multiFiltrate
Instructions for Use

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FRESENIUS
MEDICAL CARE

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2 Important information

2.1 How to use the Instructions for Use

Device designation

The multiFiltrate will be identified with "device" hereinafter.

Identification

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

Footer

The footer contains the following information:
– Company name
– Device type
– The English abbreviation for the document type and the international abbreviation for the document language, for example, IFU-EN refers to Instructions for Use in English.
– The edition identification, for example, 4A-2013 refers to edition 4A released in 2013
– The page identification, for example, 1-3 refers to chapter 1, page 3.

Organisation of the chapters

To facilitate the use of documents from Fresenius Medical Care, the organisation of the chapters has been standardised in all manuals. There may therefore be chapters within this document without any content. Chapters without content are identified.

Styles used in the document

The following text styles may be used in the document:

Style	Description
Keys and buttons	Keys and buttons on the device are shown in **bold type**. Example: **[START/RESET]** key.
➢ Instructions	Instructions are indicated by an arrow ➢. Instructions must be followed. Example: ➢ Insert the heparin syringe according to the instructions.

Illustrations

The illustrations used in the documents may differ from the original if this does not have any influence on the function.

Importance of the instructions

These Instructions for Use are part of the accompanying documents and thus an integral part of the device. They contain any information necessary for the use of the device.

The Instructions for Use must be carefully studied before attempting to operate the device.

Before the responsible organisation can begin to operate the device, the individual responsible for the operation must have been instructed by the manufacturer on how to use the device and must be thoroughly familiar with the contents of the Instructions for Use.

The device may only be operated by individuals certificated to have been instructed on the proper operation and handling of the device.

Changes

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

Reproduction

2.2 Significance of warnings

Warning

Advises the operator that failure to observe this information can result in personal injury.

2.3 Significance of notes

Note

Advises the operator that failure to observe this information can result in the following:
- Damage to the device.
- Required functions will not be executed at all or will be executed incorrectly.

2.4 Significance of tips

Tip

Information providing useful tips for easy handling.

2.5 Brief description

The device enables the performance of extracorporeal blood purification without additional equipment. Depending on the procedure used for the extracorporeal blood circuit, it operates and monitors the dialysate and substituate circuit, plus the plasma circuit.

To operate the device, five keys and a combined rotary selector / key are located on the monitor. The treatment parameters are entered using soft keys displayed on a screen, in combination with the rotary selector. While treatment is in progress, the treatment parameters are displayed.

Roller pumps are used to convey the filtrate, dialysate, substituate, and plasma, depending on the procedure. Balancing is performed gravimetrically using scales. Integrated heating elements can be used to heat the dialysate, substituate, and plasma.

In the extracorporeal blood circuit, the blood is passed through a filter or an adsorber. The blood can be continuously anticoagulated. An air bubble detector prevents the infusion of air to the patient. Any dangerous loss of blood is prevented by a blood leak detector and by monitoring of the return pressure. The inflow pressure monitoring unit detects excessive suction at the cannula or at a catheter.

The device is classified as Class II b (MDD) equipment.

2.6 Intended use

2.6.1 Intended purpose

The device is designed for the performance of extracorporeal blood purification (dialysis and apheresis) in clinics and in the area of intensive care medicine in particular.

Consumables with a service life adapted to the duration of therapy have to be used for the treatment; see specification in the operator documentation of the consumables.

2.6.2 Specification of use

The device has been specified by the manufacturer for the following purposes:

– The treatment of patients, independently of age and weight, while taking into account the device's specified technical data and the disposables used (e.g., delivery rates, fill volumes).
– Operation in suitable rooms in professional health care facilities. Normative and local regulations must be observed.

2.6.3 Treatment modes and fields of application

SCUF	– Diuretic resistant fluid retention, especially in the event of cardiac insufficiency or pulmonary oedema.
Pre CVVH, Post CVVH, Pre-Post CVVH, CVVHD, Pre CVVHDF, and Post CVVHDF	– Acute renal insufficiency. – Removal of toxic metabolic products. – Treatment of life-threatening electrolyte imbalance, e.g., hyperkalaemia. – Correction of the acid-base status, e.g., metabolic acidosis. – Diuretic resistant fluid retention, especially in the event of cardiac insufficiency or pulmonary oedema.
Haemoperfusion	– Removal of toxic substances, also protein-bound substances by adsorption.
Plasma separation	– Removal of plasma, e.g., for removing pathological immunoglobulins, for removing protein-bound toxins or for administering sufficient quantities of physiological proteins contained in donor plasma.

2.6.4 Anticoagulation of the extracorporeal blood circuit

Most patients need an anticoagulant to prevent their blood from coagulating in the extracorporeal blood circuit. This can be performed systemically, i.e., also in the patient's body, or regionally limited to the extracorporeal blood circuit.

Systemic anticoagulation

The integrated heparin pump can be used for the continuous anticoagulation of the blood.

Regional anticoagulation with citrate

Warning

Any treatment in connection with citrate anticoagulation may only be performed in intensive care units or under similarly close monitoring.

The Ci-Ca function integrated in the system permits regional anticoagulation in the extracorporeal blood circuit with citrate. Citrate anticoagulation can be used on most patients with CRRT indication. Exceptions (see chapter 2.6.7 on page 2-6).
This function is intended to be used for adults and can be especially efficient in the following cases:

– Patients with a bleeding risk, that is, patients on whom systemic anticoagulation cannot be used at all or only to a degree that is inadequate for continuous renal replacement therapy.

– Patients with whom the haemofilter rapidly and repeatedly becomes clogged when different anticoagulation methods are used.

2.6.5 Paediatric CVVH and CVVHD treatment modes

The dose of the renal replacement therapy for a paediatric treatment can be derived from the recommendations for the treatment of adults, for example, by scaling in accordance with the body surface.

Chadha et al., for example, used a CRRT dose of 2 l/h / 1.73 m² body surface (Pediatric Nephrol 2002, 17:819-824), following the recommendation of Ronco et al. (Lancet 2000, 356:26-30) to use a dose of at least 2 l/h for a typical adult with a body weight of 70 kg.

According to the prescribed procedure, the minimum dose of 100 ml/h HF solution / dialysate, which can be set in the paediatric mode of the device, corresponds to a minimum body surface of the patient of 0.087 m², which is considerably less than the typical body weight of an average newborn and which usually also permits reasonable treatments for premature infants.

According to the prescribed procedure, the maximum dose of 1500 ml/h HF solution / dialysate, which can be set in the paediatric mode of the device, corresponds to a maximum body surface of the patient of 1.04 m², which matches approximately a body weight of 30 kg.

However, it is already possible to change from the paediatric mode of the device to one of the treatment modes for adults when treating smaller patients. According to the prescribed procedure, the minimum dose of 600 ml/h HF solution / dialysate, which can be set with CVVH or CVVHD in the adult's treatment modes, corresponds to a minimum body surface of the patient of 0.52 m², which matches approximately a body weight of 11 kg.

2.6.6 Side effects

Extracorporeal treatments occasionally cause hypotension, nausea, vomiting, and cramps in some patients. Pay particular attention to the package inserts enclosed with the solutions, filters, etc., used.

During extracorporeal treatments, particularly during CRRT treatments, the concentrations of different electrolytes (sodium, potassium, calcium, magnesium, phosphate) can become too high or too low and acid-base disorders can occur. Such situations can be prevented and treated by selecting adequate CRRT solutions and by an additional substitution of electrolytes, if necessary.

Note

Electrolyte imbalances (especially hypokalaemia, hypophosphataemia) are more likely to occur with high CRRT doses, as an unbalanced composition of the CRRT solution can have a more pronounced effect.

Regional anticoagulation with citrate

- Metabolic acid-base disorders (acidosis, alkalosis)
- Systemic hypocalcemia or hypercalcemia
- Hypomagnesaemia
- Hypernatraemia
- Side effects caused by a disordered citrate metabolism

For more detailed information on situations where these risks might occur and on the options of reducing the occurrence of these risks, please refer to (see chapter 7.3.2 on page 7-17).

2.6.7 Contraindications

Systemic anticoagulation

Systemic anticoagulation is often contraindicated for bleeding patients or patients at a high risk of bleeding. Here, measures should be taken within the treatment regimen which permit a renal replacement treatment with little or no anticoagulation. A regional anticoagulation with citrate can be used, if required.

Regional anticoagulation with citrate

– Disordered citrate metabolism

An established disordered citrate metabolism is an absolute contraindication. In case of a disordered citrate metabolism, a CRRT treatment should be checked with a bicarbonate-containing HF solution (e.g., multiBic). Here, anticoagulation of the extracorporeal blood circuit may not be necessary under certain circumstances.

If, for example, a disordered citrate metabolism is suspected because of a restricted liver function, citrate anticoagulation can still be started, however under particularly intensive monitoring. In this case, the signs of systemic citrate accumulation must be observed closely. This applies especially to a decrease in the systemic ionised calcium, high calcium substitution requirements for stabilising the ionised calcium, and to an increase in systemic total calcium (see chapter 7.3.2.5 on page 7-27).

– Poisoning events that severely impact oxidative metabolism

With regional citrate anticoagulation, a quantity of citrate is unavoidably infused systemically and must be metabolised by the patient by consuming oxygen. Poisoning events that adversely influence this oxidative metabolism therefore present a contraindication for citrate anticoagulation. Evidence suggests that this is the case for poisoning with paracetamol and metformin.

– Hypocalcaemia

Any hypocalcemia already existing before the beginning of the treatment should in general be balanced by calcium substitution, for example, provided there is no different clinical indication.

Note

Any treatment in connection with citrate anticoagulation may only be performed in intensive care units or under similarly close medical monitoring.

2.6.8 Interaction with other systems

The use of tube roller pumps may lead to minimal electrostatic discharge into the tubing system due to friction on the pump segment. As the charge is very low, these discharges do not represent a direct hazard to patients or operators. If ECG units are used at the same time, these discharges may, in rare cases, cause periodic interferences of the ECG signal.

In order to minimise this interference, it is advisable to observe the recommendations of the ECG device manufacturer, e.g.:

– Correct position of the electrodes
– Use of specific electrodes with low contact impedance

2.6.9 Restrictions

Regional anticoagulation with citrate

Citrate anticoagulation is available for adult patients for CVVHD and CVVHDF.

2.6.10 Risks of regional anticoagulation

If citrate anticoagulation is used in CRRT treatments, attention must be paid to risks regarding the acid-base status and the electrolyte concentrations. Further information (see chapter 7.3.2 on page 7-17).

Interrupting the treatment

Any interruption of the treatment (by temporarily disconnecting the patient from the extracorporeal circuit) may give rise to additional risks. This applies particularly if the blood is not retransfused to the patient before the treatment is interrupted.

Retransfusion of the recirculated blood causes the risk of a high volume of citrate being infused to the patient within a short time period. This might, in particular, result in systemic hypocalcaemia. This risk is especially high if you failed to deactivate balancing during the entire recirculation phase.

2.6.11 Target group

The device may only be installed, operated, and used by individuals with the appropriate training, knowledge, and experience and for whom proof of instruction can be shown.

2.7 To be observed when working on the device

Warning

Start-up, extensions, adjustments, calibrations, maintenance procedures, modifications, or repairs must only be carried out by the manufacturer or persons authorised by the manufacturer.

Further information on installation (see chapter 9 on page 9-1).

Further information on the Technical Safety Checks and maintenance procedures (see chapter 11 on page 11-1).

Use only original spare parts.
For identifying and ordering spare parts, test equipment, and tools, always use the electronic spare parts catalog.

Transport and storage (see chapter 10 on page 10-1).

2.8 Expected service life

If the Technical Safety Checks are performed to the full extent specified and at the prescribed intervals, the safe operation of the device in the time between these procedures is guaranteed.
In addition, the manufacturer recommends to perform maintenance procedures in the same time interval to avoid device malfunction due to wear and tear.
With each Technical Safety Check, the "expected service life" according to IEC 60601-1 will therefore be prolonged until the next prescribed Technical Safety Check.

2.9 Duties of the responsible organisation

Requirements

The responsible organisaion must ensure that the following requirements are fulfilled:
- Compliance with the national or local regulations concerning the installation, operation, use, and maintenance of the device.
- Compliance with the accident prevention regulations.
- Correct and safe condition of the device.
- Permanent availability of the Instructions for Use.

Training and instruction

Before the responsible organisation can begin to operate the device, the individual responsible for the operation must have been instructed by the manufacturer on how to use the device and must be thoroughly familiar with the contents of the Instructions for Use.
The device may only be operated by individuals certificated to have been instructed on the proper operation and handling of the device.

The manufacturer offers training on this device.
The local service support organisation is available if you have further questions (see chapter 2.13 on page 2-16).

To enhance treatment quality and patient safety, the manufacturer recommends following IEC/TR 62653 "Guideline for safe operation of medical devices used for hemodialysis treatment". The guideline describes the requirements for using hemodialysis systems safely and for their intended purpose.

2.10 Operator responsibility

The addresses given herein must be used to notify the manufacturer of any unexpected operation behavior or other incidents (see chapter 2.13 on page 2-16).

Warning

Risk of injury due to device defect

If the device has the following defects, the measures given below must be taken.

Defects on the device:
– Mechanical damage
– Defective power supply connection line
– Other defects
– The device does not respond as expected
– Deterioration in the performance characteristics

Measures:

➢ An ongoing therapy must be terminated using a reinfusion. If necessary, perform reinfusion manually (see chapter 5.15 on page 5-19).

➢ The device must be taken out of service.

➢ Inform the responsible organisation or service support without delay.

The following must be observed when entering parameters:
– The parameters entered must be verified by the operator, i.e., the operator must check that the values entered are correct.
– If this check reveals a deviation between the required parameters and the parameters displayed on the device, the setting must be corrected before activating the function.
– The actual values displayed must be compared with the prescribed target values.

The device may only be operated under the operating conditions specified by the manufacturer.

2.11 Disclaimer of liability

Warning

The device has been approved for use with specific consumables and accessories (see chapter 8.1 on page 8-2).
If the responsible organisation wishes to use consumables and accessories other than those specified here, it must first check whether they are suitable by obtaining relevant information from the manufacturer, for example.
The applicable legal regulations must be complied with.

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

2.12 Warnings

2.12.1 Warnings relating to hygiene

Warning

Aseptic techniques
Use aseptic techniques for all blood-side connections and all connections in the area where sterile solutions are to be used.

2.12.2 Warnings related to therapy

Warning

Risk of cross-contamination if tubing systems without hydrophobic filters are used

➢ Only use tubing systems with hydrophobic filters in the pressure lines.

Warning

Risk of cross-contamination in the event of an incorrect response to a wet or defective hydrophobic filter

➢ Never force back any fluid with a syringe **(risk of damaging the hydrophobic filter)**.

➢ Close off the tube with the wetted / defective hydrophobic filter.

➢ Replace the relevant tubing system. In the case of a pressure line with a wet hydrophobic filter, use a replacement pressure line (accessory available from manufacturer).

If you cannot exclude the possibility that the device may have become contaminated:

➢ Take the device out of service after completing treatment.

➢ Have the device tested for contamination by service support.

If the device is contaminated, all affected parts must be disinfected or replaced by service support.

Warning

Before starting a treatment, check the following:

– All the connections of the tubing system are securely connected.
– There are no apparent leaks in the tubing system, either during or after filling (priming).
– If leaks are detected, tighten the relevant connections as needed. If necessary, replace the entire tubing system.
– The absence of air, kinks, tensions, and twists in the tubing system and the correct position of all fluid levels.

Warning

When working on the tubing system during a treatment, observe the following:

If you need to move any part of the tubing system out of position, make sure the correct layout of the entire tubing system is restored before continuing treatment, paying special attention to the correct placement of the positioners.

Warning

During the treatment, check the following at appropriate intervals:

– The condition of the patient.
– The function of the device and the extracorporeal blood circuit.
  To protect the patient against dangerous extraneous blood loss, a venous pressure monitoring system is used as a safety system for the extracorporeal blood circuit.
  However, the pressure monitoring system cannot detect extraneous blood loss in all cases. In this respect, a dislocation of the venous cannula or the occurrence of a small leak in the overpressure area of the extracorporeal blood circuit must be considered as being particularly critical.
  As a result, the extracorporeal circuit, particularly all of the tubing system connections and the venous access point, must be checked for leaks at appropriate intervals during the treatment.
– The tubing system, watching out for air ingress or possible loose connections. Particularly at the connections downstream of the air detector, negative pressure can permit air to enter into the extracorporeal blood circuit. This can be a problem for single-needle applications or when using central venous catheters.
– The fluid level of the venous bubble catcher. Correct the fluid level if necessary (target level: approx. 1 cm under the upper edge of the cap).
– The tubing system is inserted without kinks, tension, or twisting.
– Any leakages in the filtrate, substituate, and dialysate circuit.
– Any discolouration in the filtrate bag caused by blood loss.

Warning

Risk of injury due to damaged tubing systems

Risk of infection

➢ Install the tubing systems in such a way that they cannot be damaged by objects with sharp edges or pets.

2.12.3 Warnings relating to the system

Warning

Risk of injury due to device defect

If the device has the following defects, the measures given below must be taken.

Defects on the device:
– Mechanical damage
– Defective power supply connection line
– Other defects
– The device does not respond as expected
– Deterioration in the performance characteristics

Measures:

➢ An ongoing therapy must be terminated.

➢ The device must be taken out of service.

➢ Inform the responsible organisation or service support without delay.

Warning

Risk of injury if device tilts

Risk of tilting when pushing the device or leaning against it

If lateral force is exerted, this may result in tilting or slipping of the device.

➢ Observe the information on relocation and transport.

Warning

IV pole
Danger in case of excessive load (respect the maximum load)

If the load on the IV pole is too high, the device may tilt.

Ensure that the maximum allowed load on the IV pole of 6 kg is not exceeded.

2.12.4 Electrical warnings

Warning

The "type of protection against electric shock" for this device is "Protection class I". To avoid the risk of electric shock, this device may only be connected to a power supply network with a protective earth conductor.
It must be taken into consideration that, in many countries, specific regulations of the national authorities are in force.

Warning

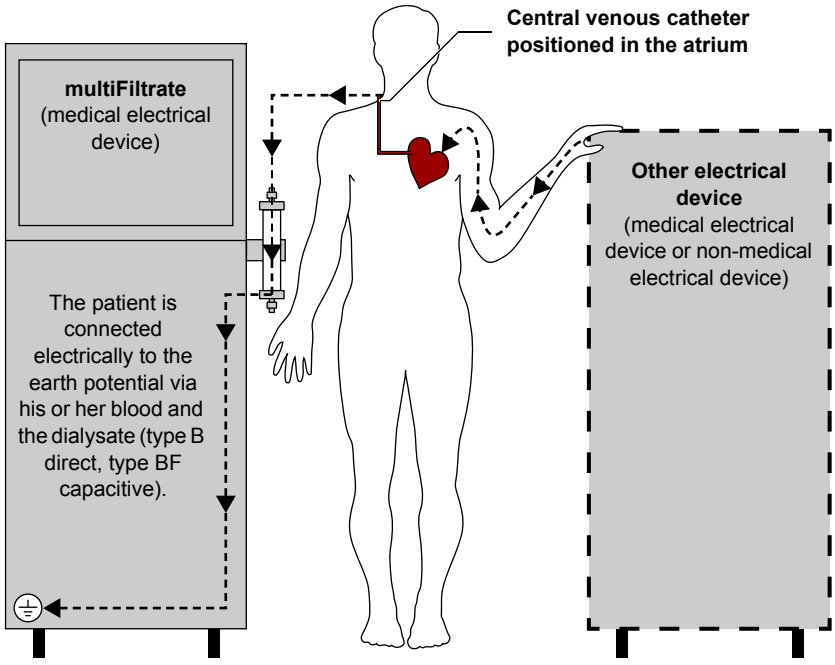
Danger to life due to electric shock

If treatments are carried out using central venous catheters positioned in the atrium, please observe the following points:

➢ Connect the device (multiFiltrate) to the equipotential bonding of the installation.

➢ Remove all other non-medical electrical devices and medical electrical devices with a touch current or patient leakage current greater than the corresponding alarm limits for type CF applied parts from the patient environment (1.5 m in all directions).

The touch current or the patient leakage current from another non-medical electrical device or medical electrical device in the patient environment can flow to the earth via the central venous catheter and via the type B or BF applied part of the device (multiFiltrate).



The alarm limits of the patient leakage current for type CF applied parts are as follows:
– 10 µA AC / DC (normal case, error-free)
– 50 µA AC / DC (the first time an error occurs)

Please address any queries to the local service support organisation.

2.12.5 Warnings relating to consumables and accessories

Warning

Consumables must be discarded after the treatment in compliance with the regulations for the disposal of potentially contaminated materials.

2.13 Addresses

Manufacturer

Fresenius Medical Care AG & Co. KGaA
61346 Bad Homburg
Germany
Phone: +49 6172 609-0
www.fmc-ag.com

International service support

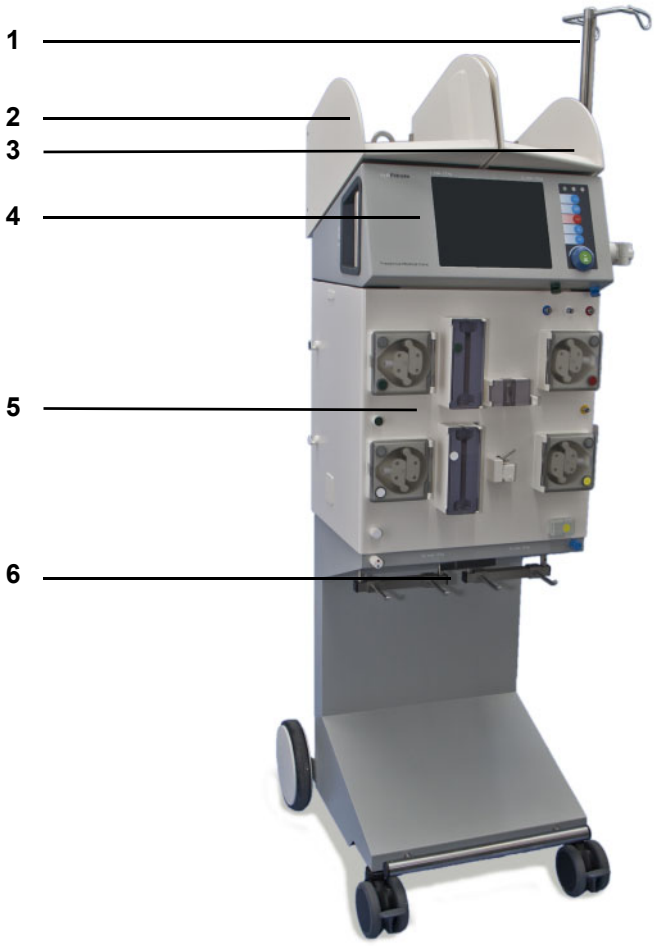
Fresenius Medical Care
Deutschland GmbH
Service Support International
Hafenstrasse 9
97424 Schweinfurt
Germany
Phone: +49 9721 678-333 (hotline)
Fax: +49 9721 678-130

Local service support

3 Design

3.1 Views of the device

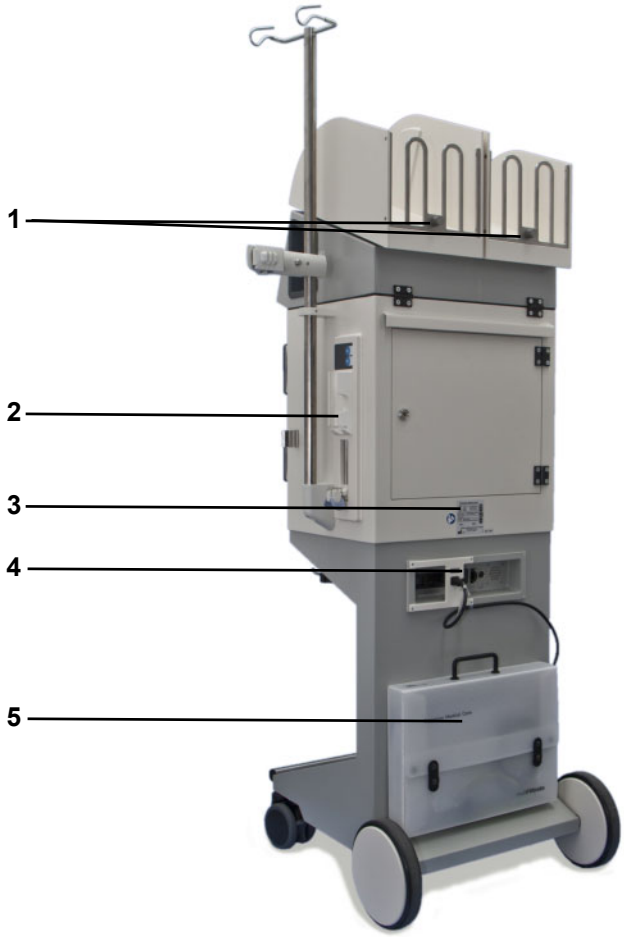
3.1.1 Front view



Legend

1 IV pole
2 Scale 1
3 Scale 2
4 Monitor
5 Extracorporeal blood circuit module
6 Scales 3 and 4

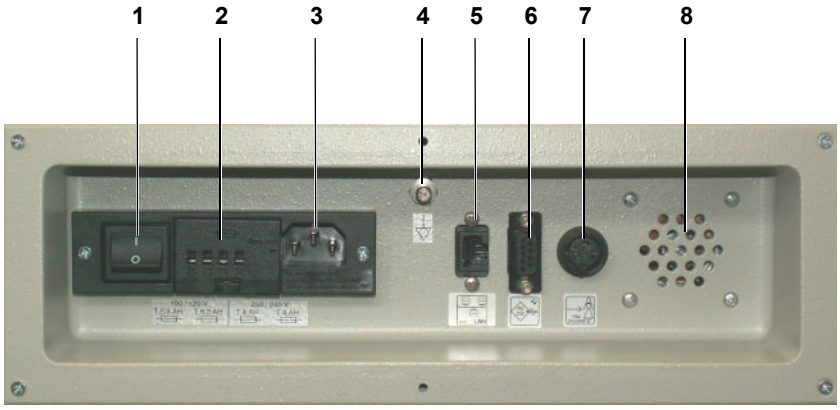
3.1.2 Rear view



Legend

1 Tube holders
2 Heparin pump
3 Identification label
4 Connector strip
5 Pocket for Instructions for Use

3.1.2.1 Connector strip

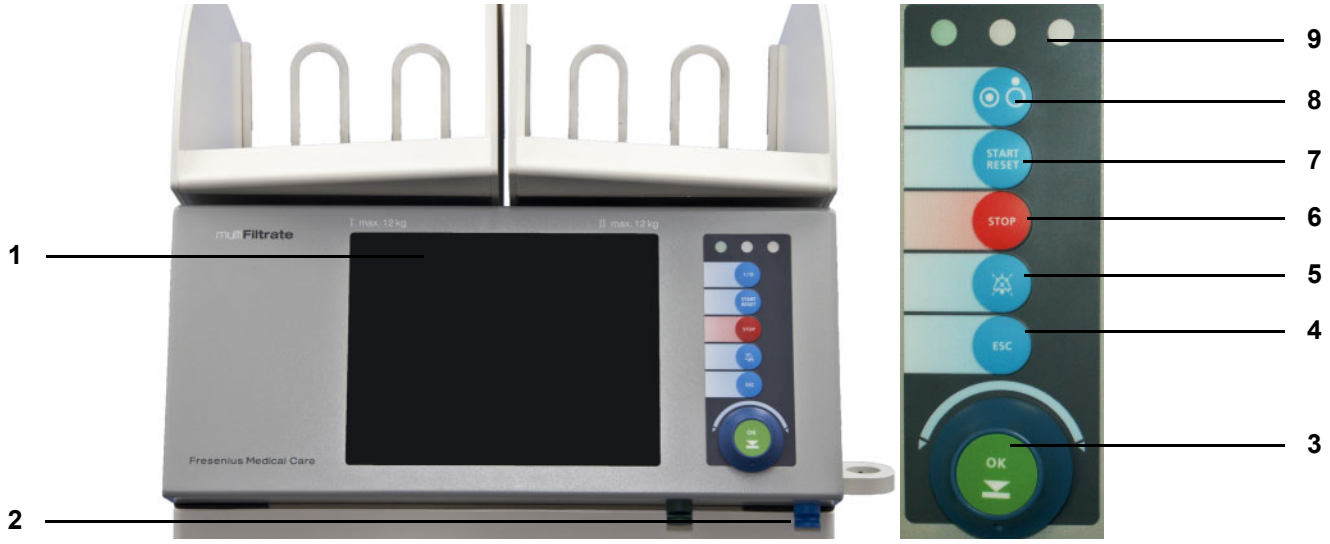


Legend

1 Power switch
2 Line voltage selector
3 Power supply connection
4 Equipotential bonding
5 10-Base-T Ethernet socket (LAN) (option)
6 RS 232, SUB-D, 9-pin
7 Alarm output
8 Loudspeaker

3.2 Controls and indicators

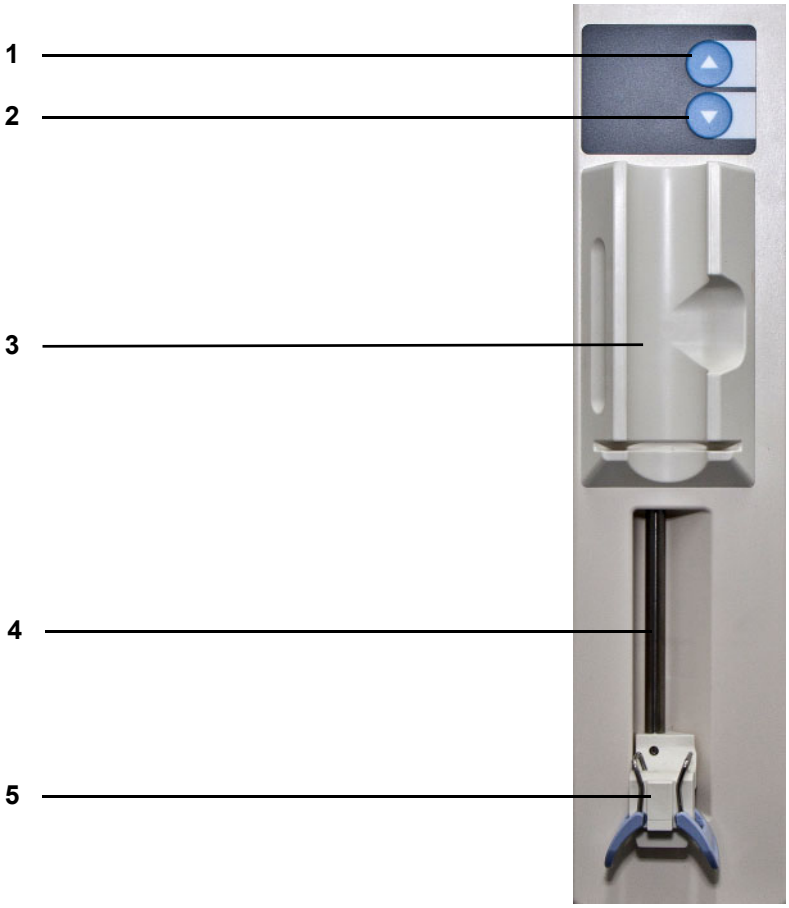
3.2.1 Monitor



Legend

1 Screen
2 Tube holders
3 Rotary selector and **[OK]** key
4 **[ESC]** key
5 **[Mute]** key
6 **[STOP]** key
7 **[START/RESET]** key
8 **[On/Off]** key
9 Status indicator
Green LED (operation)
Yellow LED (warning / preparation)
Red LED (alarm)

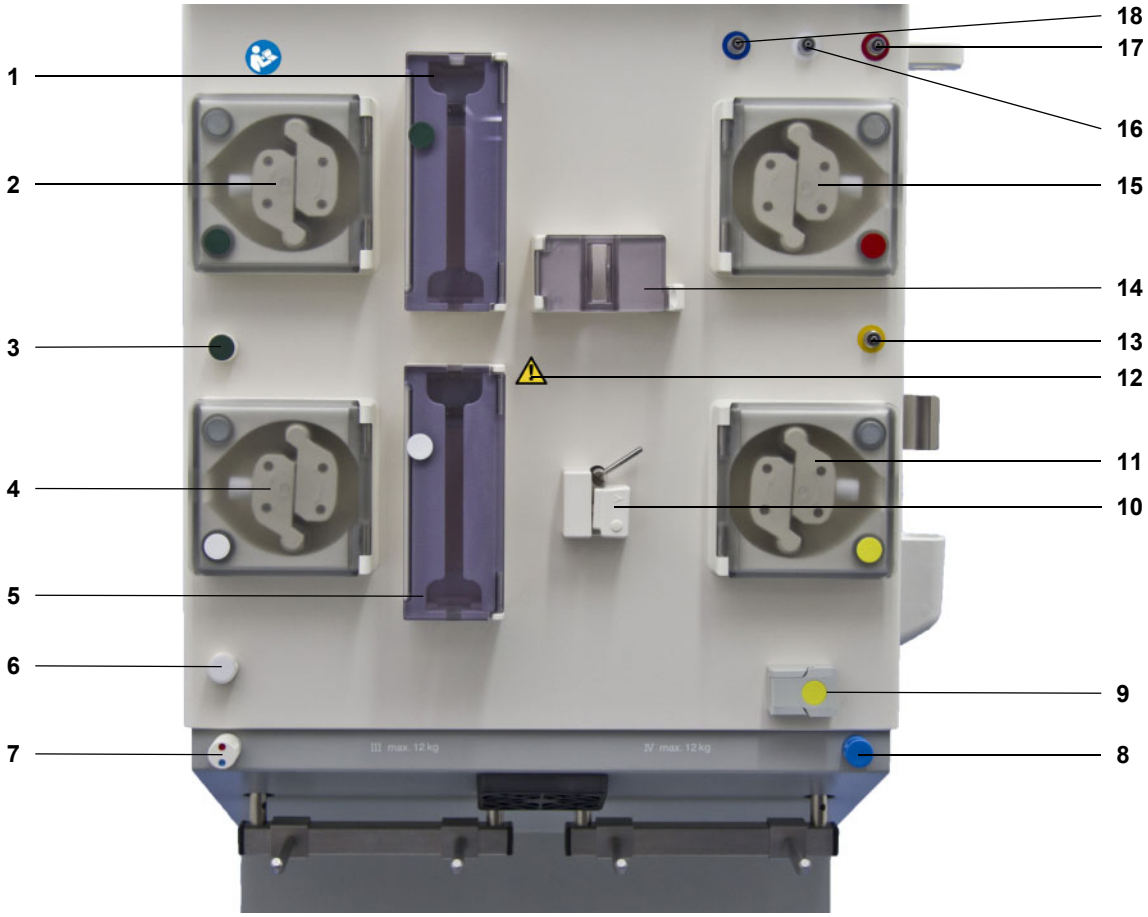
3.2.2 Heparin pump



Legend

1 The ▲ key moves the slide carriage up as long as the key is pressed.
2 The ▼ key moves the slide carriage automatically down. Pressing this key again will stop the slide carriage.
3 Syringe holder
4 Slide carriage
5 Grip handle

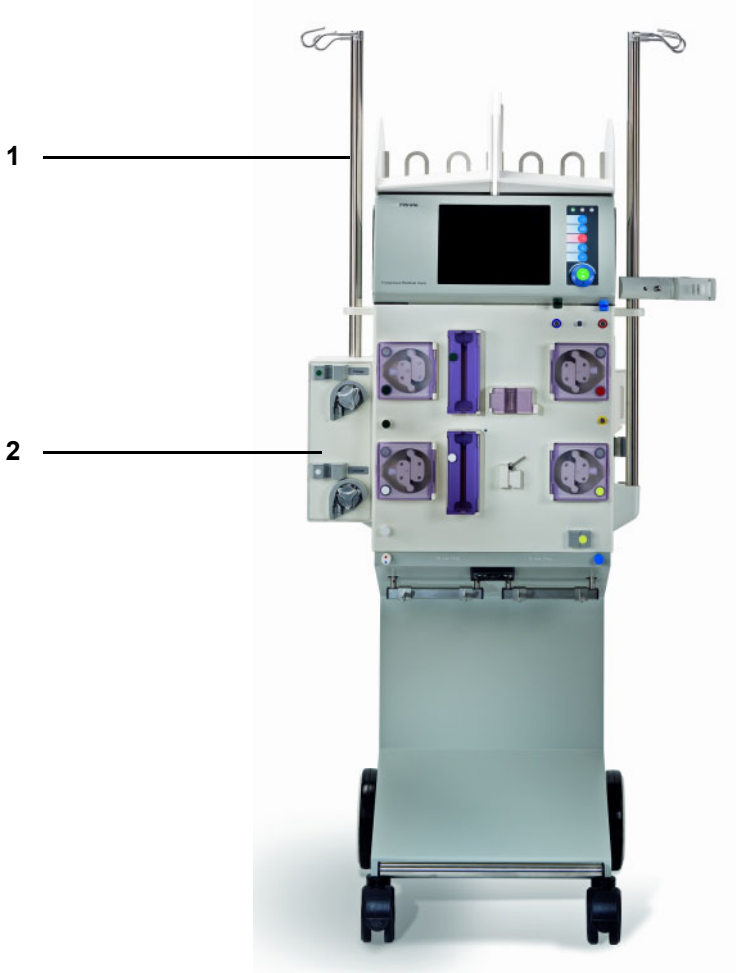
3.2.3 Extracorporeal blood circuit module



Legend

1 Dialysate heater (green dot)
2 Dialysate pump (green dot)
3 Tube holder
4 Substituate pump (white dot)
5 Substituate heater (white dot)
6 Tube holder
7 Tube holder
8 Tube holder
9 Blood leak detector
10 Venous tube clamp and optical detector
11 Filtrate pump (yellow dot)
12 Warning label: Protection against the effects of defibrillator discharge is only provided when using appropriate tubing systems (see chapter 8.1.1 on page 8-2)
13 Filtrate pressure port (yellow)
14 Air detector
15 Blood pump (red dot)
16 Pressure port before filter (white)
17 Arterial pressure port (red)
18 Venous pressure port (blue)

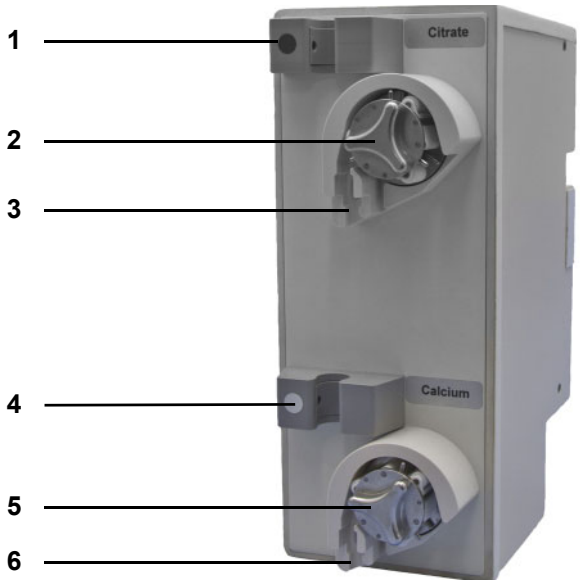
3.2.4 multiFiltrate with Ci-Ca module (option)



Legend

1 Second IV pole with connector in the IV pole bearing
2 Ci-Ca module

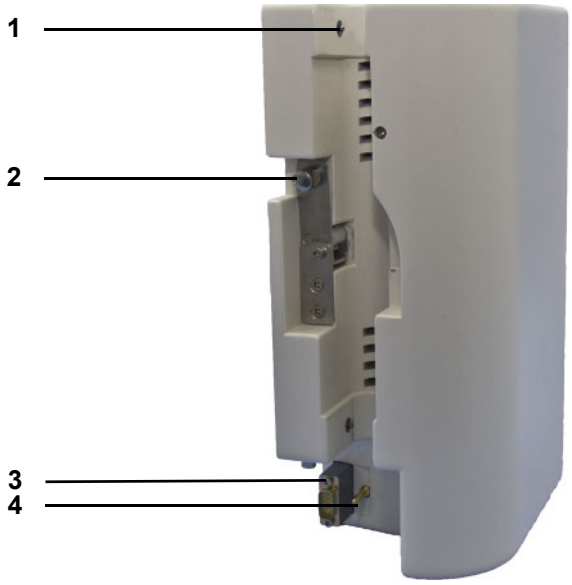
3.2.4.1 Ci-Ca module front view



Legend

1 Citrate drop counter
2 Citrate pump
3 Citrate insertion switch
4 Calcium drop counter
5 Calcium pump
6 Calcium insertion switch

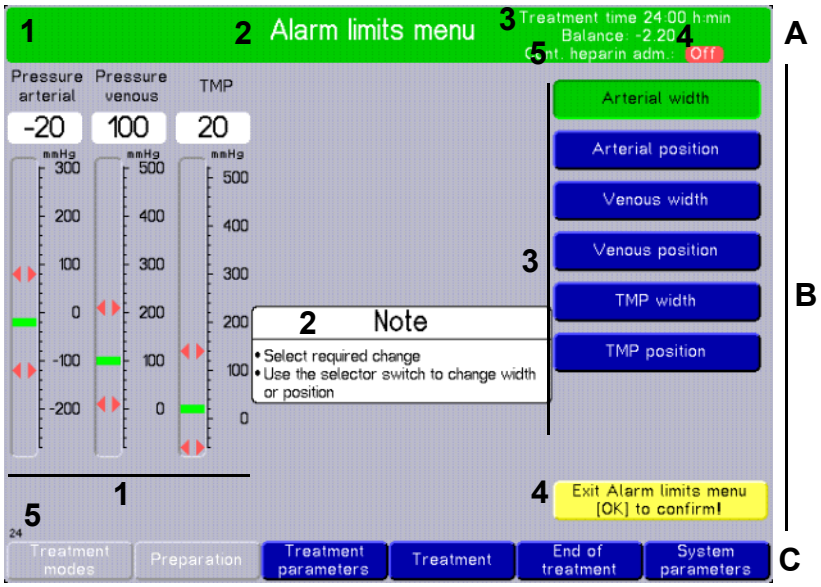
3.2.4.2 Ci-Ca module rear view



Legend

1 Holder for IV pole
2 Securing lever with pressure roll
3 Voltage supply and signal connection to the multiFiltrate
4 Earthing contact

3.3 User interface



Legend

A **Status bar**
Can have the following colours:
Blue: in preparation
Green: during treatment
Magenta: end of treatment
Grey: system parameters and service menu

1 Treatment mode
2 The current menu
3 The remaining prime and rinse volume or the treatment time
4 The current balance or balancing switched off
5 The current anticoagulant or anticoagulant switched off

B **Menu field**
1 Pressure display
2 Notes (white), warnings (yellow), alarms (red), and pressure graphs
3 Parameter fields
4 Confirmation field
5 Screen identification number

C **Menu bar**
Shows the available menus.
The currently selected menu is displayed with black characters and green background.

4 Operation

Note

The screens shown in the Instructions for Use may differ from those displayed on the device.

The values shown in the treatment screenshots are for illustrative purposes only. All treatment parameters must be entered as specified by the physician.

The device has to be operated according to the instructions on the screen.

4.1 Application principles

- **Applicable to devices with 10-Base-T Ethernet connection (LAN)**

Warning

The operator must never simultaneously touch the patient and the contact surface of the Ethernet socket or the contacts of the Ethernet data cable.

- **Applicable to all devices**

With regard to the application principles for haemodialysis systems, the following precautions have to be observed:

Warning

Backfiltration
When using Ultraflux filters and selecting low UF rates there is a possibility of local backfiltration.
Backfiltration depends on:
– The type of filter.
– The different pressure conditions on the dialysate and the blood side.
– The viscosity of the blood.

Warning

Aseptic techniques
Use aseptic techniques for all blood-side connections and all connections in the area where sterile solutions are to be used.

Warning

Risk of cross-contamination if tubing systems without hydrophobic filters are used

➢ Only use tubing systems with hydrophobic filters in the pressure lines.

Warning

Risk of cross-contamination in the event of an incorrect response to a wet or defective hydrophobic filter

➢ Never force back any fluid with a syringe **(risk of damaging the hydrophobic filter)**.

➢ Close off the tube with the wetted / defective hydrophobic filter.

➢ Replace the relevant tubing system. In the case of a pressure line with a wet hydrophobic filter, use a replacement pressure line (accessory available from manufacturer).

If you cannot exclude the possibility that the device may have become contaminated:

➢ Take the device out of service after completing treatment.

➢ Have the device tested for contamination by service support.

If the device is contaminated, all affected parts must be disinfected or replaced by service support.

Warning

IV pole
Danger in case of excessive load (respect the maximum load)

If the load on the IV pole is too high, the device may tilt.

Ensure that the maximum allowed load on the IV pole of 6 kg is not exceeded.

Warning

Tubing systems and multiFiltrate kits must be replaced no later than the service life date indicated by the manufacturer. The usable life is specified on the packaging of the tubing systems.

Warning

When inserting the tubing systems, observe the following:
The absence of air, kinks, tensions, and twists in the tubing system and the correct position of all fluid levels. Ensure that supply lines are not compressed (danger of haemolysis during treatment), since this cannot always be detected by the safety system. Use the tube holders provided.
Check the correct position of the screwed connections.

Visually check all solution bags for tightness before connecting them to the tubing system.

After the blood pump exit, there must not be any clamps placed on the blood line system.

Warning

Delivery operation of the pump(s) with open doors (blood pump, substituate pump, filtrate pump, dialysate pump)
When the doors are open and the rotor of the pump(s) is running, make sure that **no objects**, such as fingers, hair, or ballpoint pens, come into contact with the rotor.

Warning

To be observed when working on the tubing system during the treatment:
If you need to move any part of the tubing system out of position, make sure the correct layout of the entire tubing system is restored before continuing treatment, paying special attention to the correct placement of the positioners.

Warning

During the treatment, check the following at appropriate intervals:

– The condition of the patient.
– The function of the device and the extracorporeal blood circuit.
  To protect the patient against dangerous extraneous blood loss, a venous pressure monitoring system is used as a safety system for the extracorporeal blood circuit.
  However, the pressure monitoring system cannot detect extraneous blood loss in all cases. In this respect, a dislocation of the venous cannula or the occurrence of a small leak in the overpressure area of the extracorporeal blood circuit must be considered as being particularly critical.
  As a result, the extracorporeal circuit, particularly all of the tubing system connections and the venous access point, must be checked for leaks at appropriate intervals during the treatment.
– The tubing system, watching out for air ingress or possible loose connections. Particularly at the connections downstream of the air detector, negative pressure can permit air to enter into the extracorporeal blood circuit. This can be a problem for single-needle applications or when using central venous catheters.
– The fluid level of the venous bubble catcher. Correct the fluid level if necessary (target level: approx. 1 cm under the upper edge of the cap).
– The tubing system is inserted without kinks, tension, or twisting.
– Any leakages in the filtrate, substituate, and dialysate circuit.
– Any discolouration in the filtrate bag caused by blood loss.

Warning

Venous alarm limit

The lower venous alarm limit must be set as close as possible to the actual venous pressure value. Changing the alarm limit window position or width can adversely affect or even cancel out the efficiency of the safety system in identifying extraneous blood loss.

Warning

Dialysate and haemofiltration solutions

When using dialysate or haemofiltration solutions, make sure these solutions are used in accordance with the manufacturer's specifications and are at room temperature.

Warning

Citrate and calcium solutions

The citrate and calcium solutions must be at room temperature before they can be used.

Warning

The operating conditions in the extracorporeal blood circuit may lead to patient heat loss.

This depends on various factors, including the room temperature and the treatment parameters, particularly with low dialysate and substituate flow rates or if a heater is intentionally switched off.

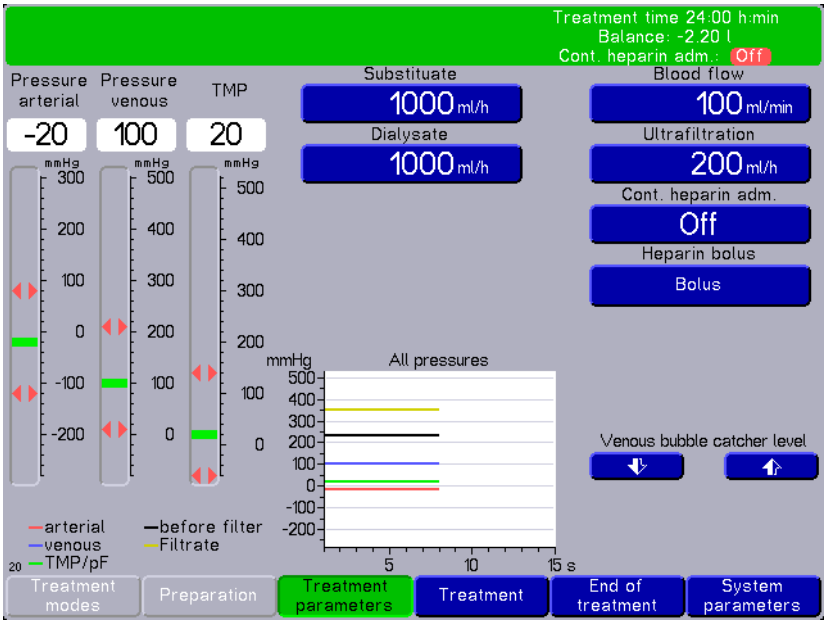
The heater of the device has been designed to heat dialysate or haemofiltration solutions and thus counteracts heat loss. As the heating must be limited for safety reasons, heat loss can not always be fully compensated. For this reason, the patient's body temperature must always be monitored.

Note

When administering medicine or connecting infusions via the arterial line, make sure the substances used will survive the dialyser.
The effectiveness of the intended treatment may depend on this.

4.2 Basic operation philosophy

4.2.1 Menu selection



Pressing the **[ESC]** key exits the current menu field and activates the menu bar. The selected menu has a green background.

Menus that can be selected are shown with **white** characters on a **blue** background. Menus that cannot be selected are shown in **grey**.

A new menu field (green background) can be selected by turning the rotary selector **[OK]**.

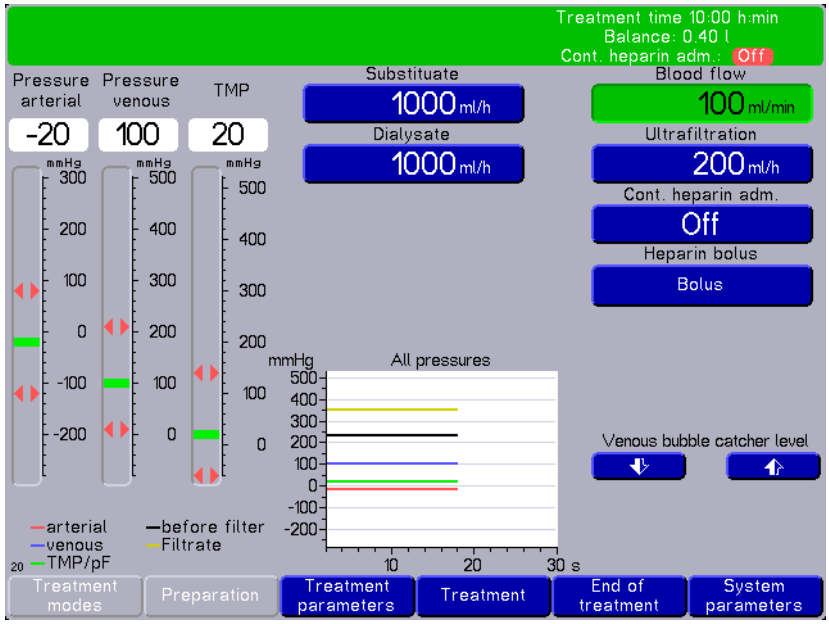
Turning the rotary selector to the right will select the menu fields on the right up to the **System parameters** field where the selection will stop even if you turn the selector further to the right.
Turning the rotary selector to the left will select the menu fields on the left up to the **Treatment modes** field where the selection will stop even if you turn the selector further to the left.

The selected menu must be confirmed by pressing the rotary selector **[OK]**.

The status bar on the screen displays the selected menu.

In the menu bar, the currently selected menu is shown with black characters on a green background.

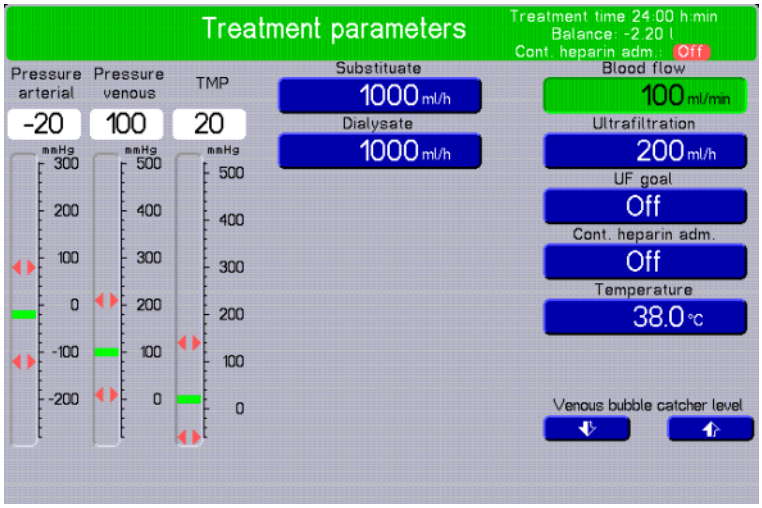
4.2.2 Treatment main screen



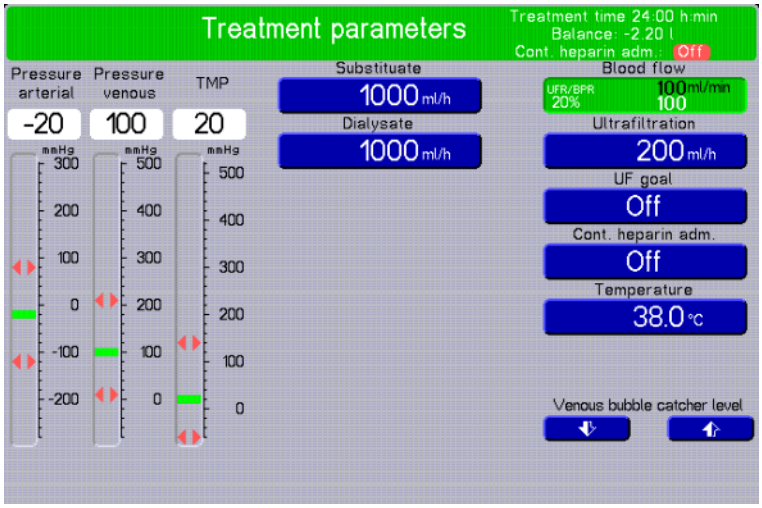
This screen is displayed during the treatment.

If another menu function is selected and entered by pressing the **[ESC]** key whilst a treatment is in progress, pressing the **[ESC]** key twice will return you to the main screen.

4.2.3 Entering treatment parameters

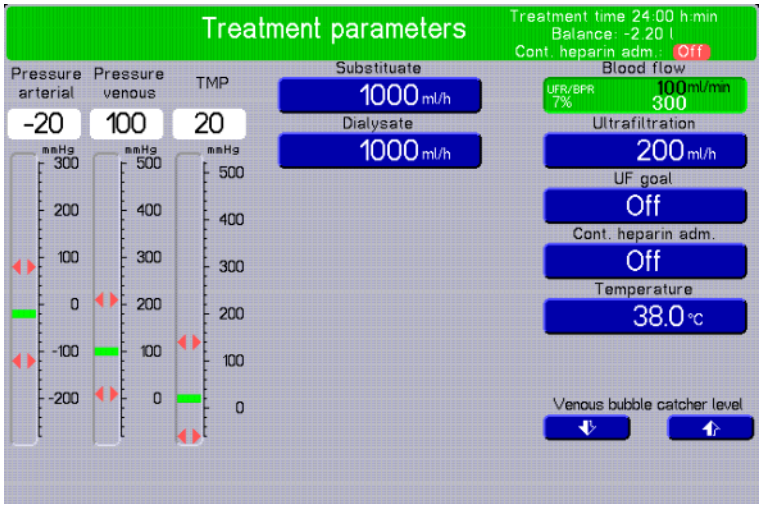


A parameter field (green background) can be selected by turning the rotary selector. Turning the rotary selector to the right will select the menu fields on the right down to the **Venous bubble catcher level** field. This field remains selected even if you turn the rotary selector further.
Turning the rotary selector to the left will select the menu fields on the left up to the **Substituate** parameter. This field remains selected even if you turn the rotary selector further.



The procedure for entering treatment parameters will be explained starting with the example of the **Blood flow**.

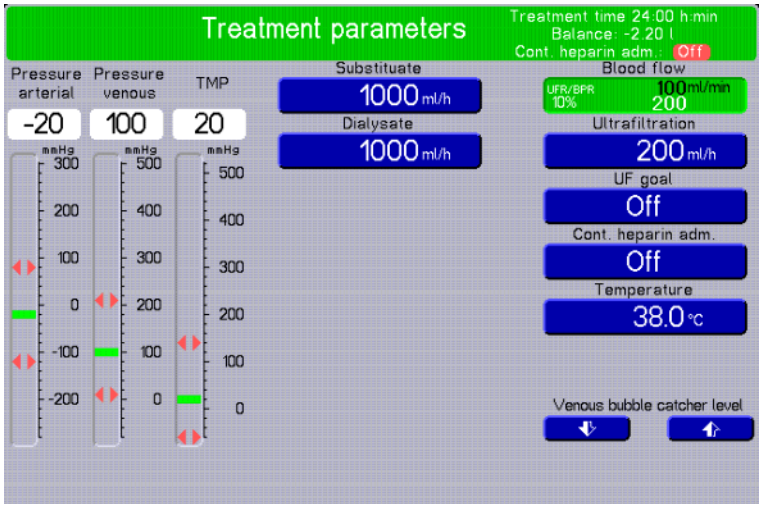
After the selected Blood flow parameter has been confirmed with **[OK]**, the currently selected actual value will be shown in black in the first line of the parameter field and the value to be changed (target value) will be shown in white in the second line.



Turning to the left will reduce, turning to the right will increase the value.

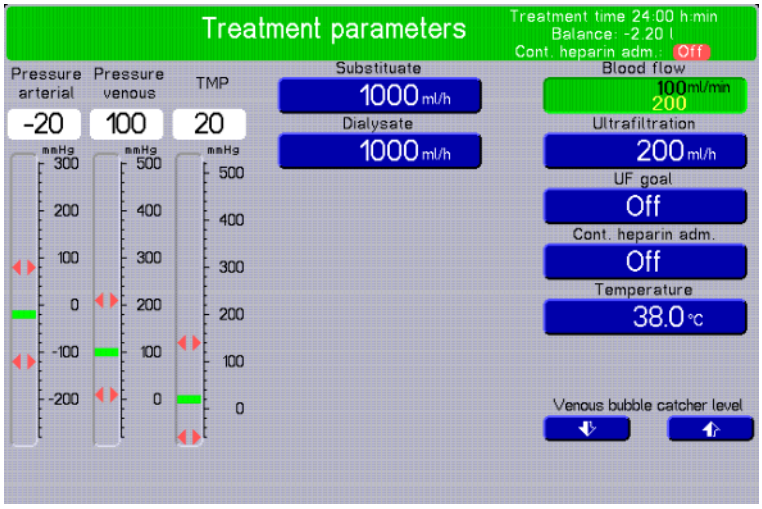
If the target value is turned to the full scale value, it will be displayed in red. This applies to both the lowest and the highest scale value.

While changing the value, the actual value will still be displayed in black. The new target value is shown in white below the actual value.

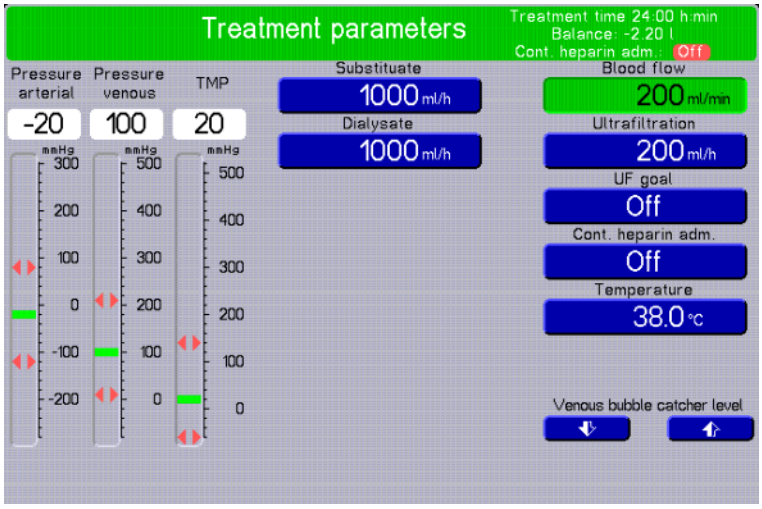


The target value is set, for example, to 200 ml/min by turning the rotary selector (the target value is shown in white).

The selected value must be confirmed by pressing the rotary selector **[OK]**.



After the set value has been confirmed with **[OK]**, the currently selected actual value will be shown in black in the first line of the parameter field and the new value (target value) will be shown in yellow in the second line.



After the new value has been stored by the system, it will be displayed in black.

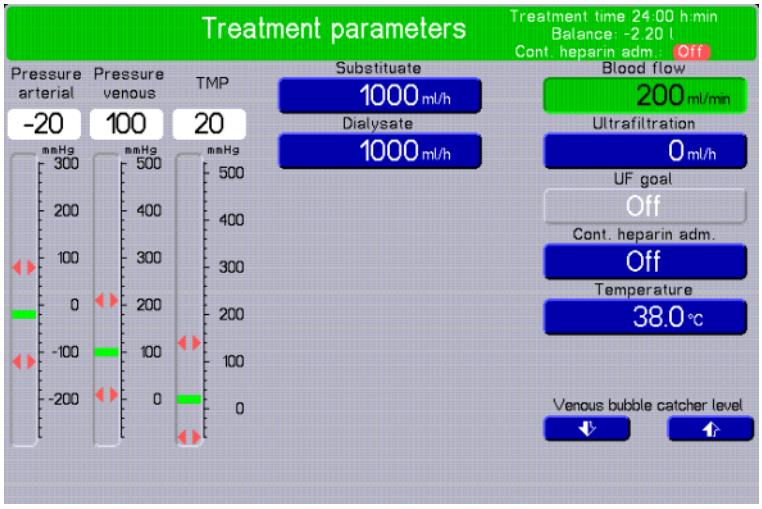
To enter all other parameters, proceed as described above.

4.3 Basic operation steps

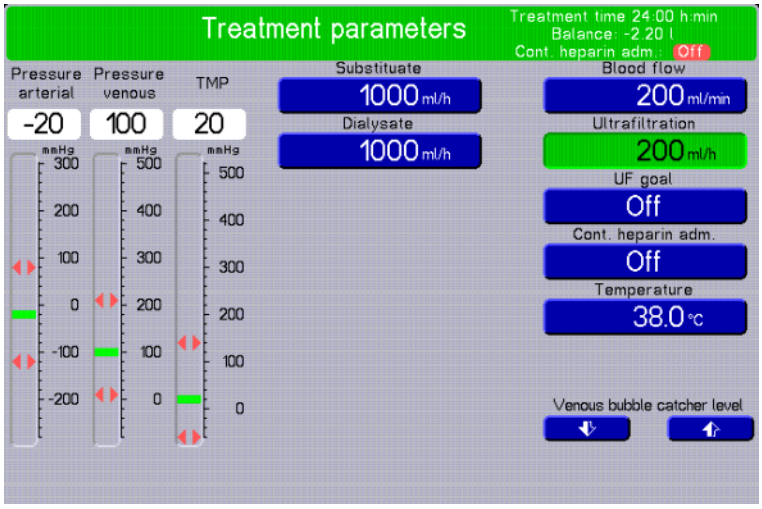
4.3.1 Entering ultrafiltration / UF goal

Note

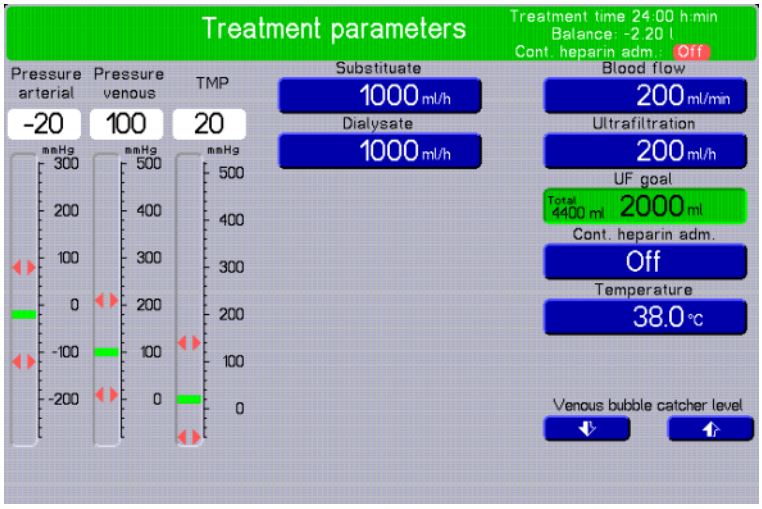
The parameter **UF goal** can only be entered in the **Treatment parameters** menu.



If ultrafiltration has not been programmed, no UF goal (grey background) can be entered.



If ultrafiltration has been programmed, a UF goal (blue background) can be entered.

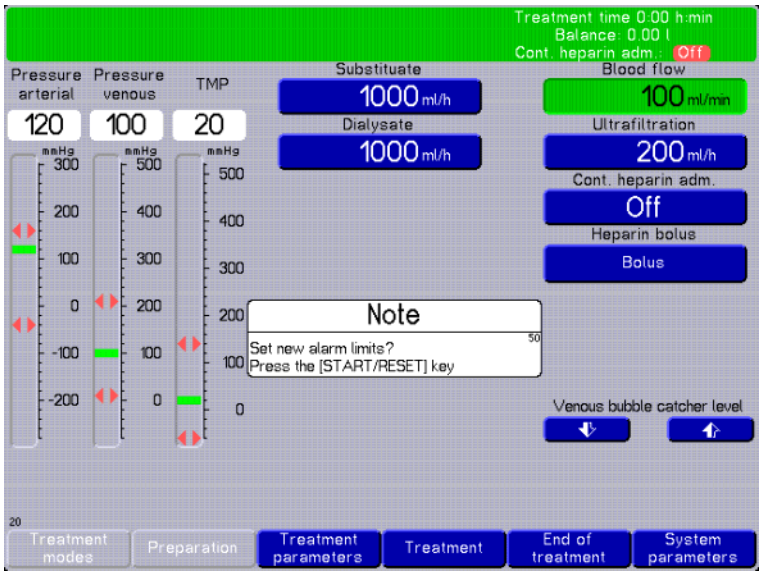


The UF goal field is used to configure the currently planned target goal.

Under "Total", the system shows the sum of the target goal and the UF volume already removed since treatment start or balance data reset.

If a UF goal is entered, ultrafiltration will be stopped and set to 0 after the UF goal has been achieved.

4.3.2 Resetting the alarm limits in alarm-free condition



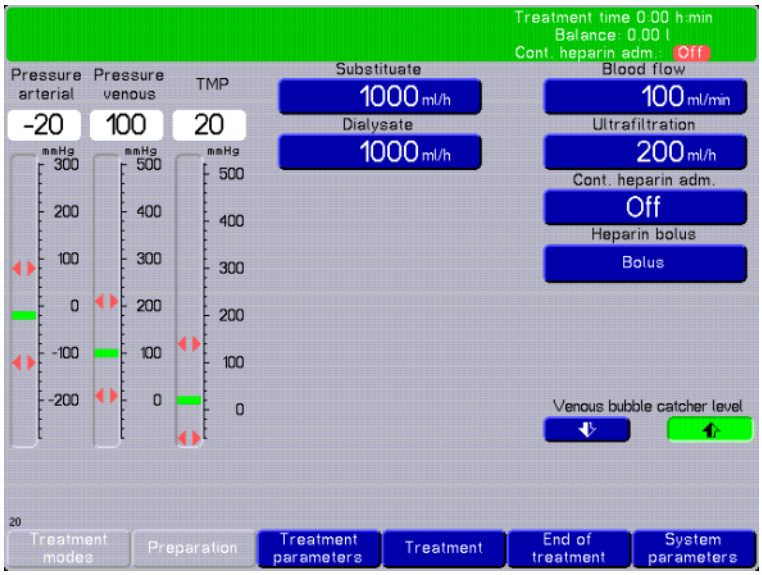
➢ Press the **[START/RESET]** key.

➢ Press the **[START/RESET]** key again.

The alarm limits will be set around the current actual value. Exception: Venous pressure (see chapter 5.5 on page 5-4)

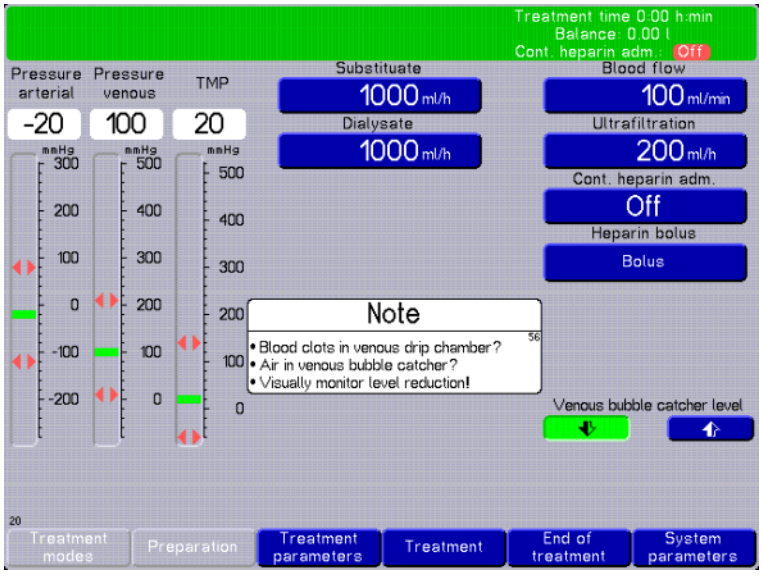
4.3.3 Raising and lowering the venous bubble catcher level

4.3.3.1 Raising the level



➢ Use the rotary selector to select **Venous bubble catcher level**, and press and hold **[OK]** until the required level has been reached.

4.3.3.2 Lowering the level



➢ Use the rotary selector to select **Venous bubble catcher level**, and press and hold **[OK]** until the required level has been reached.

4.3.4 Bolus anticoagulation

The bolus anticoagulation function may be selected both during preparation and during the treatment via the **Bolus** menu field. When changing from preparation to treatment, the bolus quantity will be set to 0.

➢ Use the rotary selector to select **Bolus** and press and hold **[OK]**.

As long as the selector is being pressed, the bolus is slowly administered at a rate of 0 ml up to 5 ml maximum (adjustable via the System parameters menu). The bolus will stop as soon as the selector is released.

If the bolus, once activated, is stopped before reaching the maximum volume, bolus administration may be continued within 5 seconds until reaching the maximum volume.

4.4 Making the device ready for operation

Note

Check the device for stability. The maximum angle of inclination must not exceed 5°.

Before turning the device on, please ensure that all scales are unloaded, that no objects are placed on the scales and that no tubing system is inserted in the Ci-Ca pumps.

The maximum loading capacity of 12 kg per scale must not be exceeded. The weighing cell can even be permanently damaged by a short-term overload (e.g., pulling or lifting the device by the scales), in which case the device can no longer be used.

4.4.1 Turning the device on

Note

The operator must check all of the status indicator lights.

Once mains power is switched on, the green LED is illuminated (dimmed). If the device is switched on via the "On / Off" key, the green LED goes out and the yellow LED is illuminated. At the end of the functional test, an audible alarm sounds and the red LED is illuminated and then changes back to yellow.

Note

After turning the device off, wait for approximately 10 seconds before turning it on again.

- ➢ Connect the device to the power supply.
- ➢ Connect the equipotential bonding connector to the rear of the multiFiltrate device.
- ➢ Press the power switch on the rear of the device.

Tip

If used tubing systems are still present in the blood circuit module, these can be removed by opening the pump cover and pressing the **[START/RESET]** key.

The green LED is illuminated.

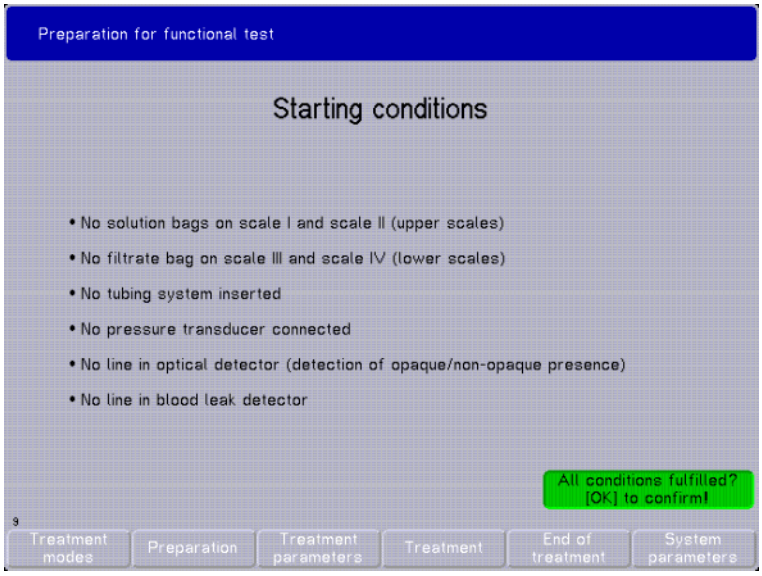
All systems are supplied with voltage.

The battery is being charged.

- ➢ Press the **[On/Off]** key for approx. 3 seconds until the yellow LED is illuminated.

The processor check starts automatically.

The software version (X.X) and the language version ("en" for English) are displayed.



➢ Use the rotary selector to select **All conditions fulfilled? [OK] to confirm!** and press **[OK]**.

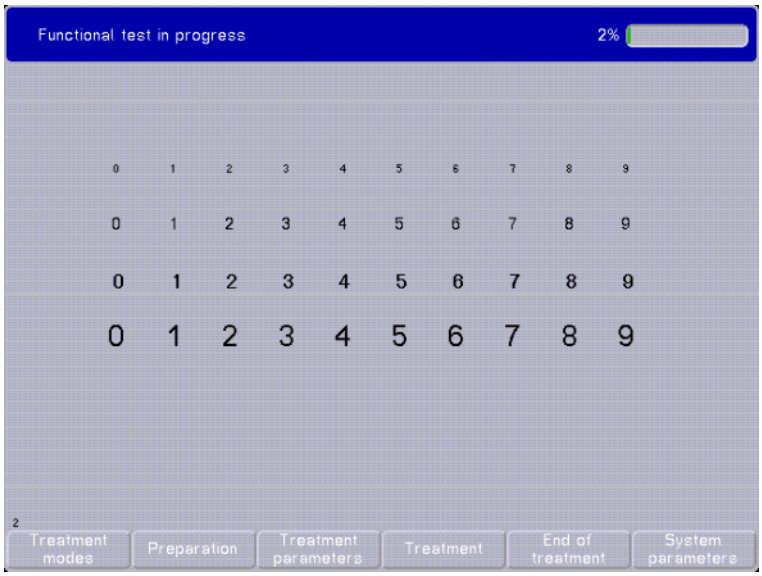
4.4.2 Starting the functional test

Note

If the multiFiltrate device is provided with a Ci-Ca module, this module must also pass the functional test after power-on, irrespective of the treatment mode to be selected. If the module fails to pass the functional test even though faults have been eliminated and the functional test has been repeated, treatment with the multiFiltrate device is not permitted.

Note

The operator must check all of the status indicator lights during the functional test.



Functional test will start automatically.

The progress bar in the status bar shows the progress of the functional test.

The operator must check that the sequence of numbers displayed is complete.

If one number is missing or if the sequence of numbers is interrupted, do not use the device!

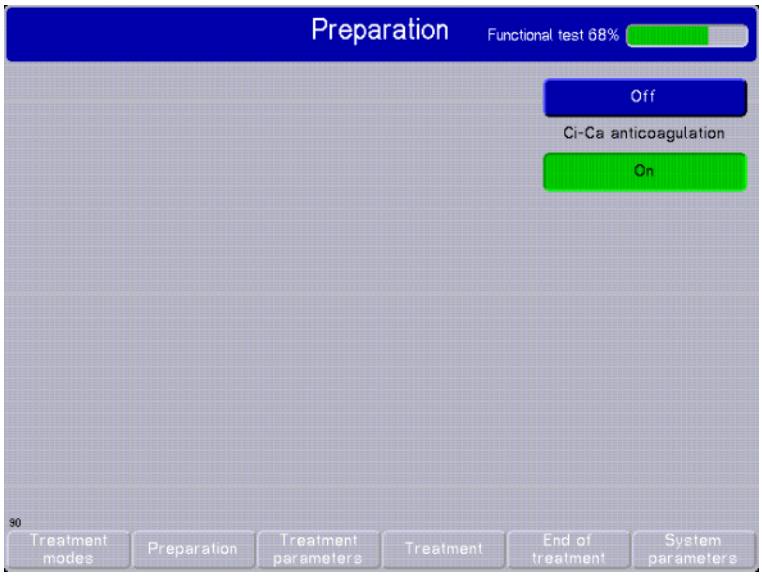
The audible alarm is checked.

4.4.3 Selecting the anticoagulation method

Note

The following screen will not appear if:

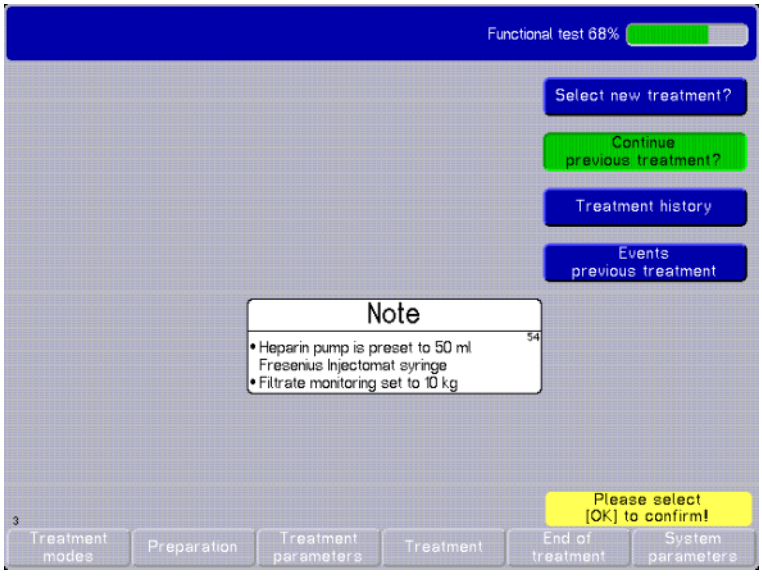
– The Ci-Ca module is not attached.
– Communication between the Ci-Ca module and the multiFiltrate device cannot be established. Contact service support.



The decision whether the treatment is to be performed with or without citrate anticoagulation can already be made during the functional test.

➢ Use the rotary selector to select **On** or **Off** and press **[OK]**.

4.4.4 Continuing the previous treatment

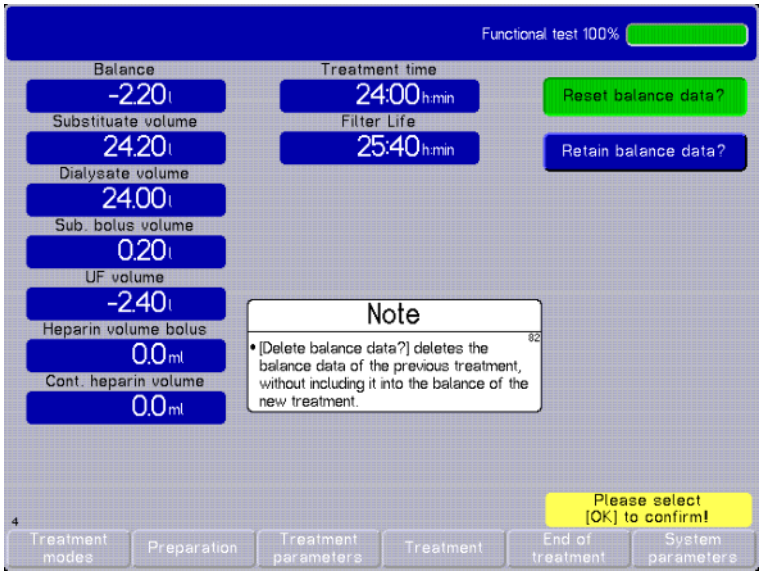


➢ Use the rotary selector to select **Continue previous treatment?** and press **[OK]**.

The last treatment that was performed will remain stored and can be continued with the old parameters.
Exception: The flow rate of the heparin pump will not be saved! The rate is set to 0 ml/h and must be reprogrammed for each treatment.

or

➢ Use the rotary selector to select **Select new treatment?** and press **[OK]**.



When the treatment is continued with the previous treatment parameters, the operator has the option to start with or without using the **Reset balance data** option.

➢ Use the rotary selector to select the required function and press **[OK]**.

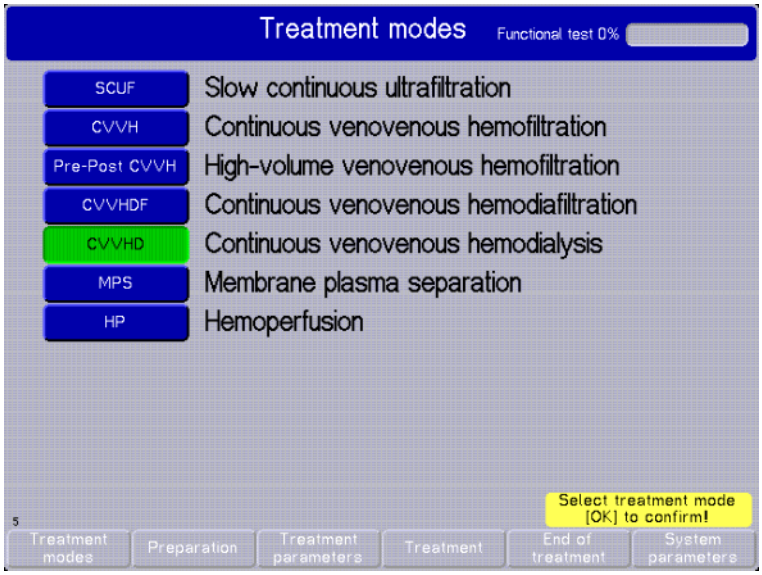
4.4.5 Selecting the treatment mode

Note

On the device, the current treatment mode is always displayed in the upper left-hand corner of the screen in the status bar.
For technical reasons, the screens shown in the Instructions for Use do not always represent the selected treatment mode.

Note

If citrate anticoagulation is activated, only the treatment modes CVVHD and CVVHDF are available.



➢ Use the rotary selector to select the required treatment mode and press **[OK]**.

The paediatric treatment modes have to be activated by the technician in the service program.

Paed. CVVH
Paed. CVVHD

4.5 CRRT treatments

General description of the CVVH, CVVHD, CVVHDF, and Pre-Post CVVH treatments with information on the differences between the individual treatments.

Make the device ready for operation (see chapter 4.4 on page 4-12).

4.5.1 Starting conditions

Note

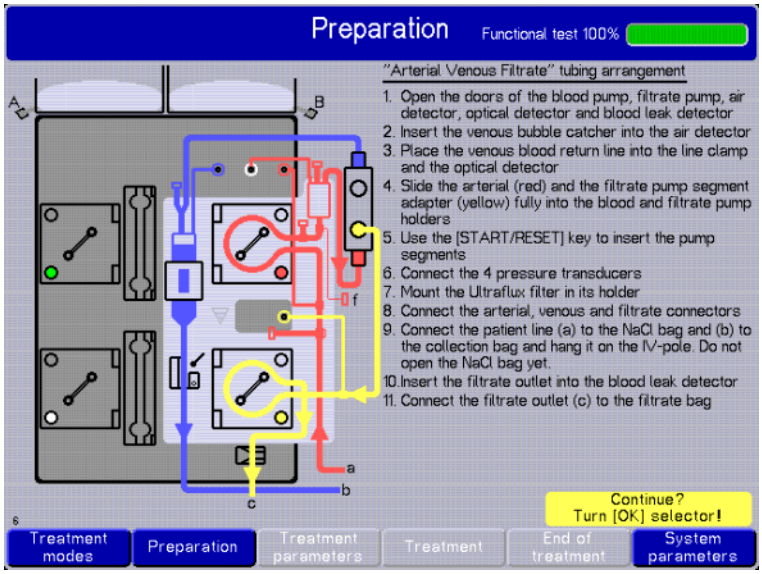
Each treatment mode has its individual starting conditions.

The operator must ensure that the starting conditions are met before using the rotary selector to select **Conditions fulfilled** and pressing **[OK]**.

4.5.2 Inserting the cassette system or AV set

4.5.2.1 Inserting the cassette system

When using an AV set continue with "Inserting the arterial blood line system" (see chapter 4.5.2.2 on page 4-18)

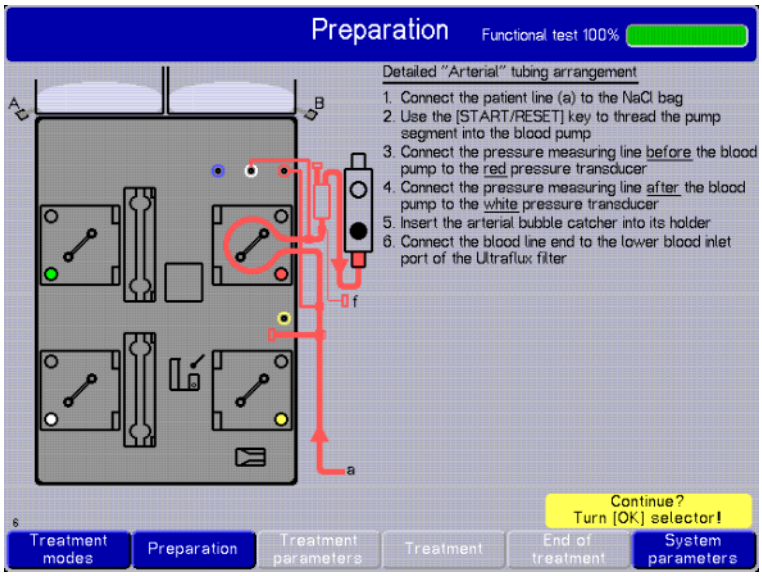


➢ Insert the cassette system according to the instructions.

➢ Turn the rotary selector clockwise until the next screen displays.

➢ Continue with "Inserting the heparin syringe" (see chapter 4.5.4 on page 4-21)

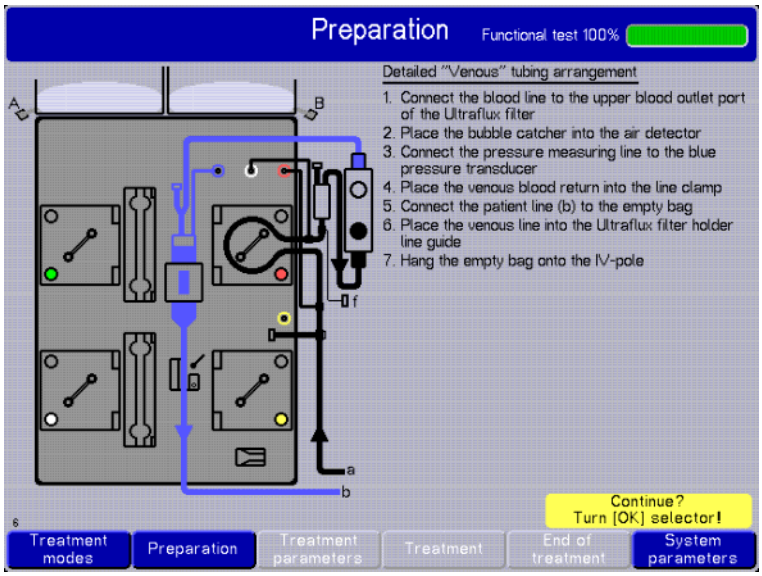
4.5.2.2 Inserting the arterial blood line system



➢ Insert the arterial blood line system according to the instructions.

➢ Turn the rotary selector clockwise until the next screen displays.

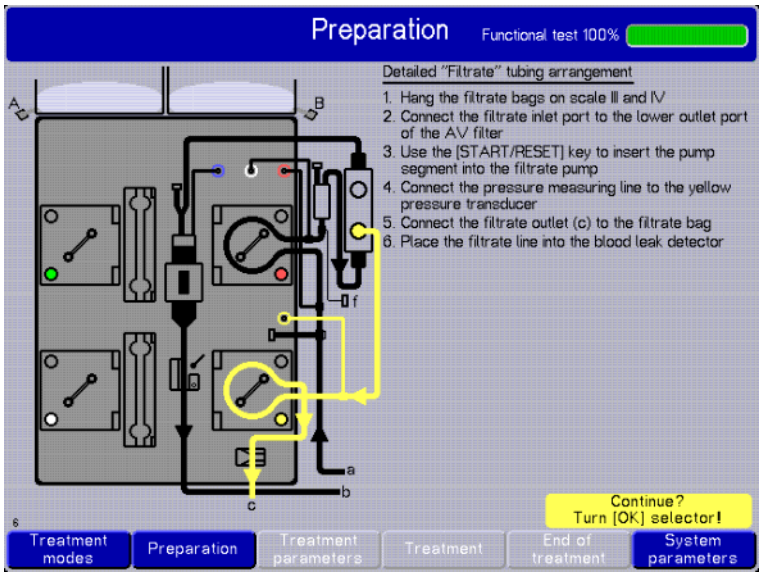
4.5.2.3 Inserting the venous blood line system



➢ Insert the venous blood line system according to the instructions.

➢ Turn the rotary selector clockwise until the next screen displays.

4.5.2.4 Inserting the filtrate line system



➢ Insert the filtrate line system according to the instructions.

➢ Turn the rotary selector clockwise until the next screen displays.

4.5.3 Inserting further tubing systems

Depending on the selected treatment mode, the tubing system for dialysate, substituate, or sub predilution and sub postdilution has to be inserted.

Note

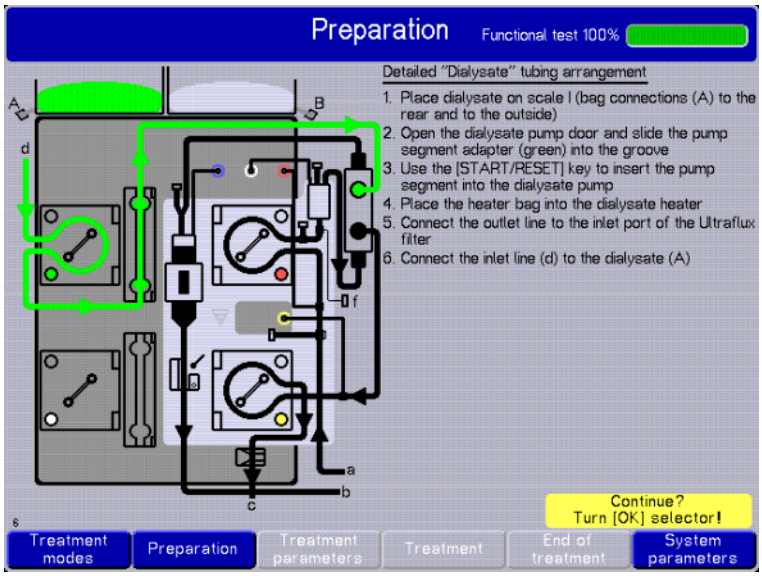
Depending on the settings, the tubing arrangement for dialysate, substituate, or sub predilution and sub postdilution may differ from the illustration on the screen. The device has to be set up in accordance with the instructions on the screen.

The settings for the tubing system may only be changed by technical service support.

Tip

With the CVVHD and CVVH (not Pre-Post) treatment modes, both scales can be loaded with solutions if 2 x HF female adapters are used on 4 x HF male adapters.

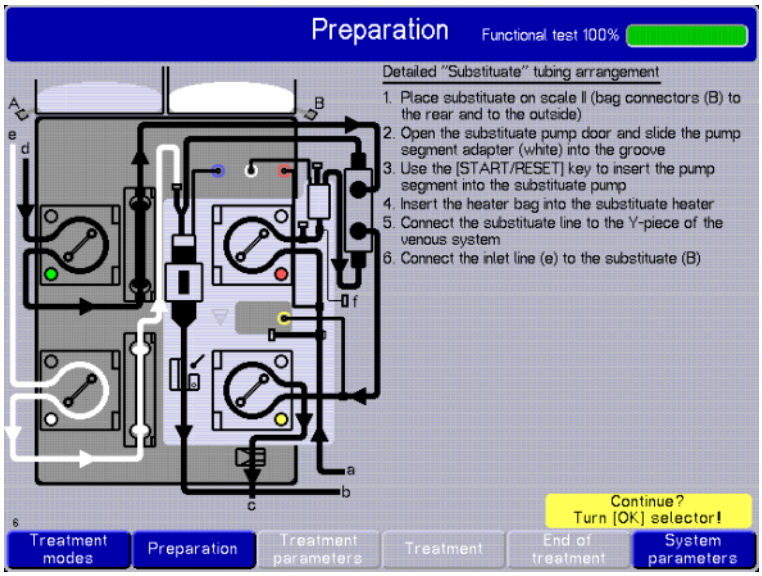
4.5.3.1 Inserting the dialysate or sub predilution tubing system (except for CVVH)



➢ Insert the dialysate or sub predilution tubing system according to the instructions.

➢ Turn the rotary selector clockwise until the next screen displays.

4.5.3.2 Inserting the substituate or sub postdilution tubing system (except for CVVHD)



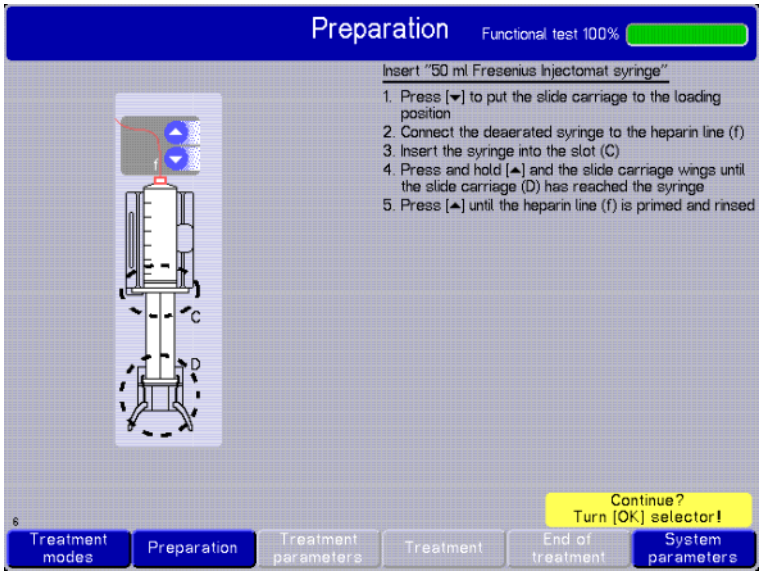
➢ Insert the substituate or sub postdilution tubing system according to the instructions.

➢ Turn the rotary selector clockwise until the next screen displays.

4.5.4 Inserting the heparin syringe

Note

If a heparin syringe is used, it must be inserted and connected before connecting the patient.



➢ Insert the heparin syringe according to the instructions.

➢ Turn the rotary selector clockwise until the next screen displays.

Note on C

The syringe wings must be placed in the syringe wing slot.

Note on D

The thumbplate of the syringe plunger must be positioned between the clamps of the grip handle.

4.5.5 Complete tubing arrangement

Warning

Patient hazard: air embolism

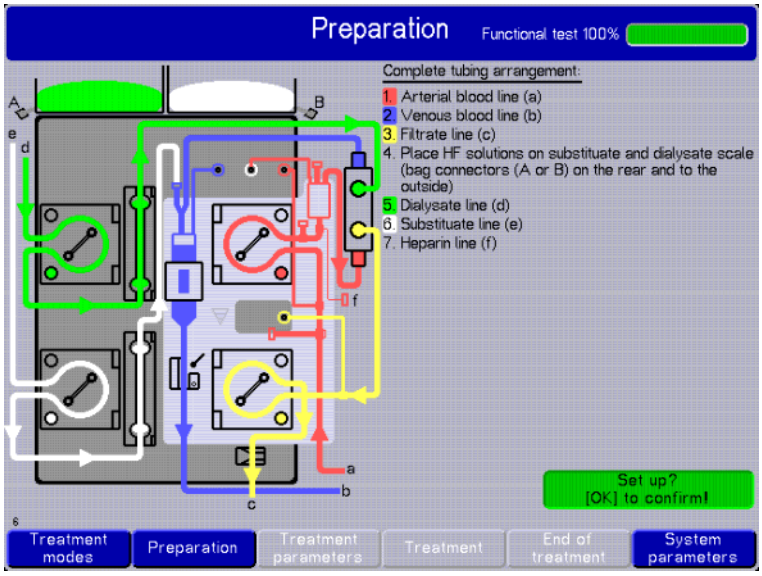
The air detector must be clean and dry.
Do not use any ultrasound-conducting objects or media.

Blood clots (coagula) can cause the air bubble detector to fail.

Note

Ensure that the filtrate bag hangs freely and does not touch any other objects.

Do not insert the filtrate tube too tightly between the blood leak detector and the filtrate bag.



This screen will be displayed immediately if the setting in the System parameters menu was set to **Complete tubing arrangement**.

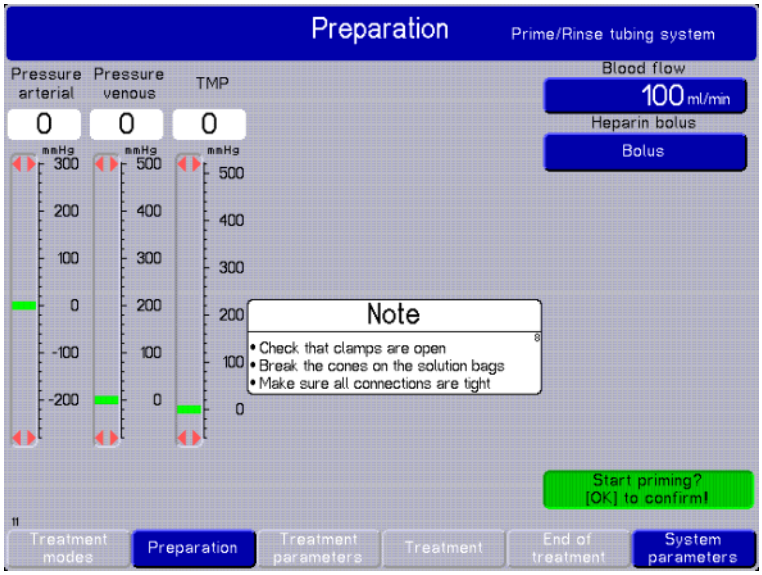
➢ Confirm the completely inserted tubing system using the rotary selector to select **Set up? [OK] to confirm!** and press **[OK]**.

4.5.6 Preparation

Note

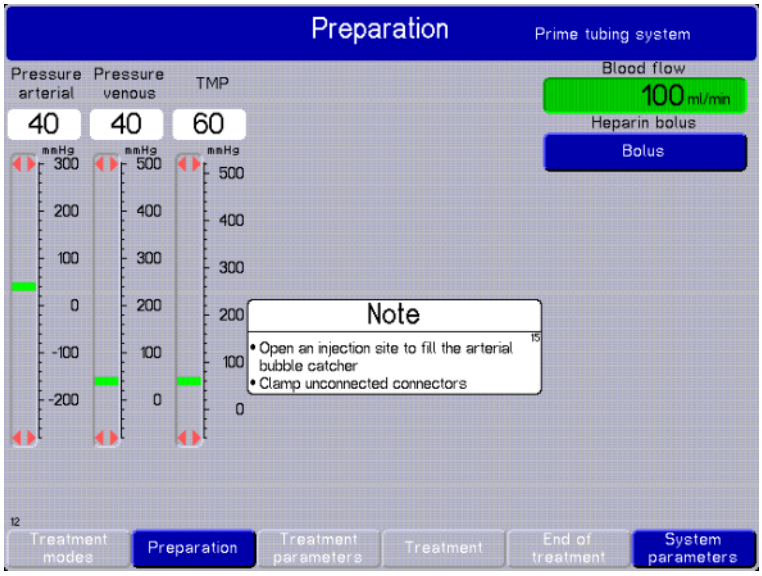
The patient must not be connected during preparation. If the optical detector senses opaque fluid during the preparation phase, the system asks whether a patient has been connected.

4.5.6.1 Priming the tubing system



➢ Use the rotary selector to select **Start priming? [OK] to confirm!** and press **[OK]**.

Heparin can be added to the NaCl solution used for priming and rinsing via the **Bolus** menu field.



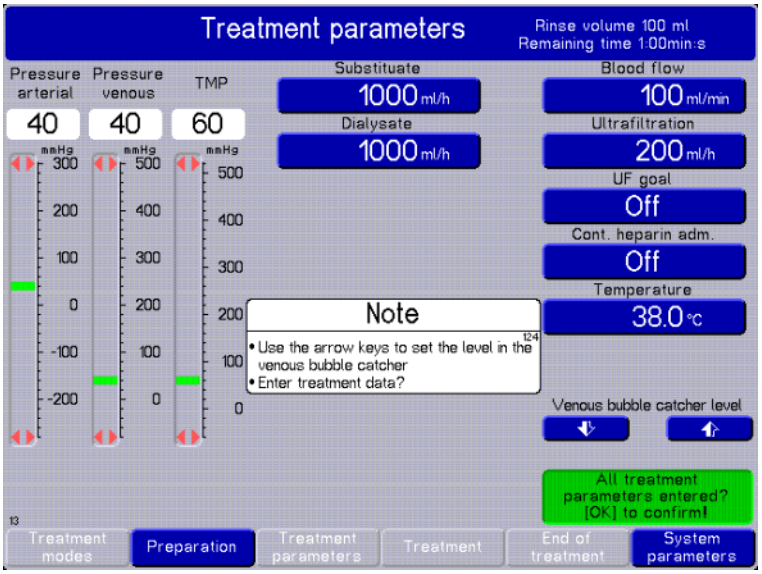
➢ Open the infusion / extraction point to prime the arterial bubble catcher.

If the amount of air in the arterial bubble catcher has decreased to a level of approx. 1 cm underneath the lid, the infusion / extraction point has to be closed.

4.5.6.2 Rinsing the tubing system / entering treatment parameters

Note

The heparin dose is to be administered as prescribed by the physician! If an initial heparin dose is to be administered, the bolus function can be used.



The ultrasonic sensor detects fluid in the venous bubble catcher. Set the venous level manually using the **Venous bubble catcher level** menu field.

Rinsing starts automatically and the screen for entering the treatment parameters appears.

Indication of the decreasing rinse volume and the remaining rinse time.

➢ Use the rotary selector to select the required treatment parameters (green background) and press **[OK]**.

The possible entries depend on the selected treatment mode.

➢ Use the rotary selector to enter the required parameters and press **[OK]**.

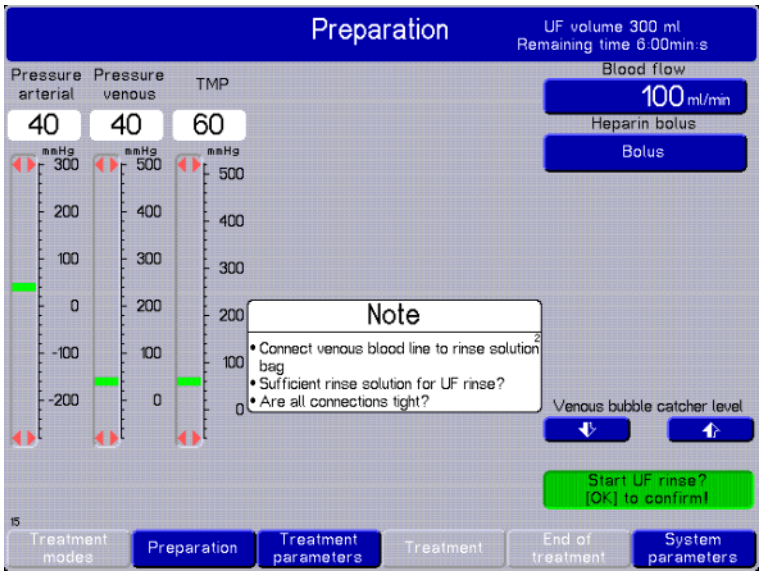
Set all treatment parameters as described above.

➢ Use the rotary selector to select **All treatment parameters entered? [OK] to confirm!** and press **[OK]**.

4.5.6.3 UF rinse

Note

When using NaCl solutions with only one connector, make sure there is enough NaCl solution.



After the rinse is completed and the pre-defined volume used, the blood pump will stop.

An audible signal will be given.

If using an NaCl solution with two connectors:

➢ Disconnect the venous patient line from the empty bag and connect it to the NaCl solution.

If using an NaCl solution with one connector:
Do not change the existing connection.

➢ Use the rotary selector to select **Start UF rinse? [OK] to confirm!** and press **[OK]**.

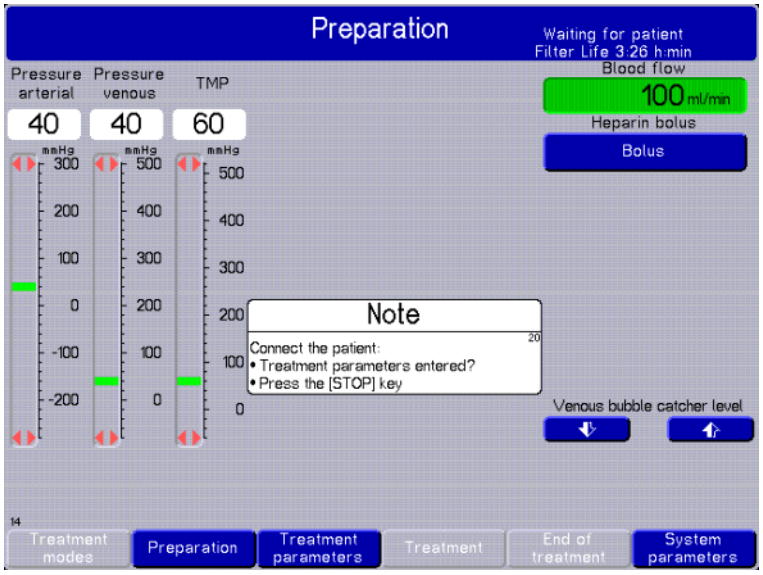
Indication of the decreasing UF volume and the remaining rinse time.

➢ Turn the filter upon notification.

4.5.6.4 Recirculation / waiting for patient

Note

The filter life, which is shown in the status bar, is automatically added to the service life of the tubing systems.



When the UF volume reaches 0 ml, the extracorporeal blood circuit is in recirculation.

If using an NaCl solution with two connectors:
Do not change the existing connection.

If using an NaCl solution with one connector:

➢ Stop recirculation by pressing the **[STOP]** key.

Press the [STOP] key for approx. 3 seconds.

➢ Connect the venous patient line to the arterial patient line using the recirculator.

➢ Continue recirculation by pressing the **[START/RESET]** key.

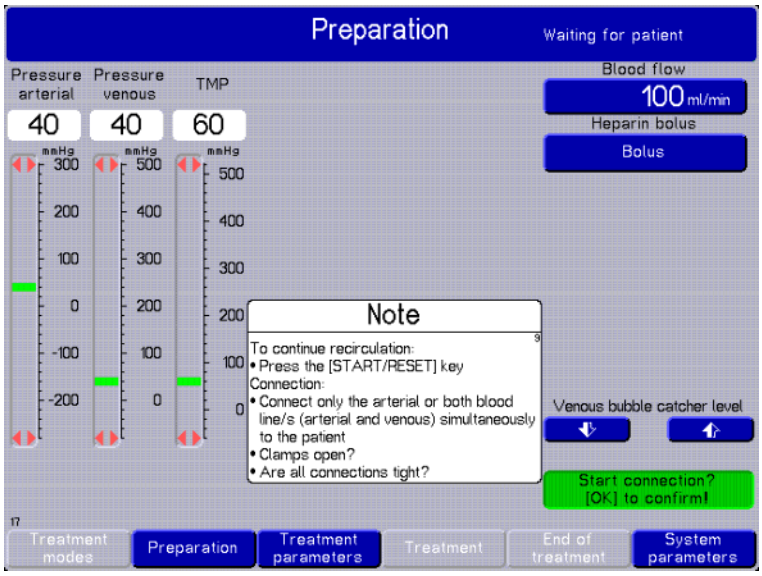
4.5.6.5 Connecting the patient

Tip

If the patient is not yet available, then recirculation can be continued by pressing the **[START/RESET]** key.

Note

In the case of CVVH or CVVHDF, connect the substituate line in predilution, if necessary.



If using an NaCl solution with two connectors:

➢ Disconnect the arterial patient line from the NaCl solution and connect it to the arterial vascular access.

or

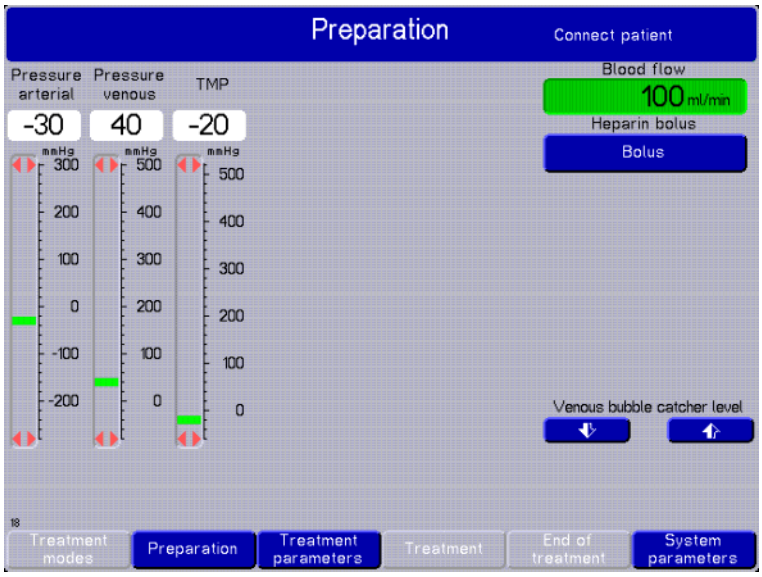
➢ Connect the arterial and venous patient line to the vascular access.

If using an NaCl solution with one connector:

➢ Connect the arterial and venous patient line to the vascular access.

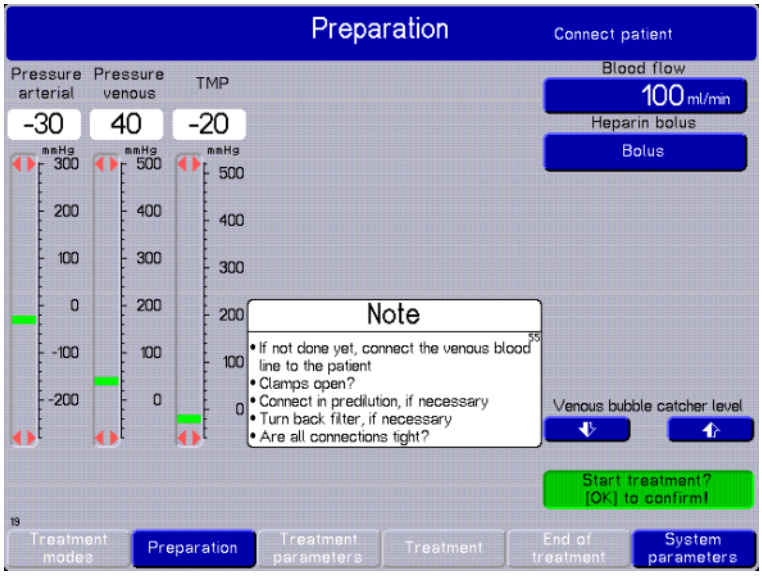
and

➢ Use the rotary selector to select **Start connection? [OK] to confirm!** and press **[OK]**.



The blood pump will deliver at the programmed rate.

Settable rate:
Cassette / adults 10 ml/min to 100 ml/min (default 100 ml/min)



The optical detector senses opaque fluid.

The blood pump is stopped.

If not done yet when using an NaCl solution with two connectors:

➢ Disconnect the venous patient line from the NaCl solution and connect it to the venous vascular access.

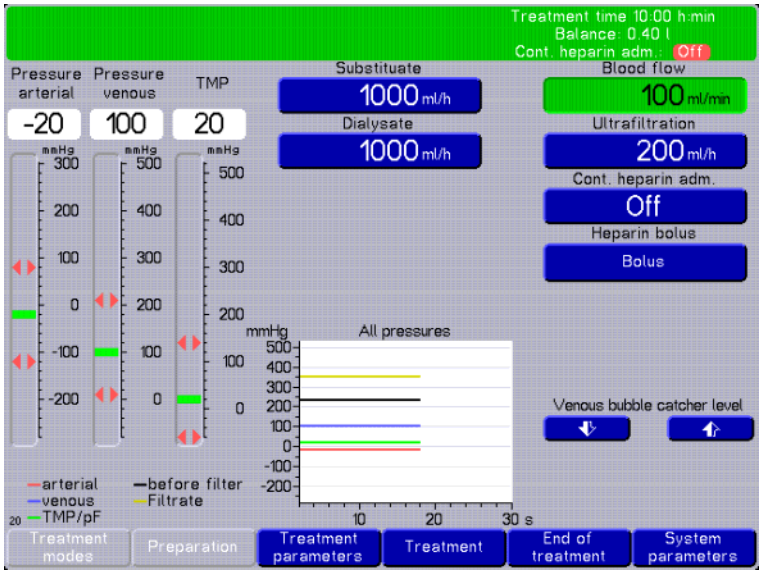
➢ Use the rotary selector to select **Start treatment? [OK] to confirm!** and press **[OK]**.

4.5.7 Treatment

Note

Once treatment has started and the blood pump has achieved its target delivery rate, the alarm limits are set automatically after approx. 10 seconds. Following this, the pressure alarm limits must be checked by the operator and adjusted individually as required.

4.5.7.1 Treatment main screen

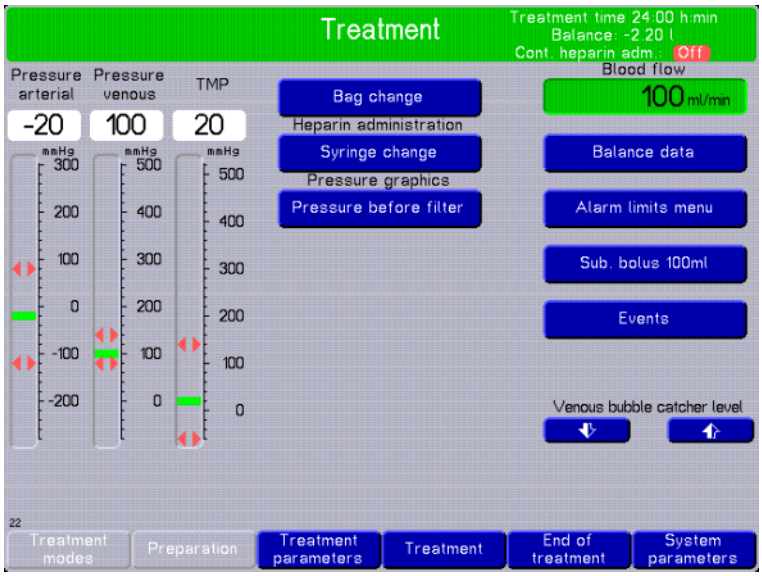


The main screen is displayed throughout the entire treatment.

Depending on the treatment mode, the menu field shows:
The current pressures (arterial, venous, TMP)
The current flow rates (dialysate, substituate, sub predilution, sub postdilution, blood flow, ultrafiltration)
Heparin

The status bar shows:
The treatment mode
The progression of the treatment time
The balance
Continuous anticoagulation on / off

4.5.7.2 Treatment menu



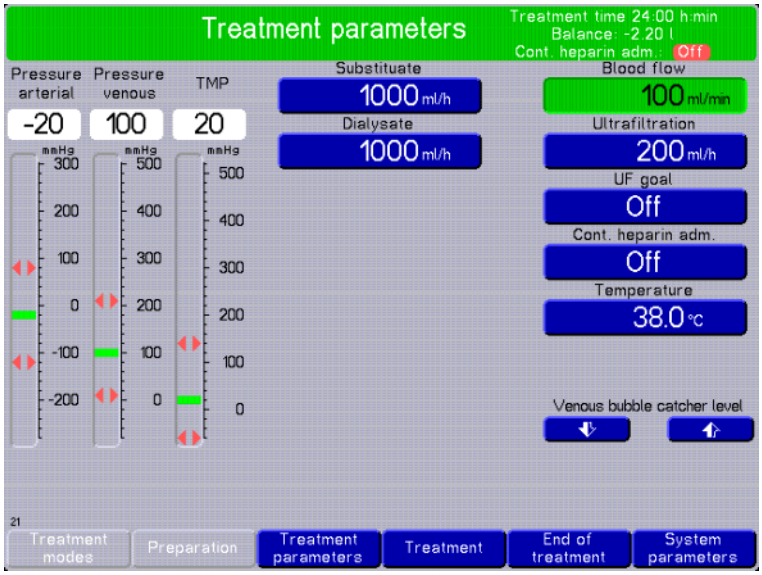
➢ Press the **[ESC]** key.

➢ Use the rotary selector to select **Treatment** from the menu bar and press **[OK]**.

The menu fields shown depend on the selected treatment mode. Detailed description (see chapter 4.11 on page 4-104).

After a timeout, the display will automatically return to the treatment main screen.

4.5.7.3 Treatment parameters



➢ Press the **[ESC]** key.

➢ Use the rotary selector to select **Treatment parameters** from the menu bar and press **[OK]**.

The treatment parameters shown depend on the selected treatment mode.

After a timeout, the display will automatically return to the treatment main screen.

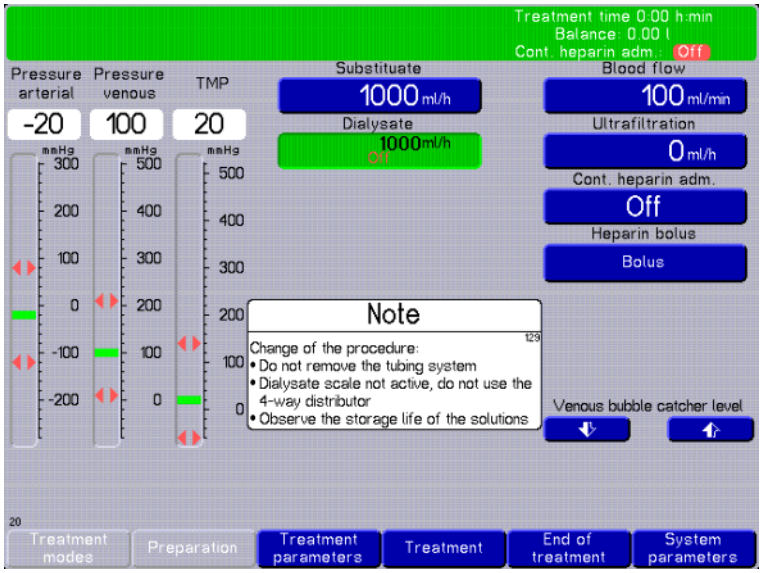
4.5.8 Change of procedure (except for CVVHD and CVVH)

Note

It is possible to stop a flow during the treatment in the CVVHDF and Pre-Post CVVH treatment modes. Only a CVVH or CVVHD will then be performed in the CVVHDF, for example. This change of procedure can be undone.

The changed treatment mode is shown in the status bar. The letter which is greyed out indicates a change of procedure.

4.5.8.1 Change of procedure to CVVH

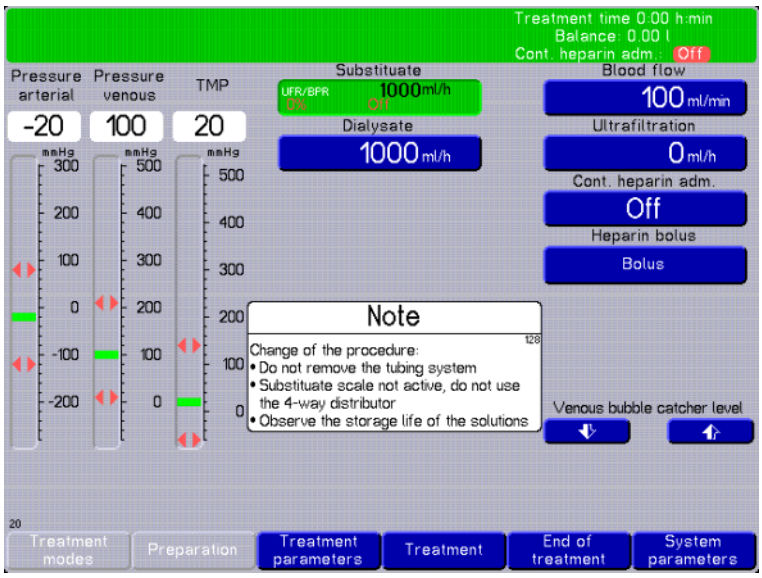


➢ Use the rotary selector to select **Dialysate** and set it to **Off**.

4.5.8.2 Change of procedure to CVVHD

Note

"Sub. bolus 100 ml" is not possible in CVVHD.



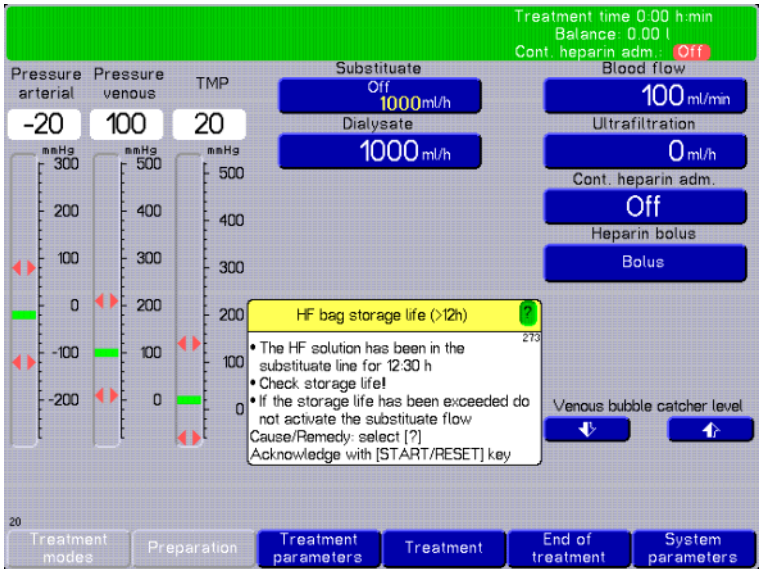
➢ Use the rotary selector to select **Substitute** and set it to **Off**.

4.5.9 Change of procedure back to CVVHDF

Warning

The storage life for opened solution bags indicated by the manufacturer must be observed. If the storage life has been exceeded, the solutions must not be used anymore.

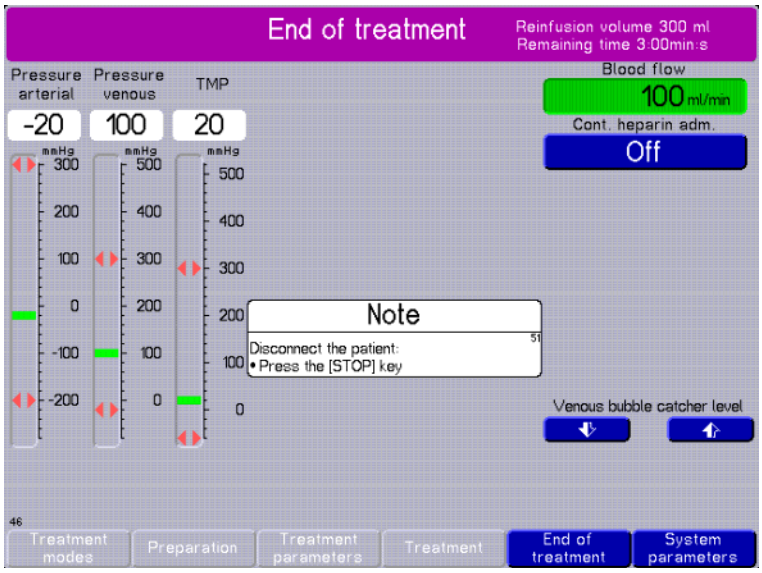
Substitute or dialysate must remain deactivated or the end of the treatment has to be initiated.



➢ Use the rotary selector to select **Substitute or Dialysate** and set the required flow.

4.5.10 End of treatment

4.5.10.1 Terminating the treatment



➢ Press the **[ESC]** key.

➢ Use the rotary selector to select **End of treatment** from the menu bar and press **[OK]** to confirm.

The blood pump is running.

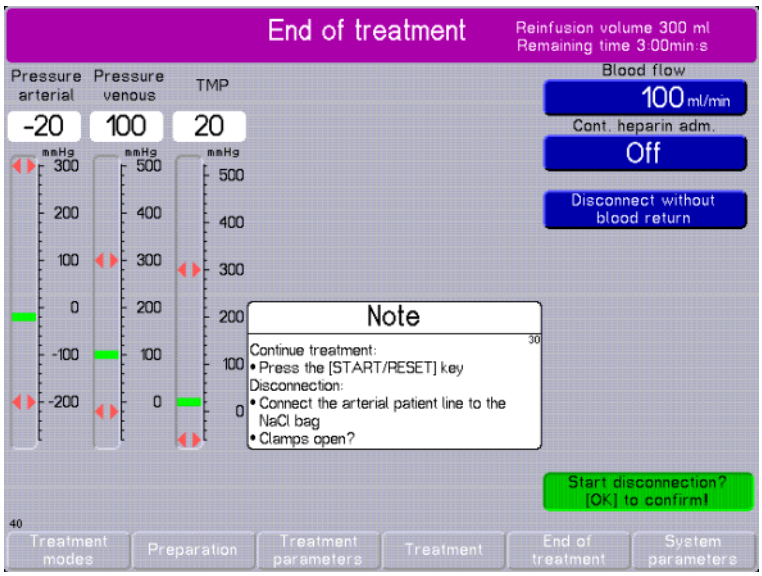
➢ Stop the treatment by pressing the **[STOP]** key.

Press the [STOP] key for approx. 3 seconds.
The venous clamp closes.
The blood pump is stopped.

or

➢ Use the **[ESC]** key to select a different menu from the menu bar.

4.5.10.2 Starting reinfusion



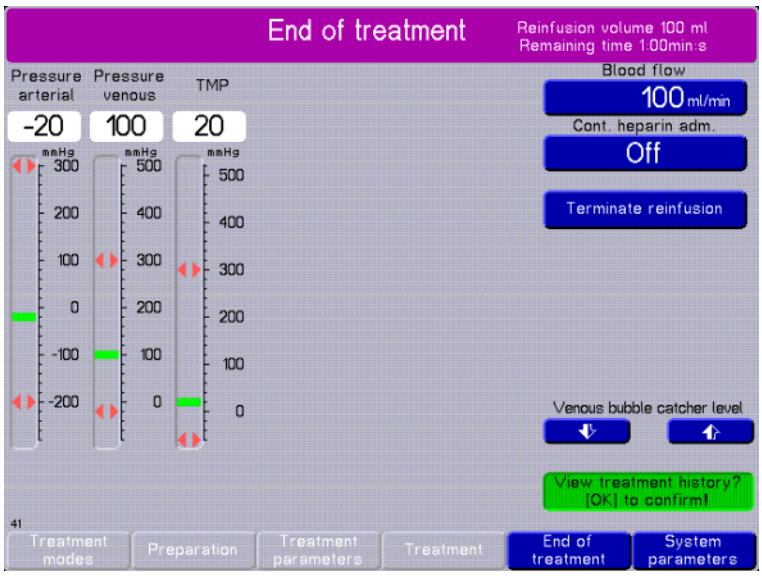
➢ Continue the treatment by pressing the **[START/RESET]** key.

or

➢ Disconnect the arterial patient line from the patient and connect it to the NaCl solution.

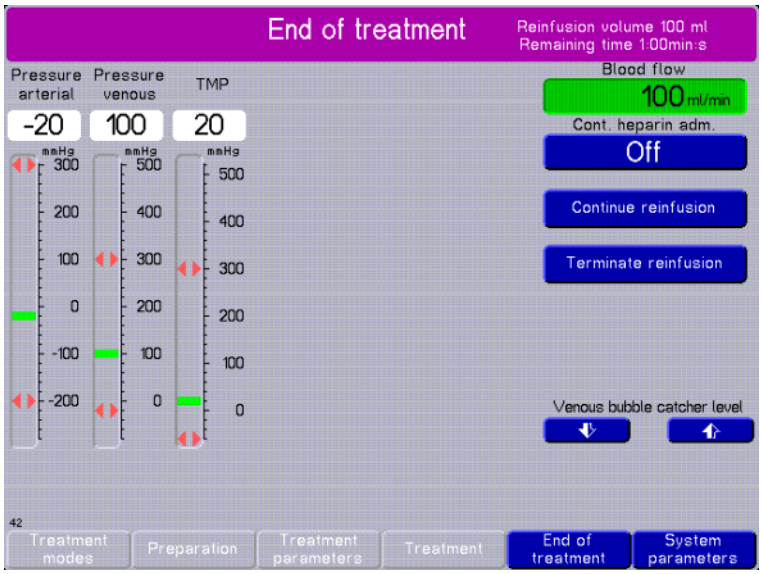
➢ Use the rotary selector to select **Start disconnection? [OK] to confirm!** and press **[OK]**.

When selecting **Disconnect without blood return**, the program will go directly to "Disconnecting the patient" without reinfusion after a safety prompt (see chapter 4.5.11 on page 4-32).



Indication of the decreasing reinfusion volume.

Selecting **View treatment history? [OK] to confirm!** will display the treatment parameters.



The optical detector senses non-opaque fluid.

➢ When selecting **Continue reinfusion**, the remaining reinfusion volume can be returned to the patient.

or

➢ Use the rotary selector to select **Terminate reinfusion** and press **[OK]**.

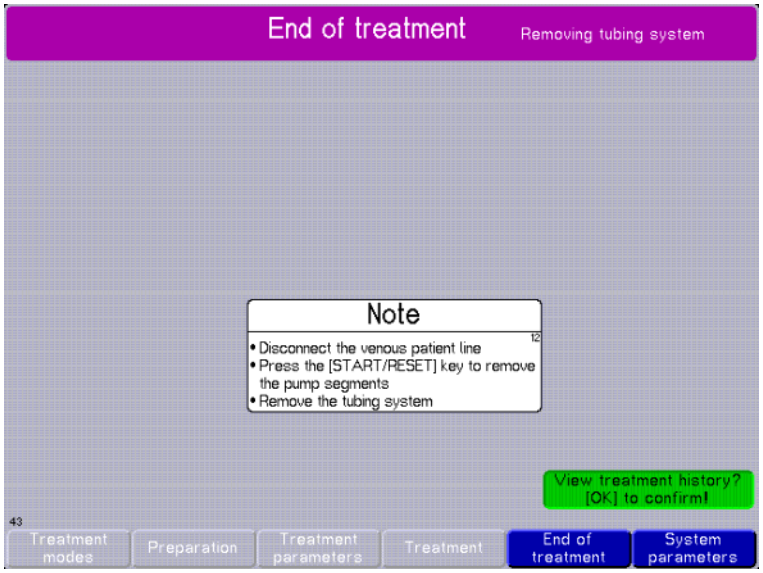
but

The treatment will be terminated automatically if the reinfusion volume is 0 ml and the optical detector senses non-opaque fluid.

4.5.11 Disconnecting the patient and removing the tubing system

Warning

Consumables must be discarded after the treatment in compliance with the regulations for the disposal of potentially contaminated materials.



➢ Disconnect the venous patient line from the patient.

➢ Remove the pump segment adapter from the groove.

➢ Press and hold the **[START/RESET]** key until the pump segment has been completely removed.

Support the removal of the pump segment by slightly pulling on it.

➢ Remove the heater bag (depending on the treatment mode) from the heater.

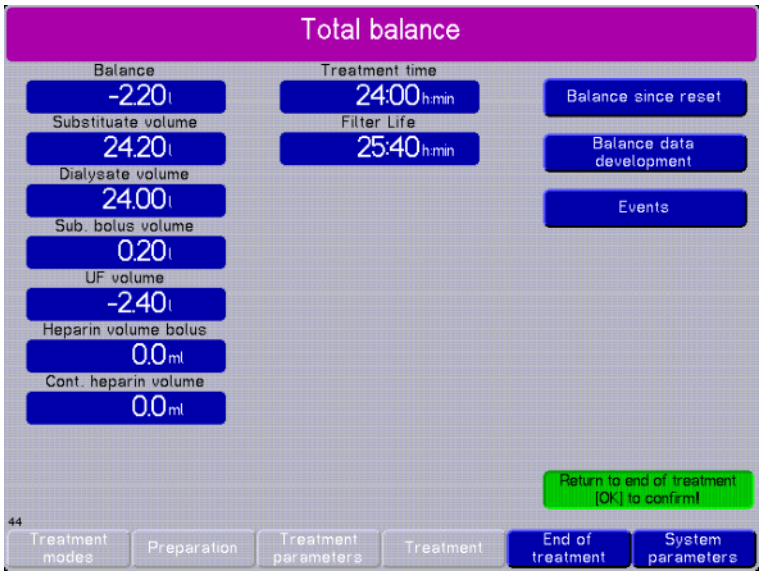
Open the clamps before and after the heater bag to facilitate removal of the bag.

➢ Remove and dispose of the tubing system.

To remove the remaining pump segments, proceed as described above.

➢ Use the rotary selector to select **View treatment history? [OK] to confirm!** Confirm with **[OK]**.

4.5.12 Treatment history



Indication of the treatment parameters for the respective treatment mode for the entire treatment.

➢ Press the **[I/O]** key to turn the device off.

4.6 CRRT treatments with citrate anticoagulation

Warning

Any treatment in connection with citrate anticoagulation may only be performed in intensive care units or under similarly close monitoring.

General description of the Ci-Ca CVVHD and Ci-Ca postCVVHDF treatments with information on the differences between the individual treatments.

Make the device ready for operation (see chapter 4.4 on page 4-12).

Note

The status bar shows **"CVVHD Ci-Ca"** or **"CVVHDF Ci-Ca Post"** as treatment mode. If the Ci-Ca module is selected, it is shown in white characters.
If the Ci-Ca module is deselected, Ci-Ca is shown in grey.

4.6.1 Starting conditions

Warning

Please be absolutely sure that the citrate and / or calcium concentrations as well as the citrate and / or calcium volume of the solutions used comply with the settings in the Setup menu of the multiFiltrate.

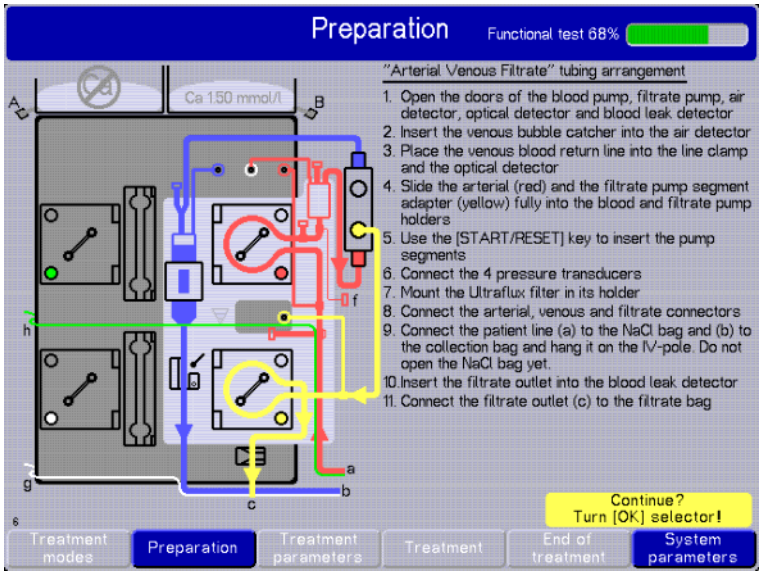
The concentration of the calcium solution used and of the calcium-containing substitution fluid must be set correctly in the **System parameters / Select Ci-Ca data** menu.

Note

Each treatment mode has its individual starting conditions.

The operator must ensure that the starting conditions are met before using the rotary selector to select **Conditions fulfilled** and pressing **[OK]**.

4.6.2 Inserting the cassette system



➢ Insert the cassette system according to the instructions.

➢ Turn the rotary selector clockwise until the next screen displays.

4.6.2.1 Inserting the citrate tube and the calcium tube

Warning

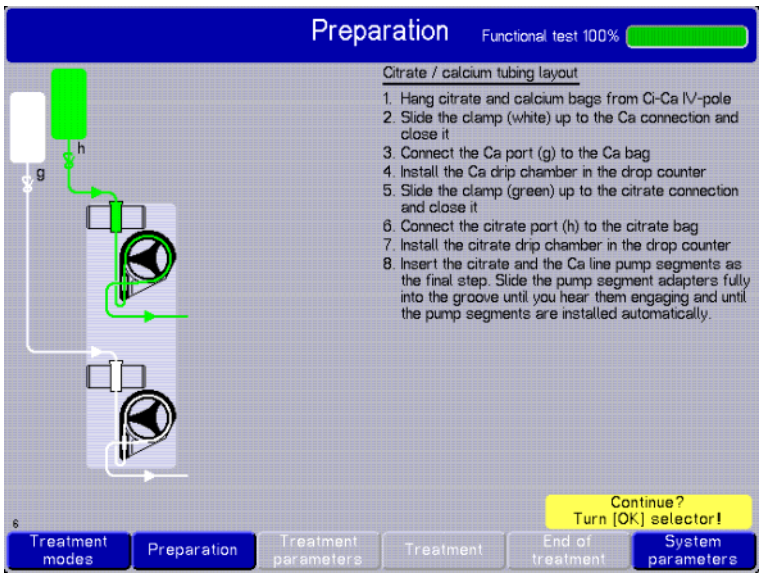
When inserting the citrate and calcium tubes, ensure that the tube segments and reservoirs for the solutions concerned are properly locked and assigned.

Warning

The citrate and calcium solutions must be at room temperature before they can be used.

Note

The following requirements must be fulfilled before inserting the Ci-Ca pump segments to be able to perform automatic priming:
– The clamps (white and green) are moved to the connectors.
– The clamps (white and green) are closed.



➢ Insert the citrate and calcium tubing system according to the instructions.

➢ Turn the rotary selector clockwise until the next screen displays.

4.6.3 Inserting further tubing systems

Depending on the selected treatment mode, the tubing system for dialysate and / or substituate has to be inserted.

Warning

Please ensure that the dialysate / substitution fluid used is suitable for the selected Ci-Ca treatment.

Note

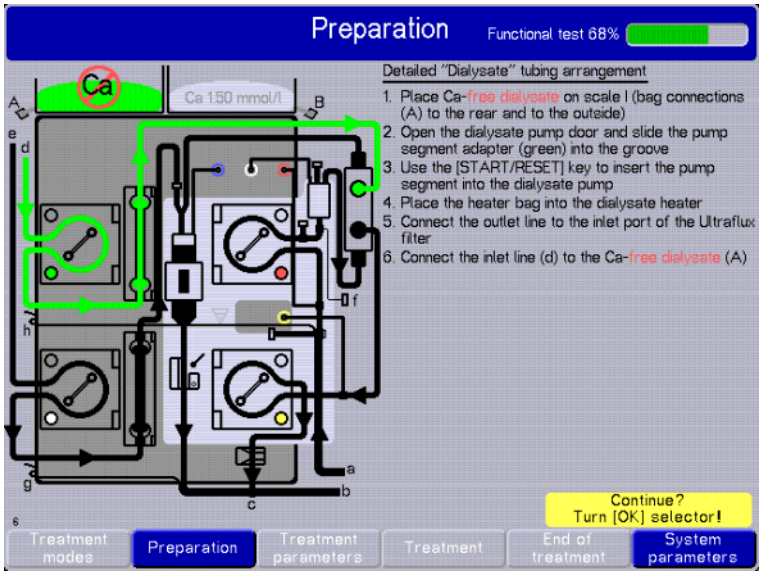
Depending on the settings, the dialysate and substituate tubing arrangement may differ from the illustration on the screen. The device has to be set up in accordance with the instructions on the screen.

The settings for the tubing system may only be changed by technical service support.

4.6.3.1 Inserting the dialysate tubing system

Warning

Ci-Ca CVVHD and Ci-Ca postCVVHDF treatments may only be performed if calcium-free dialysate is used.



➢ Insert the dialysate tubing system according to the instructions.

➢ Turn the rotary selector clockwise until the next screen displays.

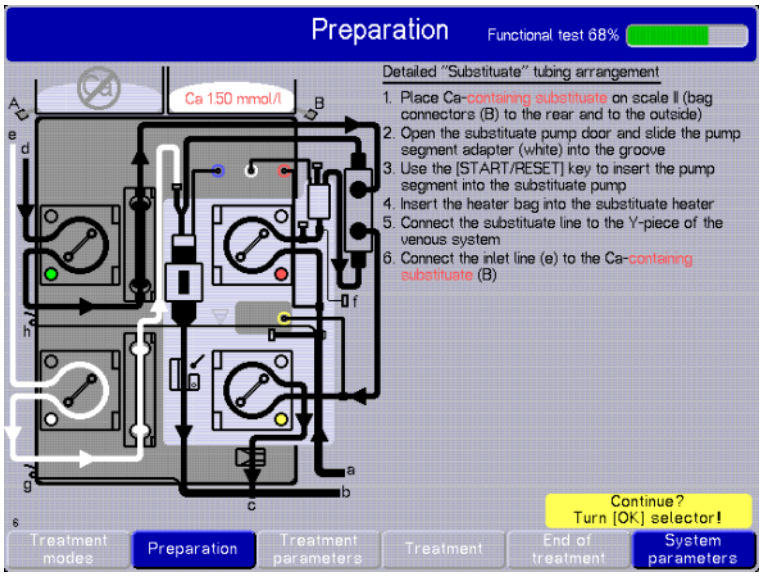
4.6.3.2 Inserting the substituate tubing system (except for CVVHD Ci-Ca)

Warning

A Ci-Ca postCVVHDF treatment may only be performed if a calcium-containing HF solution is used.

Note

For a Ci-Ca postCVVHDF treatment, the substituate line must always be connected to the postdilution port.



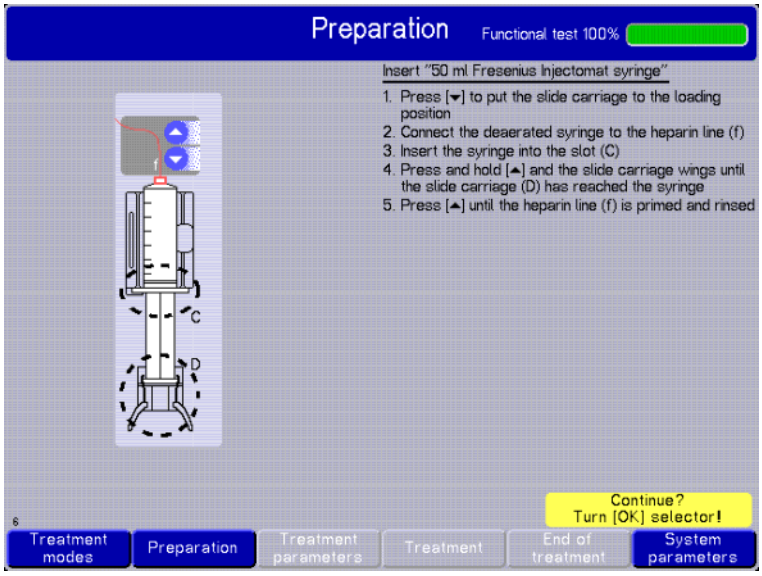
➢ Insert the substituate tubing system according to the instructions.

➢ Turn the rotary selector clockwise until the next screen displays.

4.6.4 Inserting the heparin syringe

Note

If a heparin syringe is used, it must be inserted and connected before connecting the patient.



➢ Insert the heparin syringe according to the instructions.

➢ Turn the rotary selector clockwise until the next screen displays.

Note on C

The syringe wings must be placed in the syringe wing slot.

Note on D

The thumbplate of the syringe plunger must be positioned between the clamps of the grip handle.

4.6.5 Complete tubing arrangement

Warning

Patient hazard: air embolism

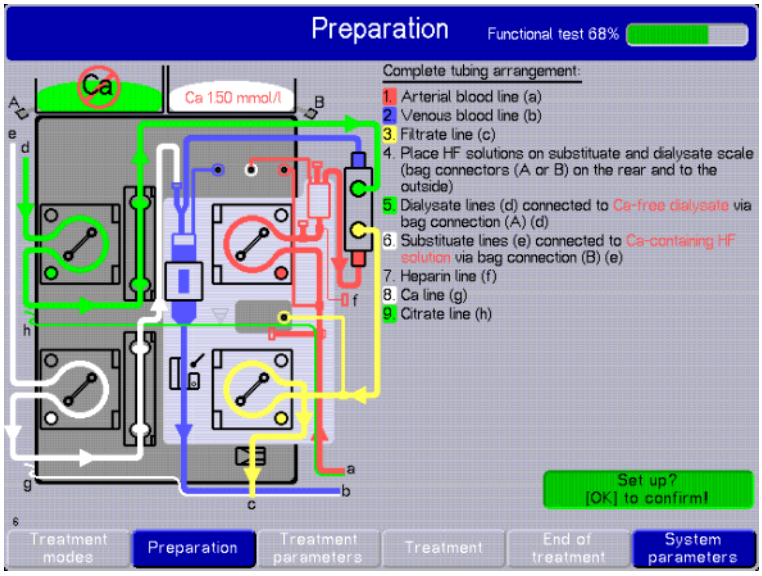
The air detector must be clean and dry.
Do not use any ultrasound-conducting objects or media.

Blood clots (coagula) can cause the air bubble detector to fail.

Note

Ensure that the filtrate bag hangs freely and does not touch any other objects.

Do not insert the filtrate tube too tightly between the blood leak detector and the filtrate bag.



This screen will be displayed immediately if the setting in the System parameters menu was set to **Complete tubing arrangement**.

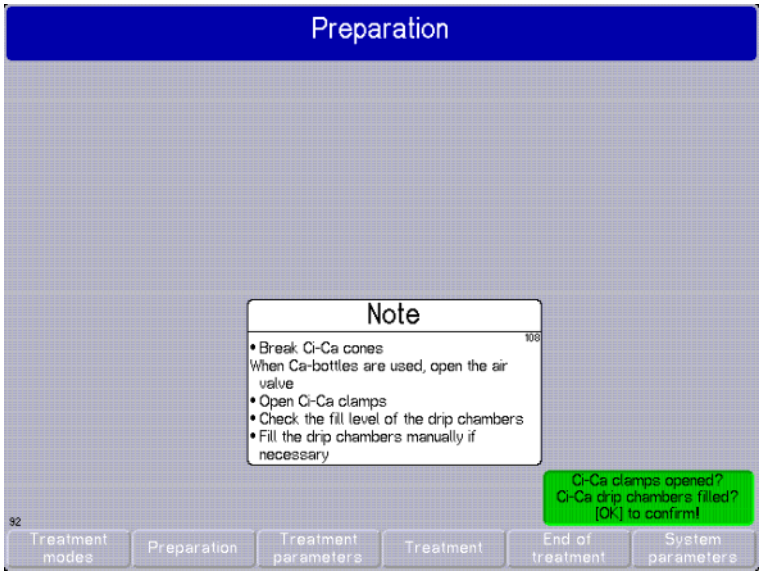
➢ Confirm the completely inserted tubing system using the rotary selector to select **Set up? [OK] to confirm!** and press **[OK]**.

4.6.6 Preparation

Note

The patient must not be connected during preparation. If the optical detector senses opaque fluid during the preparation phase, the system asks whether a patient has been connected.

4.6.6.1 Filling the citrate and calcium drip chambers

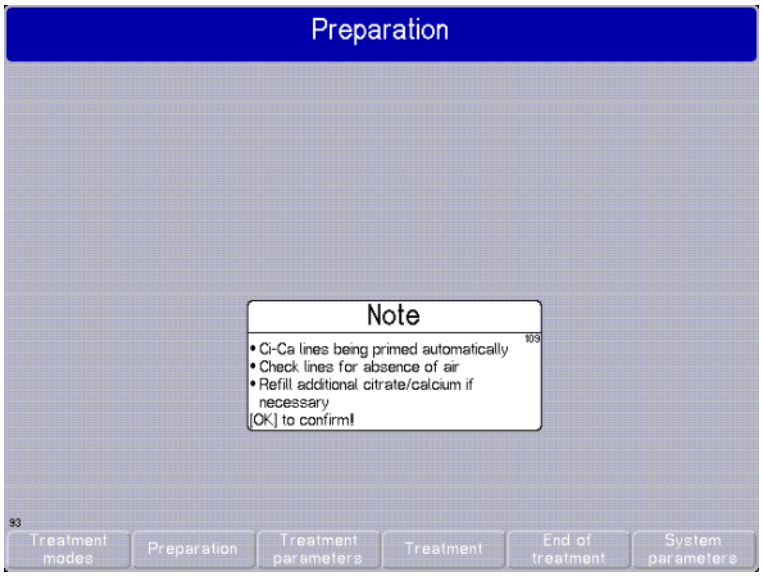


➢ Open the white and green clamps on the Ci-Ca lines and, if present, break the cones of the solution bags.

Due to the negative pressure, the drip chambers are automatically filled to a level of approx. 15 mm. If this fails, manually readjust the level.

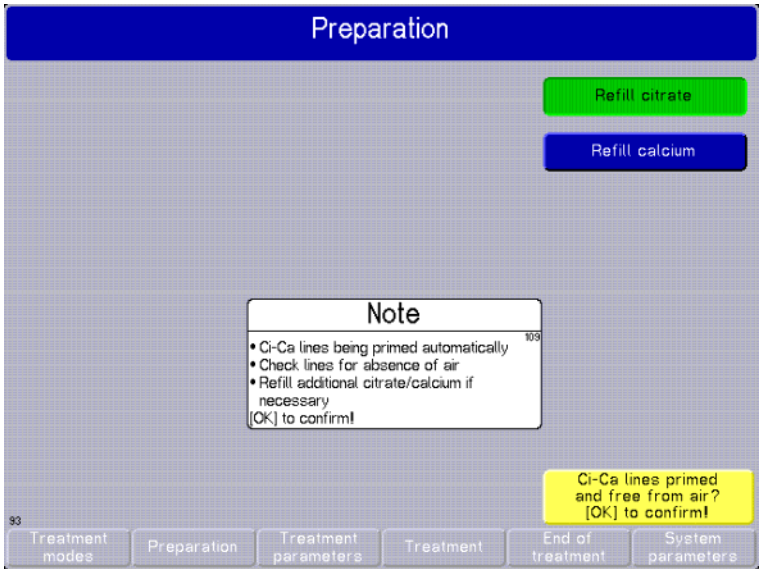
➢ Use the rotary selector to select **Ci-Ca clamps opened? Ci-Ca drip chambers filled? [OK] to confirm!** and press **[OK]**.

4.6.6.2 Priming the Ci-Ca lines



The Ci-Ca pumps fill the Ci-Ca lines with fluid for a defined time period.

In that time period, entries cannot be made on the multiFiltrate. Citrate anticoagulation cannot be deselected before the Ci-Ca lines are filled completely.



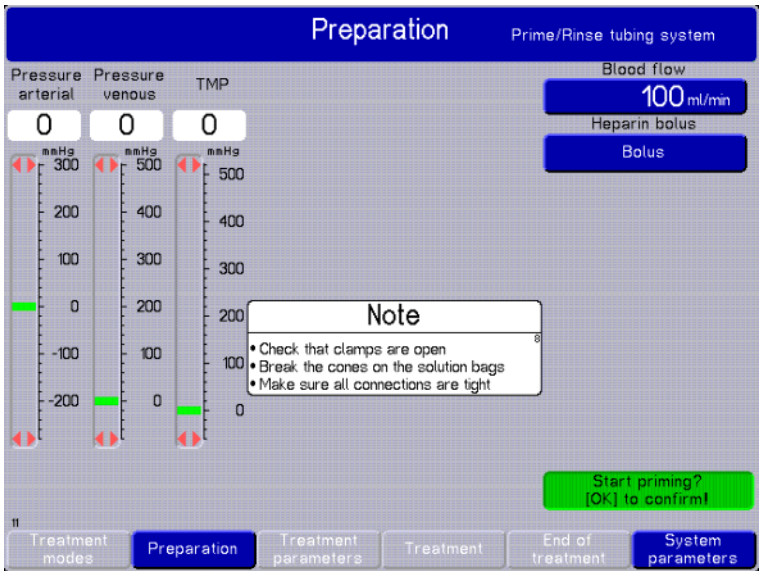
The filling level of the Ci-Ca lines can be readjusted.

➢ Use the rotary selector to select **"Refill citrate"** or **"Refill calcium"** and press **[OK]**.

The particular pump will run for one revolution. This procedure can be repeated as often as required.

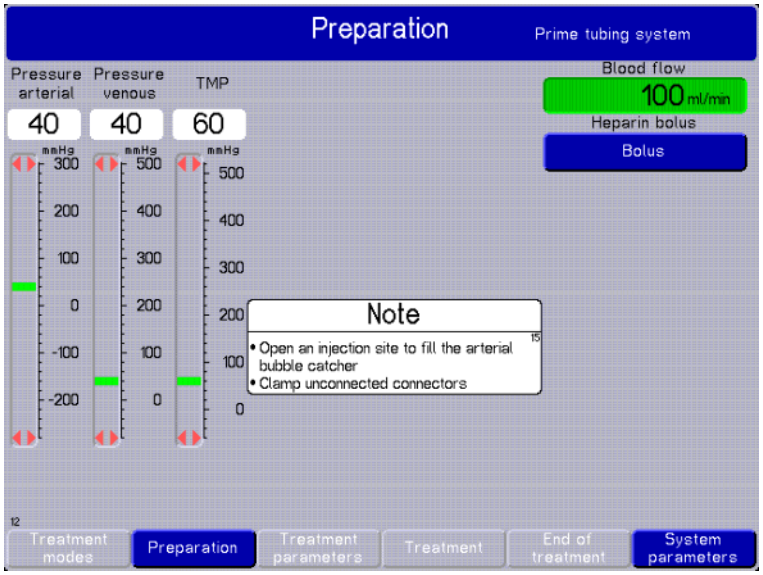
➢ Once the Ci-Ca lines are primed while being free from air, use the rotary selector to select **Ci-Ca lines primed and free from air? [OK] to confirm!** and press **[OK]**.

4.6.6.3 Priming the tubing system



➢ Use the rotary selector to select **Start priming? [OK] to confirm!** and press **[OK]**.

Heparin can be added to the NaCl solution used for priming and rinsing via the **Bolus** menu field.



➢ Open the infusion / extraction point to prime the arterial bubble catcher.

If the amount of air in the arterial bubble catcher has decreased to a level of approx. 1 cm underneath the lid, the infusion / extraction point has to be closed.

4.6.6.4 Rinsing the tubing system / entering treatment parameters

Warning

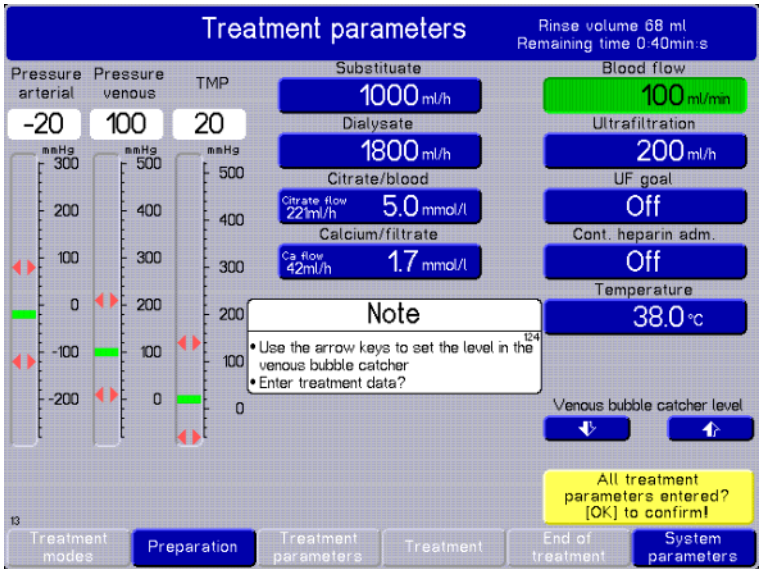
Please ensure that the ratios of blood flow to dialysate flow / substituate flow are properly set.

Note

Please set the treatment parameters (citrate dose, calcium dose, blood flow, dialysate flow) as described in chapter 7.

Note

The heparin dose is to be administered as prescribed by the physician! If an initial heparin dose is to be administered, use the bolus function.



The ultrasonic sensor detects fluid in the venous bubble catcher. Set the venous level manually using the **Venous bubble catcher level** menu field.

Rinsing starts automatically and the screen for entering the treatment parameters appears.

Indication of the decreasing rinse volume and the remaining rinse time.

➢ Use the rotary selector to select the required treatment parameters (green background) and press **[OK]**.

The possible entries depend on the selected treatment mode.

➢ Use the rotary selector to enter the required parameters and press **[OK]**.

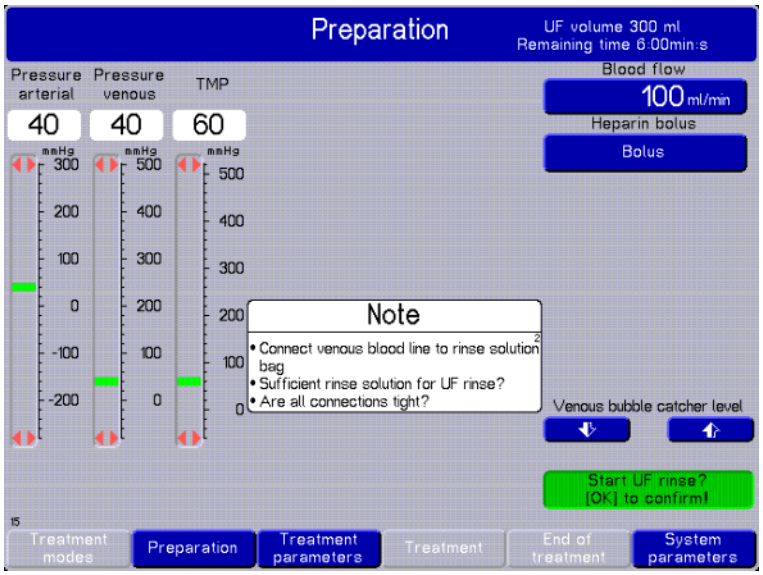
Set all treatment parameters as described above.

➢ Use the rotary selector to select **All treatment parameters entered? [OK] to confirm!** and press **[OK]**.

4.6.6.5 UF rinse

Note

When using NaCl solutions with only one connector, make sure there is enough NaCl solution.



After the rinse is completed and the pre-defined volume used, the blood pump will stop.

Audible signal

If using an NaCl solution with two connectors:

➢ Disconnect the venous patient line from the empty bag and connect it to the NaCl solution.

If using an NaCl solution with one connector:
Do not change the existing connection.

➢ Use the rotary selector to select **Start UF rinse? [OK] to confirm!** and press **[OK]**.

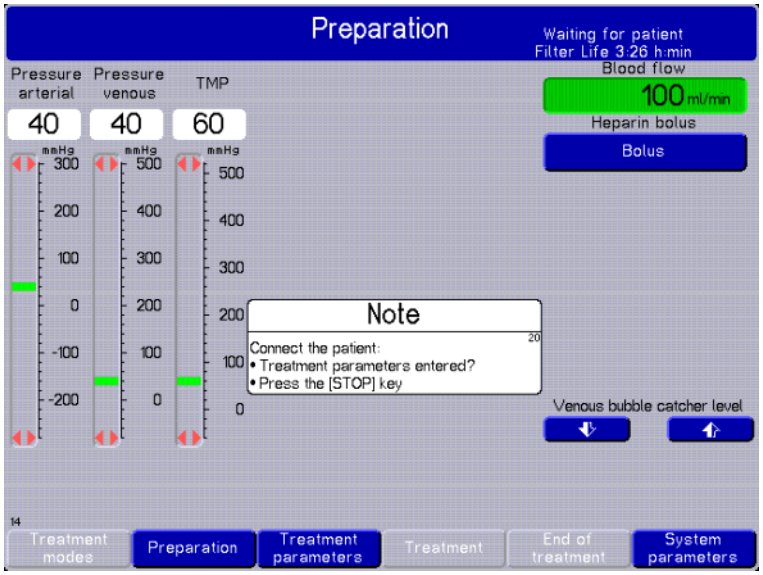
Indication of the decreasing UF volume and the remaining rinse time.

➢ Turn the filter upon notification.

4.6.6.6 Recirculation / waiting for patient

Note

The filter life, which is shown in the status bar, is automatically added to the service life of the tubing systems.



When the UF volume reaches 0 ml, the extracorporeal blood circuit is in recirculation.

If using an NaCl solution with two connectors:
Do not change the existing connection.

If using an NaCl solution with one connector:

➢ Stop recirculation by pressing the **[STOP]** key.

Press the [STOP] key for approx. 3 seconds.

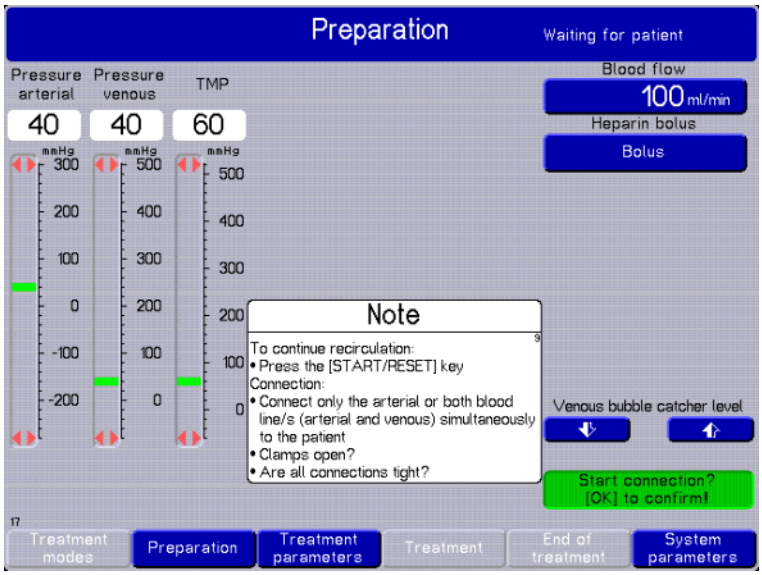
➢ Connect the venous patient line to the arterial patient line using the recirculator.

➢ Continue recirculation by pressing the **[START/RESET]** key.

4.6.6.7 Connecting the patient

Tip

If the patient is not yet available, then recirculation can be continued by pressing the **[START/RESET]** key.



If using an NaCl solution with two connectors:

➢ Disconnect the arterial patient line from the NaCl solution and connect it to the arterial vascular access.

or

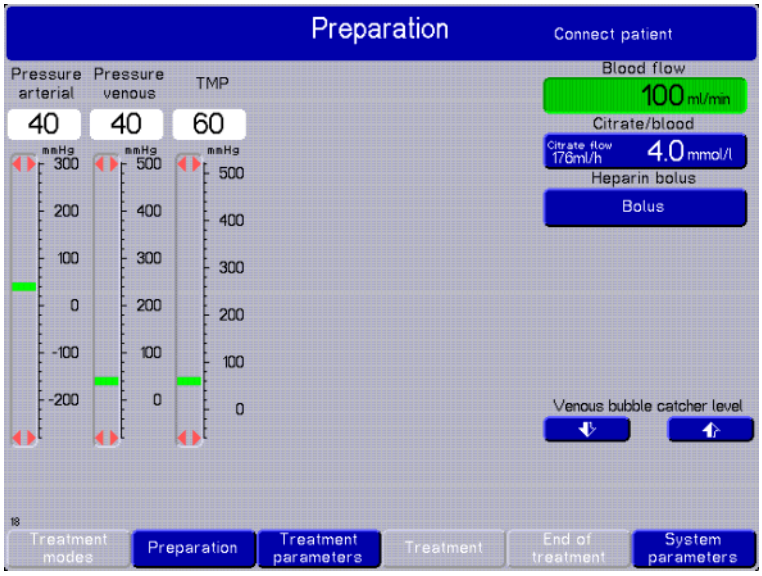
➢ Connect the arterial and venous patient line to the vascular access.

If using an NaCl solution with one connector:

➢ Connect the arterial and venous patient line to the vascular access.

and

➢ Use the rotary selector to select **Start connection? [OK] to confirm!** and press **[OK]**.

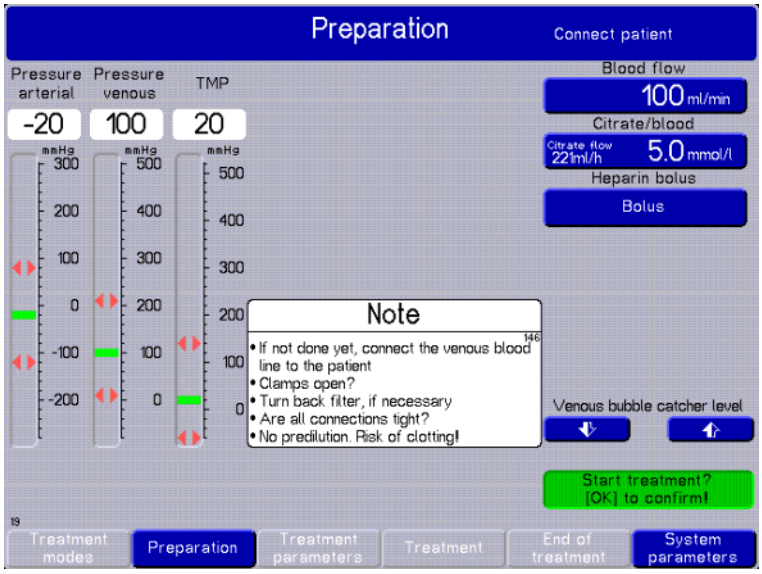


The blood pump will deliver at the programmed rate.

Settable rate:
10 ml/min to 100 ml/min
(default 100 ml/min)

The citrate pump will deliver at the corresponding rate.

It will stop if the optical detector senses opaque fluid or, for safety reasons, after 10 minutes at the latest.



The optical detector senses opaque fluid.

The blood pump is stopped.

If not done yet when using an NaCl solution with two connectors:

➢ Disconnect the venous patient line from the NaCl solution and connect it to the venous vascular access.

➢ Use the rotary selector to select **Start treatment? [OK] to confirm!** and press **[OK]**.

4.6.7 Treatment

Note

Once treatment has started and the blood pump has achieved its target delivery rate, the alarm limits are set automatically after approx. 10 seconds. Following this, the pressure alarm limits must be checked by the operator and adjusted individually as required.

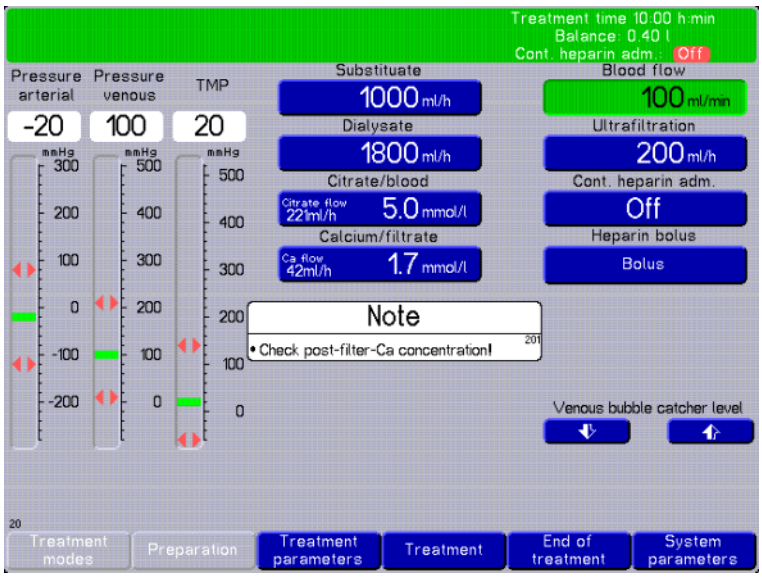
4.6.7.1 Checking the post-filter calcium concentration

Warning

When starting the treatment, define the post-filter calcium value. If the ionised calcium has not decreased at this point, it is absolutely necessary that the tubing system and the solutions used are checked.

Warning

If the measured post-filter calcium value or systemic calcium value varies significantly, please consult a physician. Observe the instructions on taking a sample (see chapter 7.3.2 on page 7-17).



5 minutes after the treatment has been started, a note is displayed, accompanied by a short audible signal. This is the prompt to check the post-filter calcium concentration now.

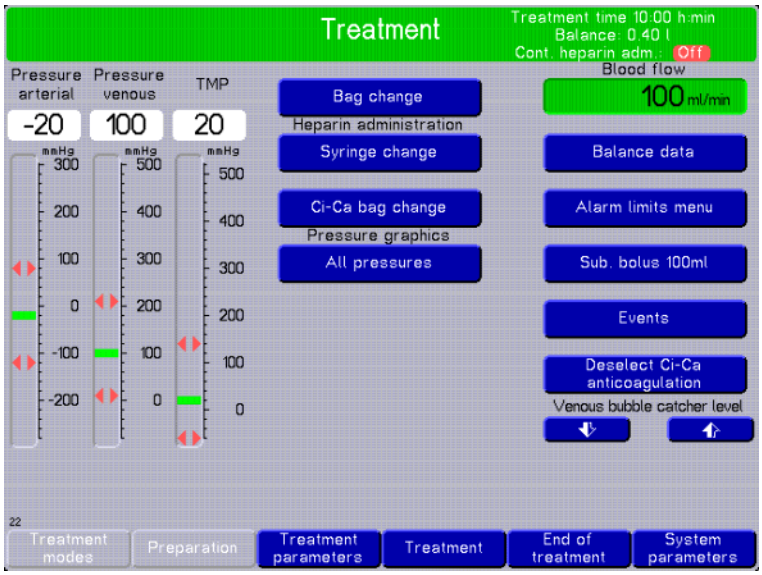
4.6.7.2 Treatment main screen

The main screen is displayed throughout the entire treatment.

Depending on the treatment mode, the menu field shows:
The current pressures (arterial, venous, TMP)
The current flow rates (dialysate, substituate in postdilution, blood flow, ultrafiltration)
Citrate / blood dose and citrate flow
Calcium / filtrate dose and calcium flow
Heparin

The status bar shows:
The treatment mode
The progression of the treatment time
The balance
Continuous anticoagulation on / off

4.6.7.3 Treatment menu



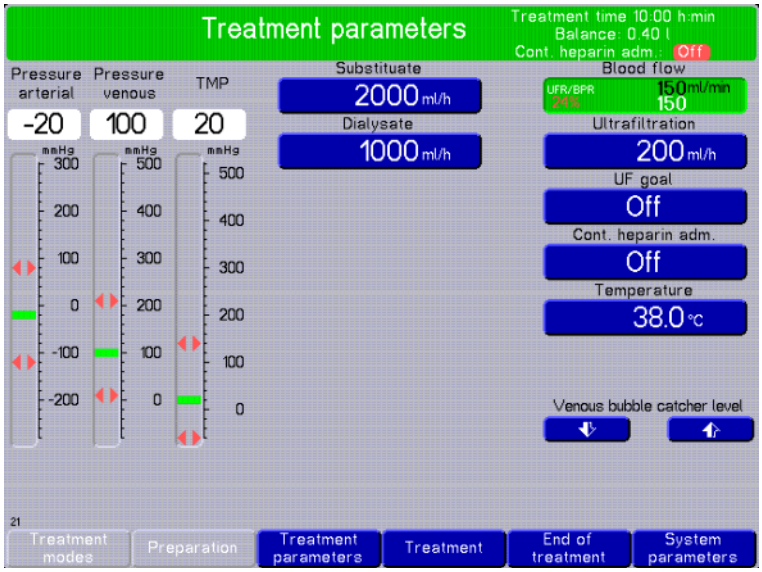
➢ Press the **[ESC]** key.

➢ Use the rotary selector to select **Treatment** from the menu bar and press **[OK]**.

The menu fields shown depend on the selected treatment mode. Detailed description (see chapter 4.11 on page 4-104).

After a timeout, the display will automatically return to the treatment main screen.

4.6.7.4 Treatment parameters



➢ Press the **[ESC]** key.

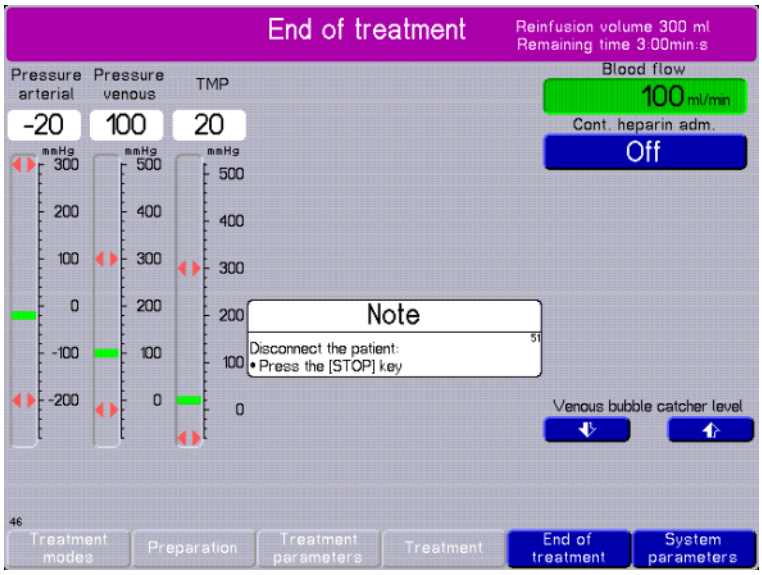
➢ Use the rotary selector to select **Treatment parameters** from the menu bar and press **[OK]**.

The treatment parameters shown depend on the selected treatment mode.

After a timeout, the display will automatically return to the treatment main screen.

4.6.8 End of treatment

4.6.8.1 Terminating the treatment



➢ Press the **[ESC]** key.

➢ Use the rotary selector to select **End of treatment** from the menu bar and press **[OK]** to confirm.

The blood pump is running.
Balance is off.
The calcium pump stops.

The citrate pump runs until the optical detector senses non-opaque fluid, but for no longer than 10 min.

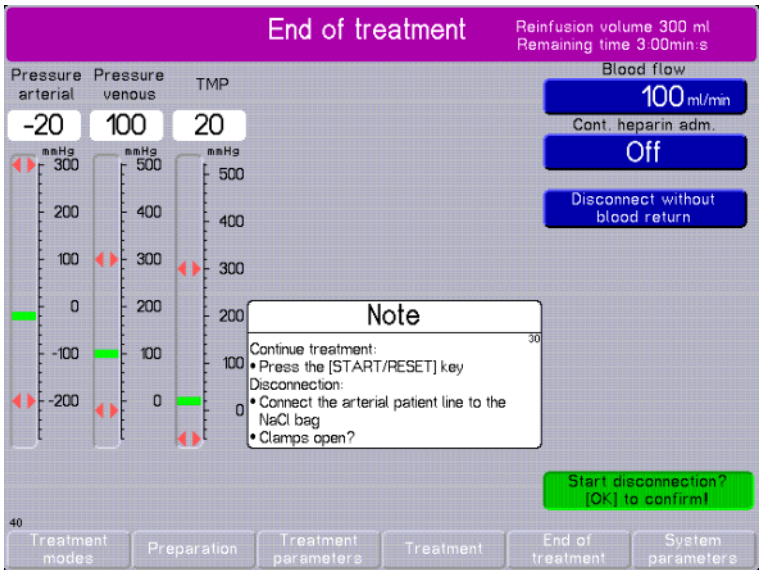
➢ Stop the treatment by pressing the **[STOP]** key.

Press the [STOP] key for approx. 3 seconds.
The venous clamp closes.
The blood pump is stopped.

or

➢ Use the **[ESC]** key to select a different menu from the menu bar.

4.6.8.2 Starting reinfusion



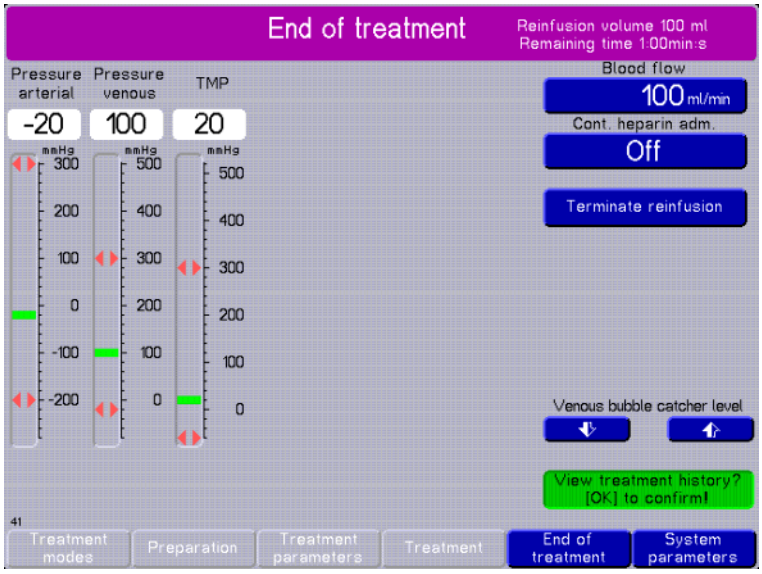
➢ Continue the treatment by pressing the **[START/RESET]** key.

or

➢ Disconnect the arterial patient line from the patient and connect it to the NaCl solution.

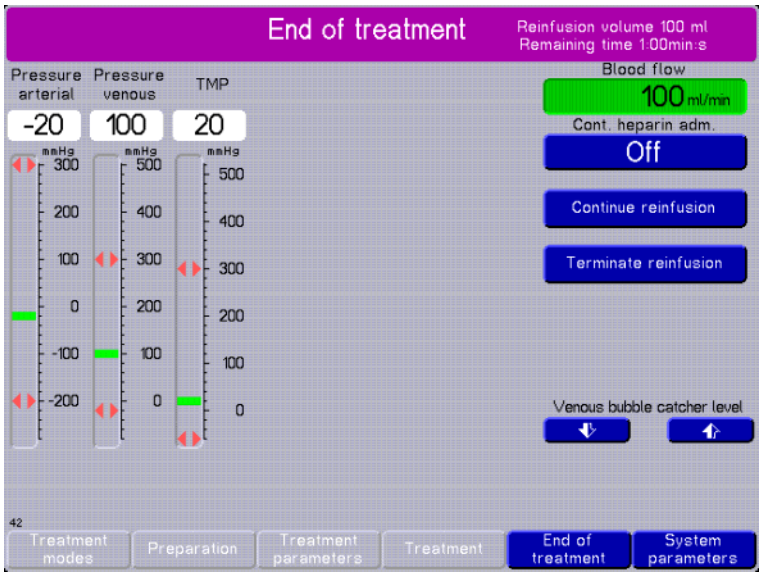
➢ Use the rotary selector to select **Start disconnection? [OK] to confirm!** and press **[OK]**.

When selecting **Disconnect without blood return**, the program will go directly to "Disconnecting the patient" without reinfusion after a safety prompt (see chapter 4.6.9 on page 4-48).



Indication of the decreasing reinfusion volume.

Selecting **View treatment history? [OK] to confirm!** will display the treatment parameters.



The optical detector senses non-opaque fluid.

➢ When selecting **Continue reinfusion**, the remaining reinfusion volume can be returned to the patient.

or

➢ Use the rotary selector to select **Terminate reinfusion** and press **[OK]**.

The citrate pump stops.

but

The treatment will be terminated automatically if the reinfusion volume is 0 ml and the optical detector senses non-opaque fluid.

The citrate pump stops.

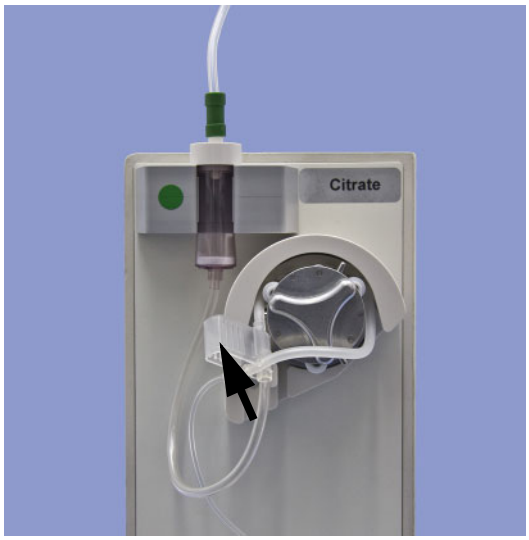
4.6.9 Disconnecting the patient and removing the tubing system

Warning

It is forbidden to remove the Ci-Ca lines manually before the patient is disconnected.

Warning

Consumables must be discarded after the treatment in compliance with the regulations for the disposal of potentially contaminated materials.



➢ Disconnect the venous patient line from the patient.

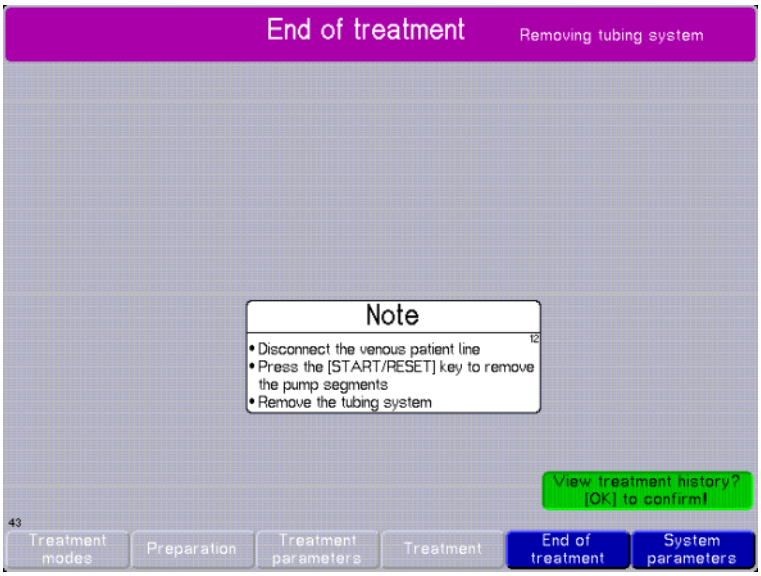
➢ Remove the calcium pump segment from the stationary part (stator) of the calcium pump at the pump segment adapter.

The rotor of the calcium pump immediately starts to remove the pump segment (2 revolutions).

➢ Remove the citrate pump segment from the stationary part (stator) of the citrate pump at the pump segment adapter.

The rotor of the citrate pump immediately starts to remove the pump segment (2 revolutions).
Support the removal of the pump segment by slightly pulling on it.

If a Ci-Ca pump segment cannot be removed completely, press the pump segment adapter into the appropriate pump once again and repeat the removal process.



➢ Remove the pump segment adapter from the groove.

➢ Press and hold the **[START/RESET]** key until the pump segment has been completely removed.

Support the removal of the pump segment by slightly pulling on it.

➢ Remove the heater bag (depending on the treatment mode) from the heater.

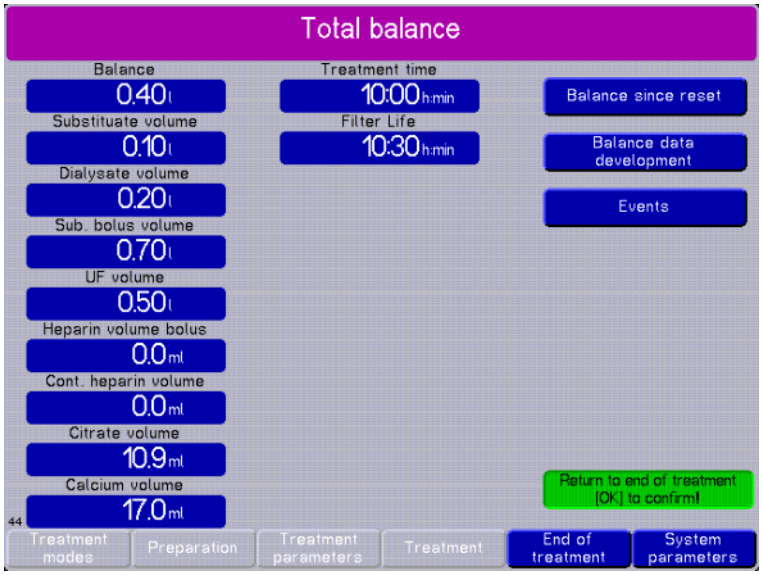
Open the clamps before and after the heater bag to facilitate removal of the bag.

➢ Remove and dispose of the tubing system.

To remove the remaining pump segments, proceed as described above.

➢ Use the rotary selector to select **View treatment history? [OK] to confirm!** Confirm with **[OK]**.

4.6.10 Treatment history



Indication of the treatment parameters for the entire treatment.

➢ Press the **[I/O]** key to turn the device off.

4.7 Paediatric CRRT treatments

General description of the paediatric CVVH and CVVHD treatments with information on the differences between the individual treatments.

Make the device ready for operation (see chapter 4.4 on page 4-12).

Note

The multiFiltrate paed CRRT / SCUF set tubing system has to be used for paediatric CVVH and CVVHD treatment modes.

The status bar shows **"Paed. CVVHD"** or **"Paed. CVVH"** as the treatment mode.

4.7.1 Starting conditions

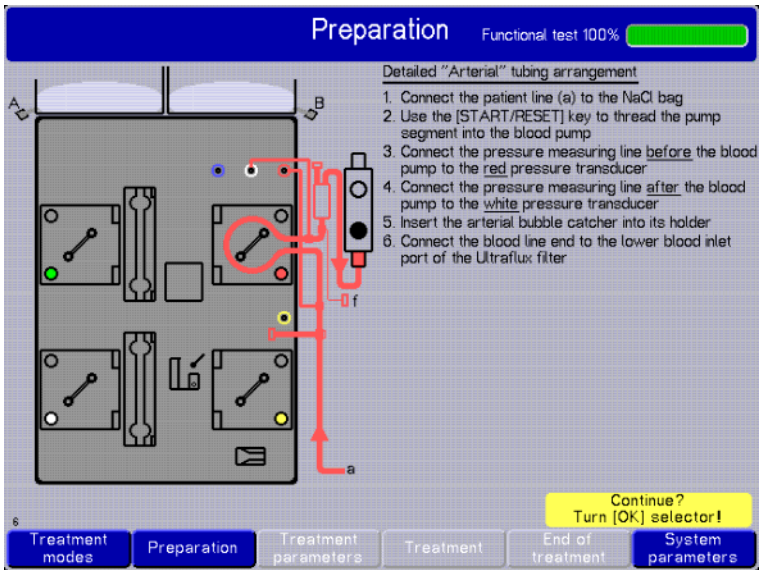
Note

Each treatment mode has its individual starting conditions.

The operator must ensure that the starting conditions are met before using the rotary selector to select **Conditions fulfilled** and pressing **[OK]**.

4.7.2 Inserting the AV set

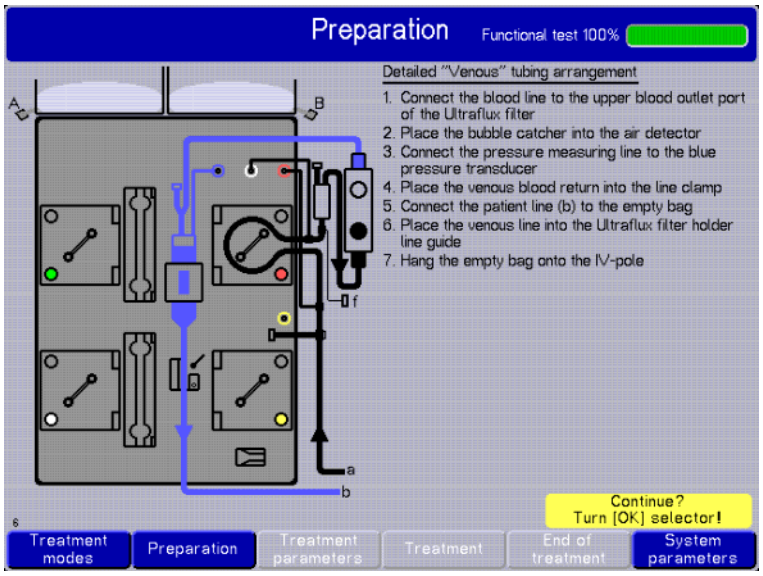
4.7.2.1 Inserting the arterial blood line system



➢ Insert the arterial blood line system according to the instructions.

➢ Turn the rotary selector clockwise until the next screen displays.

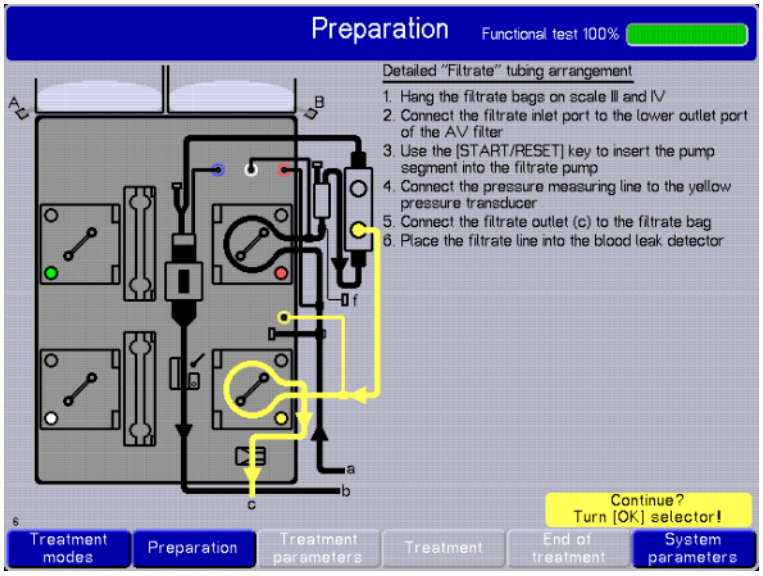
4.7.2.2 Inserting the venous blood line system



➢ Insert the venous blood line system according to the instructions.

➢ Turn the rotary selector clockwise until the next screen displays.

4.7.2.3 Inserting the filtrate line system



➢ Insert the filtrate line system according to the instructions.

➢ Turn the rotary selector clockwise until the next screen displays.

4.7.3 Inserting further tubing systems

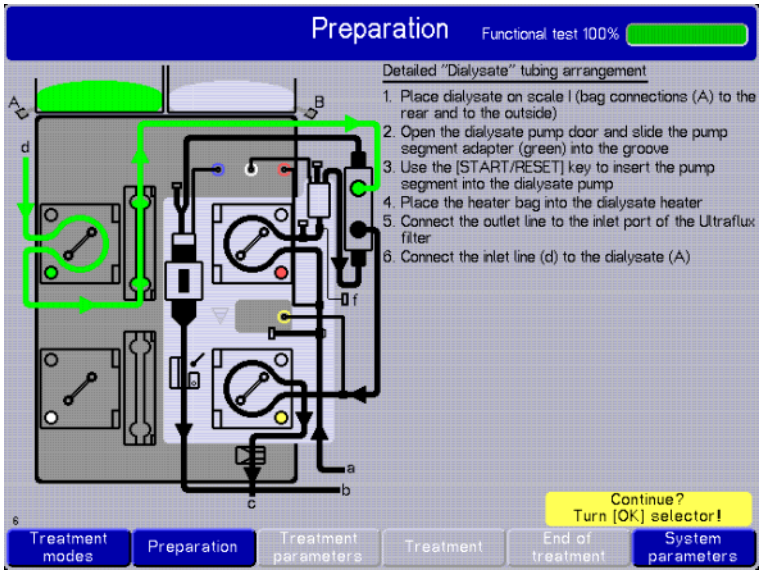
Depending on the selected treatment mode, the tubing system for dialysate or substituate has to be inserted.

Note

Depending on the settings, the dialysate or substituate tubing arrangement may differ from the illustration. The device has to be set up in accordance with the instructions on the screen.

The settings for the tubing system may only be changed by technical service support.

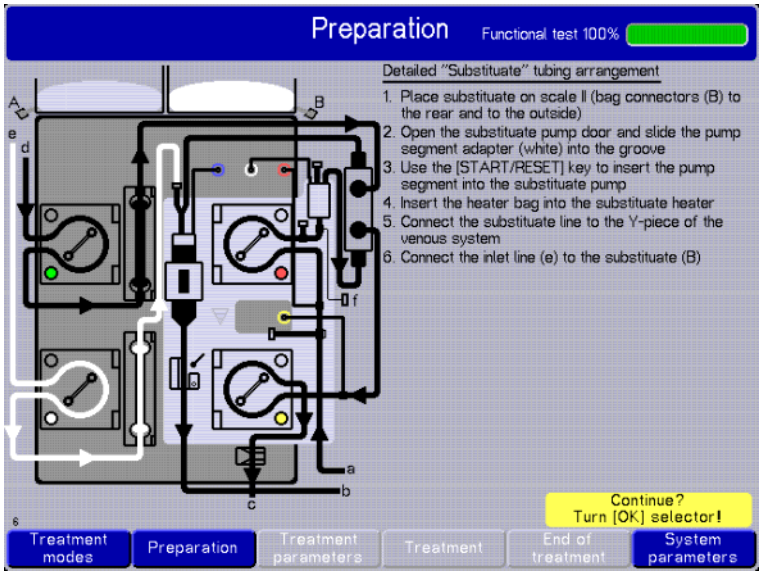
4.7.3.1 Inserting the dialysate tubing system (except for CVVH)



➢ Insert the dialysate tubing system according to the instructions.

➢ Turn the rotary selector clockwise until the next screen displays.

4.7.3.2 Inserting the substituate tubing system (except for CVVHD)



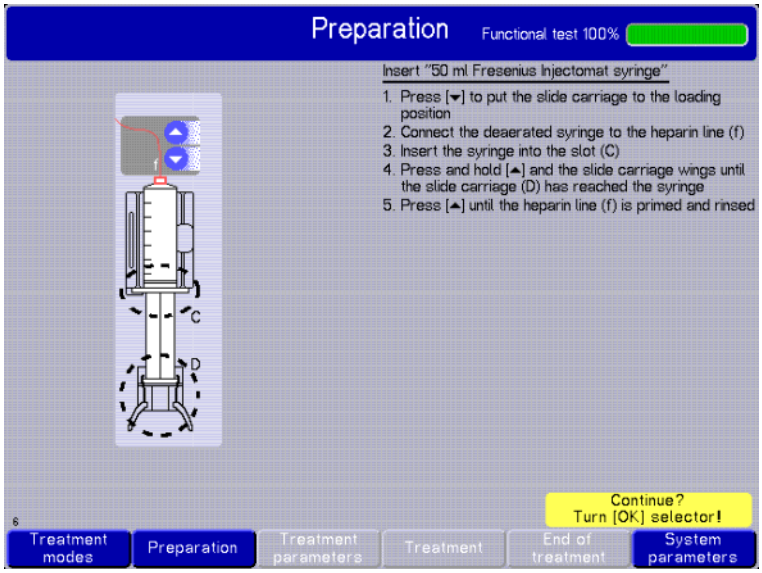
➢ Insert the substituate tubing system according to the instructions.

➢ Turn the rotary selector clockwise until the next screen displays.

4.7.4 Inserting the heparin syringe

Note

If a heparin syringe is used, it must be inserted and connected before connecting the patient.



➢ Insert the heparin syringe according to the instructions.

➢ Turn the rotary selector clockwise until the next screen displays.

Note on C

The syringe wings must be placed in the syringe wing slot.

Note on D

The thumbplate of the syringe plunger must be positioned between the clamps of the grip handle.

4.7.5 Complete tubing arrangement

Warning

Patient hazard: air embolism

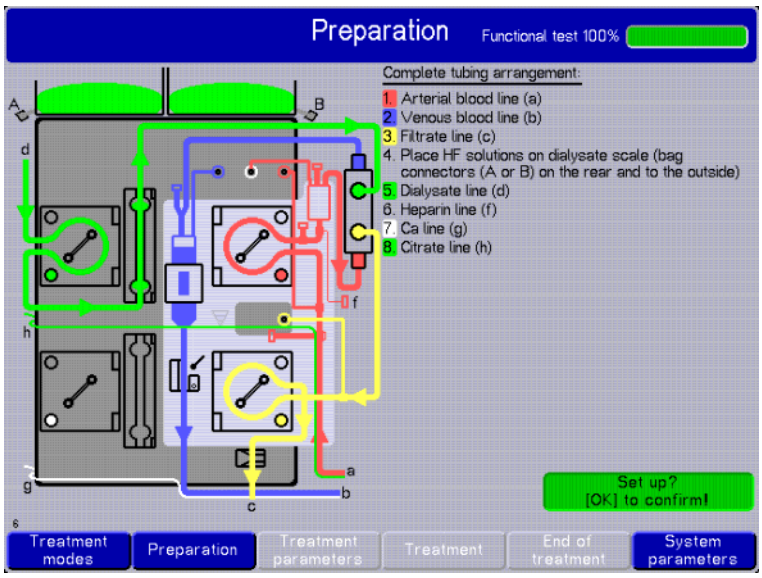
The air detector must be clean and dry.
Do not use any ultrasound-conducting objects or media.

Blood clots (coagula) can cause the air bubble detector to fail.

Note

Ensure that the filtrate bag hangs freely and does not touch any other objects.

Do not insert the filtrate tube too tightly between the blood leak detector and the filtrate bag.



This screen will be displayed immediately if the setting in the System parameters menu was set to **Complete tubing arrangement**.

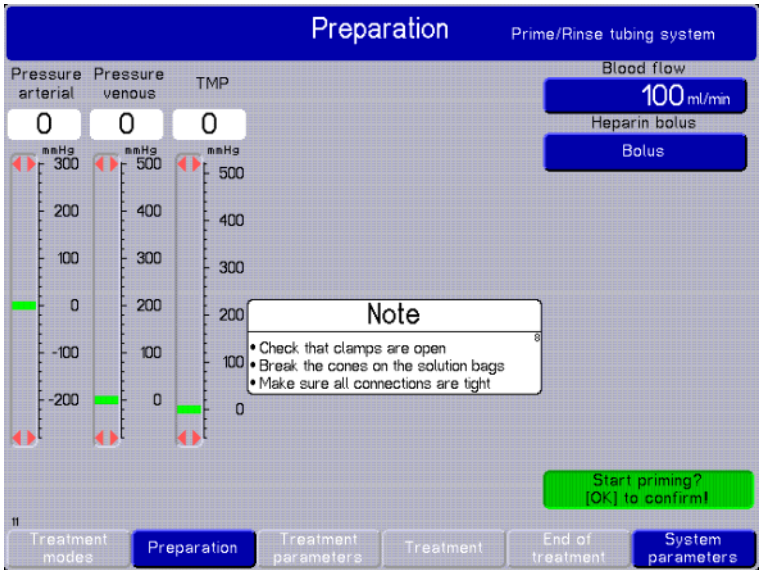
➢ Confirm the completely inserted tubing system using the rotary selector to select **Set up? [OK] to confirm!** and press **[OK]**.

4.7.6 Preparation

Note

The patient must not be connected during preparation. If the optical detector senses opaque fluid during the preparation phase, the system asks whether a patient has been connected.

4.7.6.1 Priming the tubing system



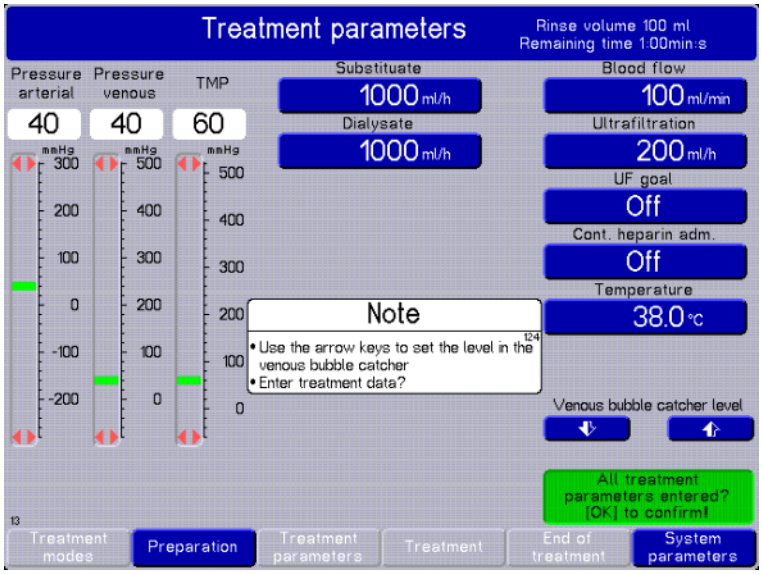
➢ Use the rotary selector to select **Start priming? [OK] to confirm!** and press **[OK]**.

Heparin can be added to the NaCl solution used for priming and rinsing via the **Bolus** menu field.

4.7.6.2 Rinsing the tubing system / entering treatment parameters

Note

The heparin dose is to be administered as prescribed by the physician! If an initial heparin dose is to be administered, the bolus function can be used.



The ultrasonic sensor detects fluid in the venous bubble catcher. Set the venous level manually using the **Venous bubble catcher level** menu field.

Rinsing starts automatically and the screen for entering the treatment parameters appears.

Indication of the decreasing rinse volume and the remaining rinse time.

➢ Use the rotary selector to select the required treatment parameters (green background) and press **[OK]**.

The possible entries depend on the selected treatment mode.

➢ Use the rotary selector to enter the required parameters and press **[OK]**.

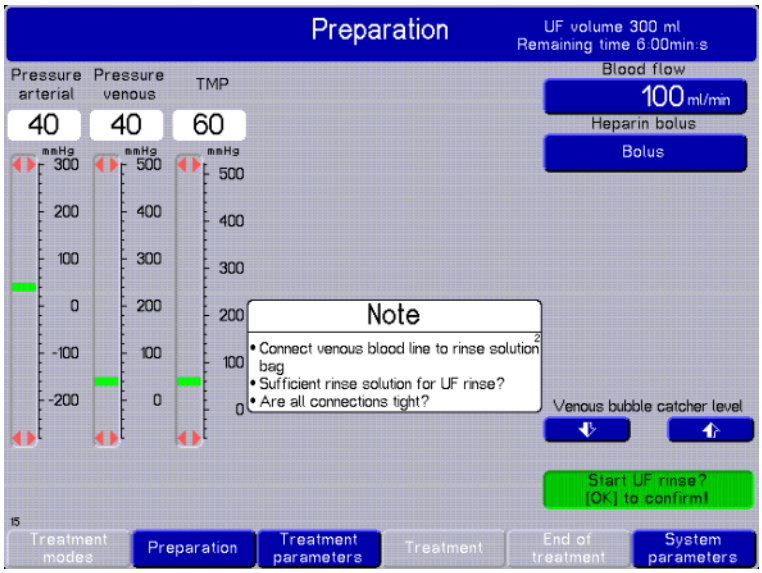
Set all treatment parameters as described above.

➢ Use the rotary selector to select **All treatment parameters entered? [OK] to confirm!** and press **[OK]**.

4.7.6.3 UF rinse

Note

When using NaCl solutions with only one connector, make sure there is enough NaCl solution.



After the rinse is completed and the pre-defined volume used, the blood pump will stop.

An audible signal will be given.

If using an NaCl solution with two connectors:

➢ Disconnect the venous patient line from the empty bag and connect it to the NaCl solution.

If using an NaCl solution with one connector:
Do not change the existing connection.

➢ Use the rotary selector to select **Start UF rinse? [OK] to confirm!** and press **[OK]**.

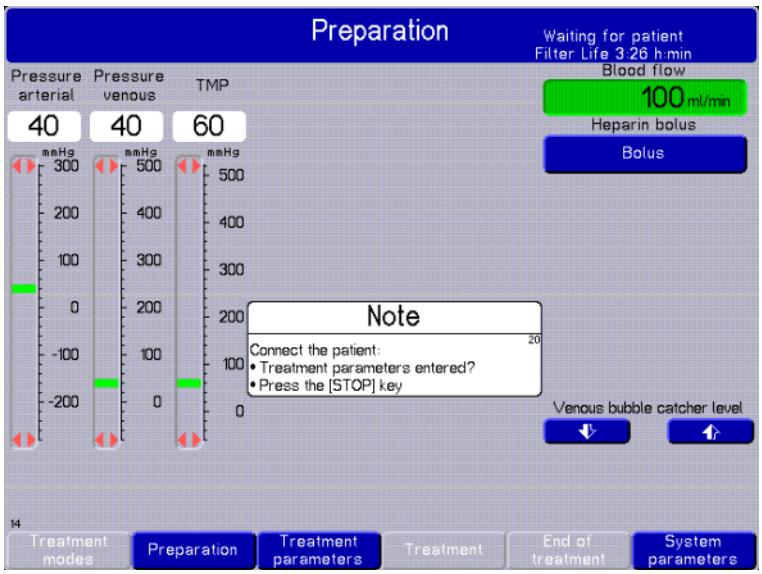
Indication of the decreasing UF volume and the remaining rinse time.

➢ Turn the filter upon notification.

4.7.6.4 Recirculation / waiting for patient

Note

The filter life, which is shown in the status bar, is automatically added to the service life of the tubing systems.



When the UF volume reaches 0 ml, the extracorporeal blood circuit is in recirculation.

If using an NaCl solution with two connectors:
Do not change the existing connection.

If using an NaCl solution with one connector:

➢ Stop recirculation by pressing the **[STOP]** key.

Press the [STOP] key for approx. 3 seconds.

➢ Connect the venous patient line to the arterial patient line using the recirculator.

➢ Continue recirculation by pressing the **[START/RESET]** key.

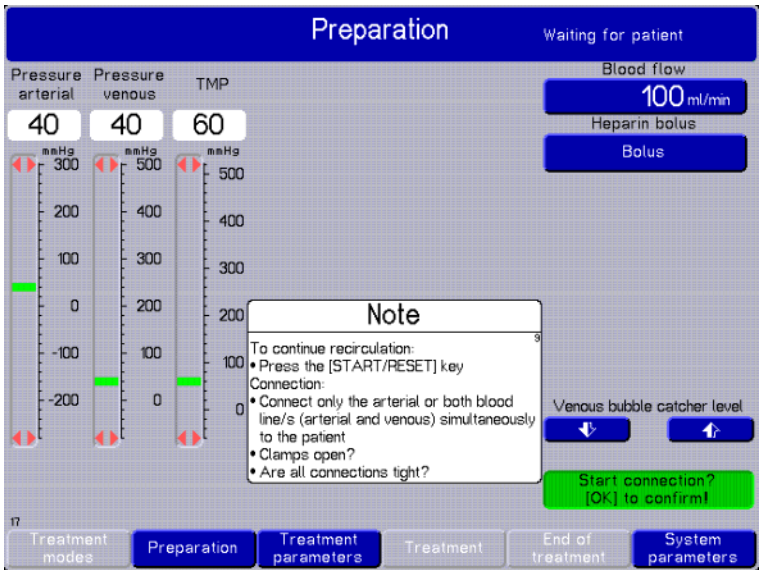
4.7.6.5 Connecting the patient

Tip

If the patient is not yet available, then recirculation can be continued by pressing the **[START/RESET]** key.

Note

In the case of CVVH, connect the substituate line in predilution, if necessary.



If using an NaCl solution with two connectors:

➢ Disconnect the arterial patient line from the NaCl solution and connect it to the arterial vascular access.

or

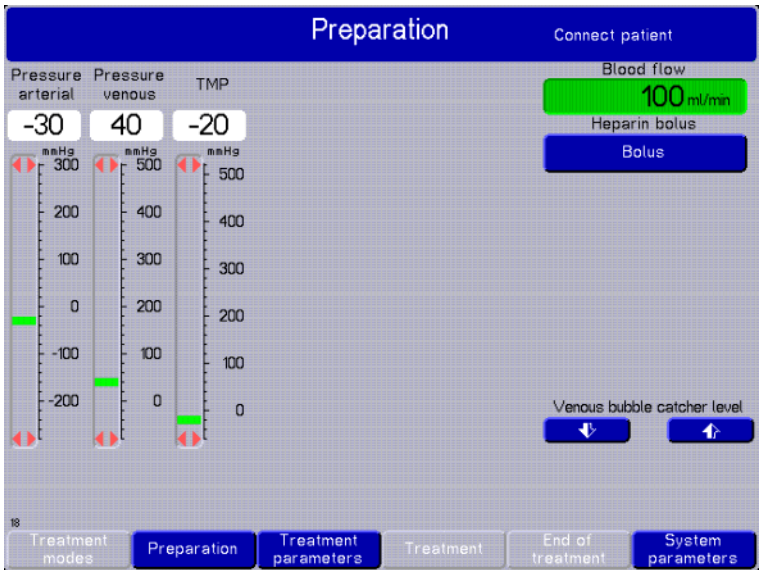
➢ Connect the arterial and venous patient line to the vascular access.

If using an NaCl solution with one connector:

➢ Connect the arterial and venous patient line to the vascular access.

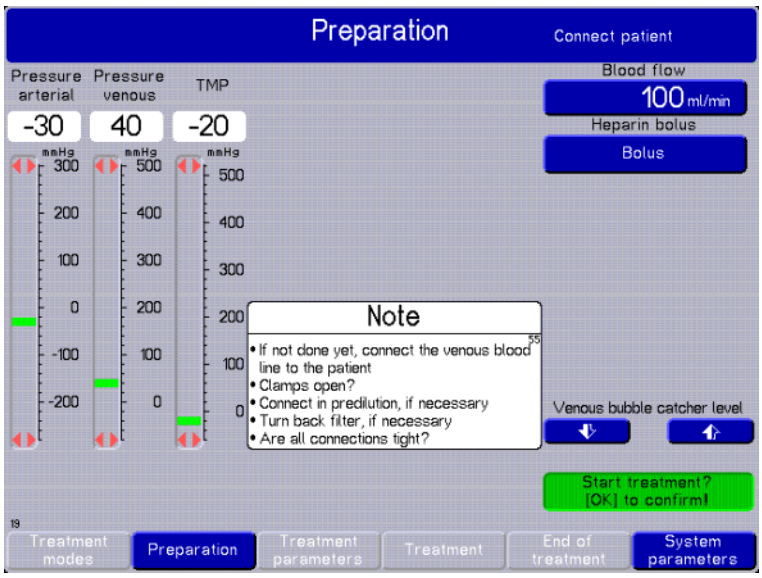
and

➢ Use the rotary selector to select **Start connection? [OK] to confirm!** and press **[OK]**.



The blood pump will deliver at the programmed rate.

Settable rate:
Paediatric 10 ml/min to 50 ml/min
(default 50 ml/min)



The optical detector senses opaque fluid.

The blood pump is stopped.

If not done yet when using an NaCl solution with two connectors:

➢ Disconnect the venous patient line from the NaCl solution and connect it to the venous vascular access.

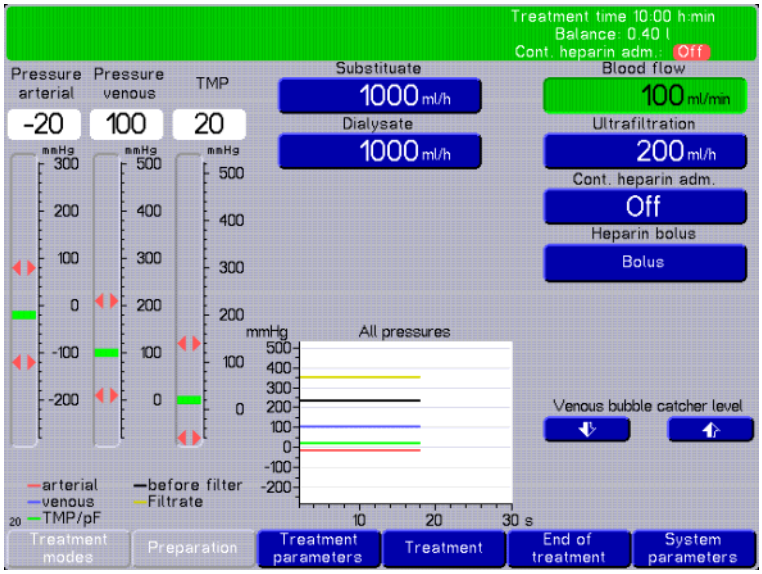
➢ Use the rotary selector to select **Start treatment? [OK] to confirm!** and press **[OK]**.

4.7.7 Treatment

Note

Once treatment has started and the blood pump has achieved its target delivery rate, the alarm limits are set automatically after approx. 10 seconds. Following this, the pressure alarm limits must be checked by the operator and adjusted individually as required.

4.7.7.1 Treatment main screen

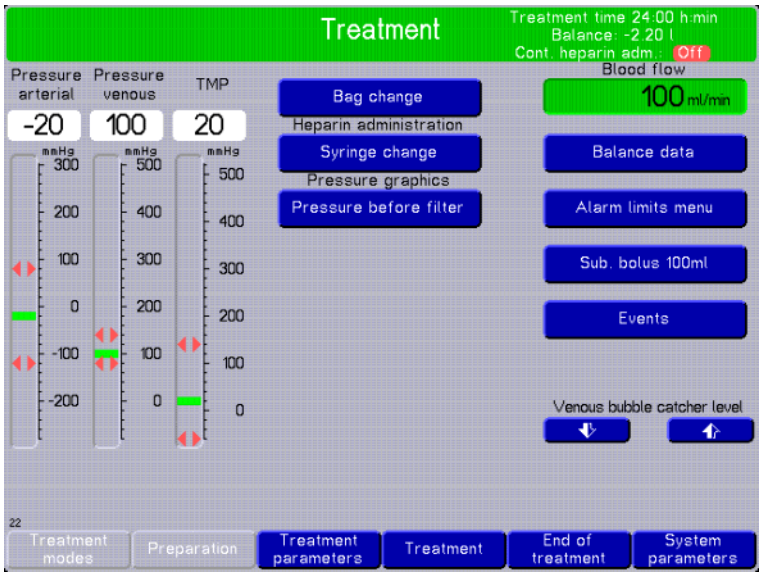


The main screen is displayed throughout the entire treatment.

Depending on the treatment mode, the menu field shows:
The current pressures (arterial, venous, TMP)
The current flow rates (dialysate, substituate, sub predilution, sub postdilution, blood flow, ultrafiltration)
Heparin

The status bar shows:
The treatment mode
The progression of the treatment time
The balance
Continuous anticoagulation on / off

4.7.7.2 Treatment menu



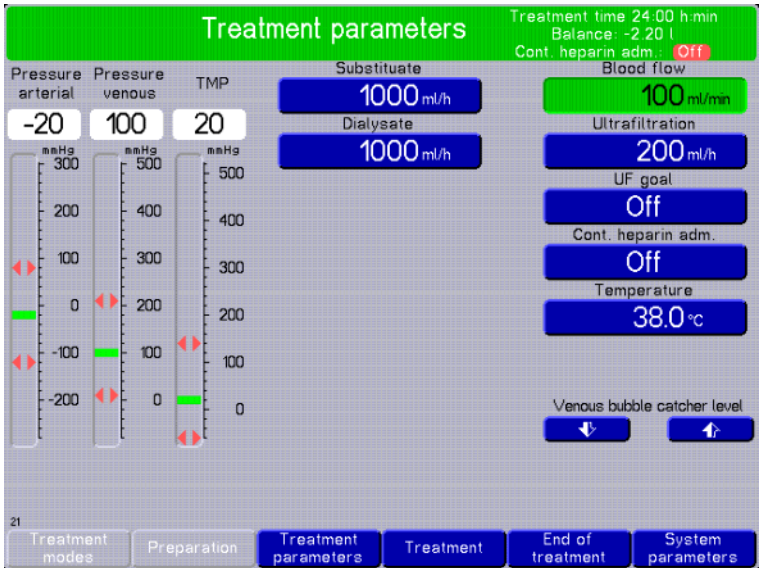
➢ Press the **[ESC]** key.

➢ Use the rotary selector to select **Treatment** from the menu bar and press **[OK]**.

The menu fields shown depend on the selected treatment mode. Detailed description (see chapter 4.11 on page 4-104).

After a timeout, the display will automatically return to the treatment main screen.

4.7.7.3 Treatment parameters



➢ Press the **[ESC]** key.

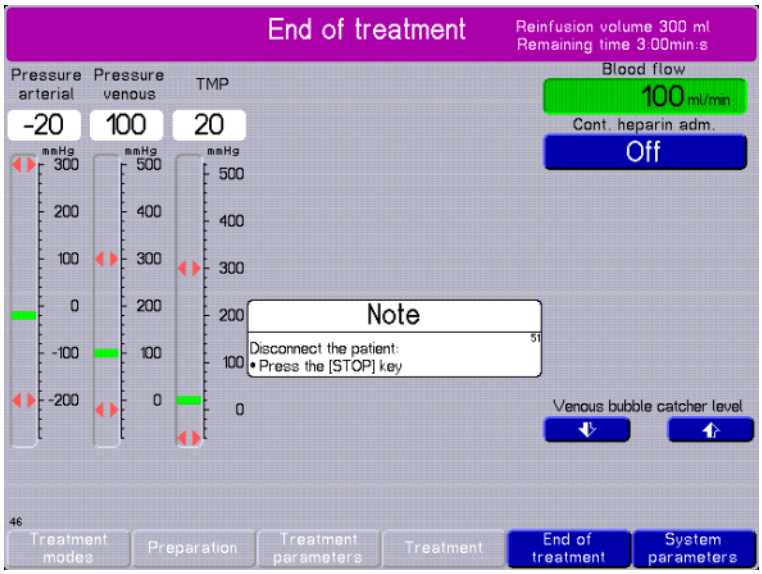
➢ Use the rotary selector to select **Treatment parameters** from the menu bar and press **[OK]**.

The treatment parameters shown depend on the selected treatment mode.

After a timeout, the display will automatically return to the treatment main screen.

4.7.8 End of treatment

4.7.8.1 Terminating the treatment



➢ Press the **[ESC]** key.

➢ Use the rotary selector to select **End of treatment** from the menu bar and press **[OK]** to confirm.

The blood pump is running.

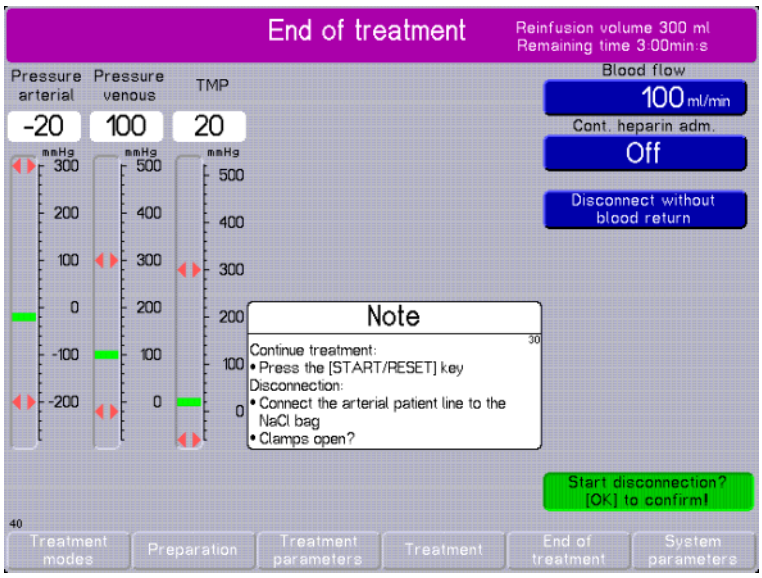
➢ Stop the treatment by pressing the **[STOP]** key.

Press the [STOP] key for approx. 3 seconds.
The venous clamp closes.
The blood pump is stopped.

or

➢ Use the **[ESC]** key to select a different menu from the menu bar.

4.7.8.2 Starting reinfusion



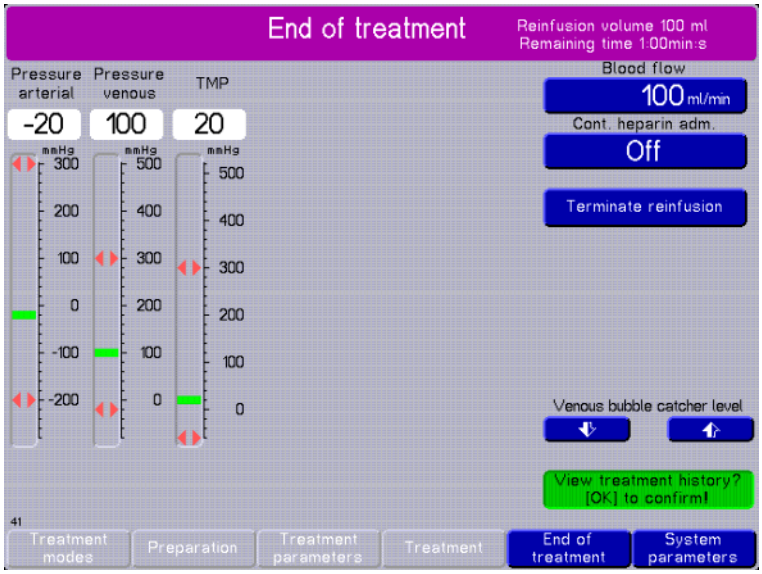
➢ Continue the treatment by pressing the **[START/RESET]** key.

or

➢ Disconnect the arterial patient line from the patient and connect it to the NaCl solution.

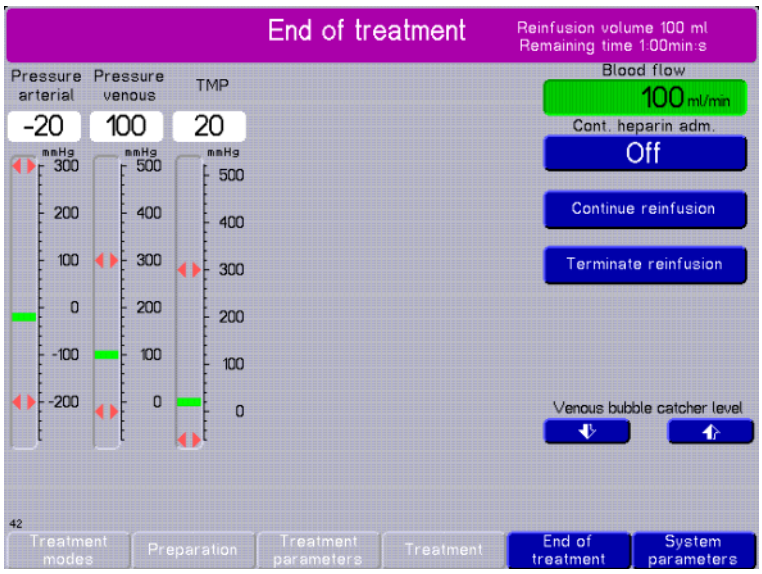
➢ Use the rotary selector to select **Start disconnection? [OK] to confirm!** and press **[OK]**.

When selecting **Disconnect without blood return**, the program will go directly to "Disconnecting the patient" without reinfusion after a safety prompt (see chapter 4.7.9 on page 4-63).



Indication of the decreasing reinfusion volume.

Selecting **View treatment history? [OK] to confirm!** will display the treatment parameters.



The optical detector senses non-opaque fluid.

➢ When selecting **Continue reinfusion**, the remaining reinfusion volume can be returned to the patient.

or

➢ Use the rotary selector to select **Terminate reinfusion** and press **[OK]**.

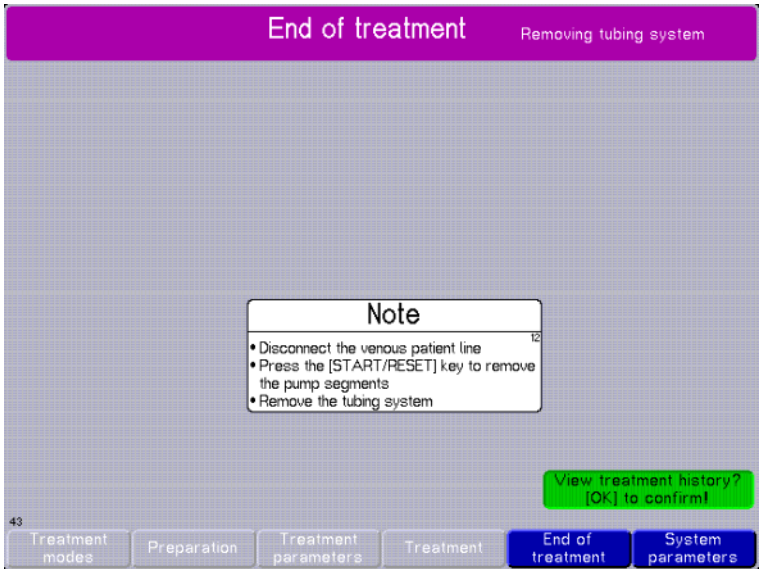
but

The treatment will be terminated automatically if the reinfusion volume is 0 ml and the optical detector senses non-opaque fluid.

4.7.9 Disconnecting the patient and removing the tubing system

Warning

Consumables must be discarded after the treatment in compliance with the regulations for the disposal of potentially contaminated materials.



➢ Disconnect the venous patient line from the patient.

➢ Remove the pump segment adapter from the groove.

➢ Press and hold the **[START/RESET]** key until the pump segment has been completely removed.

Support the removal of the pump segment by slightly pulling on it.

➢ Remove the heater bag (depending on the treatment mode) from the heater.

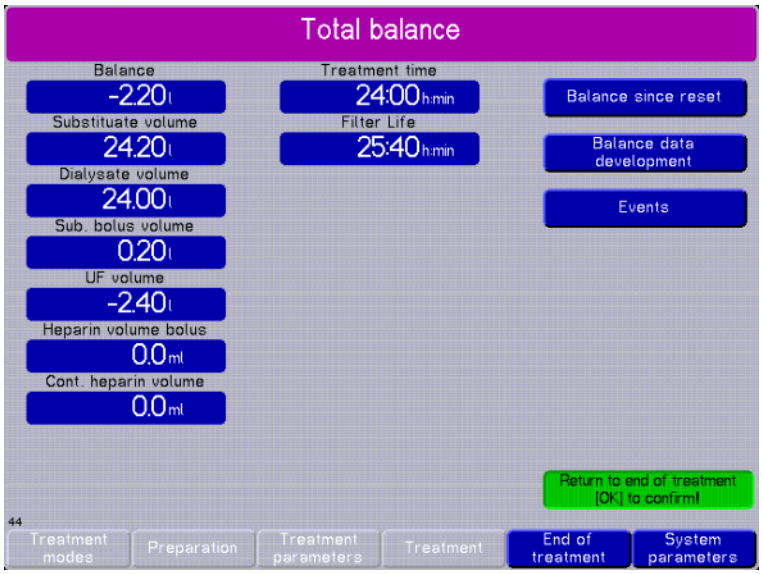
Open the clamps before and after the heater bag to facilitate removal of the bag.

➢ Remove and dispose of the tubing system.

To remove the remaining pump segments, proceed as described above.

➢ Use the rotary selector to select **View treatment history? [OK] to confirm!** Confirm with **[OK]**.

4.7.10 Treatment history



Indication of the treatment parameters for the entire treatment. The menu fields shown depend on the selected treatment mode.

➢ Press the **[I/O]** key to turn the device off.

4.8 Membrane plasma separation (MPS)

Make the device ready for operation (see chapter 4.4 on page 4-12).

4.8.1 Starting conditions

Note

Each treatment mode has its individual starting conditions.

The operator must ensure that the starting conditions are met before using the rotary selector to select **Conditions fulfilled** and pressing **[OK]**.

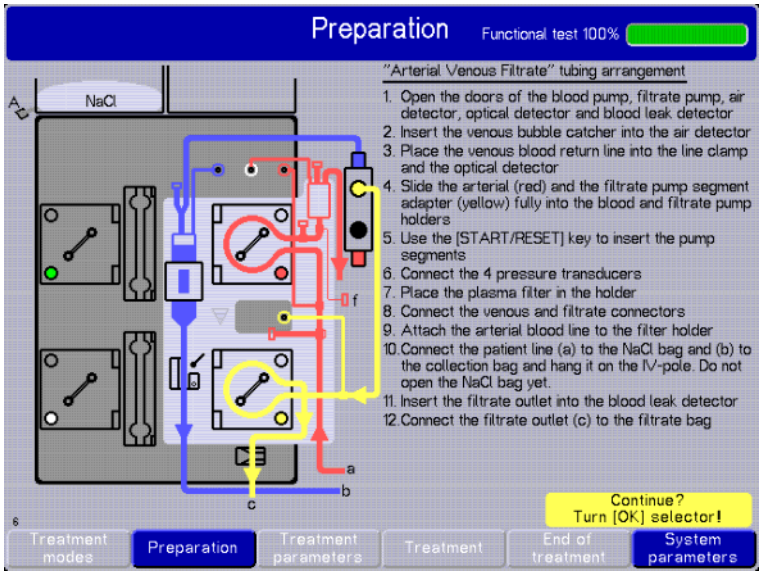
4.8.2 Inserting the cassette system or AV set

Note

Where plasma filters are supplied dry (not pre-filled), it is not necessary to fill the arterial tubing system before connecting this up to the filter. In contrast to the instructions shown on the screen, the arterial tubing system can be connected directly to the filter. If the filter's accompanying document does not require a higher volume for the UF rinse, a UF rinse volume of 300 ml is sufficient.

4.8.2.1 Inserting the cassette system

When using an AV set continue with "Inserting the arterial blood line system" (see chapter 4.8.2.2 on page 4-65)

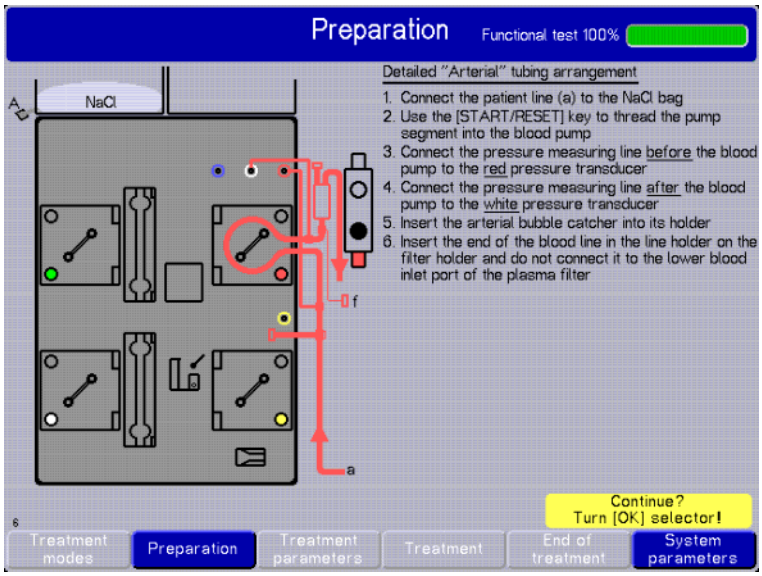


➢ Insert the cassette system according to the instructions.

➢ Turn the rotary selector clockwise until the next screen displays.

➢ Continue with "Inserting the heparin syringe" (see chapter 4.8.4 on page 4-67)

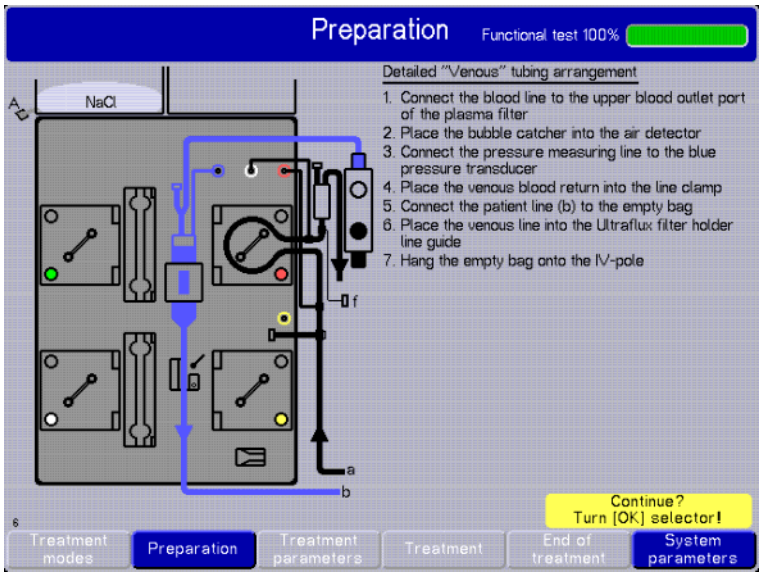
4.8.2.2 Inserting the arterial blood line system



➢ Insert the arterial blood line system according to the instructions.

➢ Turn the rotary selector clockwise until the next screen displays.

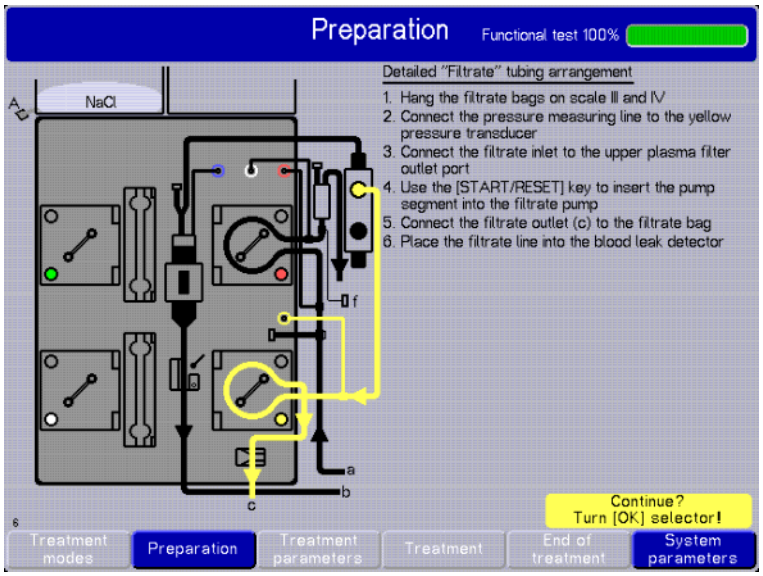
4.8.2.3 Inserting the venous blood line system



➢ Insert the venous blood line system according to the instructions.

➢ Turn the rotary selector clockwise until the next screen displays.

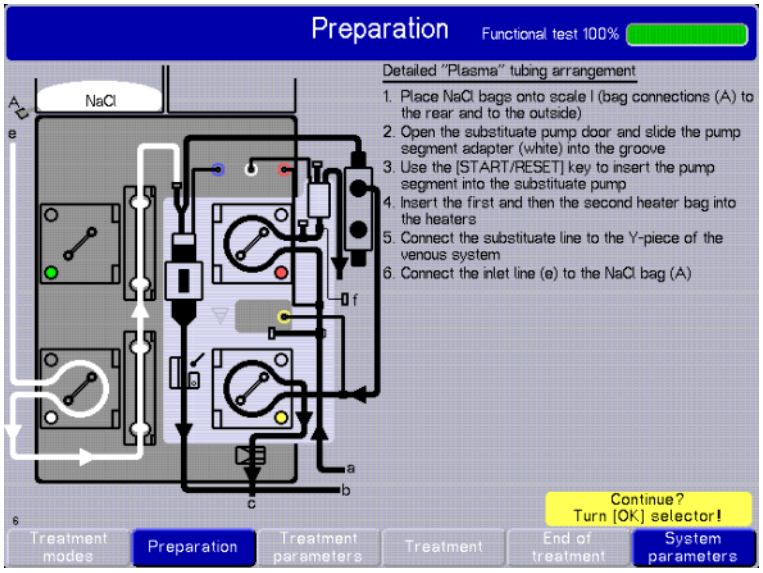
4.8.2.4 Inserting the filtrate line system



➢ Insert the filtrate line system according to the instructions.

➢ Turn the rotary selector clockwise until the next screen displays.

4.8.3 Inserting the plasma line system



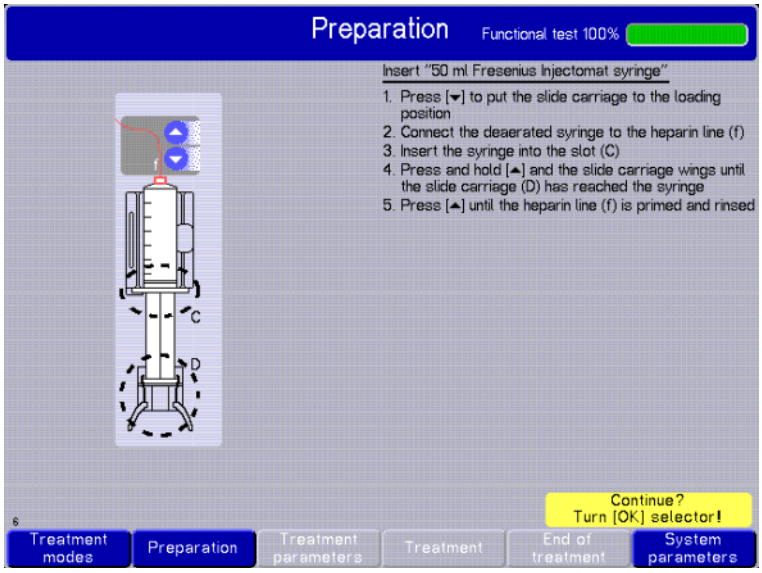
➢ Insert the plasma line system according to the instructions.

➢ Turn the rotary selector clockwise until the next screen displays.

4.8.4 Inserting the heparin syringe

Note

If a heparin syringe is used, it must be inserted and connected before connecting the patient.



➢ Insert the heparin syringe according to the instructions.

➢ Turn the rotary selector clockwise until the next screen displays.

Note on C

The syringe wings must be placed in the syringe wing slot.

Note on D

The thumbplate of the syringe plunger must be positioned between the clamps of the grip handle.

4.8.5 Complete tubing arrangement

Warning

Patient hazard: air embolism

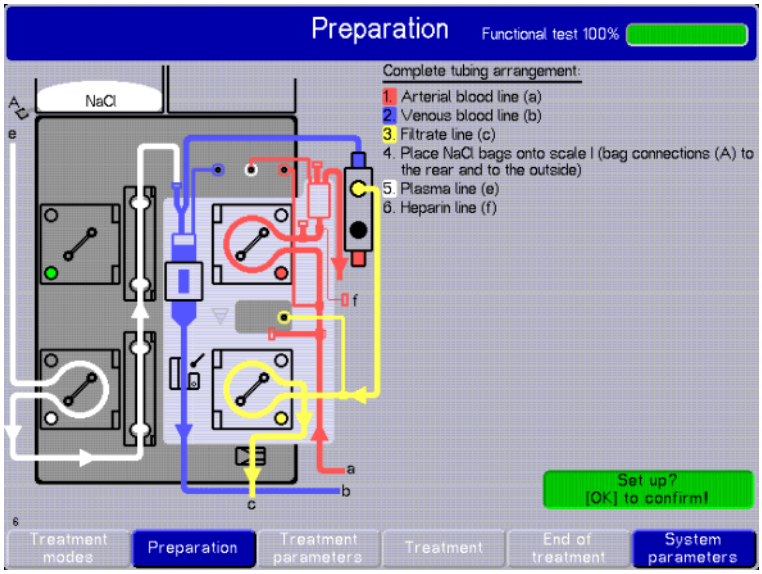
The air detector must be clean and dry.
Do not use any ultrasound-conducting objects or media.

Blood clots (coagula) can cause the air bubble detector to fail.

Note

Ensure that the filtrate bag hangs freely and does not touch any other objects.

Do not insert the filtrate tube too tightly between the blood leak detector and the filtrate bag.



This screen will be displayed immediately if the setting in the System parameters menu was set to **Complete tubing arrangement**.

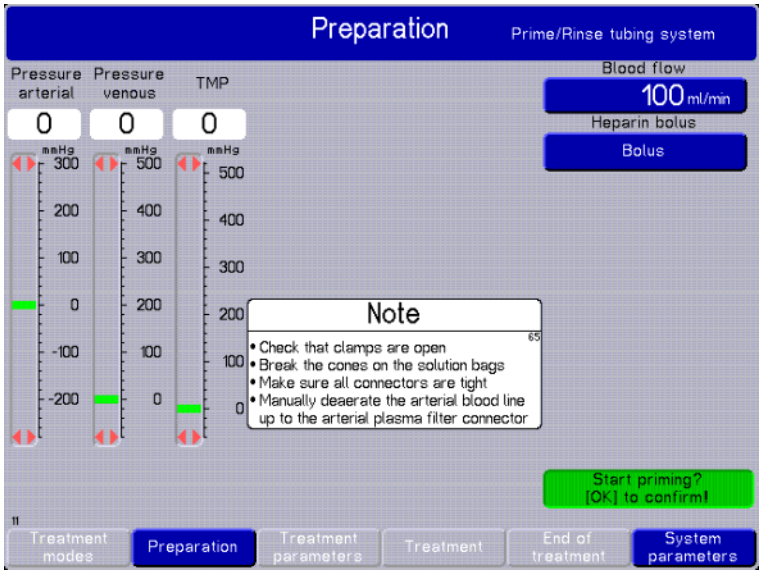
➢ Confirm the completely inserted tubing system using the rotary selector to select **Set up? [OK] to confirm!** and press **[OK]**.

4.8.6 Preparation

Note

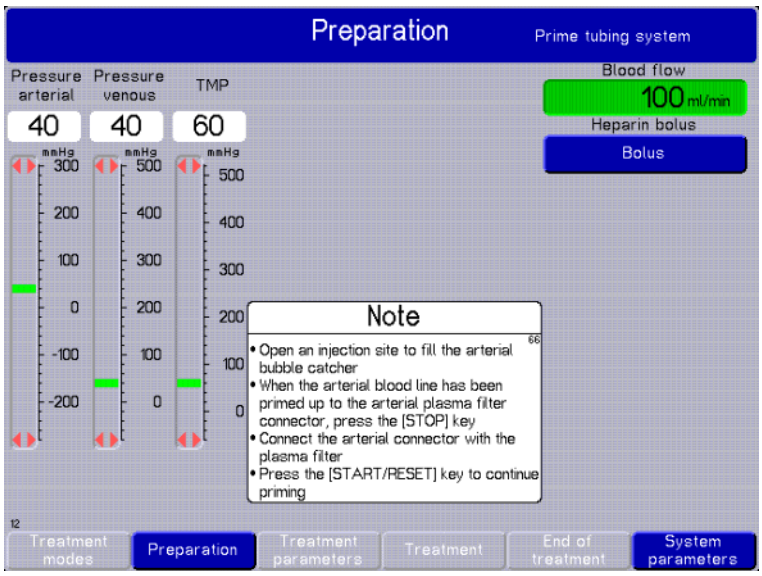
The patient must not be connected during preparation. If the optical detector senses opaque fluid during the preparation phase, the system asks whether a patient has been connected.

4.8.6.1 Priming the tubing system



➢ Use the rotary selector to select **Start priming? [OK] to confirm!** and press **[OK]**.

Heparin can be added to the NaCl solution used for priming and rinsing via the **Bolus** menu field.



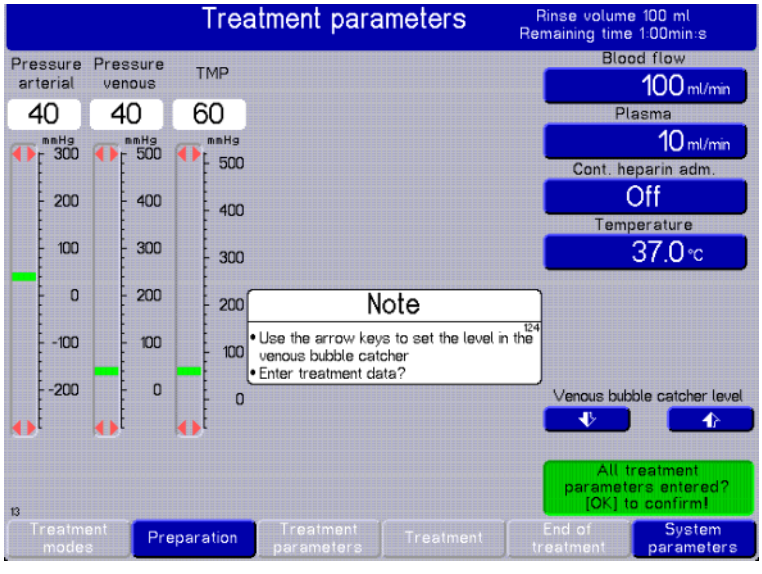
➢ Open the infusion / extraction point to prime the arterial bubble catcher.

If the amount of air in the arterial bubble catcher has decreased to a level of approx. 1 cm underneath the lid, the infusion / extraction point has to be closed.

4.8.6.2 Rinsing the tubing system / entering treatment parameters

Note

The heparin dose is to be administered as prescribed by the physician! If an initial heparin dose is to be administered, the bolus function can be used.



Indication of the decreasing rinse volume and the remaining rinse time.

The ultrasonic sensor detects fluid in the venous bubble catcher. Set the venous level manually using the **Venous bubble catcher level** menu field.

Rinsing starts automatically and the screen for entering the treatment parameters appears.

➢ Use the rotary selector to select the required treatment parameters (green background) and press **[OK]**.

➢ Use the rotary selector to enter the required parameters and press **[OK]**.

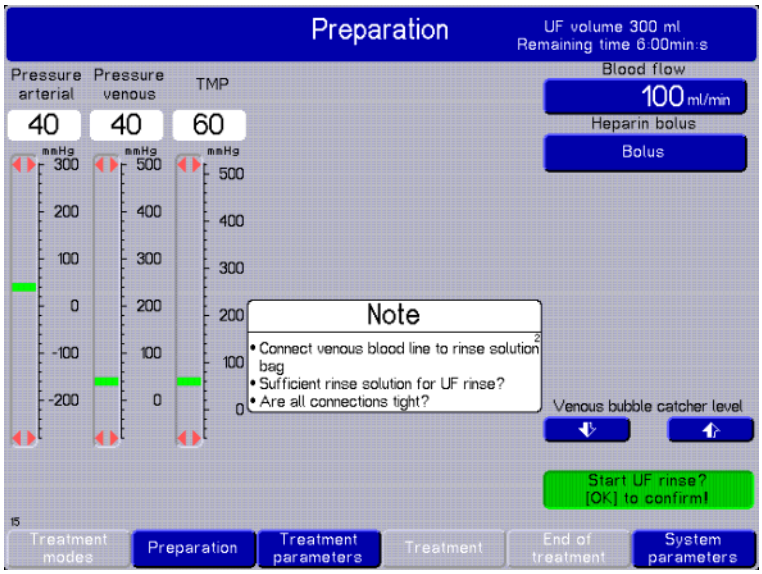
Set all treatment parameters as described above.

➢ Use the rotary selector to select **All treatment parameters entered? [OK] to confirm!** and press **[OK]**.

4.8.6.3 UF rinse

Note

When using NaCl solutions with only one connector, make sure there is enough NaCl solution.



After the rinse is completed and the pre-defined volume used, the blood pump will stop.

An audible signal will be given.

If using an NaCl solution with two connectors:

➢ Disconnect the venous patient line from the empty bag and connect it to the NaCl solution.

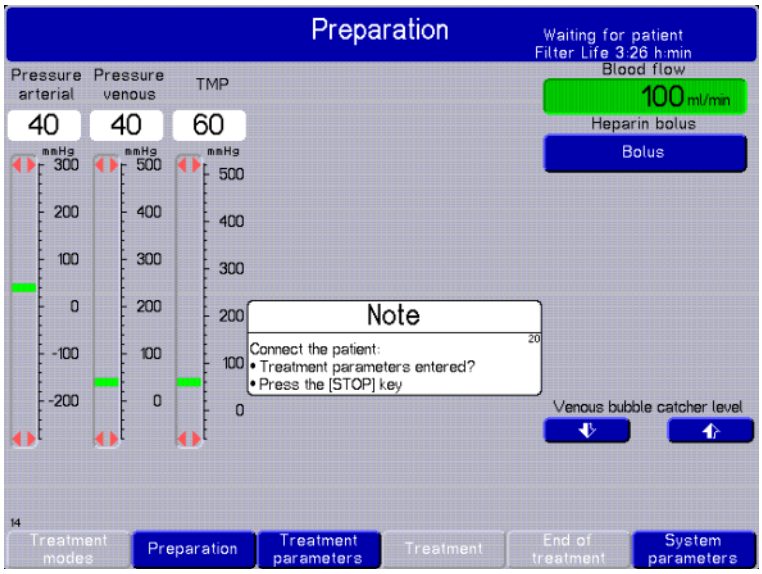
If using an NaCl solution with one connector:
Do not change the existing connection.

➢ Use the rotary selector to select **Start UF rinse? [OK] to confirm!** and press **[OK]**.

4.8.6.4 Recirculation / waiting for patient

Note

The filter life, which is shown in the status bar, is automatically added to the service life of the tubing systems.



When the UF volume reaches 0 ml, the extracorporeal blood circuit is in recirculation.

If using an NaCl solution with two connectors:
Do not change the existing connection.

If using an NaCl solution with one connector:

➢ Stop recirculation by pressing the **[STOP]** key.

Press the [STOP] key for approx. 3 seconds.

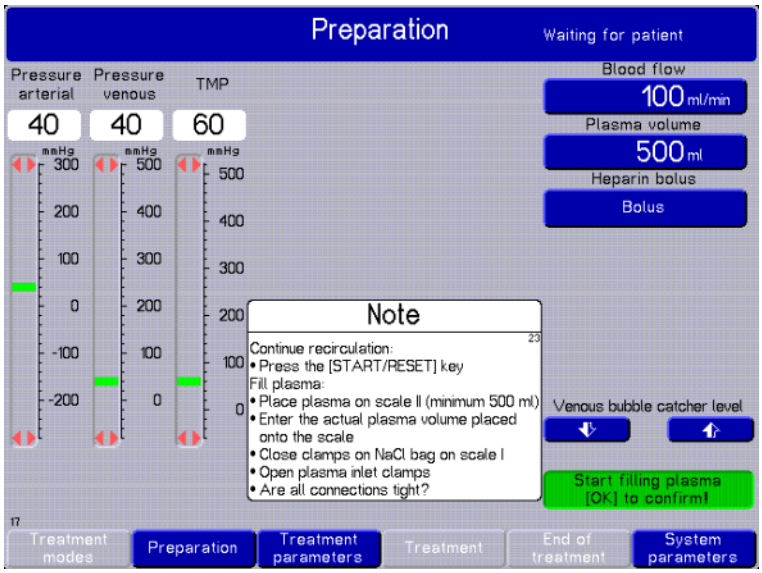
➢ Connect the venous patient line to the arterial patient line using the recirculator.

➢ Continue recirculation by pressing the **[START/RESET]** key.

4.8.6.5 Filling plasma

Tip

When using Fresenius fresh frozen plasma bags (FFP), for example, the plasma pole (part no. M28 004 1) can be used if required.

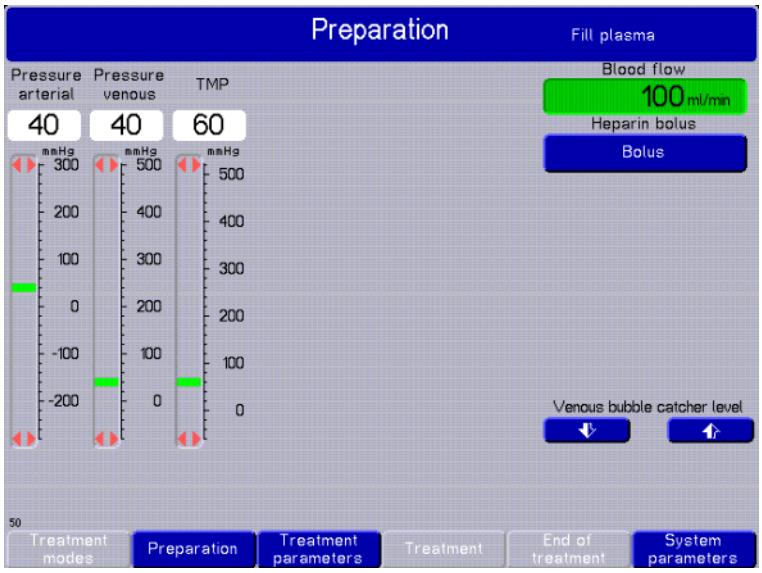


➢ Stop recirculation by pressing the **[STOP]** key.

Press the [STOP] key for approx. 3 seconds.

It is **imperative** to enter the net volume of the replacement solution.

➢ Use the rotary selector to select **Start filling plasma? [OK] to confirm!** and press **[OK]**.

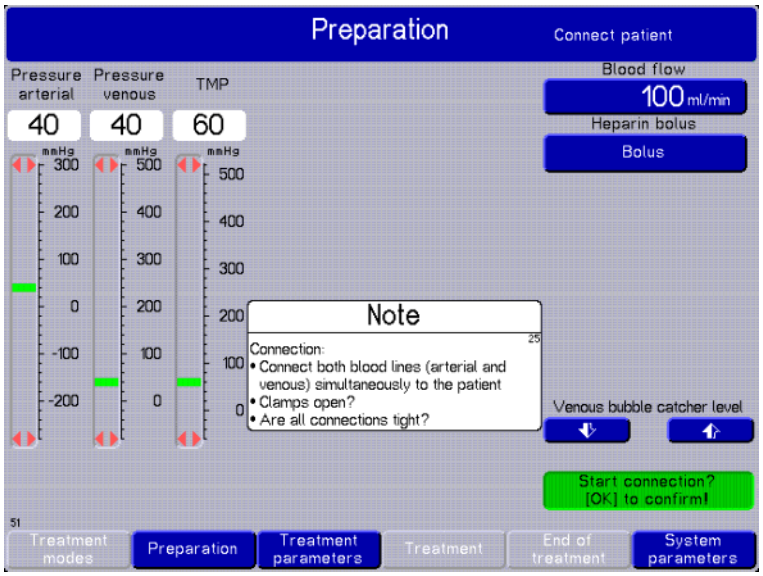


The blood pump will deliver at the programmed rate.

Settable rate:
10 ml/min to 100 ml/min (default 100 ml/min)

Time-controlled filling of plasma is in progress.

4.8.6.6 Connecting the patient



If using an NaCl solution with two connectors:

➢ Disconnect the arterial patient line from the NaCl solution and connect it to the arterial vascular access.

or

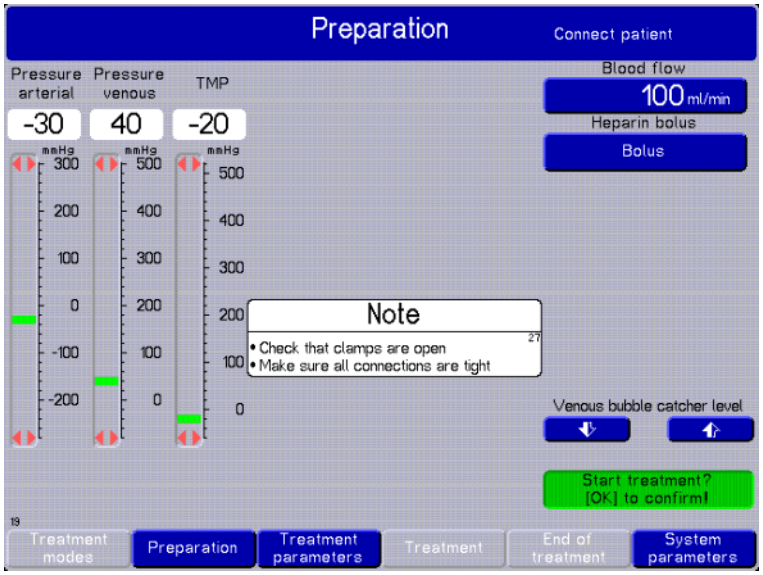
➢ Connect the arterial and venous patient line to the vascular access.

If using an NaCl solution with one connector:

➢ Connect the arterial and venous patient line to the vascular access.

and

➢ Use the rotary selector to select **Start connection? [OK] to confirm!** and press **[OK]**.



The optical detector senses opaque fluid.

The blood pump is stopped.

If not done yet when using an NaCl solution with two connectors:

➢ Disconnect the venous patient line from the NaCl solution and connect it to the venous vascular access.

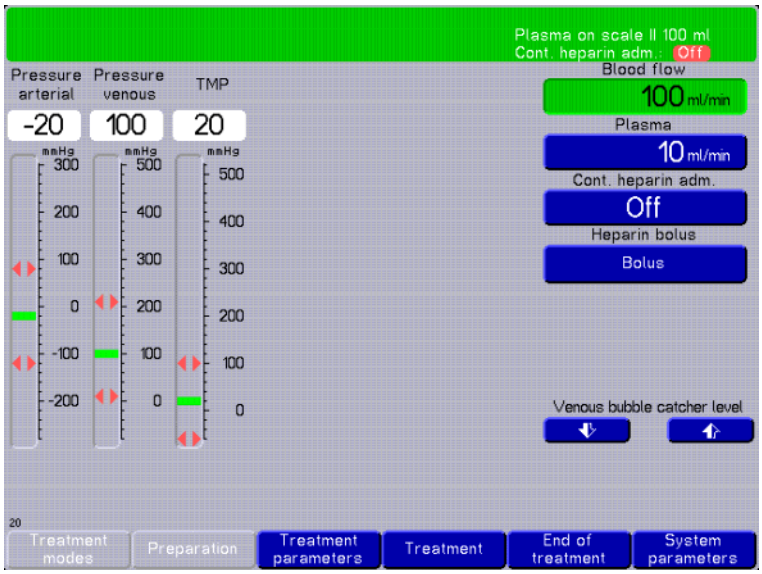
➢ Use the rotary selector to select **Start treatment? [OK] to confirm!** and press **[OK]**.

4.8.7 Treatment

Note

Once treatment has started and the blood pump has achieved its target delivery rate, the alarm limits are set automatically after approx. 10 seconds. Following this, the pressure alarm limits must be checked by the operator and adjusted individually as required.

4.8.7.1 Treatment main screen

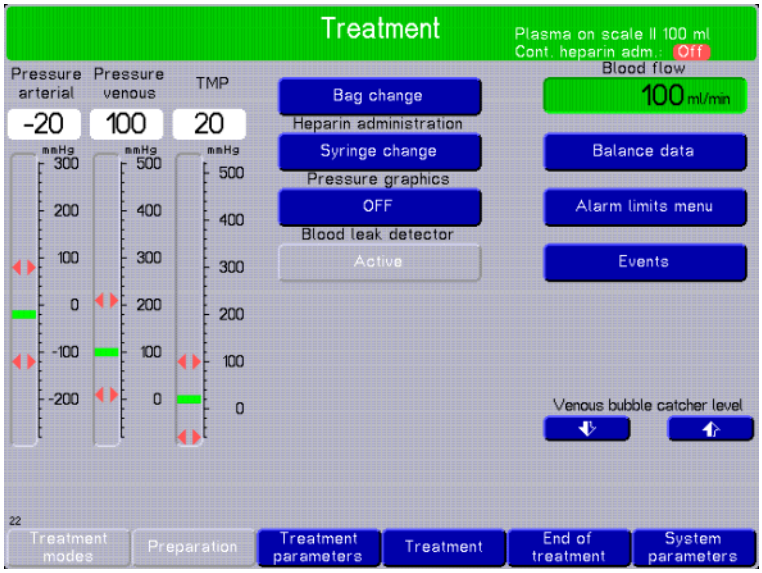


The main screen is displayed throughout the entire treatment.

Depending on the treatment mode, the menu field shows:
The current pressures (arterial, venous, TMP)
The current flow rates (plasma, blood flow, ultrafiltration)
Heparin

The status bar shows:
The treatment mode
Plasma on scale II
The balance
Continuous anticoagulation on / off

4.8.7.2 Treatment menu



➢ Press the **[ESC]** key.

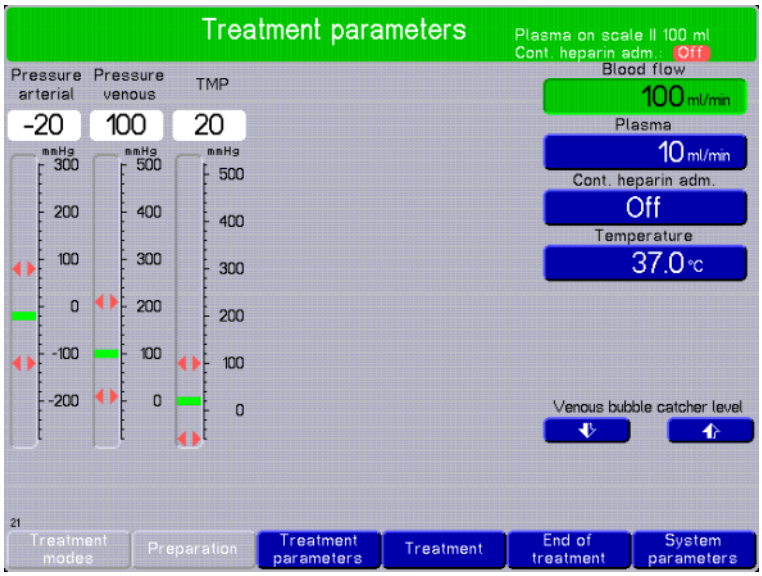
➢ Use the rotary selector to select **Treatment** from the menu bar and press **[OK]**.

The menu fields shown depend on the selected treatment mode. Detailed description (see chapter 4.11 on page 4-104).

Deactivate the blood leak detector (see chapter 5.13 on page 5-16).

After a timeout, the display will automatically return to the treatment main screen.

4.8.7.3 Treatment parameters

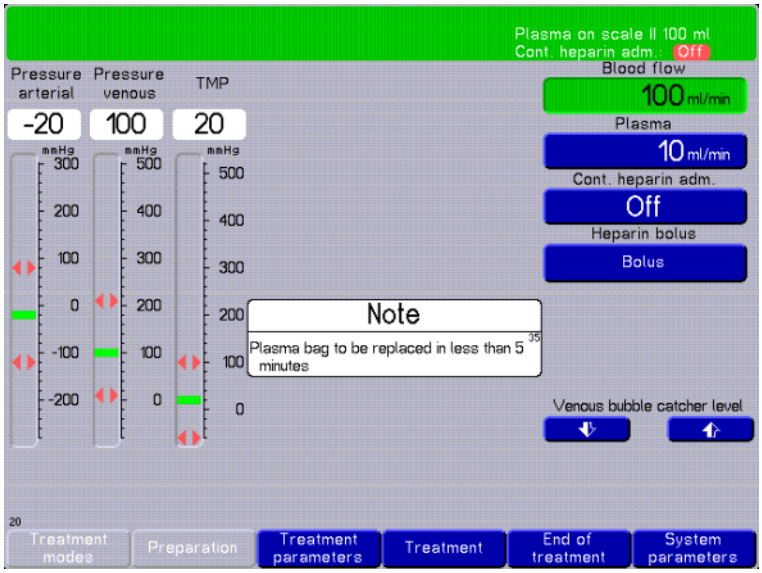


➢ Press the **[ESC]** key.

➢ Use the rotary selector to select **Treatment parameters** from the menu bar and press **[OK]**.

After a timeout, the display will automatically return to the treatment main screen.

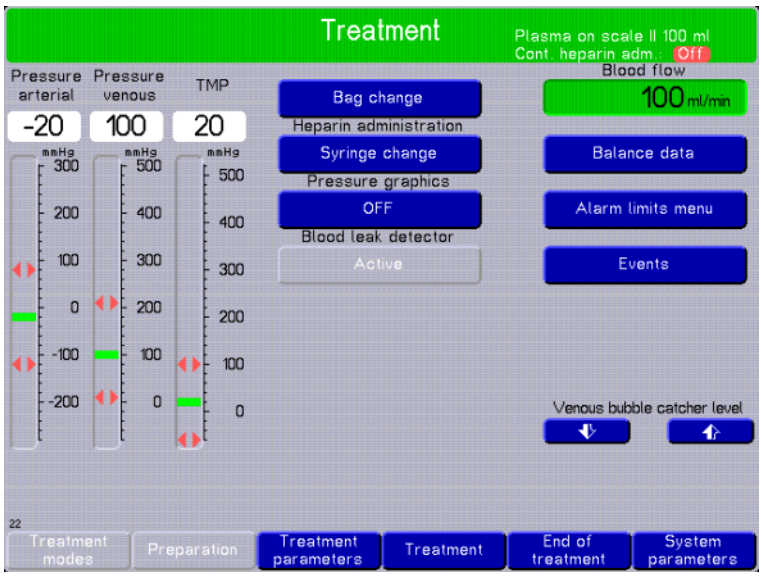
4.8.7.4 Performing a bag change



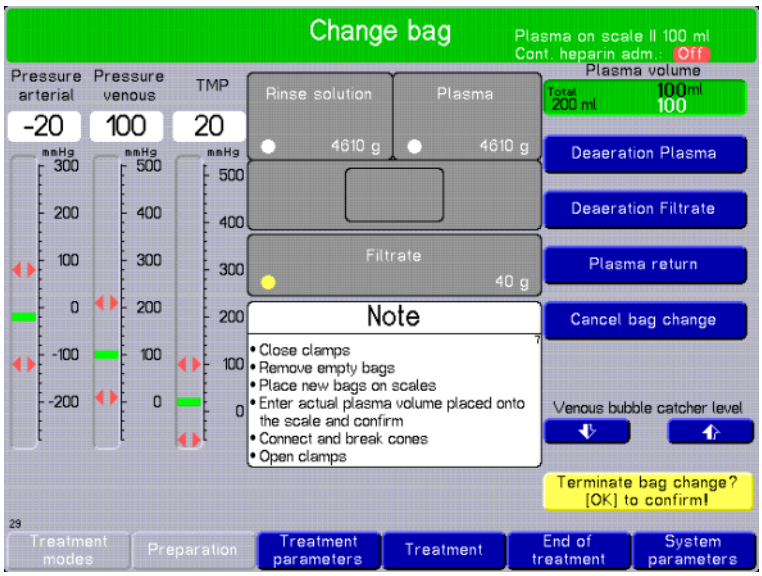
The scales alert the operator that the plasma bag will need to be replaced in 5 minutes.

➢ Press the **[ESC]** key.

➢ Use the rotary selector to select **Treatment** from the menu bar and press **[OK]**.



➢ Use the rotary selector to select **Change bag** and press **[OK]**.



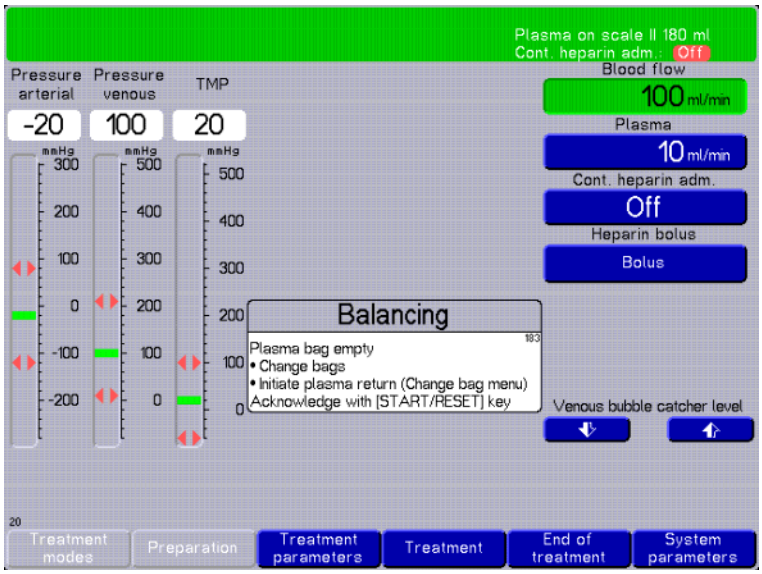
➢ Use the rotary selector to select **Plasma volume** and press **[OK]**.

It is imperative to enter the new net volume of the replacement solution.

➢ Use the rotary selector to select **Terminate bag change? [OK] to confirm!** and press **[OK]**.

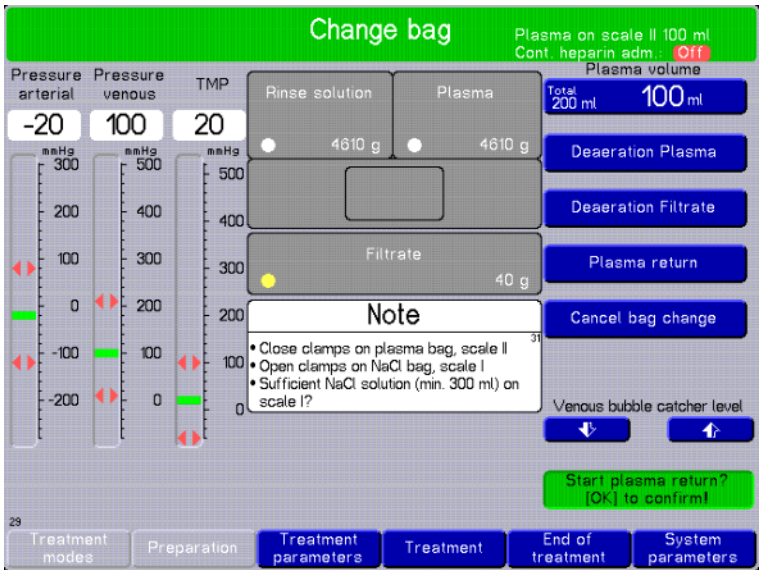
4.8.8 End of treatment

4.8.8.1 Infusing remaining plasma



The plasma is returned via the **Change bag** menu.

➢ Confirm the message by pressing the **[START/RESET]** key.

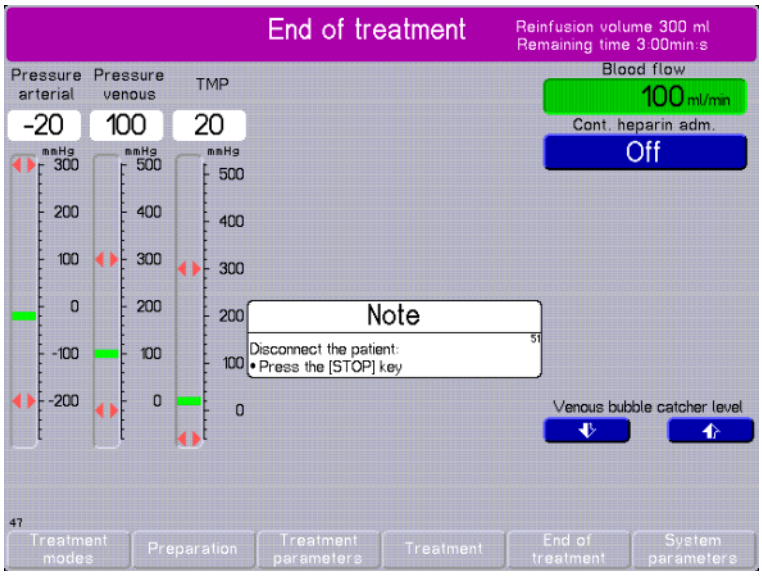


➢ Use the rotary selector to select **Plasma return** and press **[OK]**.

➢ Use the rotary selector to select **Start plasma return? [OK] to confirm!** and press **[OK]**.

The residual plasma of approx. 300 ml will be administered until the Balancing message is displayed.

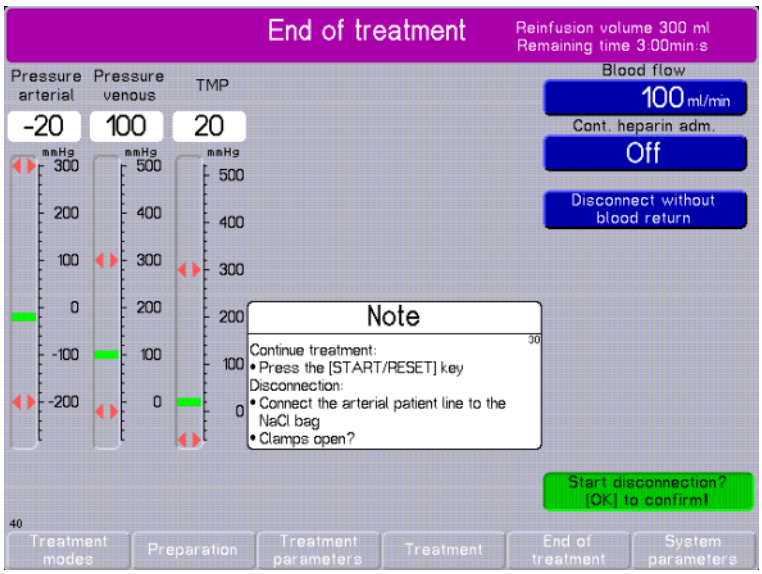
4.8.8.2 Terminating the treatment



➢ Stop the treatment by pressing the **[STOP]** key.

Press the [STOP] key for approx. 3 seconds.
The venous clamp closes.
The blood pump is stopped.

4.8.8.3 Starting reinfusion



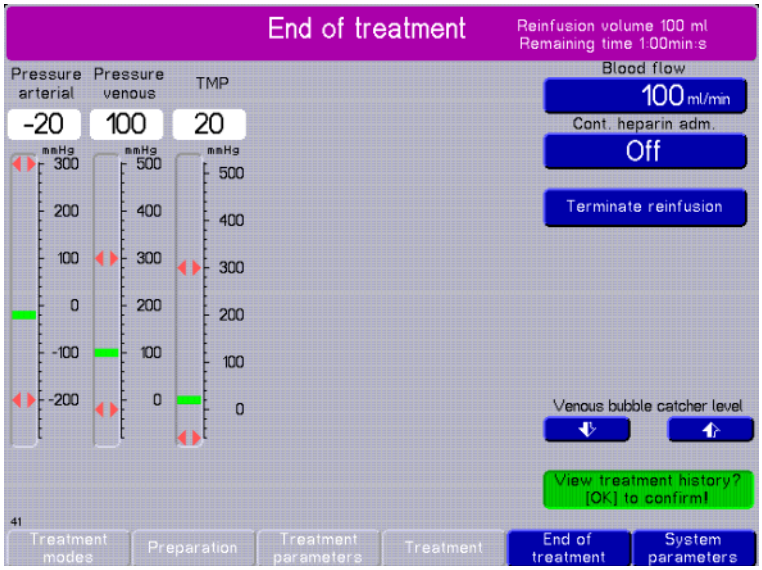
➢ Continue the treatment by pressing the **[START/RESET]** key.

or

➢ Disconnect the arterial patient line from the patient and connect it to the NaCl solution.

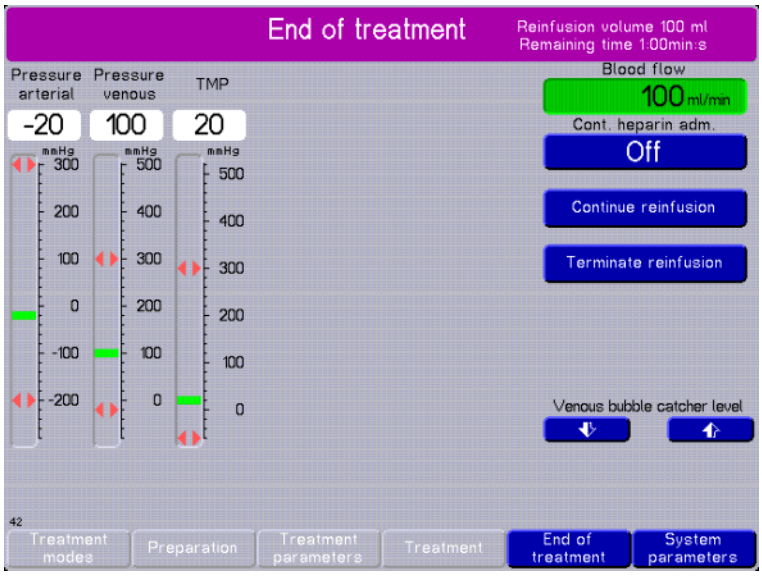
➢ Use the rotary selector to select **Start disconnection? [OK] to confirm!** and press **[OK]**.

When selecting **Disconnect without blood return**, the program will go directly to "Disconnecting the patient" without reinfusion after a safety prompt (see chapter 4.8.9 on page 4-79).



Indication of the decreasing reinfusion volume.

Selecting **View treatment history? [OK] to confirm!** will display the treatment parameters.



The optical detector senses non-opaque fluid.

➢ When selecting **Continue reinfusion**, the remaining reinfusion volume can be returned to the patient.

or

➢ Use the rotary selector to select **Terminate reinfusion** and press **[OK]**.

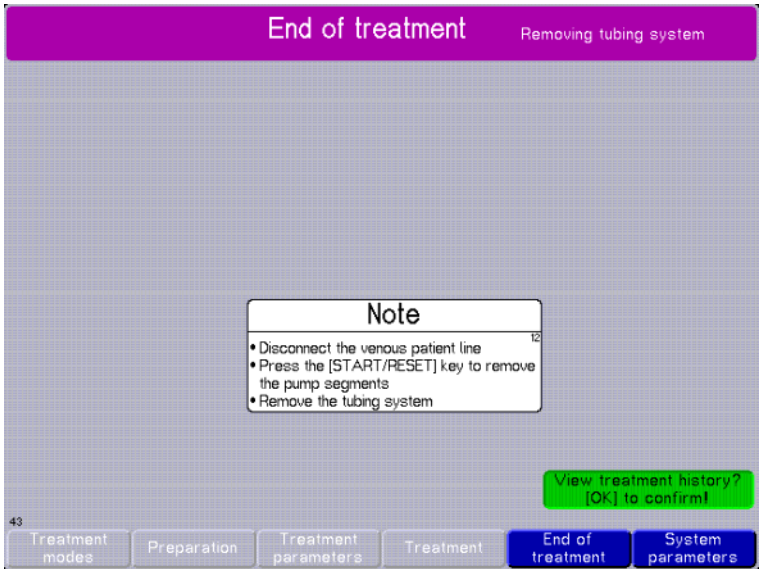
but

The treatment will be terminated automatically if the reinfusion volume is 0 ml and the optical detector senses non-opaque fluid.

4.8.9 Disconnecting the patient and removing the tubing system

Warning

Consumables must be discarded after the treatment in compliance with the regulations for the disposal of potentially contaminated materials.



➢ Disconnect the venous patient line from the patient.

➢ Remove the pump segment adapter from the groove.

➢ Press and hold the **[START/RESET]** key until the pump segment has been completely removed.

Support the removal of the pump segment by slightly pulling on it.

➢ Remove the heater bag (depending on the treatment mode) from the heater.

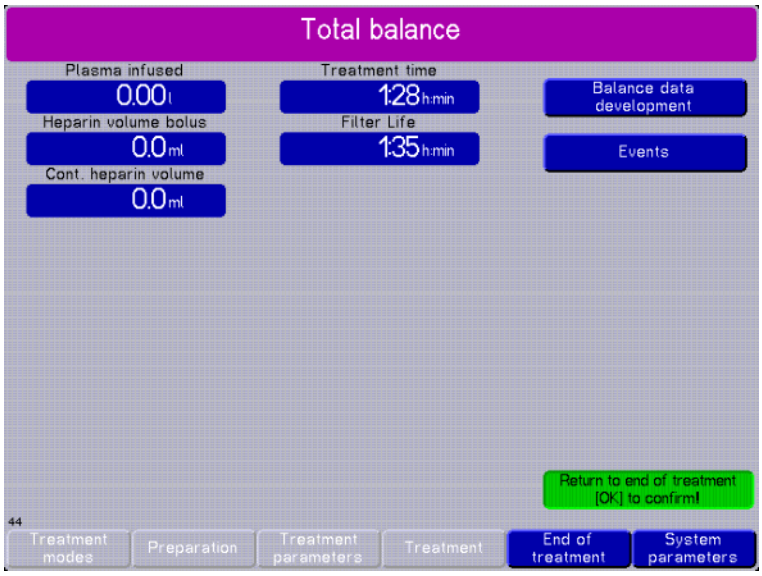
Open the clamps before and after the heater bag to facilitate removal of the bag.

➢ Remove and dispose of the tubing system.

To remove the remaining pump segments, proceed as described above.

➢ Use the rotary selector to select **View treatment history? [OK] to confirm!** Confirm with **[OK]**.

4.8.10 Treatment history



Indication of the treatment parameters for the entire treatment.

➢ Press the **[I/O]** key to turn the device off.

4.9 Slow continuous ultrafiltration (SCUF)

Prepare the device ready for operation (see chapter 4.4 on page 4-12).

Note

The multiFiltrate paed CRRT / SCUF set tubing system (part no. 501 775 1) has to be used for the SCUF treatment mode.

4.9.1 Starting conditions

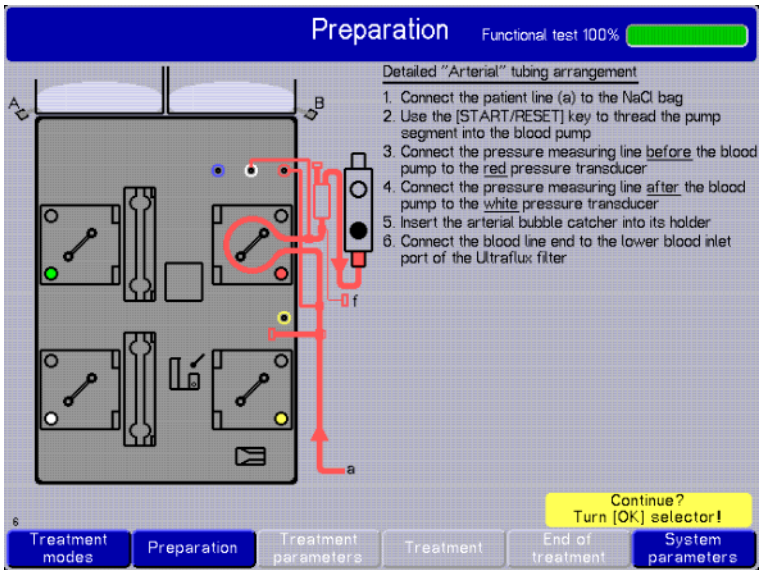
Note

Each treatment mode has its individual starting conditions.

The operator must ensure that the starting conditions are met before using the rotary selector to select **Conditions fulfilled** and pressing **[OK]**.

4.9.2 Inserting the AV set

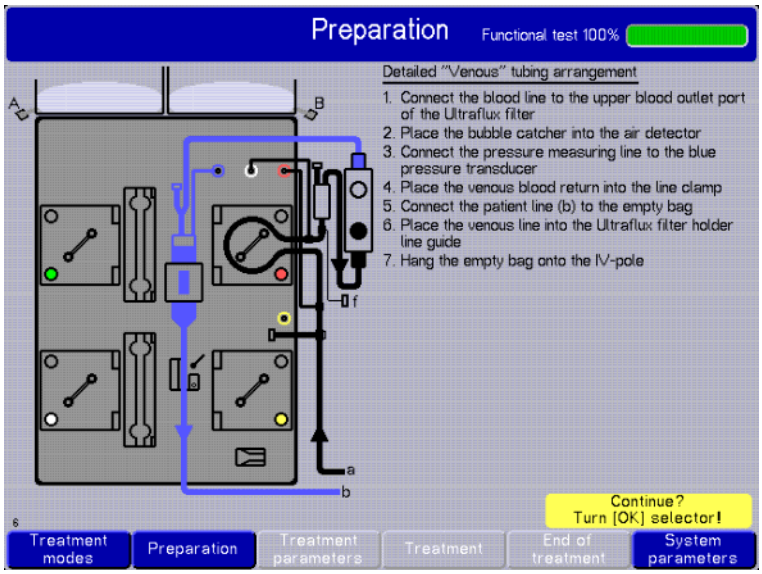
4.9.2.1 Inserting the arterial blood line system



➢ Insert the arterial blood line system according to the instructions.

➢ Turn the rotary selector clockwise until the next screen displays.

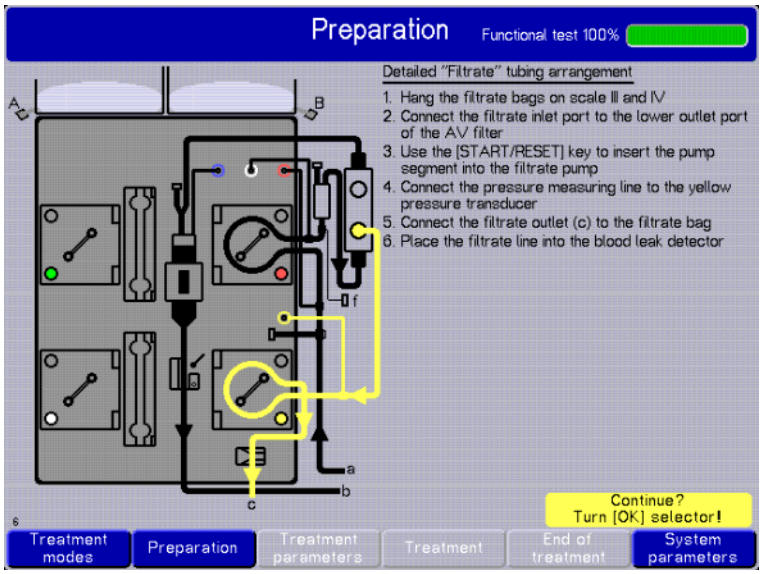
4.9.2.2 Inserting the venous blood line system



➢ Insert the venous blood line system according to the instructions.

➢ Turn the rotary selector clockwise until the next screen displays.

4.9.2.3 Inserting the filtrate line system



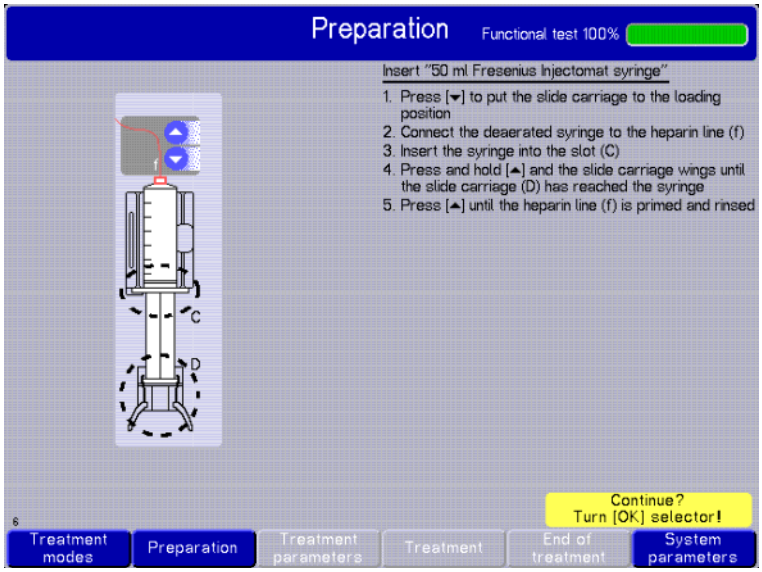
➢ Insert the filtrate line system according to the instructions.

➢ Turn the rotary selector clockwise until the next screen displays.

4.9.3 Inserting the heparin syringe

Note

If a heparin syringe is used, it must be inserted and connected before connecting the patient.



➢ Insert the heparin syringe according to the instructions.

➢ Turn the rotary selector clockwise until the next screen displays.

Note on C

The syringe wings must be placed in the syringe wing slot.

Note on D

The thumbplate of the syringe plunger must be positioned between the clamps of the grip handle.

4.9.4 Complete tubing arrangement

Warning

Patient hazard: air embolism

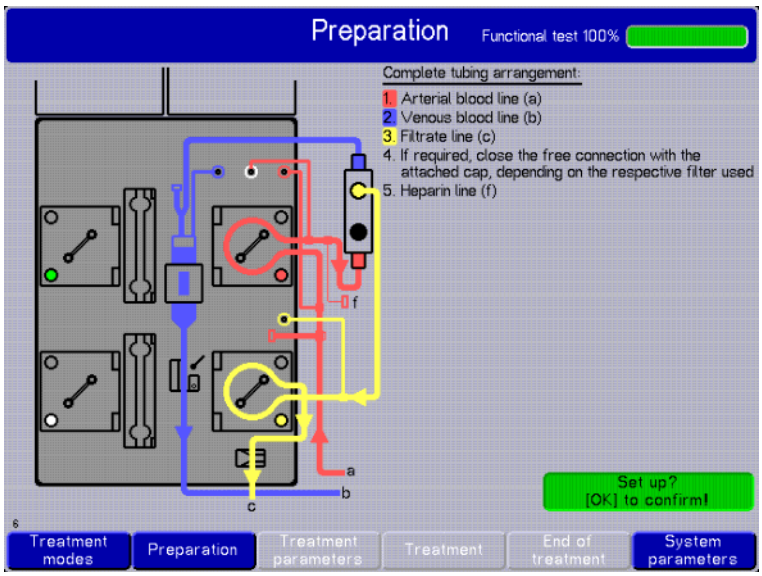
The air detector must be clean and dry.
Do not use any ultrasound-conducting objects or media.

Blood clots (coagula) can cause the air bubble detector to fail.

Note

Ensure that the filtrate bag hangs freely and does not touch any other objects.

Do not insert the filtrate tube too tightly between the blood leak detector and the filtrate bag.



This screen will be displayed immediately if the setting in the System parameters menu was set to **Complete tubing arrangement**.

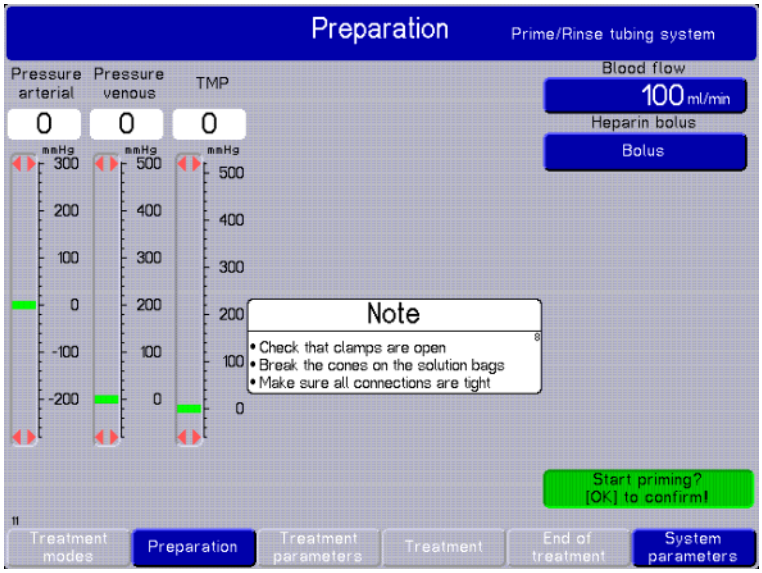
➢ Confirm the completely inserted tubing system using the rotary selector to select **Set up? [OK] to confirm!** and press **[OK]**.

4.9.5 Preparation

Note

The patient must not be connected during preparation. If the optical detector senses opaque fluid during the preparation phase, the system asks whether a patient has been connected.

4.9.5.1 Priming the tubing system



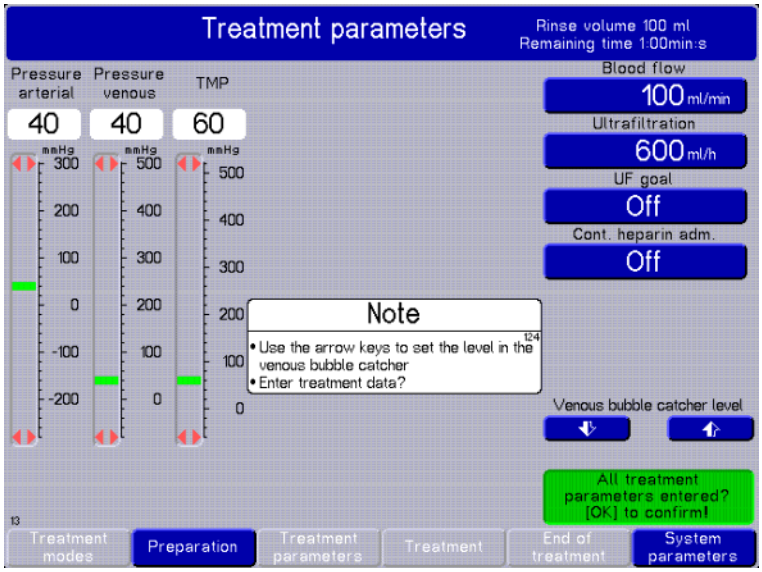
➢ Use the rotary selector to select **Start priming? [OK] to confirm!** and press **[OK]**.

Heparin can be added to the NaCl solution used for priming and rinsing via the **Bolus** menu field.

4.9.5.2 Rinsing the tubing system / entering treatment parameters

Note

The heparin dose is to be administered as prescribed by the physician! If an initial heparin dose is to be administered, the bolus function can be used.



The ultrasonic sensor detects fluid in the venous bubble catcher. Set the venous level manually using the **Venous bubble catcher level** menu field.

Rinsing starts automatically and the screen for entering the treatment parameters appears.

Indication of the decreasing rinse volume and the remaining rinse time.

➢ Use the rotary selector to select the required treatment parameters (green background) and press **[OK]**.

➢ Use the rotary selector to enter the required parameters and press **[OK]**.

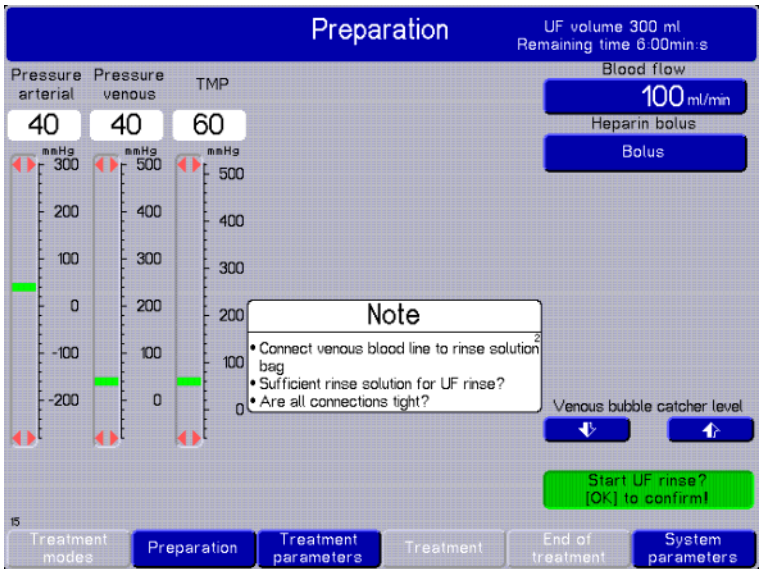
Set all treatment parameters as described above.

➢ Use the rotary selector to select **All treatment parameters entered? [OK] to confirm!** and press **[OK]**.

4.9.5.3 UF rinse

Note

When using NaCl solutions with only one connector, make sure there is enough NaCl solution.



After the rinse is completed and the pre-defined volume used, the blood pump will stop.

An audible signal will be given.

If using an NaCl solution with two connectors:

➢ Disconnect the venous patient line from the empty bag and connect it to the NaCl solution.

If using an NaCl solution with one connector:
Do not change the existing connection.

➢ Use the rotary selector to select **Start UF rinse? [OK] to confirm!** and press **[OK]**.

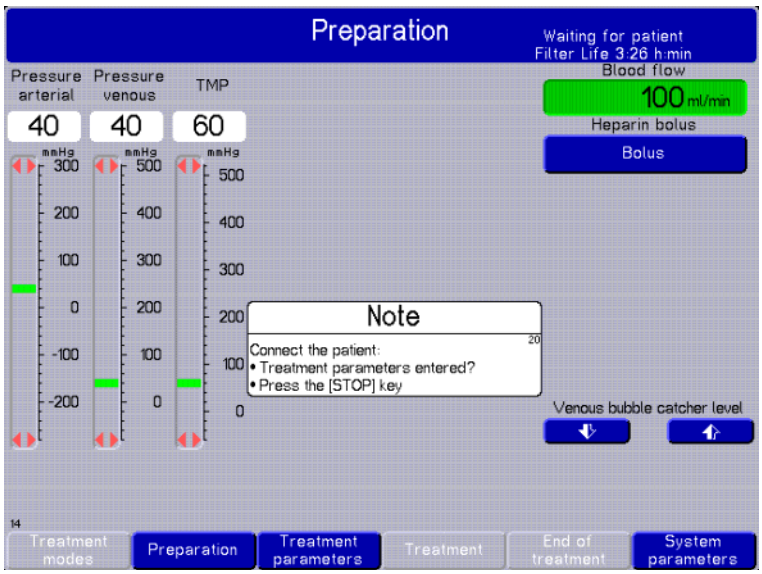
Indication of the decreasing UF volume and the remaining rinse time.

➢ Turn the filter upon notification.

4.9.5.4 Recirculation / waiting for patient

Note

The filter life, which is shown in the status bar, is automatically added to the service life of the tubing systems.



When the UF volume reaches 0 ml, the extracorporeal blood circuit is in recirculation.

If using an NaCl solution with two connectors:
Do not change the existing connection.

If using an NaCl solution with one connector:

➢ Stop recirculation by pressing the **[STOP]** key.

Press the [STOP] key for approx. 3 seconds.

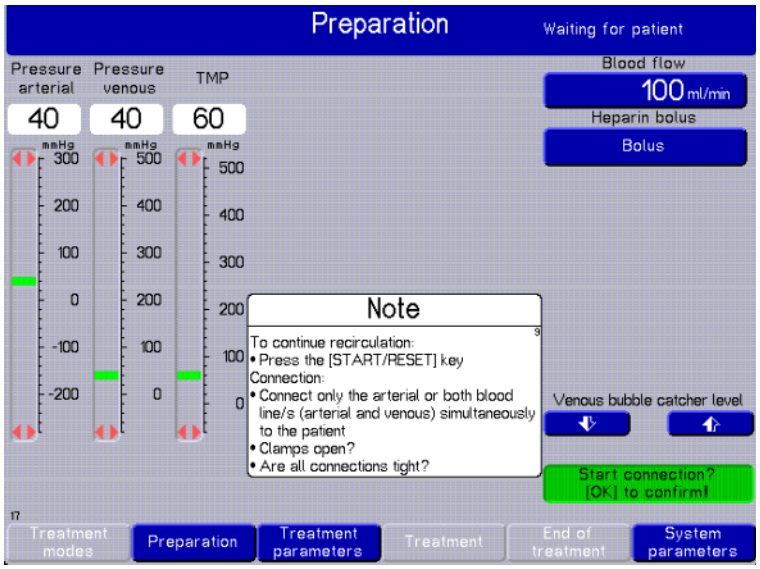
➢ Connect the venous patient line to the arterial patient line using the recirculator.

➢ Continue recirculation by pressing the **[START/RESET]** key.

4.9.5.5 Connecting the patient

Tip

If the patient is not yet available, then recirculation can be continued by pressing the **[START/RESET]** key.



If using an NaCl solution with two connectors:

➢ Disconnect the arterial patient line from the NaCl solution and connect it to the arterial vascular access.

or

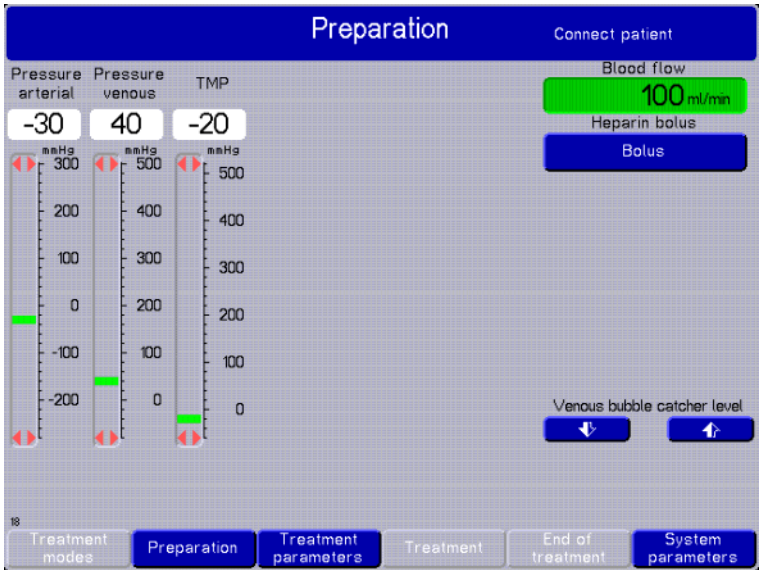
➢ Connect the arterial and venous patient line to the vascular access.

If using an NaCl solution with one connector:

➢ Connect the arterial and venous patient line to the vascular access.

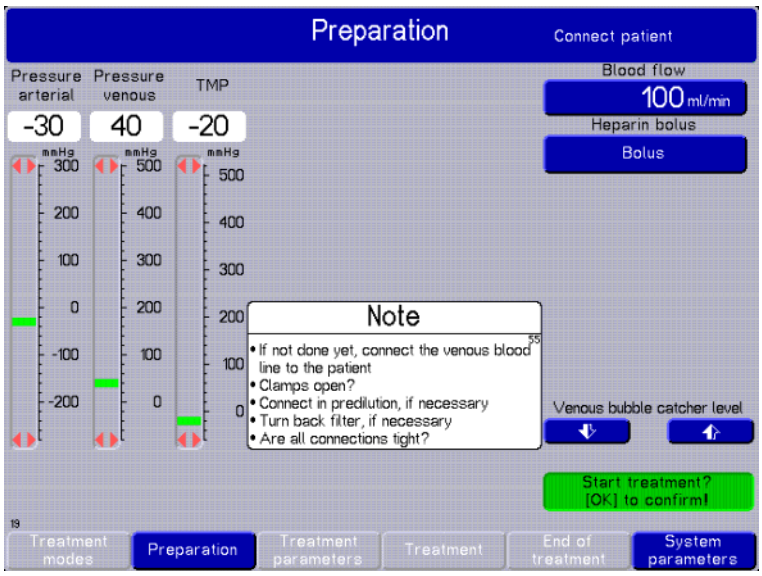
and

➢ Use the rotary selector to select **Start connection? [OK] to confirm!** and press **[OK]**.



The blood pump will deliver at the programmed rate.

Settable rate:
Cassette / adults 10 ml/min to 100 ml/min (default 100 ml/min)



The optical detector senses opaque fluid.

The blood pump is stopped.

If not done yet when using an NaCl solution with two connectors:

➢ Disconnect the venous patient line from the NaCl solution and connect it to the venous vascular access.

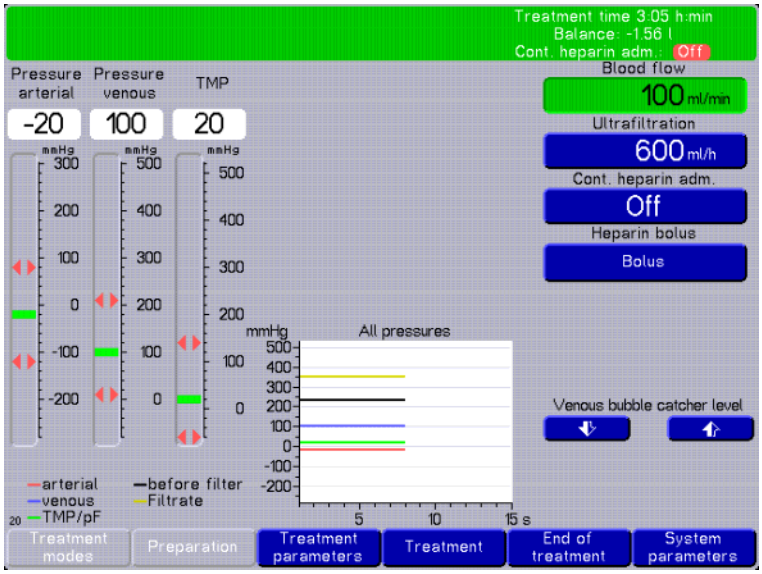
➢ Use the rotary selector to select **Start treatment? [OK] to confirm!** and press **[OK]**.

4.9.6 Treatment

Note

Once treatment has started and the blood pump has achieved its target delivery rate, the alarm limits are set automatically after approx. 10 seconds. Following this, the pressure alarm limits must be checked by the operator and adjusted individually as required.

4.9.6.1 Treatment main screen

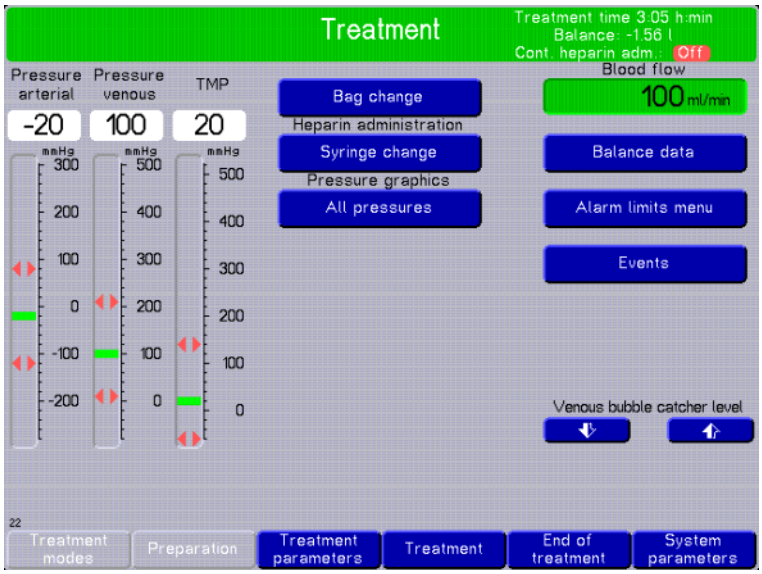


The main screen is displayed throughout the entire treatment.

Depending on the treatment mode, the menu field shows:
The current pressures (arterial, venous, TMP)
The current flow rates (blood flow, ultrafiltration)
Heparin

The status bar shows:
The treatment mode
The progression of the treatment time
The balance
Continuous anticoagulation on / off

4.9.6.2 Treatment menu



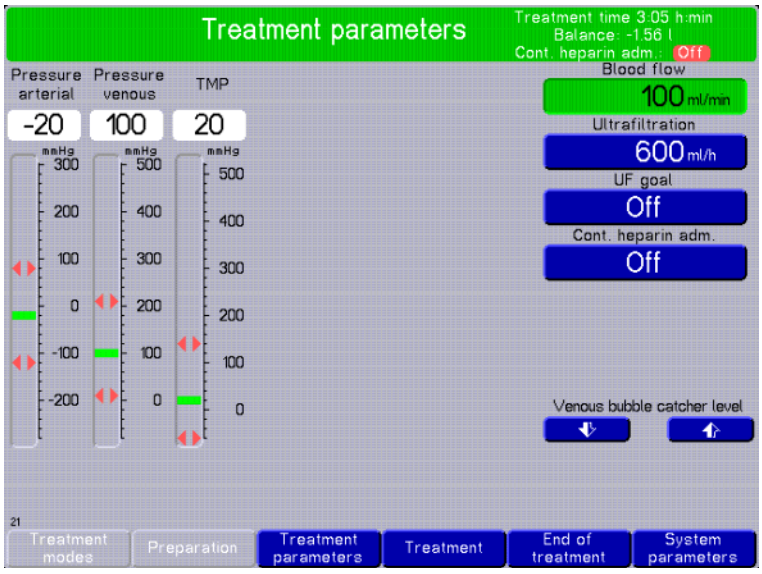
➢ Press the **[ESC]** key.

➢ Use the rotary selector to select **Treatment** from the menu bar and press **[OK]**.

The menu fields shown depend on the selected treatment mode. Detailed description (see chapter 4.11 on page 4-104).

After a timeout, the display will automatically return to the treatment main screen.

4.9.6.3 Treatment parameters



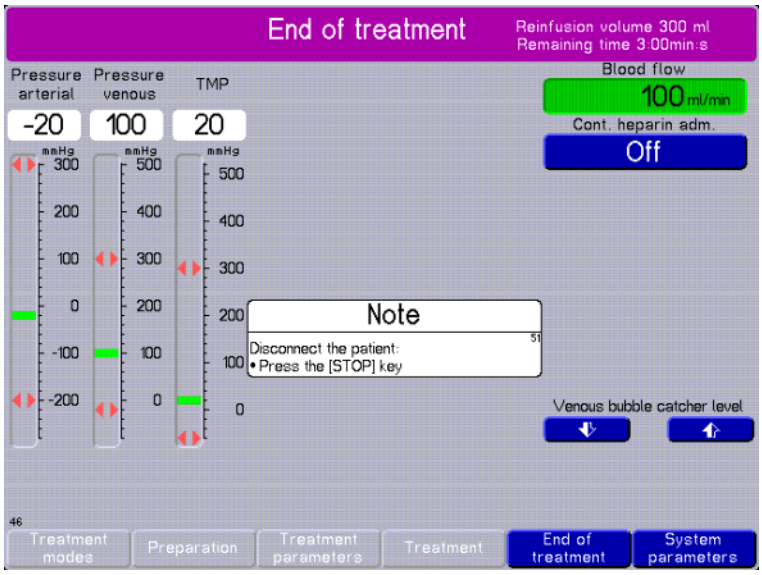
➢ Press the **[ESC]** key.

➢ Use the rotary selector to select **Treatment parameters** from the menu bar and press **[OK]**.

After a timeout, the display will automatically return to the treatment main screen.

4.9.7 End of treatment

4.9.7.1 Terminating the treatment



➢ Press the **[ESC]** key.

➢ Use the rotary selector to select **End of treatment** from the menu bar and press **[OK]** to confirm.

The blood pump is running.

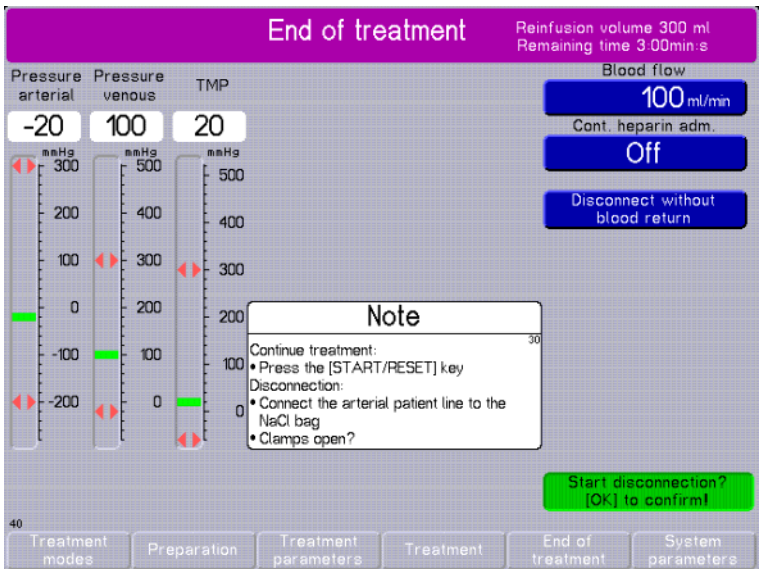
➢ Stop the treatment by pressing the **[STOP]** key.

Press the **[STOP]** key for approx. 3 seconds.
The venous clamp closes.
The blood pump is stopped.

or

➢ Use the **[ESC]** key to select a different menu from the menu bar.

4.9.7.2 Starting reinfusion



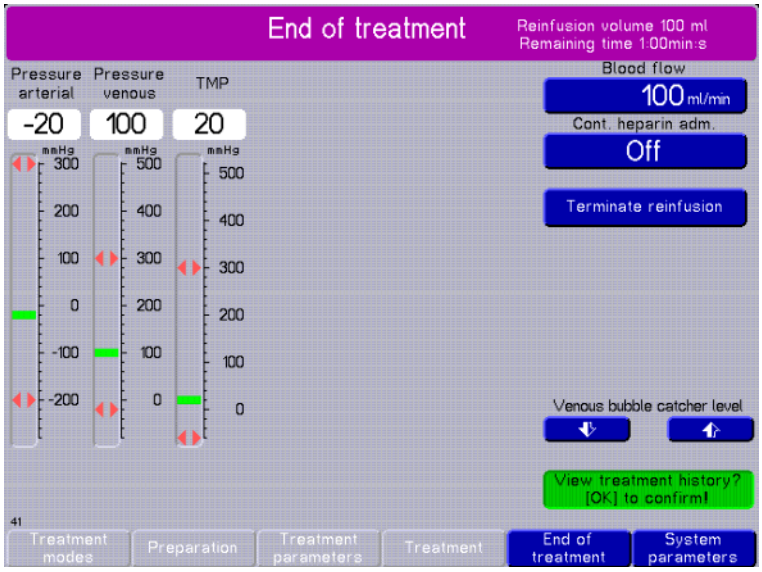
➢ Continue the treatment by pressing the **[START/RESET]** key.

or

➢ Disconnect the arterial patient line from the patient and connect it to the NaCl solution.

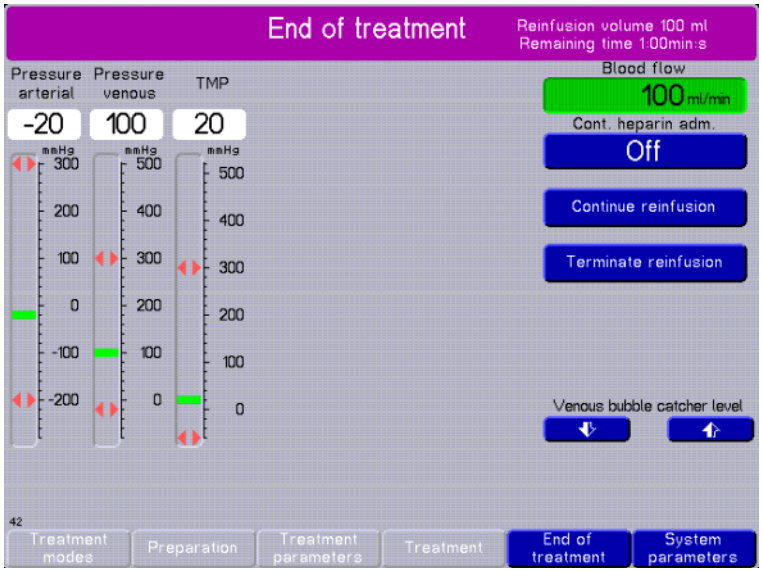
➢ Use the rotary selector to select **Start disconnection? [OK] to confirm!** and press **[OK]**.

When selecting **Disconnect without blood return**, the program will go directly to "Disconnecting the patient" without reinfusion after a safety prompt (see chapter 4.9.8 on page 4-91).



Indication of the decreasing reinfusion volume.

Selecting **View treatment history? [OK] to confirm!** will display the treatment parameters.



The optical detector senses non-opaque fluid.

➢ When selecting **Continue reinfusion**, the remaining reinfusion volume can be returned to the patient.

or

➢ Use the rotary selector to select **Terminate reinfusion** and press **[OK]**.

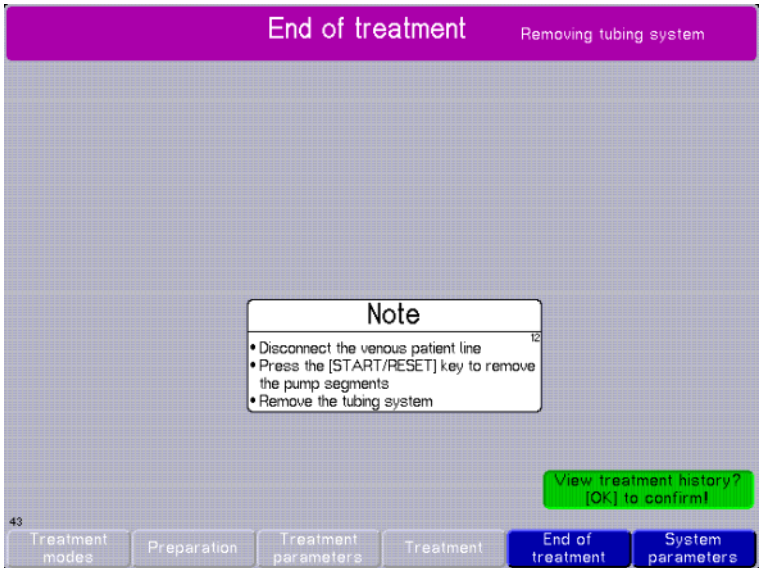
but

➢ The treatment will be terminated automatically if the reinfusion volume is 0 ml and the optical detector senses non-opaque fluid.

4.9.8 Disconnecting the patient and removing the tubing system

Warning

Consumables must be discarded after the treatment in compliance with the regulations for the disposal of potentially contaminated materials.



➢ Disconnect the venous patient line from the patient.

➢ Remove the pump segment adapter from the groove.

➢ Press and hold the **[START/RESET]** key until the pump segment has been completely removed.

Support the removal of the pump segment by slightly pulling on it.

➢ Remove the heater bag (depending on the treatment mode) from the heater.

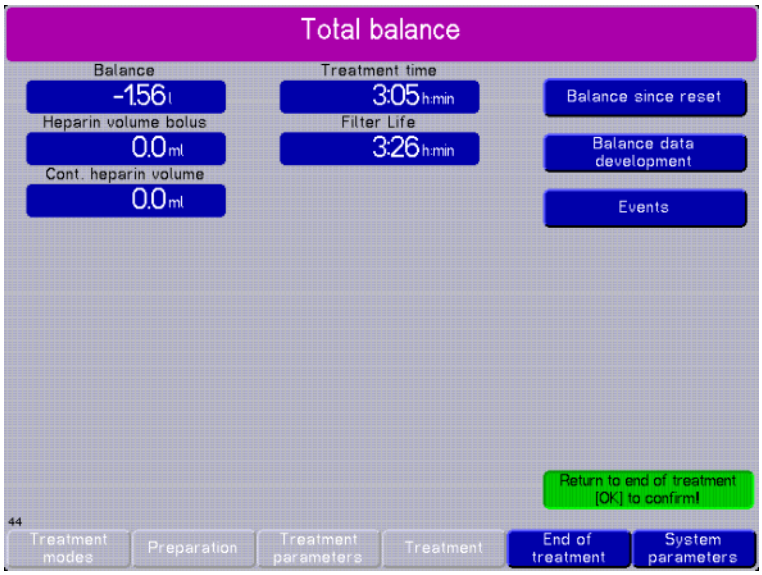
Open the clamps before and after the heater bag to facilitate removal of the bag.

➢ Remove and dispose of the tubing system.

To remove the remaining pump segments, proceed as described above.

➢ Use the rotary selector to select **View treatment history? [OK] to confirm!** Confirm with **[OK]**.

4.9.9 Treatment history



Indication of the treatment parameters for the entire treatment.

➢ Press the **[I/O]** key to turn the device off.

4.10 Haemoperfusion (HP)

Make the device ready for operation (see chapter 4.4 on page 4-12).

Warning

The information in the accompanying documents for the adsorber used must also be observed.

4.10.1 Starting conditions

Note

Each treatment mode has its individual starting conditions.

The operator must ensure that the starting conditions are met before using the rotary selector to select **Conditions fulfilled** and pressing **[OK]**.

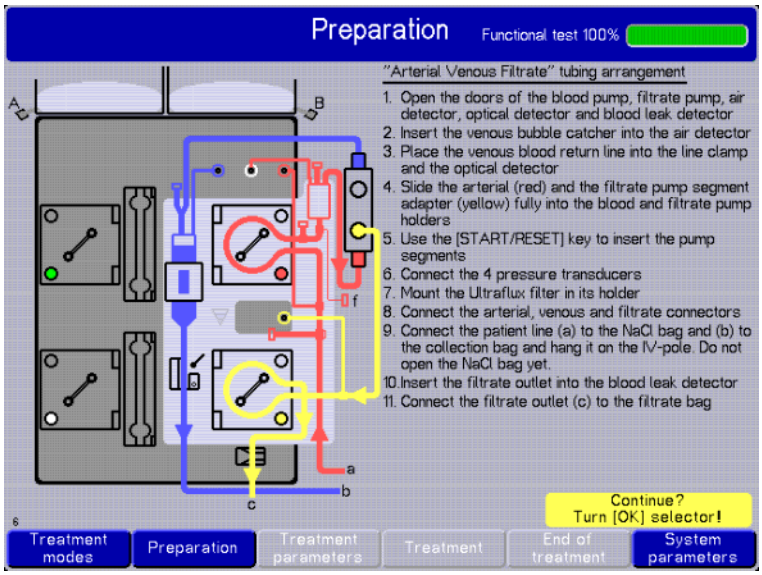
4.10.2 Inserting the cassette system or AV set

4.10.2.1 Inserting the cassette system

When using an AV set continue with "Inserting the arterial blood line system" (see chapter 4.10.2.2 on page 4-93)

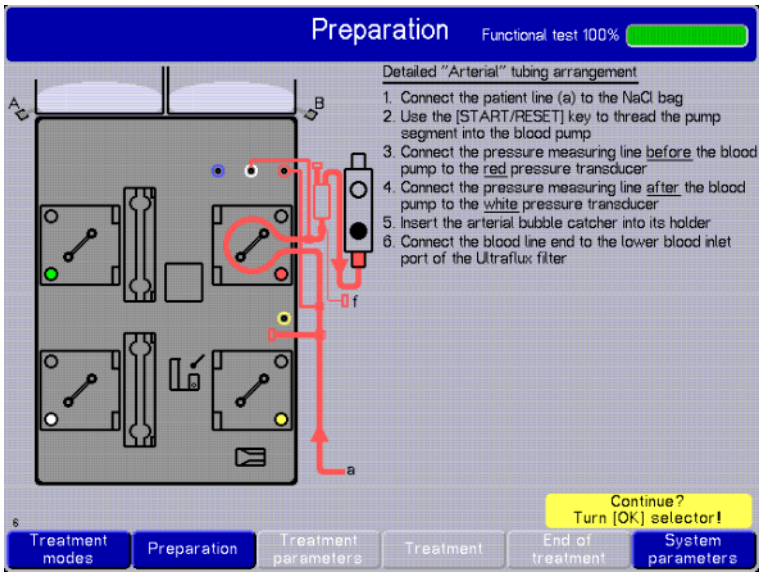
Note

If a cassette is used for HP treatment therapy, the filtrate line system has to be inserted but will not be taken into consideration by the device.



- ➢ Insert the cassette system according to the instructions.
- ➢ Turn the rotary selector clockwise until the next screen displays.
- ➢ Continue with "Inserting the heparin syringe" (see chapter 4.10.3 on page 4-94)

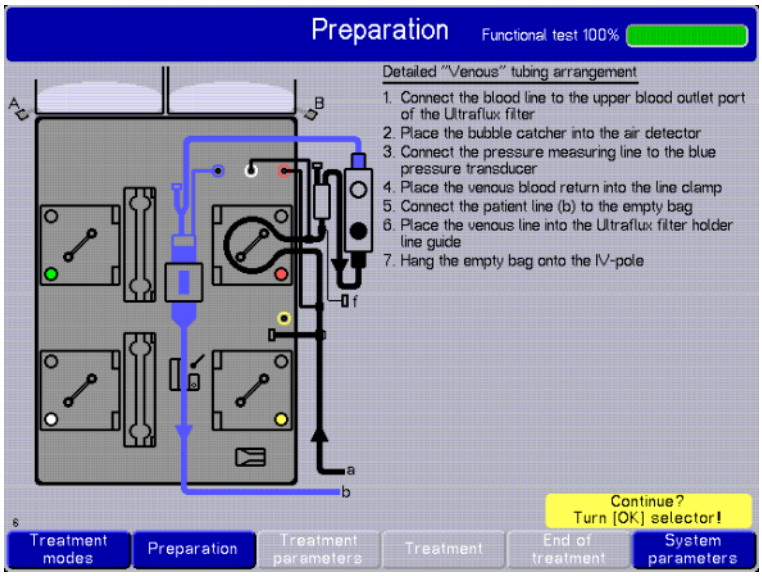
4.10.2.2 Inserting the arterial blood line system



➢ Insert the arterial blood line system according to the instructions.

➢ Turn the rotary selector clockwise until the next screen displays.

4.10.2.3 Inserting the venous blood line system



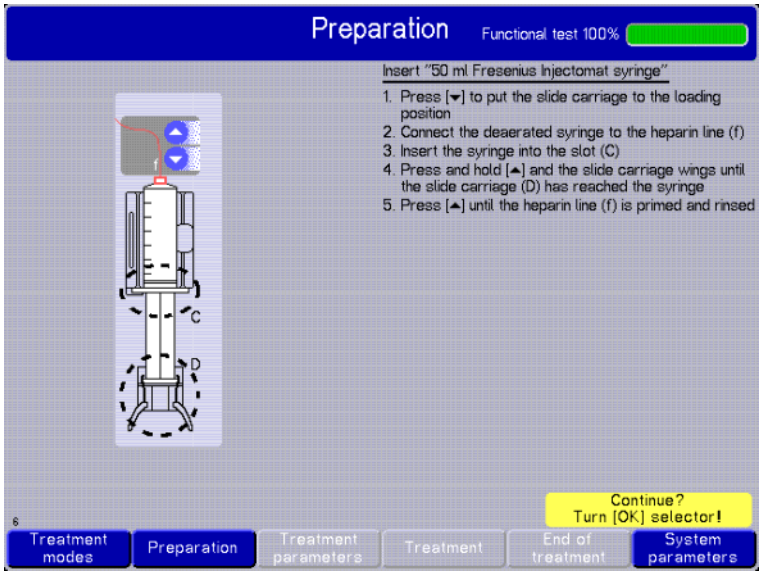
➢ Insert the venous blood line system according to the instructions.

➢ Turn the rotary selector clockwise until the next screen displays.

4.10.3 Inserting the heparin syringe

Note

If a heparin syringe is used, it must be inserted and connected before connecting the patient.



➢ Insert the heparin syringe according to the instructions.

➢ Turn the rotary selector clockwise until the next screen displays.

Note on C

The syringe wings must be placed in the syringe wing slot.

Note on D

The thumbplate of the syringe plunger must be positioned between the clamps of the grip handle.

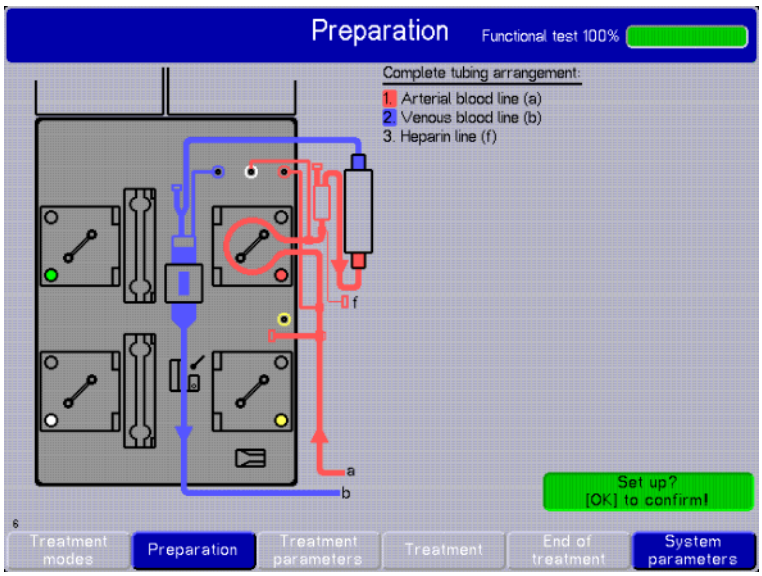
4.10.4 Complete tubing arrangement

Warning

Patient hazard: air embolism

The air detector must be clean and dry.
Do not use any ultrasound-conducting objects or media.

Blood clots (coagula) can cause the air bubble detector to fail.



This screen will be displayed immediately if the setting in the System parameters menu was set to **Complete tubing arrangement**.

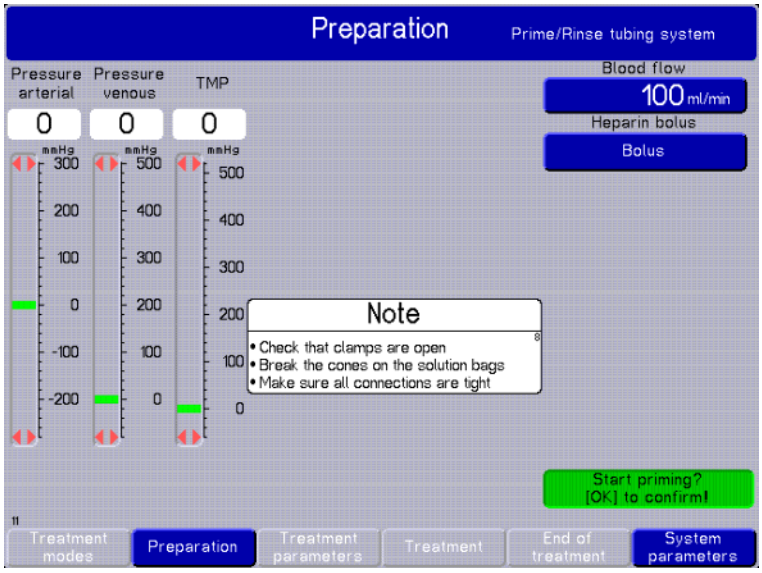
➢ Confirm the completely inserted tubing system using the rotary selector to select **Set up? [OK] to confirm!** and press **[OK]**.

4.10.5 Preparation

Note

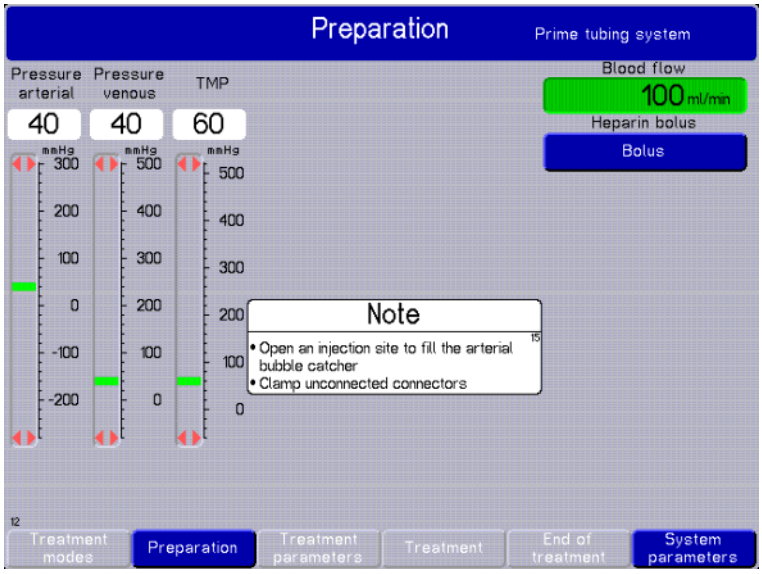
The patient must not be connected during preparation. If the optical detector senses opaque fluid during the preparation phase, the system asks whether a patient has been connected.

4.10.5.1 Priming the tubing system



➢ Use the rotary selector to select **Start priming? [OK] to confirm!** and press **[OK]**.

Heparin can be added to the NaCl solution used for priming and rinsing via the **Bolus** menu field.



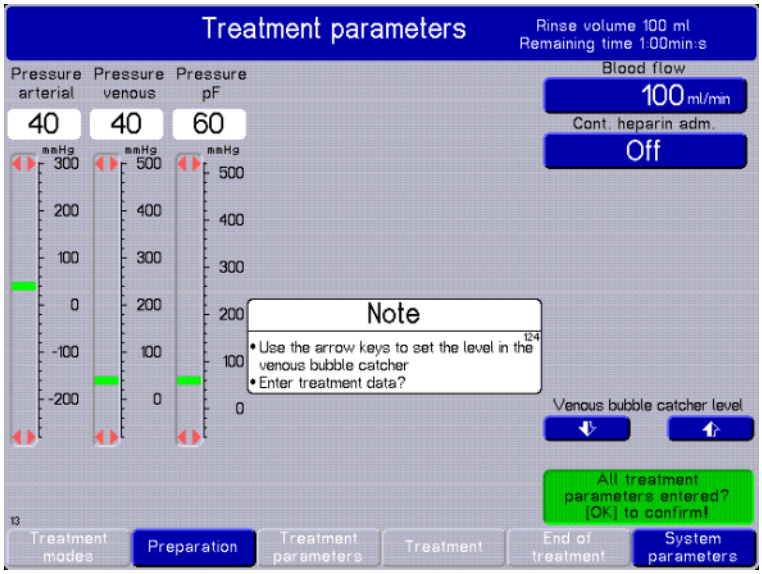
➢ Open the infusion / extraction point to prime the arterial bubble catcher.

If the amount of air in the arterial bubble catcher has decreased to a level of approx. 1 cm underneath the lid, the infusion / extraction point has to be closed.

4.10.5.2 Rinsing the tubing system / entering treatment parameters

Note

The heparin dose is to be administered as prescribed by the physician! If an initial heparin dose is to be administered, the bolus function can be used.



The ultrasonic sensor detects fluid in the venous bubble catcher. Set the venous level manually using the **Venous bubble catcher level** menu field.

Rinsing starts automatically and the screen for entering the treatment parameters appears.

Indication of the decreasing rinse volume and the remaining rinse time.

➢ Use the rotary selector to select the required treatment parameters (green background) and press **[OK]**.

➢ Use the rotary selector to enter the required parameters and press **[OK]**.

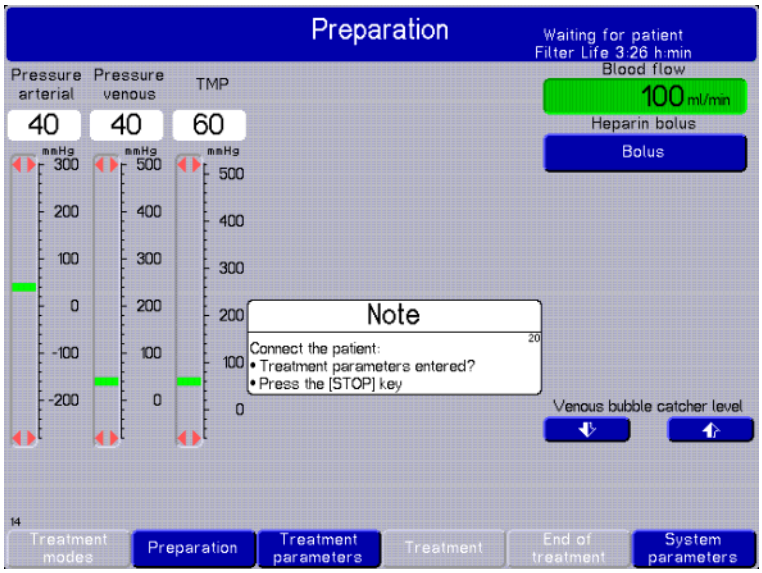
Set all treatment parameters as described above.

➢ Use the rotary selector to select **All treatment parameters entered? [OK] to confirm!** and press **[OK]**.

4.10.5.3 Recirculation / waiting for patient

Note

The filter life, which is shown in the status bar, is automatically added to the service life of the tubing systems.



After the rinse is completed and the pre-defined volume used, the blood pump will stop.

Audible signal

If using an NaCl solution with two connectors:

➢ Disconnect the venous patient line from the empty bag and connect it to the NaCl solution.

If using an NaCl solution with one connector:

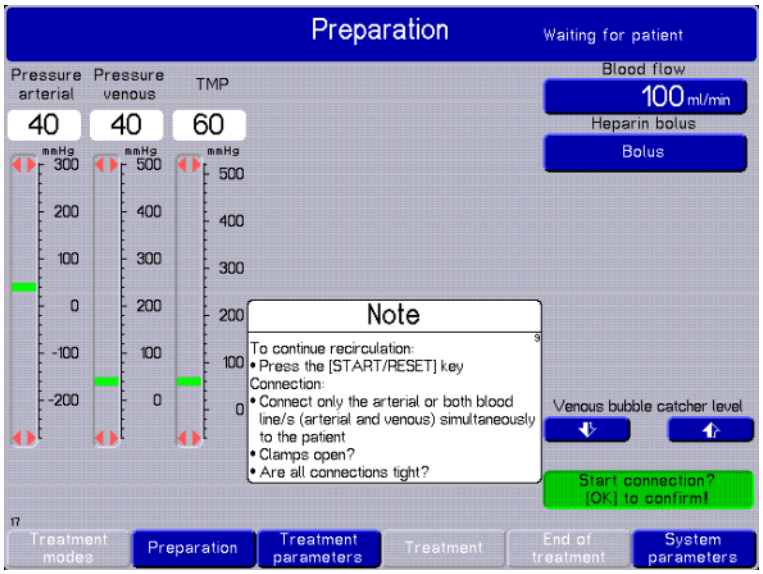
➢ Connect the venous patient line to the arterial patient line using the recirculator.

➢ Continue recirculation by pressing the **[START/RESET]** key.

4.10.5.4 Connecting the patient

Tip

If the patient is not yet available, then recirculation can be continued by pressing the **[START/RESET]** key.



If using an NaCl solution with two connectors:

➢ Disconnect the arterial patient line from the NaCl solution and connect it to the arterial vascular access.

or

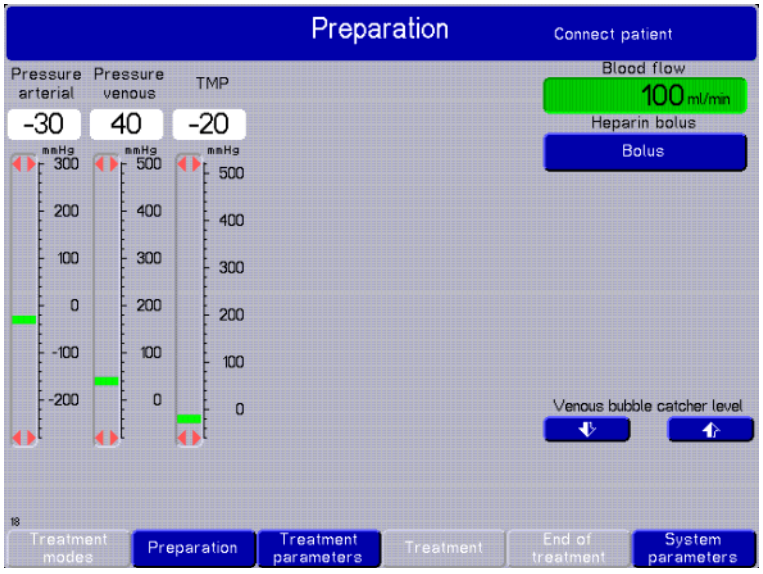
➢ Connect the arterial and venous patient line to the vascular access.

If using an NaCl solution with one connector:

➢ Connect the arterial and venous patient line to the vascular access.

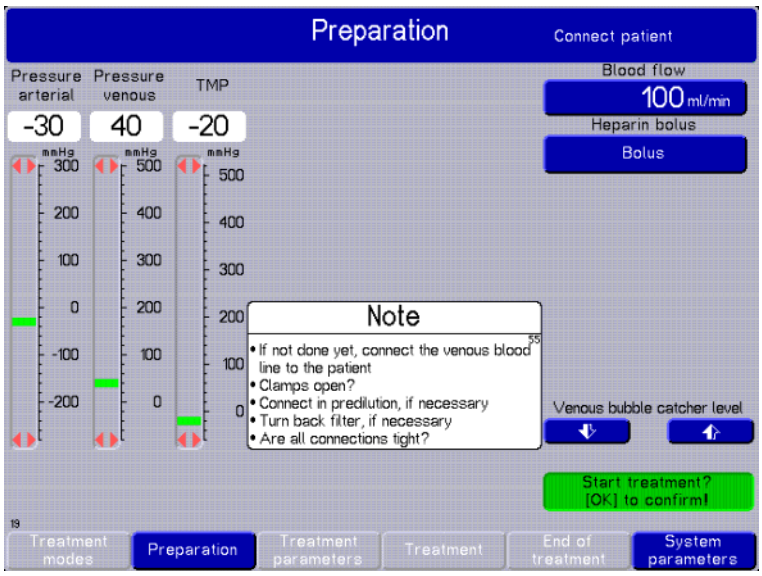
and

➢ Use the rotary selector to select **Start connection? [OK] to confirm!** and press **[OK]**.



The blood pump will deliver at the programmed rate.

Settable rate:
Cassette / adults 10 ml/min to 100 ml/min (default 100 ml/min)



The optical detector senses opaque fluid.

The blood pump is stopped.

If not done yet when using an NaCl solution with two connectors:

➢ Disconnect the venous patient line from the NaCl solution and connect it to the venous vascular access.

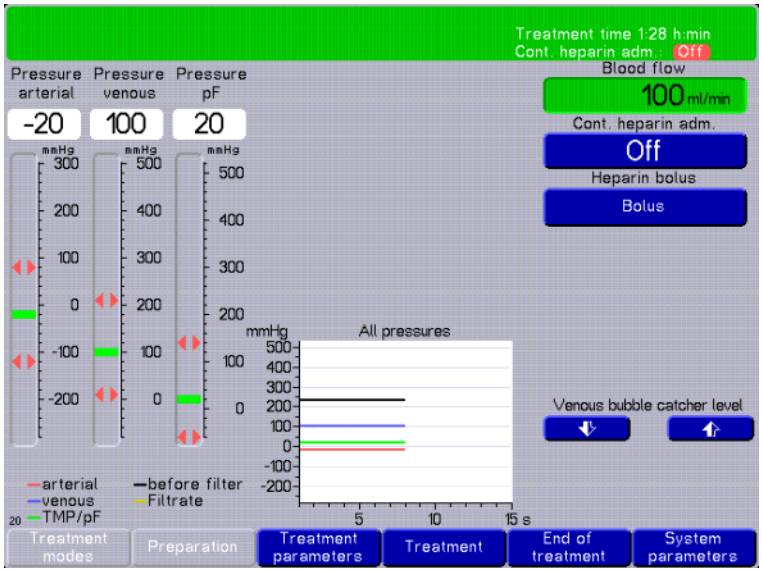
➢ Use the rotary selector to select **Start treatment? [OK] to confirm!** and press **[OK]**.

4.10.6 Treatment

Note

Once treatment has started and the blood pump has achieved its target delivery rate, the alarm limits are set automatically after approx. 10 seconds. Following this, the pressure alarm limits must be checked by the operator and adjusted individually as required.

4.10.6.1 Treatment main screen

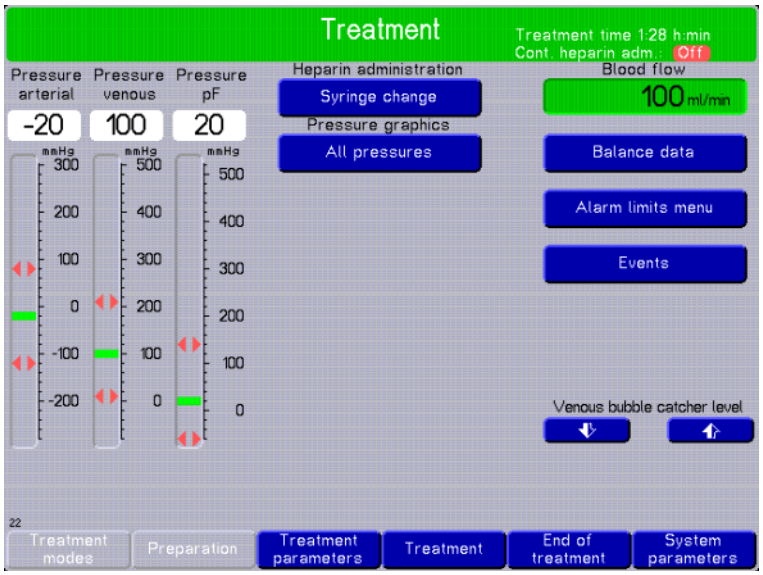


The main screen is displayed throughout the entire treatment.

Depending on the treatment mode, the menu field shows:
The current pressures (arterial, venous, pF)
The current flow rates (blood flow)
Heparin

The status bar shows:
The treatment mode
The progression of the treatment time
Continuous anticoagulation on / off

4.10.6.2 Treatment menu



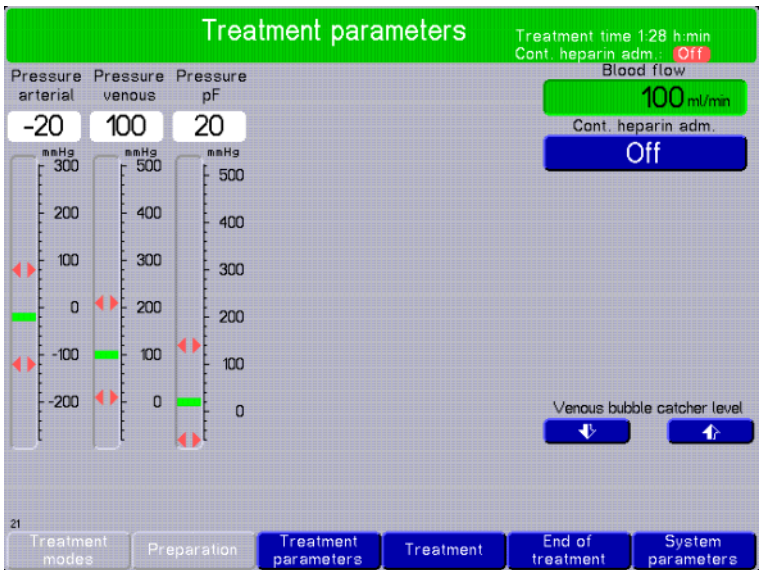
➢ Press the **[ESC]** key.

➢ Use the rotary selector to select **Treatment** from the menu bar and press **[OK]**.

The menu fields shown depend on the selected treatment mode. Detailed description (see chapter 4.11 on page 4-104).

After a timeout, the display will automatically return to the treatment main screen.

4.10.6.3 Treatment parameters



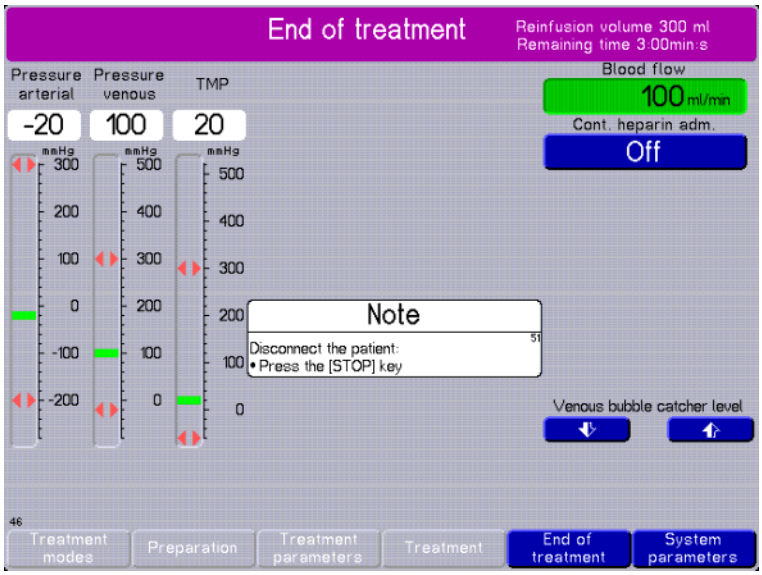
➢ Press the **[ESC]** key.

➢ Use the rotary selector to select **Treatment parameters** from the menu bar and press **[OK]**.

After a timeout, the display will automatically return to the treatment main screen.

4.10.7 End of treatment

4.10.7.1 Terminating the treatment



➢ Press the **[ESC]** key.

➢ Use the rotary selector to select **End of treatment** from the menu bar and press **[OK]** to confirm.

The blood pump is running.

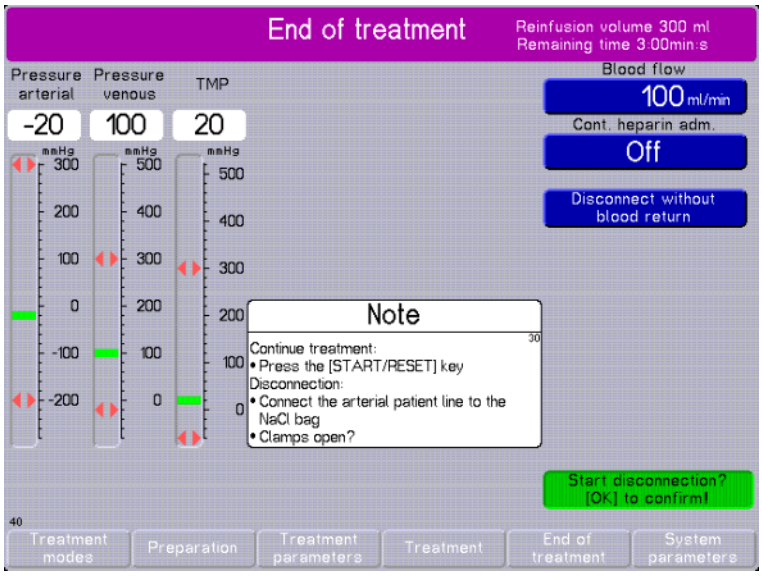
➢ Stop the treatment by pressing the **[STOP]** key.

Press the [STOP] key for approx. 3 seconds.
The venous clamp closes.
The blood pump is stopped.

or

➢ Use the **[ESC]** key to select a different menu from the menu bar.

4.10.7.2 Starting reinfusion



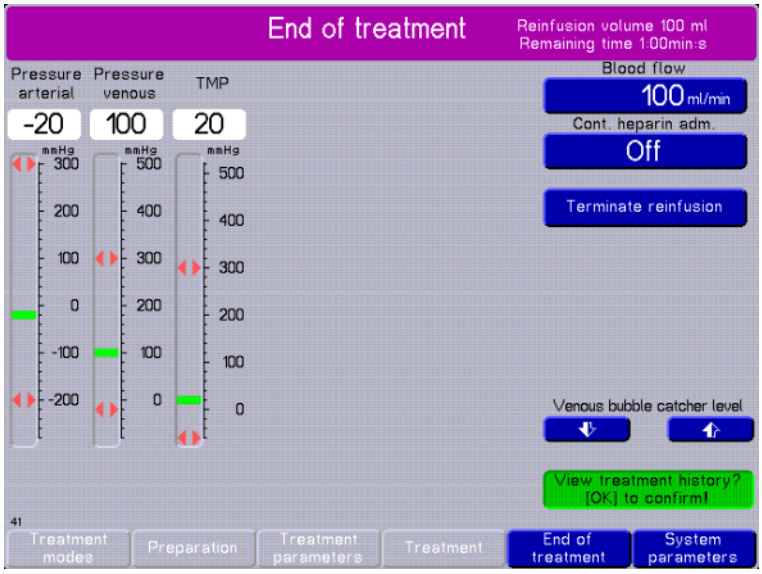
➢ Continue the treatment by pressing the **[START/RESET]** key.

or

➢ Disconnect the arterial patient line from the patient and connect it to the NaCl solution.

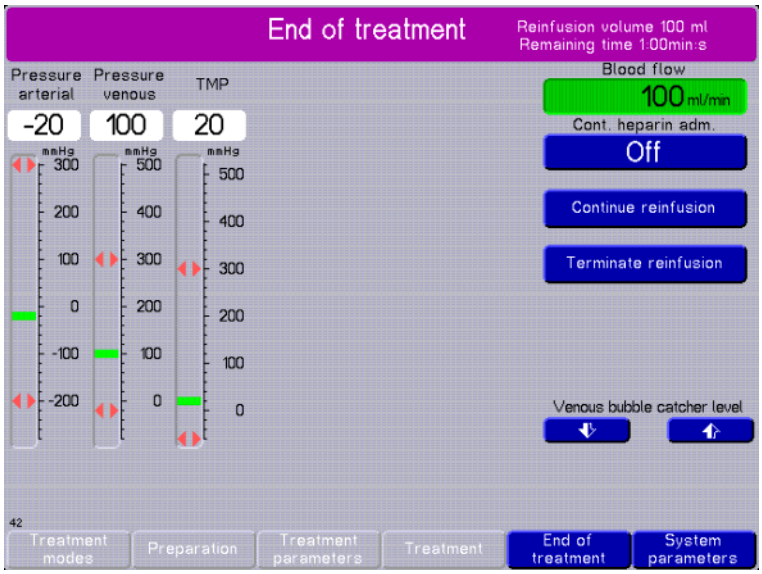
➢ Use the rotary selector to select **Start disconnection? [OK] to confirm!** and press **[OK]**.

When selecting **Disconnect without blood return**, the program will go directly to "Disconnecting the patient" without reinfusion after a safety prompt (see chapter 4.10.8 on page 4-103).



Indication of the decreasing reinfusion volume.

Selecting **View treatment history? [OK] to confirm!** will display the treatment parameters.



The optical detector senses non-opaque fluid.

➢ When selecting **Continue reinfusion**, the remaining reinfusion volume can be returned to the patient.

or

➢ Use the rotary selector to select **Terminate reinfusion** and press **[OK]**.

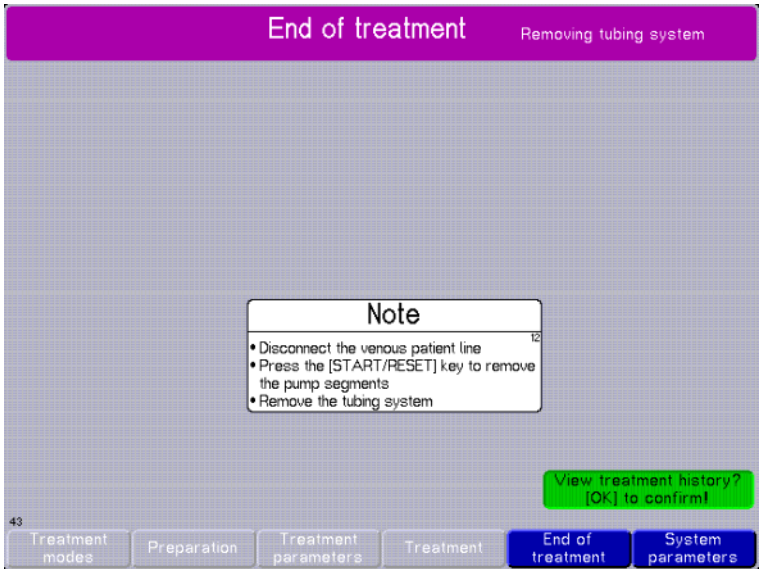
but

The treatment will be terminated automatically if the reinfusion volume is 0 ml and the optical detector senses non-opaque fluid.

4.10.8 Disconnecting the patient and removing the tubing system

Warning

Consumables must be discarded after the treatment in compliance with the regulations for the disposal of potentially contaminated materials.



➢ Disconnect the venous patient line from the patient.

➢ Remove the pump segment adapter from the groove.

➢ Press and hold the **[START/RESET]** key until the pump segment has been completely removed.

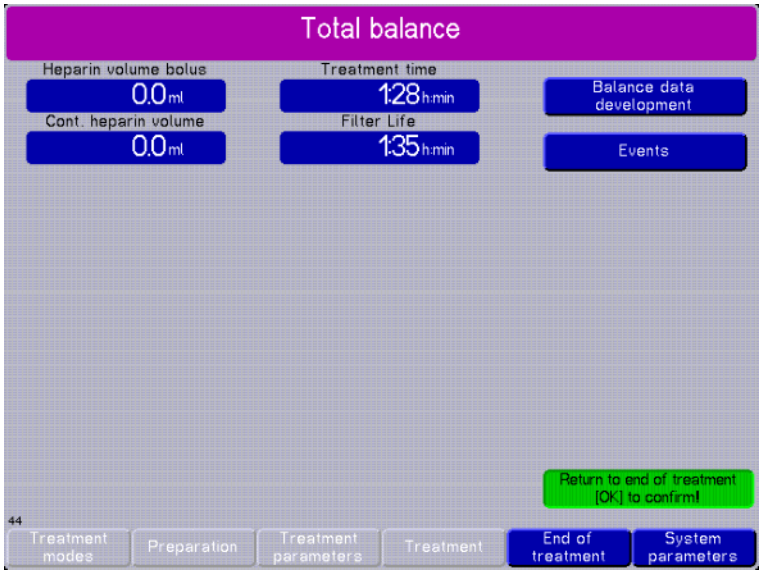
Support the removal of the pump segment by slightly pulling on it.

➢ Remove and dispose of the tubing system.

To remove the remaining pump segments, proceed as described above.

➢ Use the rotary selector to select **View treatment history? [OK] to confirm!** Confirm with **[OK]**.

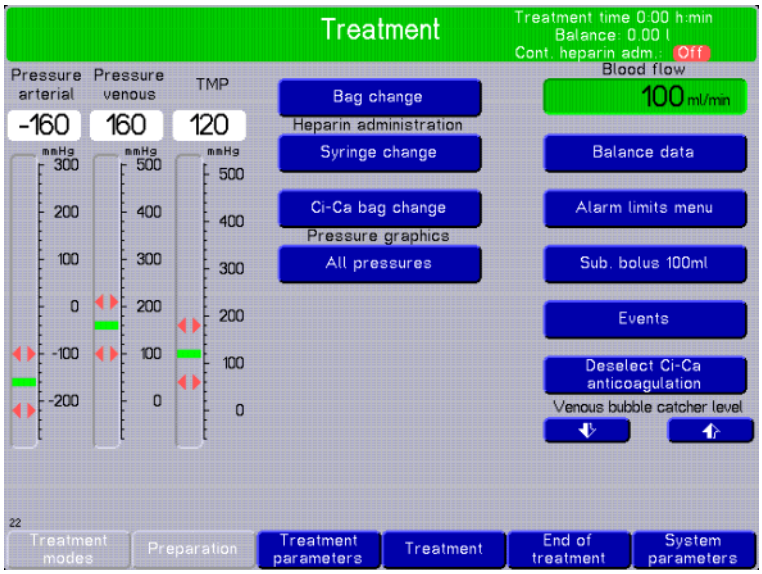
4.10.9 Treatment history



Indication of the treatment parameters for the entire treatment.

Press the **[I/O]** key to turn the device off.

4.11 Treatment menu



➢ Press the **[ESC]** key.

➢ Use the rotary selector to select **Treatment** from the menu bar and press **[OK]**.

The menu fields shown depend on the selected treatment mode.

➢ Use the rotary selector to select the required parameter field from the menu field and press **[OK]**.

After a timeout, the display will automatically return to the treatment main screen.

4.11.1 Deselecting Ci-Ca anticoagulation

Warning

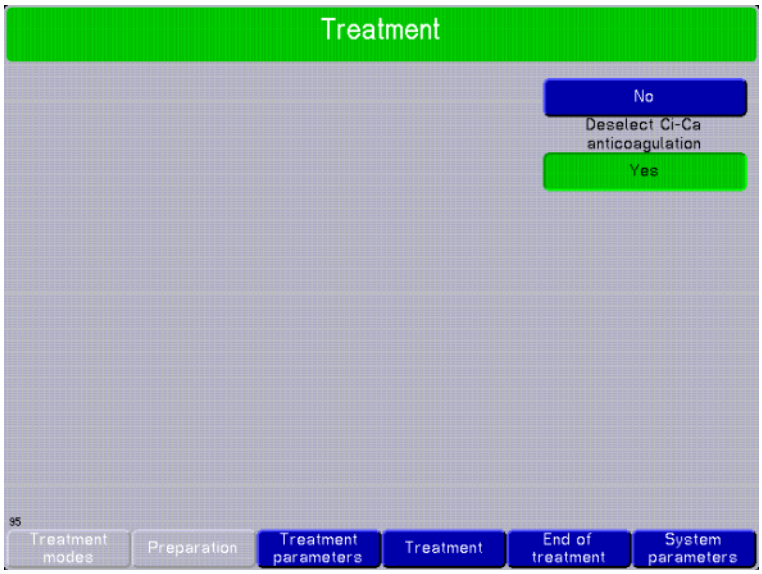
After deselecting citrate anticoagulation, the operator has to ensure an alternative anticoagulation procedure.

Warning

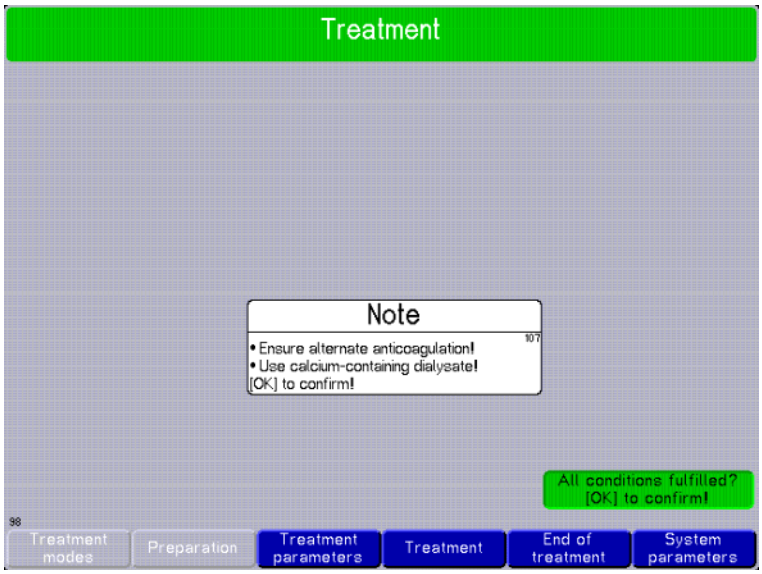
After deselecting citrate anticoagulation, the CVVHD treatment may only be continued / performed if a calcium-containing HF solution / dialysate is used.

Warning

After deselecting citrate anticoagulation, the Ci-Ca lines must not be removed from the pumps before the patient has been completely disconnected.



➢ Use the rotary selector to select **Yes** from the menu field and press **[OK]**.



➢ Use the rotary selector to select **All conditions fulfilled? [OK] to confirm!** and press **[OK]**.

After deselecting citrate anticoagulation, the multiFiltrate immediately switches to the menu for dialysate bag change.

4.11.2 Selecting Ci-Ca anticoagulation

Warning

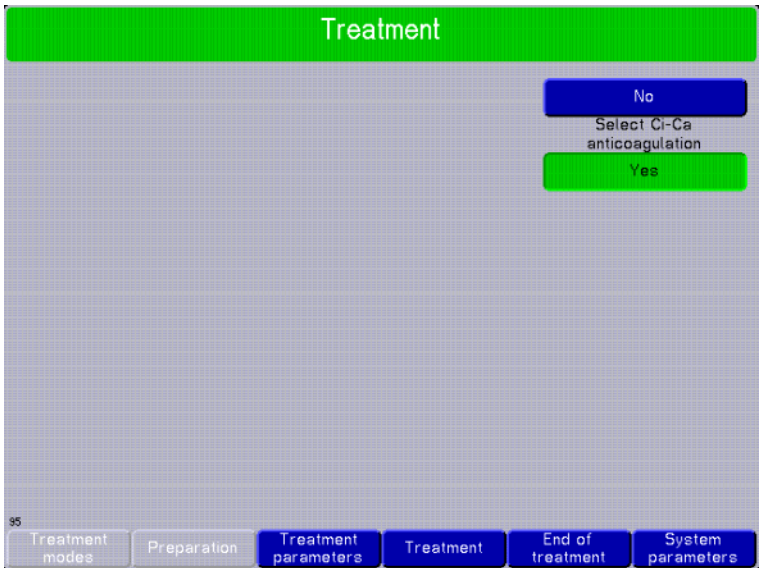
Ci-Ca CVVHD and Ci-Ca postCVVHDF treatments may only be performed if calcium-free dialysate is used.

Warning

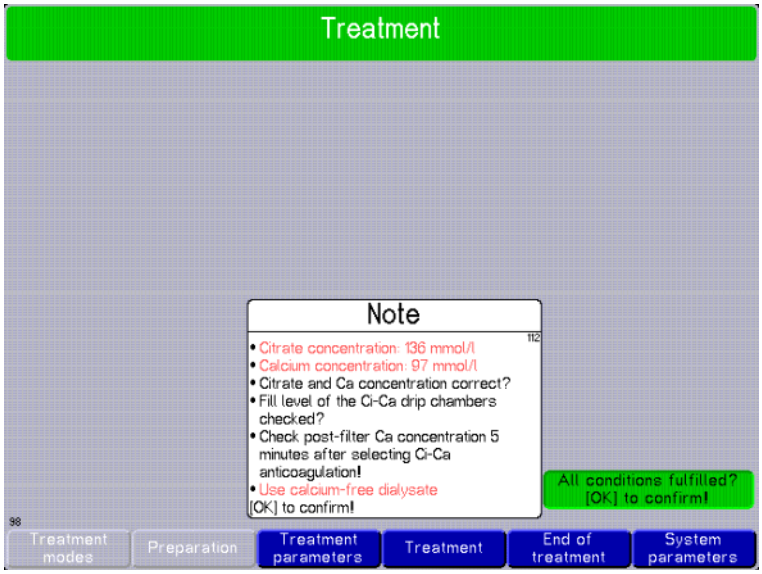
When starting the treatment, define the post-filter calcium value. If the ionised calcium has not decreased at this point, it is absolutely necessary that the tubing system and the solutions used are checked.

Warning

If the measured post-filter calcium value or systemic calcium value varies significantly, please consult a physician. Observe the instructions on taking a sample (see chapter 7.3.2 on page 7-17).



➢ Use the rotary selector to select **Yes** from the menu field and press **[OK]**.



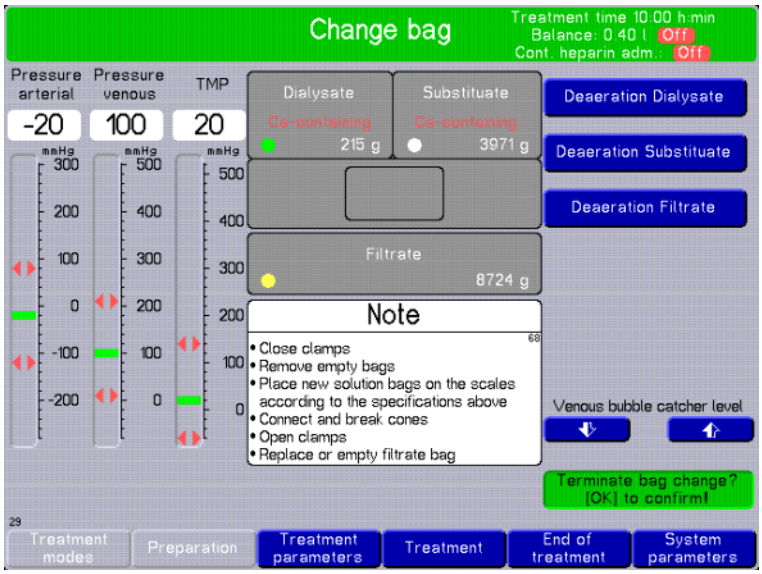
➢ Use the rotary selector to select **All conditions fulfilled? [OK] to confirm!** and press **[OK]**.

After selecting citrate anticoagulation, the multiFiltrate immediately switches to the menu for dialysate bag change.

4.11.3 Substituate / dialysate / filtrate bag change

Note

The bag change menu can be accessed:
- Manually by selecting the **Change bag** menu.
- Automatically after a bag change notification.
- Automatically after changing the procedure.
- Automatically after selecting or deselecting Ci-Ca anticoagulation.



The following information will be displayed:

The current weight on the active scale and the required HF solution.
"Not active" (red) the deactivated scales.
The current weight on the filtrate scales.

➢ Place the solution bag in question on the scales or replace it, and / or empty the filtrate bag.

In the event of presence of air in one of the tubing systems, disconnect the corresponding outlet.

➢ Use the rotary selector to select **Deaeration XXX**, and press and hold **[OK]** until all air has been removed from the tubing system. Reconnect the deaerated tubing system.

➢ Use the rotary selector to select **Terminate bag change? [OK] to confirm!** from the menu field and press **[OK]**.

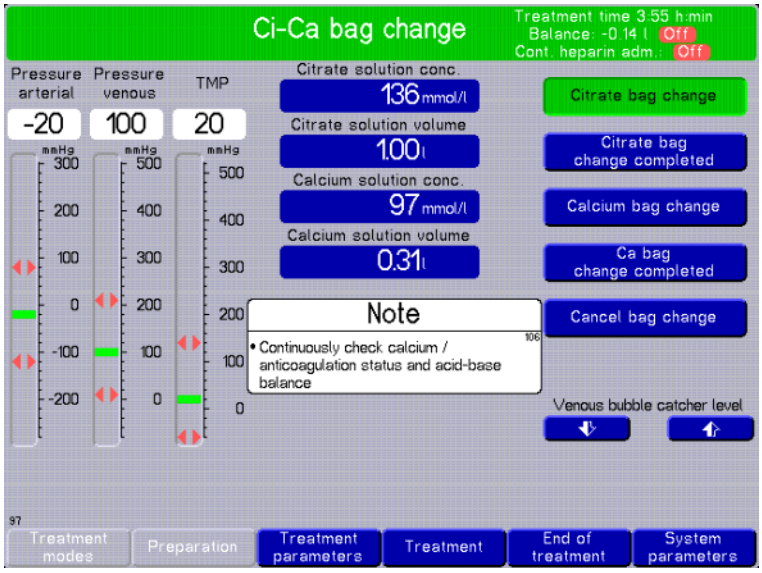
4.11.4 Ci-Ca bag change

Note

The Ci-Ca bag change menu can be accessed:
- Manually by selecting the **Ci-Ca bag change** menu.
- Automatically after a bag change notification.

Note

– When the **Ci-Ca bag change** menu is opened, balancing will be deactivated and the calcium pump will be stopped. Balancing and therefore also the calcium pump will be switched on again when you exit the menu.
– If the menu is opened due to a drop counter alarm of the citrate drop counter, the citrate pump will already be stopped when opening the **Change bag** menu.
– If the bag change lasts longer than 2 minutes (citrate pump stopped for more than 2 minutes), an alarm will be emitted.



➢ Use the rotary selector to select **Citrate bag change** or **Calcium bag change** from the menu field and press **[OK]**.

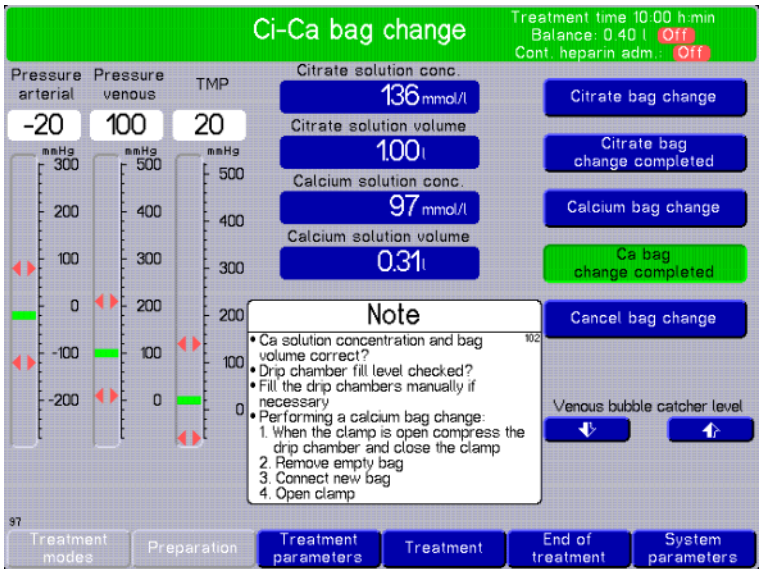
On selection of Citrate bag change, the citrate pump will be stopped.
The calcium pump has already been stopped.

➢ Replace the solution bag in question.

➢ Break the cone and manually remove any air possibly present in the line.

or

Select **Cancel bag change** to return to the Treatment menu.



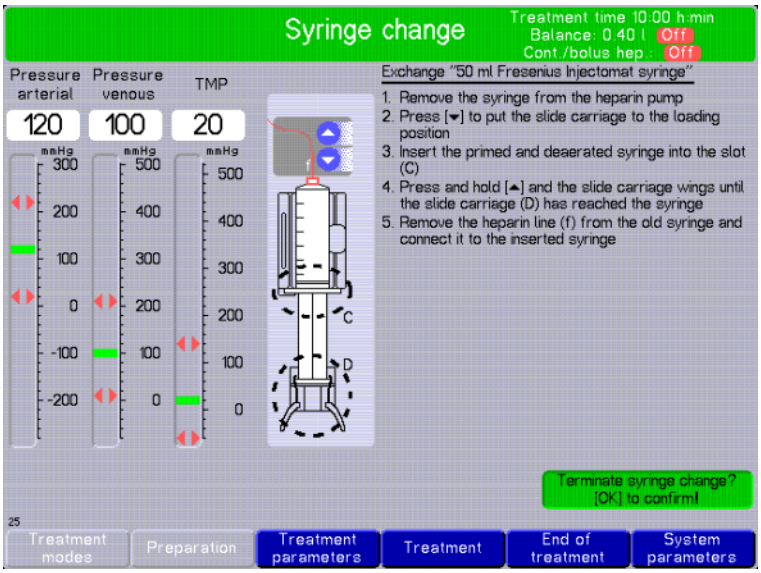
➢ Use the rotary selector to select **Citrate bag change completed** or **Ca bag change completed** from the menu field and press **[OK]**.

4.11.5 Syringe change

In the case of a syringe change, the sum of all boli remains saved, regardless of whether the OD senses non-opaque or opaque fluid. The bolus data is only deleted when changing to the treatment mode.

Note

The syringe change menu can be accessed:
– Manually by selecting the Syringe change menu.
– Automatically after a syringe change notification.



➢ Perform the syringe change according to the instructions.

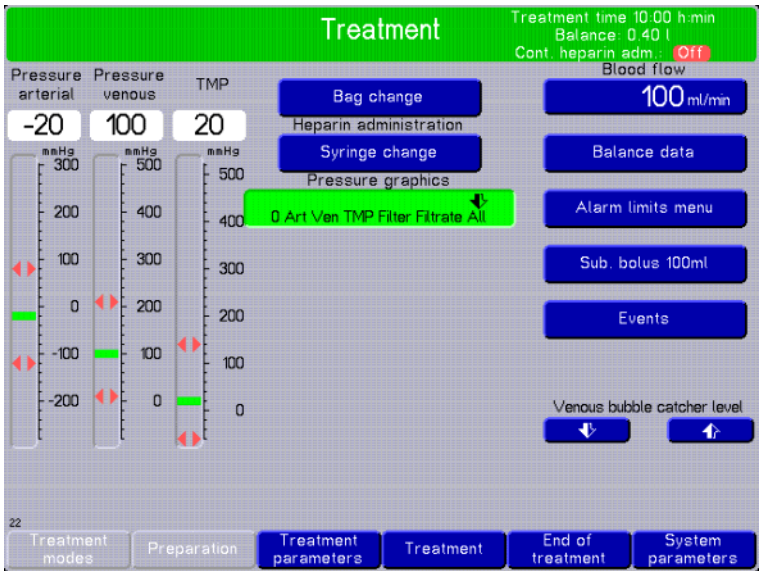
➢ Use the rotary selector to select **Terminate syringe change? [OK] to confirm!** from the menu field and press **[OK]**.

Note on C

The syringe wings must be placed in the syringe wing slot.

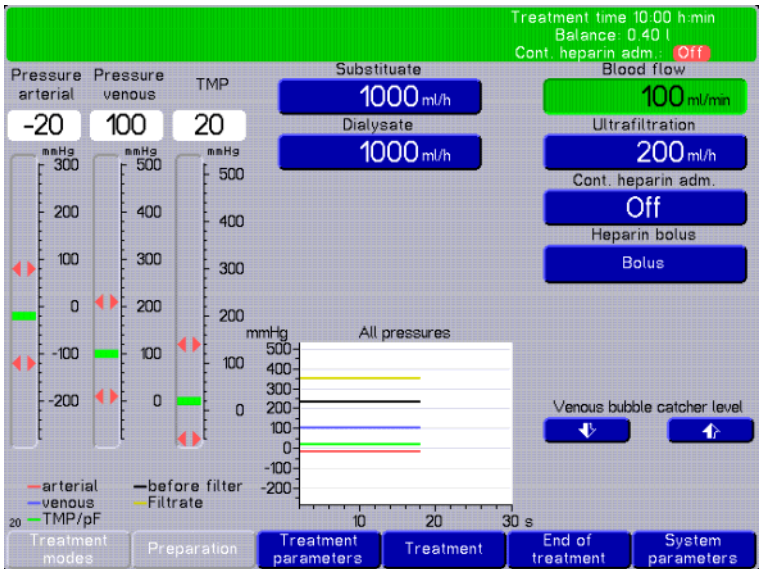
Note on D
– The thumbplate of the syringe plunger must be positioned between the clamps of the grip handle.

4.11.6 Pressure graphs



The rotary selector can be used to select the following pressure graphs and to confirm the selection with **[OK]**.

0 = no pressure graphs
Art = arterial pressure graph
Ven = venous pressure graph
TMP = pressure graph showing pressure in the filter
Filter = pressure graph showing pressure before the filter
Filtrate = pressure graph showing pressure on the filtrate side
All = Art, Ven, TMP, Filter, and Filtrate will be displayed in one graph (default)



The pressure graphs over time are displayed.

The horizontal axis is the treatment time. The scale value will be adjusted automatically in accordance with the time elapsed.

The vertical axis is the pressure value. If the value exceeds 520 mmHg, the pressures will displayed as horizontal lines on the upper edge.

4.11.7 Balance data

The balance data shown by the device is calculated from the values measured by the scales and is subject to the tolerances and possible errors specified in the performance data.

4.11.7.1 General balance information

The balance is the amount of fluid that is removed from and added to the patient during the treatment. During the CRRT treatments and SCUF, all volumes (substituate, citrate, calcium, heparin) which are added continuously are completely removed by the filtrate pump.

The heparin volumes added continuously are not removed in the MPS and HP treatments.

Substituate and heparin bolus volumes are not removed. They will be added to the balance:

Balance = UF volume + substituate bolus volume + heparin bolus volume

Example:

UF rate: 2.40 l/h
Duration of the treatment: 1 hour
Sub. bolus: 0.2 l

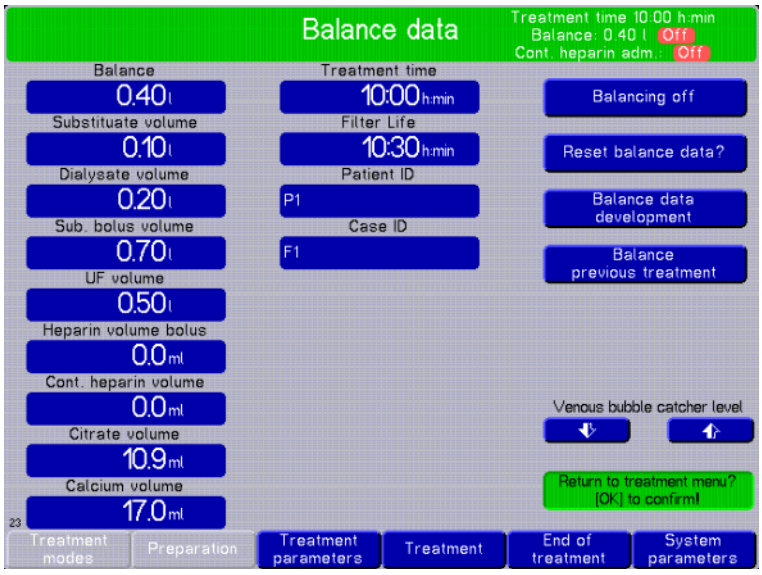
–2.20 l = –2.40 l + 0.20 l

After a treatment duration of one hour, the balance is –2.2 l.

The following has to be observed:

– The balance will be negative if fluid is removed from the patient.
– The balance will only be positive if the bolus volume is higher than the UF volume.
– The balance will normally be either even or negative.

4.11.7.2 Balance data during the treatment



Menu field:
– **Switch balancing on / off**
– **Reset balance data?**

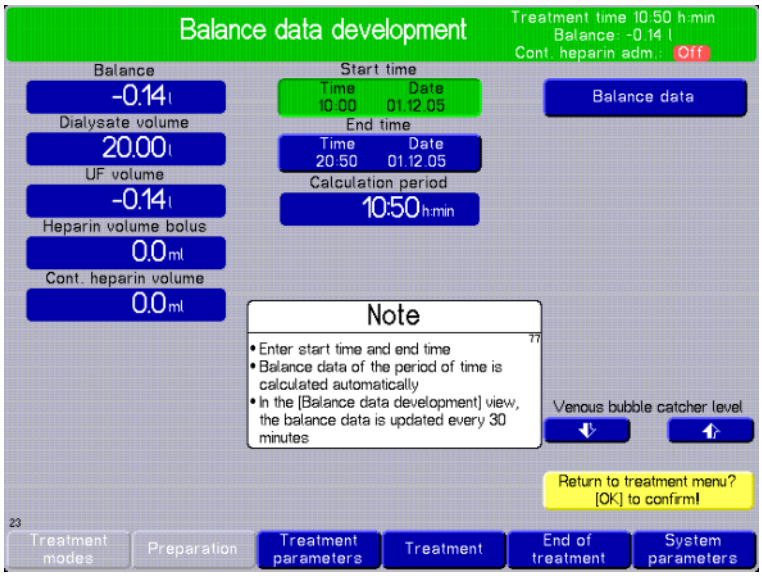
A balance data reset will reset all the cumulative volume information recorded so far to "zero". The treatment time and the filter life will not be reset.

– **Balance data development**
– **Balance previous treatment**

Display:
– **Treatment time**
– **Filter Life**

Further values displayed:
– Dependent on the treatment mode

4.11.7.3 Balance data development

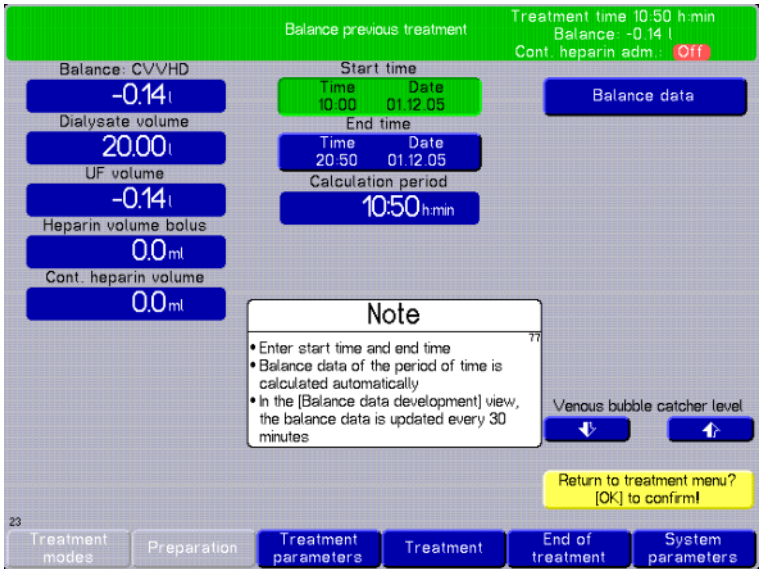


The balance data within a period of time of the ***current treatment*** can be displayed.

➢ Use the rotary selector to select **Start time** and **End time** and press **[OK]**. Enter times and press **[OK]** to confirm.

The balance data of the period of time entered is calculated automatically and displayed.

4.11.7.4 Balance data for previous treatment

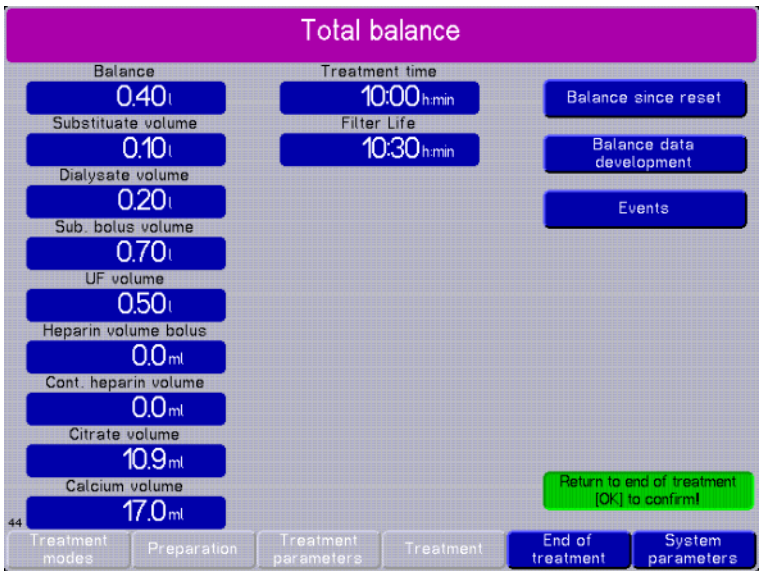


The balance data within a period of time of the ***previous treatment*** can be displayed.

➢ Use the rotary selector to select **Start time** and **End time** and press **[OK]**. Enter times and press **[OK]** to confirm.

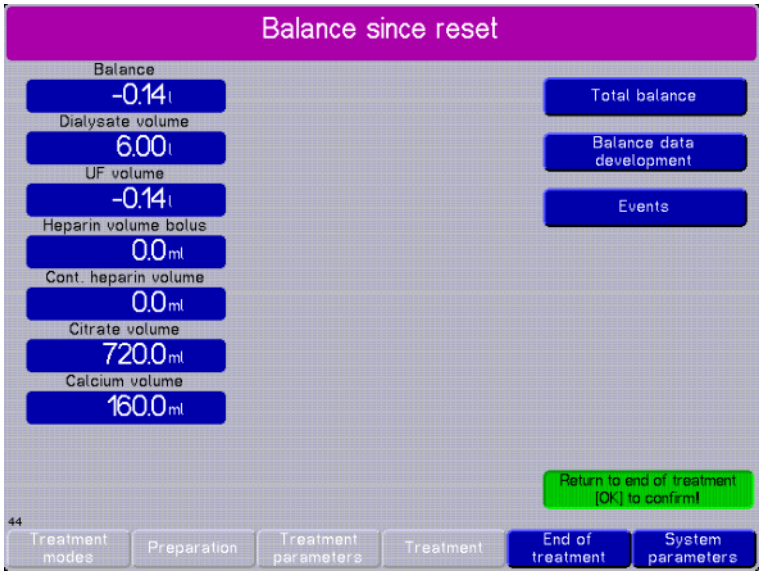
The balance data of the period of time entered is calculated automatically and displayed.

4.11.7.5 Total balance after the treatment



Indication of the treatment parameters for the entire treatment.

4.11.7.6 Balance since reset



The balance data since the last balance data reset will be displayed.

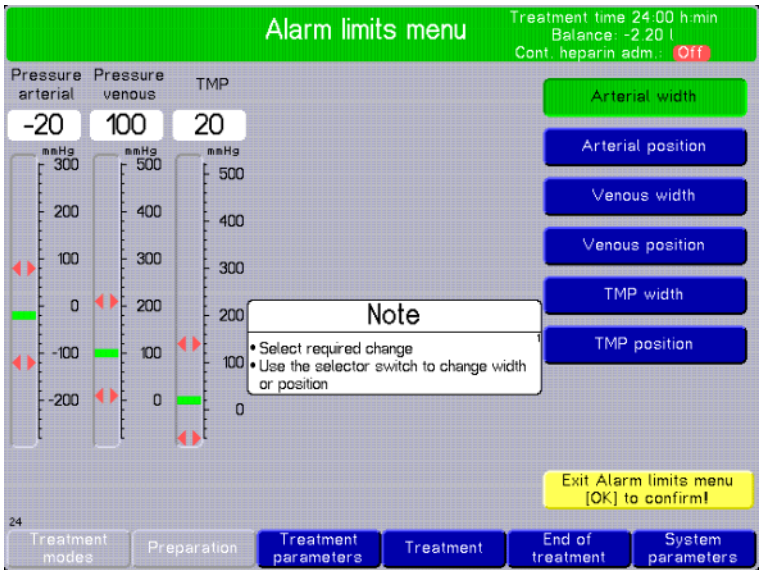
4.11.8 Alarm limits menu

Note

The system will only adopt a target and set change of the alarm limit window width / alarm limit window position after confirmation with **[OK]**.

Note

If the message **"Setting alarm limits for venous pressure and TMP. Please wait"** is displayed, the alarm limits menu is out of service. It is possible to reset the alarm limits by pressing the **[START/RESET]** key.



➢ Use the rotary selector to select the required parameter and press **[OK]**.

For HP, the pressure from filter is shown with the designation **pF** instead of **TMP**.

4.11.8.1 Preset alarm limits

Once treatment has started and the blood pump has achieved its target delivery rate, the alarm limits are set after approx. 10 seconds, as follows:

Arterial:
Centered with ±100 mmHg above / below actual pressure

Venous:
Lower alarm limit –20 mmHg below actual pressure
Upper alarm limit +100 mmHg above actual pressure

TMP:
Centered with ±100 mmHg above / below actual pressure

If the actual pressure value is near to the end of a scale, then the pressure limits will be reduced accordingly. The absolute lower alarm limit for venous pressure during treatment is +10 mmHg. The lower pressure limit is adjusted accordingly.

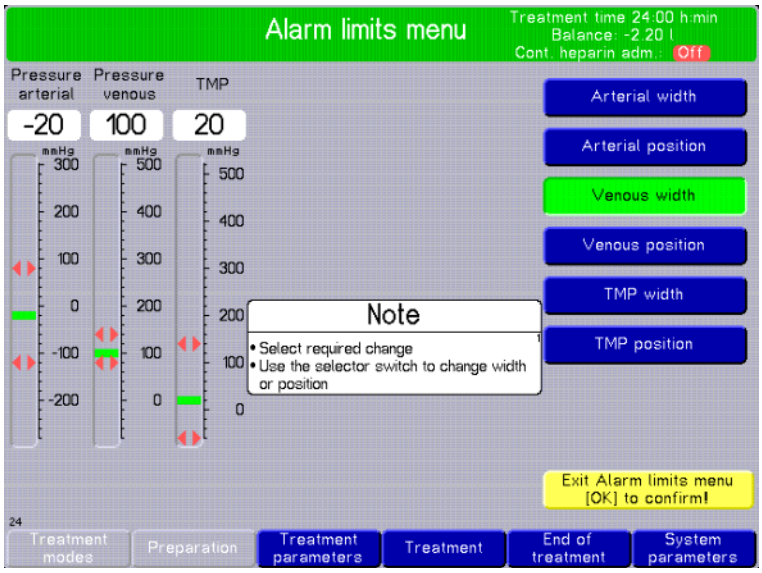
Following this, the pressure limits should be checked by the operator and adjusted individually as required.

4.11.8.2 Changing the venous width of the alarm limits window

Warning

Venous alarm limit

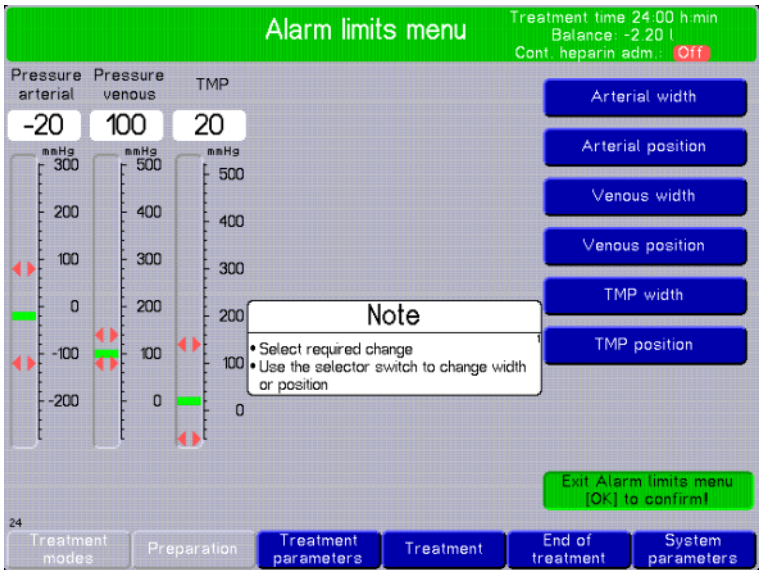
The lower venous alarm limit must be set as close as possible to the actual venous pressure value. Changing the alarm limit window position or width can adversely affect or even cancel out the efficiency of the safety system in identifying extraneous blood loss.



➢ Use the rotary selector to select **Venous width** and press **[OK]**.

➢ Use the rotary selector to enter the required window width and press **[OK]**.

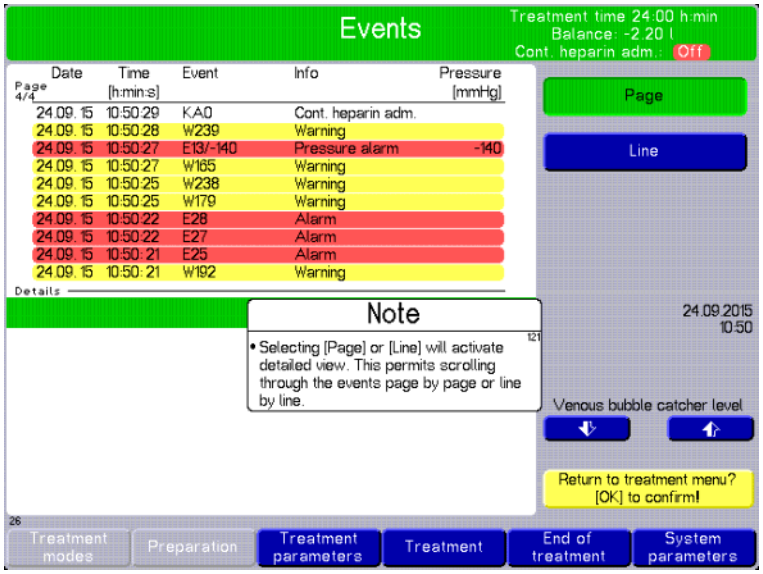
4.11.8.3 Exiting the Alarm limits menu



➢ Use the rotary selector to select **Exit Alarm limits menu? [OK] to confirm!** and press **[OK]**.

4.11.9 Events

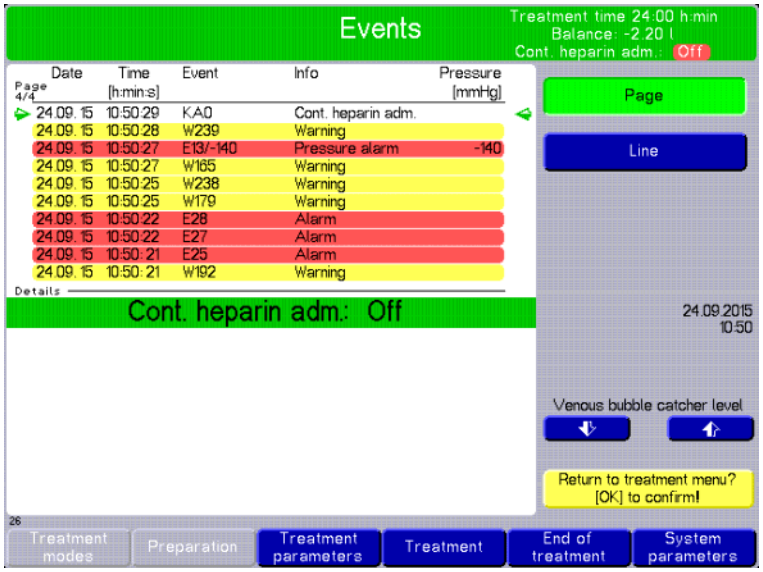
The last approx. 250 events are stored (depending on the data volume generated by the events logged). Their content is retained if the machine is switched off or if the mains power supply is interrupted.



➢ Use the rotary selector to select **Page** or **Line** and press **[OK]** to confirm.

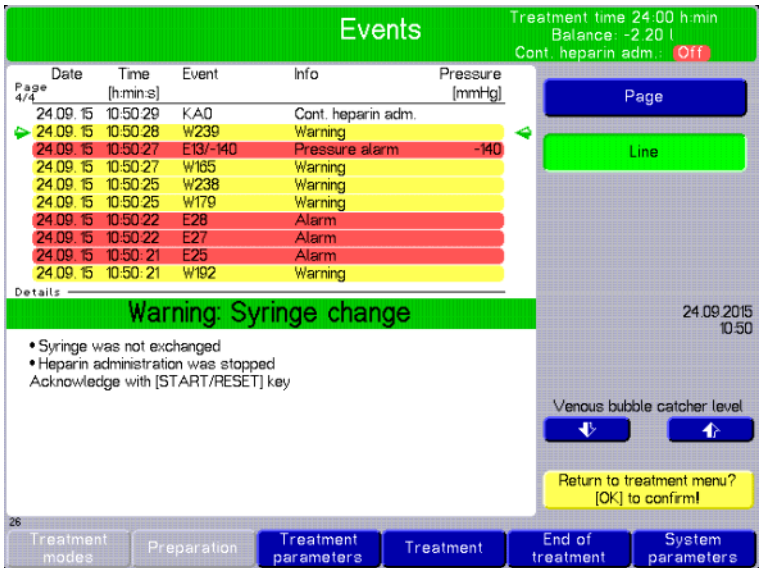
This will activate the detailed view. The detailed view in the lower part of the screen displays the text messages for warnings (yellow) and alarms (red).

Use the rotary selector to scroll the events page by page or line by line.



➢ Use the rotary selector to select **Page** and press **[OK]** to confirm.

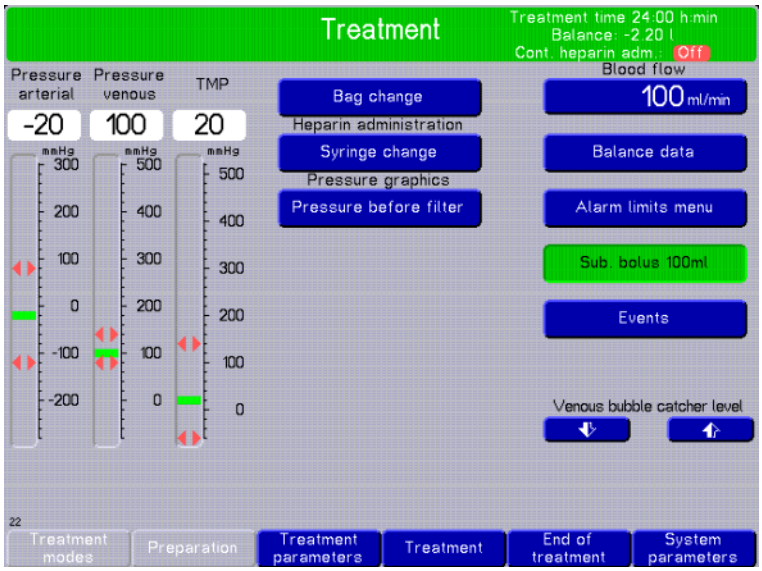
Ten events per page will be displayed when you turn the rotary selector.



➢ Use the rotary selector to select **Line** and press **[OK]** to confirm.

One event after another will be displayed when turning the rotary selector.

4.11.10 Sub. bolus 100 ml



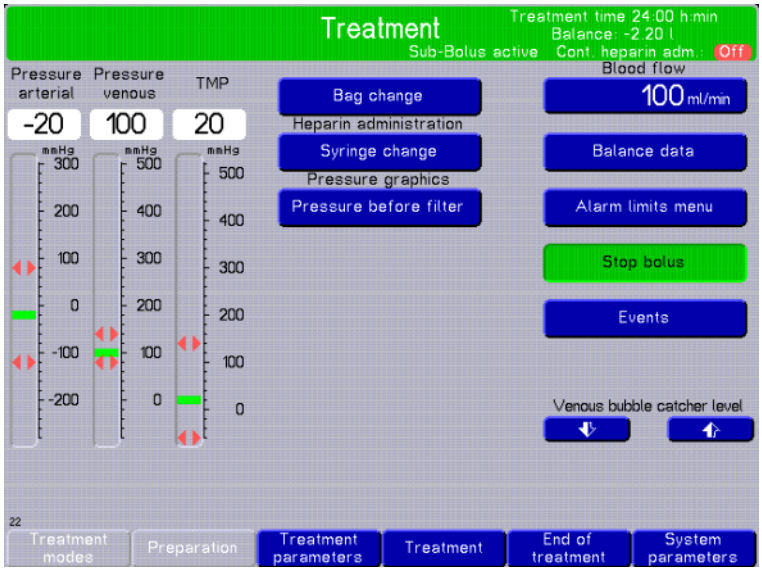
➢ Use the rotary selector to select **Sub. bolus 100 ml** and press **[OK]**.

100 ml of substitution fluid will be administered to the patient.

The bolus will be included in the calculation of the balance.

Sub. bolus cannot be administered in "Balancing off" and the following treatment modes:

- **Ci-Ca CVVHD**
- **CVVHD**
- **HP**
- **SCUF**
- **MPS**
- **Paed. CVVHD** and **Paed. CVVH**



The upper venous alarm limit is set to 300 mm/Hg.

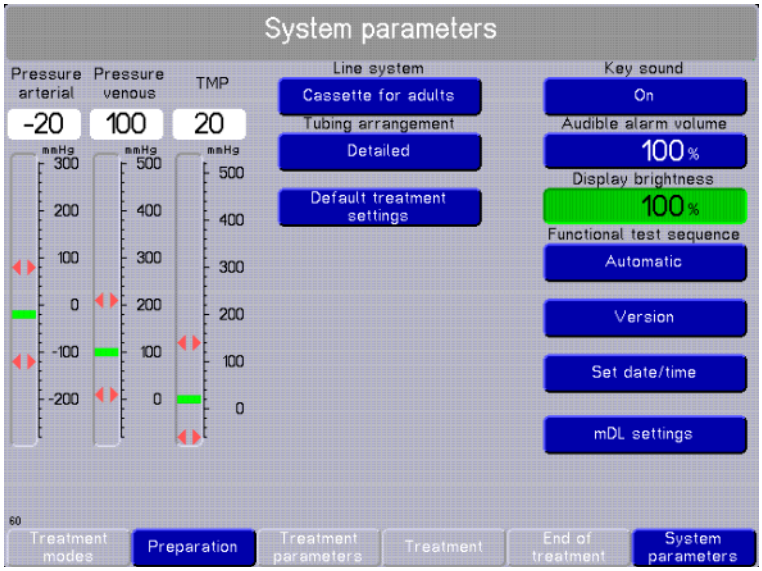
The lower TMP alarm limit is set to –60 mm/Hg.

The bolus can be stopped at any time by selecting **Stop bolus**.

4.12 System parameters

Note

The responsible organisation should define the most important configurable parameter settings itself, or confirm the default values and have these set by service support as required.



The **System parameters** menu can be accessed at any time. The fields **Key sound**, **Audible alarm volume**, and **Display brightness** can always be changed. All other parameter fields and submenus are available only until **Start priming** is executed for the tubing system or at the end of the treatment.

For Ci-Ca treatments, the **Cassette for adults** is selected under **Line system** and cannot be changed. The field **mDL settings** is only available when an mDL is integrated and activated.

The selected field must be confirmed by pressing the rotary selector **[OK]**.

Key sound — The audible feedback indicating that a key was pressed can be turned on or off.

Audible alarm volume — The volume of audible signals can be adjusted in this field.

Display brightness — The brightness of the screen can be adjusted from 50–100% in increments of 5%.

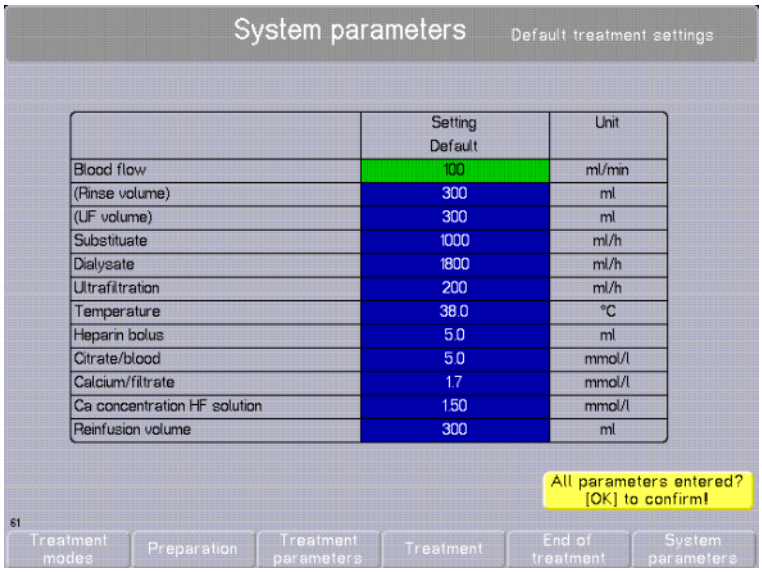
Functional test sequence — When **Detailed** is selected, all test steps will be displayed on the screen. When **Automatic** is selected, only the display test will be shown.

Version — This field can be used to view the software version.

Line system — If "Standard" or "Cassette" is selected, then the screen will support the insertion of the line system as appropriate. If a treatment mode has been chosen where no selection is possible, then the menu field is greyed out.

Tubing arrangement — When **Detailed** is selected, the installation of the line system will be shown step by step. When **Complete** is selected, the fully inserted line system will be displayed.

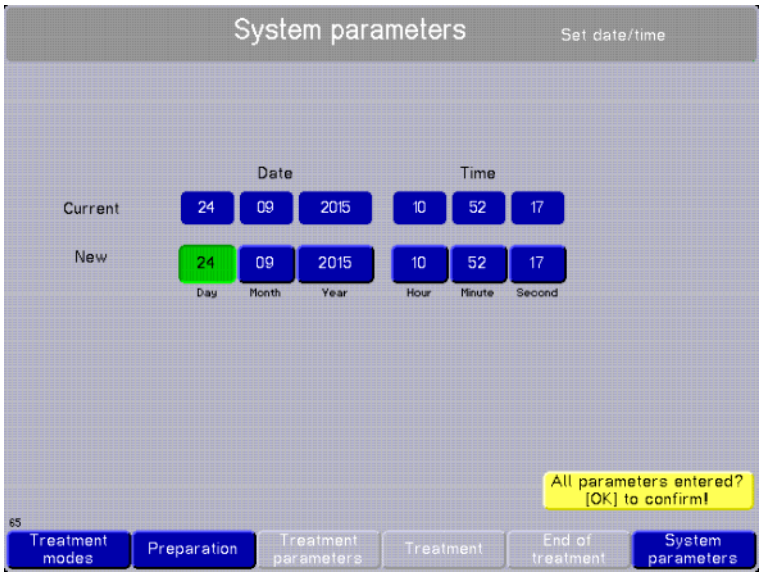
4.12.1 Default treatment settings



Standard parameters can be entered for each treatment mode. These can be changed individually for each patient in the **Treatment parameters** menu.

The parameters that were changed are not activated until the device is brought back into operation with the **[I/O]** key.

4.12.2 Setting the date / time



Set the current date and time.

4.13 Interrupting the treatment

Warning

Only disconnect the patient from the extracorporeal circuit after retransfusing the blood from the extracorporeal circuit to the patient.

In exceptional cases (e.g., reanimation becoming suddenly necessary), it may perhaps not be possible to retransfuse the blood. In such a case, please take the following measures at the very least:

– Shunt the two patient connectors via a flexible vessel, e.g., a bag filled with isotonic NaCl solution, in order to avoid a critical increase in pressure in the extracorporeal circuit.

– Deactivate balancing.

– The citrate infusion has to be stopped actively with "Deselect Ci-Ca anticoagulation".

– If the internal heparin pump is used for systemic anticoagulation, it also must be stopped.

– If you proceeded in this manner, discard the blood in the extracorporeal circuit and, if necessary, replace it with isotonic NaCl solution before reconnecting the patient.

– The stopped anticoagulation process must be restarted.

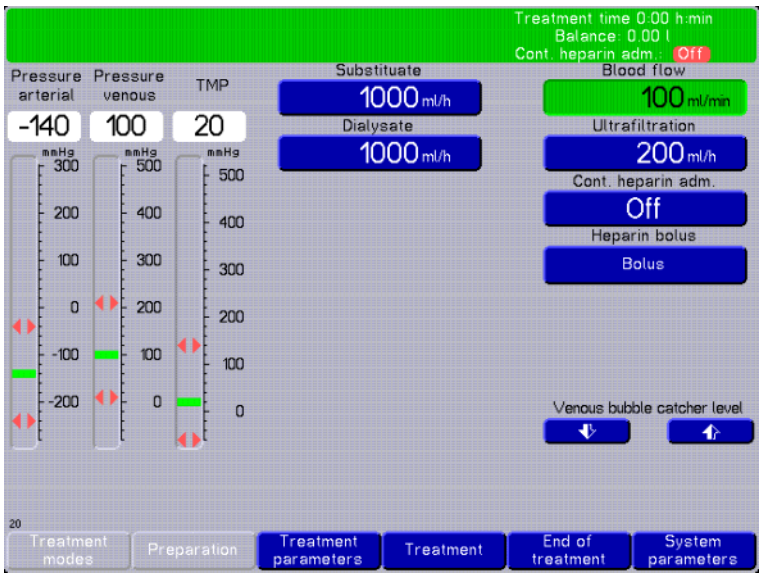
Warning

Always observe aseptic procedures when connecting and disconnecting the patient and perform the process with due care to avoid any loss of blood.

4.13.1 Disconnecting the patient / interrupting the treatment

Note

- Make sure an NaCl solution with a volume of 1 l and two connectors is available.
- The treatment should not be interrupted for more than 4 hours.
- Always observe aseptic procedures when connecting and disconnecting the patient and perform the process with due care to avoid any loss of blood.



➢ Set the blood flow to 100 ml/min and turn the heparin pump off.

➢ Stop the treatment by pressing the **[STOP]** key.

Press the [STOP] key for approx. 3 seconds.

➢ Disconnect the arterial patient line from the patient and connect it to the NaCl solution.

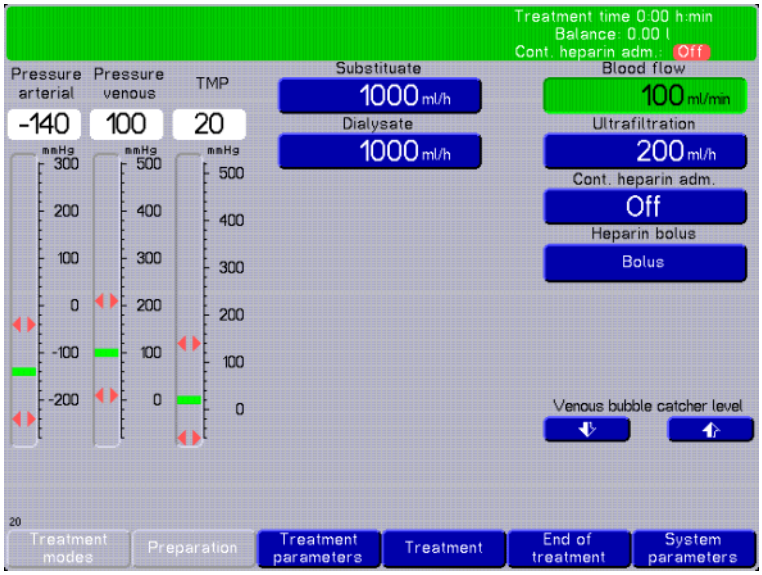
➢ Press the **[START/RESET]** key.

When the optical detector senses non-opaque fluid, disconnect the venous patient line from the patient and connect it to the NaCl solution.

➢ Press the **[START/RESET]** key.

Balancing stops automatically.
Ci-Ca pumps stop automatically.

4.13.2 Connecting the patient / continuing the treatment



➢ Stop circulation by pressing the **[STOP]** key.

Press the [STOP] key for approx. 3 seconds.

➢ Disconnect the arterial patient line from the NaCl solution and connect it to the arterial vascular access.

➢ Press the **[START/RESET]** key.

When the optical detector senses opaque fluid, disconnect the venous patient line from the NaCl solution and connect it to the venous vascular access.

➢ Continue the treatment by pressing the **[START/RESET]** key.

Balancing starts automatically.
Ci-Ca pumps start automatically.

➢ If necessary, set blood flow and heparin administration.

5 Alarm processing

5.1 Acknowledging a message repeatedly

For the safety systems, the relevant alarm limits and alarm conditions described in Chapter 12 "Specifications", under "Dialysate circuit and safety systems" and "Extracorporeal blood circuit and safety systems", also apply.

Operators must stay close enough to the device to be able to notice any emitted visual or audible alarms at all times.

Warning

Patient hazard through repeatedly acknowledging a message

➢ Always correct the problem that caused the message before acknowledging it.

Note

When alarms and warnings occur, follow the information given in the messages, as well as any explanations given in the Help function **"?"**.

If the following alarms and warnings are repeatedly acknowledged without being corrected, this can endanger the patient as follows:

Alarms / warnings	Possible patient hazard
Loss of pressure at the venous vascular access Arterial and venous pressure alarms	Extraneous blood loss Bleeding into tissue Haemolysis, through kinks in the tubing system
Anticoagulation alarms (e.g., heparin pump alarms)	Loss of blood through coagulation in the extracorporeal blood circuit Wrong dosage of anticoagulation medium
Blood leak alarms	Loss of blood into filtrate / plasma
Isolated citrate dosage with balancing switched off	Citrate accumulation / disruption of acid-base status
Low temperature warning	Hypothermia

5.2 Alarm schemes

Note

The alarm scheme selected must be evaluated to ensure it is suitable for the place of operation and the environmental conditions, and it must be specified by the responsible organisation.

The device features two alarm schemes. The chosen scheme is configured in **Service Mode**.

Any switching between schemes must be authorised and performed by – or on behalf of – the organisation responsible for the use of the device.

The alarm scheme defines the information, warnings, and alarms provided to the operator if malfunctions occur, plus the alarm conditions.

An alarm always involves a visual and an audible signal. The required information or cause of the alarm is also displayed as text on the screen.

All visual signaling of alarms and their priority is displayed using the operating status indicator. This displays the appropriate colour (red, yellow, green) in a specific flashing pattern.

The audible signals generated by alarm conditions are related to the visual display. They also use a range of tone sequences and patterns of repetition to inform the operator about the priority and the relevance of the alarm condition.

The "Old" alarm scheme displays a condition-oriented system of alarms and corresponds to the former alarm schemes provided by the Fresenius Medical Care range of devices.

The "New" alarm scheme displays the potential danger presented by an alarm situation. It assigns a priority to every alarm and is based on the alarm standard EN 60601-1-8 for medical devices used in intensive medical care.

5.2.1 Old alarm scheme

This alarm scheme defines an absolutely unambiguous relationship between the alarm situation, device response, and alarm.

Basic assignment

An alarm condition (blood alarm) stops the blood and balancing circuits: The operating status indicator is red and the system emits an audible signal.

An alarm condition (balance warning) stops the balance circuit: The operating status indicator is yellow and the signal emits an audible warning.

Internally, the alarms and warnings are given different priorities (described in the following section).

The system also offers the option of using isolated audible signals to inform the operator.

5.2.2 New alarm scheme

This scheme is based on assigning priority levels to alarm situations. Priorities correspond to the present danger level and the time before a potential hazard occurs, according to the following table:

Possible result of failing to respond to the cause of the alarm condition	Start of potential injury		
	Instant	Soon	Delayed
Death or irreversible injury	High priority	High priority	Medium priority
Reversible injury	High priority	Medium priority	Low priority
Minor injury or discomfort	Medium priority	Low priority	Low priority or no signal

The signals and tone sequences corresponding to the various priorities are assigned uniformly to a range of medical device groups: As a result, all dialysis devices will, as a rule, generate a uniform set of alarm signals.

Basic assignment

The assignments of alarm condition, priority, and device response are defined as follows:

High priority:
Red flashing operating status indicator and repeated tone sequence of 10 beeps.

Medium priority:
Yellow flashing operating status indicator and repeated tone sequence of 3 beeps.

Low priority:
Yellow steady operating status indicator and repeated tone sequence of 2 beeps.

The system also offers the option of providing information ("Warning"): Green flashing operating status indicator with repeated tone and isolated information tones.

In this way, each alarm scenario is assigned a priority that defines the alarm response of the device.

5.3 High-priority alarm conditions

Since critical alarm situations can cause the machine to be placed in Safe Mode (halting treatment), alarms with high priority are only triggered in exceptional cases, where a potential hazardous condition persists even following alarm response.

The following alarm conditions are assigned high priority in the "New" alarm scheme:

– Lower return pressure:
  Potentially, the system may become disconnected, resulting in ongoing blood loss via the access.
– Failure to detect the pump clips on the Ci-Ca pumps (no occlusion):
  Potentially, the patient may suffer air infusion or blood loss via the Ci-Ca tubing system.

In addition, the following conditions have an elevated risk and require intensive observation and monitoring:

– Override condition following blood leak.

5.4 Monitoring function suppression

Warning

When the monitoring function is suppressed, the operator is responsible for the patient's safety.

Alarm override / confirmation

Suppresses the pressure alarms (alarm limits widened to the end of the scale) for the time the blood pump starts running plus 10 seconds.

Overrides a blood leak alarm for around 2 minutes (for MPS, the blood leak detector can also be deactivated in the **Treatment** menu).

It is not possible to override the air alarm.

5.5 Alarm system

Pressure monitoring

To avoid unnecessary false alarms, the monitoring window can be temporarily extended, disabled, or its levels adjusted to the current pressure following changes to relevant parameters, pressure alarms, or issuing pump stop / start commands. These conditions are time-limited. Monitoring at the display range thresholds remains unaffected.

Air infusion

To ensure that the stringent limit values for detecting air infusion are always maintained, you may need to restrict the maximum blood flow for low-weight patients (see chapter 12.11 on page 12-14).

Note

Air infusion alarm limits are dependent on blood flow and patient weight. Full sensitivity at max. blood flow is achieved with patient weights upwards of 45 kg.

If return pressure is negative (e.g., when deploying central venous catheters) then the risk of an air infusion is present, even downstream of the air detector.

Alarm priorities	Follow-up alarms of the same priority are not signaled by the system. Follow-up alarms of higher priority are signaled in cases where the system has not already reached a safe condition.
Audible alarm suppression / mute	Silencing the audible alarm will always suppress an alarm for a duration of 2 minutes. Any new alarm that occurs will activate the silenced audible alarm.

5.6 Alarm system response

- **When starting treatment or resuming treatment after an alarm**

When starting treatment or resuming treatment after an alarm, you can delay the following alarms or widen the alarm limits for a certain period of time by pressing the **START/RESET** key.

Alarm	Response
Arterial pressure	Alarm limits widened to maximum values for the duration of the pump start-up (approx. 10 seconds)
Venous pressure	Alarm limits widened to maximum values for the duration of the pump start-up (approx. 10 seconds)
TMP	Alarm limits widened to maximum values for the duration of the pump start-up (approx. 10 seconds)
pF pressure	Alarm limits widened to maximum values for the duration of the pump start-up (approx. 10 seconds)
Blood leak	Start delayed for approx. 8 seconds

- **Overriding an alarm (temporarily deactivating an alarm system)**

Warning

While overriding the alarm system, the operator is responsible for the patient's safety.

If a pending blood leak alarm is confirmed with the **START/RESET** key, this alarm is overridden (deactivated) for a certain period of time.

Alarm	Override time
Blood leak	2 minutes

- **Suppressing the audible alarm (mute)**

The **Mute** key allows the operator to suppress (deactivate) the audible tone of a signaled alarm for a certain period of time.

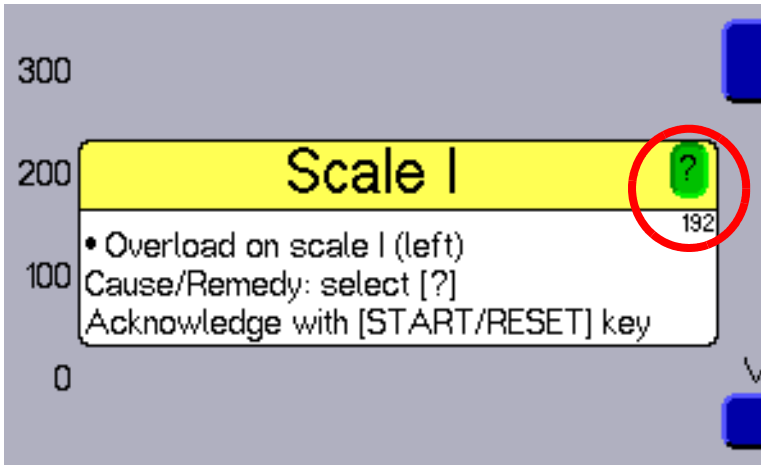
If a new alarm occurs during this time, the audible alarm tone of the new alarm is signaled regardless.

Name	Suppress time
Mute (SOUND OFF time)	2 minutes

5.7 Messages

Note

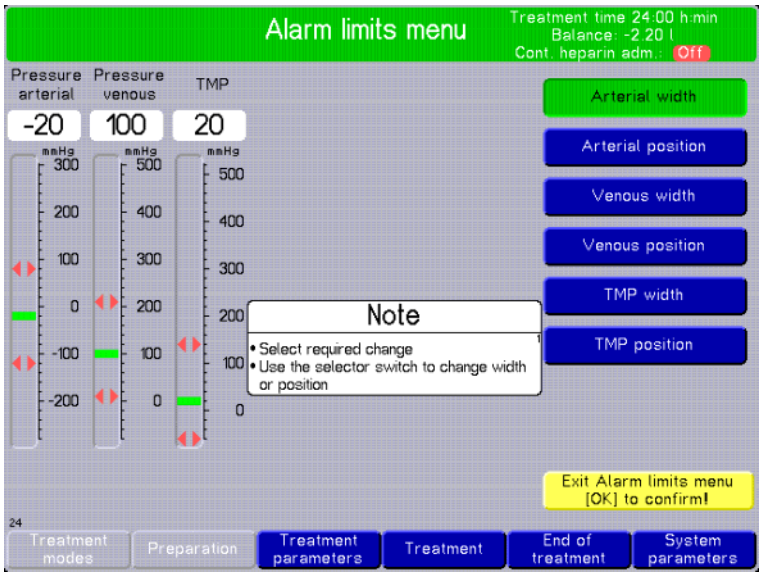
When alarms and warnings occur, follow the information given in the messages, as well as any explanations given in the Help function. If alarms are repeatedly acknowledged without resolving their causes, this can endanger the patient.



Each display message is identified by a number on the upper right corner. This number will enable the service to provide faster assistance in the event of a problem.

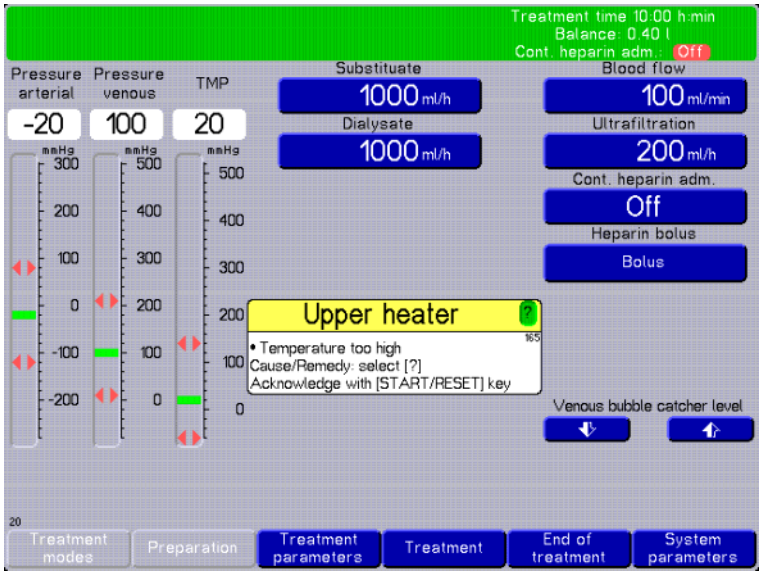
Selecting the **?** button will display additional support on how to correct the messages.

5.7.1 Note box (white)



The white boxes provide treatment-related support which the operator must always observe and implement.

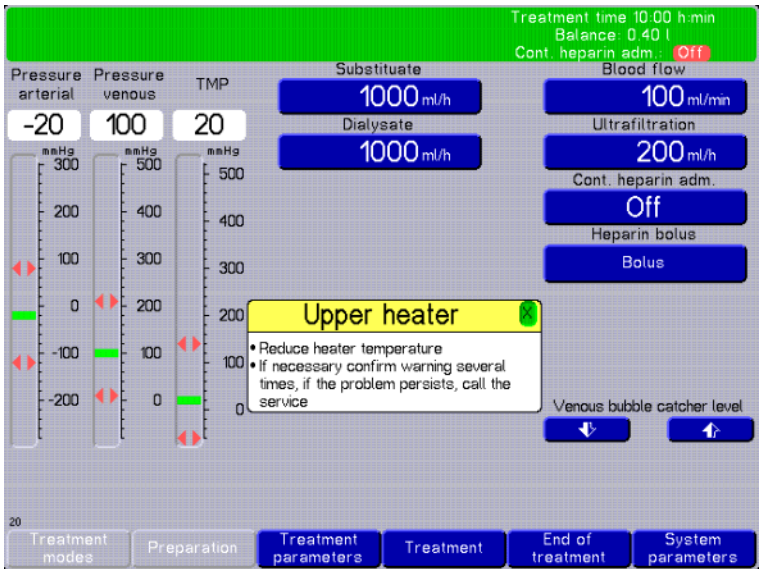
5.7.2 Warning box



The boxes alert the operator to incorrect operation or a malfunction. The warning message is shown on the title bar (yellow or grey background depending on the alarm scheme configured). The lower section of the box (white background) contains a summarised description of the possible cause.

Balance is off.

By selecting the **green question mark** with the rotary selector and pressing **[OK]**, the operator will obtain support in correcting the cause of the problem.

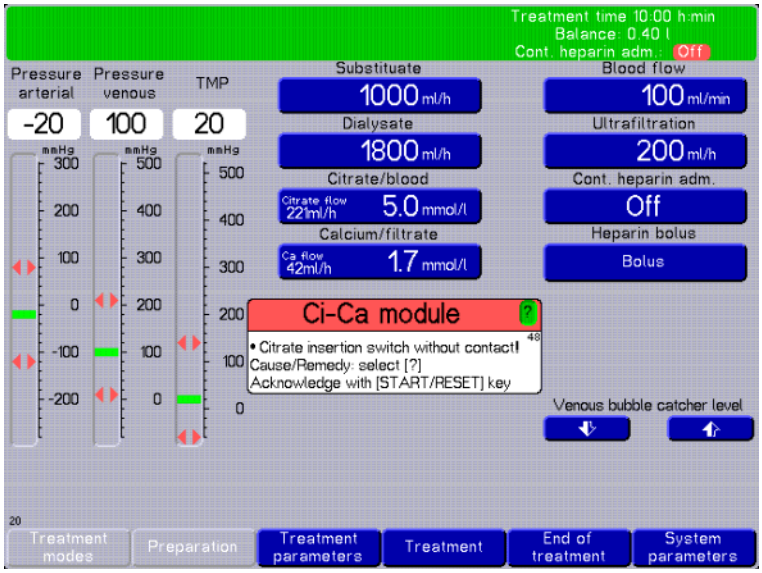


The possibilities to correct the problem will be displayed.

➢ Press the **[START/RESET]** key.

Balance is on.

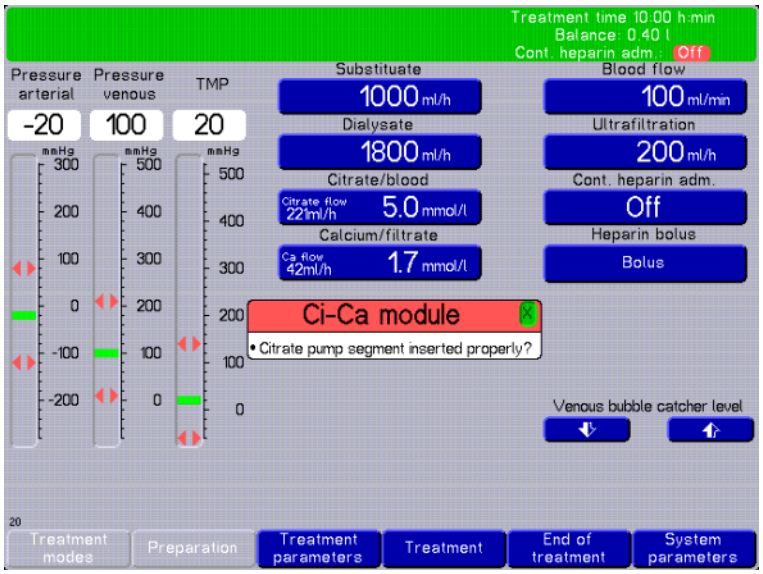
5.7.3 Alarm box



The boxes alert the operator to an alarm. The alarm message is shown on the title bar (yellow or red background depending on the alarm scheme configured). The lower section of the box (white background) contains a summarised description of the possible cause.

Balance is off.
The blood pump is stopped.

By selecting the **green question mark** with the rotary selector and pressing **[OK]**, the operator will obtain support in correcting the cause of the problem.



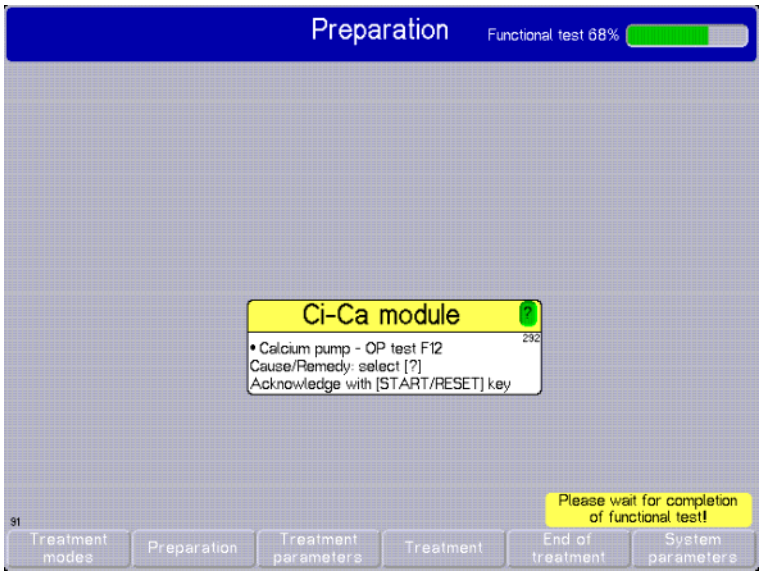
The possibilities to correct the problem will be displayed.

➢ Correct the condition causing the alarm.

➢ Press the **[START/RESET]** key.

Balance is on.
The blood pump will start at a slower speed and gradually increase to the prescribed rate. Then the required balancing pumps will start (depending on the treatment mode).

5.8 Messages during the functional test



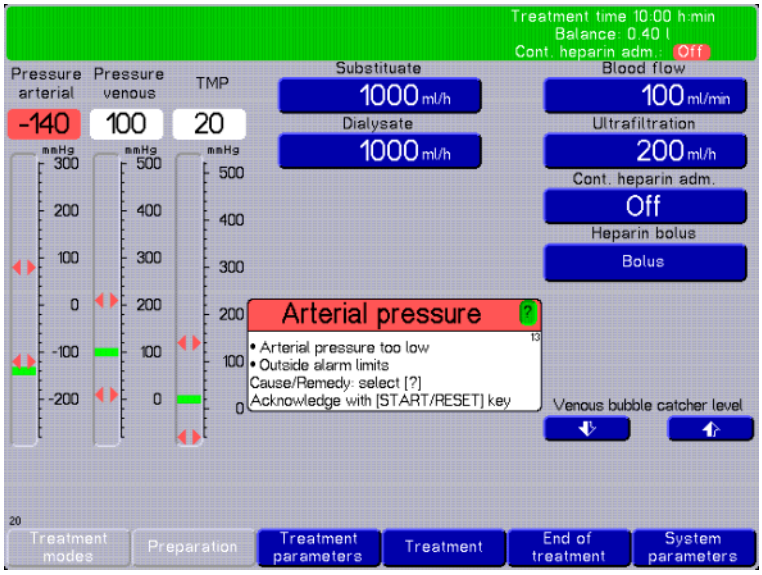
If the functional test could not be completed successfully, a warning indicating an error number will be displayed on the screen.

➢ Repeat the functional test by pressing the **[START/RESET]** key.

Note

If the functional test was not passed even after having been repeated, and if the problem cannot be corrected, call service support.

5.9 Handling alarm limits in the event of an alarm



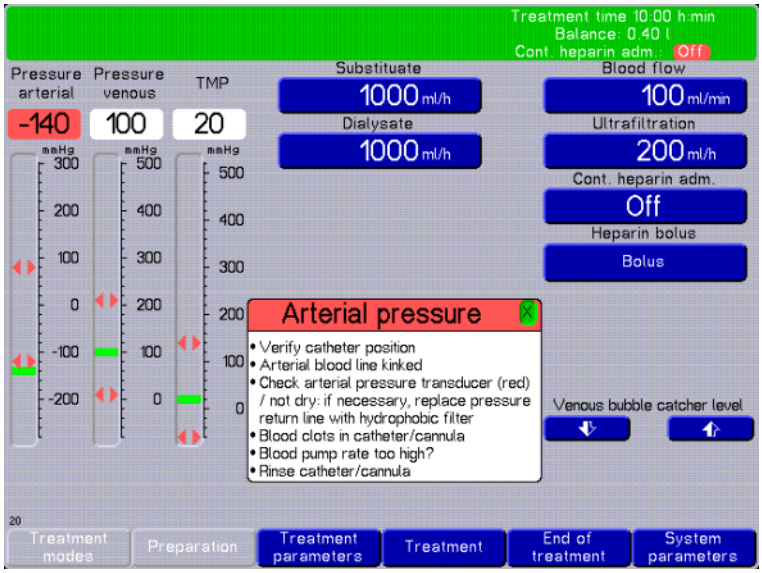
A **Pressure alarm** is displayed.

TMP, arterial, or venous

The actual value is outside the alarm limits.

Example: Arterial pressure.
The alarm limits are flashing.
The pressure display is red.
The blood pump is stopped.

➢ Use the rotary selector to select the **green question mark** and press **[OK]**.

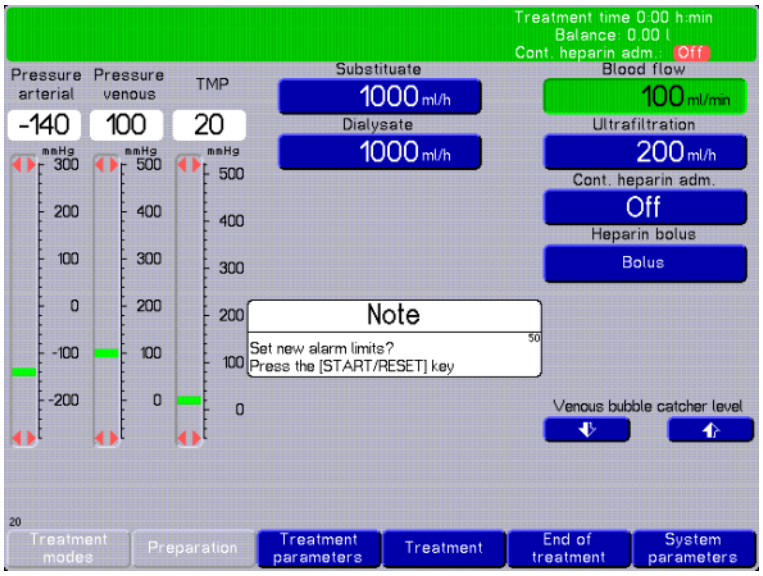


The possible causes will be displayed.

➢ Correct the condition causing the alarm.

➢ Press the **[START/RESET]** key.

The blood pump will start at a slower speed and gradually increase to the prescribed rate. Then the required balancing pumps will start (depending on the treatment mode).



After a short period of time, the alarm limits will be set to the previous limits.

or

➢ Press the **[START/RESET]** key again.

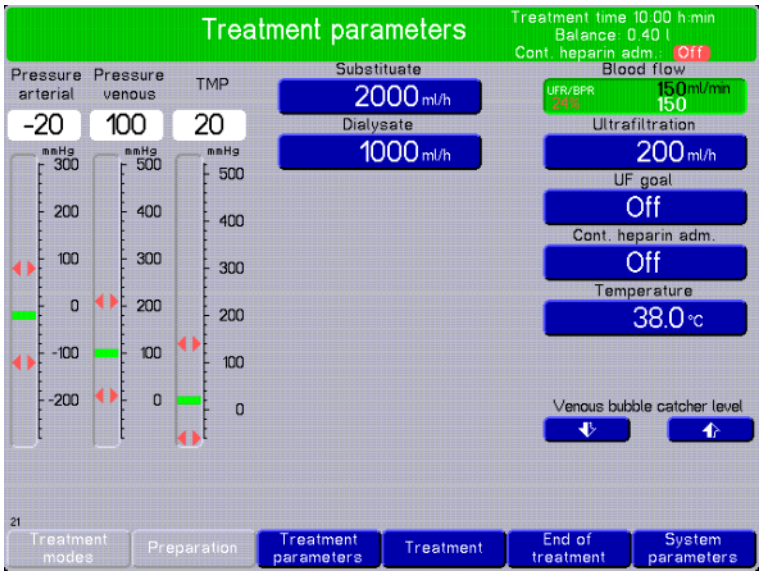
The alarm limit will be set around the current actual value.

5.10 Ratio of UF rate to BP rate

Note

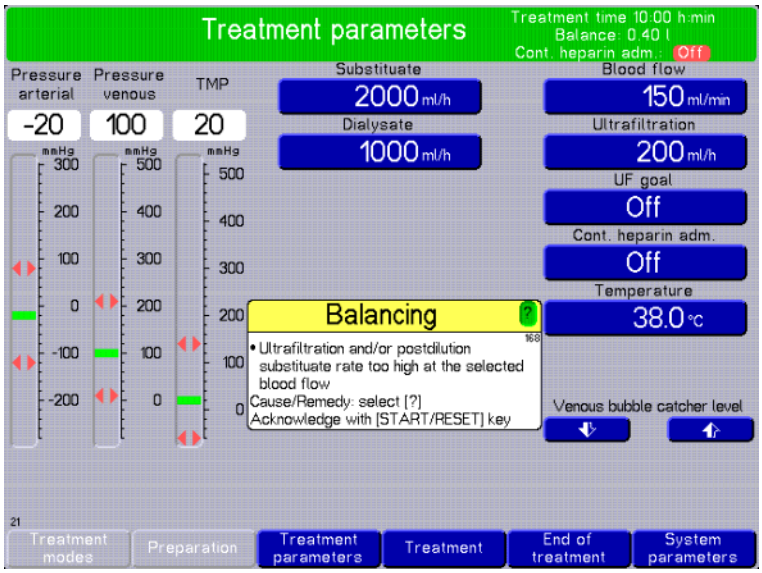
High filtrate rates in combination with low blood flow rates may lead to an inadequate concentration of blood in the haemofilter (massive increase of the TMP). To a great extent, the blood concentration required depends on the individual haemofilter. For this reason, there is a general risk of clotting in the capillaries.

To avoid this reaction, it is advisable to set the UF rate in postdilution so as not to exceed 20% of the BP rate.



Substituate + ultrafiltration = UF rate
2000 ml/h + 200 ml/h = 2200 ml/h
= 36.6 ml/min

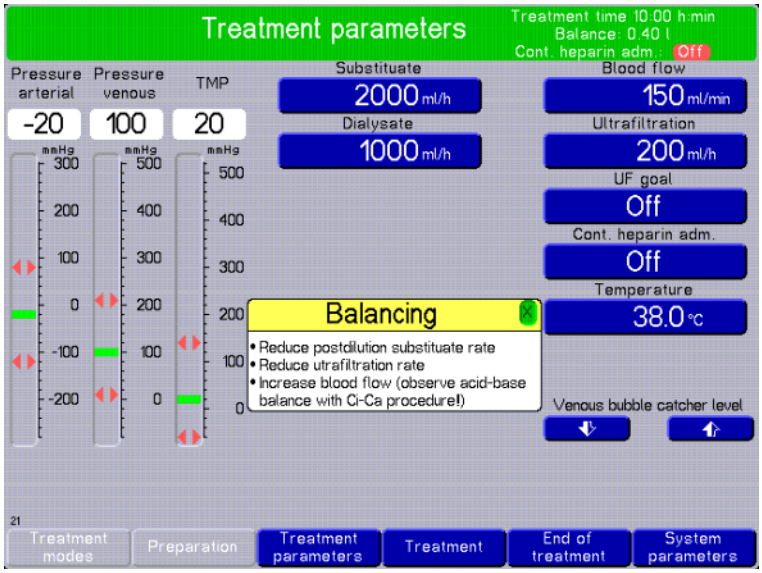
At a BP rate of 150 ml/min, this equals a UFR / BPR of 24.4%.



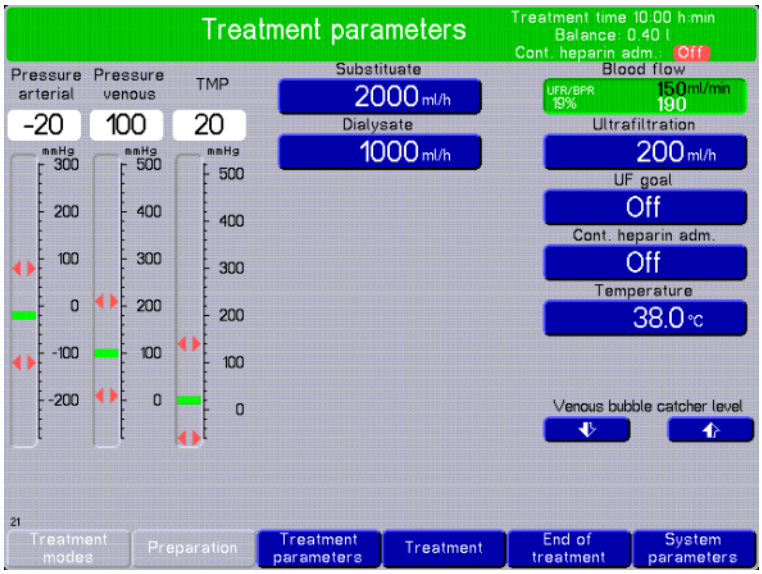
If the UFR / BPR exceeds 20%, a warning will be displayed in the following treatment modes:

CVVHD
CVVH with predilution and postdilution
CVVHDF with predilution and postdilution
Pre-Post CVVH with postdilution
Ci-Ca postCVVHDF with postdilution
MPS with postdilution

With predilution, haemoconcentration of the blood will not occur. This warning can be confirmed with the **[START/RESET]** key provided the treatment is performed in predilution or the imbalance in postdilution is required.



It is advisable to correct this imbalance by changing the parameters.



The UFR / BPR ratio will be displayed when changing the parameters.

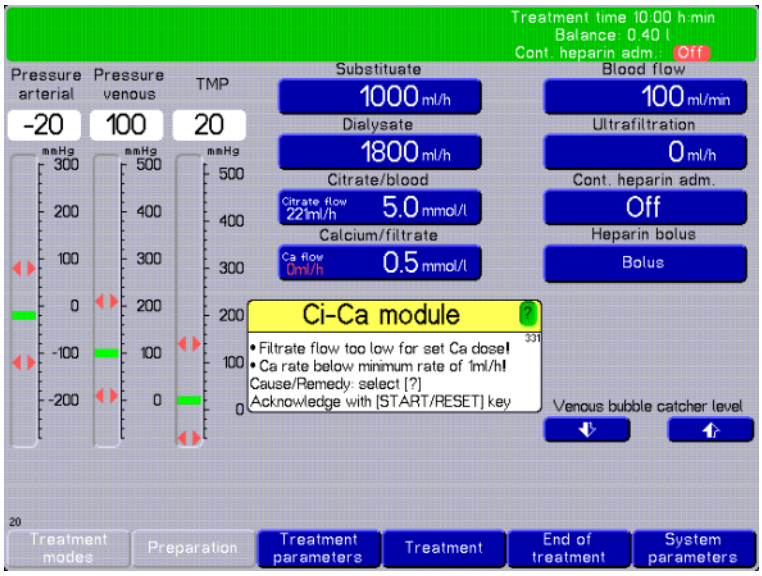
5.11 Ratio of calcium flow to filtrate flow

The calcium flow rate is calculated by the system depending on the filtrate flow (sum of the dialysate flow, substituate flow, net UF, citrate flow, and calcium flow), the set calcium dose, and the concentration of the calcium solution used, which is defined in the Setup menu of the multiFiltrate. The calcium flow is limited by the control range of the calcium pump.

Control range of the calcium pump: 10–100 ml/h

If the respective settings of the various flows and the required calcium dose result in a calcium flow outside the pump control range, a warning will be emitted.

The operator now has to adjust the waste volume appropriately by modifying the dialysate and / or substituate flow or, if necessary, also the calcium dose.



➢ Press the **[START/RESET]** key in order to override the warning for 2 minutes.

Adjust the settings accordingly.

Note

If the modifications performed are inadequate for bringing the calcium flow rate back within the control range of the calcium pump, the warning will be repeated after a few seconds.

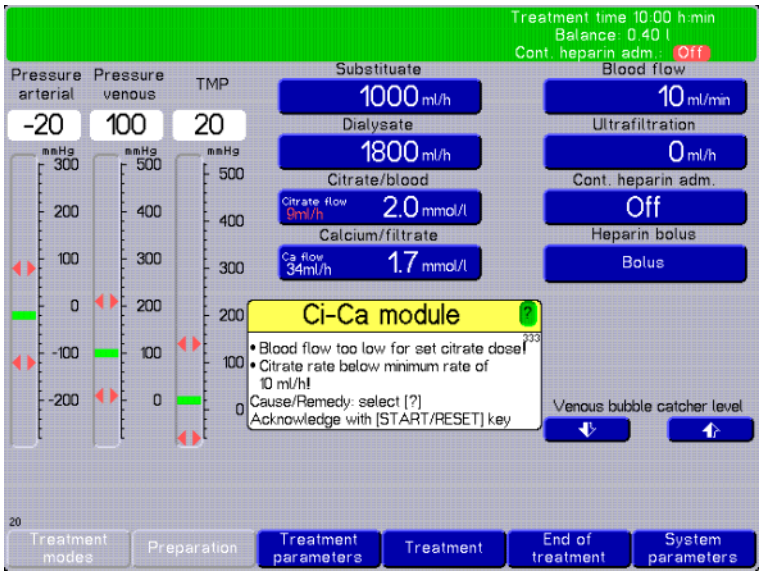
5.12 Ratio of citrate flow to BP rate

The citrate flow rate is calculated by the system depending on the set citrate dose, the set blood flow, and the concentration of the citrate solution used (set in the multiFiltrate Setup menu), and is limited by the control range of the citrate pump.

Control range of the citrate pump: 10–600 ml/h

If the settings of the initial values result in a citrate flow outside the pump control range, a warning will be emitted.

The operator now has to adjust the blood flow or, if necessary, the citrate dose to continue the treatment.



➢ Press the **[START/RESET]** key in order to override the warning for 2 minutes.

Adjust the settings accordingly.

Note

If the modifications performed are inadequate for bringing the citrate flow rate back within the control range of the citrate pump, the warning will be repeated after a few seconds.

5.13 Overriding the blood leak detector

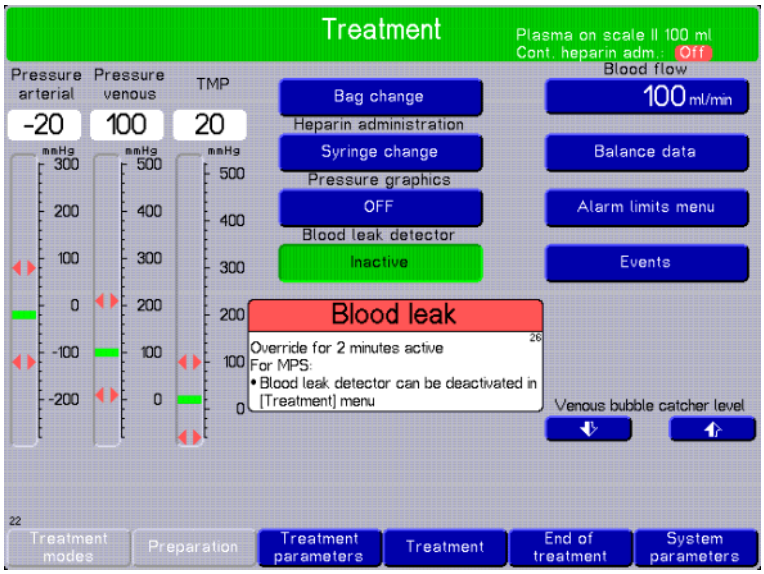
Note

The blood leak detector is the safety system which monitors haemolysis and blood leaks. For plasma separation procedures, it is possible to deactivate the blood leak detector for the duration of the current treatment. The blood leak detector is reactivated when the device is switched on again.

Warning

Patient hazard due to haemolysis or blood loss

If the blood leak detector has been overridden / deactivated, the operator is responsible for the patient's safety. It is important to pay attention to additional darkening due to a blood leak in the filtrate bag, particularly when using a permanent override for plasma separation.



If the blood leak detector detects blood in the filtrate line, this is indicated by an audible signal and a message.

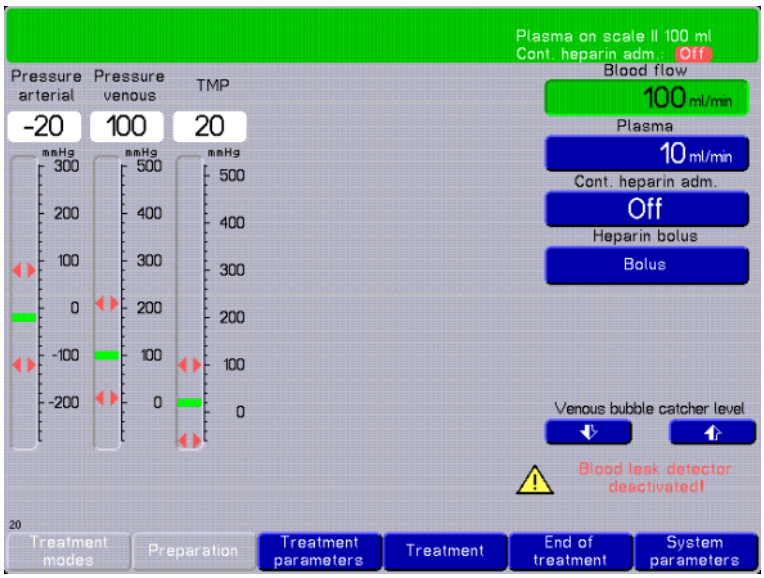
The blood pump is stopped.

➢ Continue the treatment by pressing the **[START/RESET]** key.

The blood pump is started.
The override time for the blood leak detector is 2 minutes.

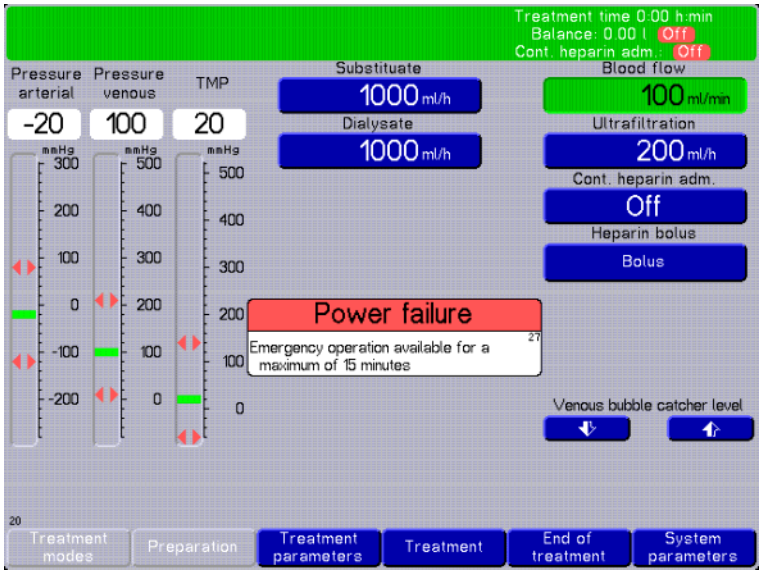
The blood leak detector can be deactivated for MPS during the override time in the **Treatment** menu:

➢ Deactivate the blood leak detector with the **[Blood leak detector]** button.



After the safety prompt to deactivate the blood leak detector has been confirmed with **[Yes]**, the blood leak detector no longer monitors for haemolysis or blood loss (**Blood leak detector deactivated!**). Monitoring can be reactivated at any time in the **Treatment** menu.

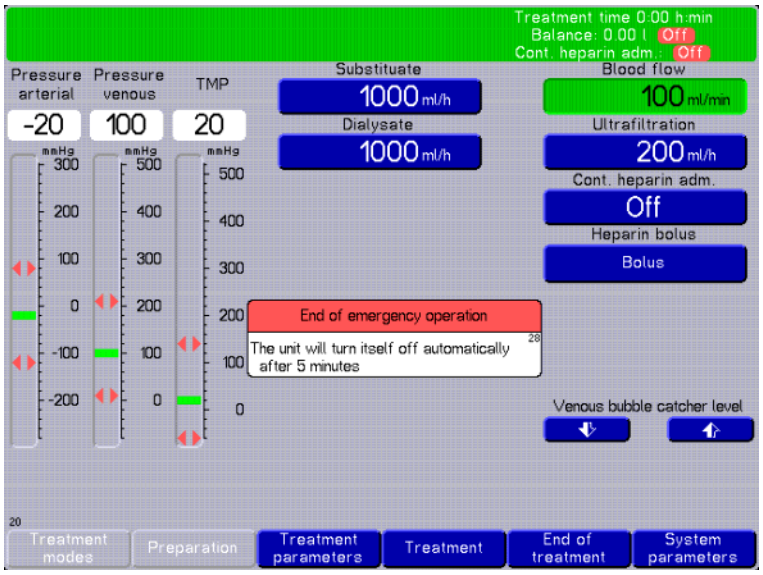
5.14 Power failure (mains failure)



A **Power failure** is displayed.

Balance is off.
The blood pump is running.
Citrate pump continues running for up to 10 minutes (then alarm due to switched-off balance).
The calcium pump is stopped.
An audible signal will be given.

When power is restored, the system will start automatically.



End of emergency operation is displayed.

Balance is off.
The blood pump is stopped.

The extracorporeal blood volume must be returned using a hand crank
(see chapter 5.15 on page 5-19).

5.15 Manual reinfusion

In the event of a prolonged power failure or a system failure, the extracorporeal blood volume must be returned to the patient using a hand crank.

Warning

Patient hazard due to air infusion

When transporting or returning blood manually, please observe the following:

➢ Only turn the blood pump hand crank in the direction of the arrow in order to avoid the risk of an air infusion via the arterial tubing system.

➢ Visually monitor the venous tubing system to check that it is free of air and therefore to avoid the risk of an air infusion.

Note

The maximum time for emergency operation may be reduced due to the increased power requirements of the Ci-Ca module.

➢ Switch off the device using the **[On/Off]** key: This will make the blood pump rotor easier to turn.

➢ Disconnect the arterial patient line and connect it to the NaCl solution. Break the cone.

➢ Remove the venous patient line from the venous clamp.

➢ Visually check that the venous tubing system is free of air.

➢ Use the hand crank to operate the blood pump.

➢ Return the blood manually.

➢ Visually monitor the venous tubing system for the entire duration of the manual transportation process to check that it is free of air.

➢ When the blood has been returned manually, close the clamps on the tubing system and remove the venous patient line.

➢ Dismantle the tubing system manually.

6 Cleaning / disinfection

Warning

Risk of infection and cross-contamination

Disinfection of the device must be performed according to the Instructions for Use. If unsuitable procedures are followed, effective disinfection or cleaning is not possible.
Only the disinfectants and cleaning agents listed in chapter 6 must be used.
The use of unsuitable disinfectants and cleaning agents can cause damage to the device that can stop it working properly.

6.1 Surface cleaning / surface disinfection

Switch the device off and disconnect it from any external power sources before cleaning and disinfection. A surface disinfection must always be performed after each treatment. Make sure that the area around sensors and actuators is clean to avoid an impairment of the functions.

Contamination caused, for example, by blood and filtrate must immediately be removed with a disposable paper towel dampened with disinfectant. The surface must then be disinfected a second time by wiping or spray disinfection. Do not use any sharp objects for cleaning.

6.2 Disinfectants and cleaning agents

The following disinfectants have been tested for use on the device. The recommended applied concentrations correspond to the specifications of the manufacturers of the disinfectants at the time of publishing these Instructions for Use. Always check the application concentration against the current product information of the disinfectants.

Incidin Extra N	Active substance base: aldehyde-free preparation Type of disinfection: wipe disinfection
ClearSurf	Active substance base: cationic surfactants Type of disinfection: wipe disinfection
Freka-NOL	Active substance base: 45% ethanol Type of disinfection: quick-acting disinfectant for wipe disinfection combined with Freka-Wipes disposable cloths
ClearSurf Wipes	Ready to use wipes Active substance base: cationic surfactants Type of disinfection: wipe disinfection

7 Functional description

7.1 Device functions

Extracorporeal blood circuit

The device features a pump-controlled extracorporeal blood circuit. The extracorporeal blood circuit is monitored during the treatment.

Balancing

Filtrate, dialysate, and substituate are transported by roller pumps. Gravimetric balancing is done with four separate scales used to weigh and balance the substituate, dialysate, and filtrate volume. The two integrated heaters reliably control the set treatment temperature, even at high dialysate and substituate flow rates.

Alarms / warnings

Alarms will stop the device. Typical reasons for alarms are potentially hazardous conditions in the extracorporeal blood circuit, e.g., pressure increases.

In case of warnings, the extracorporeal blood circuit is maintained but the balancing pumps are stopped. Typical reasons for warnings are potentially hazardous conditions in the balancing system, e.g., unexpected change of the weight on one of the scales.

Handling

The operating concept with its clear menu structure allows for easy operation. Treatment parameters and softkeys are displayed on a large screen. The device is operated with a rotary selector and additional keys, e.g., to select fields displayed on the screen.

Functional test

An automatic functional test which checks all relevant operating, display, monitoring, and alarm functions, will be initiated every time the device is turned on.

Regional anticoagulation with citrate

The optional Ci-Ca function of the system makes it possible to anticoagulate the patient’s blood in the extracorporeal circuit with citrate during a CVVHD treatment (continuous venovenous haemodialysis; Ci-Ca CVVHD) and a Post CVVHDF treatment (continuous venovenous haemodiafiltration; Ci-Ca postCVVHDF). Anticoagulation of the patient’s blood is achieved by adding citrate solution to the arterial access line. During a Ci-Ca treatment, a significant amount of calcium is removed from the patient's blood. For this reason, a calcium substituate is infused into the venous return line by the integrated calcium pump.

7.2 Description of treatments

7.2.1 Continuous renal replacement therapy (CRRT = Continuous renal replacement therapy)

Indication

The different continuous renal replacement therapies (CRRT) can be applied if not only volume removal is required but also the removal of other substances, such as urinary excreted substances (urea and creatinine). This also applies if electrolyte imbalances or disorders of the acid-base balance are to be corrected.

Vascular access

The CRRT treatments use a venovenous vascular access, i.e., blood is both removed from and, after treatment, reinfused into a vein of the patient. Usually, a large-bore central venous double-lumen catheter is used for the vascular access.

Due to the higher and more stable blood flow, the venovenous CRRT treatments have gained acceptance in contrast to the arteriovenous CRRT treatments which were also used in the past.

Types of CRRT

Continuous venovenous haemofiltration (CVVH) can be performed as a predilution procedure (Pre CVVH) or a postdilution procedure (Post CVVH). A CVVH has to be selected and the infusion of the substitution fluid has to be determined in predilution or postdilution when setting up the system.

The haemofiltration can simultaneously be performed in predilution and postdilution (Pre-Post CVVH). It is also possible to perform a haemodialysis (CVVHD) as an alternative.

Haemofiltration and haemodialysis can be combined as haemodiafiltration (CVVHDF). Depending on the infusion site of the substituate, the therapy is called Predilution CVVHDF or Postdilution CVVHDF (Pre CVVHDF and Post CVVHDF). A CVVHDF has to be selected and the infusion of the substitution fluid has to be determined in predilution or postdilution when setting up the system.

The advantages and the disadvantages of the individual therapies should be taken into consideration when choosing the continuous renal replacement therapy for the patient.

Post CVVH

Postdilution means that the substituate is not infused into the extracorporeal blood circuit until after the filter, i.e., after the ultrafiltrate has been removed. As a consequence, the blood at the filter outlet has a higher concentration of cells and proteins (haemoconcentration). This can increase the risk of coagulation in the extracorporeal blood circuit. For this reason, the filtration fraction (UFR / BPR) should not be more than 20%. If this limit is exceeded, this will be displayed on the device. If the haemoconcentration is too high, it can be reduced by increasing the blood flow or reducing the substitution in postdilution. It is also possible to select another CRRT treatment as an alternative.

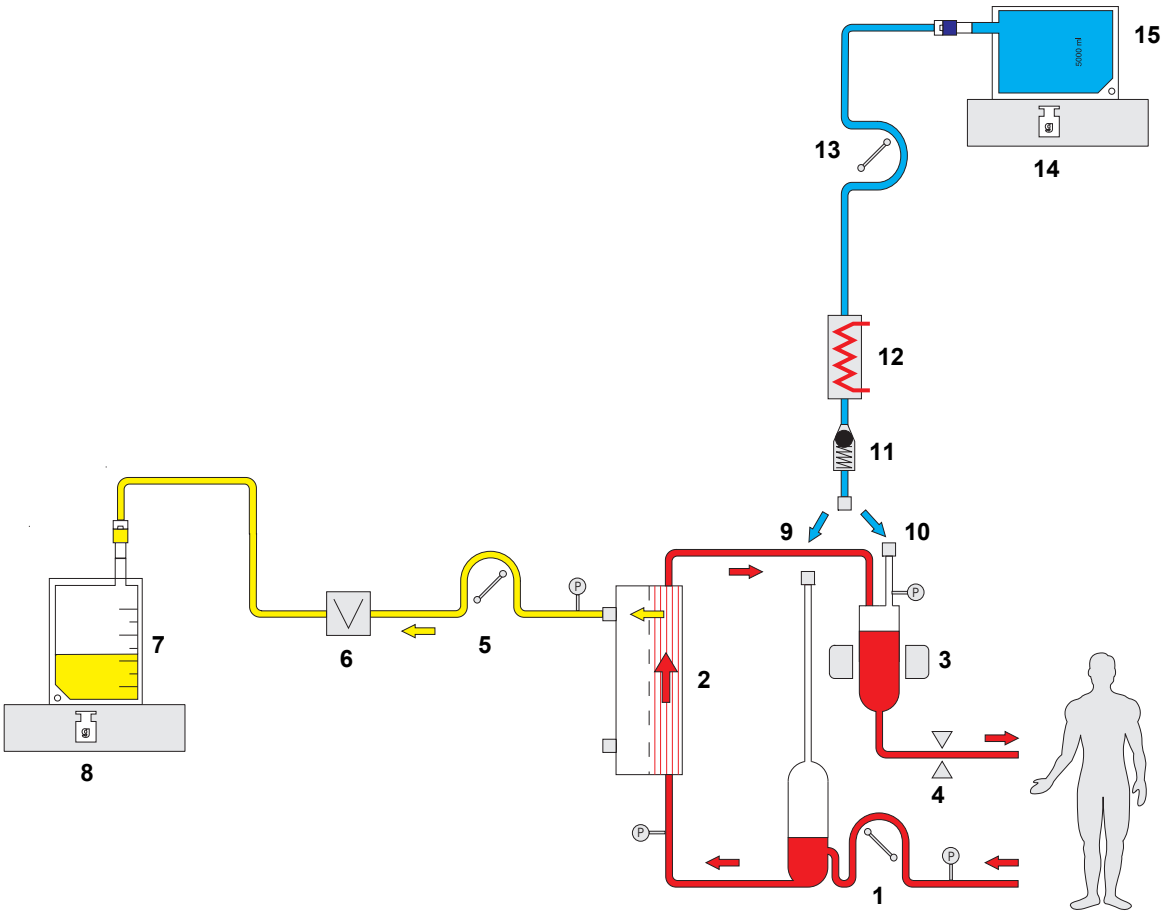
Pre CVVH

The infusion of the substituate in predilution largely avoids a haemoconcentration. The disadvantage of this procedure, however, is that all toxins in the blood are diluted which, in turn, leads to fewer toxins being removed per litre of ultrafiltrate than in Post CVVH. If the same volume of substituate is used, predilution is less effective than postdilution. The disadvantage caused by this dilution can be reduced by increasing the blood flow rate. It is also possible to select another CRRT treatment as an alternative.

Treatment parameters

CVVH (adults)	**Min.**	**Max.**	**Resolution**	**Unit**
Blood flow	10	500	10	ml/min
Ultrafiltration	Off / 10	1800	10	ml/h
UF goal	Off / 50	10,000	50	ml
Cont. heparin adm.	Off / 0.1	25	0.1	ml/h
Substituate	600	4800	50	ml/h
Temperature	Off / 35	39	0.5	°C

Fig.: CVVH flow diagram



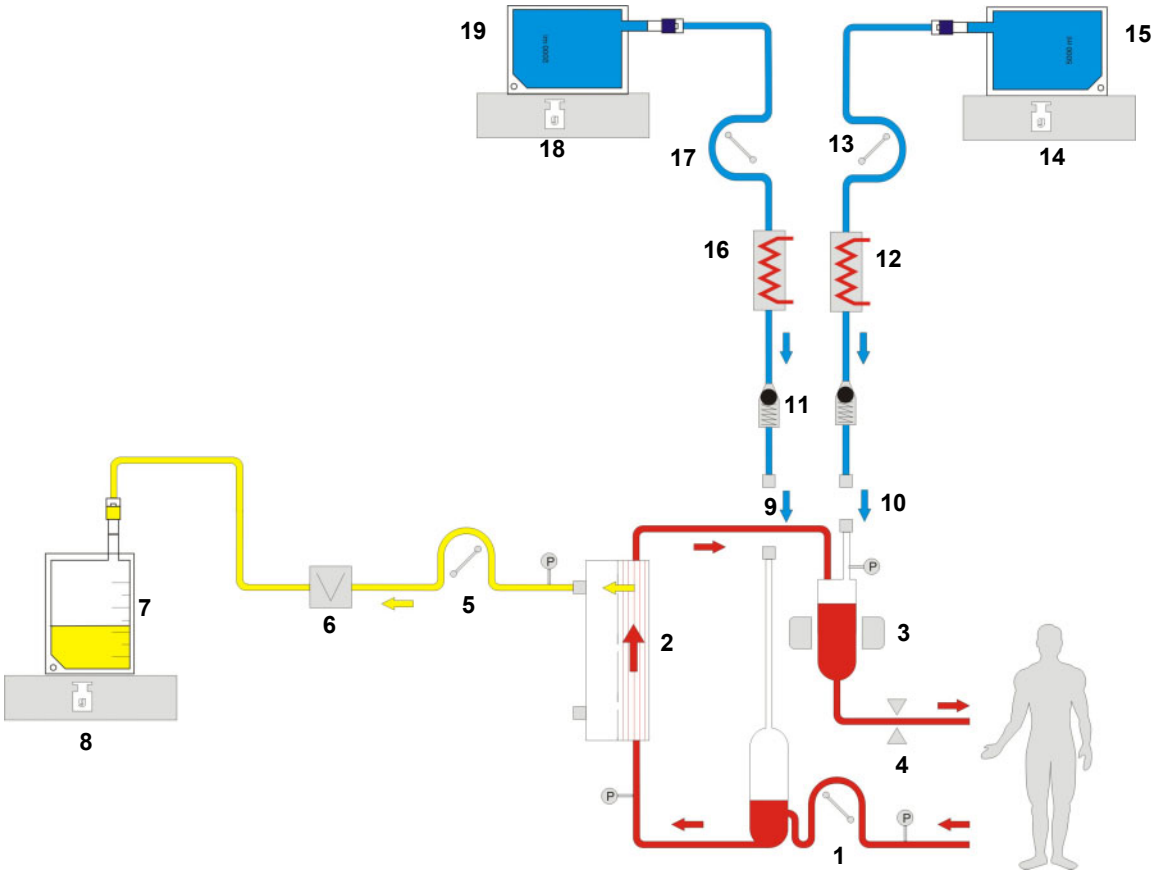
Legend

1 Blood pump
2 Haemofilter
3 Air detector
4 Venous clamp
5 Filtrate pump
6 Blood leak detector
7 Filtrate
8 Scales 3 and 4
9 Predilution
10 Postdilution
11 Check valve
12 Heater
13 Substituate pump
14 Scales 1 and 2
15 Substituate

Treatment parameters

Pre-Post CVVH	Min.	Max.	Resolution	Unit
Blood flow	10	500	10	ml/min
Ultrafiltration	Off / 10	1200	10	ml/h
UF goal	Off / 50	10,000	50	ml
Cont. heparin adm.	Off / 0.1	25	0.1	ml/h
Sub predilution	Off / 600	4800	50	ml/h
Sub postdilution	Off / 600	4800	50	ml/h
Temperature	Off / 35	39	0.5	°C

Fig.: Pre-Post CVVH flow diagram



Legend

1	Blood pump
2	Haemofilter
3	Air detector
4	Venous clamp
5	Filtrate pump
6	Blood leak detector
7	Filtrate
8	Scales 3 and 4
9	Predilution
10	Postdilution
11	Check valve
12	Heater 1
13	Substituate pump 1
14	Scale 2
15	Substituate
16	Heater 2
17	Substituate pump 2
18	Scale 1
19	Substituate

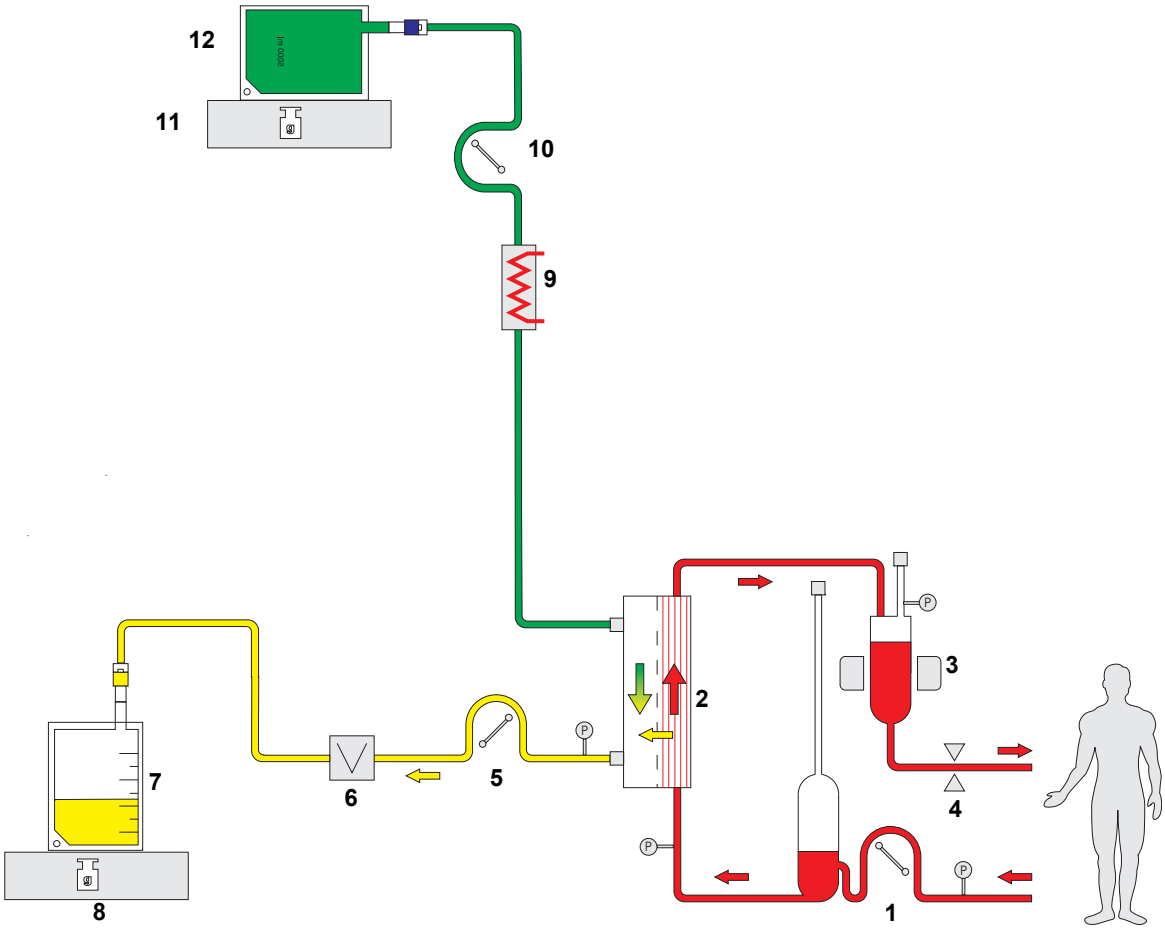
CVVHD

With CVVHD, the blood is purified mainly through dialysis. In addition to solute transport through diffusion, which is the main process for removing toxins in this case, a certain amount of convection also takes place within the filter and by volume removal. Under typical CRRT conditions, where the blood flow is considerably higher than the dialysate flow, an almost complete saturation of the dialysate with toxins of a low molecular weight, such as urea and creatinine, can normally be expected. The efficacy of a CVVHD procedure is therefore comparable with that of a Post CVVH procedure. As the speed of diffusion is relative to the molecular weight, the full saturation of the dialysate with larger, middle-molecular weight solutes may not be achieved, depending on the blood and dialysate flow rates set. The clearance rate achieved for these substances is thus lower than with Post CVVH (if the same dialysate and substituate quantities are used). This disadvantage of CVVHD can be compensated at least partially through the use of filters with a large active surface and high-flux membranes. The advantage of CVVHD lies in the possibility of setting a lower blood flow than in Pre CVVH and Post CVVH.

Treatment parameters

CVVHD (adults)	**Min.**	**Max.**	**Resolution**	**Unit**
Blood flow	10	500	10	ml/min
Ultrafiltration	Off / 10	1800	10	ml/h
UF goal	Off / 50	10,000	50	ml
Cont. heparin adm.	Off / 0.1	25	0.1	ml/h
Dialysate	600	4800	50	ml/h
Temperature	Off / 35	39	0.5	°C

Fig.: CVVHD flow diagram



Legend

1	Blood pump
2	Haemofilter
3	Air detector
4	Venous clamp
5	Filtrate pump
6	Blood leak detector
7	Filtrate
8	Scales 3 and 4
9	Heater
10	Dialysate pump
11	Scales 1 and 2
12	Dialysate

Combination of the basic treatments

These three basic treatments can be combined in pairs:

CVVHDF

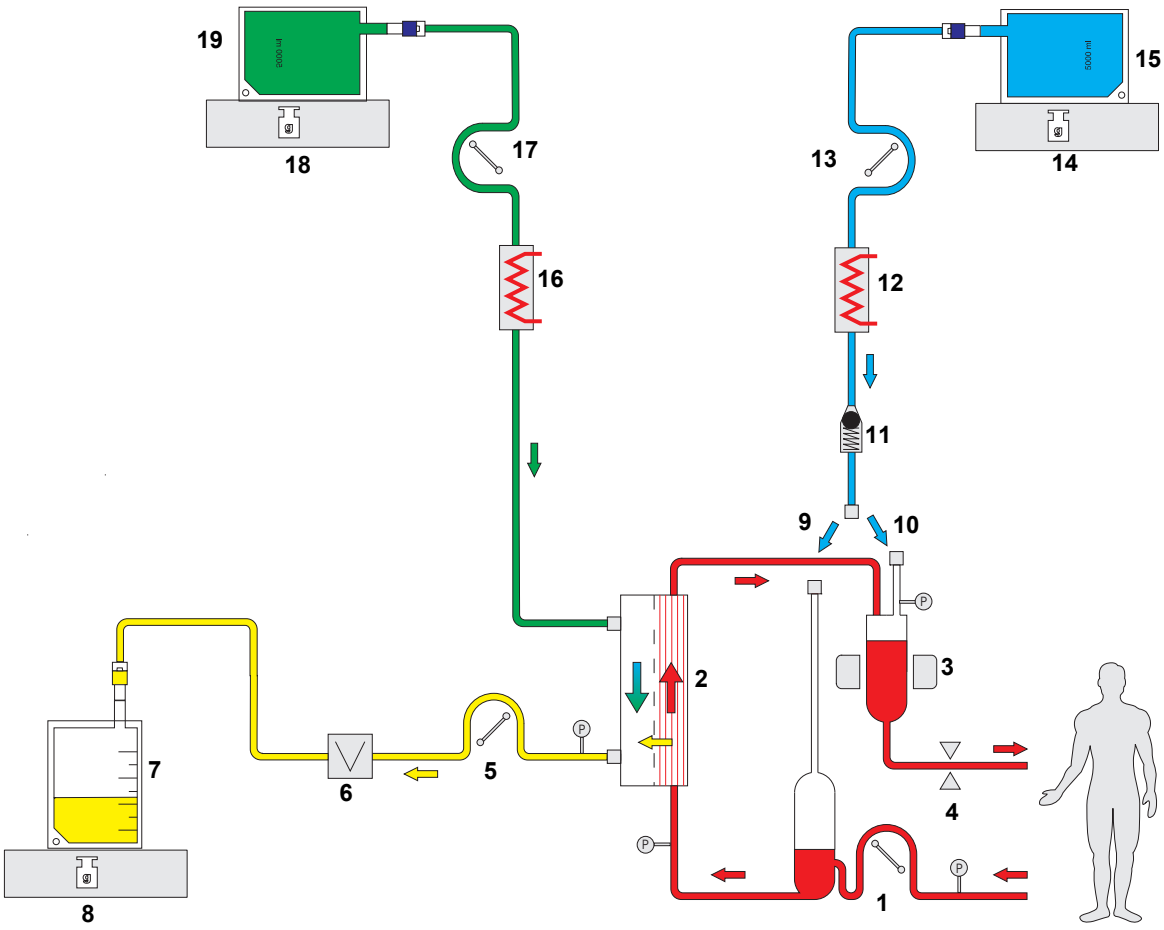
Pre CVVH + CVVHD => Pre CVVHDF

Post CVVH + CVVHD => Post CVVHDF

Pre CVVH + Post CVVH => Pre-Post CVVH

This reduces the disadvantages and combines the advantages of the separate procedures. Depending on the application conditions, the treatment can thus be optimised. For example, Post CVVHDF makes it possible to select the highest possible filtrate flow relative to the achievable blood flow and still keep haemoconcentration in the filter to within acceptable limits. The dialysis component of a Post CVVHDF procedure further increases the treatment efficacy without additional blood flow requirements, as the filtration fraction (UFR / BPR) is not affected by this.

Fig.: CVVHDF flow diagram



Legend

1 Blood pump
2 Haemofilter
3 Air detector
4 Venous clamp
5 Filtrate pump
6 Blood leak detector
7 Filtrate
8 Scales 3 and 4
9 Predilution
10 Postdilution
11 Check valve
12 Heater

13 Substituate pump
14 Scale 2
15 Substituate
16 Heater
17 Dialysate pump
18 Scale 1
19 Dialysate

Treatment parameters

CVVHDF	Min.	Max.	Resolution	Unit
Blood flow	10	500	10	ml/min
Ultrafiltration	Off / 10	1200	10	ml/h
UF goal	Off / 50	10,000	50	ml
Cont. heparin adm.	Off / 0.1	25	0.1	ml/h
Substituate	Off / 600	4800	50	ml/h
Dialysate	Off / 600	4800	50	ml/h
Temperature	Off / 35	39	0.5	°C

Efficacy of CRRT treatments

The efficacy of CRRT treatments depends largely on the total volume of formed filtrate.

Effluent

In practice, the efficacy is determined by the applied volume or the selected flows of substituate and dialysate. With the Pre CVVHDF, Post CVVHDF, and Pre-Post CVVH combined treatments, the total dose is distributed to both pumps that are used (e.g., the intended total dose in Post CVVHDF 2000 ml/h is applied as 1000 ml/h substitution in postdilution and 1000 ml/h dialysate).

It may be necessary to increase the prescribed total dose in treatments with predilution to compensate for the reduction of efficacy caused by predilution (see above).

Depending on the filter used, a reduction of the middle-molecular clearance is possible if dialysate is used (see above).

Coagulation risk in CRRT treatments

The risk of coagulation in the extracorporeal blood circuit is different in the individual CRRT treatments.

With postdilution, there is a haemoconcentration of the blood at the filter outlet, depending on the ratio of the filtrate flow to the blood flow, and on the patient's haematocrit. This is assumed to be the reason for the shorter operating lives of the filters in Post CVVH compared to Pre CVVH.

There is evidence that the coagulation activity is lower in dialysis than in haemofiltration in predilution. It was revealed that the filter operating lives are significantly longer in CVVHD than in Pre-Post CVVH, even if the limitation of the filtration fraction to 20% in Pre-Post CVVH was observed.

7.2.2 Paediatric CRRT treatments

Special treatment mode for small children

For small children, the desired CRRT efficacy (see **Adapting the CRRT prescription for children** on page 7-10) can be obtained by using the tubing system specially designed for this purpose. Furthermore, the blood-side fill volume of the tubing system was reduced compared to the standard consumables.

The Pre CVVH, Post CVVH, and CVVHD treatments can be performed with the paediatric tubing system.

Treatment parameters

CVVHD (paediatric)	**Min.**	**Max.**	**Resolution**	**Unit**
Blood flow	10	100	2	ml/min
Ultrafiltration	Off / 5	500	5	ml/h
UF goal	Off / 10	5000	10	ml
Cont. heparin adm.	Off / 0.1	25	0.1	ml/h
Dialysate	100	1500	10	ml/h
Temperature	Off / 35	39	0.5	°C

CVVH (paediatric)	**Min.**	**Max.**	**Resolution**	**Unit**
Blood flow	10	100	2	ml/min
Ultrafiltration	Off / 5	500	5	ml/h
UF goal	Off / 10	5000	10	ml
Cont. heparin adm.	Off / 0.1	25	0.1	ml/h
Substituate	100	1500	10	ml/h
Temperature	Off / 35	39	0.5	°C

Adapting the CRRT prescription for children

The dose of the renal replacement therapy for a paediatric treatment can be derived from the recommendations for the treatment of adults by scaling in accordance with the body surface, for example.

Chadha et al. (chapter 13.4 / no. 11), for example, used a CRRT dose of 2 l/h / 1.73 m² body surface multiplied with the estimated body surface of the patient, following the recommendation of Ronco et al. to use a dose of at least 2 l/h for a typical adult with a body weight of 70 kg. The value 1.73 m² is the general value for the body surface of a typical adult.

According to the prescribed procedure, the minimum dose of 100 ml/h substituate / dialysate, which can be set in the paediatric mode of the device, corresponds to a minimum body surface of the patient of 0.087 m². This value lies significantly below the typical body surface of an average newborn and usually also permits reasonable treatments for premature infants. According to the prescribed procedure, the maximum dose of 1200 ml/h substituate / dialysate, which can be set in the paediatric mode of the device, corresponds to a maximum body surface of the patient of 1.04 m², which matches approximately a body weight of 30 kg. However, it is already possible to change from the paediatric mode of the device to one of the treatment modes for adults when treating smaller patients. According to the prescribed procedure, the minimum dose of 600 ml/h substituate / dialysate, which can be set with CVVH or CVVHD in the adult's treatment modes, corresponds to a minimum body surface of the patient of 0.52 m², which matches approximately a body weight of 11 kg.

7.2.3 Membrane plasma separation (MPS)

Indication

Membrane plasma separation (MPS) is a type of therapeutic plasma exchange (TPE) and is used if pathogenic plasma components can only be removed with the highly permeable membranes of special plasma filters due to their size or specific binding to large plasma proteins, such as albumin.

Autoimmune diseases, such as Guillain-Barré syndrome, are an example of the group of diseases for which the removal of autoantibodies by TPE is an accepted therapeutic option.

In some cases, the treatment envisages a replacement of plasma components by means of infusion.

Types of TPE

TPE can be performed by centrifugation or by membrane plasma separation. The device is designed for membrane plasma separation.

Extracorporeal blood circuit and balancing

The extracorporeal blood circuit for MPS does not differ significantly from the CRRT circuit. The balancing circuit is basically comparable to that of the Post CVVH procedure. To ensure the replacement solution, e.g., donor plasma, is heated carefully, two heater bags are installed in series. This minimises the risk of local overheating.

Plasma filter

For MPS, filters with a highly permeable membrane are used, which is permeable to all plasma components, but not to cellular blood components. These filters are therefore called plasma filters.

In MPS, the plasma is filtered from the blood together with all the components that need to be removed, and a suitable replacement solution is infused applying the gravity-controlled balancing method.

Replacement solution

As the plasma removed contains colloid osmotically active proteins such as albumin, replacement solutions containing iso-oncotic colloids are typically used.

Frequently, an iso-oncotic human albumin solution is used. A lack of coagulation factors or of other essential plasma components, whether occurring as a result of the plasma exchange or otherwise, can be counteracted by using fresh frozen plasma (FFP) as a replacement solution, either completely or in part (in this case, preferably at the end of the treatment).

In some cases, such as thrombotic thrombocytopenic purpura (TTP, aka Moschcowitz syndrome), it is essential not only to remove the pathologic plasma components, but also to reinfuse normal plasma components with the replacement solution. Here, the use of FFP as the replacement solution is recommended, or, alternatively, cryoprecipitate plasma.

Efficacy

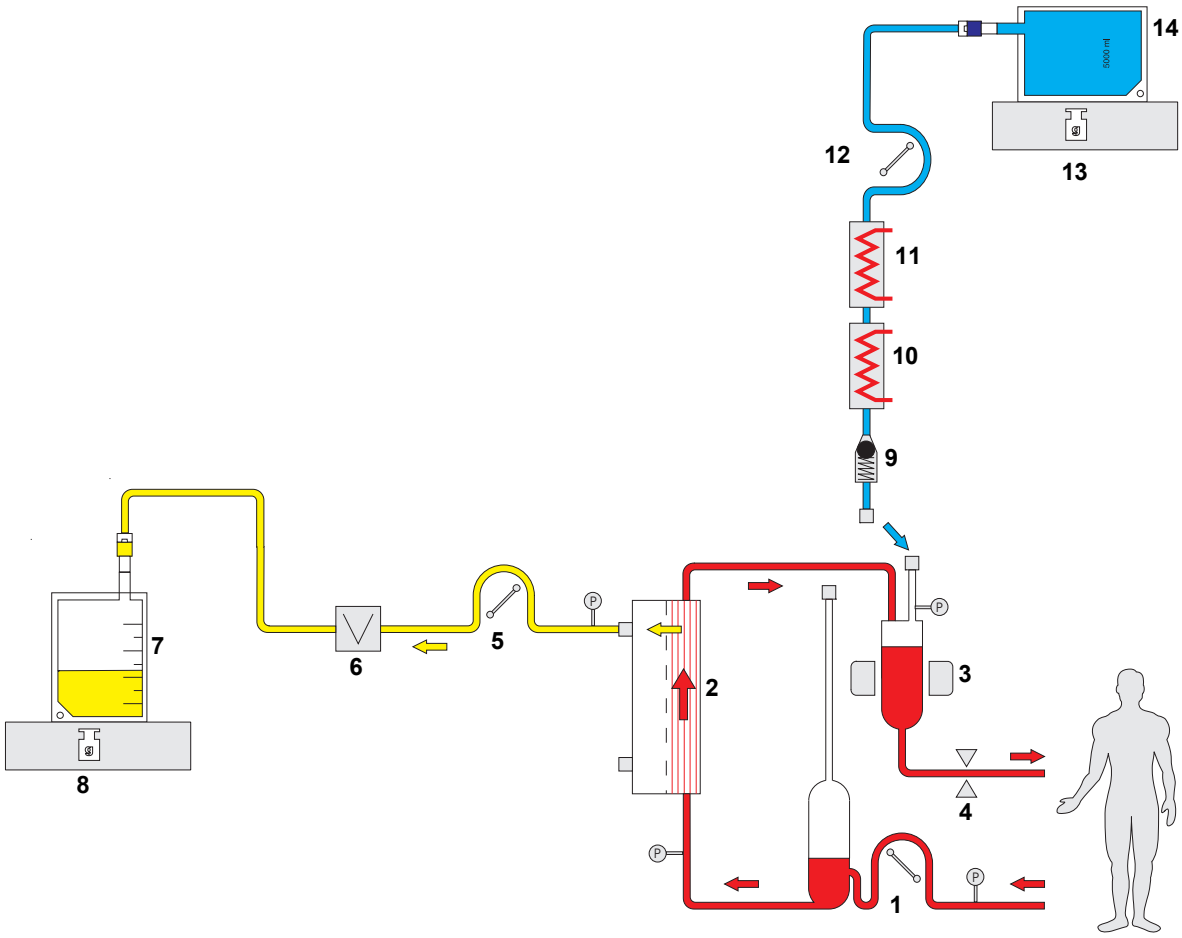
During MPS, typically one to two times the patient's plasma volume is exchanged.

Due to the decrease in plasma concentration in the substances to be removed in the course of the treatment, an MPS treatment ends as soon as the prescribed plasma volume has been replaced. If medically necessary, further MPS treatments will not be performed until the following day at the earliest.

Treatment parameters

MPS	Min.	Max.	Resolution	Unit
Blood flow	10	300	10	ml/min
Plasma	Off / 10	10	1	ml/min
Temperature	Off / 35	37	0.5	°C
Cont. heparin adm.	Off / 0.1	25	0.1	ml/h

Fig.: MPS flow diagram



Legend

1	Blood pump
2	Haemofilter
3	Air detector
4	Venous clamp
5	Filtrate pump
6	Blood leak detector
7	Filtrate
8	Scales 3 and 4
9	Check valve
10	Heater 1
11	Heater 1
12	Substituate pump
13	Scale 2
14	Plasma

7.2.4 Slow continuous ultrafiltration (SCUF)

Indication

A SCUF treatment can be indicated for the treatment of patients with fluid overload, where the primary aim is the removal of fluid and the elimination of urinary excreted solutes, or where the correction of electrolyte disturbances is clinically not indicated.

Vascular access

Just like CRRT treatments, SCUF also requires a venovenous vascular access, i.e., blood is both removed from and, after treatment, reinfused into a vein of the patient. Usually, a large-bore central venous double-lumen catheter is used for the vascular access.

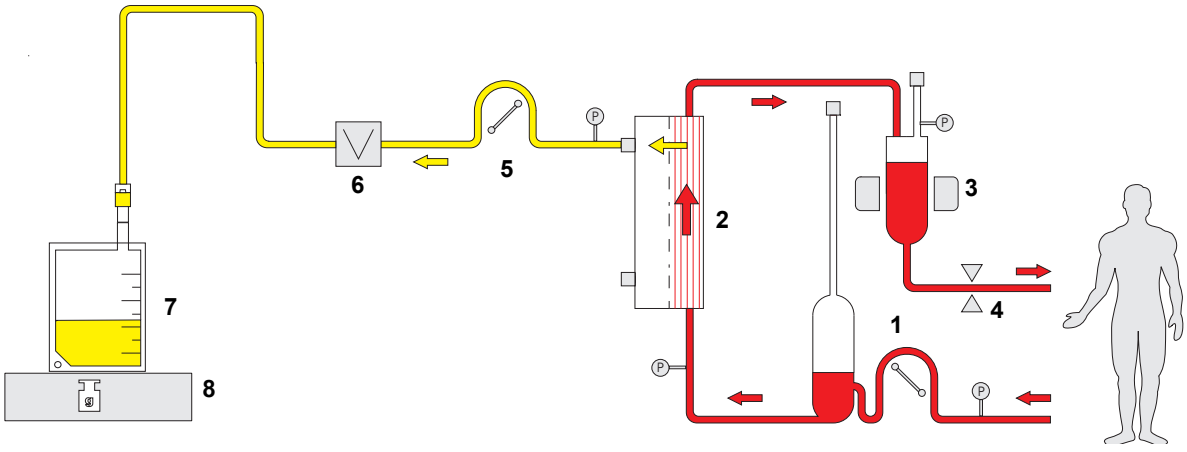
Extracorporeal blood circuit

For SCUF, the blood pump maintains the extracorporeal blood circuit, and the filtrate pump ensures the gravity-controlled removal of the necessary ultrafiltration volume. No substituate is infused, nor is any dialysate used.

Treatment parameters

SCUF	Min.	Max.	Resolution	Unit
Blood flow	10	100	2	ml/min
Ultrafiltration	0	1200	10	ml/h
UF goal	Off / 50	10,000	50	ml
Cont. heparin adm.	Off / 0.1	25	0.1	ml/h

Fig.: SCUF flow diagram



Legend

1 Blood pump
2 Haemofilter
3 Air detector
4 Venous clamp
5 Filtrate pump
6 Blood leak detector
7 Filtrate
8 Scales 3 and 4

7.2.5 Haemoperfusion (HP)

Adsorption

In haemoperfusion, toxins are removed by adsorption. It is employed to remove toxic substances from the patient's blood which cannot be removed by dialysis or haemofiltration due to proteopexy, for example. It is a possible therapy following attempted suicide with certain drugs or for the treatment of amanita poisoning. The extracorporeal blood circuit is monitored as in conventional dialysis. Any possible clot formation in the adsorber cartridge will be detected at an early stage by monitoring the adsorber inlet pressure (pre-filter pressure) between the blood pump and the adsorber cartridge.

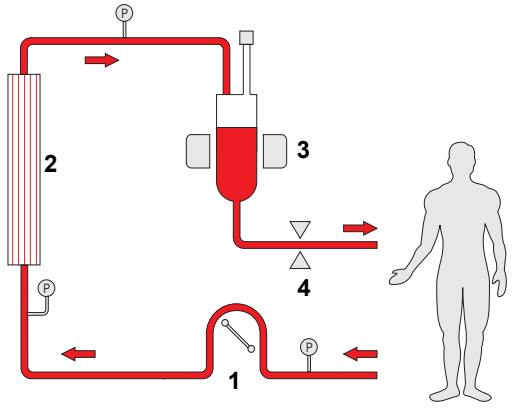
Adsorber cartridge

The patient is connected as usual to an extracorporeal circuit that is driven by a blood pump. Instead of flowing through a dialyser, the blood passes through an adsorber cartridge filled, for example, with small sorbent particles. The arrangement of the sorbent material serves to increase the adsorption surface. Inlet and outlet port of the adsorber cartridge are closed by sieves of appropriate mesh size which permit the passage of blood cells but prevent the comparatively large sorbent particles from escaping.

Treatment parameters
Available settings

HP	Min.	Max.	Resolution	Unit
Blood flow	10	500	10	ml/min
Cont. heparin adm.	Off / 0.1	25	0.1	ml/h

Fig.: Schematic of a haemoperfusion treatment (HP)



Legend

1 Blood pump
2 Adsorber cartridge
3 Air detector
4 Venous clamp

7.3 Anticoagulation

Requirement for anticoagulation

When performing extracorporeal blood treatments, anticoagulation of the blood is generally required. It prevents coagulation in the extracorporeal blood circuit and ensures an adequate operating life of the filters used.

7.3.1 Systemic anticoagulation

Systemic anticoagulants

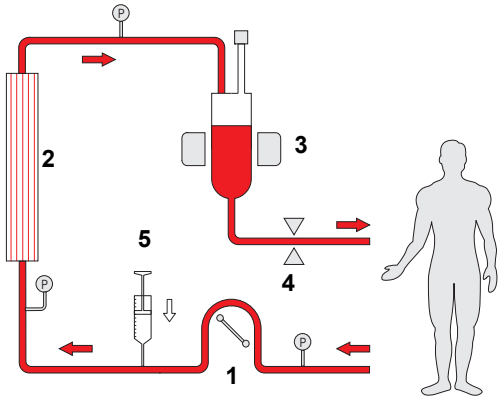
Different substances, such as unfractionated or fractionated heparin, Danaparoid, Argatroban, can be used for anticoagulation.

The selection and dosage of the suitable substance are determined by the physician. Depending on the substance, different laboratory parameters are used to control the dosage. The aPTT (activated partial thromboplastin time), for example, is a suitable parameter to assess the effect of unfractionated heparin in principle.

Integrated heparin pump for anticoagulation

A heparin pump for the continuous infusion of diluted heparin is integrated in the device. This pump can also be used to administer a bolus when required. An infusion line for anticoagulants is included in the tubing system.

Fig.: Schematic of systemic anticoagulation



Legend

1 Blood pump
2 Haemofilter
3 Air detector
4 Venous clamp
5 Heparin pump

7.3.2 Regional anticoagulation with citrate

7.3.2.1 General information on citrate anticoagulation

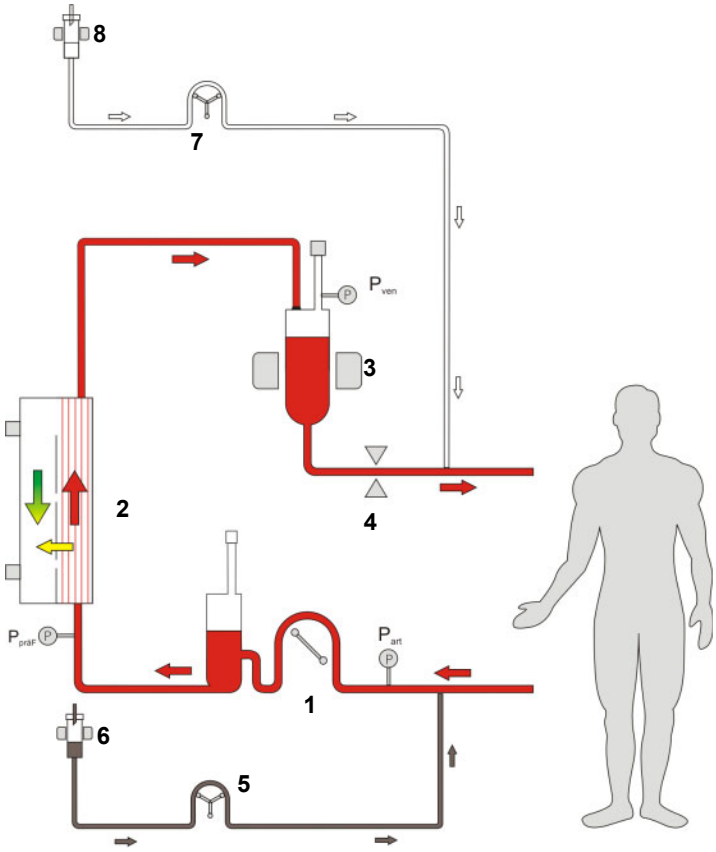
Regional anticoagulation with citrate

Citrate can be used for regional anticoagulation and is directly eliminated from the blood to a large extent by the filter during the CRRT treatment. The part of the citrate which is inevitably infused into the body is quickly metabolised by most patients. In the majority of patients, this prevents a clinically relevant increase of the systemic citrate concentration.

CVVHD with citrate anticoagulation	**Min.**	**Max.**	**Resolution**	**Unit**
Blood flow	10	200	10	ml/min
Ultrafiltration	Off / 10	1800	10	ml/h
UF goal	Off / 10	10,000	10	ml
Cont. heparin adm.	Off / 0.1	25	0.1	ml/h
Dialysate	600	4800	50	ml/h
Citrate / blood (citrate dose)	2.0	6.0	0.1	mmol/l
Calcium / filtrate (calcium dose)	0	3.0	0.1	mmol/l
Temperature	Off / 35	39	0.5	°C

postCVVHDF with citrate anticoagulation	**Min.**	**Max.**	**Resolution**	**Unit**
Blood flow	10	200	10	ml/min
Ultrafiltration	Off / 10	1200	10	ml/h
UF goal	Off / 10	14,400	50	ml
Cont. heparin adm.	Off / 0.1	25	0.1	ml/h
Dialysate	600	4800	50	ml/h
Substituate	600	2400	50	ml/h
Citrate / blood (citrate dose)	2.0	6.0	0.1	mmol/l
Calcium / filtrate (calcium dose)	0.1	3.0	0.1	mmol/l
Temperature	Off / 35	39	0.5	°C

Fig.: Schematic of regional anticoagulation



Legend

1 Blood pump
2 Haemofilter
3 Air detector
4 Venous clamp
5 Citrate pump
6 Citrate drop counter
7 Calcium pump
8 Calcium drop counter

Effect of the citrate

The citrate binds the ionised calcium that is present in the blood and forms a calcium-citrate complex. The resulting reduction of the ionised calcium concentration inhibits several steps in the coagulation cascade.

Regional citrate anticoagulation can have various consequences, including a considerable reduction of the mutual activation of the various vitamin K-dependent modified coagulation factors. The binding of these coagulation factors to activated cell membranes requires calcium which is bound to their GLA domain and is therefore only possible with sufficiently high levels of ionised calcium.

Limits of citrate anticoagulation

Citrate anticoagulation does not prevent coagulation in the extracorporeal blood circuit in all cases. This is possibly explained by the fact that activated thrombin, as opposed to prothrombin (thrombinogen, factor II), no longer has a GLA domain, which explains why the mechanism discussed above cannot be effective with thrombin.

For patients with systemic blood coagulation activation, e.g., HIT syndrome, a systemic anticoagulation may therefore be indicated in addition to the citrate anticoagulation.

Mutually compatible solutions in citrate anticoagulation

The different continuous renal replacement therapies with regional citrate anticoagulation described in the literature can differ considerably, also with regard to the adaption of the treatment to the specific patient.

Regional citrate anticoagulation requires mutually compatible solutions (solutions with citrate, other CRRT solutions depending on the procedure, solutions with calcium). These solutions must also be used with matching flows to minimise the risk of electrolyte concentration and acid-base status disorders.

The following is a specific description of the Ci-Ca CVVHD and Ci-Ca postCVVHDF treatment modes of the device.

Differences between Ci-Ca CVVHD and Ci-Ca postCVVHDF

In contrast to Ci-Ca CVVHD, an additional calcium-containing, bicarbonate-buffered substituate is infused in postdilution when performing a Ci-Ca postCVVHDF treatment. The haemoconcentration at the filter outlet should, if possible, not exceed 20%. The substituate flow can, for example, be selected as 1/6 of the blood flow (16.7 ml/min = 1000 ml/h with a blood flow of 100 ml/min). With regard to the values set on the display, this corresponds to a ratio of "10:1".

If the haemoconcentration at the filter outlet exceeds 20% due to the required calcium flow and a clinically required ultrafiltration, the substituate flow can be reduced so that this limit is not exceeded.

As a result of the substituate flow, there are also certain differences between Ci-Ca CVVHD and Ci-Ca postCVVHDF regarding the control of the acid-base status and selecting the appropriate citrate dose (see chapter 7.3.2.4 on page 7-25).

Laboratory tests during citrate anticoagulation

If citrate anticoagulation is used, the electrolyte checks that are usual in continuous renal replacement therapy (sodium, potassium, calcium, magnesium, phosphate, acid-base status) must be supplemented by close monitoring of the concentration of the systemic ionised calcium concentration and the systemic acid-base status. Usually, the same systemic blood sample can be used to determine these values.

In addition, appropriate citrate anticoagulation must be checked by determining the ionised calcium in the extracorporeal blood circuit. When performing a Ci-Ca treatment, this is checked downstream of the filter.

Note

It is absolutely necessary to ensure that the two measurements of the ionised calcium are not mistaken for each other.

The determination of the systemic ionised calcium can be interpreted as usual and is used to check the calcium substitution. The measurement of the ionised calcium in the extracorporeal blood circuit (downstream of the citrate infusion site, as seen in flow direction) is used to verify the effect of the citrate. Here, the decrease in ionised calcium concentration must be distinct.

Immediate availability of the systemic ionised calcium and acid-base status measurement

Note

During the treatment, the analyzer for determining the acid-base status and the concentrations of ionised calcium must be in the immediate vicinity so that results are directly available.

For example, in intensive care units, this can be done with an automatic blood gas analyser, which can also measure ionised calcium.

Sample collection / systemic blood sample

If the patient has an arterial access (e.g., for collection of blood samples from artificially ventilated patients or for invasive blood pressure measurement), the blood sample to check the systemic ionised calcium and the systemic acid-base status should be taken there. Values which may have been measured to control mechanical respiration can be used.

Alternatively, the sample can be collected on the venous side if the patient does not have an arterial access. This must be considered in the interpretation of the acid-base values. Here, a collection site separate from the extracorporeal blood circuit is recommended.

Alternatively, the blood sample can be taken slowly from the sampling site (red) of the access line while the blood pump is running.

Note

If the sampling site on the access line is used, it must be ensured that the blood pump is running while the sample is collected and that the blood sample is aspirated slowly to prevent citrate from being admixed by the citrate infusion.

In case of recirculation in the area of the catheter, blood which has just been returned will enter into the aspirated blood, along with some citrate. This addition of citrate leads to incorrect measurement values for the systemic ionised calcium.

Note

In situations presenting an increased risk of recirculation, e.g., reverse catheter connection or femoral catheter position, the sampling site on the access line should not be used. Unexpectedly low measurement values of the systemic ionised calcium for a sample collected at this site should always be checked by measuring a separately collected systemic sample.

Sample collection / extracorporeal blood circuit

To check the ionised calcium in the extracorporeal blood circuit, the blood sample is collected from the sampling site (blue) of the return line downstream of the filter.

Frequency of laboratory tests

The systemic acid-base status and systemic ionised calcium should be checked prior to the treatment. If there is no other clinical indication, hypocalcemia should be corrected before the start of the Ci-Ca treatment.

The ionised calcium downstream of the filter should be checked approx. 5 minutes after the start of the treatment to verify correct connection.

Note

If no significant reduction of the post-filter ionised calcium is detected during the first measurement performed 5 minutes after the start of the treatment, the treatment must be stopped immediately. This may be indicative of an incorrect connection. It is particularly important to check that the citrate and calcium solution have not been reversed.

All three laboratory parameters must be regularly checked during the Ci-Ca treatment. The intervals necessary for these regular determinations depend on the patient's clinical situation.

Note

Whenever a situation is not clear and is possibly associated with an abnormal concentration of systemic ionised calcium or with a disturbed acid-base status, these parameters should be checked immediately.

Magnesium

Since citrate forms a complex not only with calcium but also with magnesium, there is also a shift of protein-bound magnesium towards magnesium-citrate complexes which may pass through the membrane of the filter. Compared with CRRT solutions commonly used for systemic anticoagulation, the use of a slightly higher magnesium concentration in the dialysate used or an additional infusion of magnesium may be indicated.

Sodium

Hypernatraemia has been reported for some variants of citrate anticoagulation. This was caused by excessive sodium concentrations in the citrate solution used, in combination with a failure to adjust the sodium concentration in the HF solution / dialysate. Therefore, the Na concentration of Ci-Ca dialysates K2 and Ci-Ca dialysates K4 has been adjusted to 133 mmol/l.

7.3.2.2 Adequate anticoagulation in the extracorporeal blood circuit

Required citrate dose

The citrate dose is defined as the volume of citrate ions (in mmol) infused per litre of processed blood. As a result, its unit is that of a concentration. The citrate dose can be set within a range of 2 to 6 mmol/l.

In many patients, the required regional anticoagulation for a Ci-Ca CVVHD is achieved with a citrate dose of 3.5 to 4.5 mmol/l.

With Ci-Ca postCVVHDF, the use of a higher citrate dose is recommended. Here, a starting value of 5.0 mmol/l citrate dose is appropriate. This change, in comparison to Ci-Ca CVVHD, compensates for the effects of the haemofiltration component of Ci-Ca postCVVHDF on the acid-base state (see chapter 7.3.2.4 on page 7-25) and inhibits a premature increase in the concentration of ionised calcium following infusion of the calcium-rich substitution fluid at the postdilution stage.

The citrate ion concentration of the citrate solution used is required to calculate the applied citrate flow from the blood flow and the set citrate dose.

Note

The concentration of the citrate ions in the citrate solution used must be properly set in the setup of the device.

Adequate citrate anticoagulation in the extracorporeal blood circuit

The efficacy of the citrate anticoagulation is typically checked by determining the ionised calcium in the extracorporeal blood circuit. Lowering values to below 0.35 mmol/l of ionised calcium in the extracorporeal blood circuit (downstream of the filter) is associated with only a minor risk of coagulation in the extracorporeal blood circuit. For Ci-Ca postCVVHDF, lowering values slightly more has the benefit of inhibiting a premature increase in the concentration of ionized calcium following infusion of the calcium-containing substitution fluid at the postdilution stage.

Adjusting the citrate dose

If the ionised calcium measured in the extracorporeal blood circuit is lower than the required value, the citrate dose should be reduced. Accordingly, the citrate dose should be increased if the ionised calcium in the extracorporeal blood circuit is reduced insufficiently.

The citrate dose can be set in increments of 0.1 mmol/l. This increment enables fine adjustment in the event that there is a very small deviation from the target range.

After the citrate dose has been readjusted, the new setting can be checked as early as a few minutes later and readjusted if necessary. The extracorporeal fill volume should be completely exchanged at least once, and the required time therefore depends on the set blood flow. All kits for Ci-Ca treatments permit a representative check after 5 minutes even in case of a low blood flow of 80 ml/min.

7.3.2.3 Control of systemic ionised calcium

Necessity of calcium substitution

During the treatment, a proportion of the calcium-citrate complexes as well as a proportion of the ionised calcium pass from the patient's blood into the filtrate and are thus removed from the patient.

To compensate for this calcium loss, calcium solution is infused into the venous branch of the extracorporeal blood circuit. This is done with the calcium pump which is integrated in the device system.

Avoiding hypo- and hypercalcaemia

The substitution of calcium must be adapted to the patient's needs to avoid hypo- or hypercalcaemia.

Checking the calcium substitution

Adequate calcium substitution is determined by regular checks of the systemic ionised calcium.

To collect the blood sample for checking the systemic ionised calcium, observe the instructions for taking a sample / systemic blood sample (see chapter on page 7-20).

Unless clinically contraindicated, the systemic ionised calcium values should be within the normal range.

Required calcium dose

The calcium dose is defined as the volume of calcium ions (in mmol) infused per liter of filtrate produced. In Ci-Ca CVVHD, the calcium dose (displayed as calcium / filtrate ratio) can be adjusted within a range of 0.0 to 3.0 mmol/l. With Ci-Ca postCVVHDF, the calcium dose equals the overall calcium infusion, i.e., the sum of calcium infused with the calcium solution and the calcium in the substitution fluid, in relation to the filtrate flow. Unlike with Ci-Ca CVVHD, very small values for the calcium dose cannot be set for Ci-Ca postCVVHDF since it is essential that calcium is infused with the substitution fluid. In particular, a calcium dose of 0.0 mmol/l can never be set for Ci-Ca postCVVHDF. The upper configuration threshold is identical at 3.0 mmol/l.

Based on theoretical estimations and empirical experience, an average calcium dose of approximately 1.7 mmol/l is required to maintain the systemic ionised calcium within the normal range or within the target range prescribed by the physician. This value can, however, vary from patient to patient, and even fluctuate for the same patient during the course of treatment. Accordingly, it is necessary to verify the effect by measuring systemic ionised calcium and then adjust the calcium dose as required.

The direct coupling of the calcium dose to the filtrate flow has the effect that the calcium substitution is automatically adjusted to the efficacy of the treatment. This means, for example, that in case of an elevated calcium removal caused by an increase of the dialysate flow, the calcium substitution is automatically increased.

In Ci-Ca CVVHD and Ci-Ca postCVVHDF, the concentration of the calcium solution is a major parameter when calculating the infused calcium flow from the filtrate flow and the set calcium dose. In Ci-Ca postCVVHDF, the calcium concentration of the substitution fluid infused in postdilution is also considered in the calculation.

Note

The concentration of the calcium solution used must be set correctly in the **System parameters / Select Ci-Ca data** menu.

Adjusting the calcium dose if measured values are outside the target range

If the systemic ionised calcium measured is undesirably low, the calcium dose should be increased. Accordingly, the calcium dose should be reduced in case of elevated systemic ionised calcium values. Even if the calcium dose can be adjusted in increments of 0.1 mmol/l, the effect of such a change is so low that double increments, i.e., of 0.2 mmol/l, can also be used for fine adjustment. In the event of major deviations of the measured systemic ionised calcium concentration, the calcium dose can be readjusted in even greater increments, if necessary.

Delayed effect in case of changed calcium dose

Note

Unlike changes to the citrate dose, the effect of a change to the calcium dose can be assessed only after some time has passed.

This is caused by the fact that the systemic distribution volume must first develop a new balance. Depending on the efficacy of the CRRT treatment and the size of the patient (or his / her distribution volume for calcium), the first effects can already be seen after a few hours. The full effect can, however, only be assessed after approximately one day.

This is particularly important to bear in mind if several equivalent changes are made within short intervals because, in this case, there may be an excessive response (e.g., hypercalcemia if the calcium dose is increased repeatedly within short intervals).

High calcium dose: possible citrate accumulation

If the calcium dose necessary for stabilising the systemic ionised calcium is higher than 2.1 mmol/l, this might be indicative of a citrate accumulation. The device alerts the operator to this fact when setting the respective calcium doses and suggests a measurement of the total calcium. For more information on citrate accumulation (see chapter 7.3.2.5 on page 7-27).

Low calcium dose: possible evidence of a clogged membrane

If a calcium dose of less than 1.3 mmol/l is sufficient for the stabilisation of the systemic ionised calcium, this may be indicative of a clogged membrane with reduced permeability for calcium-citrate complexes. Alongside the reduced elimination of calcium and a correspondingly lower requirement for calcium substitution, an increased systemic infusion of citrate and, after metabolism, alkalosis are to be expected. A combination of low requirements for calcium substitution and metabolic alkalosis can also be indicative of a clogged membrane. A clogged membrane has severely restricted functionality and must be replaced (restart treatment following replacement of the multiFiltrate kit).

7.3.2.4 Controlling the systemic acid-base status

Differences between the various citrate procedures

The corrective measures which can be employed to obtain a normal acid-base status can differ considerably between the different citrate anticoagulation methods. The following describes the procedure within the Ci-Ca CVVHD and the Ci-Ca postCVVHDF treatments.

Background on the resulting acid-base status when using citrate anticoagulation

The citrate volume necessarily infused systemically is metabolised: Here, for each complete metabolisation of the citrate ion to carbon dioxide and water (or to other uncharged substances), three protons are also metabolised by the process. This results in the production of three bicarbonate ions. If not compensated, metabolic alkalosis would develop.

Therefore, an adapted dialysate with 20 mmol/l bicarbonate is used in Ci-Ca CVVHD and Ci-Ca postCVVHDF. This concentration is lower than that of other common CRRT solutions. Dialysis to 20 mmol/l bicarbonate leads to the removal of citrate in the filter and, to a certain extent, of bicarbonate from the blood. Viewed in isolation, this removal of buffer bases would lead to metabolic acidosis.

The required balance of buffer bases can be reached by balancing the addition of buffer bases as an effect of systemic citrate infusion and the removal of buffer bases as an effect of the dialysis against the adapted dialysate. In practice, the processes are balanced so that the systemic acid-base status of the patient is maintained within the required range.

The Ci-Ca postCVVHDF treatment is based on the Ci-Ca CVVHD. In Ci-Ca postCVVHDF, a calcium-containing bicarbonate-buffered haemofiltration solution is also infused in postdilution and filtration across the membrane is increased accordingly. As the additional filtrate is formed from the citrate-containing blood, a buffer base concentration which is above the bicarbonate in the substitution fluid (for example, 35 mmol/l) is typically to be expected in the filtrate. (The buffer base concentration is to be understood here as the total bicarbonate concentration times a factor of 3 for the metabolism of weighted citrate concentration, and in the same way as the concentrations of other metabolisable anions, such as lactate, etc.) With this approach, the additional convective component results in more buffer bases being removed than infused – including citrate, among others. This can be compensated for by increasing the citrate dose above the level required for anticoagulation in the filter – to approx. 5.0 mmol/l. Since part of the additionally infused citrate is systemically infused, this helps to equalise the buffer base balance. One positive extra effect of the increased citrate dose is that it inhibits a premature increase in the concentration of ionised calcium following infusion of the calcium-containing substitution fluid at the postdilution stage.

Derived measures for adjusting the acid-base status

If the patient shows signs of metabolic acidosis during the treatment, the administered citrate volume must be increased or the effective removal of buffer bases from the blood in the filter must be reduced. In Ci-Ca CVVHD and Ci-Ca postCVVHDF, this can be achieved by increasing the set blood flow (which automatically increases the citrate infusion) and / or by reducing the dialysate flow (which reduces the net removal of buffer bases from the blood). The latter approach will, however, also reduce the efficacy of the treatment. Alternatively, separate infusion of bicarbonate permits an additional administration of buffer bases without reducing the efficacy of the treatment or causing an additional citrate load on the metabolism.

With Ci-Ca CVVHD, by changing one of the two named flows by 20%, you can theoretically expect an effect of approx. 4 mmol/l on the systemic bicarbonate concentration or base excess. Depending on the extent of the effect intended, smaller or larger stepwise adjustments may be necessary. The proper adjusting method should be selected such that the necessary efficacy of the treatment is ensured and that the blood flow range which is achievable in practice is taken into consideration.

For Ci-Ca postCVVHDF, almost the same applies as for Ci-Ca CVVHD. However, the additional infusion of the bicarbonate-buffered substitution fluid has a stabilising effect on the resulting acid-base status. For an effect on the acid-base status, the ratio of blood to dialysate flow in Ci-Ca postCVVHDF must therefore be changed to a larger extent than in Ci-Ca CVVHD. By changing one of the two flows by 30%, you can theoretically expect an effect here of approx. 4 mmol/l on the systemic bicarbonate concentration or base excess.

Note

With Ci-Ca postCVVHDF, adjusting the blood flow – even to alter the acid-base status – also requires adjustment of the substituate flow.

Delayed effect in the case of changed blood to dialysate flow ratio

Note

In the same way as when changing the calcium dose, the effect of a changed blood to dialysate flow ratio can only be assessed some time after the change.

This is caused by the fact that the systemic distribution volume must first develop a new balance. Depending on the efficacy of the CRRT treatment and the size of the patient (or his/her distribution volume for buffer bases, or the essential systemic bicarbonate buffer base), the first effects can already be seen after a few hours. The full effect can, however, only be assessed after approximately one day.

This is particularly important to bear in mind if several equivalent changes are made within short intervals as these may cause an excessive response.

7.3.2.5 Citrate accumulation

Insufficient citrate metabolism and citrate accumulation

The systemically infused citrate is usually metabolised quickly. In patients who have or develop a metabolic disorder for citrate, the metabolism is slower. This results in an elevated systemic citrate concentration. As the systemic citrate concentration is only measured in exceptional cases in the hospital, it is assessed indirectly by its effects.

The systemically accumulated citrate also binds calcium. As a consequence, the percentage of ionised calcium in the total calcium decreases.

Generally, the shift between systemic ionised calcium and total calcium is first indicated by a drop of the systemic ionised calcium concentration, which is properly corrected by increasing the calcium dose. A calcium dose above 2.1 mmol/l (empirically determined) which is set on the device can be indicative of possible citrate accumulation. The device will show an appropriate message.

Note

If doses of up to 3 mmol/l of calcium per litre of filtrate are not sufficient to stabilise the systemic ionised calcium concentration, citrate accumulation must be assumed. In this case, citrate anticoagulation must be stopped immediately.

After a stabilization of the systemic ionised calcium by an appropriate calcium substitution, the shift in the concentration ratio of total calcium to systemic ionised calcium is shown by an increased total calcium. This increase is relative to the citrate accumulation, corresponding to the calcium-citrate complexes circulating in the blood.

An increase of the concentration ratio of total calcium to systemic ionised calcium above 2.5 is cited in literature as a sign of citrate accumulation. However, this value should not be regarded a strict limit, but as an aid for orientation.

Citrate accumulation may also cause a mild metabolic acidosis. This can, however, also be a symptom of a variety of other causes and is therefore not specific to a metabolic citrate disorder.

Alkalosis / hypercalcaemia after citrate anticoagulation

After completion of the treatment, the accumulated calcium-citrate complexes are metabolised by the patient. This may result in alkalosis and hypercalcaemia.

If clinically indicated, these risks can be reduced by continuing the CRRT treatment without citrate anticoagulation.

7.3.3 Solutions for citrate anticoagulation

Preparation

Isotonic NaCl solutions are used for priming the blood and filtrate line systems of the Ci-Ca cassette. The citrate and calcium lines are filled with the appropriate citrate and calcium solutions.

Treatment

Note

The solutions used for the treatment must be selected such that they match each other. Otherwise, there is a risk of a severe electrolyte imbalance. In addition, it must be ensured that the flow ratios of the solutions in relation to each other and to the blood flow match.

Note

The concentration of the citrate solution, the calcium solution used, and the calcium-containing substitution fluid must be set correctly in the **System parameters / Select Ci-Ca data** menu.

Depending on the citrate and calcium solutions used locally, the concentration of the citrate and calcium ions must be stored in mmol/l in the **System parameters** menu of the multiFiltrate. This is done by technical service personnel. This also applies to the filling volume of the storage containers used.

The stored concentrations and volumes can be viewed in the **Ci-Ca bag change** menu. These values must be confirmed on selection of citrate anticoagulation and whenever the **Change bag** menu is used.

Ci-Ca solutions

For Ci-Ca CVVHD and Ci-Ca postCVVHDF, the sole approved citrate solution is 4% Na_3citrate in each case, containing 136 mmol/l of citrate ions.

The concentration of the calcium solution used may be within a range from 50 to 500 mmol/l in principle.
The recommended calcium solution is one with approx. 100 mmol/l. Higher calcium concentrations lead to lower calcium flows and can increase the risk of local clot formation due to the poorer quality of intermixing that occurs at the calcium infusion site.

The citrate and calcium solutions must be suitable for infusion.

Note

Despite citrate anticoagulation, local coagulation and clot formation can occur in the tubing system during the treatment. Perform regular visual checks of the tubing system, especially in the area from the venous chamber to the connection to the return line and vascular access. If visual checks identify clot formation ("white bands") in the direction of flow, replace the treatment set downstream of the venous chamber, e.g., at the site where the calcium line discharges into the return line.

Calcium-containing substitution fluid

In addition to the solutions needed for Ci-Ca CVVHD, Ci-Ca postCVVHDF will also require a calcium-containing, bicarbonate-buffered substitution fluid. The use of a substitution fluid of this type with 1.5 mmol/l calcium and 35 mmol/l bicarbonate is recommended.

CRRT treatments	Citrate solution	HF solution / dialysate	Calcium solution
Ci-Ca CVVHD	4% Na_3citrate (corresponding to 136 mmol/l citrate) 1.0 litre bag	Ci-Ca dialysate K2, Ci-Ca dialysate K4 per 5 litre bag	$CaCl_2$ solution in the appropriate concentration (50 to 500 mmol/l calcium ions); preferably approx. 100 mmol/l
Ci-Ca postCVVHDF	4% Na_3citrate (corresponding to 136 mmol/l citrate) 1.0 litre bag	Ci-Ca dialysate K2, Ci-Ca dialysate K4 per 5 litre bag In addition, a calcium-containing, bicarbonate-buffered substitution fluid	$CaCl_2$ solution in the appropriate concentration (50 to 500 mmol/l calcium ions); preferably approx. 100 mmol/l

8 Consumables, accessories, additional equipment

Warning

The device has been approved for use with specific consumables and accessories.
If the responsible organisation wishes to use consumables and accessories other than those specified here, it must first check whether they are suitable by obtaining relevant information from the manufacturer, for example.
The applicable legal regulations must be complied with.

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

On request, the local service support organisation will provide information on further accessories, consumables, and other additional equipment.

Symbols on consumables

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

Disposables
Identified by the symbol:

Do not re-use

Use by date
Identified by the symbol:

Use by

Long-term operation
Identified by the symbol:

Indication of the max. operating time and the max. delivery volume

8.1 Consumables

8.1.1 multiFiltrate kits

The ready-to-use multiFiltrate kits comprise all tubing systems required for the respective therapy. Used in conjunction with this device, these tubing systems constitute a defibrillator-proof applied part.

Product	Part number	Description
multiFiltrate kit 2 CVVH 600	503 891 1	multiFiltrate cassette with Ultraflux® AV 600 S and substituate system
multiFiltrate kit 9 CVVH 1000	503 879 1	multiFiltrate cassette with Ultraflux® AV 1000 S and substituate system
multiFiltrate kit 3 CVVHD 600	503 892 1	multiFiltrate cassette with Ultraflux® AV 600 S and dialysate system
multiFiltrate kit 4 CVVHDF 600	503 893 1	multiFiltrate cassette with Ultraflux® AV 600 S and substituate / dialysate system
multiFiltrate kit 8 CVVHDF 1000	503 887 1	multiFiltrate cassette with Ultraflux® AV 1000 S and substituate / dialysate system
multiFiltrate kit 7 HV-CVVH 1000	503 818 1	multiFiltrate cassette with Ultraflux® AV 1000 S and Pre-Post CVVH substituate set
multiFiltrate kit CVVHD EMiC®2	F00001173	multiFiltrate cassette with Ultraflux® EMiC®2 dialyser and dialysate system
multiFiltrate kit Ci-Ca® CVVHD 1000	503 901 1	Ci-Ca multiFiltrate cassette with Ultraflux® AV 1000 S and dialysate system
multiFiltrate kit Ci-Ca® CVVHD EMiC®2	F00001172	Ci-Ca multiFiltrate cassette with Ultraflux® EMiC®2 dialyser and dialysate system
multiFiltrate kit Ci-Ca post CVVHDF	F00002290	Ci-Ca multiFiltrate cassette with Ultraflux® AV 1000 S and dialysate and substituate system
multiFiltrate kit Midi CVVHDF 400	F00003317	Ultraflux® AV 400 S, with multiFiltrate Midi AV set, substituate, dialysate, and filtrate system
multiFiltrate kit paed CRRT / SCUF	503 905 1	Ultraflux® AV paed set with multiFiltrate paed CRRT / SCUF set
multiFiltrate kit SCUF 400	F00003322	Ultraflux® AV 400 S with multiFiltrate paed CRRT / SCUF set, CAVH/D_CVVH/D dialysate system, and filtrate bag

Product	Part number	Description
multiFiltrate kit 6 MPS P2	503 895 1	multiFiltrate cassette with plasmaFlux® PSu 2S, MPS substituate system, and filtrate bag
multiFiltrate kit 16 MPS P1 *dry*	F00003316	plasmaFlux® P1 *dry*, with multiFiltrate Midi AV set, MPS substituate, filtrate system, and filtrate bag
multiFiltrate kit 16 MPS P2 *dry*	F00000215	multiFiltrate cassette with plasmaFlux® P2 *dry*, MPS substituate system and filtrate bag

8.1.2 Haemofilter / plasma filter

- **Haemofilter**

Product	Part number	Description
Ultraflux® AV paed	500 823 1	Ultraflux® haemofilter, steam-sterilised, 0.2 m^2 surface, Fresenius Polysulfone® membrane, blood fill volume 18 ml, Luer-Lock dialysate and filtrate connectors
Ultraflux® AV 400 S	500 734 1	Ultraflux® haemofilter, steam-sterilised, 0.75 m^2 surface, Fresenius Polysulfone® membrane, blood fill volume 52 ml
Ultraflux® AV 600 S	500 736 1	Ultraflux® haemofilter, steam-sterilised, 1.4 m^2 surface, Fresenius Polysulfone® membrane, blood fill volume 100 ml
Ultraflux® AV 1000 S	500 898 1	Ultraflux® haemofilter, steam-sterilised, 1.8 m^2 surface, Fresenius Polysulfone® membrane, blood fill volume 130 ml
Ultraflux® EMiC®2	500 977 1	Ultraflux® dialyser, steam-sterilised,1.8 m^2 surface, Fresenius Polysulfone® membrane, blood fill volume 130 ml

- **Plasma filter**

Product	Part number	Description
plasmaFlux® PSu 1S	500 491 1	Plasma filter (filled with sterile water), steam-sterilised, 0.3 m^2 surface, blood fill volume 36 ml, Fresenius Plasmasulfone membrane
plasmaFlux® PSu 2S	500 481 1	Plasma filter (filled with sterile water), steam-sterilised, 0.6 m^2 surface, blood fill volume 70 ml, Fresenius Plasmasulfone membrane
plasmaFlux® P1 *dry*	500 802 1	Plasma filter (delivered dry), steam-sterilised, 0.3 m^2 surface, blood fill volume 35 ml, Fresenius Polysulfone® membrane
plasmaFlux® P2 *dry*	500 803 1	Plasma filter (delivered dry), steam-sterilised, 0.6 m^2 surface, blood fill volume 67 ml, Fresenius Polysulfone® membrane

8.1.3 Dialysate and haemofiltration solutions

The individual solutions can be found in the supply list by Fresenius Medical Care, which can be obtained separately.

8.1.4 Isotonic NaCl solutions

Suitable NaCl solutions must be used.

8.1.5 Citrate solution

Product	Part number	Information
4% citrate solution	E2012	Trisodium citrate solution for regional citrate anticoagulation, 1.5 l bag

8.1.6 Disposable syringes

Product	Part number	Description
Fresenius Medical Care heparin syringe, 30 ml	503 032 1	
Fresenius Injectomat syringe, 50 ml	900 071 1	
Fresenius P syringe, 50 ml	900 076 1	

8.1.7 Other disposables

Product	Part number	Description
CAVH/D – CVVH/D dialysate connector	501 491 1	Adapter for connection of a male LL tubing system to an AV filter
2 x HF female / 4 x HF male	504 613 1	For connection of 4 HF bags to HF tubing systems
HF female PF adapter / female Luer-Lock	501 474 1	For connection of infusion systems to HF tubing systems
HF female adapter / male Luer-Lock	501 689 1	For connection of NaCl solution to the substituate system
HF female / spike adapter	501 635 1	For connection of bags with septum to substituate systems
Spike connector	501 592 1	Luer-Lock female / spike connector
Spike connector, vented	F00000520	Luer-Lock female / spike connector, ventable
SN adapter	502 785 1	Y adapter, 2 x female Luer-Lock, 1 x male Luer-Lock, for use of 2 filtrate bags
Adapter, female Luer-Lock	501 480 1	For connection of 2 male Luer-Lock connectors
Adapter, male Luer-Lock	501 477 1	For connection of 2 female Luer-Lock connectors
Collection bag, 2000 ml	501 509 1	2000 ml collection bag with female Luer-Lock connector
Filtrate bag, 10 l	502 901 1	Filtrate collection bag with drain cock, male Luer-Lock connector
Single-use filtrate bag, 10 l	502 903 1	Filtrate collection bag with male Luer-Lock for single use
Pressure measurement line	501 463 1	Complete pressure measurement line with filter, Luer-Lock connector female / male, 30 cm long
Pressure measurement line	501 915 1	Complete pressure measurement line with filter, Luer-Lock connector female / male, 60 cm long, for arterial pressure measurement
Hydrophobic filter	501 591 1	Hydrophobic filter for connection to male Luer-Lock
Check valve	850 080 1	Male / female Luer-Lock
Clamp	284 024 1	For clamping tubes
Freka-Flex transfer system	288 901 1	Infusion system with roller clamps and drip chamber

8.2 Accessories

Product	Part number	Description
Plasma pole for SUB trough	M28 004 1	

8.3 Additional equipment

Product	Part number	Description
Equipotential bonding cable	630 360 1	
Staff call cable	630 462 1	
Accessory bag without contents	M28 494 1	
Handle	M28 491 1	
Dialyser holder	677 792 1	
LAN connection cable Cat. 5; length 1 m	M28 072 1	
LAN connection cable Cat. 5; length 2 m	M28 073 1	
LAN connection cable Cat. 5; length 3 m	M28 074 1	
LAN connection cable Cat. 5; length 5 m	M28 075 1	
LAN connection cable Cat. 5; length 10 m	M28 076 1	
LAN connection cable Cat. 5; length 15 m	M28 077 1	
LAN connection cable Cat. 5; length 20 m	M28 078 1	
Crossover patch cable Cat. 5; length 3 m	M36 433 1	
Retrofit kit for power cable; length 5 m	M28 169 1	
Paediatric dialyser holder	M38 420 1	

9 Installation

9.1 Connection requirements

9.1.1 Environment

The following considerations need to be taken into account for the operating environment:
- No splash water area
- Ceilings, walls, floors: smooth, liquid-tight, scrub-resistant, suitable for wet disinfection
- Ensure adequate load-carrying capacity of the floors
- Heat emission of each device (dialysis operating mode: approx. 550 W at 20 °C room temperature)
- Space requirements of each device approx. 1 m^2
- Emergency lighting (for at least 1 hour in case of power failure)
- Distances to areas such as MRI scanner rooms

9.1.2 Power supply network

Power supply network requirements:
- The requirements specified by IEC 60364-7-710 for Group 1 rooms must be met.
- Power failures < 20 ms
- An earthing system must be installed as prescribed.
- A power socket with a protective earth conductor connection is required.
- The line cross-section and the line lengths to the wall outlet must ensure that the voltage tolerance and the function of the protective devices is always guaranteed. Recommended line cross-section to the power socket: at least 3 x 1.5 mm^2 copper core for 220 V–240 V and at least 3 x 2.5 mm^2 copper core for voltages of less than 220 V.
- Each electric circuit is protected from damage through fault conditions with an automatic, fast-acting circuit-breaker (recommendation: 16 A for 220 V–240 V and 20 A for voltages of less than 220 V).
- No more than 1 device per wall outlet and electric circuit.
- The use of multiway sockets or extension cables is prohibited.
- Residual-current devices (RCDs) which protect against dangerous shock currents in the event of fault conditions. One residual-current device (RCD less than 30 mA) for each device or electric circuit.
- Overvoltage / lightning protection in the main and emergency power supply networks.
- A connecting bolt must be available for an additional equipotential bonding conductor.

9.2 Installation / initial start-up requirements

Note

To reduce the risk of using the wrong citrate or calcium containers, only one type of container (container size and concentration) should be used throughout the hospital or a comparable organisation institution. Save the same settings for citrate and calcium containers in the setup of all devices of this organisation institution.

When bringing the device from a cooler to a warmer room, allow approx. 2 hours for the device to adjust to the ambient temperature before turning the unit on.

Charging the built-in battery

On receipt of the device, charge the battery as follows:
– Use the power cable to connect the device to the power supply.
– Actuate the power switch to turn the device on.
– Leave the device on for 10 hours.

9.3 Important information on initial start-up

For initial start-up only

The following information is only intended for the initial start-up. This information is not applicable for restarting devices that have been removed from service or have temporarily been taken out of service.

Environmental conditions

Variations in temperature during transport may cause water condensation on electrical parts. In the event of major variations in temperature, allow sufficient time for the device to adjust to the ambient temperature before start-up.

Qualification requirements of testers

The initial system start-up must only be performed by the manufacturer's service support organisation or a person authorised by it.

The initial start-up must only be performed by personnel qualified to perform the required procedures correctly based on their education, training, knowledge, and experience. Furthermore, the personnel performing the checks must be permitted to do so independently and without outside interference.

Specifications

Any information on the specifications must be observed.

Documentation

The initial start-up report and further procedural information are described in the Service Manual.

Reports are available on request.

The completion of the initial start-up must be entered in the Medical Device Register.

9.4 Electrical installation

Warning

The "type of protection against electric shock" for this device is "Protection class I". To avoid the risk of electric shock, this device may only be connected to a power supply network with a protective earth conductor.
It must be taken into consideration that, in many countries, specific regulations of the national authorities are in force.

Power supply system

The national standards and regulations must be observed when connecting the device to the power supply system.

Electromagnetic compatibility

Please observe the following during installation and start-up:
(see chapter 12.5 on page 12-5)

Protective earth conductor

When using protection class I devices, the quality of the protective earth conductor of the installation is of particular importance.

Power cable

If the power cable needs to be replaced, use only the original power cable listed in the spare parts catalog. The use of additional extension cables or multiway sockets / connectors is prohibited.

Equipotential bonding

Using the original accessories, connect the equipotential bonding conductor to the rear of the device if this is required by law or for special applications at the place of installation.

Leakage currents

If additional equipment not listed in the Accessories chapter is connected to the device, there is a danger that the permitted leakage currents will be exceeded.

10 Transport / storage

Warning

Improper use can cause damage to the cart. To avoid damaging the cart, please bear the following in mind at all times:
– Do not move the machine if the rollers are locked or obstructed.
– Move the machine slowly and carefully over uneven areas – e.g., when entering / exiting lifts or doorways.
– Orient the machine properly before moving. Preferably move the device backwards with the two big, stationary wheels ahead.

Warning

Risk of tilting when pushing the device or leaning against it

If excessive lateral force is exerted, it may result in tilting or slipping of the device.

Note

The maximum loading capacity of 12 kg per scale must not be exceeded. The weighing cell can also be permanently damaged by a short-term overload (e.g., pulling or lifting the device by the scales), in which case the device can no longer be used.

Note

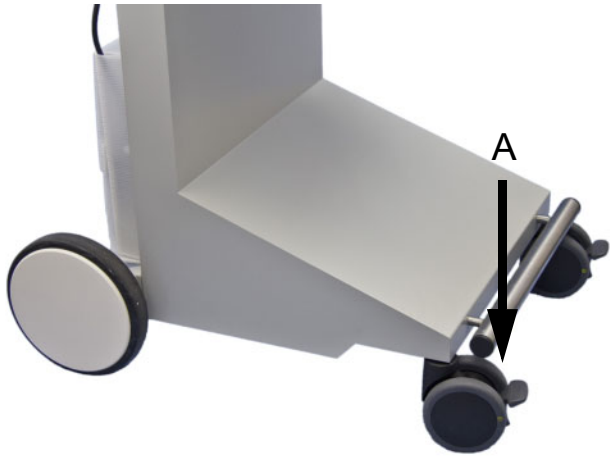
Do not push or pull on the scales trays nor on the Ci-Ca module (option) to move the device. For this purpose, only use the two handles on the upper part (monitor hood).

Do not use the handles on the upper part of the unit (monitor hood) to lift the system.

10.1 Relocation

Moving

Since the system is provided with a cart, the device can easily be relocated (by moving it on a level surface) within a building.



The cart comprises 4 wheels. The two wheels on the front (A) are each equipped with a break. The device can be swiveled, turned, or moved in any direction by means of the two handles on the upper part (monitor hood).

Locking

All breaks must be locked if the device is in its final position or in operation.

- **Relocation inside buildings during preparation (recirculation)**

Before relocating

After the device has been set up, it may only be relocated inside a building or ward.

In other words:

– The functional test is complete.
– The tubing systems (cassette) have been inserted, primed, and rinsed.
– The treatment parameters have been entered.
– The device is in the "Recirculation" mode.
– The loads on the device must not exceed the following specifications. Preferably use the front hooks.

Left IV pole	5 kg
Substituate / dialysate scale, each	12 kg
Right IV pole	6 kg

The device can be disconnected from the power supply by pulling out the power plug. The device indicates a power failure. The audible alarm can be suppressed for 2 minutes by pressing the **[Mute]** key. The device must be relocated as fast as possible, as battery operation is only possible for a limited time.

After relocating

Establish the voltage supply and confirm the alarm by pressing the **[START/RESET]** key.

Briefly perform the following checks:

– Check the connectors.
– Ensure that the filtrate bag hangs freely and does not touch any other objects.
– Visually check the tubing systems (cassette) and the solution bags for damage, leakage, and proper fit.
– Pay particular attention to "Application principles" chapter (see chapter 4.1 on page 4-1).

10.2 Transport

In general, the device has to be transported without any lines inserted and any load on the scales.

The device must not be carried. Use a lift, ramp, or similar to overcome level differences.

If the device needs to be transported to a location that is not within the immediate vicinity of its current location, then the relocation goes beyond the scope of the previous section. In this case, the full initial start-up procedure must be performed again at the destination.

When transporting the haemodialysis system in a vehicle, always protect it with the appropriate packing materials and place it either vertically or horizontally.

10.3 Storage

Note

To ensure that the internal battery is always charged and ready for use, the device has to be supplied with line voltage and the power switch has to be turned on.

The device must be stored upright in a well-ventilated room with low variations in temperature.

Maintenance of the built-in battery

On receipt of the device, charge the battery as follows:

– Use the power cable to connect the device to the power supply.
– Actuate the power switch to turn the device on.
– Leave the device on for 10 hours.

If the device is not used, repeat this procedure every six months.

- **Storage conditions**

Temperature	–20 °C to 60 °C
Relative humidity	30% to 75%, temporarily 95%
Atmospheric pressure	500 hPa to 1060 hPa

10.4 Environmental compatibility and disposal

10.4.1 Information for the responsible organisation

Within the EU member-states, the device must be disposed of in accordance with the "Directive on waste electrical and electronic equipment" (WEEE Directive). Please also observe the applicable local legal regulations.

Before returning or disposing of the device, the responsible organisation must ensure that all consumables fixed to the device are removed and that the device has been disinfected as specified by the manufacturer (see chapter 6 on page 6-1).

The responsible organisation must inform the facility in charge of dismantling and disposing of the device of the following before the disposal measures begin:

– There is a potential risk that the device is contaminated when it is returned. Therefore, the appropriate precautionary measures must be taken when dismantling the product, such as wearing personal protective equipment.

10.4.2 Information for recycling and waste disposal facilities

Within the dismantling and disposal process, the recycling and waste disposal facilities must observe the following information:

For information on the materials used, consult the relevant chapter (see chapter 12.12 on page 12-16).

Batteries and rechargeable batteries must be properly disposed of in accordance with the applicable local regulations.

The device includes electronic circuit boards and an LCD screen.

More information will be made available to waste disposal facilities on request.

11 Technical Safety Checks / maintenance procedures

11.1 Important information on the Technical Safety Checks / maintenance procedures

Technical Safety Checks (TSC)

The first TSC are required before the end of the 24th month following initial start-up after delivery from the factory. All additional TSC are required before the end of the 24th month following the last TSC performed.

Maintenance procedures (MA)

The maintenance procedures (MA) are a recommendation of the manufacturer. The maintenance procedures help ensure trouble-free operation, and must be carried out for the first time before the end of the 24th month following initial start-up after delivery from the factory. All additional maintenance procedures are required before the end of the 24th month following the last maintenance procedure performed.

Qualification requirements of testers

The checks must only be performed by the manufacturer's service support organisation or a person authorised by it.

The checks may only be performed by personnel qualified to perform them correctly based on their education, training, knowledge, and experience. Furthermore, the personnel performing the checks must be permitted to do so independently and without outside interference.

Specifications

Any information on the specifications must be observed.

Documentation

The Technical Safety Checks, the maintenance points, and further procedural information are described in the Service Manual.

Reports are available on request.

The completion of the Technical Safety Checks must be entered in the Medical Device Register.

12 Specifications

For extended specifications, please refer to the "Specifications" chapter in the Service Manual.

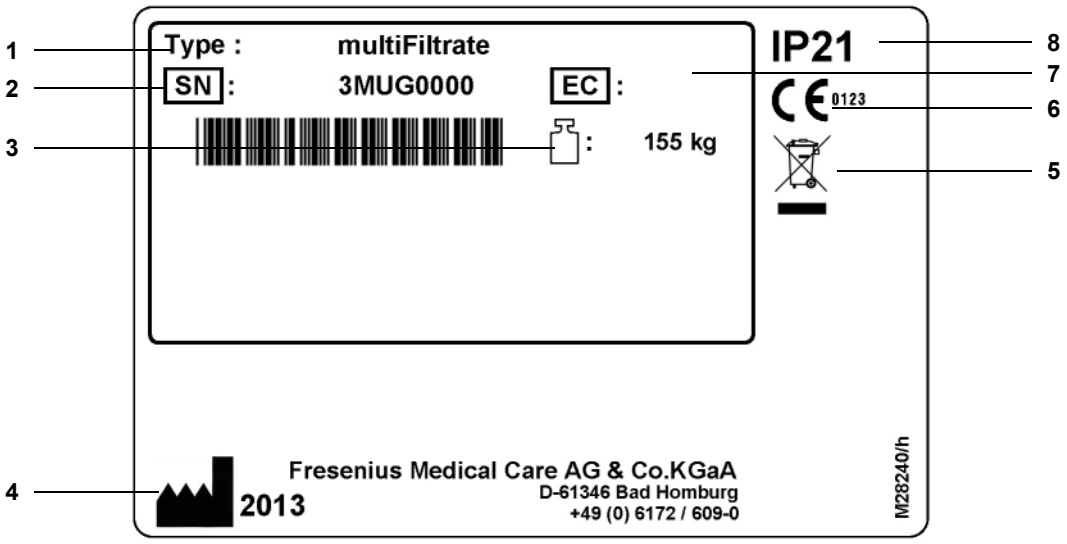
12.1 Dimensions and weight

Dimensions	Height: 172 cm (140 cm without IV poles and scales trays) Width with Ci-Ca module: 75 cm (65 cm without IV poles) Width without Ci-Ca module: 65 cm (57 cm without IV pole) Depth: 65 cm
Weight	Weight with options: approx. 100 kg Safe working load: 55 kg Maximum weight: approx. 155 kg
IV pole load-bearing capacity	Total IV pole load-bearing capacity: max. 6 kg Hook load-bearing capacity: max. 5 kg

12.2 Identification label

12.2.1 Identification label of the device

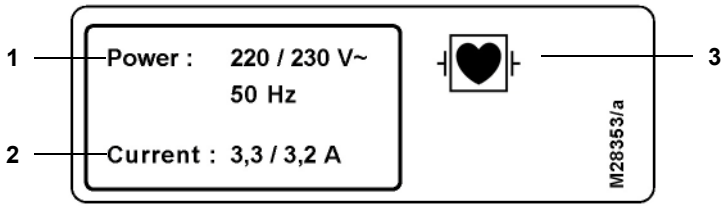
The identification label shown is only an example. Always go by the information shown on the identification label affixed to the device itself.



Legend

1 Type identification
2 Serial number
3 Maximum total weight
4 Manufacturer and year of manufacture
5 Identification of electric and electronic devices
6 CE marking
7 Equipment code (EC: Equipment Code)
8 Protection rating IP 21
2: Protection against touch and foreign bodies with a diameter of at least 12.5 mm
1: Protection against ingress of liquids: Drip-proof

12.2.2 Voltage label

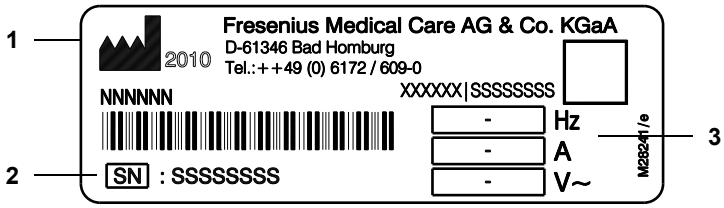


Legend

1 Connected load
2 Operating current
3 Degree of protection against electric shock

12.2.3 Identification label of the Ci-Ca module

The identification label shown is only an example. Always go by the information shown on the identification label affixed to the Ci-Ca module itself.



Legend

1 Manufacturer and year of manufacture

2 Serial number

3 Connected load

12.3 Electrical safety

Classification according to EN 60601-1, IEC 60601-1

Type of protection against electric shock

Protection class I with internal power source

Applied part

Depending on the treatment mode, the applied part comprises the extracorporeal blood circuit, the dialysate, substituate, and plasma circuits, and all components with a permanent, conductive connection to these circuits.

Degree of protection against electric shock

220 V / 230 V / 240 V
60 Hz, type BF applies

100 V / 110 V / 115 V / 120 V / 127 V
60 Hz, type CF applies

100 V / 110 V / 115 V / 120 V / 127 V / 220 V / 230 V / 240 V
50 Hz, type CF applies

Defibrillator-proof applied part

A defibrillator-proof applied part prescribes the exclusive application of disposables as approved by the manufacturer.

Samples of approved tubing systems are listed in chapter 8 (see chapter 8.1.1 on page 8-2).

Degree of protection against ingress of liquids

Drip-proof, IP 21

Leakage currents

According to EN 60601-1

12.4 Electrical supply

Line voltage	100 V AC, 50–60 Hz, 6.3 A 110 V AC, 50–60 Hz, 6.0 A 115 V AC, 50–60 Hz, 5.5 A 120 V AC, 50–60 Hz, 5.4 A 127 V AC, 50–60 Hz, 5.2 A 220 V AC, 50–60 Hz, 3.3 A 230 V AC, 50–60 Hz, 3.2 A 240 V AC, 50–60 Hz, 2.7 A (Always go by the line voltage, frequency, and operating current information specified on the identification label attached to the device itself.)
Power supply (internal)	+24 V / 18 V, battery-backed, derived from this voltage: +5 V ±0.2 V +12 V ±0.3 V -12 V ±0.3 V +24 V +1 V / –2 V
Power switch	Main power switch, all-pole, simultaneous disconnection
Battery	Lead-acid battery (maintenance-free), 18 V / ≥3 Ah Operating time approx. 15 minutes Blood circuit only, without balancing, without heater

12.5 Information on electromagnetic compatibility

12.5.1 Minimum distances between radiated interference source and the device

Medical electrical devices are subject to special precautionary measures with regard to electromagnetic compatibility (EMC).

Portable and mobile high-frequency RF communication equipment is a source of radiated electromagnetic interference that can affect medical electrical devices. This can lead to device malfunctions.

For this reason, a certain minimum distance must be kept between radiated interference sources in the vicinity of running medical electrical devices.

Warning

Patient hazard due to device malfunction

Using accessories or lines other than those specified in the Instructions for Use can lead to increased emitted interference or reduced interference immunity of the device.

➢ Check the suitability of accessories and lines which are not specified in the Instructions for Use.

Warning

Patient hazard due to possible device malfunction

A device malfunction can be caused by high-frequency electromagnetic waves (radiated interference source).

➢ Observe the minimum required distances for radiated interference sources.

For further information on "Guidance and manufacturer's declaration on EMC", refer to the Service Manual.

Minimum distances between radiated interference source and medical electrical devices

RF transmission technology	Minimum distance from medical electrical devices, including all connecting cables	Radiated interference source (examples) (One device / radiated interference source may use more than one RF transmission technology.)
GSM (Global System for Mobile Communications)	3.3 m	Cell phone, smartphone, tablet computer
UMTS (Universal Mobile Telecommunications System)		
LTE (Long-Term Evolution)		
DECT (Digital Enhanced Cordless Telecommunications)	1.2 m	Cordless phone
WLAN (Wireless Local Area Network)	0.7 m	Notebook / laptop, desktop computer, e-book reader, WLAN repeater, WLAN router, WLAN access point, WLAN print server
Bluetooth	0.2 m	Wireless keyboard, wireless mouse, wireless loudspeakers
Radio	0.1 m	Radio remote control (except device-specific radio remote controls by the manufacturer)

If a source of radiated interference uses a radio frequency technology not specified in the table, the required minimum distance to medical electrical devices can be obtained from the manufacturer.

12.5.2 Guidance and manufacturer's declaration on EMC

The information refers to the requirements of IEC 60601-1-2:2007.

- **Electromagnetic emissions**

Guidance and manufacturer's declaration on electromagnetic emissions		
The multiFiltrate device is designed for operation in an electromagnetic environment as specified below. The customer or operator of the multiFiltrate device should ensure that it is operated in such an environment.		
Interference emission measurements	**Compliance**	**Electromagnetic environment – guidelines**
RF emissions according to CISPR 11	Group 1	The multiFiltrate uses RF energy exclusively for its internal functions. As a result, its RF emissions are very low and it is unlikely that it will interfere with neighboring electronic devices.
RF emissions according to CISPR 11	Class B	The multiFiltrate device is suitable for use in all establishments, including private homes. These establishments must be directly connected to a public power supply network which also supplies power to buildings used for residential purposes.
Harmonic current emissions according to IEC 61000-3-2	Class A	
Emissions from voltage fluctuations / flicker according to IEC 61000-3-3	Compliant	

- **Electromagnetic interference immunity**

Guidance and manufacturer's declaration on electromagnetic interference immunity			
The multiFiltrate device is designed for operation in an electromagnetic environment as specified below. The customer or operator of the multiFiltrate device should ensure that it is operated in such an environment.			
Interference immunity tests	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidelines**
Electrostatic discharge (ESD) according to IEC 61000-4-2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	Floors should be made of wood or concrete or fitted with ceramic tiles. If the floor is fitted with a synthetic material, the relative humidity must be at least 30%.
Electrical fast transient / burst immunity according to IEC 61000-4-4	±2 kV for power lines ±1 kV for input and output lines	±2 kV for power lines ±1 kV for input and output lines	The quality of the supply voltage should correspond to that of a typical commercial and / or hospital environment.
Surge voltages according to IEC 61000-4-5	±1 kV differential mode voltage ±2 kV common mode voltage	Not applicable ±2 kV common mode voltage	The quality of the supply voltage should correspond to that of a typical commercial and / or hospital environment.

Voltage dips, short interruptions, and voltage variations according to IEC 61000-4-11	< 5% U_T (> 95% dip of the U_T) for 0.5 periods 40% U_T (60% dip of the U_T) for 5 periods 70% U_T (30% dip of the U_T) for 25 periods < 5% U_T (> 95% dip of the U_T) for 5 seconds	< 5% U_T (> 95% dip of the U_T) for 0.5 periods 40% U_T (60% dip of the U_T) for 5 periods 70% U_T (30% dip of the U_T) for 25 periods < 5% U_T (> 95% dip of the U_T) for 5 seconds	The quality of the supply voltage should correspond to that of a typical commercial and / or hospital environment. If the operator of the multiFiltrate device requires continuous operation, even in the event of interruptions in the energy supply, it is advisable to supply the multiFiltrate using an uninterruptible power supply or a battery.
Power frequency magnetic fields (50 / 60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should correspond to the typical values found in the commercial and hospital environment.
Note: U_T is the AC voltage before the test level is applied.			
Conducted RF disturbances according to IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	3 V_{eff}	Portable and mobile radio devices should not be any closer to the multiFiltrate device (including the lines) than the recommended safety distance, which is calculated according to the relevant equation for the transmission frequency. **Recommended safety distance:** $d = 1.2 \sqrt{P}$ For 150 kHz to < 80 MHz
Radiated RF disturbances according to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ For 80 MHz to < 800 MHz $d = 2.3 \sqrt{P}$ For 800 MHz to 2.5 GHz Where P is the nominal power of the transmitter in watts (W) in accordance with the information from the transmitter manufacturer and d is the recommended safety distance in meters (m). In accordance with an investigation on site[a], the field strength of stationary transmitters should be lower than the compliance level for all frequencies[b].  Interference is possible in the vicinity of devices which have this symbol.

Note: These guidelines may not be applicable in all cases. The diffusion of electromagnetic variables is influenced by absorption and reflections in the building, objects, and people.

a In theory, the field strength of stationary transmitters, such as base stations for cellular phones and land mobile radios, amateur radio stations, AM and FM radio, and TV transmitters, cannot be predetermined precisely. To determine the electromagnetic environment with regard to stationary transmitters, consider carrying out a study of the site. If the measured field strength at the site where the multiFiltrate device is used exceeds the aforementioned compliance level, the multiFiltrate should be observed in order to verify that it is working as intended. If unusual performance characteristics are observed, additional measures may be necessary, such as a different alignment or a different site for the multiFiltrate device.

b Above the frequency range of 150 kHz to 80 MHz, the field strength should be lower than 3 V/m.

- **Recommended safety distances between portable and mobile RF telecommunication devices and the multiFiltrate device**

Recommended safety distances between portable and mobile RF telecommunication devices and the multiFiltrate device

The multiFiltrate device is designed for operation in an electromagnetic environment in which RF disturbances are controlled. The customer or operator of the multiFiltrate device can therefore help to prevent electromagnetic interference by maintaining the minimum distance between portable and mobile RF telecommunication devices (transmitters) and the multiFiltrate device. This minimum distance depends on the output power of the communication device, as specified below.

Nominal power of the transmitter W	**Safety distance depending on the transmission frequency (m)**		
	150 kHz to < 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to < 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters whose maximum nominal power is not specified in the table above, the recommended safety distance "d" (in meters, (m)) can be determined using the equation which belongs to the relevant column, where "P" is the maximum nominal power of the transmitter in watts (W) in accordance with the information of the transmitter manufacturer.

Note: These guidelines may not be applicable in all cases. The diffusion of electromagnetic variables is influenced by absorption and reflections in the building, objects, and people.

12.6 Operating conditions

Operating temperature range	15 °C to 35 °C
Atmospheric pressure	700 hPa to 1060 hPa
Relative humidity	30% to 75%, temporarily 95%, non-condensing

Installation altitude	Maximum installation altitude up to 3000 m
Stability	Maximum admissible inclination 5°

12.7 Storage conditions

The device must be stored upright in a well-ventilated room with low variations in temperature.

Temperature	–20 °C to 60 °C
Relative humidity	30% to 75%, temporarily 95%
Atmospheric pressure	500 hPa to 1060 hPa
Maintenance of the built-in battery	On receipt of the device, charge the battery as follows: – Use the power cable to connect the device to the power supply. – Actuate the power switch to turn the device on. – Leave the device on for 10 hours. If the device is not used, repeat this procedure every six months.

12.8 External connection options

Other additional equipment connected to this device must comply with the applicable IEC or ISO standards (e.g., IEC 60950-1 for information technology equipment).

Furthermore, all device configurations must comply with the requirements specified by medical system standards (see chapter 16 and appendix I to EN 60601-1:2006).

Connecting the device to an IT network that contains components not installed and validated by the manufacturer can introduce unknown risks for patients, operators, or third parties. These risks must be identified, analysed, evaluated, and monitored by the responsible organisation. For assistance, refer to IEC 80001-1:2010 and annexes H5 and H6 of EN 60601-1:2006.

Any modifications to an IT network that has been installed and validated by the device manufacturer can introduce new risks and therefore require a repeat analysis. Especially problematic activities include:

– Changes to the IT network configuration

– Connection of additional components and devices to the IT network

– Removal of components and devices from the IT network

– Updates or upgrades of components and devices in the IT network

Note that local laws take priority over the above-mentioned normative requirements. Please address any queries to the local service support organisation.

LAN	Interface for data exchange. Electrically isolated by transformer. Connector: RJ 45 Category: CAT5 or better Length: 3 m Only devices complying with the regulations of (DIN) EN 60950-1:2006 or IEC 60950-1:2006 may be connected to the LAN ports.
RS232	Serial interface for service. Electrically isolated by optocoupler. Connector: 9-pin DSUB Length of serial line: Max. 3 m, shielded
Alarm output	For the connection of an external alarm indicator (staff call). (Potential-free alarm output. Alternating contact maximum 24 V / 24 W.) Connector: 3-pin diode plug via a shielded line; shield earthed on either side. Only the cable from the original accessories may be used. The device does not monitor whether a signal is transferred successfully to an external alarm indicator. Connecting an external alarm indicator does not influence whether visual and acoustic alarms are generated at the device.

Warning

Patient hazard due to missed alarm signals

Do not rely on external alarm signals as there is no guarantee that the alarm signals will be transferred from the device to external alarm indicators.

➢ Observe the information on processing alarms (see chapter 5 on page 5-1).

➢ Always stay close enough to the device that you will notice alarm signals at any time.

12.9 Operating programs

Functional test	Automatic test for verification of the safety systems. Starts automatically every time the device is turned on. The functional test is mandatory after turning the device power on (not after a power failure).
Preparation	Defined by the optical detector located below the venous bubble catcher. Preparation is terminated as soon as the optical detector senses opaque fluid in the blood line system.
Priming the tubing systems	Automatic priming and deaeration of the tubing systems by pressing a key. Priming will stop automatically as soon as the venous bubble catcher is filled.

Rinse / recirculation	Rinse volume: 0 ml to 5000 ml, can be set in the System parameters menu UF rinse: 300 ml to 2000 ml, can be set in the System parameters menu
Treatment	SCUF, CVVH, Pre-Post CVVH, CVVHDF, CVVHD, MPS, and HP
Bag change	Minimum plasma volume 50 ml
End of treatment / reinfusion	Reinfusion volume: 0 ml to 2000 ml, can be set in the System parameters menu
System parameters	After the functional test and selection of the therapy, the audible alarm volume, the display brightness, the key sounds, and the default values for the treatment can be defined in the Setup menu at any time. Selection of the treatment modes is inhibited whilst treatment is in progress. It is only possible to select the blood line system and to set date and time before priming / rinsing starts.
Audible alarm	Adjustment range of the sound pressure level in the System parameters menu is 65 dBA (20%) to 84 dBA (100%).

12.10 Balancing / dialysate circuit and safety systems

Blood leak detector	Response threshold smaller than or equal to 0.5 ml blood loss per minute at a haematocrit of 32% at maximum filtrate flow. Optical adsorption system (red / green ratio). The response threshold is related to the maximum filtrate flow. The initiation of a blood leak alarm also depends on the ultrafiltration rate and the size of the membrane rupture in the filter.
Flow rates	Depending on the treatment mode:

Blood flow*	10 ml/min to 500 ml/min ±10%
Substituate flow*	10 ml/min to 80 ml/min, controlled
Dialysate flow*	10 ml/min to 80 ml/min, controlled
Plasma exchange rate*	10 ml/min to 50 ml/min, controlled
Ultrafiltration rate*	0 ml/min to 30 ml/min, controlled
Filtrate rate	10 ml/min to 180 ml/min, controlled

The delivery accuracy of the replaceable pumps is ± 10%, unless regulated by the scales. If regulated (for treatment procedures with scale balancing), the individual delivery accuracy of each pump depends on the accuracy of the associated scale. In this case, the total delivery accuracy corresponds to the specified balancing accuracy.

Balancing / dialysate circuit	< 1% related to the total volume delivered during 24 hours of treatment, in horizontal position and with a maximum inclination of 5°. A deviation of ±100 ml is possible if the total volume delivered is low (typically up to 5000 ml).

Maximum balancing error during treatment

If the total balancing error exceeds 500 g / adult's treatment (50 g / paediatric treatment), the treatment must be terminated.

In normal operation (scale balancing active and error-free), even a deviation of only a few grams (depending on the flow rate) from the target value will result in a balancing warning. Malfunctions (defective scales or minor leaks) can result in larger deviations.

– Max. balancing deviation < 100 ml/h
– Greater deviations are detected within a total maximum volume deficit of 400 g (functional test of scales)

Balancing error

E = EUF + ESUB

E = balancing error
EUF = ultrafiltration error
ESUB = substitution error

Scale system

For each scale:
Max. loading capacity: 12 kg
Weighing range: 0 kg to 12 kg
Resolution: 1 g
Max. linearity deviation: ≤ ±1%

Substituate / dialysate temperature*

Treatment modes: CVVH, Pre-Post CVVH, CVVHD and CVVHDF:

Adjustment range (target temperature): 35 °C–39 °C
Resolution: 0.5 °C
Standard accuracy: +1 °C / –2 °C (on average)

The temperature at the filter depends on the flow rate plus the temperature of the solution and the environment.

– There are two alarm threshold values. If values temporarily exceed an inflow temperature of 42 °C, an override period begins without an immediate alarm. Once 5 seconds have passed, an alarm is triggered and the fluid inflow is stopped, which must be acknowledged. If values continue to exceed 42 °C, the alarm is triggered again after 5 seconds. Another alarm is triggered once the inflow temperature reaches 46 °C. This also results in the halting of the fluid inflow. The alarm can be acknowledged, but is triggered immediately again if the inflow temperature remains > 46 °C. Once the "absolute" temperature threshold has been exceeded, the heating system remains switched off for a period of 30 seconds.

Donor plasma temperature (FFP)*

Treatment mode: MPS:

– If the solution enters the system with a temperature of 20 °C and the maximum plasma rate is 50 ml/min, a temperature of 37 °C will be reached.
– The donor plasma (FFP) must be warmed to a minimum temperature of 20 °C prior to the treatment.

(* = Important performance characteristics according to IEC 60601-1)

12.11 Extracorporeal blood circuit and safety systems

Pressure transducer (art. / ven. / pre-filter pressure)

A filled pressure transducer is identified by the fact that no more pressure fluctuation is detected at the pressure transducer within 5 minutes (arterial and pre-filter pressure) or 2 minutes (venous).

Arterial pressure

Display range: –280 mmHg to +300 mmHg
Resolution: 20 mmHg
Accuracy: 10 mmHg
Alarm window width: 20 mmHg to 200 mmHg, size and position adjustable around actual pressure

Venous pressure
System safeguarding against blood loss into the environment

Display range: –80 mmHg to +500 mmHg
Resolution: 20 mmHg
Accuracy: 10 mmHg
Alarm window width: 20 mmHg to 200 mmHg, size and position adjustable around actual pressure

Minimum alarm limits:
The optical detector senses non-opaque fluid: –20 mmHg during treatment
The optical detector senses opaque fluid: 0 mmHg during treatment
The optical detector senses opaque fluid: –20 mmHg when disconnecting

When the upper venous alarm limit is exceeded, the venous clamp will not be closed to allow for release of the pressure in the system. In the event of a simultaneous air detector alarm, the clamp will close.

TMP

Display range: –60 mmHg to +520 mmHg
Resolution: 20 mmHg
Accuracy: 10 mmHg
Alarm window width: 20 mmHg to 200 mmHg, size and position adjustable around actual pressure
In MPS, the upper alarm limit is limited to 100 mmHg.
The TMP will be calculated using the following formula and will then be displayed:

$$TMP = \frac{P_{ven} + P_{PHF}}{2} - P_{Fil}$$

TMP = transmembrane pressure
Pven = venous pressure
P_{pHF} = pre-filter pressure
P_{Fil} = filtrate pressure

pF

Display range: –60 mmHg to +520 mmHg
Resolution: 20 mmHg
Accuracy: 10 mmHg
Alarm window width: 20 mmHg to 200 mmHg, size and position adjustable around actual pressure
The pF is calculated using the following formula and then displayed:

$$pF = P_{pHF} - P_{ven}$$

pF = pressure from filter
P_{ven} = venous pressure
P_{pHF} = pre-filter pressure

Pre-filter pressure

Measuring range: –50 mmHg to +750 mmHg
For haemoperfusion: –50 mmHg to +500 mmHg

Blood pump

Delivery rate: 10 ml/min to 500 ml/min
(MPS: 10 ml/min to 300 ml/min)
(Citrate anticoagulation: 10 ml/min to 200 ml/min)
(Paed. treatment: 10 ml/min to 100 ml/min)
Control accuracy: ±5%
Inner line diameter: 6.4 mm

System accuracy of the delivered blood volume: ±10% over the complete duration of the treatment for typical treatment situations.

Warning

Reduced treatment effectiveness

If the arterial pressure before the blood pump reaches extreme negative values, the blood flow may be reduced, which will affect the effectiveness of the treatment.

Time-based standstill monitoring as a safety system against blood loss through coagulation.

Operator stops the blood pump with the **[STOP]** key; immediate visual alarm, acoustic alarm after 2 minutes.

Air detector

Response threshold: drop of the fluid level, air bubbles, foam or microfoam (blood / air mixture) over the entire blood flow range of 0 ml/min to 300 ml/min or 500 ml/min
Method: ultrasonic transmission

Heparin pump

Pump type: syringe pump
Delivery rate: 0.1 ml/h to 25 ml/h
Resolution: 0.1 ml/h
Accuracy: ±5% for a delivery rate of 1 ml/h to 25 ml/h and a measurement time of 2 hours up to a counterpressure of 1.2 bars (calibrated for 30 ml Fresenius heparin syringes). With delivery rates < 1.0 ml/h, the tolerance may exceed the specified ±5% accuracy.
Bolus administration: 0.5 ml to 5 ml in increments of 0.1 ml (the maximum bolus amount to be injected is preset to 5 ml. This parameter can be set to smaller volumes in the System parameters screen).

Ci-Ca drop counter

Measuring range: 0 to 5 drops / second

Citrate pump*

Pump type: roller pump
Delivery accuracy: pressure-dependent, ±10% (above typical pressure range); for delivery rates < 6 ml/h, the deviation can be ±20%
Delivery rate: 10 to 600 ml/h (citrate / blood ratio: citrate concentration per litre of delivered blood: 2–6 mmol/l)

Calcium pump*

Pump type: roller pump
Pumping accuracy: pressure-dependent, ±10% (above typical pressure range)
Delivery rate: 0; 1 ml/h to 100 ml/h (calcium / filtrate ratio: calcium concentration per litre of filtrate: 0 mmol/l to 3 mmol/l)

While the Ci-Ca tube segments are threaded in / removed and the Ci-Ca tubes are primed, the Ci-Ca pumps are running with higher delivery rates.

(* = Important performance characteristics according to IEC 60601-1)

12.12 Materials used

Plastics

CR neoprene
NBR (Buna-N)
PA 6.6 (polyamide)
PC Gfn (Makrolon)
PE (Hostalen)
POM (Delrin)
PS (polystyrene)
PVC tube, transparent
Silicone tube, transparent, reinforced
E-HGW 2372.1 (epoxy resin laminated plastic)
Cast resin WEVO PU 127F/30
PUR hard foam (BÜFADUR 1011/1151 with flame retardant)

Metals

Al 99.5
AlCuMgPb
AlMg3
AlMgSi 0.5
AlMgSi 1
CuBe
SF-Cu hard, oxygen-free
CuZn (Ms 63)
St 37-2, 1.0035 galvanised
Steel, 1.4301
Steel, 1.4305
Spring steel, 1.4310

Electrical equipment

Motors:
Copper, cast steel, cast zinc

Stepper motors with plastic gear

Plug connectors:
Copper, tin, plated gold, glass-fiber-reinforced thermoplastic

Transformers:
Copper, polyester / polyurethane, potting compound (PU 151/20), UP resin, iron core

	Cables: Copper, PVC, Teflon Electronics: Electronic circuit boards LCD screen Lithium battery Lead-acid rechargeable batteries Adhesives: Loctite 638 Ergo 5011 Universal (high-speed adhesive) Pattex (Henkel) Stabilit Express (Henkel)
Lacquers	Insulating lacquer: ICS MODE, green, Kiroff, Fürth Primer: Warneckol Super-M-Primer, Warnecke & Böhm, Schliersee Dilution: ZANSI - 150024, Warnecke & Böhm, Schliersee Coating varnish: Durotec pur Plus, Warnecke & Böhm, Schliersee Dilution: Durotec 550007, Warnecke & Böhm, Schliersee Hardener: Pur-Plus hardener 540001, Warnecke & Böhm, Schliersee Coating varnish: 2K structural varnish, SW-Color, Bindlach Hardener: 2K hardener 3500, SW-Color, Bindlach Dilution: 2K dilution, SW-Color, Bindlach
Packaging	Corrugated cardboard, collapsible cardboard box Polyethylene, cellular rubber, internal packing

13 Definitions

13.1 Terms

Filtrate or filtrate flow

Filtrate or filtrate flow is the sum total of the dialysate, substituate, net UF, citrate flow, and calcium flow. The filtrate or filtrate flow forms the basis for the calculation of the calcium flow and is internally calculated by the system.

Acute haemodialysis treatment

Acute haemodialysis is the application of a hemodialysis therapy for the treatment of temporary renal failure or acute exogenous poisoning.

Alarm function check

The alarm function check is the verification of the proper function of the alarm equipment.

Alarm limit

The alarm limit is the measurement value which, when exceeded, will trigger an alarm.

Arterial section

The arterial section is the section of the extracorporeal circuit from the patient to the dialyser inlet port.

Arterial pressure

The arterial pressure is the pressure present at a defined site in the arterial section between the vascular access and the pump.

Exchange volume

The exchange volume is the fluid volume removed from the blood by filtration which is replaced with substituate at a ratio of 1:1.
(The respective rate is indicated in ml/h or ml/min.)

The respective rate is the indicator at which speed the exchange is performed.

Treatment time

The treatment time is the amount of time during which balancing is switched on.

Blood leak monitor

The blood leak monitor is a device used to detect blood in the filtrate or dialysate, e.g., consisting of a sensor (detector), alarm generator, and a sensitivity indicator, and controller, if necessary.

Blood pump

The blood pump is provided to transport the blood in the extracorporeal circuit.

Calcium pump

The calcium pump is used for adding calcium solution to the patient's blood.

Calcium dose

The calcium dose is the volume of calcium solution added to the patient's blood in relation to the filtrate or filtrate flow. The dose is specified in mmol per litre of filtrate (filtrate flow).

Calcium flow

The calcium flow is the volume of calcium solution supplied to the patient's blood per time unit.

Calcium rate	(see **Calcium flow** on page 13-1)
Citrate pump	The citrate pump is used for adding citrate solution to the patient's blood.
Citrate dose	The citrate dose is the volume of citrate solution added to the patient's blood in relation to the blood flow. The dose is specified in mmol per litre of blood.
Citrate flow	The citrate flow is the volume of citrate solution supplied to the patient's blood per time unit.
Citrate rate	(see **Citrate flow** on page 13-2)
Dialysate	Dialysate is the fluid used in haemodialysis that flows countercurrent to the blood and is separated from the blood only by a filter membrane.
Diffusion	Diffusion is the term used to describe the change in concentration of the solutes as they are transported in the solutions.
Insertion switch	The insertion switches are provided in the pump beds of the citrate and calcium pumps. The system uses the insertion switches to detect whether or not the respective Ci-Ca tube pump segments have been correctly inserted.
Extracorporeal circuit	The extracorporeal circuit is the section of the blood circuit outside the body.
Filtrate bag	The filtrate bag is the collection bag for the filtrate (ultrafiltrate).
Filter life	The filter life is the total time during which the blood pump is running.
Filtration	Filtration is the convective flow of solutes, e.g., water, across a membrane, which occurs in response to a hydrostatic and / or osmotic pressure gradient. Dissolved particles are also carried along (convective transport) if they are not retained by the membrane.
Haemodialysis	Haemodialysis is the diffusive exchange process between the dialysate and the blood in an extracorporeal circuit.
Haemofiltration	Haemofiltration is the ultrafiltration of plasma water and its solutes to eliminate endogenous and exogenous toxins and water while simultaneously replacing the ultrafiltrate with appropriate amounts of electrolyte solution.
Heparin pump (anticoagulant pump)	The heparin pump is used for adding the heparin anticoagulant to the patient's blood in the blood circuit.
Convection	Convection describes the transport of solutes together with the solvent (drag effect, e.g., haemofiltration).
ME device	Medical electrical device.
Non-ME device	Non-medical electrical device.
Postdilution	Adding substituate downstream of the haemofilter.

Post-filter calcium concentration	The post-filter calcium concentration indicates the efficacy of the regional citrate anticoagulation and can be used as a control parameter.
Predilution	Adding substituate upstream of the haemofilter.
Substituate	The substituate is the replacement fluid used in haemofiltration.
Systemic calcium concentration	Systemic calcium concentration is the concentration of systemic ionised calcium. This measured value is used to verify and control calcium substitution.
UF volume	The ultrafiltration volume is the fluid volume removed from the blood by filtration which is required for the patient to lose weight. (The removal rate is indicated in ml/h.)
Venous section	The venous section is the section of the extracorporeal circuit from the dialyser outlet port to the patient.
Venous return pressure	The venous return pressure is the pressure at a defined site in the venous section, e.g., in the bubble catcher.

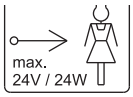
13.2 Abbreviations

Fig.	Figure
AC	Alternating current
BP	Blood pump
Ca	Calcium
Ci	Citrate
CRRT	Continuous renal replacement therapy
CVVH	Continuous venovenous haemofiltration
CVVHD	Continuous venovenous haemodialysis
CVVHDF	Continuous venovenous haemodiafiltration
DC	Direct current
HF	Haemofiltration
HP	Haemoperfusion
Pre-Post CVVH	High-volume continuous venovenous haemofiltration

LED	Light-emitting diode
LD	Air detector
MPS	Membrane plasma separation
OD	Optical detector
SCUF	Slow continuous ultrafiltration
TSC	Technical Safety Checks
TMP	Transmembrane pressure
TPE	Therapeutic plasma exchange
UF	Ultrafiltration
UFR / BFR	Ratio of ultrafiltration rate to blood pump rate

13.3 Symbols

IP 21	Ingress protection rating IP 21 2: Protection against touch and foreign bodies with a diameter of at least 12.5 mm 1: Protection against ingress of liquids: Drip-proof
IP X1	Protection against ingress of liquids: Drip-proof (IP X1)
	Degree of protection against electric shock: Type BF
	Degree of protection against electric shock: Type CF
	Degree of protection against electric shock: Defibrillator-protected applied part, type BF
	Degree of protection against electric shock: Defibrillator-protected applied part, type CF
	Alternating current
	Equipotential bonding connection
	Risk of tilting when inclined by more than 5°

I	ON (supply voltage)
O	OFF (supply voltage)
I/O	ON / OFF
	On / Off (standby)
	10Base-T Ethernet port (LAN)
CE 0123	The CE mark documents compliance with the MDD 93/42 EEC. (MDD: Medical Device Directive) Notified body: TÜV PRODUCT SERVICE 0123
	Identification of electrical and electronic devices
	Alarm output
	Serial interface (RS 232)
	Transmitter
	Manufacturer and year of manufacture
	Manufacturer
	Serial number
	Maximum total weight
	Follow Instructions for Use
	Warning – Risk of tilting when pushing the device or leaning against it
	General warning sign
	Warning – Excessive weight load (observe the maximum load)

Warning – Hot surface

Audible alarm off permanently

Mute

13.4 Consumables symbols

Caution – Consult accompanying documents; general danger

Do not re-use

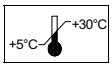
Use by

Batch code

Date of manufacture

Quantity

Catalog number



Temperature limitation

Pump segment diameter

Sterile. Sterilised using ethylene oxide

Sterile. Sterilised using irradiation

Sterile. Sterilised using steam

Max. service life and max. delivery quantity

13.5 Certificates

The local service support organisation can provide the currently applicable version of the EC certificates on request.

14 Options

14.1 Ci-Ca module (option)

Citrate-calcium unit for regional anticoagulation of the patient's blood in the extracorporeal circuit.

14.1.1 Operating programs

Ci-Ca preparation

– Starts with threading in of the citrate and calcium tube segments after citrate anticoagulation has been selected and after the functional test of the multiFiltrate device and the Ci-Ca module has been completed successfully.
– Is completed as soon as the optical detector of the multiFiltrate system senses opaque fluid.

Citrate anticoagulation

– Citrate infusion starts when connection is started.
– Calcium substitution starts as soon as the treatment is started.

Ci-Ca completion

– During the treatment, by deselecting citrate anticoagulation from the Treatment menu ("Deselect Ci-Ca anticoagulation").
– When the optical detector senses non-opaque fluid during reinfusion (end of treatment).

Removing the Ci-Ca tube segments

– After reinfusion (end of treatment) has been completed and the patient has been disconnected, the Ci-Ca tube pump segments can be removed. This is also possible by pressing the [**START/RESET**] key in standby mode.

14.1.2 Ci-Ca alarm management

● **Connection**

Citrate supply is started when the connection process is started. If the optical detector has not sensed opaque fluid after 10 minutes, the citrate supply will be turned off automatically. The citrate supply restarts automatically when the optical detector senses opaque fluid and when the treatment is started.

● **Calcium flow manually set to 0 ml/h / calcium substitution turned off**

No message is displayed.

- **Citrate / calcium rates not matching**

  A warning will be emitted that the rates are not matching and that the ratios / rates have to be adjusted appropriately. If the warning is confirmed without changing the parameters, it will be displayed again every 2 minutes. If the rate is adjusted, but is still not matching, the warning will be displayed again immediately.

- **Balancing off (consequence: calcium pump also stops)**

  After 5 minutes, a warning will be emitted, informing the operator that calcium substitution has been interrupted. After another 5 minutes, an alarm will be emitted, which will be repeated every 2 minutes.

- **HF bag change (consequence: balancing off, calcium pump also stops)**

  (see **Balancing off (consequence: calcium pump also stops)** on page 14-2)

- **Syringe change (consequence: balancing off, calcium pump also stops)**

  (see **Balancing off (consequence: calcium pump also stops)** on page 14-2)

- **Ci-Ca bag change (consequence: balancing off, calcium pump also stops)**

  (see **Balancing off (consequence: calcium pump also stops)** on page 14-2)

- **If calcium bag change is selected**

  An alarm will be emitted if bag change is not completed within 2 minutes of selecting the calcium bag change. This alarm will be repeated every 2 minutes.

- **If citrate bag change is selected**

  An alarm will be emitted if bag change is not completed within 2 minutes of selecting the citrate bag change. This alarm will be repeated every 2 minutes.

14.2 multiDataLink (option) and patient / case ID

To connect to the network of a patient data management system, the multiFiltrate is supplied with a shielded LAN connection cable (Cat. 5 patch cable), measuring 2 m in length. Further cables in various lengths can be ordered if required.

Warning

Data uploaded to a patient data management system must not be used as a basis for diagnosis and / or therapy-related decisions.

Note

The length of the network cable used should be as short as possible to reduce potential interference.

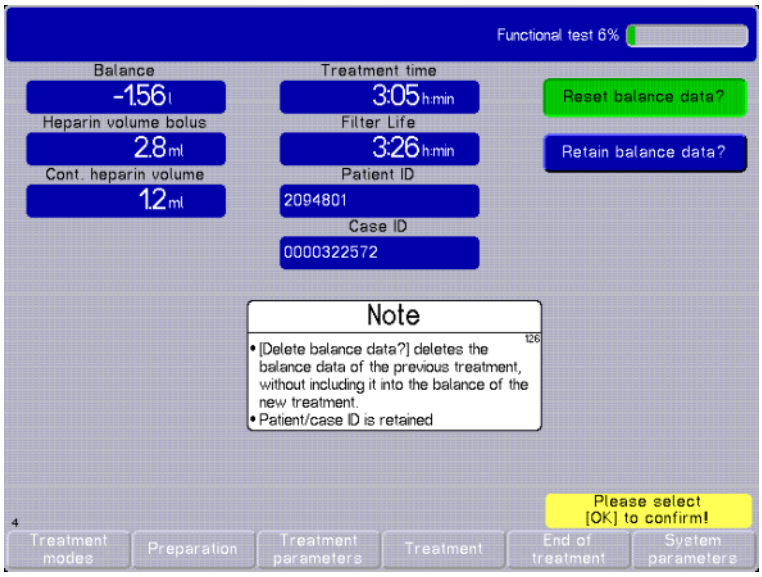
The Cat. 5 LAN connection cables listed in the following are designed to connect the multiFiltrate to a network hub or switch. Direct connection of the acute dialysis device to a PC requires a Cat. 5 crossover patch cable.

14.2.1 Requirements

– The device must be provided with the multiDataLink (mDL) option.
– mDL and patient / case ID have to be activated in the System parameters service menu.

14.2.2 Treatment with patient / case ID

14.2.2.1 Previous treatment, continuing

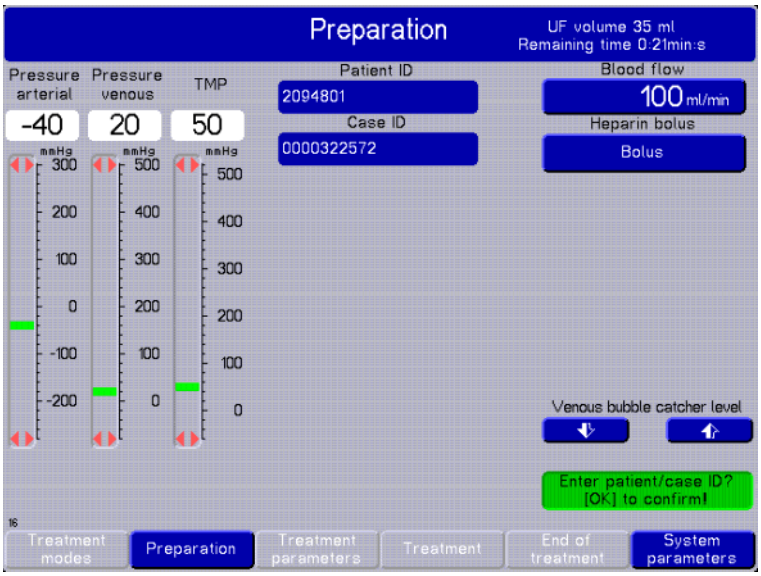


If **Continue previous treatment?** was selected, the data of the previous patient / case ID will be taken and displayed.

The operator has the option to start with or without deleting the balance data.

Use the rotary selector to select the required function and press **[OK]**.

14.2.2.2 Entering the patient / case ID in UF rinse

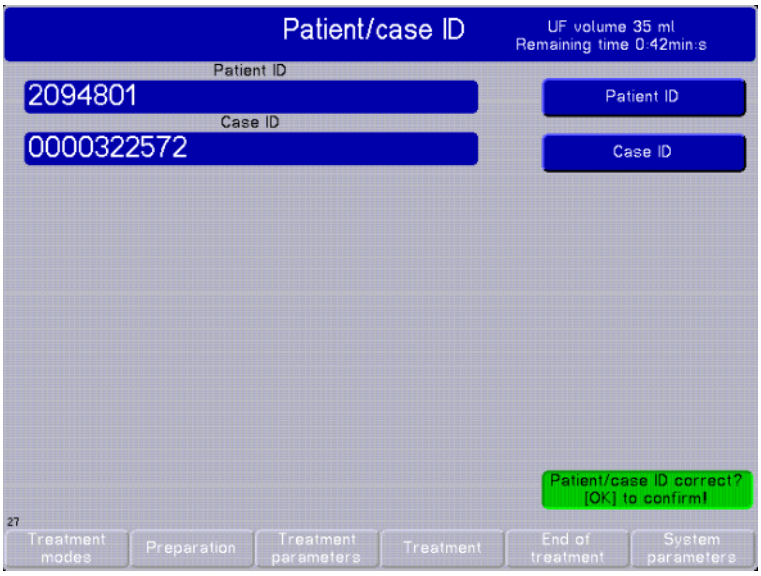


Indication of the decreasing UF volume and the remaining rinse time.

Check the currently used patient ID and case ID.

If no data has been entered yet, the fields are empty.

Use the rotary selector to select **Enter patient/case ID? [OK] to confirm!** and press **[OK]**.



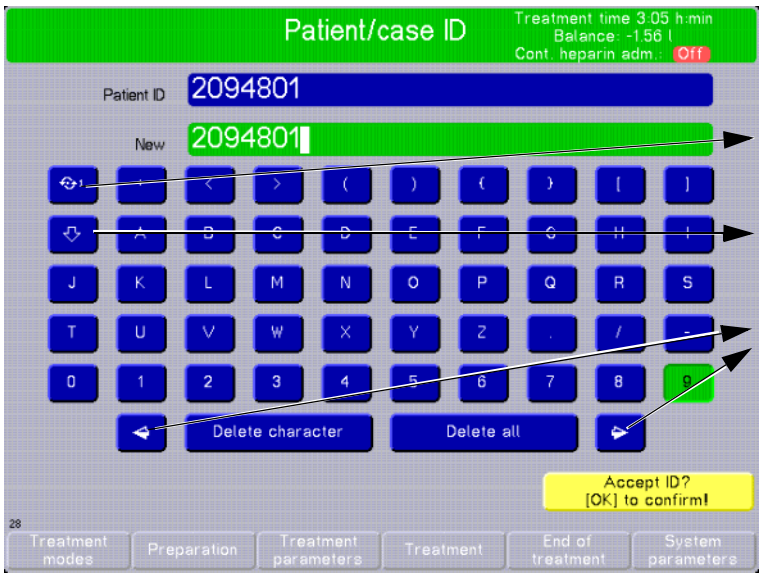
Check the currently used patient ID and case ID.

If no data has been entered yet, the fields are empty.

Use the rotary selector to select **Patient ID** or **Case ID** and press **[OK]** in order to change the patient / case ID.

or

To confirm the patient / case ID, use the rotary selector to choose **Patient/case ID correct? [OK] to confirm!** and press **[OK]**.



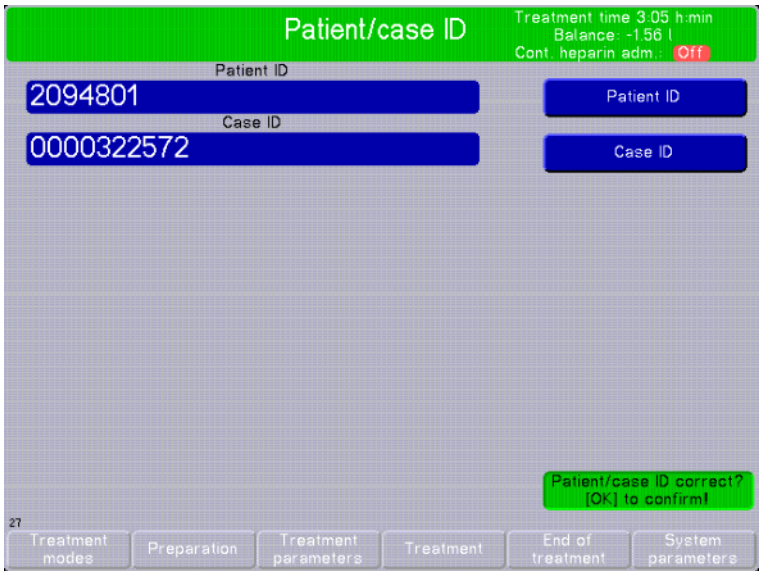
Use the rotary selector to select the required character and press **[OK]**.

Use the round arrow button to select the different special signs.

Use the arrow keys (up / down) to switch from upper to lower-case letters and vice versa.

Use the arrow keys (left / right) to change the position of the cursor in the entry window.

After entering the data use the rotary selector to select **Accept ID? [OK] to confirm!** and press **[OK]**.



After entering and checking the patient ID and / or the case ID, use the rotary selector to select **Patient/case ID correct? [OK] to confirm!** and press **[OK]**.

15 Appendix

15.1 Network

Warning

The network operator is responsible for protecting the device from excessive network load (e.g., by accumulation of broadcast messages or port scans). If necessary, the connection to the network must be established via a router or a firewall, for example.

The system configurer is responsible for the secure further processing of device data, e.g., in PC software applications.

The network operator is responsible for protecting data transferred without encryption.

The data transfer of alarm states via the network must not be used for the purpose of external alerts (staff call).

Warning

Before being applied, the treatment parameters which the device receives via the network or the PatientCard must be checked by the operator for plausibility and compliance with the medical prescription.

The data transfer of alarm states via the network must not be used for the purpose of external alerts (staff call).

Warning

There are special requirements for further processing of the data.

The network operator is responsible for ensuring that the network is available for the required data transfer.

Data corruption affecting the correctness, plausibility, and completeness of the data that is caused by the network and the server software is not detected by the device.

Note

For reasons of data protection, the operator is responsible for the safekeeping of the PatientCard.

15.2 Instructions on the use of "free software"

Content

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We would be happy to send you a CD containing a full machine-readable copy of the source text of the Linux kernel version 2.4.18, including the modified driver DMFE.o, for a period of three years starting at the time when this hemodialysis system was put into circulation (i.e., when the system was acquired). Only the usual copying and transfer costs will be charged. If you want us to send this CD to you, please inform us accordingly, by e-mail, telefax, or mail, under the address given in the Instructions for Use. Please do not forget to specify the system type and the system number.

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Version 2.1, February 1999

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