Diapact® CRRT

Instructions for use 2.1x

B BRAUN
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 are an integral part of the dialysis machine. They describe the appropriate and safe use of the dialysis machine at all stages of operation.

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

1.1.1 Validity

Article number

These instructions for use apply to Diapact® CRRT dialysis machines with the article number **7106505.**

Software version

These instructions for use apply to software versions 2.1x.

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 appropriate 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

AD	Air detector
CVVH	Continuous veno-venous haemofiltration
CVVHD	Continuous veno-venous haemodialysis
CVVHFD	Continuous veno-venous high-flux haemodialysis
HD	Haemodialysis
HFD	High-flux haemodialysis
HF	Haemofiltration
PA	Arterial pressure
PAP	Plasmaadsorption/-perfusion
PBE	Pressure at the arterial inlet of the filter
PD1	Filter inlet pressure
PD2	Filter outlet pressure
PEX	Plasma exchange
PV	Venous pressure
SCUF	Slow continuous ultrafiltration
SAD	Safety air detector
SAK	Safety clamp
TMP	Trans membrane pressure
UF	Ultrafiltration

1.2 Intended use and indication

The dialysis machine can be used for implementing and monitoring haemodialysis therapies for patients with acute or chronic renal failure and plasma therapies for patients with corresponding indication. The system can be used in hospitals, especially intensive care units, and in dialysis centers.

The following types of therapy can be carried out with the system:

- Slow continuous ultrafiltration (SCUF)
- Continuous veno-venous haemofiltration (CVVH)
- Continuous veno-venous haemodialysis (CVVHD)
- Continuous veno-venous high-flux haemodialysis (CVVHFD)
- Intermittent haemofiltration (HF)
- Intermittent haemodialysis (HD)
- Intermittent high-flux haemodialysis (HFD)
- Plasma exchange (PEX)
- Plasmaadsorption/-perfusion (PAP)

1.3 Contraindication

There are no known contraindications for acute and chronic haemodialysis as well as for plasma therapies.

The attending physician 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.

Hypersensitivity reactions caused by using the necessary tubes 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 instructions of the attending physician if the patient suffers from one of the following conditions:

- Unstable circulation
- Hypokalemia

WARNING

Dialyses for patients with a body weight of less than 30 kg require a wider safety concept than that applicable for heavier patients.

- **The Diapact® CRRT is not intended to be used on patients with a body weight less than 30 kg.**

1.5.2 Electrical hazards

The dialysis machine contains life-threatening electrical voltages. 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 repair or be disposed.

1.5.3 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.

1.5.4 Use with central-venous catheter

For cardiac application, a higher degree of protection against electric shock (type CF) is required. As electric currents can run through supply lines, via the dialysis fluid filter, the dialyzer, the catheter, the patient and every conducting object in the vicinity of the patient, electrical potential equalization must be provided. The ambient conditions of the premises should be according to DIN VDE 0100 Part 710.

1.6 Interaction with other devices

When using the dialysis machine in combination with other therapeutic devices, we recommend connecting a potential-equalization device because the leakage currents from all connected devices will accumulate.

In individual cases, interferences with an ECG monitor were observed due to electrostatic charge of the tube system in peristaltic roller pumps.

If an arrhythmia occurs, stop the therapy and record the ECG again. It is recommended to strictly follow the instructions for use of the manufacturer of the ECG monitor using high quality electrodes, originally packed and unused, to ensure especially low contact impedance between the ECG electrodes and the patient's skin and to ensure the correct placement of these electrodes. Ensure that the ECG common electrode is positioned where the best signal is observed.

1.6.1 Electromagnetic interaction

The dialysis machine has been developed and tested in compliance with IEC 601-1-2 for EMC compatibility. It can not, however, be guaranteed that no electromagnetic interaction with other devices will occur.

Examples: mobile phones, computer tomograph (CT)

We therefore recommend using mobile phones and other devices emitting strong electromagnetic radiation only at a **minimum distance**, according to the table in section 15.3 from the dialysis machine.

> **!** When other therapeutic or diagnostic medical devices are installed on or near Diapact® CRRT or when other non-medical devices are installed close to the Diapact® CRRT, the user must ensure correct operation of the Diapact® CRRT in such device combinations.

1.7 Information for the operator

1.7.1 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.

1.7.2 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.

1.7.3 Conformity

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

IEC 60601-2-16:1998 (VDE 0750 part 2-16)

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 to the valid version of System Standard IEC 60601-1-1.

Persons connecting additional devices to signal input or output components modify the 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.

Europe

In Europe, the dialysis machine is a class IIb device complying with the fundamental requirements of EC Directive for Medical Products 93/42/EEC. The CE marking confirms that the dialysis machine complies with the "Guidelines issued by the Commission for Medical Products 93/42/EEC" dated 14 June 1993.

1.7.4 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 authorized by him and
- the electrical installations of the affected room comply with the valid national requirements on the equipment in medical treatment rooms (i.e. VDE 0100 part 710 and/or IEC stipulations).

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

- has carried out a functional check on site (initial commissioning),
- has trained the persons appointed by the operator to use the device in the correct handling, use and operation of the medical product with the aid of the instructions for use, enclosed information and maintenance information

1.7.5 Technical changes

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

1.8 Disposal

Dialysis machines may be returned to the manufacturer for disposal in accordance with the applicable disposal guidelines based on Directive 2002/96/EC.

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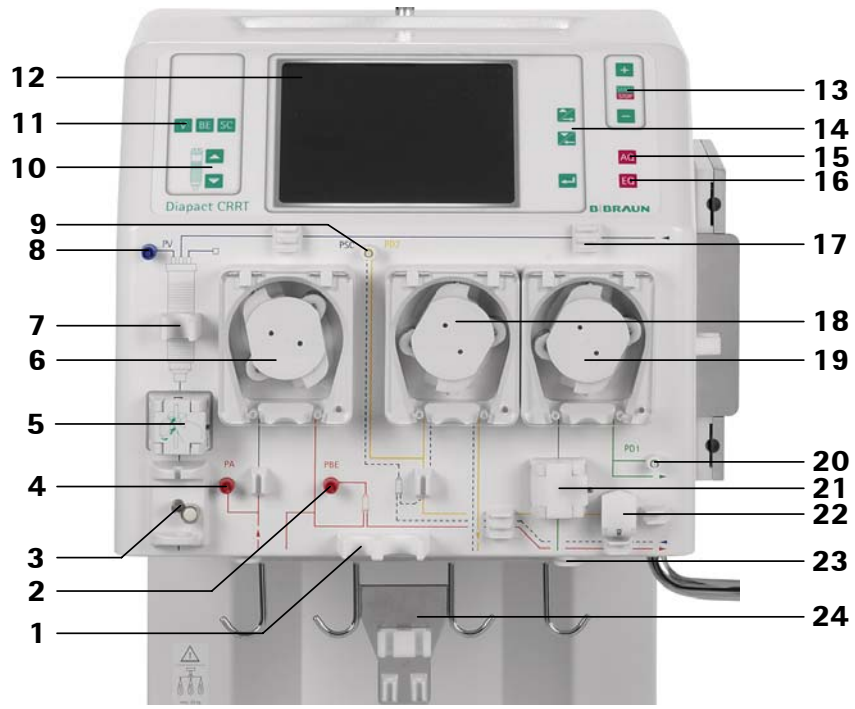
2 Product description

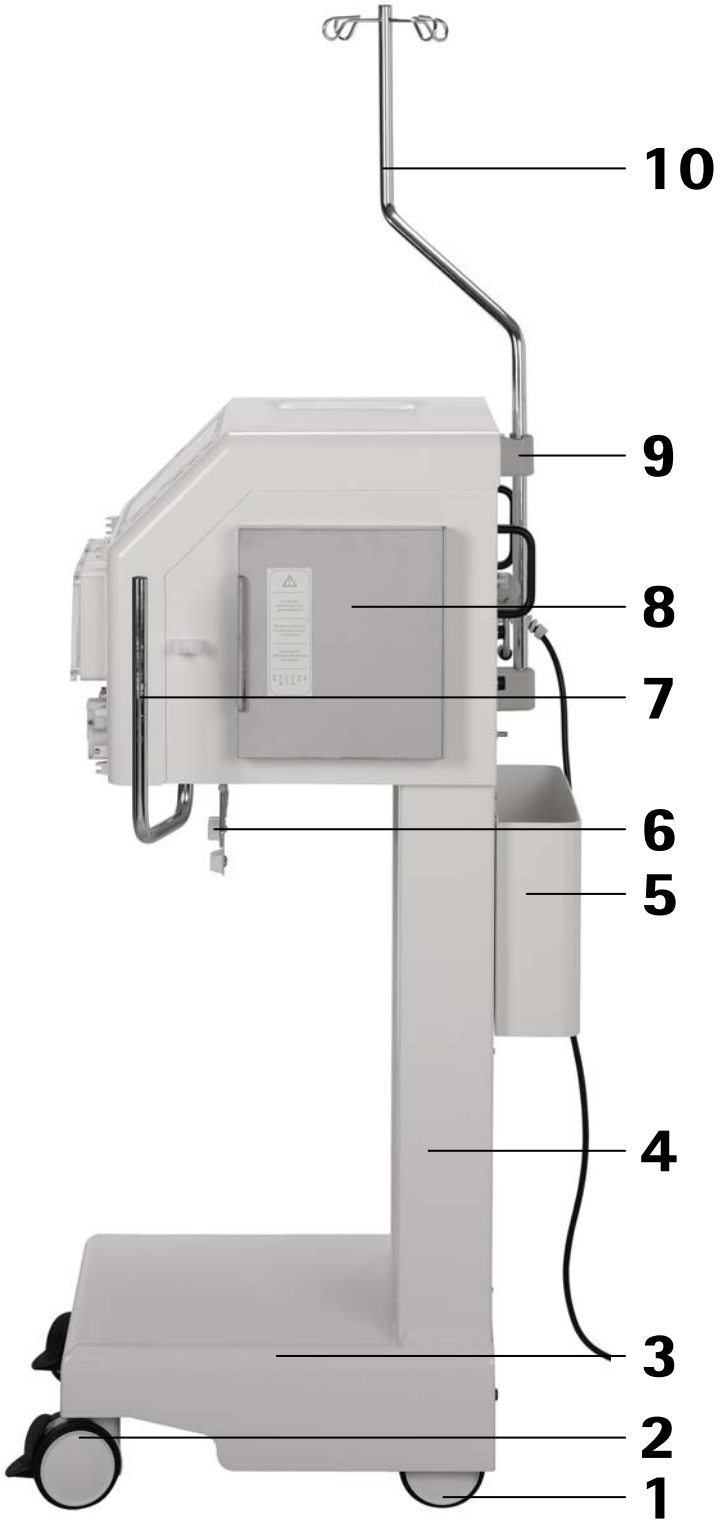
2.1 Machine

Front view



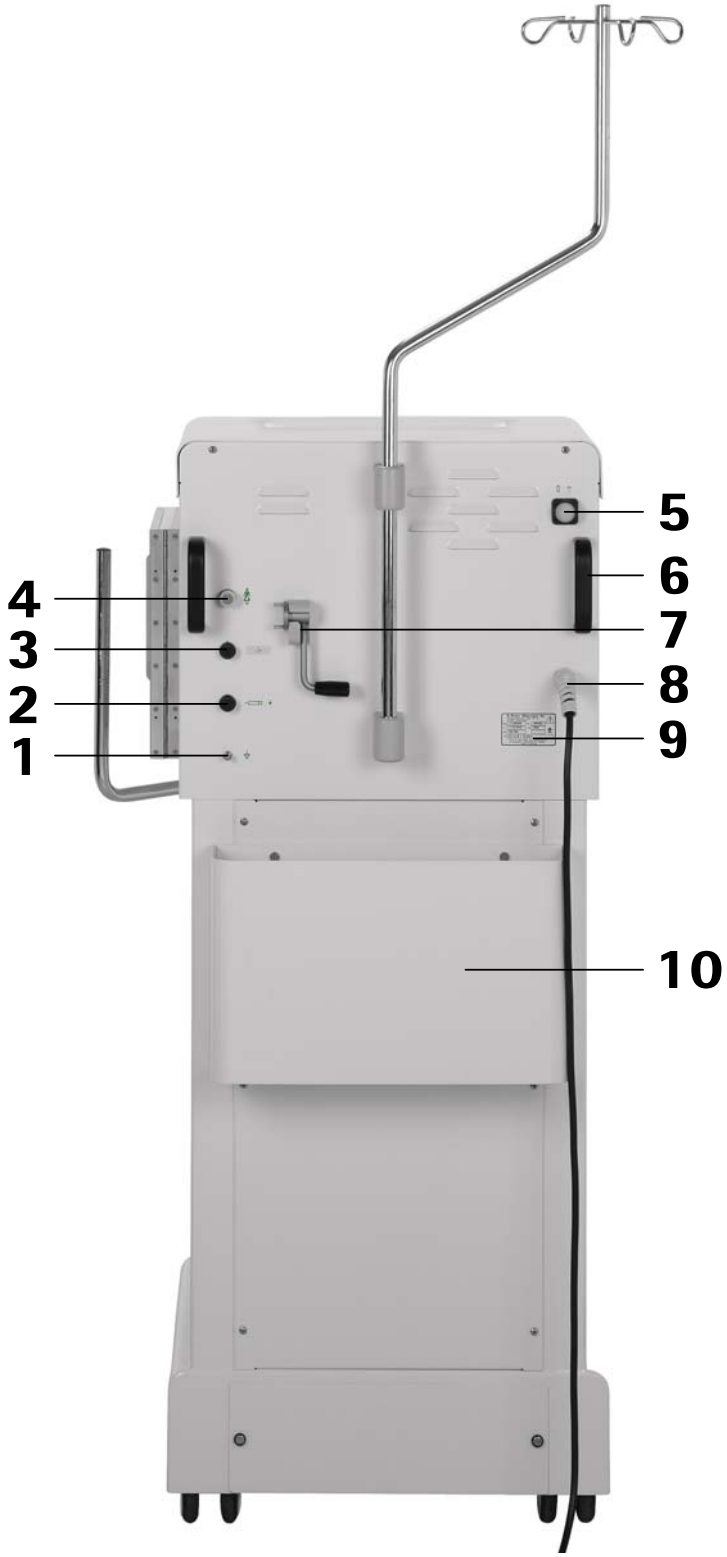
1 Fixing for arterial air trap
2 Connection for pressure sensor - pressure before filter (PBE)
3 Safety air clamp (SAK)
4 Connection for pressure sensor - arterial pressure (PA)
5 Safety air detector (SAD)
6 Blood pump (MP1)
7 Fixing for venous air trap
8 Connection for pressure sensor - venous pressure (PV)
9 Connection for pressure sensor – filter outlet pressure (PSC/PD2)
10 Keys for level regulation (up and down) of the air traps
11 Keys for chamber selection
12 Display
13 Keys for operating the blood pump
14 Keys for cursor movement and function selection
15 Key for alarm acceptance (AQ)
16 Key for input confirmation (EQ)
17 Line fixing
18 Ultrafiltration pump (MP2)
19 Substitution/dialysate pump (MP3)
20 Connection for pressure sensor – filter inlet pressure (PD1)
21 Air detector (AD)
22 Blood leak detector (BLD)
23 Holder for pre-assembled kit
24 Bag holder of the load cell with line fixing

Side view



1 Rear wheel fixed
2 Turnable front wheel with brake
3 Base
4 Base frame
5 Storage box
6 Bag holder of the load cell
7 Filter holder
8 Heater
9 Holder of the infusion pole
10 Infusion pole

Rear view



1 Potential equalization
2 External pump connection
3 RS 232 interface
4 Interface nurse call
5 Main switch
6 Handles for transportation
7 Crank for manual blood return
8 Power cable
9 Type plate
10 Storage container

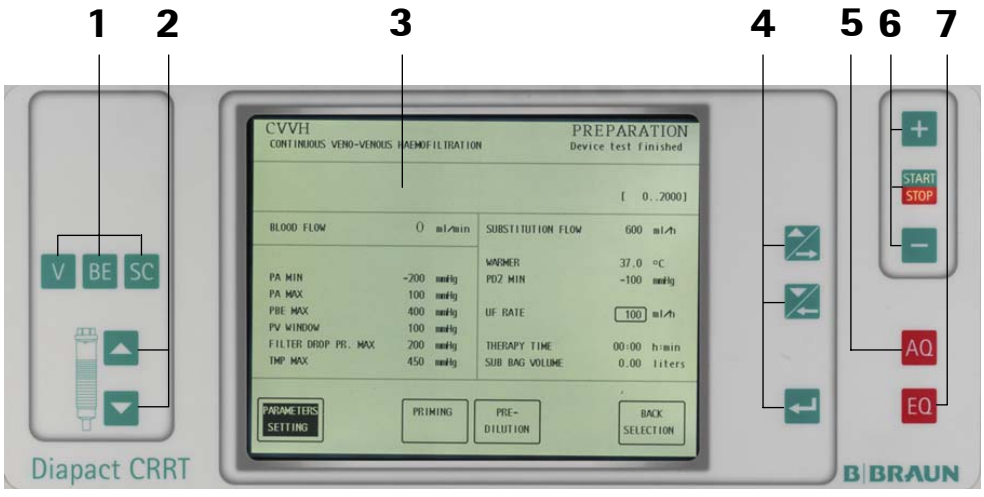
2.2 Symbols on the machine

	Observe instructions for use Observe safety information
	Application device type B Classification acc. to DIN EN 60601-1/ IEC 601-1
	Machine OFF
	Machine ON
	Alternating current
	Connection nurse call
	Connection of external computer
	Potential equalization
	Connection for perfusor

2.3 User interface

2.3.1 Control panel

Control panel



1 Keys for selection of the air trap
2 Keys for level regulation of the selected air trap
3 Display
4 Keys for data entry, selection and confirmation
5 Key for alarm acknowledgment
6 Keys to operate the blood pump
7 Key to confirm data entry

2.3.2 Keys on the control panel

	**Key for alarm acknowledgment** Every alarm situation causes an acoustic signal, the AQ key lights red and the alarm description is shown on the screen in the alarm field. The alarm tone is silenced by pressing the AQ key. The AQ key continues to light. The user solves the problem that caused the alarm and confirms by pressing the AQ key again. The AQ key light and the alarm message on the screen are extinguished. The machine returns to the phase where the alarm occurred.
	**Confirmation key** With the EQ key, status changes and safety-relevant data (e.g. blood flow, substitution flow, ultrafiltration rate) are confirmed.

2.3.2.1 Keys for chamber selection and level regulation

The initial blood level in the arterial and venous air trap and the fluid level in the filtrate air trap are set automatically by internal peristaltic pumps during priming. During therapy the fluid level in the air traps can be adapted manually by these pumps. After selection of the desired air trap the level can be raised or lowered.

	Selecting the venous air trap
	Selecting the arterial air trap
	Selecting the filtrate air trap
	Raising the fluid level
	Lowering the fluid level

2.3.2.2 Keys for data entry, selection and confirmation

	Moves the cursor upwards in the <THERAPY SELECTION> and <PARAMETERS SETTING> menus and to the right in <FUNCTION SELECTION>. Increases the selected parameter in <PARAMETERS SETTING>.
	Moves the cursor downwards in the <THERAPY SELECTION> and <PARAMETERS SETTING> menus and to the left in <FUNCTION SELECTION>. Decreases the selected parameter in <PARAMETERS SETTING>.
	Confirms the selection in <THERAPY SELECTION>, <FUNCTION SELECTION> and <PARAMETERS SETTING>. Confirms the changed parameter in <PARAMETERS SETTING>. Leaves the <PARAMETERS SETTING> menu.

2.3.2.3 Keys to operate the blood pump

The keys to operate the blood pump allow operating this pump without switching to the <PARAMETERS SETTING> menu.

+	The blood pump rate is increased by 5 ml/min increments.
START STOP	Blood pump START and STOP • LED lights up - the pump is stopped • LED does not light up - the pump runs
−	The blood pump rate is decreased by 5 ml/min increments

2.3.2.4 Special functions

Pressing the combination of keys described in the following simultaneously selects the special function.

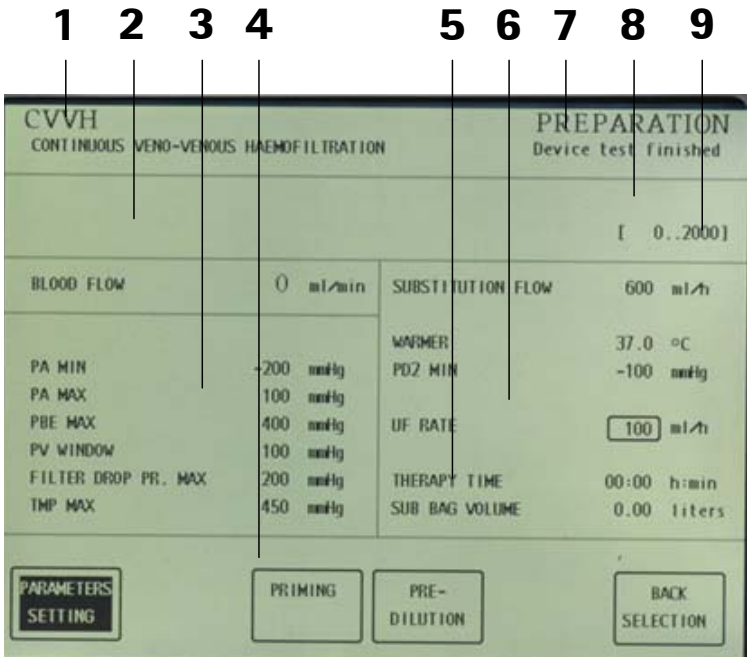
V BE +	Background brighter
V BE −	Background darker
V BE	Contrast +
V BE	Contrast -
V BE ↵	Therapy reset (1 sec during RAM test) The phase and the parameters saved for the therapy previously interrupted are cleared.
V BE SC	Language change

2.3.3 Display

The LCD display of the control panel is the central element of the user interface. It displays all relevant data in the respective therapy phase and situation.

Display

1. Therapy mode
2. Alarms, warnings, messages
3. Blood circuit parameters/data
4. Menu selection
5. Therapy time
6. Fluid circuit parameters/data
7. Therapy status
8. Safety-relevant data, supervisor field
9. Parameter range



- **Therapy mode**
  The therapy mode field displays the selected therapy mode as text (e.g. continuous veno-venous haemofiltration) and abbreviation (e.g. CVVH)
- **Therapy status**
  The therapy status field displays the actual therapy status (e.g. preparation, therapy) and the respective sub-phase (standby, therapy running, test).
- **Alarms, warnings, messages**
  This field displays alarm messages and warnings together with a brief description and the possible cause of the alarm.
- **Safety-relevant data, supervisor field**
  This field displays the new therapy status in case of a status change and the value of safety-relevant parameters (e.g. UF volume) to be confirmed or changed.
- **Parameter range**
  During parameter setting in this field, the possible range of the currently selected parameter is displayed.
- **Blood circuit parameters**
  This field shows all parameters and data of the extracorporeal blood circuit (e.g. flow rate, total volume treated, pressures etc.)
- **Fluid circuit parameters**
  This field shows all parameters and data of the fluid circuit (flow rate, temperature, pressure, total volume).
- **Therapy time**
  This field shows the actual therapy time
- **Menu selection**
  This field displays the selectable functions during the respective therapy phase.

2.4 Therapy modalities

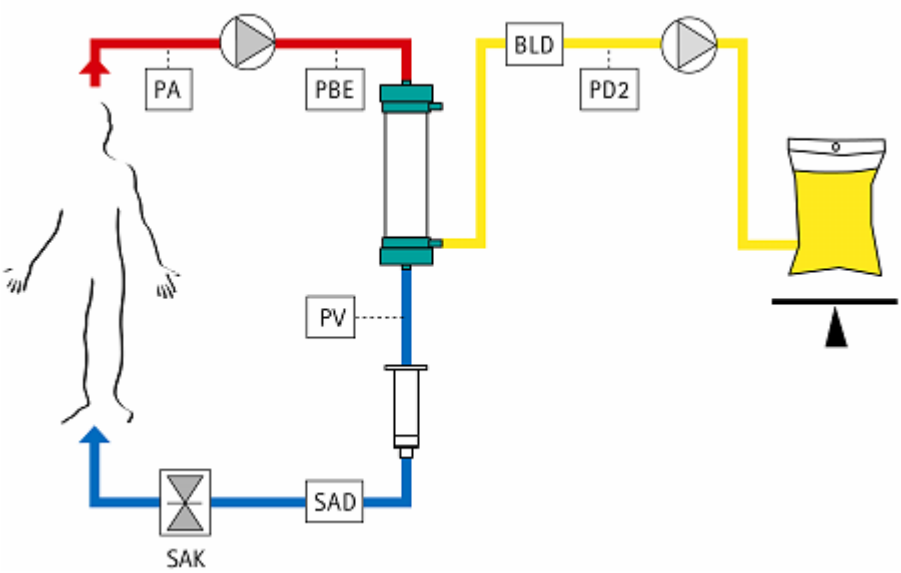
Diapact® CRRT is designed to perform continuous and intermittent renal replacement therapies for acute and chronic renal failure and plasma therapies. The continuous therapies are preferred for intensive care patients because the continuous water removal supports the circulatory stability of these patients.

Slow continuous ultrafiltration (SCUF)

In SCUF therapy the dialysis machine pumps blood through the vascular access of the patient into the haemofilter. Excess body water is slowly and continuously filtered through the haemofilter and discarded. The concentrated blood is reinfused into the patient. Since the elimination of body water is the main purpose of this therapy, a haemofilter with high water permeability characterized by a high-flux membrane is used (e.g. Diacap® Acute).

This type of therapy is indicated for patients with diuretic-resistant fluid overload.

SCUF (Slow continuous ultrafiltration)



Haemofiltration (CVVH/HF)

Haemofiltration is the most common modality used in the treatment of patients with acute renal failure.

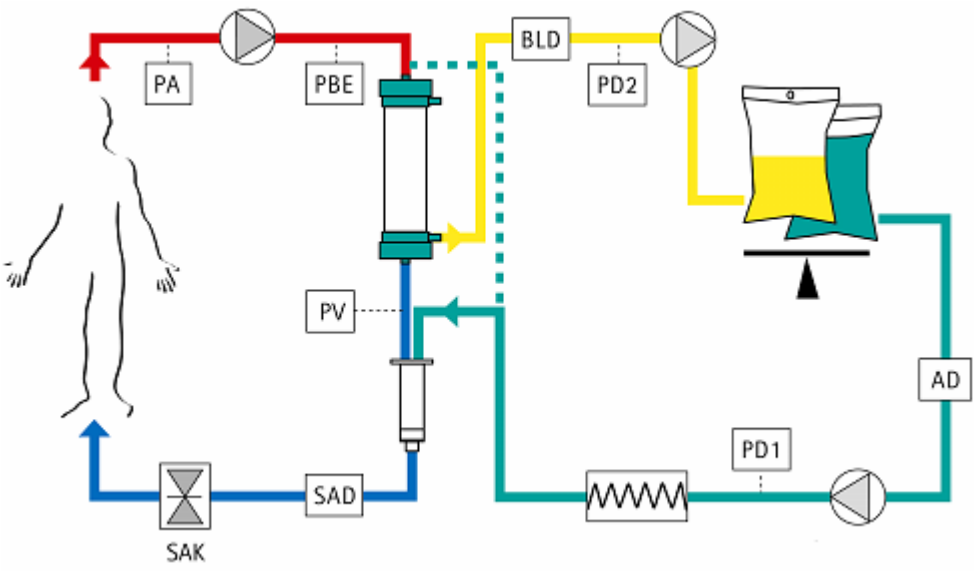
With the Diapact® CRRT, haemofiltration can be performed continuously (CVVH, continuous veno-venous haemofiltration) or intermittently (HF, haemofiltration). In the latter case, the haemofiltration is performed between 4 and 12 hours per day.

In haemofiltration (HF) the blood is pumped through the high-flux haemofilter (e.g. Diacap® Acute) where uremic toxins dissolved in the body water are withdrawn through a semipermeable membrane. High-flux membranes are used because of their high water permeability and cut-off for uremic toxins. To achieve sufficient clearance about 1000 ml of body water per hour has to be removed. Most of this fluid (about 900 ml) has to be replaced by infusion of sterile substitution fluid. The replacement can take place either before the haemofilter (predilution) or after the haemofilter (postdilution). The blood treated in this way is then reinfused into the patient.

The sterile substitution fluid (e.g. Duosol®) has a similar electrolyte composition as the plasma. The different potassium concentrations (0, 2 and 4 mmol/l) meet the needs of patients with acute renal failure and are administered according to the prescription of the attending physician.

Using haemofiltration in the predilution mode, filter clotting can be reduced while in the postdilution mode the convective clearance is higher.

Haemofiltration (HF) and continuous veno-venous haemofiltration (CVVH)

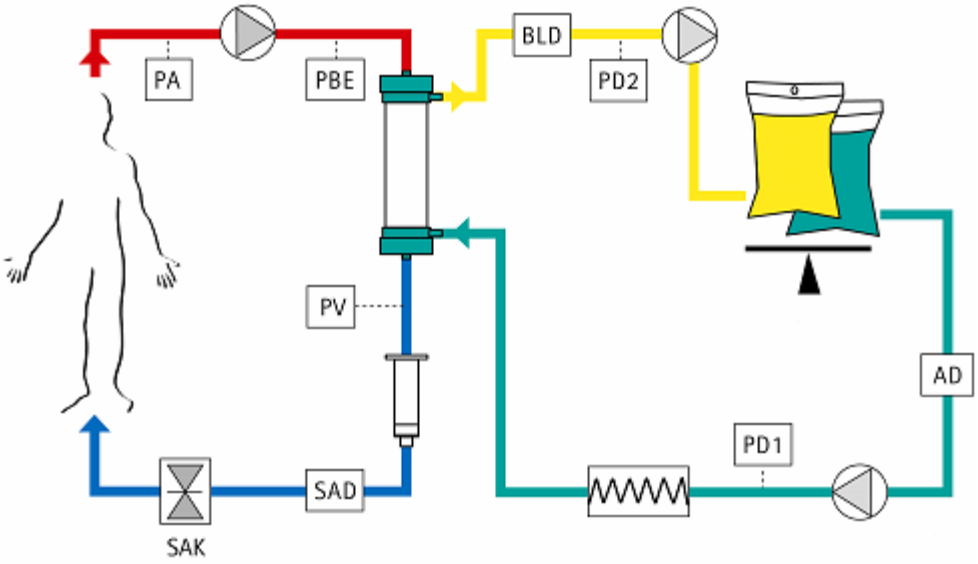


Haemodialysis (CVVHD/HD)

The dialysis machine pumps blood through a vascular access of the patient into the haemofilter. In the haemofilter, blood and dialysis fluid are separated by a semipermeable membrane and the dialysis fluid passes the blood in a countercurrent way. Uremic toxins are separated from the blood mainly by diffusion and osmosis but also by convection. The cleaned blood is then reinfused into the patient.

In dialysis therapies with the Diapact® CRRT, the substitution fluids mentioned above are used as dialysis fluids.

Haemodialysis (HD) and continuous veno-venous haemodialysis (CVVHD)



High-flux dialysis (CVVHFD/HFD)

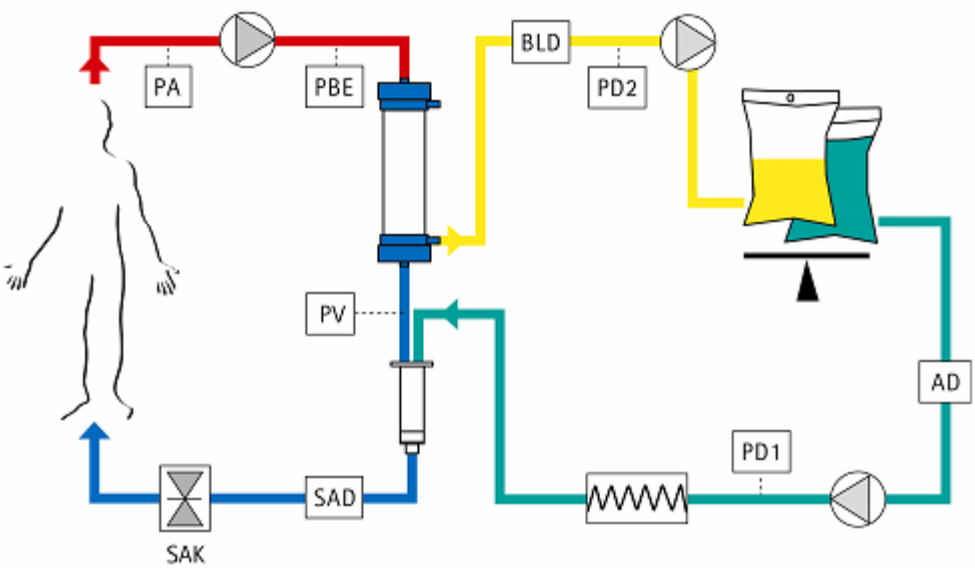
High-flux dialysis (HFD) and continuous veno-venous high-flux dialysis (CVVHFD) combine haemofiltration and haemodialysis. The substitution with the sterile solution occurs by substitution via the haemofilter. In the lower part of the haemofilter, ultrafiltration takes place and in the upper part of the filter where the transmembrane pressure is lower, the substitution fluid flows from the fluid compartment into the blood compartment. The configuration of the device is the same as for CVVH/HF.

Plasma exchange

In plasma exchange, the dialysis machine pumps blood through a vascular access of the patient into a plasmafilter where the plasma is separated from the corpuscular components of the blood. The separated plasma is discarded and before the blood is reinfused into the patient it is replaced by a substitution fluid which might be donor plasma, fresh frozen plasma or an albumin solution.

In plasma exchange, toxic substances with higher molecular weight are removed unspecifically.

Plasma exchange (PEX)

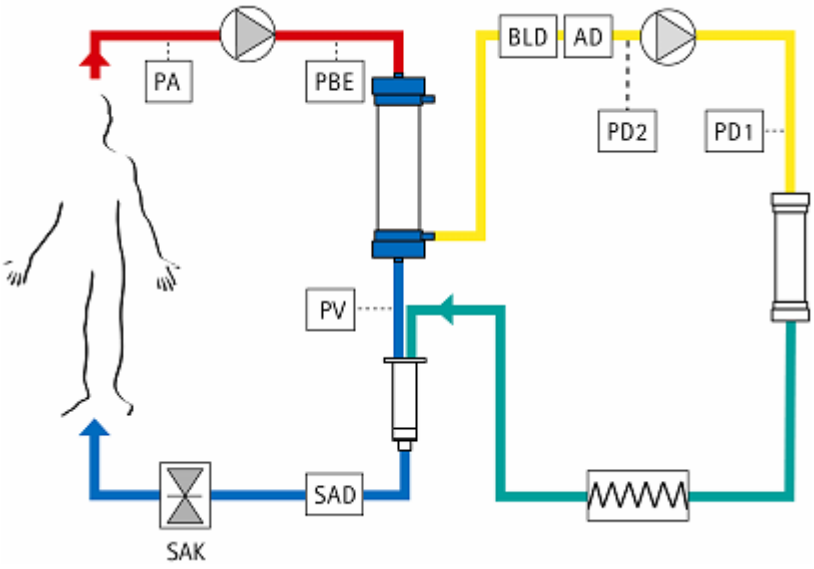


Plasma adsorption/perfusion

In plasma adsorption/perfusion, the plasma separated as described above is guided through a specific adsorber. The purified plasma is combined with the blood coming from the plasmafilter and reinfused again into the patient.

This method allows to remove, dependent on the adsorber used, specific toxic substances of higher molecular weight.

Plasma exchange (PAP)



All the therapies described above are administered according to the prescription of the attending physician.

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3 Installation and Commissioning

First installation and operation
Unpacking and first installation of the machine must be carried out by a service technician of B. Braun Avitum AG or by an authorized service technician.

3.1 Scope of supply

- Diapact® CRRT dialysis machine
- Instructions for use

Goods-in check

- ➢ Unpack the 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

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

3.2.3 Decommissioning

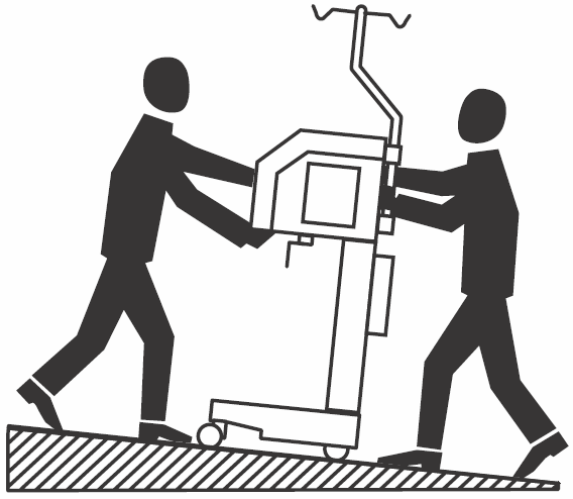
- ➢ Instruct technical service to empty the dialysis machine.
- ➢ Store the dialysis machine in ambient conditions as specified in Section 15.2.

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°.**

Transport on stairs and slopes (2 persons)

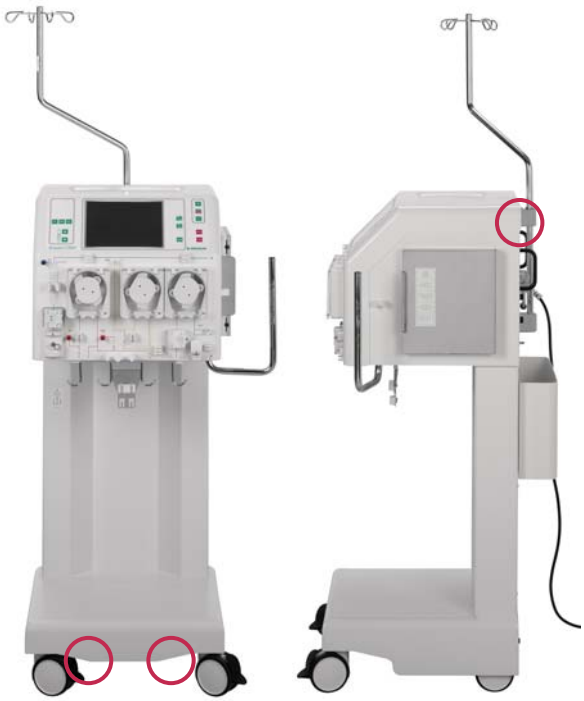


- ➢ Release both locks of front rollers.
- ➢ Wheel the dialysis machine by holding it using the handles at the rear.
- ➢ Apply both locks of front rollers.

3.3.2 Carrying

For carrying, the dialysis machine can be held at the base, at the rear, as shown in the illustration below.

Holding points for carrying the dialysis machine



CAUTION

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

- **Do not hold the machine on the filter holder or on the infusion pole when transporting.**

Risk of injury

- **Remove the infusion pole before carrying the machine.**

- Remove the infusion pole by pulling it out of its holder.
- Release roller locks.
- Tilt the dialysis machine.
- Put down the dialysis machine.
- Apply roller locks.
- Insert the infusion pole again in the respective holder.

3.4 Installation site

Ambient conditions
Observe information about ambient conditions, see Section 15.2.

3.4.1 Electrical connection

The existing mains voltage must match the voltage specified on the rating plate.

No extension cables or adapters may be used with the mains cable.

Electrical installations in the room where the dialysis machine will be operated must conform to relevant regulations, e.g. VDE 0100 Part 710 and/or IEC stipulations.

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.

3.4.2 Potentially explosive areas

Do not operate the dialysis machine in areas with risk of explosions.

3.5 Initial commissioning

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

3.6 Switching on and off

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

3.6.1 Intended switching on and off

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

3.6.2 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.
The dialysis machine continues the therapy.

If the power supply is interrupted either by a power failure or by switching off the machine, the therapy status and the parameters are saved for 4 hours in the preparation phase and for 30 minutes during the therapy phase.

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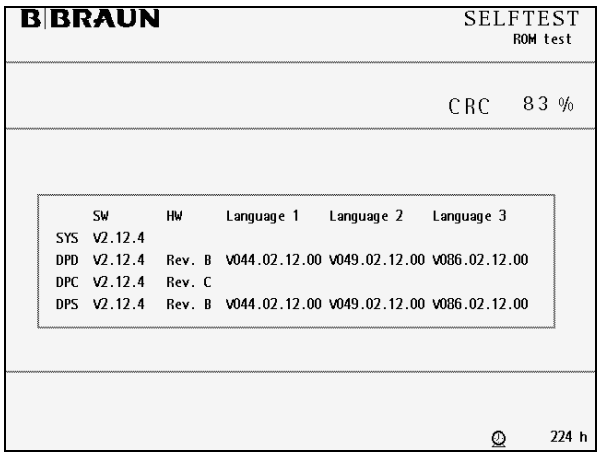
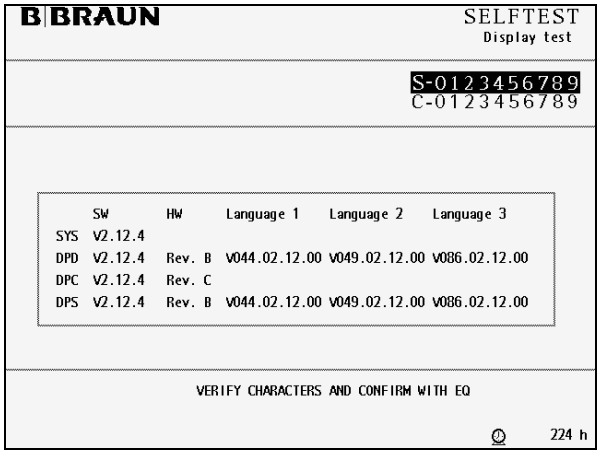
4 SCUF (Slow continuous ultrafiltration)

4.1 Switching on and initial tests

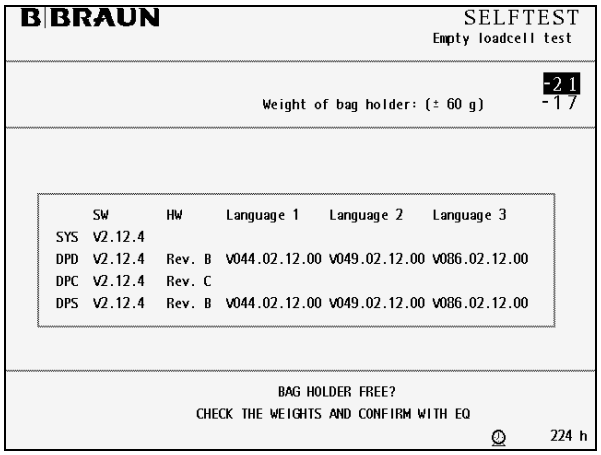


- Switch on the Diapact® CRRT with the power switch ON/OFF (I/O) on the back of the machine. The device starts with the ROM test.
- Check whether the AQ and EQ keys are lit during the ROM test.



The ROM test is followed by the display test.

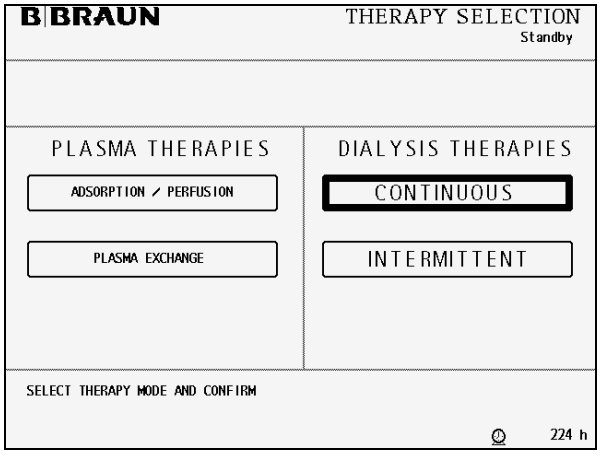
- Compare the character lines in the supervisor field and confirm by pressing the EQ key if both series are identical.
- While the EQ key is being pressed, the buzzer of the safety system is activated for 2 seconds.
- Check that the buzzer can be heard.



If the display test is passed successfully, the empty load cell test follows.

- Check whether the bag holder is empty.
- Confirm the weight values with the EQ key if they are within the allowed range. The maximum deviation between both displayed values is allowed to be ± 60 g and the values must not exceed -60 and +60 g.

4.2 Therapy selection

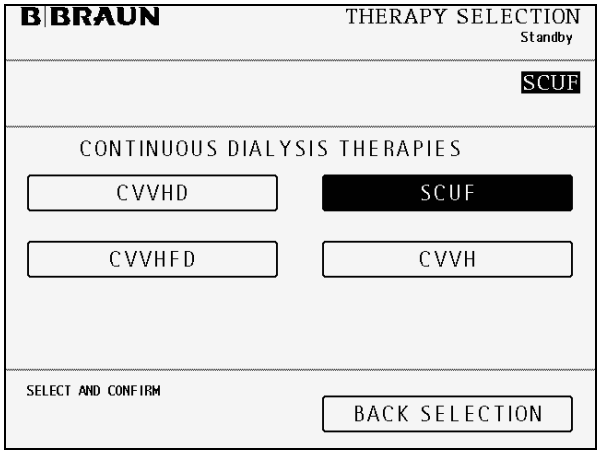


Having successfully passed the initial self tests, the machine switches to the <THERAPY SELECTION> screen to select the therapy mode.

<CONTINUOUS> dialysis therapies is selected by default.

➢ Confirm <CONTINUOUS> with the  key.

The following screen displays the possible therapy options.



<CVVH> is selected by default.

➢ Select <SCUF> using the  or the  key.

➢ Confirm the selection with the  key.

The  key lights up and SCUF is displayed in the supervisor field.

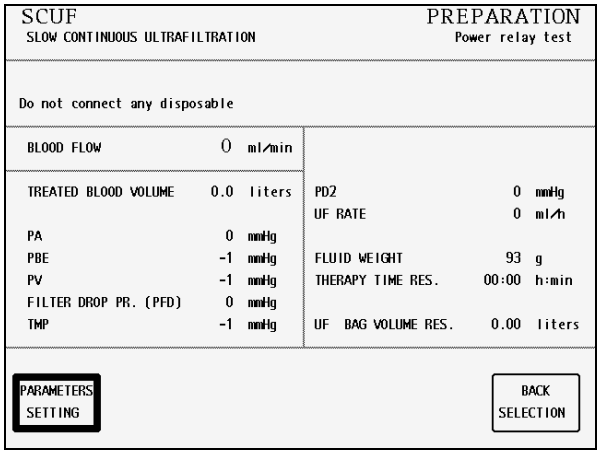
➢ Press the  key for final confirmation of the selected therapy modality.

If the selection after the confirmation with the  key is not finally confirmed with the  key, the device returns automatically to the <THERAPY SELECTION> screen where the therapy mode can be selected.

Back selection

Moving with the  or  keys to <BACK SELECTION> and confirmation with  allows to return to the screen where the therapy mode can be selected.

4.3 Preparation

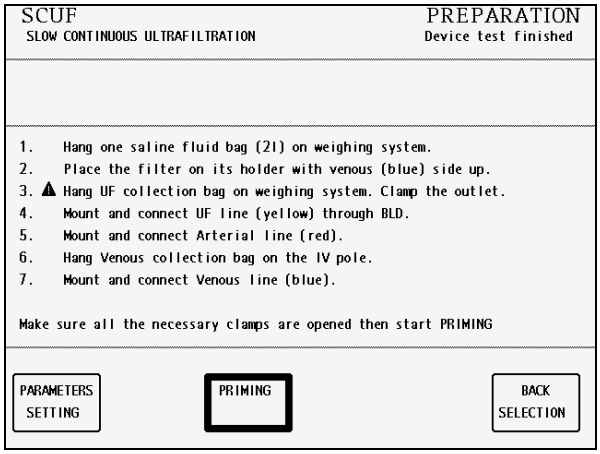


After modality selection and confirmation, the display shows the following <PREPARATION> screen.

Several tests are performed. The respective test is displayed in the therapy status field:

- Power relay test
- SAD reference test
- SAD counter test
- Red detector test
- Blood leak detector test
- Zero pressure test

4.3.1 Installation of consumable material



When the tests have been performed successfully, the <PREPARATION> screen displays <Device test finished> and the steps to set-up the machine are displayed.

The consumable material for the therapy comprises:

- SCUF kit
- Haemofilter
- 2L isotonic sodium chloride solution

➢ Follow the instructions on the screen and set-up the device as described in the following.

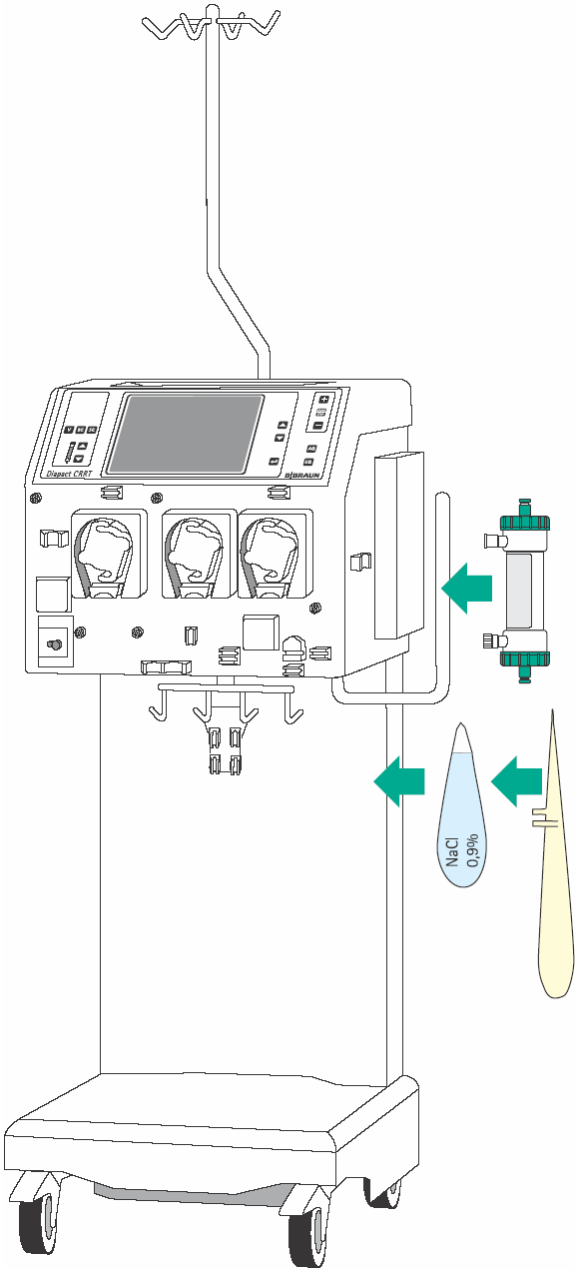
The lines of the SCUF kit are colour-coded to facilitate the set-up.
Arterial line (**red**)
Venous line (**blue**)
Ultrafiltration line (**yellow**)

Pumps used:
Blood pump (MP1)
Ultrafiltration pump (MP2)

WARNING

Risk of infection and blood loss for the patient by damaged packaging or components

- ➢ **Make sure during set-up that the packaging of the material used (line system, haemofilter, solution bags) is undamaged.**
- ➢ **During set-up check the material for integrity.**
- ➢ **Observe the respective instructions for use.**



Installation of bags and haemofilter

- Attach the collecting bags of the SCUF kit and the 2L bag with isotonic sodium chloride solution to the bag holder of the load cell.
- Fix the haemofilter into the filter holder on the right side of the machine.
- Close the clamp of the collecting bag at the tube equipped with the plug.

CAUTION

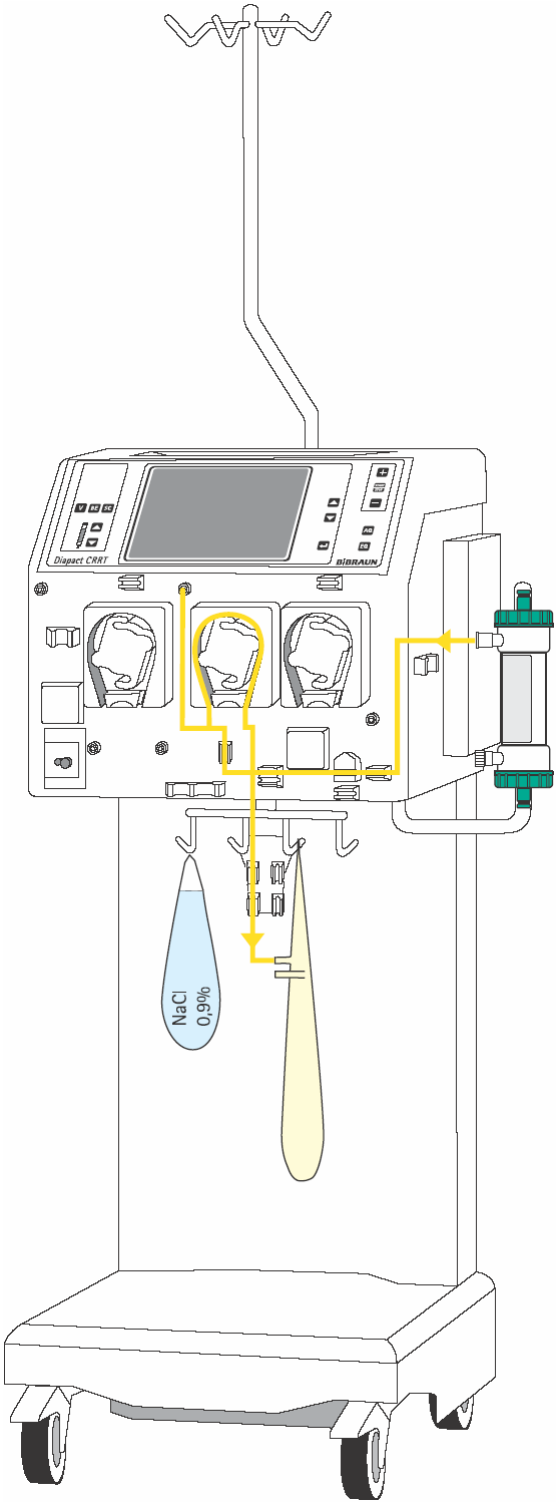
Incomplete moistening of the haemofilter during priming and rinsing may result in performance reduction.

- **Place the haemofilter into the filter holder with the arterial port downwards.**

If the weight on the load cell is unevenly distributed, there is a risk that the device may topple.

- **Distribute weight on the bag holder evenly.**

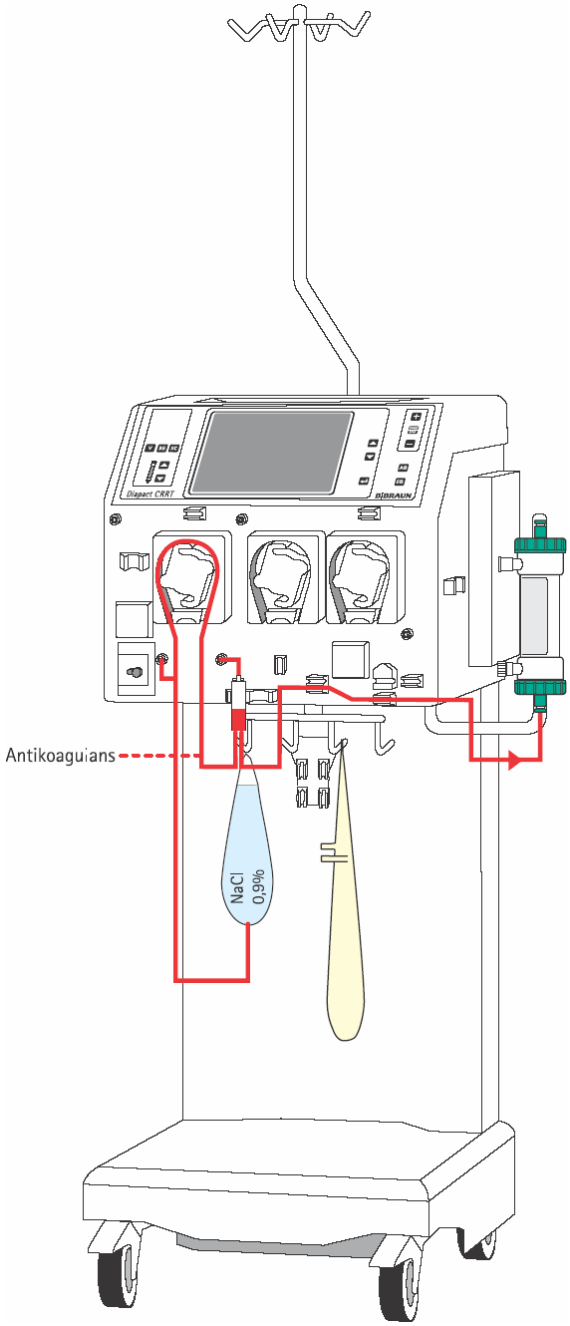
The maximal load of the load cell is 27 kg.



Insertion of the ultrafiltration line (yellow)

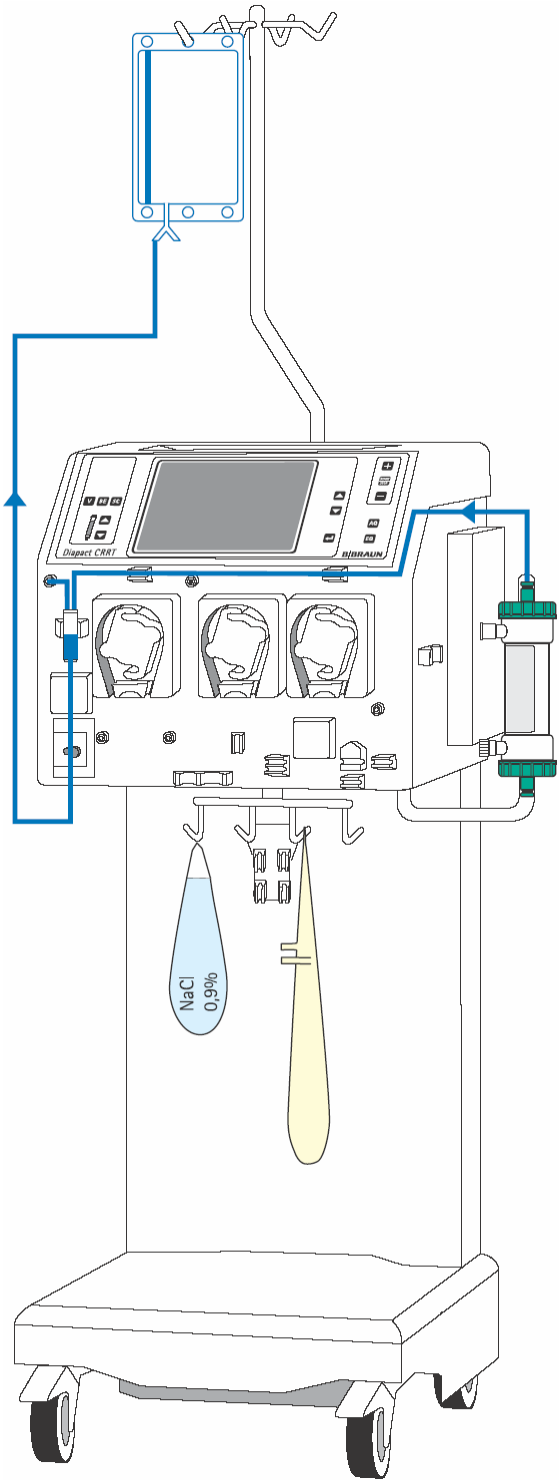
- Connect the end of the line with the Hansen connector to the upper filtrate outlet of the haemofilter.
- Insert the line coming from the haemofilter into the blood leak detector (BLD).
- Insert the pump segment into the ultrafiltration pump (MP2).
- Connect the transducer protector to the pressure sensor PSC/PD2 (white).
- Connect the Luer Lock connector to the collecting bag attached to the load cell.

i Ensure that the second filtrate-side connector, which is not used, is securely closed. It is recommended to use the Hansen connector attached on the substitution line.



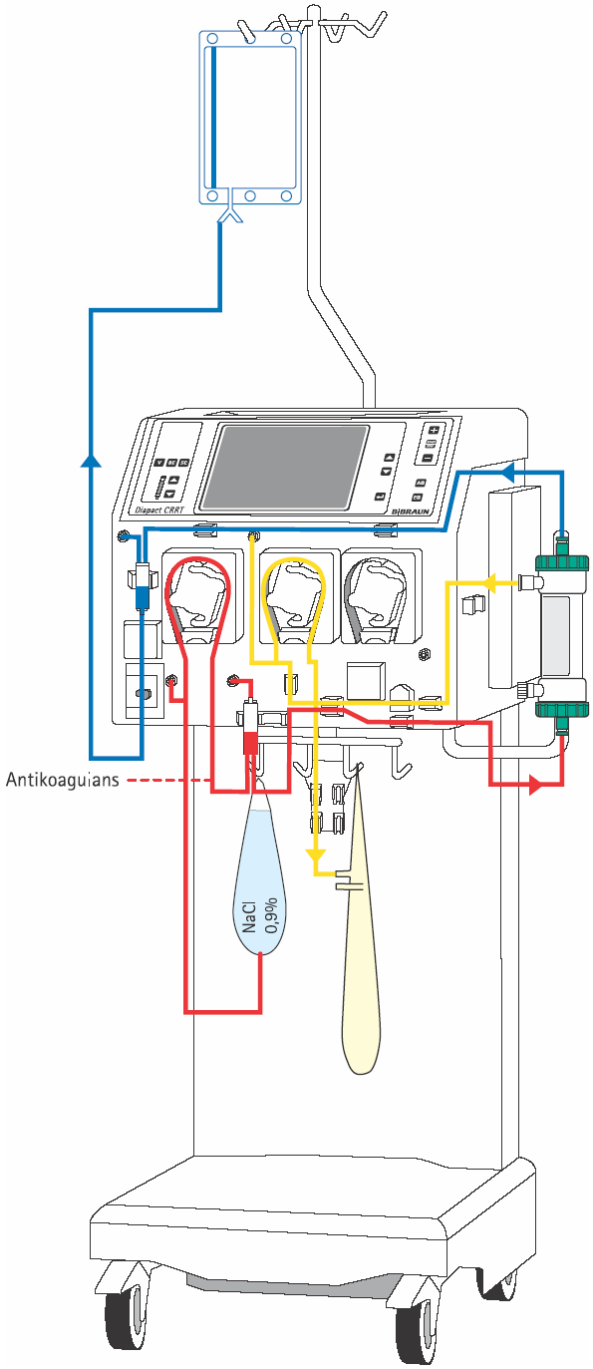
Insertion of the arterial line (red)

- Connect the end of the line with the spike/Luer Lock connector to the bag with isotonic sodium chloride solution on the bag holder of the load cell.
- Insert the pump segment into the blood pump (MP1).
- Connect the transducer protector before the blood pump to the pressure sensor PA (red).
- Insert the arterial air trap into the intended holder.
- Connect the transducer protector to the pressure sensor PBE (red).
- Connect the red Luer Lock connector to the lower blood-side connector of the haemofilter.
- If continuous heparinisation is required, connect the heparin line to the external heparin pump previously filled with heparin.
- Close the clamp of the heparin line if it is not used.
- Close the clamps at the sampling ports before and after the blood pump (MP1).



Insertion of the venous line (blue)

- Attach the rinsing bag to the infusion pole.
- Insert the venous air trap into the intended holder and fix the venous line in the line fixing above the pumps.
- Insert the venous line beneath the drip chamber into the safety air detector (SAD) and the safety air clamp (SAK) under the detector.
- Connect the transducer protector to the pressure sensor PV (blue).
- Connect the blue Luer Lock connector to the upper blood-side connector of the haemofilter.
- Close the clamp at the not used connection of the venous air trap.

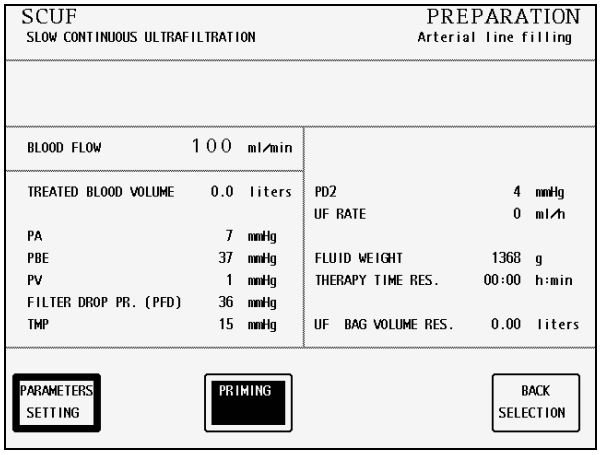


Set-up overview

- Check the set-up before starting the priming procedure.
- Take care that all connections are firmly screwed together.
- Check that all pump segments are inserted clockwise.
- Check that the following clamps are closed:
  - Sampling ports before and after the blood pump.
  - Heparin line if it is not used
  - Not used line at the venous chamber
  - Line with the plug at the collecting bag(s)
- Open the frangible pin of the sodium chloride solution bag.

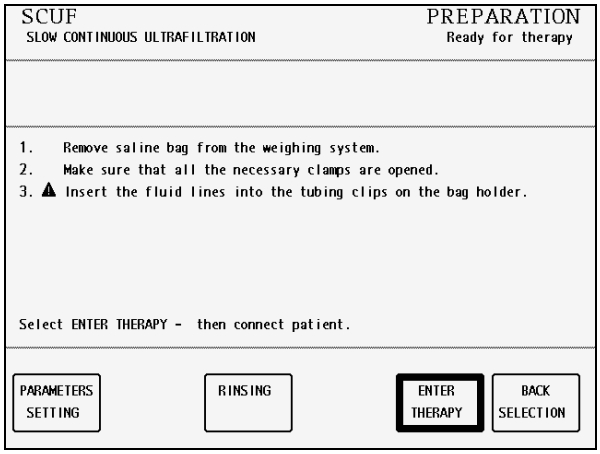
Make sure that all relevant clamps are opened and that all connections are firmly screwed together before starting the priming procedure.

4.3.2 Priming



- After set-up of the consumables and checking the connections, select <PRIMING> and confirm by pressing the  key.

The automatic priming program starts. During the priming and rinsing the following tests are performed: load cell test, ultrafiltration pump test (MP2), disposable leakage test and level regulation test. The respective step of the procedures and the test is displayed in the therapy status field.

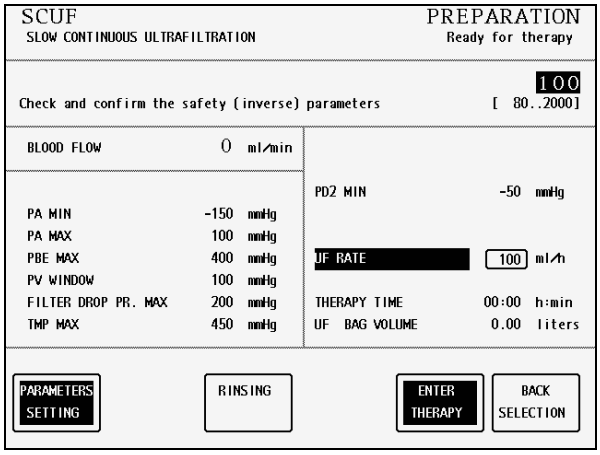


After the preparation phase has been finished, the system gives an acoustic signal and shows the <PREPARATION> screen with message <Ready for therapy> in the therapy status field.

- Remove the bag with the sodium chloride solution from the load cell and attach it to the infusion pole.
- Make sure that all relevant clamps are open.
- Select <ENTER THERAPY> and confirm by pressing the  key.

  The device switches automatically to <PARAMETERS SETTING>.

4.3.3 Parameter setting



Setting safety-relevant parameters

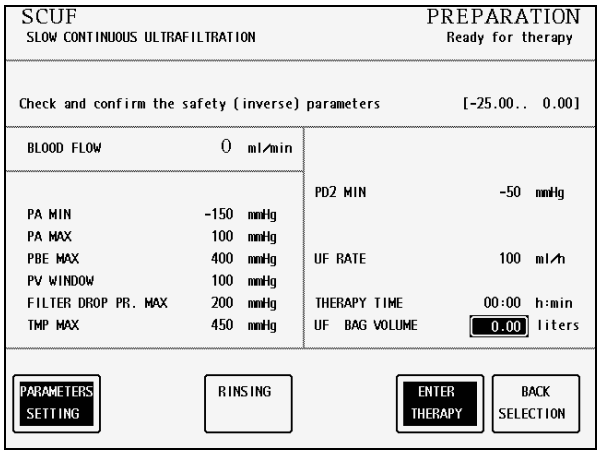
The safety-relevant parameters (ultrafiltration rate in SCUF) are displayed on a black background.

- Activate <UF rate> by pressing the  key.

  The value is inversely displayed on a black background
- If the value is accepted, confirm by pressing the  key.
- To change the value, press the  key to increase it or the  key to decrease it.
- Confirm with the  key.
  In both cases the actual value is displayed in the supervisor field, flashing on a black background.
- Compare the value displayed in the supervisor field with that shown in the fluid-side parameters field and confirm with the  key if they are identical.

  Any changes to the safety-relevant parameters must always be confirmed with the  key.

If the safety-relevant data are not confirmed, whether they are changed or not, the system will not start the therapy.



Setting treatment parameters

- Select the parameter to be set with the  or  key.
- Activate the parameter by pressing the  key.
- Change the value with the  or  key and confirm the change with the  key.
- To exit <PARAMETERS SETTING>, press the  key.

These treatment data can be set at any time during the preparation phase or the therapy if the <PARAMETERS SETTING> option is displayed.

The following data can be set in the indicated ranges:

Parameter	Unit	Default	Min	Max	Increments
Blood-side parameters					
Blood flow	ml/min	50	10/5	500	5/10
PA min.	mmHg	-150	-400	PA max.	10
PA max.	mmHg	100	PA min.	200	10
PBE max.	mmHg	400	0	500	10
PV window	mmHg	100	80	160	10
PFD max. pressure drop	mmHg	200	100	450	10
TMP max.	mmHg	450	100	600	10
Fluid-side parameters					
PD2 min.	mmHg	-50	-250	250	10
UF rate	ml/h	100	0/80	2000	10/100
UF bag volume	l	0.00	-25.00	00.00	0.10/1.00
Therapy time	h:min	00:00	00:00	72:00	0:05/0:30

In software versions 2.10 and 2.12 the minimal UF rate is 50 ml/h

Bag change volume

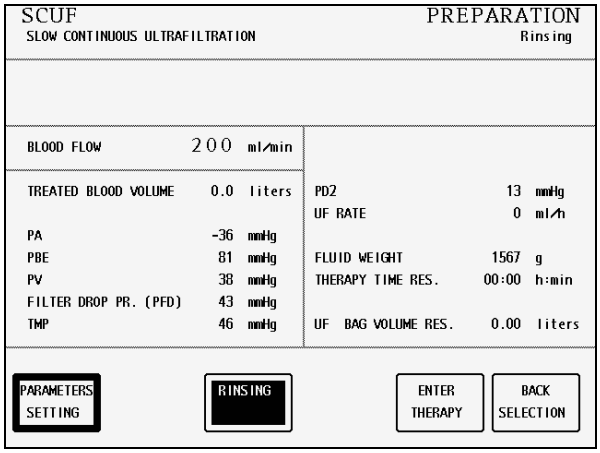
The ultrafiltration volume at which the collecting bag at the load cell has to be changed can be defined.

- Select <UF BAG VOLUME> in <PARAMETERS SETTING> and confirm with the  key.
- Set the <UF bag volume> to a **negative value** (e.g. – 6L).

When the volume of the **ultrafiltration bag** is reached during therapy, the alarm <bag volume is over (1020)> occurs

- Follow the instructions on the screen and exchange the collecting bag.

4.3.4 Menu selection in preparation



Rinsing

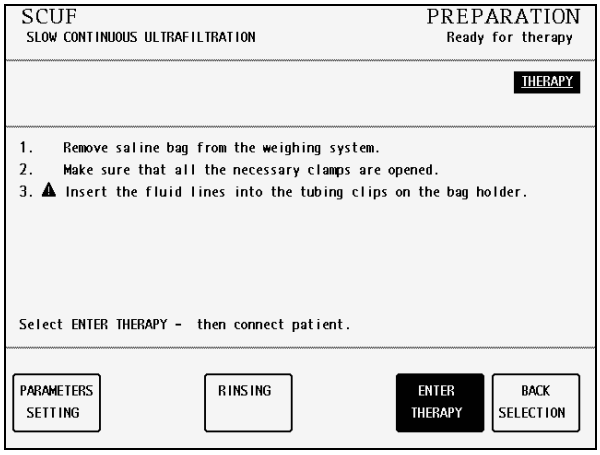
- If necessary, rinsing can be prolonged by selecting <RINSING> and confirming with the  key.
- If only the blood side has to be rinsed, the fluid side can be stopped by opening the cover of the ultrafiltration pump (MP2).
- To finish the additional rinsing, select <RINSING> again and confirm with the  key.

Back selection

Choosing back selection allows to return to the <THERAPY SELECTION> screen (Section 4.2).

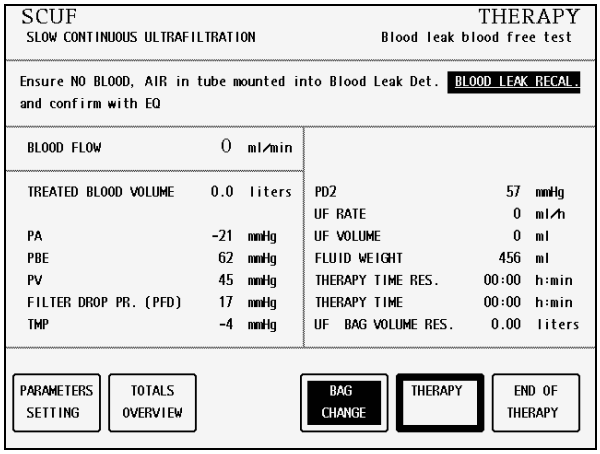
- Select <BACK SELECTION> and confirm with the  key.

4.4 Therapy



- To switch from <PREPARATION> to <THERAPY>, select <ENTER THERAPY> and confirm by pressing the  key.
- Confirm the start of the therapy by pressing the flashing  key

  while <THERAPY> is flashing in the supervisor field.



The Diapact® CRRT is now in the therapy status as indicated in the therapy status field.

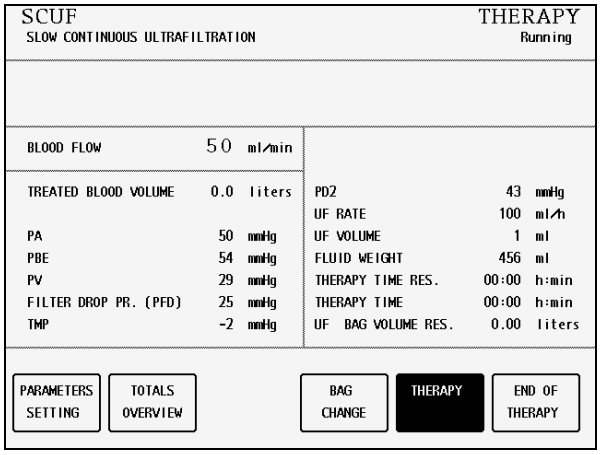
- Confirm the blood leak recalibration by pressing the  key.
- Start the blood pump for circulation by pressing the  key.

4.4.1 Connecting the patient

- Stop the blood pump.
- Connect the arterial line to the arterial access of the patient.
- Start the blood pump and adjust the flow rate using the  or  keys.
- Check that the withdrawal pressure (arterial pressure – PA) is within the prescribed range.
- When the blood starts to fill the venous line, stop the blood pump and connect the venous line to the venous access of the patient.
- Start the blood pump again and adjust the blood flow slowly dependent on the patient's condition.
- Check that the arterial and venous pressure values displayed on the screen are within the normal range.

During therapy, the arterial chamber should be about 50% filled, the venous chamber about 80%

4.4.2 Start of therapy



After the blood has been circulating for 2-3 minutes without alarms, the therapy can be started.

➢ Select <THERAPY> and activate by pressing the  key.

<THERAPY> in the menu selection field is blackened and in the therapy status field <Running> is indicated.

The treatment is now in progress and the parameter overview is displayed.

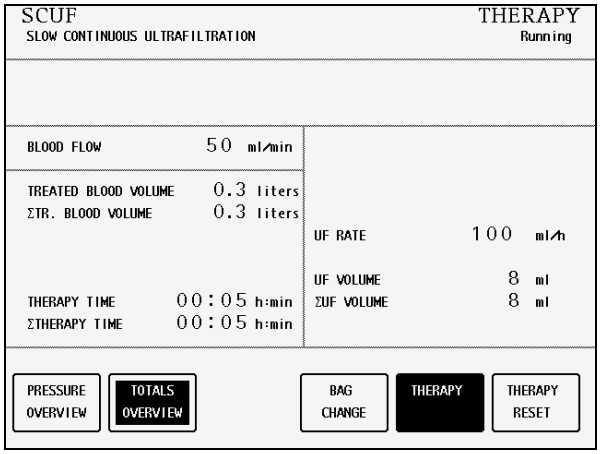
The current pressure and flow data of the blood side and the fluid side are displayed on the screen.

WARNING

Risk of blood loss and contamination for the patient

➢ **In continuous therapies, the pump segment can become damaged in the course of time. In order to avoid the risk of pump segment damage, it is recommended to change the line at the latest every 72 hours.**

4.4.3 Menu selection in therapy



Parameter setting

See Section 4.3.3

Totals overview

➢ Select <TOTALS OVERVIEW> and confirm by pressing the  key.

➢ To return to the <PARAMETERS OVERVIEW> screen select <TOTALS OVERVIEW> and then press the  key.

The <TOTAL OVERVIEWS> screen displays:

On the left (blood-side) part of the screen

- Current blood flow
- Treated blood volume of the current time segment
- Treated blood volume of the whole treatment (sum of all time segments)
- Therapy time of the current time segment
- Therapy time of the whole treatment (sum of all time segments)

On the right (fluid-side) part of the screen

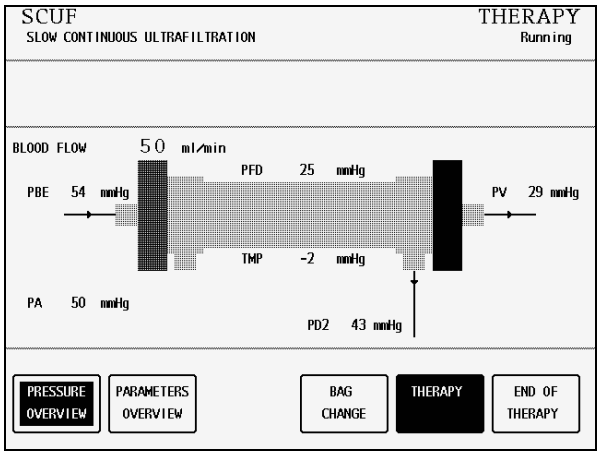
- Current ultrafiltration rate
- Ultrafiltration volume of the current time segment
- Ultrafiltration volume of the whole treatment (sum of all time segments)

Therapy reset

<THERAPY RESET> allows to adjust the current values for treated blood volume, therapy time and ultrafiltration volume to zero. The following volumes and the time are added up from the values marked with Σ.

This allows to follow the data during a certain time segment of the treatment. The system can warn the user to execute a therapy reset by setting the therapy time parameter for the required time.

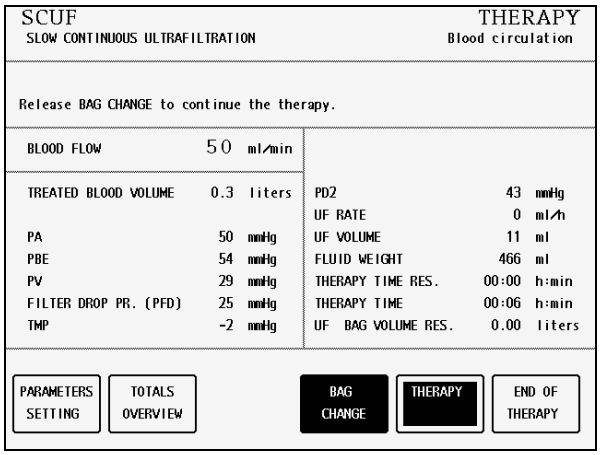
- Select <THERAPY RESET> and confirm by pressing the  key followed by the  key.



Pressure overview

<PRESSURE OVERVIEW> allows an overview of all pressures recorded in the system.

- Select <PRESSURE OVERVIEW> and confirm by pressing the  key.
- Select <PARAMETERS OVERVIEW> to return to the <PARAMETERS OVERVIEW> screen and confirm by pressing the  key.



Bag change

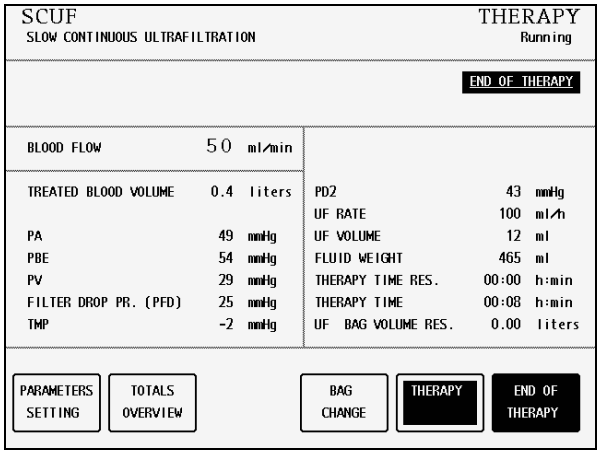
The <BAG CHANGE> option allows to change the fluid bags during a running therapy.

- Select <BAG CHANGE> and confirm by pressing the  key.

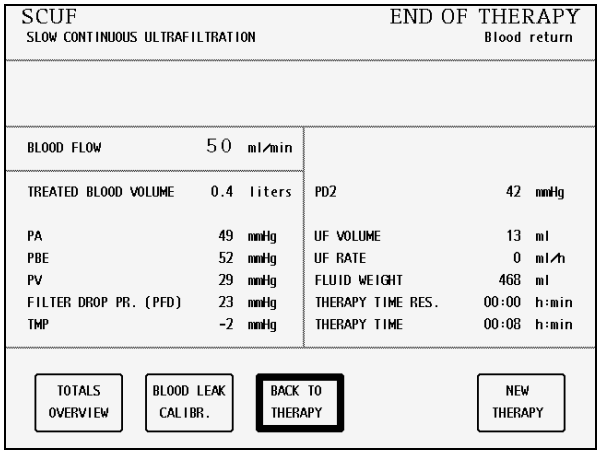
  The ultrafiltration pump (MP2) stops. The blood pump (MP1) keeps on running.
- Exchange the bag(s).
- Open the frangible pin if the bag(s) with the substitution solution is exchanged.
- Close the line equipped with the plug if the collecting bag(s) is exchanged.
- After the bag exchange, deactivate <BAG CHANGE> by pressing the  key.

  The treatment continues automatically.

4.5 End of therapy



- Select <END OF THERAPY> and confirm by pressing the  key.
- Confirm by pressing the  key.



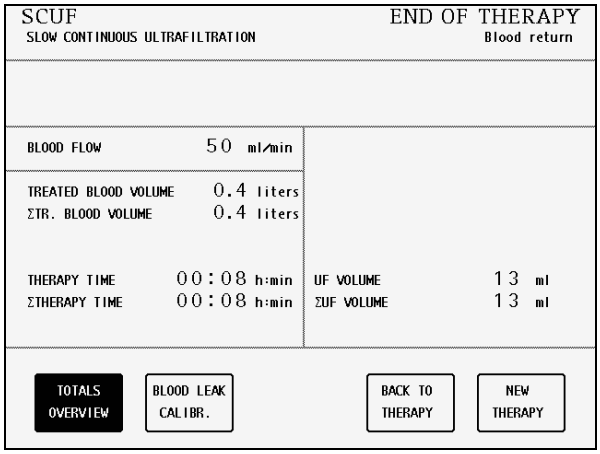
The ultrafiltration pump (MP2) stops. The blood pump (MP1) continues to run at reduced speed (50 ml/min).

4.5.1 Disconnecting the patient

- Stop the blood pump (MP1).
- Disconnect the arterial line from the patient's arterial access and connect it to a bag with isotonic saline solution.
- Start the blood pump and return the blood in the extracorporeal circuit to the patient.
- Stop the blood pump (MP1) just before the isotonic saline solution enters the patient.
- Disconnect the venous line from the patient's venous access.
- Remove disposable materials and solutions from the device.

Dispose of disposable materials and fluids which have been removed from the device in accordance with local regulations.
Therapy data are stored in the machine for 30 minutes. They can be recalled by switching on the Diapact® CRRT within this time frame.

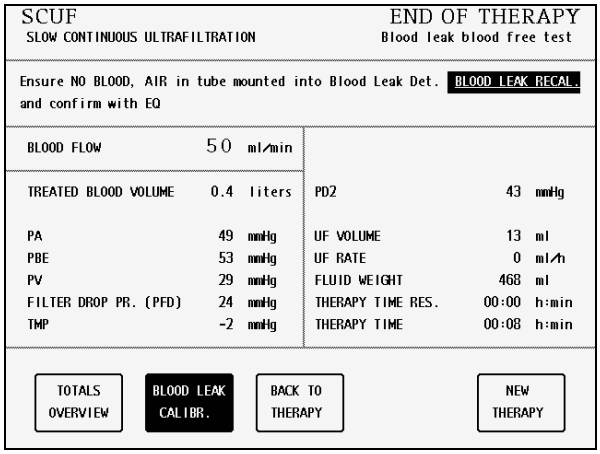
4.5.2 Menu selection at end of therapy



Totals overview

The option <TOTALS OVERVIEW> shows the summary of the pivotal treatment data as described (Section 8.4.3)

- Select <TOTALS OVERVIEW> and confirm by pressing the  key.
- To return to the <END OF THERAPY> screen, select <TOTALS OVERVIEW> and confirm with the  key.



Blood leak recalibration

The <BLOOD LEAK CALIBRATION> function allows the recalibration of the blood leak detector in case of non-acceptable alarms (e.g. elevated plasma bilirubin concentration)

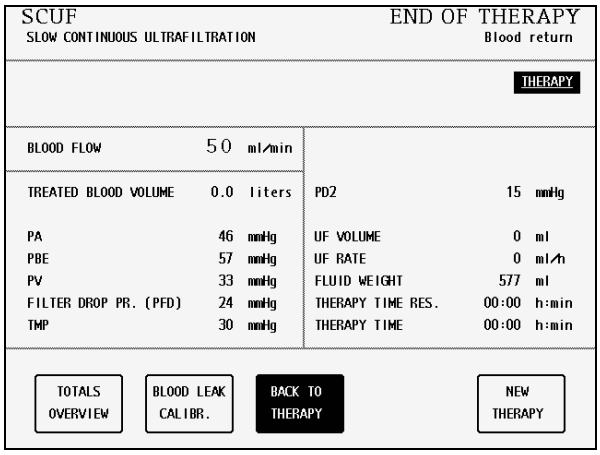
- Select “BLOOD LEAK CALIBRATION” and confirm with the  key. The  key lights up.
- Confirm with the  key.
- Select <BACK TO THERAPY> and confirm with the  key. The  key lights up.
- Confirm with the  key.
- Adapt the blood flow to the initial value.
- Start <THERAPY> by pressing the  key.

DANGER

Risk of blood loss for the patient and haemolysis

- **Before the recalibration of the blood leak detector, the haemofilter must be carefully checked for possible blood leaks and haemolysis.**
- **It is recommended to withdraw a sample (at least 2 ml) from the injection port of the filtrate line and to analyze for erythrocytes and/or free haemoglobin.**
- **The blood leak recalibration must only be performed if these tests are negative.**

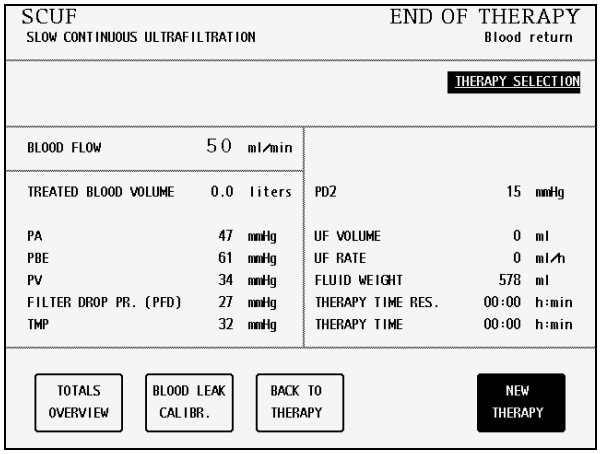
The ultrafiltration pump will not start up again until blood leak calibration has been completed.



Back to therapy

The option <BACK TO THERAPY> returns to the just finished therapy.

- Select <BACK TO THERAPY> and confirm by pressing the key. The EQ key lights up.
- Confirm by pressing the EQ key.
- Start the therapy again by pressing the key.



New therapy

The option <NEW THERAPY> allows to start a new therapy immediately after the one just finished. The device switches directly to therapy selection.

- Select <NEW THERAPY> and confirm by pressing the key. The EQ key lights up.
- Confirm by pressing the EQ key.

DANGER

Risk of blood loss and infection for the patient

- **To guarantee the safe therapy for the patient, the consumables (line system, haemofilter, solutions) used in the just finished therapy must be completely replaced.**

4.6 Special functions

Bag movement function

To avoid superfluous alarms and the resulting pump standstill, the Diapact® CRRT has a function which is actuated by slight movements of the machine during therapy.

When this function is actuated, the ultrafiltration pump stops without an alarm and starts again automatically when the initial weight (i.e. the weight before the movement of the machine or bag) is reached again.

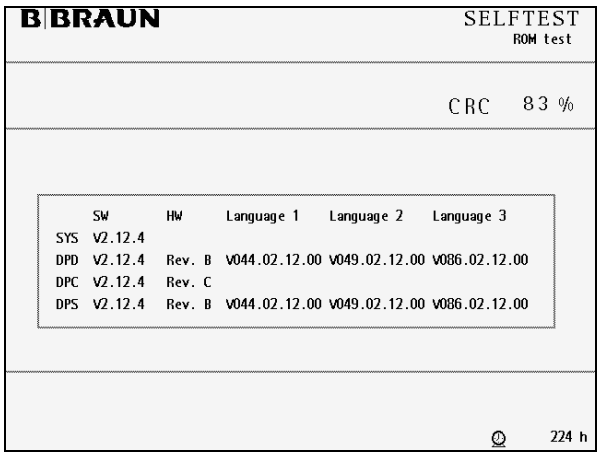
Automatic temporary reduction of the blood flow

If PA min is reached, blood flow automatically drops to 25% (but not lower than 60 ml/min) to prevent standstill of the blood pump caused by movement of the patient. The ultrafiltration pump stops also for a short time without an alarm.

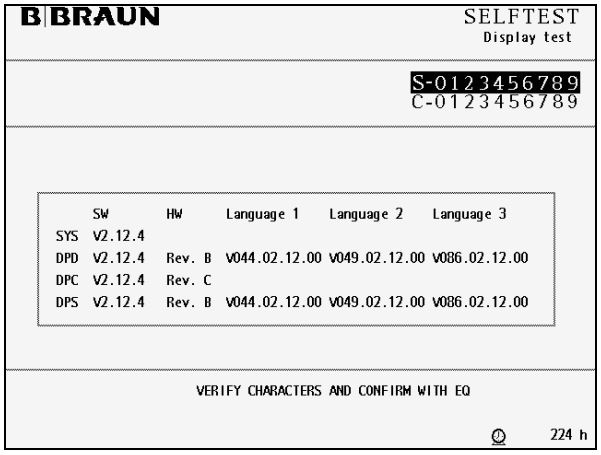
Table of contents

5 CVVH (Continuous veno-venous haemofiltration)

5.1 Switching on and initial tests

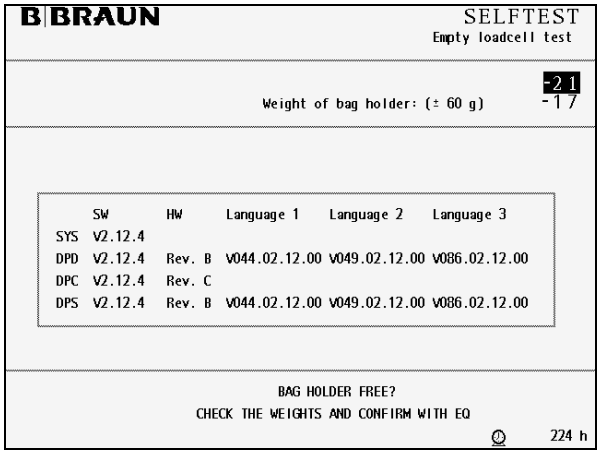


- Switch on the Diapact® CRRT with the power switch ON/OFF (I/O) on the back of the machine. The device starts with the ROM test.
- Check whether the AQ and EQ keys are lit during the ROM test.



The ROM test is followed by the display test.

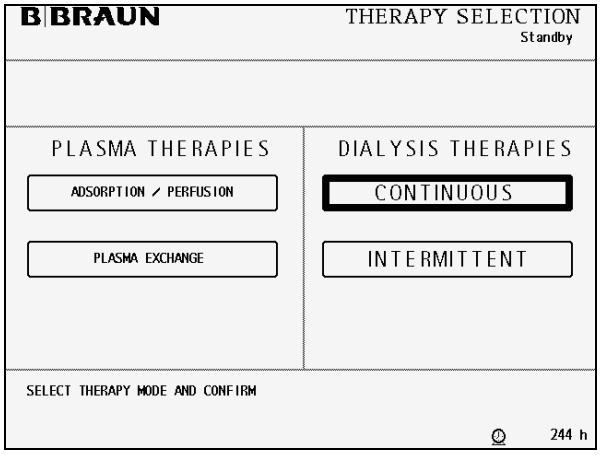
- Compare the character lines in the supervisor field and confirm by pressing the EQ key if both series are identical.
- While the EQ key is being pressed, the buzzer of the safety system is activated for 2 seconds.
- Check that the buzzer can be heard.



If the display test is passed successfully, the empty load cell test follows.

- Check whether the bag holder is empty.
- Confirm the weight values with the EQ key if they are within the allowed range. The maximum deviation between both displayed values is allowed to be ± 60 g and the values must not exceed -60 and +60 g.

5.2 Therapy selection

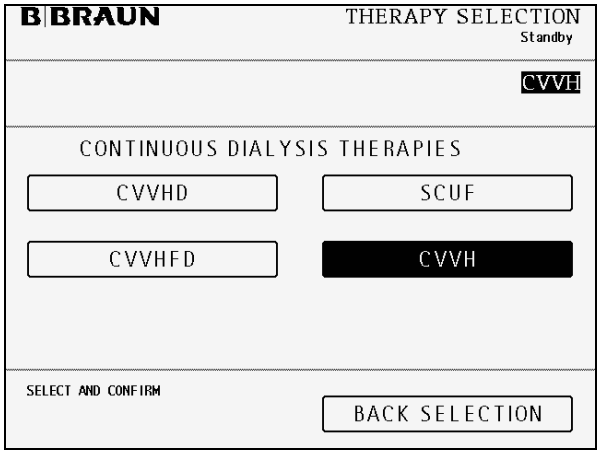


Having successfully passed the initial self tests, the machine switches to the <THERAPY SELECTION> screen to select the therapy mode.

<CONTINUOUS> dialysis therapies is selected by default.

- To select <INTERMITTENT> dialysis therapies, use the  and  keys to select the respective position.
- Confirm the selection with the  key.

The following screen displays the possible therapy options. <CVVH> is selected by default.



- Confirm <CVVH> with the  key.

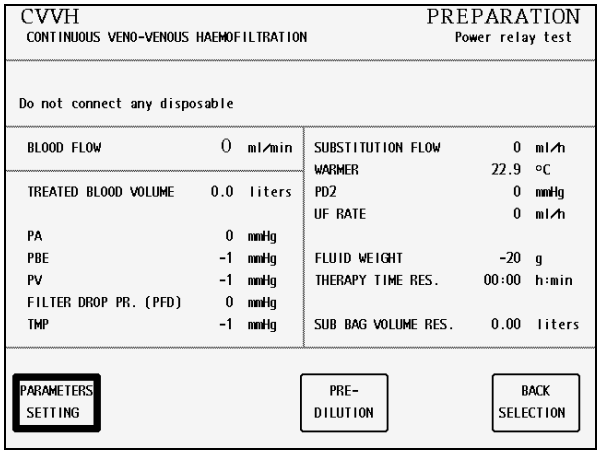
  The  key lights up and CVVH flashes in the supervisor field.
- Press the  key to confirm the selected therapy modality.

  If the selection is not confirmed with the  key, the device returns automatically to the <THERAPY SELECTION> screen where the therapy mode can be selected.

Back selection

Moving with the  or  keys to <BACK SELECTION> and confirmation with  allows to return to the screen where the therapy mode can be selected.

5.3 Preparation

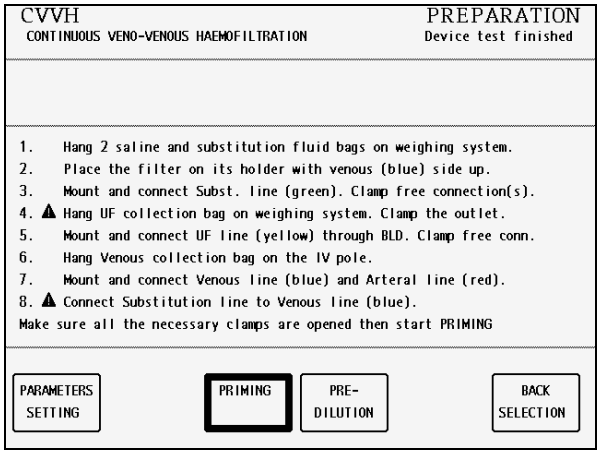


After modality selection and confirmation, the display shows the following <PREPARATION> screen.

Several tests are performed. The respective test is displayed in the therapy status field:

- Power relay test
- SAD reference test
- SAD counter test
- Red detector test
- Blood leak detector test
- Zero pressure test

5.3.1 Installation of consumable material



When the tests have been performed successfully, the <PREPARATION> screen displays <Device test finished> and the steps to set-up the machine are displayed.

The consumable material for the therapy comprises:

- HF/HD kit
- Haemofilter
- 2L isotonic sodium chloride solution
- Haemofiltration solution

➢ Follow the instructions on the screen and set-up the device as described in the following.

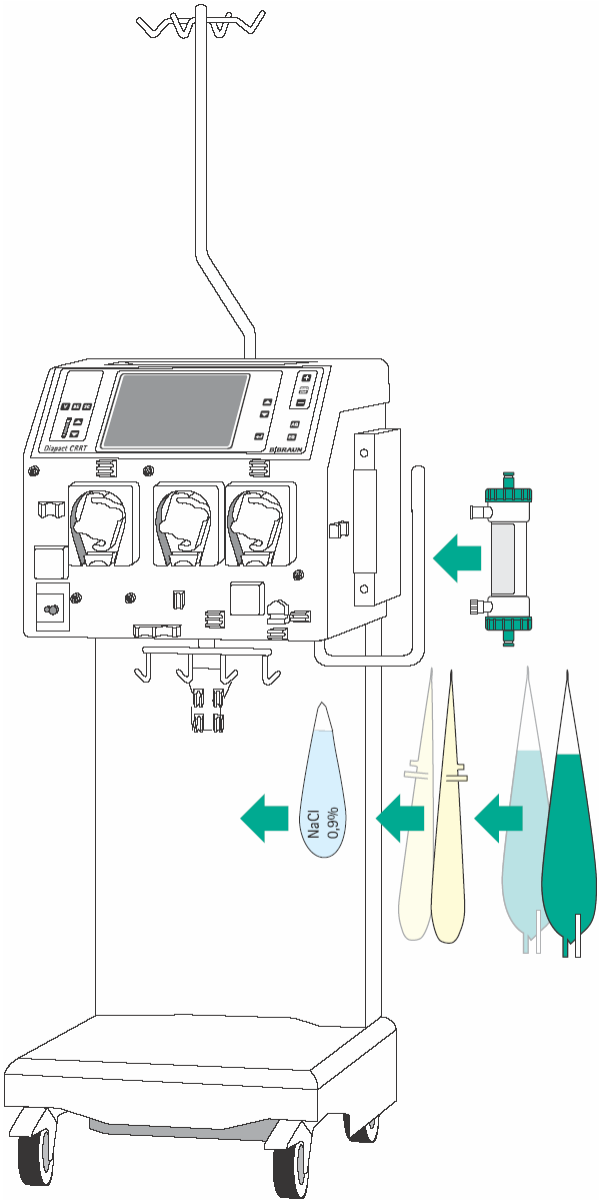
The lines of the HF/HD kit are colour-coded to facilitate the set-up.
Arterial line (**red**)
Venous line (**blue**)
Ultrafiltration line (**yellow**)
Substitution line (**green**)

Pumps used:
Blood pump (MP1)
Ultrafiltration pump (MP2)
Substitution pump (MP3)

WARNING

Risk of infection and blood loss for the patient by damaged packaging or components

➢ **Make sure during set-up that the packaging of the material used (line system, haemofilter, solution bags) is undamaged.**
➢ **During set-up check the material for integrity.**
➢ **Observe the respective instructions for use.**



Installation of bags and haemofilter

- Attach the collecting bags of the HF/HD kit, the 2L bag with isotonic sodium chloride solution and the bags with the haemofiltration solution on the bag holder of the load cell.
- Fix the haemofilter into the filter holder on the right side of the machine.
- Close the clamps of the collecting bags at the tubes equipped with plugs.

CAUTION

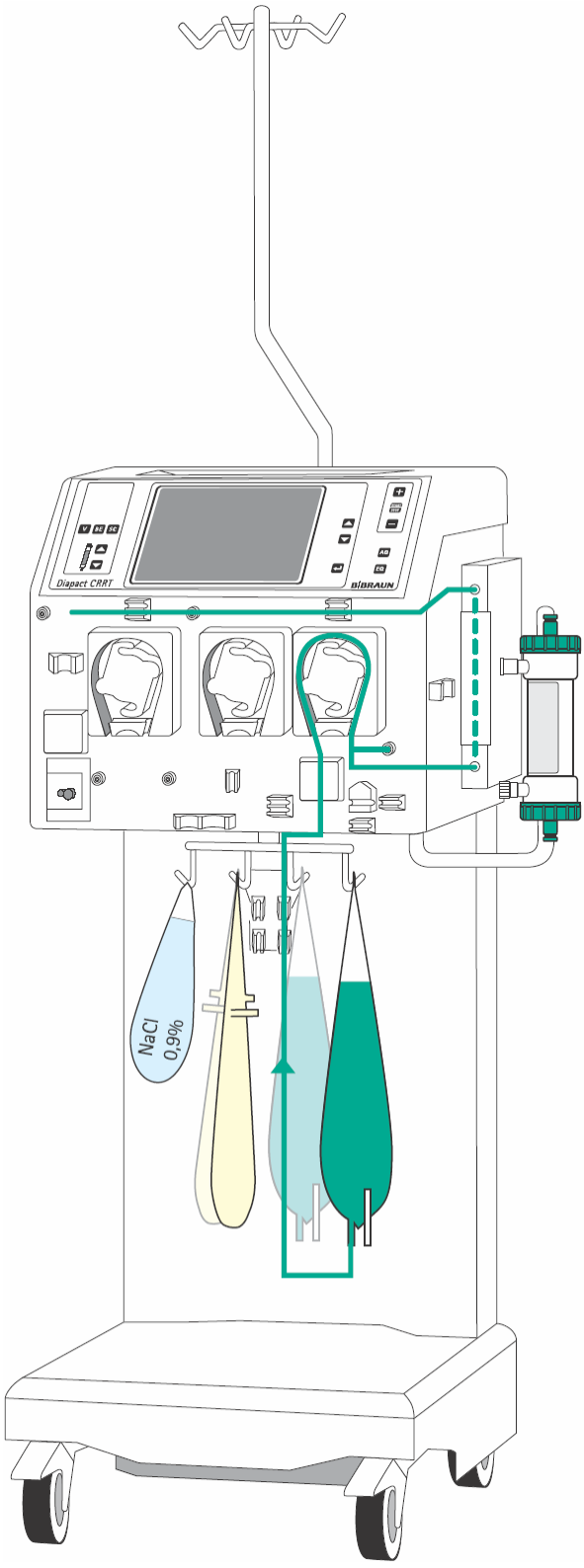
Incomplete moistening of the haemofilter during priming and rinsing may result in performance reduction.

- **Place the filter into the haemofilter holder with the arterial port (red) downwards.**

If the weight on the load cell is unevenly distributed, there is a risk that the device may topple.

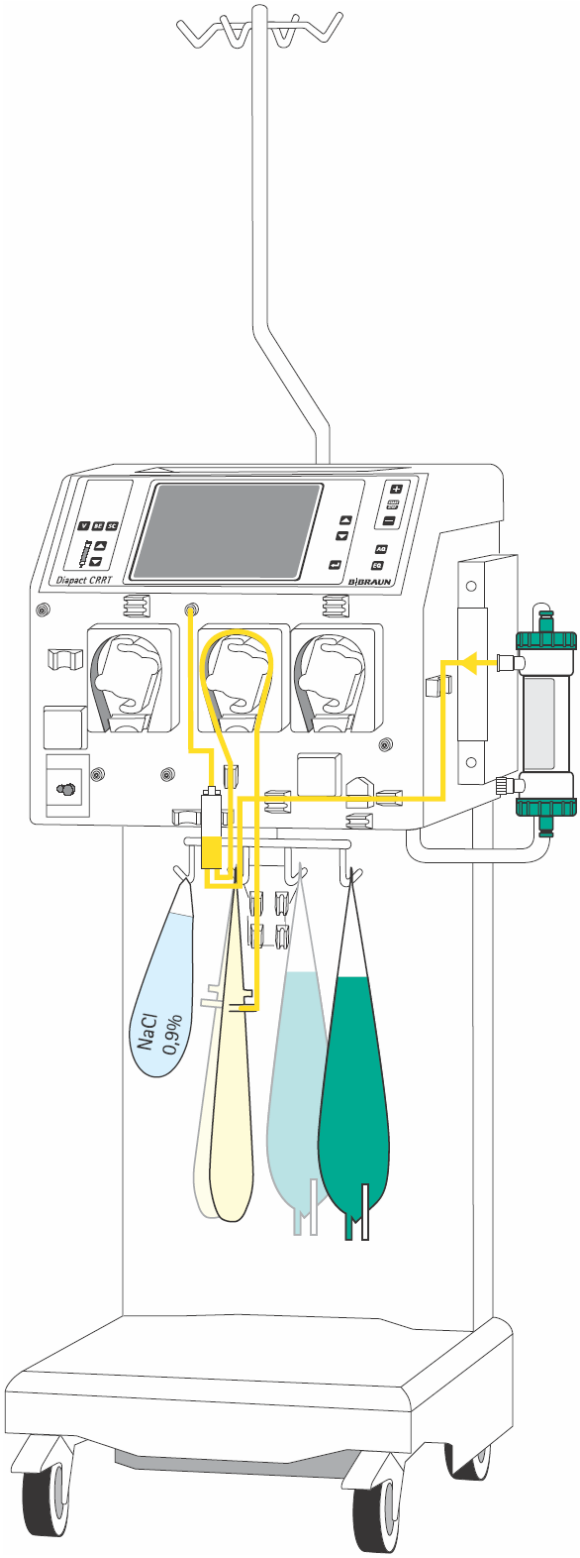
- **Distribute weight on the bag holder evenly.**

The maximal load of the load cell is 27 kg



Insertion of the substitution line (green)

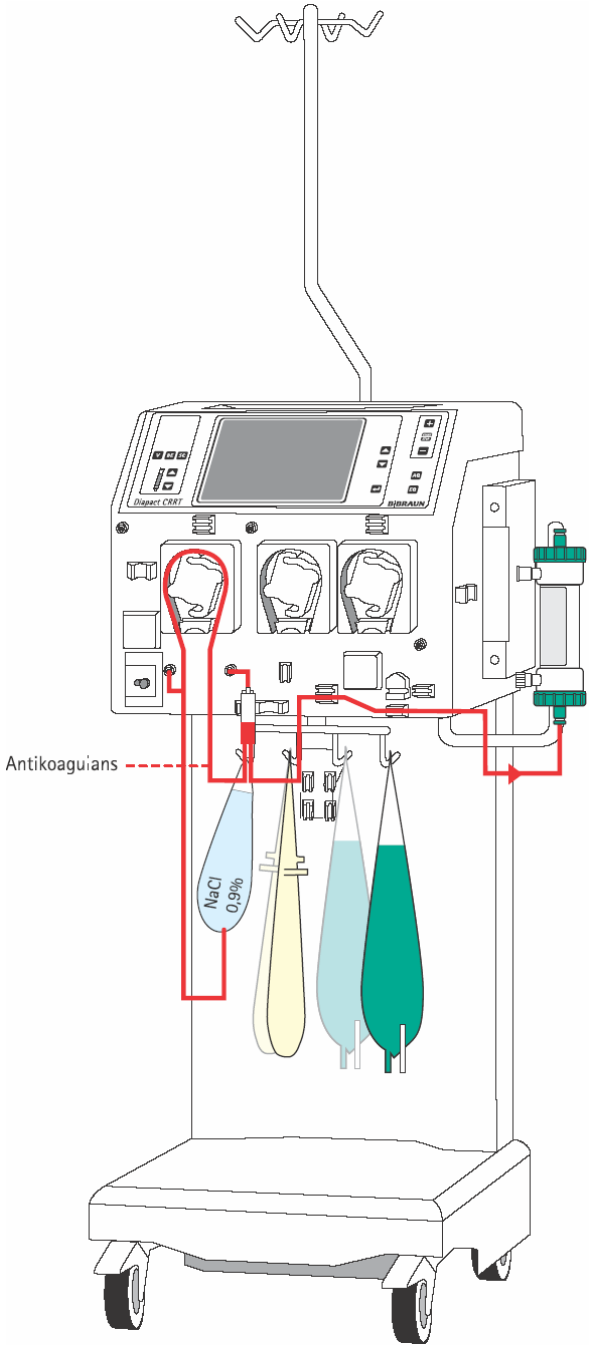
- Insert the heater bag into the plate heater and close the cover. To ensure that the bag has optimal contact to the heater, close the cover audibly.
- Insert the pump segment into the substitution pump (MP3).
- Insert the line leading from the connection of the bags with the haemofiltration solutions to the pump segment into the air detector beneath the substitution pump (MP3).
- Connect the transducer protector to the pressure sensor PD1 (white).
- Connect the line leading from the air detector to the bags with the haemofiltration solution to the bags and fix the line into the line fixing of the load cell.
- Insert the line leaving the heater at the top in the line fixing above the pumps.



Insertion of the ultrafiltration line (yellow)

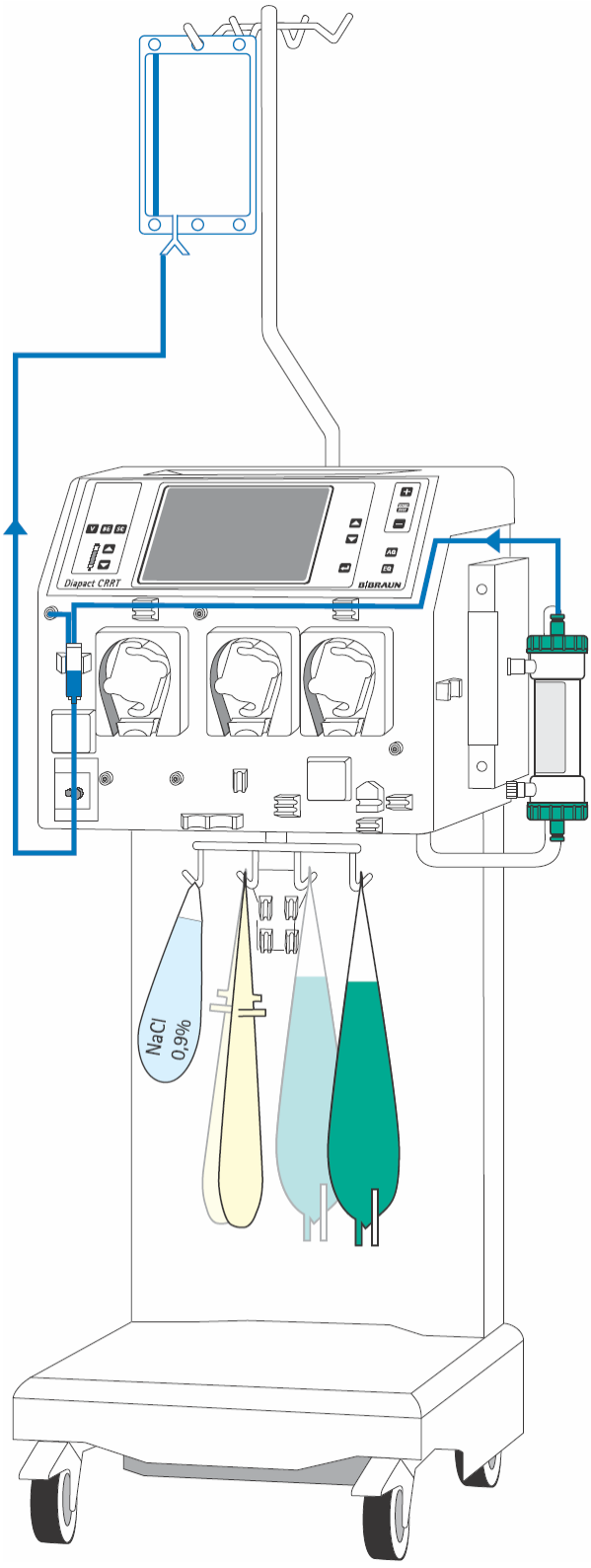
- Connect the end of the line with the Hansen connector to the upper filtrate outlet of the haemofilter.
- Insert the line coming from the haemofilter into the blood leak detector (BLD).
- Insert the pump segment into the ultrafiltration pump (MP2).
- Insert the air trap into the intended holder.
- Connect the transducer protector to the pressure sensor PSC/PD2 (white).
- Connect the Luer Lock connectors to the collecting bags and fix the line into the line fixing of the load cell.

Take care that the second filtrate-side connector, which is not used, is securely closed. It is recommended to use the Hansen connector attached on the substitution line.



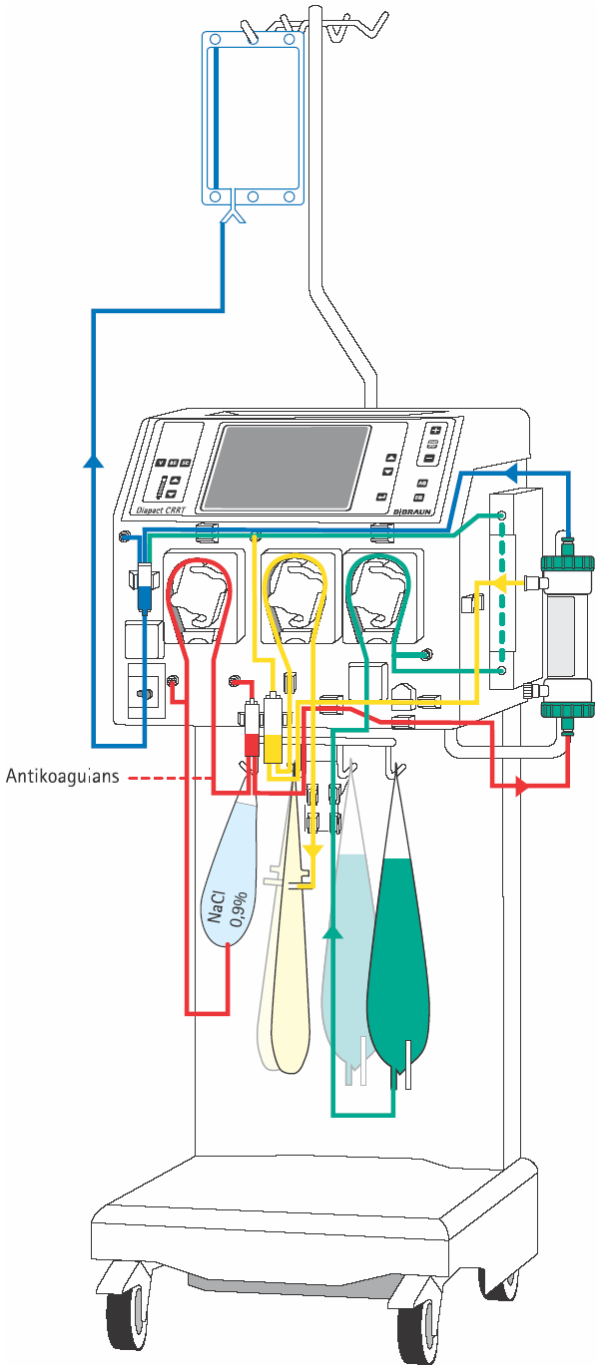
Insertion of the arterial line (red)

- Connect the end of the line with the spike/Luer Lock connector to the bag with isotonic sodium chloride solution on the bag holder of the load cell.
- Insert the pump segment into the blood pump (MP1).
- Connect the transducer protector before the blood pump to the pressure sensor PA (red).
- Insert the arterial air trap into the intended holder.
- Connect the transducer protector to the pressure sensor PBE (red).
- Connect the red Luer Lock connector to the lower blood-side connector of the haemofilter.
- If continuous heparinisation is required, connect the heparin line to the external heparin pump previously filled with heparin.
- Close the clamp of the heparin line if it is not used.
- Close the clamps at the sampling ports before and after the blood pump (MP1).



Insertion of the venous line (blue)

- Attach the rinsing bag to the infusion pole.
- Insert the venous air trap into the intended holder.
- Insert the venous line beneath the drip chamber into the safety air detector (SAD) and the safety air clamp (SAK) under the detector.
- Connect the transducer protector to the pressure sensor PV (blue).
- Connect the blue Luer Lock connector to the upper blood-side connector of the haemofilter.
- Connect the substitution line (green) to one of the Luer Lock connectors at the venous air trap and fix the line in the line fixing above the pumps.
- Close the clamp at the not used connection of the venous air trap.



Set-up overview

- ➢ Check the set-up before starting the priming procedure.
- ➢ Take care that all connections are firmly screwed together.
- ➢ Check that all pump segments are inserted clockwise.
- ➢ Check that the following clamps are closed:
  - Sampling ports before and after the blood pump
  - Heparin line if it is not used
  - Not used line at the venous chamber
  - Line with the plug at the collecting bag(s)
- ➢ Open the frangible pin of the sodium chloride solution bag and the bags with the haemofiltration solution.

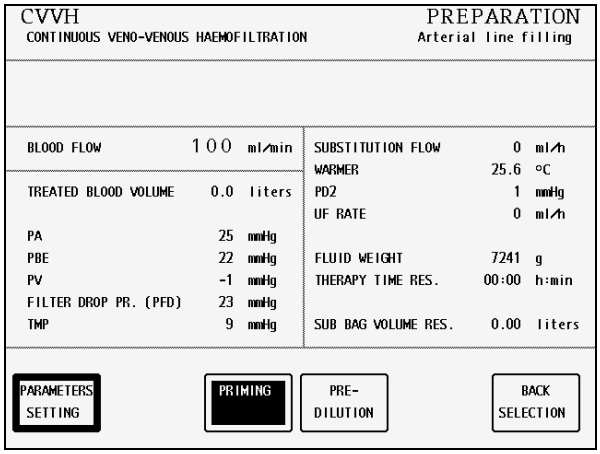
Installation of the preassembled HF/HD Kit

In the pre-assembled kit, the components of the HF/HD kit are mounted to a guide rail.

- ➢ Take hold of the guide rail of the kit with both hands and insert it into the respective holders on the machine (see also the respective instruction for use).
- ➢ Insert the pump segments clockwise.
- ➢ Connect all components as described above in this section.

i Make sure that all relevant clamps are opened and that all connections are firmly screwed together before starting the priming procedure.

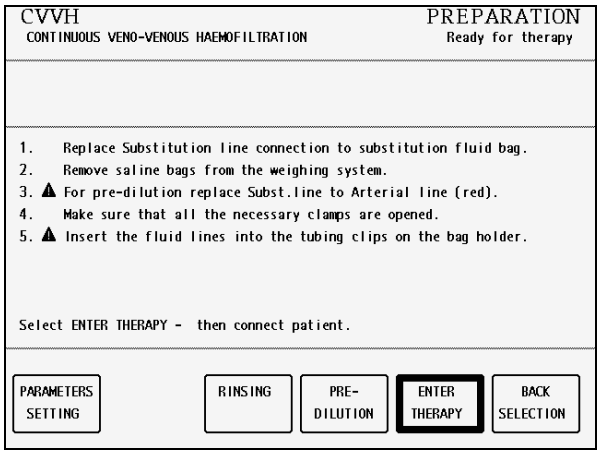
5.3.2 Priming



- After set-up of the consumables and checking the connections, select <PRIMING> and confirm by pressing the  key.

The automatic priming program starts. During the priming and rinsing the following tests are performed: load cell test, air detector test, substitution pump test (MP3), heater test, ultrafiltration pump test (MP2), disposable leakage test, level regulation test and the calibration of the pump constants takes place. The respective step of the procedures and the test is displayed in the therapy status field.

Do not move the Diapact® CRRT during calibration of the pump constants. Calibration will be repeated if it is disturbed.

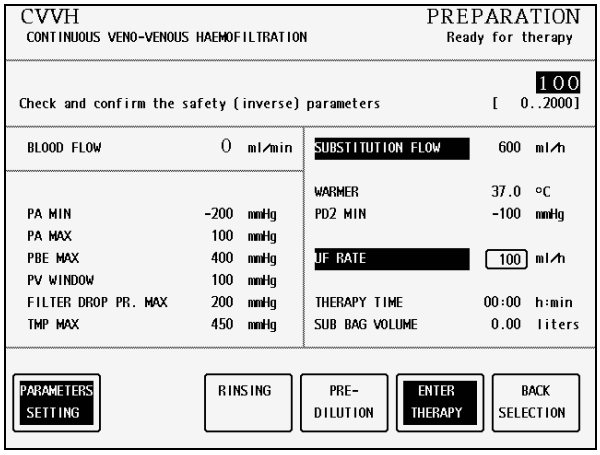


After the preparation phase has been finished, the system gives an acoustic signal and shows the <PREPARATION> screen with message <Ready for therapy> in the therapy status field.

- Remove the bag with the sodium chloride solution from the load cell and attach it to the infusion pole.
- Make sure that all relevant clamps are open.
- Select <ENTER THERAPY> and confirm by pressing the  key.

  The device switches automatically to <PARAMETERS SETTING> .

5.3.3 Parameter setting

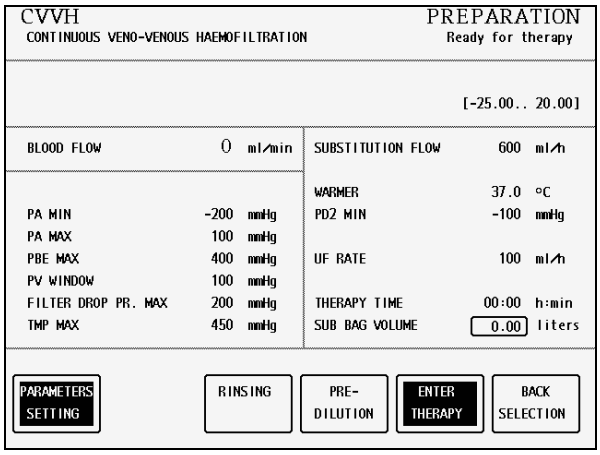


Setting safety-relevant parameters

The safety-relevant parameters (substitution flow and ultrafiltration rate in CVVH) are displayed on a black background.

- Activate <UF rate> by pressing the  key.
  The value is inversely displayed on a black background.
- If the value is accepted, confirm by pressing the  key.
- To change the value, press the  key to increase it or the  key to decrease it.
- Confirm with the  key.
  In both cases, the actual value is displayed in the supervisor field, flashing on a black background.
- Compare the value displayed in the supervisor field with that shown in the fluid-side parameters field and confirm with the  key if they are identical.
- Check and/or change the substitution flow in the same way.
- Any changes to the safety-relevant parameters must always be confirmed with the  key.

If the safety-relevant data are not confirmed, whether they are changed or not, the system will not start the therapy.



Setting treatment parameters

- Select the parameter to be set with the  or  key.
- Activate the parameter by pressing the  key.
- Change the value with the  or  key and confirm the change with the  key.
- To exit <PARAMETERS SETTING>, press the  key.

These treatment data can be set at any time during the preparation phase or the therapy if the <PARAMETERS SETTING> option is displayed.

The following data can be set in the indicated ranges:

Parameter	Unit	Default	Min	Max	Increments
Blood-side parameters					
Blood flow	ml/min	50	10/5	500	5/10
PA min.	mmHg	-200	-400	PA max.	10
PA max.	mmHg	100	PA min.	200	10
PBE max.	mmHg	400	0	500	10
PV window	mmHg	100	80	160	10
PFD max. pressure drop	mmHg	200	100	450	10
TMP max.	mmHg	450	100	600	10
Fluid-side parameters					
Substitution flow	ml/h	600	0*/300	6000	100/500
Temperature	°C	37	20	40	0.5/1.0
PD2 min.	mmHg	-100	-250	250	10
UF rate	ml/h	100	0*	2000	10/100
Substitution bag volume	l	0.00	-25.00	20.00	0.10/1.00
Therapy time	h:min	00:00	00:00	72:00	0:05/0:30

* The substitution flow can be set to zero if the UF rate is ≥ 300 ml/h. If the UF rate is below this limit, the adjustable lower limit for the substitution flow is 300 ml/h – UF rate.

In software versions 2.10 and 2.12 there is no lower limit for the substitution flow.

Bag change volume

The haemofiltration solution volume or the ultrafiltration volume at which the bags with the haemofiltration solution or the collecting bag at the load cell have to be changed can be defined. The default value is 0.

If 0 is selected, the machine gives an alarm when the haemofiltration solution is empty, as detected by the air detector underneath the ultrafiltration pump (MP3.).

- Select <SUB BAG VOLUME> in <PARAMETERS SETTING> and confirm with the  key.
- Set the <SUB bag volume> to a **positive value** (e.g. + 4.8L).

When the volume of the **haemofiltration solution bags** is spent during therapy, the alarm <bag volume is over (1020)> occurs.

- Follow the instructions on the screen and exchange the bag(s) with the haemofiltration solution.
- Set the <SUB bag volume> to a **negative value** (e.g. – 6L).

Selecting a negative <SUB bag volume> changes the display to <UF bag volume>

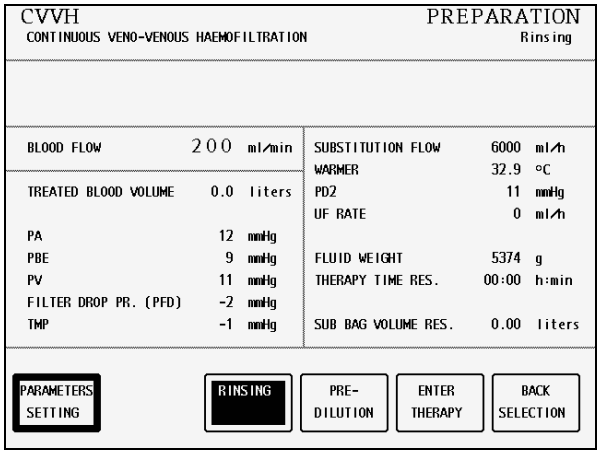
When the volume of the **ultrafiltration collecting bags** is reached during therapy, the alarm <bag volume is over (1020)> occurs

- Follow the instructions on the screen and exchange the collecting bag.

To switch between <SUB bag volume> and <UF bag volume>, it is necessary to set the parameter first to 0.

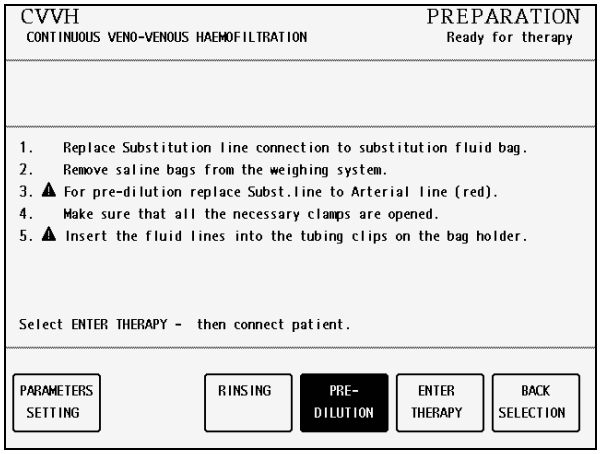
- Select <DIA bag volume> and <UF bag volume> and confirm with the  key.
- Set the parameter to 0 and confirm with the  key.
- Select <SUB bag volume> again and confirm with the  key.
- Increase or decrease the value and confirm with the  key.

5.3.4 Menu selection in preparation



Rinsing

- If necessary, rinsing can be prolonged by selecting <RINSING> and confirming with the  key.
- If only the blood side has to be rinsed, the fluid side can be stopped by opening the cover of the ultrafiltration pump (MP2).
- To finish the additional rinsing, select <RINSING> again and confirm with the  key.



Pre-dilution

- To activate the pre-dilution mode, select the option and confirm with the  key.

  The option field remains black as long as the option is activated.
- Close the clamp at the line of the venous air trap where the substitution line is connected and the clamp of the substitution line.
- Unscrew the connection of the substitution line to the venous chamber.
- Screw the substitution line to the connection of the arterial line behind the blood pump.
- Open the clamp at the arterial line where the substitution line has been connected and the clamp of the substitution line.

See also Section 5.5.2

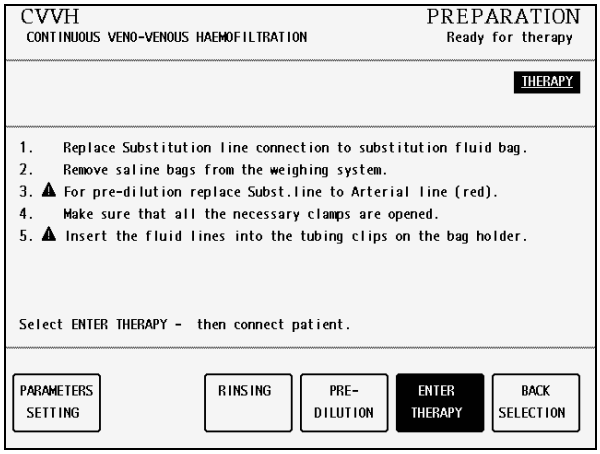
The pre-dilution mode can be selected in all screens where the option is shown. However, during the priming procedure the substitution line must be connected to the venous chamber, otherwise the device tests will not be passed. After the priming procedure has been finished, the substitution line can be connected with the arterial line as described above.

Back selection

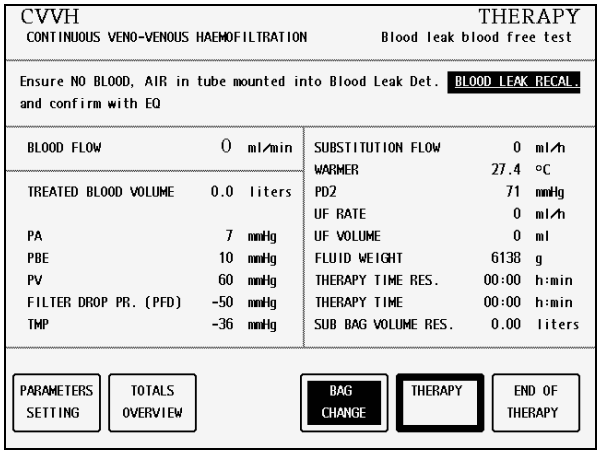
Choosing back selection allows to return to the <THERAPY SELECTION> screen.

- Select <BACK SELECTION> and confirm with the  key.

5.4 Therapy



- To switch from <PREPARATION> to <THERAPY>, select <ENTER THERAPY> and confirm by pressing the  key.
- Confirm the start of the therapy by pressing the flashing  key while <THERAPY> is flashing in the supervisor field.



The Diapact® CRRT is now in the therapy status as indicated in the therapy status field.

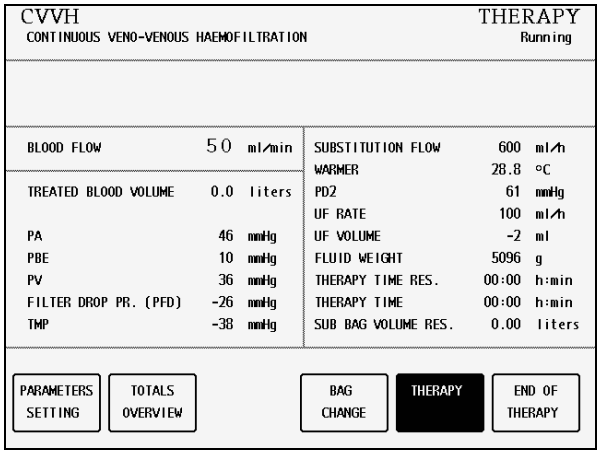
- Confirm the blood leak recalibration by pressing the  key.
- Start the blood pump for circulation by pressing the  key.

5.4.1 Connecting the patient

- Stop the blood pump.
- Connect the arterial line to the arterial access of the patient.
- Start the blood pump and adjust the flow rate using the  or  keys.
- Check that the withdrawal pressure (arterial pressure – PA) is within the prescribed range.
- When the blood starts to fill the venous line, stop the blood pump and connect the venous line to the venous access of the patient.
- Start the blood pump again and adjust the blood flow slowly dependent on the patient's condition.
- Check that the arterial and venous pressure values displayed on the screen are within the normal range.

During therapy, the arterial chamber should be about 50% filled, the venous chamber about 80%

5.4.2 Start of therapy



After the blood has been circulating for 2- 3 minutes without alarms, the therapy can be started.

➢ Select <THERAPY> and activate by pressing the key.

<THERAPY> in the menu selection field is blackened and in the therapy status field <Running> is indicated.

The treatment is now in progress and the parameter overview is displayed.

The current pressure and flow data of the blood side and the fluid side are displayed on the screen.

WARNING

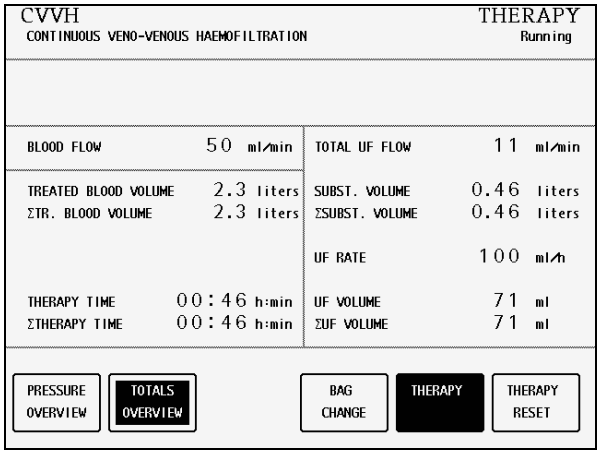
Risk of blood loss and contamination for the patient

➢ **In continuous therapies, the pump segment can become damaged with time. In order to avoid the risk of pump segment damage, it is recommended to change the line at the latest every 72 hours.**

5.4.3 Menu selection in therapy

Parameter setting

See Section 5.3.3



Totals overview

➢ Select <TOTALS OVERVIEW> and confirm by pressing the key.

➢ To return to the <PARAMETERS OVERVIEW> screen, select <TOTALS OVERVIEW> and then press the key.

The <TOTAL OVERVIEWS> screen displays:

On the left (blood-side) part of the screen

- Current blood flow
- Treated blood volume of the current time segment
- Treated blood volume of the whole treatment (sum of all time segments)
- Therapy time of the current time segment
- Therapy time of the whole treatment (sum of all time segments)

On the right (fluid-side) part of the screen

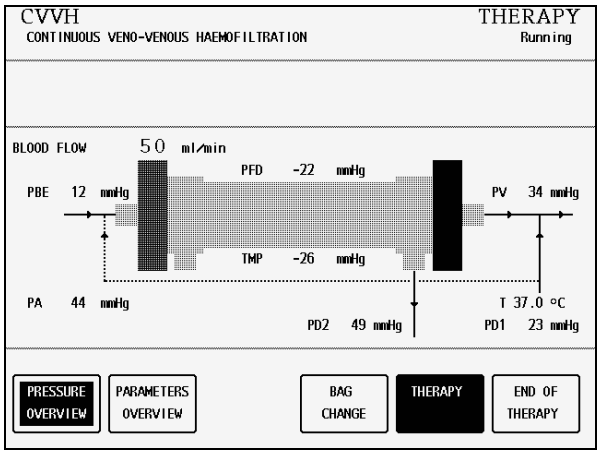
- Current ultrafiltration flow
- Substitution volume of the current time segment
- Substitution volume of the whole treatment (sum of all time segments)
- Current ultrafiltration rate
- Ultrafiltration volume of the current time segment
- Ultrafiltration volume of the whole treatment (sum of all time segments)

Therapy reset

<THERAPY RESET> allows to adjust the current values for treated blood volume, therapy time, substitution volume and ultrafiltration volume to zero. The following volumes and the time are added up from the values marked with Σ.

This allows to follow the data during a certain time segment of the treatment. The system can warn the user to execute a therapy reset by setting the therapy time parameter for the required time.

➢ Select <THERAPY RESET> and confirm by pressing the  key followed by the  key.

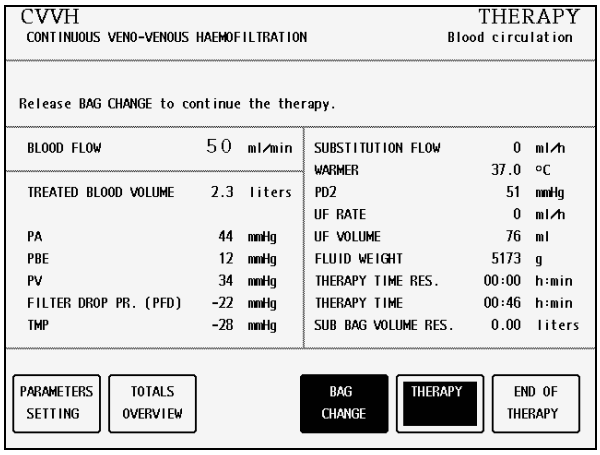


Pressure overview

<PRESSURE OVERVIEW> allows an overview of all pressures recorded in the system.

➢ Select <PRESSURE OVERVIEW> and confirm by pressing the  key.

➢ Select <PARAMETERS OVERVIEW> to return to the <PARAMETERS OVERVIEW> screen and confirm by pressing the  key.



Bag change

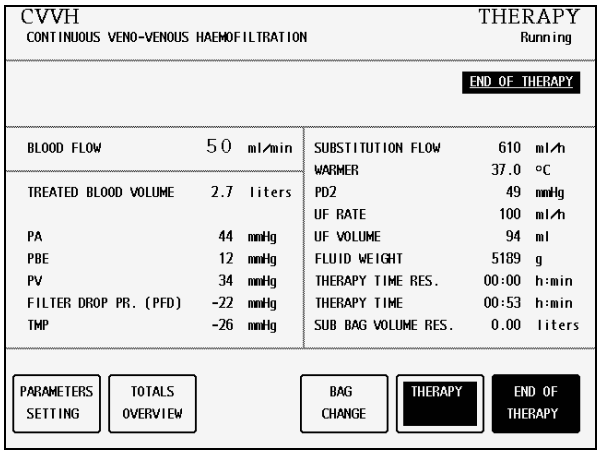
The <BAG CHANGE> option allows to change the fluid bags during a running therapy.

- Select <BAG CHANGE> and confirm by pressing the  key.

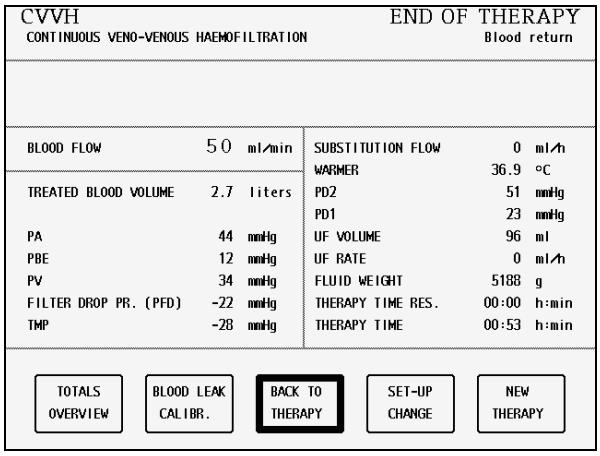
  The ultrafiltration pump (MP2) and the substitution pump (MP3) stop. The blood pump (MP1) keeps on running.
- Exchange the bag(s).
- Open the frangible pin if the bag(s) with the haemofiltration solution is exchanged.
- Close the line equipped with the plug if the collecting bag(s) is exchanged.
- After the bag exchange, deactivate <BAG CHANGE> by pressing the  key.

  The treatment continues automatically.

5.5 End of therapy



- Select <END OF THERAPY> and confirm by pressing the  key.
- Confirm by pressing the  key.



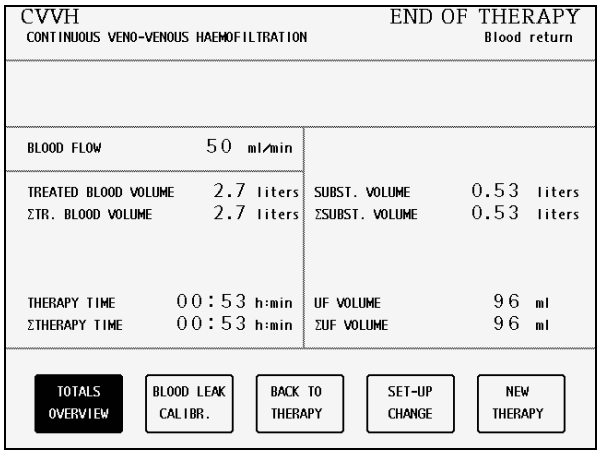
The ultrafiltration pump (MP2) and the substitution pump (MP3) stop. The blood pump (MP1) continues to run at reduced speed (50 ml/min).

5.5.1 Disconnecting the patient

- Stop the blood pump (MP1).
- Disconnect the arterial line from the patient's arterial access and connect it to a bag with isotonic saline solution.
- Start the blood pump and return the blood in the extracorporeal circuit to the patient.
- Stop the blood pump (MP1) just before the isotonic saline solution enters the patient.
- Disconnect the venous line from the patient's venous access.
- Remove disposable materials and solutions from the device.

Dispose of disposable materials and fluids which have been removed from the device in accordance with local regulations.
Therapy data are stored in the machine for 30 minutes. They can be recalled by switching on the Diapact® CRRT within this time frame.

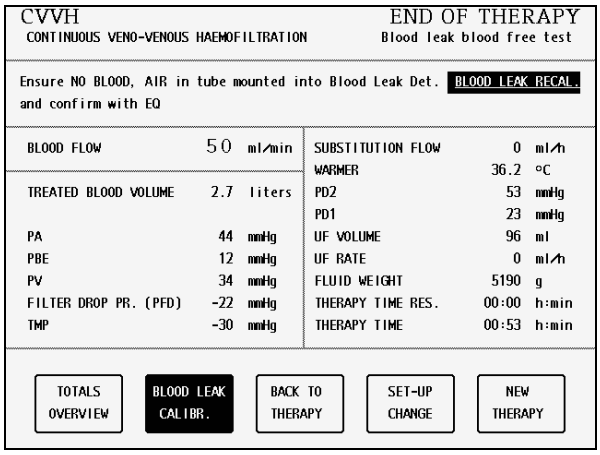
5.5.2 Menu selection at end of therapy



Totals overview

The option <TOTALS OVERVIEW> shows the summary of the pivotal treatment data as described (see Section 5.4.3)

- Select <TOTALS OVERVIEW> and confirm by pressing the  key.
- To return to the <END OF THERAPY> screen, select <TOTALS OVERVIEW> and confirm with the  key.



Blood leak recalibration

The <BLOOD LEAK CALIBRATION> function allows the recalibration of the blood leak detector in case of non-acceptable alarms (e.g. elevated plasma bilirubin concentration)

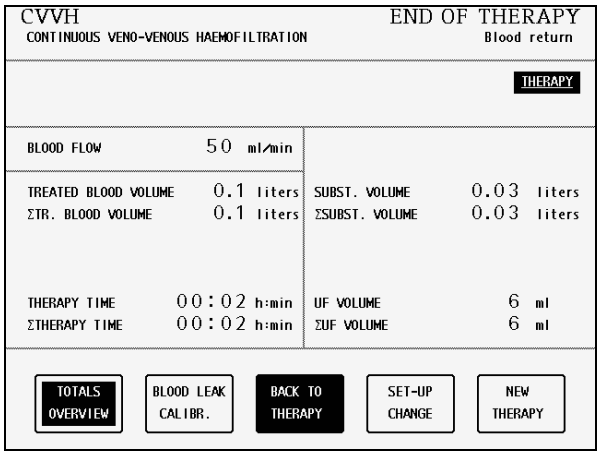
- Select “BLOOD LEAK CALIBRATION” and confirm with the  key. The  key lights up.
- Confirm with the  key.
- Select <BACK TO THERAPY> and confirm with the  key. The  key lights up.
- Confirm with the  key.
- Adapt the blood flow to the initial value.
- Start <THERAPY> by pressing the  key.

DANGER

Risk of blood loss for the patient and haemolysis

- **Before the recalibration of the blood leak detector, the haemofilter must be carefully checked for possible blood leaks and haemolysis.**
- **It is recommended to withdraw a sample (at least 2 ml) from the injection port of the filtrate line and to analyze for erythrocytes and/or free haemoglobin.**
- **The blood leak recalibration must only be performed if these tests are negative.**

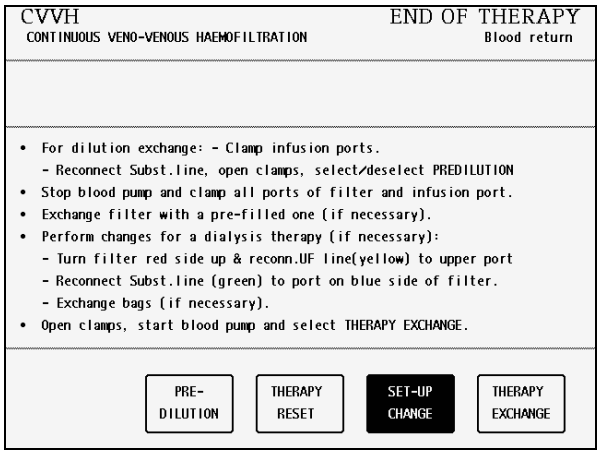
The balance pumps will not start up again until blood leak calibration has been completed.



Back to therapy

The option <BACK TO THERAPY> returns to the just finished therapy.

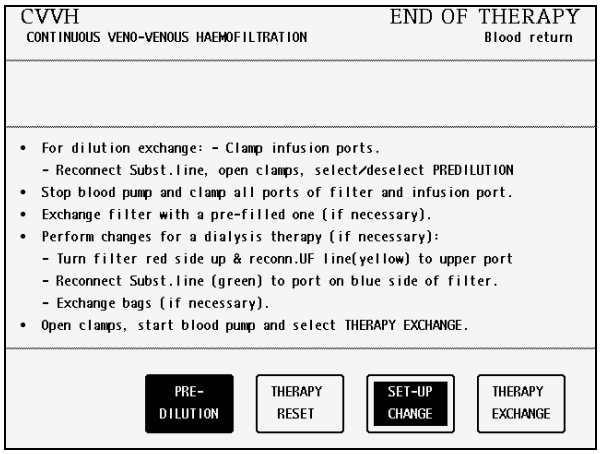
- Select <BACK TO THERAPY> and confirm by pressing the  key. The  key lights up.
- Confirm by pressing the  key.
- Start the therapy again by pressing the  key.



Set-up change

The function <SET-UP CHANGE> helps with a set-up instruction to:

- Change from post- to pre-dilution or vice versa during therapy (dilution change).
- Change from CVVH to CVVHD, CVVHDF, HF, HD or HDF during therapy (therapy change).
- Exchange the filter.



Dilution change

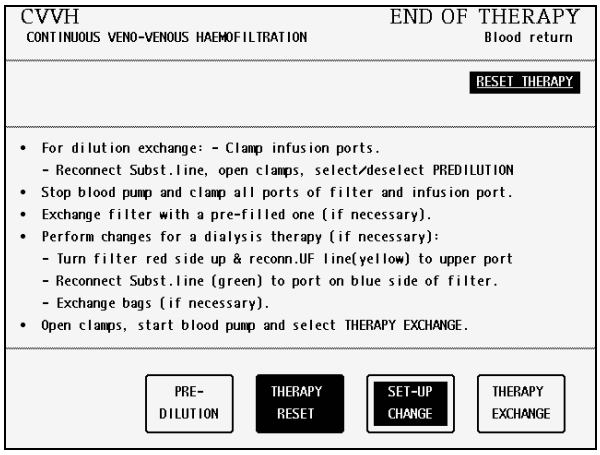
- ➢ Select <SET-UP CHANGE> and confirm by pressing the  key.
- ➢ Stop the blood pump (MP1).
- ➢ Follow the relevant procedure described below.

<u>Change from post-dilution to pre-dilution</u>

- ➢ Close the clamp of the line at the venous chamber where the substitution line is connected.
- ➢ Close the clamp at the substitution line.
- ➢ Unscrew the substitution line.
- ➢ Screw the substitution line to the arterial line at the allowed line extension after the blood pump and open the clamp at this line extension.
- ➢ Open the clamp at the substitution line.
- ➢ Select <PRE-DILUTION> in the menu using the  or  keys.
- ➢ Activate <PRE-DILUTION> by pressing the  key.
- ➢ Select <SET-UP CHANGE> and confirm by pressing the  key and continue the therapy.

Change from pre-dilution to post-dilution

- Close the clamp of the arterial line extension where the substitution line is connected.
- Close the clamp at the substitution line.
- Unscrew the substitution line.
- Screw the substitution line to one of the free lines of the venous chamber and open the clamp at this line.
- Open the clamp at the substitution line.
- Select <PRE-DILUTION> in the menu using the  or  keys.
- Deactivate <PRE-DILUTION> by pressing the  key.
- Select <SET-UP CHANGE> and confirm by pressing the  key and continue the therapy.

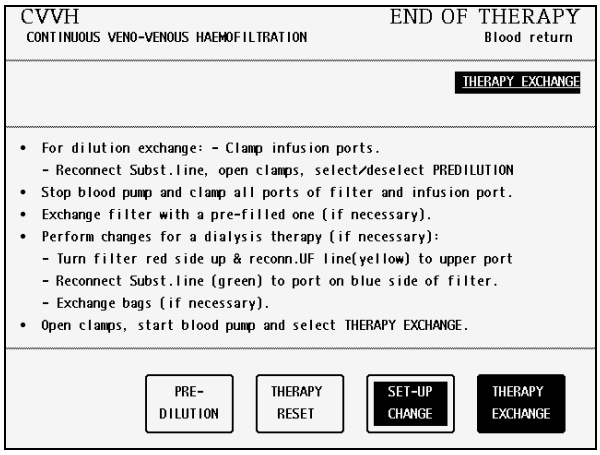


Therapy reset

The function allows to reset the just finished therapy.

- Select <THERAPY RESET> and confirm by pressing the  key followed by the  key.

See also Section 5.4.3



Therapy change

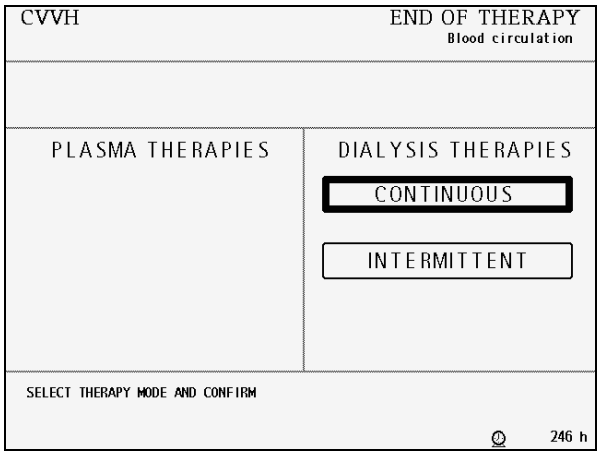
- Select <SET-UP CHANGE> and confirm by pressing the  key.
- Stop the blood pump (MP1).

To change from CVVH to CVVHD, CVVHFD, HD or HFD, close the clamp of the line at the venous air trap or the arterial line extension where the substitution line is connected.

- Close the clamp of the substitution line.
- Unscrew the substitution line from its connector, connect the second Hansen connector of the kit to the free filtrate-side port of the filter
- Connect the ultrafiltration line (**yellow**) to the port next to the arterial port of the haemofilter.
- Connect the substitution line (**green**) to the port next to the venous port of the haemofilter.
- Turn the haemofilter upside down.
- Open the clamp of the substitution line.

To change from CVVH to HF, the set-up must not be changed unless it is combined with a dilution change (see above).

- Select <THERAPY EXCHANGE> and confirm by pressing the  key. The  key lights up.
- Confirm by pressing the  key.



- Select <CONTINUOUS> or <INTERMITTENT> therapy mode using the  or  keys and confirm by pressing the  key.

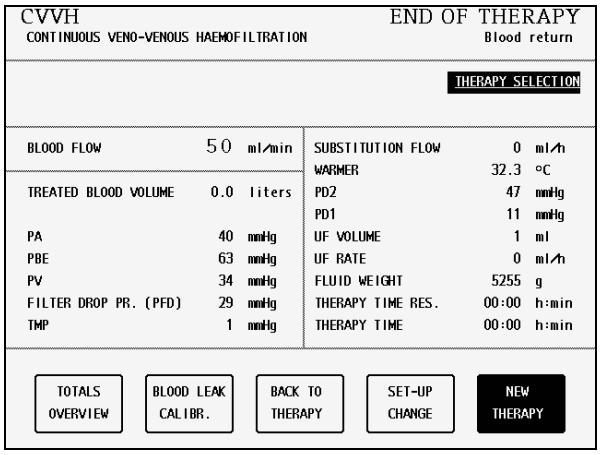
In the following screen the modality can be selected. The chosen therapy starts with the confirmation of the safety-relevant treatment data.

For further information see the Section of the therapy you have chosen.

The treatment data of the previous therapy will be retained.

Changing the haemofilter

See Section 13.5



New therapy

The option <NEW THERAPY> allows to start a new therapy immediately after the one just finished. The device switches directly to therapy selection.

- Select <NEW THERAPY> and confirm by pressing the  key. The  key lights up.
- Confirm by pressing the  key.

DANGER

Risk of blood loss and infection for the patient

- **To guarantee the safe therapy for the patient, the consumables (line system, filter, solutions) used in the just finished therapy must be completely replaced.**

5.6 Special functions

Automatic substitution flow reduction

Automatic substitution flow reduction is an automatic parameter adaptation to the current filter state undertaken by the system.

If the ultrafiltration flow cannot be achieved, the following control mechanism is performed:

If PD2 pressure reaches a value 20 mmHg above the set PD2 min. value, the substitution flow will be automatically reduced as a function of the filter state.

It can result that the required substitution volume is not reached. To guarantee that the system does not fall below the required substitution volume, the flow is automatically increased slightly, if the reduction of the substitution flow is not necessary anymore.

Ramping

This function prevents the build-up of a secondary membrane on the membrane as a result of underpressure created by jerky pump starts.

The balance pumps starts at reduced speed at the start of therapy, after every stop of the blood pump or the balance pumps, and after certain parameter changes.

To guarantee that the system does not fall below the required substitution volume, the flow is automatically increased slightly during the therapy.

The raising of the flow, as well as the continuous raising of the flow, depends on the frequency of ramping.

Bag movement function

To avoid superfluous alarms and the resulting pump standstill, the Diapact® CRRT has a function which is actuated by slight movements of the machine during therapy.

When this function is actuated, the ultrafiltration and the dialysate pumps stop without an alarm and start again automatically when the initial weight (i.e. the weight before the movement of the machine or bag) is reached again.

Automatic temporary reduction of the blood flow

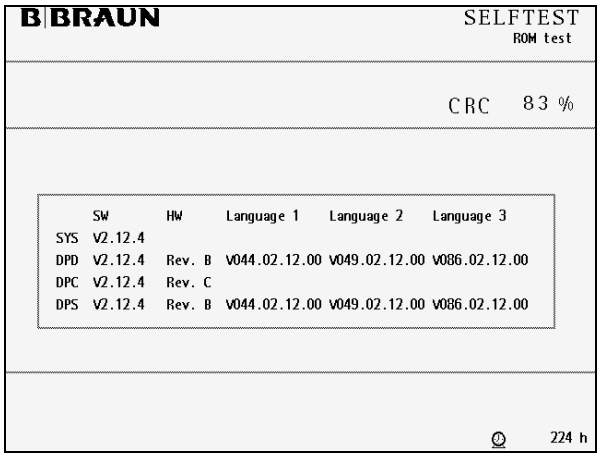
If PA min is reached, blood flow automatically drops to 25% (but not lower than 60 ml/min) to prevent standstill of the blood pump caused by movement of the patient. The ultrafiltration and the dialysate pumps stop also for a short time without an alarm.

Table of contents

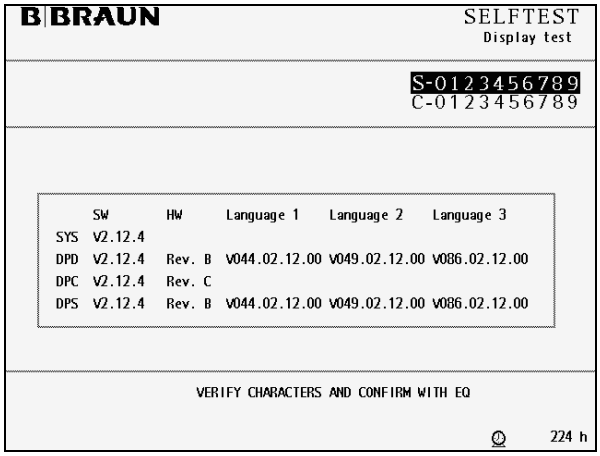
6 CVVHD (Continuous veno-venous haemodialysis)
CVVHFD (Continuous veno-venous high-flux dialysis)

Since the installation of the tube systems and the follow-up and content are the same for CVVHD and CVVHFD, these two modalities are described together in this Section.

6.1 Switching on and initial tests

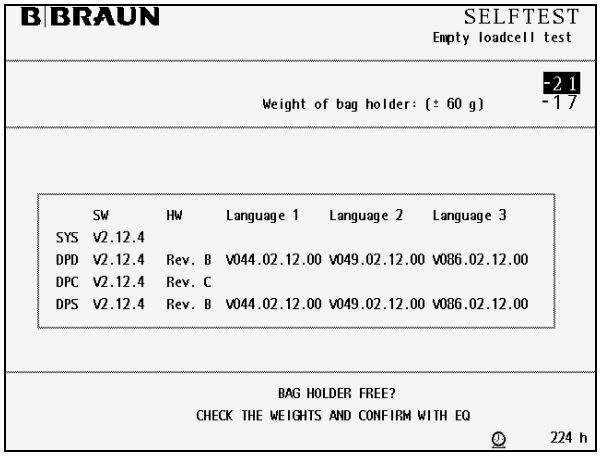


- Switch on the Diapact® CRRT with the power switch ON/OFF (I/O) on the back of the machine. The device starts with the ROM test.
- Check whether the AQ and EQ keys are lit during the ROM test.



The ROM test is followed by the display test.

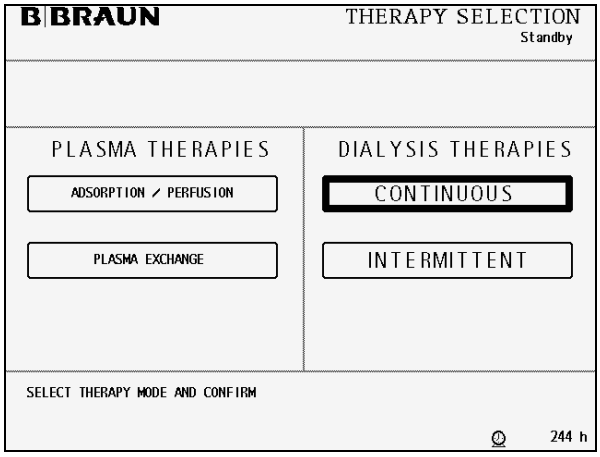
- Compare the character lines in the supervisor field and confirm by pressing the EQ key if both series are identical.
- While the EQ key is being pressed, the buzzer of the safety system is activated for 2 seconds.
- Check that the buzzer can be heard.



If the display test is passed successfully, the empty load cell test follows.

- Check whether the bag holder is empty.
- Confirm the weight values with the EQ key if they are within the allowed range. The maximum deviation between both displayed values is allowed to be ± 60 g and the values must not exceed -60 and +60 g.

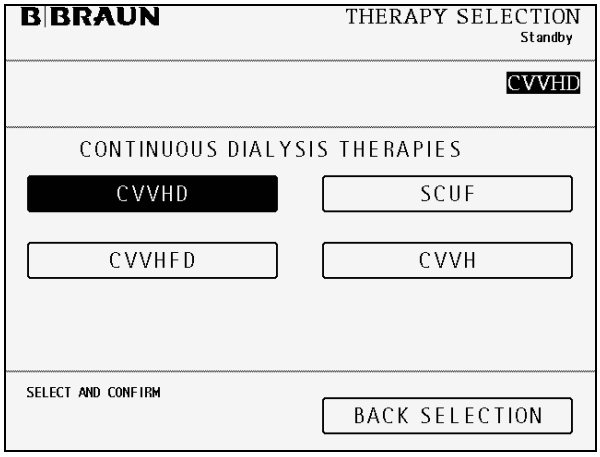
6.2 Therapy selection



Having successfully passed the initial self tests, the machine switches to the <THERAPY SELECTION> screen to select the therapy mode.

<CONTINUOUS> dialysis therapies is selected by default.

- Confirm the selection with the  key.



The following screen displays the possible therapy options. <CVVH> is selected by default.

- Select <CVVHD> or <CVVHFD> with the  or the  key.
- Confirm the selection with the  key.

  The  key lights up and CVVHD or CVVHFD flashes in the supervisor field.

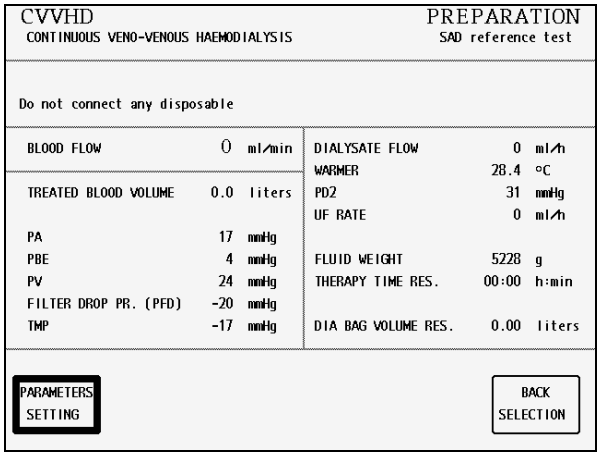
- Press the  key to confirm the selected therapy modality.

  If the selection is not confirmed with the  key, the device returns automatically to the <THERAPY SELECTION> screen where the therapy mode can be selected.

Back selection

Moving with the  or  keys to <BACK SELECTION> and confirmation with  allows to return to the screen where the therapy mode can be selected.

6.3 Preparation

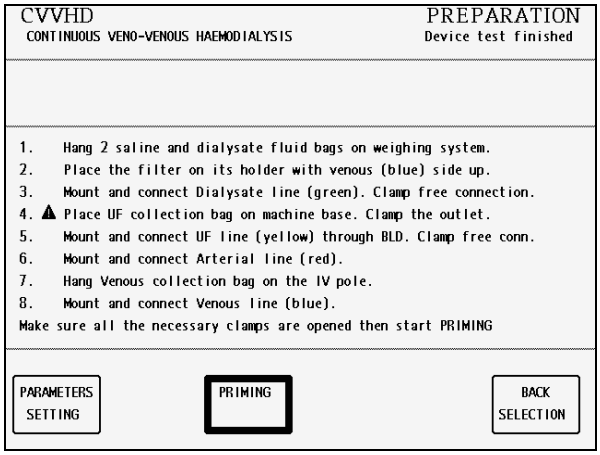


After modality selection and confirmation, the display shows the following <PREPARATION> screen.

Several tests are performed. The respective test is displayed in the therapy status field:

- Power relay test
- SAD reference test
- SAD counter test
- Red detector test
- Blood leak detector test
- Zero pressure test

6.3.1 Installation of consumable material



When the tests have been performed successfully, the <PREPARATION> screen displays <Device test finished> and the steps to set-up the machine are displayed.

The consumable material for the therapy comprises:

- HF/HD kit
- Haemofilter (low-flux filter for CVVHD,)
- 2L isotonic sodium chloride solution
- Haemofiltration solution

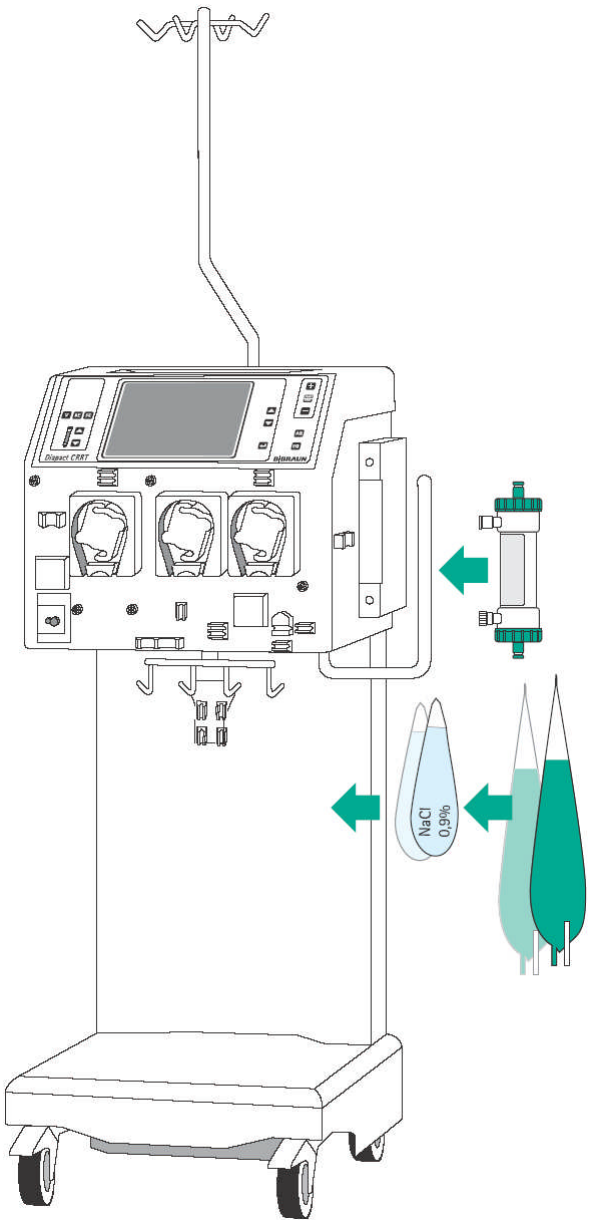
➢ Follow the instructions on the screen and set-up the device as described in the following.

The lines of the HF/HD kit are colour-coded to facilitate the set-up.
Arterial line (red)
Venous line (blue)
Ultrafiltration line / dialysate outlet line in CVVHD/CVVHFD (yellow)
Substitution line / dialysate inlet line in CVVHD/CVVHFD (green)

Pumps used:
Blood pump (MP1)
Ultrafiltration pump (MP2)
Substitution pump (MP3) / Dialysate pump in CVVHD/CVVHFD

WARNING

Risk of infection and blood loss for the patient by damaged packaging or components
➢ Make sure during set-up that the packaging of the material used (line system, haemofilter, solution bags) is undamaged.
➢ During set-up check the material for integrity.
➢ Observe the respective instructions for use.



Installation of bags and haemofilter

- Attach the 2L bag with isotonic sodium chloride solution and the bags with the haemofiltration solution on the hooks of the load cell.
- Fix the haemofilter (low-flux filter for CVVHD) into the filter holder on the right side of the machine.
- Close the clamps of the collecting bags at the tubes equipped with plugs.

CAUTION

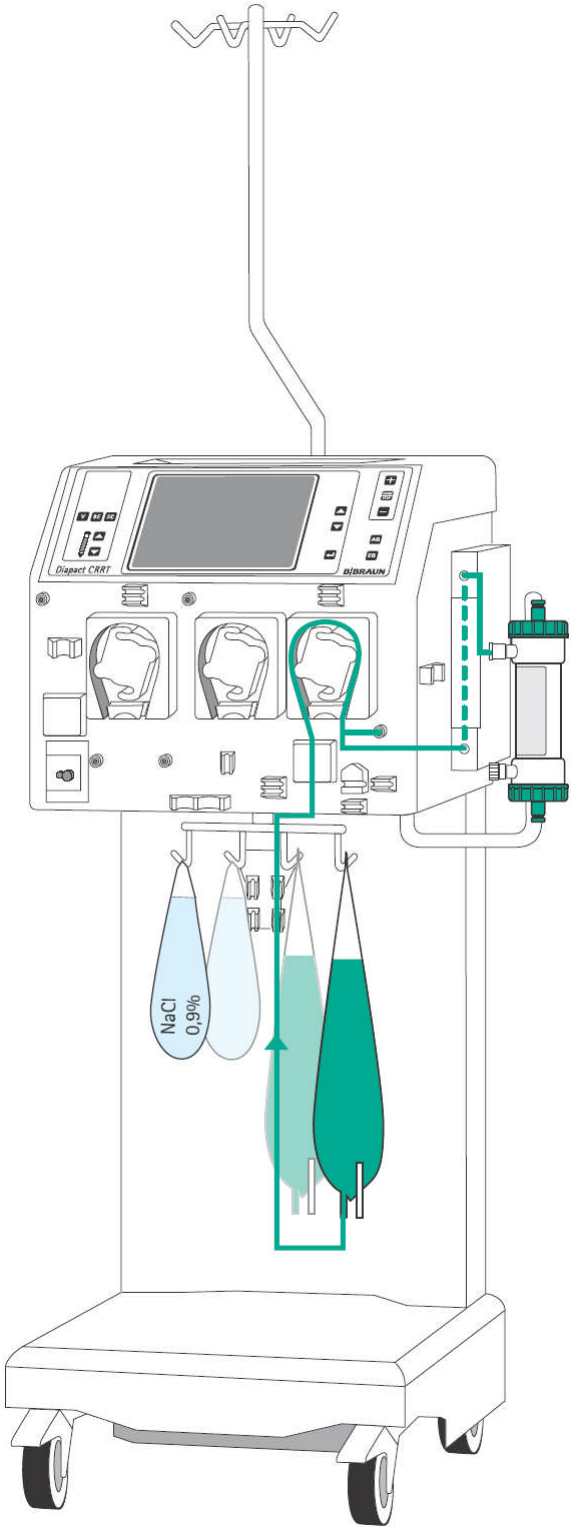
Incomplete moistening of the haemofilter during priming and rinsing may result in performance reduction.

- Place the haemofilter filter into the filter holder with the arterial port (red) downwards.

If the weight on the load cell is unevenly distributed, there is a risk that the device may topple.

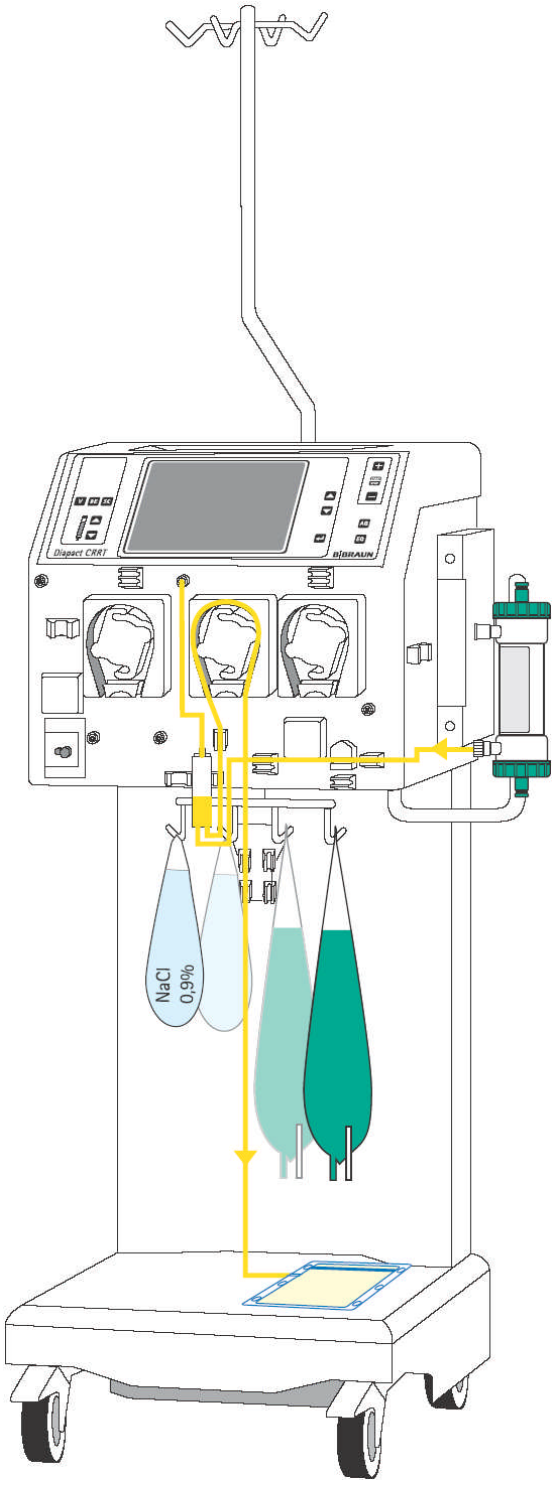
- Distribute weight on the bag holder evenly.

The maximal load of the load cell is 27 kg



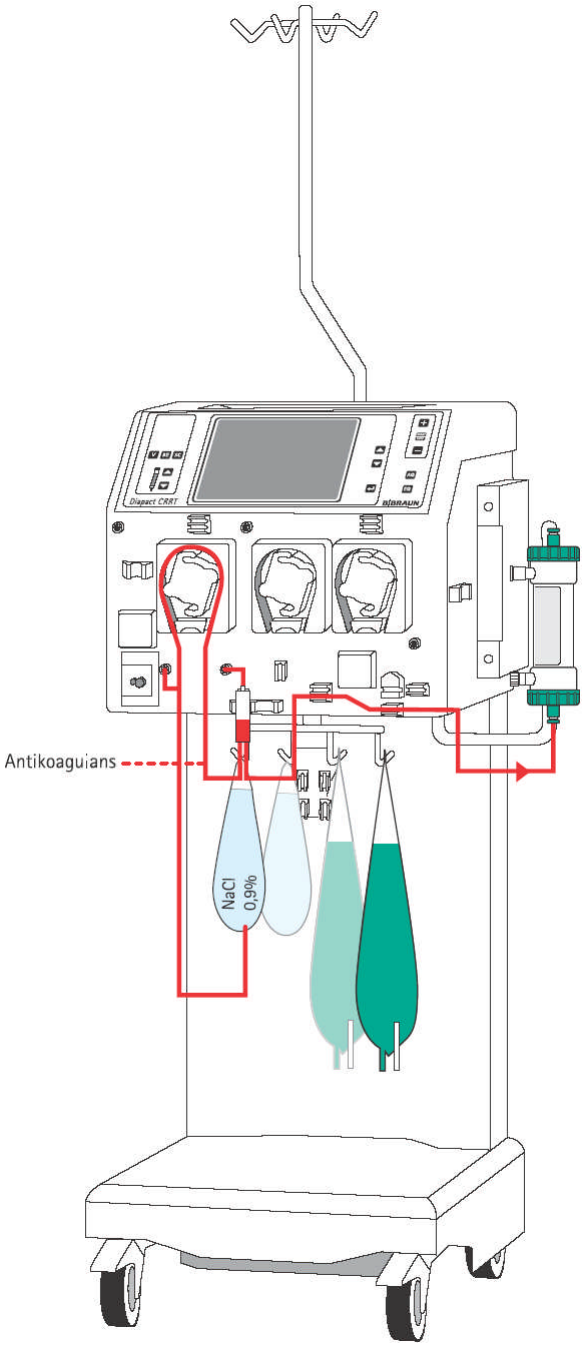
Insertion of the dialysate inlet line (green)

- Insert the heater bag into the plate heater and close the cover. To ensure that the bag has optimal contact to the heater, close the cover audibly.
- Insert the pump segment into the dialysate pump (MP3).
- Insert the line leading from the connection of the bags with the haemofiltration solutions to the pump segment into the air detector beneath the dialysate pump (MP3).
- Connect the transducer protector to the pressure sensor PD1 (white).
- Connect the line leading from the air detector to the bags with the haemofiltration solution to the bags and fix the line into the line fixing on the bag holder of the load cell.
- Connect the dialysate inlet line to the dialysate side of the haemofilter beside the venous connector.



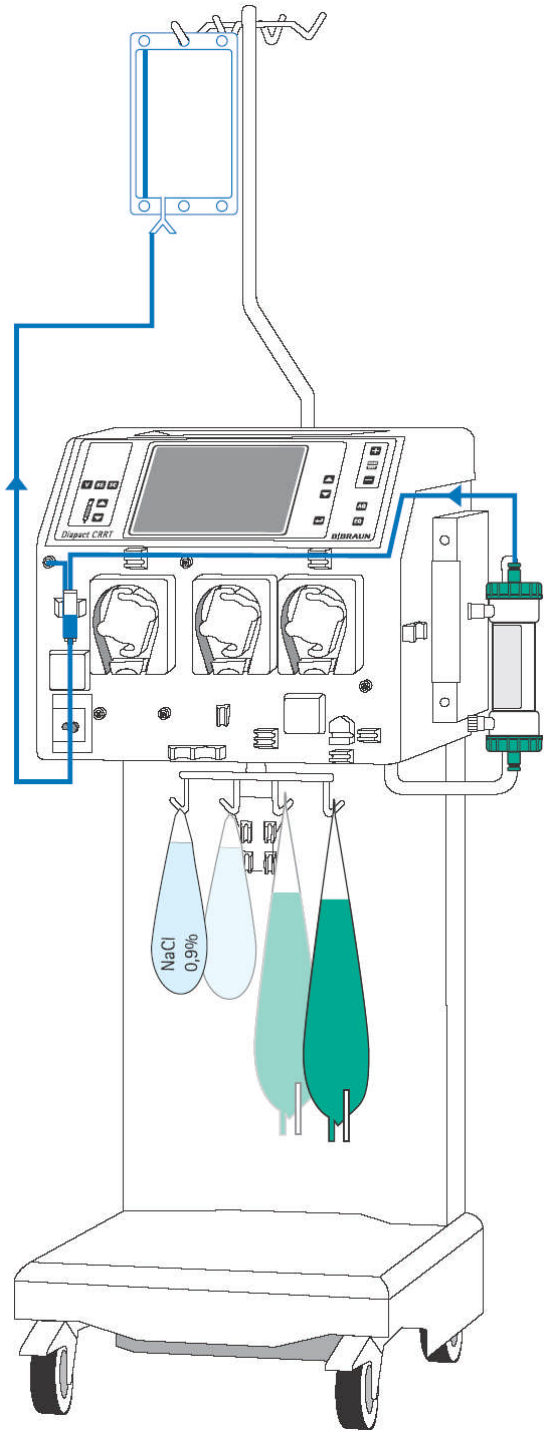
Insertion of the ultrafiltration line (yellow)

- Connect the ultrafiltration line to the dialysate side of the haemofilter beside the arterial connector.
- Insert the line coming from the haemofilter into the blood leak detector (BLD).
- Insert the pump segment into the ultrafiltration pump (MP2).
- Insert the air trap into the intended holder.
- Connect the transducer protector to the pressure sensor PSC/PD2 (white).
- Connect the Luer Lock connectors to the collecting bags and place the collecting bag on the socket of the device.



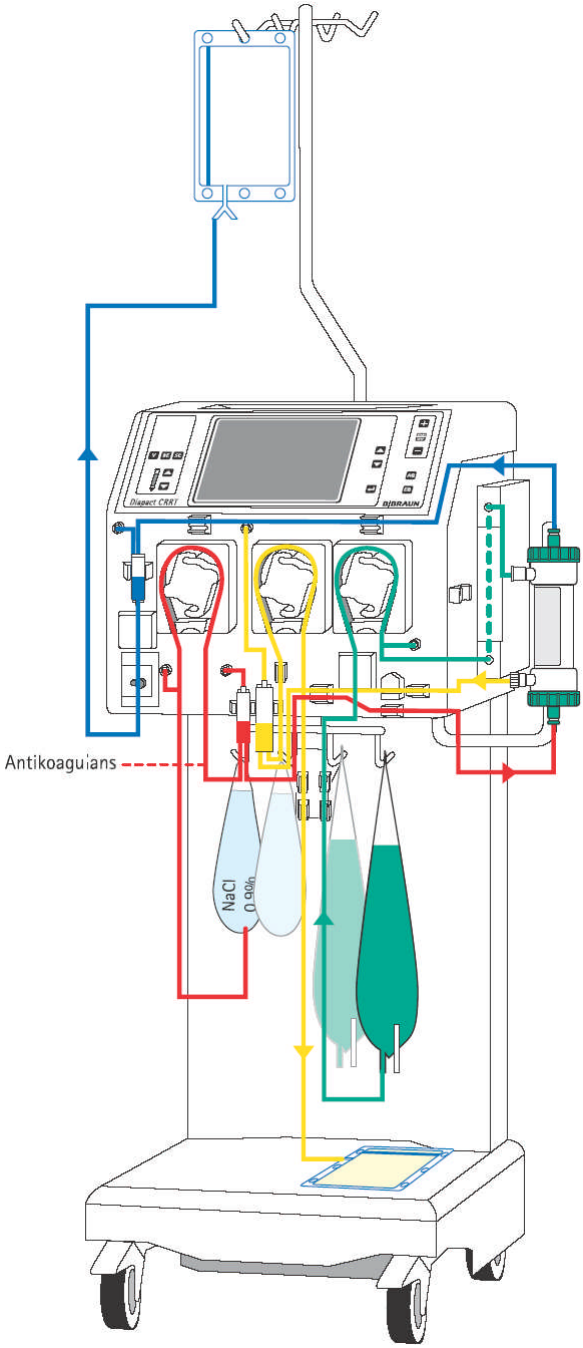
Insertion of the arterial line (red)

- Connect the end of the line with the spike/Luer Lock connector to the bag with isotonic sodium chloride solution on the bag holder of the load cell.
- Insert the pump segment into the blood pump (MP1).
- Connect the transducer protector before the blood pump to the pressure sensor PA (red).
- Insert the arterial air trap into the intended holder.
- Connect the transducer protector to the pressure sensor PBE (red).
- Connect the red Luer Lock connector to the lower blood-side connector of the haemofilter.
- If continuous heparinisation is required, connect the heparin line to the external heparin pump previously filled with heparin.
- Close the clamp of the heparin line if it is not used.
- Close the clamps at the sampling ports before and after the blood pump (MP1).



Insertion of the venous line (blue)

- Attach the rinsing bag to the infusion pole.
- Insert the venous air trap into the intended holder.
- Insert the venous line beneath the drip chamber into the safety air detector (SAD) and the safety air clamp (SAK) under the detector.
- Connect the transducer protector to the pressure sensor PV (blue).
- Connect the blue Luer Lock connector to the upper blood-side connector of the haemofilter and fix the line in the line fixing above the pumps.
- Close the clamp at the not used connection of the venous air trap.



Set-up overview

- ➢ Check the set-up before starting the priming procedure.
- ➢ Take care that all connections are firmly screwed together.
- ➢ Check that all pump segments are inserted clockwise.
- ➢ Check that the following clamps are closed:
  - Sampling ports before and after the blood pump
  - Heparin line if it is not used
  - Lines with connectors at the venous chamber
  - Line with the plug at the collecting bag(s)
- ➢ Open the frangible pin of the sodium chloride solution bag and the bags with the haemofiltration solution.

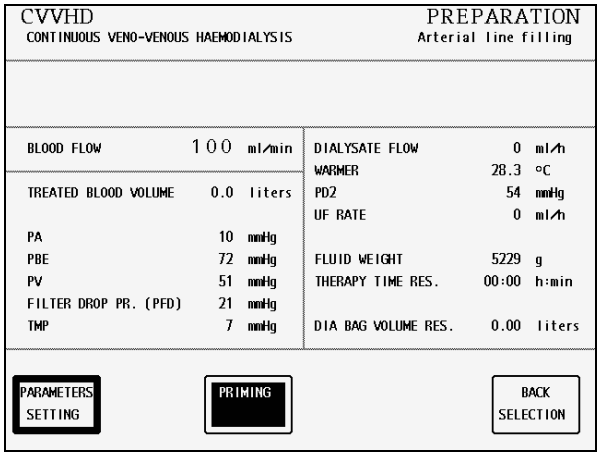
Installation of the preassembled HF/HD Kit

In the pre-assembled kit, the components of the HF/HD kit are mounted to a guide rail.

- ➢ Take hold of the guide rail of the kit with both hands and insert it into the respective holders on the machine (see also the respective instruction for use).
- ➢ Insert the pump segments clockwise.
- ➢ Connect all components as described above in this Section.

i Make sure that all relevant clamps are opened and that all connections are firmly screwed together before starting the priming procedure.

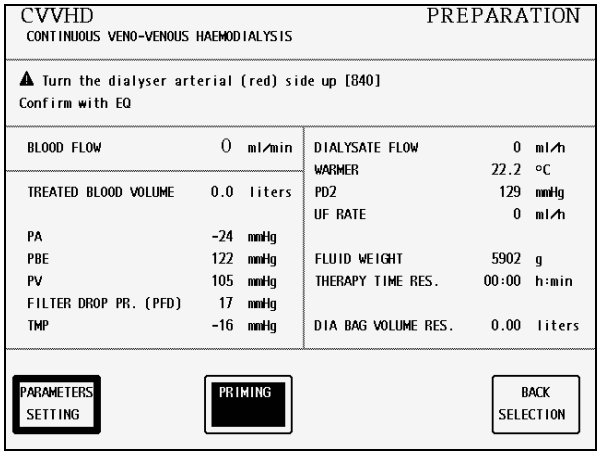
6.3.2 Priming



- After set-up of the consumables and checking the connections, select <PRIMING> and confirm by pressing the  key.

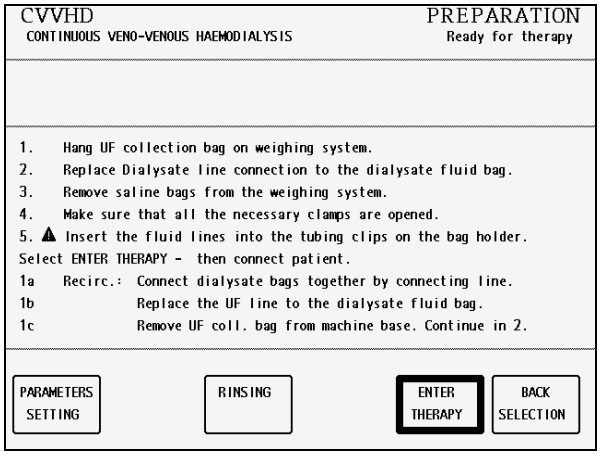
The automatic priming program starts. During the priming and rinsing the following tests are performed: load cell test, air detector test, dialysate pump test (MP3), heater test, disposable leakage test, level regulation test and the calibration of the pump constants takes place. The respective step of the procedures and the test is displayed in the therapy status field.

Do not move the Diapact® CRRT during calibration of the pump constants. Calibration will be repeated if it is disturbed.



During the priming procedure the prompt to turn the haemofilter is displayed.

- Turn the haemofilter upside down.
- Confirm by pressing the  key.



After the preparation phase has been finished, the system gives an acoustic signal and shows the <PREPARATION> screen with message <Ready for therapy> in the therapy status field.

- Remove the bag with the sodium chloride solution from the load cell and attach it to the infusion pole.

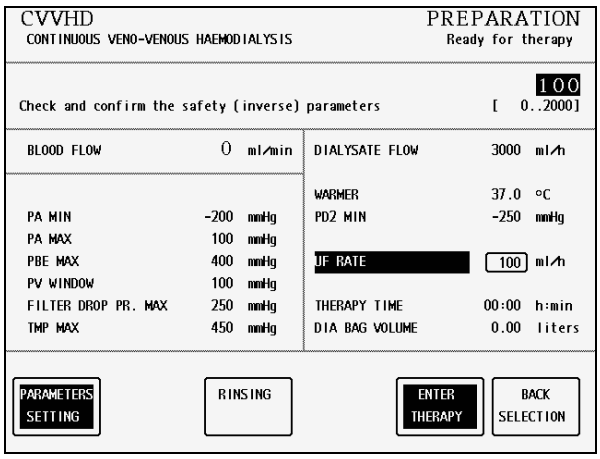
<u>Single pass</u>

- Attach the collecting bags to the bag holder of the load cell.
- Make sure that all relevant clamps are open.
- Select <ENTER THERAPY> and confirm by pressing the  key. The device switches automatically to <PARAMETERS SETTING>.

Recirculation

- Attach the collecting bags to the bag holder of the load cell.
- Connect the collecting bags and the bags with the haemofiltration solution as follows:
  - One branch of the dialysate inlet line to one collecting bag and the other branch to the ultrafiltration bag.
  - One branch of the ultrafiltration line to the collecting bag and one branch to the bag with the haemofiltration solution.
  - If necessary, connect the two bags with the haemofiltration solution with the connecting line.
- Make sure that all relevant clamps are open.
- Select <ENTER THERAPY> and confirm by pressing the  key.

6.3.3 Parameter setting

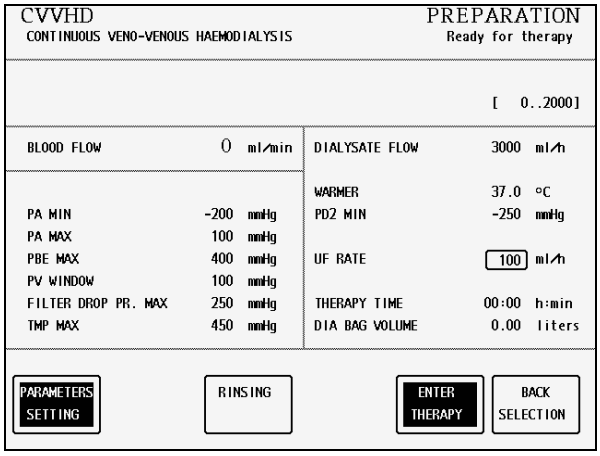


Setting safety-relevant parameters

The safety-relevant parameters (ultrafiltration rate in CVVHD and CVVHFD) are displayed on a black background.

- Activate <UF rate> by pressing the  key. The value is inversely displayed on a black background.
- If the value is accepted, confirm by pressing the  key.
- To change the value, press the  key to increase it or the  key to decrease it.
- Confirm with the  key.
  In both cases, the actual value is displayed in the supervisor field, flashing on a black background.
- Compare the value displayed in the supervisor field with that shown in the fluid-side parameters field and confirm with the  key if they are identical.
- Check and/or change the dialysate flow in the same way.
- Any changes to the safety-relevant parameters must always be confirmed with the  key.

If the safety-relevant data are not confirmed, whether they are changed or not, the system will not start the therapy.



Setting treatment parameters

- Select the parameter to be set with the  or  key.
- Activate the parameter by pressing the  key.
- Change the value with the  or  key and confirm the change with the  key.
- To exit <PARAMETERS SETTING>, press the  key.

These treatment data can be set at any time during the preparation phase or the therapy if the <PARAMETERS SETTING> option is displayed.

The following data can be set in the indicated ranges:

Parameter	Unit	Default	Min	Max	Increments
Blood-side parameters					
Blood flow	ml/min	50	10/5	500	5/10
PA min.	mmHg	-200	-400	PA max.	10
PA max.	mmHg	100	PA min.	200	10
PBE max.	mmHg	400	0	500	10
PV window	mmHg	100	80	160	10
PFD max. pressure drop	mmHg	250	100	450	10
TMP max.	mmHg	450	100	600	10
Fluid-side parameters					
Dialysate flow	ml/h	3000	0*/300	12000	5/50
Temperature	°C	37	20	40	0.5/1.0
PD2 min. CVVHD	mmHg	-250	-400	500	10
PD2 min. CVVHFD	mmHg	-50	-250	250	10
UF rate	ml/h	100	0*	2000	10/100
Dialysate bag volume	l	0.00	-25.00	20.00	0.10/1.00
Therapy time	h:min	00:00	00:00	72:00	0:05/0:30

* The dialysate flow can be set to zero if the UF rate is ≥ 300 ml/h. If the UF rate is below this limit, the adjustable lower limit for the dialysate flow is 300 ml/h – UF rate.

In software versions 2.10 and 2.12 there is no lower limit for the dialysate flow. The increment to increase or decrease the dialysate flow in the lower range is 10 ml/min.

Bag change volume

The haemofiltration solution volume or the spent dialysate volume at which the bags with the haemofiltration solution or the collecting bag at the load cell have to be changed can be defined. The default value is 0.

If 0 is selected, the machine gives an alarm when the haemofiltration solution is empty, as detected by the air detector underneath the dialysate pump (MP3.)

- Select <DIA BAG VOLUME> in <PARAMETERS SETTING> and confirm with the  key.
- Set the <DIA bag volume> to a positive value (e.g. + 4.8L).

When the volume of the haemofiltration solution bags is spent during therapy, the alarm <bag volume is over (1020)> occurs

- Follow the instructions on the screen and exchange the bag(s) with the haemofiltration solution.
- Set the <DIA bag volume> to a negative value (e.g. – 6L).

Selecting a negative <DIA bag volume> changes the display to <UF bag volume>

When the volume of the ultrafiltration collecting bags is reached during therapy, the alarm <bag volume is over (1020)> occurs

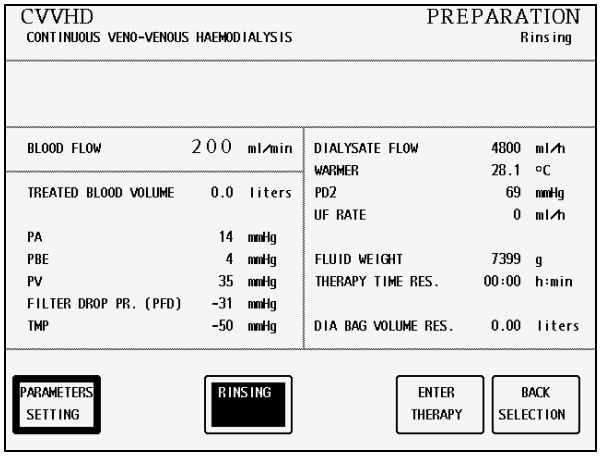
- Follow the instructions on the screen and exchange the collecting bag.

To switch between <DIA bag volume> and <UF bag volume>, it is necessary to set the parameter first to 0.

- Select <DIA bag volume> and <UF bag volume> and confirm with the  key.
- Set the parameter to 0 and confirm with the  key.
- Select <DIA bag volume> again and confirm with the  key.
- Increase or decrease the value and confirm with the  key.

! It is recommended to use the <DIA bag volume> function to avoid air in the dialysate inlet line and as a possible consequence air in the haemofilter which may reduce the efficiency of the dialysis.
It is recommended to exchange the collecting bags as well when the haemofiltration solution bags are exchanged.

6.3.4 Menu selection in preparation



Rinsing

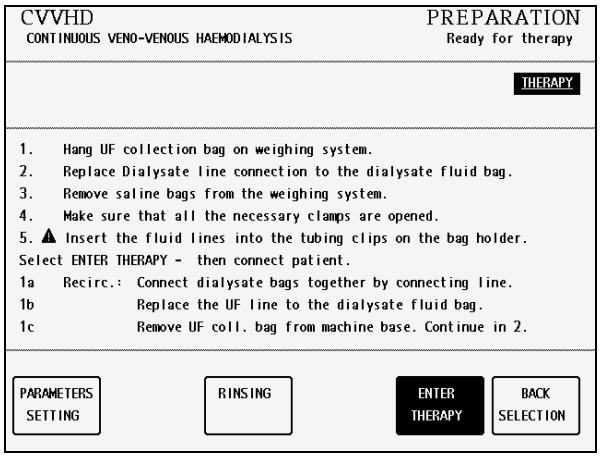
- If necessary, rinsing can be prolonged by selecting <RINSING> and confirming with the  key.
- If only the blood side has to be rinsed, the fluid side can be stopped by opening the cover of the ultrafiltration pump (MP2).
- To finish the additional rinsing, select <RINSING> again and confirm with the  key.

Back selection

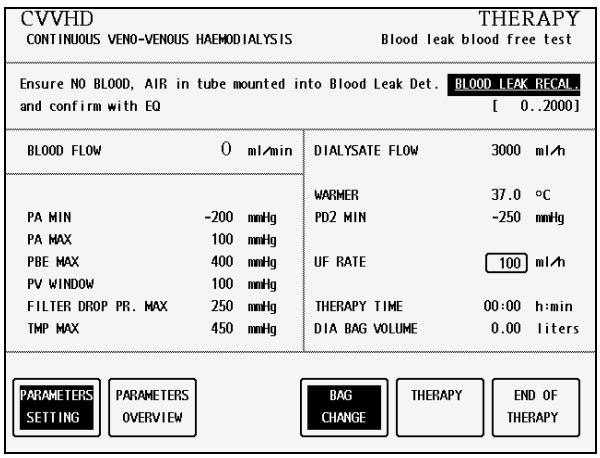
Choosing back selection allows to return to the <THERAPY SELECTION> screen (Fig. 4.2-4).

- Select <BACK SELECTION> and confirm with the  key.

6.4 Therapy



- To switch from <PREPARATION> to <THERAPY>, select <ENTER THERAPY> and confirm by pressing the  key.
- Select <ENTER THERAPY> and confirm with the  key.
- Confirm the start of the therapy by pressing the flashing  key while <THERAPY> is flashing in the supervisor field.



The Diapact® CRRT is now in the therapy status as indicated in the therapy status field.

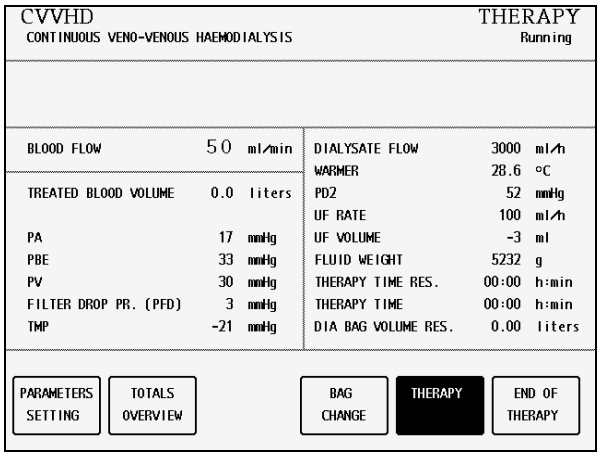
- Confirm the blood leak recalibration by pressing the  key.
- Start the blood pump for circulation by pressing the  key.

6.4.1 Connecting the patient

- Stop the blood pump.
- Connect the arterial line to the arterial access of the patient.
- Start the blood pump and adjust the flow rate using the  or  keys.
- Check that the withdrawal pressure (arterial pressure – PA) is within the prescribed range.
- When the blood starts to fill the venous line, stop the blood pump and connect the venous line to the venous access of the patient.
- Start the blood pump again and adjust the blood flow slowly dependent on the patient's condition.
- Check that the arterial and venous pressure values displayed on the screen are within the normal range.

During therapy, the arterial chamber should be about 50% filled, the venous chamber about 80%

6.4.2 Start of therapy



After the blood has been circulating for 2- 3 minutes without alarms, the therapy can be started.

- Select <THERAPY> and activate by pressing the  key.

<THERAPY> in the menu selection field is blackened and in the therapy status field <Running> is indicated.

The treatment is now in progress and the parameter overview is displayed.

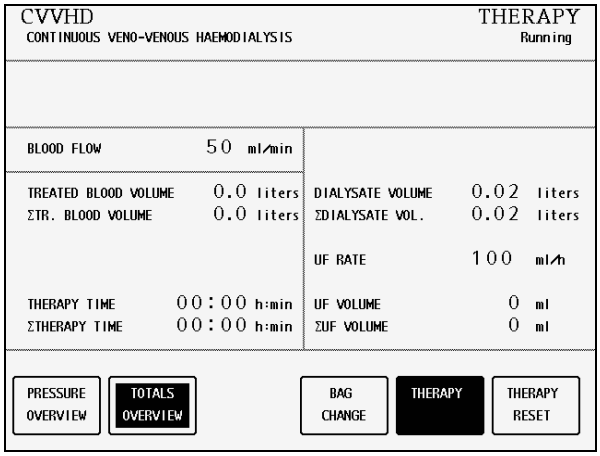
The current pressure and flow data of the blood side and the fluid side are displayed on the screen.

WARNING

Risk of blood loss and contamination for the patient

- In continuous therapies, the pump segment can become damaged in the course of time. In order to avoid the risk of pump segment damage, it is recommended to change the line at the latest every 72 hours.

6.4.3 Menu selection in therapy



Parameter setting

See Section 6.3.3

Totals overview

- Select <TOTALS OVERVIEW> and confirm by pressing the  key.
- To return to the <PARAMETERS OVERVIEW> screen, select <TOTALS OVERVIEW> and then press the  key.

The <TOTAL OVERVIEWS> screen displays:

On the left (blood-side) part of the screen

- Current blood flow
- Treated blood volume of the current time segment
- Treated blood volume of the whole treatment (sum of all time segments)
- Therapy time of the current time segment
- Therapy time of the whole treatment (sum of all time segments)

On the right (fluid-side) part of the screen

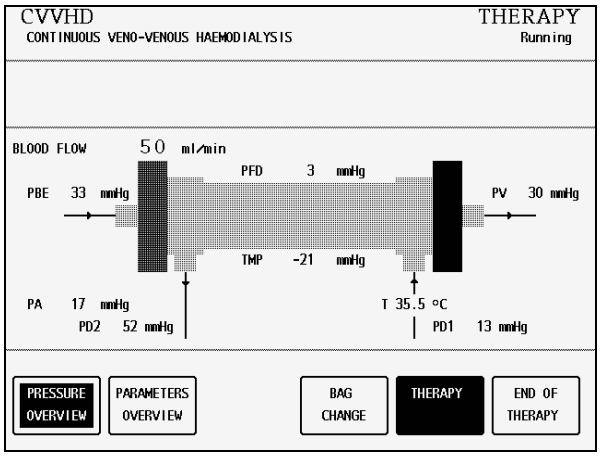
- Current ultrafiltration flow
- Dialysate volume of the current time segment
- Dialysate volume of the whole treatment (sum of all time segments)
- Current ultrafiltration rate
- Ultrafiltration volume of the current time segment
- Ultrafiltration volume of the whole treatment (sum of all time segments)

Therapy reset

<THERAPY RESET> allows to adjust the current values for treated blood volume, therapy time, dialysate volume and ultrafiltration volume to zero. The following volumes and the time are added up from the values marked with Σ.

This allows to follow the data during a certain time segment of the treatment. The system can warn the user to execute a therapy reset by setting the therapy time parameter for the required time.

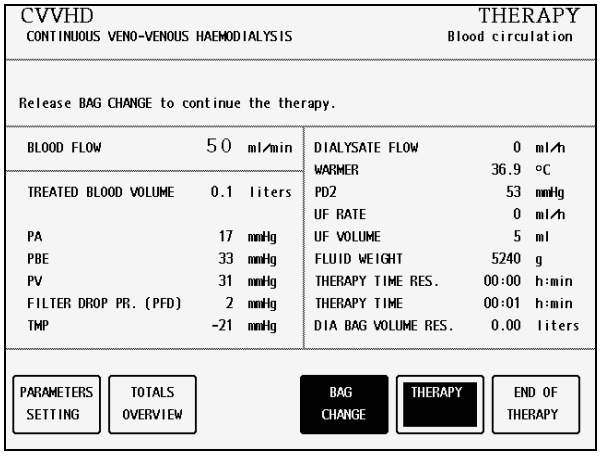
- Select <THERAPY RESET> and confirm by pressing the  key followed by the  key.



Pressure overview

<PRESSURE OVERVIEW> allows an overview of all pressures recorded in the system.

- Select <PRESSURE OVERVIEW> and confirm by pressing the  key.
- Select <PARAMETERS OVERVIEW> to return to the <PARAMETERS OVERVIEW> screen and confirm by pressing the  key.



Bag change

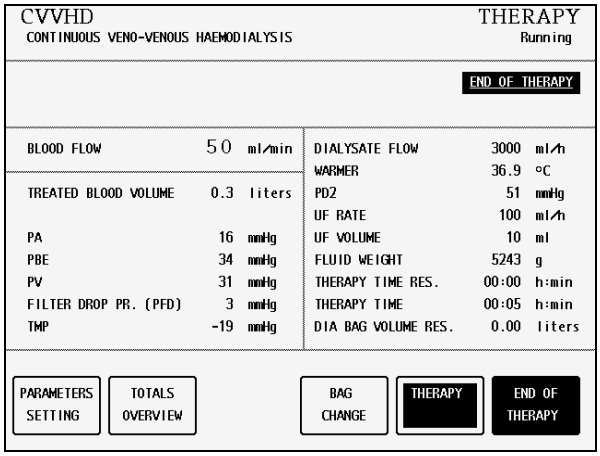
The <BAG CHANGE> option allows to change the fluid bags during a running therapy.

- Select <BAG CHANGE> and confirm by pressing the  key.

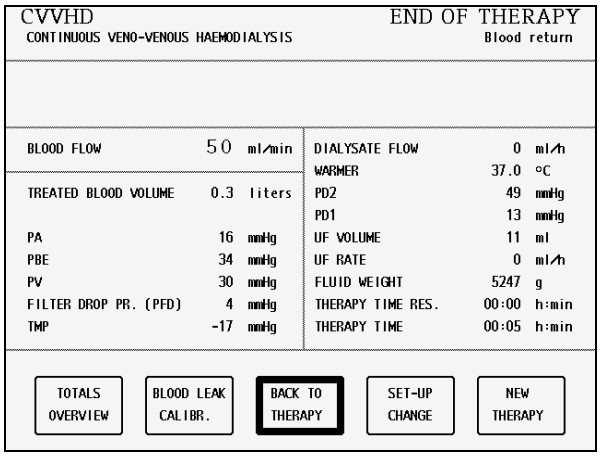
  The ultrafiltration pump (MP2) and the dialysate pump (MP3) stop. The blood pump (MP1) keeps on running.
- Exchange the bag(s).
- Open the frangible pin if the bag(s) with the haemofiltration solution is exchanged.
- Close the line equipped with the plug if the collecting bag(s) is exchanged.
- After the bag exchange, deactivate <BAG CHANGE> by pressing the  key.

  The treatment continues automatically.

6.5 End of therapy



- Select <END OF THERAPY> and confirm by pressing the  key.
- Confirm by pressing the  key.



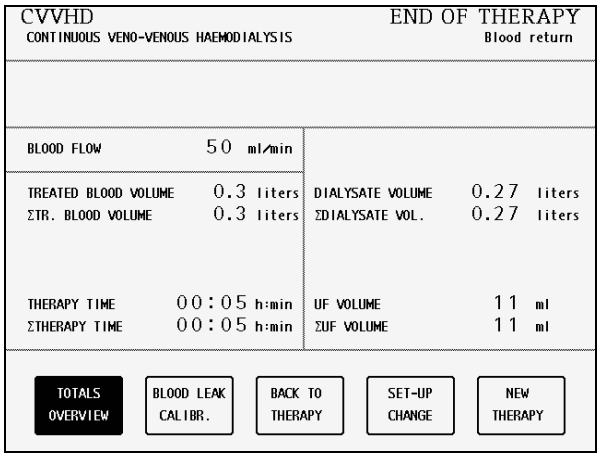
The ultrafiltration pump (MP2) and the dialysate pump stop. The blood pump (MP1) continues to run at reduced speed (50 ml/min).

6.5.1 Disconnecting the patient

- Stop the blood pump (MP1).
- Disconnect the arterial line from the patient's arterial access and connect it to a bag with isotonic saline solution.
- Start the blood pump and return the blood in the extracorporeal circuit to the patient.
- Stop the blood pump (MP1) just before the isotonic saline solution enters the patient.
- Disconnect the venous line from the patient's venous access.
- Remove disposable materials and solutions from the device.

Dispose of disposable materials and fluids which have been removed from the device in accordance with local regulations.
Therapy data are stored in the machine for 30 minutes. They can be recalled by switching on the Diapact® CRRT within this time frame.

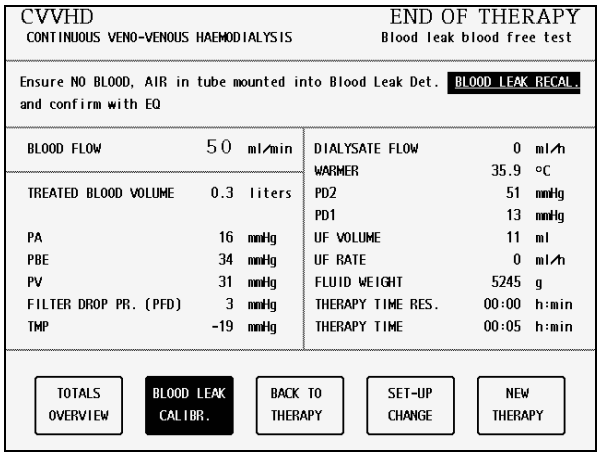
6.5.2 Menu selection at end of therapy



Totals overview

The option <TOTALS OVERVIEW> shows the summary of the pivotal treatment data as described (Section 6.4.3)

- Select <TOTALS OVERVIEW> and confirm by pressing the  key.
- To return to the <END OF THERAPY> screen, select <TOTALS OVERVIEW> and confirm with the  key.



Blood leak recalibration

The <BLOOD LEAK CALIBRATION> function allows the recalibration of the blood leak detector in case of non-acceptable alarms (e.g. elevated plasma bilirubin concentration)

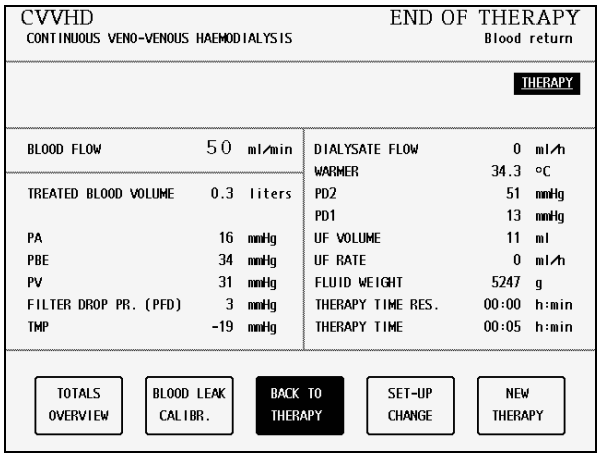
- Select “BLOOD LEAK CALIBRATION” and confirm with the  key. The  key lights up.
- Confirm with the  key.
- Select <BACK TO THERAPY> and c onfirm with the  key. The  key lights up.
- Confirm with the  key.
- Adapt the blood flow to the initial value.
- Start <THERAPY> by pressing the  key.

DANGER

Risk of blood loss for the patient and haemolysis

- Before the recalibration of the blood leak detector, the haemofilter must be carefully checked for possible blood leaks and haemolysis.
- It is recommended to withdraw a sample (at least 2 ml) from the injection port of the filtrate line and to analyze for erythrocytes and/or free haemoglobin.
- The blood leak recalibration must only be performed if these tests are negative.

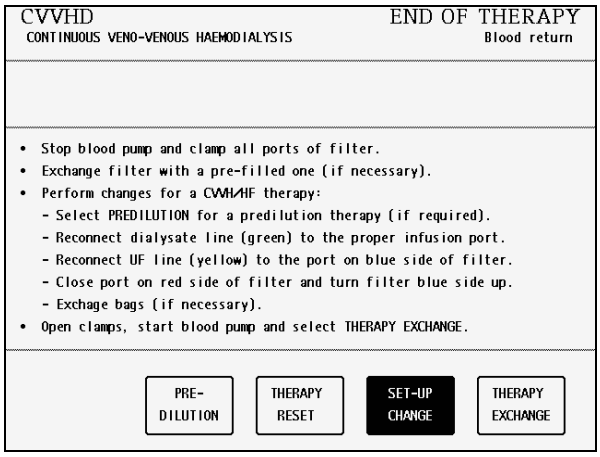
The balance pumps will not start up again until blood leak calibration has been completed.



Back to therapy

The option <BACK TO THERAPY> returns to the just finished therapy.

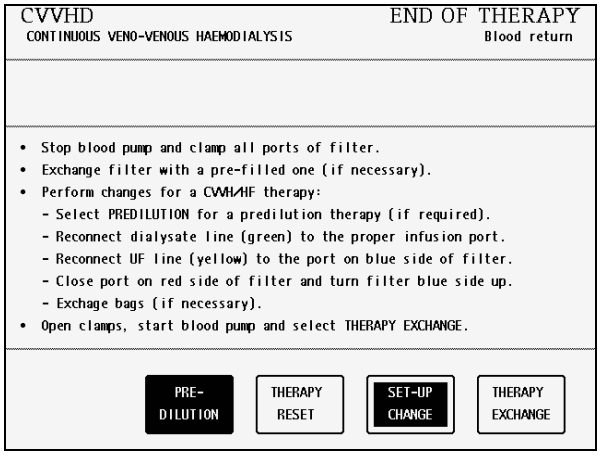
- Select <BACK TO THERAPY> and confirm by pressing the  key. The  key lights up.
- Confirm by pressing the  key.
- Start the therapy again by pressing the  key.



Set-up change

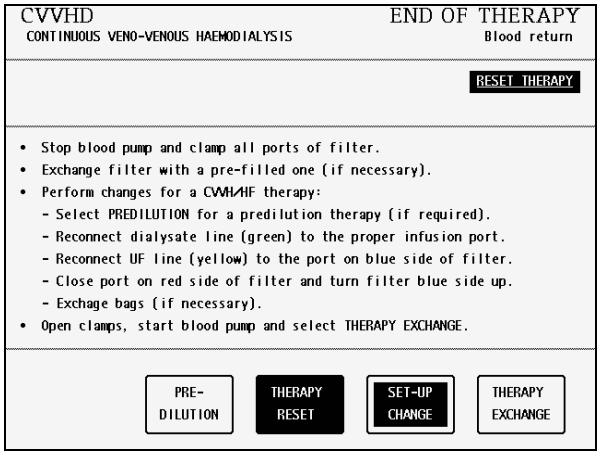
The function <SET-UP CHANGE> helps with a set-up instruction to:

- Change from CVVHD/CVVHDF to CVVH, HF, HD or HDF during therapy (therapy change).
- Exchange the filter.



Dilution setting

The function <PRE-DILUTION> allows to set the dilution mode of a new CVVH or HF therapy if this type of therapy is selected using the <THERAPY EXCHANGE> function (see below).

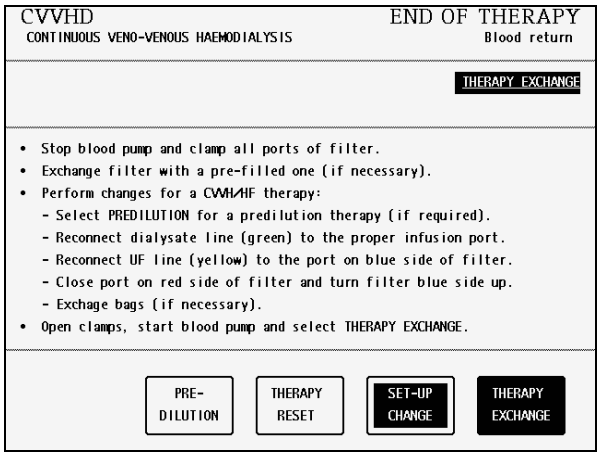


Therapy reset

The function allows to reset the just finished therapy.

➢ Select <THERAPY RESET> and confirm by pressing the  key followed by the  key.

See also Section 6.4.3



Therapy exchange

- Select <SET-UP CHANGE> and confirm by pressing the  key and follow the instructions below.
- Follow the relevant procedure described below.

To change from CVVHD/CVVHFD to CVVH or HF

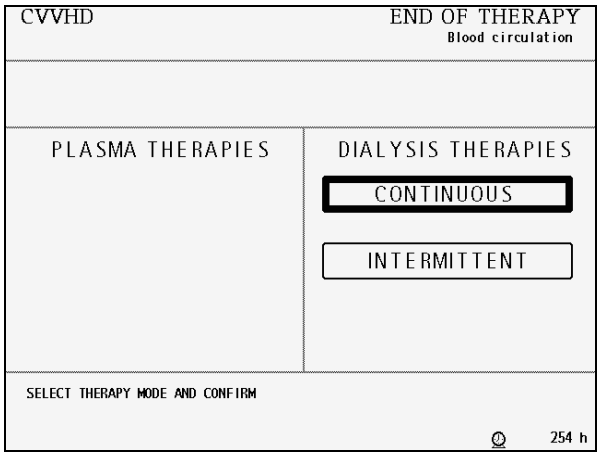
- Close the clamp of the dialysate inlet line (green) connected to the haemofilter.
- If required, select <PRE-DILUTION> with the  or the  key and activate with the  key.
- Unscrew the dialysate inlet line from the haemofilter, close the Hansen connector tightly and connect the dialysate inlet line to the venous air trap.
- Remove the dialysate outlet line (yellow) from the port next to the arterial port and connect it to the port next to the venous port of the haemofilter. Close the Hansen connector at the arterial port tightly.
- Close the port next to the arterial port with the Hansen connector.
- Turn the filter upside down.
- Open the clamp of the dialysate inlet line and the clamp of the line of the venous air trap where the dialysate inlet line is connected.

The set-up does not have to be changed to change from CVVHD/CVVHFD to HD/HFD.

- Select <THERAPY EXCHANGE> and confirm by pressing the  key. The 

key lights up.
- Confirm by pressing the 

key.



➢ Select <CONTINUOUS> or <INTERMITTENT> therapy mode using the  or  keys and confirm by pressing the  key.

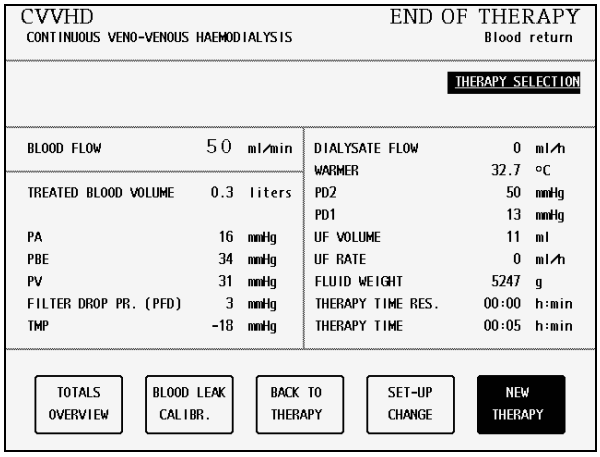
In the following screen the modality can be selected. The chosen therapy starts with the confirmation of the safety-relevant treatment parameters.

For further information see the Section of the therapy you have chosen.

The treatment data of the previous therapy will be retained.

Changing the haemofilter

see Section 13.5



New therapy

The option <NEW THERAPY> allows to start a new therapy immediately after the one just finished. The device switches directly to therapy selection.

➢ Select <NEW THERAPY> and confirm by pressing the  key. The  key lights up.

➢ Confirm by pressing the  key.

DANGER

Risk of blood loss and infection for the patient

➢ To guarantee the safe therapy for the patient, the consumables (line system, filter, solutions) used in the just finished therapy must be completely replaced.

6.6 Special functions

Bag movement function

To avoid superfluous alarms and the resulting pump standstill, the Diapact® CRRT has a function which is actuated by slight movements of the machine during therapy.

When this function is actuated, the ultrafiltration and the dialysate pumps stop without an alarm and start again automatically when the initial weight (i.e. the weight before the movement of the machine or bag) is reached again.

Automatic temporary reduction of the blood flow

If PA min is reached, blood flow automatically drops to 25% (but not lower than 60 ml/min) to prevent standstill of the blood pump caused by movement of the patient. The ultrafiltration and the dialysate pumps stop also for a short time without an alarm.

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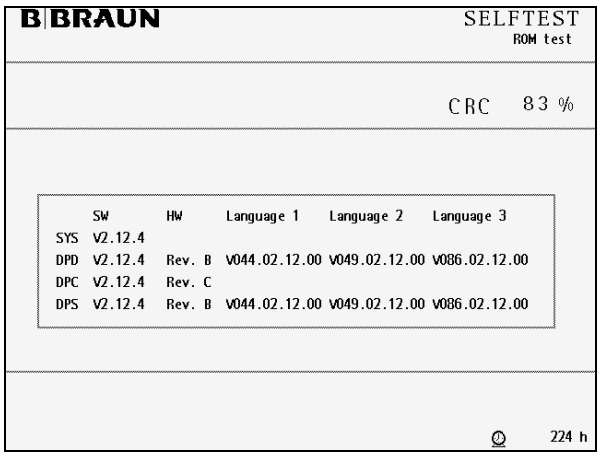
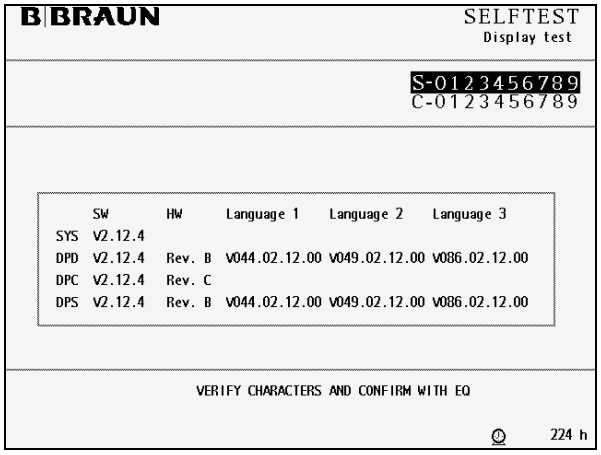
7 HF (Haemofiltration)

7.1 Switching on and initial tests

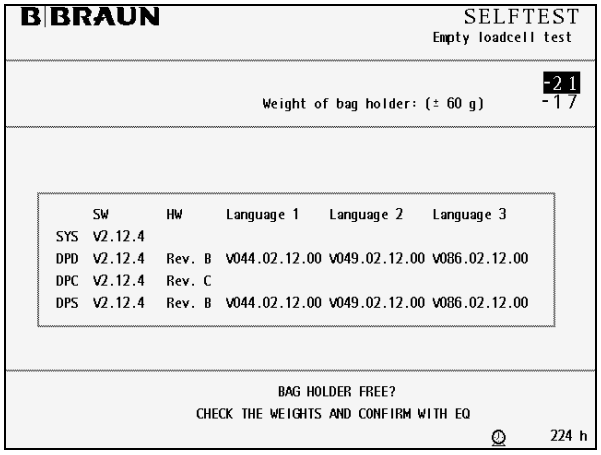


- Switch on the Diapact® CRRT with the power switch ON/OFF (I/O) on the back of the machine. The device starts with the ROM test.
- Check whether the AQ and EQ keys are lit during the ROM test.



The ROM test is followed by the display test.

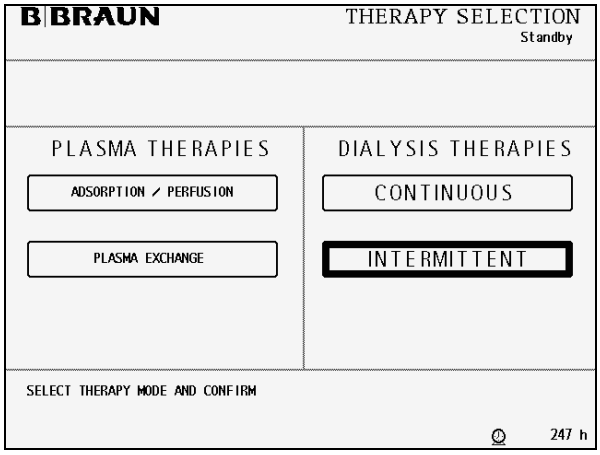
- Compare the character lines in the supervisor field and confirm by pressing the EQ key if both series are identical.
- While the EQ key is being pressed, the buzzer of the safety system is activated for 2 seconds.
- Check that the buzzer can be heard.



If the display test is passed successfully, the empty load cell test follows.

- Check whether the bag holder is empty.
- Confirm the weight values with the EQ key if they are within the allowed range. The maximum deviation between both displayed values is allowed to be ± 60 g and the values must not exceed -60 and +60 g.

7.2 Therapy selection



Having successfully passed the initial self tests, the machine switches to the <THERAPY SELECTION> screen to select the therapy mode.

<CONTINUOUS> dialysis therapies is selected by default.

- To select <INTERMITTENT> dialysis therapies, move to the respective position with the  and  keys.
- Confirm the selection with the  key.

The following screen displays the possible therapy options. <HAEMOFILTRATION> is selected by default.

- Confirm <HAEMOFILTRATION> by pressing the  key.

  The  key lights up and HF flashes in the supervisor field

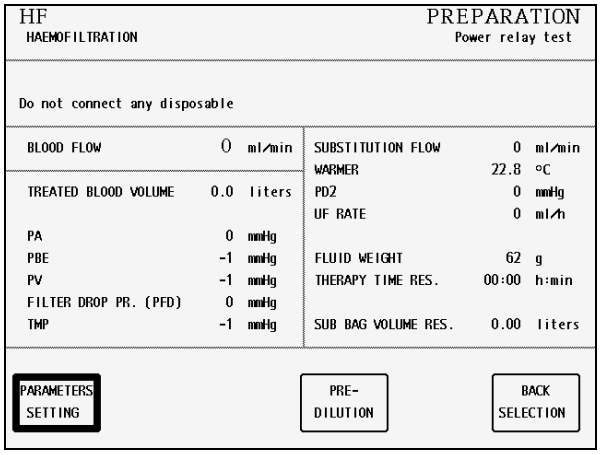
- Press the  key to confirm the selected therapy modality.

  If the selection is not confirmed with the  key, the device returns automatically to the <THERAPY SELECTION> screen where the therapy mode can be selected.

Back selection

Moving with the  or  keys to <BACK SELECTION> and confirmation with  allows to return to the screen where the therapy mode can be selected.

7.3 Preparation

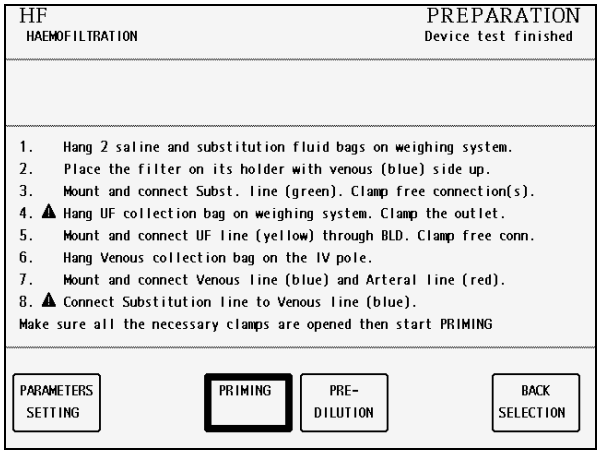


After modality selection and confirmation, the display shows the following <PREPARATION> screen.

Several tests are performed. The respective test is displayed in the therapy status field:

- Power relay test
- SAD reference test
- SAD counter test
- Red detector test
- Blood leak detector test
- Zero pressure test

7.3.1 Installation of consumable material



When the tests have been performed successfully, the <PREPARATION> screen displays <Device test finished> and the steps to set-up the machine are displayed.

The consumable material for the therapy comprises:

- HF/HD kit
- Haemofilter
- 2L isotonic sodium chloride solution
- Haemofiltration solution

➢ Follow the instructions on the screen and set-up the device as described in the following.

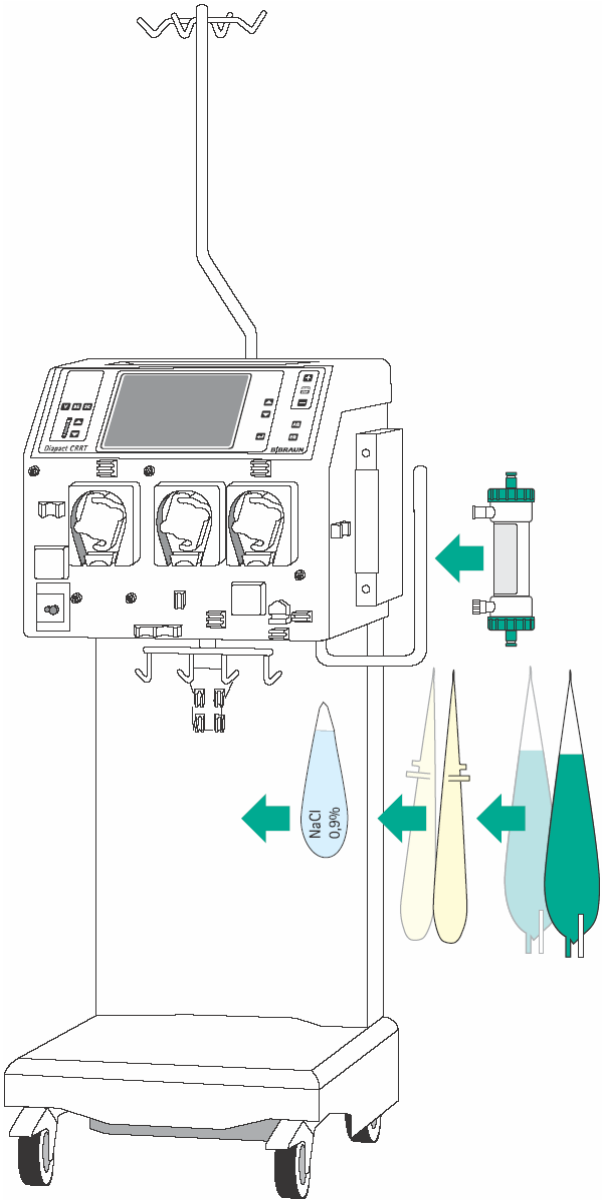
The lines of the HF/HD kit are colour-coded to facilitate the set-up.
Arterial line (**red**)
Venous line (**blue**)
Ultrafiltration line (**yellow**)
Substitution line (**green**)

Pumps used:
Blood pump (MP1)
Ultrafiltration pump (MP2)
Substitution pump (MP3)

WARNING

Risk of infection and blood loss for the patient by damaged packaging or components

➢ **Make sure during set-up that the packaging of the material used (line system, haemofilter, solution bags) is undamaged.**
➢ **During set-up check the material for integrity.**
➢ **Observe the respective instructions for use.**



Installation of bags and haemofilter

- Attach the collecting bags of the HF/HD kit, the 2L bag with isotonic sodium chloride solution and the bags with the haemofiltration solution on the bag holder of the load cell.
- Fix the haemofilter into the filter holder on the right side of the machine.
- Close the clamps of the collecting bags at the tubes equipped with plugs.

CAUTION

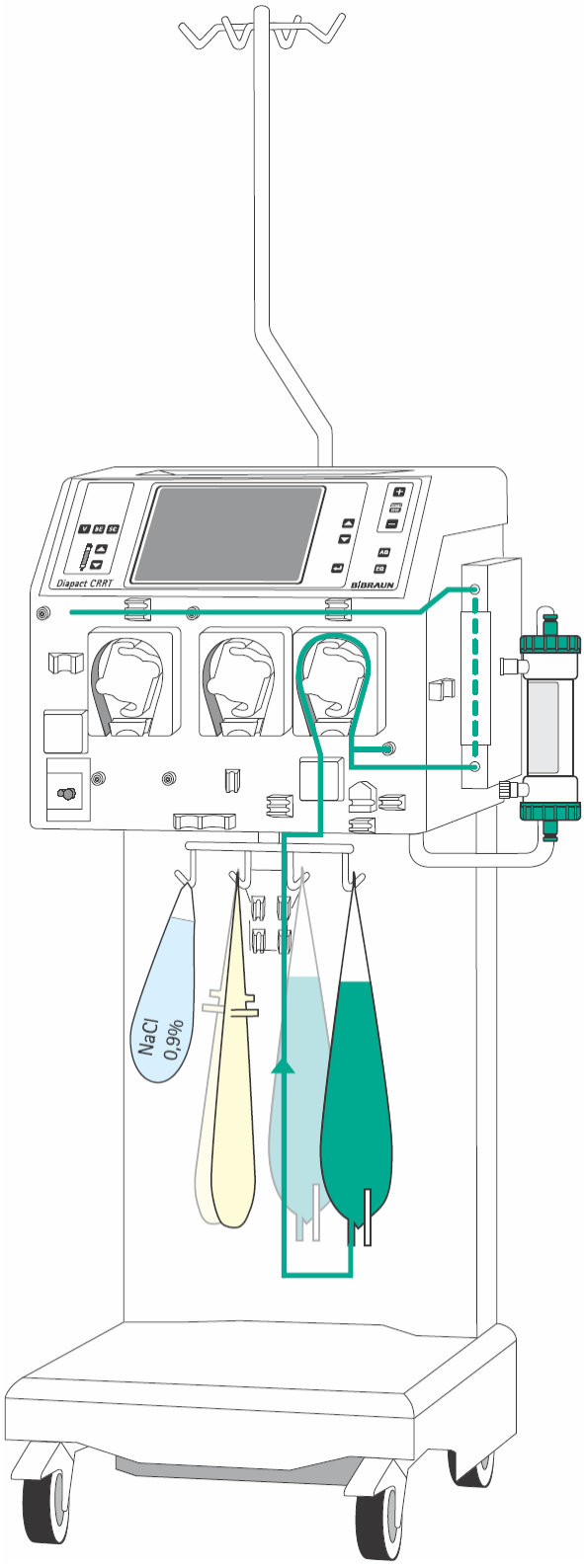
Incomplete moistening of the haemofilter during priming and rinsing may result in performance reduction.

- **Place the haemofilter into the filter holder with the arterial port (red) downwards.**

If the weight on the load cell is unevenly distributed, there is a risk that the device may topple.

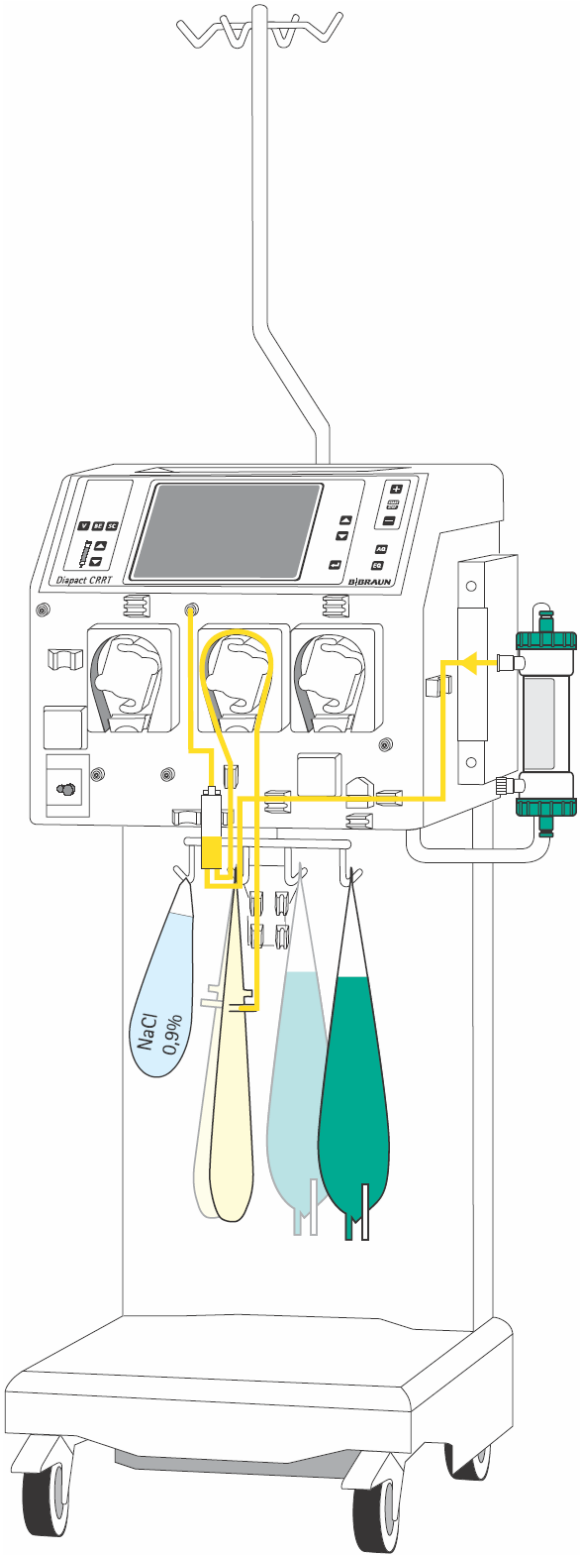
- **Distribute weight on the bag holder evenly.**

The maximal load of the load cell is 27 kg



Insertion of the substitution line (green)

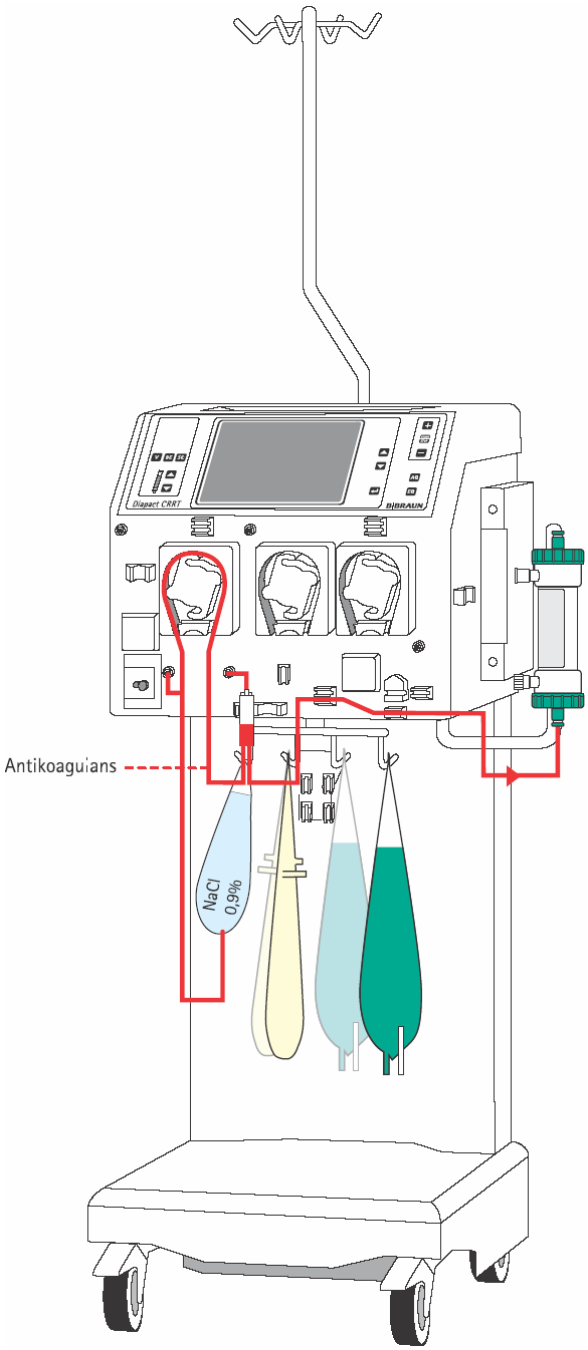
- Insert the heater bag into the plate heater and close the cover. To ensure that the bag has optimal contact to the heater, close the cover audibly.
- Insert the pump segment into the substitution pump (MP3).
- Insert the line leading from the connection of the bags with the haemofiltration solution to the pump segment into the air detector beneath the substitution pump (MP3).
- Connect the transducer protector to the pressure sensor PD1 (white).
- Connect the line leading from the air detector to the bags with the haemofiltration solution to the bags and fix the line into the line fixing of the bag holder of the load cell.
- Insert the line leaving the heater at the top in the line fixing above the pumps.



Insertion of the ultrafiltration line (yellow)

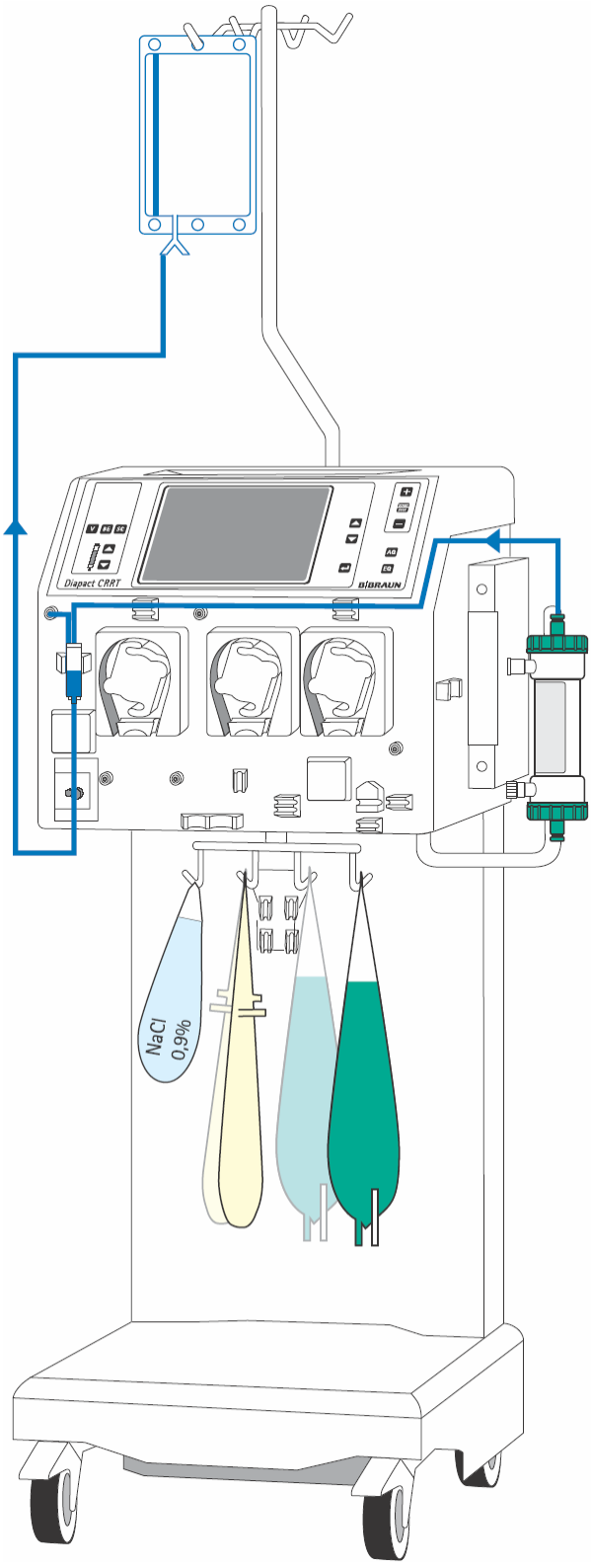
- Connect the end of the line with the Hansen connector to the upper filtrate outlet of the haemofilter.
- Insert the line coming from the haemofilter into the blood leak detector (BLD).
- Insert the pump segment into the ultrafiltration pump (MP2).
- Insert the air trap into the intended holder.
- Connect the transducer protector to the pressure sensor PSC/PD2 (white).
- Connect the Luer Lock connectors to the collecting bags and fix the line into the line fixing of the bag holder of the load cell.

Ensure that the second filtrate-side connector, which is not used, is securely closed. It is recommended to use the Hansen connector attached to the substitution line.



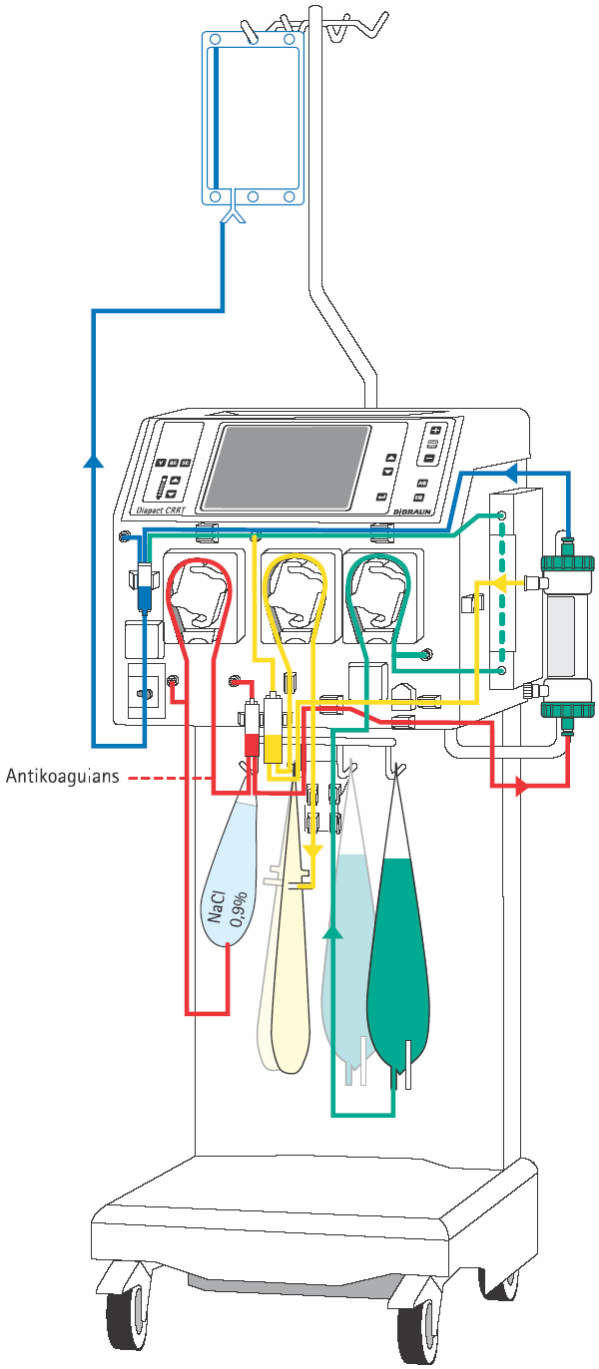
Insertion of the arterial line (red)

- Connect the end of the line with the spike/Luer Lock connector to the bag with isotonic sodium chloride solution on the bag holder of the load cell.
- Insert the pump segment into the blood pump (MP1).
- Connect the transducer protector before the blood pump to the pressure sensor PA (red).
- Insert the arterial air trap into the intended holder.
- Connect the transducer protector to the pressure sensor PBE (red).
- Connect the red Luer Lock connector to the lower blood-side connector of the haemofilter.
- If continuous heparinisation is required, connect the heparin line to the external heparin pump previously filled with heparin.
- Close the clamp of the heparin line if it is not used.
- Close the clamps at the sampling ports before and after the blood pump (MP1).



Insertion of the venous line (blue)

- Attach the rinsing bag to the infusion pole.
- Insert the venous air trap into the intended holder.
- Insert the venous line beneath the drip chamber into the safety air detector (SAD) and the safety air clamp (SAK) under the detector.
- Connect the transducer protector to the pressure sensor PV (blue).
- Connect the blue Luer Lock connector to the upper blood-side connector of the haemofilter.
- Connect the substitution line (green) to one of the Luer Lock connectors at the venous air trap and fix the line in the line fixing above the pumps.
- Close the clamp at the not used connection of the venous air trap.



Set-up overview

- ➢ Check the set-up before starting the priming procedure.
- ➢ Take care that all connections are firmly screwed together.
- ➢ Check that all pump segments are inserted clockwise.
- ➢ Check that the following clamps are closed:
  - Sampling ports before and after the blood pump
  - Heparin line if it is not used
  - Not used line at the venous chamber
  - Line with the plug at the collecting bag(s)
- ➢ Open the frangible pin of the sodium chloride solution bag and the bags with the haemofiltration solution.

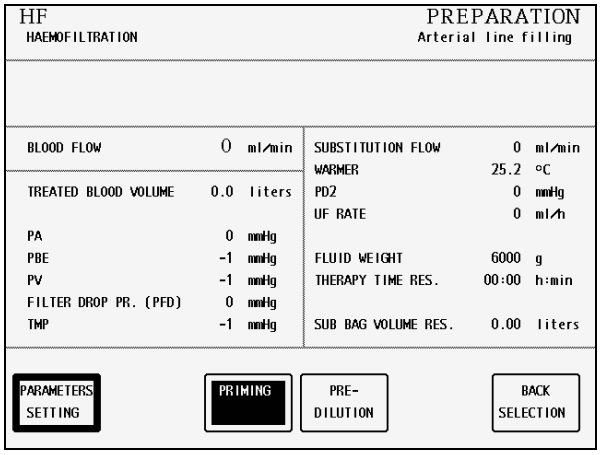
Installation of the preassembled HF/HD Kit

In the pre-assembled kit, the components of the HF/HD kit are mounted to a guide rail.

- ➢ Take hold of the guide rail of the kit with both hands and insert it into the respective holders on the machine (see also the respective instruction for use).
- ➢ Insert the pump segments clockwise.
- ➢ Connect all components as described above in this Section.

Make sure that all relevant clamps are opened and that all connections are firmly screwed together before starting the priming procedure.

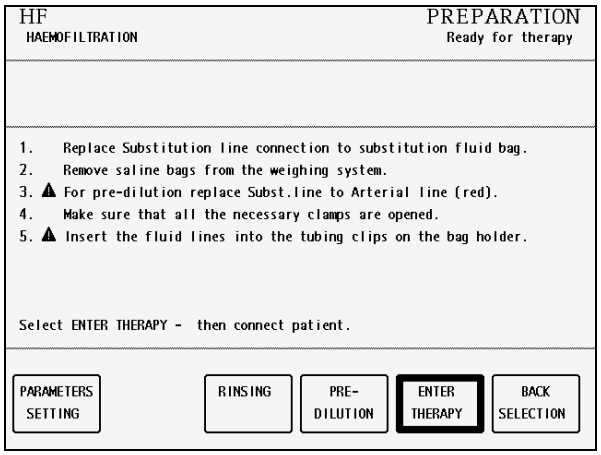
7.3.2 Priming



➢ After set-up of the consumables and checking the connections, select <PRIMING> and confirm by pressing the  key.

The automatic priming program starts. During the priming and rinsing the following tests are performed: load cell test, air detector test, substitution pump test (MP3), heater test, ultrafiltration pump test (MP2), disposable leakage test, level regulation test and the calibration of the pump constants takes place. The respective step of the procedures and the test is displayed in the therapy status field.

Do not move the Diapact® CRRT during calibration of the pump constants. Calibration will be repeated if it is disturbed.



After the preparation phase has been finished, the system gives an acoustic signal and shows the <PREPARATION> screen with message <Ready for therapy> in the therapy status field.

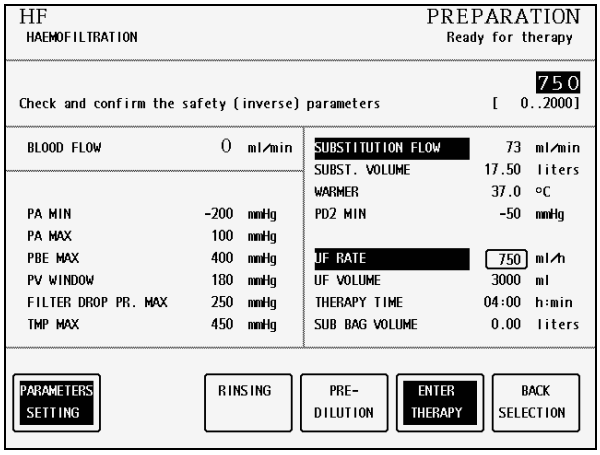
➢ Remove the bag with the sodium chloride solution from the load cell and attach it to the infusion pole.

➢ Make sure that all relevant clamps are open.

➢ Select <ENTER THERAPY> and confirm by pressing the  key.

The device switches automatically to <PARAMETERS SETTING>.

7.3.3 Parameter setting

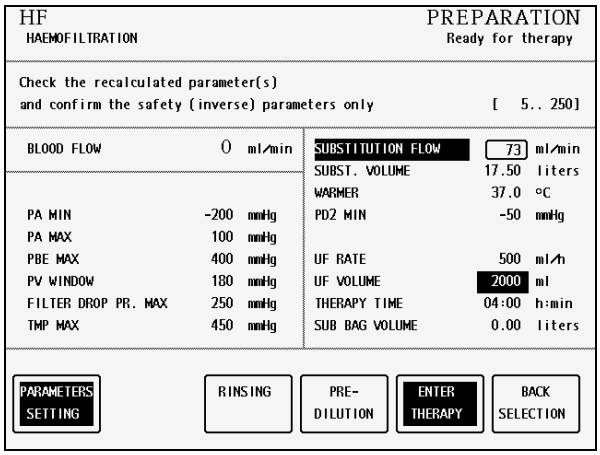


Setting safety-relevant parameters

The safety-relevant parameters (substitution flow and ultrafiltration rate in HF) are displayed on a black background.

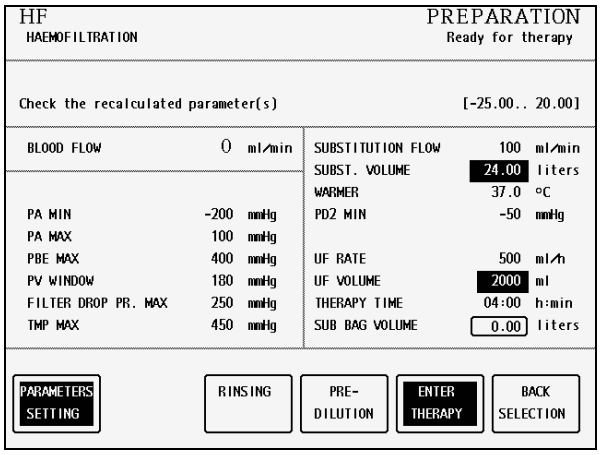
- Activate <UF rate> by pressing the  key.
  The value is inversely displayed on a black background
- If the value is accepted, confirm by pressing the  key.
- To change the value, press the  key to increase it or the  key to decrease it.
- Confirm with the  key.
  In both cases, the actual value is displayed in the supervisor field, flashing on a black background.
- Compare the value displayed in the supervisor field with that shown in the fluid-side parameters field and confirm with the  key if they are identical.
- Check and/or change the substitution flow in the same way.
- Any changes to safety-relevant parameters must always be confirmed with the  key.

If the safety-relevant data are not confirmed, whether they are changed or not, the system will not start the therapy.



If the ultrafiltration rate is changed, the ultrafiltration volume is changed accordingly in intermittent therapies. The same is true for substitution volume and substitution flow.

The values changed dependently are displayed inversely, but they do not have to be confirmed separately.



Setting treatment parameters

- Select the parameter to be set with the  or  key.
- Activate the parameter by pressing the  key.
- Change the value with the  or  key
  and confirm the change with the  key.
- To exit <PARAMETERS SETTING>, press the  key.

These treatment data can be set at any time during the preparation phase or the therapy if the <PARAMETERS SETTING> option is displayed.

The following data can be set in the indicated ranges:

Parameter	Unit	Default	Min	Max	Increments
Blood-side parameters					
Blood flow	ml/min	50	10/5	500	5/10
PA min.	mmHg	-200	-400	PA max.	10
PA max.	mmHg	100	PA min.	300	10
PBE max.	mmHg	400	0	650	10
PV window	mmHg	180	80	200	10
PFD max. pressure drop	mmHg	250	100	450	10
TMP max.	mmHg	450	100	600	10
Fluid-side parameters					
Substitution flow	ml/min	73	0*/5	250	1/10
Substitution volume	l	17.50	0.00	80.00	0.10/1.00
Temperature	°C	37	20	40	0.5/1.0
PD2 min.	mmHg	-50	-250	250	10
UF rate	ml/h	750	0*	2000	10/100
UF volume	ml	3000	0	10000	10/100
Substitution bag volume	l	0.00	-25.00	20.00	0.10/1.00
Therapy time	h:min	04:00	00:00	12:00	0:05/0:30

* The substitution flow can be set to zero if the UF rate is ≥ 300 ml/h. If the UF rate is below this limit, the adjustable lower limit for the substitution flow is (300 ml/h – UF rate)/60 ml/min.

In software versions 2.10 and 2.12 there is no lower limit for the substitution flow.

In HF, as an intermittent therapy, the change of the following variables automatically leads to a change in dependent variables.

Changed parameter	Dependently changed parameter*
Substitution flow	Substitution volume
Substitution volume	Substitution flow
UF rate	UF volume
UF volume	UF rate
Therapy time	Substitution flow UF rate

* Further parameter(s) can be changed if the dependently changed parameter is limited by the set range limit.

A change of the safety-relevant parameters (substitution flow, UF rate) must be confirmed with the EQ key. The other changed treatment parameters flash, but they do not have to be confirmed separately.

Setting the substitution/ultrafiltration volume or the therapy time to zero results in a switch from volume control to rate control. That means that zero substitution or ultrafiltration can be set only by setting the proper rate to zero.

Bag change volume

The haemofiltration solution volume or the ultrafiltration volume at which the bags with the haemofiltration solution or the collecting bag at the load cell have to be changed can be defined. The default value is 0.

If 0 is selected, the machine gives an alarm when the haemofiltration solution is empty, as detected by the air detector underneath the ultrafiltration pump (MP3.)

- Select <SUB BAG VOLUME> in <PARAMETERS SETTING> and confirm with the  key.
- Set the <SUB bag volume> to a **positive value** (e.g. + 4.8L).

When the volume of the **haemofiltration solution bags** is spent during therapy, the alarm <bag volume is over (1020)> occurs

- Follow the instructions on the screen and exchange the bag(s) with the haemofiltration solution.
- Set the <SUB bag volume> to a **negative value** (e.g. – 6L).

Selecting a negative <SUB bag volume> changes the display to <UF bag volume>

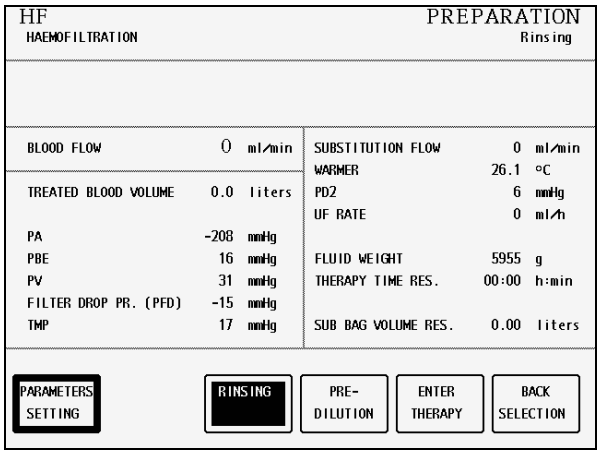
When the volume of the **ultrafiltration collecting bags** is reached during therapy the alarm <bag volume is over (1020)> occurs

- Follow the instructions on the screen and exchange the collecting bag.

To switch between <SUB bag volume> and <UF bag volume>, it is necessary to set the parameter first to 0.

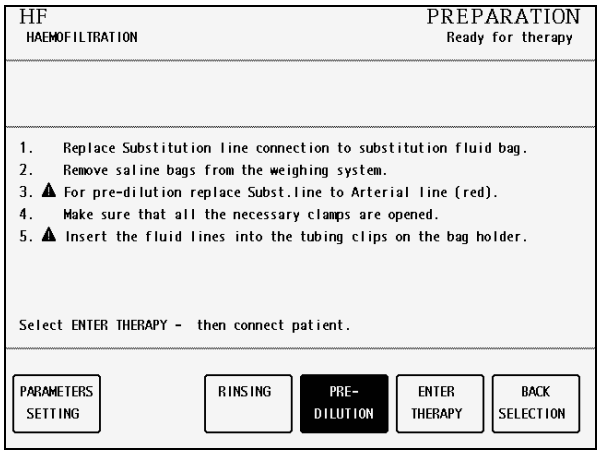
- Select <DIA bag volume> and <UF bag volume> and confirm with the  key.
- Set the parameter to 0 and confirm with the  key.
- Select <SUB bag volume> again and confirm with the  key.
- Increase or decrease the value and confirm with the  key.

7.3.4 Menu selection in preparation



Rinsing

- If necessary, rinsing can be prolonged by selecting <RINSING> and confirming with the  key.
- If only the blood side has to be rinsed, the fluid side can be stopped by opening the cover of the ultrafiltration pump (MP2).
- To finish the additional rinsing, select <RINSING> again and confirm with the  key.



Pre-dilution

- To activate the pre-dilution mode, select the option and confirm with the  key.

  The option field remains black as long as the option is activated.
- Close the clamp at the line of the venous air trap where the substitution line is connected and the clamp of the substitution line.
- Unscrew the connection of the substitution line to the venous chamber.
- Screw the substitution line to the connection of the arterial line behind the blood pump.
- Open the clamp at the arterial line where the substitution line has been connected and the clamp of the substitution line.

See also Section 7.5.2

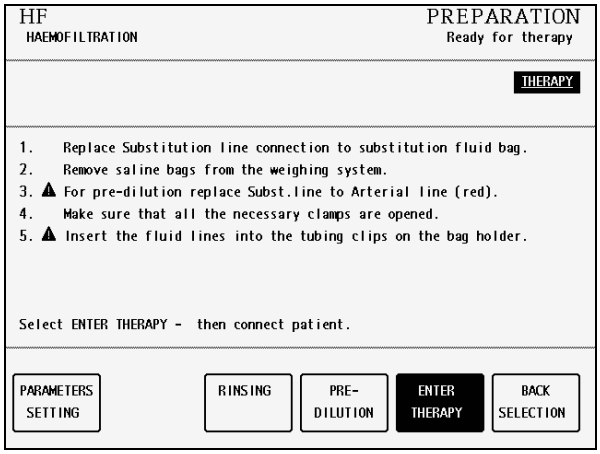
The pre-dilution mode can be selected in all screens where the option is shown. However, during the priming procedure the substitution line must be connected to the venous chamber, otherwise the device tests will not be passed. After the priming procedure has been finished, the substitution line can be connected with the arterial line as described above.

Back selection

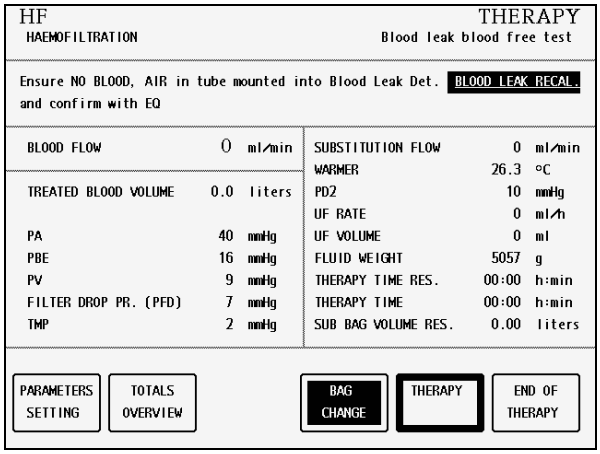
Choosing back selection allows to return to the <THERAPY SELECTION> screen.

- Select <BACK SELECTION> and confirm with the  key.

7.4 Therapy



- To switch from <PREPARATION> to <THERAPY>, select <ENTER THERAPY> and confirm by pressing the  key.
- Confirm the start of the therapy by pressing the flashing  key while <THERAPY> is flashing in the supervisor field.



The Diapact® CRRT is now in the therapy status as indicated in the therapy status field.

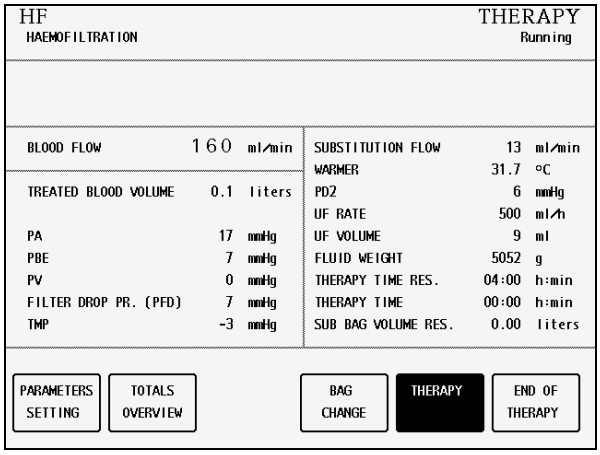
- Confirm the blood leak recalibration by pressing the  key.
- Start the blood pump for circulation by pressing the  key.

7.4.1 Connecting the patient

- Stop the blood pump.
- Connect the arterial line to the arterial access of the patient.
- Start the blood pump and adjust the flow rate using the  or  keys.
- Check that the withdrawal pressure (arterial pressure – PA) is within the prescribed range.
- When the blood starts to fill the venous line, stop the blood pump and connect the venous line to the venous access of the patient.
- Start the blood pump again and adjust the blood flow slowly dependent on the patient's condition.
- Check that the arterial and venous pressure values displayed on the screen are within the normal range.

During therapy, the arterial chamber should be about 50 % filled, the venous chamber about 80 %

7.4.2 Start of therapy



After the blood has been circulating for 2- 3 minutes without alarms, the therapy can be started.

➢ Select <THERAPY> and activate by pressing the  key.

<THERAPY> in the menu selection field is blackened and in the therapy status field <Running> is indicated.

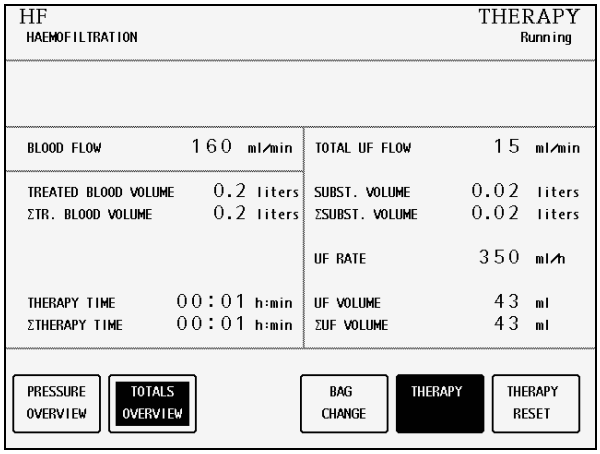
The treatment is now in progress and the parameter overview is displayed.

The current pressure and flow data of the blood side and the fluid side are displayed on the screen.

7.4.3 Menu selection in therapy

Parameter setting

See Section 7.3.3



Totals overview

➢ Select <TOTALS OVERVIEW> and confirm by pressing the  key.

➢ To return to the <PARAMETERS OVERVIEW> screen, select <TOTALS OVERVIEW> and then press the  key.

The <TOTAL OVERVIEWS> screen displays:

On the left (blood-side) part of the screen

- Current blood flow
- Treated blood volume of the current time segment
- Treated blood volume of the whole treatment (sum of all time segments)
- Therapy time of the current time segment
- Therapy time of the whole treatment (sum of all time segments)

On the right (fluid-side) part of the screen

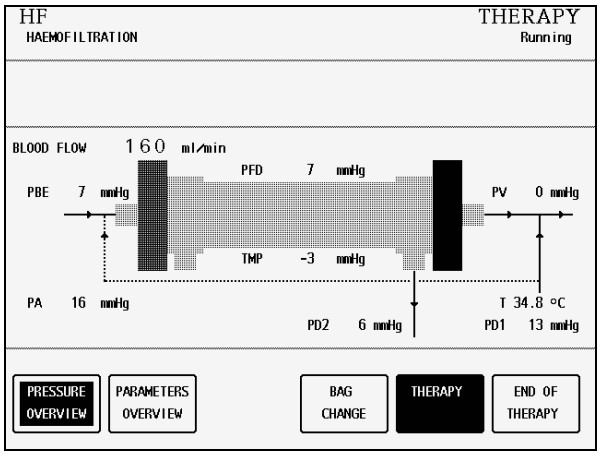
- Current ultrafiltration flow
- Substitution solution volume of the current time segment
- Substitution solution volume of the whole treatment (sum of all time segments)
- Current ultrafiltration rate
- Ultrafiltration volume of the current time segment
- Ultrafiltration volume of the whole treatment (sum of all time segments)

Therapy reset

<THERAPY RESET> allows to adjust the current values for treated blood volume, therapy time, substitution volume and ultrafiltration volume to zero. The following volumes and the time are added up from the values marked with Σ.

This allows to follow the data during a certain time segment of the treatment.

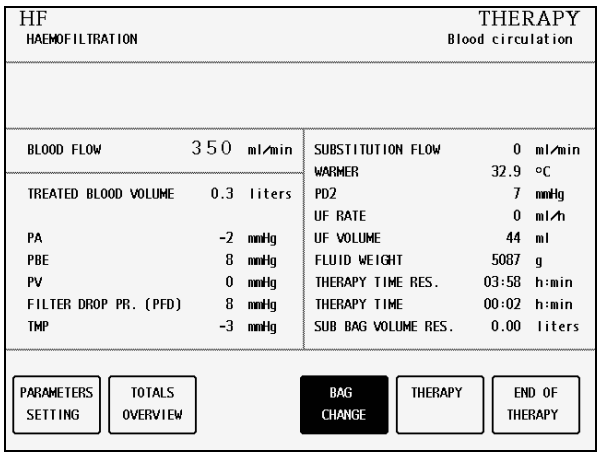
- Select <THERAPY RESET> and confirm by pressing the  key followed by the  key.



Pressure overview

<PRESSURE OVERVIEW> allows an overview of all pressures recorded in the system.

- Select <PRESSURE OVERVIEW> and confirm by pressing the  key.
- Select <PARAMETERS OVERVIEW> to return to the <PARAMETERS OVERVIEW> screen and confirm by pressing the  key.



Bag change

The <BAG CHANGE> option allows to change the fluid bags during a running therapy.

- Select <BAG CHANGE> and confirm by pressing the  key.

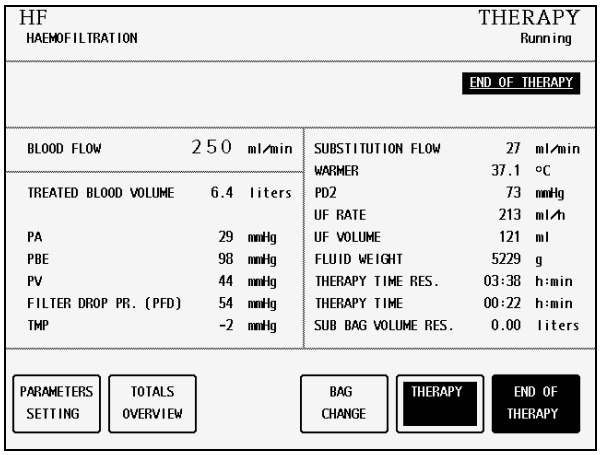
  The ultrafiltration pump (MP2) and the substitution pump (MP3) stop. The blood pump (MP1) keeps on running.
- Exchange the bag(s).
- Open the frangible pin if the bag(s) with the haemofiltration solution is exchanged.
- Close the line equipped with the plug if the collecting bag(s) is exchanged.
- After the bag exchange, deactivate <BAG CHANGE> by pressing the  key.

  The treatment continues automatically.

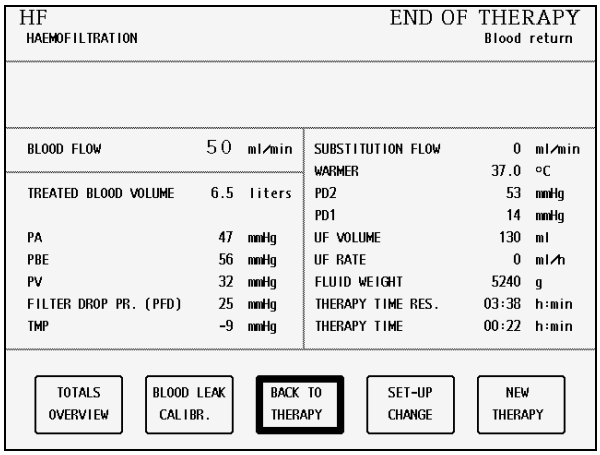
7.5 End of therapy

When the therapy time set is reached, the machine activates a warning (ready-for-therapy tone) and displays the warning message <Therapy is over> in the warning field. The balance pumps stop. Therapy can be continued by simply increasing the therapy time (directly, or indirectly by increasing substitution volume or UF volume). The warning sound is repeated in 4 minutes until <THERAPY> is deactivated.

The therapy is finished as described in the following.



- Select <END OF THERAPY> and confirm by pressing the  key.
- Confirm by pressing the  key.



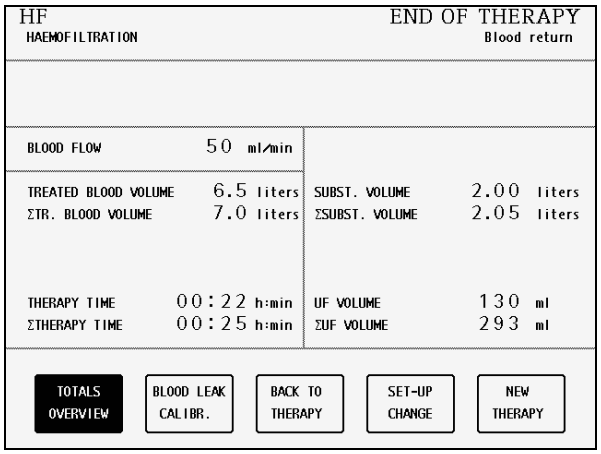
The ultrafiltration pump (MP2) and the substitution pump (MP3) stop. The blood pump (MP1) continues to run at reduced speed (50 ml/min).

7.5.1 Disconnecting the patient

- Stop the blood pump (MP1).
- Disconnect the arterial line from the patient's arterial access and connect it to a bag with isotonic saline solution.
- Start the blood pump and return the blood in the extracorporeal circuit to the patient.
- Stop the blood pump (MP1) just before the isotonic saline solution enters the patient.
- Disconnect the venous line from the patient's venous access.
- Remove disposable materials and solutions from the device.

Dispose of disposable materials and fluids which have been removed from the device in accordance with local regulations.
Therapy data are stored in the machine for 30 minutes. They can be recalled by switching on the Diapact® CRRT within this time frame.

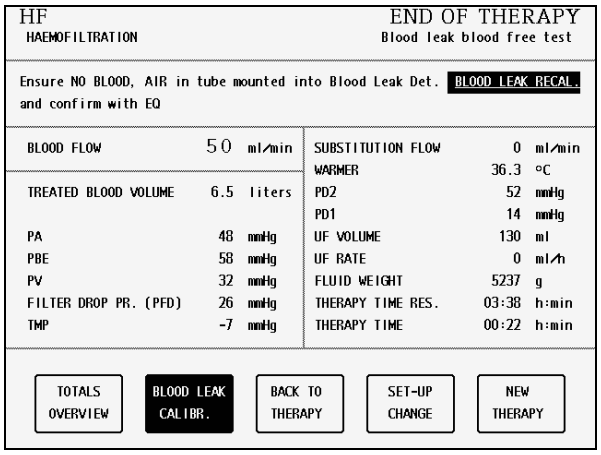
7.5.2 Menu selection at end of therapy



Totals overview

The option <TOTALS OVERVIEW> shows the summary of the pivotal treatment data as described (Section 7.4.3)

- Select <TOTALS OVERVIEW> and confirm by pressing the  key.
- To return to the <END OF THERAPY> screen, select <TOTALS OVERVIEW> and confirm with the  key.



Blood leak recalibration

The <BLOOD LEAK CALIBRATION> function allows the recalibration of the blood leak detector in case of non-acceptable alarms (e.g. elevated plasma bilirubin concentration)

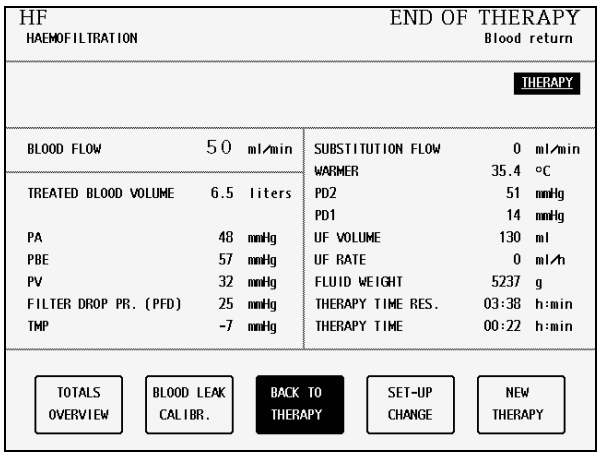
- Select “BLOOD LEAK CALIBRATION” and confirm with the key. The EQ key lights up.
- Confirm with the EQ key.
- Select <BACK TO THERAPY> and confirm with the key. The EQ key lights up.
- Confirm with the EQ key.
- Adapt the blood flow to the initial value.
- Start <THERAPY> by pressing the key.

DANGER

Risk of blood loss for the patient and haemolysis

- **Before the recalibration of the blood leak detector, the haemofilter must be carefully checked for possible blood leaks and haemolysis.**
- **It is recommended to withdraw a sample (at least 2 ml) from the injection port of the filtrate line and to analyze for erythrocytes and/or free haemoglobin.**
- **The blood leak recalibration must only be performed if these tests are negative.**

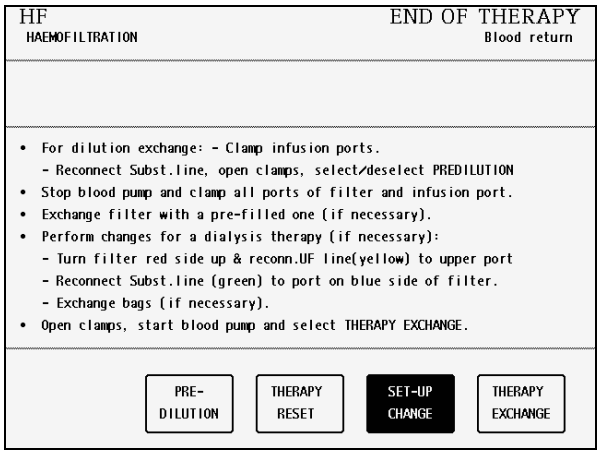
The balance pumps will not start up again until blood leak calibration has been completed.



Back to therapy

The option <BACK TO THERAPY> returns to the just finished therapy.

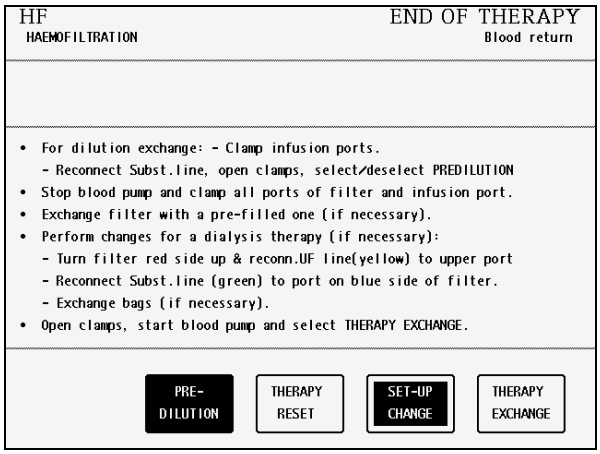
- Select <BACK TO THERAPY> and confirm by pressing the key. The EQ key lights up.
- Confirm by pressing the EQ key.
- Start the therapy again by pressing the key.



Set-up change

The function <SET-UP CHANGE> helps with a set-up instruction to:

- Change from post- to pre-dilution or vice versa during therapy (dilution change).
- Change from HF to CVVHD/CVVHDF, HD/HDF or CVVH during therapy (therapy change).
- Exchange the haemofilter.



Dilution change

➢ Select <SET-UP CHANGE> and confirm by pressing the  key.

➢ Stop the blood pump (MP1).

➢ Follow the relevant procedure described below.

<u>Change from post-dilution to pre-dilution</u>

➢ Close the clamp of the line at the venous chamber where the substitution line is connected.

➢ Close the clamp at the substitution line.

➢ Unscrew the substitution line.

➢ Screw the substitution line to the arterial line at the allowed line extension after the blood pump and open the clamp at this line extension.

➢ Open the clamp at the substitution line.

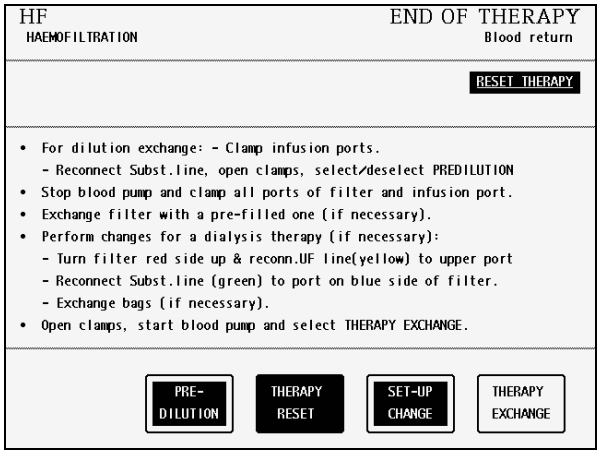
➢ Select <PRE-DILUTION> in the menu using the  or  keys.

➢ Activate <PRE-DILUTION> by pressing the  key.

➢ Select <SET-UP CHANGE> and confirm by pressing the  key and continue the therapy.

Change from pre-dilution to post-dilution

- Close the clamp of the arterial line extension where the substitution line is connected.
- Close the clamp at the substitution line.
- Unscrew the substitution line.
- Screw the substitution line to one of the free lines of the venous chamber and open the clamp at this line.
- Open the clamp at the substitution line.
- Select <PRE-DILUTION> in the menu using the  or  keys.
- Deactivate <PRE-DILUTION> by pressing the  key.
- Select <SET-UP CHANGE> and confirm by pressing the  key and continue the therapy.

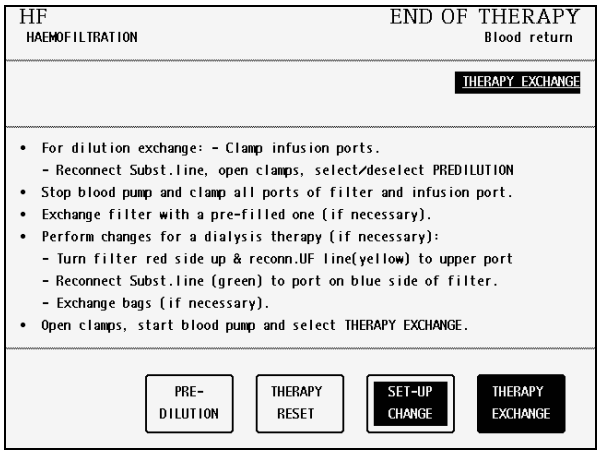


Therapy reset

The function allows to reset the just finished therapy.

- Select <THERAPY RESET> and confirm by pressing the  key followed by the  key.

See also Section 7.4.3



Therapy exchange

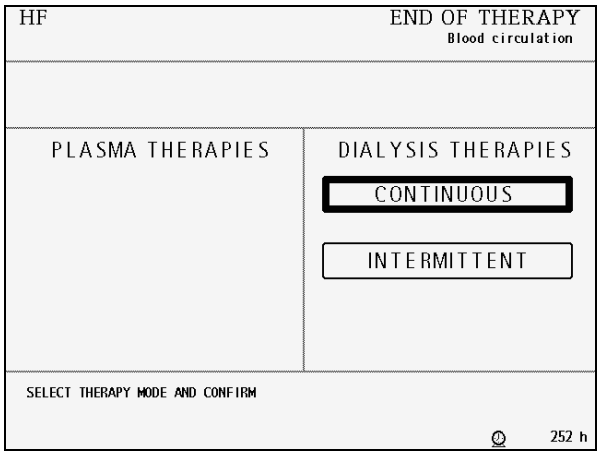
- Select <SET-UP CHANGE> and confirm by pressing the  key.
- Stop the blood pump (MP1).

To change from HF to CVVHD, CVVHFD, HD or HFD, close the clamp of the line at the venous air trap or the arterial line extension where the substitution line is connected.

- Close the clamp of the substitution line.
- Unscrew the substitution line from its connector, connect the second Hansen connector of the kit to the free filtrate-side port of the filter.
- Connect the ultrafiltration line (**yellow**) to the port next to the arterial port of the haemofilter.
- Connect the substitution line (**green**) to the port next to the venous port of the haemofilter.
- Turn the haemofilter upside down.
- Open the clamp of the substitution line.

To change from HD to CVVH, the set-up must not be changed unless it is combined with a dilution change (see above).

- Select <THERAPY EXCHANGE> and confirm by pressing the  key. The  key lights up
- Confirm by pressing the  key.



- Select <CONTINUOUS> or <INTERMITTENT> therapy mode using the  or  keys and confirm by pressing the  key.

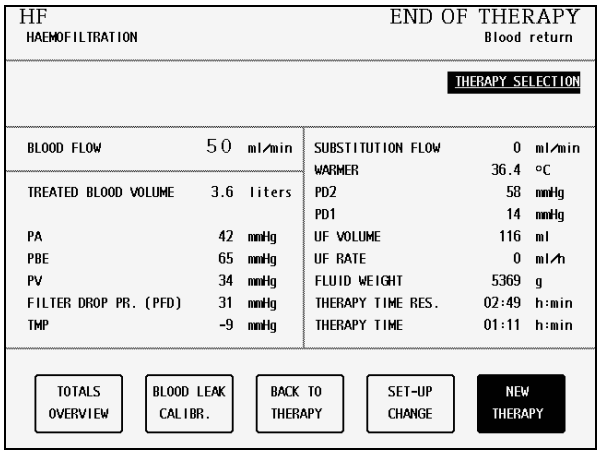
The modality can be selected in the following screen. The chosen therapy starts with the confirmation of the safety-relevant treatment data.

For further information see the Section of the therapy you have chosen.

The treatment data of the previous therapy will be retained.

Changing the haemofilter

see Section 13.5



New therapy

The option <NEW THERAPY> allows to start a new therapy immediately after the one just finished. The device switches directly to therapy selection.

- Select <NEW THERAPY> and confirm by pressing the key. The EQ key lights up.
- Confirm by pressing the EQ key.

DANGER

Risk of blood loss and infection for the patient

- **To guarantee the safe therapy for the patient, the consumables (line system, filter, solutions) used in the just finished therapy must be completely replaced.**

7.6 Special functions

Automatic substitution flow reduction

Automatic substitution flow reduction is an automatic parameter adaptation to the current filter state undertaken by the system.

If the ultrafiltration flow cannot be achieved, the following control mechanism is performed:

If PD2 pressure reaches a value 20 mmHg above the set PD2 min. value, the substitution flow will be automatically reduced as a function of the filter state.

It can result that the required substitution volume is not reached. To guarantee that the system does not fall below the required substitution volume, the flow is automatically increased slightly, if the reduction of the substitution flow is not necessary anymore.

Ramping

This function prevents the build-up of a secondary membrane on the membrane as a result of underpressure created by jerky pump starts.

The balance pumps starts at reduced speed at the start of therapy, after every stop of the blood pump or the balance pumps, and after certain parameter changes.

To guarantee that the system does not fall below the required substitution volume, the flow is automatically increased slightly during the therapy.

The raising of the flow, as well as the continuous raising of the flow, depends on the frequency of ramping.

Bag movement function

To avoid superfluous alarms and the resulting pump standstill, the Diapact® CRRT has a function which is actuated by slight movements of the machine during therapy.

When this function is actuated, the ultrafiltration and the dialysate pumps stop without an alarm and start again automatically when the initial weight (i.e. the weight before the movement of the machine or bag) is reached again.

Automatic temporary reduction of the blood flow

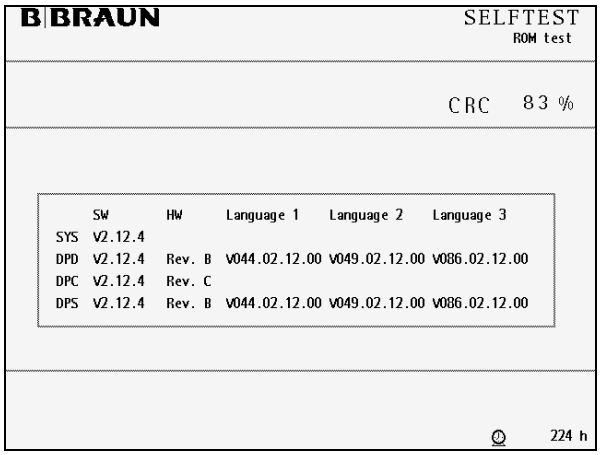
If PA min is reached, blood flow automatically drops to 25% (but not lower than 60 ml/min) to prevent standstill of the blood pump caused by movement of the patient. The ultrafiltration and the dialysate pumps stop also for a short time without an alarm.

Table of contents

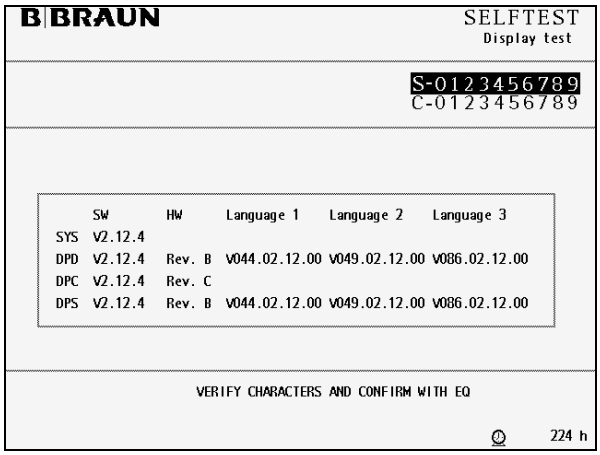
8 HD (Haemodialysis) HFD (High-flux dialysis)

Since the installation of the tube systems and the follow-up and content are the same for HD and HFD, these two modalities are described together in this Section.

8.1 Switching on and initial tests

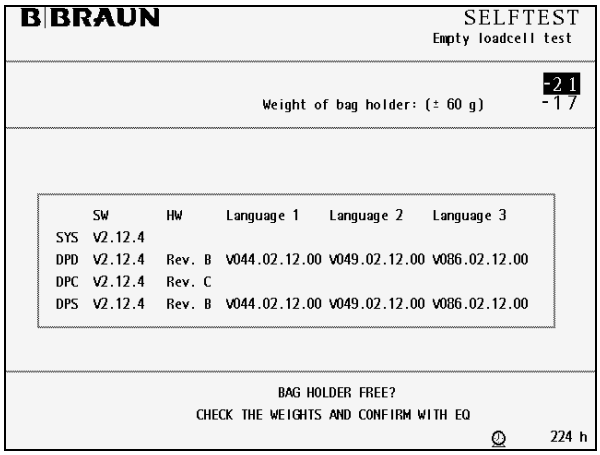


- Switch on the Diapact® CRRT with the power switch ON/OFF (I/O) on the back of the machine. The device starts with the ROM test.
- Check whether the AQ and EQ keys are lit during the ROM test.



The ROM test is followed by the display test.

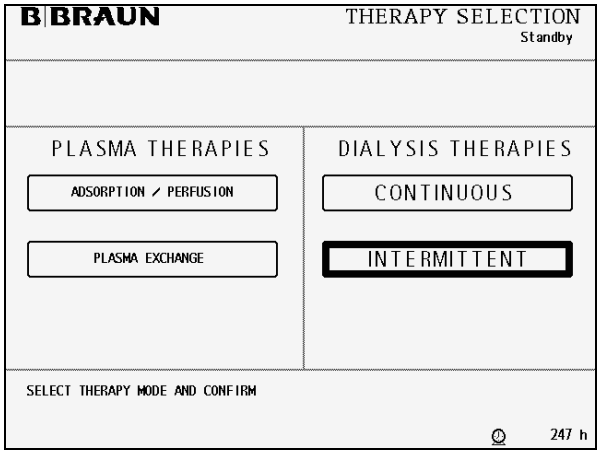
- Compare the character lines in the supervisor field and confirm by pressing the EQ key if both series are identical.
- While the EQ key is being pressed, the buzzer of the safety system is activated for 2 seconds.
- Check that the buzzer can be heard.



If the display test is passed successfully, the empty load cell test follows.

- Check whether the bag holder is empty.
- Confirm the weight values with the EQ key if they are within the allowed range. The maximum deviation between both displayed values is allowed to be ± 60 g and the values must not exceed -60 and +60 g.

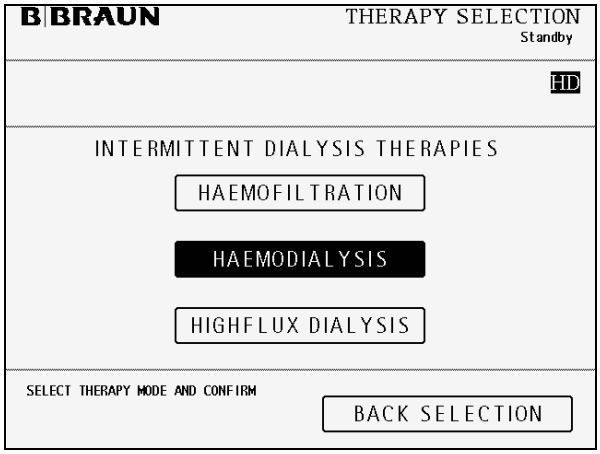
8.2 Therapy selection



Having successfully passed the initial self tests, the machine switches to the <THERAPY SELECTION> screen to select the therapy mode.

<CONTINUOUS> dialysis therapies is selected by default.

- To select <INTERMITTENT> dialysis therapies, move to the respective position with the  and  keys.
- Confirm the selection with the  key.



The following screen displays the possible therapy options. <HAEMOFILTRATION> is selected by default.

- Select <HAEMODIALYSIS> or <HIGHFLUX DIALYSIS> with the  or the  key.
- Confirm the selection with the  key.

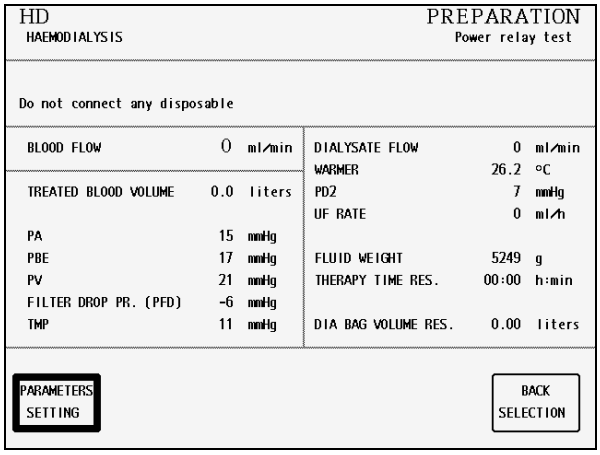
  The  key lights up and HF flashes in the supervisor field.
- Press the  key to confirm the selected therapy modality.

  If the selection is not confirmed with the  key, the device returns automatically to the <THERAPY SELECTION> screen where the therapy mode can be selected.

Back selection

Moving with the  or  keys to <BACK SELECTION> and confirmation with  allows to return to the screen where the therapy mode can be selected.

8.3 Preparation

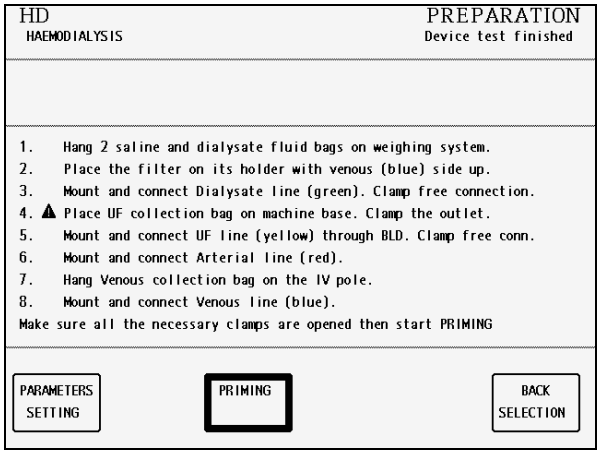


After modality selection and confirmation, the display shows the following <PREPARATION> screen.

Several tests are performed. The respective test is displayed in the therapy status field:

- Power relay test
- SAD reference test
- SAD counter test
- Red detector test
- Blood leak detector test
- Zero pressure test

8.3.1 Installation of consumable material



When the tests have been performed successfully the <PREPARATION> screen displays <Device test finished> and the steps to set-up the machine are displayed.

The consumable material for the therapy comprises:

- HF/HD kit
- Haemofilter (low-flux filter for HD)
- 2L isotonic sodium chloride solution
- Haemofiltration solution

➢ Follow the instructions on the screen and set-up the device as described in the following.

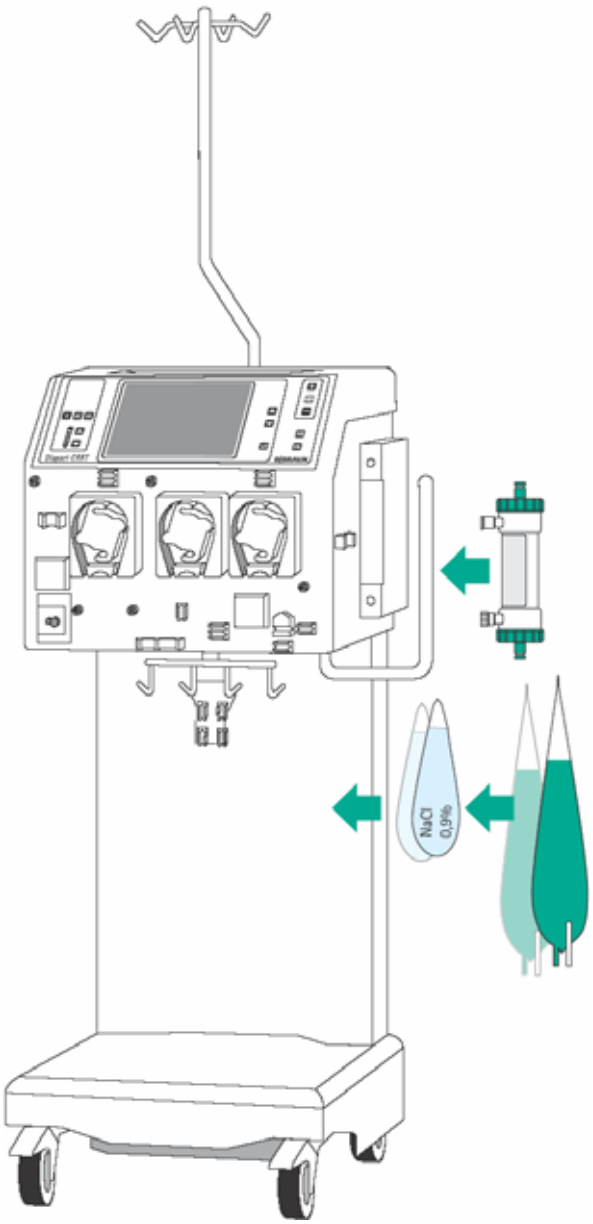
The lines of the HF/HD kit are colour-coded to facilitate the set-up.
Arterial line (**red**)
Venous line (**blue**)
Ultrafiltration line / dialysate outlet line in CVVHD/CVVHFD (**yellow**)
Substitution line / dialysate inlet line in CVVHD/CVVHFD (**green**)

Pumps used:
Blood pump (MP1)
Ultrafiltration pump (MP2)
Substitution pump (MP3) / Dialysate pump in CVVHD/CVVHFD

WARNING

Risk of infection and blood loss for the patient by damaged packaging or components

- ➢ **Make sure during set-up that the packaging of the material used (line system, haemofilter, solution bags) is undamaged.**
- ➢ **During set-up check the material for integrity.**
- ➢ **Observe the respective instructions for use.**



Installation of bags and haemofilter

- Attach the 2L bag with isotonic sodium chloride solution and the bags with the haemofiltration solution on the bag holder of the load cell.
- Fix the haemofilter (low-flux filter for HD) into the filter holder on the right side of the machine.
- Close the clamps of the collecting bags at the tubes equipped with plugs.

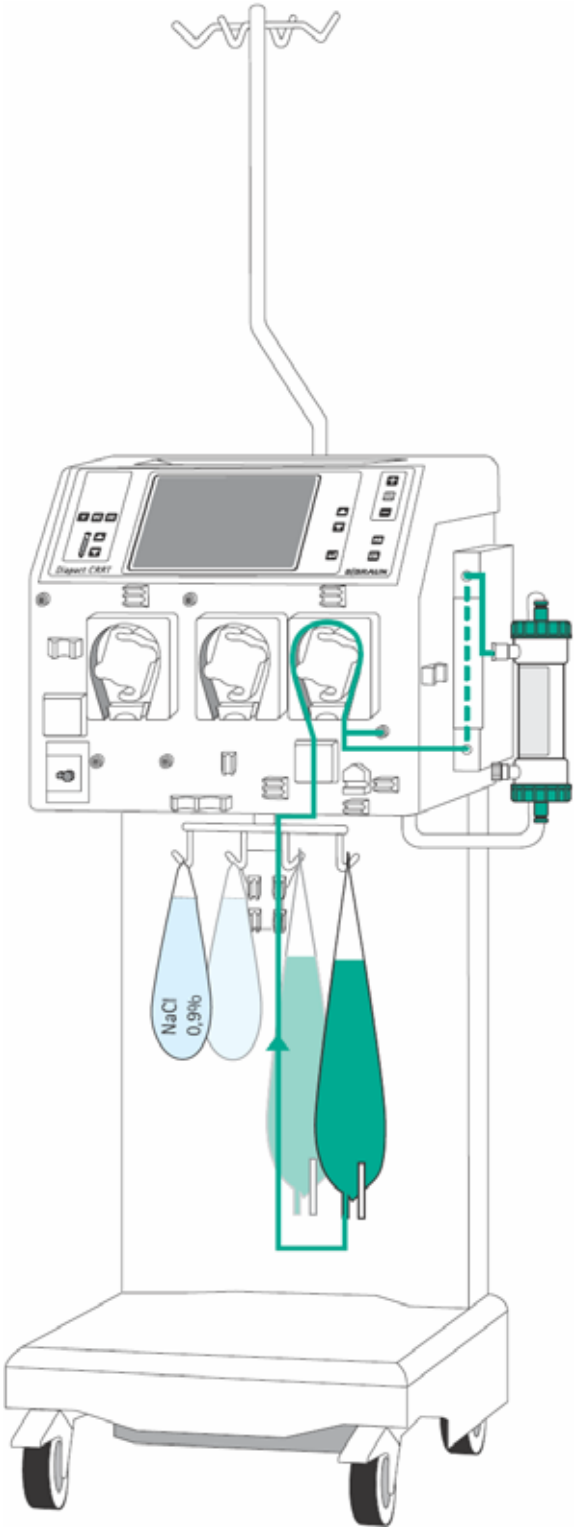
CAUTION

Incomplete moistening of the haemofilter during priming and rinsing may result in performance reduction.

- **Place the haemofilter into the filter holder with the arterial port (red) downwards.**

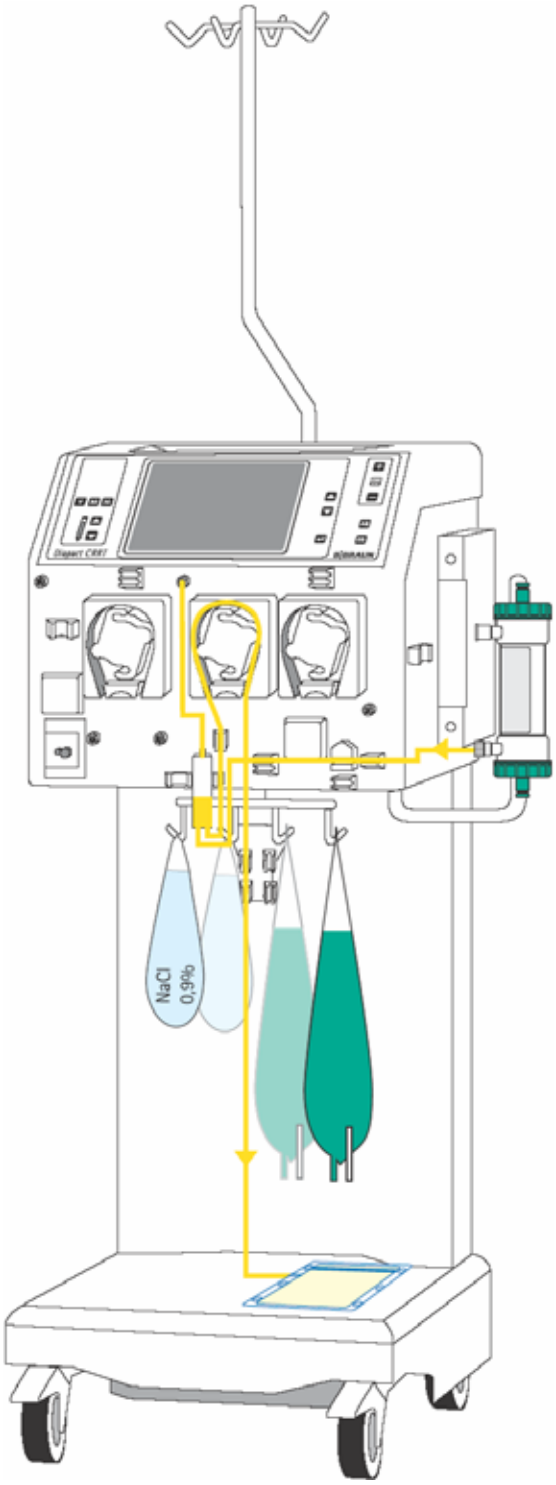
If the weight on the load cell is unevenly distributed, there is a risk that the device may topple.

- **Distribute weight on the bag holder evenly.**



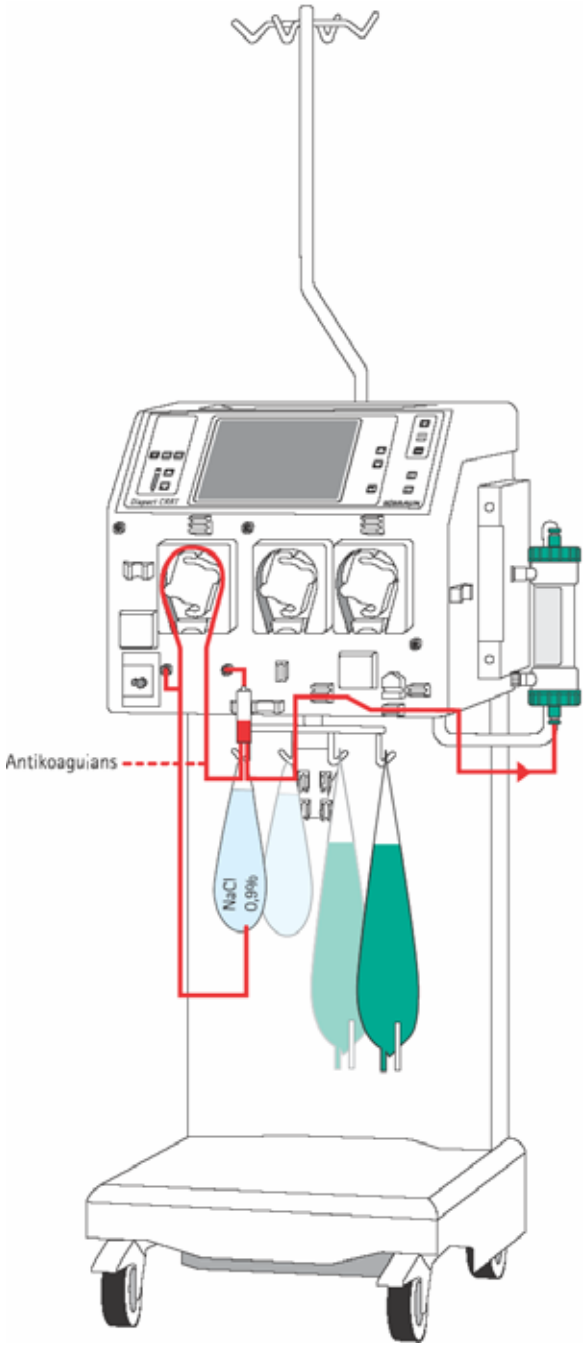
Insertion of the dialysate inlet line (green)

- Insert the heater bag into the plate heater and close the cover. To ensure that the bag has optimal contact to the heater, close the cover audibly.
- Insert the pump segment into the dialysate pump (MP3).
- Insert the line leading from the connection of the bags with the haemofiltration solution to the pump segment into the air detector beneath the dialysate pump (MP3).
- Connect the transducer protector to the pressure sensor PD1 (white).
- Connect the line leading from the air detector to the bags with the haemofiltration solution to the bags and fix the line into the line fixing of the bag holder of the load cell.
- Connect the dialysate inlet line to the dialysate side of the haemofilter beside the venous connector.



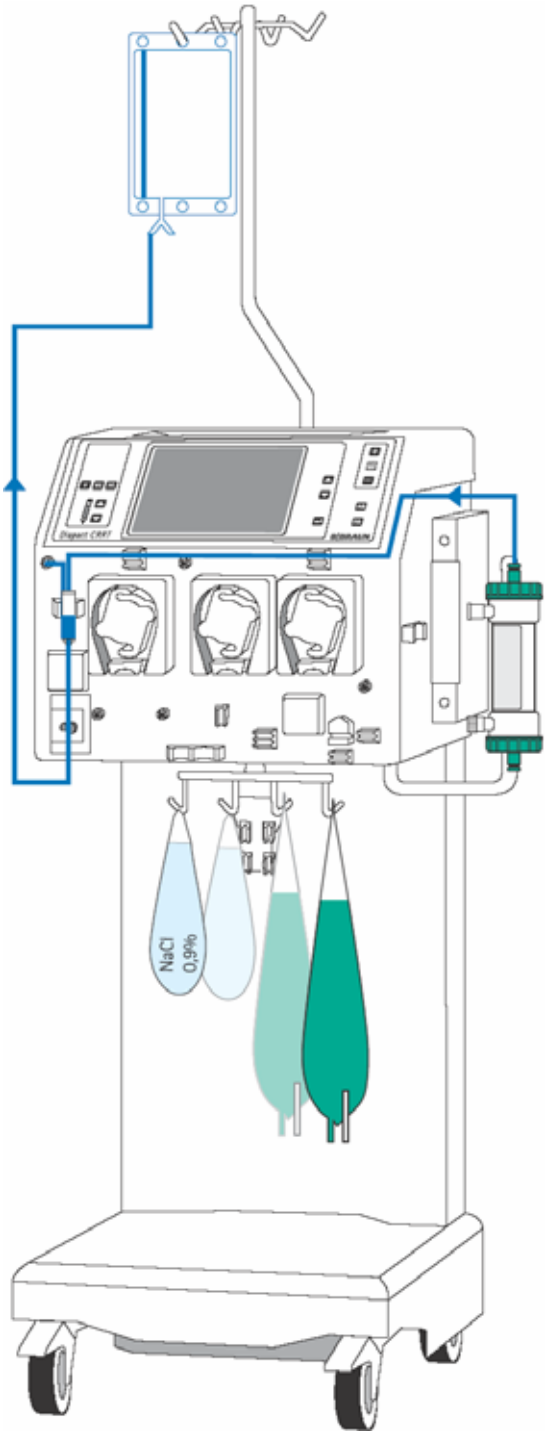
Insertion of the dialysate outlet line (yellow)

- Connect the ultrafiltration line to the dialysate side of the haemofilter next to the arterial connector.
- Insert the line coming from the haemofilter into the blood leak detector (BLD).
- Insert the pump segment into the ultrafiltration pump (MP2).
- Insert the air trap into the intended holder.
- Connect the transducer protector to the pressure sensor PSC/PD2 (white).
- Connect the Luer Lock connectors to the collecting bags and place the collecting bag on the socket of the device.



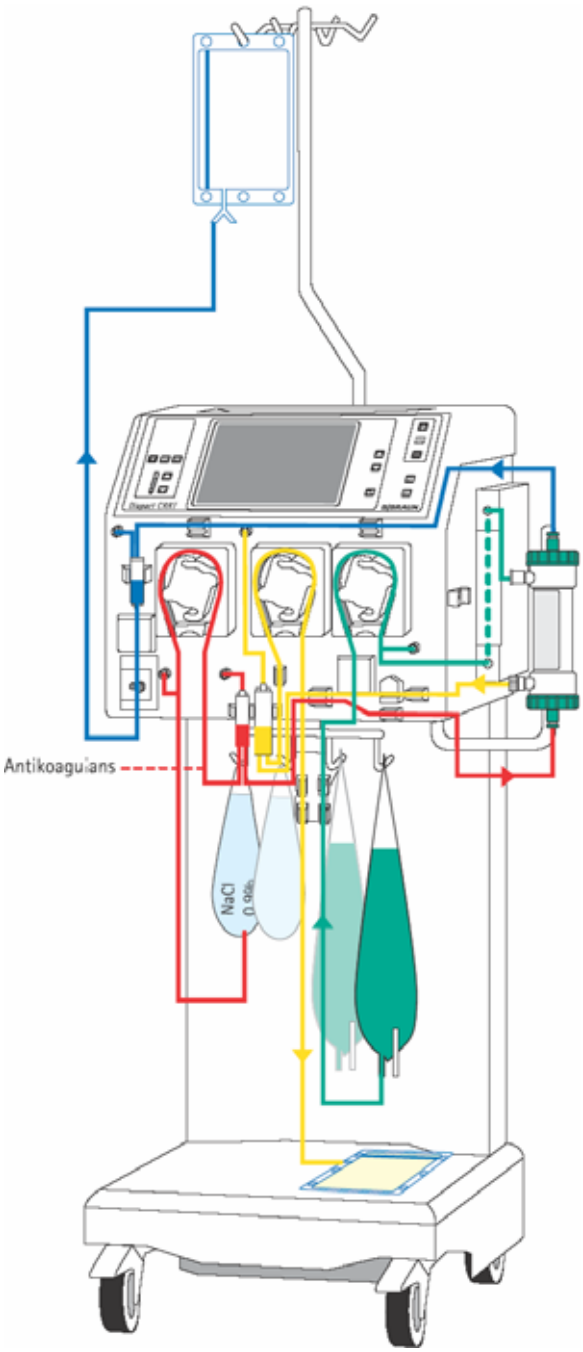
Insertion of the arterial line (red)

- Connect the end of the line with the spike/Luer Lock connector to the bag with isotonic sodium chloride solution on the bag holder of the load cell.
- Insert the pump segment into the blood pump (MP1).
- Connect the transducer protector before the blood pump to the pressure sensor PA (red).
- Insert the arterial air trap into the intended holder.
- Connect the transducer protector to the pressure sensor PBE (red).
- Connect the red Luer Lock connector to the lower blood-side connector of the haemofilter.
- If continuous heparinisation is required, connect the heparin line to the external heparin pump previously filled with heparin.
- Close the clamp of the heparin line if it is not used.
- Close the clamps at the sampling ports before and after the blood pump (MP1).



Insertion of the venous line (blue)

- Attach the rinsing bag to the infusion pole.
- Insert the venous air trap into the intended holder.
- Insert the venous line beneath the drip chamber into the safety air detector (SAD) and the safety air clamp (SAK) under the detector.
- Connect the transducer protector to the pressure sensor PV (blue).
- Connect the blue Luer Lock connector to the upper blood-side connector of the haemofilter.
- Close the clamp at the not used connection of the venous air trap.



Set-up overview

- ➢ Check the set-up before starting the priming procedure.
- ➢ Take care that all connections are firmly screwed together.
- ➢ Check that all pump segments are inserted clockwise.
- ➢ Check that the following clamps are closed:
  - Sampling ports before and after the blood pump
  - Heparin line if it is not used
  - Not used line at the venous chamber
  - Line with the plug at the collecting bag(s)
- ➢ Open the frangible pin of the sodium chloride solution bag and the bags with the haemofiltration solution.

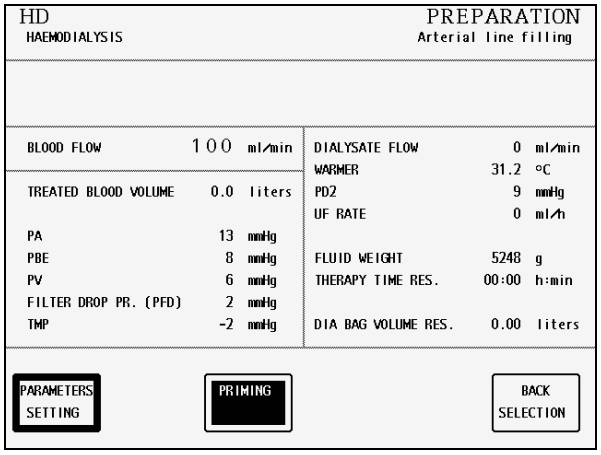
Installation of the preassembled HF/HD kit

In the pre-assembled kit the components of the HF/HD kit are mounted to a guide rail.

- ➢ Take hold of the guide rail of the kit with both hands and insert it into the respective holders on the machine (see also the respective instruction for use).
- ➢ Insert the pump segments clockwise.
- ➢ Connect all components as described above in this Section.

i Make sure that all relevant clamps are opened and that all connections are firmly screwed together before starting the priming procedure.

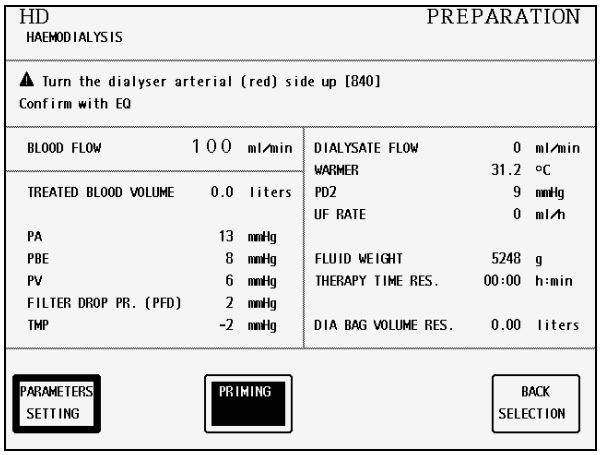
8.3.2 Priming



- After set-up of the consumables and checking the connections, select <PRIMING> and confirm by pressing the  key.

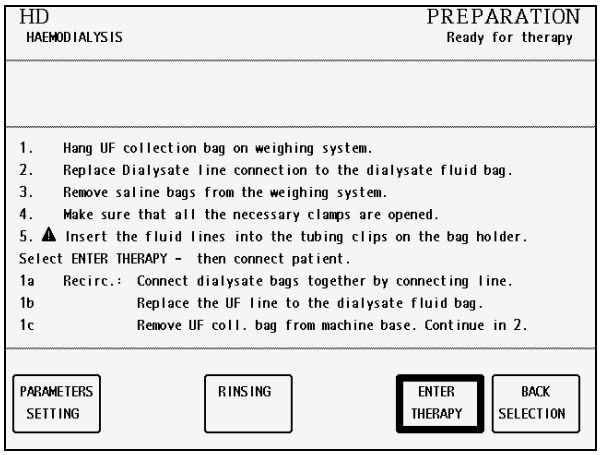
The automatic priming program starts. During the priming and rinsing the following tests are performed: load cell test, air detector test, dialysate pump test (MP3), heater test, disposable leakage test, level regulation test and the calibration of the pump constants takes place. The respective step of the procedures and the test is displayed in the therapy status field.

Do not move the Diapact® CRRT during calibration of the pump constants. Calibration will be repeated if it is disturbed.



During the priming procedure the prompt to turn the haemofilter is displayed.

- Turn the haemofilter upside down.
- Confirm by pressing the  key.



After the preparation phase has been finished, the system gives an acoustic signal and shows the <PREPARATION> screen with the message <Ready for therapy> in the therapy status field.

- Remove the bag with the sodium chloride solution from the load cell and attach it to the infusion pole.

Single pass

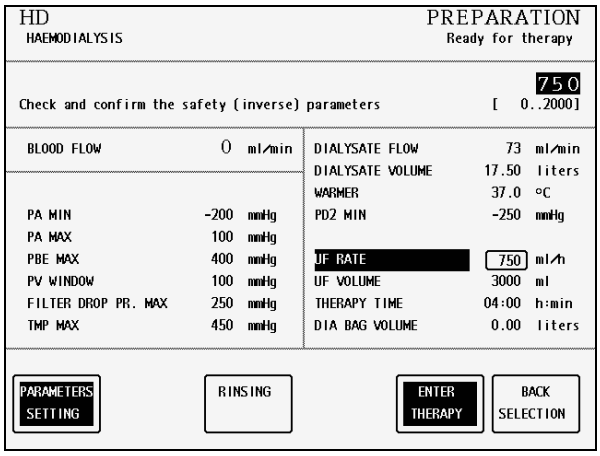
- Attach the collecting bags to the bag holder of the load cell.
- Make sure that all relevant clamps are open.
- Select <ENTER THERAPY> and confirm by pressing the  key.

The device switches automatically to <PARAMETERS SETTING>.

Recirculation

- ➢ Attach the collecting bags to the bag holder of the load cell.
- ➢ Connect the collecting bags and the bags with the haemofiltration solution as follows:
  - One branch of the dialysate inlet line to one collecting bag and the other branch to the ultrafiltration bag.
  - One branch of the ultrafiltration line to the collecting bag and one branch to the bag with the haemofiltration solution.
  - If necessary, connect the two bags with the haemofiltration solution with the connecting line.
- ➢ Make sure that all relevant clamps are open.
- ➢ Select <ENTER THERAPY> and confirm by pressing the  key.
  The device switches automatically to <PARAMETERS SETTING>.

8.3.3 Parameter setting



Setting safety-relevant parameters

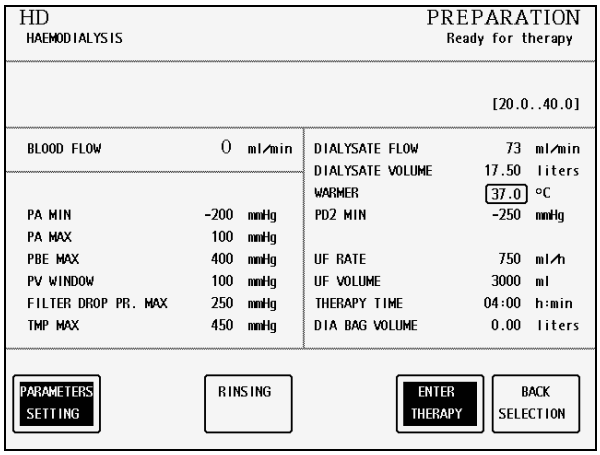
The safety-relevant parameters (ultrafiltration rate in HD/HFD) are displayed on a black background.

- ➢ Activate <UF rate> by pressing the  key.
  The value is inversely displayed on a black background.
- ➢ If the value is accepted, confirm by pressing the  key.
- ➢ To change the value, press the  to increase it or the  key to decrease it.
- ➢ Confirm with the  key.
  In both cases the actual value is displayed in the supervisor field, flashing on a black background.
- ➢ Compare the value displayed in the supervisor field with that shown in the fluid-side parameters field and confirm with the  key if they are identical.
- ➢ Any changes to safety-relevant parameters must always be confirmed with the  key.

If the safety-relevant data are not confirmed, whether they are changed or not, the system will not start the therapy.

If the ultrafiltration rate is changed, the ultrafiltration volume is changed accordingly in intermittent therapies.

The values changed dependently are displayed inversely, but they do not have to be confirmed separately.



Setting treatment parameters

- Select the parameter to be set with the  or  key.
- Activate the parameter by pressing the  key.
- Change the value with the  or  key
  and confirm the change with the  key.
- To exit <PARAMETERS SETTING>, press the  key.

These treatment data can be set at any time during the preparation phase or the therapy if the <PARAMETERS SETTING> option is displayed.

The following data can be set in the indicated ranges:

Parameter	Unit	Default	Min	Max	Increments
Blood-side parameters					
Blood flow	ml/min	50	10/5	500	5/10
PA min.	mmHg	-200	-400	PA max.	10
PA max.	mmHg	100	PA min.	300	10
PBE max.	mmHg	400	0	500	10
PV window	mmHg	100	80	160	10
PFD max. pressure drop	mmHg	250	100	450	10
TMP max.	mmHg	450	100	600	10
Fluid-side parameters					
Dialysate flow	ml/min	73	0*/5	400	5/50
Dialysate volume	l	17.50	0*	120.00	0.10/1.00
Temperature	°C	37	20	40	0.5/1.0
PD2 min. **HD**	mmHg	-250	-400	500	10
PD2 min. **HFD**	mmHg	-50	-250	250	10
UF rate	ml/h	750	0*	2000	10/100
UF volume	ml	3000	0	10000	10/100
Dialysate bag volume	l	0.00	-25.00	20.00	0.10/1.00
Therapy time	h:min	04:00	00:00	12:00	0:05/0:30

* The dialysate flow can be set to zero if the UF rate is ≥ 300 ml/h. If the UF rate is below this limit, the adjustable lower limit for the dialysate flow is (300 ml/h – UF rate)/60 ml/min.
In software versions 2.10 and 2.12 there is no lower limit for the dialysate flow. The increment to increase or decrease the dialysate flow in the lower range is 10 ml/min.

In HD and HFD, as intermittent therapies, the change of the following variables automatically leads to a change in dependent variables.

Changed parameter	Dependently changed parameter*
Dialysate flow	Dialysate volume
Dialysate volume	Dialysate flow
UF rate	UF volume
UF volume	UF rate
Therapy time	Dialysate flow UF rate

* Further parameter(s) can be changed if the dependently changed parameter is limited by the set range limit.

A change of the safety-relevant parameters (dialysate flow, UF rate) must be confirmed with the EQ key. The dependently changed treatment parameters flash, but they do not have to be confirmed separately.

Setting the dialysate/ultrafiltration volume or the therapy time to zero results in a switch from volume control to rate control. That means that zero substitution or ultrafiltration can be set only by setting the proper rate to zero.

Bag change volume

The haemofiltration solution volume or the spent dialysate volume at which the bags with the haemofiltration solution or the collecting bag at the load cell have to be changed can be defined. The default value is 0.

If 0 is selected, the machine gives an alarm when the haemofiltration solution is empty, as detected by the air detector underneath the dialysate pump (MP3.)

- Select <DIA BAG VOLUME> in <PARAMETERS SETTING> and confirm with the  key.
- Set the <DIA bag volume> to a **positive value** (e.g. + 4.8L).

When the volume of the **haemofiltration solution bags** is spent during therapy, the alarm <bag volume is over (1020)> occurs

- Follow the instructions on the screen and exchange the bag(s) with the haemofiltration solution.
- Set the <DIA bag volume> to a **negative value** (e.g. – 6L).

Selecting a negative <DIA bag volume> changes the display to <UF bag volume>

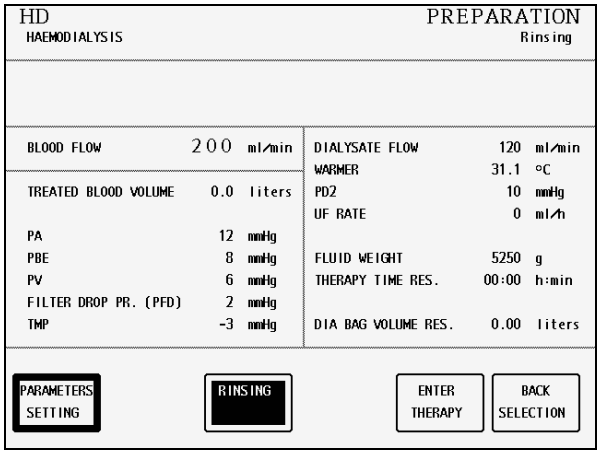
When the volume of the **ultrafiltration collecting bags** is reached during therapy the alarm <bag volume is over (1020)> occurs

- Follow the instructions on the screen and exchange the collecting bag.

To switch between <DIA bag volume> and <UF bag volume>, it is necessary to set the parameter first to 0.

- Select <DIA bag volume> and <UF bag volume> and confirm with the  key.
- Set the parameter to 0 and confirm with the  key.
- Select <DIA bag volume> again and confirm with the  key.
- Increase or decrease the value and confirm with the  key.

8.3.4 Menu selection in preparation



Rinsing

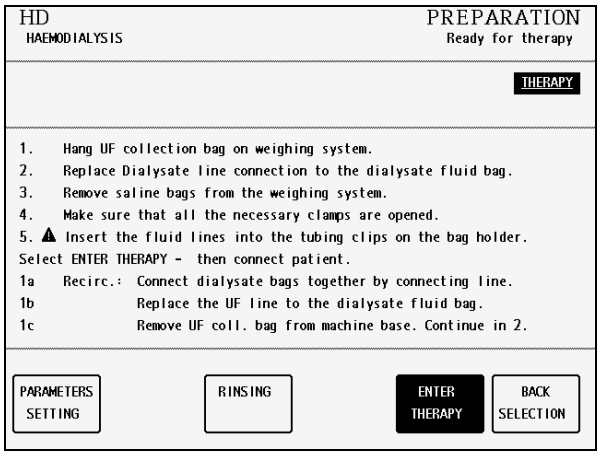
- If necessary, rinsing can be prolonged by selecting <RINSING> and confirming with the  key.
- If only the blood side has to be rinsed, the fluid side can be stopped by opening the cover of the ultrafiltration pump (MP2).
- To finish the additional rinsing, select <RINSING> again and confirm with the  key.

Back selection

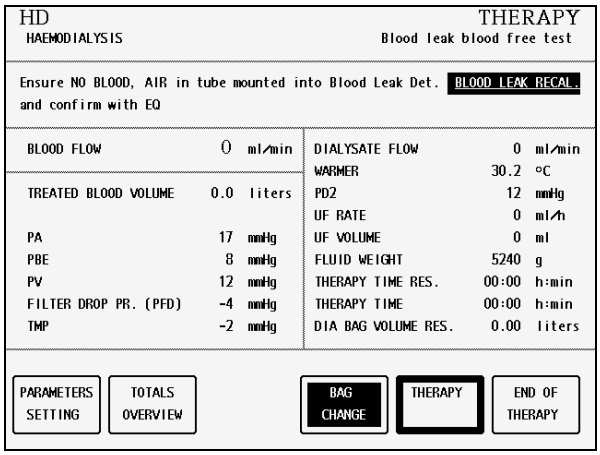
Choosing back selection allows to return to the <THERAPY SELECTION> screen.

- Select <BACK SELECTION> and confirm with the  key.

8.4 Therapy



- To switch from <PREPARATION> to <THERAPY>, select <ENTER THERAPY> and confirm by pressing the  key.
- Confirm the start of the therapy by pressing the flashing  key while <THERAPY> is flashing in the supervisor field.



The Diapact® CRRT is now in the therapy status as indicated in the therapy status field.

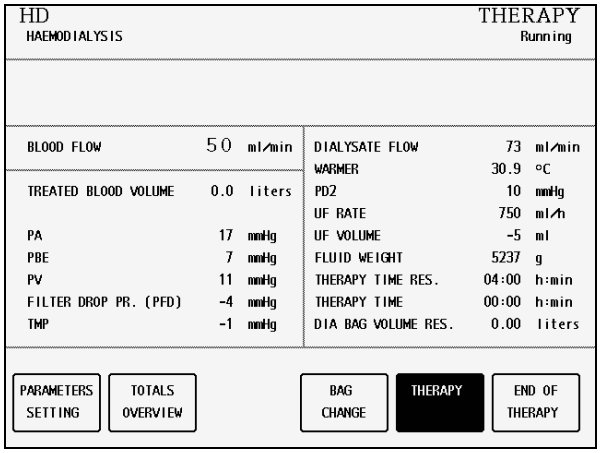
- Confirm the blood leak recalibration by pressing the  key.
- Start the blood pump for circulation by pressing the  key.

8.4.1 Connecting the patient

- Stop the blood pump.
- Connect the arterial line to the arterial access of the patient.
- Start the blood pump and adjust the flow rate using the  or  keys.
- Check that the withdrawal pressure (arterial pressure – PA) is within the prescribed range.
- When the blood starts to fill the venous line, stop the blood pump and connect the venous line to the venous access of the patient.
- Start the blood pump again and adjust the blood flow slowly dependent on the patient's condition.
- Check that the arterial and venous pressure values displayed on the screen are within the normal range.

During therapy, the arterial chamber should be about 50% filled, the venous chamber about 80%

8.4.2 Start of therapy



After the blood has been circulating for 2- 3 minutes without alarms, the therapy can be started.

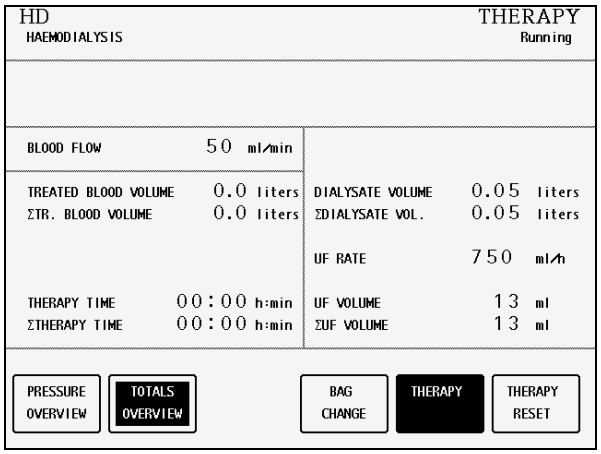
- Select <THERAPY> and activate by pressing the  key.

<THERAPY> in the menu selection field is blackened and in the therapy status field <Running> is indicated.

The treatment is now in progress and the parameter overview is displayed.

The current pressure and flow data of the blood side and the fluid side are displayed on the screen.

8.4.3 Menu selection in therapy



Parameter setting

See Section 8.3.3

Totals overview

➢ Select <TOTALS OVERVIEW> and confirm by pressing the  key.

➢ To return to the <PARAMETERS OVERVIEW> screen, select <TOTALS OVERVIEW> and then press the  key.

The <TOTAL OVERVIEWS> screen displays:

On the left (blood-side) part of the screen

- Current blood flow
- Treated blood volume of the current time segment
- Treated blood volume of the whole treatment (sum of all time segments)
- Therapy time of the current time segment
- Therapy time of the whole treatment (sum of all time segments)

On the right (fluid-side) part of the screen

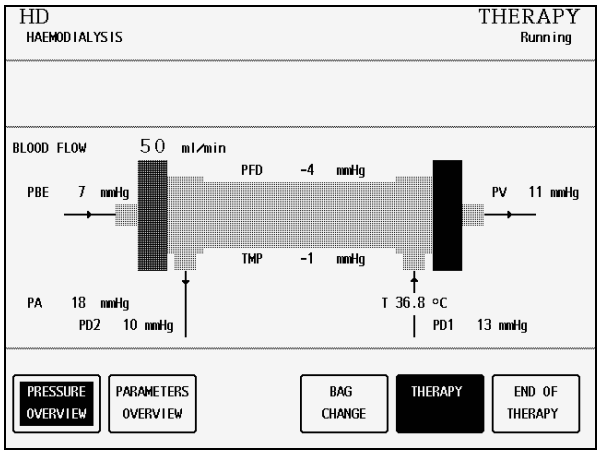
- Current ultrafiltration flow
- Dialysate volume of the current time segment
- Dialysate volume of the whole treatment (sum of all time segments)
- Current ultrafiltration rate
- Ultrafiltration volume of the current time segment
- Ultrafiltration volume of the whole treatment (sum of all time segments)

Therapy reset

<THERAPY RESET> allows to adjust the current values for treated blood volume, therapy time, dialysate volume and ultrafiltration volume to zero. The following volumes and the time are added up from the values marked with Σ.

This allows to follow the data during a certain time segment of the treatment.

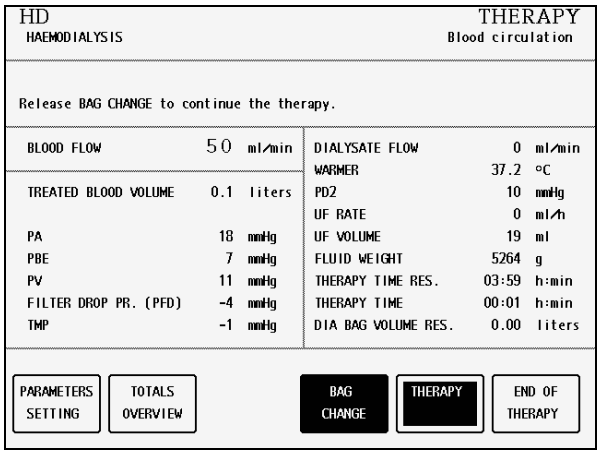
➢ Select <THERAPY RESET> and confirm by pressing the  key followed by the  key.



Pressure overview

<PRESSURE OVERVIEW> allows an overview of all pressures recorded in the system.

- Select <PRESSURE OVERVIEW> and confirm by pressing the  key.
- Select <PARAMETERS OVERVIEW> to return to the <PARAMETERS OVERVIEW> screen and confirm by pressing the  key.



Bag change

The <BAG CHANGE> option allows to change the fluid bags during a running therapy.

- Select <BAG CHANGE> and confirm by pressing the  key.

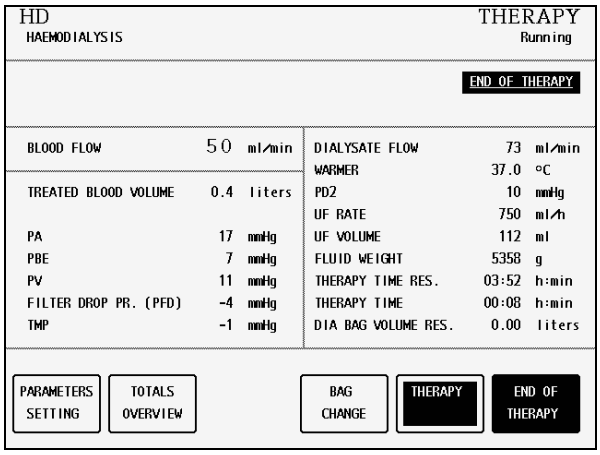
  The ultrafiltration pump (MP2) and the dialysate/substitution pump (MP3) stop. The blood pump (MP1) keeps on running.
- Exchange the bag(s).
- Open the frangible pin if the bag(s) with the haemofiltration solution is exchanged.
- Close the line equipped with the plug if the collecting bag(s) is exchanged.
- After the bag exchange, deactivate <BAG CHANGE> by pressing the  key.

  The treatment continues automatically.

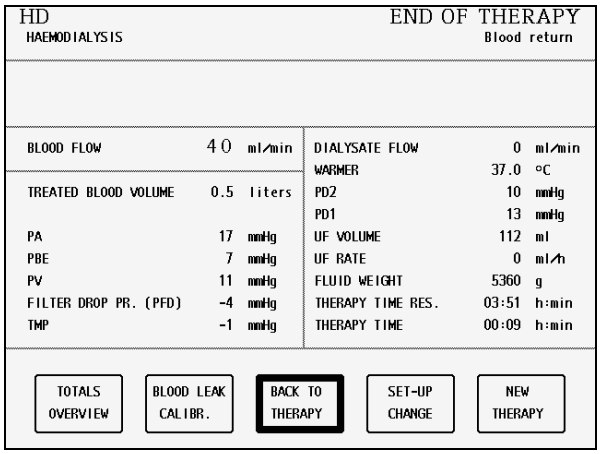
8.5 End of therapy

When the therapy time set is reached, the machine activates a warning (ready-for-therapy tone) and displays the warning message <Therapy is over> in the warning field. The balance pumps stop. Therapy can be continued by simply increasing the therapy time (directly, or indirectly by increasing dialysate volume or UF volume). The warning sound is repeated in 4 minutes until <THERAPY> is deactivated.

The therapy is finished as described in the following.



- Select <END OF THERAPY> and confirm by pressing the  key.
- Confirm by pressing the  key.



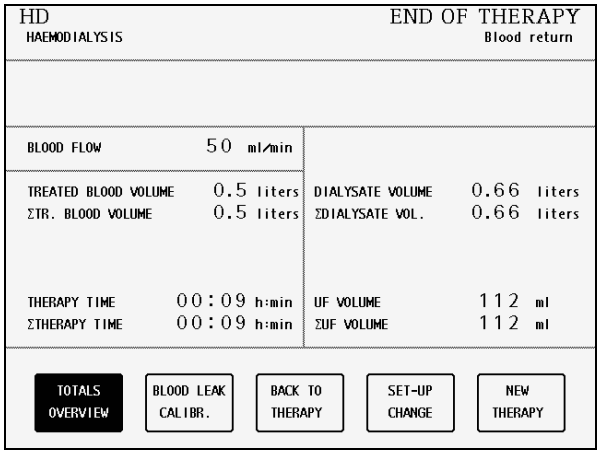
The ultrafiltration pump (MP2) and the dialysate pump (MP3) stop. The blood pump (MP1) continues to run at reduced speed (50 ml/min).

8.5.1 Disconnecting the patient

- Stop the blood pump (MP1).
- Disconnect the arterial line from the patient's arterial access and connect it to a bag with isotonic saline solution.
- Start the blood pump and return the blood in the extracorporeal circuit to the patient.
- Stop the blood pump (MP1) just before the isotonic saline solution enters the patient.
- Disconnect the venous line from the patient's venous access.
- Remove disposable materials and solutions from the device.

Dispose of disposable materials and fluids which have been removed from the device in accordance with local regulations.
Therapy data are stored in the machine for 30 minutes. They can be recalled by switching on the Diapact® CRRT within this time frame.

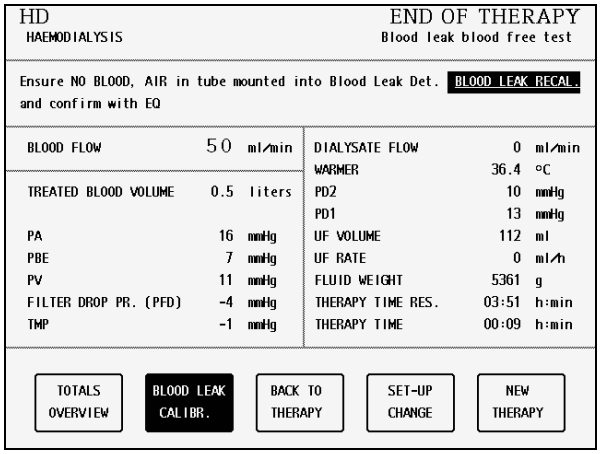
8.5.2 Menu selection at end of therapy



Totals overview

The option <TOTALS OVERVIEW> shows the summary of the pivotal treatment data as described (Section 8.4.3)

- Select <TOTALS OVERVIEW> and confirm by pressing the  key.
- To return to the <END OF THERAPY> screen, select <TOTALS OVERVIEW> and confirm with the  key.



Blood leak recalibration

The <BLOOD LEAK CALIBRATION> function allows the recalibration of the blood leak detector in case of non-acceptable alarms (e.g. elevated plasma bilirubin concentration)

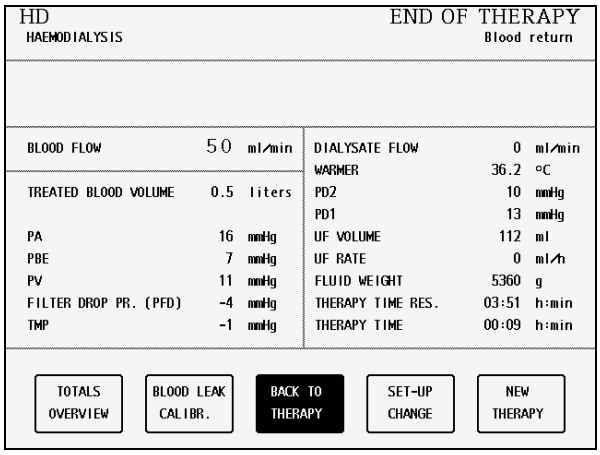
- Select “BLOOD LEAK CALIBRATION” and confirm with the  key. The  key lights up.
- Confirm with the  key.
- Select <BACK TO THERAPY> and confirm with the  key. The  key lights up.
- Confirm with the  key.
- Adapt the blood flow to the initial value.
- Start <THERAPY> by pressing the  key.

DANGER

Risk of blood loss for the patient and haemolysis

- **Before the recalibration of the blood leak detector, the haemofilter must be carefully checked for possible blood leaks and haemolysis.**
- **It is recommended to withdraw a sample (at least 2 ml) from the injection port of the filtrate line and to analyze for erythrocytes and/or free haemoglobin.**
- **The blood leak recalibration must only be performed if these tests are negative.**

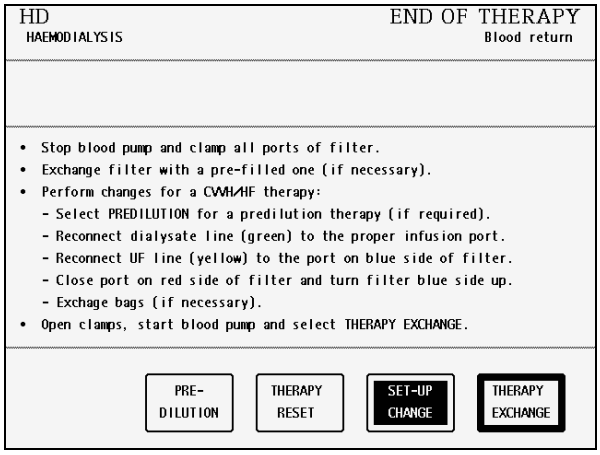
The balance pumps will not start up again until blood leak calibration has been completed.



Back to therapy

The option <BACK TO THERAPY> returns to the just finished therapy.

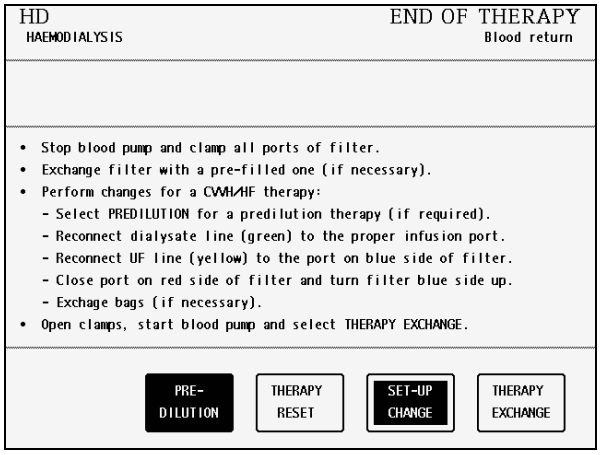
- Select <BACK TO THERAPY> and confirm by pressing the  key. The  key lights up.
- Confirm by pressing the  key.
- Start the therapy again by pressing the  key.



Set-up change

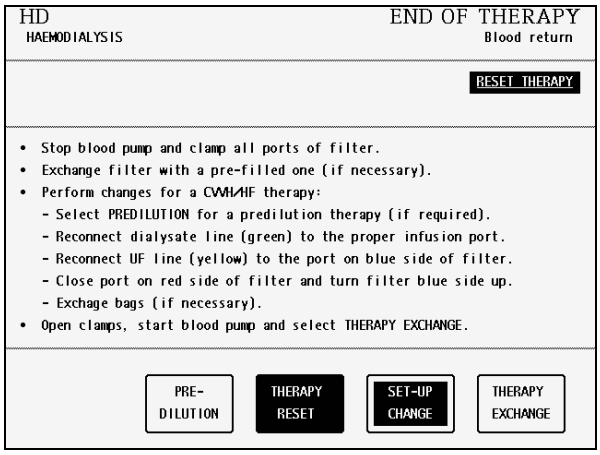
The function <SET-UP CHANGE> helps with a set-up instruction to:

- Change from HD/HDF to CVVH CVVHD or CVVHDF, during therapy (therapy change).
- Exchange the haemofilter.



Dilution setting

The function <PRE-DILUTION> allows to set the dilution mode of a new CVVH or HF therapy if this type of therapy is selected using the <THERAPY EXCHANGE> function (see below).

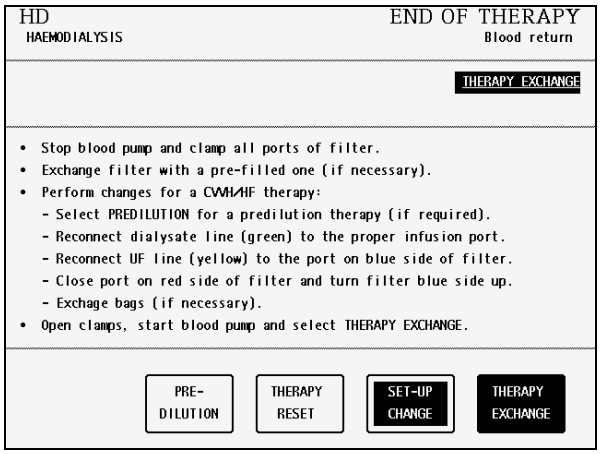


Therapy reset

The function allows to reset the just finished therapy.

➢ Select <THERAPY RESET> and confirm by pressing the  key followed by the  key.

See also Section 8.4.3



Therapy exchange

➢ Select <SET-UP CHANGE> and confirm by pressing the  key and follow the instructions below.

➢ Follow the relevant procedure described below.

To switch from HD/HFD to CVVH or HF

➢ Close the clamp of the dialysate inlet line (green) line connected to the haemofilter.

➢ If required, select <PRE-DILUTION> with the  or the  key and activate with the  key.

➢ Unscrew the dialysate inlet line from the haemofilter, close the Hansen connector tightly and connect the dialysate inlet line to the venous air trap.

➢ Remove the dialysate outlet line (**yellow**) from the port next to the arterial port and connect it to the port next to the venous port of the haemofilter. Close the Hansen connector at the arterial port tightly.

➢ Close the port next to the arterial port with the Hansen connector.

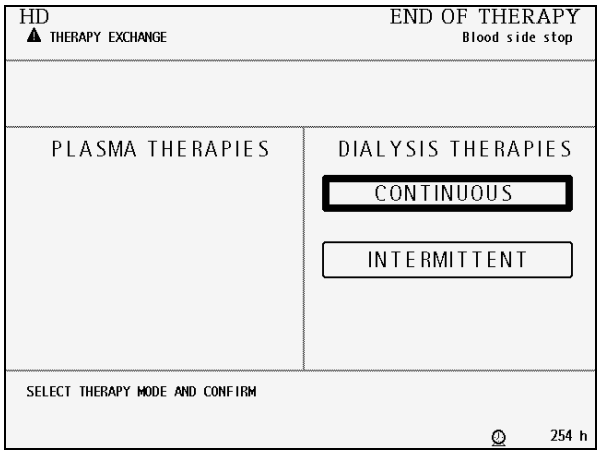
➢ Turn the haemofilter upside down.

➢ Open the clamp of the dialysate inlet line and of the line of the venous air trap where the dialysate inlet line is connected.

To change from HD/HFD to CVVHD/CVVHFD the set-up must not be changed.

➢ Select <THERAPY EXCHANGE> and confirm by pressing the  key. The  key lights up.

➢ Confirm by pressing the  key.



➢ Select <CONTINUOUS> or <INTERMITTENT> therapy mode using the  or  keys and confirm by pressing the  key.

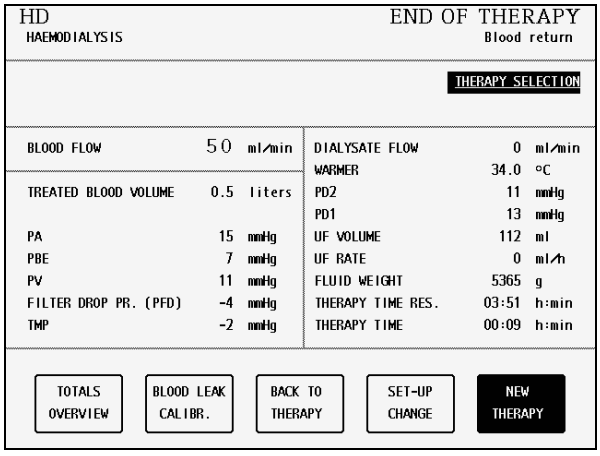
The modality can be selected in the following screen. The chosen therapy starts with the confirmation of the safety-relevant treatment data.

For further information see the Section on the therapy you have chosen.

The treatment data of the previous therapy will be retained.

Changing the haemofilter

See Section 13.5



New therapy

The option <NEW THERAPY> allows to start a new therapy immediately after the one just finished. The device switches directly to therapy selection.

➢ Select <NEW THERAPY> and confirm by pressing the  key. The  key lights up.

➢ Confirm by pressing the  key.

DANGER

Risk of blood loss and infection for the patient

➢ **To guarantee the safe therapy for the patient, the consumables (line system, filter, solutions) used in the just finished therapy must be completely replaced.**

8.6 Special functions

Bag movement function

To avoid superfluous alarms and the resulting pump standstill, the Diapact® CRRT has a function which is actuated by slight movements of the machine during therapy.

When this function is actuated, the ultrafiltration and the dialysate pumps stop without an alarm and start again automatically when the initial weight (i.e. the weight before the movement of the machine or bag) is reached again.

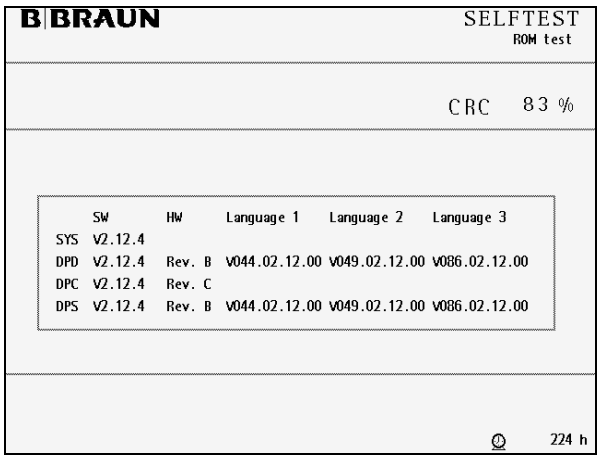
Automatic temporary reduction of the blood flow

If PA min is reached, blood flow automatically drops to 25% (but not lower than 60 ml/min) to prevent standstill of the blood pump caused by movement of the patient. The ultrafiltration and the dialysate pumps stop also for a short time without an alarm.

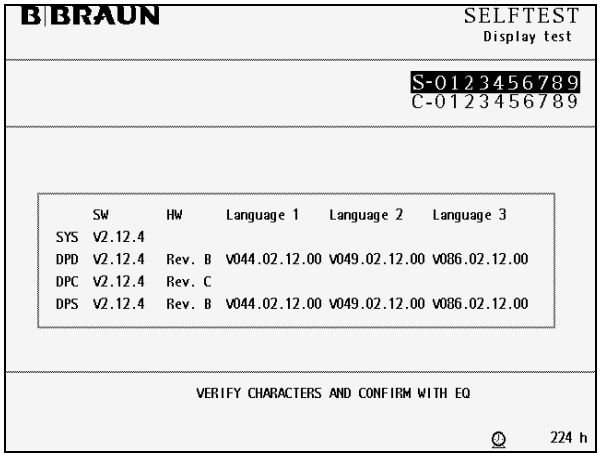
Table of contents

9 PEX (Plasma exchange)

9.1 Switching on and initial tests

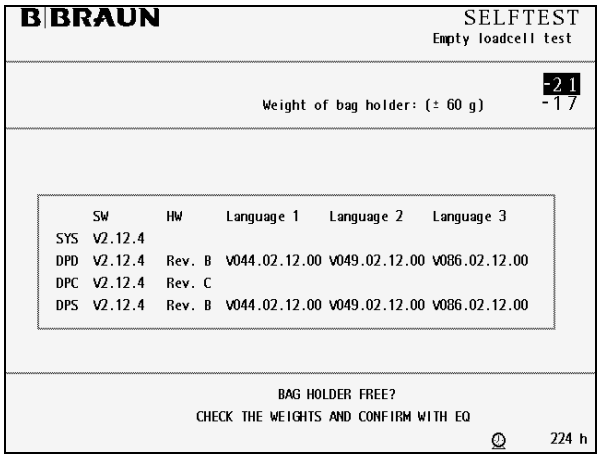


- Switch on the Diapact® CRRT with the power switch ON/OFF (I/O) on the back of the machine. The device starts with the ROM test.
- Check whether the AQ and EQ keys are lit during the ROM test.



The ROM test is followed by the display test.

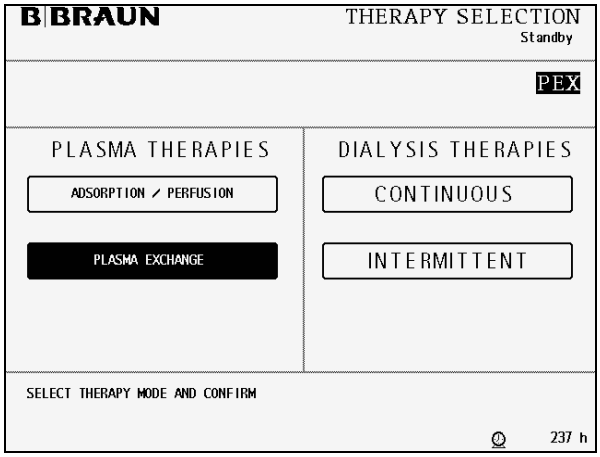
- Compare the character lines in the supervisor field and confirm by pressing the EQ key if both series are identical.
- While the EQ key is being pressed, the buzzer of the safety system is activated for 2 seconds.
- Check that the buzzer can be heard.



If the display test is passed successfully, the empty load cell test follows.

- Check whether the bag holder is empty.
- Confirm the weight values with the EQ key if they are within the allowed range. The maximum deviation between both displayed values is allowed to be ± 60 g and the values must not exceed -60 and +60 g.

9.2 Therapy selection



Having successfully passed the initial self tests, the machine switches to the <THERAPY SELECTION>.

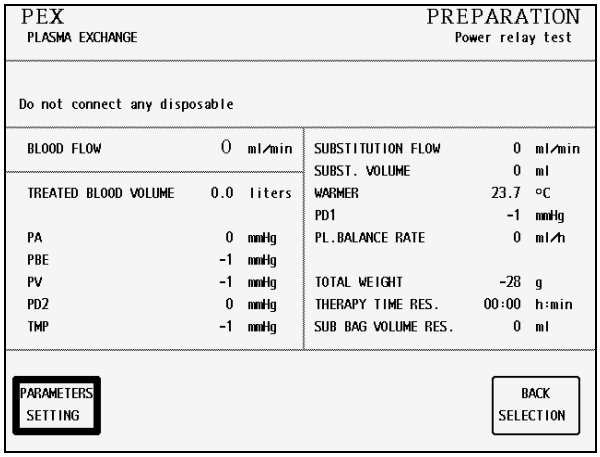
<CONTINUOUS> dialysis therapies is selected by default.

- To select <PLASMA EXCHANGE>, move to the respective position with the  and  keys.
- Confirm <PLASMA EXCHANGE> with the  key.

  <PLASMA EXCHANGE> flashes in the supervisor field.

- Press the  key for final confirmation.

9.3 Preparation

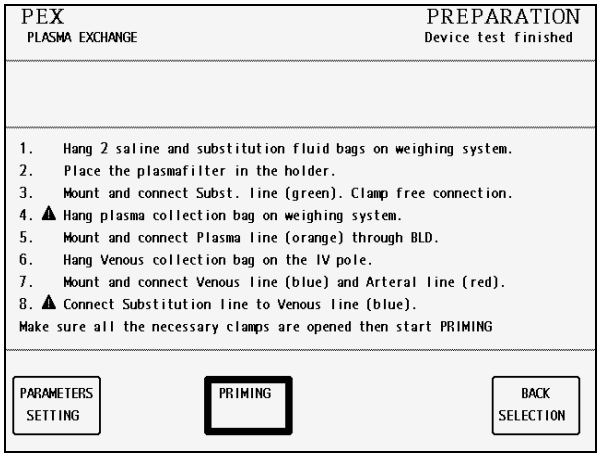


After modality selection and confirmation, the display shows the following <PREPARATION> screen.

Several tests are performed. The respective test is displayed in the therapy status field:

- Power relay test
- SAD reference test
- SAD counter test
- Red detector test
- Blood leak detector test
- Zero pressure test

9.3.1 Installation of consumable material



When the tests have been performed successfully, the <PREPARATION> screen displays <Device test finished> and the steps to set-up the machine are displayed.

The consumable material for the therapy comprises:

- PEX kit
- Plasmafilter
- 2 x 2L isotonic sodium chloride solution
- Substitution solution according to the prescription of the attending physician

➢ Follow the instructions on the screen and set-up the device as described in the following.

The lines of the HF/HD kit are colour-coded to facilitate the set-up.

Arterial line (**red**)
Venous line (**blue**)
Substitution line (**green**)
Plasma outlet line (**yellow**)

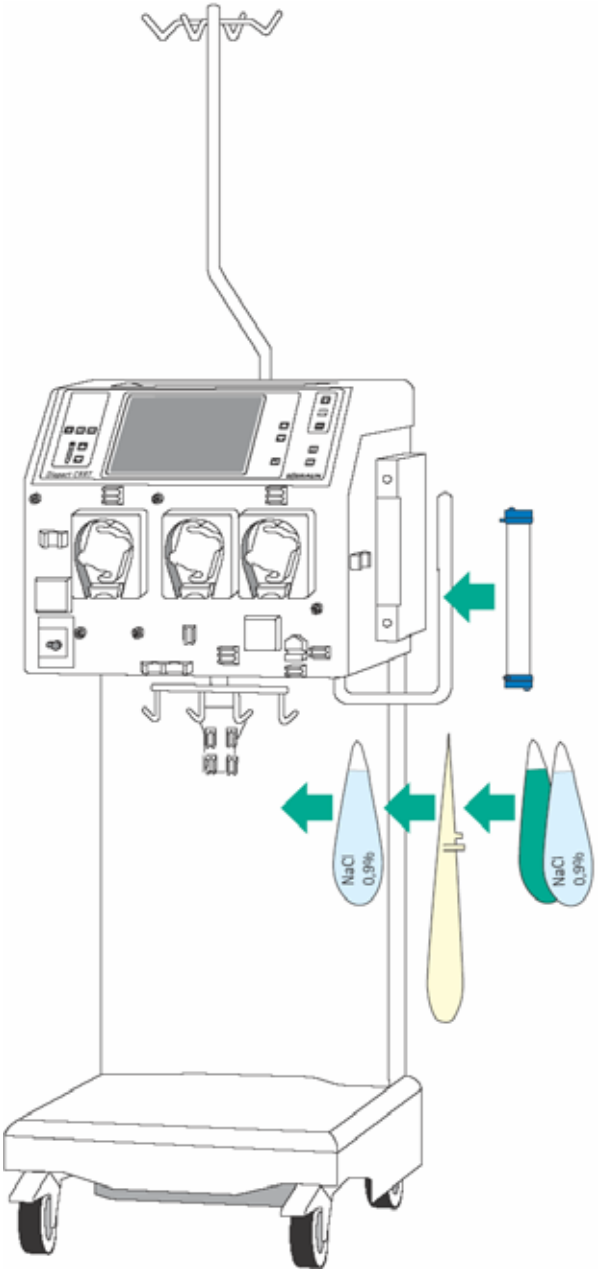
Pumps used

Blood pump (MP1)
Ultrafiltration pump (MP2) / Plasma pump in PEX
Substitution pump (MP3)

WARNING

Risk of infection and blood loss for the patient by damaged packaging or components

➢ **Make sure during set-up that the packaging of the material used (line system, plasmafilter, solution bags) is undamaged.**
➢ **During set-up check the material for integrity.**
➢ **Observe the respective instructions for use.**



Installation of bags and plasmafilter

- Attach the collecting bags of the PEX, the two 2L bags with isotonic sodium chloride solution and the bags with the substitution solution on the bag holder of the load cell.
- Fix the plasmafilter into the filter holder on the right side of the machine.
- Close the clamps of the collecting bags on the tubes equipped with plugs.

CAUTION

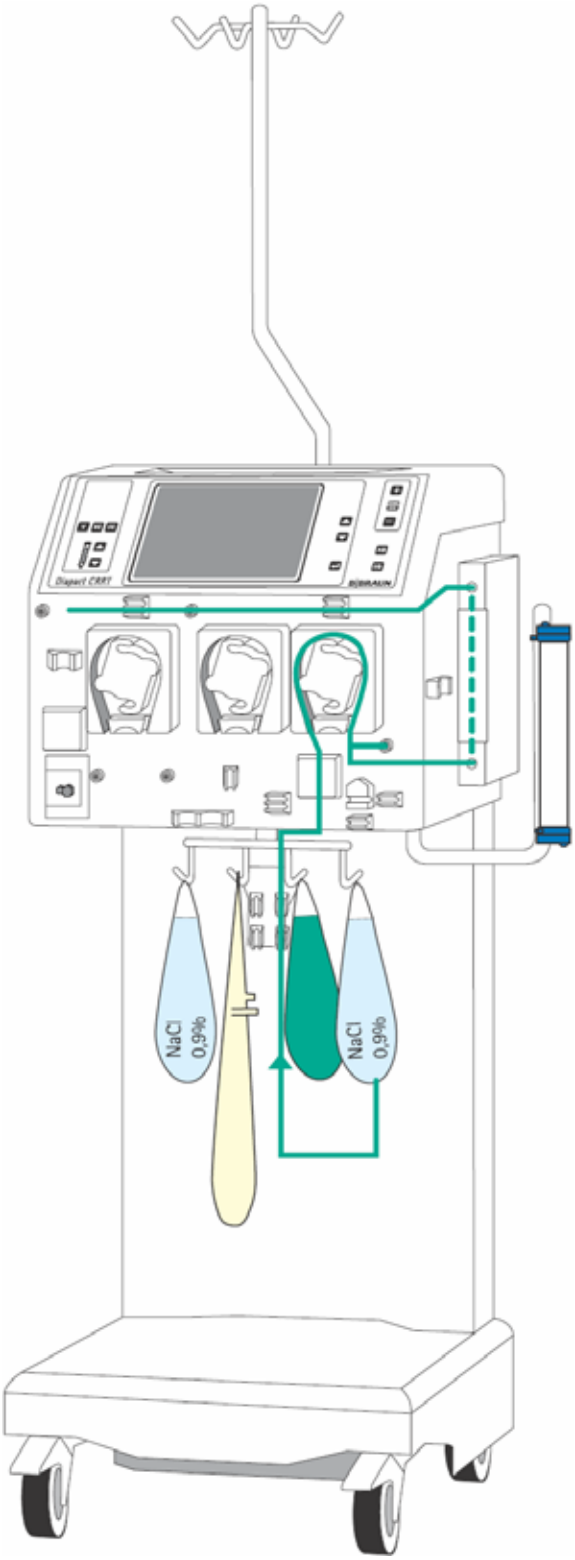
Incomplete moistening of the plasmafilter during priming and rinsing may result in performance reduction.

- **Place the filter into the filter holder with the arterial port (red) downwards.**

If the weight on the load cell is unevenly distributed, there is a risk that the device may topple.

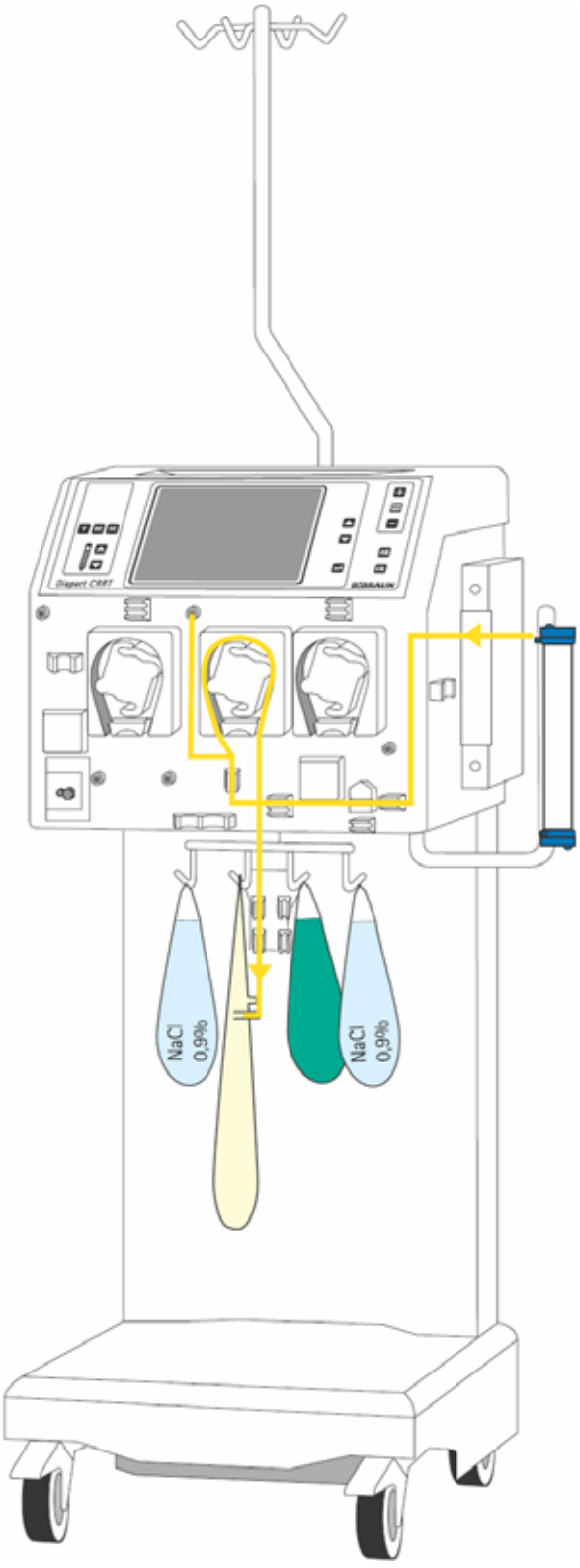
- **Distribute weight on the bag holder evenly.**

The maximal load of the load cell is 27 kg.



Insertion of the substitution line (green)

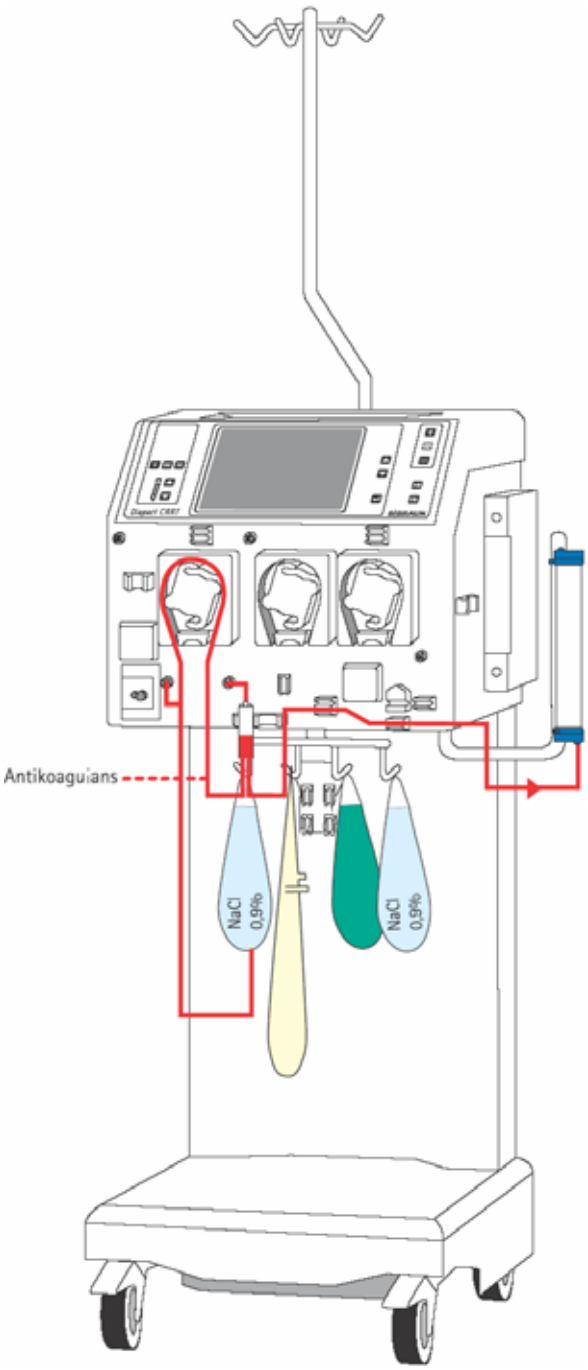
- Insert the heater bag into the plate heater and close the cover. To ensure that the bag has optimal contact to the heater, close the cover audibly.
- Insert the pump segment into the substitution pump (MP3).
- Insert the line leading from the connection of the bags with the substitution solutions to the pump segment into the air detector beneath the substitution pump (MP3).
- Connect the transducer protector to the pressure sensor PD1 (white).
- Connect the line leading from the air detector to the bags with the substitution solution to the bags and fix the line in the holder on the load cell.
- Insert the line leaving the heater at the top in the line fixing above the pumps.



Insertion of the plasma outlet line (yellow)

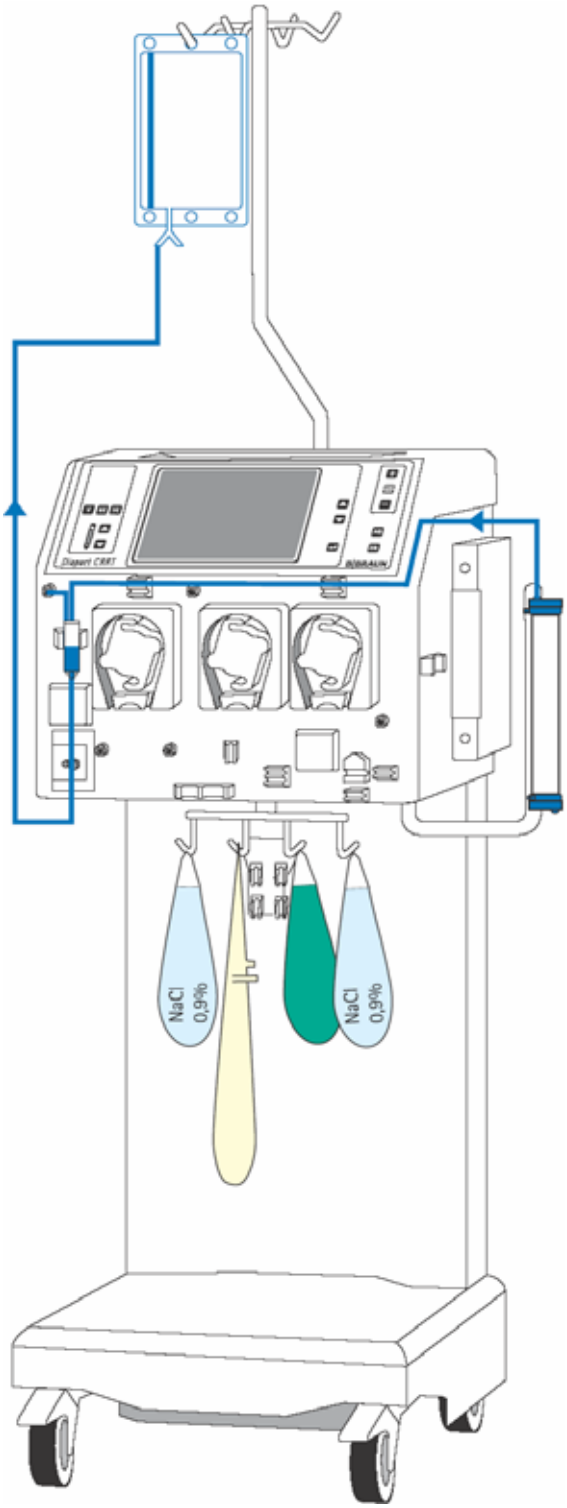
- Connect the end of the line with the Hansen connector to the upper filtrate outlet of the plasmafilter. Dependent on the connector at the filter remove the Hansen adapter.
- Insert the line coming from the plasmafilter into the blood leak detector (BLD).
- Insert the pump segment into the plasma pump (MP2).
- Insert the air trap into the intended holder.
- Connect the transducer protector to the pressure sensor PSC/PD2 (white).
- Connect the Luer Lock connectors to the collecting bags and fix the line in the bag holder on the load cell.

Take care that the second filtrate-side connector, which is not used, is securely closed.



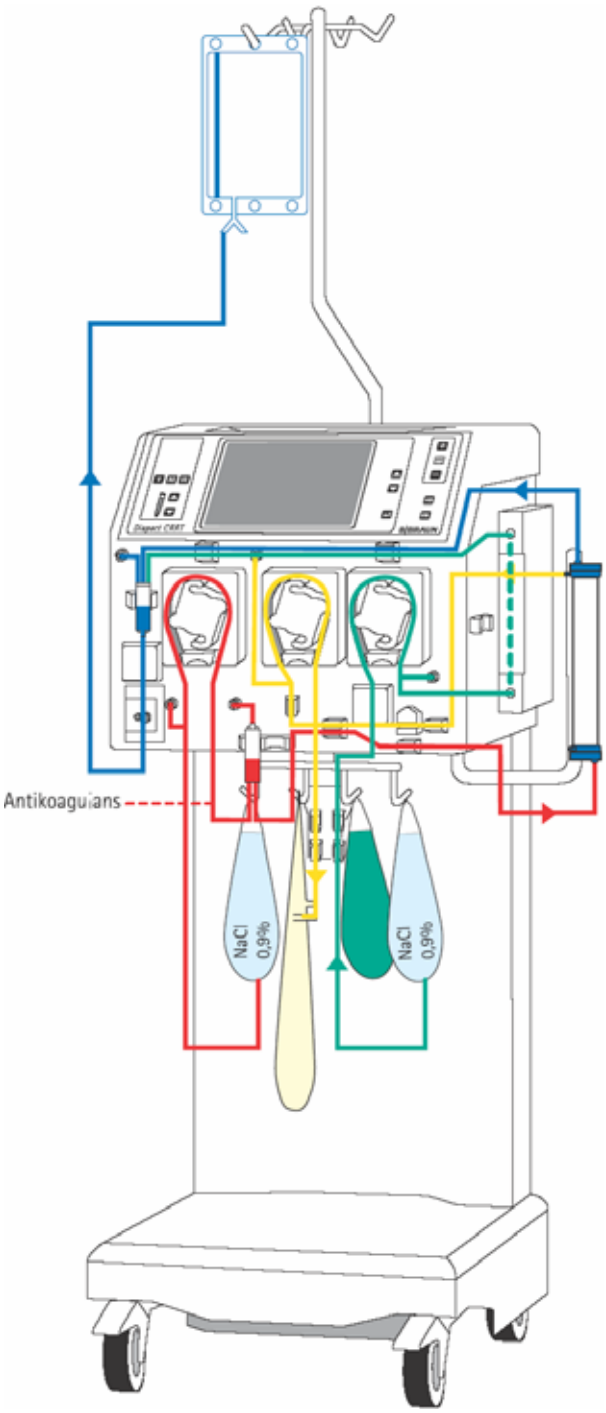
Insertion of the arterial line (red)

- Connect the end of the line with the spike/Luer Lock connector to the bag with isotonic sodium chloride solution on the bag holder of the load cell.
- Insert the pump segment into the blood pump (MP1).
- Connect the transducer protector before the blood pump to the pressure sensor PA (red).
- Insert the arterial air trap into the intended holder.
- Connect the transducer protector to the pressure sensor PBE (red).
- Connect the red Luer Lock connector to the lower blood-side connector of the plasmafilter.
- If continuous heparinisation is required, connect the heparin line to the external heparin pump previously filled with heparin.
- Close the clamp of the heparin line if it is not used.
- Close the clamps at the sampling ports before and after the blood pump (MP1).



Insertion of the venous line (blue)

- Attach the rinsing bag to the infusion pole.
- Insert the venous air trap into the intended holder.
- Insert the venous line beneath the drip chamber into the safety air detector (SAD) and the safety air clamp (SAK) under the detector.
- Connect the transducer protector to the pressure sensor PV (blue).
- Connect the blue Luer Lock connector to the upper blood-side connector of the haemofilter.
- Connect the substitution line (green) to one of the Luer Lock connectors at the venous air trap.
- Close the clamp at the not used connection of the venous air trap.

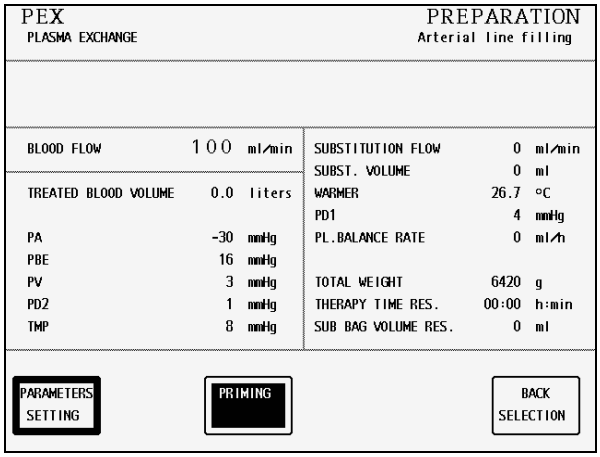


Set-up overview

- ➢ Check the set-up before starting the priming procedure.
- ➢ Take care that all connections are firmly screwed together.
- ➢ Check that all pump segments are inserted clockwise.
- ➢ Check that the following clamps are closed:
  - Sampling ports before and after the blood pump
  - Heparin line if it is not used
  - Not used line at the venous chamber
  - Line with the plug at the collecting bag(s)
- ➢ Open the frangible pin of the sodium chloride solution bags and the bags with the substitution solution.

i Make sure that all relevant clamps are opened and that all connections are firmly screwed together before starting the priming procedure.

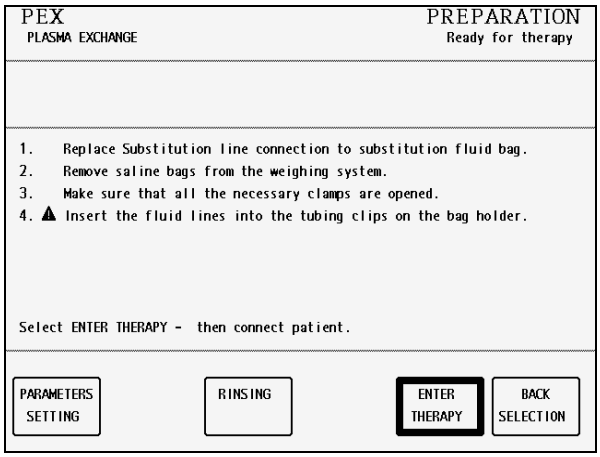
9.3.2 Priming



➢ After set-up of the consumables and checking the connections, select <PRIMING> and confirm by pressing the  key.

The automatic priming program starts. During the priming and rinsing the following tests are performed: load cell test, air detector test, substitution pump test (MP3), heater test, plasma pump test (MP2), disposable leakage test, level regulation test and the calibration of the pump constants takes place. The respective step of the procedures and the test is displayed in the therapy status field.

Do not move the Diapact® CRRT during calibration of the pump constants. Calibration will be repeated if it is disturbed.



After the preparation phase has been finished, the system gives an acoustic signal and shows the <PREPARATION> screen with message <Ready for therapy> in the therapy status field.

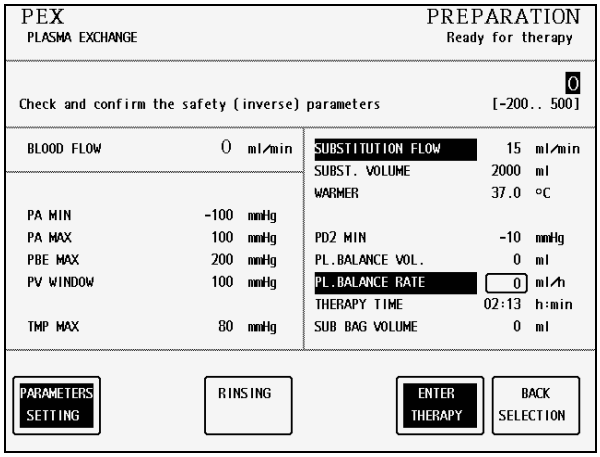
➢ Remove the bag with the sodium chloride solution from the load cell and attach it to the infusion pole.

➢ Make sure that all relevant clamps are open.

➢ Select <ENTER THERAPY> and confirm by pressing the  key.

The device switches automatically to <PARAMETERS SETTING>.

9.3.3 Parameter setting



Setting safety-relevant parameters

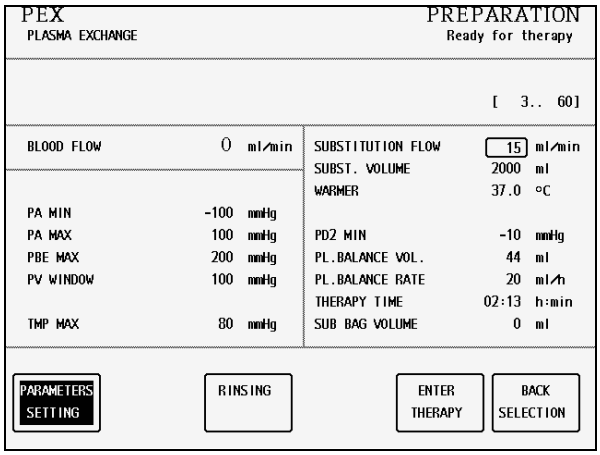
The safety-relevant parameters (substitution flow and plasma balance rate in PEX) are displayed on a black background.

- Activate <PL BALANCE RATE> by pressing the key.

  The value is inversely displayed on a black background.
- If the value is accepted, confirm by pressing the key.
- To change the value, press the key to increase it or the key to decrease it.
- Confirm with the key.'
  In both cases the actual value is displayed in the supervisor field, flashing on a black background.
- Compare the value displayed in the supervisor field with that shown in the fluid-side parameters field and confirm with the EQ key if they are identical.
- Check and/or change the substitution flow in the same way.

  Any changes to the safety-relevant parameters must always be confirmed with the EQ key.

If the safety-relevant data are not confirmed, whether they are changed or not, the system will not start the therapy.



Setting treatment parameters

- Select the parameter to be set with the  or  key.
- Activate the parameter by pressing the  key.
- Change the value with the  or  key
  and confirm the change with the  key.
- To exit <PARAMETERS SETTING>, press the  key.

These treatment data can be set at any time during the preparation phase or the therapy if the <PARAMETERS SETTING> option is displayed.

The following data can be set in the indicated ranges:

Parameter	Unit	Default	Min	Max	Increments
Blood-side parameters					
Blood flow	ml/min	50	10/5	300	5/10
PA min.	mmHg	-100	-400	PA max.	10
PA max.	mmHg	100	PA min.	200	10
PBE max.	mmHg	200	0	500	10
PV window	mmHg	100	80	160	10
TMP max.	mmHg	80	20	150	10
Fluid-side parameters					
Substitution flow	ml/h	15	0*/2*	60	1/5
Substitution volume	ml	2000	0	12000	100/500
Temperature	°C	37	20	37	0.5/1.0
PD2 min.	mmHg	-10	-250	250	10
Plasma balance volume	ml	0	-2000	3000	10/100
Plasma balance rate	ml/h	0	-200	500	10/100
Substitution bag volume	ml	0	-25000	20000	100/1000
Therapy time	h:min	02:13	00:00	08:00	0:05/0:30

* The substitution flow can be set to zero if the plasma balance rate is ≥ 180 ml/h (150 ml/h in software 2.10 and 2.12). If the plasma balance rate is below this limit, then the settable lower limit for the substitution flow is (180 ml/h (150 ml/h in software 2.10 and 2.12)– plasma balance rate)/60 ml/min.

In software versions 2.10 and 2.12 there is no lower limit for the substitution flow.

In PEX, as an intermittent therapy, the change of the following variables automatically leads to a change in dependent variables.

Changed parameter	Dependently changed parameter*
Substitution flow	Therapy time Plasma balance rate
Substitution volume	Therapy time Plasma balance rate
Plasma balance volume	Plasma balance rate
Plasma balance rate	Plasma balance volume
Therapy time	Substitution flow Plasma balance rate

* Further parameter(s) can be changed if the dependently changed parameter is limited by the set range limit.

A change of the safety-relevant parameters (substitution flow, plasma balance rate) must be confirmed with the 

key.
The other changed treatment parameters flash, but they do not have to be confirmed separately.

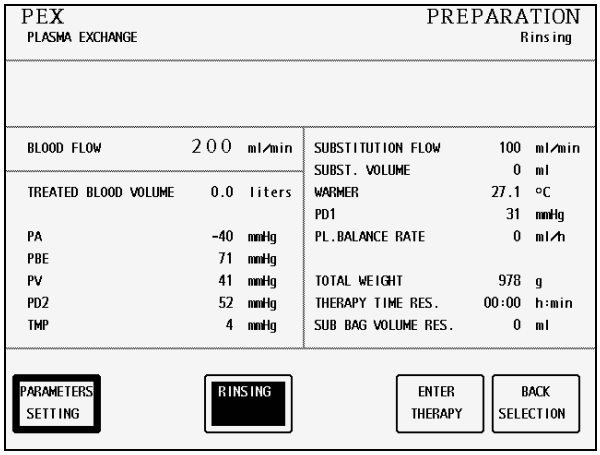
Setting the substitution volume or the therapy time to zero results in a switch from volume control to rate control. That means that zero substitution or ultrafiltration can be set only by setting the proper rate to zero.

Bag change volume
The substitution fluid volume at which the substitution bag(s) at the load cell has to be changed can be defined.

- Select <SUB BAG VOLUME> in <PARAMETERS SETTING> and confirm with the  key.
- Set the substitution bag volume to a positive value (e.g. + 2000 ml).

  When the value is reached during therapy, the alarm <bag volume is over (1020)> occurs
- Follow the instructions on the screen and exchange the substitution bag(s).

9.3.4 Menu selection in preparation



Rinsing

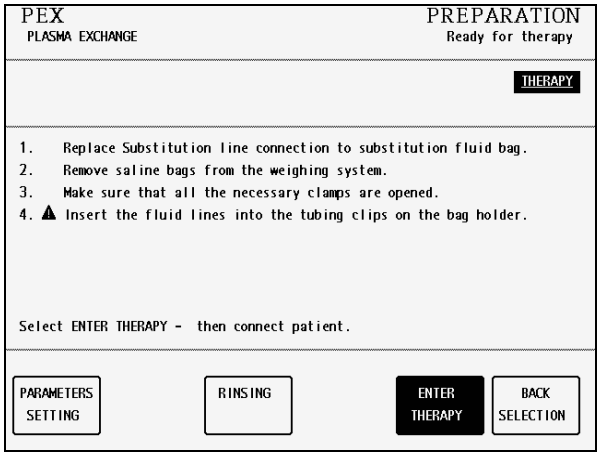
- If necessary, rinsing can be prolonged by selecting <RINSING> and confirming with the  key.
- If only the blood side has to be rinsed, the fluid side can be stopped by opening the cover of the plasma pump (MP2).
- To finish the additional rinsing, select <RINSING> again and confirm with the  key.

Back selection

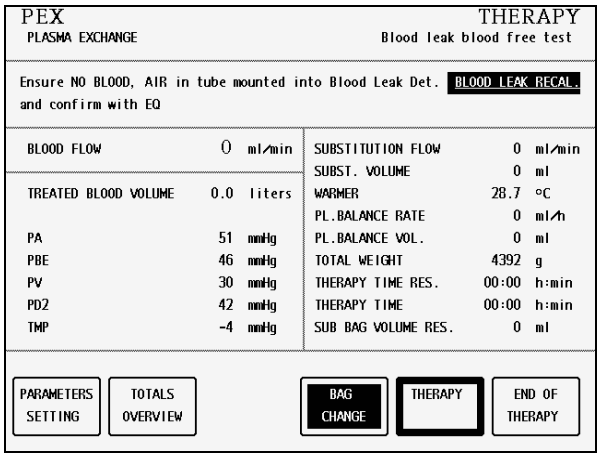
Choosing back selection allows to return to the <THERAPY SELECTION> screen.

- Select <BACK SELECTION> and confirm with the  key.

9.4 Therapy



- To switch from <PREPARATION> to <THERAPY>, select <ENTER THERAPY> and confirm by pressing the  key.
- Confirm the start of the therapy by pressing the flashing  key while <THERAPY> is flashing in the supervisor field.



The Diapact® CRRT is now in the therapy status as indicated in the therapy status field.

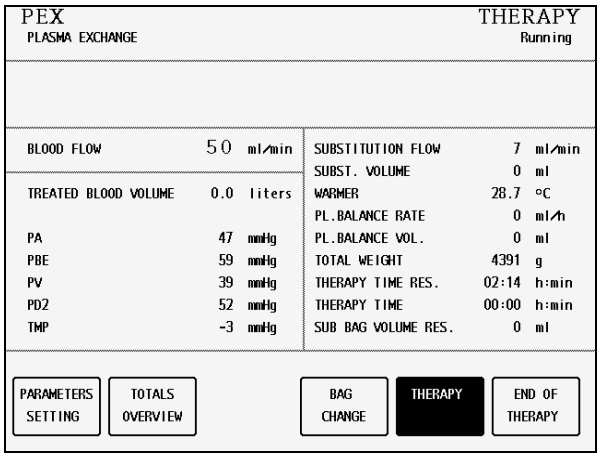
- Confirm the blood leak recalibration by pressing the  key.
- Start the blood pump for circulation by pressing the  key.

9.4.1 Connecting the patient

- Stop the blood pump.
- Connect the arterial line to the arterial access of the patient.
- Start the blood pump and adjust the flow rate using the  or  keys.
- Check that the withdrawal pressure (arterial pressure – PA) is within the prescribed range.
- When the blood starts to fill the venous line, stop the blood pump and connect the venous line to the venous access of the patient.
- Start the blood pump again and adjust the blood flow slowly dependent on the patient's condition.
- Check that the arterial and venous pressure values displayed on the screen are within the normal range.

During therapy, the arterial chamber should be about 50% filled, the venous chamber about 80%.

9.4.2 Start of therapy



After the blood has been circulating for 2- 3 minutes without alarms, the therapy can be started.

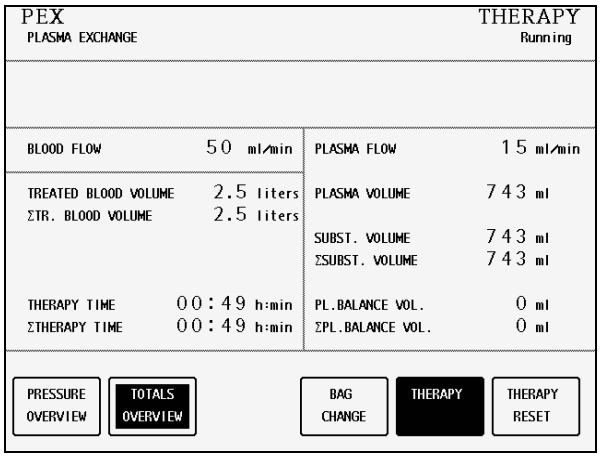
- Select <THERAPY> and activate by pressing the  key.

<THERAPY> in the menu selection field is blackened and in the therapy status field <Running> is indicated.

The treatment is now in progress and the parameter overview is displayed.

The current pressure and flow data of the blood side and the fluid side are displayed on the screen.

9.4.3 Menu selection in therapy



Parameter setting

See Section 9.3.3

Totals overview

➢ Select <TOTALS OVERVIEW> and confirm by pressing the  key.

➢ To return to the <PARAMETERS OVERVIEW> screen, select <TOTALS OVERVIEW> and then press the  key.

The <TOTAL OVERVIEWS> screen displays:

On the left (blood-side) part of the screen

- Current blood flow
- Treated blood volume of the current time segment
- Treated blood volume of the whole treatment (sum of all time segments)
- Therapy time of the current time segment
- Therapy time of the whole treatment (sum of all time segments)

On the right (fluid-side) part of the screen

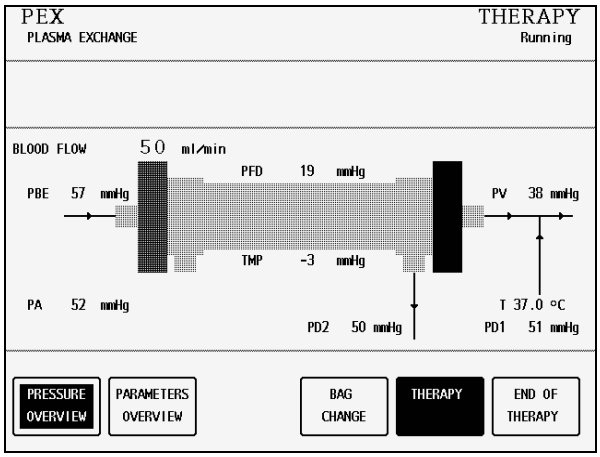
- Current plasma flow
- Current plasma volume
- Substitution solution volume of the current time segment
- Substitution solution volume of the whole treatment (sum of all time segments)
- Current ultrafiltration rate
- Plasma balance volume of the current time segment
- Plasma balance volume of the whole treatment (sum of all time segments)

Therapy reset

<THERAPY RESET> allows to adjust the current values for treated blood volume, therapy time, substitution volume and plasma balance volume to zero. The following volumes and the time are added up from the values marked with Σ.

This allows to follow the data during a certain time segment of the treatment.

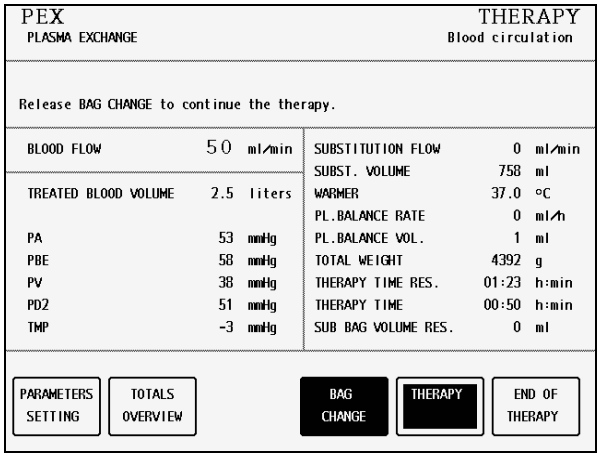
➢ Select <THERAPY RESET> and confirm by pressing the  key.



Pressure overview

<PRESSURE OVERVIEW> allows an overview of all pressures recorded in the system.

- Select <PRESSURE OVERVIEW> and confirm by pressing the  key.
- Select <PARAMETERS OVERVIEW> to return to the <PARAMETERS OVERVIEW> screen and confirm by pressing the  key followed by the  key.



Bag change

The <BAG CHANGE> option allows to change the fluid bags during a running therapy.

- Select <BAG CHANGE> and confirm by pressing the  key.

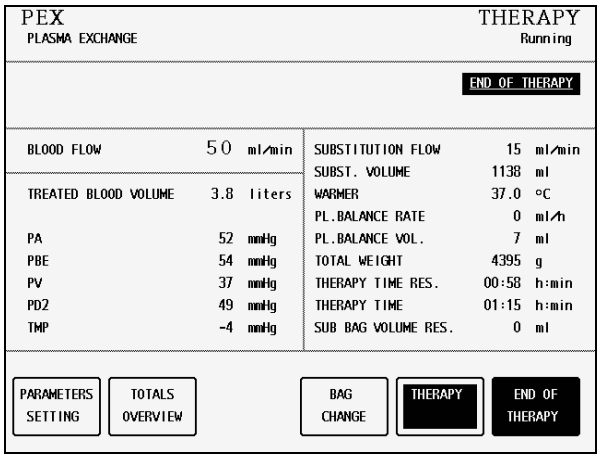
  The plasma pump (MP2) and the substitution pump (MP3) stop. The blood pump (MP1) keeps on running.
- Exchange the bag(s).
- Open the frangible pin if the bag(s) with the substitution solution is exchanged.
- Close the line equipped with the plug if the collecting bag(s) is exchanged.
- After the bag exchange, deactivate <BAG CHANGE> by pressing the  key.

  The treatment continues automatically.

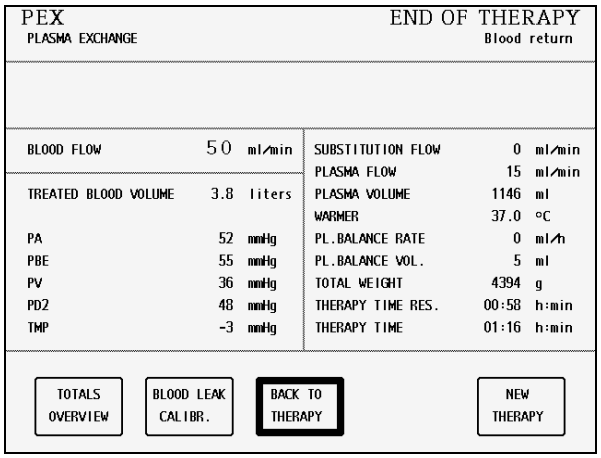
9.5 End of therapy

When the therapy time set is reached, the machine activates a warning (ready-for-therapy tone) and displays the warning message <Therapy is over> in the warning field. The balance pumps stop. Therapy can be continued by simply increasing the therapy time (directly, or indirectly by increasing substitution volume). The warning sound is repeated in 4 minutes until <THERAPY> is deactivated.

The therapy is finished as described in the following.



- Select <END OF THERAPY> and confirm by pressing the  key.
- Confirm by pressing the  key.



The plasma pump (MP2) and the substitution pump (MP3) stop. The blood pump (MP1) continues to run at reduced speed (50 ml/min).

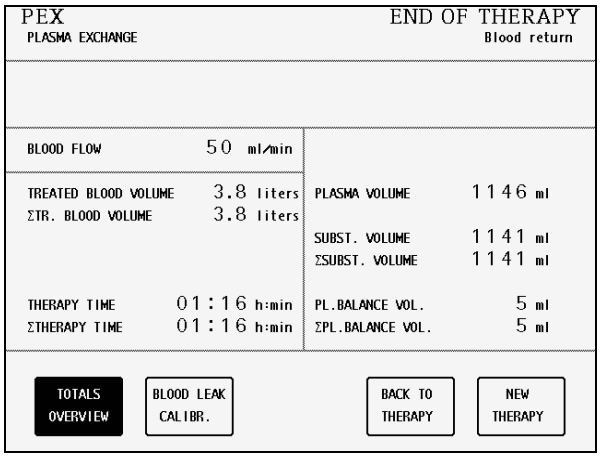
9.5.1 Disconnecting the patient

- Stop the blood pump (MP1).
- Disconnect the arterial line from the patient's arterial access and connect it to a bag with isotonic saline solution.
- Start the blood pump and return the blood in the extracorporeal circuit to the patient.
- Stop the blood pump (MP1) just before the isotonic saline solution enters the patient.
- Disconnect the venous line from the patient's venous access.
- Remove disposable materials and solutions from the device.

Dispose of disposable materials and fluids which have been removed from the device in accordance with local regulations.

Therapy data are stored in the machine for 30 minutes. They can be recalled by switching on the Diapact® CRRT within this time frame.

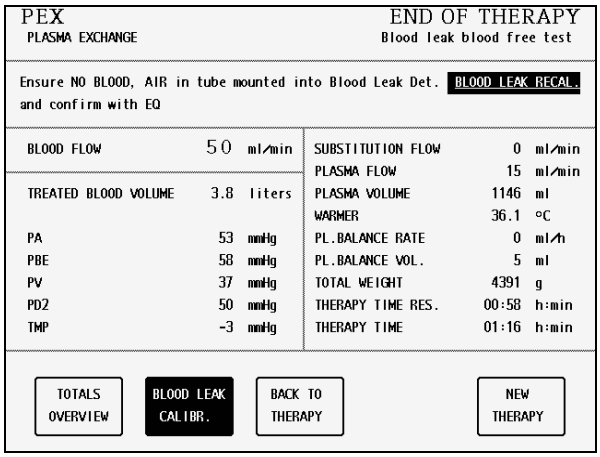
9.5.2 Menu selection at end of therapy



Totals overview

The option <TOTALS OVERVIEW> shows the summary of the pivotal treatment data as described (see Section 9.4.3).

- Select <TOTALS OVERVIEW> and confirm by pressing the  key.
- To return to the <END OF THERAPY> screen, select <TOTALS OVERVIEW> and confirm with the  key.



Blood leak recalibration

The <BLOOD LEAK CALIBRATION> function allows the recalibration of the blood leak detector in case of non-acceptable alarms (e.g. elevated plasma bilirubin concentration).

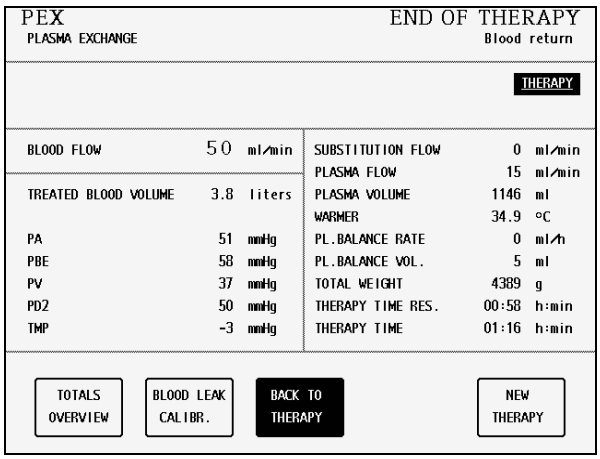
- Select “BLOOD LEAK CALIBRATION” and confirm with the key. The EQ key lights up.
- Confirm with the EQ key.
- Select <BACK TO THERAPY> and confirm with the key. The EQ key lights up.
- Confirm with the EQ key.
- Adapt the blood flow to the initial value.
- Start <THERAPY> by pressing the key.

DANGER

Risk of blood loss for the patient and haemolysis

- **Before the recalibration of the blood leak detector, the filter must be carefully checked for possible blood leaks and haemolysis.**
- **It is recommended to withdraw a sample (at least 2 ml) from the injection port of the filtrate line and to analyze for erythrocytes and/or free haemoglobin.**
- **The blood leak recalibration must only be performed if these tests are negative.**

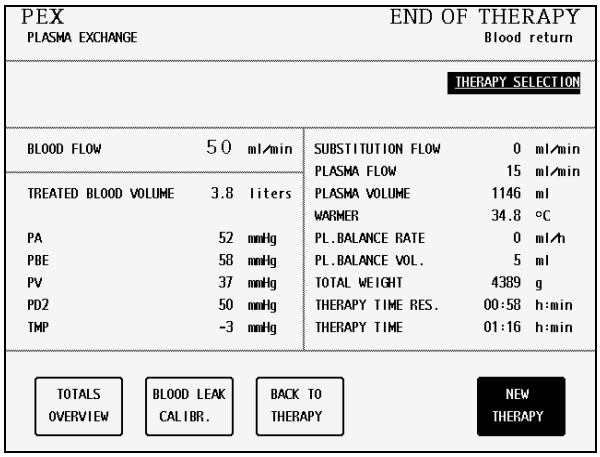
The balance pumps will not start up again until blood leak calibration has been completed.



Back to therapy

The option <BACK TO THERAPY> returns to the just finished therapy.

- Select <BACK TO THERAPY> and confirm by pressing the key. The EQ key lights up.
- Confirm by pressing the EQ key.
- Start the therapy again by pressing the key.



New therapy

The option <NEW THERAPY> allows to start a new therapy immediately after the one just finished. The device switches directly to therapy selection.

- Select <NEW THERAPY> and confirm by pressing the  key. The  key lights up.
- Confirm by pressing the  key.

DANGER

Risk of blood loss and infection for the patient

- **To guarantee the safe therapy for the patient, the consumables (line system, plasmafilter, solution bags) used in the just finished therapy must be completely replaced.**

9.6 Special functions

Automatic substitution flow reduction

Automatic substitution flow reduction is an automatic parameter adaptation to the current filter state undertaken by the system.

If the ultrafiltration flow cannot be achieved, the following control mechanism is performed:

If PD2 pressure reaches a value 20 mmHg above the set PD2 min. value, the substitution flow will be automatically reduced as a function of the filter state.

It can result that the required substitution volume is not reached. To guarantee that the system does not fall below the required substitution volume, the flow is automatically increased slightly, if the reduction of the substitution flow is not necessary anymore.

Ramping

This function prevents the build-up of a secondary membrane on the membrane as a result of underpressure created by jerky pump starts.

The balance pumps starts at reduced speed at the start of therapy, after every stop of the blood pump or the balance pumps, and after certain parameter changes.

To guarantee that the system does not fall below the required substitution volume, the flow is automatically increased slightly during the therapy.

The raising of the flow, as well as the continuous raising of the flow, depends on the frequency of ramping.

Bag movement function

To avoid superfluous alarms and the resulting pump standstill, the Diapact® CRRT has a function which is actuated by slight movements of the machine during therapy.

When this function is actuated, the ultrafiltration and the dialysate pumps stop without an alarm and start again automatically when the initial weight (i.e. the weight before the movement of the machine or bag) is reached again.

Automatic temporary reduction of the blood flow

If PA min is reached, blood flow automatically drops to 25% (but not lower than 60 ml/min) to prevent standstill of the blood pump caused by movement of the patient. The ultrafiltration and the dialysate pumps stop also for a short time without an alarm.

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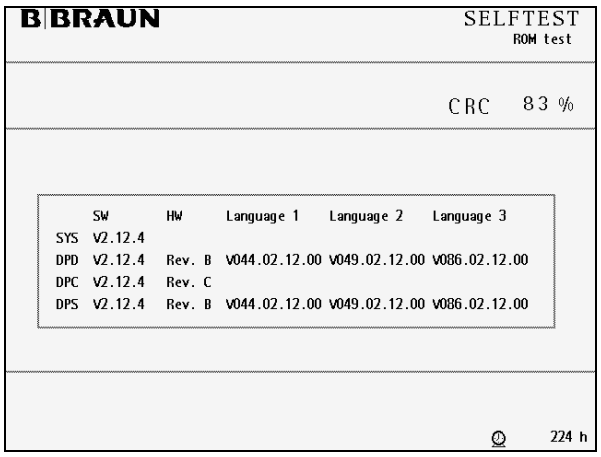
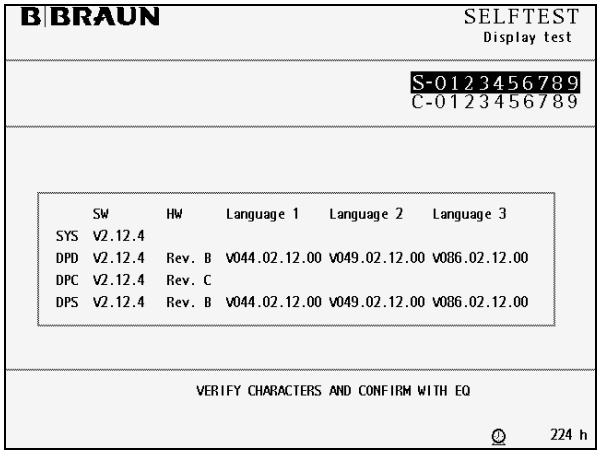
10 PAP (Plasma adsorption/perfusion)

10.1 Switching on and initial tests

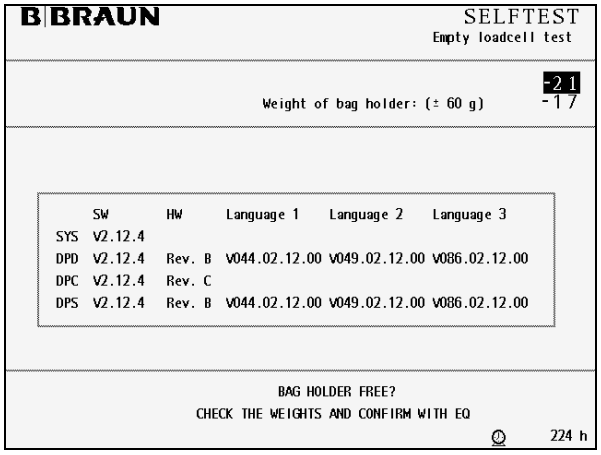


- Switch on the Diapact® CRRT with the power switch ON/OFF (I/O) on the back of the machine. The device starts with the ROM test.
- Check whether the AQ and EQ keys are lit during the ROM test.



The ROM test is followed by the display test.

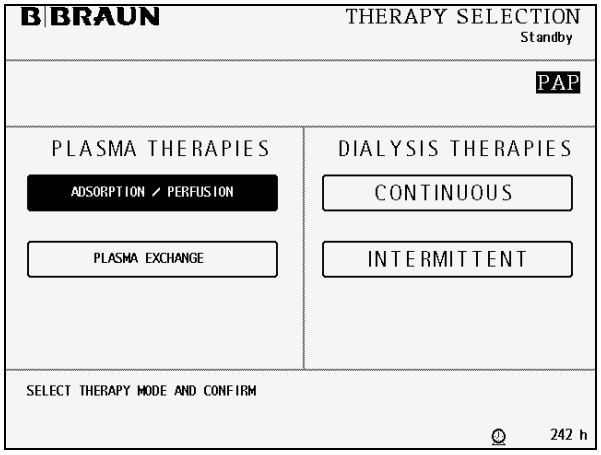
- Compare the character lines in the supervisor field and confirm by pressing the EQ key if both series are identical.
- While the EQ key is being pressed, the buzzer of the safety system is activated for 2 seconds.
- Check that the buzzer can be heard.



If the display test is passed successfully, the empty load cell test follows.

- Check whether the bag holder is empty.
- Confirm the weight values with the EQ key if they are within the allowed range. The maximum deviation between both displayed values is allowed to be ± 60 g and the values must not exceed -60 and +60 g.

10.2 Therapy selection



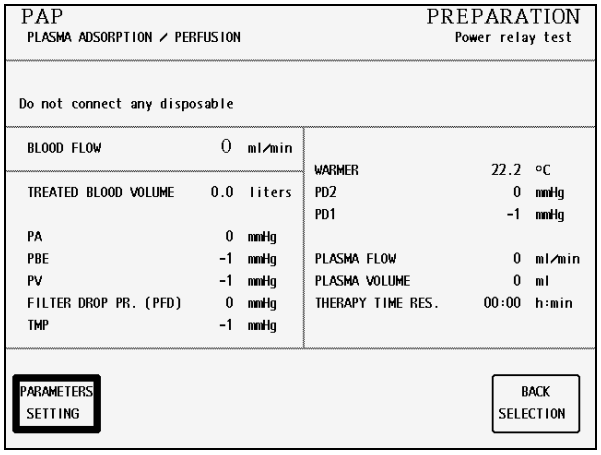
Having successfully passed the initial self tests the machine switches to the <THERAPY SELECTION>.

<CONTINUOUS> dialysis therapies is selected by default.

- To select <ADSORPTION/PERFUSION> move to the respective position with the  and  keys.
- Confirm <<ADSORPTION/PERFUSION> with the  key.

  <ADSORPTION/PERFUSION> flashes in the supervisor field.
- Press the  key for final confirmation.

10.3 Preparation

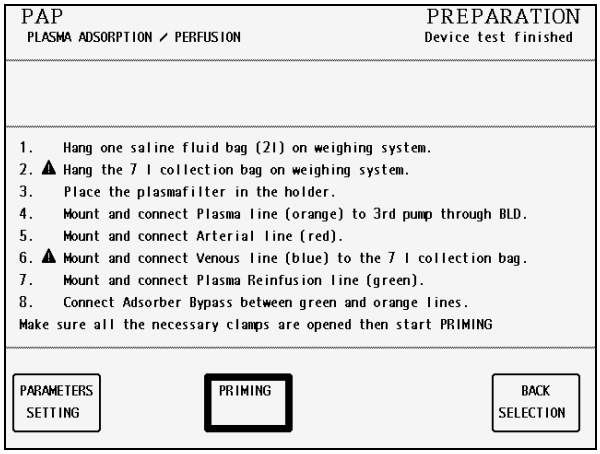


After modality selection and confirmation, the display shows the following <PREPARATION> screen.

Several tests are performed. The respective test is displayed in the therapy status field:

- Power relay test
- SAD reference test
- SAD counter test
- Red detector test
- Blood leak detector test
- Zero pressure test

10.3.1 Installation of consumable material



When the tests have been performed successfully the <PREPARATION> screen displays <Device test finished> and the steps to set-up the machine are displayed.

The consumable material for the therapy comprises:

- PAP kit
- Plasmafilter
- 2 x 2L isotonic sodium chloride solution
- Adsorber according to the prescription of the attending physician

➢ Follow the instructions on the screen and set-up the device as described in the following.

The lines of the HF/HD kit are colour-coded to facilitate the set-up.

Arterial line (**red**)
Venous line (**blue**)
Plasma line (**yellow**)
Plasma reinfusion line (**green**)

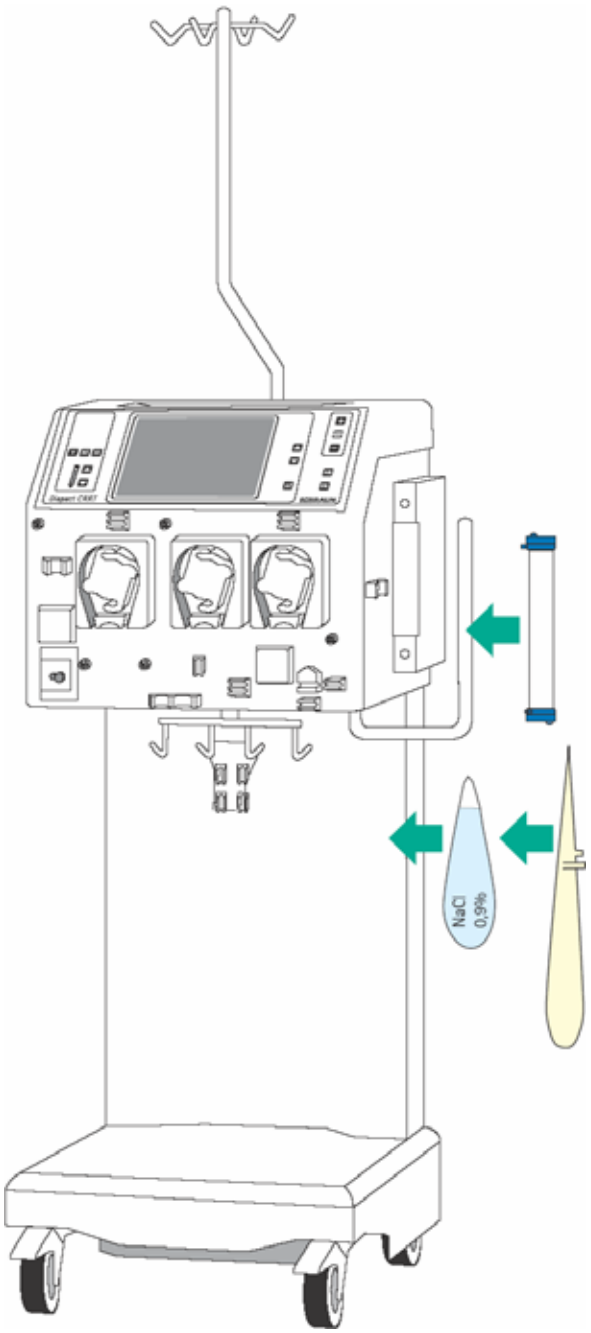
Pumps used:

Blood pump (MP1)
Substitution pump (MP3) / Plasma pump in PAP

WARNING

Risk of infection and blood loss for the patient by damaged packaging or components

- ➢ **Make sure during set-up that the packaging of the material used (line system, plasma filter, solution bags) is undamaged.**
- ➢ **During set-up check the material for integrity.**
- ➢ **Observe the respective instructions for use.**



Installation of bags and filter

- Attach one of the 2L bag with isotonic sodium chloride solution and the collecting bag to the bag holder of the load cell.
- Fix the plasmafilter into the filter holder on the right side of the machine.

CAUTION

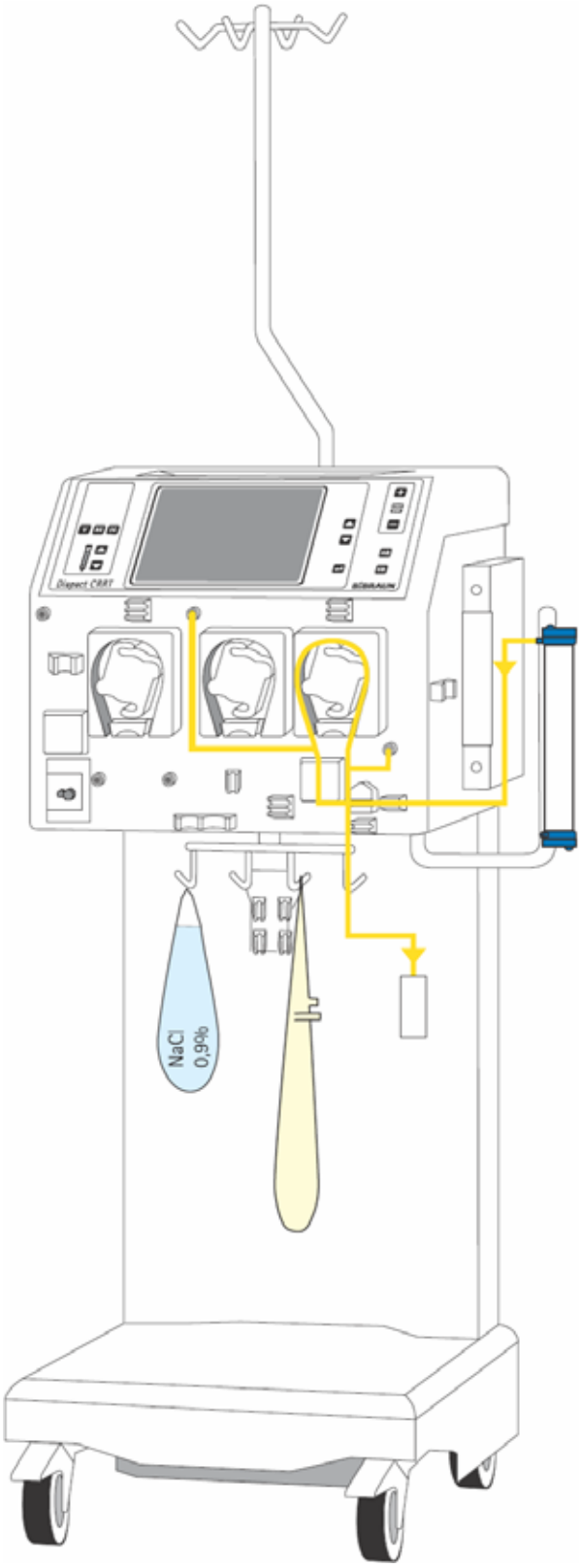
Incomplete moistening of the plasmafilter during priming and rinsing may result in performance reduction.

- **Place the filter into the filter holder with the arterial port (red) downwards.**

If the weight on the load cell is unevenly distributed, there is a risk that the device may topple.

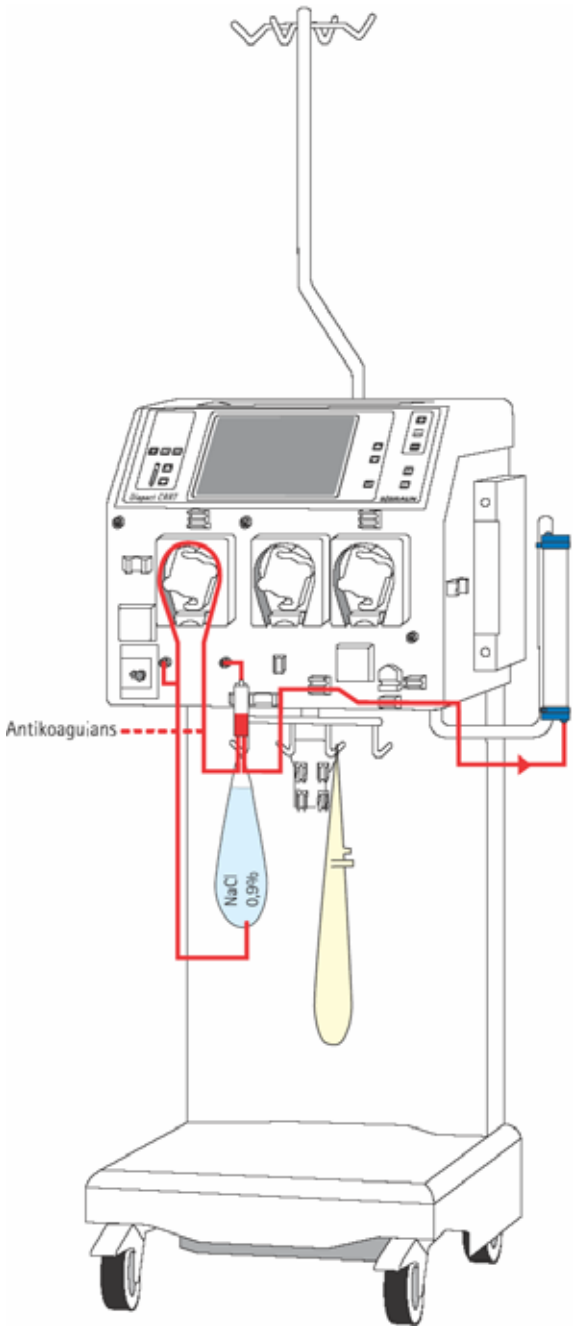
- **Distribute weight on the bag holder evenly.**

The maximal load of the load cell is 27 kg.



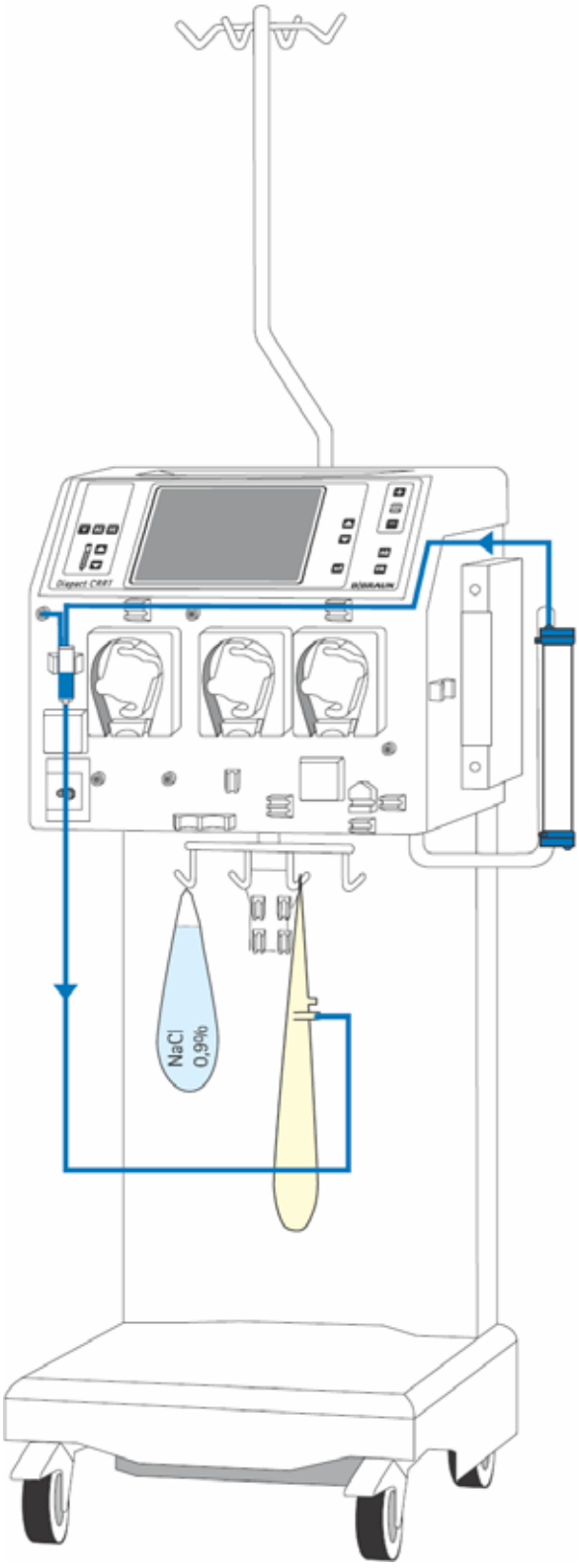
Insertion of the plasma outlet line (yellow)

- Connect the plasma outlet line to the filtrate side of the filter next to the venous connector.
- Insert the line coming from the plasmafilter into the blood leak detector (BLD).
- Insert the pump segment into the plasma pump (MP3).
- Insert the line leaving the pump on the left side into the air detector.
- Connect the transducer protector before the pump to the pressure sensor PSC/PD2 (white).
- Connect the transducer protector after the pump to the pressure sensor PD1 (white).
- Connect the line with the Luer Lock connector to the adsorber bypass adapter.



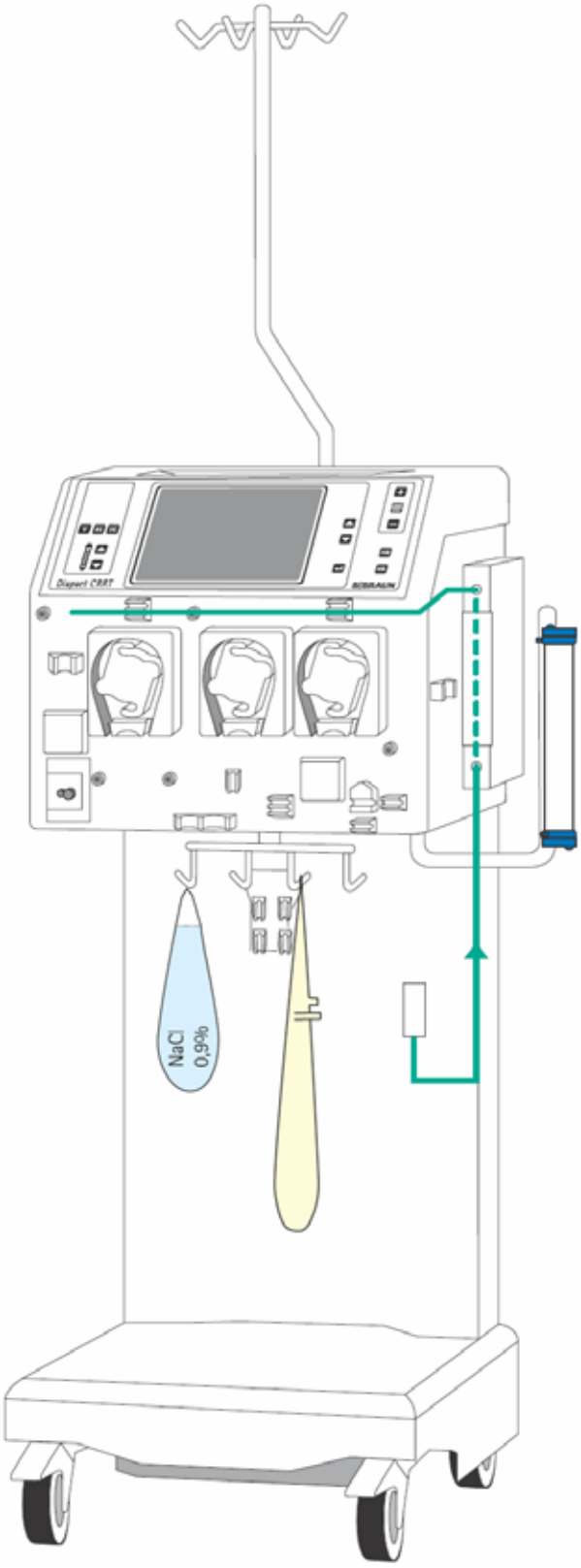
Insertion of the arterial line (red)

- Connect the end of the line with the spike/Luer Lock connector to the bag with isotonic sodium chloride solution on the bag holder of the load cell.
- Insert the pump segment into the blood pump (MP1).
- Connect the transducer protector before the blood pump to the pressure sensor PA (red).
- Insert the arterial air trap into the intended holder.
- Connect the transducer protector to the pressure sensor PBE (red).
- Connect the red Luer Lock connector to the lower blood-side connector of the plasmafilter.
- If continuous heparinisation is required, connect the heparin line to the external heparin pump previously filled with heparin.
- Close the clamp of the heparin line if it is not used.
- Close the clamps at the sampling ports before and after the blood pump (MP1).



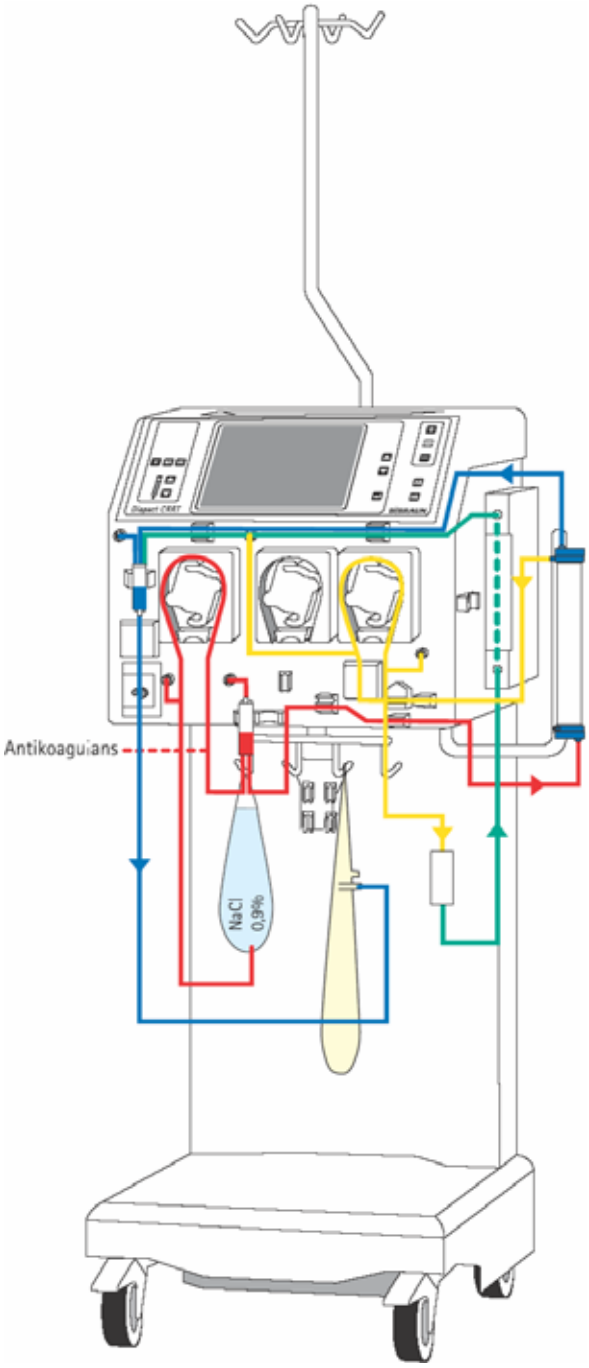
Insertion of the venous line (blue)

- Connect the blue Luer Lock connector to the upper blood-side connector of the plasmafilter.
- Insert the venous air trap into the intended holder and fix the line in the line fixing above the pumps.
- Insert the venous line beneath the air trap into the safety air detector (SAD) and the safety air clamp (SAK) under the detector.
- Connect the end of the line with the collecting bag attached to the load cell.
- Connect the transducer protector to the pressure sensor PV (blue).
- Close the clamps at the not used connection of the air trap.



Insertion of the plasma reinfusion line (green)

- Insert the heater bag into the plate heater and close the cover. To ensure that the bag has optimal contact to the heater, close the cover audibly.
- Connect the plasma reinfusion line leaving the upper part of the heater to the venous air trap and fix the line in the line fixing above the pumps.
- Connect the plasma reinfusion line leaving the lower part of the heater to the adsorber bypass adapter.

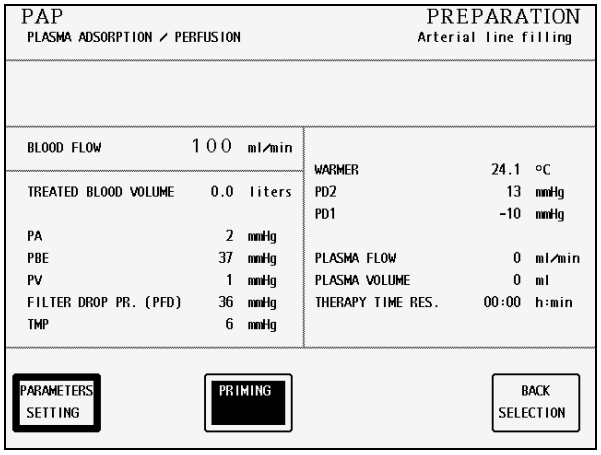


Set-up overview

- ➢ Check the set-up before starting the priming procedure.
- ➢ Take care that all connections are firmly screwed together.
- ➢ Check that all pump segments are inserted clockwise.
- ➢ Check that the following clamps are closed:
  - Sampling ports before and after the blood pump
  - Heparin line if it is not used
  - Not used line at the venous chamber
  - Line with the plug at the collecting bag
- ➢ Open the frangible pin of the sodium chloride solution bag.

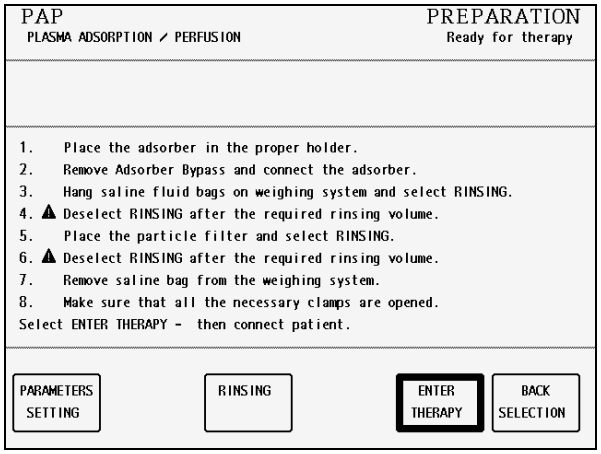
i Make sure that all relevant clamps are opened and that all connections are firmly screwed together before starting the priming procedure.

10.3.2 Priming



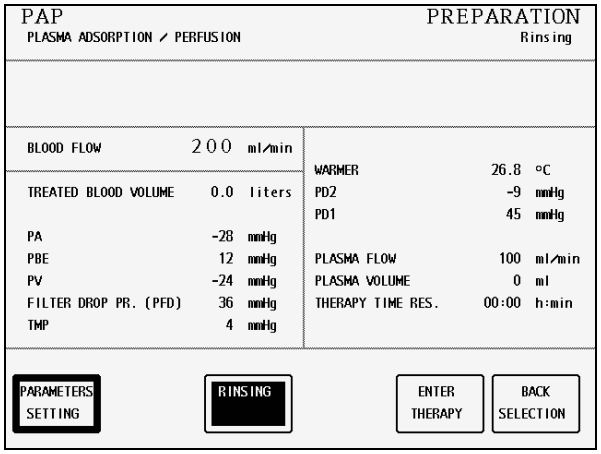
- After set-up of the consumables and checking the connections, select <PRIMING> and confirm by pressing the  key.

The automatic priming program starts. During the priming and rinsing the following tests are performed: air detector test, disposable leakage test, and level regulation takes place. The respective step of the procedures and the test is displayed in the therapy status field.



After the preparation phase has been finished, the system gives an acoustic signal and shows the <PREPARATION> screen with message <Ready for therapy> in the therapy status field.

- Place the adsorber in the intended holder.
- Clamp the line before and after the adsorber bypass.
- Remove the adsorber bypass and connect the adsorber.
- Remove the clamps.
- Attach the second bag with isotonic saline solution to the hooks of the load cell.

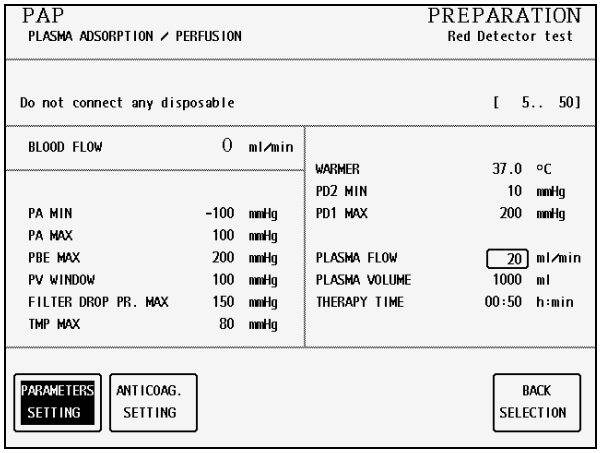


- Select <RINSING> and confirm with the  key.
- Rinse the adsorber with as much sodium chloride solution as specified in the instruction for use.
- Deactivate rinsing when the necessary rinsing volume is reached.
- Remove the bag with the sodium chloride solution from the load cell and attach it to the infusion pole.
- Make sure that all relevant clamps are open.
- Select <ENTER THERAPY> and confirm by pressing the  key.

The device switches automatically to <PARAMETERS SETTING>.

Follow carefully the instructions on using the adsorber fitted.

10.3.3 Parameter setting



- Select <PARAMETERS SETTING> to enter the individual treatment data.
- Confirm with the  key.
- Select the parameter to be set with the  or  key.
- Activate the parameter by pressing the  key.
- Change the value with the  or  key
  and confirm the change with the  key.
- To exit <PARAMETERS SETTING>, press the  key.

These treatment data can be set at any time during the preparation phase or the therapy if the <PARAMETERS SETTING> option is displayed.

The following data can be set in the indicated ranges:

Parameter	Unit	Default	Min	Max	Increments
Blood-side parameters					
Blood flow	ml/min	50	10/5	300	5/10
PA min.	mmHg	-100	-400	PA max.	10
PA max.	mmHg	100	PA min.	200	10
PBE max.	mmHg	200	0	500	10
PV window	mmHg	100	80	160	10
PFD max. pressure drop	mmHg	150	100	450	10
TMP max.	mmHg	80	20	150	10
Fluid-side parameters					
Plasma flow	ml/h	20	5	50	1/5
Temperature	°C	37	20	37	0.5/1.0
PD2 min.	mmHg	10	-250	250	10
PD1 max.	mmHg	200	50	400	10
Plasma volume	ml	1000	0	6000	100/500
Plasma flow	ml/min	20	5	50	1/5
Therapy time	h:min	0:50	00:00	08: 00	0:05/0:30

These treatment data can be set at any time during the preparation phase or the therapy if the <PARAMETERS SETTING> option is displayed.

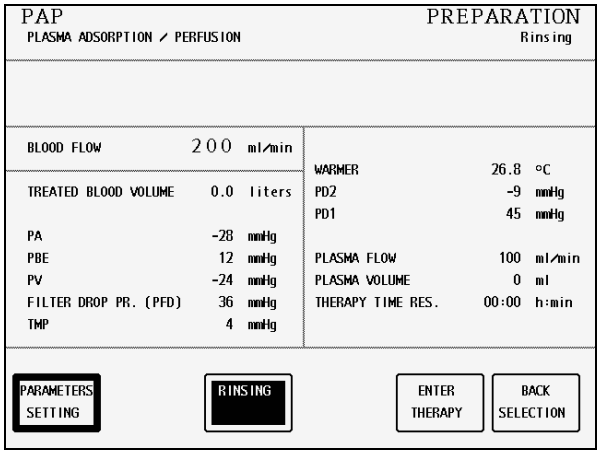
In PAP, as an intermittent therapy, the change of the following variables automatically leads to a change in dependent variables.

Changed parameter	Dependently changed parameter
Plasma flow	Therapy time
Plasma volume	Therapy time
Therapy time	Plasma flow

The dependently changed treatment parameters flash, but they do not have to be confirmed separately.

Setting the plasma volume or the therapy time to zero results in a switch from volume control to rate control.

10.3.4 Menu selection in preparation



Rinsing

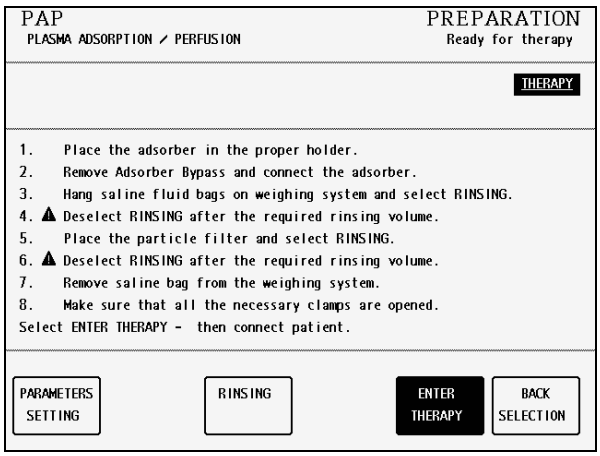
- If necessary, rinsing can be prolonged by selecting <RINSING> and confirming with the  key.
- If only the blood side has to be rinsed, the fluid side can be stopped by opening the cover of the plasma pump (MP3).
- To finish the additional rinsing select <RINSING> again and confirm with the  key.

Back selection

Choosing back selection allows to return to the <THERAPY SELECTION> screen.

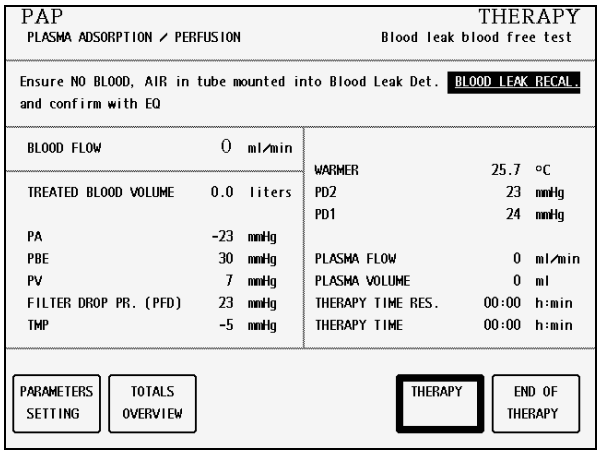
- Select <BACK SELECTION> and confirm with the  key.

10.4 Therapy



- To switch from <PREPARATION> to <THERAPY>, select <ENTER THERAPY> and confirm by pressing the  key.
- Confirm the start of the therapy by pressing the flashing 

key while <THERAPY> is flashing in the supervisor field.



The Diapact® CRRT is now in the therapy status as indicated in the therapy status field.

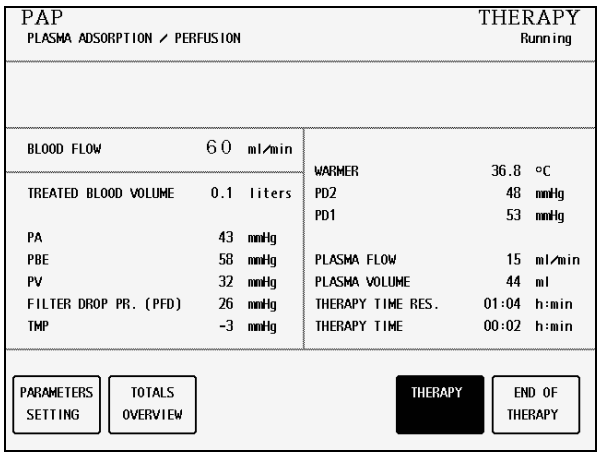
- Confirm the blood leak recalibration by pressing the EQ key.
- Start the blood pump for circulation by pressing the START STOP key.

10.4.1 Connecting the patient

- Stop the blood pump.
- Connect the arterial line to the arterial access of the patient.
- Start the blood pump and adjust the flow rate using the + or − keys.
- Check that the withdrawal pressure (arterial pressure – PA) is within the prescribed range.
- When the blood starts to fill the venous line, stop the blood pump and connect the venous line to the venous access of the patient.
- Start the blood pump again and adjust the blood flow slowly dependent on the patient's condition.
- Check that the arterial and venous pressure values displayed on the screen are within the normal range.

i During therapy, the arterial chamber should be about 50% filled, the venous chamber about 80%

10.4.2 Start of therapy



After the blood has been circulating for 2- 3 minutes without alarms, the therapy can be started.

- Select <THERAPY> and activate by pressing the ↵ key.

<THERAPY> in the menu selection field is blackened and in the therapy status field <Running> is indicated.

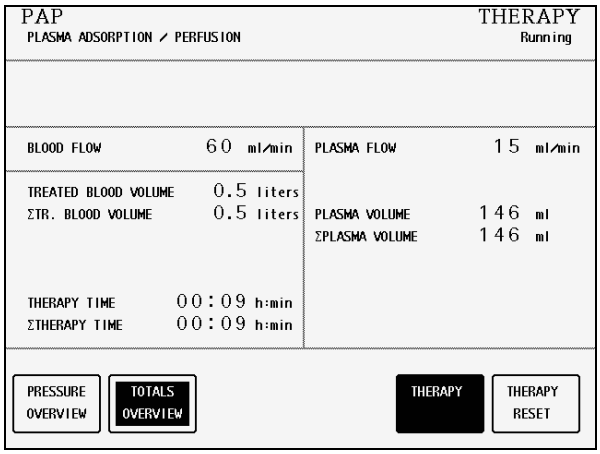
The treatment is now in progress and the parameter overview is displayed.

The current pressure and flow data of the blood side and the fluid side are displayed on the screen.

10.4.3 Menu selection in therapy

Parameter setting

See Section 10.3.3



Totals overview

- Select <TOTALS OVERVIEW> and confirm by pressing the  key.
- To return to the <PARAMETERS OVERVIEW> screen, select <TOTALS OVERVIEW> press the  key.

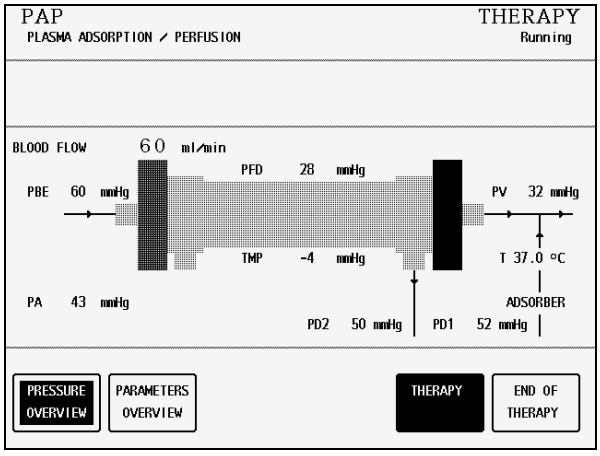
The <TOTAL OVERVIEWS> screen displays:

On the left (blood-side) part of the screen

- Current blood flow
- Treated blood volume of the current time segment
- Treated blood volume of the whole treatment (sum of all time segments)
- Therapy time of the current time segment
- Therapy time of the whole treatment (sum of all time segments)

On the right (fluid-side) part of the screen

- Current plasma flow
- Plasma volume of the current time segment
- Plasma volume of the whole treatment (sum of all time segments)



Pressure overview

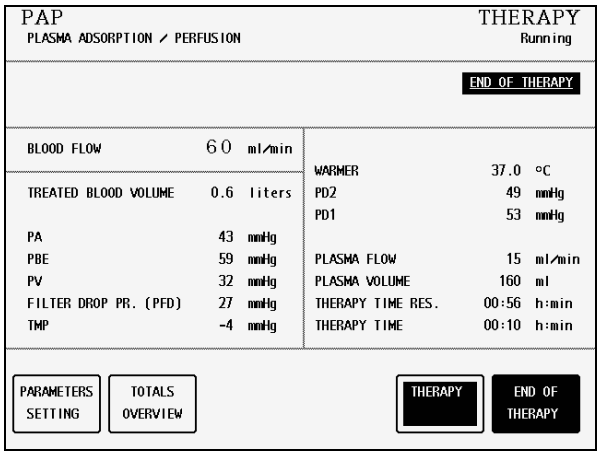
<PRESSURE OVERVIEW> allows an overview of all pressures recorded in the system.

- Select <PRESSURE OVERVIEW> and confirm by pressing the  key.
- Select <PARAMETERS OVERVIEW> to return to the <PARAMETERS OVERVIEW> screen and confirm by pressing the  key.

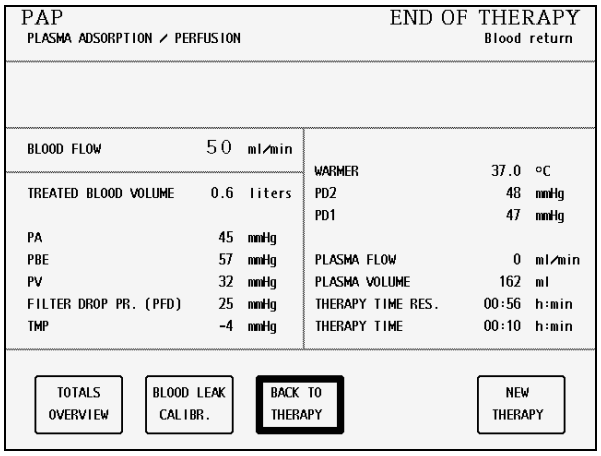
10.5 End of therapy

When the therapy time set is reached, the machine activates a warning (ready-for-therapy tone) and displays the warning message <Therapy is over> in the warning field. The balance pumps stop. Therapy can be continued by simply increasing the therapy time (directly, or indirectly by increasing plasma volume or UF volume). The warning sound is repeated in 4 minutes until <THERAPY> is deactivated.

The therapy is finished as described in the following.



- Select <END OF THERAPY> and confirm by pressing the  key.
- Confirm by pressing the  key.



The plasma pump (MP3) and the substitution pump (MP3) stop. The blood pump (MP1) continues to run at reduced speed (50 ml/min).

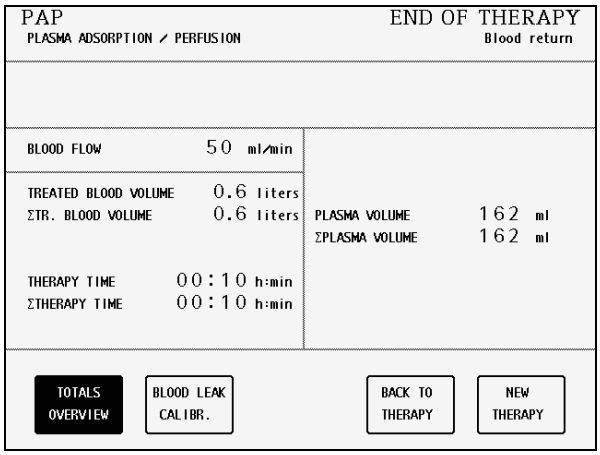
10.5.1 Disconnecting the patient

- Stop the blood pump (MP1).
- Disconnect the arterial line from the patient's arterial access and connect it to a bag with isotonic saline solution.
- Start the blood pump and return the blood in the extracorporeal circuit to the patient.
- Stop the blood pump (MP1) just before the isotonic saline solution enters the patient.
- Clamp the venous line directly after the plasmafilter.
- Remove the pump segment from the plasma pump and start the blood pump again to reinfuse the plasma into the patient.
- Disconnect the venous line from the patient's venous access.
- Remove disposable materials and solutions from the device.

Dispose of disposable materials and fluids which have been removed from the device in accordance with local regulations.

Therapy data are stored in the machine for 30 minutes. They can be recalled by switching on the Diapact® CRRT within this time frame.

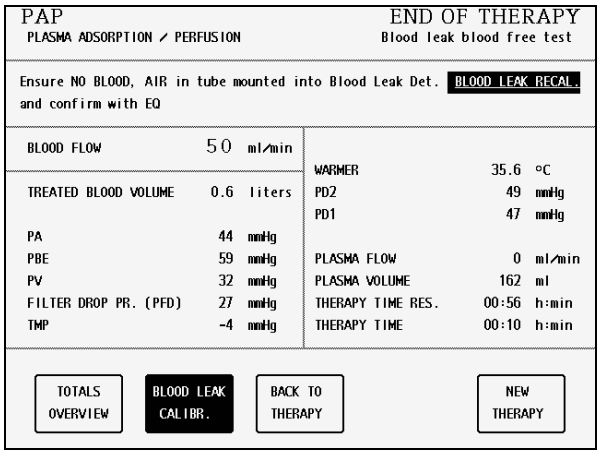
10.5.2 Menu selection at end of therapy



Totals overview

The option <TOTALS OVERVIEW> shows the summary of the pivotal treatment data as described (see Section 10.4.3)

- Select <TOTALS OVERVIEW> and confirm by pressing the  key.
- To return to the <END OF THERAPY> screen, select <TOTALS OVERVIEW> and confirm with the  key.



Blood leak recalibration

The <BLOOD LEAK CALIBRATION> function allows the recalibration of the blood leak detector in case of non-acceptable alarms (e.g. elevated plasma bilirubin concentration).

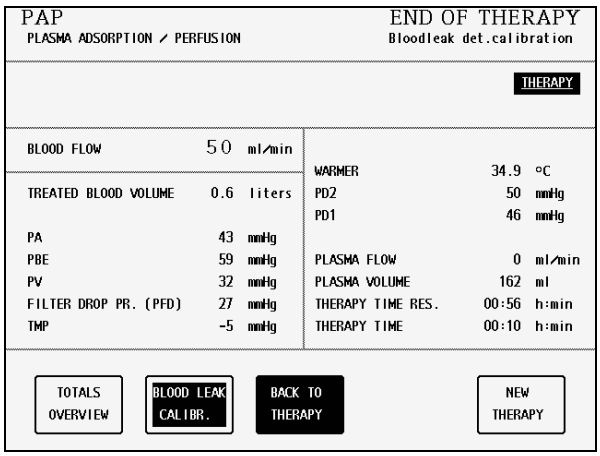
- Select “BLOOD LEAK CALIBRATION” and confirm with the key. The EQ key lights up.
- Confirm with the EQ key.
- Select <BACK TO THERAPY> and confirm with the key. The EQ key lights up.
- Confirm with the EQ key.
- Adapt the blood flow to the initial value.
- Start <THERAPY> by pressing the key.

DANGER

Risk of blood loss for the patient and haemolysis

- **Before the recalibration of the blood leak detector, the filter must be carefully checked for possible blood leaks and haemolysis.**
- **It is recommended to withdraw a sample (at least 2 ml) from the injection port of the filtrate line and to analyze for erythrocytes and/or free haemoglobin.**
- **The blood leak recalibration must only be performed if these tests are negative.**

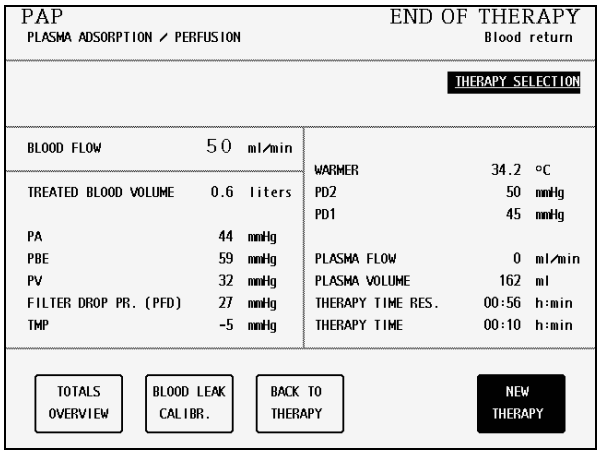
The plasma pump will not start up again until blood leak calibration has been completed.



Back to therapy

The option <BACK TO THERAPY> returns to the just finished therapy.

- Select <BACK TO THERAPY> and confirm by pressing the key. The EQ key lights up.
- Confirm by pressing the EQ key.
- Start the therapy again by pressing the key.



New therapy

The option <NEW THERAPY> allows to start a new therapy immediately after the one just finished. The device switches directly to therapy selection.

- Select <NEW THERAPY> and confirm by pressing the  key. The  key lights up.
- Confirm by pressing the  key.

DANGER

Risk of blood loss and infection for the patient

- **To guarantee the safe therapy for the patient, the consumables (line system, filter, solutions) used in the just finished therapy must be completely replaced.**

10.6 Special functions

Automatic temporary reduction of the blood flow

If PA min is reached, blood flow automatically drops to 25% (but not lower than 60 ml/min) to prevent standstill of the blood pump caused by movement of the patient. The ultrafiltration and the dialysate pumps stop also for a short time without an alarm.

Table of contents

11 Perfusor interface

11.1 General information

The option Diapact® Perfusor Interface allows to connect the

- Perfusor compact S or the
- Perfusor fm

to the Diapact® CRRT as anticoagulation pump in all therapies.

The respective perfusor is connected to Diapact® CRRT via a special interface cable that also provides the power supply for the perfusor. Data concerning the anticoagulation are entered on the Diapact® CRRT user interface.

!	The Diapact® Perfusor interface is approved only to be operated with the Perfusor compact S or the Perfusor fm. The Diapact® Perfusor interface is approved only for the anticoagulant infusion with the Diapact® CRRT. Do not connect the power cable of the perfusor when using it connected to the Diapact® CRRT. The attending physician is responsible for the applied anticoagulant dose. Observe the instructions for use of the Perfusor compact S or the Perfusor fm.

11.2 Connecting the perfusor

- ➢ Attach the perfusor holder to the IV pole of the Diapact® CRRT.
- ➢ Insert the perfusor into the holder.
- ➢ Connect the Diapact® CRRT with the interface cable to the respective perfusor.

  The interface cable is connected to the Diapact® CRRT at the interface marked in the Figure and to the perfusor at the respective interface at the rear of the perfusor.

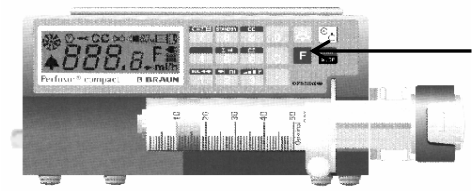
11.3 Preparing Diapact® CRRT and perfusor for therapy

- Prepare the Diapact® CRRT for therapy as described in the respective Section.
- Deaerate the anticoagulation line manually or using the anticoagulation bolus function during priming and rinsing.
- Connect the anticoagulation line to the syringe filled with the anticoagulant.
- Insert the syringe into the perfusor.

WARNING

Using a non CE marked syringe might significantly change the technical specification of the perfusor and lead to inadequate anticoagulation therapy.

- **Use only CE marked sterile syringes with standardized Luer Lock connector. For further information, see the list of applicable syringes in the instructions for use of the respective perfusor.**

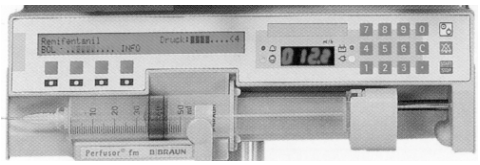


Perfusor compact S

The type of syringe is indicated on the display of the perfusor.

- Accept the type of syringe by pressing the F-key of the perfusor.

CC for Communication Control flashes in the display. In this mode the perfusor is ready for communication with the Diapact® CRRT.

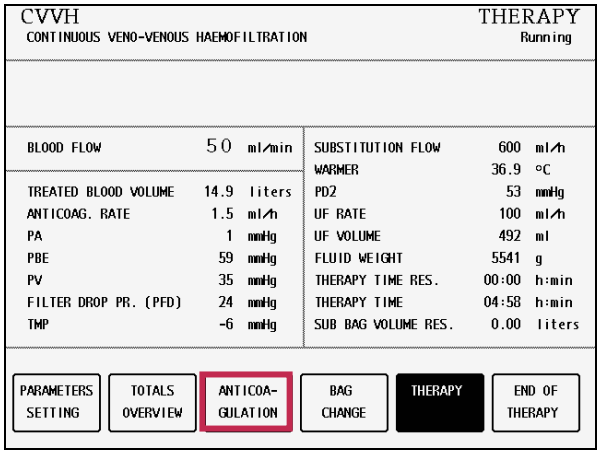


Perfusor fm

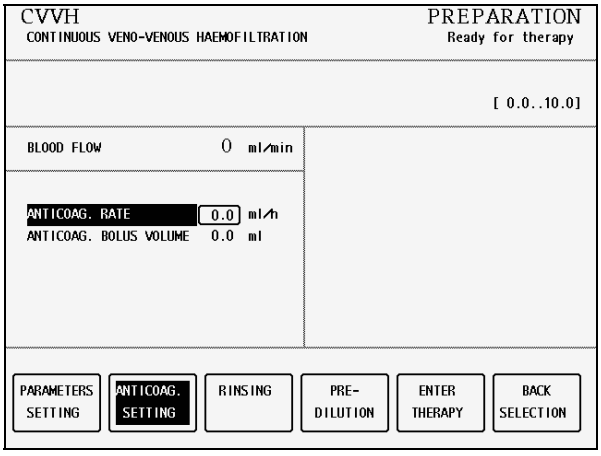
The type of syringe is indicated on the display of the perfusor. The type of syringe used is detected automatically.

CC for Communication Control flashes in the display. In this mode the perfusor is ready for communication with the Diapact® CRRT

11.4 Setting the anticoagulation parameters



The anticoagulation parameters can be set or changed at any time during preparation and therapy when the <ANTICOAGULATION> menu item is displayed.



Before starting the therapy

At the end of the preparation phase after <PARAMETERS SETTING>, the screen switches automatically to <ANTICOAGULATION SETTING>.

- Set the anticoagulation rate by selecting the respective parameter with the  or the  key and confirming with the  key.

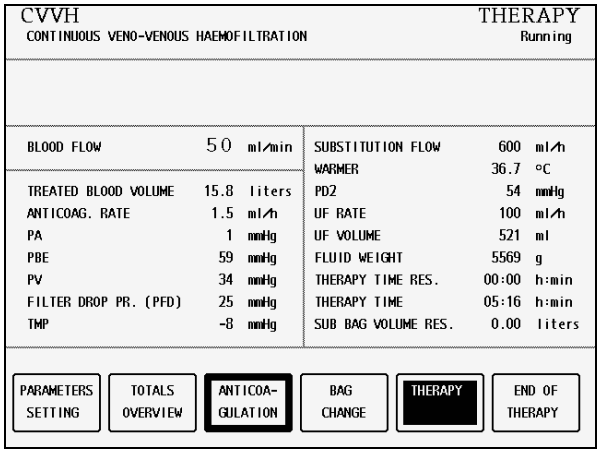
  The  key flashes and the set anticoagulation rate is displayed in the supervisor field.
- Compare the value displayed in the supervisor field with that shown in the fluid-side parameters field and confirm with the  key if they are identical.
- To set the anticoagulation bolus volume, select the parameter with the  or the  key and confirm with the  key.
- To return to <PARAMETERS OVERVIEW>, press the  key.

How to perform the anticoagulant bolus is described in Section 11.6.

If anticoagulation rate and anticoagulation bolus volume are set to 0, the therapy will run without application of anticoagulant.

Software 2.12 and 2.12.x

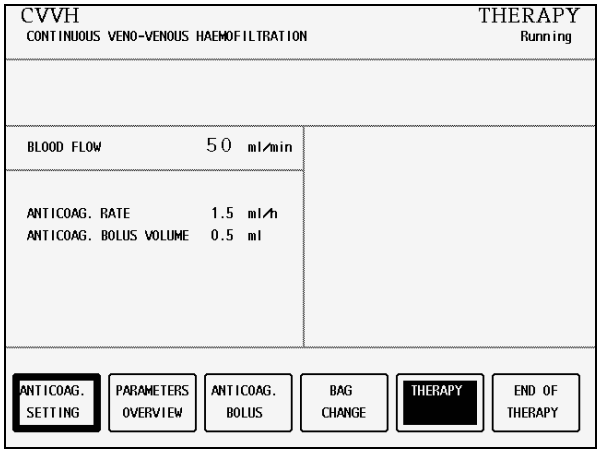
The display changes automatically from <PARAMETERS SETTING> and <ANTICOAGULATION SETTING> to <PARAMETERS OVERVIEW> if there is no cursor movement and no parameter is being edited or to be checked for longer than one minute.



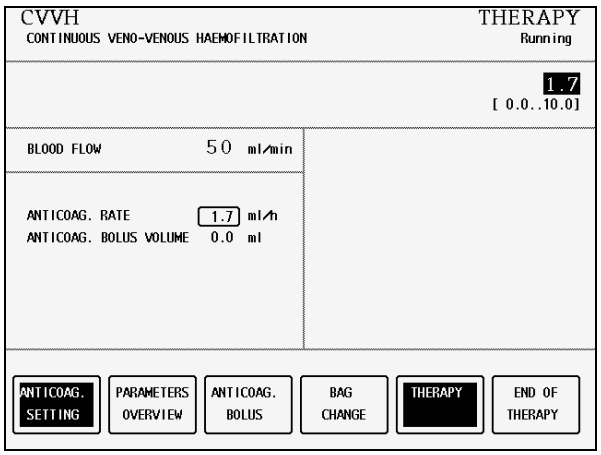
During the therapy (or preparation phase)

The anticoagulation parameters can be set at any time when the <ANTICOAGULATION> menu item can be selected.

- To change the anticoagulation parameters, select <ANTICOAGULATION> with  or the  key.
- Confirm the selection with the  key.



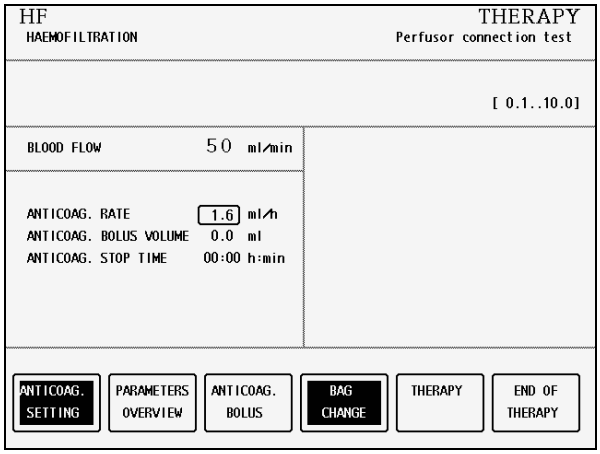
- Select <ANTICOAGULATION SETTING> with the  or the  key.
- Confirm the selection with the  key.



- Select the <Anticoagulation rate> with the  or the  key.
- Confirm the selection with the  key.
- Increase the selected value with the  key or decrease it with the  key.
- Confirm the change with the  key. The  key flashes.
- Compare the value displayed in the supervisor field with that shown in the fluid-side parameters field and confirm with the  key if they are identical.

- Return to <PARAMETERS OVERVIEW> by pressing the  key.
- To set the anticoagulation bolus volume, select the parameter with the  or the  key and confirming with the  key.
- To return to <PARAMETERS OVERVIEW>, press the  key.

How to perform the anticoagulant bolus is described in Section 11.6



Intermittent therapies

An additional anticoagulation stop time is available in intermittent and plasma therapies.

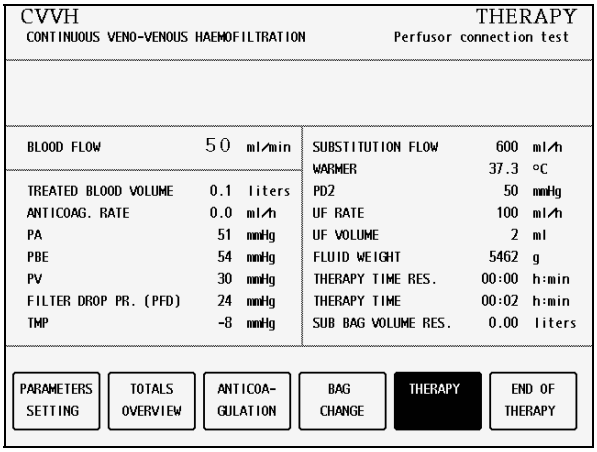
The time set indicates the time before the end of the therapy when the infusion of the anticoagulant stops.

If the anticoagulation time is set to 00:00 the anticoagulant is infused until the end of the therapy.

The following data can be set in the indicated ranges:

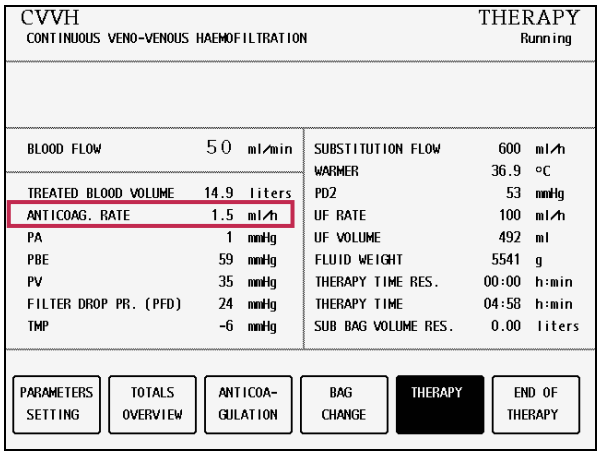
Parameter	Unit	Default	Min	Max	Increments
Blood-side parameters					
Anticoagulation rate	ml/h	0	0	10	0.1/0.5
Anticoagulation bolus volume	ml	0	0	10	0.1/0.5
Anticoagulation stop time (intermittent therapies)	h:min	0	00:00	02:00	00:05/ 00:30

11.5 Anticoagulation parameters during therapy

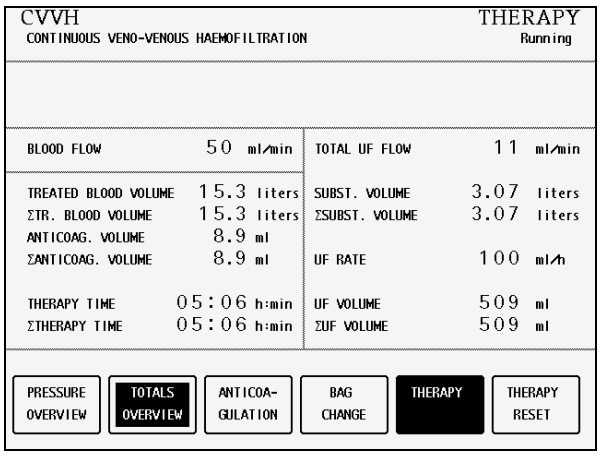


After the start of the therapy, the connection between the Diapact® CRRT and the perfusor is tested. <Perfusor connection test> is displayed in the status field. A threefold sound accompanies the test.

The therapy then starts with the set anticoagulation rate.



The current anticoagulation rate is displayed on the left side of the <PARAMETERS OVERVIEW> screen during the therapy.



The total amount of anticoagulant can be followed in the <TOTALS OVERVIEW> screen.

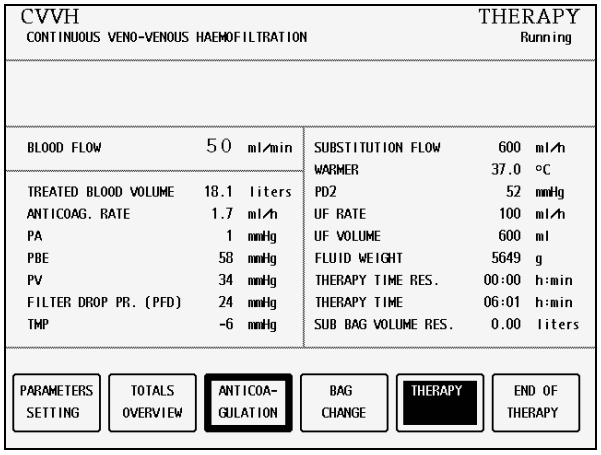
Together with the parameters displayed in the respective therapy,

- the anticoagulation volume of the current time segment and
- the anticoagulation volume of the whole treatment (sum of all time segments)

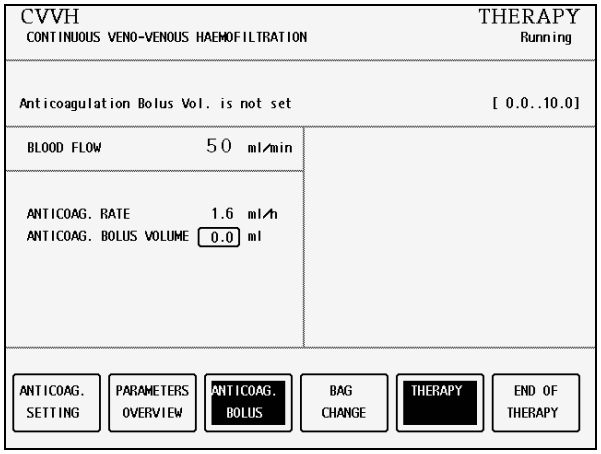
are displayed additionally with the blood-side parameters

Both values are the sum of the continuously applied volume and the bolus volume.

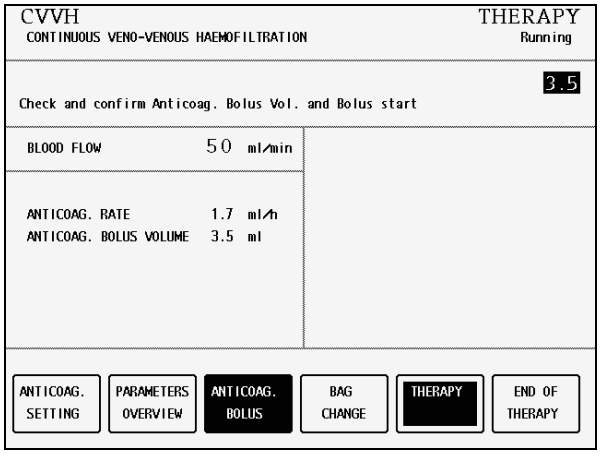
11.6 Anticoagulation bolus



- To administer an anticoagulant bolus select <ANTICOAGULATION> with  or the  key.
- Confirm the selection with the  key.

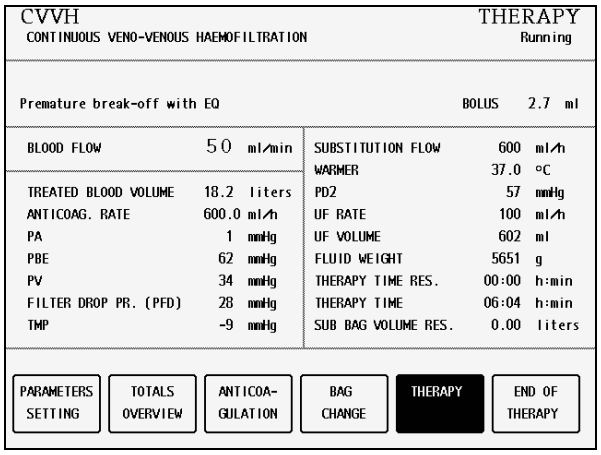


- Select <ANTICOAGULATION BOLUS> with the  or the  key.
- Confirm the selection with the  key.



- If <Anticoagulation bolus volume> was not set before (i.e. 0.0 ml), <ANTICOAGULATION SETTING> is opened.
- Increase the selected value with the  key or decrease it with the  key.
- Confirm the change with the  key.
  The changed or earlier set value flashes in the supervisor field. Compare the two values, they must be identical.
- Confirm the value with the  key.

  The screen switches to <PARAMETERS OVERVIEW>.



The progress of the anticoagulation bolus is displayed in the range field in the upper right part of the display.

<Premature break-off with EQ> is displayed in the message field, indicating that the bolus can be finished at any time by pressing the EQ key.

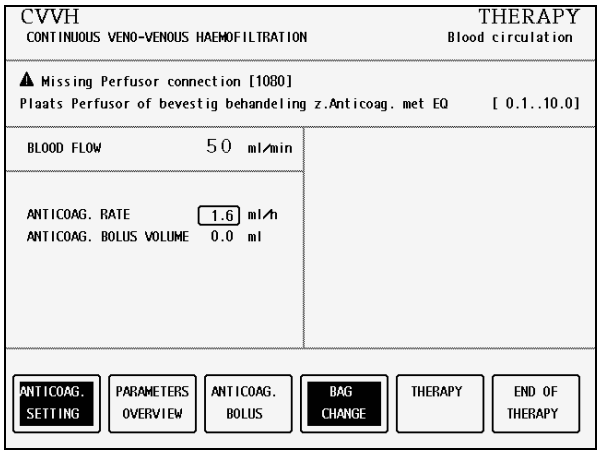
The anticoagulation bolus is interrupted automatically in the following situations:

- Manual blood pump stop
- Blood-side alarm
- Perfusor-related alarm
- Power failure
- Manual stop of the perfusor
- Switching-off the perfusor

If the anticoagulation bolus volume is already set in a previous phase of the therapy select <ANTICOAGULATION BOLUS> in the <ANTICOAGULATION> screen and proceed as previously described

!	The successful end of the anticoagulation bolus must be carefully monitored.

⚠ WARNING	**Incorrect use of the Diapact® Perfusor Interface option may increase the patient's bleeding risk.** ➢ **The anticoagulation infusion is exclusively controlled by the Diapact® CRRT. So do not start or stop the perfusor manually, especially not during an active perfusor related alarm.** ➢ **The patient's coagulation status must be checked regularly. PTT and ACT are the recommended parameters.** ➢ **It is not allowed to treat one patient with Diapact® CRRT and another patient with the Perfusor fm or Perfusor Compact S connected to the Diapact® CRRT.** ➢ **It is recommended to connect the perfusor before the disposable leakage start-up test. If the perfusor is connected after that test special care must be taken to guarantee the correct connection.**



If the perfusor is connected incorrectly or not switched on the alarm <Missing Perfusor connection [1080]> is displayed.

If anticoagulation is required

- Eliminate the cause of the alarm.
- Confirm the elimination of the cause by pressing the AQ key.

If the therapy shall not be performed with anticoagulation:

- Confirm the message by pressing the EQ key.

All anticoagulation parameters are set automatically to zero. If anticoagulation is required during therapy, the perfusor has to be connected and the parameters have to be set.

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12 Maintenance and cleaning

12.1 External cleaning

 **WARNING**	**Electric shock and fire hazard!** ➢ **Ensure that no fluid enters the machine.**

 **WARNING**	**Damage to surface by unknown ingredients!** ➢ **Ensure that the disinfectant is pure active chlorine.** ➢ **B.Braun will assume no liability for any damage caused to the device through usage of cleaning agents with unknown constituents.**

- Clean housing parts and monitor with ethanol (max. 70%) or isopropanol (max. 60%) based cleaning agents. Hypochlorite-based agents may not exceed a concentration of 0.1% and may not be used on the monitor foil.
- Use cleaning and disinfection agents only in accordance with the respective instructions for use.

12.2 Servicing and technical safety check

12.2.1 Maintenance

Regular servicing is recommended at intervals of max. 12 months. Such service involves checking the correct functioning of the dialysis machine and the replacement of expendable parts to ensure the fault-free operation of the dialysis machine.

This regular service may only be carried out by authorized persons.

Service manual and technical training

A full service manual can only be provided in connection with technical training.

12.2.2 Technical safety check (TSC)

In Germany, the technical safety check must be carried out every 12 months, as stipulated by VDE 0751:2001 (version: 12/2002). For all other countries, we recommend keeping to an annual provision of TSC.

- The dialysis machine should be checked by persons that have been appropriately trained or have the required expertise or experience and do not require instructions for the check.
- Carry out check in accordance with TSC servicing list enclosed in the Appendix.
- Results of the technical safety check should be documented, e.g. by applying a test plaque to the product.
- The test report must be kept by the operator as part of the documentation.

12.2.3 Accessories, disposable items and expendable parts

Only accessories, disposable items and spare parts may be used that do not pose a technical safety risk and demonstrably comply with Medical Devices Directive 93/42/EEC (MDD).

To ensure the full functionality of the dialysis machine, we recommend using products by B. Braun Avitum AG.

12.3 Technical service and guarantee

12.3.1 Guarantee

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

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

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

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13 Alarms and remedial actions

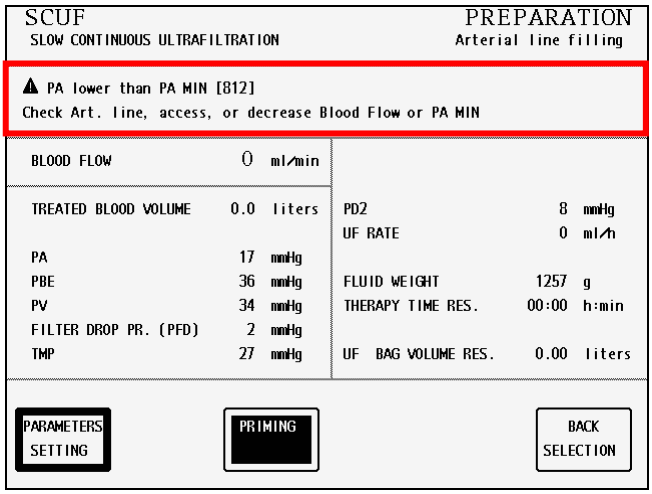
13.1 Displaying and resetting alarms

If an alarm situation occurs

- the machine alarms acoustically.
  Blood-side alarms provoke a sharp continuous tone and fluid-side alarms an intermittent tone.
- the AQ key lights up
- the alarm reason is displayed in the first line of the alarm field on the screen. With some alarms further explanation text is displayed in the second line suggesting remedial actions.

> **Operation in case of alarm tone failure**
> The buzzer for the alarm tone is tested in the preparation phase.
> ➢ Listen for the alarm tone during the preparation phase as described in the respective sections.
> ➢ If the buzzer fails within a therapy, the supervisor assumes the control.
> ➢ If problems with the buzzer occur, do not operate the device and call the technical service.

Alarm field



➢ Press the AQ key to mute the alarm.

➢ Eliminate the alarm reason.

➢ Press the AQ key to continue.
If the reason for the alarm is not eliminated, the alarm is repeated after 30 or 60 sec.

Operation in case of display failure
In case of a failure of the display, all monitoring functions and the external keys remain active.

- ➢ To prevent any disconcertment of the operator and the patient, it is recommended to terminate the therapy. This requires particular attention by the operator.
- ➢ Return the blood to the patient as described in the Sections "Disconnecting the patient" and in the respective sections where the therapy is described.
  This can be done since the external
   and  keys and the  key
  are active and progress is monitored visually

13.2 Alarms and reactions

13.2.1 Alarms during preparation

During preparation (priming and self-tests) alarms may occur which interrupt the tests and the preparation. These alarms are often due to incorrect operation, incorrect mounting of the lines or a failed component.

Machine reactions:

- Preparation and self-testing are stopped.
- Acoustic alarm (continuous tone, same as blood-side alarm).
- Name of the failed test is displayed in the therapy status field.
- Alarm message is displayed in the alarm field.
  Error code 902 indicates a controller self-test failure and error code 904 a supervisor self-test failure.
- The  key lights up.

The acoustic signal can be muted by pressing the  key once. Having eliminated the cause of the alarm, the failed test can be repeated by pressing the  key again.

Self-test alarms

Alarm/Message	Code	Cause(s)	Remedial action
Display Control Board self-test failed	900	• Test failed	➢ Repeat test by pressing  twice or ➢ Switch the machine off and on again
Supervisor self-test failed	904	• Supervisor internal memory failure • Calibration data test failed	➢ Switch the machine off and on again
		• Device failure	➢ Contact technical service.
Therapy status: **Power relay test** Controller self-test failed (902)	902	• Test failure	➢ Repeat test by pressing  twice or ➢ Switch the machine off and on again
		• Technical failure	➢ Contact technical service

Alarm/Message	Code	Cause(s)	Remedial action
Therapy status: **SAD reference test** Supervisor self-test failed (904)	904	• Test failure	➢ Repeat test by pressing AQ twice or ➢ Switch the machine off and on again
		• Technical failure	➢ Contact technical service
Therapy status: **SAD counter test** Supervisor test failed (904)	904	• Test failure	➢ Repeat test by pressing AQ twice or ➢ Switch the machine off and on again
		• Technical failure	➢ Contact technical service
Therapy status: **Red detector test** Controller self-test failed (902)	902	• Test failure	➢ Repeat test by pressing AQ twice or ➢ Switch the machine off and on again
		• Technical failure	➢ Contact technical service
Therapy status: **Blood leak detector test** Supervisor self-test failed (904)	904	• Test failure	➢ Repeat test by pressing AQ twice or ➢ Switch the machine off and on again
		• Technical failure	➢ Contact technical service
Therapy status: **Zero pressure test** Controller self-test failed (902)	902	• Disconnected pressure lines	➢ Connect the pressure lines to the pressure transducer(s) and repeat the test by pressing AQ twice or ➢ Switch the machine off and on again
Supervisor self-test failed (904)	904	• Deviation between two sensors > 20 mmHg	➢ Recalibration by technical service
		• Technical failure	➢ Contact technical service
Therapy status: **Load cell test** Controller self-test failed (902)	902	• Wrong configuration of the consumables	➢ Install the correct consumables for the respective therapy or correct the installation
		• Pump segment twisted	➢ Correct orientation of pump segments
Supervisor self-test failed (904)	904	• Frangible pin of saline bag seal closed	➢ Open frangible pin of the saline bag
		• Saline bag not on the load cell	➢ Place the saline bag on bag holder of the load cell
		• Device failure	➢ Contact technical service

Alarm/Message	Code	Cause(s)	Remedial action
Therapy status: **Air detector test (AD)** Controller self-test failed (902)	902	• Wrong installation of the consumables	➢ Correct installation of the consumables
		• Frangible pin of the bags with haemofiltration solution closed	➢ Open the frangible pin of the bags with the haemofiltration solution
		• Line was not empty at beginning of test	➢ Repeat the test
		• Device failure	➢ Contact technical service
Therapy status: **Dialysate pump test** or **Substitution pump test (MP3)** Controller self-test failed (902) Supervisor self-test failed (904)	902 904	• Wrong installation of the consumables	➢ Correct installation of the consumables
		• Pump segment twisted	➢ Correct the installation of the pump segments
		• Size of pump segment does not correspond to the selected therapy	➢ Adapt line kit to therapy
		• Air in filter (dialysate pump test)	➢ Screw filter connection tight ➢ Deaerate the filter
		• Device failure	➢ Contact technical service
Therapy status: **Ultrafiltration pump test** or **Plasma pump test (MP2)** Controller self-test failed (902) Supervisor self-test failed (904)	902 904	• Wrong installation of the consumables	➢ Correct installation of the consumables
		• Pump segment twisted	➢ Correct the installation of the pump segments
		• Size of pump segment does not correspond to the selected therapy	➢ Adapt line kit to therapy
		• Air in filter	➢ Screw filter connection tight ➢ Deaerate the filter
		• Device failure	➢ Contact technical service
Therapy status: **Heating test** Controller self-test failed (902) Supervisor self-test failed (904)	902 904	• Malfunction of the heater	➢ Repeat test ➢ Switch the machine off and on again
		• Device failure	➢ Contact technical service

Alarm/Message	Code	Cause(s)	Remedial action
Therapy status: **Disposable leakage test** Controller self-test failed (902) Supervisor self-test failed (904)	902 904	• Pressure loss in system	➢ Screw the connections tight and/or correct the installation of the consumables
		• Gap in SAK	➢ Contact technical service
		• Hydrophobic filter(s) wet	➢ Exchange the concerned hydrophobic filter
Therapy status: **Level regulation test** Controller self-test failed (902)	902	• Pressure loss in internal system	➢ Contact technical service
		• Device failure	➢ Contact technical service

Other alarms during preparation

Alarm/Message	Code	Machine reactions	Cause(s)	Remedial action
Pump calibration disturbed. It will be restarted	1023	Pump calibration stops	• Disturbance on the load cell	➢ Repeat pump calibration by pressing AQ twice ➢ Do not touch the machine during calibration
Saline bag for blood-side priming is empty	1025	Final or optional rinsing stops	• Priming saline bag is empty	➢ Connect a new saline bag and press AQ twice

Further alarms (such as high pressure alarms) protecting the line system may occur during the preparation phase. The cause of these alarms can be identified in the following sections. If these alarm occur in the preparation phase, the machine reaction is the same as described above.

13.2.2 Blood-side alarms during therapy

Machine reactions:

- All the pumps are stopped
- SAK is closed
- Heater is switched off
- Acoustic alarm (blood-side alarm with continuous tone)
- Alarm message in the alarm field on the screen
- 

light is turned on.

Alarm/Message	Code	Cause(s)	Remedial action
Air in blood return line	802	• Drop of blood level in the venous line	➢ Adjust blood level (see remedying SAD alarms in Section 13.3)
		• Turbulences due to too high blood flow	➢ Adapt blood flow
		• Line in the SAD deformed	➢ Re-position the line in the SAD
		• SAD cover not closed correctly	➢ Adjust position of the line in the SAD and close the cover correctly
		• Device failure	➢ Contact technical service
PV higher than PV max	806	• Blood pump velocity too high	➢ Decrease blood flow
		• Upper PV limit exceeded	➢ Adjust thresholds
		• Catheter or fistula needle not optimally positioned or lumen displaced	➢ Correct position of catheter or fistula needle
		• Clotting in venous chamber	➢ Change venous line or line system
		• Device failure	➢ Contact technical service
PV lower than PV min	808	• Blood pump velocity too low	➢ Increase blood flow
		• Lower PV limit value exceeded	➢ Adjust thresholds
		• Catheter or fistula needle disconnected	➢ Reconnect catheter or fistula needle
		• Pressure sensor leaky	➢ Screw the connection between pressure line and pressure transducer tight
		• Level regulator leaky	➢ Contact technical service
		• Patient's position too low in relation to the device	➢ Increase the height of the patient's bed
		• Device failure	➢ Contact technical service
PA higher than PA max	810	• No blood flow	➢ Start blood flow
		• Catheter or fistula needle disconnected	➢ Reconnect catheter or fistula needle
		• Thresholds set inadequately	➢ Adjust thresholds

Alarm/Message	Code	Cause(s)	Remedial action
PA lower than PA min	812	• Blood pump velocity too high	➢ Adapt the blood flow to the patient situation
		• Thresholds set inadequately	➢ Adjust thresholds
		• Catheter or fistula needle not optimally positioned or lumen displaced	➢ Correct position of catheter or fistula needle
		• Device failure	➢ Contact technical service
PBE higher than PBE max	814	• Blood flow too high	➢ Adapt the blood flow to the filter size
		• Line kinked	➢ Straighten the lines
		• Clotting	➢ Exchange the haemofilter ➢ Check and adapt anticoagulation if necessary
PBE lower than PBE min	816	• Pressure line to PBE pressure transducer not connected	➢ Connect the pressure line to the pressure transducer PBE
PFD higher than PFD max	822	• Decrease in filter performance	➢ Rinse the filter
		• Insufficient anticoagulation	➢ Check and adapt anticoagulation
		• Filter clotting	➢ Exchange the filter (see Section 13.5)
Blood pump cover open	824	• Blood pump cover open	➢ Close blood pump cover
		• Device failure	➢ Contact technical service
Blood pump stopped. Are you sure?	830	• Blood pump stopped	➢ Start blood pump again
		• Device failure	➢ Contact technical service
Air bubbles in blood return line	892	• Small air bubbles in the venous line	➢ Check venous line and venous chamber against leak ➢ Check connections of lines ➢ Check the level in the venous chamber. If required fill it manually. ➢ After removing any air bubble from the SAD, acknowledge the alarm
Blood pump flow disturbed	1001	• Pump segment stuck within the pump	➢ Check pump segment and insert it correctly
		• Device failure	➢ Contact technical service

13.2.3 Fluid-side alarms during therapy

Machine reactions:

- Fluid pumps are stopped
- Heater switched off
- Acoustic alarm (fluid-side alarm with intermittent tone)
- Alarm message in the alarm field on the screen
- The AQ key lights up.

Alarm/Message	Code	Cause(s)	Remedial action
High removal ratio of blood	832	Ratio blood flow: filtrate flow > 40 % in dialysis therapies > 50 % in plasma therapies	➢ Lower substitution flow and/or increase blood flow
Blood leakage (probable filter damage)	838	➢ Membrane rupture	➢ Check membrane for rupture, if no membrane rupture can be detected, recalibrate BLD (see Section 13.4)
		➢ Air in blood leak detector	➢ Remove air bubbles from line
		➢ Device failure	➢ Contact technical service
Air in plasma outlet line	842	➢ Leak in plasma outlet line	➢ Exchange plasma outlet line
		➢ Disconnection	➢ Screw the connection of the plasma outlet line tight
		➢ Air in the line, bag empty	➢ Change the bag(s)
		➢ Line deformed	➢ Re-position the plasma outlet line in the AD
		➢ AD cover not correctly closed	➢ Close AD cover completely
		➢ Device failure	➢ Contact technical service
Air in solution line (green)	844	➢ Air in the substitution line, bag empty	➢ Change bag(s)
		➢ Line deformed	➢ Re-position the plasma outlet line in the AD
		➢ AD cover not closed correctly	➢ Close AD cover completely
		➢ Device failure	➢ Contact technical service
PD1 upper limit	848	➢ Line kinked	➢ Straighten the line and position the heater bag correctly into the heater
		➢ Clamp closed	➢ Open clamp
		➢ Blood-side pressure too high	➢ Check venous line and catheter placement and connection
PD1 lower limit	850	➢ Disconnection of the green line	➢ Screw the connection of the substitution line tight
PD2 upper limit	852	➢ Blood-side pressure too high and green line is not mounted into the pump	➢ Mount line correctly and correct blood-side pressure

Alarm/Message	Code	Cause(s)	Remedial action
TMP higher than TMP max	856	➢ Ultrafiltration too high	➢ Reduce ultrafiltration
		➢ PV too high	➢ Check venous line and remove possible kinks ➢ Check catheter connection and correct it if necessary
		➢ Filter clotting	➢ Rinse or exchange filter or change line kit
High warmer temperature	858	➢ Fluid flow disturbed	➢ Check the fluid flow and eliminate possible disturbances
		➢ Device failure	➢ Contact technical service
Bag is moving	866	➢ Bags moved	➢ Stop bag movement and start therapy
Weighing system overload	868	➢ Too much weight on the load cell (> 26.8 kg)	➢ Reduce weight on the load cell
		➢ Device failure	➢ Contact technical service
Unexpected weight change	872	➢ Change in weight < 200 g	➢ Select cause on the display by pressing the  key: ➢ Select <**Unchanged bags**> if the bags were not changed or if no bags were added or removed. ➢ Select <**Changed bags**> if bags were changed or if bags were added or removed. ➢ Confirm with  Do not press the  key !
UF greater than expected	876	➢ Wrong input/output balance > 120/150/180 g	➢ Take care that the bags on the load cell hang freely
		➢ Closed clamp	➢ Check bag and fluid line clamps to be open
		➢ Substitution line kinked	➢ Straighten substitution line
The limit is increased in 30 g increments. The increments must be acknowledged. When the limit reaches +180 g, therapy is interrupted.			
UF less than expected	878	• Wrong input/output balance < -120/-150/-180 g	➢ Take care that the bags on the load cell hang freely
		• Leakage of bag(s)	➢ Replace leaking bag(s)
		• False input/output balance	➢ Take care that the bags on the load cell hang freely
		• Ultrafiltration line kinked	➢ Straighten ultrafiltration line
The limit is decreased in 30 g increments. The increments must be acknowledged. When the limit reaches -180 g, therapy is interrupted..			

Alarm/Message	Code	Cause(s)	Remedial action
UF pump cover open	880	• Pump cover open	➢ Close pump cover
		• Device failure	➢ Contact technical service
Dialysate pump cover open	882	• Pump cover open	➢ Close pump cover
		• Device failure	➢ Contact technical service
Substitution pump cover open	884	• Pump cover open	➢ Close pump cover
		• Device failure	➢ Contact technical service
Plasma pump cover open	886	• Pump cover open	➢ Close pump cover
		• Device failure	➢ Contact technical service
Clotting danger	914	• PD2 min limit value exceeded by 50 mmHg (high-flux filter)	➢ Increase blood flow
		• Reduced filter surface	➢ Adapt anticoagulation. ➢ Rinse the filter or exchange it if necessary
Removal not achievable	915	• PD2 min limit value exceeded by 50 mmHg (Low-flux filter)	➢ Decrease substitution and/or increase blood flow
		• Leakage of the collecting bag	➢ Replace bag
		• Reduced filter surface	➢ Adapt anticoagulation. ➢ Rinse the filter or exchange it if necessary
Unexpected weight change > 200 g	940	• Change in weight > 200 g due to bag change without selecting the <bag change> function	➢ Complete bag change and start therapy again
UF pump flow disturbed	1004	• Pump segment stuck within the pump	➢ Check pump segment and insert it correctly
		• Device failure	➢ Contact technical service
Substitution pump flow disturbed	1005	• Pump segment stuck within the pump	➢ Check pump segment and insert it correctly
		• Device failure	➢ Contact technical service
Dialysate pump flow disturbed	1006	• Pump segment stuck within the pump	➢ Check pump segment and insert it correctly
		• Device failure	➢ Contact technical service
Plasma pump flow disturbed	1007	• Pump segment stuck within the pump	➢ Check pump segment and insert it correctly
		• Device failure	➢ Contact technical service
Bag volume is over	1020	• Maximum ultrafiltrate collecting bag volume reached • Maximum substitution bag volume reached	➢ Change the concerned bag and start therapy again by releasing Bag Change ➢ Select <End Of Therapy> if desired

Alarms occurring using the Perfusor interface

Machine reactions:

- Acoustic alarm (heparin alarm tone)
- Alarm message in the alarm field on the screen
- The AQ key lights up.
- The perfusor stops.

Alarm/Message	Code	Cause(s)	Remedial action
Perfusor failure	927	• Perfusor communication disturbed	➢ Connect Perfusor correctly
		• Perfusor status is not as expected	➢ Correct Perfusor status
Syringe alarm in Perfusor	1027	• Syringe empty	➢ Replace empty syringe with a filled syringe
		• Wrong connection of syringe	➢ Correct connection of the syringe
		• Missing syringe	➢ Insert syringe
Missing Perfusor connection	1080	• Missing connection between Diapact® CRRT and perfusor	➢ Connect perfusor to Diapact® CRRT and press AQ or ➢ Confirm therapy without anticoagulation by pressing EQ.

13.2.4 Hardware alarms during therapy

The following alarms may occur during a treatment as consequence of a hardware failure.

Alarm/Message	Code	Machine reaction	Cause(s)	Remedial action
FATAL ERROR: DPD-DPC Communication time-out!	–	• Whole system communication stops resulting in - Stop of all the pumps - SAK is closed - Heater is switched off • Acoustic alarm (continuous buzzer sound) • Alarm message in the alarm field on the screen	• Display controller recognised a controller communication fault • Controller recognised a Display controller communication fault	➢ Switch the device off and on again ➢ Contact technical service
FATAL ERROR: DPD-DPS Communication time-out!	–	See above	• Display controller recognised a supervisor communication error • Supervisor recognised a Display controller communication fault	➢ Switch the device off and on again ➢ Contact technical service
Blood air detector (SAD) failure	804	See blood-side alarm (Section 13.2.2)	• Self-test of the safety air detector failed.	➢ Switch the device off and on again ➢ Contact technical service
Blood leak sensor failure	836	See fluid-side alarm (Section 13.2.3)	• Self-test of the blood leak sensor failed.	➢ Repeat the test by pressing AQ.
			• Device failure	➢ Contact technical service
Cyclical weight preamplifier test failed	862	See fluid-side alarm (Section 13.2.3)	• Self-test of the weight preamplifier failed	➢ Acknowledge with the AQ key.
			• Device failure	➢ Contact technical service
Safety 12 V failure	888	See blood-side alarm (Section 13.2.2) with system failure tone	• Fault in the safety voltage	➢ Switch the device off and on again ➢ Contact technical service
24 V failed	890	See blood-side alarm (Section 13.2.2) with system failure tone	• Fault in the 24 V voltage supply	➢ Switch the device off and on again ➢ Contact technical service
Supervisor error!	896	See blood-side alarm (Section 13.2.2) with system failure tone	• Controller recognised supervisor fault	➢ Switch the device off and on again ➢ Contact technical service

13.2.5 Protection system (supervisor) alarms

Diapact® CRRT has a protective system which can intervene independently of the control system and thus guarantee safe treatment conditions for the patient. The alarms are displayed optically and acoustically.

If protection system alarms occur, they are

- **acceptable (A)**
  This type of alarm can be accepted in the same way as the control system alarms by pressing the
  

  key. If the alarm cause is eliminated, the therapy can be continued.
- **non-acceptable (NA)**
  This type of alarms occurs in situations which might become dangerous for the patient. The alarms cannot be accepted by pressing the
  

  key. The device must be switched off and on again. If the alarm persists, the therapy must be stopped and the patient must be disconnected.

Machine reactions in case of supervisor alarms:

- All pumps stop
- Heater is switched off
- SAK is closed
- Acoustic alarm (continuous urgent tone)
- Alarm message blinking inversely in the supervisor alarm field

Supervisor alarms are activated only if the control system does not keep the system in the proper (blood side or fluid side) safety state.

Alarm/Message	Accept.	Cause(s)	Remedial action
-	NA	• Supervisor internal or communication failure	➢ Switch the machine off and on again
		• Device failure	➢ Disconnect the patient and contact technical service
There is no alarm message on the screen if this failure occurs			
SYSTEM ERROR	NA	• Supervisor internal failure	➢ Switch the machine off and on again
		• Device failure	➢ Disconnect the patient and contact technical service
There is no alarm message on the screen if this failure occurs			
SELFTEST ERROR	NA	• Any of the necessary self-tests is not passed when entering therapy	➢ Switch the machine off and on again
SAFETY CHECK ERROR	NA	• Any of the necessary safety parameter checks is not performed when entering therapy	➢ Switch the machine off and on again
THERAPY PUMP RUNS	A	• Any pump (MP2 or MP3) runs when it should stop	➢ Acknowledge with the AQ key
		• Device failure	➢ Contact technical service.
SAD SENSOR ERROR	A	• Safety air detector (SAD) self-test failure	➢ Acknowledge the alarm
		• Device failure	➢ Disconnect the patient and contact technical service

Alarm/Message	Accept.	Cause(s)	Remedial action
SAD FUNC. ERROR	NA	• Safety air detector (SAD) functional failure	➢ Switch the machine off and on again
		• Device failure	➢ Disconnect the patient and contact technical service
SAD REF. ERROR	A	• Safety air detector (SAD) reference voltage failure	➢ Acknowledge the alarm
		• Device failure	➢ Disconnect the patient and contact technical service
AIR IN BLOOD	A	• Air in the venous line	➢ Remove the air from the venous line as described in Section 13.3
BUBBLES IN BLOOD	A	• Small air bubbles in the venous line	➢ Check venous line and venous chamber for leaks ➢ Check connections of lines ➢ Check the level in the venous chamber. If required fill it manually. ➢ Remove the air bubbles from the venous line as described in Section 13.3
BLD TEST ERROR	A	• Blood leak detector (BLD) self-test failure	➢ Switch the machine off and on again.
		• Device failure	➢ Contact technical service
BLOOD LEAKAGE	A	• Membrane rupture	➢ Check membrane for rupture, if no membrane rupture can be detected, recalibrate BLD as described in Section 13.4
		• Air in blood leak detector	➢ Remove air bubbles from line
		• Device failure	➢ Contact technical service
PV HIGH	A	• Blood pump velocity too high	➢ Decrease blood flow
		• Upper PV limit exceeded	➢ Adapt thresholds
		• Catheter or fistula needle not optimally positioned or lumen displaced	➢ Reposition catheter or fistula needle
		• Clotting in venous chamber	➢ Change tube system
		• Device failure	➢ Contact technical service
PV LOW	A	• Blood pump velocity too low	➢ Increase blood flow
		• Lower PV limit value exceeded	➢ Adapt limits
		• Catheter or fistula needle disconnected	➢ Reconnect catheter or fistula needle
		• Pressure sensor leaky	➢ Check pressure sensor
		• Level regulator leaky	➢ Call technical service
		• Patient lying too low	➢ Increase the height of the patient's bed
		• Device failure	➢ Contact technical service

Alarm/Message	Accept.	Cause(s)	Remedial action
PA HIGH	A	• No blood flow	➢ Check blood flow
		• Catheter or fistula needle disconnected	➢ Reconnect catheter or fistula needle
		• Limit value setting	➢ Reset upper threshold
		• Device failure	➢ Contact technical service
PA LOW	A	• Blood pump velocity too high	➢ Adapt the blood flow to the patient's situation
		• Limit value setting	➢ Reset the lower limit value
		• Catheter or fistula needle not optimally positioned or lumen displaced	➢ Check the position of the catheter or the fistula needle
		• Device failure	➢ Contact technical service
BLOOD PUMP STOP	A	• Blood pump stopped for more than 2 min	➢ Start blood pump again
PD2 HIGH	A	• Blood-side pressure too high and green line is not mounted into the pump	➢ Mount line correctly and correct blood-side pressure
PD2 LOW	A	• Disconnection of the substitution line	➢ Screw the connection of the substitution line tight
TEMPERATURE HIGH	A	• Temperature is too high (over 41 or 45 °C)	➢ Accepting the alarm allows to continue the therapy without the heater. The function can be activated again by switching the unit off and on again. The user can decide whether to continue the therapy with or without the heater.
		• Device failure	➢ Contact technical service
UF VOLUME HIGH	NA	• Wrong input/output balance > 300 g	➢ After checking the patient's proper weight and eliminating the problem reset the therapy ➢ Interrupt the therapy and disconnect the patient if no problem can be detected
		• Closed clamp	➢ Check and open the clamps
		• Substitution line kinked	➢ Remove the kinks in the line
		• Device failure	➢ Contact technical service
UF VOLUME LOW	NA	• Wrong input/output balance < -300 g	➢ After checking the patient's proper weight and eliminating the problem reset the therapy ➢ Interrupt the therapy and disconnect the patient if no problem can be detected
		• Leakage of bag(s)	➢ Exchange the leaking bag using the <bag change> function
		• Ultrafiltration line kinked	➢ Remove the kinks in the line
		• Device failure	➢ Contact technical service

Alarm/Message	Accept.	Cause(s)	Remedial action
UF RATE HIGH	A	• UF removal is higher than expected	➢ Acknowledge with the AQ key.
		• Device failure	➢ Contact technical service
UF RATE LOW	A	• UF removal is lower than expected	➢ Acknowledge with the AQ key.
		• Device failure	➢ Contact technical service
SUB FLOW HIGH	A	• Substitution infusion is higher than expected	➢ Acknowledge with the AQ key.
		• Device failure	➢ Contact technical service
SUB FLOW LOW	A	• Substitution infusion is lower than expected	➢ Acknowledge with the AQ key.
		• Device failure	➢ Contact technical service
WEIGHT TEST ERROR	A	• Weight preamplifier self-test failure	➢ Acknowledge with the AQ key.
		• Device failure	➢ Contact technical service
LOADCELL DISTURBED	A	• Too much or no weight on the load cell	➢ Reduce the weight on the load cell
		• Bags moved/Weight change	➢ Check the bag on the load cell ➢ See clearance of alarms 866, 868, 872 during therapy.
		• Device failure	➢ Contact technical service
PERFUSOR ERROR	A	• Perfusor communication disturbed	➢ Connect perfusor correctly
		• Perfusor status is not as expected	➢ Correct perfusor status

13.2.6 Warning messages during therapy

To give important relevant information to the user, warning messages are displayed in the second line of the alarm field, they become audible with a single warning tone or in every 30 sec. No pumps are stopped and the therapy is not interrupted. They are cleared automatically, if the cause of the warning is eliminated.

Alarm/Message	Code	Machine reactions	Cause(s)	Remedial action
PA higher than PA max	810	• Blood flow is reduced to 25% (max. 60 ml/min) for 3 sec. • Fluid pumps stop for 3 sec.	• Patient moving	
PA lower than PA min	812	• Blood flow is reduced to 25% (max. 60 ml/min) for 3 sec. • Fluid pumps stop for 3 sec.	• Patient moving	

Alarm/Message	Code	Machine reactions	Cause(s)	Remedial action
High removal ratio of blood	832		• Ratio blood flow: filtrate flow > 25 % in dialysis therapies > 35 % in plasma therapies	➢ Decrease substitution flow and/or increase blood flow
Blood leakage (probable filter damage)	838		• Blood leakage alarm was acknowledged and a new alarm is inhibited for 60 sec	➢ Nothing (membrane rupture had to be eliminated before)
High warmer temperature	858	• Warning tone every min. • Heater is switched off	• Temperature is above the set temperature + 2 °C	➢ Reduce set temperature
			• Fluid flow disturbed	➢ Remove the cause of the flow disturbance
			• Variation value too high	➢ Decrease temperature in max. 2 °C steps
			• Device failure	➢ Contact technical service
Low warmer temperature	861	• Warning tone every 2 min.	• Temperature is below the set temperature - 2 °C: • Substitution/dialysate fluid is too cold	Reduce flow rate or warm up the bags
			• Variation value too high	➢ Increase temperature in max. 3 °C steps
			• Technical failure	➢ Contact technical service
Weighing system empty	870	• Warning tone every 4 min.	• No weight on the load cell	➢ Connect bag to the load cell
			• Device failure	➢ Contact technical service
Clotting danger	914	• Warning tone every 4 min. • Substitution/Plasma flow reduced or stopped	• PD2 min limit value reached (high-flux filter)	➢ Increase blood flow
			• Reduced filter surface	➢ Adapt anticoagulation. ➢ Rinse the filter or exchange it if necessary
Removal not achievable	915	• Warning tone every 4 min. • Substitution/Plasma flow is reduced or stopped	• PD2 min limit value reached (low-flux filter)	➢ Decrease substitution and/or increase blood flow
			• Reduced filter surface	➢ Adapt anticoagulation. ➢ Rinse the filter or exchange if necessary

Alarm/Message	Code	Machine reactions	Cause(s)	Remedial action
Perfusor failure	927	• Warning tone every 2 min.	• Perfusor communication disturbed	➢ Connect Perfusor correctly
			• Perfusor status is not as expected	➢ Correct Perfusor status
Blood return line empty	930	• Warning tone once	• Blood return line empty after blood return in End Of Therapy	➢ Select Therapy Selection or ➢ Switch the device off
Substitution flow reduced. Check PD2.	931	• Warning tone once • Substitution flow is reduced or stopped	• PD2 min + 20 mmHg value reached	➢ Increase blood flow
			• Reduced filter surface	➢ Adapt anticoagulation. ➢ Rinse the filter or exchange if necessary
Therapy stopped! Are you sure?	932	• Warning tone every 4 min.	• Therapy pumps are stopped for more than 4 minutes	➢ Start therapy
Warmer 24 V switched off by Supervisor	933	• Warning tone once	• Supervisor heating alarm switched off the warmer power supply	➢ Switch the device off and on again, if heating is necessary
Release Bag Change to continue the therapy	936		• Bag Change is active	➢ Release Bag Change
Perfusor alarm	937	• Warning tone once	• Alarm on the Perfusor	➢ Check alarm cause on Perfusor and correct its cause
Auto plasma reduction	938	• Warning tone once • Plasma flow is reduced or stopped	• PD2 min + 20 mmHg value reached	➢ Increase blood flow
			• Reduced filter surface	➢ Adapt anticoagulation. ➢ Rinse the filter or exchange if necessary
Battery low in Perfusor	939	• Warning tone once	• Battery low in Perfusor	➢ Replace battery in Perfusor
Therapy is over	942	• Therapy end tone • Fluid pumps stop	• Therapy time reached the required time	➢ Increase therapy time, if necessary ➢ Enter <End Of Therapy>
Pump calibration. Do not touch the machine.	1022		• Pump calibration is running	➢ Do not touch the machine during calibration to complete it without any disturbance

13.3 Remedying SAD alarms

In case of air in the area of the SAD, the tube clamp (SAK) 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, in case of SAD alarms as well.

The alarm which indicates air in the venous line is displayed in the alarm field 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 first deletes the alarm at least 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 air bubbles in the venous line have triggered the alarm, these bubbles must be removed as follows:

- Acknowledge the alarm by pressing the AQ key.
- Clamp the venous line above the venous chamber.
  This prevents blood from being sucked from the dialyzer.
- Select the level regulation by pressing the V key, the key lights up.
- Keep the ▲ key pressed until the PV reaches – 50 mm Hg.
  As the air is located in the region of the patient inlet, it must be moved back to the venous bubble trap by this vacuum action.
- The SAK will open.
- The blood level in the venous bubble catcher is raised.
- Press the AQ key to delete the alarm.
- Remove the clamps from the venous line.
- The therapy continues.
- If some air remains in that region, the process must be repeated.

13.4 Manual blood return

!	In case of a power failure during dialysis and where no emergency power supply is available, the blood must be returned manually to the patient.

⚠ 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 with two persons and with the utmost care.**

Positioning the crank

- Remove crank from rear of dialysis machine.
- Open (left) blood pump lid and insert crank into the roller rotor.
- Disconnect arterial side from patient as described in the respective therapy Section.
- Remove venous line from the SAK.
- Evenly operate the blood pump using the crank. Observe appropriate speed and maintain an adequate blood level in the venous bubble trap.
- Monitor the venous patient inlet continuously, 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.

13.5 Blood leak recalibration

The <BLOOD LEAK CALIBRATION> function allows the recalibration of the blood leak detector in case of non-acceptable alarms (e.g. elevated plasma bilirubin concentration)

DANGER

Risk of blood loss for the patient and haemolysis

- **Before the recalibration of the blood leak detector, the filter must be carefully checked for possible blood leaks and haemolysis.**
- **It is recommended to withdraw a sample (at least 2 ml) from the injection port of the filtrate line and to analyse for erythrocytes and/or free haemoglobin.**
- **The blood leak recalibration must only be performed if these tests are negative.**

- Select <END OF THERAPY> and confirm with the key.
  The EQ key lights up.
- Confirm with the EQ key.
- Select “BLOOD LEAK CALIBRATION” and confirm with the key.
  The EQ key lights up.
- Confirm with the EQ key.
- Select <BACK TO THERAPY> and confirm with the key.
  The EQ key lights up.
- Confirm with the EQ key.
- Adapt the blood flow to the initial value.
- Start <THERAPY> by pressing the key.

The balance pumps will not start up again until blood leakage calibration has been completed.

13.6 Exchange of haemofilter

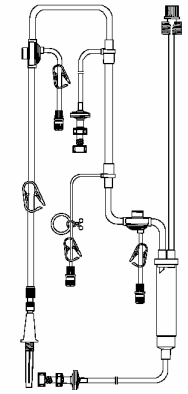
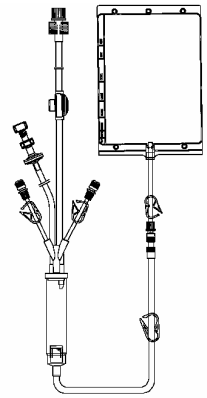
- Select <SET-UP CHANGE> and confirm with the  key.
- Stop the blood pump (MP1).
- Close all lines leading to and from the filter with a clamp.
- Unscrew the lines from the filter and discard the filter.
- Place the new thoroughly rinsed filter into the filter holder.
- Connect the arterial, venous and filtrate lines to the filter.
- Select <SET-UP CHANGE> and confirm with the  key.
  The therapy continues.

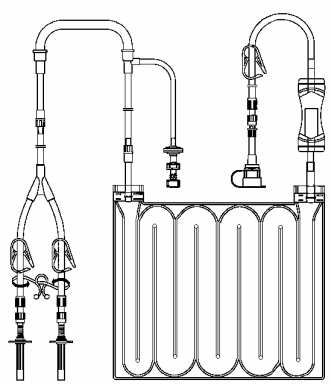
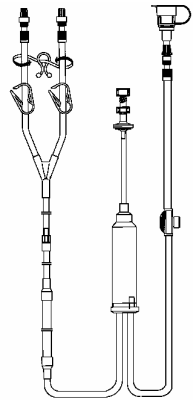
 **DANGER**	**Risk of air embolism and infection for the patient** ➢ **Use aseptic techniques to exchange the filter to avoid contamination of the connectors and, as a result, of the patient as well.** ➢ **Use only filters rinsed with a sufficient amount of isotonic sodium chloride solution to remove the air from the filter.** ➢ **Observe carefully the instructions for use of the filter.**

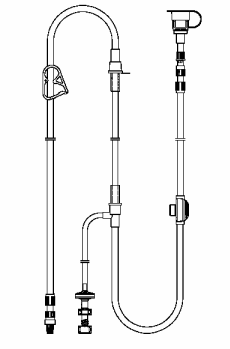
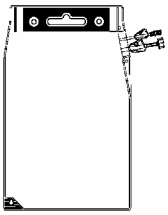
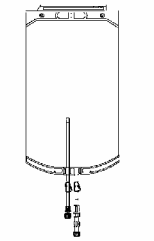
Table of content

14 Accessories

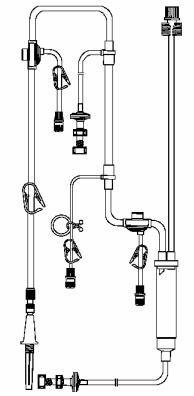
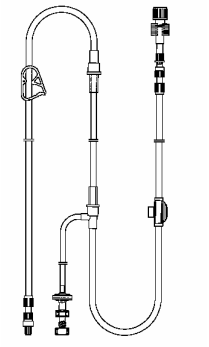
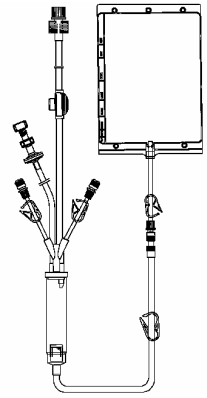
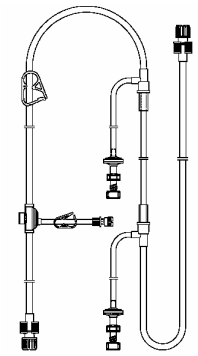
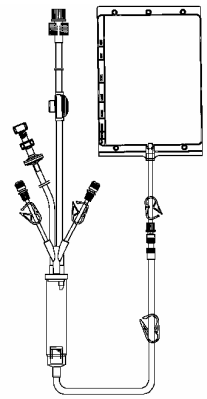
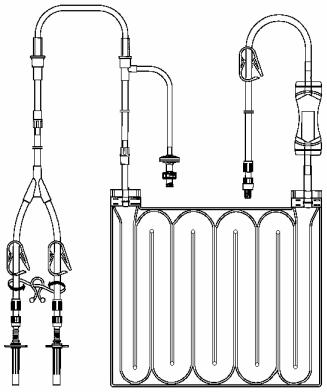
14.1 Diapact® kits for dialysis

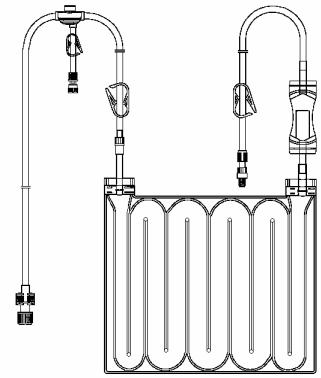
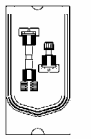
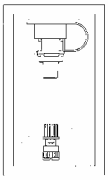
	HF/HD Kit	HF/HD Kit pre-assembled	HF/HD Kit recirculation	HF/HD Kit high volume	SCUF Kit
	7210349	7210492	7210657	7210635	7210351
Arterial line 7210353 	X	X	X	X	X
Venous line 7210208 	X	X	X	X	X

	HF/HD Kit	HF/HD Kit pre-assembled	HF/HD Kit recirculation	HF/HD Kit high volume	SCUF Kit
	7210349	7210492	7210657	7210635	7210351
Substitution/ dialysate inlet line 7210357 	X	X	X	-	-
Substitution/ dialysate inlet line 7210636 As 7210357 with 4 bag connectors	-	-	-	X	-
Ultrafiltration/ dialysate outlet line 7210358 	X	X	X	-	-
Ultrafiltration/ dialysate outlet line 7210637 As 7210358 with 4 bag connectors	-	-	-	X	-

	HF/HD Kit	HF/HD Kit pre-assembled	HF/HD Kit recirculation	HF/HD Kit high volume	SCUF Kit
	7210349	7210492	7210657	7210635	7210351
Ultrafiltration line 7210362 	-	-	-	-	X
Collecting bag 7210631 	X	X	-	X	X
Collecting bag 7210298 	-	-	X	-	-
Connection line 7210008	-	-	X	-	-

14.2 Diapact® kits for plasma therapies

	PEX Kit	PAP Kit		PEX Kit	PAP Kit
	7210348	7210352		7210348	7210352
Arterial line 7210353e 	X	X	**Substitution line** 7210355 	X	
Venous line 7210208 	X		**Plasma line** 7210365 		X
Venous line 7210668 	X		**Plasma outlet line** 7210360 	X	

	PEX Kit	PAP Kit		PEX Kit	PAP Kit
	7210348	7210352		7210348	7210352
Plasma reinfusion line 7210364 		X	**Adsorber bypass** 7210633 		X
Plasmafilter adapter 7210497 	X		**Hansen connector** 7210641 		X

14.3 Device accessories

Name	Article no.
Filter holder	7107426
Cable to connect nurse call	8700160/1
DCI cable Cable for data transfer	7702841
Perfusor® Compact S	Country specific
Perfusor® fm	Country specific

14.4 Options

Name	Article no.
Diapact® Perfusor interface (DPI) Option to connect Perfusor® Compact S or Perfusor® fm	7102505
Diapact® data interface (DDI) Interface description to connect Diapact® CRRT to patient data management systems	7106603

14.5 Others

Name	Article no.
Haemofilter	
Diacap® Acute S	7203900
Diacap® Acute M	7203919
Diacap® Acute L	7203927
Plasmafilter	
Haemoselect® M 0.3	7061006
Haemoselect® L 0.5	7061007
Substitution solution	
Duosol® without potassium	Country specific
Duosol® with 2 mmol/l potassium	Country specific
Duosol® with 4 mmol/l potassium	Country specific
Adapter	
Connector for plasmafilter	7060150

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15 Technical specification

15.1 General technical specifications

Description	Values
Nominal voltage	110 ÷ 240 V AC
Nominal frequency	50/60 Hz
Nominal current	max. 3.5 A
Connected load	800 VA
Categorization	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	< 100 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)	480 x 1260 ×500 mm
Housing material	Aluminium, corrosion-proof
Empty weight	45 kg

15.2 Ambient conditions

Description	Values
Operation	
Temperature	+15 to +40 °C
Relative humidity	30% to 90%
Atmospheric pressure	700 to 1060 mbar
Transportation and storage (dry)	
Temperature	-20 to +55°C
Relative humidity	10% to 90%
Atmospheric pressure	700–1060 mbar

15.3 Recommended safe distances

Recommended safe distances in metres (m) between portable or mobile HF telecommunication devices and the Diapact® CRRT dialysis machine

The dialysis machine Diapact® CRRT is intended for use in ambient conditions with controlled high-frequency disturbance variables. The user can avoid electromagnetic disturbances by maintaining the distance between Diapact® CRRT and HF telecommunication devices, following the values in the table below, in dependency on 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 manufacturers information, to use the right formula from above.

Remark 1: For 60 MHz and 600 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 humans.

For transmitters with other output ratings, the recommended safe distance can be calculated with the above formulas.

15.4 Extracorporeal circulation

Description	**Data**
Blood pump	Roller pump with automatic motor switch-off when lid is opened, backstop
Flow rate	10 ÷ 500 ml/min 10 ÷ 300 ml/min in plasma therapies
Tolerance	< 10%
Operating pressure range	-220 ÷ +500 mmHg
Protective system	Mechanical reverse motion protection Rotation detector, blood pump stopped state is checked after the first start of the therapy pump(s)
Protective system override time	120 sec (blood pump stop alarm)
Protective system control	Start-up test during the preparation phase
Arterial inlet pressure (PA) measurement	Electronic pressure sensor with digital display
Range	–400 to +650 mmHg
Tolerance	±10 mmHg
Limits	-200 to +100 mmHg -100 to +100 mmHg in plasma therapies, adjustable
Adjustable range	-400 to +200 mmHg -400 to +300 mmHg in intermittent therapies
Protective system	Single pressure transducer, double channel evaluation
Protective system override time:	Absolute limits can be overridden during therapy. Window limits can be overridden (expanded) by stopping the blood pumps.
Protective system control	Start-up test during the preparation phase
Muting acoustic alarm	60 sec
Pressure measurement at arterial inlet of dialyzer (PBE)	Electronic pressure sensor with digital display
Range	-400 to +650 mmHg
Tolerance	±10 mmHg
Limits	0 to +400 mmHg 0 to +200 mmHg in plasma therapies, adjustable
Adjustable range	0 to +500 mmHg 0 to +650 mmHg in HF therapies
Muting acoustic alarm	60 sec

Description	Data
Venous return pressure (PV) measurement	Electronic pressure sensor with digital display
Range	-400 to +650 mmHg
Tolerance	±10 mmHg
Limits	Blood pump stop, flow change: -20 to +300 mmHg -20 to +380 mmHg, absolute, expanded window Running pumps: 0 to +300 mmHg 0 to +380 mmHg, absolute, expanded window –40 to +60 mmHg -40 to +140 mmHg in HF relative to the actual pressure value stored after 10 sec from reaching stabilised flows (closed window with adjustable upper limit). This stored base value automatically follows the pressure variation slowly (0.4 mmHg/min).
Adjustable range	80 to 160 mmHg 80 to 200 mmHg in HF therapy, window size relative)
Protective system	Single pressure transducer, double channel evaluation
Protective system override time	Window limits can be overridden (expanded) by stopping the blood pump Absolute limits cannot be overridden during therapy
Protective system control	Start-up test during the preparation phase
Muting acoustic alarm	60 sec
Safety air detector (SAD)	Ultrasound detector
Sensitivity	Air bolus > 100 µl Summarized air bubbles 0 ÷ 10000 µl configurable default 2000 µl
Protective system	Ultrasound detector with double channel electronics and evaluation
Protective system override time	Cannot be overridden during therapy Exclusion for 20 sec possible in <End of therapy> phase only for returning the blood (by following the safety procedure)
Protective system control	Start-up test during preparation phase Automatic, cyclical check during therapy
Muting acoustic alarm	60 sec
Safety clamp (SAK)	Close the venous line to the patient if Safety Air Detector causes an alarm or in all blood pump stop conditions (redundant function)

15.5 Dialysate / filtrate system

Description	**Values**
Air detector (AD)	Ultrasound detector to detect air bubbles or empty line
Limit	300 µl air bolus
Acoustic alarm mute	60 sec
Substitution/dialysate pump	Roller pump with automatic motor switch-off when lid is opened, digitally displayed flow, manual operating possible Automatic pump calibration except PAP therapy
Flow range	**Continuous therapies** CVVH 0/300 ÷ 6000 ml/h CVVHD, CVVHFD 0/300 ÷ 12000 ml/h **Intermittent therapies** HF 0/5 ÷ 250 ml/min HD, HFD 0/5 ÷ 400 ml/min **Plasma therapies** PEX 0/2 ÷ 60 ml/min PAP 5 ÷ 50 ml/min
Tolerance	**Continuous and intermittent therapies** < +4 % at 4 h < +6 % at 72 h **Plasma therapies** PEX < ±3 % PAP < ±10 %
Pressure range	-220 to +500 mmHg
Protective system	Mechanical reverse motion protection Rotation detector to monitor substitution flow
Protective system override time	It cannot be overridden during therapy
Protective system control	Start-up test during the preparation phase
Filter inlet pressure (PD1)	Electronic single pressure transducer, digitally displayed pressure
Range	-400 to +650 mmHg
Tolerance	± 10 mmHg
Limits	-50 to +400 mmHg **PAP** -50 to +10 mmHg
Adjustable range	**PAP only** +50 to +400 mmHg
Muting acoustic alarm	60 sec

Description	Values
Plate warmer	Solution warming system based on thermal energy transfer between the temperature controlled metal plate and the solution flowing through a plastic meander bag
Range	0 to +50 °C plate temperature
Tolerance	± 0.1 K plate temperature (if the heating power does not reach 100 %
Limits	**Continuous and intermittent therapies** 41°C for 10 sec 45°C for 1 sec **Plasma therapies** 38°C for 10 sec 41°C for 1 sec
Adjustable range	**Continuous and intermittent therapies** 20 ÷ 40°C plate temperature **Plasma therapies** 20 ÷ 37°C plate temperature
Protective system	Temperature sensor measuring plate temperature (PTC1000) independent from control system
Protective system override time	In case of temperature alarm, the plate warmer is switched off by the protective system until the regular end of the therapy.
Protective system control	Start-up test during the preparation phase
Muting acoustic alarm	60 sec (control system alarm only)
Blood Leak Detector (BLD)	Photometric detector
Detection limit	≥ 2.5 ml blood in 1000 ml saline (tested with bovine blood HTK 32 %)
Protective system	Single photometric detector, double channel evaluation
Protective system override time	60 sec after acknowledging a blood leakage alarm
Muting acoustic alarm	60 sec
Protective system control	Start-up test during the preparation phase Automatic calibration before starting therapy Automatic, cyclic self-test during therapy Recalibration during therapy in <End of Therapy> function
Filter outlet pressure (PD2)	Electronic pressure transducer, digitally displayed pressure
Range	-400 to +650 mmHg
Tolerance	± 10 mmHg
Limits	CVVH -150 to +480 mmHg CVVHD, HD -300 to +480 mmHg SCUF, CVVHFD, HF, HFD -100 to +480 mmHg PEX -60 to +480 mmHg PAP -40 to +480 mmHg Lower limit adjustable in each therapy
Adjustable range	-250 to +250 mmHg CVVHD, HD -400 to +500 mmHg
Muting acoustic alarm	60 sec

Description	Values
Ultrafiltration pump	Roller pump with automatic motor switch-off when lid is opened, digitally displayed flow, manual operating possible Exact pump speed regulated by the volumetric balance loop-back control to the electronic weighing system
Range	**Continuous and intermittent therapies** 0 to 2000 ml/h (ultrafiltration)) **SCUF** 0/80 to 2000 ml/h (ultrafiltration) **PEX** -200 to +500 ml/h (plasma balance)
Tolerance	For volumetric balance control, see tolerance of load cell
Pressure range	-220 to +500 mmHg
Protective system	Mechanical backward rotation prevention Rotation detector to monitor UF flow
Protective system override time	It cannot be overridden during therapy
Protective system control	Start-up test during the preparation phase
Load cell	Weighing system with volumetric balance loop-back control to ultrafiltration pump velocity
Range	0 – 27000 g (absolute)
Tolerance:	±30 g (balance) additional max. ± 20 g at each incorrect bag exchange
Limits	±120 g control system ±300 g second channel protective system
Display resolution:	1 g
Protective system	Mechanical overload protection at 31.0 kg
Protective system overriding	After reaching the alarm limit, this is increased to ±150 or to max. ±180 g during therapy Second channel protective system cannot be overridden
Mute acoustic alarm	60 sec for control system alarm only
Protective system control	Start-up test during the preparation phase Cyclical load cell test

15.6 Interfaces

Staff-call connection 	max. 24V/1 A/24 VA (polarity as desired)
Potential equalisation line connection (to DIN 42801) 	
External pump connection 	Interface for the connection of the perfusor if the option Diapact® Perfusor Interface is used, information available on request
Interface connection with external computer 	Option DDI, information available on request **Intended use of the interface with an external computer** An external computer (e.g. laptop) or computer system can be connected to the Diapact® CRRT. Only a specially isolated serial RS232 cable (Diapact DCI cable, art. no. 7702841) is approved for this connection. The intended use of the interface is: • Collection of therapy data during a therapy (data output) and transfer to patient data management systems (PDMS) using the interface description Diapact® Data Interface (DDI). • Collection of therapy data during a therapy (data output) with the Diapact® CRRT Trend Viewer for service reasons. • Sensor calibration, testing and system configuration (data input/output) in the technical support and maintenance (TSM) by the Diapact® CRRT Monitor.

!	**Collection of therapy data** Therapy data collected using the Diapact® Data Interface (DDI) and a Patient Data Management System must be checked, verified and evaluated by the attending physician before they lead to a possible change of the respective therapy.

Commissioning Record

For **Diapact CRRT**

The **commissioning** (setting into service) according to the specified check list, with reference to the service manual and operating manual must be performed and documented before the machine is handed over to the user.

Type: ..... No.: .....

Year of Purchase: ..... User: .....

.....

Operating Hours: ..... h Inventory No.: .....

SW Version: .....

Manufacturer:

B. Braun Avitum AG
Schwarzenberger Weg 73-79, 34212 Melsungen, Germany

					OK
1.	**Visual Inspection**				
1.1	Clean/complete; no damages/moisture influences; unit rollers are moveable; machine record book present				❑
1.2	Type plate, labels and inscriptions present and legible				❑
1.3	Check tight seat of mains supply (power supply line, strain relief) as well as connectors, screw terminals and boards				❑
2.	**Function Inspection (Document Measurement Values)**				
Pay attention to the starting procedure of the machine in order to check the main components!					
2.1	Switch on machine:	- Character sets that appear on the screen are checked, acknowledge with EQ key!			❑
		- No weight on weight system is checked, acknowledge with EQ key!			❑
		- Select CVVH therapy			❑
2.2	LC Display:	- Function, image display, alarm signal, function of the keys			❑
2.3	Blood Pump:	- Alarm cover, one-way bearing			❑
2.4	Fluid Pump:	- Alarm cover, one-way bearing			❑
2.5	Ultrafiltration Pump:	- Alarm cover, one-way bearing			❑
2.6	Venous Tubing Clamp:	- Function and moveability			❑
2.6.1		- Gap 1.4 mm (+ 0.1)		..... **[mm]**	❑
2.7	Arterial Pressure PA:	- Comparison measurement at	- 400 =	..... **[mmHg]**	❑
	(permissible tolerance ±10 mmHg)		0 =	..... **[mmHg]**	❑
2.8	Inlet Pressure PBE:	- Comparison measurement at	0 =	..... **[mmHg]**	❑
	(permissible tolerance ±10 mmHg)		+ 400 =	..... **[mmHg]**	❑
2.9	Venous Pressure PV:	- Comparison measurement at	0 =	..... **[mmHg]**	❑
	(permissible tolerance ±10 mmHg)		+ 400 =	..... **[mmHg]**	❑
2.10	Pressure PD1:	- Comparison measurement at	0 =	..... **[mmHg]**	❑
	(permissible tolerance ±10 mmHg)		+ 400 =	..... **[mmHg]**	❑
2.11	Pressure PD2/PSC:	- Comparison measurement at	0 =	..... **[mmHg]**	❑
	(permissible tolerance ±10 mmHg)		+ 400 =	..... **[mmHg]**	❑
			- 400 =	..... **[mmHg]**	❑
2.12	Power Fail Function:	- Check function, duration of a constant audible alarm > 1 minute (Activate buzzer in power supply, i.e. switch on machine and disconnect mains plug)			❑
3.	**Electrical Safety Check According to EN 60601-1/IEC 601-1**				
3.1	Measure Mains Voltage			..... **[V~]**	❑
3.2	Protective Earth Conductor Resistance < 0.2 Ω:	- Potential equalization bolt		..... **[Ω]**	❑
	(Machine incl. power supply cord)	- Screw connection plate warmer		..... **[Ω]**	❑
3.3	Earth Leakage Current ≤ 0.5 mA:	- During heat-up phase		..... **[mA]**	❑
3.4	Patient Leakage Current < 0.1 mA:	- Under normal conditions		..... **[mA]**	❑

				OK
4.	**Setting into Service (Monitor) According to Operating Manual/Service Manual**			
4.1	Temperature:	- Comparison measurement at 37 ^{0}C (- 1.5 + 0.5)	..... **[^{0}C]**	❑
4.2	Weight System:			
4.2.1	Load cell comparison measurement (with reference weight) at:	+ _____._____ g =	..... **[g]**	
	(permissible tolerance ± 50 g)	Difference between Reference/Actual Value =	_____ **[g]**	❑
4.2.2	Load cell comparison measurement (without reference weight) at:	0 g =	..... **[g]**	
	(permissible tolerance ± 50 g)	Difference between Set/Actual Value =	_____ **[g]**	❑
4.3	Pressures:	- Comparison measurement at PA/PV (tolerance ± 20 mmHg)	..... [mmHg]	❑
4.4	Blood Leak Detector:	- Test alarm function passed		❑
4.5	Safety Air Detector (SAD):	- Test alarm function passed		❑

Applied Accessories/Disposables: .....
.....

Applied Measurement Equipment:

Temperature: ..... * **ID/Serial No.:** .....

Pressure: ..... * **ID/Serial No.:** .....

Electrical Safety Check: ..... * **ID/Serial No.:** .....

Reference Weight: ..... * **ID/Serial No.:** .....

* If applicable

The commissioning was performed and the machine was handed over to the user

Name of Service Technician: .....

Name of Company: .....

....
Date / Signature

User: .....
Date / Signature

Technical Safety Inspection with Preventive Maintenance

For **Diapact CRRT**

The technical safety inspection must be performed and documented every **12 months**, according to the specified check list and with reference to the service manual and operating manual.
The preventive maintenance is recommended every **12 months**, according to the specified check list and with reference to the service manual and operating manual and should be documented.

Type: ..... No.: .....

Year of Purchase: ..... User: .....

.....

Operating Hours: ..... h Inventory No.: .....

SW Version: .....

Manufacturer:

B. Braun Avitum AG
Schwarzenberger Weg 73-79, 34212 Melsungen, Germany

Technical Safety Inspection ..... ❑

Technical Safety Inspection with Preventive Maintenance ..... ❑

S	M	S = Technical Safety Inspection Points; M = Preventive Maintenance Points	No	Yes	OK
		1. Visual Inspection, Function Inspection (Document Measurement Values and if necessary Calibrate) and Maintenance Procedures			
S		1.1 Machine: clean/complete; no damages/moisture influences; unit rollers are moveable; machine record book present; no special incidents; type plate, labels and inscriptions present and legible	❑	❑	❑
	M	1.2 Clean interior space and exterior surfaces	❑	❑	❑
S		1.3 Check mains supply (power supply line, connectors and screw terminals)	❑	❑	❑
	M	1.4 Check level regulation pump LRP and replace all internal filters	❑	❑	❑
	M	1.5 Tight seat of boards and connectors	❑	❑	❑
	M	1.6 Check protection covers and protective conductor			
	M	1.7 Tight seat of connectors, tubings and clamps	❑	❑	❑
	M	1.8 Fan in power supply clean	❑	❑	❑
	M	1.9 LC Display: Tight seat	❑	❑	❑
	M	1.10 Check parameters in Diapact CRRT Monitor Program:			
		1.10.1 SAD Alarm Volume (DPC=2000, DPS=3000)			❑
		1.10.2 Pumps: - Tube constants: (3 x 6: DPC/DPS=1764; 7 x 10: DPC/DPS=8052)			❑
		1.10.3 - Characteristics (Gain 4050; Offset: 80)			❑
		1.10.4 UF (continuous/intermittent therapy: 25%; plasma therapy: 35%)			❑
S		1.11 LC Display:			
		1.11.1 Function of the keys, display illumination	❑	❑	❑
		1.11.2 Image display, geometry	❑	❑	❑
		1.11.3 Alarm signal	❑	❑	❑
S		1.12 Blood Pump: - Alarm cover, one-way bearing			❑
S		1.13 Fluid Pump: - Alarm cover, one-way bearing			❑
S		1.14 Ultrafiltration Pump: - Alarm cover, one-way bearing			❑
S		1.15 Venous Tubing Clamp: - Function and moveability	❑	❑	❑
		1.15.1 Gap 1.4 mm (+ 0.1)	❑	❑	❑
S		1.16 Arterial Pressure PA: - Comparison measurement at: - 400 =..... **[mmHg]**			❑
		(permissible tolerance ±10 mmHg) 0 =..... **[mmHg]**			❑
S		1.17 Inlet Pressure PBE: - Comparison measurement at: + 400 =..... **[mmHg]**			❑
		(permissible tolerance ±10 mmHg) 0 =..... **[mmHg]**			❑
S		1.18 Pressure PD1: - Comparison measurement at: + 400 =..... **[mmHg]**			❑
		(permissible tolerance ±10 mmHg) 0 =..... **[mmHg]**			❑

S	M	S = Technical Safety Inspection Points; M = Preventive Maintenance Points			No	Yes	OK
S		1.19 Pressure PD2/PSC:	- Comparison measurement at:	+ 400 =..... **[mmHg]**			❑
		(permissible tolerance ±10 mmHg)		0 =..... **[mmHg]**			❑
S		1.20 Venous Pressure PV:	- Comparison measurement at:	+ 400 =..... **[mmHg]**			❑
		(permissible tolerance ±10 [mmHg])		0 =..... **[mmHg]**			❑
S		1.21 Staff Call (Option):	- Function or contact continuity passed		❑	❑	❑
S		1.22 Balance System					
		1.22.1 Load cell comparison measurement (with reference weight) at:		+ ____._____ g =..... **[g]**			
		(permissible tolerance ± 50 g)		Difference between Reference/Actual Value = _____ **[g]**			❑
		1.22.2 Load cell comparison measurement (without reference weight) at:		0 g =..... **[g]**			
		(permissible tolerance ± 50 g)		Difference between Set/Actual Value = _____ **[g]**			❑
S		1.22.3 Power Fail Function:	- Check function, duration of a constant audible alarm > 1 minute (activate buzzer in power supply, i.e. switch on machine and disconnect mains plug)				❑
		2. Electrical Safety Check According to EN 60601-1/IEC 601-1					
S		2.1 Measure mains voltage		..... **[V~]**			❑
S		2.2 Protective earth conductor resistance < 0.2 Ω	- Potential equalization bolt rear panel (exterior)	..... **[Ω]**			❑
		(Machine incl. power supply line)	- Screw connection plate warmer	..... **[Ω]**			❑
S		2.3 Earth leakage current ≤ 0.5 mA	- During heat-up phase	..... **[mA]**			❑
S		2.4 Patient leakage current < 0.1 mA	- Under normal conditions	..... **[mA]**			❑
		3. Setting into Service According to Operating Manual					
S		3.1 Switch on Machine:	- Selftest passed		❑	❑	❑
		3.1.1 Buzzer:	- Test passed		❑	❑	❑
S		3.2 Temperature	- Comparison measurement at 37 °C (-1.5; +0.5)	..... **[°C]**			❑
S		3.3 Saferty Air Detector (SAD):	- Test alarm function passed		❑	❑	❑
S		3.4 Ultrafiltration	- Comparison measurement at 500 ml/h (±15)	..... **[ml/h]**			❑
S		3.5 Blood Leak Detector (BLD):	- Test alarm function passed		❑	❑	❑
CHECK RESULTS: Defects were detected, which could endanger patients, users or third parties.					❑	❑	❑

Applied Accessories/Disposables: .....

.....

Applied Measurement Equipment:

Temperature: ..... * **ID/Serial No.:** .....

Pressure: ..... * **ID/Serial No.:** .....

Electrical Safety Check: ..... * **ID/Serial No.:** .....

Reference Weight: ..... * **ID/Serial No.:** .....

* If applicable

Must actions be taken with reference to maintenance	❑	❑	❑

Note next appointment: .....

The technical safety inspection or technical safety inspection with preventive maintenance was performed correctly.

Name of Service Technician: .....

..... Date / Signature

Name of Company: .....

User: .....

Date / Signature