrate, e.g. SW 325A.
- ➢ 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.

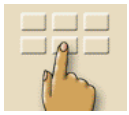
For acetate dialysis:

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

  The dialysis machine continues the automatic test sequence.

4.5 Setting the rinsing parameters

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



➢ Touch icons.

The rinsing parameters are displayed.

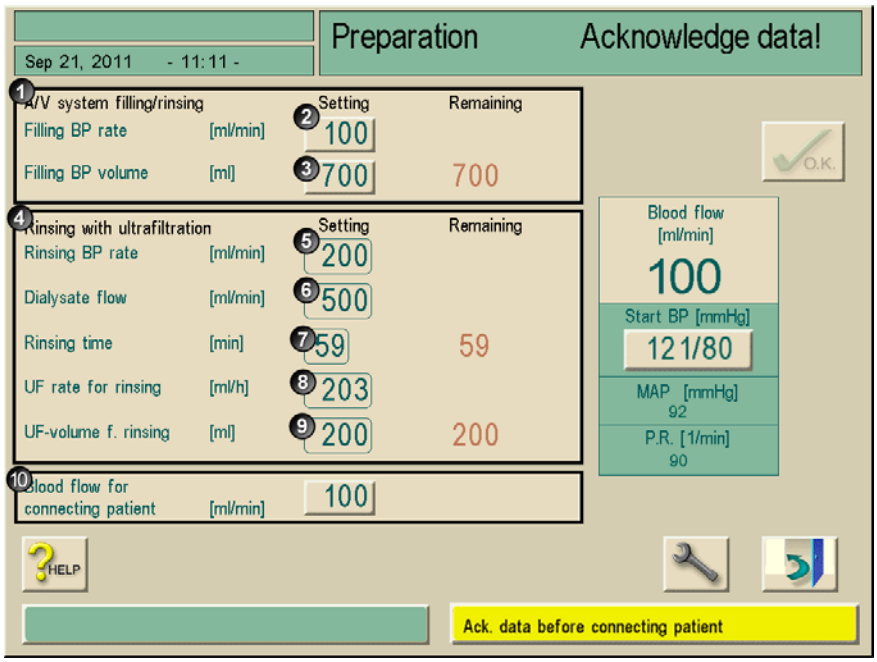


Fig. 4-7 "Rinsing parameters" screen

➢ 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 dialyser 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
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 f. rinsing	0 – 2950 ml when rinsing with a physiological saline solution	–
10	Blood flow for connecting patient	50 – 600 ml/min	–

➢ 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.

4.6 Inserting and rinsing the tube system

4.6.1 Inserting the tube system

The blood pump tube segment in the AV system must have the dimensions 8 x 12 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 tube system and dialysis machine!

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

WARNING

Risk to patient due to haemolysis or blood loss when using a faulty blood tubing system!

- **Check to ensure that the tube 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 infection as a result of contamination of the hydrophobic pressure sensor filter on the tube 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 tubing system per use of a rinsing bucket.

- **Ensure hygienic handling of the blood lines.**

Legend

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 dialyser (optional)
9 Arterial chamber
10 Dialyser

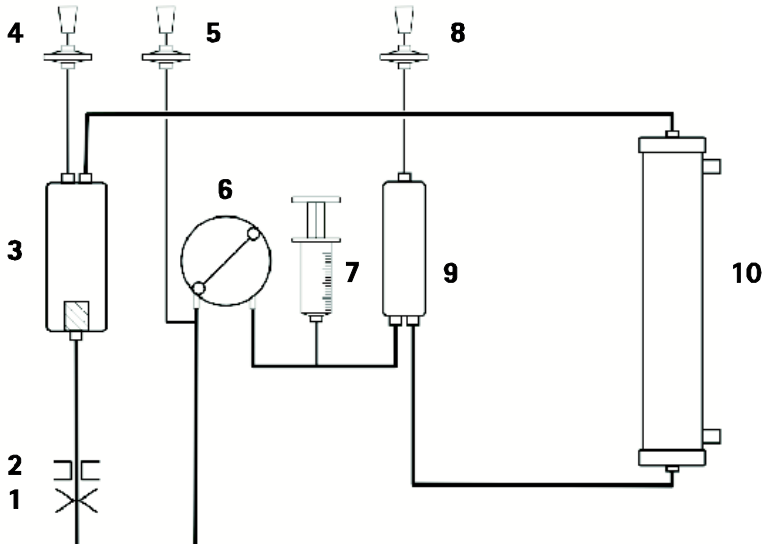


Fig. 4-8 Schematic view of extracorporeal circulation system used in haemodialysis

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

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

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

CAUTION

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

- **Check to ensure that the tube system and pump segments are not being damaged at the insertion.**
- **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 tube system has been damaged through the insertion, replace it by a new one.**

- Close lid of (left) blood pump.

i

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.

- Connect pressure sensor connector (if present) to PBE sensor connection.
- Connect arterial and venous tube system to dialyser observing the colour-coding. Do not yet remove the stops (if existent) on the lateral Hansen connectors.
- 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.
- Insert venous bubble catcher into fixing.
- Open lid of air detector.
- Insert tube into air detector and close lid.
- Connect venous patient connection to the empty bag.
- Insert blood tube system into fixings.

CAUTION

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

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

i

If a tube 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.

WARNING

Risk of contamination of the priming bag if administration set is connected and bloodside pressure test failure because of wet transducer protector membrane!

- **Set level in the drip chamber of the administration set.**
- **If there is no air inside the drip chamber, change priming bag because of possible contamination.**
- **Change priming bag in case of bloodside pressure test failure.**

4.6.2 Rinsing and testing the tube system

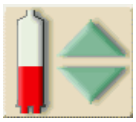
- Open the clamp in the line to the physiological saline bag.
- Start blood pump by pressing the + button on the monitor.

The tube system will fill with physiological saline solution. The blood side of the dialysis circuit is rinsed and automatically tested for any leaks.

4.6.3 Level regulation (if present)

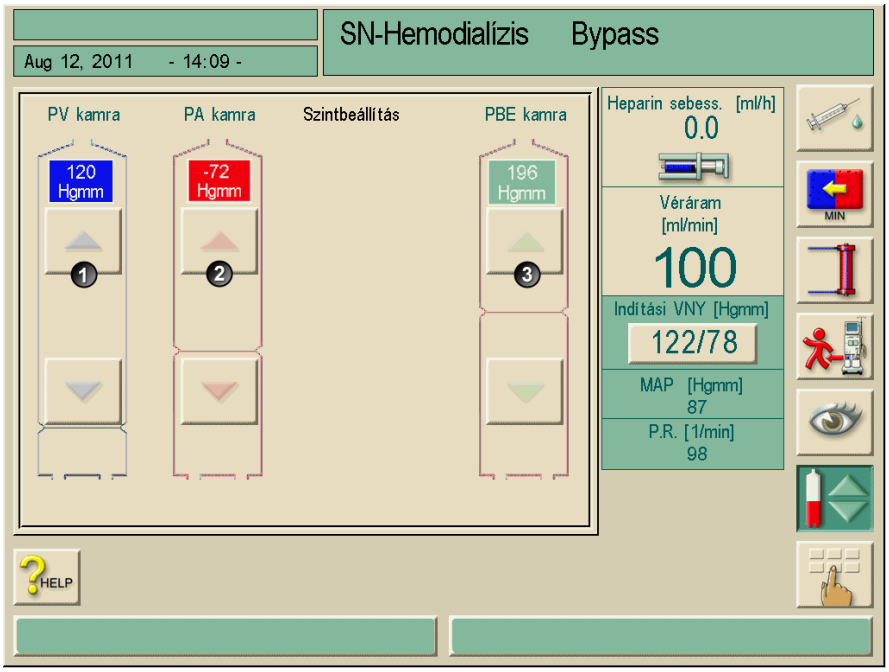
The level regulation system allows the user to set saline levels in the blood line chambers for preparation by screen touch.

- 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.



- Touch icon

The level window opens.



Legend

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

Fig. 4-9 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).

i 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

- Touch icon gently with one touch
- Observe level
- Touch again for the correct setting if necessary

Level decreasing

- Touch icon gently with one touch
- Observe level
- Touch again for the correct setting if necessary

- To leave the level regulation function, touch icon again

4.7 Preparing the heparin pump

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

4.7.1 Inserting the heparin syringe

Legend

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

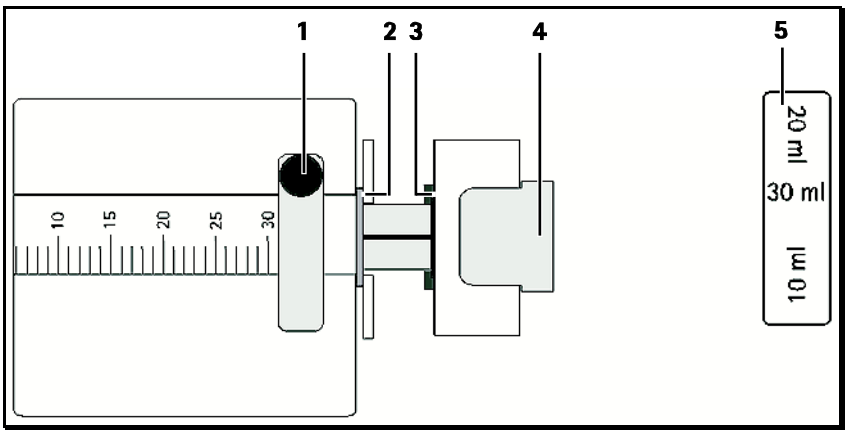


Fig. 4-10 Heparin syringe

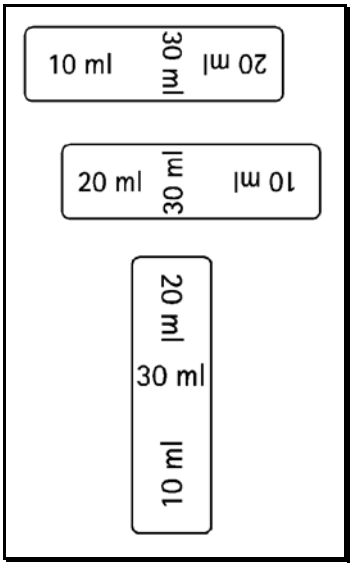


Fig. 4-11 Position of the syringe stop depending on syringe size

- Set syringe stop **5** in such a way that the syringe size can be read.
- Release unlocking lever **4** and pull out drive mechanism.
- Lift and turn syringe bracket **1**.
- 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.

- Close syringe bracket.

4.7.2 Venting the heparin line

- Before inserting the syringe, manually vent heparin line.

or

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

4.8 Setting the treatment parameters

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

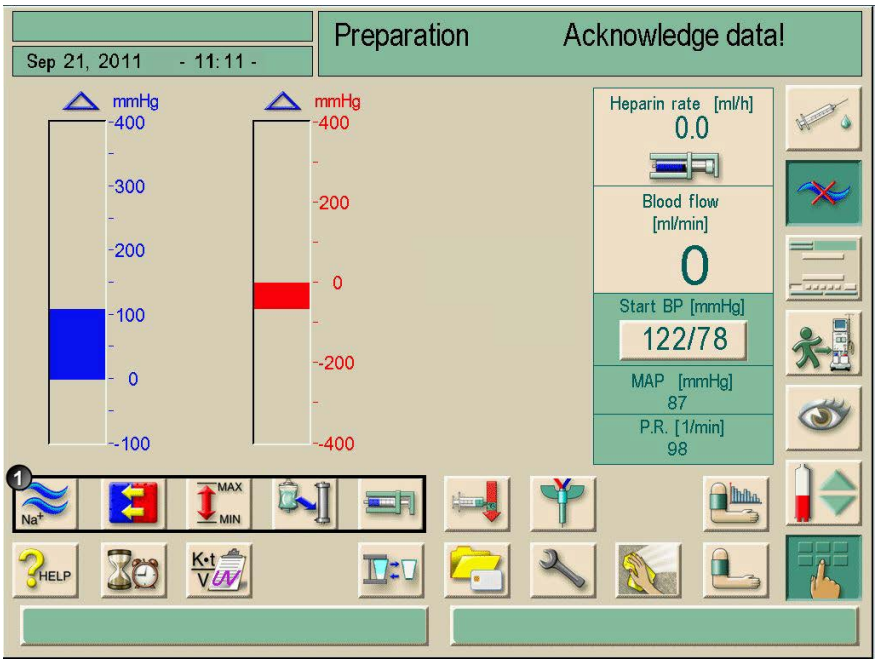
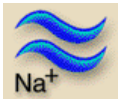
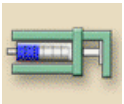


Fig. 4-12 Preparation window "Parameters"

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

Icon	Parameter group	Reference
	Dialysate parameters	Page 4-19
	Ultrafiltration parameters	Page 4-21
	Pressure limit settings	Page 4-24
	Heparinisation data	Page 4-26

4.8.1 Setting the dialysate parameters

➢ Touch icon in preparation window.
The dialysate parameters are displayed.

Fig. 4-13 "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 haemodialysis concentrate and an alkaline bicarbonate haemodialysis 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	–
6	Dialysate Flow	300–800 ml/min continuously adjustable	–
7	Profiles	–	Alternatively, profiles can be selected for the respective parameter, see section 11.2.

The actual temperature at the dialyser 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 10.

4.8.2 Monitoring the dialysate

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

- ➢ Once the conductivity of the dialysate has stabilised (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.
- ➢ Analyse 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 machine due to calcium depositions at pH value >7.5 during bicarbonate dialysis!

➢ Observe correct setting of pH value.

4.8.3 Setting the ultrafiltration parameters

- ➢ Touch icon in preparation window.
  The ultrafiltration parameters will be displayed.

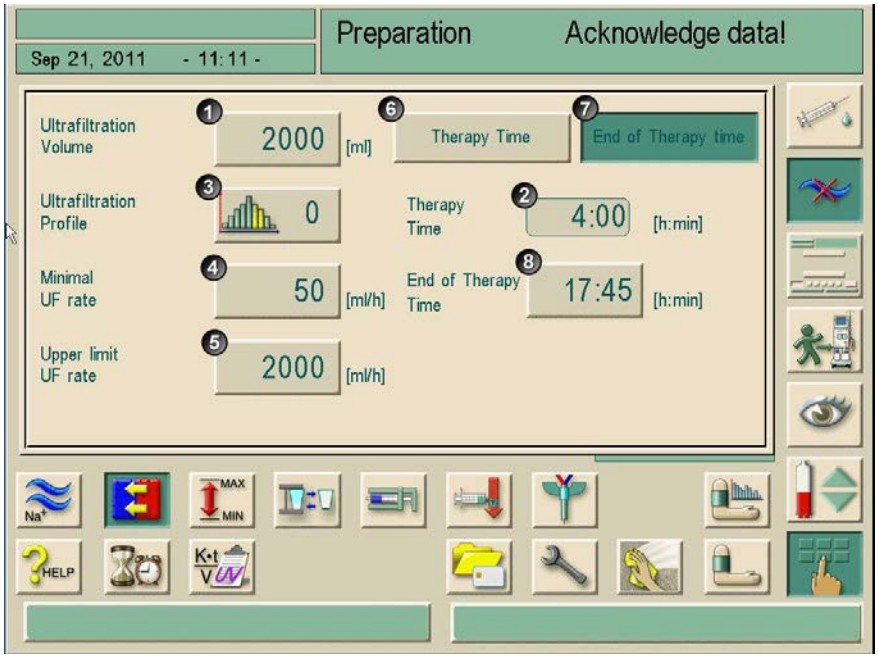


Fig. 4-14 "Ultrafiltration parameters" screen

➢ 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
3	Ultra filtration Profile	-	For selecting an ultrafiltration profile or choosing sequential therapy, see section 11.3
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

➢ Touch the buttons 6 and 2 in figure 4-14.
Set value by + / - or use the keypad to enter the value.

Set the absolute end of therapy time

➢ Touch the buttons 7 and 8 in figure 4-14.

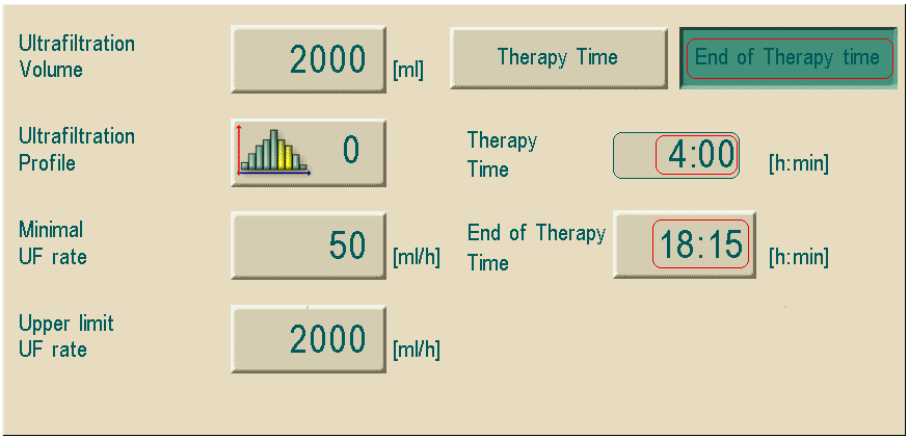


Fig. 4–15 Ultrafiltration parameters

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. 4-16 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.

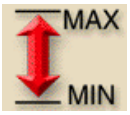
!	The set end of therapy time will not be extended by Bypass phases.

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

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

!	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 ↵.

4.8.4 Setting the pressure limits



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

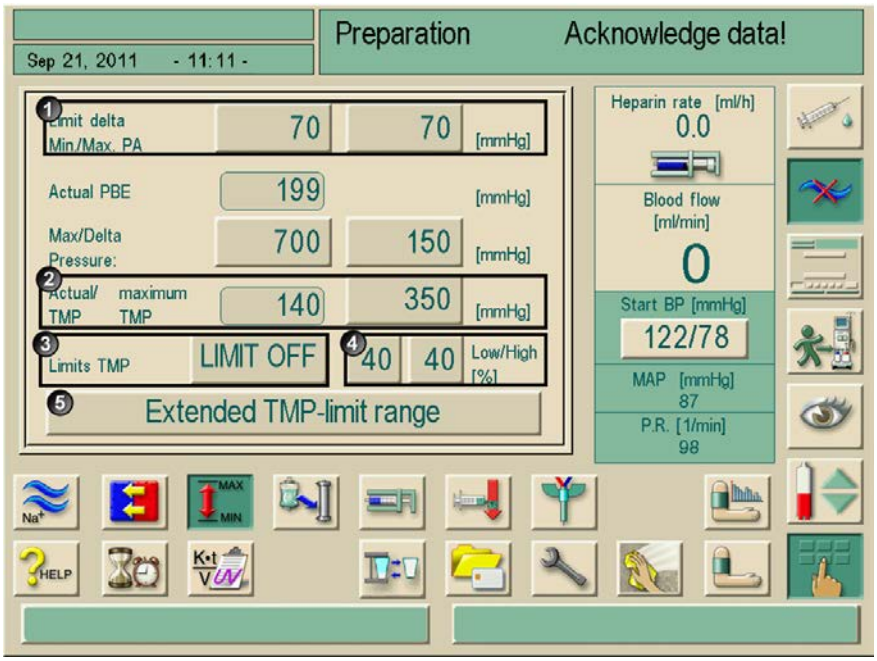


Fig. 4–17 "Pressure limits" screen

➢ Set pressure limits according to the table below.

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 dialyser manufacturer
3	Limits TMP	ON/OFF	Monitoring the TMP at the dialyser
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

Danger 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 dialyser is controlled by an automatically set limits window.

The size of the limits window is entered as a percentage of the actual value (see Fig. 4-17). The limits window is, therefore, independent of the dialyser in use.

When the limits window is switched off, the control of the dialyser-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 dialysers (see Fig. 4-17). This function has to be enabled in TSM.

➢ 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

Danger 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.**

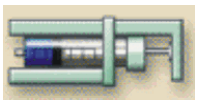
➢ **In case of technical defect, call technical service.**

i

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).

4.8.5 Setting the heparin parameters



➢ Touch icon in preparation window.
The heparin parameters are displayed.

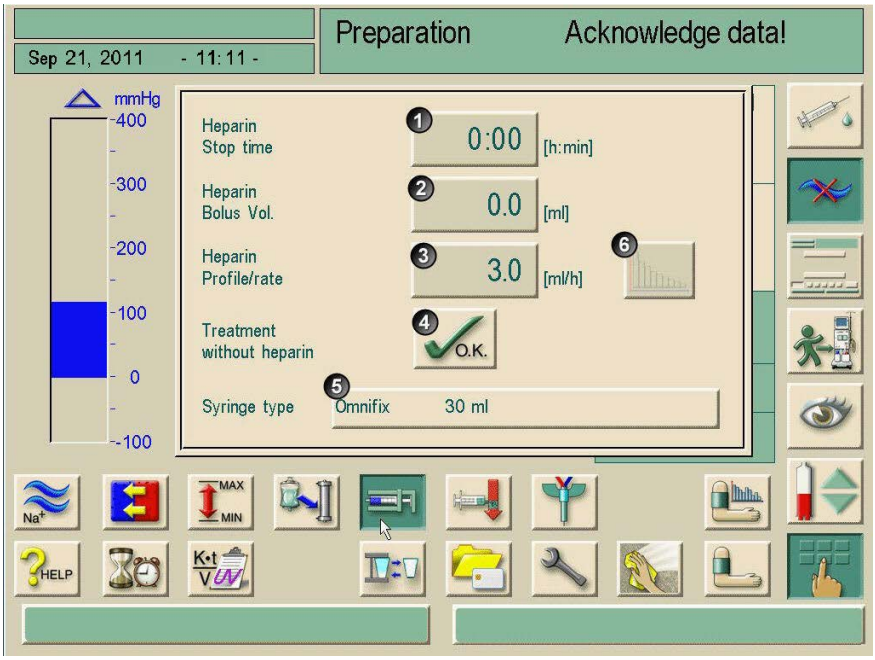


Fig. 4-18 "Heparin parameters" screen

➢ 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.**

CAUTION

Blood clotting in the extracorporeal system!

- **Ensure that the heparin pump is switched on after entering a delivery rate.**

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.

4.9 Rinsing the dialyser

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

- Take dialyser tubes from rinsing bridge and connect to dialyser. Observe colour-coding.
- Connect the dialyser inlet coupling (blue) to the Luer Lock connection of the venous line.
- Connect the dialyser outlet coupling (red) to the Luer Lock connection of the arterial line.
- Turn dialyser so that the blue connection is facing downward.
- Confirm correct connection of dialyser by pressing the Enter key ↵ on the monitor.

The dialyser is filled and rinsed.

- Adjust level as follows:

– Fill chamber in front of the dialyser 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.

- Ensure that the blood tube system and the dialyser are filled and rinsed with physiological saline solution.
- Ensure that all levels in the chambers have been set correctly.
- Confirm correct settings by pressing Enter key ↵ on the monitor.

The dialysis machine is testing the blood tube system.

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

4.10 Stand-by mode

The dialysis machine features a stand-by 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 stand-by mode!

Infection risk to the patient!

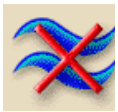
- **Do not run the dialysis machine in stand-by mode over prolonged periods.**
- **The recommended duration of stand-by mode depends on the water quality and the environmental conditions (according to the hygiene plan of the dialysis centre).**

4.10.1 Activating the stand-by mode

Depending on the service program setting performed by technical service, there are the following ways in which the stand-by 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 stand-by mode



➢ Touch icon.
The dialysis machine is in stand-by mode.

4.10.2 Switching off the stand-by mode

The max. duration of the stand-by 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 stand-by mode:

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

Manual switch-off of stand-by mode

➢ Touch icon again.
The machine is in bypass mode. The dialysate is circulated without passing through the dialyser.

4.11 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 device if necessary.

Already entered treatment parameters will remain unchanged.

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

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

4.12 Changing the bicarbonate cartridge during preparation

It is possible to exchange a bic cartridge during preparation. (see also chapter 10.4)

Table of contents

5 Initiating haemodialysis

5.1 Checking the 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.

➢ 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.

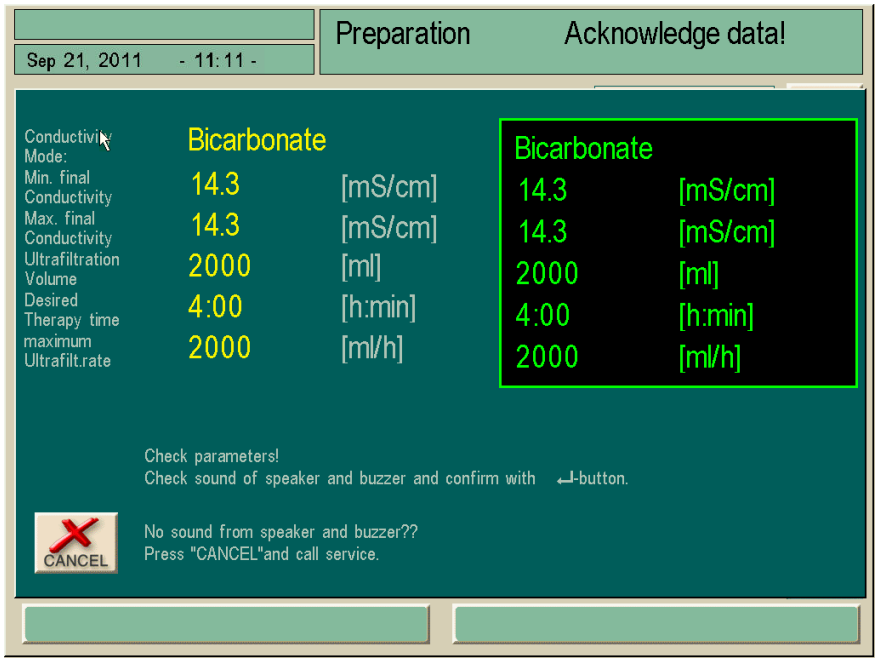


Fig. 5-1 "Patient data" screen

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.

➢ Call technical service.

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

The treatment screen appears.

5.2 Connecting the patient and starting haemodialysis

WARNING

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

➢ **Connect electrical ground on the dialysis machine, see section 1.5.2.**

5

!

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.

Legend

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

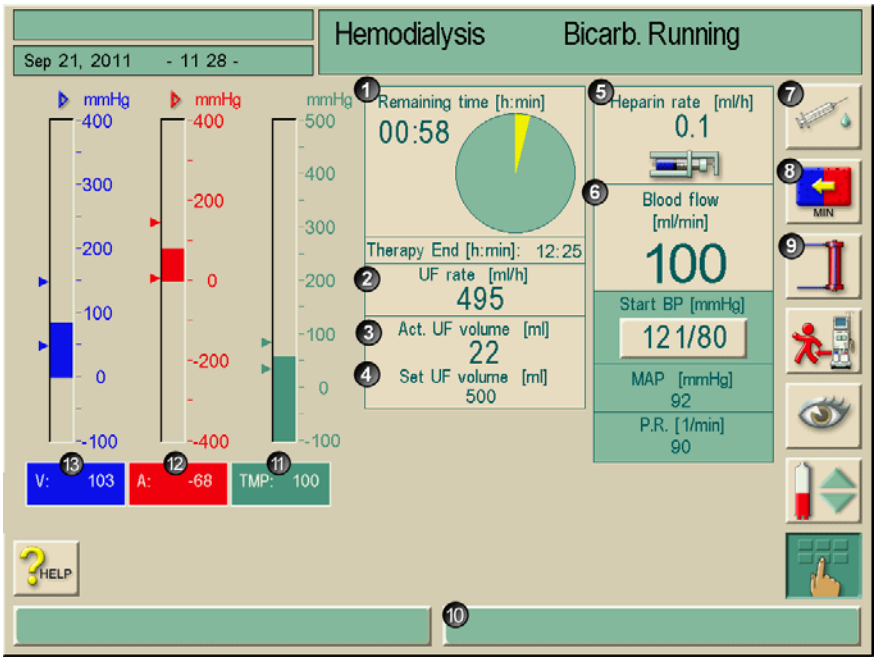


Fig. 5-2 "Haemodialysis" treatment screen

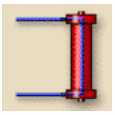
i

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

➢ Connect patient arterially.
➢ Start blood pump by pressing **START/STOP** button on monitor.
➢ Set blood flow
➢ Fill blood tube system with blood.

The blood pump stops automatically if blood is detected on the red sensor in the safety air detector (SAD).

- ➢ Connect patient venously.
- ➢ Start blood pump.
- ➢ Touch icon.



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

The signal lamps on the monitor switch to green.

WARNING

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

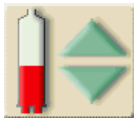
➢ Ensure that the blood flow is high enough.

➢ Ensure that the cross-section of the cannula is big enough.

5.2.1 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 is obligated to check for correct setting of the levels in the chambers.



➢ Touch icon

The level window opens.

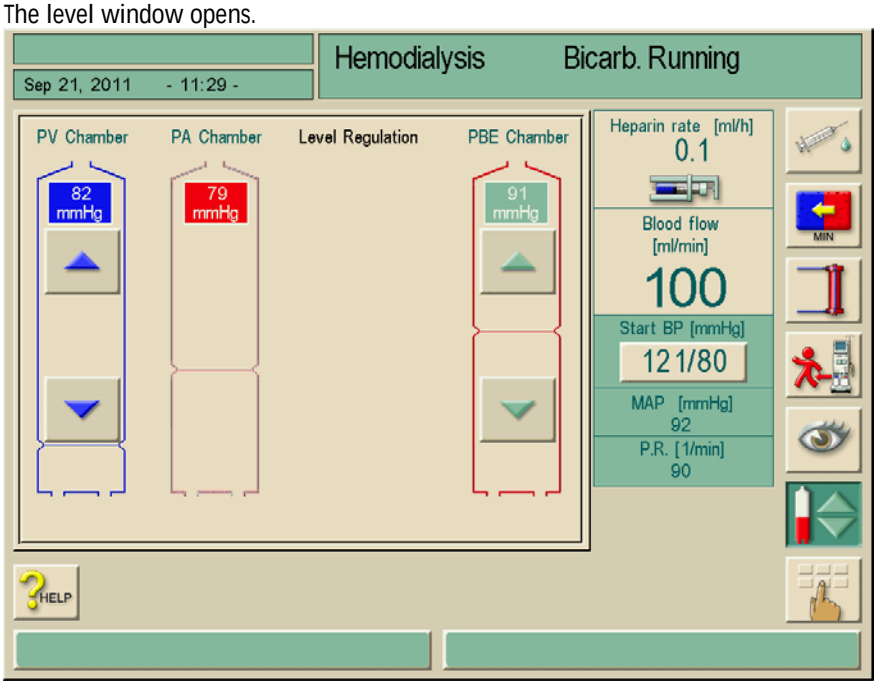


Fig. 5-3 Level regulation screen

Level increasing

- Touch icon gently with one touch
- Observe level
- Touch again for the correct setting if necessary

Level decreasing

- Touch icon gently with one touch
- Observe level
- Touch again for the correct setting if necessary

- To leave the level regulation function, touch icon again

i

- 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 transducer protector on the tube system!

- **Replace the machine-side transducer protector 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 reduced dialysis effectivity!

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

5.3 During haemodialysis

WARNING

Risk to patient due to blood loss if cannulas get disconnected or slip out!

Standard monitoring function of the dialysis machine cannot safely detect that such a situation has arisen!

- **Ensure that the access to the patient always remains fully visible during therapy.**
- **Ensure that cannulas are adequately fixed.**
- **Regularly check patient access.**
- **Venous lower limit should preferably be > 0 mmHg.**

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.**

5.3.1 Monitoring the blood-side pressure limits

Venous return flow pressure (PV)

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 width and thresholds of the limits window are set in the service program by the 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 haematocrit 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.

- 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.

i When setting the limits window ensure that the upper limit is as negative as possible.

Blood-side entry pressure at the dialyser (PBE)

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

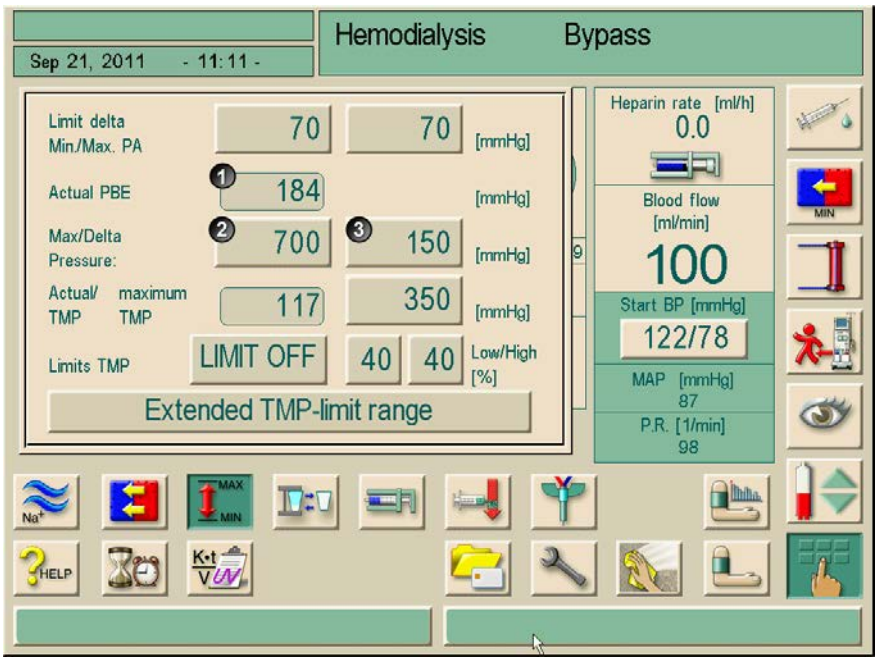


Fig. 5-4 "Alarm limits" screen during therapy

Additionally to the maximum PBE value (**2**), a so-called Delta (**3**) could be adjusted. Delta represents a limiting value which lies above the average actual value of the PBE. It serves as monitoring the accumulation of a secondary membrane. The average actual value of the PBE is determined by the Dialog+ within the first five minutes after starting the therapy and stored as an reference value in the SW. Changes of pressure by variation of blood flow are automatically considered (e. g.: Average actual value of PBE at 155 mmHg, plus Delta 150 mmHg, the outcome of this is a PBE limiting value of 305 mmHg). Achieving this limiting value a yellow warning text appears.

Exeeding 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.

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

5.3.2 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.

i 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

➢ 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

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

UF compensation

Technical service can determine in the service program how treatment is to be continued after a minimum UF rate phase.

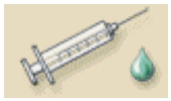
UF compensation YES

After temporary treatment with minimum UF rate, the preselected UF volume will be nearly reached 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 reached in the preset UF time.

5.3.3 Heparin bolus



➢ Touch icon.

A safety message will be displayed.

➢ Confirm heparin bolus by pressing Enter key ↵ on monitor.

The heparin bolus preset in the heparin parameters is activated.

WARNING

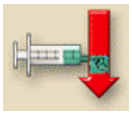
Risk of blood loss due to blood clotting in case of insufficient anticoagulation!

➢ 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 heparinised.

5.3.4 Arterial bolus

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



➢ Touch icon.

The set-up window for the arterial bolus is displayed.

➢ Enter bolus volume.

Legend

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

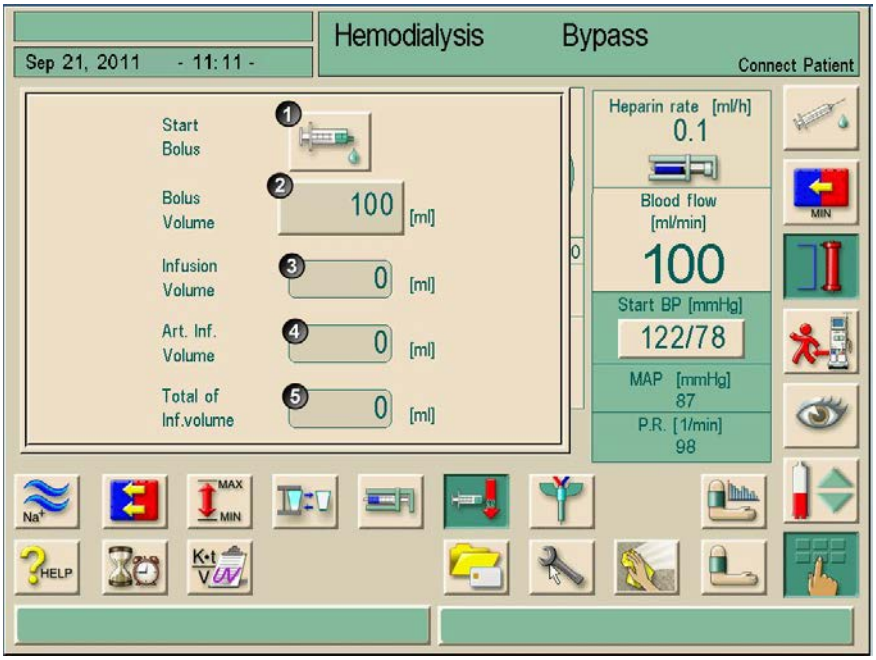


Fig. 5-5 Set-up window for arterial bolus

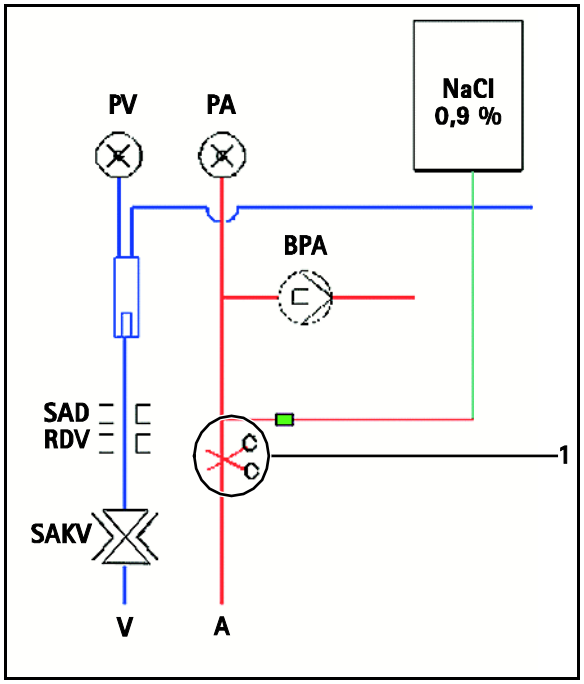
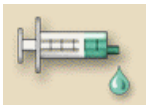


Fig. 5-6 Clamping off the arterial patient inlet



- Touch icon.
  The blood pump stops automatically and a safety message appears on the screen.
- Connect bag with physiological saline solution to arterial infusion connector.
- Clamp off arterial bolus **1** if necessary.
- Confirm arterial bolus by pressing the Enter key ↵ on 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**.

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

WARNING

Risk of sodium imbalance and patient overload!

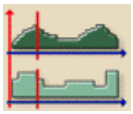
- **In case of a blood pump failure during an arterial bolus or reinfusion, complete bolus manually.**
- **In case of a prematurely closed venous clamp, complete arterial bolus via hydrostatic infusion.**

!

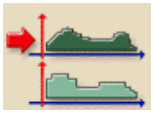
If the arterial bolus was terminated by an alarm, the entire bolus quantity will be infused upon reactivation of the arterial bolus.

5.3.5 Graphical representation of treatment parameters (trend)

➢ Touch icon.
A screen with the graphical representation icon appears.



➢ Touch icon.



➢ Touch icon
The following screen is displayed.

Legend

1 Trend group
2 Activate pre-adjustment from TSM
3 Edit a trend group
4 Safe and leave window
5 Safe not and leave window

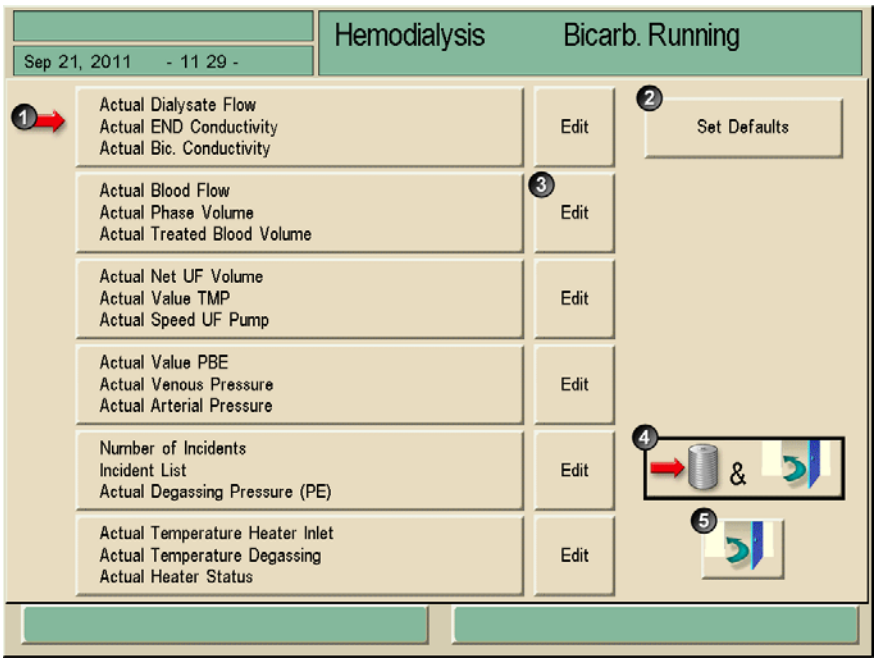


Fig. 5-7 Trend groups

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

How to edit individual trend groups is described in chapter 11.10.

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

Legend

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

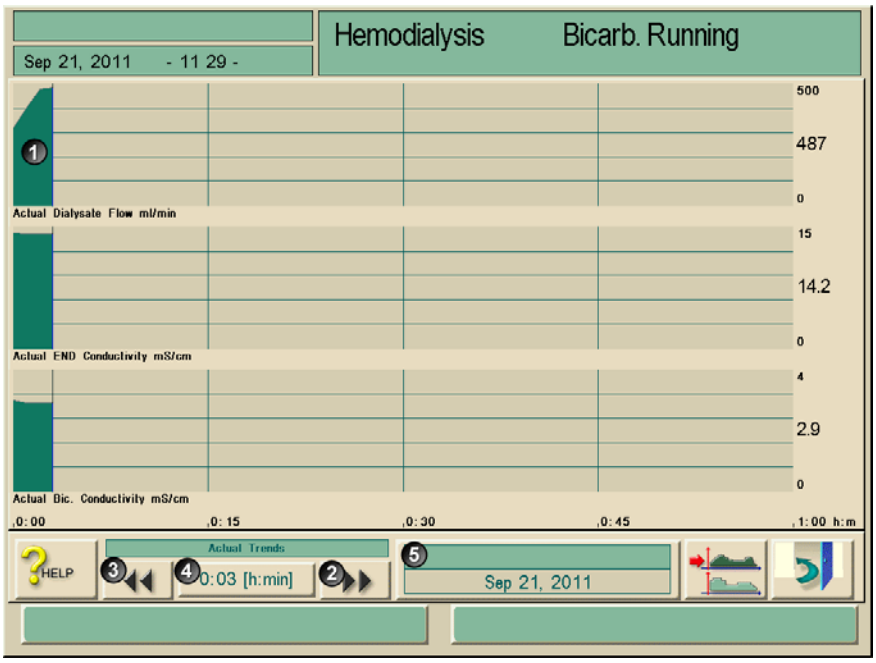


Fig. 5-8 Graphic representation of treatment parameters

Treatment parameters at a defined point in time

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

1st option:

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

2nd option:

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

Call history of trend data

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

➢ Touch field **5**.

The following screen is displayed.

Legend

1 Actual therapy

2 All therapies, max. 20

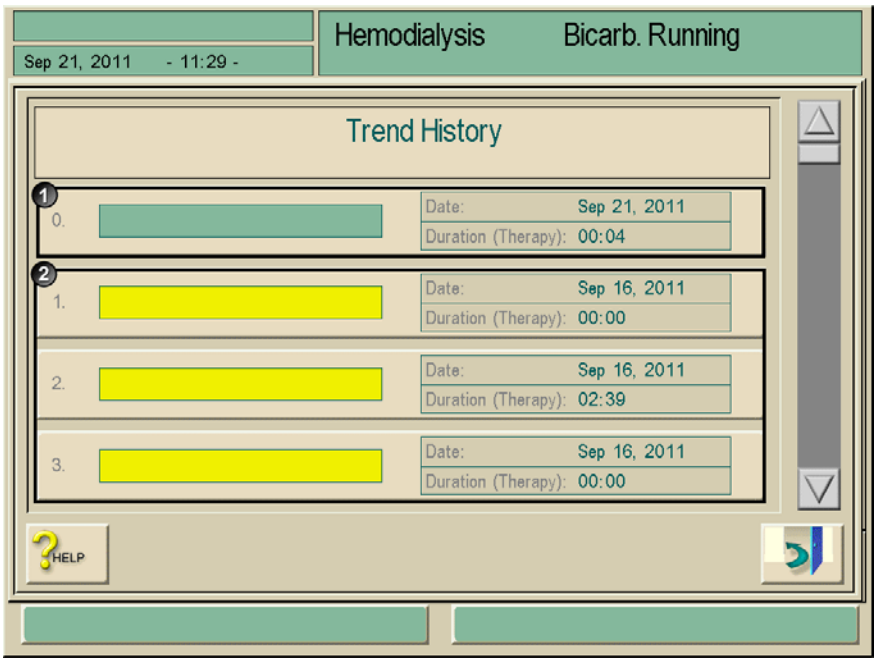


Fig. 5-9 "Trend-History" screen

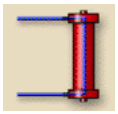
➢ To open the graphic representation touch respective field.

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

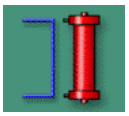
Patient names only appear if they are manually entered before therapy or if a therapy card is used.

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

5.3.6 Interrupting the haemodialysis (bypass)



➢ Touch icon.
The dialysis machine switches to the bypass mode. The haemodialysis is interrupted. The signal lamps on the monitor switch to yellow. The icon changes its display.



➢ Touch icon again.
The bypass mode is terminated, the treatment is continued.

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

5.4 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 adjusted treatment time is shown instead of the remaining time with a minus symbol in front. The graphics will be displayed in red.

5.4.1 Terminating treatment

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

5.4.2 Continuing treatment

➢ Touch icon.
After entering new treatment parameters, the haemodialysis 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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6 End of haemodialysis therapy

6.1 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:

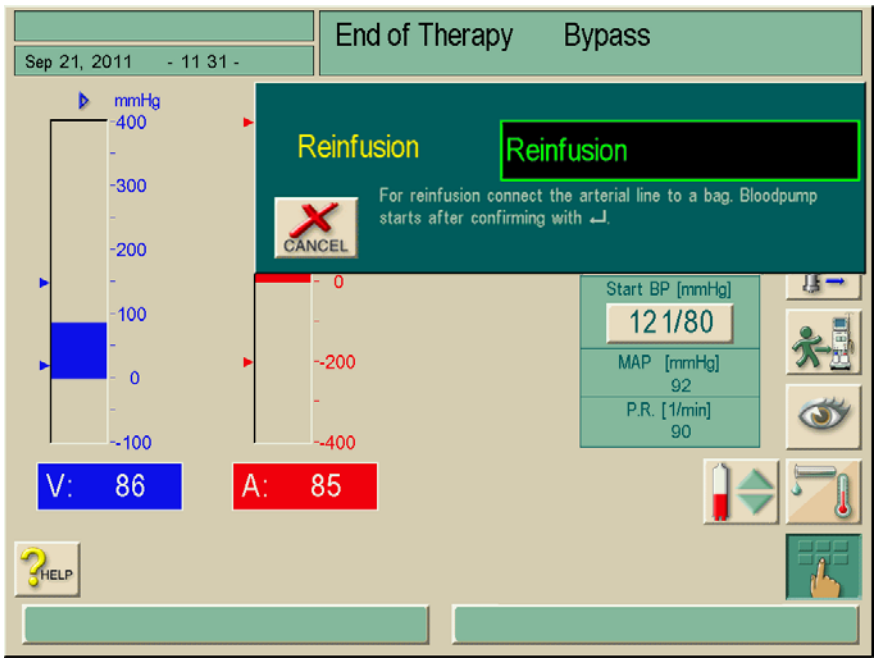


Fig. 6-1 "Confirm reinfusion" screen

WARNING

Danger of air embolism in case of reinfusion with air!

➢ **Only carry out reinfusion with fluids.**

➢ Remove arterial connection from patient.
➢ Connect arterial line to infusion bag containing physiological saline solution.
➢ Confirm arterial disconnection by pressing the Enter key ↵ on monitor.

The blood pump starts the reinfusion. The reinfusion screen appears.

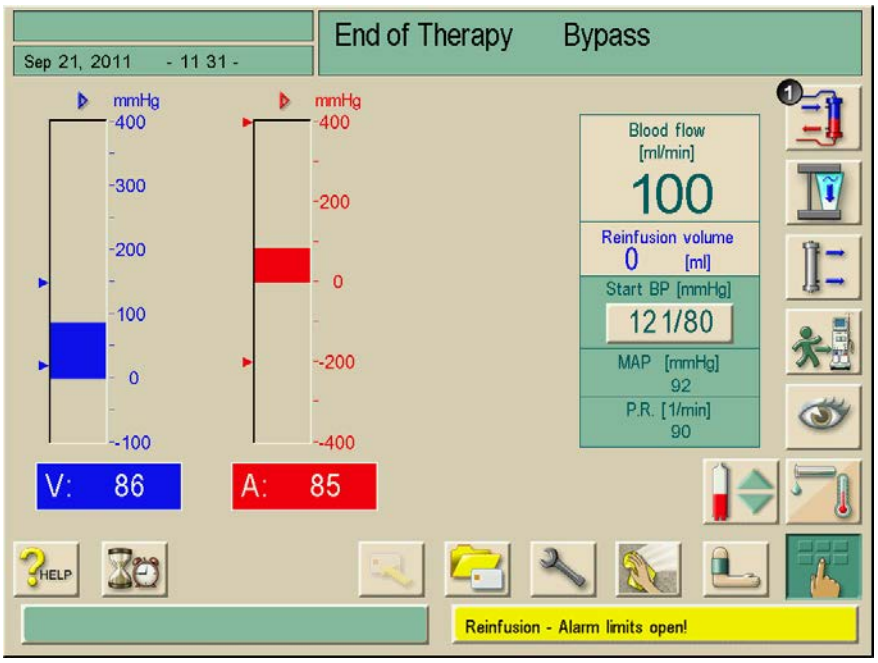


Fig. 6-2 "Reinfusion" screen

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

➢ To continue reinfusion, start blood pump by pressing **START/STOP** button on 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.

➢ To continue the reinfusion process, confirm by pressing the Enter key ↵ on monitor.

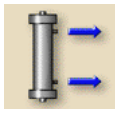
The dialysis machine will carry out reinfusion of another 400 ml, or reinfusion for 5 minutes.

➢ Disconnect venous patient connection.

i The screen "Confirm reinfusion" (Fig. 6-1) appears only if configured accordingly in the service program. Otherwise, reinfusion must be called up by pressing icon **1** (Fig. 6-2).

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

6.2 Emptying the dialyser



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

The dialysis machine must be disinfected, see chapter 7.

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

6.3 Emptying the cartridge after dialysis

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

Emptying the cartridge before the dialyser is emptied

➢ Leave both couplings on the dialyser.
➢ Touch icon and confirm by pressing the Enter key ↵ on the monitor.

The cartridge is emptied automatically.

Emptying cartridge after the dialyser is emptied

➢ Connect both couplings to the rinsing bridge.
➢ Touch icon and confirm by pressing the Enter key ↵ on the monitor.

The cartridge is emptied automatically.

i	The functions ”Empty dialyser” 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 dialyser or the rinsing bridge. If the blue coupling is connected to the rinsing bridge, the dialyser is emptied.

6.4 Overview of the therapy carried out

➢ Touch icon.

An overview with the actual values appears for the following values:

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

More parameters can be displayed by actuating the respective icons.

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7 Disinfection

7.1 Procedure and disinfectants

For cleaning the housing and monitor, see section 12.1.
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

i 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.

7.2 Preparing for disinfection

WARNING

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

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

WARNING

Chemical burns hazard for users if concentrated disinfectants are sprayed or spilled!

- **Take appropriate measures, e.g. wear protective clothing, goggles and face mask.**
- **Rinse off splashes on skin and clothing with clear water.**

WARNING

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 device.

- 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.

7.2.1 Positioning the disinfectant container

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

7.2.2 Selecting the disinfection program

Selecting the disinfection program before the dialysis

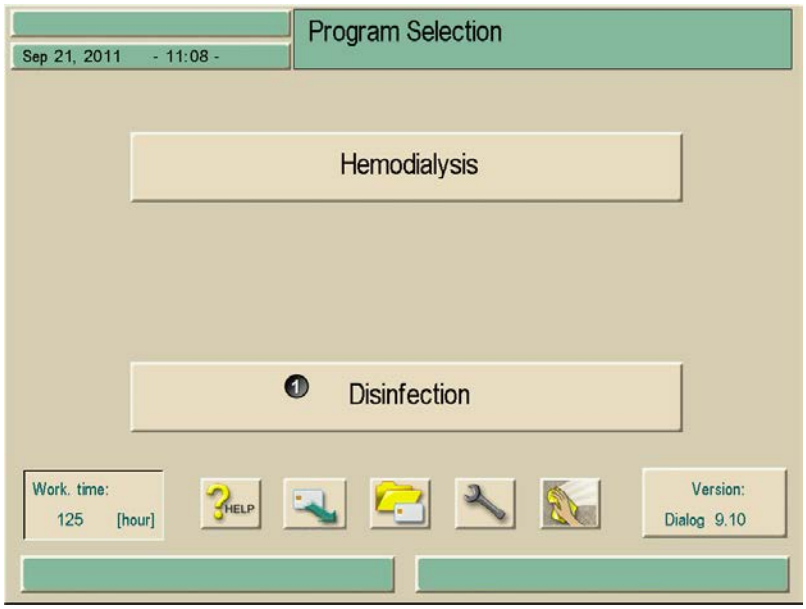


Fig. 7-1 Program selection

➢ Touch field **1**.
The screen listing the different disinfection programs appears.

Legend

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

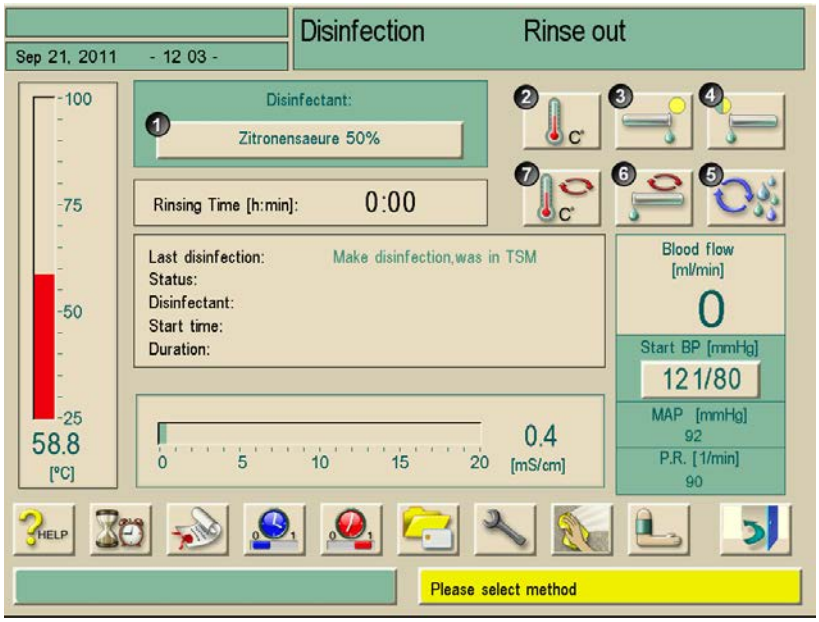


Fig. 7-2 Selection of disinfection program

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

Selecting the disinfection program after dialysis

➢ Touch icon.

The screen with the different disinfection programs is displayed, see Figure 7-2.

➢ Select disinfectant in field 1.

➢ Select disinfection program through icons **2** to **7**.

7.3 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 11.2

7.3.1 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 11.1.

7.3.2 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.

➢ Touch icon.

A screen showing the settings of the weekly disinfection program appears:

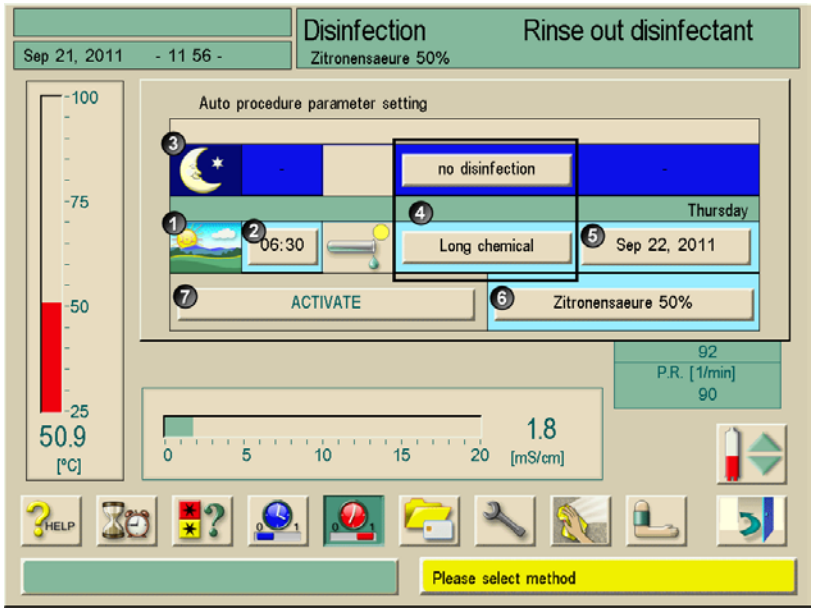


Fig. 7-3 Automatic switch-on

➢ Set the parameters:
- Start time with field **2**
- Disinfection program with field **4**
- Date with field **5**
- Disinfectant with field **6**

➢ Activate settings with field **7**.

An information window about the automatic switch-off will be displayed.

In case of a night disinfection **3** (moon), the dialysis machine switches off automatically on completion of the disinfection cycle.

In case of a daytime disinfection **1** (sun), the machine switches to "Preparation" after the disinfection cycle, or it remains in rinse-out mode depending on the settings performed in the service program by technical service.

➢ Confirm information by pressing the Enter key ↵ .

The dialysis machine switches off after the disinfection cycle. At the set time, the dialysis machine switches on again and carries out the set disinfection.

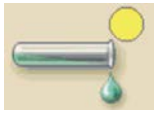
!	Leave mains switch of dialysis machine switched on. Ensure that sufficient disinfectant is connected. Disinfection must in each case be reactivated for the following day.

7.4 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.**



➢ Select disinfectant, e.g. “citric acid 50 %”.

➢ Touch icon.

The sequence of the disinfection program is displayed in field **1**.

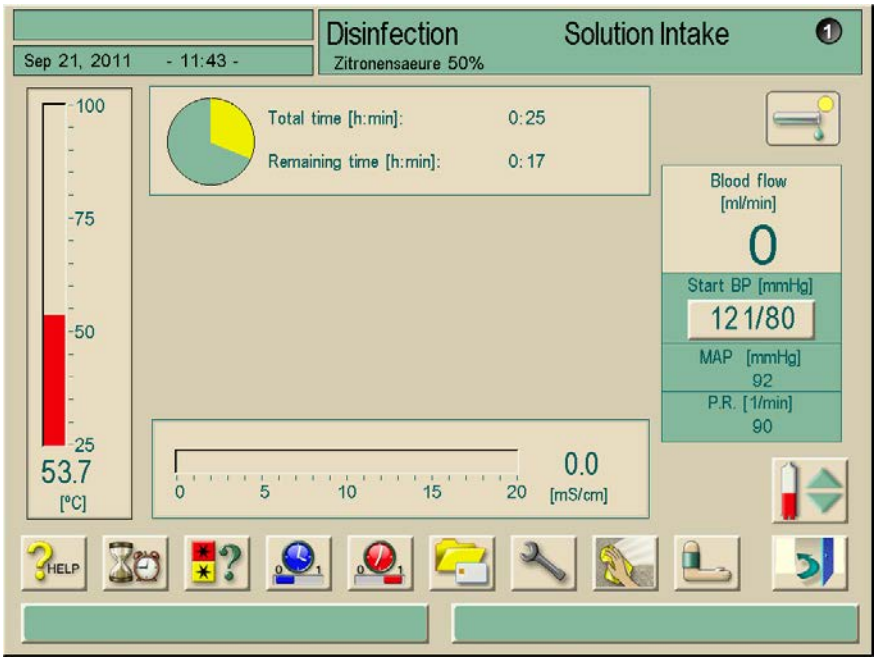


Fig. 7-4 ”Chemical disinfection” screen

Sequence

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

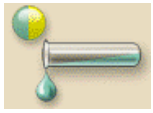
- Automatic rinse-out
- Aspiration of disinfectant and start of heating cycle
- Disinfection phase: Exposure and circulation
- Rinse-out phase

End disinfection

➢ Check if system is free of disinfectant, see section 7.8.

7.5 Short chemical disinfection

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



➢ Activate icon.
The short chemical disinfection is carried out.
➢ Check if system is free of disinfectant, see section 7.8.

7.6 Thermal disinfection

> **!** 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.

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

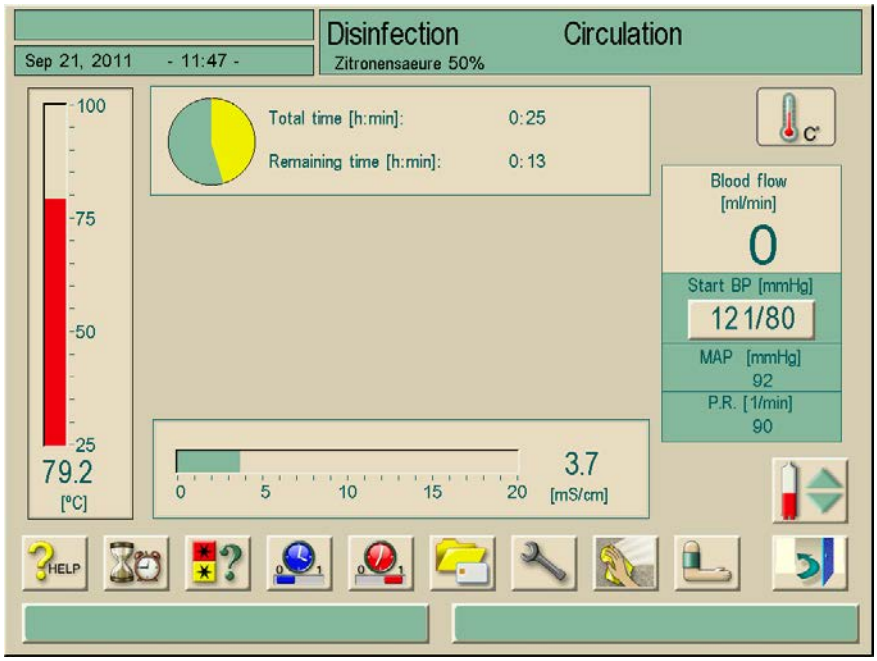


Fig. 7-5 "Thermal disinfection" screen

After activation, thermal disinfection is carried out as follows:

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

7.7 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.

i

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.**

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.**

7.7.1 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.

➢ Touch icon.

The following screen appears:

Legend

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

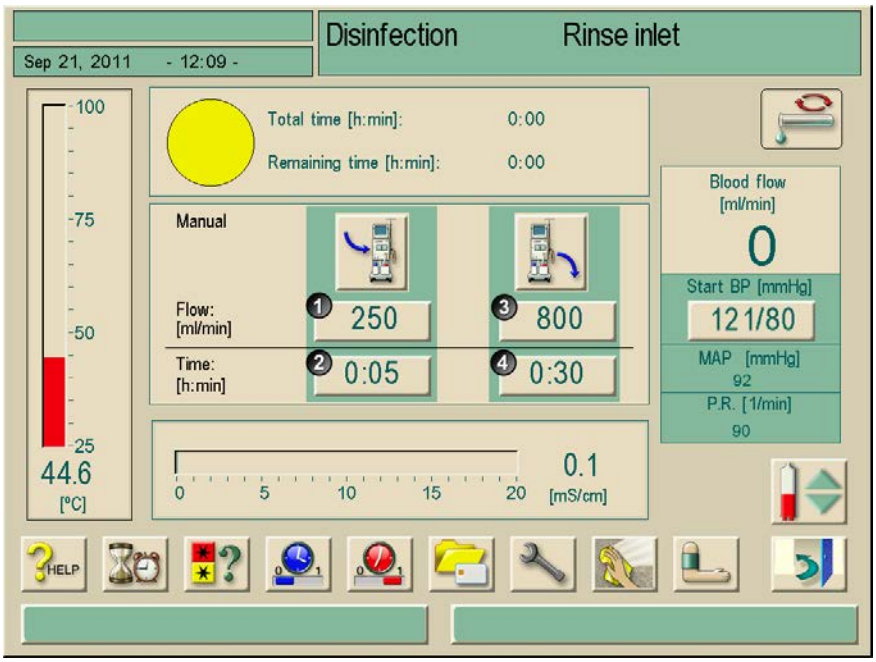


Fig. 7-6 "Disinfection" screen

➢ 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:

➢ Touch icon.

Inlet supply is started and stopped after the preset time.

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

➢ Touch icon.

Rinsing of the dialysis machine supply line is started and stopped after the preset time.

➢ Check supply line and dialysis machine for disinfectants.

7.7.2 Automatic chemical disinfection with disinfectant from central water supply

This disinfection method should only be performed by staff who are 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.

- ➢ Select disinfection screen.
- ➢ Touch icon.

The following screen appears.

Legend

1. Day disinfection
2. Set time
3. Night disinfection
4. Select disinfection programm
5. Set date
6. Select disinfectant
7. Activate week progamm

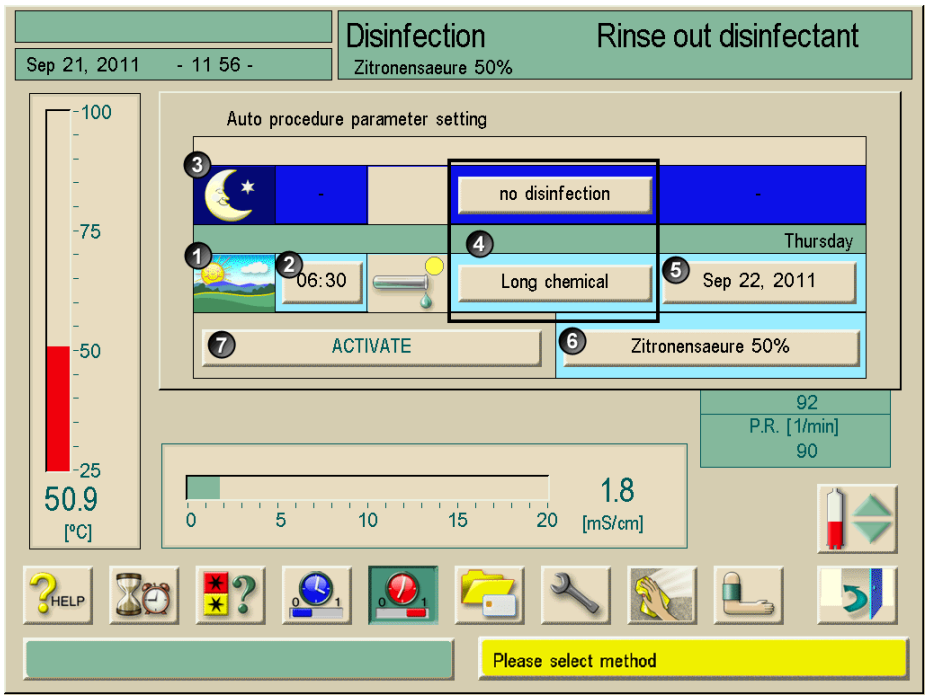


Fig. 7-7 "Disinfection" screen

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

  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.

!	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**:

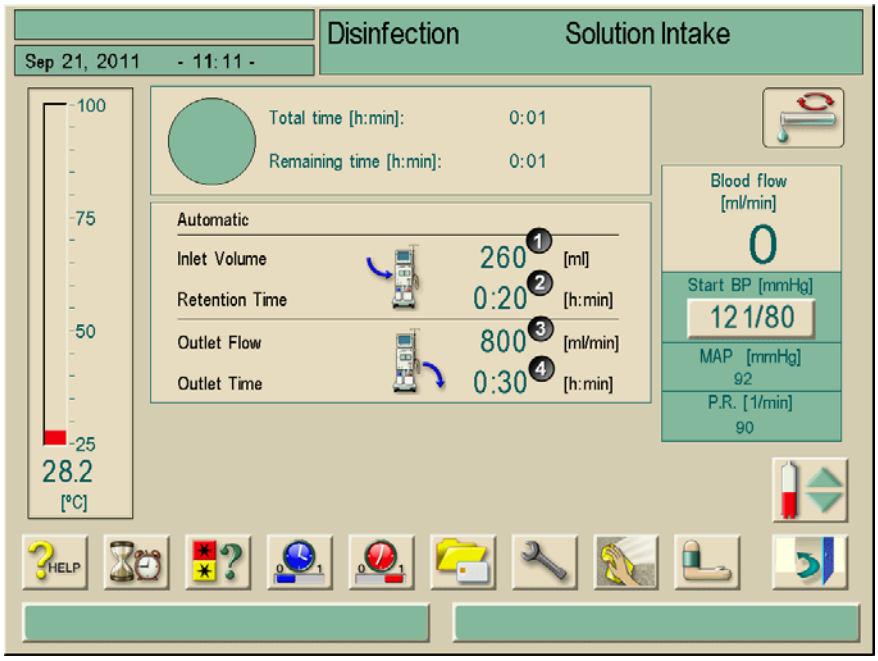


Fig. 7-8 Screen “Disinfection”

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 7.3).

WARNING	**Risk of poisoning the patient with disinfectants left 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.**

7.7.3 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.

➢ Touch icon.

The following screen appears and the program starts.

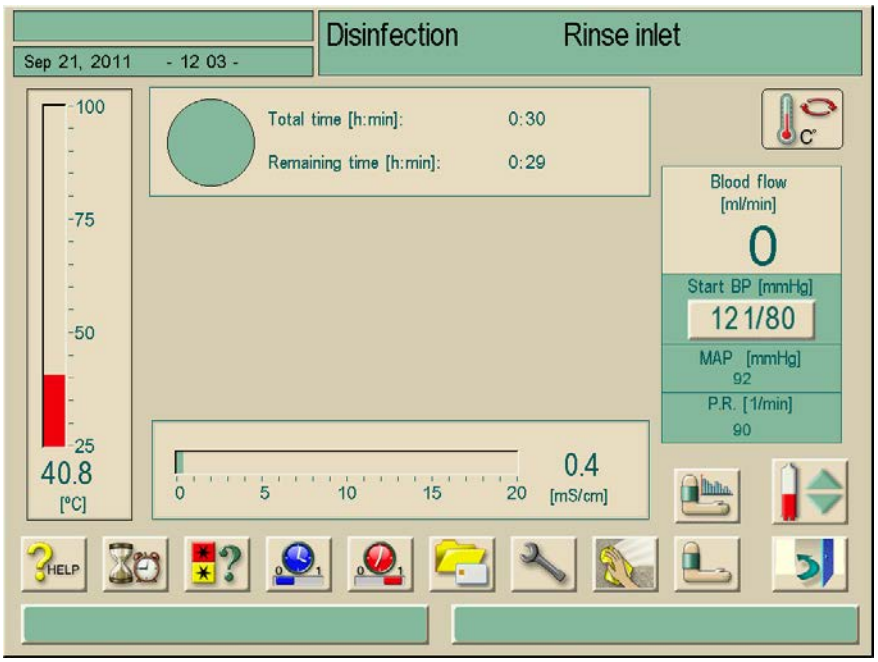


Fig. 7-9 Screen “central thermal disinfection“

7.7.4 Rinsing the permeate inlet

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

➢ Touch icon.
The following screen appears and the program is started.

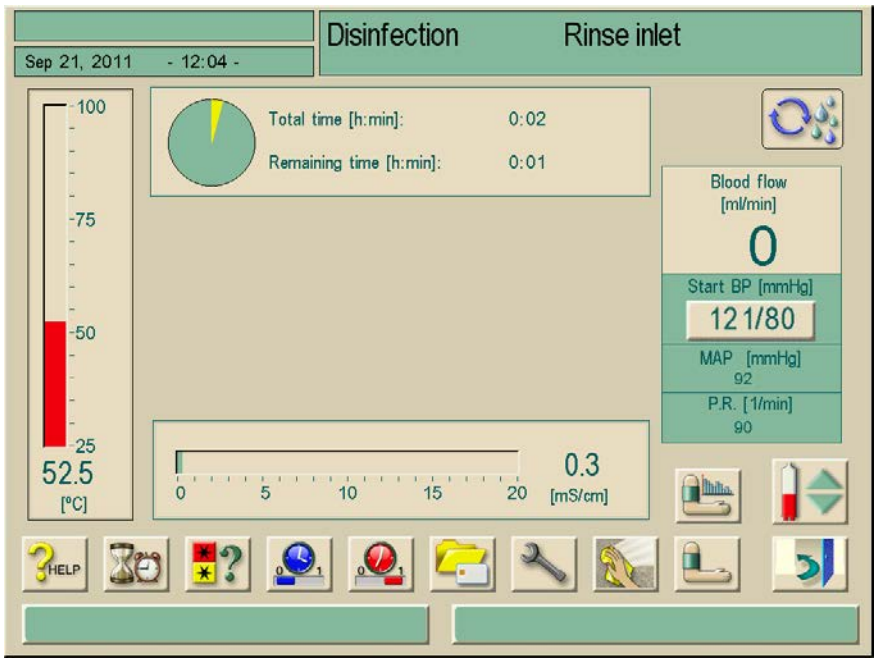


Fig. 7-10 "Rinse permeate inlet" screen

7.8 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!**

! 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:

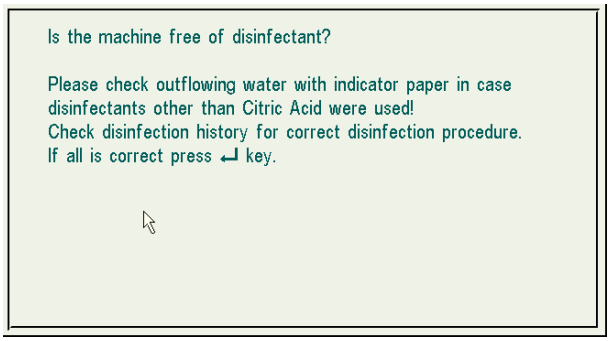


Fig. 7-11 Information window "Disinfectant residue check"

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

If the dialysis machine still contains some disinfectant:

➢ Continue rinsing of dialysis machine and repeat indicator test.

If dialysis machine is free from disinfectant:

- ➢ Press Enter key ↵ on monitor.
- ➢ 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.

7.9 Decalcification

!	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.

7.9.1 Automatic descaling

i	Effective descaling of the DF filter is influenced by the preset contact time and the temperature used during the cleaning cycle. 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.

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

- After the patient is disconnected from the machine, empty the dialyzer as usual.
- 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.

- Ensure connection of acid concentrate coupling to concentrate source.
- 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:

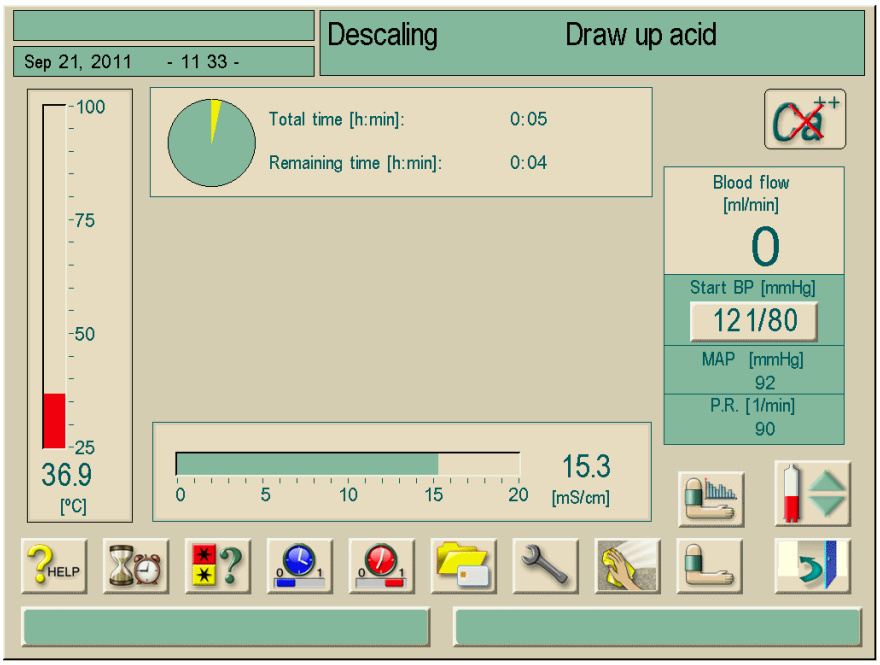


Fig. 7-12 "Descaling" screen – Acid drawing up

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

The following screen appears:

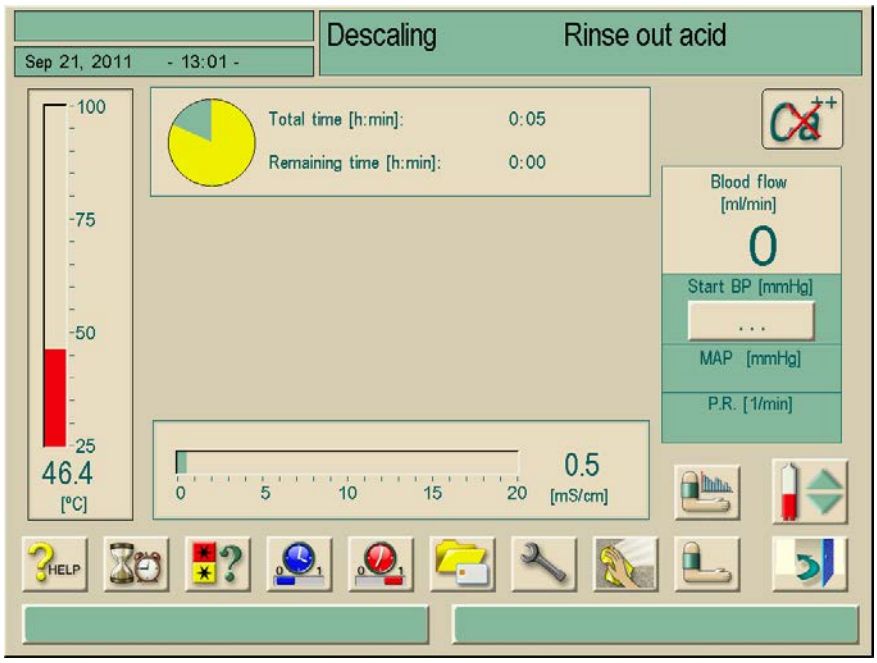


Fig. 7-13 "Descaling" screen – Acid rinse out

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.

7.10 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.

➢ Touch icon.

An information window appears.

i

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.

➢ To terminate the disinfection, press Enter key ↵ on monitor.

The "Select disinfection program" screen is displayed, see Fig. 7-2. You can select a different disinfection program.

7.11 Disposal of old dialysis appliance

i The Dialysis machine has to be disinfected according to regulations before disposal.
For information about the disposal see chapter 1.7.

Table of contents

8 HDF-online/HF-online

In addition to haemodialysis, Dialog+ HDF-online also offers the therapy types haemodiafiltration and haemofiltration, in which the substitution solution is prepared online by the dialysis machine.

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

The operator 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.**

8.1 Preparing for haemodiafiltration/haemofiltration

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 device before a new treatment especially after extended idle times.**

8.1.1 Calling up haemodiafiltration/haemofiltration

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

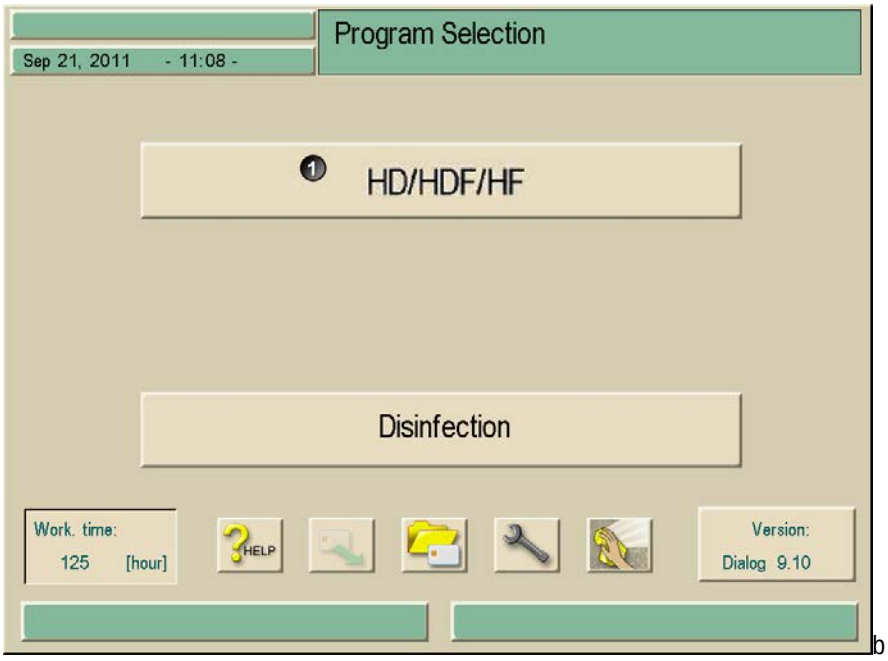


Fig. 8-1 Main screen "HD/HDF/HF"

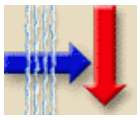
➢ Touch field **1**.

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

8.1.2 Connecting the concentrate

See section 4.

8.1.3 Entering the substitution parameters



➢ Touch icon.
A screen showing the substitution parameters is displayed.

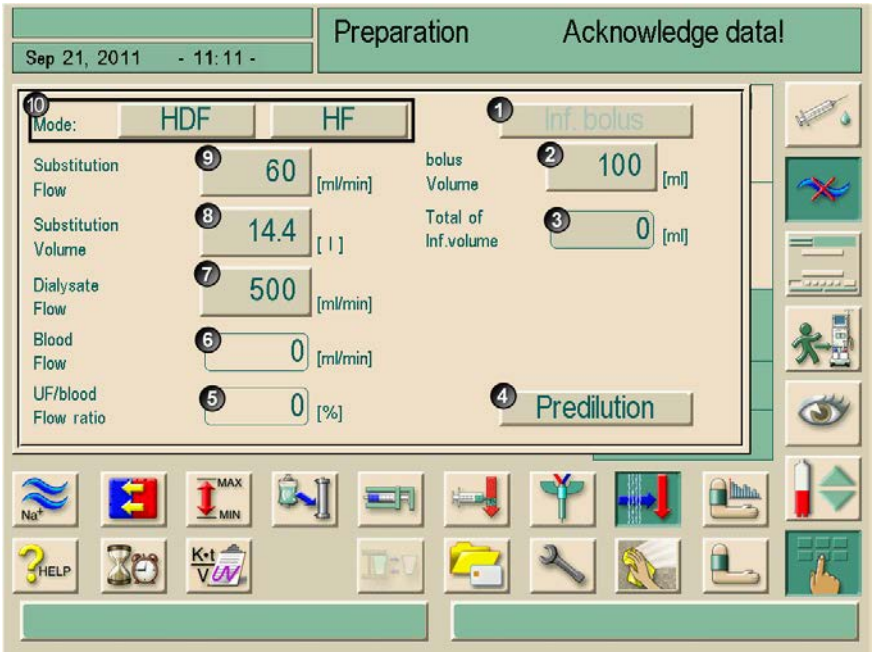


Fig. 8-2 "Substitution parameters HDF" screen

➢ For haemodiafiltration touch field **HDF**,
for haemofiltration touch field **HF**.
The online system for substitution is activated now.

i

In this way the HDF/HF mode can be activated even during a running haemodialysis. 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!

➢ 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.
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.

8.1.4 Inserting the tube system

Legend

1 Venous pressure sensor
2 Arterial pressure sensor
3 Arterial blood pump
4 Heparin pump
5 Pressure sensor dialyser input pressure
6 Dialyser
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

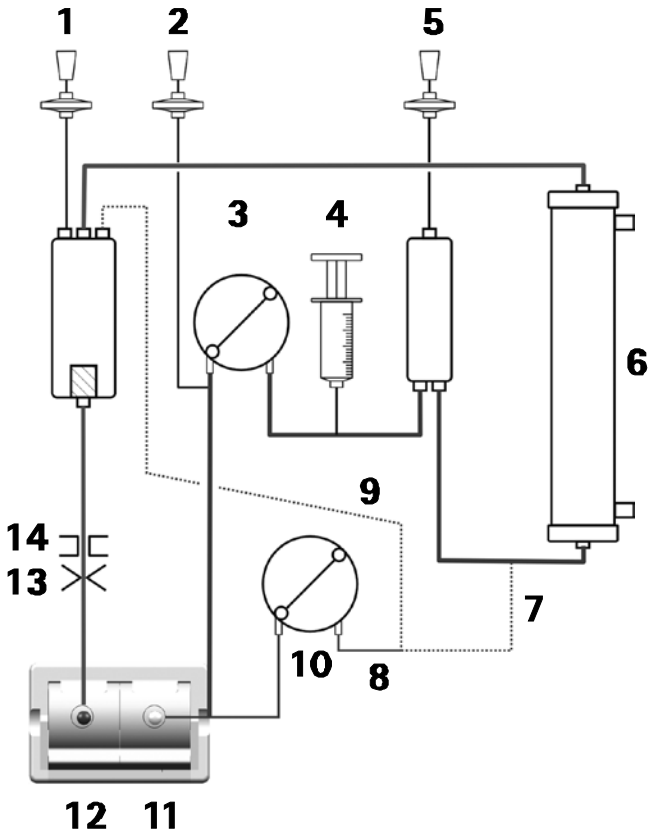


Fig. 8-3 Tube system for HDF/HF therapy, connected for online rinsing

8.1.5 Filling and rinsing the tube system with substitution solution from the online system

The Dialog+ HDF-online dialysis machine allows filling and rinsing the blood tube system and the dialyser with the substitution solution prepared by the machine. The rinsing liquid is taken from the machine and recycled back to it.

i 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:

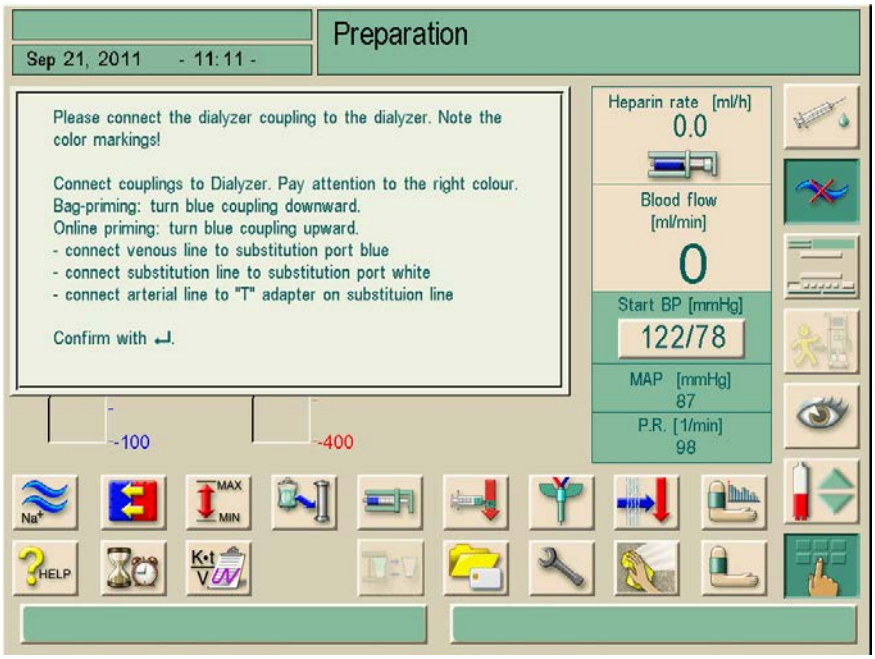


Fig. 8-4 Information window for connection

- Take dialyser connections from rinsing bridge and connect to dialyser. Observe colour-coding.
- Turn dialyser with blue connection facing **upward**.
- Open substitution port outlet **2** and connect substitution line.
- 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 dialyser.
- Connect arterial patient connection to the Luer-lock connector of the substitution line between substitution port outlet and substitution pump.
- Insert pump segment of the substitution line into the venous blood pump.
- Connect venous patient connection to substitution port reflow **1**.
- Confirm correct connection of dialyser and substitution line by pressing Enter key ↵ on the monitor.

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

After approx. 10 seconds the following information window appears:

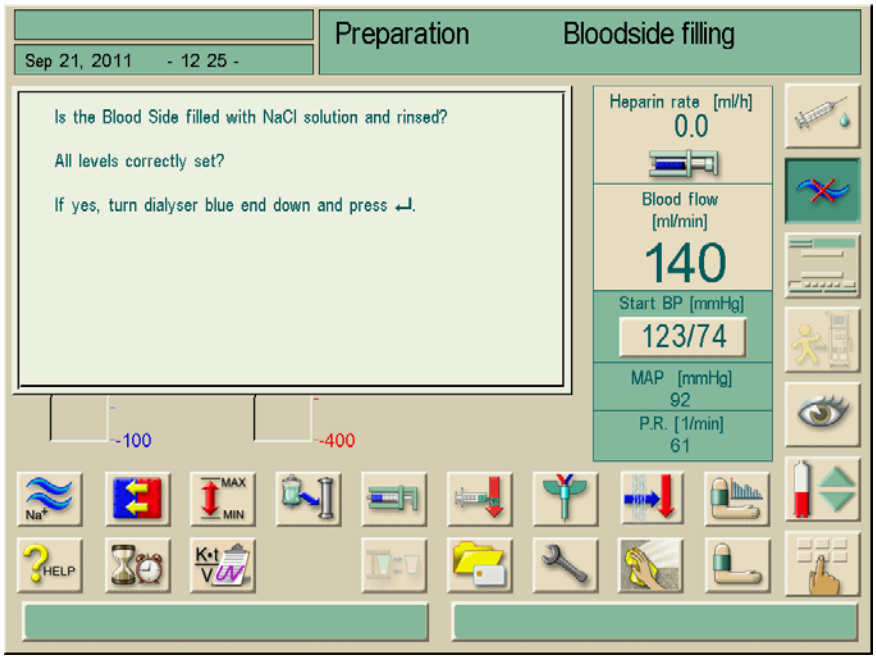


Fig. 8-5 Information window for level adjustment

- Set level as follows:
  - Fill chamber in front of the blood-side dialyser inlet to about half full.
  - Fill venous drip chamber up to approx. 1 cm from the top.
- Make sure the blood line and the dialyser are completely filled with solution before confirming the window and turning the dialyser.
- Confirm correct settings by pressing the Enter key ↵ on the monitor.

  The dialysis machine will test the blood tube system and the substitution lines.

  As soon as the automatic test is passed successfully, the rinsing program starts running with the set rinsing parameters.

i The dialysis machine can also be conditioned with rinsing solution from bags, see section 4.

8.1.6 Inspecting the tube 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 the complete therapy.**

8.2 Preparing for standard haemodialysis with online fluid

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

- Set-up standard double-needle blood line system as usual without connecting the arterial and venous patient Luer-Lock connectors.
- In Program Selection, select "HD/HDF/HF".
  The confirmation window (figure 8-4) appears.
- Take dialyser connections from rinsing bridge and connect to dialyser. Observe colour-coding.
- Turn dialyser with blue connection facing **downward**.
- Connect the arterial line to the substitution port outlet (white).
- Connect the venous line to the substitution port reflow (blue).
- Confirm correct connection of dialyser by pressing the Enter key ↵ on the monitor.

The blood line is filled with saline from the online port. Follow description on page 8-9.

Legend

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

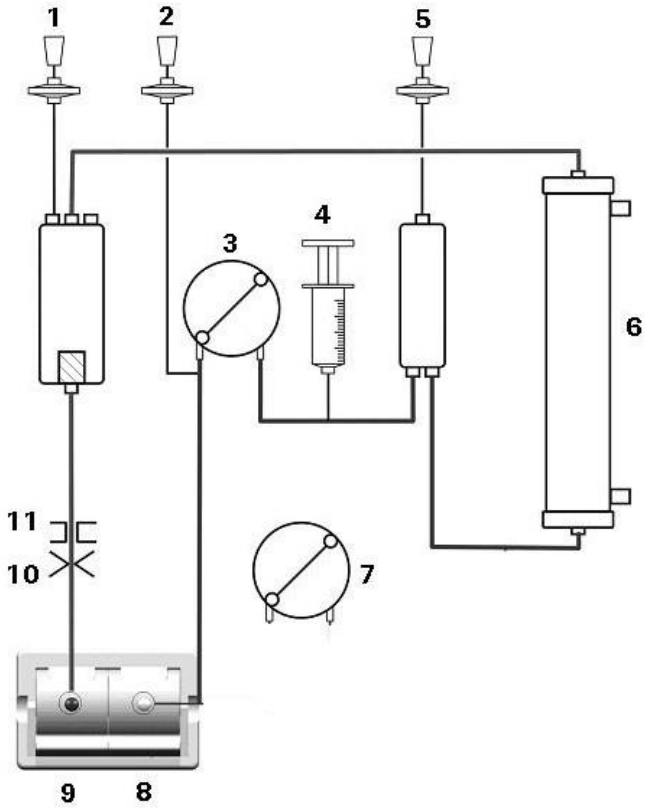


Fig. 8-6 Tube system for HD with online fluid

8.3 Carry out haemodiafiltration/haemofiltration

8.3.1 Connect patient and start haemodiafiltration/haemofiltration

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 selftest.**
- **It is recommended to use only substitution lines produced by B. Braun.**
- **Other systems than those produced by B. Braun must have a non-return valve.**

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

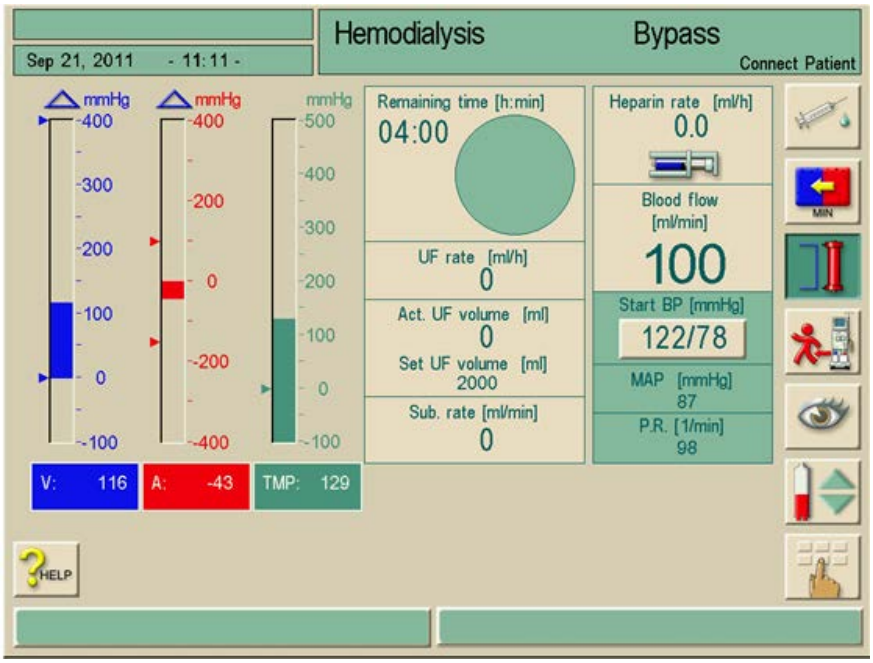


Fig. 8-7 Therapy screen "HDF/HF"

WARNING

Poisoning danger for 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!

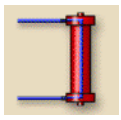
- **Observe hygiene aspects when connecting the arterial and venous lines.**
- **Do not touch the connectors with your bare hands.**
- **If necessary, disinfect with a suitable disinfectant.**

WARNING

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

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

- Remove the arterial line from the substitution line and connect it to the patient.
- Start blood pump by pressing **START/STOP** button on monitor.
  The blood pump operates automatically at the preset rate.
- Fill blood tube system with blood.
  The blood pump stops automatically if blood is detected at the red sensor downstream from the safety air detector.

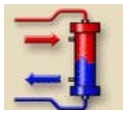


- ➢ Remove the venous line from substitution port reflow and connect it to the patient.
- ➢ Close the substitution port.
- ➢ Start blood pump by pressing **START/STOP** button on monitor.
- ➢ Touch icon.

  The dialysis machine switches to main connection and the haemodiafiltration/haemofiltration 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).



- ➢ Press the icon to continue patient connection after interruption.

8.3.2 During haemodiafiltration/haemofiltration

In the same way as during haemodialysis, the following additional functions are available during haemodiafiltration/haemofiltration:

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

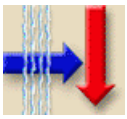
  Administering an infusion bolus is also possible.

Infusion bolus

CAUTION

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

➢ Keep an NaCl-bag ready for infusion or reinfusion.



- ➢ Touch icon.

The substitution parameters and infusion bolus screen is displayed.

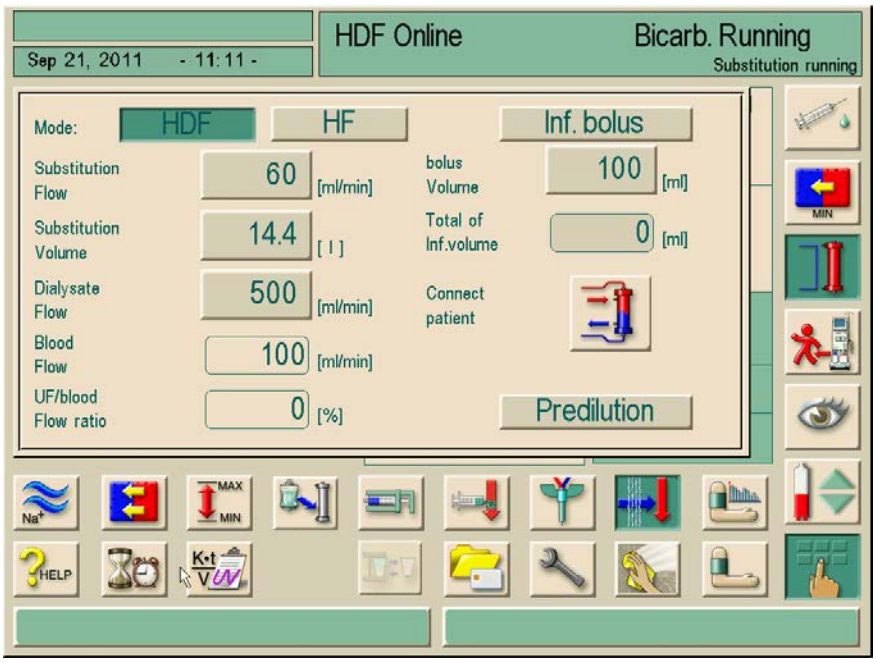


Fig. 8-8 "Substitution parameters HDF" screen

- Adjust bolus volume if necessary. To end this, touch field **bolus Volume** and enter new setting.
- Touch field **Inf. bolus** and acknowledge information by pressing ↵ 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

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

Bolus administration is stopped.

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

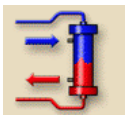
8.4 Finish haemodiafiltration/haemofiltration

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.

➢ Touch icon.
A query window "End of Therapy" pops up.
➢ Confirm end of treatment by pressing Enter key ↵ on the monitor.
The treatment is finished.

8.4.1 Reinfusion with substitution solution

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



➢ Touch icon.
The following screen is displayed:

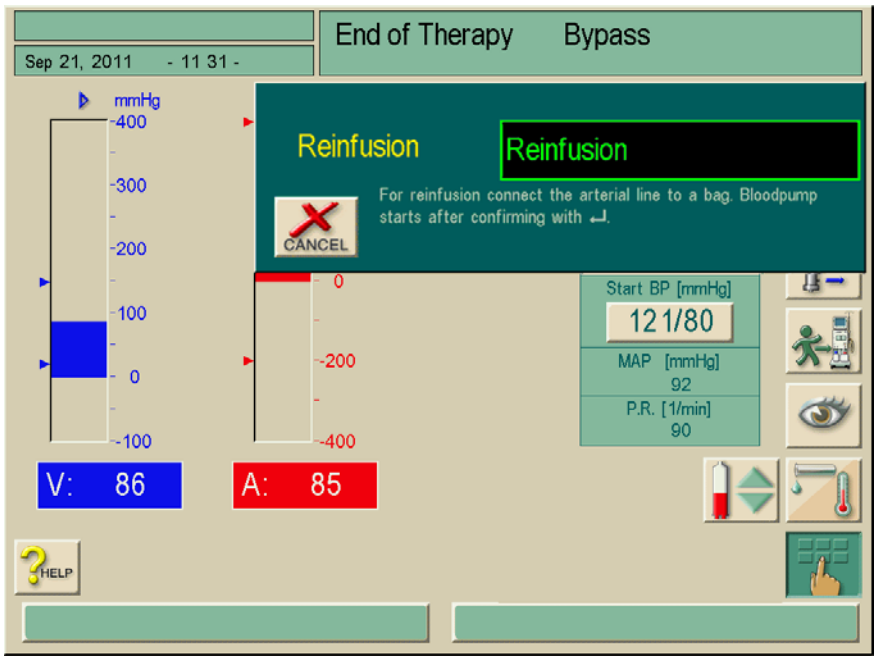


Fig. 8-9 "Confirm reinfusion" screen

The "Confirm reinfusion" screen (Fig. 8-9) appears only if configured accordingly in the service program. Otherwise, reinfusion must be called up by pressing icon **1** (Fig. 8-10).

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:

- Remove arterial connection from patient.
- Connect the arterial line to the rinsing connector of the substitution line between substitution port and substitution pump.
- 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:

- Fill the adapter line manually with saline.
- Connect adapter line to the substitution port outlet (see figure 8-3).
- Connect arterial line to the adapter.
- Confirm reinfusion phase by pressing Enter key ↵ on the monitor. The blood pump is started.

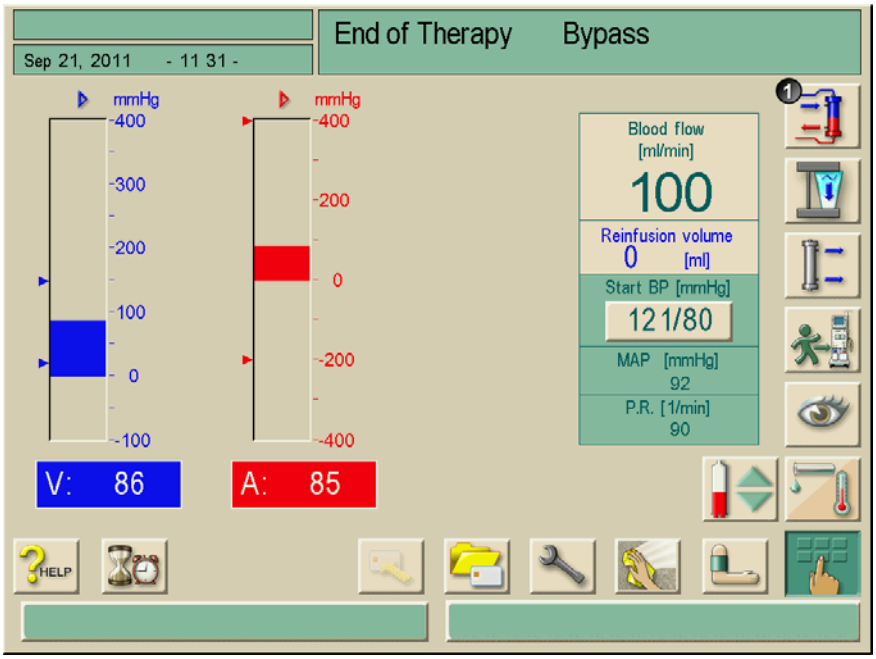


Fig. 8-10 "End of Therapy" screen with reinfusion activated

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

- 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.
- Disconnect venous patient connection.

It is also possible to connect the arterial line directly to the port outlet without an adapter line. 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.**

8.4.2 Emptying the dialyser

See section 6.2.

8.5 Disinfection

8.5.1 Regular disinfection

The regular disinfection after a dialysis and in the morning prior to the first dialysis is described in chapter 7.

WARNING

Changes to the material characteristics of the housing, encapsulation and capillaries of the filter due to unsuitable disinfectants!

Endangering of patient! Dialyser is no longer safe to operate!

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

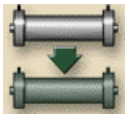
WARNING

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.**

8.5.2 Displaying the online filter data



- Touch icon.

  The remaining operating time and the number of dialyses performed are displayed.

8.5.3 Changing the online filter

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

Fig. 8-11 Information window "Filter change"

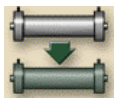
WARNING

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 centre).**
- **Do not use the filters after the filter service life has expired because, otherwise, the required quality of substitution solution cannot be ensured.**

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

➢ Touch icon.
The selection menu appears.



➢ Touch icon.

The following window appears:

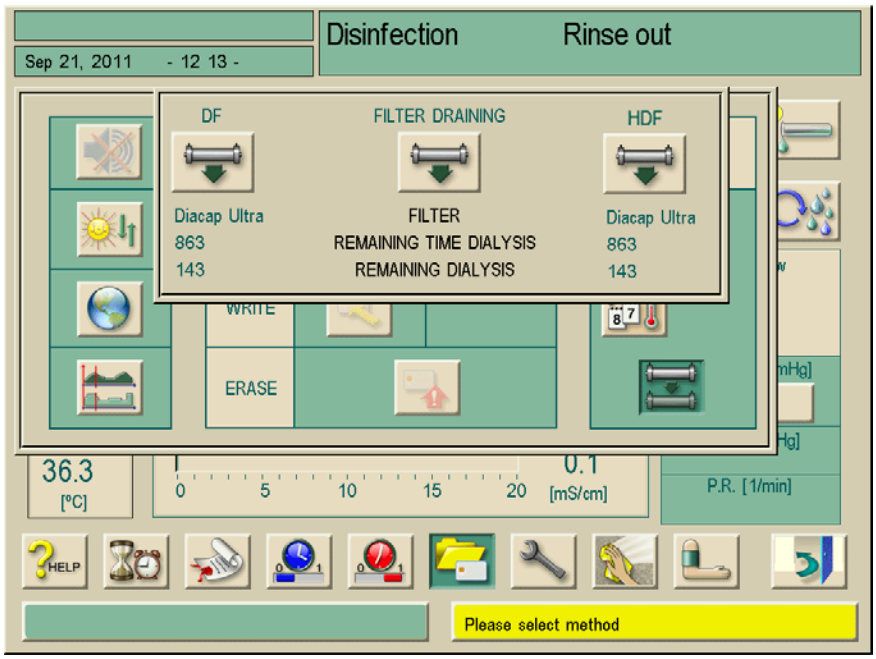
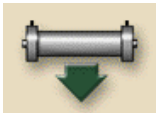


Fig. 8-12 Information window "Empty filters"



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

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

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

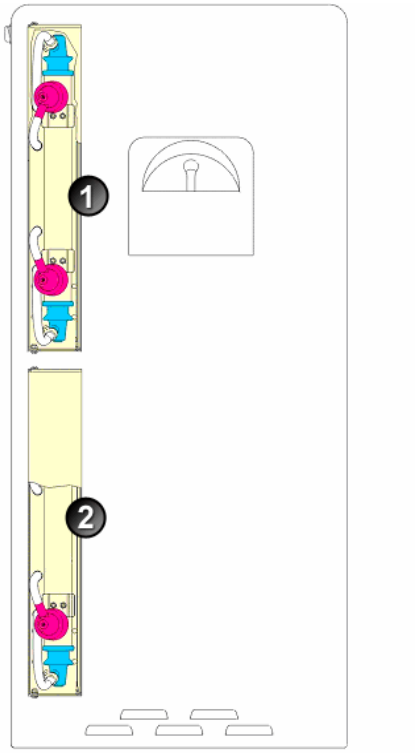


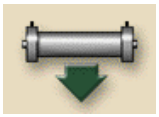
Fig. 8-13 Filter housing with cover

WARNING

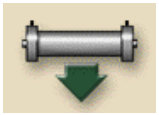
Risk to patient due to ultrafiltration deviation.

Kinked connection tubes can cause ultrafiltration deviations.

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



- To complete the filter change, touch the middle icon "EMPTY FILTERS" once more.
- Close the substitution port.



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

8.5.4 Sampling of substitution fluid

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

- Prepare the device as usual.
- Insert the substitution line.
- Start therapy (without patient).
- Adjust substitution rate to 200 ml/min.
- Extract the required amount for your sample from the infusion connection of the substitution line.
- End therapy.
- Start disinfection.

Table of contents

9 Single-needle procedure

9.1 Single-needle cross-over (SN-CO)

i 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 4., 5. and 6.

9.1.1 Preparing the therapy

Insert tubes

The following is required:

- SN-CO tube system
- Dialog+ with two blood pumps

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

i SN-CO can also be activated or selected with a therapy in progress.
If the PBS pressure sensor is connected during an ongoing therapy, and the SN-CO 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.

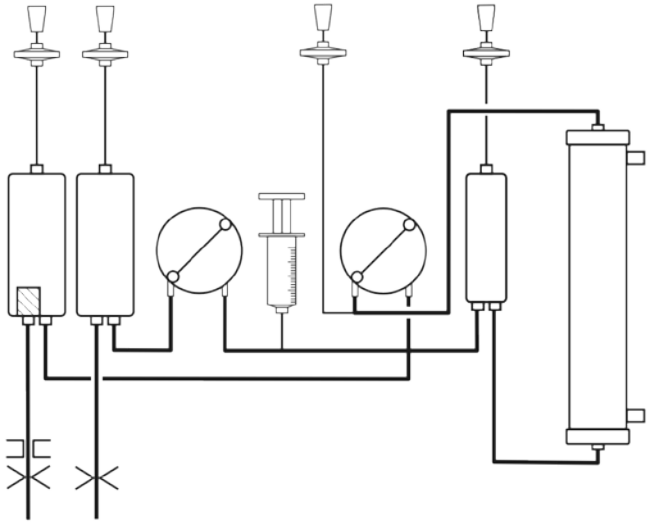


Fig. 9-1 Single-needle cross-over (SN-CO) tube system

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 tube system is fully intact.**

Setting the SN-CO mode

➢ Touch icon.

Legend

1 Set SN-CO parameters
2 Activate SN-CO parameters
3 Connect patient
4 Call up single-needle selection

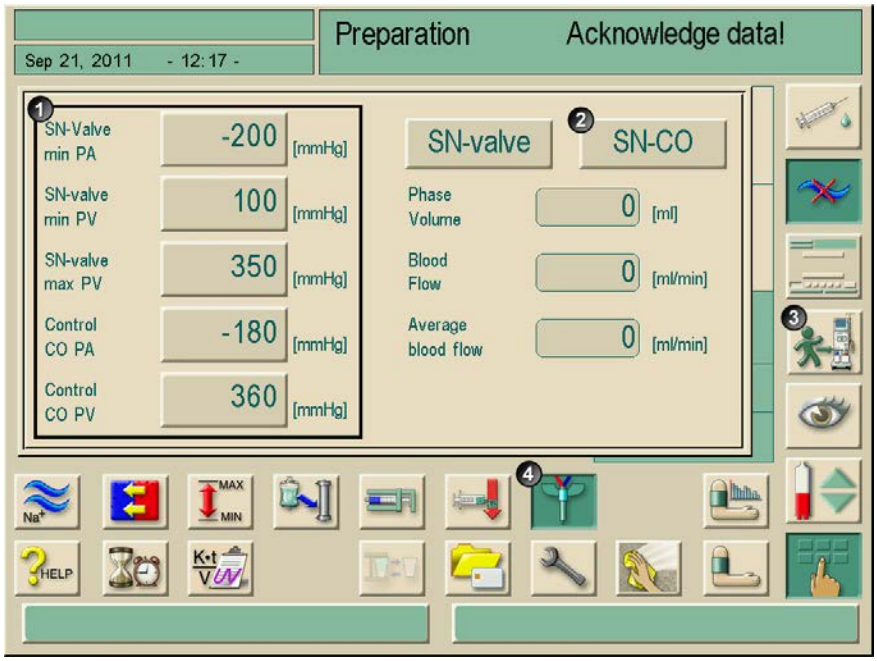


Fig. 9-2 Single-needle cross-over (SN-CO)

➢ Touch SN-CO field.
Fields not needed will be hidden.

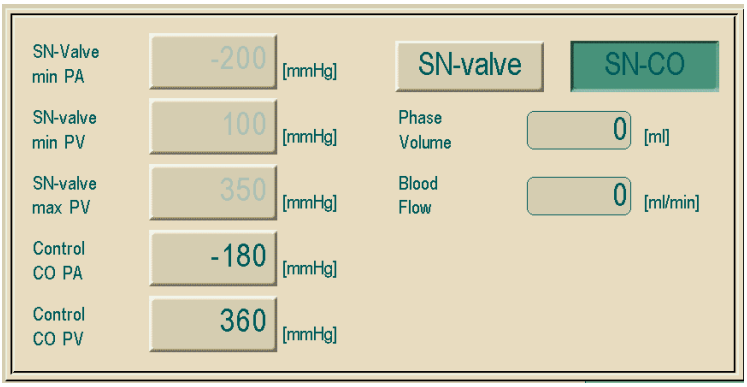


Fig. 9-3 SN-CO parameters

➢ Fill and rinse tube system, see section 4.5.
➢ 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.

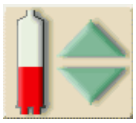
9

9.1.2 Level regulation (if present)

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 SN-CO mode, the blood level regulation requires a previous blood pump stop automatically performed by the machine.



➢ Touch icon

The level window opens. All chambers are paled (inactive).

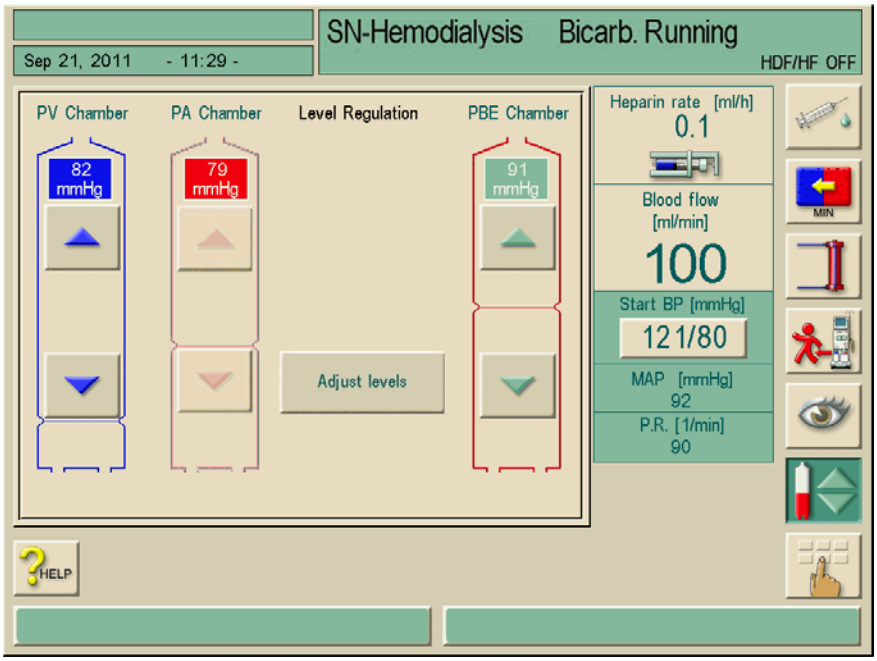


Fig. 9-4 Level regulation screen in single-needle

9

➢ Touch button
A supervisor window opens.

➢ Confirm by pressing the Enter key.
Blood pump stops automatically.
A pressure equalisation is performed by opening the arterial and venous clamp.
The chambers are active and ready to adjust.

Level increasing

➢ Touch icon gently with one touch and observe level.
➢ Touch again for the correct setting if necessary.

Level decreasing

➢ 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.

➢ To determine the level regulation process, press button “Adjust levels”
or
➢ 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.**
- **Call technical service for manometer protection filter change.**

WARNING

Risk of reduced dialysis effectivity!

- **Ensure that no air enters into the dialyser when decreasing the level in the arterial and in the PBE chamber.**

9.1.3 Running the therapy

- Touch icon.
  The dialysing machine switches to connection mode.
- Confirm patient data, see section 5.1.
- Connect arterial tube.
- 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.
- Start blood pumps.
- Fill tube system with blood.
- Stop blood pumps.
- Connect venous tube to patient.
- Restart blood pumps.
  - At 150 ml/min for central catheter
  - At approx. 100 to 120 ml/min for fistula connection

  The dialysis is started.
- Increase blood pumping rate, taking into account the phase volume.

i

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 effectiveness 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	Arterial 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 mmHg

- ➢ 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**.

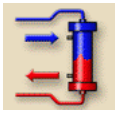
During dialysis

- ➢ Observe levels in arterial and venous chamber.
  If necessary, change levels in field **SN chamber level**, see below.
- ➢ 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
- ➢ In case of repeated alarms "Phase volume to low": Briefly reduce pump speed.

The limits are reset.

9.1.4 Ending the therapy

The therapy ends automatically or after touching the respective icon. Also observe the following steps.



- ➢ Leave tube segment of venous blood pump in venous blood pump.
- ➢ Always start reinfusion by pressing the appropriate icon.
- ➢ Disconnect patient, see chapter 6.

Alternatively, it can be re-infused by double-needle mode.

- ➢ Touch field **2** in SN-CO window (Fig. 9-2).
- ➢ Deactivate SN-CO.
- ➢ Disconnect the patient (see chapter 6).

9.2 Single-needle valve (SN-valve)

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 4., 5. and 6.

9.2.1 Preparing the therapy

Inserting tubes

The following is required:

- AV set for SN-valve (venous chamber 100 ml) or normal AV set for Dialog+ (venous chamber 30 ml)
- For Dialog+ single-pump machine: Option SN-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 SN-valve option are used!

➢ **Set phase volume >12 ml.**

➢ Insert standard arterial tube.
➢ Push arterial tube through arterial tube clamp (if present).
➢ Insert venous tube.
➢ Place venous tube through venous tube clamp.
➢ Connect pressure sensors PA, PBE, PV. Check for secure seat.

SN-valve can also be selected during a running therapy.

Setting the SN-valve mode

➢ Touch icon.

The following screen appears:

Legend

1 Set min. arterial control pressure
2 Set venous control pressure
3 Activate SN-valve parameters
4 Connect patient
5 Call-up single-needle selection

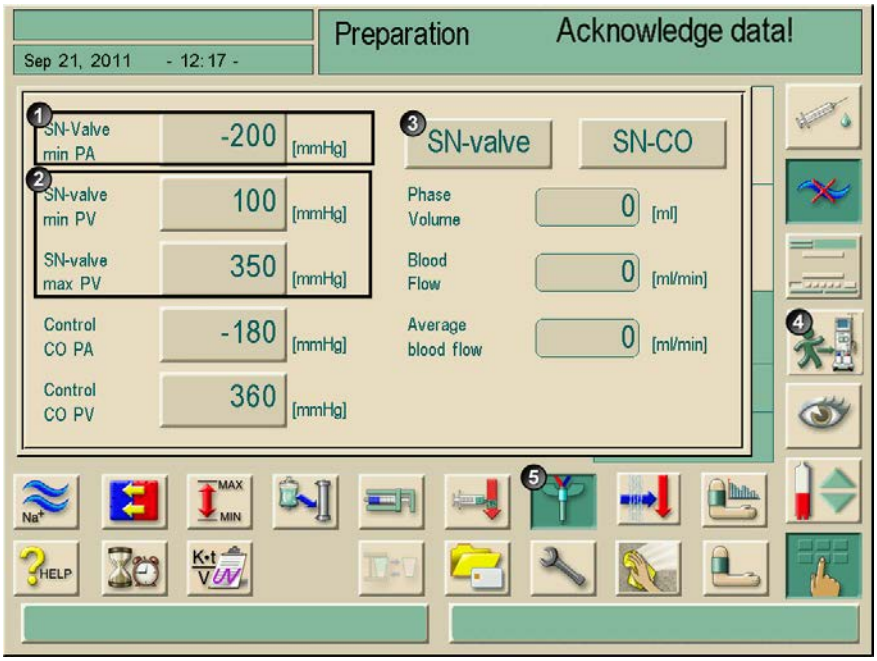


Fig. 9-5 Single-needle valve (SN-valve)

> ! It is possible to set a lower max. limit to protect the arterial pressure limit.

➢ Touch field **SN-valve**.

The field lights up in green.

The preset control pressures **min. PV** and **max. PV** are displayed.

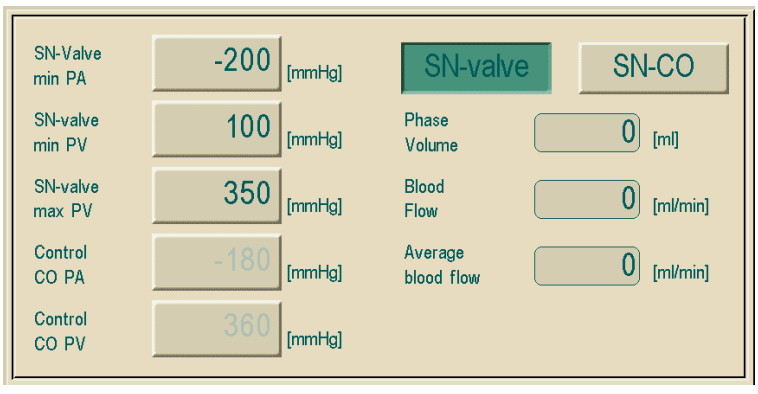


Fig. 9-6 SN-valve parameters

In order to achieve the highest effective blood flow at minimum recirculation, the control pressures must be set for an optimum phase volume.

9.2.2 Running the therapy

➢ Touch icon.
The dialysis machine switches to therapy mode.
➢ Confirm patient data, see section 5.1.
➢ Connect patient, see section 5.2.
➢ Fill tube system with blood. Fill level in venous chamber to only approx. 35 % in order to achieve a good phase volume.
➢ 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 SN-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.

i 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 9.1.2.

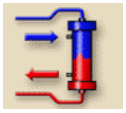
9

Recommendation

Lower venous control pressure min PV	Upper venous control pressure max PV
120 to 150 mmHg	up to 300 mmHg

➢ 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**.
➢ 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
➢ Observe level in venous chamber.
If necessary, change level via field **SN chamber level**.
➢ If necessary, adjust min. PV and max. PV, see section 4.7.
The optimum return flow time is set automatically.

9.2.3 Ending the therapy



The therapy ends automatically or after touching the respective icon, see section 5.4. Also, observe the following steps.

- Leave tube segment of venous blood pump in venous blood pump.
- Always start reinfusion by pressing the appropriate icon.
- Disconnect patient, see chapter 6.

Table of contents

10 Use of options

10.1 ABPM blood pressure monitoring

The option ABPM (automatic blood pressure monitoring) allows non-invasive, oscillometric blood pressure measurements.

The blood pressure can be measured in the operating modes Preparation, Therapy and Disinfection.

ABPM blood pressure monitoring 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 colour display of blood pressure and pulse curves
- Documentation of readings with time stamps
- Readings outside the limits are coloured

WARNING

Risk of haematoma formation caused by frequent blood pressure measurements of patients who take coumarins or other anticoagulant substances.

!

The automatic blood pressure monitoring function does not release operators 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.

10.1.1 Handling of old/new cuffs with the option 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. 10-1 Male coupling on the machine

Fig. 10-2 Tubing female/female

- ➢ Check if your Dialog+ contains the male coupling (Fig. 10-1).
- ➢ Use tubing with two female couplings (Fig. 10-2).
- ➢ Connect tubing with one female coupling to machine.
- ➢ Connect same tubing with the other female coupling to cuff.
- ➢ For further measurement, follow the instructions in chapter 10.1.2 Cuff.

Fig. 10-3 Female coupling on the machine

Fig. 10-4 Tubing female/male

- Check if your Dialog+ contains the female coupling (Fig. 10-3).
- Use tubing with one female coupling and one male coupling (Fig. 10-4).
- Connect tubing with male ending to machine
- Connect tubing with female ending to cuff.
- For further measurement, follow the instructions in chapter 10.1.2 Cuff.

10.1.2 Cuff

The cuffs delivered by B. Braun are 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 for usage with the machine, e.g. by independent bodies.**

The following cuffs can be used for ABPM blood pressure monitoring:

- 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.**

- Vent cuff prior to application. Compress cuff to let air escape.

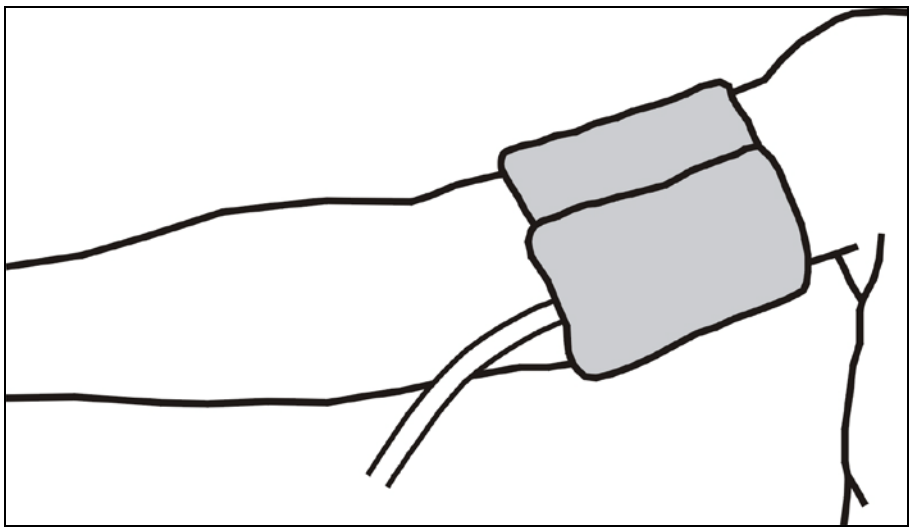


Fig. 10-5 Cuff

- Apply cuff tightly in a suitable place around upper arm of the patient.
- Place marking on inside of cuff over artery.
- Ensure that cuff tube is not kinked.
- If applicable, set measuring cycle to the desired time interval (1 - 60 min depending on the clinical situation).

!

- Do not apply cuff to limbs used for intravenous infusion or haemodialysis.
- Apply cuff tightly making certain that there is no venous flow-back or skin discolouration.
- 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/sterilising the cuff

> ! Never autoclave the cuff.

- ➢ Ensure that no fluid enters the tube connections during cleaning.
- ➢ Only clean cuff with soapy water or an alcohol solution (e.g. Meliseptol).

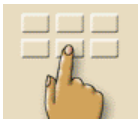
Sterilising the cuff

- ➢ Only sterilise the cuff with ethylene oxide (ETO).

Connecting the cuff tube to the dialysis machine

- ➢ Connect cuff tube to tube connection for blood pressure measurements at the dialysis machine. Ensure correct seat of connections.

10.1.3 Settings



- ➢ Touch icon.

The settings menu appears.

- ➢ Touch icon.

The ABPM main view appears:

Legend

1. Set the alarm limits
2. Set the cycle time, in minutes
3. Activate/deactivate cyclical measurement
4. Start/Stop ABPM

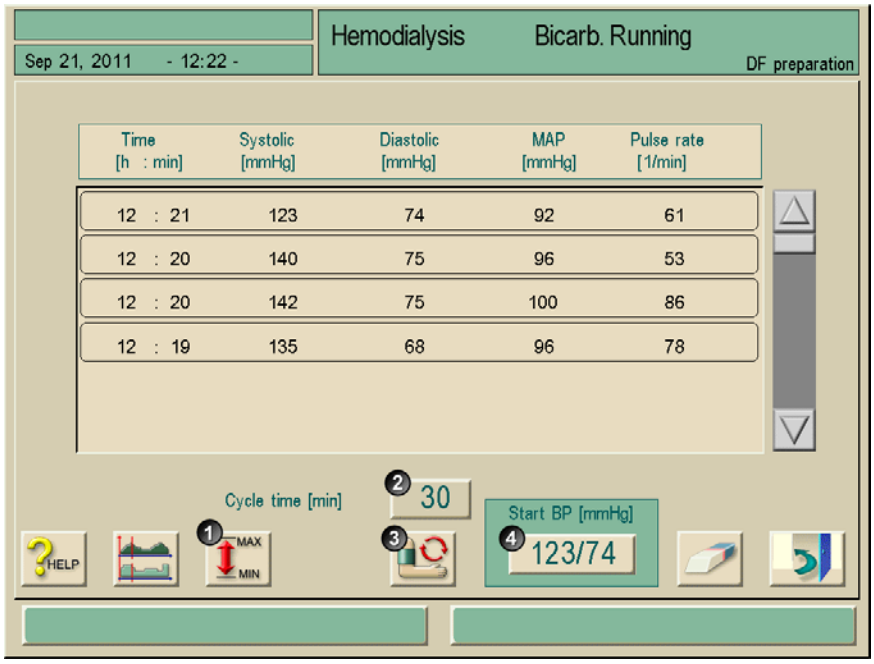


Fig. 10-6 "ABPM main view" screen

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

➢ To set the measuring period (cycle time: 1 to 60 minutes), touch icon **2**.

➢ To activate/deactivate the cyclic measurements within the set time interval, touch icon **3**.

i The TSM allows a preset to determine whether the cyclic measurements are terminated by changing to Disinfection mode.

Setting the alarm limits

➢ To view and set the alarm limits, touch icon **1**.
The following screen appears:

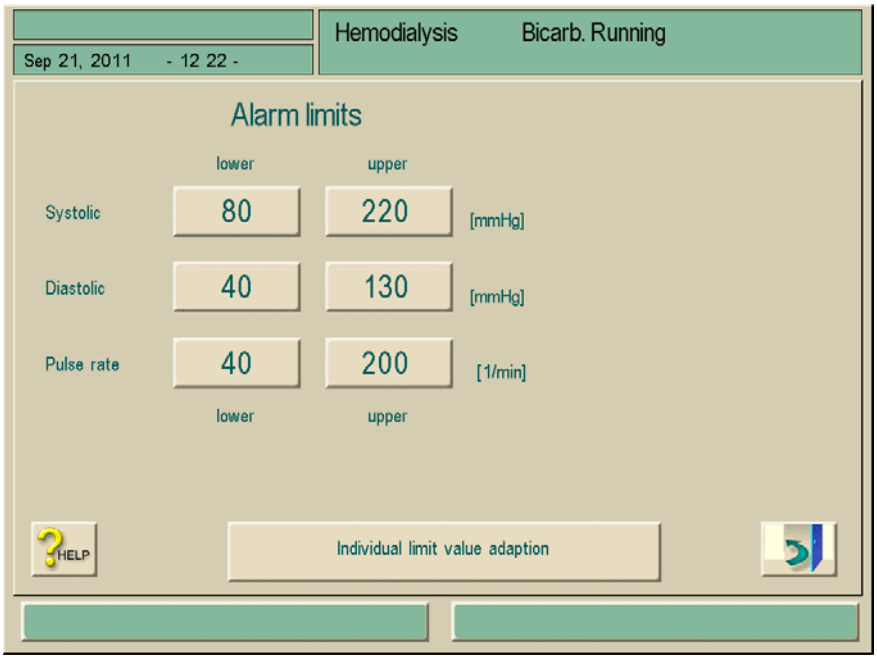


Fig. 10-7 "Alarm limits" screen

You can accept or adjust the alarm limits.

Option 1: Manual setting of alarm limits:

➢ Touch the limit to be set.

➢ Enter new setting via the keypad.

Option 2: To set the alarm limit based on the last measuring result:

➢ Touch field Individual limit adaption.

New limit settings are suggested on a coloured background.

➢ Confirm limit settings by pressing Enter key ↵ on 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

!

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,

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.

10.1.4 Start/stop measurement

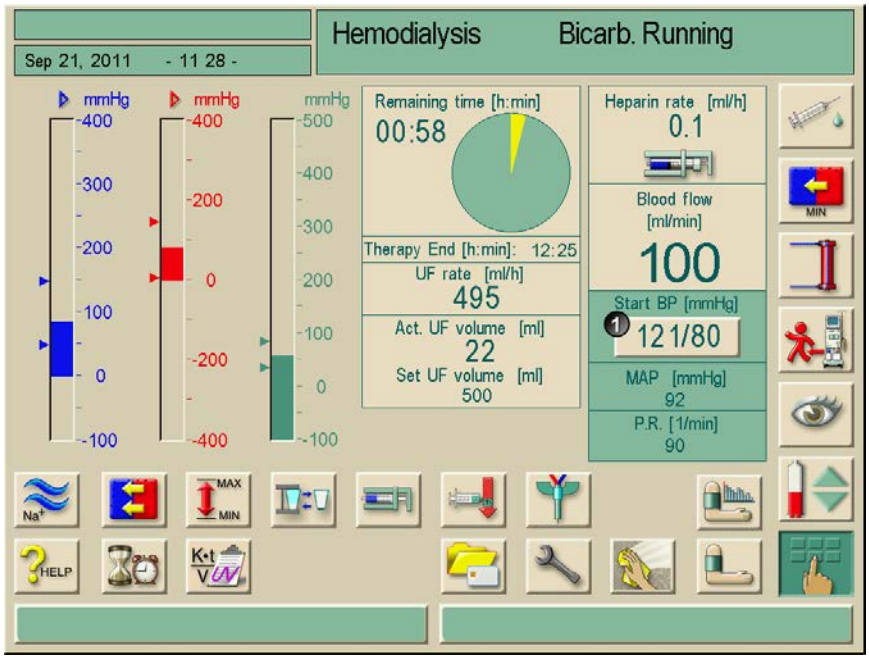


Fig. 10-8 "Therapy" screen

➢ Touch field **1** on the "Therapy" screen (Fig. 10-4) and field **4** in the "ABPM main menu" window (Fig. 10-2).

The last values measured for the systolic and diastolic pressure and the pulse rate are being displayed.

➢ To stop an ongoing blood pressure measurement, touch the respective field again.

10.1.5 Showing and graphically displaying measured values

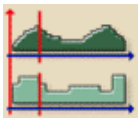
Important!

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.



➢ Touch icon in ABPM main window (Fig. 10-2).

The following screen appears:

Legend

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

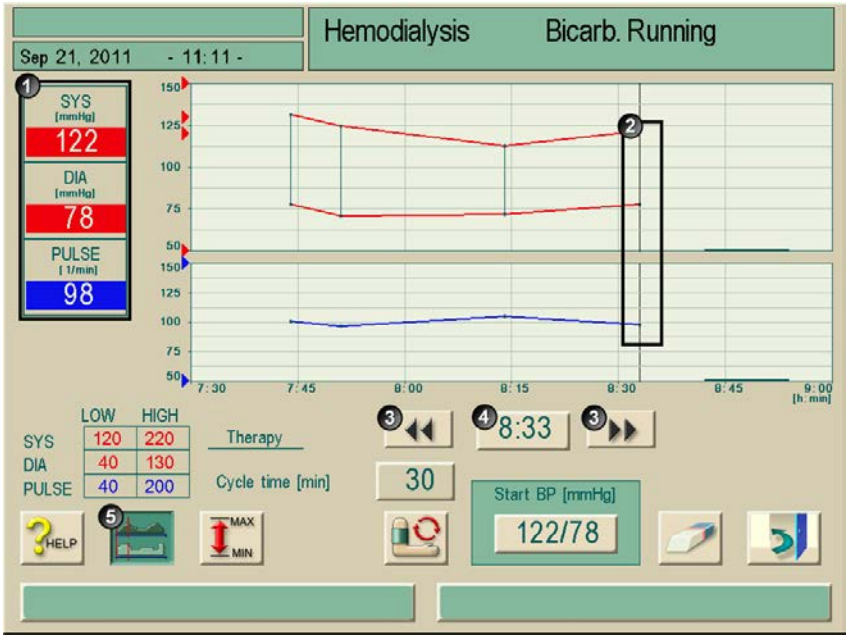


Fig. 10-9 Graphical representation of measured results

There are three different formats for graphic display.

➢ To switch between display formats: Touch number field **1**.

10.2 bioLogic RR Comfort – automatic blood pressure stabilisation with the guideline method

10.2.1 Mode of operation

The automatic blood pressure stabilisation bioLogic RR Comfort is a supplement to the bioLogic RR system. In the previous application the patient's blood pressure is measured in five-minute intervals and interpreted for ultrafiltration regulation.

The new 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 3.5 hours.

The guideline method searches in the saved curves of a patient for that with the best correlation and accepts it as the guideline. This guideline is then used together with the current blood pressure progression for UF control.

At the same time, the system allows the automated extension of the measuring intervals mentioned above to reduce the measuring stress for the patient. In contrast to bioLogic RR, the intervals can be 15, 20 or 30 instead of 5 minutes. The result is a reduction of the measuring frequency by approx. 40 % on average. The measuring intervals are extended depending on the ultrafiltration volume (see Fig. 10-6). If hypotensive crises occur, the extended intervals are reduced again to 5 minutes until the patient's blood pressure has stabilised.

All blood pressure curves are recorded so that a maximum total of 100 curves can be available. The storage medium used is the patient therapy card (see chapter 11). Additional manual RR measurements, e.g. during a longer interval, are taken into account by the system.

The bioLogic RR Comfort option is only available in combination with the ABPM option.

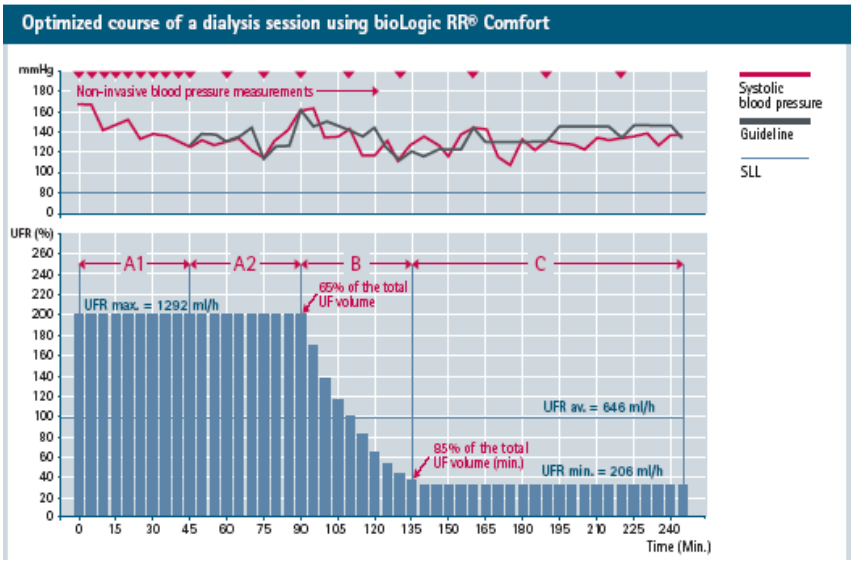
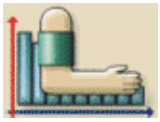


Fig. 10-10 Measuring intervals

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

10.2.2 Setting of systolic blood pressure lower limit (SLL) and maximum ultrafiltration rate



➢ Touch the icon in the “Preparation” or “Therapy” mode.
The following screen is displayed:

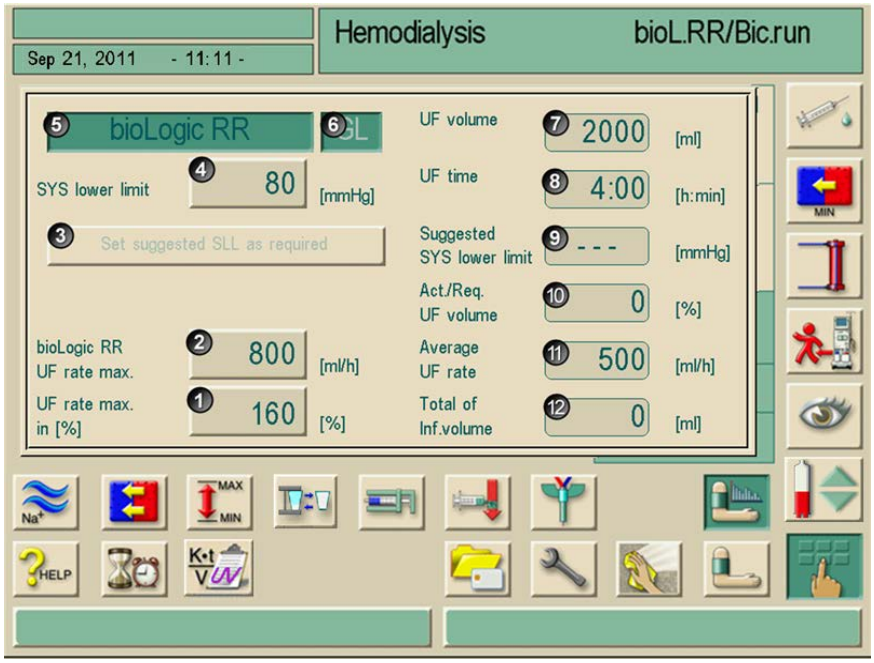


Fig. 10-11 “bioLogic RR Parameter“ screen

➢ Set the parameters for bioLogic RR Comfort according to the following table.

Item	Text	Range	Description
1	Max. UF rate in %	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

! 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

! 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.

i For medical reasons, all values can also be adapted during the therapy.

10.2.3 Setting of suggested systolic blood pressure lower limit (SLL)

- Touch the "Set suggested SLL as required" field. The value shown on button **4**, Fig. 10-7, is accepted.
- Optionally, set a value with button **4**.

!	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.

i	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.

i	The "Set suggested SLL as..." function can be activated/deactivated in the TSM.

10.2.4 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.**

- **bioLogic RR** and **Comfort** fields in the "bioLogic RR Parameter" screen.
- Touch button **6**, Fig. 10-7.

  Depending on the current status, automatic blood pressure stabilisation is started or terminated.

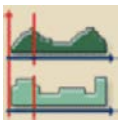
i	Saving blood pressure curves requires the therapy card or the option Nexadia. When the option is used for the first time, it must be activated manually. As from the second usage the guideline function is activated automatically.

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!

10.2.5 Graphical representation of ultrafiltration and blood pressure progression

➢ Touch the icon in the "ABPM Main Overview" screen (Fig. 10-2).
An overview with the icon for graphical representation is displayed.



➢ Touch icon.
The following screen is displayed:

Legend

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 representations

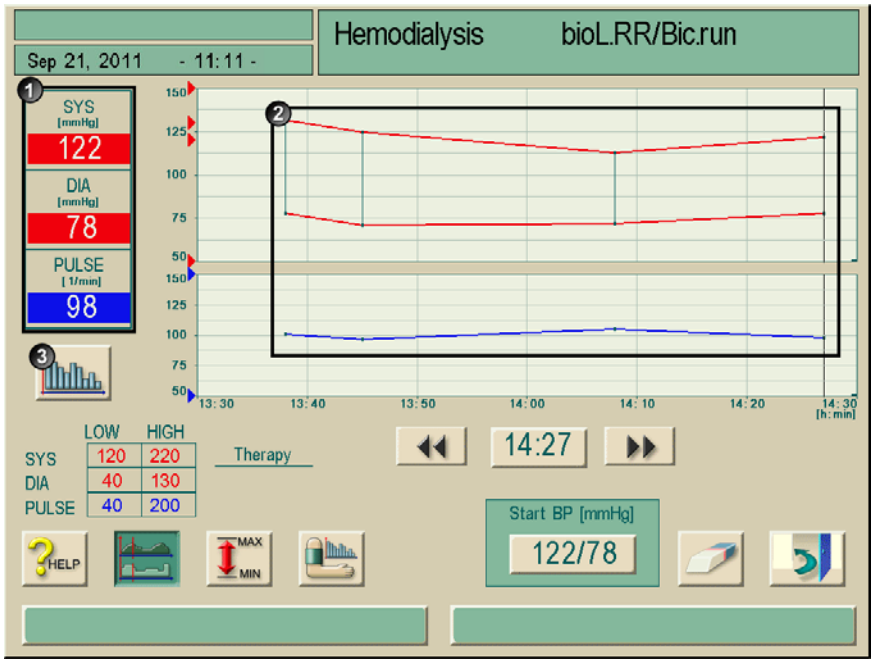


Fig. 10-12 Graphical representation of blood pressure and pulse

➢ Touch icon.

The following screen with the representation of the bioLogic RR parameters is displayed:

Legend

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.

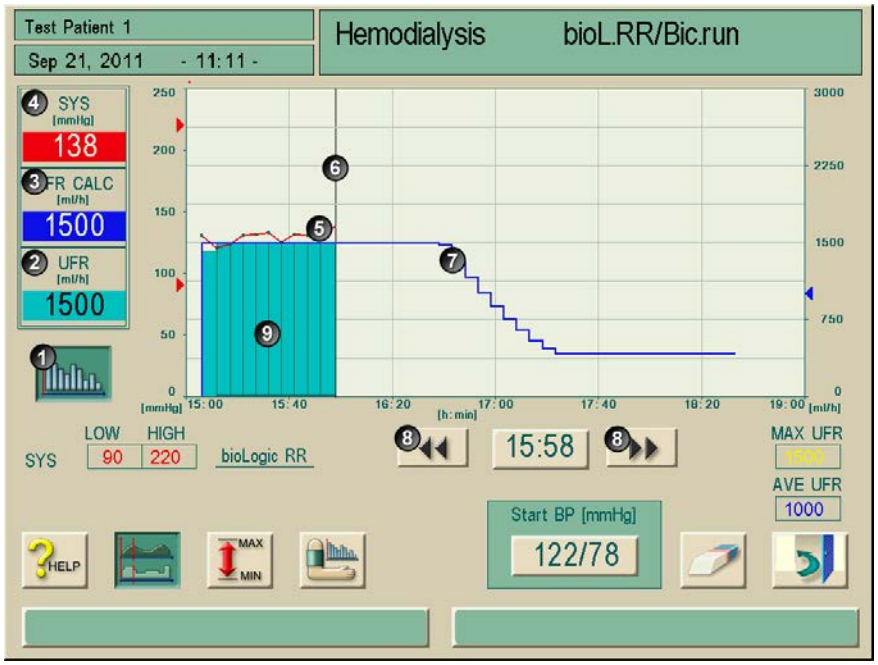


Fig. 10–13 Graphical representation, progression of ultrafiltration

10.3 Adimea

If the option Adimea is selected, the theoretical calculation of the effectiveness as described in chapter 2.8 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 behaviour 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.

10.3.1 Setting the parameters

- Input of patient weight before dialysis (Fig. 10-10, **1**). Setting the parameter enables the calculation and display of Kt/V, URR and UV absorption.
- Input/adaptation of the target Kt/V value (Fig. 10-10, **2**).
- Enable/disable target warning (Fig. 10-10, **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.

Legend

1 Input of patient weight before dialysis
2 Input/adaptation of the target Kt/V value
3 Enable/disable target warning

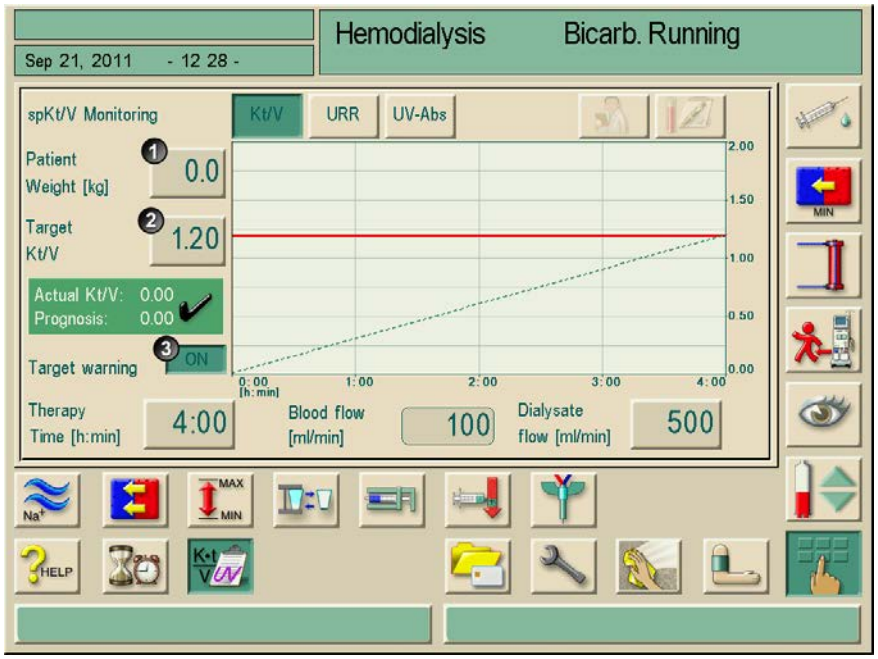


Fig. 10-14 Setting parameters

10.3.2 Graphic representation during therapy

- 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 coloured 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

Legend

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

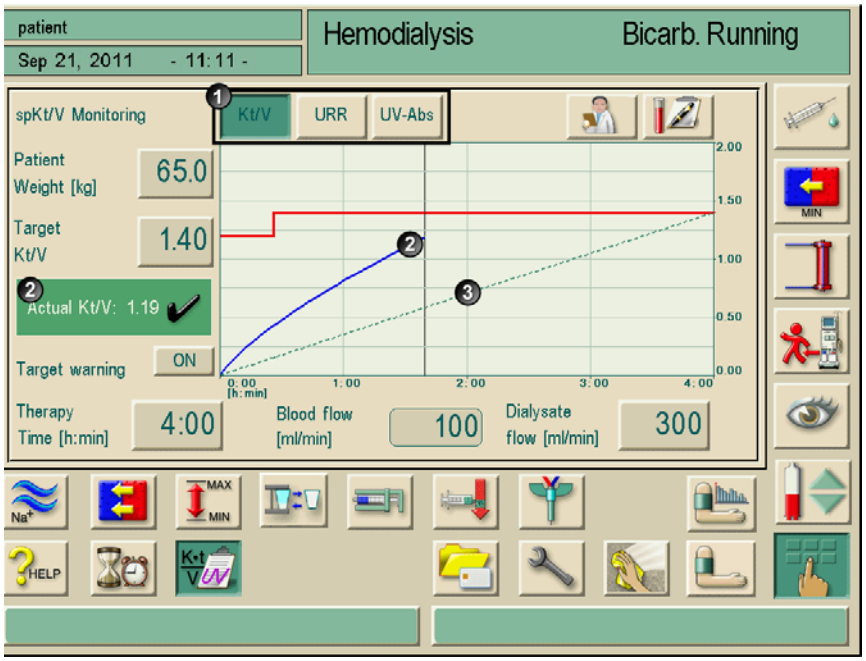


Fig. 10-15 Graphical display

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In haemodialysis (HD) mode the user gets a “prognosis” of the estimated Kt/V value at the end of therapy. It is displayed numerically (Fig. 10-12, 1) and graphically (Fig. 10-12, 2). The blue actual progress line will be extended from the actual therapy status in order to predict the therapy progress.

This functionality is not available in HDF and Single-needle mode.

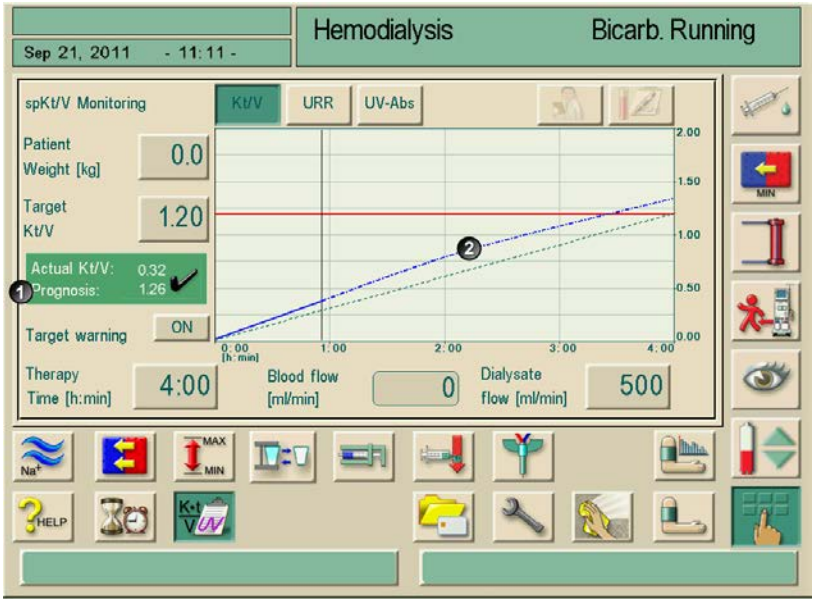


Fig. 10-16 Numerical and graphical display of the prognosis

10.3.3 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. 10-13, 1) has already been below the green dashed orientation line (Fig. 10-13, 2) or if it could fall below it within the remaining therapy time (Fig. 10-14).

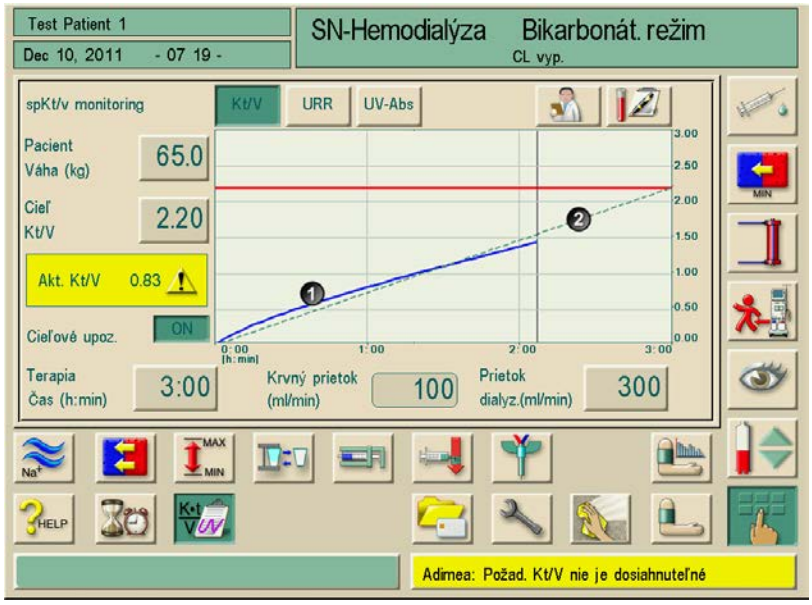


Fig. 10–17 Graphical display of blue actual progress line below green dashed orientation line

In the second case the blue line (Fig. 10-14, 1) will be extended by a red dashed line (Fig. 10-14, 2) predicting that the target value will not be reached.

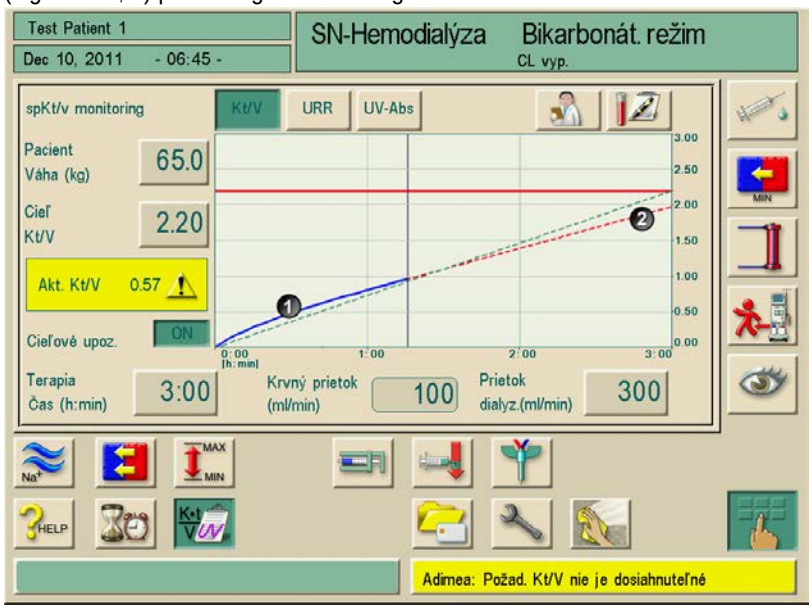


Fig. 10–18 Graphical display of parameters at the end of therapy

➢ Adapt the parameters according to the following table:

	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 the +/- 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.**

10.3.4 Extended functionality when using the patient therapy card

Using the patient therapy 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.

➢ Touch the icon.

Up to 12 completed therapies are displayed:

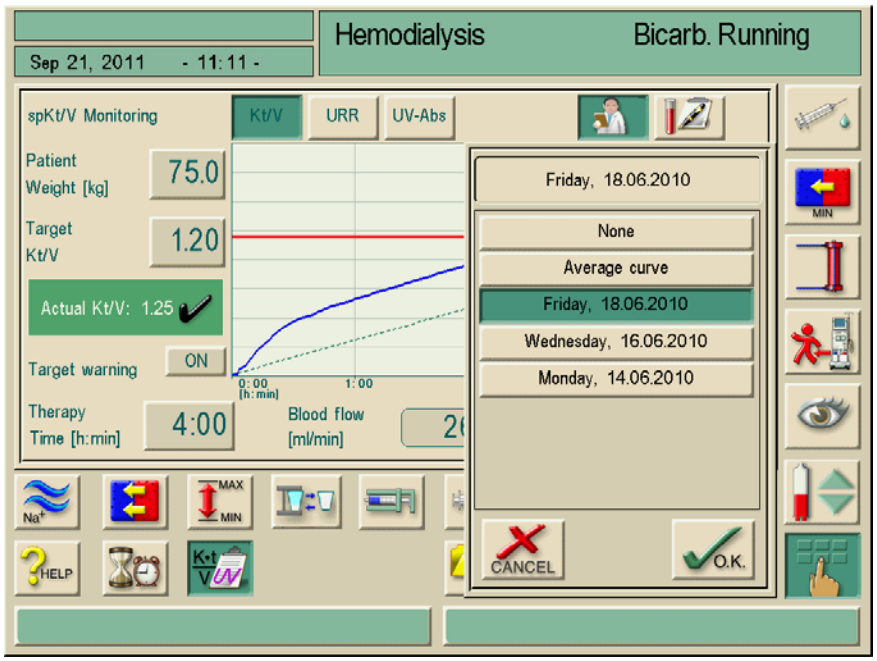


Fig. 10-19 Display of up to 12 stored therapies

➢ By touching one of the displayed therapies the screen showing the black dashed progress line (Fig. 10-16, 1) opens:

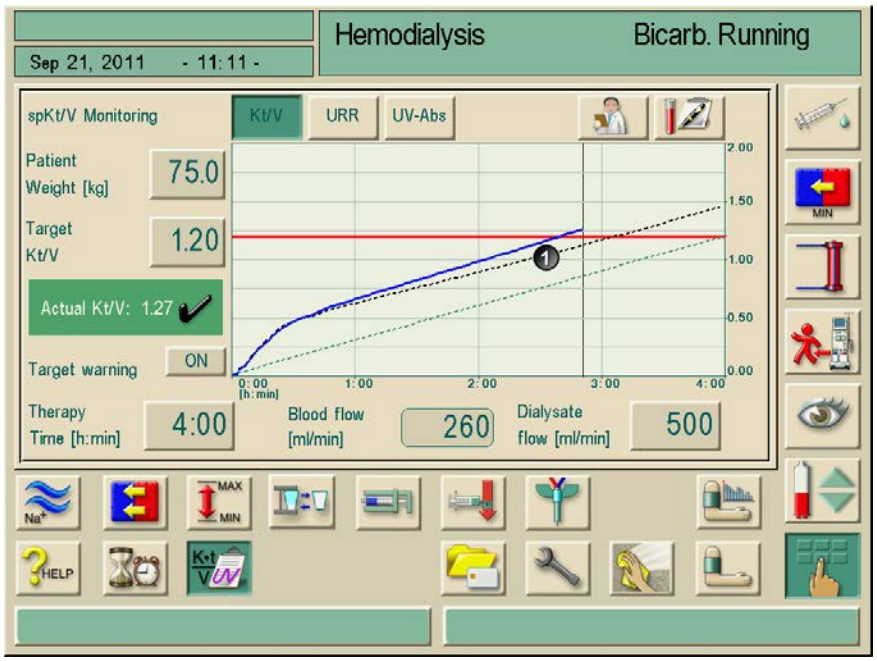


Fig. 10-20 Display of the black dashed progress line

10.3.5 Kt/V table

➢ Touch the icon.
The data are read from the therapy card and displayed on the screen

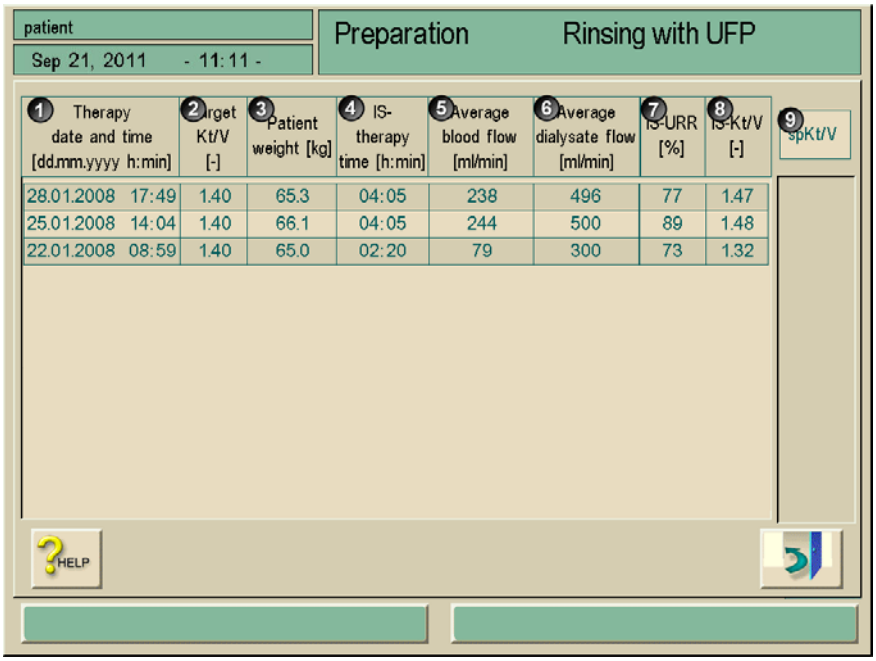


Fig. 10-21 "Kt/V Table" Screen

	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

➢ Touch the icon to exit the display.

10.4 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.

10.4.1 Inserting the cartridge

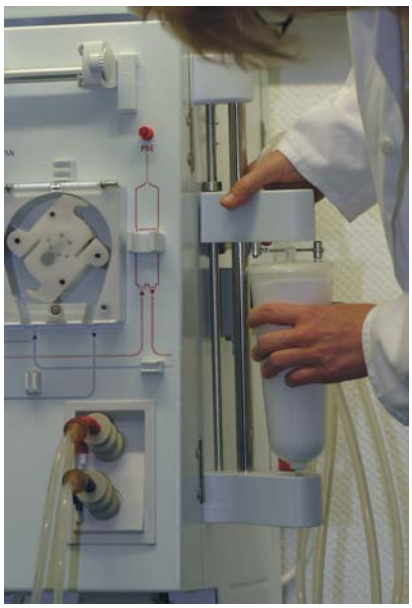


Fig. 10-22 Inserting a cartridge

- ➢ Press in lateral button at top fixing and pull up top fixing as far as possible.
- ➢ 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!

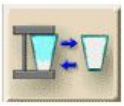
➢ **When closing the cartridge holder do not bruise hands or fingers!**

➢ To close the cartridge holder, press top fixing centrally onto the cartridge.
The cartridge is pierced, automatically vented and filled with permeate.

10.4.2 Changing the cartridge during dialysis

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



➢ Touch icon.

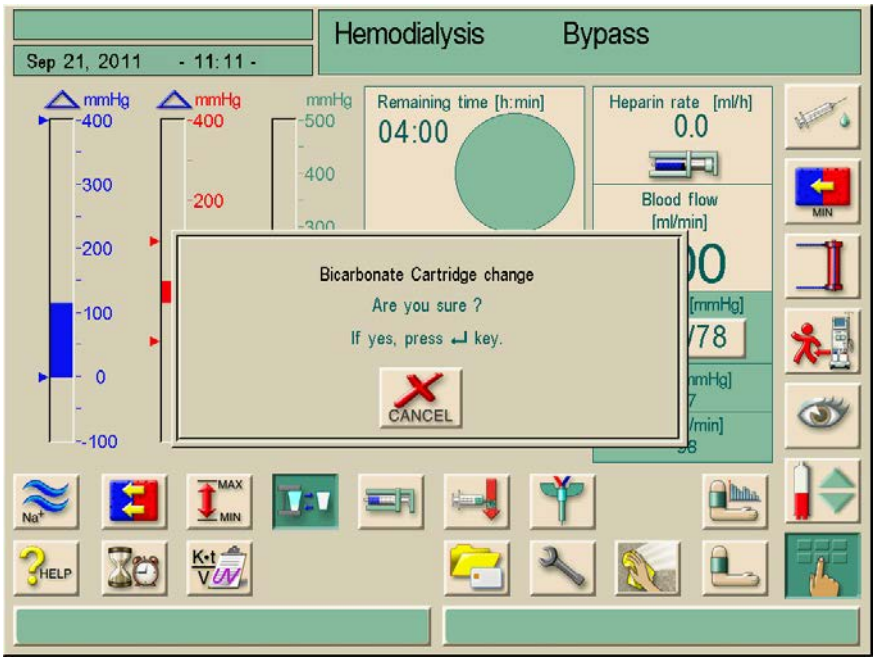


Fig. 10-23 Bicarbonate cartridge change

➢ A confirmation window appears, confirm by pressing the Enter key ↵.
The cartridge will be drained (in case TSM Bic cartridge **with** draining is selected).

An information window appears after some seconds.

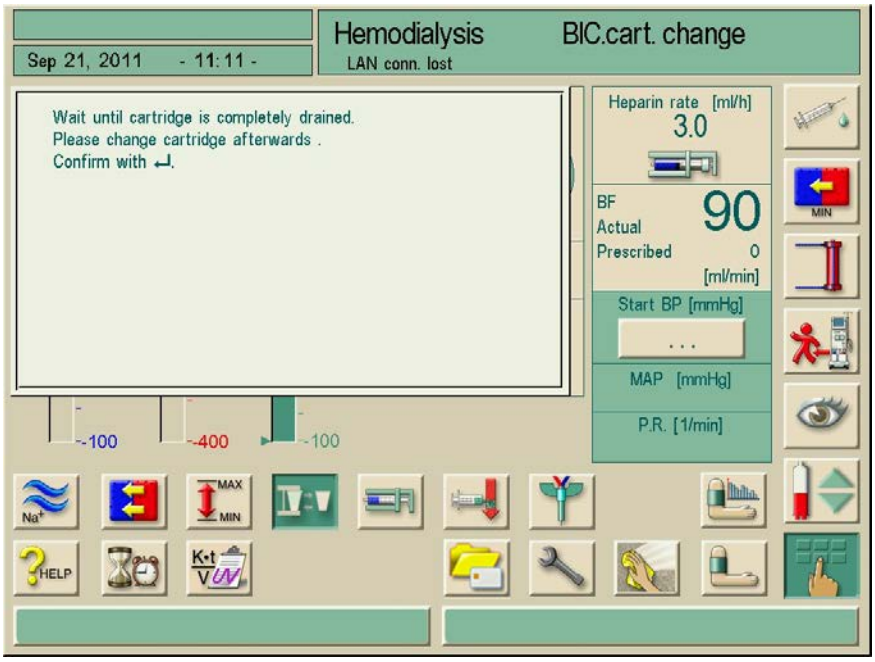
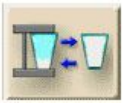


Fig. 10-24 Bicarbonate cartridge change with draining

- Insert new cartridge.
- After inserting the new cartridge, confirm by pressing the Enter key ↵ .
  The machines prepares the new Bic cartridge.

Without draining



➢ Touch icon.

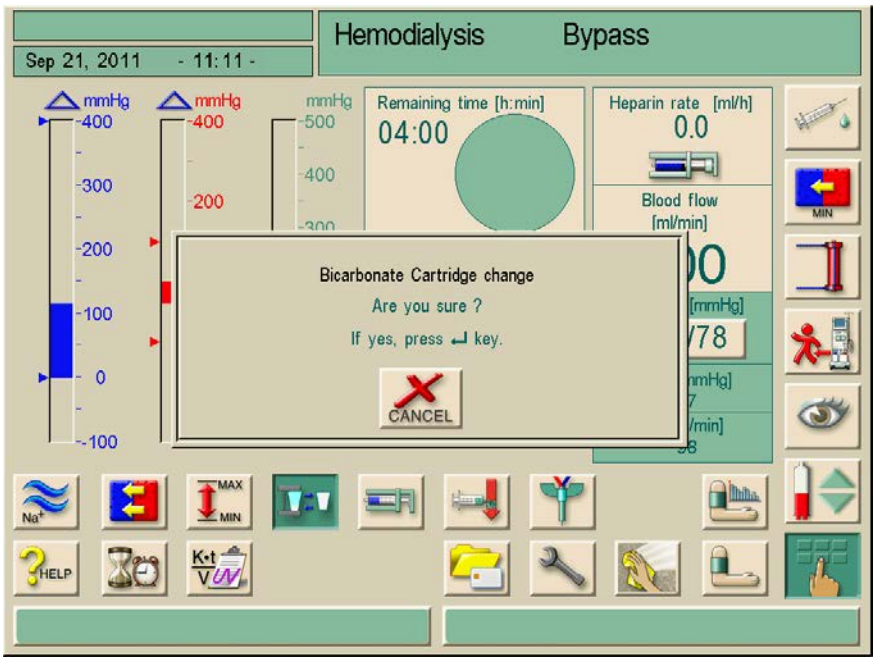


Fig. 10-25 Bicarbonate cartridge change

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➢ 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.

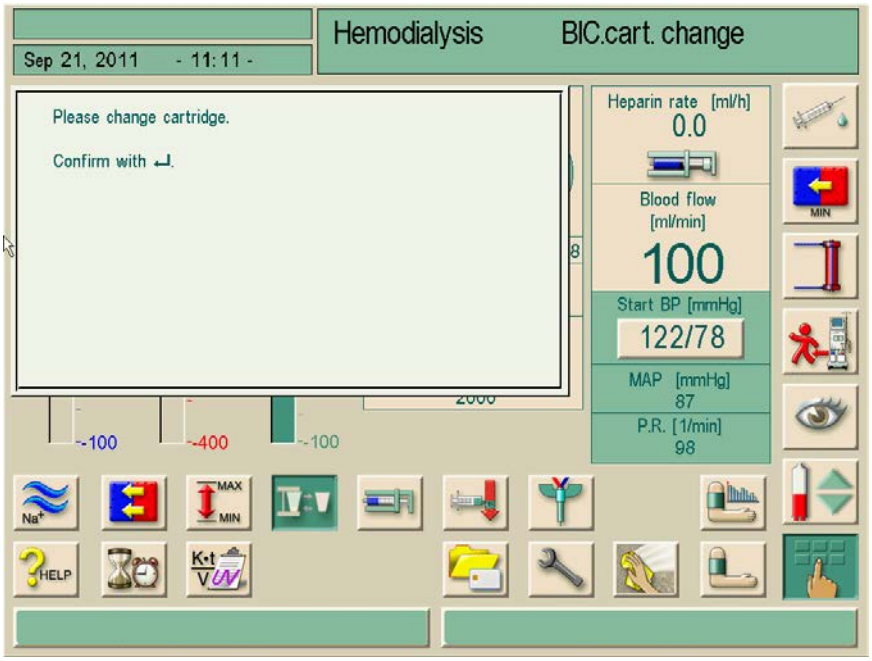

Fig. 10-26 Bicarbonate cartridge change without draining

10.4.3 Emptying the cartridge after dialysis

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

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The functions "Empty dialyser" 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 dialyser or the rinsing bridge.

If the blue coupling is connected to the rinsing bridge, the dialyser is emptied.

10.5 Central concentrate supply

Fig. 10-27 "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.

- 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 colour-coding!

The concentrate connections of the dialysis machine are, thus, directly connected to the wall connections of the central concentrate supply.

10.6 Dialysis fluid filter

10.6.1 Use and mode of operation

The dialysis fluid filter is a hollow-fiber filter. It is used for performing haemodialysis 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.


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.**

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.

The dialysis fluid filter may only be operated with permeate or dialysate.

The dialysis fluid filter must be changed at the latest when the following warning window is displayed on the screen:

Fig. 10-28 "Filter change" warning window

10.6.2 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.

The number of hours or therapies is set by the technician in the TSM. It is recommended to change the filter after 150 therapies or 900 operating hours.

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, see figure 10-25)

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.**

➢ Touch icon.
A screen is displayed.

➢ Touch icon.
The following screen is displayed:

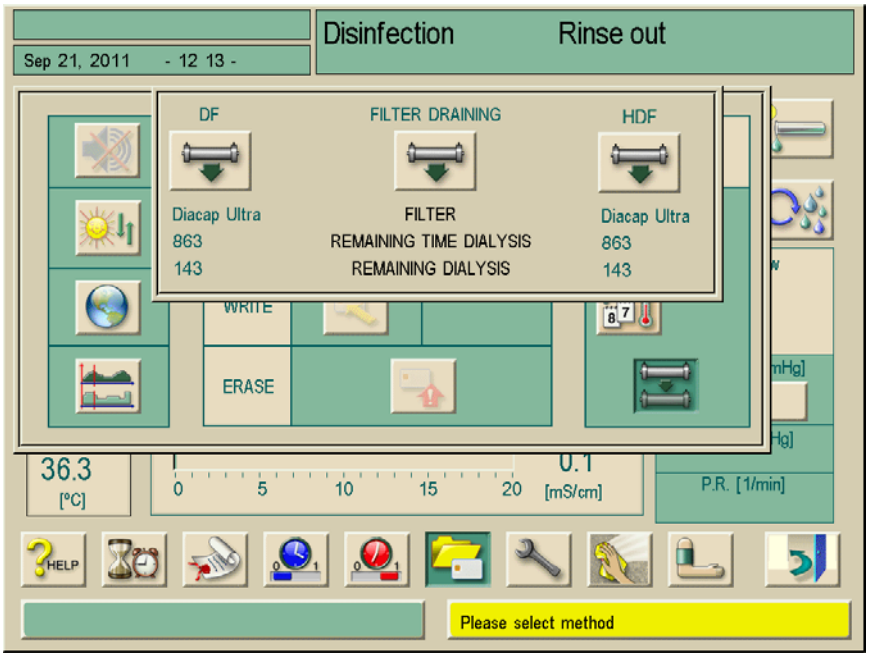


Fig. 10-29 "Filter draining" warning window

The remaining dialysis time and the number of performed dialyses are displayed.

➢ Touch the "FILTER DRAINING" icon.
A prompt to remove the dialyser feed connector is displayed.

➢ Remove the dialyser feed connector.
The filter is drained and vented. After approx. 90 s, the message "DF filter drained" is displayed.

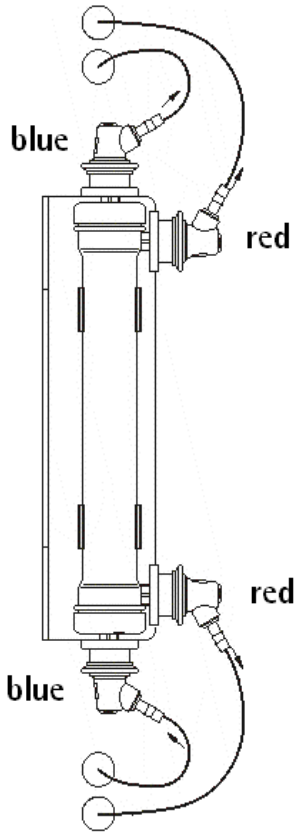


Fig. 10-30 Dialysis fluid filter change

- Remove all couplings (red and blue) from the filter. Catch the fluid escaping in the process.
- Hold old filter centrally and remove it from the clamping brackets of the filter holder.
- Hold new filter centrally and press it into the clamping brackets of the filter holder.
- Push blue couplings onto dialysate couplings on the filter caps.
- Push red couplings onto lateral dialysate connections.
- Reset data with the dialysis machine switched on.

After filter installation/change

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 dialyses data must be reset, see section 10.6.3.

10.6.3 Resetting the data

Preconditions

- The dialysis machine is switched on.
- The disinfection selection screen is displayed.

➢ Touch icon.
A screen appears.

➢ Touch icon.
The following screen appears:

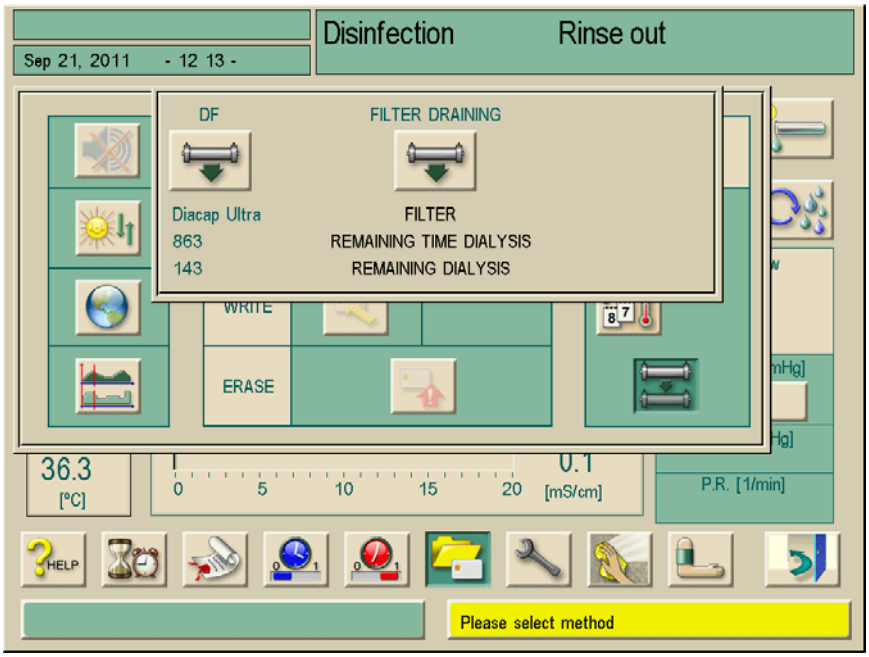
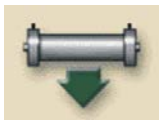


Fig. 10-31 "Select Disinfection" screen with active window "Filter change"



➢ Touch icon to reset operating time and number of dialyses.
➢ Confirm query by pressing the Enter key ↵ on the monitor.

10.6.4 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)

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.**

!

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.**

10.6.5 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:

- Prepare the equipment.
- Start therapy (without patient, no bypass).
- Disinfect the injection socket in the sample port.
- Connect the Luer syringe to the injection socket.
- If required, switch off the TMP limiting value window.
- Slowly withdraw the sample with a suitable syringe with a Luer connector.
- Place the sample taken into a suitable container. Avoid contact with the container.
- Terminate the therapy.
- Disinfect the equipment.

Legend

1 Sample port with injection socket
2 Dialyser coupling with closed membrane port

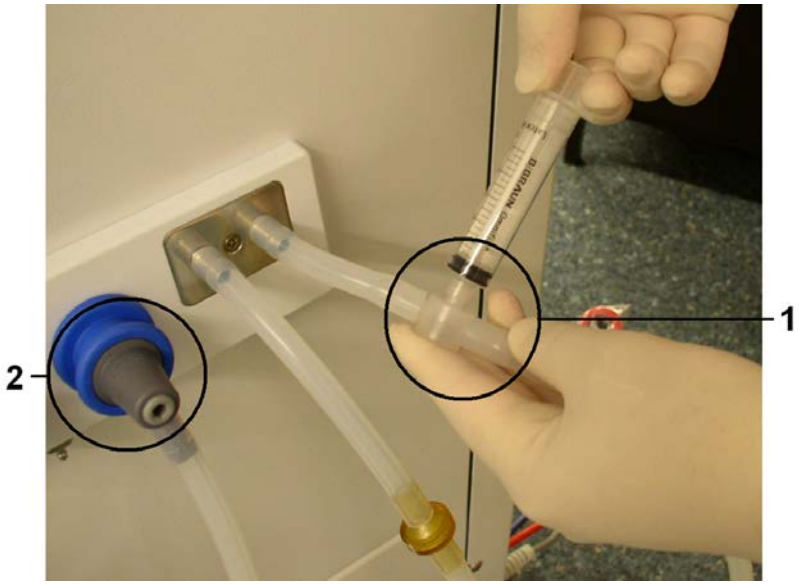


Fig. 10-32 Sample port

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:

- Once the conductivity of the dialysate has stabilised (after approx. 5 minutes), disinfect the sample port.
- Slowly take a sample from the sample port at the dialysis fluid DF tubing, using a small syringe, e.g. a 2 ml syringe (see Fig. 10-28).
- Analyse 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.**

10.7 Emergency power supply/battery

The battery operation mode serves for maintaining the extracorporeal blood circulation in case of a mains power failure.

In such event, 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.

This message must be confirmed.

Active functions during battery operation

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 monitoring
- Single-needle operation
- Arterial bolus with 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:

- Dialysate treatment
- Ultrafiltration
- Substitution, for HDF/HF-online
- Bolus administration, for HDF/HF-online
- Emptying the dialyser 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 function 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.

10.7.1 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.

10.7.2 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.).**

10.7.3 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.

10.8 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.

10.8.1 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.

10.8.2 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.

10.8.3 Staff call

The staff call is used for integrating the dialysis machine into an existing staff call system.

!

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.

10.9 Crit-Line Interface

10.9.1 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:

- Haematocrit 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 Therapy Card and can be recalled as trends.

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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 the 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 equalisation connecting the Crit-Line unit to an installed potential equalisation pin in the dialysis centre if catheter patients are treated.**
- **Place the Crit-Line mains adapter in a dry area.**
- **Do not connect the Crit-Line potential equalisation 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 haematocrit 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. haematocrit 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 DialogP+P 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!**

10.9.2 Set-up and connection with the Dialog+

- Attach the cuvette between the arterial line and the dialyser.
- 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:
  - Connect potential equalisation cable (Art. No. 7106605) to potential equalisation bolt on the back of the Crit-Line unit.
  - Connect other end of the potential equalisation cable to the facility potential equalisation connector.
- Connect power plug of Crit-Line unit to wall or operate the unit on battery.
- Plug in and tighten the Crit-Line unit serial adapter RS232 socket with the DSI interface RS232 plug of the Dialog+.
- 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™.

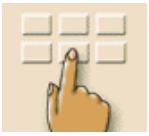
WARNING

Hazard of incorrect Delta BV value during therapy!

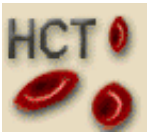
- **If the unit is switched on during therapy mode, the software calculates the relative blood volume based on the first valid haematocrit value which results in an incorrect Delta BV value.**
- **Start the measurement immediately after therapy start.**

10.9.3 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.



- Touch the icon in the “Preparation“ or “Therapy“ mode.
- The settings overview is displayed.



- Touch the icon.
- The Crit-Line main screen is displayed.

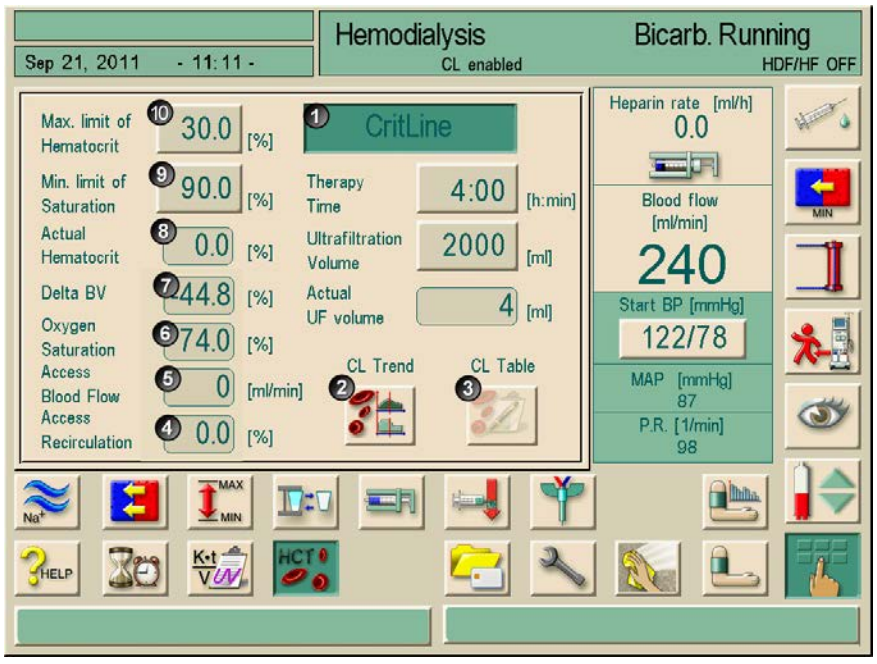


Fig. 10-33 Crit-Line Main Window

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 Therapy 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 haematocrit (HCT)	20-70 %	Display of currently measured haematocrit value (in %)
9	Min. limit of saturation	55-100 %	Display of lower oxygen saturation limit (in %)
10	Max. limit of haematocrit	20-70 %	Display of upper haematocrit 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 haematocrit 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.

➢ Touch the icon.

➢ Touch the icon.

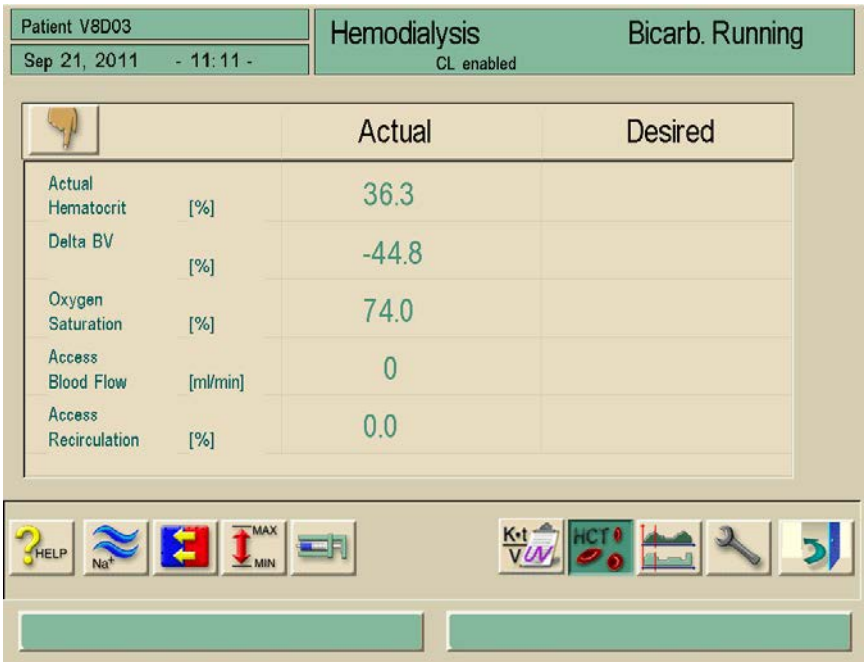


Fig. 10-34 Crit-Line Overview

10.9.4 Graphical presentation of trends

When button 2 in Fig. 10-29 touched, the trends of haematocrit, 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 group can be edited by touching the trend button (5) (see chapter 11.10).

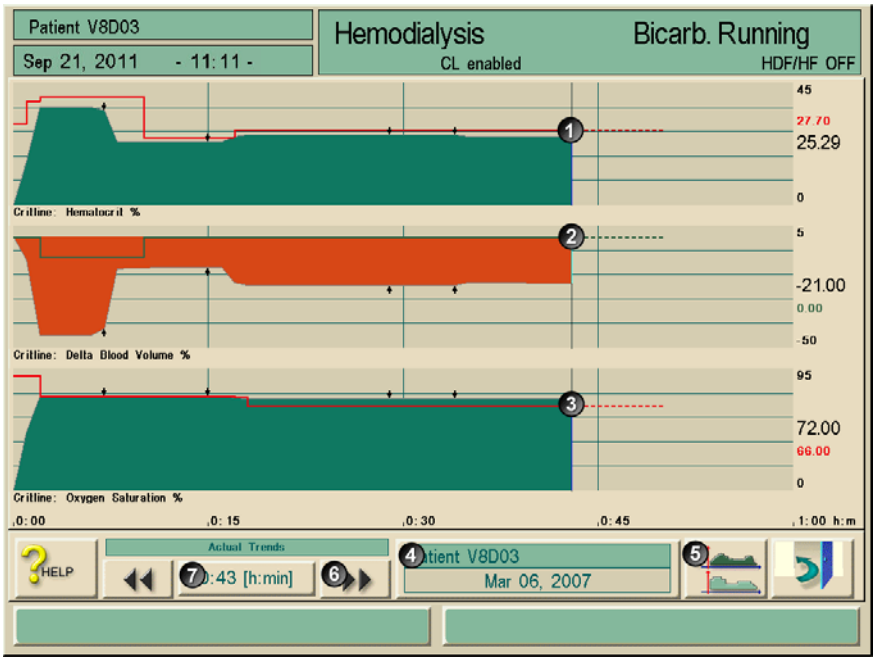


Fig. 10-35 Crit-Line Trends

The haematocrit and Delta BV limits are also displayed. The HCT limit (1) corresponds to the value set in Fig. 10-29 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:

➢ Directly enter the time (7) in the Time window.

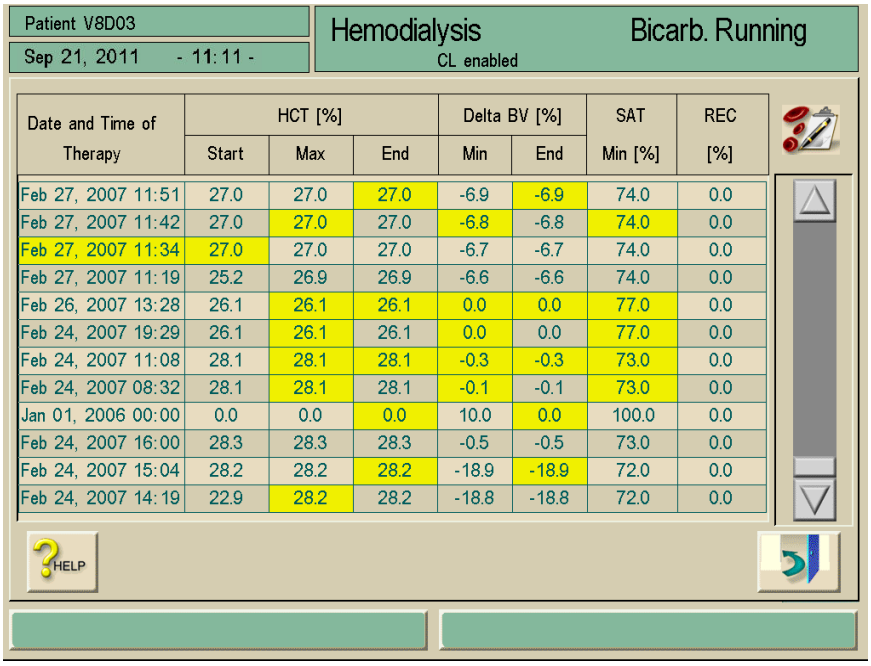
2nd option:

➢ Move the time reference line by using the icons << or >> (6).

10.9.5 Reading of the data from the patient therapy card

Touch button 3 in Fig. 10-29 The saved data are read from the patient therapy card and displayed. The table saves up to 50 Crit-Line progressions and includes the following parameters:

- Date and time
- Haematocrit: Start value, maximum, end value
- Delta BV: Minimum and end value
- Oxygen saturation minimum
- Recirculation



Date and Time of Therapy	HCT [%]			Delta BV [%]		SAT	REC
	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. 10-36 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

11 Configuration

11.1 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.

Legend

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

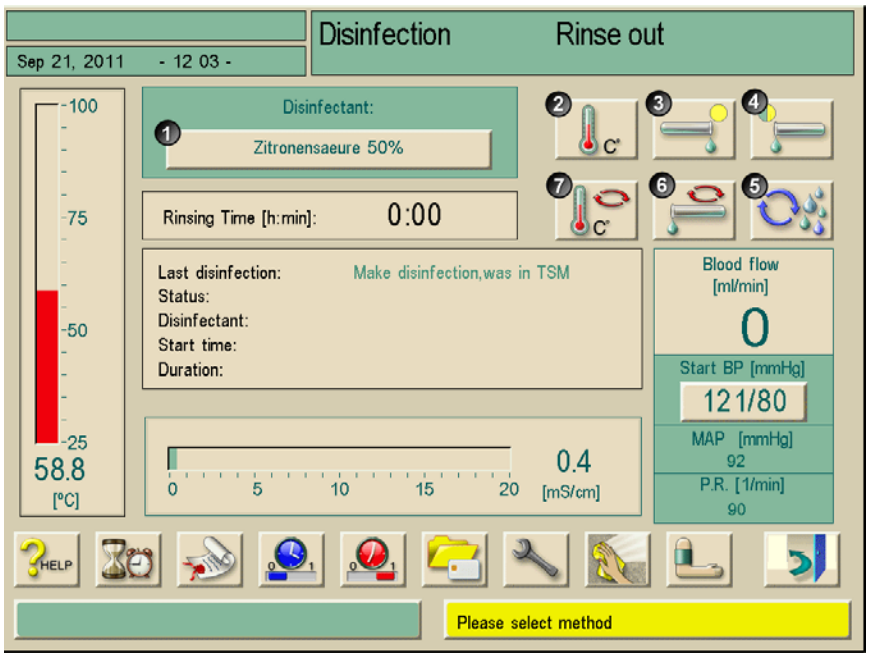


Fig. 11-1 Selection of disinfection program

➢ Touch icon in Disinfection mode

A window will open.

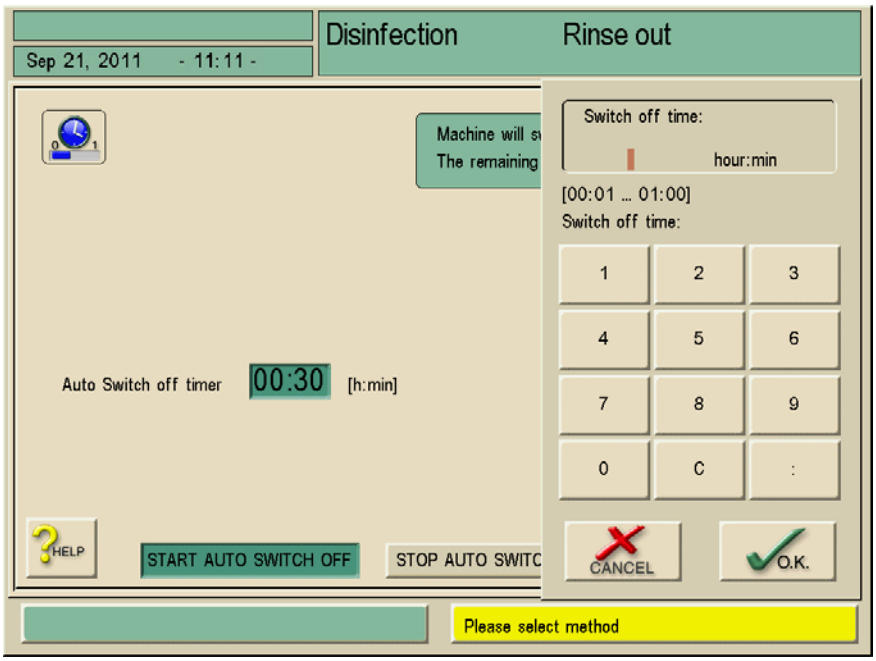


Fig. 11-2 "Auto Switch-Off" screen

- Set time by using the number buttons.
- Accept time by touching icon **O.K.**
- To start program, press the **Start Auto switch off button**.
- To change the time-out, enter anytime in Disinfection Selection or Disinfection.
- To stop the program, press the **Stop Auto switch off button**.

!	Leave mains switch of dialysis machine switched on. Ensure that sufficient disinfectant is connected.

11.2 Weekly disinfection program

The weekly program “Weekly disinfection program” simplifies the configuration of the operations.

➢ Touch icon in Disinfection mode (see **Fig. 11-1**).
The following window opens:

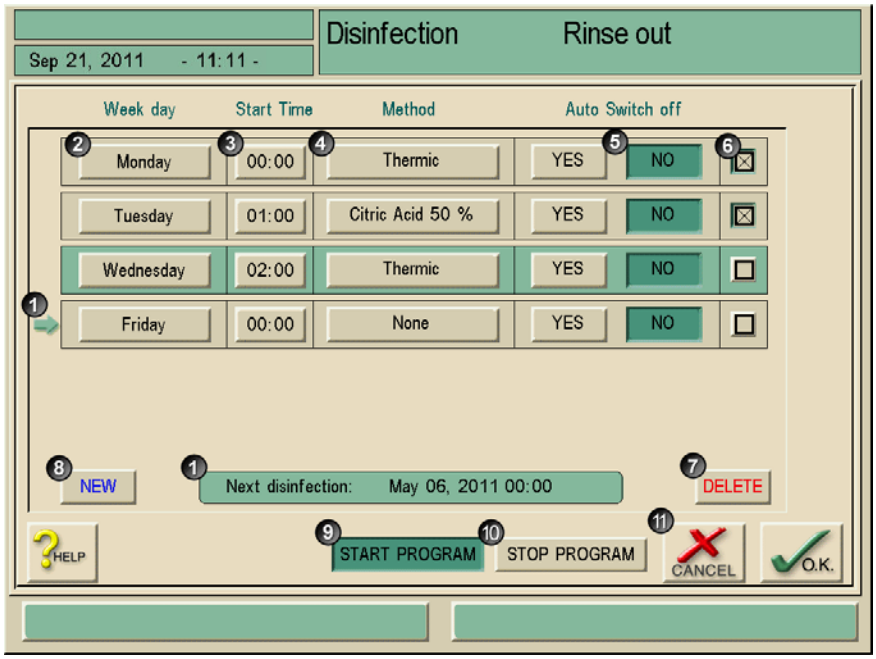


Fig. 11-3 Scheduled auto disinfection screen

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

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	-	Mark rows 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

! Leave mains switch of dialysis machine switched on.
Ensure that sufficient disinfectant is connected.

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

11.3 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.

➢ Touch icon on disinfection screen.

The weekly disinfection program screen is displayed.

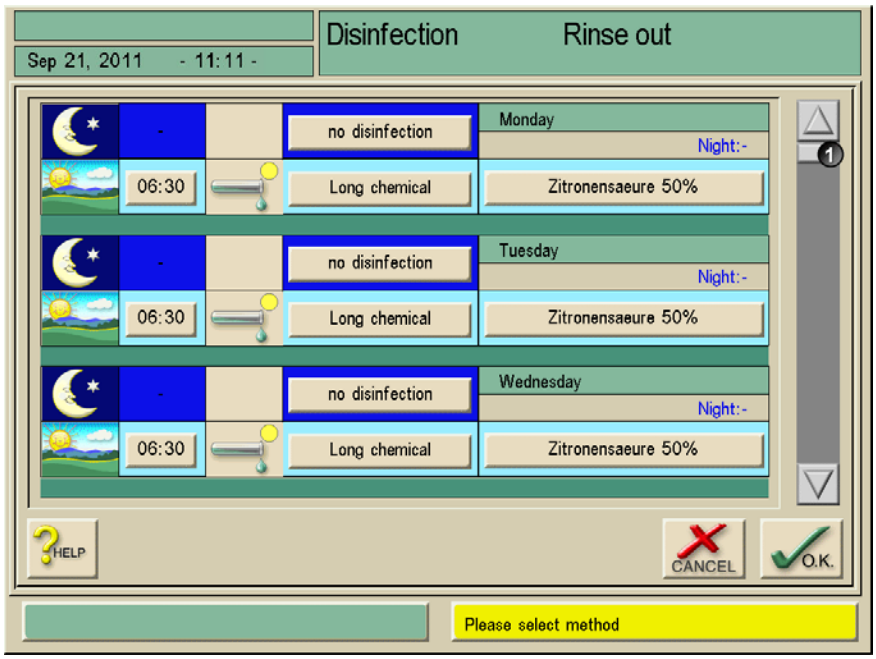


Fig. 11-4 Weekly disinfection program (Example)

Fig. 11-4 shows the set-up for the following disinfection modes:

Day/time	Description
Monday	
0.00 hrs.	A thermal, central disinfection is carried out. The machine switches on automatically and off again after disinfection.
6.30 hrs.	A chemical disinfection with citric acid 50 % is carried out. The machine remains switched on after disinfection.
Tuesday	
0.00 hrs.	The unit is rinsed from the central water supply. The machine switches itself on automatically and off again after rinsing.
6.30 hrs.	A chemical disinfection with citric acid 50 % is carried out.
Wednesday	
During night	No disinfection is carried out.
6.30 hrs.	A chemical disinfection with citric acid 50 % is carried out. The machine remains switched on after disinfection.

➢ Use scroll bar **1** to move to other weekdays.

➢ 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)

i

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.

11.4 Configuring profiles

11.4.1 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.

11.4.2 Setting profile parameters

The setting of the parameters is explained using the conductivity (Na^+) profile as an example.

Legend

1 Profile settings
2 Enter therapy parameters
3 Heparinisation data
4 Pressure limits
5 Ultrafiltration data
6 Dialysate parameters

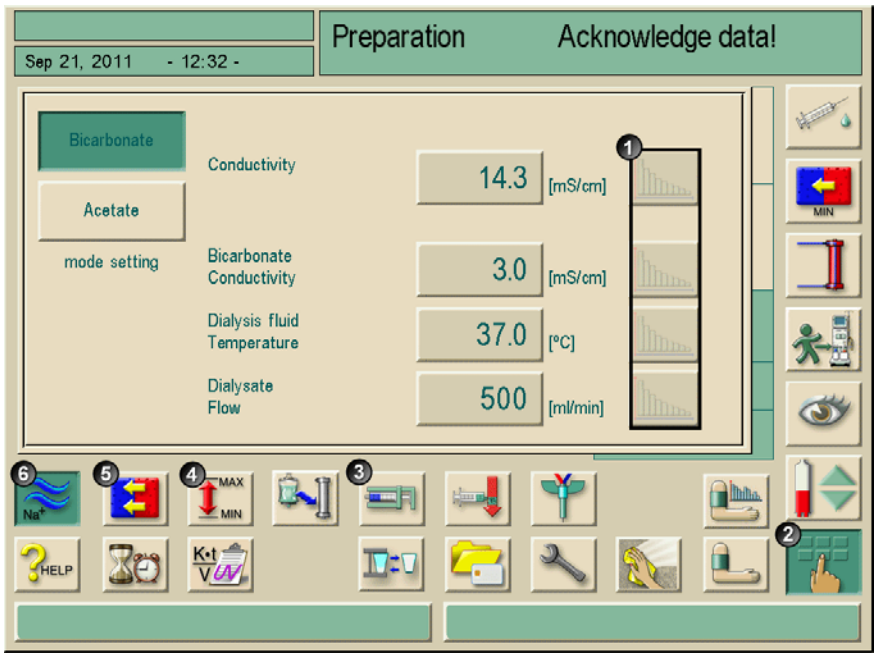


Fig. 11-5 "Conductivity" screen

➢ Touch icon **2**.
➢ Touch icon **6**.
➢ Touch icon **1**.

Legend

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

The following screen appears:

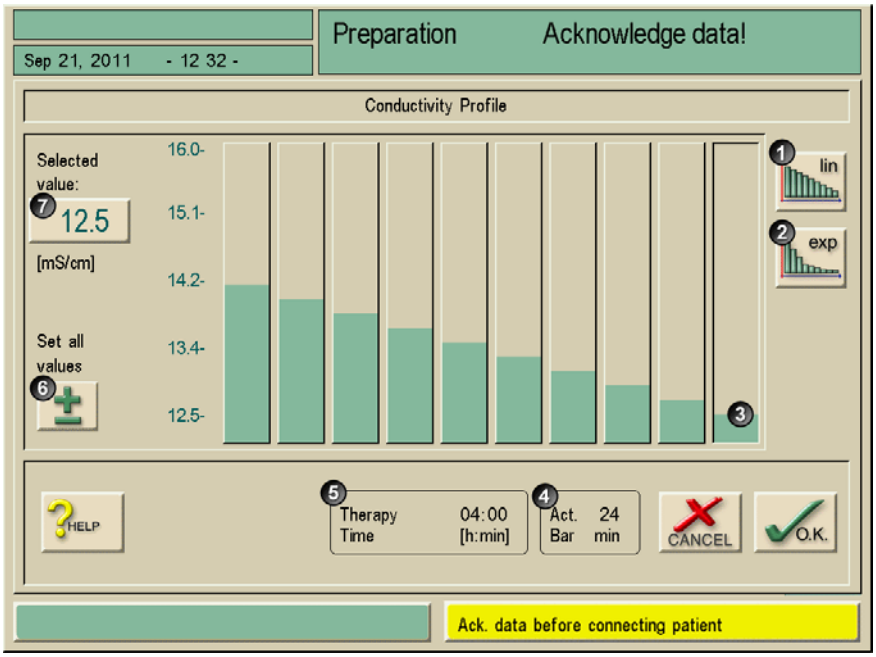


Fig. 11-6 "Profile parameters" screen

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

- Adjust values by moving each parameter bar **3** on the touch screen, using your finger.

Option 2: Direct entry

- Touch the parameter bar to be adjusted.
- Touch icon **7**.
- Enter value directly via the keypad or through icons **+/-**.
- Accept value by touching icon **O.K.**

Option 3: Automatic (linear/exponential) distribution

- Select first parameter bar.
- Touch icon **7**.
- Enter value via keypad and confirm with icon **O.K.**
- Select last parameter bar.
- Touch icon **7**.
- Enter value via keypad and confirm with icon **O.K.**
- 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.

- Positioning the finger at the first or last bar.
- Move the finger over all bars along the desired developing profile.

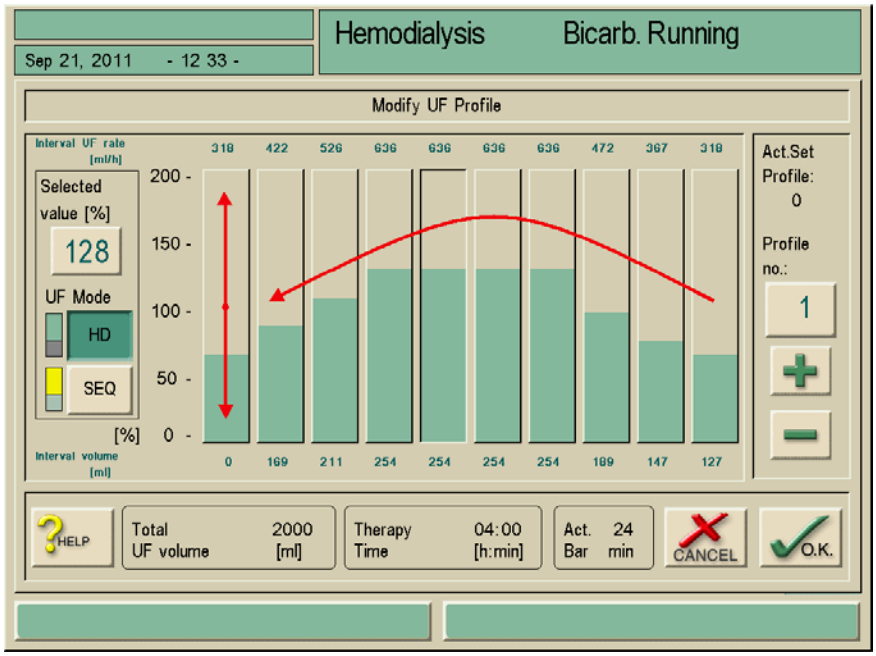


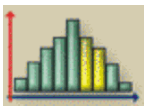
Fig. 11-7 Edit profile

11.5 UF profiles

11.5.1 Select UF profiles

Apart from the individual settings, the dialysis machine offers standardised ultrafiltration profiles. As another option, an individual UF profile can be preselected at any time and stored on the patient therapy card or via BSL after the dialysis therapy. The profile table contains descriptions to the different profiles.

➢ Touch icon.
The "UF parameters" screen appears.



➢ Touch icon.
The "UF profile" screen appears.
The UF rate setting is specified above each parameter bar.

Legend

1 Profile number
2 Next profile number
3 Previous profile number
4 UF without dialysate (sequential therapy)
5 UF with dialysate

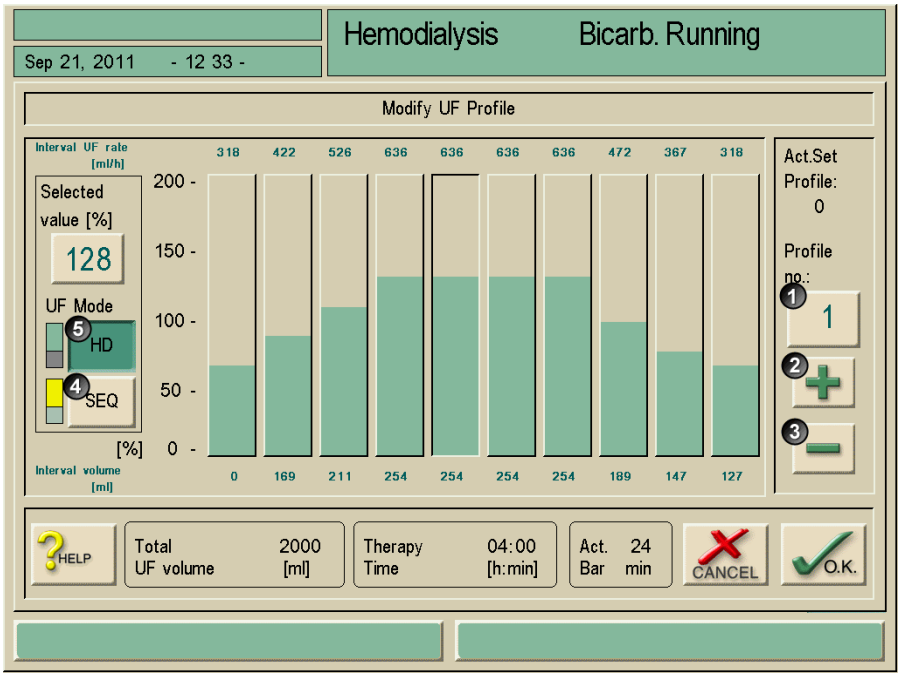


Fig. 11-8 "UF profile" screen

➢ Touch icon **2** or **3** to select other UF profiles.

Apart from the even ultrafiltration profile (profile 0), nine other UF profiles are available.

➢ Touch icon **4** or **5** to change from "Dialysate flow (HD)" mode to sequential therapy (SEQ).

The sequential phase is highlighted in yellow.

11

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

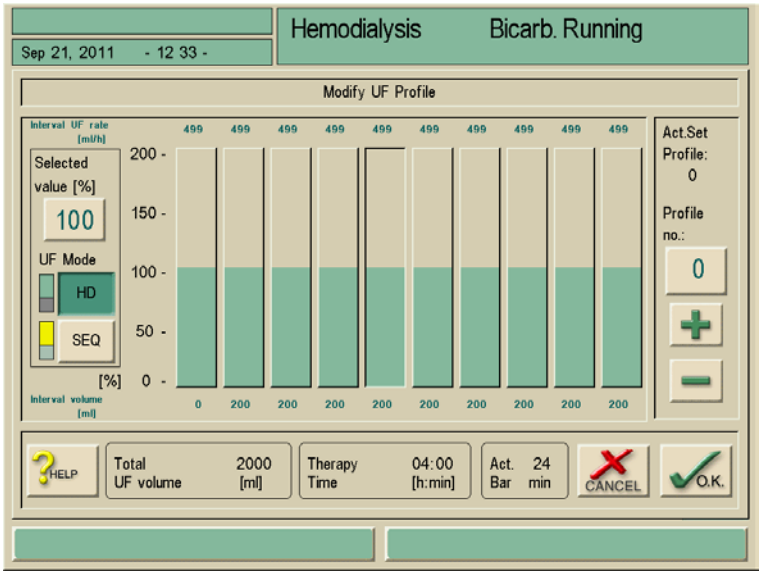
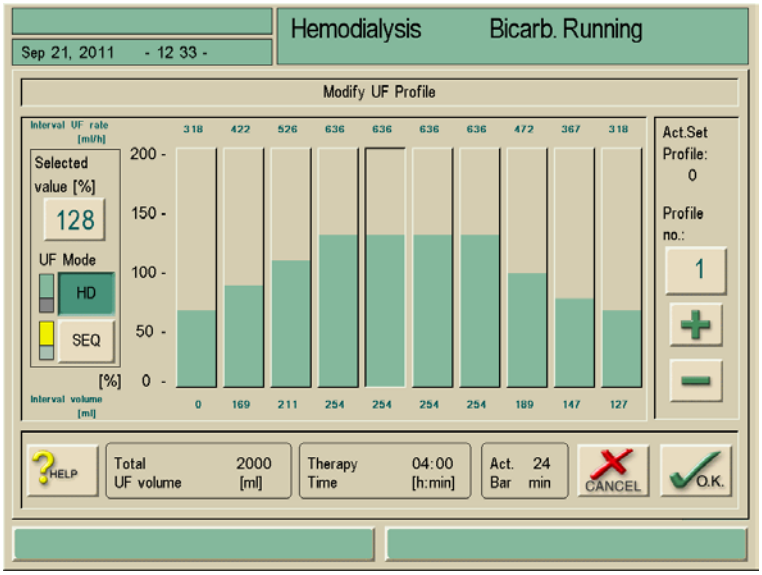
Risk of cardiovascular instability through high UF exposure!

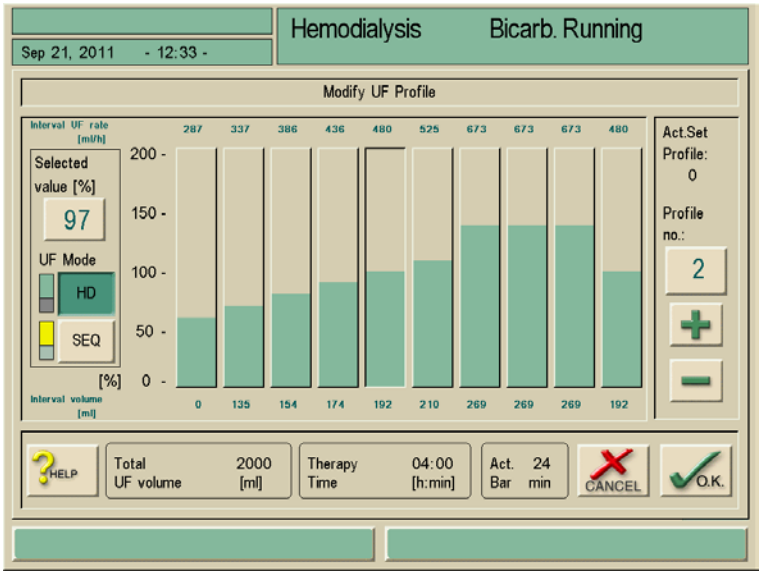
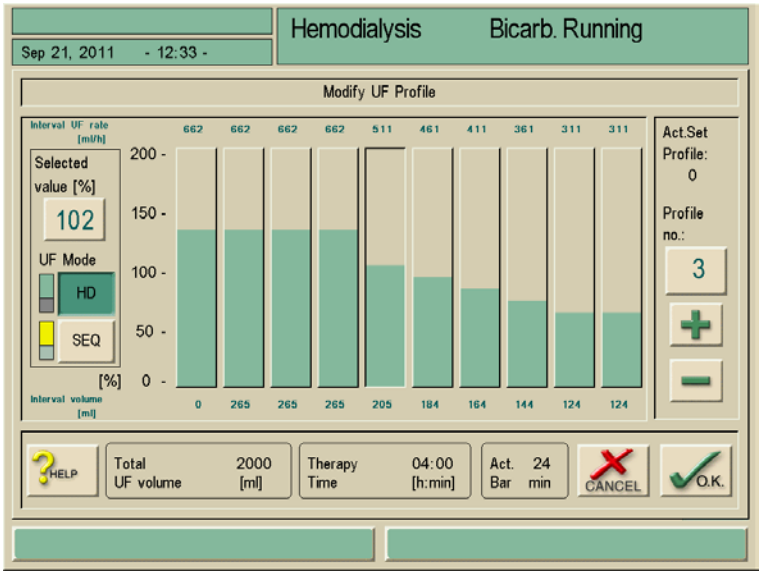
➢ **Regard to the patients individual constitution by adjusting the UF profile.**

➢ **The responsible physician should be informed.**

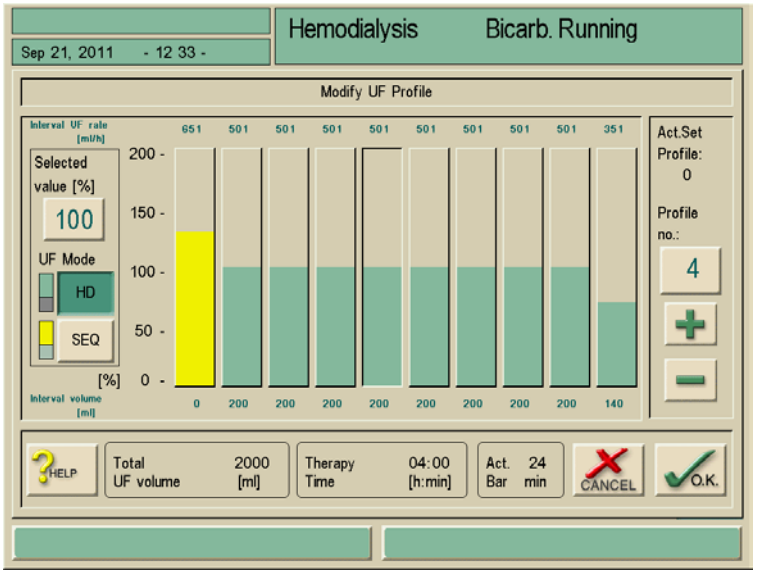
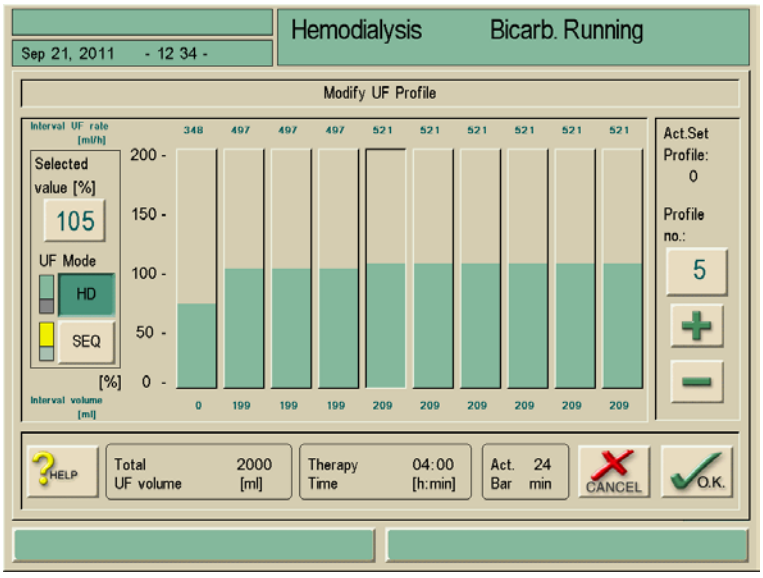
During automatic calculation, the last bar is adjusted depending on the total value.

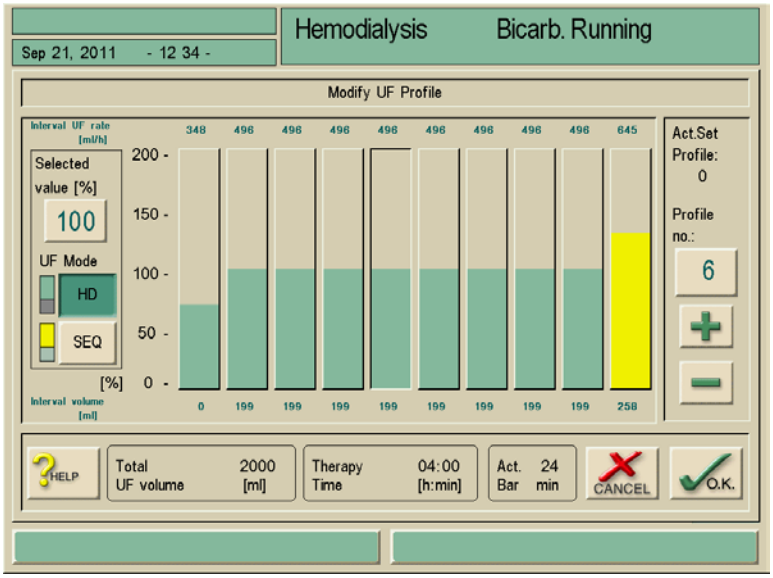
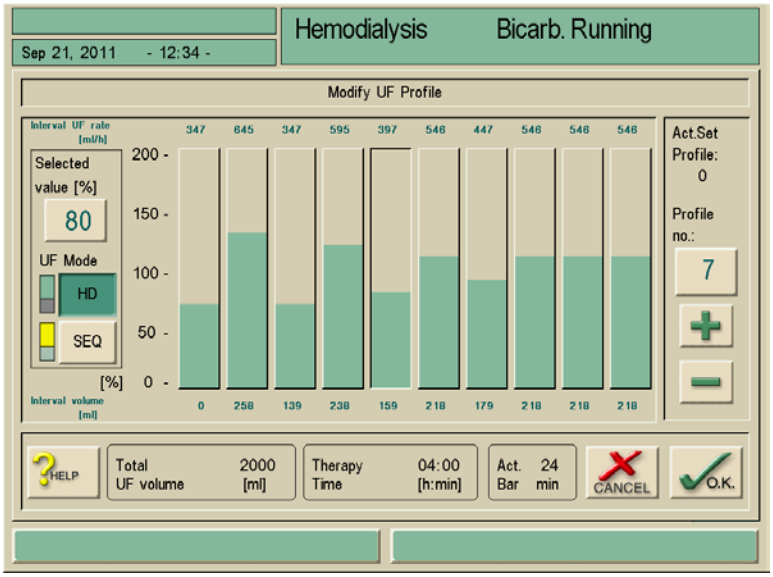
11.5.2 UF profile table

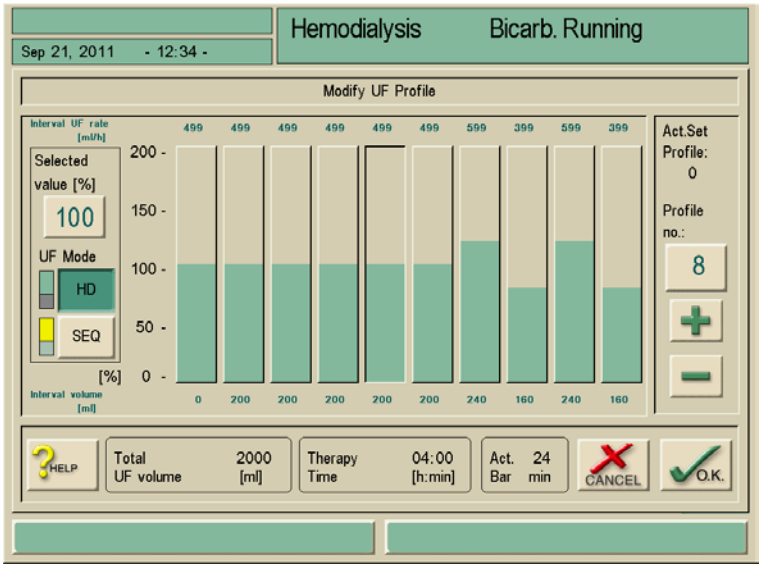
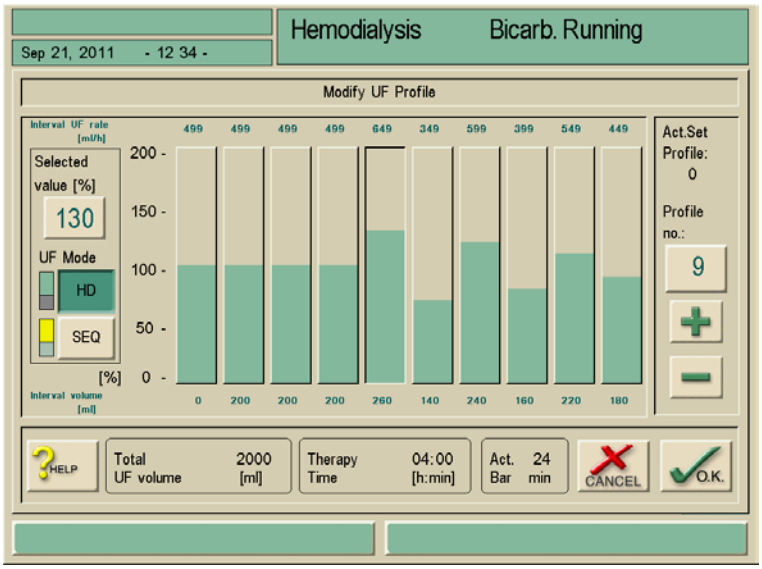
Profile no.	Description
0	Standard profile - Constant UF rate over entire therapy time. 
1	Particularly gentle therapy start and end phases, due to stepped UF rate increase/reduction. 

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. 

11

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. 

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.

11.6 Patient therapy card

The Card reader can be installed as an option on Dialog+ machines.

The patient therapy 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 therapy card should be ordered from B. Braun to have a certified quality standard.

11.6.1 Erasing data from patient therapy card

➢ Touch icon.
The selection menu appears.
➢ Insert therapy card into drive.

➢ Touch icon
All data on the patient therapy card will be erased!

11.6.2 Entering the patient name

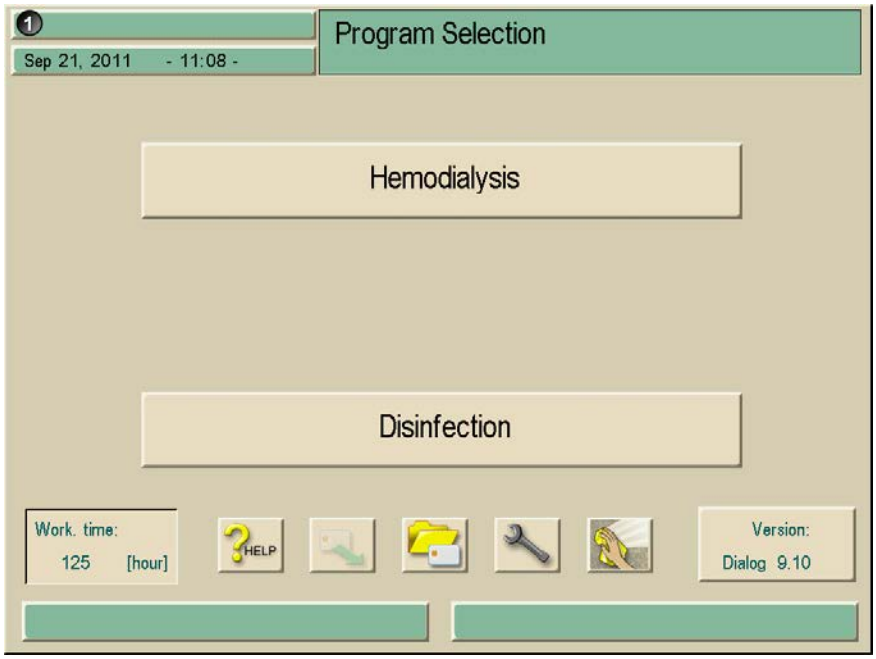


Fig. 11-9 Recording the patient name

The patient name can be entered in field **1** of the input screen.

➢ Touch field **1**.
The keyboard appears on the screen.

Fig. 11-10 Patient name keyboard

Legend

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

➢ Enter patient name in field **1** using the keyboard, and confirm with icon **O.K.**

When working with the patient therapy card, an additional field "Patient number" is displayed in the "Patient Overview" screen. This helps to differentiate between patients with the same name.

11.6.3 Reading patient data

Patient data can only be read in the Therapy selection and Preparation modes.

- Insert patient therapy card into Card reader.
- Touch icon.

The read-in operation is displayed on the screen.

- Check data in overview. Change to second page, where applicable.

If the patient therapy card contains data that for technical reasons cannot be read by the dialysis machine, this red icon appears.

- 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.

- Accept all parameters by touching the **O.K.** icon appearing in the bottom right corner.

By inserting the patient therapy card in Therapy selection or Preparation, data is read automatically.

11

11.6.4 Storing patient data (parameter settings)

- Touch icon after changing the parameter settings.

The patient data are stored on a patient therapy card.

- Save effectiveness data (KtV), see section 11.7.

Machines operated with option Nexadia BSL have other saving options. These are described in the respective instructions for use.

11.7 Entering parameters for computing the effectiveness of the dialysis

- Ensure that patient therapy card has been inserted into the dialysis machine.
- Touch icon.

  A screen for entering patient data for calculation of the theoretical effectiveness opens.

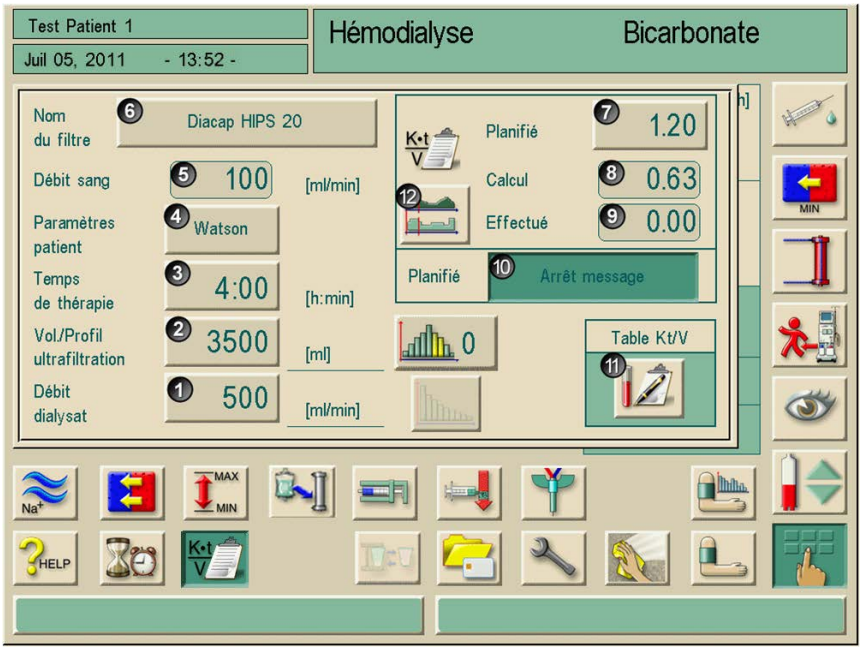


Fig. 11-11 Input window for calculating the effectiveness (Kt/V values)

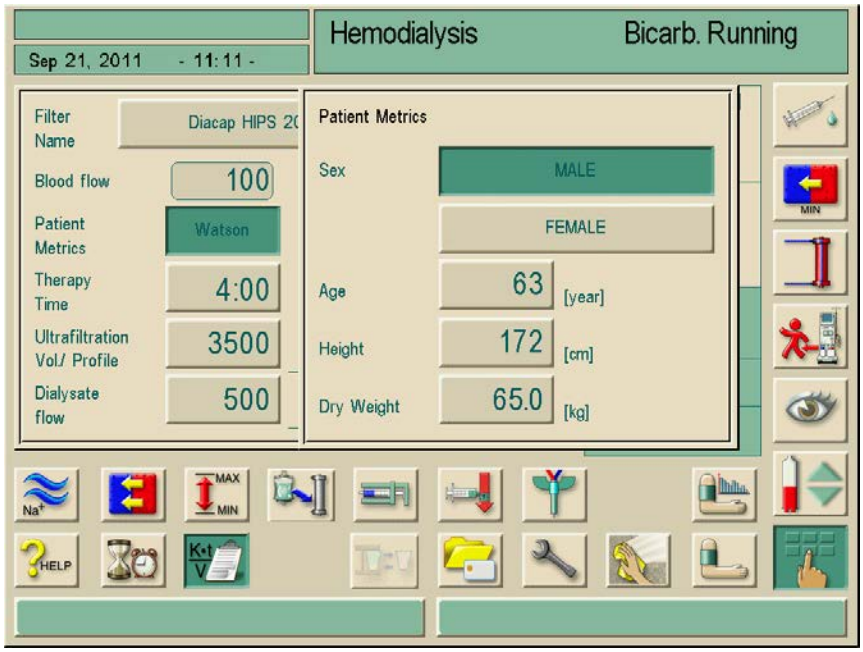


Fig. 11-12 Input window patient data after touching “Watson“ icon (Kt/UV)

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 dialyser 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
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 therapy card
12	Kt/V graphics	Opens a graphical display of the planned and actual Kt/V progression

➢ 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

➢ Touch icon (**11**).

The Kt/V results are transferred from the patient therapy card and shown in a screen:

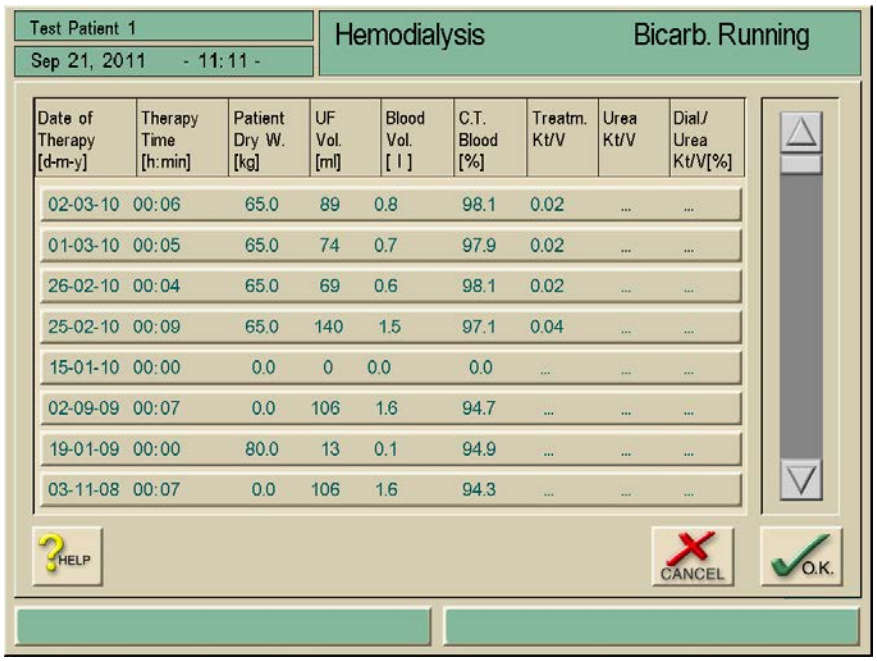


Fig. 11-13 "Table Kt/V values" screen

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.

➢ Touch appropriate line.

A screen for entering the laboratory results appears:

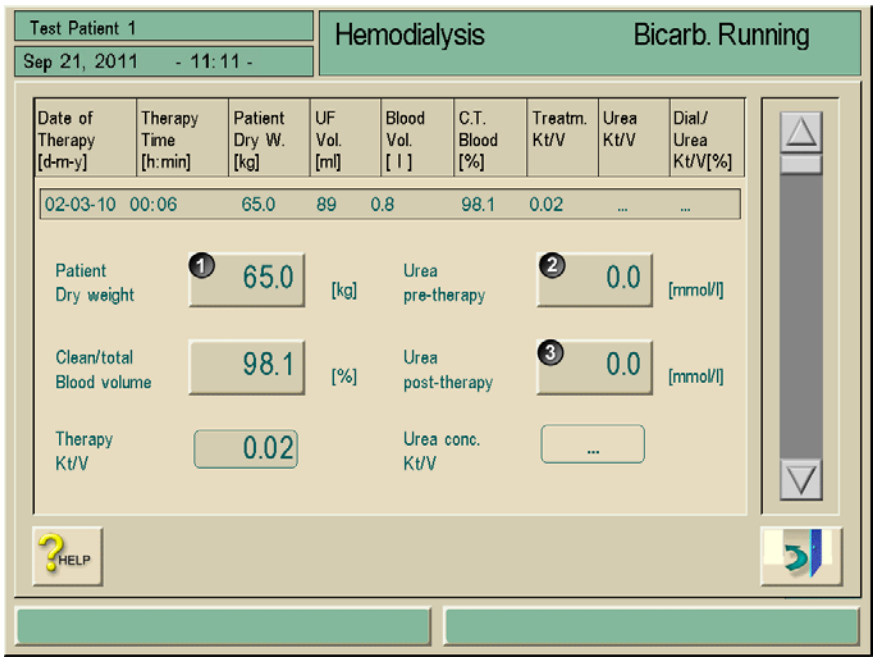


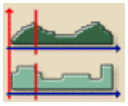
Fig. 11-14 Entering laboratory results

➢ 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**)

➢ Touch icon.

The table with the current Kt/V figures is displayed. Changed figures are automatically saved to the patient therapy card.

Show graphics



➢ Touch icon

A graphical display of the projected and actual Kt/V progression is shown.

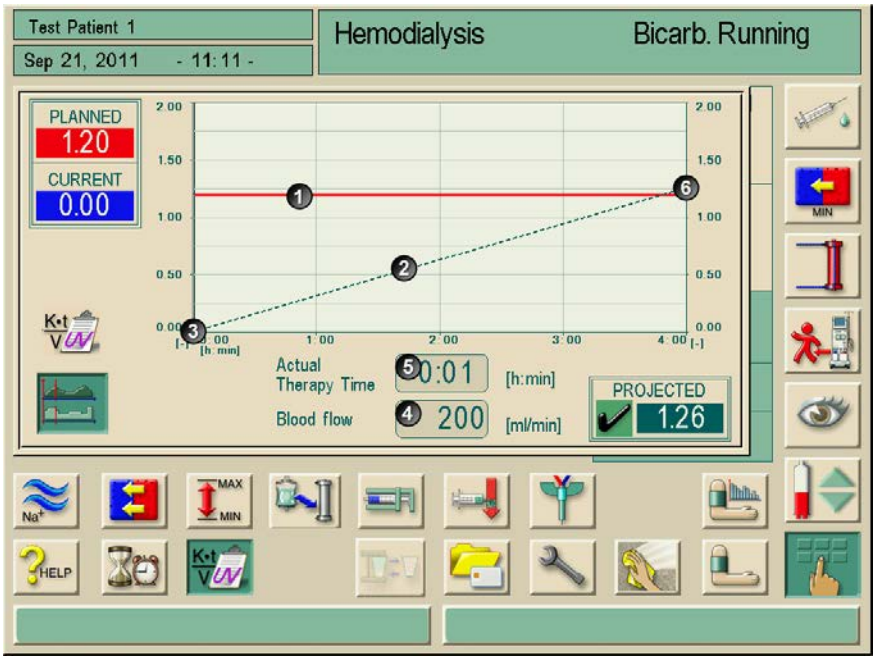


Fig. 11-15 Graphical display of Kt/V progression (Projected O.K.)

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

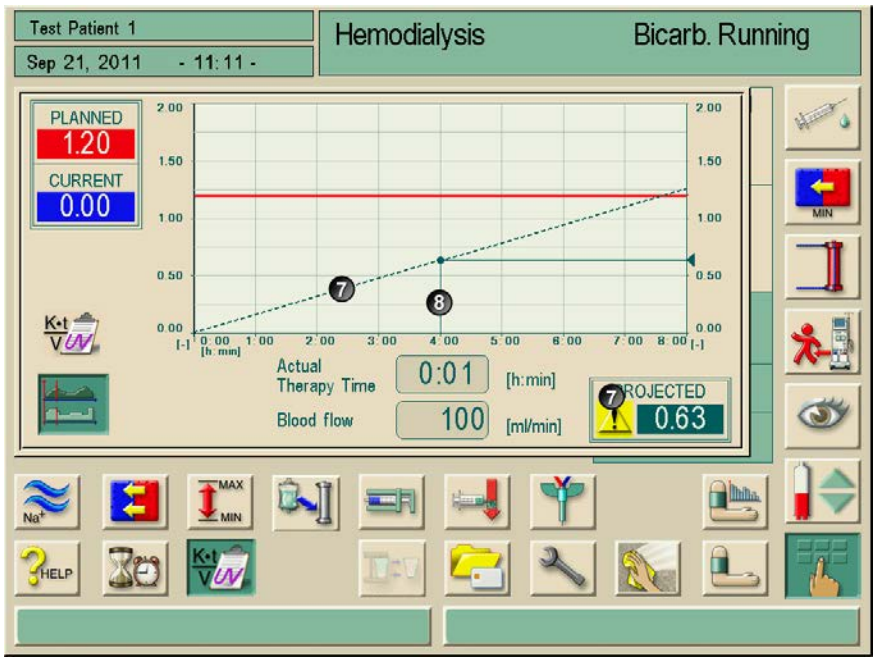


Fig. 11–16 Graphical display of Kt/V progression (Projected not O.K.)

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

➢ Touch icon on the ”Table Kt/V value” screen.

The screen is closed. All entered data are stored on the patient therapy card. When closing the screen by touching the icon **CANCEL**, no data are stored.

11.8 Adjusting the 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

➢ Touch icon.

The data management screen appears.

➢ Touch icon.

The screen for adjusting the brightness is displayed.

To set the brightness manually:

➢ Adjust brightness using the slide displayed on the screen.

"Manual" is displayed at the centre of the screen.

To set the brightness for daytime:

➢ Activate field **Daytime settings**.

"Daytime" is displayed at the centre of the screen.

To set the brightness for nighttime:

➢ Activate the field **Nighttime settings**.

"Nighttime" is displayed at the centre of the screen.

Screensaver

To activate the screensaver:

➢ Touch the field **Yes** next to the field **Screensaver on**.

To deactivate the screensaver:

➢ Touch field **No**.

➢ To close the screen, touch the "Brightness adjustment" icon.

!	It is recommended to activate the screen saver.

➢ 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.

11.9 Select language of screen text

Depending on the languages available in the TSM, you can choose the language for the screen text.

Procedure

➢ Touch icon

The data management screen appears.

➢ Touch icon

The screen with all available languages appears.

Fig. 11-17 Screen “available languages“

➢ Touch row with selected language

➢ Touch button for changing the language.

Screen text appears in chosen language.

11.10 Edit parameter of trend groups

You can edit the combination of parameters within the trend group.

➢ Call screen “Overview trend groups“ as described in chapter 5.3.5.

Legend

1 Field trend group
2 Button “edit group”
3 Choose TSM presettings
4 Leave screen and save changes
5 Leave screen without saving

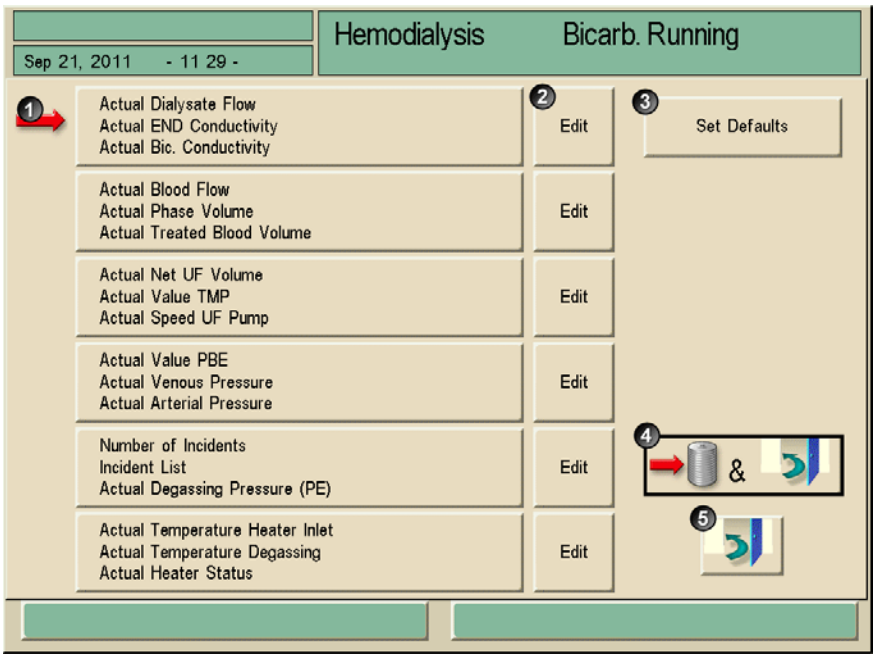


Fig. 11-18 Screen “Overview trend groups“

Single groups could be edited individually with parameters of your own choice.

➢ Touch favoured button.

The following screen appears.

Legend

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

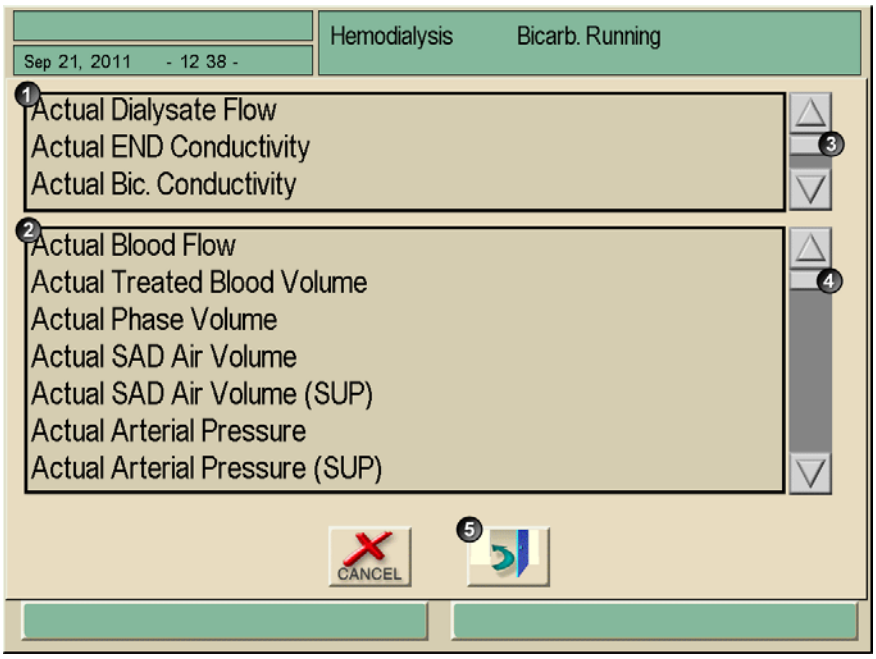


Fig. 11-19 Edit trend groups

- ➢ Touch parameter which is to be replaced in field **1**.
  Parameter will be marked by a frame.
- ➢ Search desired parameter in list **2** and touch it.
  The marked parameter will be replaced.
- ➢ Choose next parameter and replace as described.

- ➢ Touch icon to leave the screen.
  The screen “overview trend groups” appears.

- ➢ Touch icon to save the new trend group.
  In the TSM preset trend groups could be set up again.

- ➢ Touch icon.

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12 Maintenance and cleaning

12.1 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 appropiate desinfectant.**
- **In case of surface contamination with blood, disinfect and clean properly.**
- **In case of contamination of pressure connectors with blood, disinfect and clean properly.**

- 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.
- Use cleaning and disinfection agents only in accordance with the respective instructions for use.

Wiping the monitor during operation

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

!

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

!

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	10 %	B. Braun
Clorox Bleach	0,8 %	Clorox Company, USA

12.2 Preventive maintenance and technical safety inspection

12.2.1 Regular preventive maintenance

A regular preventive maintenance (service) is recommended **every 12 months** according to the specified check list in the service manual and with reference to the instructions for use. The preventive maintenance includes the replacement of wear and tear parts to ensure the fault-free operation of the dialysis machine.

This regular preventive maintenance (service) may only be carried out by trained personnel.

Depending on the setting in TSM, another maintenance interval can be set (see service manual chapter 5). If ≤ 5 % of the set time remains the following window (Fig. 12-1) appears once at the change from End of Therapy to Disinfection.

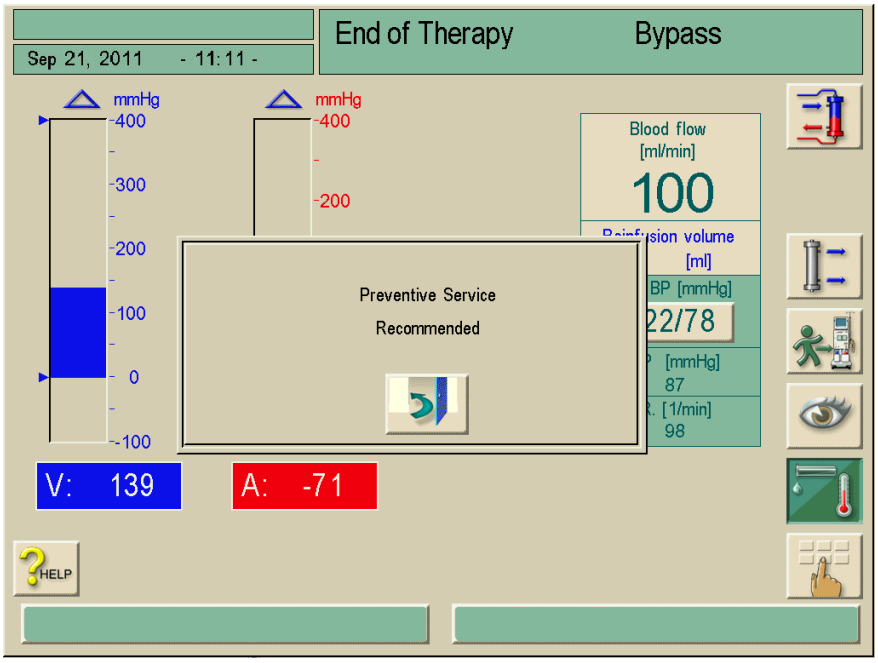

Fig. 12-1 Preventive Service Recommended

If the set maintenance interval is reached, the above mentioned window appears at every change to disinfection mode.

Battery (emergency power supply option)

The battery should be replaced after 5 years to maintain the full functionality of this option. For correct disposal of the battery please refer to service manual.

Service manual and technical training

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

12.2.2 Technical safety inspection

The 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.

- The dialysis machine should be checked by persons who have been appropriately trained or have the required expertise or experience and do not require instructions for the check.
- Results of the technical safety inspection shall be documented, e.g. by applying an inspection label to the dialysis machine.
- The technical safety inspection must be kept by the responsible organisation (user) as part of their documentation.

12.2.3 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.

12.3 Technical service and warranty

12.3.1 Warranty

For the dialysis machine, B. Braun Avitum AG provides a warranty in line with statutory requirements. The warranty includes the repair or replacement of parts that have been damaged because of design, manufacturing or material faults.

The warranty becomes void if the owner or third parties carry out modifications or repairs to the dialysis machine.

The warranty does not include the remedying of faults caused by manipulation, incorrect treatment or normal wear.

12.4 Disposal of old dialysis machines

i

Disinfect the dialysis machine in due form before disposal!

For further information see chapter 1.7.

Table of contents

13 Alarms and remedial action

13.1 Display and reset alarms

Legend

1 Comment field
2 Information field
3 Alarm field
4 Alarm list
5 Call up comments

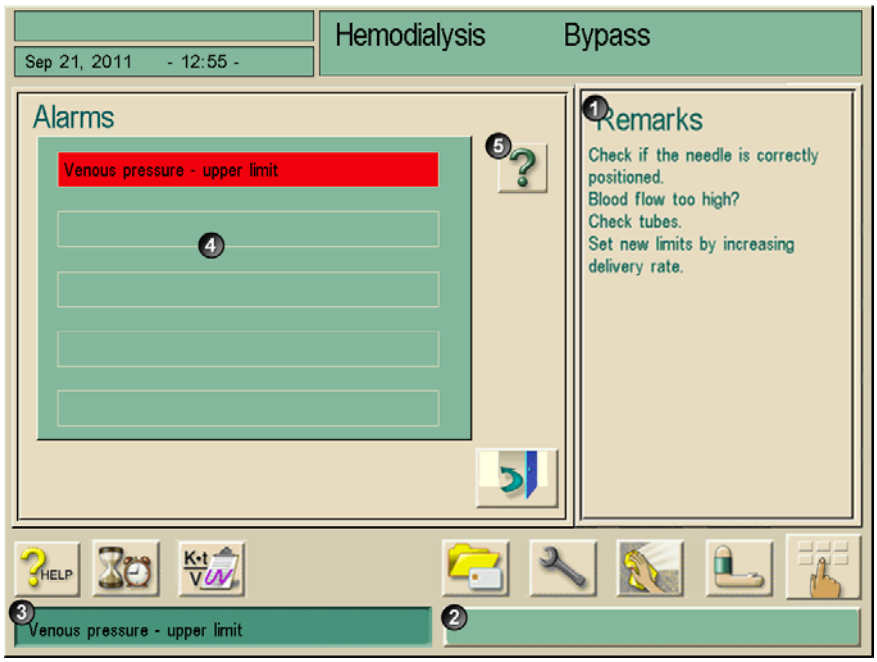

Fig. 13-1 Alarm display

- 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.

13

! The service technician can activate an alternative alarm sound in the TSM, which differs from the continuing alarm sound in an alternating melody.

! At failure or disturbance of the loudspeakers, the security system will activate the power supply buzzer to report an alarm acoustically.
➢ Please inform your service technician.

i Alarms are shown in the alarm list in the order of their occurrence. The triggering alarm is shown in the alarm field.
Upon resetting the triggering alarm all subsequent alarms are also deleted.

! The user is responsible for the reset of an alarm and subsequently for the monitoring of the suppressed parameters of the dialysis machine.

Resetting a blood-side alarm

➢ Press "Reset alarm" button.

The acoustic signal is switched off.

➢ Remedy the cause(s) of the alarm.

➢ Press "Reset alarm" button.

The dialysis machine is reset to its previous operating condition.

Resetting a dialysate-side alarm

➢ Press "Reset alarm" button.

The acoustic signal is switched off.

The background colour 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.

i

Warnings or information appear in information window **2**. Information field **2** flashes when more than one information notice has been triggered.

The information field **1** also contains a code number. Note down the code number, in case you need to contact technical service with possible queries.

➢ Touch information field **2**.

The alarm list **4** is displayed.

!

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.

To prevent any disconcertion of operator and patient, it is recommended to terminate the therapy. This requires particular attention of the operator.

The blood pump can be controlled via the +/– keys and the START/STOP key.

In case of alarms, special attention must be paid to the blood tube 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.

13.2 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:

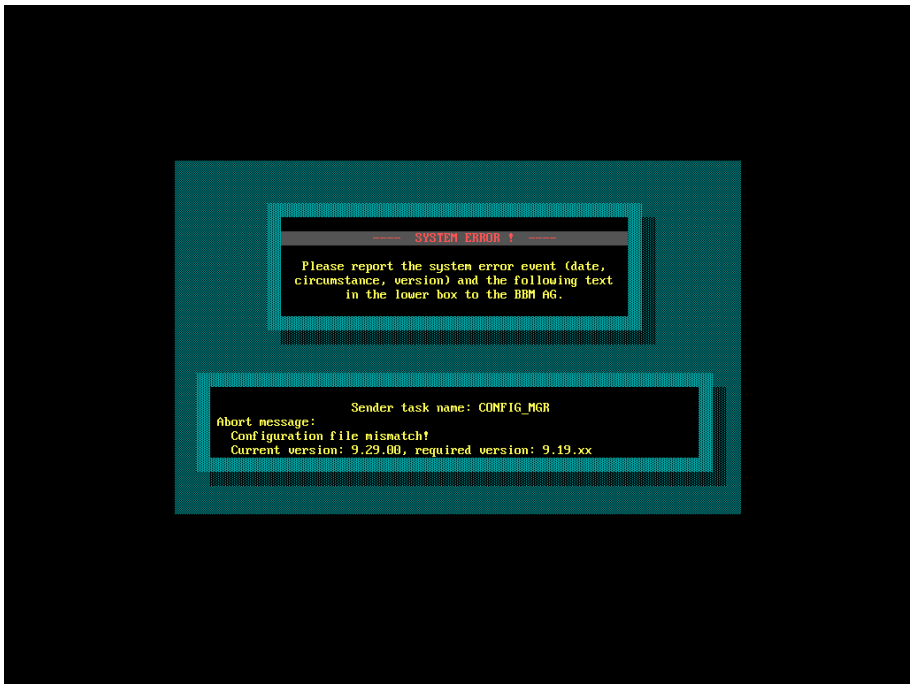

Fig. 13-2 System error message

The error message will always be displayed in English language.
The error message might be shown as raw text or as blank screen (see chapter 13.1).

13

Required user action

- Switch machine off and on again. The machine will restore therapy parameters and the previous state.
- After restart, press the Alarm mute key on the monitor twice to mute and confirm the alarm “System restored after power failure”.
- Press the Start/Stop key on the monitor as soon as it is illuminated to start the blood flow.
- 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 13.5 Manual Blood Return) and disconnect the patient.

13.3 Alarms and consequences

13.3.1 Dialysis alarms

Alarm/message/code	Cause	Remedial action
Arterial pressure upper limit (code 1050) 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) 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.
Check AV line for PA monitoring (SUP) (code 1980)	A connection of the arterial line was not detected at PA.	➢ If an AV line for pressure measuring is present, please connect it to the PA pressure sensor.
PBE upper limit (code 1048) The blood-sided dialyser inlet pressure exceeds the set limit.	Excessive pump speed.	➢ Adjust blood flow to dialyser and tube conditions. ➢ Readjust limit.
	Blood-side pressure increase in dialyser (clotting).	➢ Check dialyser for clotting.
	Tube kinked.	➢ Check tubing system.
	Technical defect.	➢ Contact technical service.
PBE lower limit (code 1049) The blood-side dialyser inlet pressure dropped below 10 mmHg.	Tube leaking.	➢ Check tubing system.
	Tube kinked downstream of blood pump.	
	Technical defect.	➢ Contact technical service.
Venous pressure upper limit (code 1052) 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.

Alarm/message/code	Cause	Remedial action
Venous pressure lower limit – Check access (code 1053) The venous pressure is lower than the lower limit.	Pump speed too low.	➢ Adapt blood flow to patient conditions.
	Pressure measuring 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.
Phase volume too low (code 1067) 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 position of needle/catheter.
	Alarm limits: Min. 12 ml	
Phase volume too high (code 1064) Pressure rise at venous pressure sensor too low during pump phase.	Phase volume significantly lower than average.	➢ Check that all arterial patient tube is in place in the arterial clamp. ➢ Increase blood flow. ➢ Possibly set closer control pressures. ➢ Check tube system for leaks and entering air.
	Alarm limits: Min. 12 ml	
DF and/or HDF filter holder open (code 1047)	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.
HDF-online filter test failed! (code 1151)	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.

Alarm/message/code	Cause	Remedial action
SAD (SUP) **(code 1958)** **SAD – Air!** **(code 1058)**	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.
	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.
SAD: sensor error (SUP) **(code 1961)** **SAD – sensor error** **(code 1059)**	External sound pulses.	➢ Disconnect patient.
	Measuring frequency smaller than 600 Hz.	
	Technical defect.	➢ Contact technical service.
SAD function ref. (SUP) **(code 1962)** The alarm level is outside the calibration value +/-50 mV.	Technical defect.	➢ Contact technical service.
Pump cover open (arterial) **(code 1062)** 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.

Alarm/message/code	Cause	Remedial action
Pump cover open (SN/Subst) (code 1063) 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.
No heparin delivery –syringe empty? (code 1065)	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.
Substitution disturbed – leakage? (code 1089)	Substitution volume on scales differs from the total substitution volume.	➢ Check tube system for leaks and kinks.
	Technical defect.	➢ Contact technical service.
Water supply disturbed (code 1022) 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.	
Degassing insufficient (code 1111) The degasification pressure does not reach the set value.	Technical defect.	➢ If alarm cannot be reset, contact technical service.
Temperature too high (code 1034) The mean temperature over a filling chamber cycle (250 ms sampling time) measured at TSD exceeds 41 °C.	Irregular dialysate flow.	➢ If alarm cannot be reset, contact technical service.
	Technical defect.	

Alarm/message/code	Cause	Remedial action
Temperature too low (code 1033) The mean temperature over a filling chamber cycle (250 ms sampling time) measured at TSD was 1 °C lower than the set value.	Irregular dialysate flow.	➢ If alarm cannot be reset, contact technical service.
	Technical defect.	
Bicarbonate conductivity limit (code 1028) 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.
Bicarbonate mixing ratio (code 1030) The mixing ratio H_2O 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.
Bicarbonate mixing ratio (SUP) (code 1950) The mixing ratio H_2O 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 (code 1029) 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	Cause	Remedial action
Final conductivity limit (SUP) (code 1951) 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.
Concentrate mixing ratio (code 1031) The mixing ratio H_2O 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 cartridge not correctly connected (code 1018) The cartridge could not be filled	Bicarbonate cartridge probably not lanced correctly.	➢ Check if it fits the holder correctly.
Malfunction of chamber system sensors (code 1023) 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 device. ➢ Call a technician.

Alarm/message/code	Cause	Remedial action
UF balance? Air leakage in dialyser couplings (code 1026) During the dialysis, the valve (VLA) had to be opened more than 20 times due to air (level below bottom electrode) in the bubble catcher.	Dialyser not filled without air inclusions.	➢ Vent dialyser (water side).
	Dialyser connection leaking.	➢ Check dialyser connections.
	Technical defect.	➢ Contact technical service.
DF pressure < –400 mmHg (code 1020) The dialysate pressure downstream of the dialyser (PDA) is below –400 mmHg.	Dialyser UF factor too small for set UF rate.	➢ Use dialyser 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.
Dialyser TMP limits exceeded (code 1017) 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 heparinisation.
	Dialyser factor too small.	➢ Use dialyser with larger factor.
	Technical defect.	➢ Contact technical service.
Actual UF volume deviation (code 1816) 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.
High UF volume error–terminate dialysis (code 1826) The UF volume deviates more than 400ml.	Technical defect.	➢ Contact technical service.
UF volume exceeded (SUP) (code 1966) UF volume has been reached.	Technical defect.	➢ Contact technical service.

Alarm/message/code	Cause	Remedial action
Max. UF rate exceeded (SUP) (code 1953) The required UFR is 20 ml/h higher than the specified max. UFR.	UF volume too high.	➢ Decrease UF volume, increase UF time
	Dialyser factor too small.	➢ Use dialyser with higher factor.
	Technical defect.	➢ Contact technical service.
Blood Leak (SUP) (code 1955)	Rupture in dialyser.	➢ Change dialyser.
	Technical defect.	➢ Contact technical service.
Blood leak, sensor dirty (code 1044) The blood concentration measured at the sensor (BL) is negative.	Sensor dirty.	➢ Call technical service.
	Air on dialysate-side.	➢ Reset alarm.
	Technical defect.	➢ Contact technical service.
+/- 12 V power supply insufficient (code 1008) Voltage level +12VAN or -12VAN is over the tolerance.	Technical defect.	➢ Contact technical service.
System restored after power failure (code 600) Power failure during Preparation/Treatment	Technical defect. The system was restored.	➢ Reestablish power supply.
Blood recognised in Preparing/Disinfection The red detector has recognised blood in Preparing/Disinfection.	Patient connected in Preparing/Disinfection.	➢ If self test isn't ended, disconnect patient. ➢ If self test is ended, change to Therapy.
Art. bolus vol. > 300 ml (SUP) (code 2026)	Arterial bolus volume exceeded 300 ml.	➢ Please call a technician.

13.3.2 ABPM alarms

Alarm/message/code	Cause	Remedial action
ABPM: Systolic pressure too high (code 9100)	Systolic pressure exceeds the set upper limit.	➢ Repeat measurement. ➢ Select individual limit adjustment. ➢ Manually change individual limits. ➢ Inform doctor.
ABPM: Systolic pressure too low (code 9101)	Systolic pressure is below the set limit.	➢ Repeat measurement. ➢ Select individual limit adjustment. ➢ Manually change individual limits. ➢ Inform doctor.
ABPM: Diastolic pressure too high (code 9103)	Diastolic pressure exceeds a set upper limit.	➢ Repeat measurement. ➢ Select individual limit adjustment. ➢ Manually change individual limits. ➢ Inform doctor.
ABPM: Diastolic pressure too low (code 9104)	Diastolic pressure drops below a set lower limit.	➢ Repeat measuring. ➢ Select individual limit adjustment. ➢ Manually change individual limits. ➢ Inform doctor.
ABPM: Internal communication disturbed (code 9138)	ABPM not operational; no further measurements possible.	➢ Carry out pulse measuring with separate RR device, or manually.
ABPM: Pulse rate too high (code 9169)	Pulse frequency exceeds upper limit.	➢ Repeat measurement. ➢ Select individual limit adjustment. ➢ Manually change individual limits. ➢ Inform doctor.
ABPM: Pulse rate too low (code 9170)	Pulse frequency lower than lower limit.	➢ Repeat measurement. ➢ Select individual limit adjustment. ➢ Manually change individual limits. ➢ Inform doctor.
ABPM: Module failure please switch off/on (code 9172)	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: Air leak – check cuff connection (code 9300)	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)	Blood pressure module has performed a safety switch-off. Message 9172 remains on the display after confirmation.	➢ Switch dialysis machine off and on again; all data remain stored.

Alarm/message/code	Cause	Remedial action
ABPM: Inflation pressure not reached (code 9302)	–	➢ Check cuff for correct position. ➢ Re-apply cuff if necessary. ➢ Repeat measurement.
ABPM: Pulsation not detected (code 9303)	–	➢ Check connections to ABPM and cuff. ➢ Measure pulse manually.
ABPM: Excessive arm movement (code 9304)	Excessive arm movement by patient.	➢ Check patient's arm position.
ABPM: Systolic BP > max. cuff pressure (code 9305)	Considerable increase in blood pressure since last measurement.	➢ Carry out pulse measuring with separate RR device, or manually.
ABPM: Pulse measurement disturbed (code 9306)	–	➢ Check cuff for correct position. ➢ Carry out pulse measuring with separate RR device, or manually.
ABPM: Irregular pulse (code 9307)	–	➢ Check cuff for correct position. ➢ Carry out pulse measuring with separate RR device, or manually.
ABPM: Reading took too long (code 9308)	The max. measuring time of 110 seconds is exceeded.	➢ Carry out pulse measurement with separate RR device, or manually.
ABPM: Pulse beat over 100 beats (code 9309)	The max. measuring time of 110 seconds is exceeded.	➢ Carry out pulse measurement with separate RR device, or manually.
ABPM: Cuff pressure > 320 mmHg (code 9310)	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)	–	➢ Check cuff for correct position. ➢ Carry out pulse measurement with separate RR device, or manually.

13.3.3 Crit-Line alarms

Alarm/Messages/Code	Cause	Remedial action
HCT is over limit (Dialog) (code 930)	UF rate or volume too high. Limit at the Dialog too low.	➢ Reduce UF rate or volume ➢ Adapt limit at the Dialog
HCT reading failed (code 931)	Crit-Line device is switched off. Connection disturbed. Technical defect.	➢ Check Crit-Line device and connection to Dialog ➢ Call technician if necessary
No blood detected in Crit-Line (code 932)	Sensor not placed correctly at blood chamber.	➢ Check sensor and blood chamber ➢ Call technician if necessary
Sensor obstruction in Crit-Line (code 933)	Foreign material/dirt between sensor and blood chamber.	➢ Check/clean sensor or remove material ➢ Call technician if necessary
SAT is under limit (code 935)	Patient O_2 undersupply limit is too high.	➢ Call doctor ➢ Adapt limit
HCT is over limit (Dialog) (code 940)	UF rate or volume too high. Limit at the Dialog too low.	➢ Reduce UF rate or volume ➢ Adapt limit at the Dialog
HCT reading failed (code 941)	Crit-Line device is switched off. Connection disturbed. Technical defect.	➢ Check Crit-Line device and connection to Dialog ➢ Call technician if necessary
Crit-Line communication failed (code 942)	Crit-Line not switched on. Connection disturbed. Technical defect.	➢ Check Crit-Line device and connection to Dialog ➢ Call technician if necessary
Please initiate Crit-Line monitor! (code 943)	Crit-Line measurement not started.	➢ Start Crit-Line measurement
HCT is over limit (Crit-Line) (code 944)	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)	HCT limit not set or default not confirmed.	➢ Set value or confirm
SAT is under limit (code 946)	Patient O2 undersupply limit is too high.	➢ Call doctor ➢ Adapt limit

13.3.4 Level regulation alarms

Alarm/message/code	Cause	Remedial action
Volume limit level regulation (code 1011)	Max. blood volume exceeds 190 ml.	➢ Check for tubing leaks
Timeout level regulation (code 1024)	Level regulation period is limited to 3 minutes.	➢ Set level in less than 3 minutes
Blood pump is running (code 2028)	Blood pump must not run in Emptying Dialyser or when SAD-alarm-resolving is active.	➢ Stop blood pump
Volume limit level regulation (code 2039)	Max. blood volume exceeds 220 ml.	➢ Check for tubing leaks
Arterial pressure monitoring error (code 2041)	Insufficient arterial pressure pulsation.	➢ Set levels correctly ➢ Ensure that hydrophobic filters are fluid free
Valve position level regulation (code 2042)	Wrong valve position.	➢ Contact technician
Venous pressure monitoring error (code 2043)	Insufficient venous pressure pulsation.	➢ Set levels correctly
PBE pressure monitoring error (code 2044)	Insufficient PBE pressure pulsation.	➢ Set levels correctly ➢ Ensure that hydrophobic filters are fluid-free
PBS pressure monitoring error (code 2045)	Insufficient PBS pressure pulsation.	➢ Ensure that hydrophobic filters are fluid-free

13.3.5 Adimea alarms

Alarm/message/code	Cause	Remedial action
Adimea: Target Kt/V will not be reached (code 1550)	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)	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 call technician.
	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)	Sensor is not present.	➢ Call technician
	Physical interruption or electromagnetic disturbances on the USB communication interface.	
Adimea: Calibration failed (code 1553)	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 cannot warm up (code 1554)	The photodiodes of the sensor are defective.	➢ Call technician
	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)	Accuracy of sensor is not fully reached.	➢ Call technician
	Sensor was disabled during therapy because of warming up problems.	

13.3.6 bioLogic RR Comfort alarms

Alarm/message/code	Cause	Remedial action
bioL. RR UF volume cannot be reached (code 3000)	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)	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)	Internal error occurred in bioLogic RR.	➢ Press bioLogic RR button. Alarm disappears automatically.
bioL. RR No reading request (code 3003)	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)	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 cancelled (code 3101)	UF profile was set before bioLogic RR button was pressed. Set UF profile is cancelled.	➢ Press bioLogic RR button. Alarm disappears automatically. bioLogic RR sets the profile.
bioL. RR SYS Lower Limit reduced (code 3102)	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.
bioL. RR Missing reading (code 3103)	3 minutes without successful blood pressure reading since the request of bioLogic RR algorithm.	➢ Press bioLogic RR button. Alarm disappears automatically.

13.3.7 Online alarms

Alarm/message/code	Cause	Remedial action
Open Subst-port (white) (code 1056)	Substitution port(s) is/are closed.	➢ Open substitution port(s) outlet for filter draining in order to aerate the filter.
Substitution port outlet open (code 1078)	Substitution port outlet is open.	➢ Close outlet port. ➢ If the port is closed and the alarm is still displayed, call technician.
Substitution port outlet closed (code 1079)	Substitution port outlet is closed.	➢ Open outlet port. ➢ If the port is opened and the alarm is still displayed, call technician.
Substitution port inlet open (code 1080)	Substitution inlet port open.	➢ Close inlet port. ➢ If the port is closed and the alarm is still displayed, call technician.
Substitution port inlet closed (code 1081)	Substitution inlet port closed.	➢ Open inlet port. ➢ If the port is opened and the alarm is still displayed, call technician.
Pump cover open (substitution) (code 1093)	Pump cover is open.	➢ Close cover.
Start without self test (SUP) (code 1969)	Self tests have not been done.	➢ Press AQ button twice. ➢ Switch off/on device. ➢ If alarm persists, call technician.
HDF alarm has blood pump stopped (SUP) (code 1977)	Blood pump was stopped due to HDF alarm.	➢ Check substitution hardware. ➢ Switch off/on substitution. ➢ If necessary, call technician.
Leakage in the Subst. system (SUP) (code 1993)	Leakage in the substitution system.	➢ Check the substitution system ➢ If necessary, switch off HDF.
UF volume too high (SUP) (code 1994)	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)	It is no longer possible to increase limit value extension.	➢ Switch off HDF. ➢ Check patient weight.
UF rate too low (SUP) (code 1997)	UF rate too low.	➢ Switch off HDF. ➢ Check patient weight.
HDFO: Bolus volume too high (SUP) (code 2016)	Supervisor detected too high bolus volume.	➢ Press "Reset alarm" button to reset. If not possible call technician. ➢ Disconnect patient.
Check substitution line for tightness (code 2017)	Substitution line not properly connected.	➢ Check substitution line correct connection. ➢ Check substitution line for leakage.
	Leakage.	
HDF test failed (SUP) (code 2018)	Supervisor detected too high bolus rate.	➢ Press "Reset alarm" button to reset. ➢ If not possible, call technician.
HDFO: OSP activated (SUP) (code 2020)	Technical defect.	➢ Press "Reset alarm" button to reset. If not possible, call technician. ➢ Disconnect patient.
	Online substitution pump (OSP) rotates when dialyser inlet valve (VDE)/dialyser outlet valve (VDA) is closed.	

Alarm/message/code	Cause	Remedial action
HDFO: VSB or VSAA opened (SUP) (code 2021)	Technical defect. Substitution connection outlet valve (VSAA) is open.	➢ Press "Reset alarm" button to reset. If not possible, call technician. ➢ Disconnect patient. ➢ Make a disinfection.
HDFO: VBE opened (SUP) (code 2022)	Technical defect. Filter vent valve (VBE) is open. Online dialysis not possible.	➢ Press "Reset alarm" button to reset. If not possible, call technician. ➢ Disconnect patient.
HDFO: DF system not rinsed (SUP) (code 2023)	Technical defect. Water part not rinsed after disinfection.	➢ Press "Reset alarm" button to reset. If not possible, call technician. ➢ Disconnect patient.
HDF Inf. bolus volume too high (SUP) (code 2030)	Supervisor detected too high bolus rate.	➢ Press "Reset alarm" button to reset. If not possible, call technician. ➢ Disconnect patient.
Ratio gross UF/blood flow too low (code 2059)	UF rate exceeds a defined percentage of the blood flow.	➢ Increase blood flow. ➢ Reduce substitution flow.
HDF/UF alarm limits expanded (code 2070)	Any of the UF TLC or LLS alarm limits have been expanded.	➢ Leave Therapy or End of Therapy.

13.4 Remedying SAD alarms

i 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.

! 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:

- Clamp tube between venous bubble catcher and dialyser.
- Press Enter key ↵ on the monitor to open the window “increase venous level”.
- To increase the venous level press the “increase venous level” icon.
- When the air has been removed, open clamp between venous bubble catcher and dialyser 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:

- Clamp tube between venous bubble catcher and dialyser.

This prevents blood from being sucked from the dialyser.

- 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 inlet, it must be moved back to the venous bubble catcher by this vacuum action.

- Press Enter key ↵ son monitor.

Venous clamp opens briefly.

Blood flows back from the patient inlet and the air is moved into the venous bubble catcher.

- Remove clamp between venous bubble catcher and dialyser.
- 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.

13.5 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.

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.**

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)

- Remove crank from rear of dialysis machine.
- Open (left) blood pump lid and insert crank into the roller rotor.
- Disconnect arterial side from patient, see section 6.1.
- Remove venous line from the SAKV.
- Evenly operate the blood pump using the crank. Observe appropriate speed and maintain an adequate blood level in the venous bubble catcher.
- Continue to monitor venous patient inlet, which may not contain any air.
- When the physiological saline solution reaches the venous tube clamp, close the clamp.
- Disconnect the patient on the venous side.

13.6 Omission of acoustic signals

13.6.1 Omission of acoustic signals for alarm

The sounds are omitted for the following alarms:

ID	Text
600	System restored

13.6.2 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!
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

14.1 Options

Name	Article no. (REF)
Nexadia – BSL: Card reader and networking device*	7102230
ABPM: Automatic blood pressure monitoring	7102226
bioLogic RR Comfort for card reader: Automatic blood pressure stabilisation with template method (only with option ABPM)	7105324
Bicarbonate cartridge holder	7105171
Sample port dialysate	7102867
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 Equalisation Kit	7106605
Card reader incl. 5 cards	7105230

! * 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.
Dialyser 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 base storage (max. 30 kg, e.g. single bed - RO unit)	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 Other accessories

B. Braun currently offers accessories from the following product areas:

- Dialysers with polysulfone membrane for high and low flux
- Haemofilters
- AV systems
- Dialysis concentrates and bicarbonate powder cartridges
- Fistula cannulas
- Rinsing solutions
- Haemofiltration solutions
- Disinfectants

For further information please contact your B. Braun representative.

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15 Technical data

15.1 General technical data

Description	Values	
Nominal voltage	120 V~ ± 10 % 230 V~ ± 10 %	
Nominal frequency	120 V ~/ 230 V~ ± 5 % 50 Hz / 60 Hz ± 5 %	
Nominal current	16 A at 120 V~ max. 10 A at 230 V~	
Connected load	1.92 kW at 120 V~ 2.5 kW at 230 V~	
Mains cord		
Current-voltage-rating	20 A at 120 V~ max. 10 A at 230 V~	
Minimum cross section of single strand	3.3 mm^2 (AWG12) for 120 V~	1.5 mm^2 for 230 V~
Withstand voltage of single strand (L-N, L-PN, N-PE)	min. 2 kV~, 50 Hz, ≥1 min	
Average energy consumption	approx. 1.5 kW/h	
Heat emission	approx. 230 W/h	
Categorisation	II b according to EC Directive for Medical Devices 93/42/EEC	
Classification	Type B, IEC 60601-1	
Device leakage current	< 500 µA~	
Patient leakage current	< 10 µA~	
Protection class	IP21 (Protection against foreign bodies > 12 mm and vertically falling drip water) DIN EN 60529	
Electrical ground	via optional cable	
Dimensions (W × H × D)	approx. 510 × 1678 × 637 mm	
Housing material	Aluminum, corrosion-proof	
Empty weight	approx. 85 kg	

Description	Values
Water supply	Water suitable for dialysis
Pressure range	0.5 – 6 bar
Water inlet temperature for dialysate preparation	10 – 30°C
Water inlet temperature for disinfection	max. 95°C
Alarm ”No water”	from separate monitoring device
Concentrate supply	from container or central supply 0 – 1 bar

For information regarding fuse ratings and battery specifications please refer to service manual.

15.2 Ambient conditions

Description	Values
Operation	
Temperature	+10 to +40 °C
Relative humidity	15 % – 70 %
Atmospheric pressure	700 – 1060 mbar
Transportation and storage (dry)	
Temperature	-20 to +60 °C
Relative humidity	15 % – 80 %
Atmospheric pressure	700 – 1060 mbar

15.3 Recommended safe distances

Recommended safe distances in meter (m) between portable or mobile HF telecommunication devices and the Dialog+ dialysis machine			
The dialysis machine Dialog+ is made for the use in ambient conditions with controlled High-Frequency disturbance variables. The user can avoid electromagnetic disturbances by keeping the distance between Dialog+ and HF-telecommunication devices following the values in the table below in dependency to the output power of those devices.			
Nominal output P of transmitter (Watt)	Safe distance (d) depending on 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 2,5 GHz $d = 2.33 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.20	1.20	2.30
10	3.80	3.80	7.30
100	12	12	23
For transmitters with other output power ratings, the recommended safety distance (m) can be calculated with the above formulas. Heed the max. power rating (W), in accordance to the manufacturer's information, to use the formula from above. **Remark 1**: For 80 MHz and 800 MHz use the higher frequency range. **Remark 2**: This guideline may be not practicable in some cases. The propagation of electromagnetic quantity will be influenced by adsorption and reflexion of the building, equipment and human.			

Find more information about electromagnetic compatibility (EMC), radio disturbance and IEC 60601-1-2 in the service manual, chapter 8.

15.4 Dialysate system

Description	Values
Temperature setting range	33 – 40 °C
Temperature tolerance at standard ambient temperature	+0.5°C to -1.5°C
Limits	± 1 °C (of set specified value)
Excessive-temperature protection	41 °C
Protection system	Temperature sensor
Bridging time of protection system	Cannot be bridged during dialysis
Deactivation of acoustic alarm	120 s
Heating power	1800 W
Conditioning	Conductivity regulated
Operating regime	Conductivity bicarbonate 2 – 4 mS/cm, 4 – 7 mS/cm Overall conductivity 12.5 – 16.0 mS/cm
Tolerance	±0.2 mS/cm
Measurement	Temperature-compensated (reference temperature 25 °C)
Protection system	Monitoring through second conductivity sensor with different geometry
Limit	±5 % (of set value)
Bridging time of protection system	cannot be bridged during dialysis
Deactivation of acoustic alarm	180 s
Flow	300 – 800 ml/min
DF tolerance at dialysis machine	±5 % (of specified value) at 300 - 800 ml/min
Bridging time of protection system	Not bridgeable via balance chamber filling times during dialysis
Deactivation of acoustic alarm	300 s

Description	Values
Dialysate pressure range area	+400 to –450 mmHg
Tolerance (PDA)	±10 mmHg
Upper limit	+400 mmHg
Lower limit	–450 mmHg
Deactivation of acoustic alarm	120 s
Blood leak detector	Red sensitive
Tolerance	10 %
Alarm threshold	>0.5 ml/min blood at HKT 45 % >0.35 ml/min blood at HKT 25 % (AAMI)
Bridging time	Not bridgeable during dialysis
Deactivation of acoustic alarm	120 s
Ultrafiltration	Volume-controlled via balance chambers, ultrafiltration through ultrafiltration pump Sequential ultrafiltration (Bergström)
Operating range	0– 4000 ml/h
Overall accuracy *	$F = F_{bal} + F_{UF}$
F_{bal}	± 0.2 ml/chamber cycle
F_{UF}	Ultrafiltration pump tolerance <1 %
Protection system	Speed monitoring of UF pump with an accuracy of <1 %; System will alarm 200 ml beyond given value or 10 % beyond preset UF rate.
Bridging time of protection system	Not bridgeable during dialysis
Deactivation of acoustic alarm	120 s

* The overall accuracy **F** is the sum of two 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

Description	Values
Trans membrane pressure	
Limit range (max. TMP)	300 – 700 mmHg
Absolute alarm limit	-100 mmHg
Limit window	adjustable (2 % - 99 %)
Tolerance	Calculated through PBE, PDA and PV
Bridging time of protection system	Not bridgeable during dialysis
Deactivation of acoustic alarm	120 s
Degassing system	Mechanically regulated through the degassing valve and the degassing pump
Tolerance	± 50 mmHg
Disinfection **During disinfection processes dialysis is blocked.** **Reports on the effectiveness of the individual disinfection programs can be obtained from the manufacturer**	
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 at approx. 85 °C at the dialyser couplings

15.5 Extracorporeal circulation

Description	Values
Blood pump	2-roller pump with automatic motor switch-off when lid is opened, backstop, low haemolysis. For 8/12 mm or (optional) 7/10 mm pump tubes
Pumping rate	50 – 600 ml/min (8/12 mm) 50 - 400 ml/min (7/10 mm) Adjustable in 10 ml steps
Tolerance interval	< 10 % for blood pressure up to -150 mmHg Tolerance between 10% and 25% for blood pressure up to -200 mmHg
Working pressure range	Intake pressure up to –390 mmHg Pumping pressure 0 – 1725 mmHg
Heparin pump	Syringe pump for 10 – 30 ml syringes
Pumping rate	0.1 – 10 ml/h in steps of 0.5 ml/h or 0.1 ml/h, can be turned off, bolus: 600 ml/h
Tolerance interval	< ±10 %
Pressure range	0 to +480 mmHg
Safety air detector	SAD (Safety air detector), based on ultrasound
Sensitivity	Air bubbles at > 50 µl, micro foam with cumulated volume **Limit values double-needle:** 0.2 ml at 0 – 200 ml/min SAD flow 0.3 ml at 200 – 400 ml/min SAD flow 0.5 ml at > 400 ml/min SAD flow **Limit values single-needle:** 0.7 ml at 1200 ml/min constant SAD flow
Protection system	Ultrasound detector, automatic cyclical checks during entire operating phase
Bridging time of protective system	Not bridgeable during dialysis only in end phase for approx. 30 ml (has to be activated at TSM)
Red sensor	in SAD housing
Function	Detects blood in tube system
Modes of operation	1st mode of operation: The blood pump is stopped as soon as the red sensor detects blood when connected at this site. → Alarm caused
	2nd mode of operation: If the red sensor detects blood at this point, a heparin bolus is administered. This function can be disabled by technical service in the service program.
	3rd mode of operation: If no blood is detected at this site in the End Therapy mode, the blood pump is stopped.
	4th mode of operation: If blood is detected during preparation or disinfection, the blood pump is stopped → Alarm caused

Description	Values
Pressure measurement at arterial inlet of dialyser (PBE)	Electronic pressure sensor
Operating range	0 – 700 mmHg
Tolerance interval	±10 mmHg
Limit	Adjustable within operating range
Protection system	Test prior to start of therapy
Arterial inlet pressure (PA) measurement	Electronic pressure sensor with digital quasi-analogue display
Operating range	–400 to +400 mmHg
Tolerance	±10 mmHg
Limit	–400 to +400 mmHg adjustable within operating range, adjustable interval width for dynamic limits window
Protection system	Electronic pressure sensor, test prior to start of therapy
Deactivation of acoustic alarm	120 s
Venous return pressure (PV) measurement	Electronic pressure sensor with digital quasi-analogue display
Operating range	20 – 390 mmHg (adjustable in service program)
Tolerance	±10 mmHg
Limit	Alarm window around operating value Configurable alarm window (20–200 mmHg) After blood pump adjustment, the alarm window is re-centred.
Protection system	Test prior to start of therapy Venous window of 20 – 390 mmHg. Venous limits are monitored by the function and control systems.
Bridging time of protection system	Not bridgeable during dialysis
Deactivation of acoustic alarm	120 s

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

15.7 Technical data HDF/HF-online

Description	Values
HDF (Haemodiafiltration)	
Substitution rate	20 – 400 ml/min ±10 %
Dialysate processing	500 – 800 ml/min ±10 %
Infusion bolus	50 – 250 ml ±10 %
HF (Haemofiltration)	
Substitution rate	20 – 400 ml/min ±10 %
Infusion bolus	50 – 250 ml ±10 %
Online filter	
Operating time	150 treatments (900 h), see filter instructions for use

15.8 ABPM blood pressure monitoring

Description	Values
Cuff pressure range	0 – 320 mmHg
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 25 - 240 mmHg Diastole 15 - 220 mmHg
Accuracy	±3 mmHg or ±2 %
Blood pressure determination time	Typical 25 sec. (Adult with blood pressure 120/80 and 80 BPM)
Pulse rate determination	30 – 240 BPM
Pulse rate accuracy	±2 % or 2 BPM
Overpressure cut-off	300 mmHg +10 %
Time of alarm suppression	< 1 s
Deactivation of acoustic alarm	120 s
Defibrillation	Protected applied part
Safety class	Safety class I, Type BF

15.9 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

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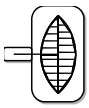
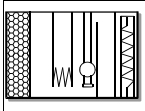
16 Appendix

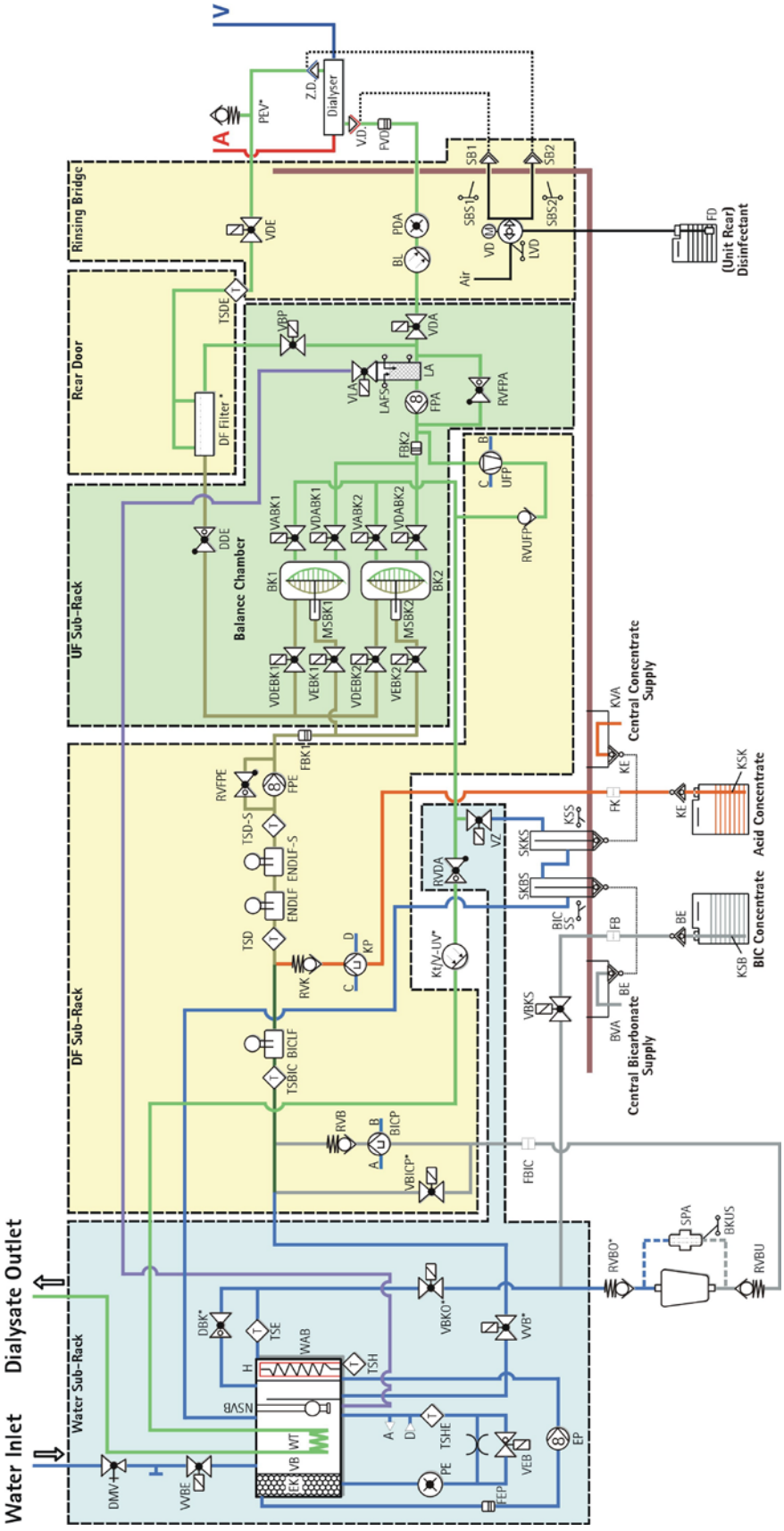
16.1 Flow diagrams

16.1.1 Key to flow diagrams

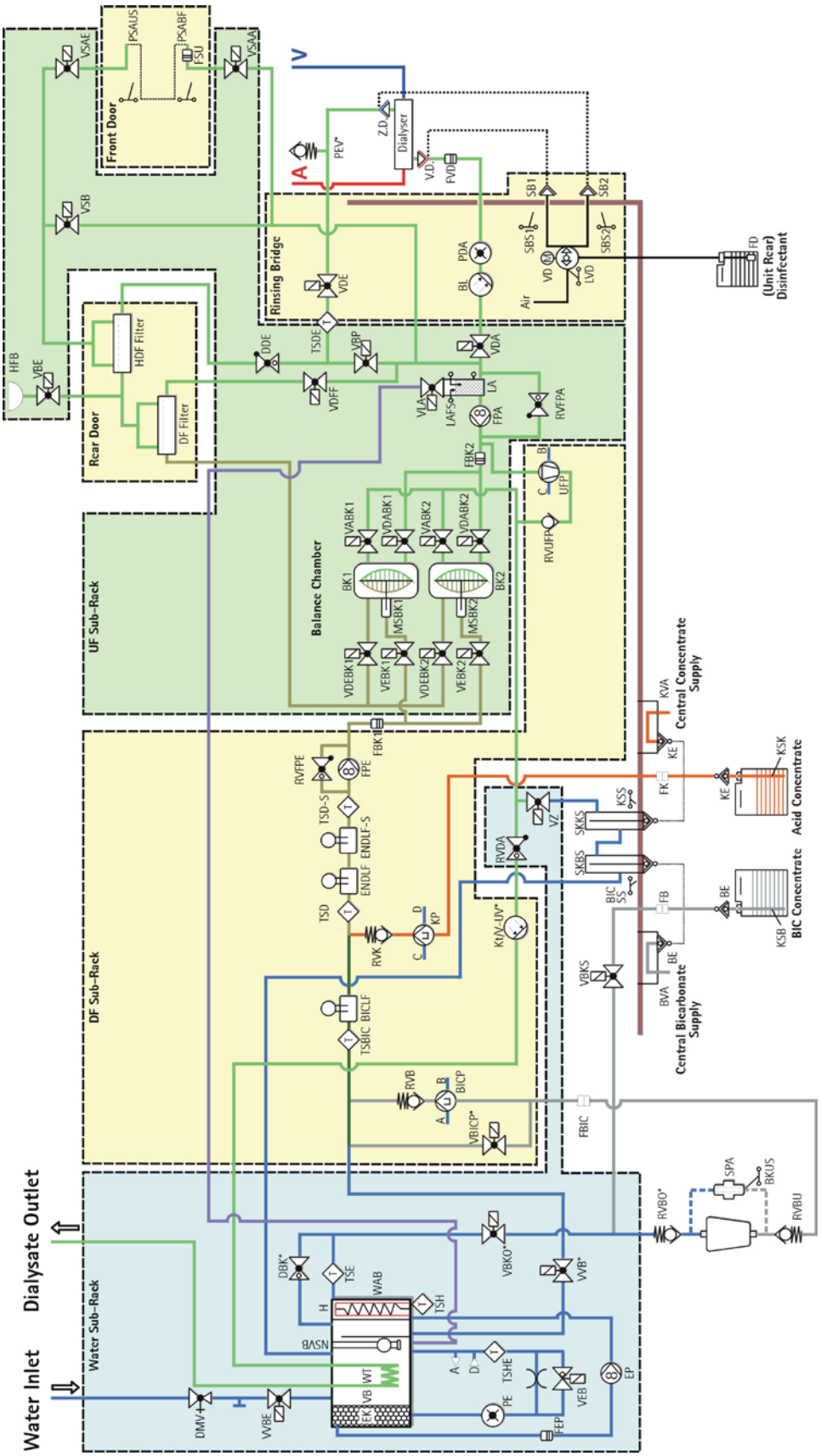
Symbol	Abbreviation	Description
	BICLF ENDLF ENDLF-S	Bicarbonate conductivity sensor END conductivity sensor END conductivity sensor supervisor
	BICP BPA BPV	Bicarbonate concentrate pump Arterial blood pump Venous blood pump
	BICSS KSS	Bicarbonate rinsing connection sensor Concentrate rinsing connection sensor
	BK1 MSBK1 BK2 MSBK2	Balance chamber 1 Membrane position sensor balance chamber 1 Balance chamber 2 Membrane position sensor balance chamber 2
	BL	Blood leak detector
	BVA KVA	Bicarbonate supply connection Concentrate supply connection
	DDE RVDA RVFPA RVFPE	Dialyser inlet check valve Dialysate check valve Flow pump outlet check valve Flow pump inlet check valve
	DMV	Pressure reduction valve
	EP FPE FPA	Degassing pump Inlet flow pump Outlet flow pump
	WA	Water block with integrated upline tank, level sensor, double-stage heater, heat exchanger and degassing chamber
	PA PBE PBS PDA PE PV	Arterial pressure sensor Blood inlet pressure sensor Blood control pressure sensor Dialysate outlet pressure sensor Degassing pressure sensor Venous pressure sensor
	VEB	Degassing bypass valve

Symbol	Abbreviation	Description
	DBK	Bicarbonate cartridge throttle
	VABK1/2, VBE, VBICP, VBKO, VBKS, VBP, VDA, VDABK1/2, VDE, VDEBK1/2, VEBK1/2, VLA, VSAE, VSB, VVB, VVBE, VZ	Solenoid valve
	TSE TSHE TSH TSBIC TSD TSD_S	Degassing temperature sensor Heater inlet temperature sensor Thermal fuse heater Bicarbonate temperature sensor Dialysate temperature sensor Dialysate temperature sensor supervisor
	RVB RVBO RVBU RVK	Bicarbonate check valve Top bicarbonate check valve Bottom bicarbonate check valve Concentrate check valve

16.1.2 Flow diagram Dialog+



16.1.3 Flow diagram Dialog+ HDF-online



16.2 Technical safety inspection and preventive maintenance

The 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.

The preventive maintenance is recommended every 12 months according to the specified check list in the service manual and with reference to the instructions for use.