# Diapact<sup>®</sup> CRRT

# Instructions for use 2.1x







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

IFU 38919907 / Rev. 04 / 2008-04



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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 |
|---|--|
|   | USC.   |
|   | 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.

| 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 |

There are three levels of warning notices:

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



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

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

> This symbol marks the instructions for action.

i

## 1.1.4 Abbreviations

| AD     | Air detector                                   |
|--------|--|
|        |  |
| CVVHD  | Continuous veno-venous naemoulalysis           |
| 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



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<sup>®</sup> 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- $\mu$ m 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.

# Safe handling

#### 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<br>Diapact <sup>®</sup> CRRT or when other non-medical devices are installed close to the<br>Diapact <sup>®</sup> CRRT, the user must ensure correct operation of the Diapact <sup>®</sup> CRRT in<br>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 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



- 4 Base frame
- **5** Storage box

- Bag holder of the load cell
- 8 Heater
- **9** Holder of the infusion pole
- 10 Infusion pole

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# 2 Product description

# 2.2

Symbols on the machine

| $\land$            | Observe instructions for use<br>Observe safety information                    |
|--------------------|---|
| *                  | Application device type B<br>Classification acc. to DIN EN 60601-1/ IEC 601-1 |
| <b>л</b><br>0      | Machine OFF   |
| <b>~</b>           | Machine ON  |
| 2                  | Alternating current   |
| ¢                  | Connection nurse call   |
| $\diamond$         | Connection of external computer   |
| $\bigtriangledown$ | Potential equalization  |
|                    | Connection for perfusor   |

# 2.3 User interface

2.3.1

# 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

| 10 | Key for alarm acknowledgment   |
|----|--|
| AU | 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. |
| FO | Confirmation key   |
| EQ | 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.

| V  | Selecting the venous air trap   |
|----|---------------------------------|
| BE | Selecting the arterial air trap |
| SC | 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="">.</function></parameters></therapy>  |
|---|--|
|   | Increases the selected parameter in <parameters setting="">.</parameters>  |
| 1 | Moves the cursor downwards in the <therapy selection=""> and <parameters setting=""> menus and to the left in <function selection="">.</function></parameters></therapy> |
|   | Decreases the selected parameter in <parameters setting="">.</parameters>  |
| t | Confirms the selection in <therapy selection="">, <function selection=""> and <parameters setting="">.</parameters></function></therapy>                                 |
|   | Confirms the changed parameter in <parameters setting="">.</parameters>  |
|   | Leaves the <parameters setting=""> menu.</parameters>  |

# 2 Product description

# 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<br>STOP | <ul><li>Blood pump START and STOP</li><li>LED lights up - the pump is stopped</li><li>LED does not light up - the pump runs</li></ul> |
| -             | 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)<br>The phase and the parameters saved for the therapy previously interrupted are<br>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.

|      |   | 12                         | 3 4        | 4<br>      |                    | 5                  | 5 6    | 57    | 2 '<br>  | 8 9              | 9          |
|------|---|----------------------------|------------|------------|--------------------|--------------------|--------|-------|----------|------------------|------------|
| Disp | ay  | CVVH                       |            |            |                    |                    |        | PR    | EPA      | ITAS             | ON         |
| 1    | Therapy mode                              | CONTINUOUS VEN             | 0-VENOUS F | LAEMOF     | IL TRATIO          | N                  |        | Devi  | ce test  | finist           | hed        |
| 2    | Alarms, warnings,<br>messages             |                            |            |            |                    |                    |        |       | r        | 0.20             | 2001       |
| 3    | Blood circuit                             | BLOOD FLOW                 |            | 0          | aldain             | SURSTIT            | TITION | FLOW  | 1        | 020              |            |
| 4    | Menu selection                            |                            |            |            |                    | 3003111            | urron  | r.cow |          | 00 1117          | 'n         |
| 5    | Therapy time                              | PA MIN                     |            | -200       | milig              | PD2 HIN            |        |       | 37<br>-1 | .0 ∘C<br>00 mm#  | ig .       |
| 0    | parameters/data                           | PA MAX<br>PBE MAX          |            | 100<br>400 | numilig<br>numilig | UF RATE            |        |       |          | n at             | th.        |
| 7    | Therapy status                            | PV WINDOW                  |            | 100        | milig              |                    |        |       |          |                  |            |
| 8    | Safety-relevant data,<br>supervisor field | FILTER DROP PR.<br>THP MAX | MAX        | 200<br>450 | nniig<br>nniig     | THERAPT<br>SUB BAG | VOLUN  | Æ     | 00:0     | 00 h:m<br>00 lit | rin<br>ers |
| 9    | Parameter range                           |                            |            |            |                    |                    | _      |       | ć        |                  | _          |
|      |   | SETTING                    |            | PRI        | MING               | PRE-<br>DILUTIO    | N      |       | SI       | BACK             | N          |

## • 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 th

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<sup>®</sup> 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<sup>®</sup> Acute).

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



#### Haemofiltration (CVVH/HF)

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

With the Diapact<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>) 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.



# 2 Product description

# Diapact<sup>®</sup> CRRT



## 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<sup>®</sup> CRRT, the substitution fluids mentioned above are used as dialysis fluids.



#### 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.

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

#### 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.



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

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| 3     | Installation and Commissioning  |
|-------|---|
|       | <b>First installation and operation</b><br>Unpacking and first installation of the machine must be carried out by a service<br>technician of B. Braun Avitum AG or by an authorized service technician. |
| 3.1   | Scope of supply   |
|       | Diapact <sup>®</sup> 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.  |

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# 3.3 Transportation

# 3.3.1 Wheeling

| $\Lambda$ | <ul> <li>Risk of damage if dialysis machine is tilted by &gt; 10°!</li> <li>➢ Have two or more persons at hand for transporting the machine on stairs and inclined areas.</li> </ul> |
|-----------|--|
| CAUTION   | $\succ$ 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.

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# 3.3.2 Carrying

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



- 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   |  |  |  |  |  |  |
|-------|---|--|--|--|--|--|--|
|       | !   | <b>Ambient conditions</b><br>Observe information about ambient conditions, see Section 15.2.   |  |  |  |  |  |
| 3.4.1 | Electrical connecti   | ion  |  |  |  |  |  |
|       | The existing mains vo   | Itage must match the voltage specified on the rating plate.  |  |  |  |  |  |
|       | No extension cables of  | or adapters may be used with the mains cable.  |  |  |  |  |  |
|       | Electrical installation:<br>regulations, e.g. VDE (                 | s in the room where the dialysis machine will be operated must conform to relevant 0100 Part 710 and/or IEC stipulations.  |  |  |  |  |  |
|       | Regulations and devine information, ask tech                        | viations specific to the individual country must also be observed. For further nical service.  |  |  |  |  |  |
|       | The dialysis machine  | must be properly grounded.   |  |  |  |  |  |
| 3.4.2 | Potentially explosi   | ve areas   |  |  |  |  |  |
|       | Do not operate the di   | alysis machine in areas with risk of explosions.   |  |  |  |  |  |
| 3.5   | Initial commissioni<br>Initial commissioning                        | ing<br>should be carried out by the responsible technical service.   |  |  |  |  |  |
| 3.6   | Switching on and  | off  |  |  |  |  |  |
|       | !   | <ul> <li>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.</li> <li>Only switch on dialysis machine after it has reached room temperature.</li> <li>Observe requirements on installation site.</li> </ul> |  |  |  |  |  |
| 3.6.1 | Intended switching  | g on and off   |  |  |  |  |  |
|       | <ul> <li>Press mains switc</li> <li>The dialysis machine</li> </ul> | r<br>h.<br>ine switches from ON to OFF status or vice versa.   |  |  |  |  |  |
| 3.6.2 | Accidental pressing   | g of the mains switch  |  |  |  |  |  |
|       | In case of accidenta<br>dialysis session, proc                      | Ily switching off the dialysis machine by actuating the mains switch during a eed as follows:  |  |  |  |  |  |
|       | <ul> <li>Press mains switc</li> <li>The dialysis mach</li> </ul>    | h again.<br>ine 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

| В | BIBF | AUN     | ]      |               |               | SEL        | FTE<br>ROMIT | ST<br>est |
|---|------|---------|--------|---------------|---------------|------------|--------------|-----------|
|   |      |         |        |               |               | CRC        | 83           | %         |
|   |      |         |        |               |               |            |              |           |
|   |      | S₩      | HW     | Language 1    | Language 2    | Language 3 |              |           |
|   | SYS  | v2.12.4 |        | 5 5           | 5 5           |            |              |           |
|   | DPD  | v2.12.4 | Rev. B | v044.02.12.00 | v049.02.12.00 | V086.02.12 | .00          |           |
|   | DPC  | v2.12.4 | Rev. C |               |               |            |              |           |
|   | DPS  | v2.12.4 | Rev. B | v044.02.12.00 | v049.02.12.00 | v086.02.12 | .00          |           |
|   |      |         |        |               |               |            |              | 4         |
|   |      |         |        |               |               |            |              |           |
|   |      |         |        |               |               | Q          |              | 224 h     |

- 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 and keys are lit during the ROM test.

| BF  | AUN     | 1      |                 |               | SELFT<br>Display      | ES7<br>test |
|-----|---------|--------|-----------------|---------------|-----------------------|-------------|
|     |         |        |                 | S             | 5-0123456<br>-0123456 | 789<br>789  |
|     |         |        |                 |               |                       |             |
|     | S₩      | HW     | Language 1      | Language 2    | Language 3            |             |
| SYS | v2.12.4 |        |                 |               |                       |             |
| DPD | v2.12.4 | Rev. B | v044.02.12.00   | V049.02.12.00 | 0 V086.02.12.00       |             |
| DPC | v2.12.4 | Rev. C |                 |               |                       |             |
| DPS | v2.12.4 | Rev. B | v044.02.12.00   | v049.02.12.00 | 0 V086.02.12.00       |             |
|     |         | VEF    | RIFY CHARACTERS | AND CONFIRM V | ∦ITH EQ               |             |
|     |         |        |                 |               | Ø                     | 224         |

The ROM test is followed by the display test.

 Compare the character lines in the supervisor field and confirm by pressing the



key if both series are identical.

- > While the key is being pressed, the buzzer of the safety system is activated for 2 seconds.
- > Check that the buzzer can be heard.

| BF  | RAUN    | 2      |                |                | SELFT<br>Empty loadcell |
|-----|---------|--------|----------------|----------------|-------------------------|
|     |         |        | Weight o       | f bag holder:∣ | (± 60 g)                |
|     |         |        |                |                |                         |
| CVC | SW 12.4 | HW     | Language 1     | Language 2     | Language 3              |
| 212 | V2.12.4 | Pay P  | V044 02 12 00  | V049 07 17 00  | V026 02 12 00           |
| DPC | v2.12.4 | Rev C  | ¥044.02.12.00  | ¥045.02.12.00  | ¥000.02.12.00           |
| DPS | v2.12.4 | Rev. B | v044.02.12.00  | v049.02.12.00  | v086.02.12.00           |
|     |         |        |                |                |                         |
|     |         |        | BAG HO         | LDEK FREE?     |                         |
|     |         | CHE    | CK THE WEIGHTS | AND CONFIRM M  |                         |

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



key if they are within the allowed range. The maximum deviation between both displayed values is allowed to be  $\pm$  60 g and the values must not exceed -60 and +60 g.

# 4.2 Therapy selection

| BBRAUN                          | THERAPY SELECTION<br>Standby | Having successfully passed the initial self tests, the machine switches to the <therapy selection=""></therapy> |
|---------------------------------|------------------------------|---|
|                                 |                              | screen to select the therapy mode.  |
| PLASMA THERAPIES                | DIALYSIS THERAPIES           | default.  |
| ADSORPTION / PERFUSION          | CONTINUOUS                   | Confirm <continuous> with the</continuous>  |
| PLASMA EXCHANGE                 | INTERMITTENT                 | key.  |
|                                 |                              | The following screen displays the possible therapy  |
| SELECT THERAPY MODE AND CONFIRM |                              | options.  |
|                                 | <u>Ø</u> 224 h               |   |
| BBRAUN                          | THERAPY SELECTION<br>Standby | <cvvh> is selected by default.</cvvh>   |
|                                 | SCUF                         | Select <scuf> using the key</scuf>  |
| CONTINUOUS DIALY                | SIS THERAPIES                | <ul> <li>Confirm the selection with the</li> </ul>  |
| CVVHD                           | SCUF                         |   |
| CVVHFD                          | CVVH                         | key.  |
|                                 |                              | The <b>EQ</b> key lights up and SCUF is displayed in  |
| SELECT AND CONFIRM              |                              | the supervisor field.   |
|                                 | BACK SELECTION               | <ul> <li>Press the EQ key for final confirmation of the selected therapy modality.</li> </ul>                   |
|                                 |                              | If the selection after the confirmation with the  |
|                                 |                              | key is not finally confirmed with the   |

EQ

key, the device returns automatically to the <THERAPY SELECTION> screen where the therapy mode can be selected.

# **Back selection**





allows to return to the screen where the therapy mode can be selected.

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 Preparation

| o not connect any dispo | sable |        |     |                 |       |        |
|-------------------------|-------|--------|-----|-----------------|-------|--------|
| BLOOD FLOW              | 0     | ml∕min |     |                 |       |        |
| TREATED BLOOD VOLUME    | 0.0   | liters | PD2 |                 | 0     | mmHq   |
|                         |       |        | UF  | RATE            | 0     | mi∕n   |
| PA                      | 0     | mmHg   |     |                 |       |        |
| PBE                     | -1    | mmHg   | FLU | ID WEIGHT       | 93    | g      |
| PV                      | -1    | mmHg   | THE | RAPY TIME RES.  | 00:00 | h:min  |
| FILTER DROP PR. (PFD)   | 0     | mmHg   |     |                 |       |        |
| TMP                     | -1    | mmHg   | UF  | BAG VOLUME RES. | 0.00  | liters |
|                         |       |        |     |                 |       |        |

## 4.3.1 Installation of consumable material

SCUF PREPARATION When the tests have been performed successfully, the SLOW CONTINUOUS ULTRAFILTRATION Device test finished <PREPARATION> screen displays <Device test finished> and the steps to set-up the machine are displayed. 1. Hang one saline fluid bag (21) on weighing system The consumable material for the therapy comprises: Place the filter on its holder with venous (blue) side up 2 SCUF kit 3. ▲ Hang UF collection bag on weighing system. Clamp the outlet. 4. Mount and connect UF line (yellow) through BLD. Haemofilter • 5. Mount and connect Arterial line (red). 2L isotonic sodium chloride solution 6. Hang Venous collection bag on the IV pole. 7. Mount and connect Venous Line (blue). Make sure all the necessary clamps are opened then start PRIMING > Follow the instructions on the screen and set-up the device as described in the following. PARAMETERS BACK PRIMING SETTING SELECTION

The lines of the SCUF kit are colour-coded to facilitate the set-up. Arterial line (red) Venous line (blue) Ultrafiltration line (yellow) Ĩ Pumps used: Blood pump (MP1) Ultrafiltration pump (MP2) 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,  $\geq$ haemofilter, solution bags) is undamaged. WARNING  $\geq$ During set-up check the material for integrity.  $\geq$ Observe the respective instructions for use.

# 4 SCUF



#### 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.

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.

CAUTION

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.

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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.

# 4 SCUF



#### 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.

# 4 SCUF



#### 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.

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

# Diapact<sup>®</sup> CRRT

### 4.3.2 Priming

| SCUF<br>SLOW CONTINUOUS ULTRAI | ON  | PRE<br>Arteria | PARA               | TION      |              |
|--------------------------------|-----|----------------|--------------------|-----------|--------------|
|                                |     |                |                    |           |              |
| BLOOD FLOW                     | 100 | ml∕min         |                    |           |              |
| TREATED BLOOD VOLUME           | 0.0 | liters         | PD2<br>UF RATE     | 4<br>0    | mmHg<br>ml∕h |
| PA                             | 7   | mmHg           |                    |           |              |
| PBE                            | 37  | mmHg           | FLUID WEIGHT       | 1368      | g            |
| PV                             | 1   | mmHg           | THERAPY TIME RES.  | 00:00     | h:min        |
| FILTER DROP PR. (PFD)          | 36  | mmHg           |                    |           |              |
| TMP                            | 15  | mmHg           | UF BAG VOLUME RES. | 0.00      | liters       |
| PARAMETERS<br>SETTING          | PRI | MING           |                    | B<br>SELE | ACK          |

| SCUF<br>SLOW CONTINUOUS ULTRAFILTRATION        | PREPARATION<br>Ready for therapy   |
|--|------------------------------------|
|  |                                    |
| 1. Remove saline bag from the weighing system  | M.                                 |
| 2. Make sure that all the necessary clamps a   | re opened.                         |
| 3. A Insert the fluid lines into the tubing cl | ips on the bag holder.             |
| Select ENTER THERAPY - then connect patient.   |                                    |
| PARAMETERS<br>SETTING                          | ENTER<br>THERAPY BACK<br>SELECTION |

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



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



The device switches automatically to <PARAMETERS SETTING>.

#### 4 SCUF

#### 4.3.3 Parameter setting

| Check and confirm the | safety ( | inverse) | parameters    | 100<br>[ 802000]  | SCUF) are d  |
|-----------------------|----------|----------|---------------|-------------------|--------------|
| BLOOD FLOW            | 0        | ml∕min   | PD2 MIN       | -50 mmHa          | > Activate   |
| PA MIN                | -150     | mmHg     |               | <b>,</b>          | k            |
| PA MAX                | 100      | mmHg     |               | _                 |              |
| PBE MAX               | 400      | mmHg     | UF RATE       | 100 ml⊿h          | The valu     |
| PV WINDOW             | 100      | mmHg     |               |                   | backara      |
| FILTER DROP PR. MAX   | 200      | mmHg     | THEKAPY TIME  | 00:00 h:min       | Dackyru      |
| IMP MAX               | 450      | mmHg     | UF BAG VULUME | U.UU liters       | If the value |
|                       |          |          | (             |                   |              |
| PARAMETERS<br>SETTING | RIN      | ISING    | ENTER         | BACK<br>SELECTION | k k          |
|                       |          |          |               |                   |              |

#### ety-relevant parameters

elevant parameters (ultrafiltration rate in isplayed on a black background.

<UF rate> by pressing the



ie is inversely displayed on a black und

lue is accepted, confirm by pressing the



nge the value, press the

key to increase it or the key to decrease it.



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



i

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

| SCUF<br>SLOW CONTINUOUS ULTRAI | PREPARATION<br>Ready for therapy |          |               |                                   |
|--------------------------------|----------------------------------|----------|---------------|-----------------------------------|
| heck and confirm the :         | safety (                         | inverse) | parameters    | [-25.00 0.00]                     |
| BLOOD FLOW                     | 0                                | ml∕min   |               |                                   |
|                                |                                  |          | PD2 MIN       | -50 mmHg                          |
| PA MIN                         | -150                             | mmHg     |               |                                   |
| PA MAX                         | 100                              | mmHg     |               |                                   |
| PBE MAX                        | 400                              | mmHg     | UF RATE       | 100 ml≁h                          |
| PV WINDOW                      | 100                              | mmHg     |               |                                   |
| FILTER DROP PR. MAX            | 200                              | mmHg     | THERAPY TIME  | 00:00 h:min                       |
| TMP MAX                        | 450                              | mmHg     | uf bag volume | 0.00 liters                       |
| PARAMETERS<br>SETTING          | RIN                              | ISING    |               | ENTER<br>HERAPY BACK<br>SELECTION |

#### Setting treatment parameters





> Activate the parameter by pressing the

key.

> Change the value with the







key.

➤ To exit <PARAMETERS SETTING>, press the

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

| 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                   | mmHg   | 200     | 100     | 450     | 10         |
| max. pressure drop    |        |         |         |         |            |
| 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         |        | 0.00    | -25.00  | 00.00   | 0.10/1.00  |
| Therapy time          | h:min  | 00:00   | 00:00   | 72:00   | 0:05/0:30  |

The following data can be set in the indicated ranges:

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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



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 <br/>bag volume is over (1020)> occurs

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

#### 4.3.4 Menu selection in preparation

| SCUF<br>SLOW CONTINUOUS ULTRAFILTRATION |     |        | PR                | EPARA        | TION   |
|---|-----|--------|-------------------|--------------|--------|
|   |     |        |                   |              |        |
| BLOOD FLOW                              | 200 | ml∕min |                   |              |        |
| TREATED BLOOD VOLUME                    | 0.0 | liters | PD2               | 13           | mmHq   |
|   |     |        | UF RATE           | 0            | mi∕n   |
| PA                                      | -36 | mmHg   |                   |              |        |
| PBE                                     | 81  | mmHg   | FLUID WEIGHT      | 1567         | g      |
| PV                                      | 38  | mmHg   | THERAPY TIME RES. | 00:00        | h:min  |
| FILTER DROP PR. (PFD)                   | 43  | mmHg   |                   |              |        |
| тмр                                     | 46  | mmHg   | UF BAG VOLUME RES | . 0.00       | liters |
| PARAMETERS<br>SETTING                   | RIN | SING   | ENTE              | R<br>PY SELE | ACK    |

#### Rinsing

If necessary, rinsing can be prolonged by selecting <RINSING> and confirming with the



- 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



#### **Back selection**

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

Select <BACK SELECTION> and confirm with the



# Diapact<sup>®</sup> CRRT

#### 4.4 Therapy

| SCUF   | PREPARATION                     |
|--|---------------------------------|
| SLOW CONTINUOUS ULTRAFILTRATION                          | Ready for therapy               |
|  | THERAPY                         |
| I. Remove saline bag from the weighing sy                | stem.                           |
| <ol><li>Make sure that all the necessary clamp</li></ol> | s are opened.                   |
| 3. 🔺 Insert the fluid lines into the tubing              | clips on the bag holder.        |
|  |                                 |
|  |                                 |
|  |                                 |
|  |                                 |
|  |                                 |
| select ENTER THERAPY - then connect nationt              |                                 |
| Select ENTER THERAPY - then connect patient              | •                               |
| Select ENTER THERAPY - then connect patient              |                                 |
| Select ENTER THERAPY - then connect patient              | ENTER BACK                      |
| Select ENTER THERAPY - then connect patient              | ENTER BACK<br>THERAPY SELECTION |

| SCUF<br>SLOW CONTINUOUS ULTRAF                 | ON       | Blood leak b | THEF<br>lood fre       | RAPY<br>e test |              |
|--|----------|--------------|------------------------|----------------|--------------|
| Ensure NO BLOOD, AIR in<br>and confirm with EQ | tube m   | iounted i    | nto Blood Leak Det. BL | DOD LEAK       | RECAL.       |
| BLOOD FLOW                                     | 0        | ml∕min       |                        |                |              |
| TREATED BLOOD VOLUME                           | 0.0      | liters       | PD2<br>UF RATE         | 57<br>0        | mmHg<br>ml∕h |
| PA   | -21      | mmHg         | UF VOLUME              | 0              | ml           |
| PBE  | 62       | mmHg         | FLUID WEIGHT           | 456            | ml           |
| PV   | 45       | mmHg         | THERAPY TIME RES.      | 00:00          | h:min        |
| FILTER DROP PR. (PFD)                          | 17       | mmHg         | THERAPY TIME           | 00:00          | h:min        |
| TMP  | -4       | mmHg         | UF BAG VOLUME RES.     | 0.00           | liters       |
|  | <b>`</b> |              |                        |                |              |
| PARAMETERS TOTALS                              |          |              | BAG THERAPY            | EN             | DOF          |
| SETTING OVERVIEW                               | J        |              | CHANGE                 | THE            | RAPY         |

#### 4.4.1 Connecting the patient

To switch from <PREPARATION> to <THERAPY>, select <ENTER THERAPY> and confirm by pressing the



 Confirm the start of the therapy by pressing the flashing



while <THERAPY> is flashing in the supervisor field.

The Diapact<sup>®</sup> CRRT is now in the therapy status as indicated in the therapy status field.

 Confirm the blood leak recalibration by pressing the



- Start the blood pump for circulation by pressing the STOP kev.
- > 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



- 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.

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

## 4 SCUF

#### 4.4.2 Start of therapy

| SCUF<br>SLOW CONTINUOUS ULTRAF | ILTRATI |        | THERAPY<br>Running |             |
|--------------------------------|---------|--------|--------------------|-------------|
| BLOOD FLOW                     | 50      | ml⊿min |                    |             |
| TREATED BLOOD VOLUME           | 0.0     | liters | PD2                | 43 mmHg     |
|                                |         |        | UF RATE            | 100 ml≁n    |
| PA                             | 50      | mmHg   | UF VOLUME          | 1 ml        |
| PBE                            | 54      | mmHg   | FLUID WEIGHT       | 456 m.l     |
| PV                             | 29      | mmHg   | THERAPY TIME RES.  | 00:00 h:min |
| FILTER DROP PR. (PFD)          | 25      | mmHg   | THERAPY TIME       | 00:00 h:min |
| TMP                            | -2      | mmHg   | UF BAG VOLUME RES. | 0.00 liters |
|                                | 1       |        |                    |             |
| SETTING OVERVIEW               |         |        | CHANGE             | 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



<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.



#### 4.4.3 Menu selection in therapy

#### Parameter setting

See Section 4.3.3

| SCUF<br>SLOW CONTINUOUS ULTRAFILTRATION |               | THERAPY<br>Running |
|---|---------------|--------------------|
|   |               |                    |
| BLOOD FLOW 50 ml/min                    |               |                    |
| TREATED BLOOD VOLUME 0.3 liters         |               |                    |
| $\Sigma$ TR. BLOOD VOLUME 0.3 liters    | UF RATE       | 100 ml≁n           |
|   | uf volume     | 8 m.t              |
| THERAPY TIME 00:05 h:min                | ΣUF VOLUME    | 8 m.               |
| ΣTHERAPY TIME 00:05 h:min               |               |                    |
| PRESSURE<br>OVERVIEW                    | BAG<br>Change | THERAPY<br>RESET   |

#### **Totals overview**

Select <TOTALS OVERVIEW> and confirm by pressing the



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



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  $\Sigma.$ 

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



#### Pressure overview

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

Select <PRESSURE OVERVIEW> and confirm by pressing the



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



#### Bag change

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

Select <BAG CHANGE> and confirm by pressing the



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



The treatment continues automatically.



| SCUF<br>SLOW CONTINUOUS ULTRAFI       | BI     | THERAPY<br>Blood circulation |                       |           |              |
|---------------------------------------|--------|------------------------------|-----------------------|-----------|--------------|
| Release BAG CHANGE to co              | ntinue | the the                      | rapy.                 |           |              |
| BLOOD FLOW                            | 50     | ml∕min                       |                       |           |              |
| TREATED BLOOD VOLUME                  | 0.3    | liters                       | PD2                   | 43        | mmHg         |
| På                                    | 50     | mmHa                         |                       | 11        | mizri<br>mi  |
| PBE                                   | 54     | mmHa                         | FLUID WEIGHT          | 466       | mi           |
| PV                                    | 29     | mmHg                         | THERAPY TIME RES.     | 00:00     | h:min        |
| FILTER DROP PR. (PFD)                 | 25     | mmHg                         | THERAPY TIME          | 00:06     | h:min        |
| TMP                                   | -2     | mmHg                         | UF BAG VOLUME RES.    | 0.00      | liters       |
| ) [                                   | h      |                              |                       |           |              |
| PARAMETERS TOTALS<br>SETTING OVERVIEW |        |                              | BAG THERAPY<br>CHANGE | EN<br>THE | D OF<br>Rapy |

#### 4.5 End of therapy

| SCUF<br>SLOW CONTINUOUS ULTRAFT | THERAPY<br>Running |        |                    |                 |               |
|---------------------------------|--------------------|--------|--------------------|-----------------|---------------|
|                                 |                    |        |                    | <u>end of t</u> | HERAPY        |
| BLOOD FLOW                      | 50                 | ml∕min |                    |                 |               |
| TREATED BLOOD VOLUME            | 0.4                | liters | PD2                | 43              | mmHq          |
|                                 |                    |        | UF RATE            | 100             | ml⊿n          |
| PA                              | 49                 | mmHg   | UF VOLUME          | 12              | mi            |
| PBE                             | 54                 | mmHg   | FLUID WEIGHT       | 465             | ml            |
| PV                              | 29                 | mmHg   | THERAPY TIME RES.  | 00:00           | h:min         |
| FILTER DROP PR. (PFD)           | 25                 | mmHg   | THERAPY TIME       | 80:00           | h:min         |
| TMP                             | -2                 | mmHg   | UF BAG VOLUME RES. | 0.00            | liters        |
| PARAMETERS<br>SETTING OVERVIEW  | ]                  |        | BAG<br>CHANGE      | EN<br>THE       | ID OF<br>Rapy |

Select <END OF THERAPY> and confirm by pressing the

key.

> Confirm by pressing the



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

| SCUF                   |        |        | END O             | F THE | RAPY   |
|------------------------|--------|--------|-------------------|-------|--------|
| SLOW CONTINUOUS ULTRAF | LTRATI | ON     |                   | Blood | return |
|                        |        |        |                   |       |        |
|                        |        |        |                   |       |        |
|                        |        |        |                   |       |        |
|                        |        |        |                   |       |        |
|                        |        |        | [                 |       |        |
| BLOOD FLOW             | 50     | ml∕min |                   |       |        |
|                        |        |        |                   |       |        |
| TREATED BLOOD VOLUME   | 0.4    | liters | PD2               | 47    | maHa   |
|                        | •••    |        |                   |       |        |
|                        | 40     |        |                   | 13    |        |
| PA                     | 49     | mmHg   | UF VULUME         | 13    | mı     |
| PBE                    | 52     | mmHg   | UF RATE           | 0     | ml∕n   |
| PV                     | 29     | mmHg   | FLUID WEIGHT      | 468   | ml     |
| FILTER DROP PR. (PFD)  | 23     | mmHq   | THERAPY TIME RES. | 00:00 | h:min  |
| тмр                    | -7     | mmHa   | THERAPY TIME      | 00:08 | h:min  |
|                        | 2      | mining |                   | 00.00 |        |
|                        |        |        | A                 |       |        |
|                        |        |        |                   |       |        |
| TOTALS BLOOD           | LEAK   | BACK   | TO                | NEW   |        |
| OVERVIEW CALIE         | BR.    | THER   | APY               | THERA | PY     |
|                        |        |        |                   | L     |        |

#### 4.5.1 Disconnecting the patient

i

- 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<sup>®</sup> CRRT within this time frame.

## 4.5.2 Menu selection at end of therapy

| Blood return  | Totals overview  |
|---|--|
|   | The option <totals overview=""> shows the summary<br/>of the pivotal treatment data as described (Section<br/>8.4.3)</totals>  |
|   | <ul> <li>Select &lt; TOTALS OVERVIEW&gt; and confirm</li> </ul>  |
|   | by pressing the  |
| UF VOLUME 13 ml<br>ΣUF VOLUME 13 ml                       | <ul> <li>key.</li> <li>To return to the <end of="" therapy=""> screen, select <totals overview=""> and confirm with the</totals></end></li> </ul>  |
| BACK TO<br>THERAPY THERAPY                                | key.   |
| END OF THERAPY  | Blood leak recalibration   |
| to Blood Leak Det. BLOOD LEAK RECAL.                      | The <blood calibration="" leak=""> function allows the recalibration of the blood leak detector in case of non-acceptable alarms (e.g. elevated plasma bilirubin</blood>   |
|   | concentration)   |
| PD2 43 mmHg   | Select "BLOOD LEAK CALIBRATION" and  |
| UF VOLUME 13 ml<br>UF RATE 0 ml≁h<br>FLUID WEIGHT 468 ml  | kov lights up  |
| THERAPY TIME RES. 00:00 h:min<br>THERAPY TIME 00:08 h:min | <ul> <li>Confirm with the</li> </ul>   |
| TO NEW<br>PY THERAPY                                      | EQ key.  |
|   | Select <back therapy="" to=""> and confirm with the</back>   |
|   | key. The key lights up.  |
|   | Confirm with the EQ key  |
|   | Key. Adapt the blood flow to the initial value.  |
|   | <ul> <li>Start <therapy> by pressing the</therapy></li> </ul>  |
|   |  |
|   | UF VOLUME 13 ml<br>2UF VOLUME 13 ml<br>BACK TO NEW<br>THERAPY THERAPY<br>Blood leak blood free test<br>to Blood Leak Det. DIOD LEAK RECAL.<br>PD2 43 mmHg<br>UF VOLUME 13 ml<br>UF RATE 0 ml/h<br>FLUID WEIGHT 468 ml<br>THERAPY TIME RES. 00:00 h:min<br>THERAPY RES. 00:00 h:min<br>TH |

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.

i

DANGER

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

# 4 SCUF

|  |   |   | <u>THERAPY</u>   | The option <back therapy="" to=""> returns to the just finished therapy.</back>  |
|--|---|---|--|--|
| BLOOD FLOW 5   | 0 ml≁min  |   |  | <ul> <li>Select <back therapy="" to=""> and confirm by<br/>pressing the</back></li> </ul>  |
| TREATED BLOOD VOLUME C   | .0 liters   | PD2   | 15 mmHg  | FO   |
| PA   | 46 mmHq   | UF VOLUME   | 0 ml   | key. The key lights up.  |
| PBE  | 57 mmHg   | UF RATE   | 0 ml≁h   |  |
| PV   | 33 mmHg   | FLUID WEIGHT  | 577 ml   | Confirm by pressing the  |
| FILTER DROP PR. (PFD)  | 24 mmHg   | THERAPY TIME RES.   | 00:00 h:min  | FO   |
| TMP  | 30 mmHg   | THERAPY TIME  | 00:00 h:min  | EU   |
|  |   |   |  | Key.   |
| TOTALS BLOOD LEA   | K BACK  | ТО  | NEW  | Start the therapy again by pressing the  |
|  | THEP  | APY   | THERAPY  |  |
|  |   |   |  |  |
|  |   |   |  | key.   |
|  |   | _   |  | key.   |
| SCUE   |   | END O   | F THERAPY  | key.   |
| SCUF   | ATION   | END O   | F THERAPY<br>Blood return  | New therapy  |
| SCUF   | ATION   | END O   | F THERAPY<br>Blood return  | New therapy         The option <new therapy=""> allows to start a new</new>  |
| SCUF   | ATION   | END O   | F THERAPY<br>Blood return  | New therapy         The option <new therapy=""> allows to start a new therapy immediately after the one just finished. The</new>   |
| SCUF   | ATION   | END O   | F THERAPY<br>Blood return  | New therapy         The option <new therapy=""> allows to start a new therapy immediately after the one just finished. The dwice switches directly to therapy selection</new>  |
| SCUF<br>SLOW CONTINUOUS ULTRAFILTF   | ATION<br>O mi/min   | END O   | F THERAPY<br>Blood return  | 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.</new>  |
| SCUF<br>SLOW CONTINUOUS ULTRAFILTF<br>BLOOD FLOW 5   | ATION<br>O ml/min   | END O   | F THERAPY<br>Blood return  | <ul> <li>key.</li> <li>New therapy</li> <li>The option <new therapy=""> allows to start a new therapy immediately after the one just finished. The device switches directly to therapy selection.</new></li> <li>Select <new therapy=""> and</new></li> </ul>  |
| SCUF<br>SLOW CONTINUOUS ULTRAFILTF<br>BLOOD FLOW 5<br>TREATED BLOOD VOLUME C   | ATION<br>O ml∕min<br>.0 liters  | END O   | F THERAPY<br>Blood return<br>HHERAPY SELECTION<br>15 mmHg  | <ul> <li>key.</li> <li>New therapy</li> <li>The option <new therapy=""> allows to start a new therapy immediately after the one just finished. The device switches directly to therapy selection.</new></li> <li>Select <new therapy=""> and confirm by pressing the</new></li> </ul>  |
| SCUF<br>SLOW CONTINUOUS ULTRAFILTF<br>BLOOD FLOW 5<br>TREATED BLOOD VOLUME C   | ATION<br>0 ml∕min<br>.0 liters  | END O   | F THERAPY<br>Blood return<br>HHRADY SELECTION<br>15 mmHg   | <ul> <li>key.</li> <li>New therapy</li> <li>The option <new therapy=""> allows to start a new therapy immediately after the one just finished. The device switches directly to therapy selection.</new></li> <li>Select <new therapy=""> and confirm by pressing the</new></li> </ul>  |
| SCUF<br>SLOW CONTINUOUS ULTRAFILTF<br>BLOOD FLOW 5<br>TREATED BLOOD VOLUME C   | ATION<br>Oml≁min<br>.0 liters<br>47 nmHg  | END O   | F THERAPY<br>Blood return<br>IHERAPY SELECTION<br>15 unitig<br>0 ml  | <ul> <li>key.</li> <li>New therapy</li> <li>The option <new therapy=""> allows to start a new therapy immediately after the one just finished. The device switches directly to therapy selection.</new></li> <li>Select <new therapy=""> and confirm by pressing the FO</new></li> </ul>   |
| SCUF<br>SLOW CONTINUOUS ULTRAFILTF<br>BLOOD FLOW 5<br>TREATED BLOOD VOLUME C   | ATION<br>O mi∕min<br>.0 liters<br>47 mmHg<br>61 mmHg  | END O   | F THERAPY<br>Blood return<br>THERAPY SELECTION<br>15 mmHg<br>0 ml<br>0 ml/h  | <ul> <li>key.</li> <li>New therapy</li> <li>The option <new therapy=""> allows to start a new therapy immediately after the one just finished. The device switches directly to therapy selection.</new></li> <li>Select <new therapy=""> and confirm by pressing the key. The Key lights up.</new></li> </ul>  |
| SCUF<br>SLOW CONTINUOUS ULTRAFILTF<br>BLOOD FLOW 5<br>TREATED BLOOD VOLUME C<br>PA<br>PBE<br>PV<br>ELITER DROP PR (PEP)  | ATION<br>O ml∠min<br>.0 liters<br>47 mmHg<br>61 mmHg<br>34 mmHg   | END O<br>PD2<br>UF VOLUME<br>UF RATE<br>FLUID VEIGHT<br>THERAPY TIME RES                  | F THERAPY<br>Blood return<br>INERAPY SELECTION<br>15 mmHg<br>0 ml<br>0 ml/n<br>578 ml<br>00:00 ml                      | <ul> <li>key.</li> <li>New therapy</li> <li>The option <new therapy=""> allows to start a new therapy immediately after the one just finished. The device switches directly to therapy selection.</new></li> <li>Select <new therapy=""> and confirm by pressing the key. The Key lights up.</new></li> </ul>  |
| SCUF<br>SLOW CONTINUOUS ULTRAFILTF<br>BLOOD FLOW 5<br>TREATED BLOOD VOLUME C<br>PA<br>PBE<br>PV<br>FILTER DROP PR. (PFD)<br>TMP                                | ATION<br>O mi∕min<br>.0 liters<br>47 mmHg<br>61 mmHg<br>34 mmHg<br>27 mmHg<br>23 mmHg                       | END O<br>PD2<br>UF VOLUME<br>UF RATE<br>FLUID VEIGHT<br>THERAPY TIME RES.<br>THERAPY TIME | F THERAPY<br>Blood return<br>INTERATY SELECTION<br>15 unitig<br>0 ul<br>0 ul/h<br>578 ul<br>00:00 h:win<br>00:00 h:win | <ul> <li>key.</li> <li>New therapy</li> <li>The option <new therapy=""> allows to start a new therapy immediately after the one just finished. The device switches directly to therapy selection.</new></li> <li>Select <new therapy=""> and confirm by pressing the key. The key. The key lights up.</new></li> <li>Confirm by pressing the</li> </ul>  |
| SCUF<br>SLOW CONTINUOUS ULTRAFILTF<br>BLOOD FLOW 5<br>TREATED BLOOD VOLUME C<br>PA<br>PBE<br>PV<br>FILTER DROP PR. (PFD)<br>TMP                                | ATION<br>O mi∕min<br>.0 liters<br>47 nmHg<br>61 nmHg<br>34 nmHg<br>34 nmHg<br>332 nmHg                      | END O<br>PD2<br>UF VOLUME<br>UF RATE<br>FLUID WEIGHT<br>THERAPY TIME RES.<br>THERAPY TIME | F THERAPY<br>Blood return<br>THERAPY SELECTION<br>15 mmHg<br>0 ml<br>0 ml/n<br>578 ml<br>00:00 h:min<br>00:00 h:min    | <ul> <li>key.</li> <li>New therapy</li> <li>The option <new therapy=""> allows to start a new therapy immediately after the one just finished. The device switches directly to therapy selection.</new></li> <li>Select <new therapy=""> and confirm by pressing the key. The key lights up.</new></li> <li>Confirm by pressing the formula to the second sec</li></ul> |
| SCUF<br>SLOW CONTINUOUS ULTRAFILTF<br>BLOOD FLOW 5<br>TREATED BLOOD VOLUME C<br>PA<br>PBE<br>PV<br>FILTER DROP PR. (PFD)<br>TMP                                | ATION<br>O mi∠min<br>.0 liters<br>47 mmHg<br>61 mmHg<br>34 mmHg<br>32 mmHg                                  | END O   | F THERAPY<br>Blood return<br>IHERAPY SELECTION<br>15 mmHg<br>0 ml<br>0 ml/h<br>578 ml<br>00:00 h:min<br>00:00 h:min    | <ul> <li>key.</li> <li>New therapy</li> <li>The option <new therapy=""> allows to start a new therapy immediately after the one just finished. The device switches directly to therapy selection.</new></li> <li>Select <new therapy=""> and confirm by pressing the key. The key lights up.</new></li> <li>Confirm by pressing the key lights up.</li> </ul>  |
| SCUF<br>SLOW CONTINUOUS ULTRAFILTF<br>BLOOD FLOW 5<br>TREATED BLOOD VOLUME C<br>PA<br>PBE<br>PV<br>FILTER DROP PR. (PFD)<br>TMP                                | ATION<br>O mi∠min<br>.0 liters<br>47 nmHg<br>34 nmHg<br>32 nmHg<br>32 nmHg<br>K BACK                        | END O<br>PD2<br>UF VOLUME<br>UF RATE<br>FLUID WEIGHT<br>THERAPY TIME RES.<br>THERAPY TIME | F THERAPY<br>Blood return<br>IHERAPY SELECTION<br>15 mmHg<br>0 ml<br>0 ml/h<br>578 ml<br>00:00 h:min<br>00:00 h:min    | <ul> <li>key.</li> <li>New therapy</li> <li>The option <new therapy=""> allows to start a new therapy immediately after the one just finished. The device switches directly to therapy selection.</new></li> <li>Select <new therapy=""> and confirm by pressing the key. The key lights up.</new></li> <li>Confirm by pressing the key.</li> </ul>  |
| SCUF<br>SLOW CONTINUOUS ULTRAFILTF<br>BLOOD FLOW 5<br>TREATED BLOOD VOLUME C<br>PA<br>PPE<br>PV<br>FILTER DROP PR. (PFD)<br>TMP<br>TOTALS BLOOD LEF<br>CALIBR. | O ml∠min<br>O liters<br>ATION<br>O liters<br>AT mmHg<br>AT mmHg<br>AT mmHg<br>AT mmHg<br>AT mmHg<br>AT mmHg | END O   | F THERAPY<br>Blood return<br>THEPAPY SELECTION<br>15 mmHg<br>0 ml<br>0 ml<br>578 ml<br>00:00 h:min<br>00:00 h:min      | <ul> <li>key.</li> <li>New therapy</li> <li>The option <new therapy=""> allows to start a new therapy immediately after the one just finished. The device switches directly to therapy selection.</new></li> <li>Select <new therapy=""> and confirm by pressing the key. The key lights up.</new></li> <li>Confirm by pressing the key.</li> </ul>  |

And the second second

4.6 Special functions

#### Bag movement function

To avoid superfluous alarms and the resulting pump standstill, the Diapact<sup>®</sup> 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.

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## 5 CVVH (Continuous veno-venous haemofiltration)

### 5.1 Switching on and initial tests

| B | BR  | AUN     | 1      |               |               | SEL        | FTE<br>ROMIT | ST<br>est |
|---|-----|---------|--------|---------------|---------------|------------|--------------|-----------|
|   |     |         |        |               |               | CRC        | 83           | %         |
|   |     |         |        |               |               |            |              |           |
|   |     | SW      | HW     | Language 1    | Language 2    | Language 3 |              |           |
|   | SYS | v2.12.4 |        |               |               |            |              |           |
|   | DPD | v2.12.4 | Rev. B | v044.02.12.00 | v049.02.12.00 | V086.02.12 | .00          |           |
|   | DPC | v2.12.4 | Rev. C |               |               |            |              |           |
|   | DPS | v2.12.4 | Rev. B | v044.02.12.00 | v049.02.12.00 | V086.02.12 | .00          |           |
|   |     |         |        |               |               |            |              | 4         |
|   |     |         |        |               |               |            |              |           |
|   |     |         |        |               |               | Ø          | . :          | 224 h     |

- 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 and keys are lit during the ROM test.

| BF  | AUN     | 1      |                |              | SELFT<br>Display       | EST<br>test             |
|-----|---------|--------|----------------|--------------|------------------------|-------------------------|
|     |         |        |                | S            | 5-0123456<br>C-0123456 | <mark>789</mark><br>789 |
|     |         |        |                |              |                        |                         |
|     | SW      | HW     | Language 1     | Language 2   | Language 3             |                         |
| SYS | v2.12.4 |        |                |              |                        |                         |
| DPD | v2.12.4 | Rev. B | V044.02.12.00  | v049.02.12.0 | 0 V086.02.12.00        |                         |
| DPC | v2.12.4 | Rev. C |                |              |                        |                         |
| DPS | v2.12.4 | Rev. B | v044.02.12.00  | v049.02.12.0 | 0 V086.02.12.00        |                         |
|     |         |        |                |              |                        |                         |
|     |         | VEF    | IFY CHARACTERS | AND CONFIRM  | WITH EQ                |                         |
|     |         |        |                |              | Q                      | 224 H                   |

The ROM test is followed by the display test.

 Compare the character lines in the supervisor field and confirm by pressing the



key if both series are identical.

- > While the key is being pressed, the buzzer of the safety system is activated for 2 seconds.
- > Check that the buzzer can be heard.

| BIBR | AUN     | 1      | SELFTEST<br>Empty loadcell test |               |                 |                         |  |
|------|---------|--------|---------------------------------|---------------|-----------------|-------------------------|--|
|      |         |        | Weight o                        | f bag holder: | (± 60 g)        | <mark>-21</mark><br>-17 |  |
|      | SW      | HW     | Lannuane 1                      | l annuane 2   | Lannuane 3      |                         |  |
| SYS  | v2.12.4 |        | Language                        | cunguage z    | Lunguage        |                         |  |
| DPD  | v2.12.4 | Rev. B | v044.02.12.00                   | v049.02.12.00 | 0 V086.02.12.00 |                         |  |
| DPC  | v2.12.4 | Rev. C |                                 |               |                 |                         |  |
| DPS  | v2.12.4 | Rev. B | v044.02.12.00                   | v049.02.12.0  | 0 V086.02.12.00 |                         |  |
| L    |         |        | Bag Hoi                         | DER FREE?     |                 |                         |  |
|      |         | CHE    | CK THE WEIGHTS                  | AND CONFIRM   | WITH EQ         |                         |  |
|      |         |        |                                 |               | 0               | 224                     |  |

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 constraint 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

| BBRAUN                          | THERAPY SELECTION<br>Standby | Having successfully passed the initial self tests, the machine switches to the <therapy selection=""> screen to select the therapy mode.</therapy> |
|---------------------------------|------------------------------|--|
| PLASMA THERAPIES                | DIALYSIS THERAPIES           | <continuous> dialysis therapies is selected by<br/>default.</continuous>   |
| ADSORPTION / PERFUSION          | CONTINUOUS                   | To select <intermittent> dialysis</intermittent>   |
| PLASMA EXCHANGE                 | INTERMITTENT                 | therapies, use the<br>and keys<br>to select the respective position.   |
| SELECT THERAPY MODE AND CONFIRM |                              | Confirm the selection with the key.  |

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

**B**BRAUN THERAPY SELECTION  $\triangleright$ Confirm <CVVH> with the Standby CVVH key. CONTINUOUS DIALYSIS THERAPIES key lights up and CVVH flashes in the CVVHD SCUF The supervisor field. CVVHFD CVVH key to confirm the selected  $\triangleright$ Press the therapy modality. SELECT AND CONFIRM If the selection is not confirmed with the BACK SELECTION EQ

> 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

| )o not connect any dispo | sable |        |                     |       |        |
|--------------------------|-------|--------|---------------------|-------|--------|
| BLOOD FLOW               | 0     | ml∕min | SUBSTITUTION FLOW   | 0     | ml∕h   |
|                          |       |        | WARMER              | 22.9  | ٥C     |
| TREATED BLOOD VOLUME     | 0.0   | liters | PD2                 | 0     | nmHg   |
|                          |       |        | UF RATE             | 0     | ml∕h   |
| PA                       | 0     | mmHg   |                     |       |        |
| PBE                      | -1    | mmHg   | FLUID WEIGHT        | -20   | g      |
| PV                       | -1    | mmHg   | THERAPY TIME RES.   | 00:00 | h:min  |
| FILTER DROP PR. (PFD)    | 0     | mmHg   |                     |       |        |
| тмр                      | -1    | mmHg   | SUB BAG VOLUME RES. | 0.00  | liters |

#### 5.3.1 Installation of consumable material

| CVVH<br>CONTINUOUS VENO-VENOUS HAEMOFILTRATION  | PREPARATION<br>Device test finished  | When the<br><prepar <br="">finished&gt;<br/>displayed.</prepar> |
|---|--|---|
| <ol> <li>Hang 2 saline and substitution fluid bags</li> <li>Place the filter on its holder with venou:</li> <li>Mount and connect Subst. line (green). Cl:</li> <li>A Hang UF collection bag on weighing system</li> <li>Mount and connect UF line (yellow) through</li> <li>Hang Venous collection bag on the IV pole</li> <li>Mount and connect Venous line (blue) and a</li> <li>Connect Substitution line to Venous line I</li> <li>Make sure all the necessary clamps are opened to</li> </ol> | on weighing system.<br>s (blue) side up.<br>amp free connection(s).<br>. Clamp the outlet.<br>h BLD. Clamp free conn.<br>Arteral line (red).<br>(blue).<br>hen start PRIMING | The consu<br>• HF<br>• Ha<br>• 2L<br>• Ha                       |
| PARAMETERS<br>SETTING   | N BACK<br>SELECTION  | Follow the de   |

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

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.

| i | The lines of the HF/HD kit are colour-coded to facilitate the set-up.<br>Arterial line ( <b>red</b> )<br>Venous line ( <b>blue</b> )<br>Ultrafiltration line ( <b>yellow</b> )<br>Substitution line ( <b>green</b> )  |
|---|---|
| 1 | Pumps used:<br>Blood pump (MP1)<br>Ultrafiltration pump (MP2)<br>Substitution pump (MP3)  |
|   | <ul> <li>Risk of infection and blood loss for the patient by damaged packaging or components</li> <li>Make sure during set-up that the packaging of the material used (line system, haemofilter, solution bags) is undamaged.</li> <li>During set-up check the material for integrity.</li> <li>Observe the respective instructions for use.</li> </ul> |



#### 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.

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

CAUTION

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.

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### 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.

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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).

# 5 CVVH



#### 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.

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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

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| CVVH<br>continuous veno-venous | PRE<br>N Arteria | PARA<br>I line f | TION                |           |             |
|--------------------------------|------------------|------------------|---------------------|-----------|-------------|
| BLOOD FLOW                     | 100              | ml∕min           | SUBSTITUTION FLOW   | 0         | ml∕h<br>∘r  |
| TREATED BLOOD VOLUME           | 0.0              | liters           | PD2                 | 25.0      | -c.<br>mmHq |
|                                |                  |                  | UF RATE             | 0         | ml∕n        |
| PA                             | 25               | mmHg             |                     |           |             |
| PBE                            | 22               | mmHg             | FLUID WEIGHT        | 7241      | g           |
| PV                             | -1               | mmHg             | THERAPY TIME RES.   | 00:00     | h:min       |
| FILTER DROP PR. (PFD)          | 23               | mmHg             |                     |           |             |
| TMP                            | 9                | mmHg             | SUB BAG VOLUME RES. | 0.00      | liters      |
| PARAMETERS<br>SETTING          | PRI              | MING             | PRE-<br>DILUTION    | B<br>SELE | ACK         |

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



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<sup>®</sup> CRRT during calibration of the pump constants. Calibration will be repeated if it is disturbed.

| CVVH   | PREPARATION          |
|--|----------------------|
| CONTINUOUS VENO-VENOUS HAEMOFILTRATION                             | Ready for therapy    |
|  | · · ·                |
|  |                      |
|  |                      |
|  |                      |
| 1. Replace Substitution line connection to sub-                    | stitution fluid bag. |
| 2. Remove saline bags from the weighing system                     | -                    |
| 3 A For nre-dilution replace Subst line to Arte                    | rial line (red)      |
| A Make sure that all the necessary clamps are                      | opened               |
| $\mathbf{F}$ <b>A</b> incast the fluid lines into the tubing align | opened.              |
| 5. A insert the rula rines into the tubing crip:                   | s on the bag horder. |
|  |                      |
|  |                      |
|  |                      |
| Select ENTER THERAPY - then connect patient.                       |                      |
|  |                      |
|  |                      |
| PARAMETERS RINSING PRE-  | ENTER BACK           |
| SETTING DILUTION   | THERAPY SELECTION    |

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



The device switches automatically to <PARAMETERS SETTING> .

### 5.3.3 Parameter setting

| CVVH<br>Continuous veno-venou: | s haemof | ILTRATIO | PRE<br>N Rea                   | PARATION<br>dy for therapy |
|--------------------------------|----------|----------|--------------------------------|----------------------------|
| Check and confirm the :        | safety ( | inverse) | parameters                     | 100<br>[ 02000]            |
| BLOOD FLOW                     | 0        | ml∕min   | SUBSTITUTION FLOW              | 600 ml≁h                   |
|                                |          |          | WARMER                         | 37.0 °C                    |
| PA MIN                         | -200     | mmHg     | PD2 MIN                        | -100 mmHg                  |
| PA MAX                         | 100      | mmHg     |                                |                            |
| PBE MAX                        | 400      | mmHg     | UF RATE                        | [100] mi⊿h                 |
| PV WINDOW                      | 100      | mmHg     |                                |                            |
| FILTER DROP PR. MAX            | 200      | mmHg     | THERAPY TIME                   | 00:00 h:min                |
| TMP MAX                        | 450      | mmHg     | SUB BAG VOLUME                 | 0.00 liters                |
|                                |          |          | L                              |                            |
| ARAMETERS<br>SETTING           | RIN      | SING     | PRE- ENTER<br>DILUTION THERAPY | BACK<br>SELECTION          |

#### 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



The value is inversely displayed on a black background.

➢ If the value is accepted, confirm by pressing the



> To change the value, press the

key to increase it or the key to decrease it.



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



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

# 5 CVVH

|                     |      |        |                   | [-25.00 20.00] |
|---------------------|------|--------|-------------------|----------------|
| BLOOD FLOW          | 0    | ml∕min | SUBSTITUTION FLOW | 600 ml≁n       |
|                     |      |        | WARMER            | 37.0 ∘C        |
| PA MIN              | -200 | mmHg   | PD2 MIN           | -100 mmHg      |
| PA MAX              | 100  | mmHg   |                   |                |
| PBE MAX             | 400  | mmHg   | UF RATE           | 100 ml⊿h       |
| PV WINDOW           | 100  | mmHg   |                   |                |
| FILTER DROP PR. MAX | 200  | mmHg   | THERAPY TIME      | 00:00 h:min    |
| TMP MAX             | 450  | mmHg   | SUB BAG VOLUME    | 0.00 liters    |
|                     |      |        |                   |                |
| PARAMETERS          | KIN  | SING   | PRE- ENTER        | BACK           |

#### Setting treatment parameters

> Select the parameter to be set with the



> Activate the parameter by pressing the

key.

> Change the value with the







key.

➤ To exit <PARAMETERS SETTING>, press the

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

| 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                     | mmHg   | 200     | 100     | 450     | 10         |
| max. pressure drop      |        |         |         |         |            |
| 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 |        | 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 following data can be set in the indicated ranges:

<sup>\*</sup> The substitution flow can be set to zero if the UF rate is  $\geq$  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.

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#### 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



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 <br/>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



- Set the parameter to 0 and confirm with the
  - key.
- Select <SUB bag volume> again and confirm with the



Increase or decrease the value and confirm with the



# 5 CVVH

### 5.3.4 Menu selection in preparation

| CVVH<br>CONTINUOUS VENO-VENOUS  | HAEMOF   | ILTRATION   | PRE   | PARATION<br>Rinsing             |
|---|--|---|---|---------------------------------|
|   |  |   |   |                                 |
| BLOOD FLOW  | 200  | ml∕min  | SUBSTITUTION FLOW   | 6000 ml∕h<br>32.9.∞C            |
| TREATED BLOOD VOLUME  | 0.0  | liters  | PD2<br>UF BATE  | 11 mmHg<br>0 ml∠h               |
| PA  | 12   | mmHq  |   |                                 |
| PBE   | 9  | mmHg  | FLUID WEIGHT  | 5374 g                          |
| PV  | 11   | mmHg  | THERAPY TIME RES.   | 00:00 h:min                     |
| FILTER DROP PR. (PFD)   | -2   | mmHg  |   |                                 |
| TMP   | -1   | mmHg  | SUB BAG VOLUME RES.   | 0.00 liters                     |
| CVVH<br>Continuous veno-venous  | HAEMOF   | ILTRATION   | PRE<br>I Rea  | PARATION                        |
| <ol> <li>Replace Substitut</li> <li>Remove saline bag</li> <li>▲ For pre-dilution</li> <li>Hake sure that al</li> <li>▲ Insert the fluid</li> </ol> | ion lin<br>s from<br>replace<br>l the n<br>lines i | e connect<br>the weigh<br>Subst.li<br>ecessary<br>nto the t | ion to substitution fl<br>ing system.<br>ne to Arterial line (r<br>clamps are opened.<br>ubing clips on the bag | luid bag.<br>red).<br>1 holder. |
| Select ENTER THERAPY -  | then c   | onnect pa   | itient.   |                                 |
| PARAMETERS  | RIN  | SING  | PRE- ENTER<br>DILUTION THERAPY  | BACK                            |

#### Rinsing

If necessary, rinsing can be prolonged by selecting <u><RINSING></u> and confirming with the



- 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



#### **Pre-dilution**

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



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

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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



#### 5.4 Therapy

| 1,   |                                    |
|--|------------------------------------|
| CVVH   | PREPARATION                        |
| CONTINUOUS VENO-VENOUS HAEMOFILTRATION                                 | Ready for therapy                  |
|  | THERAPY                            |
| <ol> <li>Replace Substitution line connection to subst</li> </ol>      | itution fluid bag.                 |
| 2. Remove saline bags from the weighing system.                        |                                    |
| 3. A For pre-dilution replace Subst. line to Arteri                    | ial line (red).                    |
| A Wake sure that all the necessary clamps are c                        | nened                              |
| <b>r</b> $\mathbf{A}$ increases the finite line into the tables of the | the bas heldes                     |
| 5. A insert the rivia lines into the tubing clips                      | on the bag holder.                 |
| Select ENTER THERAPY - then connect patient.                           |                                    |
|  |                                    |
| PARAMETERS<br>SETTING RINSING PRE-<br>DILUTION                         | ENTER<br>THERAPY BACK<br>SELECTION |
|  |                                    |

| CVVH THERAPY<br>CONTINUOUS VENO-VENOUS HAEMOFILTRATION Blood leak blood free test |        |           |                        |          |        |  |
|---|--------|-----------|------------------------|----------|--------|--|
| Ensure NO BLOOD, AIR in<br>and confirm with EQ                                    | tube m | iounted i | nto Blood Leak Det. BL | ood leak | RECAL. |  |
| BLOOD FLOW  | 0      | ml∕min    | SUBSTITUTION FLOW      | 0        | ml∕h   |  |
|   |        |           | WARMER                 | 27.4     | °C     |  |
| TREATED BLOOD VOLUME  | 0.0    | liters    | PD2                    | 71       | mmHg   |  |
|   |        |           | UF RATE                | 0        | ml∕h   |  |
| PA  | 7      | mmHg      | UF VOLUME              | 0        | mi     |  |
| PBE   | 10     | mmHg      | FLUID WEIGHT           | 6138     | g      |  |
| PV  | 60     | mmHg      | THERAPY TIME RES.      | 00:00    | h:min  |  |
| FILTER DROP PR. (PFD)   | -50    | mmHg      | THERAPY TIME           | 00:00    | h:min  |  |
| TMP   | -36    | mmHg      | SUB BAG VOLUME RES.    | 0.00     | liters |  |
|   |        |           |                        |          |        |  |
| PARAMETERS TOTALS   | 1      |           | BAG THERAPY            | EN       | DOF    |  |
| SETTING OVERVIEW  | J      |           | CHANGE                 | THE      | RAPY   |  |

#### 5.4.1 Connecting the patient

To switch from <PREPARATION> to <THERAPY>, select <ENTER THERAPY> and confirm by pressing the



Confirm the start of the therapy by pressing the flashing



key while <THERAPY> is flashing in the supervisor field.

The Diapact<sup>®</sup> CRRT is now in the therapy status as indicated in the therapy status field.

 Confirm the blood leak recalibration by pressing the



 Start the blood pump for circulation by pressing the

STOP key.

- 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



- 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 the rapy, the arterial chamber should be about 50% filled, the venous chamber about 80%

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# 5 CVVH

#### 5.4.2 Start of therapy

| CVVH<br>CONTINUOUS VENO-VENOUS HAEMOFILTRATION |     |        |                   |               | RAPY<br>Sunning |
|--|-----|--------|-------------------|---------------|-----------------|
| BLOOD FLOW                                     | 50  | ml∕min | SUBSTITUTION FLOW | ≠ 600<br>28.8 | ml∕h<br>∘r      |
| TREATED BLOOD VOLUME                           | 0.0 | liters | PD2               | 61            | mmHq            |
|  |     |        | UF RATE           | 100           | mi∕n            |
| PA   | 46  | mmHg   | UF VOLUME         | -2            | ml              |
| PBE  | 10  | mmHg   | FLUID WEIGHT      | 5096          | g               |
| PV   | 36  | mmHg   | THERAPY TIME RES  | . 00:00       | h:min           |
| FILTER DROP PR. (PFD)                          | -26 | mmHg   | THERAPY TIME      | 00:00         | h:min           |
| ТМР  | -38 | mmHg   | SUB BAG VOLUME RI | ES. 0.00      | liters          |
| PARAMETERS TOTALS                              | 1   |        | BAG               | RAPY          | ID OF           |
| SETTING OVERVIEW                               |     |        | CHANGE            | THE           | RAPY            |

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

Select <THERAPY> and activate by pressing the



<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.



#### 5.4.3 Menu selection in therapy



#### Parameter setting

See Section 5.3.3

#### Totals overview

Select <TOTALS OVERVIEW> and confirm by pressing the



 To return to the <PARAMETERS OVERVIEW> screen, select <TOTALS OVERVIEW>



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  $\Sigma.$ 

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





#### Pressure overview

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

Select <PRESSURE OVERVIEW> and confirm by pressing the



Select <PARAMETERS OVERVIEW> to return to the <PARAMETERS OVERVIEW> screen and <u>confirm</u> by pressing the



| CVVH<br>Continuous veno-venous                                     | THERAPY<br>Blood circulation |        |                    |        |        |  |  |  |
|--|------------------------------|--------|--------------------|--------|--------|--|--|--|
| Release BAG CHANGE to continue the therapy.                        |                              |        |                    |        |        |  |  |  |
| BLOOD FLOW   | 50                           | ml∕min | SUBSTITUTION FLOW  | 0      | ml≁n   |  |  |  |
|  |                              |        | WARMER             | 37.0   | °C     |  |  |  |
| TREATED BLOOD VOLUME   | 2.3                          | liters | PD2                | 51     | mmHg   |  |  |  |
|  |                              |        | UF RATE            | 0      | ml∕h   |  |  |  |
| PA   | 44                           | mmHg   | UF VOLUME          | 76     | ml     |  |  |  |
| PBE  | 12                           | mmHg   | FLUID WEIGHT       | 5173   | g      |  |  |  |
| PV   | 34                           | mmHg   | THERAPY TIME RES.  | 00:00  | h:min  |  |  |  |
| FILTER DROP PR. (PFD)  | -22                          | mmHg   | THERAPY TIME       | 00:46  | h∶min  |  |  |  |
| тмр  | -28                          | mmHg   | SUB BAG VOLUME RES | . 0.00 | liters |  |  |  |
| PARAMETERS<br>SETTING TOTALS<br>OVERVIEW CHANGE THERAPY<br>THERAPY |                              |        |                    |        |        |  |  |  |

#### Bag change

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

Select <BAG CHANGE> and confirm by pressing the



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



The treatment continues automatically.

### 5.5 End of therapy

| CVVH<br>CONTINUOUS VENO-VENOUS HAEMOFILTRATION |     |        |                     |                 | THERAPY<br>Running |  |
|--|-----|--------|---------------------|-----------------|--------------------|--|
|  |     |        | I                   | <u>end of t</u> | HERAPY             |  |
| BLOOD FLOW                                     | 50  | ml∕min | SUBSTITUTION FLOW   | 610             | ml≁n               |  |
|  |     |        | WARMER              | 37.0            | °C                 |  |
| TREATED BLOOD VOLUME                           | 2.7 | liters | PD2                 | 49              | nmHg               |  |
|  |     |        | UF RATE             | 100             | ml∕h               |  |
| PA   | 44  | mmHg   | UF VOLUME           | 94              | ml                 |  |
| PBE  | 12  | mmHg   | FLUID WEIGHT        | 5189            | g                  |  |
| PV   | 34  | mmHg   | THERAPY TIME RES.   | 00:00           | h:min              |  |
| FILTER DROP PR. (PFD)                          | -22 | mmHg   | THERAPY TIME        | 00:53           | h:min              |  |
| TMP  | -26 | mmHg   | SUB BAG VOLUME RES. | 0.00            | liters             |  |
| PARAMETERS<br>SETTING OVERVIEW                 | ]   |        | BAG<br>CHANGE       | EN<br>THE       | D OF<br>Rapy       |  |

| CVVH END OF THERAP<br>CONTINUOUS VENO-VENOUS HAEMOFILITATION Blood return |     |        |                   |       | RAPY<br>return |  |
|---|-----|--------|-------------------|-------|----------------|--|
|   | 50  | mlamin |                   |       | mlah           |  |
| BLOOD FLOW  |     |        | WARMER            | 36 9  | ۵C             |  |
| TREATED BLOOD VOLUME  | 2.7 | liters | PD2               | 51    | mmHq           |  |
|   |     |        | PD1               | 23    | nmHg           |  |
| PA  | 44  | mmHg   | UF VOLUME         | 96    | ml             |  |
| PBE   | 12  | mmHg   | UF RATE           | 0     | ml∕h           |  |
| PV  | 34  | mmHg   | FLUID WEIGHT      | 5188  | g              |  |
| FILTER DROP PR. (PFD)   | -22 | mmHg   | THERAPY TIME RES. | 00:00 | h:min          |  |
| тмр   | -28 | mmHg   | THERAPY TIME      | 00:53 | h:min          |  |
| TOTALS BLOOD LEAK BACK TO SET-UP NEW CHANGE THERAPY                       |     |        |                   |       |                |  |

Select <END OF THERAPY> and confirm by pressing the

Confirm by pressing the



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.

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

### 5.5.2 Menu selection at end of therapy

| CVVH END OF THERAPY<br>CONTINUOUS VENO-VENOUS HAEMOFILTRATION Blood return  | Totals overview   |
|---|---|
|   | The option <totals overview=""> shows the summary<br/>of the pivotal treatment data as described<br/>(see Section 5.4.3)</totals> |
| BLOOD FLOW 50 ml/min  | $\sim$ Select <totals overview=""> and</totals>   |
| TREATED BLOOD VOLUME     2.7 liters     SUBST. VOLUME     0.53 liters       ΣTR. BLOOD VOLUME     2.7 liters     SSUBST. VOLUME     0.53 liters | confirm by pressing the key.  |
| THERAPY TIME         OO:53 h:min         UF VOLUME         96 ml           ΣTHERAPY TIME         OO:53 h:min         ΣUF VOLUME         96 ml   | To return to the <end of="" therapy=""> screen,<br/>select <totals overview=""> and confirm with the</totals></end>               |
| TOTALS BLOOD LEAK BACK TO SET-UP NEW CHANGE THERAPY   | key.  |

| Ensure NO BLOOD, AIR in to<br>and confirm with EQ   | be mounted into Blood Leak Det. BLOOD LEAK RECA  | The <blood calibration="" leak=""> function allows the recalibration of the blood leak detector in case of non-</blood>   |
|---|--|---|
| BLOOD FLOW<br>TREATED BLOOD VOLUME<br>PA<br>PBE<br>PV<br>FILTER DROP PR. (PFD)<br>TMP<br>TOTALS<br>OVERVIEW<br>BLOOD L<br>CAL IBR | 50     m1/min     SUBSTITUTION FLOW     0     m1/n       2.7     liters     PD2     53     mnHg       9D1     23     mnHg     12     23     mnHg       12     mnHg     UF VOLUME     96     m1/n       34     mnHg     UF RATE     0     m1/n       34     mnHg     FLUID WEIGHT     5190     g       -22     mnHg     THERAPY TIME RES.     00:00     h:mi       -30     mmHg     THERAPY TIME     00:53     h:mi | <ul> <li>acceptable alarms (e.g. elevated plasma bilirubin concentration)</li> <li>Select "BLOOD LEAK CALIBRATION" and confirm with the</li> <li>key. The EO key lights up.</li> <li>Confirm with the</li> <li>key.</li> <li>Select <back therapy="" to=""> and confirm with the</back></li> <li>key. The EO key lights up.</li> <li>Confirm with the</li> <li>key. The EO key lights up.</li> <li>Confirm with the</li> <li>key. The EO key lights up.</li> <li>Confirm with the</li> <li>key. The EO key lights up.</li> <li>Start <therapy> by pressing the</therapy></li> <li>key.</li> </ul> |
|   | <ul> <li>Risk of blood loss for the pat</li> <li>Before the recalibration of carefully checked for pos</li> <li>It is recommended to wit the filtrate line and to an</li> <li>The blood leak recalibration</li> </ul>  | ent and haemolysis<br>of the blood leak detector, the haemofilter must be<br>sible blood leaks and haemolysis.<br>hdraw a sample (at least 2 ml) from the injection port of<br>nalyze for erythrocytes and/or free haemoglobin.<br>on must only be performed if these tests are negative.   |

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

| LUNT I MUUUS VENU-1                   | renvus haemuf         |                  | 1                               | THERAPY                    | Th<br>fir |
|---------------------------------------|-----------------------|------------------|---------------------------------|----------------------------|-----------|
| BLOOD FLOW                            | 50                    | ml⊿min           |                                 |                            | ≻         |
| REATED BLOOD VOL<br>ETR. BLOOD VOLUME | UME 0.1<br>: 0.1      | liters<br>liters | SUBST. VOLUME<br>ΣSUBST. VOLUME | 0.03 liters<br>0.03 liters |           |
| THERAPY TIME<br>THERAPY TIME          | 00:02<br>00:02        | h:min<br>h:min   | UF VOLUME<br>ZUF VOLUME         | 6 m.<br>6 m.               |           |
| TOTALS<br>OVERVIEW                    | BLOOD LEAK<br>CALIBR. | BACK             | TO SET-UP<br>CHANGE             | NEW                        |           |

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#### Back to therapy

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

Select <BACK TO THERAPY> and confirm by pressing the







key.

Start the therapy again by pressing the


THERAPY

RESET

PRE-DILUTION SET-UP

CHANGE

THERAPY

EXCHANGE

#### 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



- Stop the blood pump (MP1).
- > Follow the relevant procedure described below.

#### Change from post-dilution to pre-dilution

- 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



Activate <PRE-DILUTION> by pressing the



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



| CVVH   | END OF THERAPY |  |  |  |  |  |
|--|----------------|--|--|--|--|--|
| CONTINUOUS VENO-VENOUS HAEMOFILTRATION   | Blood return   |  |  |  |  |  |
|  | RESET THERAPY  |  |  |  |  |  |
|  |                |  |  |  |  |  |
| • For dilution exchange: - Clamp infusion p  | orts.          |  |  |  |  |  |
| - Reconnect Subst.line, open clamps, select/deselect PREDILUTION                     |                |  |  |  |  |  |
| <ul> <li>Stop blood pump and clamp all ports of filter and infusion port.</li> </ul> |                |  |  |  |  |  |
| <ul> <li>Exchange filter with a pre-filled one (if necessary).</li> </ul>            |                |  |  |  |  |  |
| <ul> <li>Perform changes for a dialysis therapy (if necessary):</li> </ul>           |                |  |  |  |  |  |
| - Turn filter red side up & reconn.UF line(yellow) to upper port                     |                |  |  |  |  |  |
| - Reconnect Subst.line (green) to port on blue side of filter.                       |                |  |  |  |  |  |
| - Exchange hans (if necessary)   |                |  |  |  |  |  |
| Open clawos start blood nuwn and select THERAPY FYCHANGE                             |                |  |  |  |  |  |
| <ul> <li>linen clamps start blood nump and select.</li> </ul>                        |                |  |  |  |  |  |

RESET

DILUTION

CHANGE

EXCHANGE

### 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

| CVVH<br>CONTINUOUS VENO-VENOUS HAEMOFILTRATION  | END OF   | THERAPY<br>Blood return           |
|---|--|-----------------------------------|
|   | Ī  | HERAPY EXCHANGE                   |
| <ul> <li>For dilution exchange: - Clamp infusion ports.<br/>- Reconnect Subst.line, open clamps, select/dt</li> <li>Stop blood pump and clamp all ports of filter</li> <li>Exchange filter with a pre-filled one (if nece</li> <li>Perform changes for a dialysis therapy (if nee</li> <li>Turn filter red side up &amp; reconn.UF line(yel</li> <li>Reconnect Subst.line (green) to port on blue</li> <li>Exchange bags (if necessary).</li> <li>Open clamps, start blood pump and select THER/</li> </ul> | esselect PREDI<br>and infusion<br>essary).<br>cessary):<br>llow) to uppe<br>e side of fil<br>APY EXCHANGE. | LUTION<br>port.<br>r port<br>ter. |

RESET

CHANGE

EXCHANGE

DILUTION

#### Therapy change

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



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



> Confirm by pressing the



 Select <CONTINUOUS> or <INTERMITTENT> therapy mode using the



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

| СVVН                            | END OF THERAPY<br>Blood circulation |
|---------------------------------|-------------------------------------|
|                                 |                                     |
| PLASMA THERAPIES                | DIALYSIS THERAPIES                  |
|                                 | CONTINUOUS                          |
|                                 | INTERMITTENT                        |
| SELECT THERAPY MODE AND CONFIRM |                                     |
|                                 | O 246 b                             |

# **CVVH**

| CVVH<br>Continuous veno-venous           | HAEMOI               | ILTRATIO                     | END OF  | F THEI<br>Blood<br>HERAPY SE | RAPY<br>return             | New therapy<br>The option <new therapy=""> allows to start a new<br/>therapy immediately after the one just finished. The</new> |
|--|----------------------|------------------------------|---|------------------------------|----------------------------|---|
| BLOOD FLOW<br>TREATED BLOOD VOLUME       | 50<br>0.0            | ml∕min<br>liters             | SUBSTITUTION FLOW<br>WARMER<br>PD2<br>PD1                 | 0<br>32.3<br>47<br>11        | ml∕h<br>°C<br>mmHg<br>mmHa | <ul> <li>Select <new therapy=""> and confirm<br/>by pressing the</new></li> </ul>   |
| PA<br>PBE<br>PV<br>FILTER DROP PR. (PFD) | 40<br>63<br>34<br>29 | mmHg<br>mmHg<br>mmHg<br>mmHg | UF VOLUME<br>UF RATE<br>FLUID WEIGHT<br>THERAPY TIME RES. | 1<br>0<br>5255<br>00:00      | ml<br>ml∕h<br>g<br>h:min   | key. The <b>EO</b> key lights up.   |
| TMP<br>TOTALS<br>OVERVIEW<br>CALIB       | 1<br>LEAK<br>R.      | mmHg<br>BACK<br>THER/        | THERAPY TIME<br>TO<br>APY CHANGE                          | 00 : 00<br>NEW<br>THER       | h:min<br>#<br>APY          | EQ key.   |



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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<sup>®</sup> 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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### 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

| BBRAUN         SELFTEST<br>ROM test           CRC         8.3 %           SYS         V2.12.4           DPD         V2.12.4           Rev. B         V044.02.12.00 V049.02.12.00 V086.02.12.00           DPC         V2.12.4           Rev. C         DPS           DPS         V2.12.4           Rev. B         V044.02.12.00 V049.02.12.00 V086.02.12.00                              | <ul> <li>Switch on the Diapact<sup>®</sup> CRRT with the power switch ON/OFF (I/O) on the back of the machine. The device starts with the ROM test.</li> <li>Check whether the AO and EO keys are lit during the ROM test.</li> </ul>  |
|---|--|
| © 224 h<br>BIBRAUN SELFTEST<br>Display test   | The ROM test is followed by the display test.  |
| SW         HW         Language 1         Language 2         Language 3           SYS         V2.12.4         Rev. B         V044.02.12.00         V049.02.12.00         V086.02.12.00           DPC         V2.12.4         Rev. C         DPS         V2.12.4         Rev. B         V044.02.12.00         V049.02.12.00         V086.02.12.00   | <ul> <li>Compare the character lines in the supervisor field and confirm by pressing the EO key if both series are identical.</li> <li>While the EO key is being pressed, the buzzer of the safety system is activated for 2 seconds.</li> <li>Check that the buzzer can be heard.</li> </ul>          |
| VERIFY CHARACTERS AND CONFIRM WITH EQ<br>Q 224 h  |  |
| BBRAUN<br>Empty loadcell test<br>Weight of bag holder: (± 60 g)<br>SW HW Language 1 Language 2 Language 3<br>SYS V2.12.4  | <ul> <li>If the display test is passed successfully, the empty load cell test follows.</li> <li>Check whether the bag holder is empty.</li> <li>Confirm the weight values with the key if they are within the allowed range. The maximum deviation between both displayed values is allowed</li> </ul> |
| DPD         V2.12.4         Rev. B         V044.02.12.00         V049.02.12.00         V086.02.12.00           DPC         V2.12.4         Rev. C         DPS         V2.12.4         Rev. B         V044.02.12.00         V049.02.12.00         V086.02.12.00           BAG         HOLDER         FREE?         CHECK         THE WEIGHTS AND CONFIRM WITH EQ         Q         224 h | to be $\pm$ 60 g and the values must not exceed -60 and +60 g.   |

### 6.2 Therapy selection

| Therapy selection  |   |
|--|---|
| B BRAUN       THERAPY SELECTION<br>Standby         PLASMA THE RAPIES       DIALYSIS THE RAPIES         ADSORPTION / PERFUSION       CONTINUOUS         PLASMA EXCHANGE       INTE RMITTENT         SELECT THERAPY MODE AND CONFIRM       Q         244 h | <ul> <li>Having successfully passed the initial self tests, the machine switches to the <therapy selection=""> screen to select the therapy mode.</therapy></li> <li><continuous> dialysis therapies is selected by default.</continuous></li> <li>Confirm the selection with the key.</li> </ul> |
| B BRAUN THERAPY SELECTION<br>Standby   | The following screen displays the possible therapy options. <cvvh> is selected by default.<br/>➤ Select <cvvhd> or <cvvhfd> with the</cvvhfd></cvvhd></cvvh>  |
| CONTINUOUS DIALYSIS THERAPIESCVVHDSCUFCVVHFDCVVH   | <ul> <li>or the key.</li> <li>Confirm the selection with the key.</li> </ul>  |
| SELECT AND CONFIRM   | <ul> <li>The EQ key lights up and CVVHD or CVVHFD flashes in the supervisor field.</li> <li>Press the EQ key to confirm the selected therapy modality.</li> </ul>   |
|  | If the selection is not confirmed with the<br>EQ<br>key, the device returns automatically to the<br><therapy selection=""> screen where the therapy<br/>mode can be selected.</therapy>   |
|  | Back selection<br>Moving with the or keys to<br><back selection=""> and confirmation with</back>  |

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allows to return to the screen where the therapy mode can be selected.

#### 6.3 Preparation

| o not connect any dispo | osable |        |                     |       |        |
|-------------------------|--------|--------|---------------------|-------|--------|
| BLOOD FLOW              | 0      | ml∕min | DIALYSATE FLOW      | 0     | ml∕h   |
|                         | 0 0    | litors | WAKMEK<br>PD2       | 28.4  | oC.    |
| INEATED BEOOD VOEDNE    | 0.0    | inters | UF RATE             | 0     | mil∕h  |
| PA                      | 17     | mmHg   |                     |       |        |
| PBE                     | 4      | mmHg   | FLUID WEIGHT        | 5228  | g      |
| PV                      | 24     | mmHg   | THERAPY TIME RES.   | 00:00 | h:min  |
| FILTER DROP PR. (PFD)   | -20    | mmHg   |                     |       |        |
| TMP                     | -17    | mmHg   | DIA BAG VOLUME RES. | 0.00  | liters |

#### Installation of consumable material 6.3.1

| CVVHD<br>CONTINUOUS VENO-VENOUS HAEHODIALYSIS  | PREPARATION<br>Device test finished   | When the tests have been<br><preparation> screen c<br/>finished&gt; and the steps to<br/>displayed.</preparation> |
|--|---|---|
| <ol> <li>Hang 2 saline and dialysate fluid bags or</li> <li>Place the filter on its holder with venou</li> <li>Mount and connect Dialysate line (green).</li> <li>A Place UF collection bag on machine base.</li> <li>Mount and connect UF line (yellow) throug</li> <li>Mount and connect Arterial line (red).</li> <li>Hang Venous collection bag on the IV pole</li> <li>Mount and connect Venous line (blue).</li> <li>Make sure all the necessary clamps are opened to</li> </ol> | n weighing system.<br>us (blue) side up.<br>. Clamp free connection.<br>Clamp the outlet.<br>gh BLD. Clamp free conn.<br>e.<br>then start PRIMING | The consumable material<br>• HF/HD kit<br>• Haemofilter (low-f<br>• 2L isotonic sodium<br>• Haemofiltration so    |
| PARAMETERS<br>SETTING  | BACK<br>SELECTION   | <ul> <li>Follow the instruction<br/>the device as describe</li> </ul>   |

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 •

performed successfully, the displays < Device test o set-up the machine are

for the therapy comprises:

- flux filter for CVVHD,)
- chloride solution
- olution
- s on the screen and set-up d in the following.

| i | The lines of the HF/HD kit are colour-coded to facilitate the set-up.<br>Arterial line (red)<br>Venous line (blue)<br>Ultrafiltration line / dialysate outlet line in CVVHD/CVVHFD (yellow)<br>Substitution line / dialysate inlet line in CVVHD/CVVHFD (green)   |
|---|---|
| - | Pumps used:<br>Blood pump (MP1)<br>Ultrafiltration pump (MP2)<br>Substitution pump (MP3) / Dialysate pump in CVVHD/CVVHFD   |
|   | <ul> <li>Risk of infection and blood loss for the patient by damaged packaging or components</li> <li>Make sure during set-up that the packaging of the material used (line system, haemofilter, solution bags) is undamaged.</li> <li>During set-up check the material for integrity.</li> <li>Observe the respective instructions for use.</li> </ul> |



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.

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

CAUTION



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.

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

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### 6.3.2 Priming

| CVVHD<br>Continuous veno-venous | 5 Haemoe | DIALYSIS | PRE<br>Arteria      | EPARA<br>al line f | TION       |
|---------------------------------|----------|----------|---------------------|--------------------|------------|
| BLOOD FLOW                      | 100      | ml∕min   | DIALYSATE FLOW      | 0<br>28.3          | ml∕h<br>∘r |
| TREATED BLOOD VOLUME            | 0.0      | liters   | PD2                 | 54                 | mmHg       |
|                                 |          |          | UF RATE             | 0                  | ml∕h       |
| PA                              | 10       | mmHg     |                     |                    |            |
| PBE                             | 72       | mmHg     | FLUID WEIGHT        | 5229               | g          |
| PV                              | 51       | mmHg     | THERAPY TIME RES.   | 00:00              | h:min      |
| FILTER DROP PR. (PFD)           | 21       | mmHg     |                     |                    |            |
| TMP                             | 7        | mmHg     | DIA BAG VOLUME RES. | 0.00               | liters     |
| PARAMETERS<br>SETTING           | PRI      | MING     |                     | B<br>SELE          | ACK        |

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



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.

| CVVHD<br>CONTINUOUS VENO-VENOUS  | HAEMODIALYSIS   | PREPA  | RATION  | During the priming procedure the prompt to turn the<br>baemofilter is displayed   |
|--|---|--|---|---|
| ▲ Turn the dialyser art<br>Confirm with EQ   | erial (red) si  | de up [840]  | <ul> <li>Turn the haemofilter upside down.</li> </ul>   |   |
| BLOOD FLOW<br>TREATED BLOOD VOLUME<br>PA<br>PBE<br>PV<br>FILTER DROP PR. (PFD)<br>TMP<br>PARAMETERS<br>SETTING   | O ml∠min<br>O.O liters<br>-24 mmHg<br>122 mmHg<br>105 mmHg<br>17 mmHg<br>-16 mmHg<br>PRIMING            | DIALYSATE FLOW<br>WARMER 22<br>PD2<br>UF RATE<br>FLUID WEIGHT 9<br>THERAPY TIME RES. 00<br>DIA BAG VOLUME RES. 0         | 0 ml/n<br>22.2 °C<br>129 mmHg<br>0 ml/n<br>5902 g<br>0:00 h:min<br>0.00 liters<br>BACK<br>SELECTION                     | Confirm by pressing the key.  |
| CVVHD<br>Cont inuous veno-venous   | HAEMODIALYSIS   | PREPA<br>Ready 1   | ARATION<br>for therapy  | After the preparation phase has been finished, the system gives an acoustic signal and shows the<br><preparation> screen with message <ready for="" therapy=""> in the therapy status field</ready></preparation> |
| <ol> <li>Hang UF collection</li> <li>Replace Dialysate</li> <li>Remove saline bags</li> <li>Make sure that al</li> <li>Insert the fluid</li> <li>Select ENTER THERAPY -</li> </ol> | h bag on weighi<br>line connectio<br>from the weig<br>the necessary<br>lines into the<br>then connect p | ng system.<br>n to the dialysate fluid ba<br>hing system.<br>clamps are opened.<br>tubing clips on the bag ho<br>atient. | ag.<br>I der.   | <ul> <li>Remove the bag with the sodium chloride solutio<br/>from the load cell and attach it to the infusion<br/>pole.</li> </ul>  |
| 1a   Recirc.:   Connect     1b   Replace     1c   Remove to  | dialysate bags<br>the UF line to<br>JF coll. bag fr   | together by connecting lir<br>the dialysate fluid bag.<br>om machine base. Continue i                                    | 1e.<br>in 2.  | <ul> <li>Single pass</li> <li>➤ Attach the collecting bags to the bag holder of the load cell</li> </ul>  |
| PARAMETERS<br>SETTING  | RINSING   | ENTER<br>THERAPY   | <ul> <li>Make sure that all relevant clamps are open.</li> <li>Select <enter therapy=""> and confirm</enter></li> </ul> |   |

- lution on
- of the
- 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



### 6.3.3 Parameter setting

| Check and confirm the saf | fetv í |          |                |         | 100    |
|---------------------------|--------|----------|----------------|---------|--------|
|                           | , (    | inverse) | parameters     | [ 0.    | .2000] |
| BLOOD FLOW                | 0      | ml∕min   | DIALYSATE FLOW | 3000    | ml≁n   |
|                           |        |          | WARMER         | 37.0    | ٥C     |
| PA MIN                    | -200   | mmHg     | PD2 MIN        | -250    | mmHg   |
| PA MAX                    | 100    | mmHg     |                |         |        |
| PBE MAX                   | 400    | mmHg     | UF RATE        | [ 100 ] | ml∕h   |
| PV WINDOW                 | 100    | mmHg     |                |         |        |
| FILTER DROP PR. MAX       | 250    | mmHg     | THERAPY TIME   | 00:00   | h:min  |
| TMP MAX                   | 450    | mmHg     | DIA BAG VOLUME | 0.00    | liters |

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



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 <u>must always be confirmed with the</u>



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

| CVVHD<br>CONTINUOUS VENO-VENOUS HAEMODIALYSIS |      |        |                | PREPARATION<br>Ready for therapy |
|---|------|--------|----------------|----------------------------------|
|   |      |        |                | [ 02000]                         |
| BLOOD FLOW                                    | 0    | ml∕min | DIALYSATE FLOW | 3000 ml∕n                        |
|   |      |        | WARMER         | 37.0 °C                          |
| PA MIN  | -200 | mmHg   | PD2 MIN        | -250 mmHg                        |
| PA MAX  | 100  | mmHg   |                |                                  |
| PBE MAX                                       | 400  | mmHg   | UF RATE        | [100] ml≁h                       |
| PV WINDOW                                     | 100  | mmHg   |                |                                  |
| FILTER DROP PR. MAX                           | 250  | mmHg   | THERAPY TIME   | 00:00 h:min                      |
| TMP MAX                                       | 450  | mmHg   | DIA BAG VOLUME | 0.00 liters                      |
|   |      |        |                |                                  |
| PARAMETERS                                    | RIN  | ISING  |                | ENTER BACK<br>HERAPY SELECTION   |
|   |      |        |                |                                  |

Setting treatment parameters

> Select the parameter to be set with the





key.

 $\geq$ 

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To exit <PARAMETERS SETTING>, press the

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

| 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                   | mmHg   | 250     | 100     | 450     | 10         |
| max. pressure drop    |        |         |         |         |            |
| 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  | 1      | 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 following data can be set in the indicated ranges:

The dialysate flow can be set to zero if the UF rate is  $\geq$  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.

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#### 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



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 <br/>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 <br/>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



Set the parameter to 0 and confirm with the



Select <DIA bag volume> again and confirm with the



Increase or decrease the value and <u>confirm</u> with the



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

| CVVHD<br>Continuous veno-venous | 5 HAEMOD | IALYSIS | PRE                 | PARA  | TION<br>tinsing |
|---------------------------------|----------|---------|---------------------|-------|-----------------|
| BLOOD FLOW                      | 200      | ml∕min  | DIALYSATE FLOW      | 4800  | ml∕h<br>∘r      |
| TREATED BLOOD VOLUME            | 0.0      | liters  | PD2                 | 69    | mmHg            |
|                                 |          |         | UF RATE             | 0     | ml∕h            |
| PA                              | 14       | mmHg    |                     |       |                 |
| PBE                             | 4        | mmHg    | FLUID WEIGHT        | 7399  | g               |
| PV                              | 35       | mmHg    | THERAPY TIME RES.   | 00:00 | h:min           |
| FILTER DROP PR. (PFD)           | -31      | mmHg    |                     |       |                 |
| ТМР                             | -50      | mmHg    | DIA BAG VOLUME RES. | 0.00  | liters          |
| PARAMETERS<br>SETTING           | RIN      | SING    | ENTER<br>THERAPY    | B     | IACK<br>ICTION  |

#### Rinsing

If necessary, rinsing can be prolonged by selecting <u><RINSING></u> and confirming with the



- 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



### Back selection

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

Select <BACK SELECTION> and confirm with the



### 6.4 Therapy

| CVVHD   | PREPARATION                     |  |  |  |  |  |
|---|---------------------------------|--|--|--|--|--|
| CONTINUOUS VENO-VENOUS HAEMODIALYSIS                            | Ready for therapy               |  |  |  |  |  |
|   |                                 |  |  |  |  |  |
|   | THERAPY                         |  |  |  |  |  |
| 1. Hang UF collection bag on weighing system.                   |                                 |  |  |  |  |  |
| <ol><li>Replace Dialysate line connection to the di</li></ol>   | alysate fluid bag.              |  |  |  |  |  |
| <ol><li>Remove saline bags from the weighing system</li></ol>   | 1.                              |  |  |  |  |  |
| <ol><li>Make sure that all the necessary clamps are</li></ol>   | e opened.                       |  |  |  |  |  |
| 5. $lacksquare$ Insert the fluid lines into the tubing clip     | is on the bag holder.           |  |  |  |  |  |
| Select ENTER THERAPY - then connect patient.                    |                                 |  |  |  |  |  |
| 1a Recirc.: Connect dialysate bags together by connecting line. |                                 |  |  |  |  |  |
| 1b Replace the UF line to the dialysate fluid bag.              |                                 |  |  |  |  |  |
| 1c Remove UF coll. bag from machine                             | base. Continue in 2.            |  |  |  |  |  |
| PARAMETERS<br>SETTING   | ENTER BACK<br>THERAPY SELECTION |  |  |  |  |  |

| CVVHD<br>CONTINUOUS VENO-VENOUS HAEMODIALYSIS  |          |           | Blood leak b           | THERAPY<br>lood free test   |
|--|----------|-----------|------------------------|-----------------------------|
| Ensure NO BLOOD, AIR in<br>and confirm with EQ | ı tube m | iounted i | nto Blood Leak Det. BL | 00D LEAK RECAL.<br>[ 02000] |
| BLOOD FLOW                                     | 0        | ml∕min    | DIALYSATE FLOW         | 3000 ml∕n                   |
|  |          |           | WARMER                 | 37.0 °C                     |
| PA MIN   | -200     | mmHq      | PD2 MIN                | -250 mmHq                   |
| PA MAX   | 100      | mmHg      |                        |                             |
| PBE MAX  | 400      | mmHa      | UF BATE                | [100] ml∕h                  |
| PV WINDOW                                      | 100      | mmHa      |                        |                             |
| FILTER DROP PR. MAX                            | 250      | mmHg      | THERAPY TIME           | 00:00 h:min                 |
| TMP MAX  | 450      | mmHg      | DIA BAG VOLUME         | 0.00 liters                 |
| PARAMETERS<br>SETTING OVERVIEW                 |          |           | BAG<br>CHANGE          | END OF<br>Therapy           |

To switch from <PREPARATION> to <THERAPY>, select <ENTER THERAPY> and confirm by pressing the



key.

- Select <ENTER THERAPY> and confirm with the
- Confirm the start of the therapy by pressing the flashing



key while <THERAPY> is flashing in the supervisor field.

The Diapact<sup>®</sup> CRRT is now in the therapy status as indicated in the therapy status field.

 Confirm the blood leak recalibration by pressing the



 Start the blood pump for circulation by pressing the



#### Connecting the patient 6.4.1

- 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



- > 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

| CVVHD<br>CONTINUOUS VENO-VENOUS | HAEMOD I ALYS IS                          | THERAPY<br>Running                 | After the blood has been circulating for 2- 3 minutes without alarms, the therapy can be started.       |
|---------------------------------|---|------------------------------------|---|
|                                 |   |                                    | Select <therapy> and activate by pressing the</therapy>   |
| BLOOD FLOW                      | 50 ml/min DIALYSATE FL                    | LOW 3000 ml⊿h<br>39.6 oc           | kev   |
| TREATED BLOOD VOLUME            | 0.0 liters PD2                            | 28.0 °C<br>52 mmHg<br>100 mL∕h     | Koj.  |
| PA                              | 17 mmHg UF VOLUME                         | -3 ml                              | <therapy> in the menu selection field is blackened</therapy>  |
| PBE                             | 33 mmHg FLUID WEIGHT                      | T 5232 g                           | and in the therapy status field < Running> is indicated   |
| PV<br>Eliter Drop pr (ped)      | 30 mmHg THEKAPTTIME<br>3 mmHg THERAPTTIME | EKES. UU:UU h:min<br>E AA:AA h:min |   |
| ТМР                             | -21 mmHg DIA BAG VOLU                     | JME RES. 0.00 liters               | overview is displayed.  |
| PARAMETERS<br>SETTING OVERVIEW  | BAG<br>CHANGE                             | THERAPY<br>END OF<br>THERAPY       | The current pressure and flow data of the blood side<br>and the fluid side are displayed on the screen. |

| WARNING NARY WARNING Not block loss and contamination for the patient<br>WARNING Not block loss and contamination for the patient<br>> 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

#### CVVHD THERAPY CONTINUOUS VENO-VENOUS HAEMODIALYSIS Runn i na 50 ml/min BLOOD FLOW TREATED BLOOD VOLUME 0.0 liters DIALYSATE VOLUME 0.02 liters ΣTR. BLOOD VOLUME 0.0 liters EDIALYSATE VOL. 0.02 liters 100 mi⊿n UF BATE THERAPY TIME 00:00 h:min UF VOLUME 0 ml ΣTHERAPY TIME 00:00 h:min ΣUF VOLUME 0 ml PRESSURE TOTALS BAG THERAPY THERAPY OVERVIEW CHANGE OVERVIEW RESET

### Totals overview

Select <TOTALS OVERVIEW> and confirm by pressing the



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



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  $\Sigma.$ 

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



# 6 CVVHD / CVVHFD



| CVVHD<br>Continuous veno-venous haemodialysis |         |         | BI                  | THEI<br>ood circu | RAPY         |
|---|---------|---------|---------------------|-------------------|--------------|
| Release BAG CHANGE to co                      | ontinue | the the | rapy.               |                   |              |
| BLOOD FLOW                                    | 50      | ml∕min  | DIALYSATE FLOW      | 0                 | ml∕h         |
|   |         |         | WARMER              | 36.9              | ٥C           |
| TREATED BLOOD VOLUME                          | 0.1     | liters  | PD2                 | 53                | mmHg         |
|   |         |         | UF RATE             | 0                 | ml∕h         |
| PA  | 17      | mmHg    | UF VOLUME           | 5                 | ml           |
| PBE   | 33      | mmHg    | FLUID WEIGHT        | 5240              | g            |
| PV  | 31      | mmHg    | THERAPY TIME RES.   | 00:00             | h:min        |
| FILTER DROP PR. (PFD)                         | 2       | mmHg    | THERAPY TIME        | 00:01             | h:min        |
| TMP   | -21     | mmHg    | DIA BAG VOLUME RES. | 0.00              | liters       |
| PARAMETERS TOTALS<br>SETTING OVERVIEW         | ]       |         | BAG<br>CHANGE       | EN<br>THE         | D OF<br>RAPY |

### 6.5 End of therapy

| CVVHD<br>Continuous veno-venous   | HAEMOD | IALYSIS |                     | THE             | RAPY         |
|-----------------------------------|--------|---------|---------------------|-----------------|--------------|
|                                   |        |         |                     | <u>end of t</u> | HERAPY       |
| BLOOD FLOW                        | 50     | ml∕min  | DIALYSATE FLOW      | 3000            | ml⊿n<br>≎C   |
| TREATED BLOOD VOLUME              | 0.3    | liters  | PD2                 | 50.9<br>51      | ∾c<br>nmHg   |
|                                   |        |         | UF RATE             | 100             | ml∕h         |
| PA                                | 16     | mmHg    | UF VOLUME           | 10              | ml           |
| PBE                               | 34     | mmHg    | FLUID WEIGHT        | 5243            | g            |
| PV                                | 31     | mmHg    | THERAPY TIME RES.   | 00:00           | h:min        |
| FILTER DROP PR. (PFD)             | 3      | mmHg    | THERAPY TIME        | 00:05           | h:min        |
| тмр                               | -19    | mmHg    | DIA BAG VOLUME RES. | 0.00            | liters       |
| PARAMETERS<br>SETTING<br>OVERVIEW | ]      |         | BAG<br>CHANGE       | EN<br>THE       | D OF<br>Rapy |

#### Pressure overview

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

 Select <PRESSURE OVERVIEW> and confirm by pressing the



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



#### Bag change

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

Select <BAG CHANGE> and confirm by pressing the



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



The treatment continues automatically.

Select <END OF THERAPY> and confirm by pressing the



> Confirm by pressing the



## Diapact<sup>®</sup> CRRT

| CVVHD<br>Continuous veno-venous | Haemod      | IALYSIS       | END OF              | THEI<br>Blood | RAPY<br>return |
|---------------------------------|-------------|---------------|---------------------|---------------|----------------|
|                                 |             |               |                     |               |                |
| BLOOD FLOW                      | 50          | ml∕min        | DIALYSATE FLOW      | 0             | ml≁h           |
|                                 |             |               | WARMER              | 37.0          | °C             |
| TREATED BLOOD VOLUME            | 0.3         | liters        | PD2                 | 49            | nmHg           |
|                                 |             |               | PD1                 | 13            | mmHg           |
| PA                              | 16          | mmHg          | UF VOLUME           | 11            | ml             |
| PBE                             | 34          | mmHg          | UF RATE             | 0             | ml∕n           |
| PV                              | 30          | mmHg          | FLUID WEIGHT        | 5247          | g              |
| FILTER DROP PR. (PFD)           | 4           | mmHg          | THERAPY TIME RES.   | 00:00         | h:min          |
| тмр                             | -17         | mmHg          | THERAPY TIME        | 00:05         | h∶min          |
| TOTALS<br>OVERVIEW CALIE        | LEAK<br>IR. | BACK<br>Ther/ | TO SET-UP<br>Change | NEW<br>THERA  | r<br>PY        |

6.5.1 Disconnecting the patient

The ultrafiltration pump (MP2) and the dialysate pump stop. The blood pump (MP1) continues to run at

Stop the blood pump (MP1).

reduced speed (50 ml/min).

- 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.

i

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

6.5.2 Menu selection at end of therapy

|   | 15   |
|---|--|
| CVVHD<br>CONTINUOUS VENO-VENOUS HAEMODIALYSI                | END OF THERAPY<br>Blood return                                   |
|   |  |
| BLOOD FLOW 50 ml/mi   | 1  |
| TREATED BLOOD VOLUME 0.3 lite<br>ZTR. BLOOD VOLUME 0.3 lite | rs DIALYSATE VOLUME 0.27 liters<br>rs DIALYSATE VOL. 0.27 liters |
| THERAPY TIME 00:05 h:min<br>ΣTHERAPY TIME 00:05 h:min       | n UF VOLUME 11 mi<br>α ΣUF VOLUME 11 mi                          |
| TOTALS BLOOD LEAK DVERVIEW CALIBR. TH                       | X TO<br>ERAPY CHANGE NEW<br>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



To return to the <END OF THERAPY> screen, select <TOTALS OVERVIEW> and confirm with the



# 6 CVVHD / CVVHFD



i

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

| CVVHD<br>CONTINUOUS VENO-VENOUS HAEMODIALYSIS                       |     |        | END OF            | THEI<br>Blood | RAPY<br>return |
|---|-----|--------|-------------------|---------------|----------------|
|   |     |        |                   | I             | HERAPY         |
| BLOOD FLOW  | 50  | ml∕min | DIALYSATE FLOW    | 0             | ml∕h           |
|   |     |        | WARMER            | 34.3          | ٥C             |
| TREATED BLOOD VOLUME  | 0.3 | liters | PD2               | 51            | mmHg           |
|   |     |        | PD1               | 13            | mmHg           |
| PA  | 16  | mmHg   | UF VOLUME         | 11            | ml             |
| PBE   | 34  | mmHg   | UF RATE           | 0             | mi∕n           |
| PV  | 31  | mmHg   | FLUID WEIGHT      | 5247          | g              |
| FILTER DROP PR. (PFD)   | 3   | mmHg   | THERAPY TIME RES. | 00:00         | h:min          |
| TMP   | -19 | mmHg   | THERAPY TIME      | 00:05         | h:min          |
| TOTALS BLOOD LEAK BACK TO SET-UP NEW CALIBR. THERAPY CHANGE THERAPY |     |        |                   |               |                |

Back to therapy

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

Select <BACK TO THERAPY> and confirm by pressing the



Confirm by pressing the



key.

⊳

Start the therapy again by pressing the



SET-UP

CHANGE

THERAPY

EXCHANGE

PRE-

DILUTION

THERAPY RESET

END OF THERAPY

Blood return

Set-up change

#### CVVHD / CVVHFD 6

CVVHD

6-22

The function allows to reset the just finished therapy.

Select <THERAPY RESET> and confirm by pressing the

# 6 CVVHD / CVVHFD



#### 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

lor the low 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 \_\_\_\_\_





> Confirm by pressing the



APY ation
Select <CONTINUOUS> or <INTERMITTENT> therapy mode using the



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

EQ

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 \_\_\_\_\_



Confirm by pressing the

key

Risk of blood loss and infection for the patient

Ø

254 h

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

DANGER

\_\_\_\_\_

6-24





### 6.6 Special functions

### Bag movement function

To avoid superfluous alarms and the resulting pump standstill, the Diapact<sup>®</sup> 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

| BRACN   | SELFTEST<br>ROM test  | Switch on the Diapact <sup>®</sup> CRRT with the power<br>switch ON/OFF (I/O) on the back of the machine.  |
|---|---|--|
| SW         HW         Language           SYS         V2.12.4         Rev. B         V044.02.           DPD         V2.12.4         Rev. C         DPC         V2.12.4         Rev. C           DPS         V2.12.4         Rev. B         V044.02.                      | CRC 83 %  | <ul> <li>The device starts with the ROM test.</li> <li>Check whether the AO and EO keys are lit during the ROM test.</li> </ul>  |
|   |   |  |
| BBRAUN  | SELFTEST<br>Display test  | The ROM test is followed by the display test.  |
| BBRAUN  | SELFTEST<br>Display test<br>S=0123456789<br>C-0123456789  | <ul> <li>The ROM test is followed by the display test.</li> <li>Compare the character lines in the supervisor field and confirm by pressing the</li> </ul>   |
| BBRAUN  | SELFTEST<br>Display test<br>S-0123456789<br>C-0123456789  | <ul> <li>The ROM test is followed by the display test.</li> <li>Compare the character lines in the supervisor field and confirm by pressing the</li> </ul>   |
| BRAUN   | SELFTEST<br>Display test<br>S-0123456789<br>C-0123456789  | <ul> <li>The ROM test is followed by the display test.</li> <li>Compare the character lines in the supervisor field and confirm by pressing the</li> <li>EO</li> <li>key if both series are identical.</li> </ul>  |
| B BRAUN   | SELFTEST<br>Display test<br>S-0123456789<br>C-0123456789  | <ul> <li>The ROM test is followed by the display test.</li> <li>Compare the character lines in the supervisor field and confirm by pressing the</li> <li>EO</li> <li>key if both series are identical.</li> </ul>  |
| SW HW Language<br>SYS V2.12.4<br>DPD V2.12.4 Rev. B V044.02.<br>DPC V2.12.4 Rev. C  | SELFTEST<br>Display test<br>S-0123456789<br>C-0123456789<br>1 Language 2 Language 3<br>12.00 V049.02.12.00 V086.02.12.00                                      | <ul> <li>The ROM test is followed by the display test.</li> <li>Compare the character lines in the supervisor field and confirm by pressing the</li> <li>EO</li> <li>key if both series are identical.</li> <li>While the EO</li> <li>key is being pressed, the buzzer of the series are identical.</li> </ul>   |
| SW         HW         Language           SYS         V2.12.4         PD         V2.12.4           DPD         V2.12.4         Rev. B         V044.02.           DPC         V2.12.4         Rev. C         DPS           DPS         V2.12.4         Rev. C         DPS | SELFTEST<br>Display test<br>S-0123456789<br>C-0123456789<br>1 Language 2 Language 3<br>12.00 V049.02.12.00 V086.02.12.00<br>12.00 V049.02.12.00 V086.02.12.00 | <ul> <li>The ROM test is followed by the display test.</li> <li>Compare the character lines in the supervisor field and confirm by pressing the</li> <li>EO</li> <li>key if both series are identical.</li> <li>While the EO</li> <li>key is being pressed, the buzzer of the safety system is activated for 2 seconds.</li> </ul>                                 |
| SW         HW         Language           SYS         V2.12.4         Rev. B         V044.02.           DPD         V2.12.4         Rev. C         DPS         V2.12.4         Rev. B         V044.02.   | SELFTEST<br>Display test<br>S=0123456789<br>C=0123456789<br>1 Language 2 Language 3<br>12.00 v049.02.12.00 v086.02.12.00<br>12.00 v049.02.12.00 v086.02.12.00 | <ul> <li>The ROM test is followed by the display test.</li> <li>Compare the character lines in the supervisor field and confirm by pressing the </li> <li>key if both series are identical.</li> <li>While the </li> <li>key is being pressed, the buzzer of the safety system is activated for 2 seconds.</li> <li>Check that the buzzer can be heard.</li> </ul> |
| B BRAUN<br>SW HW Language<br>SYS V2.12.4<br>DPD V2.12.4 Rev. B V044.02.<br>DPC V2.12.4 Rev. C<br>DPS V2.12.4 Rev. B V044.02.<br>VERIFY CHARA  | SELFTEST<br>Display test<br>S=0123456789<br>C-0123456789<br>1 Language 2 Language 3<br>12.00 V049.02.12.00 V086.02.12.00<br>12.00 V049.02.12.00 V086.02.12.00 | <ul> <li>The ROM test is followed by the display test.</li> <li>Compare the character lines in the supervisor field and confirm by pressing the EO key if both series are identical.</li> <li>While the EO key is being pressed, the buzzer o the safety system is activated for 2 seconds.</li> <li>Check that the buzzer can be heard.</li> </ul>                |

|     | BRAUN   |        | SELFTEST<br>Empty loadcell test          |                         |  |
|-----|---------|--------|--|-------------------------|--|
|     |         |        | Weight of bag holder: (± 60 g)           | <mark>-21</mark><br>-17 |  |
| r   |         |        |  |                         |  |
|     | SW      | HW     | Language 1 Language 2 Language 3         |                         |  |
| SYS | v2.12.4 |        |  |                         |  |
| DPD | V2.12.4 | Rev. B | V044.02.12.00 V049.02.12.00 V086.02.12.0 | 0                       |  |
| DPC | V2.12.4 | Rev. C |  |                         |  |
| DPS | V2.12.4 | Rev. B | v044.02.12.00 v049.02.12.00 v086.02.12.0 | 0                       |  |
|     |         |        |  |                         |  |
|     |         | CUT    | BAG HOLDER FREE?                         |                         |  |
|     |         | CHE    | UK THE WEIGHTS AND CONFIRM WITH EQ       | 224                     |  |

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 they are within the allowed range. The maximum deviation between both displayed values is allowed to be  $\pm$  60 g and the values must not exceed -60 and +60 g.

### 7.2 Therapy selection

| BBRAUN                          | THERAPY SELECTION<br>Standby | Having successfully passed the initial self tests, the machine switches to the <therapy selection=""> screen to select the therapy mode</therapy> |
|---------------------------------|------------------------------|---|
| PLASMA THERAPIES                | DIALYSIS THERAPIES           | <continuous> dialysis therapies is selected by</continuous>   |
| ADSORPTION > PERFUSION          | CONTINUOUS                   | <ul> <li>To select <intermittent> dialysis therapies, move</intermittent></li> </ul>  |
| PLASMA EXCHANGE                 | INTERMITTENT                 | and keys.   |
|                                 |                              | Confirm the selection with the  |
| SELECT THERAPY MODE AND CONFIRM | Q 247 b                      | key.  |
|                                 | <u>U</u> 247 N               |   |
| BBRAUN                          | THERAPY SELECTION<br>Standby | The following screen displays the possible therapy options. <haemofiltration> is selected by default.</haemofiltration>                           |
|                                 | HE                           | <ul> <li>Confirm <haemofiltration> by pressing the</haemofiltration></li> </ul>   |
| INTERMITTENT DIA                | LYSIS THERAPIES              | kev.  |
| HAEMOFIL                        | TRATION                      |   |
| HAEMOD                          | IALYSIS                      | The <b>EQ</b> key lights up and HF flashes in the   |
| HIGHFLUX                        | DIALYSIS                     | supervisor field  |
| SELECT THERAPY MODE AND CONFIRM | BACK SELECTION               | Press the key to confirm the selected therapy modality.   |
|                                 |                              | If the selection is not confirmed with the  |
|                                 |                              | EQ  |
|                                 |                              | key, the device returns automatically to the<br><therapy selection=""> screen where the therapy<br/>mode can be selected.</therapy>               |
|                                 |                              | 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

| o not connect any dispo | sable |        |                     |       |        |
|-------------------------|-------|--------|---------------------|-------|--------|
| BLOOD FLOW              | 0     | ml∕min | SUBSTITUTION FLOW   | 0     | ml∕mir |
|                         |       |        | WARMER              | 22.8  | ٥C     |
| TREATED BLOOD VOLUME    | 0.0   | liters | PD2                 | 0     | nmHg   |
|                         |       |        | UF RATE             | 0     | ml∕h   |
| PA                      | 0     | mmHg   |                     |       |        |
| PBE                     | -1    | mmHg   | FLUID WEIGHT        | 62    | g      |
| PV                      | -1    | mmHg   | THERAPY TIME RES.   | 00:00 | h:min  |
| FILTER DROP PR. (PFD)   | 0     | mmHg   |                     |       |        |
| тмр                     | -1    | mmHg   | SUB BAG VOLUME RES. | 0.00  | liter  |

#### 7.3.1 Installation of consumable material

HF PREPARATION When the tests have been performed successfully, the HAEMOFILTRATION Device test finished <PREPARATION> screen displays <Device test finished> and the steps to set-up the machine are displayed. 1. Hang 2 saline and substitution fluid bags on weighing system. The consumable material for the therapy comprises: 2. Place the filter on its holder with venous (blue) side up. • HF/HD kit 3. Mount and connect Subst. line (green). Clamp free connection(s). 4.  $\clubsuit$  Hang UF collection bag on weighing system. Clamp the outlet. Haemofilter • 5. Mount and connect UF line (yellow) through BLD. Clamp free conn. 2L isotonic sodium chloride solution • 6. Hang Venous collection bag on the IV pole. 7. Mount and connect Venous line (blue) and Arteral line (red). Haemofiltration solution . 8. A Connect Substitution line to Venous line (blue). Make sure all the necessary clamps are opened then start PRIMING > Follow the instructions on the screen and set-up PARAMETERS PRE-BACK PRIMING the device as described in the following. SETTING DILUTION SELECTION

|            | The lines of the HF/HD kit are colour-coded to facilitate the set-up.   |
|------------|---|
|            | Venous line (hue)   |
|            | Ultrafiltration line (yellow)   |
| i          | Substitution line (green)   |
| _          | Pumps used:   |
|            | Blood pump (MP1)  |
|            | Ultrafiltration pump (MP2)  |
|            | Substitution pump (MP3)   |
|            |   |
| ^          | Risk of infection and blood loss for the patient by damaged packaging or components                                     |
| <u>/!\</u> | Make sure during set-up that the packaging of the material used (line system, haemofilter, solution bags) is undamaged. |
| WARNING    | During set-up check the material for integrity.   |
|            | Observe the respective instructions for use.  |

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



#### 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.

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

CAUTION

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.

7 HF

- 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.

i

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.

7 HF

- 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.

7 HF

- 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.

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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

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| HF<br>HAEMOFILTRATION | PREPARATION<br>Arterial line filling |        |                     |           |              |
|-----------------------|--------------------------------------|--------|---------------------|-----------|--------------|
|                       |                                      |        |                     |           |              |
| BLOOD FLOW            | 0                                    | ml∕min | SUBSTITUTION FLOW   | 0         | ml∕min       |
|                       |                                      |        | WARMER              | 25.2      | °C           |
| TREATED BLOOD VOLUME  | 0.0                                  | liters | PD2                 | 0         | nmHg         |
|                       |                                      |        | UF RATE             | 0         | ml∕h         |
| PA                    | 0                                    | mmHg   |                     |           |              |
| PBE                   | -1                                   | mmHg   | FLUID WEIGHT        | 6000      | g            |
| PV                    | -1                                   | mmHg   | THERAPY TIME RES.   | 00:00     | h:min        |
| FILTER DROP PR. (PFD) | 0                                    | mmHg   |                     |           |              |
| тмр                   | -1                                   | mmHg   | SUB BAG VOLUME RES. | 0.00      | liters       |
| PARAMETERS<br>SETTING | PRI                                  | MING   | PRE-<br>DILUTION    | B<br>SELE | ACK<br>CTION |

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



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<sup>®</sup> CRRT during calibration of the pump constants. Calibration will be repeated if it is disturbed.

| HF<br>HAEMOFILTRATION  |   | PREPARATION<br>Ready for therapy   |  |
|--|---|--|--|
| <ol> <li>Replace Sub</li> <li>Remove sali</li> <li>A For pre-dil</li> <li>Make sure t</li> <li>Insert the</li> </ol> | stitution line connection t<br>ne bags from the weighing s<br>ution replace Subst.line to<br>nat all the necessary clamp<br>Iluid lines into the tubing | o substitution fluid bag.<br>ystem.<br>Arterial line (red).<br>s are opened.<br>clips on the bag holder. |  |
| Select ENTER THER  | APY – then connect patient  |  |  |
| PARAMETERS<br>SETTING  | R INS ING PR<br>DILU  | E-<br>TION THERAPY SELECTION   |  |

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



The device switches automatically to <PARAMETERS SETTING>.

| HF<br>HAEMOFILTRATION   | EPARATION<br>eady for therapy |                   |                              |
|-------------------------|-------------------------------|-------------------|------------------------------|
| Check and confirm the s | safety (inverse               | ) parameters      | <mark>750</mark><br>[ 02000] |
| BLOOD FLOW              | 0 ml≁min                      | SUBSTITUTION FLOW | 73 ml∕min                    |
|                         |                               | SUBST. VOLUME     | 17.50 liters                 |
|                         |                               | WARMER            | 37.0 °C                      |
| PA MIN                  | -200 mmHg                     | PD2 MIN           | -50 mmHg                     |
| PA MAX                  | 100 mmHg                      |                   |                              |
| PBE MAX                 | 400 mmHg                      | UF RATE           | [750] ml⊿h                   |
| PV WINDOW               | 180 mmHg                      | UF VOLUME         | 3000 ml                      |
| FILTER DROP PR. MAX     | 250 mmHg                      | THERAPY TIME      | 04:00 h:min                  |
| TMP MAX                 | 450 mmHg                      | SUB BAG VOLUME    | 0.00 liters                  |
|                         |                               |                   |                              |
| PARAMETERS              | RINSING                       | PRE- ENTER        | BACK                         |
| SETTING                 |                               | DILUTION THERAP   | Y SELECTION                  |
|                         |                               |                   |                              |

#### 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



The value is inversely displayed on a black background

▶ If the value is accepted, confirm by pressing the



To change the value, press the

key to increase it or the kev to decrease it.



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



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

HF PREPARATION HARMOR LL TRATION Ready for therapy Check the recalculated parameter(s) [ 5.. 250] and confirm the safety (inverse) parameters only SUBSTITUTION FLOW 0 ml⊿min [ 73] ml∕min BLOOD FLOW SUBST. VOLUME 17.50 liters 37.0 °C WARMER -200 mmHg PD2 MIN -50 mmHg PA MIN PA MAX 100 mmHg 500 ml≁h PBE MAX 400 mmHg UF RATE PV WINDOW 180 mmHg UF VOLUME 2000 ml 04:00 h:min FILTER DROP PR. MAX 250 THERAPY TIME mmHg 450 SUB BAG VOLUME 0.00 liters TMP MAX mmHq PRE-PARAMETERS RINSING ENTER BACK SETTING DILUTION THERAPY SELECTION

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.

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| HF<br>HAEMOFILTRATION  | REPARATION<br>Ready for therapy |        |                        |                   |
|------------------------|---------------------------------|--------|------------------------|-------------------|
| Check the recalculated | paramet                         | er(s)  |                        | [-25.00 20.00]    |
| BLOOD FLOW             | 0                               | ml∕min | SUBSTITUTION FLOW      | 100 ml/min        |
|                        |                                 |        | SUBST. VULUME          | 24.00 liters      |
| PA MIN                 | -200                            | mmHq   | PD2 MIN                | -50 mmHq          |
| PA MAX                 | 100                             | mmHg   |                        | _                 |
| PBE MAX                | 400                             | mmHg   | UF RATE                | 500 ml≁h          |
| PV WINDOW              | 180                             | mmHg   | UF VOLUME              | 2000 ml           |
| FILTER DROP PR. MAX    | 250                             | mmHg   | THERAPY TIME           | 04:00 h:min       |
| TMP MAX                | 450                             | mmHg   | SUB BAG VOLUME         | 0.00 liters       |
| PARAMETERS<br>SETTING  | RIN                             | ISING  | PRE-<br>DILUTION THERA | BACK<br>SELECTION |

#### Setting treatment parameters

> Select the parameter to be set with the



> Activate the parameter by pressing the

key.

> Change the value with the







➤ 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.

| 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                     | mmHg   | 250     | 100     | 450     | 10         |
| max. pressure drop      |        |         |         |         |            |
| TMP max.                | mmHg   | 450     | 100     | 600     | 10         |
| Fluid-side parameters   |        |         |         |         |            |
| Substitution flow       | ml/min | 73      | 0*/5    | 250     | 1/10       |
| Substitution volume     | 1      | 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 | 1      | 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 following data can be set in the indicated ranges:

\* The substitution flow can be set to zero if the UF rate is  $\geq$  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.

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



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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.)

 $\geq$ Select <SUB BAG VOLUME> in <PARAMETERS SETTING> and confirm with the



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 <br/>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



> Set the parameter to 0 and confirm with the



Select <SUB bag volume> again and confirm with the



 Increase or decrease the value and confirm with the



### 7.3.4 Menu selection in preparation

| HF<br>HAEMOFILTRATION | PREPARATION<br>Rins ing |        |             |          |       |        |
|-----------------------|-------------------------|--------|-------------|----------|-------|--------|
|                       |                         |        |             |          |       |        |
| BLOOD FLOW            | 0                       | ml∕min | SUBSTITUTIO | N FLOW   | 0     | ml∕min |
|                       |                         |        | WARMER      |          | 26.1  | °C     |
| TREATED BLOOD VOLUME  | 0.0                     | liters | PD2         |          | 6     | mmHg   |
|                       | 200                     |        | UF KAIE     |          | U     | ml∕h   |
| РА                    | -208                    | mmHg   |             |          |       |        |
| PBE                   | 16                      | mmHg   | FLUID WEIGH | IT       | 5955  | g      |
| PV                    | 31                      | mmHg   | THERAPY TIM | IE RES.  | 00:00 | h:min  |
| FILTER DROP PR. (PFD) | -15                     | mmHg   |             |          |       |        |
| TMP                   | 17                      | mmHg   | sub bag vol | UME RES. | 0.00  | liters |
|                       | ,                       |        |             |          |       |        |
| PARAMETERS            | RIN                     | SING   | PRE-        | ENTER    | в     | ACK    |
| SETTING               |                         |        | DILUTION    | THERAPY  | SELE  | CTION  |

#### Rinsing

If necessary, rinsing can be prolonged by selecting <<u>RINSING</u>> and confirming with the



- 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



# Diapact<sup>®</sup> CRRT

| HF<br>HAEMOFILTRATION   |   |   | PREP<br>Ready   | ARATION<br>for therapy    |
|---|---|---|---|---------------------------|
| <ol> <li>Replace Sub</li> <li>Remove salin</li> <li>A For pre-dilu</li> <li>Make sure ti</li> <li>Insert the</li> </ol> | stitution line conne<br>ne bags from the wei<br>ution replace Subst.<br>at all the necessar<br>fluid lines into the | ection to subst<br>ighing system.<br>.line to Arteri<br>ry clamps are o<br>e tubing clips | itution flui<br>al line (red<br>ppened.<br>on the bag h | id bag.<br>1).<br>nolder. |
| Select ENTER THER   | APY – then connect  | patient.  |   |                           |
| PARAMETERS  | RINSING   | PRE-<br>DILUTION  | ENTER<br>THERAPY  | BACK                      |

#### **Pre-dilution**

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



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



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### 7.4 Therapy

| HF<br>Haemofiltration   | PREPARATION<br>Ready for therapy                                 |
|---|--|
|   | <u>THERAPY</u>   |
| <ol> <li>Replace Substitution line connection to substi</li> <li>Remove saline bags from the weighing system.</li> <li>▲ For pre-dilution replace Subst.line to Arteria</li> <li>Make sure that all the necessary clamps are op</li> <li>▲ Insert the fluid lines into the tubing clips of</li> <li>Select ENTER THERAPY - then connect patient.</li> </ol> | tution fluid bag.<br>  line (red).<br>ened.<br>n the bag holder. |
| PARAMETERS<br>SETTING RINSING PRE-<br>DILUTION  | ENTER BACK<br>THERAPY SELECTION                                  |

| HF<br>HAEMOFIL TRATION  |     | THERAPY<br>Blood leak blood free test |                     |       |        |  |  |  |
|---|-----|---------------------------------------|---------------------|-------|--------|--|--|--|
| Ensure NO BLOOD, AIR in tube mounted into Blood Leak Det. BLOOD LEAK RECAL. and confirm with EQ |     |                                       |                     |       |        |  |  |  |
| BLOOD FLOW  | 0   | ml∕min                                | SUBSTITUTION FLOW   | 0     | ml∕min |  |  |  |
|   |     |                                       | WARMER              | 26.3  | °C     |  |  |  |
| TREATED BLOOD VOLUME  | 0.0 | liters                                | PD2                 | 10    | mmHg   |  |  |  |
|   |     |                                       | UF RATE             | 0     | ml≁h   |  |  |  |
| PA  | 40  | mmHg                                  | UF VOLUME           | 0     | ml     |  |  |  |
| PBE   | 16  | mmHg                                  | FLUID WEIGHT        | 5057  | g      |  |  |  |
| PV  | 9   | mmHg                                  | THERAPY TIME RES.   | 00:00 | h:min  |  |  |  |
| FILTER DROP PR. (PFD)   | 7   | mmHg                                  | THERAPY TIME        | 00:00 | h:min  |  |  |  |
| TMP   | 2   | mmHg                                  | SUB BAG VOLUME RES. | 0.00  | liters |  |  |  |
|   |     |                                       |                     |       |        |  |  |  |
| PARAMETERS TOTALS   | 1   |                                       | BAG THERAPY         | EN    | DOF    |  |  |  |
| SETTING OVERVIEW  | J   |                                       | CHANGE              | THE   | RAPY   |  |  |  |

### 7.4.1 Connecting the patient

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To switch from <PREPARATION> to <THERAPY>, select <ENTER THERAPY> and confirm by pressing the



 Confirm the start of the therapy by pressing the flashing



key while <THERAPY> is flashing in the supervisor field.

The  $\text{Diapact}^{\circledast}$  CRRT is now in the therapy status as indicated in the therapy status field.

 Confirm the blood leak recalibration by pressing the



 Start the blood pump for circulation by pressing the

stop key.

- 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



- 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 %

| HF<br>HAEMOFILTRATION                 |     |        |                       | THEI       | RAPY         |
|---------------------------------------|-----|--------|-----------------------|------------|--------------|
| BLOOD FLOW                            | 160 | ml∕min | SUBSTITUTION FLOW     | 13<br>31.7 | ml∕min<br>∘r |
| TREATED BLOOD VOLUME                  | 0.1 | liters | PD2                   | 6          | nmHg         |
|                                       |     |        | UF RATE               | 500        | ml∕h         |
| PA                                    | 17  | mmHg   | uf volume             | 9          | ml           |
| PBE                                   | 7   | mmHg   | FLUID WEIGHT          | 5052       | g            |
| PV                                    | 0   | mmHg   | THERAPY TIME RES.     | 04:00      | h:min        |
| FILTER DROP PR. (PFD)                 | 7   | mmHg   | THERAPY TIME          | 00:00      | h:min        |
| ТМР                                   | -3  | mmHg   | SUB BAG VOLUME RES.   | 0.00       | liters       |
| PARAMETERS TOTALS<br>SETTING OVERVIEW | ]   |        | BAG THERAPY<br>CHANGE | EN         | D OF<br>Rapy |

### 7.4.3 Menu selection in therapy

| HF<br>HAEMOFILTRATION  |                                 | THEI         | RAPY<br>Sunning  |
|--|---------------------------------|--------------|------------------|
|  |                                 |              |                  |
| BLOOD FLOW 160 ml⊿min  | TOTAL UF FLOW                   | 15           | ml∕min           |
| TREATED BLOOD VOLUME         0.2 liters           ΣTR. BLOOD VOLUME         0.2 liters | SUBST. VOLUME<br>ΣSUBST. VOLUME | 0.02<br>0.02 | liters<br>liters |
|  | UF RATE                         | 350          | ml∕n             |
| THERAPY TIME 00:01 h:min<br>ΣTHERAPY TIME 00:01 h:min                                  | uf volume<br>Zuf volume         | 43<br>43     | mi<br>mi         |
| PRESSURE<br>OVERVIEW OVERVIEW  | BAG<br>CHANGE                   | THE          | RAPY<br>SET      |

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

Select <THERAPY> and activate by pressing the



<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.

#### Parameter setting

See Section 7.3.3

#### Totals overview

Select <TOTALS OVERVIEW> and confirm by pressing the



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



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  $\Sigma.$ 

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

Select <THERAPY RESET> and confirm by pressing the



#### Pressure overview

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

 Select <PRESSURE OVERVIEW> and confirm by pressing the



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



#### Bag change

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

Select <BAG CHANGE> and confirm by pressing the



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



The treatment continues automatically.



| HF<br>HAEMOFILTBATION          |     |        | BI                  | THEI<br>ood circu | RAPY         |
|--------------------------------|-----|--------|---------------------|-------------------|--------------|
| BLOOD FLOW                     | 350 | ml∕min | SUBSTITUTION FLOW   | 0                 | ml∕min       |
| TREATED BLOOD VOLUME           | 0.3 | liters | WARMER<br>PD2       | 32.9<br>7         | °C<br>nmHa   |
|                                | 010 |        | UF RATE             | 0                 | mi∧n         |
| PA                             | -2  | mmHg   | UF VOLUME           | 44                | ml           |
| PBE                            | 8   | mmHg   | FLUID WEIGHT        | 5087              | g            |
| PV                             | 0   | mmHg   | THERAPY TIME RES.   | 03:58             | h:min        |
| FILTER DROP PR. (PFD)          | 8   | mmHg   | THERAPY TIME        | 00:02             | h:min        |
| тмр                            | -3  | mmHg   | SUB BAG VOLUME RES. | 0.00              | liters       |
| PARAMETERS<br>SETTING OVERVIEW |     |        | BAG<br>CHANGE       | EN<br>THE         | D OF<br>Rapy |

HF HAEMOFIL TRATION 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



THERAPY

END OF THERAPY

Runn i ng

Confirm by pressing the



| HF<br>HAEMOFILTRATION  |     |        | END OF            | THEI<br>Blood | RAPY<br>return |  |  |
|--|-----|--------|-------------------|---------------|----------------|--|--|
|  |     |        |                   |               |                |  |  |
| BLOOD FLOW   | 50  | ml∕min | SUBSTITUTION FLOW | 0             | ml∕min         |  |  |
|  |     |        | WARMER            | 37.0          | °C             |  |  |
| TREATED BLOOD VOLUME   | 6.5 | liters | PD2               | 53            | nmHg           |  |  |
|  |     |        | PD1               | 14            | nmHg           |  |  |
| PA   | 47  | mmHg   | UF VOLUME         | 130           | ml             |  |  |
| PBE  | 56  | mmHg   | UF RATE           | 0             | ml∕h           |  |  |
| PV   | 32  | mmHg   | FLUID WEIGHT      | 5240          | g              |  |  |
| FILTER DROP PR. (PFD)  | 25  | mmHq   | THERAPY TIME RES. | 03:38         | h:min          |  |  |
| ТМР  | -9  | mmHg   | THERAPY TIME      | 00:22         | h:min          |  |  |
| TOTALS<br>OVERVIEW CALIBR. BACK TO<br>THERAPY CHANGE THERAPY |     |        |                   |               |                |  |  |



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

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#### 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

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| HF<br>HAEMOFILTRATION |                 | END            | OF THERAPY<br>Blood return | Totals overview  |
|-----------------------|-----------------|----------------|----------------------------|--|
|                       |                 |                |                            | The option <totals ovi<br="">of the pivotal treatment<br/>(Section 7.4.2)</totals> |
| BLOOD FLOW            | 50 ml≁min       |                |                            |  |
| TREATED BLOOD VO      | LUME 6.5 liters | SUBST. VOLUME  | 2.00 liters                | confirm by pressing  |
| ΣTR. BLOOD VOLUM      | E 7.0 liters    | ΣSUBST. VOLUME | 2.05 liters                |  |
| THERAPY TIME          | 00:22 h:min     | uf volume      | 130 mi                     | To return to the <en< td=""></en<>   |
| ΣTHERAPY TIME         | 00:25 h:min     | Σuf volume     | 293 mi                     | <totals overview<="" p=""></totals>  |
| TOTALS                | BLOOD LEAK      | TO SET-UP      | NEW                        | key.   |
| OVERVIEW              | CALIBR. THER    | APY CHANGE     | THERAPY                    |  |

ERVIEW> shows the summary data as described

- RVIEW> and the
- ND OF THERAPY> screen, select /> and confirm with the

# Diapact<sup>®</sup> CRRT

| HF<br>HAEMOFILTRATION<br>Ensure NO BLOOD, AIR in tu<br>and confirm with EQ  | END OF THERAPY<br>Blood leak blood free test<br>ube mounted into Blood Leak Det. BLOOD LEAK RECAL.  | <b>Blood leak recalibration</b><br>The <blood calibration="" leak=""> function allows the recalibration of the blood leak detector in case of non-</blood>  |
|---|---|---|
| BLOOD FLOW     S       TREATED BLOOD VOLUME     P       PA     PBE       PV     FILTER DROP PR. (PFD)       TOTALS     BLOOD LE       OVERVIEW     BLOOD LE | 50     ml/min     SUBSTITUTION FLOW     0     ml/min       6.5     liters     PD2     52     mmHg       48     mmHg     UF     14     mmHg       32     mmHg     UF     RATE     0     ml/min       32     mmHg     FLUID WEIGHT     5237     g       26     mmHg     THERAPY TIME     00:22     h:min       7     mdHg     HERAPY TIME     00:22     h:min | <ul> <li>Select "BLOOD LEAK CALIBRATION" and confirm with the event with the even even the even the even even even the even even the even even even the even even even the even even even even even the even even even even even even even ev</li></ul> |
|   | <ul> <li>Risk of blood loss for the patier</li> <li>Before the recalibration of carefully checked for possib</li> <li>It is recommended to withd the filtrate line and to anal</li> <li>The blood leak recalibration</li> </ul>   | It and haemolysis<br>the blood leak detector, the haemofilter must be<br>le blood leaks and haemolysis.<br>raw a sample (at least 2 ml) from the injection port of<br>yze for erythrocytes and/or free haemoglobin.<br>In must only be performed if these tests are negative.   |

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

| STITUTION FLOW<br>MER 3 | 0<br>0<br>5.4<br>51  | HERAPY<br>ml∕min<br>°C   |
|-------------------------|--|--|
| STITUTION FLOW<br>HER 3 | 0<br>15.4<br>51  | ml∕min<br>∘C   |
| der 3                   | 15.4<br>51   | °C   |
|                         | 51   |  |
|                         |  | mmHg   |
|                         | 14   | mmHg   |
| /olume                  | 130  | ml   |
| RATE                    | 0  | ml∕h   |
| ID WEIGHT 5             | 5237   | g  |
| RAPY TIME RES. 03       | 3:38   | h:min  |
| RAPY TIME 00            | ):22   | h:min  |
|                         | NOLUME<br>KATE<br>DA WEIGHT 5<br>KAPY TIME RES. 03<br>KAPY TIME 00<br>SET-UP<br>CHANGE 1 | NOLUME         130           KATE         0           D WEIGHT         5237           KAPY TIME RES.         03:38           KAPY TIME         00:22           SET-UP         NEW           CHANGE         THERA |

### Back to therapy

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

➢ Select <BACK TO THERAPY> and confirm by pressing the





> Confirm by pressing the



> Start the therapy again by pressing the key.

i



7

HF

| HF   | END OF THERAPY  |
|--|---|
| Haemofiltration  | Blood return  |
|  |   |
| <ul> <li>For dilution exchange: - Clamp infusion port<br/>- Reconnect Subst.line, open clamps, select.</li> <li>Stop blood pump and clamp all ports of filte<br/>Exchange filter with a pre-filled one (if n<br/>Perform changes for a dialysis therapy (if<br/>- Turn filter red side up &amp; reconn.UF line()<br/>- Reconnect Subst.line (green) to port on bi<br/>- Exchange bags (if necessary).</li> <li>Open clamps, start blood pump and select THI</li> </ul> | ts.<br>rdeselect PREDILUTION<br>er and infusion port.<br>ecessary).<br>hecessary):<br>yellow) to upper port<br>lue side of filter.<br>ERAPY EXCHANGE. |
| PRE-   | SET-UP  |
| DILUTION RESET   | CHANGE EXCHANGE   |

### 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



- Stop the blood pump (MP1).
- > Follow the relevant procedure described below.

### Change from post-dilution to pre-dilution

- 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



Activate <PRE-DILUTION> by pressing the



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

er 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



See also Section 7.4.3

| Η                            | F END O  | F THERAPY     |  |  |  |  |  |
|------------------------------|--|---------------|--|--|--|--|--|
| HAEMOFILTRATION Blood return |  |               |  |  |  |  |  |
|                              |  |               |  |  |  |  |  |
|                              |  | RESET THERAPY |  |  |  |  |  |
|                              |  |               |  |  |  |  |  |
| •                            | For dilution exchange: - Clamp infusion ports.                                       |               |  |  |  |  |  |
|                              | - Reconnect Subst.line, open clamps, select/deselect PREDILUTION                     |               |  |  |  |  |  |
| •                            | <ul> <li>Stop blood pump and clamp all ports of filter and infusion port.</li> </ul> |               |  |  |  |  |  |
| •                            | <ul> <li>Exchange filter with a pre-filled one (if necessary).</li> </ul>            |               |  |  |  |  |  |
| ٠                            | <ul> <li>Perform changes for a dialysis therapy (if necessary):</li> </ul>           |               |  |  |  |  |  |
|                              | - Turn filter red side up & reconn.UF line(yellow) to up                             | per port      |  |  |  |  |  |
|                              | - Reconnect Subst.line (green) to port on blue side of filter.                       |               |  |  |  |  |  |
|                              | - Exchange bags (if necessary).  |               |  |  |  |  |  |
| •                            | Open clamps, start blood pump and select THERAPY EXCHANG                             | Ε.            |  |  |  |  |  |
|                              |  |               |  |  |  |  |  |







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



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



Confirm by pressing the



Select <CONTINUOUS> or <INTERMITTENT> therapy mode using 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

HF END OF THERAPY Blood circulation PLASMA THERAPIES DIALYSIS THERAPIES CONTINUOUS INTERMITTENT SELECT THERAPY MODE AND CONFIRM

7

HF

The

| HF<br>HAEMOFILTRATION   |             |              | END O                       | F THEI<br>Blood | RAPY<br>return | New therapy  |
|-------------------------|-------------|--------------|-----------------------------|-----------------|----------------|--|
|                         |             |              |                             | THERAPY SE      | LECTION        | The option <new therapy=""> allows to start a new therapy immediately after the one just finished. The device switches directly to therapy selection</new> |
| BLOOD FLOW              | 50          | ml∕min       | SUBSTITUTION FLOW<br>WARMER | 0<br>36.4       | ml∕min<br>∘C   | <ul> <li>Select <new therapy=""> and</new></li> </ul>  |
| TREATED BLOOD VOLUME    | 3.6         | liters       | PD2                         | 58              | nmHg           | confirm by pressing the  |
| PA                      | 42          | mmHg         | PD1<br>UF VOLUME            | 14<br>116       | mmHg<br>m I    | FO   |
| PBE                     | 65          | mmHg         | UF RATE                     | 0               | ml∕h           | key. The key lights up.  |
| FILTER DROP PR. (PFD)   | 34<br>31    | mm∺g<br>mmHg | THERAPY TIME RES.           | 5309<br>02:49   | g<br>h∶min     | Confirm by pressing the  |
| TMP                     | -9          | mmHg         | THERAPY TIME                | 01:11           | h∶min          |  |
| TOTALS<br>OVERVIEW CALI | LEAK<br>BR. | BACK<br>THER | TO SET-UP<br>APY CHANGE     | NEW<br>THER     | #<br>APY       | EQ key.  |



 $\geq$ 

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<sup>®</sup> 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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# 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

| B BRAUN<br>SELFTEST<br>ROM test<br>CRC 83 %<br>SW HW Language 1 Language 2 Language 3<br>SYS V2.12.4<br>DPD V2.12.4 Rev. B V044.02.12.00 V049.02.12.00 V086.02.12.00<br>DPC V2.12.4 Rev. C<br>DPS V2.12.4 Rev. B V044.02.12.00 V049.02.12.00 V086.02.12.00<br>224 h  | <ul> <li>Switch on the Diapact<sup>®</sup> CRRT with the power switch ON/OFF (I/O) on the back of the machine. The device starts with the ROM test.</li> <li>Check whether the AO and EO keys are lit during the ROM test.</li> </ul>   |
|--|---|
| B BRAUN SELFTEST<br>Display test   | The ROM test is followed by the display test.   |
| SW         HW         Language 1         Language 2         Language 3           SYS         V2.12.4         Rev. B         V044.02.12.00         V049.02.12.00         V086.02.12.00           DPC         V2.12.4         Rev. C         DPS         V2.12.4         Rev. B         V044.02.12.00         V049.02.12.00         V086.02.12.00  | <ul> <li>Compare the character lines in the supervisor field and confirm by pressing the EQ key if both series are identical.</li> <li>While the EQ key is being pressed, the buzzer of the safety system is activated for 2 seconds.</li> <li>Check that the buzzer can be heard.</li> </ul> |
| verify characters and confirm with Eq. $\underline{\mathbb{O}}$ 224 h  |   |
| B BRAUN SELFTEST<br>Empty loadcell test<br>-21   | If the display test is passed successfully, the empty load cell test follows.   |
| Weight of bag holder: (± 60 g)         -17           SW         HW         Language 1         Language 2         Language 3           SYS         V2.12.4         PPD         V2.12.4         Rev. B         V044.02.12.00         V049.02.12.00         V086.02.12.00           DPC         V2.12.4         Rev. C         DPS         V2.12.4         Rev. B         V044.02.12.00         V049.02.12.00         V086.02.12.00 | <ul> <li>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.</li> </ul>   |
| BAG HOLDER FREE?<br>CHECK THE WEIGHTS AND CONFIRM WITH EQ<br>Q 224 h   |   |

# 8 HD / HFD

## 8.2 Therapy selection

| B BRAUN THERAPY SELEC'  | TION<br>tandby Having successfully passed the initial self tests, the<br>machine switches to the <therapy selection=""><br/>screen to select the therapy mode.<br/><continuous> dialysis therapies is selected by</continuous></therapy>  |
|---|---|
| PLASMA THERAPIES     DIALYSIS THERAP       ADSORPTION > PERFUSION     CONTINUOUS       PLASMA EXCHANGE     INTERMITTENT | <ul> <li>default.</li> <li>To select <intermittent> dialysis therapies, move to the respective position with the and keys.</intermittent></li> </ul>  |
| SELECT THERAPY MODE AND CONFIRM   | <ul> <li>Confirm the selection with the key.</li> </ul>   |
| B BRAUN THERAPY SELEC'  | TION<br>tandby The following screen displays the possible therapy<br>options. <haemofiltration> is selected by default<br/>Select <haemodialysis> or</haemodialysis></haemofiltration>  |
| INTERMITTENT DIALYSIS THERAPIES<br>HAEMOFILTRATION  | <pre></pre> |
| HAEMODIALYSIS<br>HIGHFLUX DIALYSIS  | <ul> <li>Confirm the selection with the key.</li> </ul>   |
| SELECT THERAPY MODE AND CONFIRM BACK SELECTION  | The EO key lights up and HF flashes in the supervisor field.  |
|   | <ul> <li>Press the EQ key to confirm the selected therapy modality.</li> </ul>  |
|   | If the selection is not confirmed with the<br>EO<br>key, the device returns automatically to the<br><therapy selection=""> screen where the therapy<br/>mode can be selected.</therapy>   |
|   | Back selection  |

Moving with the or keys to <<u>BACK</u> SELECTION> and confirmation with



allows to return to the screen where the therapy mode can be selected.

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 Preparation

| TLD<br>HAEMODIALYSIS   |        | PREPARATION<br>Power relay test |                     |       |        |
|------------------------|--------|---------------------------------|---------------------|-------|--------|
| o not connect any disp | osable |                                 |                     |       |        |
| BLOOD FLOW             | 0      | ml∕min                          | DIALYSATE FLOW      | 0     | ml/min |
|                        |        |                                 | WARMER              | 26.2  | ٥C     |
| TREATED BLOOD VOLUME   | 0.0    | liters                          | PD2                 | 7     | mmHg   |
|                        |        |                                 | UF RATE             | 0     | ml∕h   |
| PA                     | 15     | mmHg                            |                     |       |        |
| PBE                    | 17     | mmHg                            | FLUID WEIGHT        | 5249  | g      |
| PV                     | 21     | mmHg                            | THERAPY TIME RES.   | 00:00 | h:min  |
| FILTER DROP PR. (PFD)  | -6     | mmHg                            |                     |       |        |
| TMP                    | 11     | mmHg                            | DIA BAG VOLUME RES. | 0.00  | liters |

#### 8.3.1 Installation of consumable material

| HD PREPARATION Device test finished   | When the tests have been performed successfully to<br><preparation> screen displays <device test<br="">finished&gt; and the steps to set-up the machine are<br/>displayed.</device></preparation>                       |  |  |  |
|---|---|--|--|--|
| <ol> <li>Place the filter on its holder with venous (blue) side up.</li> <li>Mount and connect Dialysate line (green). Clamp free connection.</li> <li>A Place UF collection bag on machine base. Clamp the outlet.</li> <li>Mount and connect UF line (yellow) through BLD. Clamp free conn.</li> <li>Mount and connect Arterial line (red).</li> <li>Hang Venous collection bag on the ly pole.</li> <li>Mount and connect Venous line (blue).</li> <li>Make sure all the necessary clamps are opened then start PRIMING</li> </ol> | <ul> <li>The consumable material for the therapy comprises:</li> <li>HF/HD kit</li> <li>Haemofilter (low-flux filter for HD)</li> <li>2L isotonic sodium chloride solution</li> <li>Haemofiltration solution</li> </ul> |  |  |  |
| PARAMETERS PRIMING BACK SELECTION   | Follow the instructions on the screen and set-up<br>the device as described in the following.   |  |  |  |

| i | The lines of the HF/HD kit are colour-coded to facilitate the set-up.<br>Arterial line (red)<br>Venous line (blue)<br>Ultrafiltration line / dialysate outlet line in CVVHD/CVVHFD (yellow)<br>Substitution line / dialysate inlet line in CVVHD/CVVHFD (green)   |
|---|---|
|   | Pumps used:<br>Blood pump (MP1)<br>Ultrafiltration pump (MP2)<br>Substitution pump (MP3) / Dialysate pump in CVVHD/CVVHFD   |
|   | <ul> <li>Risk of infection and blood loss for the patient by damaged packaging or components</li> <li>Make sure during set-up that the packaging of the material used (line system, haemofilter, solution bags) is undamaged.</li> <li>During set-up check the material for integrity.</li> <li>Observe the respective instructions for use.</li> </ul> |



#### 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.

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.

CAUTION



#### 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.

# 8 HD / HFD



### 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.

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

i

### 8.3.2 Priming

i

| HD<br>HAEMODIALYSIS   |     |        | PREPARATION         |           |              |
|-----------------------|-----|--------|---------------------|-----------|--------------|
|                       |     |        | Arteria             |           |              |
| BLOOD FLOW            | 100 | ml∕min | DIALYSATE FLOW      | 0         | ml∕min       |
| TREATED BLOOD VOLUME  | 0.0 | liters | WARMER<br>PD7       | 31.2      | °C<br>mmHa   |
|                       | 0.0 |        | UF RATE             | 0         | mi∕h         |
| PA                    | 13  | mmHg   |                     |           |              |
| PBE                   | 8   | mmHg   | FLUID WEIGHT        | 5248      | g            |
| PV                    | 6   | mmHg   | THERAPY TIME RES.   | 00:00     | h:min        |
| FILTER DROP PR. (PFD) | 2   | mmHg   |                     |           |              |
| тмр                   | -2  | mmHg   | DIA BAG VOLUME RES. | 0.00      | liters       |
| PARAMETERS<br>SETTING | PRI | MING   | 5                   | B<br>SELE | ACK<br>CTION |

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



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<sup>®</sup> CRRT during calibration of the pump constants. Calibration will be repeated if it is disturbed.

by pressing the

key.

The device switches automatically to

<PARAMETERS SETTING>.

| HD<br>HAEMODIALYSIS   |                               | PRE                      | PARATION                    | During the priming procedure the prompt to turn the   |
|---|-------------------------------|--------------------------|-----------------------------|---|
| ▲ Turn the dialyser ar<br>Confirm with EQ   | terial (red) si               | de up [840]              |                             | <ul> <li>Turn the haemofilter upside down.</li> </ul>   |
| BLOOD FLOW  | 100 ml/min                    | DIALYSATE FLOW           | 0 ml≁min                    | <ul> <li>Confirm by pressing the</li> </ul>   |
| TREATED BLOOD VOLUME  | 0.0 liters                    | WARMER<br>PD2<br>UF RATE | 31.2 ∘C<br>9 mmHg<br>0 ml∕h | EQ key.   |
| PA  | 13 mmHg                       |                          |                             |   |
| PBE   | 8 mmHg                        | FLUID WEIGHT             | 5248 g                      |   |
| PV  | 6 mmHg                        | THERAPY TIME RES.        | 00:00 h:min                 |   |
| FILTER DROP PR. (PFD)   | 2 mmHg                        |                          | 0.00                        |   |
| HD<br>Haemodialysis   |                               | PRE<br>Rea               | PARATION<br>dy for therapy  | After the preparation phase has been finished, the system gives an acoustic signal and shows the                                    |
|   |                               |                          |                             | therapy> in the therapy status field.   |
| <ol> <li>Hang UF collection bag on weighing system.</li> <li>Replace Dialysate line connection to the dialysate fluid bag.</li> <li>Remove saline bags from the weighing system.</li> <li>Make sure that all the necessary clamps are opened.</li> <li>▲ Insert the fluid lines into the tubing clips on the bag holder.</li> </ol> |                               |                          | d bag.<br>holder.           | <ul> <li>Remove the bag with the sodium chloride solution<br/>from the load cell and attach it to the infusion<br/>pole.</li> </ul> |
| 1a Recirc.: Connect   | dialysate bags                | together by connecting   | line.                       | Single ness   |
| 1b Replace  | the UF line to                | the dialysate fluid ba   | g.                          | Single pass   |
|   |                               |                          |                             | <ul> <li>Attach the collecting bags to the bag holder of the<br/>load cell.</li> </ul>  |
| PARAMETERS<br>SETTING   | PARAMETERS RINSING ENTER BACK |                          | BACK                        | Make sure that all relevant clamps are open.  |
|   |                               |                          |                             | Soloct CENTED THEDADY, and confirm  |
|   |                               |                          |                             |   |

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## 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



The device switches automatically to <PARAMETERS SETTING>.

# 8.3.3 Parameter setting

| HD<br>HAEMODIALYSIS   |                 | PRI<br>Re          | EPARATION<br>ady for therapy |
|-----------------------|-----------------|--------------------|------------------------------|
| Check and confirm the | safety (inverse | ) parameters       | 750<br>[ 02000]              |
| BLOOD FLOW            | 0 ml⊿min        | DIALYSATE FLOW     | 73 ml∕min                    |
|                       |                 | - DIALYSATE VOLUME | 17.50 liters                 |
|                       |                 | WARMER             | 37.0 °C                      |
| PA MIN                | -200 mmHg       | PD2 MIN            | -250 mmHg                    |
| PA MAX                | 100 mmHg        |                    |                              |
| PBE MAX               | 400 mmHg        | UF RATE            | [750] ml⊿h                   |
| PV WINDOW             | 100 mmHg        | UF VOLUME          | 3000 ml                      |
| FILTER DROP PR. MAX   | 250 mmHg        | THERAPY TIME       | 04:00 h:min                  |
| TMP MAX               | 450 mmHg        | DIA BAG VOLUME     | 0.00 liters                  |
|                       |                 |                    |                              |
| PARAMETERS<br>SETTING | RINSING         | ENTER<br>THERAPY   | BACK                         |

### 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



The value is inversely displayed on a black background.

> If the value is accepted, confirm by pressing the



To change the value, press the





- 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 <u>always</u> be confirmed with the



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

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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.

| HD<br>Haemodialysis |      |        | PR<br>I          | REPARATION<br>Ready for therapy |
|---------------------|------|--------|------------------|---------------------------------|
|                     |      |        |                  | [20.040.0]                      |
| BLOOD FLOW          | 0    | ml/min | DIALYSATE FLOW   | 73 ml≁min                       |
|                     |      |        | DIALYSATE VOLUME | 17.50 liters                    |
|                     |      |        | WARMER           | [37.0] °C                       |
| PA MIN              | -200 | mmHg   | PD2 MIN          | -250 mmHg                       |
| PA MAX              | 100  | mmHg   |                  |                                 |
| PBE MAX             | 400  | mmHg   | UF RATE          | 750 ml≁n                        |
| PV WINDOW           | 100  | mmHg   | UF VOLUME        | 3000 m I                        |
| FILTER DROP PR. MAX | 250  | mmHg   | THERAPY TIME     | 04:00 h:min                     |
| TMP MAX             | 450  | mmHa   | DIA BAG VOLUME   | 0.00 liters                     |

### Setting treatment parameters

> Select the parameter to be set with the



 $\succ$  Activate the parameter by pressing the



> Change the value with the



and confirm the change with the



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<br>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          | I      | 17.50   | 0*      | 120.00  | 0.10/1.00  |
| Temperature               | °C     | 37      | 20      | 40      | 0.5/1.0    |
| PD2 min. <b>HD</b>        | mmHg   | -250    | -400    | 500     | 10         |
| PD2 min. <b>HFD</b>       | 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      | 1      | 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                        |
| * Eurthor paramotor(s) can b | a changed if the dependently   |

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

EQ

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





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### 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



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 <br/>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 <br/>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



Set the parameter to 0 and confirm with the



Select <DIA bag volume> again and confirm with the



 Increase or decrease the value and confirm with the



# Diapact<sup>®</sup> CRRT

# 8.3.4 Menu selection in preparation

| HD<br>Haemod I alys is |     |        | PRE                 | PARA  | TION         |
|------------------------|-----|--------|---------------------|-------|--------------|
| BLOOD FLOW             | 200 | ml∕min | DIALYSATE FLOW      | 120   | ml∕min<br>∘c |
| TREATED BLOOD VOLUME   | 0.0 | liters | PD2                 | 10    | mmHg         |
|                        |     |        | UF RATE             | 0     | ml∕h         |
| PA                     | 12  | mmHg   |                     |       |              |
| PBE                    | 8   | mmHg   | FLUID WEIGHT        | 5250  | g            |
| PV                     | 6   | mmHg   | THERAPY TIME RES.   | 00:00 | h:min        |
| FILTER DROP PR. (PFD)  | 2   | mmHg   |                     |       |              |
| ТМР                    | -3  | mmHg   | DIA BAG VOLUME RES. | 0.00  | liters       |
| PARAMETERS<br>SETTING  | RIN | ISING  | ENTER<br>THERAPY    | B     | ACK          |

### Rinsing

If necessary, rinsing can be prolonged by selecting <u><RINSING></u> and confirming with the



- 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



# **Back selection**

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

Select <BACK SELECTION> and confirm with the



# 8.4 Therapy

| HD<br>HAEMODIALYSIS                              | PREPARATION<br>Ready for therapy |
|--|----------------------------------|
|  | <b><u>THERAPY</u></b>            |
| 1. Hang UF collection bag on weighing system.    |                                  |
| 2. Replace Dialysate line connection to the di   | ialysate fluid bag.              |
| 3. Remove saline bags from the weighing system   | n.                               |
| 4. Make sure that all the necessary clamps are   | e opened.                        |
| 5. 🛦 Insert the fluid lines into the tubing clip | os on the bag holder.            |
| Select ENTER THERAPY - then connect patient.     |                                  |
| 1a Recirc.: Connect dialysate bags together t    | by connecting line.              |
| 1b Replace the UF line to the dialys             | sate fluid bag.                  |
| 1c Remove UF coll. bag from machine              | base. Continue in 2.             |
| PARAMETERS<br>SETTING                            | ENTER BACK<br>THERAPY SELECTION  |

| HD   |        |           |                        | THEF      | RAPY         |
|--|--------|-----------|------------------------|-----------|--------------|
|  |        |           | Blood leak b           | lood fre  | e test       |
| THE ROUTHETS IS                                |        |           | brood reak b           |           | c test       |
| Ensure NO BLOOD, AIR in<br>and confirm with EQ | tube m | ounted in | nto Blood Leak Det. BL | DOD LEAK  | RECAL.       |
| BLOOD FLOW                                     | 0      | ml∕min    | DIALYSATE FLOW         | 0         | ml∕min       |
|  |        |           | WARMER                 | 30.2      | °C           |
| TREATED BLOOD VOLUME                           | 0.0    | liters    | PD2                    | 12        | mmHg         |
|  |        |           | UF RATE                | 0         | ml∕h         |
| PA   | 17     | mmHg      | uf volume              | 0         | ml           |
| PBE  | 8      | mmHg      | FLUID WEIGHT           | 5240      | g            |
| PV   | 12     | mmHg      | THERAPY TIME RES.      | 00:00     | h:min        |
| FILTER DROP PR. (PFD)                          | -4     | mmHg      | THERAPY TIME           | 00:00     | h:min        |
| TMP  | -2     | mmHg      | DIA BAG VOLUME RES.    | 0.00      | liters       |
| PARAMETERS<br>SETTING OVERVIEW                 | ]      |           | BAG<br>CHANGE          | EN<br>THE | D OF<br>RAPY |

To switch from <PREPARATION> to <THERAPY>, select <ENTER THERAPY> and confirm by pressing the



 Confirm the start of the therapy by pressing the flashing



key while <THERAPY> is flashing in the supervisor field.

The Diapact<sup>®</sup> CRRT is now in the therapy status as indicated in the therapy status field.

 Confirm the blood leak recalibration by pressing the



Start the blood pump for circulation by pressing the



# 8 HD / HFD

# 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



- 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 the rapy, the arterial chamber should be about 50% filled, the venous chamber about 80%

## 8.4.2 Start of therapy

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| HD<br>Haemodialysis               |     |        |                     | THEI       | RAPY<br>Sunning |
|-----------------------------------|-----|--------|---------------------|------------|-----------------|
| BLOOD FLOW                        | 50  | ml⊿min | DIALYSATE FLOW      | 73         | ml/min          |
| TREATED BLOOD VOLUME              | 0.0 | liters | PD2                 | 30.9<br>10 | or<br>mmHa      |
| THEATED BEOOD TOESHE              | 0.0 | inters | UF RATE             | 750        | mi⊿h            |
| PA                                | 17  | mmHg   | UF VOLUME           | -5         | ml              |
| PBE                               | 7   | mmHg   | FLUID WEIGHT        | 5237       | g               |
| PV                                | 11  | mmHg   | THERAPY TIME RES.   | 04:00      | h:min           |
| FILTER DROP PR. (PFD)             | -4  | mmHg   | THERAPY TIME        | 00:00      | h:min           |
| тмр                               | -1  | mmHg   | DIA BAG VOLUME RES. | 0.00       | liters          |
| PARAMETERS<br>SETTING<br>OVERVIEW | ]   |        | BAG<br>CHANGE       | EN         | D OF<br>Rapy    |

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

Select <THERAPY> and activate by pressing the



<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

| HD<br>HAEMODIALYSIS                       |                          |                                     | THERAPY<br>Runn ing        |
|---|--------------------------|-------------------------------------|----------------------------|
|   |                          |                                     |                            |
| BLOOD FLOW                                | 50 ml⊿min                |                                     |                            |
| TREATED BLOOD VOLUME<br>ΣTR. BLOOD VOLUME | 0.0 liters<br>0.0 liters | DIALYSATE VOLUME<br>ZDIALYSATE VOL. | 0.05 liters<br>0.05 liters |
|   |                          | UF RATE                             | 750 mi⊿n                   |
| THERAPY TIME Ο C<br>ΣTHERAPY TIME Ο C     | ):00 h:min<br>):00 h:min | uf volume<br>Zuf volume             | 13 mi<br>13 mi             |
| PRESSURE<br>OVERVIEW                      |                          | BAG<br>CHANGE                       | THERAPY<br>RESET           |

## Parameter setting

See Section 8.3.3

# Totals overview

Select <TOTALS OVERVIEW> and confirm by pressing the



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



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  $\Sigma.$ 

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

Select <THERAPY RESET> and confirm by pressing the



# 8 HD / HFD

| HD<br>Haemod I alys is      |     |                 | THERAPY<br>Running             |
|-----------------------------|-----|-----------------|--------------------------------|
| BLOOD FLO₩ 50 ml/min        | PED | _1 motio        |                                |
| PBE 7 mnHg<br>              |     | - <b>7</b> ming | PV 11 mnHg<br>→→               |
|                             | TMP | -1 mmHg         |                                |
| PA 18 mmiHg<br>PD2 10 mmiHg |     |                 | †<br>⊺36.8 °C<br>  PD1 13 mmHg |
| PRESSURE<br>OVERVIEW        |     | BAG<br>Change   | THERAPY END OF<br>THERAPY      |

| HD<br>HAEMODIALYSIS              |         |         | Blo                 | THEF<br>od circu | RAPY<br>lation |
|----------------------------------|---------|---------|---------------------|------------------|----------------|
| Release BAG CHANGE to co         | ontinue | the the | rapy.               |                  |                |
| BLOOD FLOW                       | 50      | ml∕min  | DIALYSATE FLOW      | 0                | ml∕min         |
|                                  |         |         | WARMER              | 37.2             | ٥C             |
| TREATED BLOOD VOLUME             | 0.1     | liters  | PD2                 | 10               | nmHg           |
|                                  |         |         | UF RATE             | 0                | ml∕h           |
| PA                               | 18      | mmHg    | UF VOLUME           | 19               | ml             |
| PBE                              | 7       | mmHg    | FLUID WEIGHT        | 5264             | g              |
| PV                               | 11      | mmHg    | THERAPY TIME RES.   | 03:59            | h:min          |
| FILTER DROP PR. (PFD)            | -4      | mmHg    | THERAPY TIME        | 00:01            | h:min          |
| тмр                              | -1      | mmHg    | DIA BAG VOLUME RES. | 0.00             | liters         |
| PARAMETERS<br>SETTING<br>VERVIEW | ]       |         | BAG<br>CHANGE       | EN<br>THE        | D OF<br>Rapy   |

# 8.5 End of therapy

### Pressure overview

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

Select <PRESSURE OVERVIEW> and confirm by pressing the



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



## Bag change

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

Select <BAG CHANGE> and confirm by pressing the



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



The treatment continues automatically.

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.

# Diapact<sup>®</sup> CRRT

| HD<br>HAEMODIALYSIS               |     |        |                     | THEI            | RAPY            |
|-----------------------------------|-----|--------|---------------------|-----------------|-----------------|
|                                   |     |        |                     | <u>END OF T</u> | HERAPY          |
| BLOOD FLOW                        | 50  | ml∕min | DIALYSATE FLOW      | 73              | ml∕min          |
|                                   | 0.4 | 1:4    | WARMER              | 37.0            | °C              |
| INFULTION RECORD ANTIME           | 0.4 | liters |                     | 10              | mmeng<br>mitzto |
| PA                                | 17  | mmHa   |                     | 112             | ml              |
| PBE                               | 7   | mmHq   | FLUID WEIGHT        | 5358            | q               |
| PV                                | 11  | mmHg   | THERAPY TIME RES.   | 03:52           | h:min           |
| FILTER DROP PR. (PFD)             | -4  | mmHg   | THERAPY TIME        | 80:00           | h:min           |
| TMP                               | -1  | mmHg   | DIA BAG VOLUME RES. | 0.00            | liters          |
| PARAMETERS<br>SETTING<br>VVERVIEW | ]   |        | BAG<br>CHANGE       | EN              | D OF<br>Rapy    |
| HD<br>HAEMODIALYSIS               |     |        | END OF              | THEI<br>Blood   | RAPY<br>return  |

 Select <END OF THERAPY> and confirm by pressing the



- Confirm by pressing the
  - EQ key.

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

| HD<br>HAEMODIALYSIS            |             |              | END OF                  | F THEI<br>Blood | RAPY<br>return |
|--------------------------------|-------------|--------------|-------------------------|-----------------|----------------|
|                                |             |              |                         |                 |                |
| BLOOD FLOW                     | 40          | ml⊿min       | DIALYSATE FLOW          | 0               | ml∕min         |
|                                |             |              | WARMER                  | 37.0            | °C             |
| TREATED BLOOD VOLUME           | 0.5         | liters       | PD2                     | 10              | mmHg           |
|                                |             |              | PD1                     | 13              | mmHg           |
| PA                             | 17          | mmHg         | UF VOLUME               | 112             | ml             |
| PBE                            | 7           | mmHq         | UF RATE                 | 0               | ml∕h           |
| PV                             | 11          | mmHq         | FLUID WEIGHT            | 5360            | q              |
| FILTER DROP PR. (PFD)          | -4          | mmHq         | THERAPY TIME RES.       | 03:51           | h:min          |
| TMP                            | -1          | mmHg         | THERAPY TIME            | 00:09           | h:min          |
|                                | •••••••     |              | L                       |                 |                |
| TOTALS BLOOD<br>OVERVIEW CALIE | LEAK<br>IR. | BACK<br>Ther | TO SET-UP<br>APY CHANGE | NEV<br>THERA    | r<br>PY        |

# 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.

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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<sup>®</sup> CRRT within this time frame.

#### HD / HFD 8

#### Menu selection at end of therapy 8.5.2

| HD<br>HAEMODIALYSIS   | END OF THERAPY<br>Blood return  | Totals overview  |
|---|---|--|
| HD<br>HAEMODIALYSIS<br>BLOOD FLOW 50<br>TREATED BLOOD VOLUME 0.9<br>ZTR. BLOOD VOLUME 0.9<br>THERAPY TIME 00:01<br>TOTALS<br>OVERVIEW BLOOD LEAK<br>CALIBR.<br>HD<br>HAEMODIALYSIS<br>Ensure NO BLOOD, AIR in tube m<br>and confirm with E0<br>BLOOD FLOW 50<br>TREATED BLOOD VOLUME 0.5<br>PA 16<br>PBE 7<br>PV 11<br>FILTER DROP PR. (PFD) -4<br>TMP -1 | END OF THERAPY<br>Blood return<br>m1/min<br>5 liters<br>5 liters<br>5 liters<br>DIALYSATE VOLUME<br>5 liters<br>DIALYSATE VOLUME<br>1 1 2 ml<br>BACK TO<br>THERAPY<br>END OF THERAPY<br>Blood leak blood free test<br>0 nl/min<br>DIALYSATE FLOW<br>MARMER<br>11/2 ml<br>BLOOD LEAK RECAL<br>m1/min<br>DIALYSATE FLOW<br>0 ml/min<br>MARMER<br>36.4 °C<br>10 mmHg<br>UF VOLUME<br>112 ml<br>0 nl/min<br>MARMER<br>36.4 °C<br>10 mmHg<br>UF VOLUME<br>112 ml<br>0 ml/min<br>MARMER<br>112 ml<br>0 ml/min<br>MARMER<br>112 ml<br>0 ml/min<br>MARMER<br>112 ml<br>13 mmHg<br>0 FLUID WEIGHT<br>13 mHg<br>0 UF VOLUME<br>112 ml<br>0 ml/m<br>112 ml<br>0 ml/m<br>114 man<br>0 UF VOLUME<br>115 ml/m<br>114 ml<br>0 ml/m<br>114 ml<br>114 ml | <ul> <li>Totals overview The option <totals overview=""> shows the summary of the pivotal treatment data as described (Section 8.4.3) <li>Select <totals overview=""> and confirm by pressing the key. </totals></li> <li>To return to the <end of="" therapy=""> screen, select <totals overview=""> and confirm with the  Key. </totals></end></li> <li>Blood leak recalibration The <blood calibration="" leak=""> function allows the recalibration of the blood leak detector in case of non-acceptable alarms (e.g. elevated plasma bilirubin concentration) </blood></li> <li>Select "BLOOD LEAK CALIBRATION" and confirm with the  Key. Confirm with the  Key. </li> <li>Select <back therapy="" to=""> and confirm with the  Key. Select <back therapy="" to=""> and confirm with the  Key. Adapt the blood flow to the initial value. Start <therapy> by pressing the  Key</therapy></back></back></li></totals></li></ul> |
| DANGER  | Risk of blood loss for the patie<br>Before the recalibration of<br>carefully checked for possi<br>It is recommended to with<br>the filtrate line and to ana<br>The blood loak recalibration   | ent and haemolysis<br>the blood leak detector, the haemofilter must be<br>ble blood leaks and haemolysis.<br>draw a sample (at least 2 ml) from the injection port of<br>alyze for erythrocytes and/or free haemoglobin.<br>In must only be performed if these tests are pegative.   |
| i   | The blood leak recalibration  | t up again until blood leak calibration has been completed.  |

# Diapact<sup>®</sup> CRRT

HD

HAEMODIALYSIS

| HLD<br>Haemod Ialys Is   |             |              | END OI                  | Blood        | CAP Y        |
|--------------------------|-------------|--------------|-------------------------|--------------|--------------|
| BLOOD FLOW               | 50          | ml∕min       | DIALYSATE FLOW          | 0<br>36.2    | ml∕min<br>∘r |
| TREATED BLOOD VOLUME     | 0.5         | liters       | PD2                     | 10           | mmHg         |
|                          |             |              | PD1                     | 13           | nmHg         |
| PA                       | 16          | mmHg         | uf volume               | 112          | ml           |
| PBE                      | 7           | mmHg         | UF RATE                 | 0            | ml∕h         |
| PV                       | 11          | mmHg         | FLUID WEIGHT            | 5360         | g            |
| FILTER DROP PR. (PFD)    | -4          | mmHg         | THERAPY TIME RES.       | 03:51        | h:min        |
| тмр                      | -1          | mmHg         | THERAPY TIME            | 00:09        | h:min        |
| TOTALS<br>OVERVIEW CALIE | LEAK<br>BR. | BACK<br>THER | TO SET-UP<br>APY CHANGE | NEW<br>THERA | ı<br>IPY     |

| HD<br>HAEMODIALYSIS  | END OF THERAPY<br>Blood return                                   |  |  |  |  |  |
|--|--|--|--|--|--|--|
|  |  |  |  |  |  |  |
| • Stop blood pump and clamp all ports of                                       | filter.  |  |  |  |  |  |
| • Exchange filter with a pre-filled one (                                      | (if necessary).  |  |  |  |  |  |
| • Perform changes for a CVVH/HF therapy:                                       |  |  |  |  |  |  |
| - Select PREDILUTION for a predilution   | therapy (if required).   |  |  |  |  |  |
| - Reconnect dialysate line (green) to t  | the proper infusion port.  |  |  |  |  |  |
| - Reconnect UF line (yellow) to the po   | rt on blue side of filter.                                       |  |  |  |  |  |
| - Close port on red side of filter and   | - Close port on red side of filter and turn filter blue side up. |  |  |  |  |  |
| - Exchage bags (if necessary).   |  |  |  |  |  |  |
| <ul> <li>Open clamps, start blood pump and select THERAPY EXCHANGE.</li> </ul> |  |  |  |  |  |  |
| PRE-<br>DILUTION RESET   | SET-UP<br>CHANGE EXCHANGE  |  |  |  |  |  |

### Back to therapy

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

Select <BACK TO THERAPY> and confirm by pressing the \_\_\_\_\_





### 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.

| • | Ston blood numn and clamn all norts of filter.                   |
|---|--|
|   | Exchange filter with a pre-filled one (if necessary).            |
| • | Perform changes for a CWH/HF therapy:                            |
|   | - Select PREDILUTION for a predilution therapy (if required).    |
|   | - Reconnect dialysate line (green) to the proper infusion port.  |
|   | - Reconnect UF line (yellow) to the port on blue side of filter. |
|   | - Close port on red side of filter and turn filter blue side up. |
|   | - Exchage bags (if necessary).                                   |
| • | Open clamps, start blood pump and select THERAPY EXCHANGE.       |
|   |  |
|   | PRE- THERAPY SET-UP THERAPY                                      |

RESET

CHANGE

EXCHANGE

PKE-DILUTION

### **Dilution setting**

END OF THERAPY Blood return

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).

# 8 HD / HFD

# Diapact<sup>®</sup> CRRT



key.

air trap.

tightly.

Hansen connector.

inlet line is connected.

> Turn the haemofilter upside down.

Unscrew the dialysate inlet line from the

haemofilter, close the Hansen connector tightly and connect the dialysate inlet line to the venous

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

> Close the port next to the arterial port with the

Open the clamp of the dialysate inlet line and of the line of the venous air trap where the dialysate

# Diapact<sup>®</sup> CRRT

HD A THERAPY EXCHANGE

PLASMA THERAPIES

SELECT THERAPY MODE AND CONFIRM

# 8 HD / HFD

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

 Select <THERAPY EXCHANGE> and confirm by pressing the



Select <CONTINUOUS> or <INTERMITTENT>



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

| HD<br>haemodialysis      |             |               |               | END (            | )F THEF<br>Blood  | RAPY<br>return |
|--------------------------|-------------|---------------|---------------|------------------|-------------------|----------------|
|                          |             |               |               |                  | <u>Therapy se</u> | LECTION        |
| BLOOD FLOW               | 50          | ml∕min        | DIALYSA       | TE FLOW          | 0                 | ml∕min         |
| TREATED BLOOD VOLLIME    | 0.5         | liters        | WARMER<br>PD2 |                  | 34.U<br>11        | °C<br>mmHa     |
|                          |             |               | PD1           |                  | 13                | nmHg           |
| PA                       | 15          | mmHg          | UF VOLU       | ME               | 112               | ml             |
| PBE                      | 7           | mmHg          | UF RATE       |                  | 0                 | ml∕h           |
| PV                       | 11          | mmHg          | FLUID W       | EIGHT            | 5365              | g              |
| FILTER DROP PR. (PFD)    | -4          | mmHg          | THERAPY       | TIME RES.        | 03:51             | h:min          |
| TMP                      | -2          | mmHg          | THERAPY       | TIME             | 00:09             | h:min          |
| TOTALS<br>OVERVIEW CALIE | LEAK<br>3R. | BACK<br>THER/ | TO<br>Apy     | SET-UP<br>Change | NEW<br>THERA      | PY             |

# 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



Risk of blood loss and infection for the patient

END OF THERAPY

DIALYSIS THERAPIES

CONTINUOUS

INTERMITTENT

Blood side stop

254 h

Ø

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

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# 8 HD / HFD

# 8.6 Special functions

## Bag movement function

To avoid superfluous alarms and the resulting pump standstill, the Diapact<sup>®</sup> 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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#### PEX (Plasma exchange) 9

#### Switching on and initial tests 9.1

| B BRAUN SELFTEST<br>ROM test   | Switch on the Diapact <sup>®</sup> CRRT with the power<br>switch ON/OFF (I/O) on the back of the machine.   |
|--|---|
| SW       HW       Language 1       Language 2       Language 3         SYS       V2.12.4       Rev. B       V044.02.12.00       V049.02.12.00       V086.02.12.00         DPC       V2.12.4       Rev. C       DPS       V2.12.4       Rev. B       V044.02.12.00       V049.02.12.00       V086.02.12.00         DPS       V2.12.4       Rev. B       V044.02.12.00       V049.02.12.00       V086.02.12.00 | <ul> <li>The device starts with the ROM test.</li> <li>Check whether the AQ and EQ keys are lit during the ROM test.</li> </ul>   |
| B BRAUN SELFTEST<br>Display test<br>S-0123456789<br>C-0123456789   | <ul> <li>The ROM test is followed by the display test.</li> <li>Compare the character lines in the supervisor field and confirm by pressing the</li> <li>EO</li> <li>key if both series are identical.</li> </ul> |
| SW         HW         Language 1         Language 2         Language 3           SYS         V2.12.4         Rev. B         V044.02.12.00         V049.02.12.00         V086.02.12.00           DPC         V2.12.4         Rev. C         DPS         V2.12.4         Rev. B         V044.02.12.00         V049.02.12.00         V086.02.12.00  | <ul> <li>While the buzzer of the safety system is activated for 2 seconds.</li> <li>Check that the buzzer can be heard.</li> </ul>  |
| VERIFY CHARACTERS AND CONFIRM WITH EQ  |   |
| BIBRAUN SELFTEST<br>Empty loadcel1 test  | If the display test is passed successfully, the empty   |
| ■21<br>Weight of bag holder: (± 60 g) = -17  | <ul> <li>Check whether the bag holder is empty.</li> </ul>  |

Weight of bag holder: (± 60 g)

Language 1 Language 2 Language 3

DPD V2.12.4 Rev. B V044.02.12.00 V049.02.12.00 V086.02.12.00

DPS V2.12.4 Rev. B V044.02.12.00 V049.02.12.00 V086.02.12.00

BAG HOLDER FREE? CHECK THE WEIGHTS AND CONFIRM WITH EQ

Ø

224 h



> Confirm the weight values with the key if they are within the allowed range. The maximum deviation between both displayed values is allowed to be  $\pm$  60 g and the values must not exceed -60 and +60 g.

S₩

SYS V2.12.4

DPC V2.12.4 Rev. C

H₩

# 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



Confirm <PLASMA EXCHANGE> with the



 ${\sc eq}$  PLASMA EXCHANGE> flashes in the supervisor field.

> Press the key for final confirmation.

# 9.3 Preparation

| PEX<br>plasma exchange  |        |        | PRE<br>Po           | PARA      | TION<br>y test |
|-------------------------|--------|--------|---------------------|-----------|----------------|
| Do not connect any disp | osable |        |                     |           |                |
| BLOOD FLOW              | 0      | ml∕min | SUBSTITUTION FLOW   | 0         | ml∕min         |
|                         |        |        | SUBST. VOLUME       | 0         | ml             |
| TREATED BLOOD VOLUME    | 0.0    | liters | WARMER              | 23.7      | °C             |
|                         |        |        | PD1                 | -1        | mmHg           |
| PA                      | 0      | mmHg   | PL.BALANCE RATE     | 0         | ml∕h           |
| PBE                     | -1     | mmHg   |                     |           |                |
| PV                      | -1     | mmHg   | TOTAL WEIGHT        | -28       | g              |
| PD2                     | 0      | mmHg   | THERAPY TIME RES.   | 00:00     | h:min          |
| TMP                     | -1     | mmHg   | SUB BAG VOLUME RES. | 0         | ml             |
| PARAMETERS<br>SETTING   |        |        |                     | B<br>SELE | ACK            |

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

| PEX<br>PLASMA EXCHANGE<br>1. Hang 2 saline and sub<br>2. Place the plasma filte<br>3. Mount and connect Sub<br>4. ▲ Hang plasma collection<br>5. Mount and connect Pla<br>6. Hang Venous collection<br>7. Mount and connect Ven<br>8. ▲ Connect Substitution<br>Make sure all the necessary  | PREPARATION<br>Device test finished<br>stitution fluid bags on weighing system.<br>r in the holder.<br>st. line (green). Clamp free connection.<br>n bag on weighing system.<br>sma line (orange) through BLD.<br>n bag on the IV pole.<br>bus line (blue) and Arteral line (red).<br>line to Venous line (blue).<br>clamps are opened then start PRIMING | <ul> <li>When the tests have been performed successfully, the <preparation> screen displays <device finished="" test=""> and the steps to set-up the machine are displayed.</device></preparation></li> <li>The consumable material for the therapy comprises: <ul> <li>PEX kit</li> <li>Plasmafilter</li> <li>2 x 2L isotonic sodium chloride solution</li> <li>Substitution solution according to the prescription of the attending physician</li> </ul> </li> </ul> |  |  |
|--|---|--|--|--|
| PARAMETERS<br>SETTING  | PRIMING<br>BACK<br>SELECTION  | Follow the instructions on the screen and set-up<br>the device as described in the following.  |  |  |
| i  | The lines of the HF/HD kit are cold<br>Arterial line ( <b>red</b> )<br>Venous line ( <b>blue</b> )<br>Substitution line ( <b>green</b> )<br>Plasma outlet line ( <b>yellow</b> )<br>Pumps used<br>Blood pump (MP1)<br>Ultrafiltration pump (MP2) / F<br>Substitution pump (MP3)   | pur-coded to facilitate the set-up.<br>Plasma pump in PEX  |  |  |
| <ul> <li>Risk of infection and blood loss for the patient by damaged packaging or componen</li> <li>Make sure during set-up that the packaging of the material used (line system, plasmafilter, solution bags) is undamaged.</li> <li>During set-up check the material for integrity.</li> <li>Observe the respective instructions for use.</li> </ul> |   |  |  |  |



### 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.

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.

CAUTION

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.

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## 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.

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

# 9 PEX

# 9.3.2 Priming

i

| PEX<br>plasma exchange |     |        | PRE<br>Arteria      | PARA      | TION   |
|------------------------|-----|--------|---------------------|-----------|--------|
|                        |     |        |                     |           |        |
| BLOOD FLOW             | 100 | ml∕min | SUBSTITUTION FLOW   | 0         | ml∕min |
|                        |     |        | SUBST. VOLUME       | 0         | ml     |
| TREATED BLOOD VOLUME   | 0.0 | liters | WARMER              | 26.7      | °C     |
|                        |     |        | PD1                 | 4         | nmHg   |
| PA                     | -30 | mmHg   | PL.BALANCE RATE     | 0         | ml∕h   |
| PBE                    | 16  | mmHg   |                     |           |        |
| PV                     | 3   | mmHg   | TOTAL WEIGHT        | 6420      | g      |
| PD2                    | 1   | mmHg   | THERAPY TIME RES.   | 00:00     | h:min  |
| TMP                    | 8   | mmHg   | SUB BAG VOLUME RES. | 0         | ml     |
| PARAMETERS<br>SETTING  | PRI | MING   | 5                   | B<br>SELE | ACK    |

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



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<sup>®</sup> CRRT during calibration of the pump constants. Calibration will be repeated if it is disturbed.

| PEX<br>plasma exchange  |  | PREPARATION<br>Ready for therapy  |
|---|--|---|
| <ol> <li>Replace Subst</li> <li>Remove saline</li> <li>Make sure that</li> <li>A Insert the fl</li> </ol> | itution line connection to<br>bags from the weighing sys<br>it all the necessary clamps<br>uid lines into the tubing c | substitution fluid bag.<br>tem.<br>are opened.<br>lips on the bag holder. |
| Select ENTER THERAF   | Y - then connect patient.  |   |
| PARAMETERS<br>SETTING   | RINSING  | ENTER BACK<br>THERAPY SELECTION   |

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



The device switches automatically to <PARAMETERS SETTING>.

# 9.3.3 Parameter setting

| PEX<br>Plasma exchange |              |          | PREPARATIO<br>Ready for therapy |                 |  |
|------------------------|--------------|----------|---------------------------------|-----------------|--|
| Check and confirm      | the safety ( | inverse) | parameters                      | 0<br>[-200 500] |  |
| BLOOD FLOW             | 0            | ml∕min   | SUBSTITUTION FLOW               | 15 ml∠min       |  |
|                        |              |          | SUBST. VOLUME                   | 2000 ml         |  |
|                        |              |          | WARMER                          | 37.0 °C         |  |
| PA MIN                 | -100         | mmHg     |                                 |                 |  |
| PA MAX                 | 100          | mmHg     | PD2 MIN                         | -10 mmHg        |  |
| PBE MAX                | 200          | mmHg     | PL.BALANCE VOL.                 | 0 m l           |  |
| PV WINDOW              | 100          | mmHg     | PL.BALANCE RATE                 | [ 0] mi∕h       |  |
|                        |              |          | THERAPY TIME                    | 02:13 h:min     |  |
| TMP MAX                | 80           | mmHg     | SUB BAG VOLUME                  | 0 m l           |  |
|                        | _            |          |                                 |                 |  |
| ARAMETERS              | RIN          | SING     | ENTER                           | BACK            |  |
| SETTING                |              |          | THERAPY                         | SELECTION       |  |

### 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



The value is inversely displayed on a black background.

If the value is accepted, confirm by pressing the



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



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

| PEX<br>PLASMA EXCHANGE |      |        | PREPARATION<br>Ready for therapy             |                              |  |
|------------------------|------|--------|--|------------------------------|--|
|                        |      |        |  | [ 3 60]                      |  |
| BLOOD FLOW             | 0    | ml/min | SUBSTITUTION FLOW<br>SUBST. VOLUME<br>WARMER | mi∕min<br>2000 ml<br>37.0 ∘C |  |
| PA MIN                 | -100 | mmHa   |  |                              |  |
| PA MAX                 | 100  | mmHq   | PD2 MIN                                      | -10 mmHg                     |  |
| PBE MAX                | 200  | mmHq   | PL.BALANCE VOL.                              | 44 m 1                       |  |
| PV WINDOW              | 100  | mmHg   | PL.BALANCE RATE<br>THERAPY TIME              | 20 ml≁h<br>02:13 h:min       |  |
| TMP MAX                | 80   | mmHg   | SUB BAG VOLUME                               | 0 ml                         |  |
| PARAMETERS<br>SETTING  | RIN  | ISING  | ENTER<br>THERAPY                             | BACK<br>SELECTION            |  |

### Setting treatment parameters





> Activate the parameter by pressing the

key.

Change the value with the







key.

➤ To exit <PARAMETERS SETTING>, press the

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

| 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 following data can be set in the indicated ranges:

\* The substitution flow can be set to zero if the plasma balance rate is  $\geq$  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.

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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



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 <u>SETTING</u>> and confirm with the



Set the substitution bag volume to a positive value (e.g. + 2000 ml).

When the value is reached during therapy, the alarm <br/>bag volume is over (1020)> occurs

Follow the instructions on the screen and exchange the substitution bag(s).

# 9 PEX

# 9.3.4 Menu selection in preparation

| PEX<br>plasma exchange |           |              | PRE                               | PARA            | TION<br>insing   |
|------------------------|-----------|--------------|-----------------------------------|-----------------|------------------|
| BLOOD FLOW             | 200       | ml∕min       | SUBSTITUTION FLOW                 | 100             | ml∕min           |
| TREATED BLOOD VOLUME   | 0.0       | liters       | SUBST. VOLUME<br>WARMER<br>PD1    | 0<br>27.1<br>31 | ml<br>∘C<br>mmHa |
| PA<br>PBE              | -40<br>71 | mmHg<br>mmHa | PL.BALANCE RATE                   | 0               | mi∕h             |
| PV<br>PD2              | 41<br>52  | mmHg<br>mmHa | TOTAL WEIGHT<br>THERAPY TIME BES. | 978<br>00:00    | g<br>h:min       |
| тмр                    | 4         | mmHg         | SUB BAG VOLUME RES.               | 0               | ml               |
| PARAMETERS<br>SETTING  | RIN       | SING         | ENTER<br>THERAPY                  | E               | ACK              |

### Rinsing

If necessary, rinsing can be prolonged by selecting <u><RINSING></u> and confirming with the



- 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



# **Back selection**

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

Select <BACK SELECTION> and confirm with the



# 9.4 Therapy

| PEX<br>plasma exchange   | PREPARATION<br>Ready for therapy  |
|--|---|
|  | THERAPY   |
| <ol> <li>Replace Substitution line connection</li> <li>Remove saline bags from the weighing</li> <li>Make sure that all the necessary clam</li> <li>A Insert the fluid lines into the tubin</li> </ol> | to substitution fluid bag.<br>system.<br>ps are opened.<br>g clips on the bag holder. |
| Select ENTER THERAPY - then connect patien   | t.  |
| PARAMETERS<br>SETTING  | ENTER<br>THERAPY BACK<br>SELECTION  |

| PEX<br>PLASMA EXCHANGE                         |        |            | Blood leak b           | THEF<br>lood fre | RAPY<br>e test |
|--|--------|------------|------------------------|------------------|----------------|
| Ensure NO BLOOD, AIR in<br>and confirm with EQ | tube m | iounted in | nto Blood Leak Det. BL | DOD LEAK         | RECAL.         |
| BLOOD FLOW                                     | 0      | ml∕min     | SUBSTITUTION FLOW      | 0                | ml∕min         |
|  |        |            | SUBST. VOLUME          | 0                | mi             |
| TREATED BLOOD VOLUME                           | 0.0    | liters     | WARMER                 | 28.7             | ٥C             |
|  |        |            | PL.BALANCE RATE        | 0                | ml∕h           |
| PA   | 51     | mmHg       | PL.BALANCE VOL.        | 0                | ml             |
| PBE  | 46     | mmHq       | TOTAL WEIGHT           | 4392             | q              |
| PV   | 30     | mmHg       | THERAPY TIME RES.      | 00:00            | -<br>h∶min     |
| PD2  | 42     | mmHg       | THERAPY TIME           | 00:00            | h:min          |
| TMP  | -4     | mmHg       | SUB BAG VOLUME RES.    | 0                | ml             |
| PARAMETERS<br>SETTING OVERVIEW                 | ]      |            | BAG<br>CHANGE          | EN<br>THE        | D OF<br>Rapy   |

To switch from <PREPARATION> to <THERAPY>, select <ENTER THERAPY> and confirm by pressing the



Confirm the start of the therapy by pressing the flashing



key while <THERAPY> is flashing in the supervisor field.

The Diapact<sup>®</sup> CRRT is now in the therapy status as indicated in the therapy status field.

 Confirm the blood leak recalibration by pressing the



 Start the blood pump for circulation by pressing the



# 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



- 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

| PEX<br>plasma exchange           |          |              |  | THEF           | RAPY<br>unning |
|----------------------------------|----------|--------------|--|----------------|----------------|
| BLOOD FLOW                       | 50       | ml/min       | SUBSTITUTION FLOW                          | 7              | ml∕min         |
| TREATED BLOOD VOLUME             | 0.0      | liters       | SUBST. VOLUME<br>WARMER<br>DI DALANCE PATE | 0<br>28.7<br>0 | ml<br>∘C       |
| PA                               | 47       | nmHg         | PL.BALANCE VOL.                            | 0<br>0<br>4201 | mi             |
| PBE<br>PV                        | 39<br>59 | mmHg         | THERAPY TIME RES.                          | 4391<br>02:14  | y<br>h:min     |
| PD2<br>TMP                       | -3       | mmHg<br>mmHg | THERAPY TIME<br>SUB BAG VOLUME RES.        | 00:00<br>0     | h:min<br>mi    |
| PARAMETERS<br>SETTING<br>VERVIEW | ]        |              | BAG<br>CHANGE                              | EN             | D OF<br>RAPY   |

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

- Select <THERAPY> and activate by proceing the
  - activate by pressing the



<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

| PEX<br>plasma exchange          |                  | THERAPY<br>Running |
|---------------------------------|------------------|--------------------|
|                                 |                  |                    |
| BLOOD FLOW $50 \text{ mizmin}$  | PLASMA FLOW      | 15 ml/min          |
| TREATED BLOOD VOLUME 2.5 liters | plasma volume    | 743 mi             |
|                                 | SUBST. VOLUME    | 743 ml<br>742 ml   |
|                                 | ZSUBST. VOLUME   | 745 11             |
| THERAPY TIME 00:49 h:min        | PL.BALANCE VOL.  | 0 m i              |
| ΣTHERAPY TIME 00:49 h:min       | ΣPL.BALANCE VOL. | Oml                |
|                                 |                  |                    |
| PRESSURE                        | BAG THERAPY      | THERAPY            |
| OVERVIEW                        | CHANGE           | RESET              |

## **Totals overview**

 Select <TOTALS OVERVIEW> and confirm by pressing the



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



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  $\Sigma.$ 

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

Select <THERAPY RESET> and

confirm by pressing the



# Diapact<sup>®</sup> CRRT

| PEX                  |     |              | THERAPY     |
|----------------------|-----|--------------|-------------|
| PLASMA EXCHANGE      |     |              | Runn ing    |
|                      |     |              |             |
|                      |     |              |             |
|                      |     |              |             |
|                      |     |              |             |
| BLOOD FLOW 50 mLowin |     |              |             |
|                      |     | 10 malla     |             |
|                      | PFU | 19 mmHg      |             |
| PBE 57 mmHg          |     |              |             |
|                      |     |              |             |
|                      |     |              | ł           |
|                      | TMP | -3 mmHq      |             |
|                      |     |              |             |
| PA 52 modela         |     |              | T 37 0 °C   |
| TA 32 ming           |     | BD3 F0       | DD1 E1      |
|                      |     | PDZ SU mming | PUI SIMMAHG |
|                      |     |              |             |
|                      |     |              |             |
| PRESSURE PARAMETERS  |     | BAG THERAPY  | END OF      |
| OVERVIEW OVERVIEW    |     | CHANGE       | THERAPY     |
|                      |     |              |             |

| PEX<br>plasma exchange           |         |         | BI                  | THEI<br>lood circu | RAPY         |
|----------------------------------|---------|---------|---------------------|--------------------|--------------|
| Release BAG CHANGE to co         | ontinue | the the | rapy.               |                    |              |
| BLOOD FLOW                       | 50      | ml∕min  | SUBSTITUTION FLOW   | 0                  | ml/min       |
|                                  |         |         | SUBST. VOLUME       | 758                | ml           |
| TREATED BLOOD VOLUME             | 2.5     | liters  | WARMER              | 37.0               | ۰C           |
|                                  |         |         | PL.BALANCE RATE     | 0                  | ml∕h         |
| PA                               | 53      | mmHg    | PL.BALANCE VOL.     | 1                  | ml           |
| PBE                              | 58      | mmHg    | TOTAL WEIGHT        | 4392               | g            |
| PV                               | 38      | mmHg    | THERAPY TIME RES.   | 01:23              | h:min        |
| PD2                              | 51      | mmHg    | THERAPY TIME        | 00:50              | h:min        |
| тмр                              | -3      | mmHg    | SUB BAG VOLUME RES. | 0                  | ml           |
| PARAMETERS<br>SETTING<br>VERVIEW | ]       |         | BAG<br>CHANGE       | EN<br>THE          | D OF<br>Rapy |

### Pressure overview

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

Select <PRESSURE OVERVIEW> and confirm by pressing the



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



# Bag change

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

Select <BAG CHANGE> and confirm by pressing the



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



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



 $\succ$  Confirm by pressing the



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

|                      |     |        |                     | <u>end of t</u> | HERAPY   |
|----------------------|-----|--------|---------------------|-----------------|----------|
| BLOOD FLOW           | 50  | ml/min | SUBSTITUTION FLOW   | 15              | ml/mir   |
| TREATED BLOOD VOLUME | 3.8 | liters | SUBST. VOLUME       | 1138<br>37 0    | ml<br>∘r |
|                      | 5.0 | mens   | PL.BALANCE RATE     | 0               | n∐⊿h     |
| PA                   | 52  | mmHg   | PL.BALANCE VOL.     | 7               | ml       |
| PBE                  | 54  | mmHg   | TOTAL WEIGHT        | 4395            | g        |
| PV                   | 37  | mmHg   | THERAPY TIME RES.   | 00:58           | h:min    |
| PD2                  | 49  | mmHg   | THERAPY TIME        | 01:15           | h:min    |
| тмр                  | -4  | mmHg   | SUB BAG VOLUME RES. | 0               | ml       |
|                      |     |        |                     |                 |          |
| PARAMETERS TOTALS    | ן   |        | BAG                 |                 | D OF     |
|                      |     |        | CHANCE              | тис             | DADY     |

| PEX<br>plasma exchange  |             |              | END OF THERAPY<br>Blood return |       |         |
|-------------------------|-------------|--------------|--------------------------------|-------|---------|
|                         |             |              |                                |       |         |
| BLOOD FLOW              | 50          | ml∕min       | SUBSTITUTION FLOW              | 0     | ml∕min  |
|                         |             |              | PLASMA FLOW                    | 15    | ml∕min  |
| TREATED BLOOD VOLUME    | 3.8         | liters       | plasma volume                  | 1146  | ml      |
|                         |             |              | WARMER                         | 37.0  | ٥C      |
| PA                      | 52          | mmHg         | PL.BALANCE RATE                | 0     | ml∕h    |
| PBE                     | 55          | mmHg         | PL.BALANCE VOL.                | 5     | ml      |
| PV                      | 36          | mmHg         | TOTAL WEIGHT                   | 4394  | g       |
| PD2                     | 48          | mmHg         | THERAPY TIME RES.              | 00:58 | h:min   |
| тмр                     | -3          | mmHg         | THERAPY TIME                   | 01:16 | h:min   |
| TOTALS<br>OVERVIEW CALI | LEAK<br>BR. | BACK<br>Ther | ТО<br>Ару                      | NEW   | r<br>PY |

# 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.

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

## 9.5.2 Menu selection at end of therapy

| ) EX                                 |                                  | END OF THERAPY                                   |                               |
|--------------------------------------|----------------------------------|--|-------------------------------|
| ?LASMA EXCHANGE                      |                                  | Blood return                                     |                               |
| BLOOD FLOW                           | 50 ml/min                        |  |                               |
| TREATED BLOOD VO<br>ΣTR. BLOOD VOLUM | LUME 3.8 liters<br>IE 3.8 liters | PLASMA VOLUME<br>SUBST. VOLUME<br>ΣSUBST. VOLUME | 1146 mi<br>1141 mi<br>1141 mi |
| THERAPY TIME                         | 01:16 h:min                      | PL.BALANCE VOL.                                  | 5 mi                          |
| ΣTHERAPY TIME                        | 01:16 h:min                      | ΣPL.BALANCE VOL.                                 | 5 mi                          |
| TOTALS                               | BLOOD LEAK                       | BACK TO  | NEW                           |
| OVERVIEW                             | CALIBR.                          | THERAPY  | THERAPY                       |

### otals 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



To return to the <END OF THERAPY> screen, select <TOTALS OVERVIEW> and confirm with the



| PEA<br>PLASMA EXCHANGE<br>Ensure NO BLOOD, AIR in tube<br>and confirm with EQ   | END OF<br>Blood leak t<br>mounted into Blood Leak Det.  | ODD LEAK RECAL.   | Blood leak recalibration<br>The <blood calibration="" leak=""> function allows the<br/>recalibration of the blood leak detector in case of non-</blood>  |
|---|---|---|--|
| BLOOD FLOW         50           TREATED BLOOD VOLUME         3.8           PA         53           PBE         58           PV         37           PD2         50           OTTMP         -3 | mi∕min SUBSTITUTION FLOW<br>PLASMA FLOW<br>PLASMA FLOW<br>PLASMA VOLUME<br>WARMER<br>mmHg PL.BALANCE RATE<br>PL.BALANCE VOL.<br>mmHg TOTAL WEIGHT<br>HERAPY TIME RES.<br>mmHg<br>BACK TO<br>THERAPY | 0 ml/min<br>15 ml/min<br>1146 ml<br>36.1 °C<br>0 ml/h<br>5 ml<br>4391 g<br>00:58 h:min<br>01:16 h:min<br>NEW<br>THERAPY | <ul> <li>acceptable alarms (e.g. elevated plasma bilirubin concentration).</li> <li>Select "BLOOD LEAK CALIBRATION" and confirm with the elevated plasma bilirubin and confirm and confirm and confirm and confirm an</li></ul> |
|   | Risk of blood loss fo<br>Before the recal<br>checked for post   | r the patient<br>ibration of th<br>sible blood le   | and haemolysis<br>he blood leak detector, the filter must be carefully<br>eaks and haemolysis.   |

- 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. ۶

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

| PEX<br>plasma exchange        |             |              | END OF THERAPY<br>Blood return |              |          |
|-------------------------------|-------------|--------------|--------------------------------|--------------|----------|
|                               |             |              |                                |              | HERAPY   |
| BLOOD FLOW                    | 50          | ml∕min       | SUBSTITUTION FLOW              | 0            | ml∕min   |
|                               |             |              | PLASMA FLOW                    | 15           | ml∕min   |
| TREATED BLOOD VOLUME          | 3.8         | liters       | PLASMA VOLUME                  | 1146         | ml       |
|                               |             |              | WARMER                         | 34.9         | ٥C       |
| PA                            | 51          | mmHg         | PL.BALANCE RATE                | 0            | ml∕h     |
| PBE                           | 58          | mmHg         | PL.BALANCE VOL.                | 5            | ml       |
| PV                            | 37          | mmHg         | TOTAL WEIGHT                   | 4389         | g        |
| PD2                           | 50          | mmHg         | THERAPY TIME RES.              | 00:58        | h:min    |
| TMP                           | -3          | mmHg         | THERAPY TIME                   | 01:16        | h:min    |
| TOTALS BLOOD<br>OVERVIEW CALI | LEAK<br>BR. | BACK<br>THER | TO<br>APY                      | NEW<br>There | /<br>\PY |

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# 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.
| tart a new<br>inished. The | y<br>NEW THERAPY> allows to start<br>rediately after the one just finis | New t<br>The op<br>therap | ERAPY<br>d return<br>SELECTION       | D OF THE<br>Blood           | END   |                      |                    | PEX<br>plasma exchange             |
|----------------------------|---|---------------------------|--------------------------------------|-----------------------------|---|----------------------|--------------------|------------------------------------|
| 1011.                      | NEW THERAPY> and<br>by pressing the                                     | > Se                      | ) ml≁min<br>5 ml≁min<br>6 ml<br>3 ∘C | LOW 0<br>15<br>1146<br>34.8 | SUBSTITUTION FLOW<br>PLASMA FLOW<br>PLASMA VOLUME<br>WARMER | ml≁min<br>liters     | 50<br>3.8          | BLOOD FLOW<br>TREATED BLOOD VOLUME |
|                            | ey. The key lights up.  | -                         | o ml∕n<br>5 ml<br>∋ g                | E 0<br>5<br>4389            | PL.BALANCE RATE<br>PL.BALANCE VOL.<br>TOTAL WEIGHT          | mmHg<br>mmHg<br>mmHg | 52<br>58<br>37     | PA<br>PBE<br>PV                    |
|                            | by pressing the<br>3y.  | > Co                      | 3 h:min<br>5 h:min<br>EW             | ES. 00:58<br>01:16          | THERAPY TIME RES.<br>THERAPY TIME                           | mmHg<br>mmHg<br>BACK | 50<br>-3<br>D LEAK | PD2<br>TMP<br>TOTALS BLOOI         |
|                            | ·)·   |                           | ew<br>Rapy                           | NE                          | C TO<br>RAPY  | BACK<br>Ther         | D LEAK<br>IBR.     | TOTALS BLOOD<br>OVERVIEW CAL       |



#### 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<sup>®</sup> 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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# Diapact<sup>®</sup> CRRT

#### 10 PAP (Plasma adsorption/perfusion)

#### 10.1 Switching on and initial tests

| B BRAUN<br>SELFTEST<br>ROM test<br>C RC 83 %<br>SW HW Language 1 Language 2 Language 3<br>SYS V2.12.4<br>DPD V2.12.4 Rev. B V044.02.12.00 V049.02.12.00 V086.02.12.00<br>DPC V2.12.4 Rev. C<br>DPS V2.12.4 Rev. C<br>DPS V2.12.4 Rev. B V044.02.12.00 V049.02.12.00 V086.02.12.00   | <ul> <li>Switch on the Diapact<sup>®</sup> CRRT with the power switch ON/OFF (I/O) on the back of the machine. The device starts with the ROM test.</li> <li>Check whether the AO and EO keys are lit during the ROM test.</li> </ul> |
|---|---|
| Q         224 h           B/BRAUN         SELFTEST<br>Display test           S=012.3456789<br>C-012.3456789   | <ul> <li>The ROM test is followed by the display test.</li> <li>➤ Compare the character lines in the supervisor field and confirm by pressing the</li> </ul>  |
| SW         HW         Language 1         Language 2         Language 3           SYS         V2.12.4         BV0         V2.12.4         Rev. B         V044.02.12.00         V049.02.12.00         V086.02.12.00           DPC         V2.12.4         Rev. C         DPS         V2.12.4         Rev. B         V044.02.12.00         V049.02.12.00         V086.02.12.00 | <ul> <li>key if both series are identical.</li> <li>While the key is being pressed, the buzzer of the safety system is activated for 2 seconds.</li> <li>Check that the buzzer can be heard.</li> </ul>                               |
| VERIFY CHARACTERS AND CONFIRM WITH EQ   |   |

224 h Ø

| BBR | AUN     |        | SEL<br>Empty load                      | .FTEST<br>icell test |
|-----|---------|--------|--|----------------------|
|     |         |        | Weight of bag holder: (± 60 g)         | - <u>21</u><br>-17   |
|     |         |        |  |                      |
|     | SW      | HW     | Language 1 Language 2 Language 3       | 3                    |
| SYS | v2.12.4 |        |  |                      |
| DPD | v2.12.4 | Rev. B | V044.02.12.00 V049.02.12.00 V086.02.12 | 2.00                 |
| DPC | v2.12.4 | Rev. C |  |                      |
| DPS | V2.12.4 | Rev. B | v044.02.12.00 v049.02.12.00 v086.02.12 | 2.00                 |
|     |         |        |  |                      |
|     |         | CUT    | BAG HOLDER FREE?                       |                      |
|     |         | CHE    | UK THE WEIGHTS AND CONFIRM WITH EQ     | 224 6                |

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 they are within the allowed range. The maximum deviation between both displayed values is allowed to be  $\pm$  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

➤ To select <ADSORPTION/PERFUSION> move to the respective position with the



Confirm <<ADSORPTION/PERFUSION> with the

<ADSORPTION/PERFUSION> flashes in the supervisor field.

EQ Press the key for final confirmation.  $\triangleright$ 

#### 10.3 Preparation

| PAP<br>PLASMA ADSORPTION / PEF | RFUSTON | Pl     | REPARA<br>Power rela | TION<br>y test |             |
|--------------------------------|---------|--------|----------------------|----------------|-------------|
| Do not connect any dispo       | osable  |        |                      |                |             |
| BLOOD FLOW                     | 0       | ml∕min |                      |                |             |
|                                | 0.0     | 1:4    | WAKMEK               | 22.2           | °C<br>maile |
| INEATED BLOOD VOLUME           | 0.0     | inters | PD2                  | -1             | molia       |
| PA                             | Û       | mmHa   | 101                  | -1             | in ing      |
| PBE                            | -1      | mmHq   | PLASMA FLOW          | 0              | ml∠min      |
| PV                             | -1      | mmHq   | PLASMA VOLUME        | 0              | ml          |
| FILTER DROP PR. (PFD)          | 0       | mmHg   | THERAPY TIME RES.    | 00:00          | h:min       |
| тмр                            | -1      | mmHg   |                      |                |             |
| PARAMETERS<br>SETTING          |         |        |                      | E              | ACK         |

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

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| PAP<br>plasma adsorption / perfusion          | PREPARATION<br>Device test finished |
|---|-------------------------------------|
|   |                                     |
| 1. Hang one saline fluid bag (21) on weighin  | ng system.                          |
| 2. 🛦 Hang the 7 I collection bag on weighing  | system.                             |
| 3. Place the plasmafilter in the holder.      |                                     |
| 4. Mount and connect Plasma line (orange) to  | o 3rd pump through BLD.             |
| 5. Mount and connect Arterial line (red).     |                                     |
| 6. A Mount and connect Venous line (blue) to  | the 7 I collection bag.             |
| 7. Mount and connect Plasma Reinfusion line   | (green).                            |
| 8. Connect Adsorber Bypass between green an   | dorange lines.                      |
| Make sure all the necessary clamps are opened | then start PRIMING                  |
|   |                                     |
| PARAMETERS PRIMING<br>SETTING                 | BACK<br>SELECTION                   |

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





#### 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.

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

 $\succ$  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.

CAUTION



#### 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.

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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

| PAP<br>Plasma adsorption ≠ pi | ERFUS I ON | PR<br>Arter | EPARA<br>ial line f | TION      |              |
|-------------------------------|------------|-------------|---------------------|-----------|--------------|
| BLOOD FLOW                    | 100        | ml∕min      |                     | 24.1      |              |
| TREATED BLOOD VOLUME          | 0.0        | liters      | PD2                 | 13        | nmHg         |
| PA                            | 2          | mmHg        | וטי                 | -10       | nmHg         |
| PBE                           | 37         | mmHg        | PLASMA FLOW         | 0         | ml∕min       |
| PV                            | 1          | mmHg        | PLASMA VOLUME       | 0         | ml           |
| FILTER DROP PR. (PFD)         | 36         | mmHg        | THERAPY TIME RES.   | 00:00     | h:min        |
| тмр                           | 6          | mmHg        |                     |           |              |
| PARAMETERS<br>SETTING         | PRI        | MING        | 5                   | B<br>SELE | ACK<br>CTION |

| PAP   | PREPARATION                             |
|---|---|
| plasma adsorption > perfusion   | Ready for therapy                       |
| <ol> <li>Place the adsorber in the proper holder.</li> <li>Remove Adsorber Bypass and connect the adsorbe</li> <li>Hang saline fluid bags on weighing system and</li> <li>A Deselect RINSING after the required rinsing vo</li> <li>Place the particle filter and select RINSING.</li> <li>A Deselect RINSING after the required rinsing vo</li> <li>Remove saline bag from the weighing system.</li> <li>Make sure that all the necessary clamps are op</li> <li>Select ENTER THERAPY - then connect patient.</li> </ol> | r.<br>select RINSING.<br>lume.<br>lume. |
| PARAMETERS  | ENTER BACK                              |
| SETTING   | THERAPY SELECTION                       |

| PAP<br>PLASMA ADSORPTION / PL | PRE | PARA<br>R    | TION<br>insing    |            |                  |
|-------------------------------|-----|--------------|-------------------|------------|------------------|
|                               |     |              |                   |            |                  |
| BLOOD FLOW                    | 200 | ml∕min       |                   |            |                  |
| TREATED BLOOD VOLUME          | 0.0 | liters       | WARMER<br>PD2     | 26.8<br>-9 | °C<br>mmHg       |
|                               | 20  |              | PD1               | 45         | nmHg             |
| PA                            | -28 | mmHg<br>mmHg | PLASMA FLOW       | 100        | m L <i>e</i> min |
| PV                            | -24 | mmHq         | PLASMA VOLUME     | 0          | ml               |
| FILTER DROP PR. (PFD)         | 36  | mmHg         | THERAPY TIME RES. | 00:00      | h:min            |
| тмр                           | 4   | mmHg         |                   |            |                  |
| PARAMETERS<br>SETTING         | RIN | ISING        | ENTER<br>THERAPY  | B          | ACK<br>CTION     |

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



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.

key.

- Attach the second bag with isotonic saline solution to the hooks of the load cell.
- Select <RINSING> and confirm with the
- 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



The device switches automatically to <PARAMETERS SETTING>.

Follow carefully the instructions on using the adsorber fitted.

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#### 10.3.3 Parameter setting

| PAP<br>PLASMA ADSORPTION / PL  | ERFUS I ON |              |                    | PREPARA<br>Red Detecto | TION<br>r test | >            | Select <parameter<br>individual treatment</parameter<br> |
|--------------------------------|------------|--------------|--------------------|------------------------|----------------|--------------|--|
| Do not connect any disp        | osable     |              | I                  | [5                     | 50]            | $\checkmark$ | Confirm with the   |
| BLOOD FLOW                     | 0          | ml∕min       | WARMER             | 37.0                   | ٥C             |              | key.   |
| PA MIN                         | -100       | mmHq         | PD2 MIN<br>PD1 MAX | 10<br>200              | mmHg<br>mmHq   | ≻            | Select the parameter                                     |
| PA MAX                         | 100<br>200 | mmHg<br>mmHa |                    |                        |                |              | ^/ ▼/  |
| PV WINDOW                      | 100        | mmHg         | PLASMA VOLUME      | 1000                   | ml             |              | or key.  |
| FILTER DROP PR. MAX<br>TMP MAX | 150<br>80  | mmHg<br>mmHa | THERAPY TIME       | 00:50                  | h:min          | ≻            | Activate the parame                                      |
|                                |            |              | <u> </u>           |                        |                |              | -  |
| PARAMETERS ANTICOAG.           | 7          |              |                    | В                      | ACK            |              | key.   |
| SETTING                        |            |              |                    | SELE                   | CTION          | $\succ$      | Change the value wi                                      |
|                                |            |              |                    |                        |                | I            | ^/ ▼/  |

- ERS SETTING> to enter the nt data.
- er to be set with the

neter by pressing the

with the





➤ 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<br>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.

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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

| PAP<br>PLASMA ADSORPTION / PL | ERFUS I ON |        | PR                | EPARA<br>R | TION<br>insing |
|-------------------------------|------------|--------|-------------------|------------|----------------|
| BLOOD FLOW                    | 200        | ml/min |                   |            |                |
|                               |            |        | WARMER            | 26.8       | °C             |
| TREATED BLOOD VOLUME          | 0.0        | liters | PD2<br>PD1        | -9         | mmHg<br>mm⊎a   |
| PA                            | -28        | mmHa   | 101               | 40         | imiriy         |
| PBE                           | 12         | mmHg   | PLASMA FLOW       | 100        | ml∕min         |
| PV                            | -24        | mmHg   | PLASMA VOLUME     | 0          | ml             |
| FILTER DROP PR. (PFD)         | 36         | mmHg   | THERAPY TIME RES. | 00:00      | h:min          |
| тмр                           | 4          | mmHg   |                   |            |                |
| PARAMETERS<br>SETTING         | RIN        | SING   | ENTER<br>THERAP1  | r B        | ACK            |

#### Rinsing

If necessary, rinsing can be prolonged by selecting <RINSING> and confirming with the



- 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



#### **Back selection**

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

➢ Select <BACK SELECTION> and confirm with the



### 10.4 Therapy



To switch from <PREPARATION> to <THERAPY>, select <ENTER THERAPY> and confirm by pressing the



 Confirm the start of the therapy by pressing the flashing



key while <THERAPY> is flashing in the supervisor field.

# Diapact<sup>®</sup> CRRT

| BLOOD FLOW O m1/min WARMER                |               |        |
|---|---------------|--------|
| WARMER                                    |               |        |
|   | 25.7          | ٥C     |
| IREATED BLOOD VOLUME U.U TITERS PD2       | 23            | nmHg   |
| PD1                                       | 24            | nmHg   |
| PA -23 mmHg                               |               |        |
| PBE 30 mmHg PLASMA FLOW                   | / 0           | ml∕mir |
| PV 7 mmHg PLASMA VOLU                     | IME O         | ml     |
| FILTER DROP PR. (PFD) 23 mmHg THERAPY TIM | IE RES. 00:00 | h:min  |
| TMP -5 mmHg THERAPY TIM                   | IE 00:00      | h:min  |

### 10.4.1 Connecting the patient

The Diapact<sup>®</sup> CRRT is now in the therapy status as indicated in the therapy status field.

 Confirm the blood leak recalibration by pressing the



 Start the blood pump for circulation by pressing the



- > 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



- 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.

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

### 10.4.2 Start of therapy

| PAP<br>PLASMA ADSORPTION / PEP | THERAPY<br>Running |        |                   |       |               |
|--------------------------------|--------------------|--------|-------------------|-------|---------------|
|                                |                    |        |                   |       |               |
| BLOOD FLOW                     | 60                 | ml∕min | LIADUED           | 26.0  | 26            |
|                                | n 1                | litors | WARMER<br>PD2     | 30.0  | molia         |
| TREATED BEOOD VOLUME           | 0.1                | inters | PD1               | 53    | mmHa          |
| PA                             | 43                 | mmHq   |                   |       |               |
| PBE                            | 58                 | mmHg   | PLASMA FLOW       | 15    | ml∕min        |
| PV                             | 32                 | mmHg   | PLASMA VOLUME     | 44    | mi            |
| FILTER DROP PR. (PFD)          | 26                 | mmHg   | THERAPY TIME RES. | 01:04 | h:min         |
| тмр                            | -3                 | mmHg   | THERAPY TIME      | 00:02 | h:min         |
| PARAMETERS<br>SETTING OVERVIEW | ]                  |        | THERAPY           | EN    | ID OF<br>Rapy |

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

Select <THERAPY> and activate by pressing the



<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

PLASMA ADSORPTION / PERFUSION

60 ml⊿min

0.5 liters

0.5 liters

00:09 h:min

00:09 h:min

PLASMA FLOW

plasma volume Σplasma volume

THERAPY

PAP

BLOOD FLOW

TREATED BLOOD VOLUME

TOTALS

OVERVIEW

ΣTR. BLOOD VOLUME

THERAPY TIME

ΣTHERAPY TIME

PRESSURE

OVERVIEW

#### Parameter setting

See Section 10.3.3

## Totals overview

THERAPY

Runn i na

15 ml⊿min

146 ml

146 ml

THERAPY

RESET

 Select <TOTALS OVERVIEW> and confirm by pressing the



To return to the <PARAMETERS OVERVIEW> screen, select <TOTALS OVERVIEW> press the



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



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



### 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



 $\succ$  Confirm by pressing the



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

| PLASMA ADSORPTION / PEF | RFUSION |        |                   | R     | unn ing |
|-------------------------|---------|--------|-------------------|-------|---------|
| BLOOD FLOW              | 60      | ml∕min |                   |       |         |
|                         |         |        | WARMER            | 37.0  | ٥C      |
| TREATED BLOOD VOLUME    | 0.6     | liters | PD2               | 49    | nmHg    |
|                         |         |        | PD1               | 53    | nmHg    |
| PA                      | 43      | mmHg   |                   |       |         |
| PBE                     | 59      | mmHg   | PLASMA FLOW       | 15    | ml∕mir  |
| PV                      | 32      | mmHg   | PLASMA VOLUME     | 160   | ml      |
| FILTER DROP PR. (PFD)   | 27      | mmHg   | THERAPY TIME RES. | 00:56 | h:min   |
| ТМР                     | -4      | mmHg   | THERAPY TIME      | 00:10 | h:min   |
| PARAMETERS TOTALS       | 1       |        | THERAP            | Y EN  | D OF    |
| SETTING OVERVIEW        |         |        |                   | THE   | RAPY    |

| PAP<br>PLASMA ADSORPTION / PEF | RFUS 10N    | I             | END O             | F THEI<br>Blood | RAPY<br>return |
|--------------------------------|-------------|---------------|-------------------|-----------------|----------------|
|                                |             |               |                   |                 |                |
| BLOOD FLOW                     | 50          | ml∕min        |                   |                 | _              |
|                                |             |               | WARMER            | 37.0            | °C             |
| TREATED BLOOD VOLUME           | 0.6         | liters        | PD2               | 48              | mmHg           |
|                                |             |               | 101               | 4/              | mmHg           |
| PA                             | 45          | mmHg          |                   |                 |                |
| PBE                            | 57          | mmHg          | PLASMA FLOW       | 0               | ml∕min         |
| PV                             | 32          | mmHg          | plasma volume     | 162             | ml             |
| FILTER DROP PR. (PFD)          | 25          | mmHg          | THERAPY TIME RES. | 00:56           | h:min          |
| TMP                            | -4          | mmHg          | THERAPY TIME      | 00:10           | h:min          |
| TOTALS<br>OVERVIEW CALIE       | LEAK<br>3R. | BACK<br>THER/ | TO<br>APY         | NEW<br>THERA    | ı<br>IPY       |

## 10 PAP

### 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<sup>®</sup> CRRT within this time frame.

#### 10.5.2 Menu selection at end of therapy

i

| PLASMA ADSORPTION               | PERFUSION                   | END OF THERAPY<br>Blood return |                |  |
|---------------------------------|-----------------------------|--------------------------------|----------------|--|
| BLOOD FLOW<br>TREATED BLOOD VOL | 50 mi/min<br>UME 0.6 liters |                                | 162 m          |  |
| THERAPY TIME                    | 00:10 h:min                 | ΣPLASMA VOLUME                 | 162 mi         |  |
| ΣTHERAPY TIME                   | 00:10 h:min                 |                                |                |  |
| TOTALS<br>OVERVIEW              | BLOOD LEAK<br>CALIBR.       | BACK TO<br>THERAPY             | NEW<br>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



To return to the <END OF THERAPY> screen, select <TOTALS OVERVIEW> and confirm with the



# Diapact<sup>®</sup> CRRT

| Ensure NO BLOOD, AIR in tube<br>and confirm with EO<br>BLOOD FLOW 5 C<br>TREATED BLOOD VOLUME 0.0<br>PA 44<br>PBE 53<br>PV 32<br>TMP -4<br>TOTALS BLOOD LEAK<br>OVERVIEW CALIBR. | mounted into Blood Leak Det. BLOOD LEAK R<br>ml/min<br>i liters PD2 49 m<br>PD1 47 m<br>0 mmHg PLASMA FLOW 0 m<br>i nmHg PLASMA VOLUME 162 m<br>nmHg THERAPY TIME RES. 00:56 h<br>1 mmHg THERAPY TIME RES. 00:10 h<br>BACK T0 NEW THERAPY | <ul> <li>The <blood calibration="" leak=""> function allows the recalibration of the blood leak detector in case of non-acceptable alarms (e.g. elevated plasma bilirubin concentration).</blood></li> <li>Select "BLOOD LEAK CALIBRATION" and confirm with the end of the blood leak detector in case of non-acceptable alarms (e.g. elevated plasma bilirubin concentration).</li> <li>Select "BLOOD LEAK CALIBRATION" and confirm with the end of the blood leak detector in case of non-acceptable alarms (e.g. elevated plasma bilirubin concentration).</li> <li>Select "BLOOD LEAK CALIBRATION" and confirm with the end of the blood leak detector in case of non-acceptable alarms (e.g. elevated plasma bilirubin concentration).</li> <li>Select "BLOOD LEAK CALIBRATION" and confirm with the end of the blood leak detector in case of non-acceptable alarms (e.g. elevated plasma bilirubin concentration).</li> <li>Select "BLOOD LEAK CALIBRATION" and confirm with the end of the blood leak detector in case of non-acceptable alarms (e.g. elevated plasma bilirubin concentration).</li> <li>Confirm with the end of the blood flow to the initial value.</li> <li>Start <therapy> by pressing the end of the key.</therapy></li> </ul> |
|--|---|---|
| DANGER   | <ul> <li>Risk of blood loss for the p</li> <li>➢ Before the recalibration checked for possible blood loss for the filtrate line and to</li> <li>➢ The blood leak recalibration</li> </ul>   | atient and haemolysis<br>n of the blood leak detector, the filter must be carefully<br>bod leaks and haemolysis.<br>Vithdraw a sample (at least 2 ml) from the injection port of<br>analyze for erythrocytes and/or free haemoglobin.<br>ation must only be performed if these tests are negative.  |

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

| PAP<br>Plasma adsorption > per | FUS 10     | 4            | END OF<br>Bloodleak | F THE<br>det.calit | RAPY<br>pration | Back to therapy<br>The option <back therapy="" to=""> returns to the just<br/>finished therapy.</back> |
|--------------------------------|------------|--------------|---------------------|--------------------|-----------------|--|
| BLOOD FLOW                     | 50         | ml∕min       | MARMER              | 9 <b>1</b> 9       | oC              | Select <back therapy="" to=""> and<br/>confirm by pressing the</back>                                  |
| TREATED BLOOD VOLUME           | 0.6        | liters       | PD2<br>PD1          | 50<br>50           | nmHg<br>mmHa    | FO   |
| PA                             | 43         | mmHg         |                     |                    |                 | key. The key lights up.  |
| PBE                            | 59         | mmHg         | PLASMA FLOW         | 0                  | ml∕min          |  |
| PV                             | 32         | mmHg         | plasma volume       | 162                | ml              | Confirm by pressing the  |
| FILTER DROP PR. (PFD)          | 27         | mmHg         | THERAPY TIME RES.   | 00:56              | h:min           | FO   |
| TMP                            | -5         | mmHg         | THERAPY TIME        | 00:10              | h:min           | EU   |
| TOTALS<br>OVERVIEW CALIE       | LEAK<br>R. | BACK<br>THER | TO<br>APY           | NEV<br>THER/       | √<br>APY        | <ul> <li>Start the therapy again by pressing the key.</li> </ul>                                       |

i

| PAP<br>PLASMA ADSORPTION / PER | FUSION           |                      | END C                               | )F THEI<br>Blood      | RAPY<br>return       | <b>New therapy</b><br>The option <new therapy=""> allows to start a new</new>                       |
|--------------------------------|------------------|----------------------|-------------------------------------|-----------------------|----------------------|---|
|                                | <b></b>          |                      | 1                                   | <u>THERAPY SE</u>     | LECTION              | therapy immediately after the one just finished. The device switches directly to therapy selection. |
| BLOOD FLOW                     | 50               | ml/min               | WARMER                              | 34.2                  | ٥C                   | Select <new therapy=""> and confirm</new>   |
| TREATED BLOOD VOLUME           | 0.6              | liters               | PD2                                 | 50                    | mmHg                 | by pressing the   |
| PA<br>PBE<br>PV                | 44<br>59<br>32   | mmHg<br>mmHg<br>mmHq | PD1<br>Plasma flow<br>Plasma volume | 45<br>0<br>162        | mmHg<br>ml∕min<br>ml | key. The EO key lights up.  |
| FILTER DROP PR. (PFD)          | 27               | mmHg                 | THERAPY TIME RES.                   | 00:56                 | h:min                | Confirm by pressing the   |
| TOTALS<br>OVERVIEW<br>CALIB    | -5<br>LEAK<br>R. | mmHg<br>BACK<br>THER | THERAPY TIME<br>TO<br>APY           | 00:10<br>New<br>There | h:min<br>V<br>APY    | EQ key.   |



Risk of blood loss and infection for the patient To guarantee the safe therapy for the patie

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.

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#### 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<sup>®</sup> CRRT via a special interface cable that also provides the power supply for the perfusor. Data concerning the anticoagulation are entered on the Diapact<sup>®</sup> CRRT user interface.



#### 11.2 Connecting the perfusor



- Attach the perfusor holder to the IV pole of the Diapact<sup>®</sup> CRRT.
- Insert the perfusor into the holder.
- Connect the Diapact<sup>®</sup> CRRT with the interface cable to the respective perfusor.

The interface cable is connected to the Diapact<sup>®</sup> 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<sup>®</sup> CRRT and perfusor for therapy

- > Prepare the Diapact<sup>®</sup> 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.

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  $\triangleright$ further information, see the list of applicable syringes in the instructions for use of the respective perfusor.

888.a.F

#### 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

7 8 9 0 4 5 6 C A · 2 0 120 0 





#### 11.4 Setting the anticoagulation parameters

| CVVH<br>Continuous veno-venous    | THERAPY<br>Runn ing |                |                     |           |              |
|-----------------------------------|---------------------|----------------|---------------------|-----------|--------------|
| BLOOD FLOW                        | 50                  | ml∕min         | SUBSTITUTION FLOW   | 600       | ml∕n         |
| TREATED BLOOD VOLUME              | 14 9                | liters         | PD7                 | 53        | oC<br>mmHa   |
| ANTICOAG, BATE                    | 1.5                 | mi⊿h           | UF BATE             | 100       | mi⊿n         |
| PA                                | 1                   | mmHa           | UF VOLUME           | 492       | ml           |
| PBE                               | 59                  | mmHq           | FLUID WEIGHT        | 5541      | q            |
| PV                                | 35                  | mmHg           | THERAPY TIME RES.   | 00:00     |              |
| FILTER DROP PR. (PFD)             | 24                  | mmHg           | THERAPY TIME        | 04:58     | h:min        |
| тмр                               | -6                  | mmHg           | SUB BAG VOLUME RES. | 0.00      | liters       |
| PARAMETERS<br>SETTING<br>OVERVIEW | ANT                 | TCOA-<br>ATTON | BAG<br>CHANGE       | EN<br>THE | D OF<br>Rapy |

| CVVH<br>CONTINUOUS VENO-VENO           | US HAEMOFILTRATION     | PREPARATION<br>Ready for therapy           |
|--|------------------------|--|
|  |                        | [ 0.010.0]                                 |
| BLOOD FLOW                             | 0 ml⊿min               |  |
| ANTICOAG. RATE<br>ANTICOAG. BOLUS VOLU | ■0.0 ml⁄h<br>ME 0.0 ml |  |
| PARAMETERS<br>SETTING                  | . RINSING              | PRE-<br>DILUTION THERAPY BACK<br>SELECTION |

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



key and confirming with the





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



➤ 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.

| CVVH<br>CONTINUOUS VENO-VENOUS HAEMOFILTRATION   | THERAPY<br>Running  | During the therapy (or preparation phase)  |
|--|---|--|
| BLOOD FLOW     5.0     m1/min     SUBSTITUTION FLOW       TREATED BLOOD VOLUME     15.8     liters     PD2       ANTICOAG. RATE     1.5     m1/n     UF RATE       PA     1     mmHg     UF VOLUME       PBE     59     mmHg     FLUID WEIGHT       PV     34     mmHg     FLUID WEIGHT       FILTER DROP PR. (PFD)     25     mmHg     SUB BAG VOLUME RES.       PARAMETERS     TOTALS     ANTICOA-     BAG | 600 ml/h<br>36.7 °C<br>54 mmHg<br>100 ml/h<br>521 ml<br>5569 g<br>00:00 h:min<br>05:16 h:min<br>0.00 liters<br>■<br>END OF<br>THERAPY | <ul> <li>The anticoagulation parameters can be set at any time when the <anticoagulation> menu item can be selected.</anticoagulation></li> <li>To change the anticoagulation parameters, select <anticoagulation> with</anticoagulation></li> <li>or the confirment of the selection with the key.</li> <li>Confirment the selection with the key.</li> </ul> |
| CVVH<br>CONTINUOUS VENO-VENOUS HAEMOFILTRATION   | THERAPY<br>Running  | <ul> <li>Select <anticoagulation setting=""> with the<br/>or the key.</anticoagulation></li> </ul>   |
| BLOOD FLOW 50 ml≠min<br>ANTICOAG. RATE 1.5 ml≠h<br>ANTICOAG. BOLUS VOLUME 0.5 ml   |   | Confirm the selection with the key.  |
| ANTICOAG.<br>SETTING<br>OVERVIEW<br>BOLUS<br>BAG<br>CHANGE   | END OF<br>THERAPY   |  |
| CVVH<br>CONTINUOUS VENO-VENOUS HAEMOFILTRATION   | THERAPY<br>Running<br>1.7   | <ul> <li>Select the <anticoagulation rate=""> with the</anticoagulation></li> <li>or the key.</li> </ul>   |
| BLOOD FLOW 50 ml/min   |   | <ul> <li>Confirm the selection with the</li> <li>key</li> </ul>  |
| ANTICOAG. RATE <u>[1.7]</u> mi/h<br>ANTICOAG. BOLUS VOLUME 0.0 ml  |   | <ul> <li>Increase the selected value with the</li> <li>key or decrease it with the</li> </ul>  |
| ANTICOAG.<br>SETTING OVERVIEW ANTICOAG.<br>BOLUS CHANGE THERAPY  | END OF<br>THERAPY   | Confirm the change with the key. The key flashes.  |
|  |   | <ul> <li>Compare the value displayed in the supervisor field with that shown in the fluid-side parameters field and confirm with the</li> <li>EO</li> <li>key if they are identical.</li> </ul>  |

Return to <PARAMETERS OVERVIEW> by pressing the



To set the anticoagulation bolus volume, select the parameter with the



To return to <PARAMETERS OVERVIEW>, press the key.

How to perform the anticoagulant bolus is described in Section 11.6  $\,$ 

| HF<br>HAEMOFILTRATION           | THERAPY<br>Perfusor connection test |
|---------------------------------|-------------------------------------|
|                                 | [ 0.110.0]                          |
| BLOOD FLOW 50 ml/min            |                                     |
| ANTICOAG. RATE 1.6 ml/h         |                                     |
| ANTICOAG. STOP TIME 00:00 h:min |                                     |
|                                 |                                     |
|                                 |                                     |
| SETTING OVERVIEW BOLUS          | CHANGE THERAPY                      |

#### 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<br>(intermittent therapies) | h:min | 0       | 00:00 | 02:00 | 00:05/<br>00:30 |

CVVH

CONTINUOUS VENO-VENOUS HAEMOFILTRATION

#### 11.5 Anticoagulation parameters during therapy

| -                              | •      |          | -                   | ••          |
|--------------------------------|--------|----------|---------------------|-------------|
| CVVH<br>CONTINUOUS VENO-VENOUS | HAEMOR | ILTRATIO | N Perfusor o        | THERAPY     |
|                                |        |          |                     |             |
| BLOOD FLOW                     | 50     | ml∕min   | SUBSTITUTION FLOW   | 600 ml≁n    |
|                                |        |          | WARMER              | 37.3 °C     |
| TREATED BLOOD VOLUME           | 0.1    | liters   | PD2                 | 50 mmHg     |
| ANTICOAG. RATE                 | 0.0    | ml∕n     | UF RATE             | 100 ml≁h    |
| PA                             | 51     | mmHg     | uf volume           | 2 ml        |
| PBE                            | 54     | nmHg     | FLUID WEIGHT        | 5462 g      |
| PV                             | 30     | nmHg     | THERAPY TIME RES.   | 00:00 h:min |
| FILTER DROP PR. (PFD)          | 24     | mmHg     | THERAPY TIME        | 00:02 h:min |
| тмр                            | -8     | mmHg     | SUB BAG VOLUME RES. | 0.00 liters |
|                                |        |          |                     |             |
| PARAMETERS TOTALS              |        |          | BAG                 | END OF      |
|                                | GII    | ATION    | CHANGE              | THERAPY     |
|                                | J      |          |                     |             |

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.

| BLOOD FLOW            | 50    | ml∕min | SUBSTITUTI | ON FLOW   | 600<br>36 9 | ml∕n<br>∘⊂ |
|-----------------------|-------|--------|------------|-----------|-------------|------------|
| TREATED BLOOD VOLUME  | 14.9  | liters | PD2        |           | 53          | -c<br>mmHg |
| ANTICOAG. RATE        | 1.5   | mi∕n   | UF RATE    |           | 100         | ml∕h       |
| PA                    | 1     | mmHg   | UF VOLUME  |           | 492         | ml         |
| PBE                   | 59    | mmHg   | FLUID WEIG | HT        | 5541        | g          |
| PV                    | 35    | mmHg   | THERAPY TI | ME RES.   | 00:00       | h:min      |
| FILTER DROP PR. (PFD) | 24    | mmHg   | THERAPY TI | ME        | 04:58       | h:min      |
| TMP                   | -6    | mmHg   | sub bag vo | LUME RES. | 0.00        | liters     |
|                       | ````` |        |            |           |             |            |
| PARAMETERS TOTALS     | ANT   | ICOA-  | BAG        | THERAPY   | EN          | DOF        |
| SETTING OVERVIEW      | GUL   | ATION  | CHANGE     |           | THE         | RAPY       |
|                       |       |        |            |           |             |            |

THERAPY

Runn i ng

| CVVH<br>CONTINUOUS VENO-VENOUS HAEMOFILTRATION   |                  |                | THE  | THERAPY<br>Running |  |  |
|--|------------------|----------------|------|--------------------|--|--|
|  |                  |                |      |                    |  |  |
| BLOOD FLOW   | 50 ml≁min        | TOTAL UF FLOW  | 11   | ml∕min             |  |  |
| TREATED BLOOD VOLUME   | 15.3 liters      | SUBST. VOLUME  | 3.07 | liters             |  |  |
| ΣTR. BLOOD VOLUME  | 15.3 liters      | ΣSUBST. VOLUME | 3.07 | liters             |  |  |
| ANTICOAG. VOLUME<br>ΣΑΝΤΙCOAG. VOLUME  | 8.9 ml<br>8.9 ml | UF RATE        | 100  | ml≁h               |  |  |
| THERAPY TIME   | )5:06 h:min      | UF VOLUME      | 509  | ml                 |  |  |
| ΣTHERAPY TIME C  | )5:06 h:min      | ΣUF VOLUME     | 509  | ml                 |  |  |
| PRESSURE<br>OVERVIEW OVERVIEW OV |                  |                |      |                    |  |  |

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.

# Diapact<sup>®</sup> CRRT

### 11.6 Anticoagulation bolus

| BLOOD FLOW     50 m1/min     SUBSTITUTION FLOW       TREATED BLOOD VOLUME     18.1 liters     WARMER       ANTICOAG. RATE     1.7 m1/h     UF RATE       PA     1 mmHg     UF VOLUME       PBE     58 mmHg     FLUID WEIGHT       PV     34 mmHg     THERAPY TIME RES.       FILTER DROP PR. (PFD)     24 mmHg     SUB BAG VOLUME RES.       PARAMETERS     TOTALS     ANTICOA-       GULATION     CHANGE     THERAPY | 600 ml/h<br>37.0 °C<br>52 mmHg<br>100 ml/h<br>600 ml<br>5649 g<br>00:00 h:min<br>06:01 h:min<br>0.00 liters<br>END OF<br>THERAPY | <ul> <li>Confirm the selection with the key.</li> <li>Key.</li> </ul>  |
|---|--|--|
| CVVH<br>CONTINUOUS VENO-VENOUS HAEMOFILTRATION Anticoagulation Bolus Vol. is not set BLOOD FLOW 50 ml/min ANTICOAG. RATE 1.6 ml/m ANTICOAG. BOLUS VOLUME 0.0 ml ANTICOAG. SETTING PARAMETERS VVERVIEW ANTICOAG. BAG CHANGE IHERAPY  | THERAPY<br>Running<br>[ 0.010.0]<br>[ 0.010.0]   | <ul> <li>Select <anticoagulation bolus=""> with the or the wey.</anticoagulation></li> <li>Confirm the selection with the key.</li> </ul>  |
| CVVH<br>CONTINUOUS VENO-VENOUS HAEMOFILTRATION       7         Check and confirm Anticoag. Bolus Vol. and Bolus start       8         BLOOD FLOW       5.0 ml/min         ANTICOAG. RATE       1.7 ml/h<br>3.5 ml         ANTICOAG.       BOLUS VOLUME         SETTING       PARAMETERS<br>OVERVIEW       ANTICOAG.   | THERAPY<br>Running<br>3.5<br>END OF<br>THERAPY   | <ul> <li>If <anticoagulation bolus="" volume=""> was not set before (i.e. 0.0 ml), <anticoagulation setting=""> is opened.</anticoagulation></anticoagulation></li> <li>Increase the selected value with the key or decrease it with the key.</li> <li>Confirm the change with the key.</li> <li>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.</li> <li>Confirm the value with the</li> </ul> |

The screen switches to <PARAMETERS OVERVIEW>.

ļ

| CVVH<br>CONTINUOUS VENO-VENOUS HAEMOFILTRATION |          |                |                    | THE           | THERAPY<br>Running |  |
|--|----------|----------------|--------------------|---------------|--------------------|--|
| Premature break-off with                       | n EQ     |                |                    | BOLUS         | 2.7 ml             |  |
| BLOOD FLOW                                     | 50       | ml∕min         | SUBSTITUTION FLOW  | 600<br>37_0   | ml≁h<br>∘r         |  |
| TREATED BLOOD VOLUME                           | 18.2     | liters         | PD2                | 57            | mmHq               |  |
| ANTICOAG. RATE                                 | 600.0    | ml∕n           | UF RATE            | 100           | mi∕n               |  |
| PA   | 1        | mmHg           | UF VOLUME          | 602           | ml                 |  |
| PBE  | 62       | mmHg           | FLUID WEIGHT       | 5651          | g                  |  |
| PV   | 34       | mmHg           | THERAPY TIME RES.  | 00:00         | h:min              |  |
| FILTER DROP PR. (PFD)                          | 28       | mmHg           | THERAPY TIME       | 06:04         | h:min              |  |
| ТМР  | -9       | mmHg           | SUB BAG VOLUME RES | . 0.00        | liters             |  |
| PARAMETERS<br>SETTING<br>OVERVIEW              | ANT GUL/ | ICOA-<br>Ation | BAG<br>CHANGE      | IPY EI<br>Thi | ND OF<br>Erapy     |  |

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



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.



| CVVH<br>Continuous veno-veno                 | DUS HAEMOFILTRATION                              | THERAPY<br>Blood circulation  |
|--|--|-------------------------------|
| ▲ Missing Perfusor →<br>Plaats Perfusor of b | connection [1080]<br>evestig behandeling z.Antic | 20ag.met EQ [0.110.0]         |
| BLOOD FLOW                                   | 50 ml≁min  |                               |
| ANTICOAG. RATE<br>ANTICOAG. BOLUS VOLI       | <u>[1.6]</u> ml∕n<br>JHE 0.0 ml                  |                               |
| ANTICOAG.<br>SETTING                         | ERS ANT I COAG.<br>BOLUS CHANGE                  | THERAPY<br>THERAPY<br>THERAPY |

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



If the therapy shall not be performed with anticoagulation:

Confirm the message by pressing the



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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|  | Maintenance and cleaning<br>External cleaning<br>Servicing and technical safety check<br>Maintenance<br>Technical safety check (TSC)<br>Accessories, disposable items and expendable parts<br>Technical service and guarantee<br>Guarantee |
# 12 Maintenance and cleaning

# 12.1 External cleaning

| • |   |
|---|---|
|   | <ul> <li>Electric shock and fire hazard!</li> <li>Ensure that no fluid enters the machine.</li> </ul> |

| ^        | Damage to surface by unknown ingredients!                            |
|----------|--|
|          | Ensure that the disinfectant is pure active chlorine.                |
| <u> </u> | B.Braun will assume no liability for any damage caused to the device |
| WARNING  | 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 Maintenance and cleaning

## 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

•

Alarm field

 $\geq$ 

• the machine alarms acoustically. Blood-side alarms provoke a sharp continuous tone and fluid-side alarms an intermittent tone.



• 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.

| ! | <ul> <li>Operation in case of alarm tone failure</li> <li>The buzzer for the alarm tone is tested in the preparation phase.</li> <li>Listen for the alarm tone during the preparation phase as described in the respective sections.</li> <li>If the buzzer fails within a therapy, the supervisor assumes the control.</li> <li>If problems with the buzzer occur, do not operate the device and call the technical service.</li> </ul> |
|---|--|
|---|--|



Press the AQ key to mute the alarm.

> Eliminate the alarm reason.

Press the 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  |
|---|---|
| 1 | 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<br>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 the keys and the stop 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-<br>test failed | 900  | Test failed  | Repeat test by pressing<br>AQ<br>twice or |
|  |      |  | Switch the machine off and<br>on again    |
| Supervisor self-test failed                | 904  | <ul> <li>Supervisor internal memory<br/>failure</li> </ul> | Switch the machine off and<br>on again    |
|  |      | <ul> <li>Calibration data test failed</li> </ul>           |   |
|  |      | Device failure   | Contact technical service.                |
| Therapy status:                            |      | • Test failure   | Repeat test by pressing                   |
| Power relay test                           |      |  | AQ twice or                               |
| Controller self-test failed                | 902  |  | Switch the machine off and<br>on again    |
| (702)                                      |      | Technical failure  | Contact technical service                 |

| Alarm/Message                     | Code | Cause(s)                                    | Remedial action   |
|-----------------------------------|------|---|---|
| Therapy status:                   |      | Test failure                                | Repeat test by pressing   |
| SAD reference test                |      |   | AQ twice or   |
| Supervisor self-test failed       | 904  |   | <ul> <li>Switch the machine off and<br/>on again</li> </ul>     |
| (904)                             |      | Technical failure                           | Contact technical service                                       |
| Therapy status:                   |      | Test failure                                | Repeat test by pressing   |
| SAD counter test                  |      |   | AQ twice or   |
| Supervisor test failed (904)      | 904  |   | <ul> <li>Switch the machine off and<br/>on again</li> </ul>     |
|                                   |      | Technical failure                           | Contact technical service                                       |
| Therapy status:                   |      | • Test failure                              | Repeat test by pressing   |
| Red detector test                 |      |   | AQ twice or   |
| Controller self-test failed       | 902  |   | <ul> <li>Switch the machine off and<br/>on again</li> </ul>     |
|                                   |      | Technical failure                           | Contact technical service                                       |
| Therapy status:                   |      | Test failure                                | Repeat test by pressing   |
| Blood leak detector test          |      |   | AQ twice or   |
| Supervisor self-test failed       | 904  |   | Switch the machine off and<br>on again                          |
|                                   |      | Technical failure                           | Contact technical service                                       |
| Therapy status:                   |      | Disconnected pressure lines                 | Connect the pressure lines to<br>the pressure transducer(s) and |
| Zero pressure test                |      |   | repeat the test by pressing                                     |
| Controller self-test failed       | 902  |   | twice or  |
| (902)                             |      |   | Switch the machine off and<br>on again                          |
| Supervisor self-test failed (904) | 904  | Deviation between two sensors     > 20 mmHg | Recalibration by technical<br>service                           |
|                                   |      | Technical failure                           | Contact technical service                                       |
| Therapy status:                   |      | Wrong configuration of the                  | Install the correct   |
| Load cell test                    |      | consumables                                 | respective therapy or correct<br>the installation               |
| Controller self-test failed (902) | 902  | Pump segment twisted                        | <ul> <li>Correct orientation of pump<br/>segments</li> </ul>    |
| Supervisor self-test failed       | 904  | Frangible pin of saline bag seal closed     | <ul> <li>Open frangible pin of the<br/>saline bag</li> </ul>    |
| (904)                             |      | Saline bag not on the load cell             | Place the saline bag on bag<br>holder of the load cell          |
|                                   |      | Device failure                              | Contact technical service                                       |

| Alarm/Message   | Code | Cause(s)   | Remedial action  |
|---|------|--|--|
| Therapy status:<br>Air detector test (AD)             |      | Wrong installation of the consumables  | <ul> <li>Correct installation of the<br/>consumables</li> </ul>                                  |
| Controller self-test failed                           | 902  | <ul> <li>Frangible pin of the bags with<br/>haemofiltration solution<br/>closed</li> </ul>   | <ul> <li>Open the frangible pin of the<br/>bags with the haemofiltration<br/>solution</li> </ul> |
| (702)   |      | <ul> <li>Line was not empty at<br/>beginning of test</li> </ul>                              | Repeat the test  |
|   |      | Device failure   | Contact technical service  |
| Therapy status:<br>Dialysate pump test                |      | <ul> <li>Wrong installation of the<br/>consumables</li> </ul>                                | <ul> <li>Correct installation of the<br/>consumables</li> </ul>                                  |
| or  |      | Pump segment twisted   | <ul> <li>Correct the installation of the<br/>pump segments</li> </ul>                            |
| Substitution pump test<br>(MP3)                       |      | <ul> <li>Size of pump segment does<br/>not correspond to the selected<br/>therapy</li> </ul> | Adapt line kit to therapy  |
| Controller self-test failed (902)                     | 902  | Air in filter (dialysate pump test)  | <ul> <li>Screw filter connection tight</li> <li>Deaerate the filter</li> </ul>                   |
| Supervisor self-test failed (904)                     | 904  | Device failure   | <ul> <li>Contact technical service</li> </ul>  |
| Therapy status:                                       |      | Wrong installation of the consumables  | <ul> <li>Correct installation of the<br/>consumables</li> </ul>                                  |
| <b>Ultrafiltration pump test</b><br>or                |      | Pump segment twisted   | <ul> <li>Correct the installation of the<br/>pump segments</li> </ul>                            |
| Plasma pump test (MP2)<br>Controller self-test failed | 902  | • Size of pump segment does not correspond to the selected therapy                           | Adapt line kit to therapy  |
| (902)   |      | • Air in filter  | <ul><li>Screw filter connection tight</li><li>Deaerate the filter</li></ul>                      |
| Supervisor self-test failed (904)                     | 904  | Device failure   | Contact technical service  |
| Therapy status:                                       |      | Malfunction of the heater  | ➢ Repeat test  |
| Heating test  |      |  | Switch the machine off and<br>on again   |
| Controller self-test failed (902)                     | 902  | Device failure   | <ul> <li>Contact technical service</li> </ul>  |
| Supervisor self-test failed (904)                     | 904  |  |  |

| Alarm/Message                        | Code | Cause(s)                           | Remedial action                                    |
|--------------------------------------|------|------------------------------------|--|
| Therapy status:                      |      | • Pressure loss in system          | Screw the connections tight                        |
| Disposable leakage test              |      |                                    | and/or correct the installation of the consumables |
|                                      | 902  | • Gap in SAK                       | Contact technical service                          |
| (902)                                | 702  | Hydrophobic filter(s) wet          | Exchange the concerned<br>hydrophobic filter       |
| Supervisor self-test failed (904)    | 904  |                                    |  |
| Therapy status:                      |      | • Pressure loss in internal system | Contact technical service                          |
| Level regulation test                |      | Device failure                     | Contact technical service                          |
| Controller self-test failed<br>(902) | 902  |                                    |  |

#### Other alarms during preparation

| Alarm/Message  | Code | Machine<br>reactions            | Cause(s)  | Remedial action  |
|--|------|---------------------------------|---|--|
| Pump calibration<br>disturbed. It will be<br>restarted | 1023 | Pump calibration<br>stops       | Disturbance on<br>the load cell                     | <ul> <li>Repeat pump calibration<br/>by pressing<br/>twice</li> <li>Do not touch the machine<br/>during calibration</li> </ul> |
| Saline bag for blood-side priming is empty             | 1025 | Final or optional rinsing stops | <ul> <li>Priming saline<br/>bag is empty</li> </ul> | <ul> <li>Connect a new saline bag<br/>and press</li> <li>AQ<br/>twice</li> </ul>   |

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

AQ

light is turned on.

| Alarm/Message            | Code | Cause(s)   | Remedial action   |
|--------------------------|------|--|---|
| Air in blood return line | 802  | Drop of blood level in the<br>venous line                                    | <ul> <li>Adjust blood level (see<br/>remedying SAD alarms in<br/>Section 13.3)</li> </ul> |
|                          |      | Turbulences due to too high<br>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<br>the SAD and close the cover<br>correctly                |
|                          |      | Device failure   | Contact technical service   |
| PV higher than PV max    | 806  | <ul> <li>Blood pump velocity too high</li> </ul>                             | Decrease blood flow   |
|                          |      | Upper PV limit exceeded  | Adjust thresholds   |
|                          |      | Catheter or fistula needle not<br>optimally positioned or lumen<br>displaced | <ul> <li>Correct position of catheter or<br/>fistula needle</li> </ul>                    |
|                          |      | Clotting in venous chamber   | Change venous line or line<br>system  |
|                          |      | Device failure   | Contact technical service   |
| PV lower than PV min     | 808  | <ul> <li>Blood pump velocity too low</li> </ul>                              | Increase blood flow   |
|                          |      | Lower PV limit value exceeded  | Adjust thresholds   |
|                          |      | Catheter or fistula needle     disconnected                                  | Reconnect catheter or fistula<br>needle   |
|                          |      | Pressure sensor leaky  | Screw the connection<br>between pressure line and<br>pressure transducer tight            |
|                          |      | Level regulator leaky  | Contact technical service   |
|                          |      | Patient's position too low in relation to the device                         | Increase the height of the<br>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<br>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<br>patient situation                                 |
|                                     |      | Thresholds set inadequately  | Adjust thresholds  |
|                                     |      | Catheter or fistula needle not<br>optimally positioned or lumen<br>displaced | <ul> <li>Correct position of catheter or<br/>fistula needle</li> </ul>           |
|                                     |      | Device failure   | Contact technical service  |
| PBE higher than PBE max             | 814  | Blood flow too high  | Adapt the blood flow to the<br>filter size                                       |
|                                     |      | Line kinked  | Straighten the lines   |
|                                     |      | Clotting   | Exchange the haemofilter   |
|                                     |      |  | Check and adapt<br>anticoagulation if necessary                                  |
| PBE lower than PBE min              | 816  | Pressure line to PBE pressure transducer not connected                       | <ul> <li>Connect the pressure line to<br/>the pressure transducer PBE</li> </ul> |
| PFD higher than PFD max             | 822  | Decrease in filter performance   | > Rinse the filter   |
|                                     |      | Insufficient anticoagulation   | <ul> <li>Check and adapt<br/>anticoagulation</li> </ul>                          |
|                                     |      | Filter clotting  | <ul> <li>Exchange the filter (see<br/>Section 13.5)</li> </ul>                   |
| Blood pump cover open               | 824  | Blood pump cover open  | Close blood pump cover   |
|                                     |      | Device failure   | Contact technical service  |
| Blood pump stopped.                 | 830  | Blood pump stopped   | Start blood pump again   |
| Are you sure?                       |      | Device failure   | > Contact technical service  |
| Air bubbles in blood return<br>line | 892  | Small air bubbles in the<br>venous line                                      | Check venous line and venous<br>chamber against leak                             |
|                                     |      |  | Check connections of lines   |
|                                     |      |  | Check the level in the venous<br>chamber. If required fill it<br>manually.       |
|                                     |      |  | After removing any air bubble<br>from the SAD, acknowledge<br>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 Key lights up.

| Alarm/Message                             | Code | Cause(s)   | Remedial action   |
|---|------|--|---|
| High removal ratio of blood               | 832  | Ratio blood flow: filtrate flow<br>> 40 % in dialysis therapies<br>> 50 % in plasma therapies        | Lower substitution flow<br>and/or increase blood flow   |
| Blood leakage<br>(probable filter damage) | 838  | Membrane rupture   | Check membrane for rupture,<br>if no membrane rupture can<br>be detected, recalibrate BLD<br>(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  | <ul> <li>Screw the connection of the<br/>plasma outlet line tight</li> </ul>                                    |
|   |      | Air in the line, bag empty   | Change the bag(s)   |
|   |      | ➤ Line deformed  | Re-position the plasma outlet<br>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,<br>bag empty   | Change bag(s)   |
|   |      | > Line deformed  | Re-position the plasma outlet<br>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<br>position the heater bag<br>correctly into the heater                                 |
|   |      | Clamp closed   | > Open clamp  |
|   |      | Blood-side pressure too high   | <ul> <li>Check venous line and<br/>catheter placement and<br/>connection</li> </ul>                             |
| PD1 lower limit                           | 850  | Disconnection of the green<br>line   | Screw the connection of the<br>substitution line tight  |
| PD2 upper limit                           | 852  | <ul> <li>Blood-side pressure too high<br/>and green line is not mounted<br/>into the pump</li> </ul> | Mount line correctly and<br>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<br>possible kinks  |
|                          |                            |   | Check catheter connection<br>and correct it if necessary  |
|                          |                            | ➤ Filter clotting   | Rinse or exchange filter or<br>change line kit  |
| High warmer temperature  | 858                        | Fluid flow disturbed  | <ul> <li>Check the fluid flow and<br/>eliminate possible<br/>disturbances</li> </ul>                |
|                          |                            | 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<br>cell (> 26.8 kg)                               | Reduce weight on the load<br>cell   |
|                          |                            | Device failure  | Contact technical service   |
| Unexpected weight change | 872                        | Change in weight < 200 g  | <ul> <li>Select cause on the display by pressing the key:</li> </ul>                                |
|                          |                            |   | Select < Unchanged bags> if<br>the bags were not changed or<br>if no bags were added or<br>removed. |
|                          |                            |   | Select < Changed bags> if<br>bags were changed or if bags<br>were added or removed.                 |
|                          |                            |   | Confirm with EQ Do not press the AQ key !   |
| UF greater than expected | 876                        | Wrong input/output balance<br>> 120/150/180 g                                 | Take care that the bags on<br>the load cell hang freely   |
|                          |                            | > Closed clamp  | Check bag and fluid line<br>clamps to be open   |
|                          |                            | Substitution line kinked  | Straighten substitution line  |
| The limi<br>acknowl      | t is increas<br>edged. Wh  | ed in 30 g increments. The increment<br>en the limit reaches +180 g, therapy  | is must be<br>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 limi<br>acknowl      | t is decreas<br>ledged. Wh | sed in 30 g increments. The incremen<br>ien the limit reaches -180 g, therapy | ts must be<br>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          | 884  | Pump cover open  | Close pump cover   |
| open                             |      | 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<br>by 50 mmHg (high-flux filter)  | Increase blood flow  |
|                                  |      | Reduced filter surface   | > Adapt anticoagulation.   |
|                                  |      |  | Rinse the filter or exchange it<br>if necessary  |
| Removal not achievable           | 915  | <ul> <li>PD2 min limit value exceeded<br/>by 50 mmHg (Low-flux filter)</li> </ul>  | Decrease substitution and/or<br>increase blood flow  |
|                                  |      | Leakage of the collecting bag  | ➢ Replace bag  |
|                                  |      | Reduced filter surface   | <ul> <li>Adapt anticoagulation.</li> <li>Rinse the filter or exchange it if necessary</li> </ul>   |
| Unexpected weight change > 200 g | 940  | Change in weight > 200 g due<br>to bag change without<br>selecting the <bag change=""><br/>function</bag>                        | Complete bag change and<br>start therapy again   |
| UF pump flow disturbed           | 1004 | Pump segment stuck within the pump   | Check pump segment and<br>insert it correctly  |
|                                  |      | Device failure   | Contact technical service  |
| Substitution pump flow disturbed | 1005 | Pump segment stuck within the pump   | Check pump segment and<br>insert it correctly  |
|                                  |      | Device failure   | Contact technical service  |
| Dialysate pump flow disturbed    | 1006 | Pump segment stuck within the pump   | Check pump segment and<br>insert it correctly  |
|                                  |      | Device failure   | Contact technical service  |
| Plasma pump flow disturbed       | 1007 | Pump segment stuck within the pump   | Check pump segment and<br>insert it correctly  |
|                                  |      | Device failure   | Contact technical service  |
| Bag volume is over               | 1020 | <ul> <li>Maximum ultrafiltrate<br/>collecting bag volume reached</li> <li>Maximum substitution bag<br/>volume reached</li> </ul> | <ul> <li>Change the concerned bag<br/>and start therapy again by<br/>releasing Bag Change</li> <li>Select <end of="" therapy=""> if<br/>desired</end></li> </ul> |

#### Alarms occurring using the Perfusor interface

Machine reactions:

- Acoustic alarm (heparin alarm tone)
- Alarm message in the alarm field on the screen



- The key lights up.
- The perfusor stops.

| Alarm/Message               | Code | Cause(s)   | Remedial action  |
|-----------------------------|------|--|--|
| Perfusor failure            | 927  | <ul> <li>Perfusor communication<br/>disturbed</li> </ul>                                 | Connect Perfusor correctly   |
|                             |      | <ul> <li>Perfusor status is not as<br/>expected</li> </ul>                               | <ul> <li>Correct Perfusor status</li> </ul>  |
| Syringe alarm in Perfusor   | 1027 | Syringe empty  | Replace empty syringe with a<br>filled syringe   |
|                             |      | Wrong connection of syringe  | <ul> <li>Correct connection of the<br/>syringe</li> </ul>                                  |
|                             |      | Missing syringe  | Insert syringe   |
| Missing Perfusor connection | 1080 | <ul> <li>Missing connection between<br/>Diapact<sup>®</sup> CRRT and perfusor</li> </ul> | <ul> <li>Connect perfusor to Diapact<sup>®</sup><br/>CRRT and press</li> <li>Or</li> </ul> |
|                             |      |  | <ul> <li>Confirm therapy without<br/>anticoagulation by pressing</li> </ul>                |

## 13.2.4 Hardware alarms during therapy

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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:<br>DPD-DPC<br>Communication<br>time-out! | -    | <ul> <li>Whole system<br/>communication stops<br/>resulting in         <ul> <li>Stop of all the pumps</li> <li>SAK is closed</li> <li>Heater is switched<br/>off</li> </ul> </li> <li>Acoustic alarm<br/>(continuous buzzer<br/>sound)</li> <li>Alarm message in the<br/>alarm field on the<br/>screen</li> </ul> | <ul> <li>Display controller<br/>recognised a controller<br/>communication fault</li> <li>Controller recognised a<br/>Display controller<br/>communication fault</li> </ul> | <ul> <li>Switch the device off<br/>and on again</li> <li>Contact technical<br/>service</li> </ul> |
| FATAL ERROR:<br>DPD-DPS<br>Communication<br>time-out! | -    | See above   | <ul> <li>Display controller<br/>recognised a supervisor<br/>communication error</li> <li>Supervisor recognised<br/>a Display controller<br/>communication fault</li> </ul> | <ul> <li>Switch the device off<br/>and on again</li> <li>Contact technical<br/>service</li> </ul> |
| Blood air detector<br>(SAD) failure                   | 804  | See blood-side alarm<br>(Section 13.2.2)  | Self-test of the safety<br>air detector failed.  | <ul> <li>Switch the device off<br/>and on again</li> <li>Contact technical<br/>service</li> </ul> |
| Blood leak sensor 8<br>failure                        | 836  | See fluid-side alarm<br>(Section 13.2.3)  | Self-test of the blood<br>leak sensor failed.  | Repeat the test by pressing   |
|   |      |   | Device failure   | Contact technical<br>service  |
| Cyclical weight<br>preamplifier test<br>failed        | 862  | See fluid-side alarm<br>(Section 13.2.3)  | Self-test of the weight preamplifier failed  | Acknowledge with the AQ key.  |
|   |      |   | Device failure   | <ul> <li>Contact technical<br/>service</li> </ul>   |
| Safety 12 V failure                                   | 888  | See blood-side alarm<br>(Section 13.2.2) with<br>system failure tone  | Fault in the safety voltage  | <ul> <li>Switch the device off<br/>and on again</li> <li>Contact technical<br/>service</li> </ul> |
| 24 V failed   | 890  | See blood-side alarm<br>(Section 13.2.2) with<br>system failure tone  | Fault in the 24 V voltage supply   | <ul> <li>Switch the device off<br/>and on again</li> <li>Contact technical<br/>service</li> </ul> |
| Supervisor error!                                     | 896  | See blood-side alarm<br>(Section 13.2.2) with<br>system failure tone  | Controller recognised<br>supervisor fault  | <ul> <li>Switch the device off<br/>and on again</li> <li>Contact technical<br/>service</li> </ul> |

#### 13.2.5 Protection system (supervisor) alarms

Diapact<sup>®</sup> 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          | <ul> <li>Supervisor internal or<br/>communication failure</li> </ul>  | Switch the machine off and on again  |
|                    |             | Device failure  | <ul> <li>Disconnect the patient and<br/>contact technical service</li> </ul> |
|                    | There is no | alarm message on the screen if this fail  | lure occurs  |
| SYSTEM ERROR       | NA          | Supervisor internal failure   | Switch the machine off and on again  |
|                    |             | Device failure  | <ul> <li>Disconnect the patient and<br/>contact technical service</li> </ul> |
|                    | There is no | alarm message on the screen if this fail  | lure occurs  |
| SELFTEST ERROR     | NA          | <ul> <li>Any of the necessary self-tests is<br/>not passed when entering therapy</li> </ul>                     | <ul> <li>Switch the machine off and on<br/>again</li> </ul>                  |
| SAFETY CHECK ERROR | NA          | <ul> <li>Any of the necessary safety<br/>parameter checks is not performed<br/>when entering therapy</li> </ul> | Switch the machine off and on again  |
| THERAPY PUMP RUNS  | A           | <ul> <li>Any pump (MP2 or MP3) runs when<br/>it should stop</li> </ul>  | Acknowledge with the<br>AQ<br>key  |
|                    |             | Device failure  | Contact technical service.   |
| SAD SENSOR ERROR   | A           | Safety air detector (SAD) self-test failure   | Acknowledge the alarm  |
|                    |             | Device failure  | <ul> <li>Disconnect the patient and<br/>contact technical service</li> </ul> |

| 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   | <ul> <li>Disconnect the patient and<br/>contact technical service</li> </ul>  |
| SAD REF. ERROR   | A       | Safety air detector (SAD) reference voltage failure                          | Acknowledge the alarm   |
|                  |         | Device failure   | <ul> <li>Disconnect the patient and<br/>contact technical service</li> </ul>  |
| AIR IN BLOOD     | A       | • Air in the venous line   | Remove the air from the venous<br>line as described in Section 13.3   |
| BUBBLES IN BLOOD | A       | Small air bubbles in the venous line   | <ul> <li>Check venous line and venous<br/>chamber for leaks</li> </ul>  |
|                  |         |  | Check connections of lines  |
|                  |         |  | Check the level in the venous<br>chamber. If required fill it<br>manually.  |
|                  |         |  | Remove the air bubbles from the<br>venous line as described in Section<br>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<br>membrane rupture can be<br>detected, recalibrate BLD as<br>described in Section 13.4 |
|                  |         | Air in blood leak detector   | Remove air bubbles from line  |
|                  |         | Device failure   | Contact technical service   |
| PV HIGH          | А       | Blood pump velocity too high   | Decrease blood flow   |
|                  |         | Upper PV limit exceeded  | Adapt thresholds  |
|                  |         | Catheter or fistula needle not<br>optimally positioned or lumen<br>displaced | <ul> <li>Reposition catheter or fistula<br/>needle</li> </ul>   |
|                  |         | Clotting in venous chamber   | Change tube system  |
|                  |         | Device failure   | Contact technical service   |
| PV LOW           | А       | Blood pump velocity too low  | Increase blood flow   |
|                  |         | Lower PV limit value exceeded  | Adapt limits  |
|                  |         | Catheter or fistula needle     disconnected                                  | <ul> <li>Reconnect catheter or fistula<br/>needle</li> </ul>  |
|                  |         | Pressure sensor leaky  | Check pressure sensor   |
|                  |         | Level regulator leaky  | Call technical service  |
|                  |         | Patient lying too low  | Increase the height of the patient's<br>bed   |
|                  |         | Device failure   | Contact technical service   |

| Alarm/Message    | Accept. | Cause(s)   | Remedial action   |
|------------------|---------|--|---|
| PA HIGH          | А       | No blood flow  | Check blood flow  |
|                  |         | Catheter or fistula needle     disconnected                                    | <ul> <li>Reconnect catheter or fistula<br/>needle</li> </ul>  |
|                  |         | Limit value setting  | Reset upper threshold   |
|                  |         | Device failure   | Contact technical service   |
| PA LOW           | А       | Blood pump velocity too high   | Adapt the blood flow to the<br>patient's situation  |
|                  |         | Limit value setting  | Reset the lower limit value   |
|                  |         | Catheter or fistula needle not<br>optimally positioned or lumen<br>displaced   | <ul> <li>Check the position of the catheter<br/>or the fistula needle</li> </ul>  |
|                  |         | 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<br>green line is not mounted into the<br>pump | Mount line correctly and correct<br>blood-side pressure   |
| PD2 LOW          | A       | • Disconnection of the substitution line                                       | <ul> <li>Screw the connection of the<br/>substitution line tight</li> </ul>   |
| TEMPERATURE HIGH | A       | • Temperature is too high (over 41 or 45 °C)                                   | Accepting the alarm allows to<br>continue the therapy without the<br>heater. The function can be<br>activated again by switching the<br>unit off and on again. The user can<br>decide whether to continue the<br>therapy with or without the<br>heater. |
|                  |         | Device failure   | Contact technical service   |
| UF VOLUME HIGH   | NA      | Wrong input/output balance > 300 g   | <ul> <li>After checking the patient's proper<br/>weight and eliminating the<br/>problem reset the therapy</li> </ul>  |
|                  |         |  | Interrupt the therapy and<br>disconnect the patient if no<br>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 < -<br>300 g                                      | <ul> <li>After checking the patient's proper<br/>weight and eliminating the<br/>problem reset the therapy</li> <li>Interrupt the therapy and<br/>disconnect the patient if no<br/>problem can be detected</li> </ul>                                    |
|                  |         | • Leakage of bag(s)  | Exchange the leaking bag using<br>the <bag change=""> function</bag>  |
|                  |         | 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<br>AO<br>key.  |
|                    |         | Device failure                                | Contact technical service   |
| UF RATE LOW        | A       | UF removal is lower than expected             | Acknowledge with the<br>AQ<br>key.  |
|                    |         | Device failure                                | Contact technical service   |
| SUB FLOW HIGH      | A       | Substitution infusion is higher than expected | Acknowledge with the<br>AQ<br>key.  |
|                    |         | Device failure                                | Contact technical service   |
| SUB FLOW LOW       | A       | Substitution infusion is lower than expected  | Acknowledge with the<br>AQ<br>key.  |
|                    |         | Device failure                                | Contact technical service   |
| WEIGHT TEST ERROR  | A       | Weight preamplifier self-test failure         | Acknowledge with the<br>AO<br>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  |
|                    |         |   | <ul> <li>See clearance of alarms 866, 868,<br/>872 during therapy.</li> </ul> |
|                    |         | Device failure                                | Contact technical service   |
| PERFUSOR ERROR     | А       | Perfusor communication disturbed              | Connect perfusor correctly  |
|                    |         | Perfusor status is not as expected            | <ul> <li>Correct perfusor status</li> </ul>                                   |

# 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<br>PA max | 810  | Blood flow is reduced<br>to 25% (max. 60<br>ml/min) for 3 sec. | Patient moving |                 |
|                          |      | • Fluid pumps stop for 3 sec.                                  |                |                 |
| PA lower than<br>PA min  | 812  | Blood flow is reduced<br>to 25% (max. 60<br>ml/min) for 3 sec. | Patient moving |                 |
|                          |      | • Fluid pumps stop for 3 sec.                                  |                |                 |

| Alarm/Message                                | Code | Machine reactions  | Cause(s)  | Remedial action  |
|--|------|--|---|--|
| High removal<br>ratio of blood               | 832  |  | <ul> <li>Ratio blood flow:<br/>filtrate flow</li> <li>25 % in dialysis<br/>therapies</li> <li>35 % in plasma<br/>therapies</li> </ul> | <ul> <li>Decrease substitution<br/>flow and/or increase<br/>blood flow</li> </ul>                        |
| Blood leakage<br>(probable filter<br>damage) | 838  |  | <ul> <li>Blood leakage alarm<br/>was acknowledged and<br/>a new alarm is<br/>inhibited for 60 sec</li> </ul>                          | <ul> <li>Nothing (membrane<br/>rupture had to be<br/>eliminated before)</li> </ul>                       |
| High warmer<br>temperature                   | 858  | Warning tone every<br>min.   | • Temperature is above<br>the set temperature + 2<br>°C   | <ul> <li>Reduce set<br/>temperature</li> </ul>   |
|  |      |  | Fluid flow disturbed  | Remove the cause of<br>the flow disturbance  |
|  |      |  | <ul> <li>Variation value too<br/>high</li> </ul>  | Decrease temperature<br>in max. 2 °C steps   |
|  |      |  | Device failure  | <ul> <li>Contact technical<br/>service</li> </ul>  |
| Low warmer 861<br>temperature                | 861  | Warning tone every 2     min.  | <ul> <li>Temperature is below<br/>the set temperature - 2<br/>°C:</li> <li>Substitution/dialysate</li> </ul>                          | Reduce flow rate or warm up the bags   |
|  |      |  | fluid is too cold   | > Increase temperature   |
|  |      |  | high  | in max. 3 °C steps   |
|  |      |  | Technical failure   | <ul> <li>Contact technical<br/>service</li> </ul>  |
| Weighing<br>system empty                     | 870  | <ul> <li>Warning tone every 4 min.</li> </ul>  | <ul> <li>No weight on the load<br/>cell</li> </ul>  | <ul> <li>Connect bag to the<br/>load cell</li> </ul>   |
|  |      |  | Device failure  | <ul> <li>Contact technical<br/>service</li> </ul>  |
| Clotting danger                              | 914  | <ul> <li>Warning tone every 4<br/>min.</li> <li>Substitution/Plasma<br/>flow reduced or<br/>stopped</li> </ul> | PD2 min limit value<br>reached (high-flux<br>filter)  | Increase blood flow  |
|  |      |  | Reduced filter surface  | <ul> <li>Adapt anticoagulation.</li> <li>Rinse the filter or<br/>exchange it if<br/>necessary</li> </ul> |
| Removal not<br>achievable                    | 915  | <ul> <li>915 Warning tone every 4 min.</li> <li>Substitution/Plasma flow is reduced or stopped</li> </ul>      | PD2 min limit value<br>reached (low-flux filter)  | <ul> <li>Decrease substitution<br/>and/or increase blood<br/>flow</li> </ul>                             |
|  |      |  | Reduced filter surface  | <ul> <li>Adapt anticoagulation.</li> <li>Rinse the filter or<br/>exchange if necessary</li> </ul>        |

| Alarm/Message  | Code | Machine reactions   | Cause(s)  | Remedial action  |
|--|------|---|---|--|
| Perfusor failure                                     | 927  | Warning tone every 2     min.   | Perfusor     communication     disturbed  | <ul> <li>Connect Perfusor<br/>correctly</li> </ul>   |
|  |      |   | Perfusor status is not as     expected  | Correct Perfusor status  |
| Blood return line<br>empty                           | 930  | Warning tone once   | Blood return line empty<br>after blood return in<br>End Of Therapy                        | <ul> <li>Select Therapy<br/>Selection or</li> <li>Switch the device off</li> </ul>                         |
| Substitution<br>flow reduced.<br>Check PD2.          | 931  | <ul><li>Warning tone once</li><li>Substitution flow is</li></ul>      | PD2 min + 20 mmHg<br>value reached  | Increase blood flow  |
|  |      |   | Reduced filter surface  | <ul> <li>Adapt anticoagulation.</li> <li>Rinse the filter or<br/>exchange if necessary</li> </ul>          |
| Therapy<br>stopped! Are<br>you sure?                 | 932  | Warning tone every 4     min.   | <ul> <li>Therapy pumps are<br/>stopped for more than<br/>4 minutes</li> </ul>             | ➤ Start therapy  |
| Warmer 24 V<br>switched off by<br>Supervisor         | 933  | Warning tone once   | <ul> <li>Supervisor heating<br/>alarm switched off the<br/>warmer power supply</li> </ul> | Switch the device off<br>and on again, if<br>heating is necessary  |
| Release Bag<br>Change to<br>continue the<br>therapy  | 936  |   | Bag Change is active  | Release Bag Change   |
| Perfusor alarm                                       | 937  | Warning tone once   | Alarm on the Perfusor   | <ul> <li>Check alarm cause on<br/>Perfusor and correct its<br/>cause</li> </ul>                            |
| Auto plasma reduction                                | 938  | <ul> <li>Warning tone once</li> <li>Plasma flow is reduced</li> </ul> | PD2 min + 20 mmHg<br>value reached  | Increase blood flow  |
|  |      | or stopped  | Reduced filter surface  | Adapt anticoagulation.   |
|  |      |   |   | Rinse the filter or<br>exchange if necessary   |
| Battery low in<br>Perfusor                           | 939  | Warning tone once   | Battery low in Perfusor   | <ul> <li>Replace battery in<br/>Perfusor</li> </ul>  |
| Therapy is over                                      | 942  | <ul><li>Therapy end tone</li><li>Fluid pumps stop</li></ul>           | Therapy time reached<br>the required time   | <ul> <li>Increase therapy time,<br/>if necessary</li> <li>Enter <end of<br="">Therapy&gt;</end></li> </ul> |
| Pump<br>calibration. Do<br>not touch the<br>machine. | 1022 |   | Pump calibration is<br>running  | Do not touch the<br>machine during<br>calibration to complete<br>it without any<br>disturbance             |

#### 13.3 Remedying SAD alarms

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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.

| ! |
|---|
|   |

#### 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
- Clamp the venous line above the venous chamber. This prevents blood from being sucked from the dialyzer.
- Select the level regulation by pressing the 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







- > 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)



#### 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 select key. The therapy continues.



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Diapact<sup>®</sup> CRRT

## 14 Accessories

# 14.1 Diapact<sup>®</sup> kits for dialysis

|                          | HF/HD Kit | HF/HD Kit<br>pre-<br>assembled | HF/HD Kit<br>recirculation | HF/HD Kit<br>high volume | SCUF Kit |
|--------------------------|-----------|--------------------------------|----------------------------|--------------------------|----------|
|                          | 7210349   | 7210492                        | 7210657                    | 7210635                  | 7210351  |
| Arterial line<br>7210353 | X         | X                              | X                          | X                        | X        |
| Venous line<br>7210208   | X         | X                              | X                          | Х                        | X        |

# Diapact<sup>®</sup> CRRT

|   | HF/HD Kit | HF/HD Kit<br>pre- | HF/HD Kit<br>recirculation | HF/HD Kit<br>high volume | SCUF Kit |
|---|-----------|-------------------|----------------------------|--------------------------|----------|
|   |           | assembled         |                            |                          |          |
|   | 7210349   | 7210492           | 7210657                    | 7210635                  | 7210351  |
| Substitution/<br>dialysate inlet line<br>7210357  |           |                   |                            |                          |          |
|   | x         | X                 | X                          | -                        | -        |
| Substitution/<br>dialysate inlet line<br>7210636<br>As 7210357 with 4 bag<br>connectors     | -         | -                 | -                          | x                        | -        |
| Ultrafiltration/<br>dialysate outlet line<br>7210358  | X         | X                 | X                          | -                        | -        |
| Ultrafiltration/<br>dialysate outlet line<br>7210637<br>As 7210358 with 4 bag<br>connectors | -         | -                 | -                          | X                        | -        |

|                                 | HF/HD Kit | HF/HD Kit<br>pre-<br>assembled | HF/HD Kit<br>recirculation | HF/HD Kit<br>high volume | SCUF Kit |
|---------------------------------|-----------|--------------------------------|----------------------------|--------------------------|----------|
|                                 | 7210349   | 7210492                        | 7210657                    | 7210635                  | 7210351  |
| Ultrafiltration line<br>7210362 | -         | -                              | -                          | -                        | X        |
| Collecting bag<br>7210631       | x         | x                              | -                          | Х                        | x        |
| Collecting bag<br>7210298       | -         | _                              | x                          | -                        | -        |
| Connection line 7210008         | -         | -                              | x                          | -                        | -        |

# 14.2 Diapact<sup>®</sup> kits for plasma therapies



|                                   | PEX Kit | PAP Kit |                             | PEX Kit | PAP Kit |
|-----------------------------------|---------|---------|-----------------------------|---------|---------|
|                                   | 7210348 | 7210352 |                             | 7210348 | 7210352 |
| Plasma reinfusion line<br>7210364 |         | X       | Adsorber bypass<br>7210633  |         | X       |
| Plasmafilter adapter<br>7210497   | х       |         | Hansen connector<br>7210641 |         | x       |

## 14.3 Device accessories

| Name                                 | Article no.      |
|--------------------------------------|------------------|
| Filter holder                        | 7107426          |
| Cable to connect nurse call          | 8700160/1        |
| DCI cable<br>Cable for data transfer | 7702841          |
| Perfusor® Compact S                  | Country specific |
| Perfusor® fm                         | Country specific |

# 14.4 Options

| Name  | Article no. |
|---|-------------|
| Diapact® Perfusor interface (DPI)<br>Option to connect Perfusor® Compact S or Perfusor® fm  | 7102505     |
| Diapact <sup>®</sup> data interface (DDI)<br>Interface description to connect Diapact <sup>®</sup> CRRT to patient data management<br>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 <sup>®</sup> L 0.5              | 7061007          |
| Substitution solution                       |                  |
| Duosol® without potassium                   | Country specific |
| Duosol <sup>®</sup> with 2 mmol/l potassium | Country specific |
| Duosol <sup>®</sup> 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                       | Туре В, IEC 60601-1  |
| Device leakage current               | < 500 µA   |
| Patient leakage current              | < 100 µA   |
| Protection class                     | IP21<br>(Protection against foreign bodies > 12 mm and vertically falling drip<br>water)<br>DIN EN 60529 |
| Electrical ground                    | via optional cable   |
| Dimensions (W $\times$ H $\times$ 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 Technical specification

### 15.3 Recommended safe distances

Recommended safe distances in metres (m) between portable or mobile HF telecommunication devices and the Diapact<sup>®</sup> CRRT dialysis machine

The dialysis machine Diapact<sup>®</sup> CRRT is intended for use in ambient conditions with controlled highfrequency disturbance variables. The user can avoid electromagnetic disturbances by maintaining the distance between Diapact<sup>®</sup> 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<br>transmitter<br>(Watt) | Safe distance (d) depending on transmitting frequency |   |   |  |
|--|---|---|---|--|
|  | 150 kHz to 80 MHz<br>d = 1.2 $\sqrt{P}$               | 80 MHz to 800 MHz<br>d = 1.2 $\sqrt{P}$ | 800 MHz to 2.5 GHz<br>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<br>10 ÷ 300 ml/min in plasma therapies   |
| Tolerance  | < 10%  |
| Operating pressure range                                 | -220 ÷ +500 mmHg   |
| Protective system  | Mechanical reverse motion protection<br>Rotation detector, blood pump stopped state is checked after the first<br>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)<br>measurement              | Electronic pressure sensor with digital display  |
| Range  | -400 to +650 mmHg  |
| Tolerance  | ±10 mmHg   |
| Limits   | -200 to +100 mmHg<br>-100 to +100 mmHg in plasma therapies, adjustable   |
| Adjustable range   | -400 to +200 mmHg<br>-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.<br>Window limits can be overridden (expanded) by stopping the blood<br>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<br>0 to +200 mmHg in plasma therapies, adjustable   |
| Adjustable range   | 0 to +500 mmHg<br>0 to +650 mmHg in HF therapies   |
| Muting acoustic alarm                                    | 60 sec   |

| Description                                | Data  |
|--|---|
| Venous return pressure (PV)<br>measurement | Electronic pressure sensor with digital display   |
| Range                                      | -400 to +650 mmHg   |
| Tolerance                                  | ±10 mmHg  |
| Limits                                     | Blood pump stop, flow change:<br>-20 to +300 mmHg<br>-20 to +380 mmHg, absolute, expanded window<br>Running pumps:<br>0 to +300 mmHg<br>0 to +380 mmHg, absolute, expanded window<br>-40 to +60 mmHg<br>-40 to +140 mmHg in HF<br>relative to the actual pressure value stored after 10 sec from<br>reaching stabilised flows (closed window with adjustable<br>upper limit). This stored base value automatically follows the<br>pressure variation slowly (0.4 mmHg/min). |
| Adjustable range                           | 80 to 160 mmHg<br>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<br>pump<br>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<br>Summarized air bubbles 0 ÷ 10000 μl configurable<br>default 2000 μl   |
| Protective system                          | Ultrasound detector with double channel electronics and evaluation  |
| Protective system override time            | Cannot be overridden during therapy<br>Exclusion for 20 sec possible in <end of="" therapy=""> phase only for<br/>returning the blood (by following the safety procedure)</end>   |
| Protective system control                  | Start-up test during preparation phase<br>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,<br>digitally displayed flow, manual operating possible<br>Automatic pump calibration except PAP therapy |  |  |
| Flow range                      | $\begin{array}{llllllllllllllllllllllllllllllllllll$  |  |  |
| Tolerance                       | Continuous and intermittent therapies<br>< +4 % at 4 h<br>< +6 % at 72 h<br>Plasma therapies<br>PEX $< \pm 3 \%$<br>PAP $< \pm 10 \%$                                   |  |  |
| Pressure range                  | -220 to +500 mmHg   |  |  |
| Protective system               | Mechanical reverse motion protection<br>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<br>PAP -50 to +10 mmHg   |  |  |
| Adjustable range                | <b>PAP only</b> +50 to +400 mmHg  |  |  |
| Muting acoustic alarm           | 60 sec  |  |  |

| Description                     | Values   |  |  |
|---------------------------------|--|--|--|
| Plate warmer                    | Solution warming system based on thermal energy transfer between<br>the temperature controlled metal plate and the solution flowing<br>through a plastic meander bag   |  |  |
| Range                           | 0 to +50 °C plate temperature  |  |  |
| Tolerance                       | $\pm$ 0.1 K plate temperature (if the heating power does not reach 100 %   |  |  |
| Limits                          | Continuous and intermittent therapies<br>41°C for 10 sec<br>45°C for 1 sec<br>Plasma therapies<br>38°C for 10 sec<br>41°C for 1 sec  |  |  |
| Adjustable range                | Continuous and intermittent therapies<br>20 ÷ 40°C plate temperature<br>Plasma therapies<br>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                 | $\geq$ 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<br>Automatic calibration before starting therapy<br>Automatic, cyclic self-test during therapy<br>Recalibration during therapy in <end of="" therapy=""> function</end> |  |  |
| Filter outlet pressure (PD2)    | Electronic pressure transducer, digitally displayed pressure   |  |  |
| Range                           | -400 to +650 mmHg  |  |  |
| Tolerance                       | ± 10 mmHg  |  |  |
| Limits                          | CVVH-150 to +480 mmHgCVVHD, HD-300 to +480 mmHgSCUF, CVVHFD, HF, HFD-100 to +480 mmHgPEX-60 to +480 mmHgPAP-40 to +480 mmHgLower limit adjustable in each therapy  |  |  |
| Adjustable range                | -250 to +250 mmHg<br>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,<br>digitally displayed flow, manual operating possible<br>Exact pump speed regulated by the volumetric balance loop-back<br>control to the electronic weighing system |
| Range                           | Continuous and intermittent therapies<br>0 to 2000 ml/h (ultrafiltration))<br>SCUF<br>0/80 to 2000 ml/h (ultrafiltration)<br>PEX<br>-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<br>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:                      | $\pm 30$ g (balance) additional max. $\pm$ 20 g at each incorrect bag exchange  |
| Limits                          | ±120 g control system<br>±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.<br>±180 g during therapy<br>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<br>Cyclical load cell test   |

15.6

Interfaces

| Staff-call<br>connection                                       | max. 24V/1 A/24 VA (polarity as desired)   |
|--|--|
| Potential<br>equalisation line<br>connection<br>(to DIN 42801) |  |
| $\diamond$   |  |
| External pump connection                                       | Interface for the connection of the perfusor if the option Diapact® Perfusor Interface is used, information available on request   |
|  |  |
| Interface connection<br>with external<br>computer              | <ul> <li>Option DDI, information available on request</li> <li>Intended use of the interface with an external computer</li> <li>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.</li> <li>The intended use of the interface is: <ul> <li>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).</li> <li>Collection of therapy data during a therapy (data output) with the Diapact® CRRT Trend Viewer for service reasons.</li> <li>Sensor calibration, testing and system configuration (data input/output) in the technical support and maintenance (TSM) by the Diapact® CRRT Monitor.</li> </ul> </li> </ul> |
|  | Collection of therapy data   |
| !  | Therapy data collected using the Diapact <sup>®</sup> Data Interface (DDI) and a Patient Data Management System must be checked, verified and evaluated by the attending   |

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.

| Туре:             | No.:  |
|-------------------|-------|
| Year of Purchase: | User: |
|                   |       |

ОК

• •

Operating Hours: ...... h Inventory No.: .....

#### SW Version: .....

#### Manufacturer:

B. Braun Avitum AG

\_

Schwarzenberger Weg 73-79, 34212 Melsungen, Germany

| 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 Value   | ies)   |  |   |
| Pay at | tention to the starting procedure of the ma   | chine in order to check the main compo   | nents!   |   |
| 2.1    | Switch on machine:  | - Character sets that appear on the screen are che   | ecked, acknowledge with EQ key!                      |   |
|        |   | - No weight on weight system is checked, acknowledge with EQ key!  |  |   |
| 2.2    |   | - Select CVVH therapy  | f the laws   |   |
| 2.2    | LC Display:   | - Function, image display, alarm signal, function o  | r the keys   |   |
| 2.3    | Blood Pump:   | - Alarm cover, one-way bearing   |  |   |
| 2.4    | Fluid Pump:   | - Alarm cover, one-way bearing   |  |   |
| 2.0    | Veneus Tubing Clamp:  | - Alarm cover, one-way bearing   |  |   |
| 2.0    | venous rubing clamp.  |  |  |   |
| 2.6.1  |   | - Gap 1.4 mm (+ 0.1)   | [mm]   | U |
| 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 = <b>[mmHq]</b>                                    |   |
|        | (permissible tolerance $\pm 10$ mmHg)   |  | + 400 = <b>[mmHg]</b>                                |   |
| 29     | Venous Pressure PV·   | - Comparison measurement at  | 0 = [mmHa]   |   |
| 2.7    | (permissible tolerance +10 mmHa)  | companion model offer at   | + 400 - [mmHa]                                       |   |
|        |   |  | + 400 –  | _ |
| 2.10   | Pressure PD1:   | - Comparison measurement at  | 0 = [mmHg]   |   |
|        | (permissible tolerance ±10 mmHg)  |  | + 400 = <b>[mmHg]</b>                                |   |
| 2.11   | Pressure PD2/PSC:   | - Comparison measurement at  | 0 = <b>[mmHg]</b>                                    |   |
|        | (permissible tolerance $\pm 10$ mmHg)   |  | + 400 = [mmHq]                                       |   |
|        |   |  | - 400 = [mmHa]                                       |   |
|        |   |  |  |   |
| 2.12   | Power Fail Function:  | <ul> <li>Check function, duration of a constant audible al<br/>(Activate buzzer in power supply, i.e. switch on r</li> </ul> | arm > 1 minute<br>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 $\Omega$ :<br>(Machine incl. power supply cord)                           | <ul> <li>Potential equalization bolt</li> <li>Screw connection plate warmer</li> </ul>                                       | [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]   |   |

|   |  |  |                                |        | ОК |
|---|--|--|--------------------------------|--------|----|
| 4.  | Setting into Service (Monitor) According to Ope                      | rating Manual/Service Manual                       |                                |        |    |
| 4.1   | Temperature:   | - Comparison measurement at 37 <sup>O</sup> C (- 1 | 1.5 + 0.5)                     | [°C]   |    |
| 4.2<br>4.2.1  | Weight System:<br>Load cell comparison measurement (with reference w | eight) at:   | + g =                          | [g]    |    |
|   | (permissible tolerance $\pm$ 50 g)                                   | Difference bet                                     | tween Reference/Actual Value = | [g]    |    |
| 4.2.2   | Load cell comparison measurement (without referenc                   | e weight) at:                                      | 0 g =                          | [g]    |    |
|   | (permissible tolerance $\pm$ 50 g)                                   | Differe  | nce between Set/Actual Value = | [g]    |    |
| 4.3   | Pressures:   | - Comparison measurement at PA/PV (to              | lerance ± 20 mmHq)             | [mmHa] |    |
| 4.4   | Blood Leak Detector:   | - Test alarm function passed                       |                                |        |    |
| 4.5   | Safety Air Detector (SAD):   | - Test alarm function passed                       |                                |        |    |
| Applied Measurement Equipment:  |  | Temperature:                                       | * ID/Serial No.:               |        |    |
| 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                                   |                                |        |    |
|   |  | 5  |                                |        |    |

### Technical Safety Inspection with Preventive Maintenance

| Foi | Dia  | apact Cl                 | CRRT The technical safety according to the specoperating manual.<br>The preventive main specified check list and                 | The technical safety inspection must be performed and documented every <b>12 months</b> , according to the specified check list and with reference to the service manual and operating manual.<br>The preventive maintenance is recommended every <b>12 months</b> , according to the specified check list and with reference to the service manual and operating manual and |       |  |  |  |  |  |
|-----|--|--------------------------|--|--|-------|--|--|--|--|--|
|     |  |                          | should be documente  | should be documented.  |       |  |  |  |  |  |
|     |  |                          | Туре:  | No.:   |       |  |  |  |  |  |
|     |  |                          | Year of Purchase:  | User:  |       |  |  |  |  |  |
|     |  |                          | Operating Hours:<br>SW Version:  | Operating Hours: h Inventory No.:<br>SW Version:   |       |  |  |  |  |  |
| Ma  | nut  | facturer                 | r: B. Braun Avitum AG<br>Schwarzenberger We  | B. Braun Avitum AG<br>Schwarzenberger Weg 73-79, 34212 Melsungen, Germany  |       |  |  |  |  |  |
| Te  | chni   | cal Saf                  | fety Inspection  |  |       |  |  |  |  |  |
| Te  | chni   | cal Saf                  | fety Inspection with Preventive Maintenance  | cenance  |       |  |  |  |  |  |
|     |  | í                        |  |  |       |  |  |  |  |  |
| S   | <b>S</b> M S = Technical Safety Inspection Points; M = Preventive Maintenance Points |                          |  |  | es 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 present; no special incidents; type plate, labels and inscriptions | rollers are moveable; machine record book  | ם נ   |  |  |  |  |  |
|     | м  | 1.2                      | Clean interior space and exterior surfaces   |  | ם נ   |  |  |  |  |  |
| S   |  | 1.3                      | Check mains supply (power supply line, connectors and screw te   | rminals) 🗖 🗖   | ם נ   |  |  |  |  |  |
|     | М  | 1.4                      | Check level regulation pump LRP and replace all internal filters   |  | ם נ   |  |  |  |  |  |
|     | м  | 1.5                      | Fight seat of boards and connectors  |  | ם נ   |  |  |  |  |  |
|     | м  | 1.6                      | Check protection covers and protective conductor   |  |       |  |  |  |  |  |
|     | м  | 1.7                      | Tight seat of connectors, tubings and clamps   |  | ם נ   |  |  |  |  |  |
|     | м  | 1.8                      | Fan in power supply clean  |  | ם     |  |  |  |  |  |
|     | м  | 1.9                      | LC Display: Tight seat   |  | ם נ   |  |  |  |  |  |
|     | м  | 1.10                     | 1.10 Check parameters in Diapact CRRT Monitor Program:<br>1.10.1 SAD Alarm Volume (DPC=2000, DPS=3000)                           |  | _     |  |  |  |  |  |
|     |  | 1.10.1                   |  |  | 🗖     |  |  |  |  |  |
|     |  |                          |  |  |       |  |  |  |  |  |
|     |  | 1.10.2                   | Pumps: - Tube constants: (3 x 6: DPC/DPS=1764; 7 x 10: DF  | C/DPS=8052)  | 🗖     |  |  |  |  |  |
|     |  | 1.10.3                   | - Characteristics (Gain 4050; Offset: 80)  |  |       |  |  |  |  |  |
| L   |  | 1.10.4                   | UF (continuous/intermittent therapy: 25%; plasma therapy: 35%)   |  | 🗖     |  |  |  |  |  |
| S   |  | 1.11<br>1.11.1<br>1.11.2 | Function of the keys, display illumination<br>Image display, geometry  |  |       |  |  |  |  |  |

| 1.<br>1.1 | .11.2  | Alarm signal  |  |   |  |   |   |
|-----------|--|---|--|---|--|---|---|
| 1.1       | .12  | Blood Pump:   | - Alarm cover, one-way bearing   |   |  |   |   |
| 1.1       | .13  | Fluid Pump:   | - Alarm cover, one-way bearing   |   |  |   |   |
| 1.1       | .14  | Ultrafiltration Pump:   | - Alarm cover, one-way bearing   |   |  |   |   |
| 1.1       | .15  | Venous Tubing Clamp:  | - Function and moveability   |   |  |   |   |
| 1.1       | .15.1  | Gap 1.4 mm (+ 0.1)  |  |   |  |   |   |
| 1.1       | .16  | Arterial Pressure PA:   | - Comparison measurement at:   | - 400 = <b>[mmH</b>   |  | mHg]  |   |
|           |  | (permissible tolerance $\pm 10$ mmHg)   |  | 0 = [mmHg]  |  | mHg]  | '□  |
| 1.1       | .17  | Inlet Pressure PBE:   | - Comparison measurement at:   | ement at: + 400 =   |  | mHg]  |   |
|           |  | (permissible tolerance $\pm 10$ mmHg)   |  | 0 =   | 0 = [mmHg]   |   |   |
| 1.1       | .18  | Pressure PD1:   | - Comparison measurement at:   | + 400 =   | [mr  | mHg]  |   |
|           |  | (permissible tolerance $\pm 10$ mmHg)   |  | 0 =   | [mr  | mHg]  |   |
|           | 1.<br>1.<br>1.<br>1.<br>1.<br>1.<br>1.<br>1.<br>1.<br>1.<br>1.<br>1. | 1.11.2         1.11.3         1.12         1.13         1.14         1.15         1.15.1         1.16         1.17         1.18 | 1.11.2       Image display, geometry         1.11.3       Alarm signal         1.12       Blood Pump:         1.13       Fluid Pump:         1.14       Ultrafiltration Pump:         1.15       Venous Tubing Clamp:         1.15.1       Gap 1.4 mm (+ 0.1)         1.16       Arterial Pressure PA:<br>(permissible tolerance ±10 mmHg)         1.17       Inlet Pressure PBE:<br>(permissible tolerance ±10 mmHg)         1.18       Pressure PD1:<br>(permissible tolerance ±10 mmHg) | 1.1.1.2       Image display, geometry         1.11.3       Alarm signal         1.12       Blood Pump:       - Alarm cover, one-way bearing         1.13       Fluid Pump:       - Alarm cover, one-way bearing         1.14       Ultrafiltration Pump:       - Alarm cover, one-way bearing         1.15       Venous Tubing Clamp:       - Function and moveability         1.15.1       Gap 1.4 mm (+ 0.1)       - Comparison measurement at:         (permissible tolerance ±10 mmHg)       - Comparison measurement at:         1.17       Inlet Pressure PBE:       - Comparison measurement at:         (permissible tolerance ±10 mmHg)       - Comparison measurement at:         1.18       Pressure PD1:       - Comparison measurement at:         (permissible tolerance ±10 mmHg)       - Comparison measurement at: | 1.11.2       Image display, geometry         1.11.3       Alarm signal         1.12       Blood Pump:       - Alarm cover, one-way bearing         1.13       Fluid Pump:       - Alarm cover, one-way bearing         1.14       Ultrafiltration Pump:       - Alarm cover, one-way bearing         1.15       Venous Tubing Clamp:       - Function and moveability         1.15.1       Gap 1.4 mm (+ 0.1)       - Comparison measurement at:       - 400 =         1.16       Arterial Pressure PA:       - Comparison measurement at:       - 400 =         (permissible tolerance ±10 mmHg)       0 =       0 =         1.18       Pressure PD1:       - Comparison measurement at:       + 400 =         (permissible tolerance ±10 mmHg)       0 = | 1.11.2       Image display, geometry         1.11.3       Alarm signal         1.12       Blood Pump:         1.12       Blood Pump:         1.13       Fluid Pump:         1.14       Ultrafiltration Pump:         1.15       Venous Tubing Clamp:         1.16       Arterial Pressure PA:         (permissible tolerance ±10 mmHg)       - Comparison measurement at:         1.17       Inlet Pressure PBE:         (permissible tolerance ±10 mmHg)       0 = | 1.11.2       Image display, geometry       Image display, geometry         1.11.3       Alarm signal       Image display, geometry         1.11.3       Alarm signal       Image display, geometry         1.12       Blood Pump:       - Alarm cover, one-way bearing         1.13       Fluid Pump:       - Alarm cover, one-way bearing         1.14       Ultrafiltration Pump:       - Alarm cover, one-way bearing         1.15       Venous Tubing Clamp:       - Function and moveability       Image display, geometry         1.15       Venous Tubing Clamp:       - Function and moveability       Image display, geometry       Image display, geometry         1.15       Venous Tubing Clamp:       - Function and moveability       Image display, geometry       Image display, geometry         1.15       Gap 1.4 mm (+ 0.1)       Image display, geometry       Image display, geometry       Image display, geometry       Image display, geometry         1.16       Arterial Pressure PA:       - Comparison measurement at:       - 400 = |

| S   | Μ  | S = 1  | echnical Safety Inspection Points; M =  | = Preventive Maintenance Points  |                  | No   | Yes        | ОК |  |  |
|---|--|--|---|--|------------------|------|------------|----|--|--|
| s   |  | 1.19   | Pressure PD2/PSC:   | - Comparison measurement at:   | + 400 =          | [m   | mHg]       |    |  |  |
|   |  |  | (permissible tolerance ±10 mmHg)  |  | 0 =              | [m   | mHg]       |    |  |  |
| S   |  | 1.20   | Venous Pressure PV:   | - Comparison measurement at:   | + 400 =          | [m   | mHg]       |    |  |  |
|   |  |  | (permissible tolerance ±10 [mmHg])  |  | 0 =              | [m   | mHg]       |    |  |  |
| s   |  | 1.21   | Staff Call (Option):  | - Function or contact continuity passed  |                  |      |            |    |  |  |
| s   |  | 1.22   | Balance System  |  |                  |      | <b>I</b>   |    |  |  |
|   |  | 1.22.1   | Load cell comparison measurement (wit   | th reference weight) at: +   | g =              |      | <b>[g]</b> |    |  |  |
|   |  |  | (permissible tolerance ± 50 g)  | Difference between Reference   | /Actual Value =  |      | _ [g]      |    |  |  |
|   |  | 1.22.2   | Load cell comparison measurement (wit   | hout reference weight) at:   | 0 g =            |      | [g]        |    |  |  |
| _   |  | 1 2 2 2  | (permissible tolerance ± 50 g)  Difference between Set/Actual Value =   |  |                  | [g]  |            |    |  |  |
| 2   |  | 1.22.3   | Power Fail Function:  | <ul> <li>Check function, duration of a constant audible alarm &gt; 1 minute (activate<br/>buzzer in power supply, i.e. switch on machine and disconnect mains plug)</li> </ul> |                  |      |            |    |  |  |
|   |  | 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)   |  |                  |      |            |    |  |  |
| s   |  | 2.3  | Farth leakage current < 0.5 mA - During beat-up phase   |  |                  |      | [mA]       |    |  |  |
| s   |  | 2.4 Patient leakage current < 0.1 mA - Under normal conditions |   |  |                  | [mA] |            |    |  |  |
|   |  |  |   |  |                  |      |            |    |  |  |
|   |  | 3.   | Setting into Service According to Op  | erating 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  | 3 Saferty Air Detector (SAD):       - Test alarm function passed         4 Ultrafiltration       - Comparison measurement at 500 ml/h (±15) |  |                  |      |            |    |  |  |
| s   |  | 3.4  |   |  | 1 (±15) [m       |      | ml/h]      |    |  |  |
| S   |  | 3.5  | Blood Leak Detector (BLD):  | - Test alarm function passed   |                  |      |            |    |  |  |
| СН  | CHECK RESULTS: Defects were detected, which could endanger patients, users or third parties. |  |   |  |                  |      |            |    |  |  |
| Ар  | plie   | ed Acces   | sories/Disposables:   |  |                  |      |            |    |  |  |
| Ap  | plie   | ed Meas  | urement Equipment:  | Temperature:   | * ID/Serial No.: |      |            |    |  |  |
|   |  |  |   | Pressure:  | * ID/Serial No.: |      |            |    |  |  |
|   |  |  |   | Electrical Safety Check:   | * ID/Serial No.: |      |            |    |  |  |
|   |  |  |   | Reference Weight:  | * ID/Serial No.: |      |            |    |  |  |
| M.  | uct  | actions  | ha takan with rafaranaa ta maintananaa  | * If applicable  |                  |      |            |    |  |  |
| No  | usi.<br>hte  | next an  | pointment.  |  |                  |      |            |    |  |  |
| The technical safety inspection or technical safety<br>inspection with preventive maintenance was<br>performed correctly. |  |  | safety inspection or technical safety<br>th preventive maintenance was  | Name of Service Technician:  | Name of Company: |      |            |    |  |  |
|   |  |  | rrectly.  |  |                  |      |            |    |  |  |
|   |  |  |   | Date / Signature   |                  |      |            |    |  |  |
| <b>User:</b><br>Date / Signature  |  |  |   | User:  |                  |      |            |    |  |  |
|   |  |  |   | Date / Signature   |                  |      |            |    |  |  |