SILENCIA

Instructions for Use

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Edition: 07A-2022
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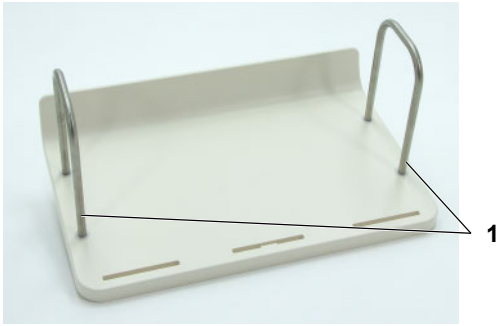
Part no.: F50007972
CE 0123

SILENCIA

FRESENIUS MEDICAL CARE

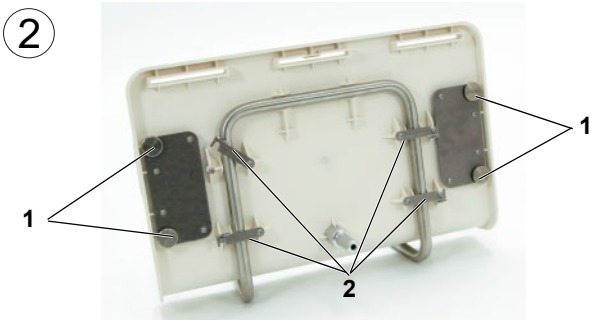
SILENCIA assembly

1



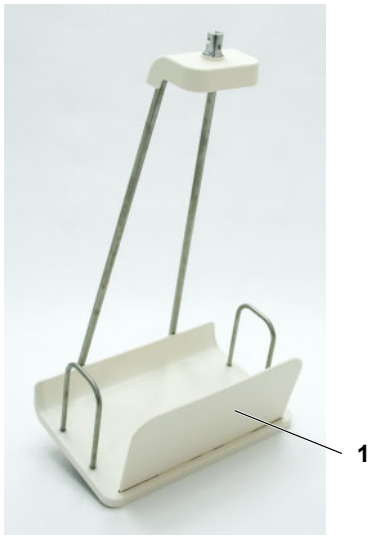
1. Remove the bag rests from the foam insert and place them in the openings provided on the drain tray.

2



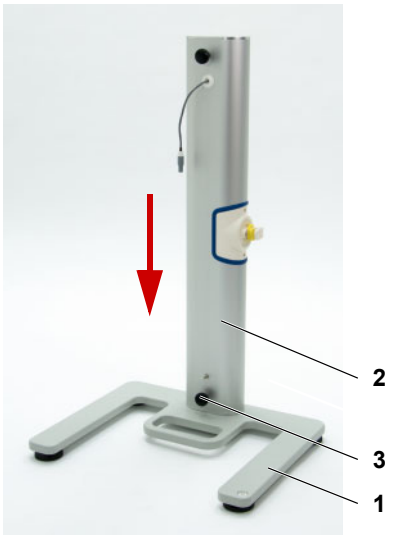
1. Secure each bag rest using two screws each.
2. Position the drain tray on the drain tray suspension and close the four locking levers.

3



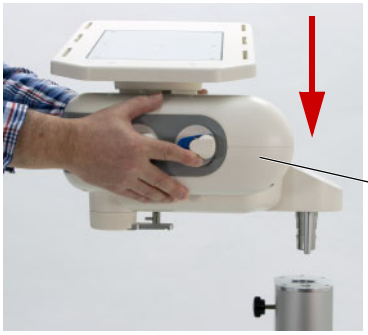
1. Insert the side panel in the drain tray with the peripheral edge facing inwards.

4



1. Place the pedestal on a level surface at the treatment location and align it horizontally.
2. Insert the mounting stand into the pedestal from above.
   Ensure that the mounting stand is the right way round. The plug on the mounting stand must be at the top.
3. Secure the mounting stand to the pedestal by tightening the screw.

5



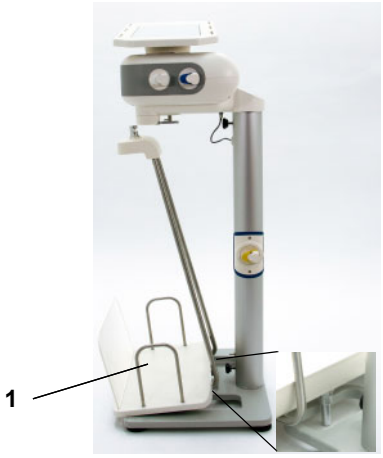
1. Hold the base unit by the sides and fit horizontally to the mounting stand.

   Do not hold the base unit by the heating tray during this step!

6

1. Secure the base unit to the mounting stand by tightening the screw.
2. Insert the mounting stand plug into the socket on the bottom of the base unit.
   Make sure that the plug clicks into place in the socket.

7

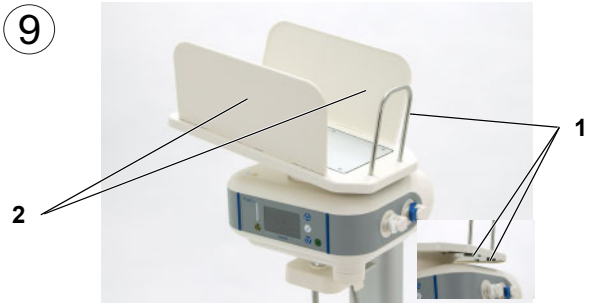


1. Position the drain tray suspension beneath the base unit.
   Place the pin located on the bottom of the drain tray into the rectangular opening in the pedestal.

8

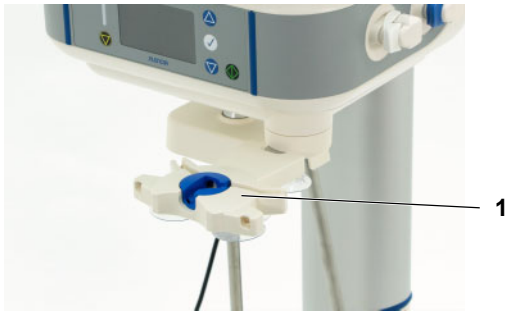
1. Fix the drain tray to the holder on the underside of the base unit.
   Make sure that the pin on the underside of the drain tray is placed in the rectangular opening in the pedestal.

9



1. Secure the bag rest to the heating tray using two screws.
2. Insert the side panels into the heating tray with the peripheral edge facing inwards.

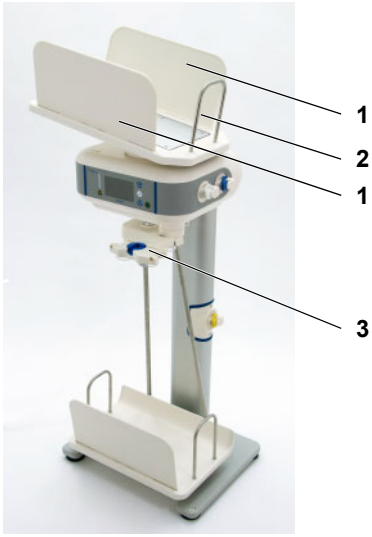
10



1. Fit the organizer onto the mount.

SILENCIA disassembly

1

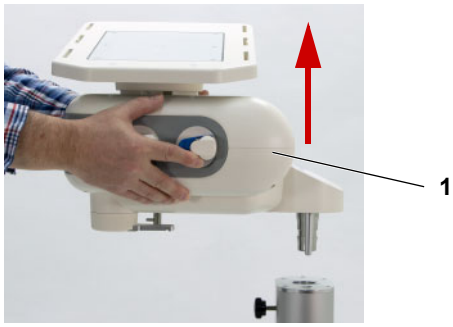


1. Remove the side panels from the heating tray.
2. Loosen the screws on the bag rest and remove the bag rest.
   Store the screws in the plastic bag provided.
3. Remove the organizer from the mount.

2

1. Remove the drain tray from the holder on the underside of the base unit.
   Set the drain tray aside.
2. Disconnect the mounting stand plug.
3. Loosen the screw on the mounting stand.

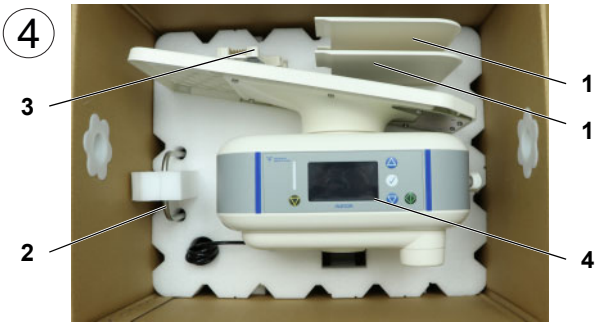
3



1. Hold the base unit by the sides and remove it from the mounting stand as shown in the image.

   Do not hold the base unit by the heating tray during this step!

4

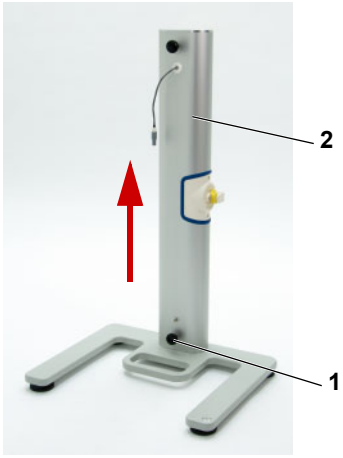


Place the following parts in the foam insert:

1. Side panels
2. Bag rest
3. Organizer
4. Base unit

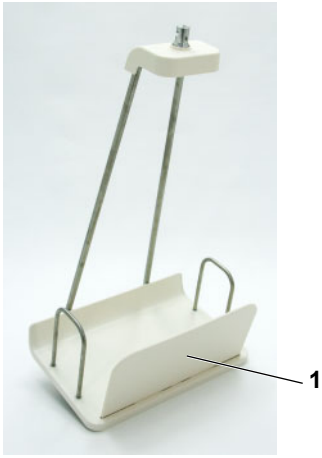
Position the foam insert, lay the Instructions for Use in place, and close the box.

5



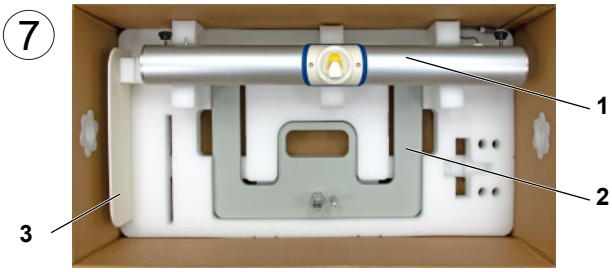
1. Loosen the screw.
2. Lift the mounting stand and unhook it from the pedestal.

6



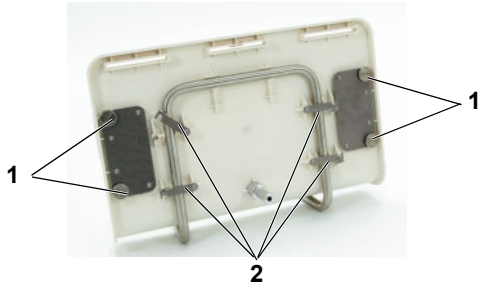
1. Remove the side panel from the drain tray.

7



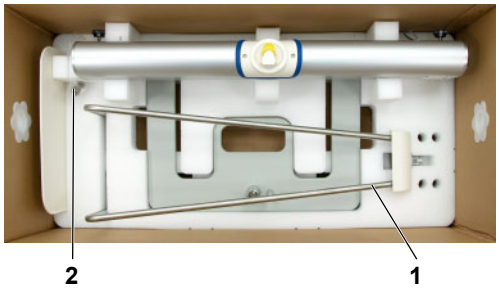
1. Place the mounting stand in the foam insert.
2. Place the pedestal in the foam insert.
3. Place the side panel in the foam insert.

8



1. Loosen the screws on the bag rests, and remove the bag rests.
2. Open the locking levers on the drain tray.

9



1. Place the drain tray suspension in the foam insert.
2. Store the screws in the plastic bag provided and secure it to the foam insert.

10

1. Secure the bag rests to the foam insert.
2. Position the foam inserts.
3. Place the drain tray in the foam insert and close the box.

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2 Important information

2.1 How to use the Instructions for Use

Device type

In this document, unless otherwise stated, the word "device" on its own always refers to the SILENCIA device.

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
- Document edition
- Document date of issue
- Document part number

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, e.g., IFU-EN refers to Instructions for Use in English.
- Edition identification, e.g., 07A-2022 means edition 07A released in 2022
- Page identification

Organization of the chapters

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

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: **Example** key/button

Style	Description
➢ Instruction	➢ Instructions are indicated by an arrow ➢. Instructions must be followed. ➢ Example: ➢ Carry out instruction.
1. Numbered Instruction 2. ... 3. ...	Long passages containing instructions can be shown as numbered lists. Instructions must be followed. Example: 1. Carry out instruction.

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 for Use

The Instructions for Use are part of the accompanying documents and are an essential part of the device. They contain all the information necessary for operating the device.

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

Changes

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

Reproduction

Reproduction, even in part, is only permitted with written approval.

2.2 Significance of warnings

Advises the operator that failure to comply with the measures for preventing the hazard may result in serious to life-threatening injuries.

Warning

Type and cause of hazard

Possible consequences if the hazard arises.

➢ Measures for averting the hazard.

Warnings can deviate from the above template in the following cases:
– If a warning describes several hazards.
– If a warning cannot be assigned to a specific hazard.

2.3 Significance of notes

Note

Advises the operator that failure to observe this information may result in the following:
– Damage to the device.
– Desired functions not being executed at all, or not being executed correctly.

2.4 Significance of tips

Tip

Information providing useful tips for easy handling.

2.5 Brief description

Peritoneal dialysis (PD) is a method for treating patients with kidney failure. Treatment carried out using an automated peritoneal dialysis device, also known as a cycler, is referred to as automated peritoneal dialysis (APD). APD is normally performed overnight. The device manages the inflow and outflow of dialysis solution and automatically controls the dwell duration based on the prescription.

The device SILENCIA provides the option of performing a CCPD, NIPD or tidal dialysis or performing an adapted APD.

The clinical benefits of peritoneal dialysis treatment of patients with renal insufficiency include the prevention of the otherwise fatal course of the disease through detoxification and control of the fluid balance.

Technology

The device comprises the following important elements:
– Color display with user guidance.
– Tubing system with an integrated Vario-Connector for preparation and post-processing of dialysis treatment.
– PIN technology at the patient connector.
– Therapy management with automatic balancing.
– Timer function that allows dialysis solution to be automatically heated at the desired time.
– Patient card: saving patient data, prescription data and treatment data on a mobile patient card. Up to nine different prescriptions as well as the treatment reports of more than one year can be saved on the patient card.

2.6 Intended purpose and related definitions

2.6.1 Intended purpose

Control, operation, and monitoring of the peritoneal dialysis treatment.

2.6.2 Medical indication

Chronic renal insufficiency requiring renal replacement therapy.

2.6.3 Intended patient population

The device has been specified by the manufacturer for the treatment of patients with a body weight of 20 kg or more, irrespective of their age, under consideration of the specified technical data of the device (e.g., volume).

2.6.4 Intended user group and intended environment

The device must only be installed, operated and used by individuals with the appropriate training, knowledge and experience and who are certified to have been trained.

The device has been specified by the manufacturer for the operation in rooms suitable for peritoneal dialysis located in professional health care facilities, or for the home health care environment.

It is not intended for use in intensive care units.

2.7 Side effects

Occasional occurrence of the following peritoneal dialysis (PD) treatment-related side effects is reported in current literature: exit-site infections, tunnel infections, peritonitis, abdominal pain, abdominal bloating and reflux, hernias, edema (genital edema, leg edema, hydrothorax, swelling around exit site), back pain (musculoskeletal), pneumoperitoneum, encapsulating peritoneal sclerosis (EPS), loss of renal function, loss of peritoneal membrane function, UF loss, hypoalbuminemia (hypoproteinemia), hypovitaminosis, hyper/hyponatremia, acidosis/alkalosis.

Furthermore, side effects pertaining to the cycler may occur:
inflow pain, pain during outflow, hyperthermia/hypothermia, hypervolemia, overfilling of the peritoneal cavity, suction of the peritoneum with subsequent pain or injury of the peritoneum.

Additional side effects might be attributable to other products used at the same time during therapy, e.g., hypersensitivity reactions due to catheter material and disinfectants; and as a result of the PD solutions: increased blood sugar levels, hyperlipidemia, increase in body weight due to the continuous uptake of glucose from the PD solutions; tachycardia, hypovolemia, hypotension, dizziness, ischemic colitis, and necrotizing enteritis due to excessively high UF with the osmotic agent; hypervolemia, hypertension, and dyspnea caused by excessively low UF with the osmotic agent; electrolyte disturbances.

2.8 Contraindications

The following PD treatment-related contraindications are reported in the current literature: massive obesity, large abdominal hernias that cannot be repaired, previous extensive abdominal surgery, a non-functional peritoneum due to the presence of adhesions, fibrosis, or malignant diseases, colostomy, ileostomy, ileal conduit, cystic kidneys, poor lung function, chronic inflammatory bowel disease, and poor cardiac condition.

NIPD should be used only in patients with a small BSA, fast membrane transport and sufficient RRF. Ultimately, PD is absolutely contraindicated only if the peritoneal cavity is obliterated, the peritoneal membrane is not functional, or the PD catheter cannot be implanted. All other health conditions are relative contraindications.

In children there are several conditions that constitute absolute contraindications: omphalocele, bladder exstrophy, gastroschisis, diaphragmatic hernia, obliterated peritoneal cavity and peritoneal membrane failure.

Additional contraindications might be attributable to the PD solutions or other products used during the PD treatment, e.g., known hypersensitivity reactions to the materials and substances of the PD catheter or disinfectants.

2.9 Interaction with other systems

Peritoneal dialysis can alter the pharmacokinetics of drugs, depending upon the route of administration of the drug and the rate of removal via the dialysate. This can necessitate dose adaptations.

2.10 Therapy restrictions

NIPD should be performed on patients with residual renal function. Otherwise, detoxification may be insufficient.

2.11 Considerations for working on the device

Warning

Risk of injury for the patient and operator as a result of improper servicing performed on the device

Improper servicing can impair the safe functioning of the device.

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

All steps and information required for repairs to the device are included in the technical descriptions in the Service Manual.

For more information on installation, (see Chapter 9 on page 189).

For additional information on Technical Safety Checks and maintenance procedures, please refer to the appropriate chapter (see Chapter 11 on page 221).

Use only spare parts approved by the manufacturer.

To identify and order spare parts, test equipment, and tools, always use the electronic Spare Parts Catalog.

Transport and storage (see Chapter 10 on page 219).

2.12 Expected service life

If the Technical Safety Checks are performed to the full extent specified and at the prescribed intervals, the device will continue to operate safely in the meantime.
In addition, the manufacturer recommends that maintenance procedures be performed at the same time intervals to avoid device malfunctions caused by 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.

2.13 Duties of the responsible organization

Requirements

The responsible organization is obligated to ensure that the following requirements are met:

- Compliance with national or local regulations regarding installation, operation, use, and maintenance.
- Compliance with accident prevention regulations.
- Keeping the device in a proper and safe condition.
- Availability of the Instructions for Use at all times.
- The device must only be operated under the operating conditions specified by the manufacturer.
- The national or local data protection directives must be complied with.
- The patient cards must be kept in a safe place so that they cannot be stolen.

Training and instruction

Before the responsible organization may start operating the device, the individual responsible for operation must have been verifiably instructed by the manufacturer in how to use the device and must be thoroughly familiar with the contents of the Instructions for Use.

The device must only be operated by individuals who have been trained and certified in the proper operation and handling of the device.

The manufacturer offers training courses for this device.

For further questions, please contact the local service support organization (see Chapter 2.18 on page 33).

Incident reporting

Within the EU Member States, the user must report any serious incident that has occurred in relation to the device to the manufacturer according to the labeling () and to the competent authority of the Member State in which the user is established.

Therapy information

The way in which relevant therapy information is conveyed to the patient is at the discretion of the attending physician.

2.14 Operator responsibility

For reasons of data protection, the operator is responsible for the safekeeping of the patient card.
Whenever the patient card is passed on, it is the duty of the responsible organization to comply with the national or local data protection directives.

The attending physician should be consulted whenever the difficulties are device-, procedure- or health-related.

2.15 Disclaimer of liability

Warning

Chapter 8 (see Chapter 8 on page 185) contains a list of consumables and accessories that are suitable for use with this device and can be used safely with it.

The manufacturer cannot vouch for other consumables and accessories than those listed in this chapter being suitable for use with this device. The manufacturer can also not make any assertions that the safety and performance of the device will remain unimpaired if consumables and accessories other than those listed in this chapter are used.

If other consumables and accessories are used, their suitability must be verified beforehand. This can be performed using the information in the instructions for use for the relevant consumables and accessories, for example.

The manufacturer accepts no liability for damage to the device resulting from the use of unsuitable consumables or accessories.

2.16 Warnings

2.16.1 Hygiene warnings

Warning

Risk of contamination from non-compliance with hygiene measures

Improper handling during connection can lead to contact with the opening of the patient connector.
This may lead to microbial contamination.

➢ We recommend wearing a face mask, washing your hands and the spaces between your fingers with medical-grade hand wash, and then applying hand sanitizer.

➢ Use aseptic technique when connecting the patient.

➢ The patient line must be tightly sealed.

➢ Observe the hygiene practices of the dialysis center and the hygiene regulations in force.

2.16.2 Therapy warnings

Warning

Patient hazard from overly rapid withdrawal of fluid in patients with ascites

Overly rapid withdrawal of fluid can lead to circulatory problems.

➢ If these patients mobilize large volumes of ascites during outflow, medical supervision with appropriate therapeutic measures is required.

2.16.3 System warnings

Warning

Patient hazard from a device malfunction

If the device is used outside the specified storage and operating conditions, the device may not operate safely.

➢ The specified storage and operating conditions must be followed.

Warning

Risk of injury from a device defect

A treatment cannot be performed properly and safely with a defective device.

➢ Do not perform treatments with a defective device.

➢ Take the device out of service and disconnect it from the power supply.

➢ If the treatment is stopped due to an alarm (system error/device fault), follow the instructions of the attending physician.

➢ Inform the responsible organization or service support.

A device defect is present in the following cases, for example:
– Mechanical damage
– Damaged power supply cord
– Unexpected device responses
– Deteriorated device performance

Warning

Choking hazard from loose cables and lines

Children can be strangled by loose electrical cables and lines.

Ensure that the cables and lines do not present a hazard for children.

Warning

Choking hazard from small parts

Children can swallow and choke on small parts.

➢ Keep loose small parts out of the reach of children.

2.16.4 Electrical safety warnings

Warning

Risk of injury from electric shock

Contact with a damaged power supply cord can cause electric shocks.

➢ The power supply cord must be laid so as to ensure that it cannot be damaged by sharp-edged objects or by pets.

Warning

Risk of suffocation from smoke inhalation

An overload of electrical extension cords can lead to overheating with the formation of smoke.

➢ The use of power strips and extension cords is prohibited.

2.16.5 Warnings regarding consumables and accessories

Warning

Risk of contamination from reuse of the SILENCIA Vario system

The SILENCIA Vario system is a single-use item.
Reuse can lead to patient contamination.

➢ Only use the SILENCIA Vario system once to supply the patient with dialysis fluid.

➢ Only use the empty solution bags as a drain system once.

Warning

Risk of cross-contamination as a result of contaminated consumables

Improper disposal may lead to the transmission of microbes to third parties (cross-contamination).

➢ After treatment, dispose of the tubing system and drainage bag in compliance with local regulations for handling potentially contaminated materials.

2.17 SVHC (REACH)

Information on SVHC pursuant to Article 33 of regulation (EC) no. 1907/2006 (“REACH”) is available on the following web page:

www.freseniusmedicalcare.com/en/svhc

2.18 Addresses

Manufacturer

Fresenius Medical Care AG & Co. KGaA
Else-Kröner-Str. 1
61352 Bad Homburg
GERMANY
Phone: +49 6172 609-0
www.freseniusmedicalcare.com

International service

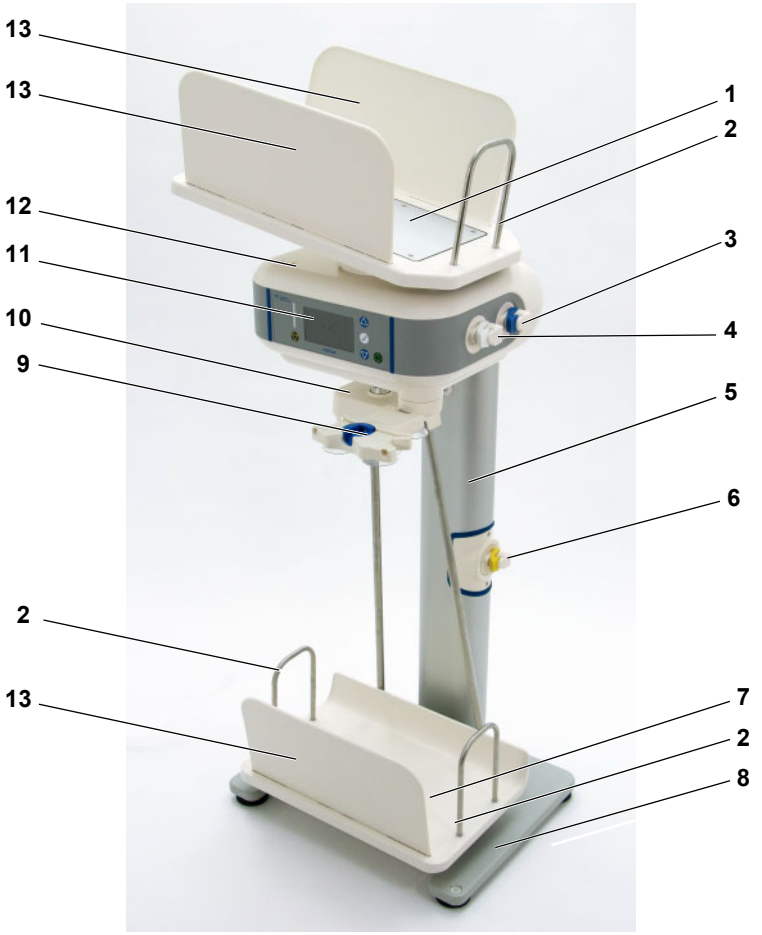
Fresenius Medical Care Deutschland GmbH
Technical Operations
Technical Coordination Office (TCO)
Hafenstrasse 9
97424 Schweinfurt
GERMANY

Local service

3 Device layout

3.1 Views

3.1.1 Front view



1 Heating tray
The heating tray is used to hold and heat the solution bags.

2 Bag rest
The bag rest keeps the solution bags from sliding.

3 Inflow valve – blue (last bag)
The inflow valve – blue (last bag) regulates the flow of dialysis solution from the “last bag” solution bag to the patient if called for in the prescription.

4 Inflow valve – white
The inflow valve – white regulates the flow of dialysis solution from the solution bags to the patient.

5 Mounting stand

6 Drain valve
The drain valve regulates the flow of dialysis solution from the patient to the drainage bags.

7 Drain tray
The drain tray holds the drainage bags.

8 Pedestal

9 Organizer with clip
Used to hold the patient connector and facilitates simple and secure connection and disconnection of the patient.
The mount on the organizer rotates and can be moved beneath the base unit when it is not needed.

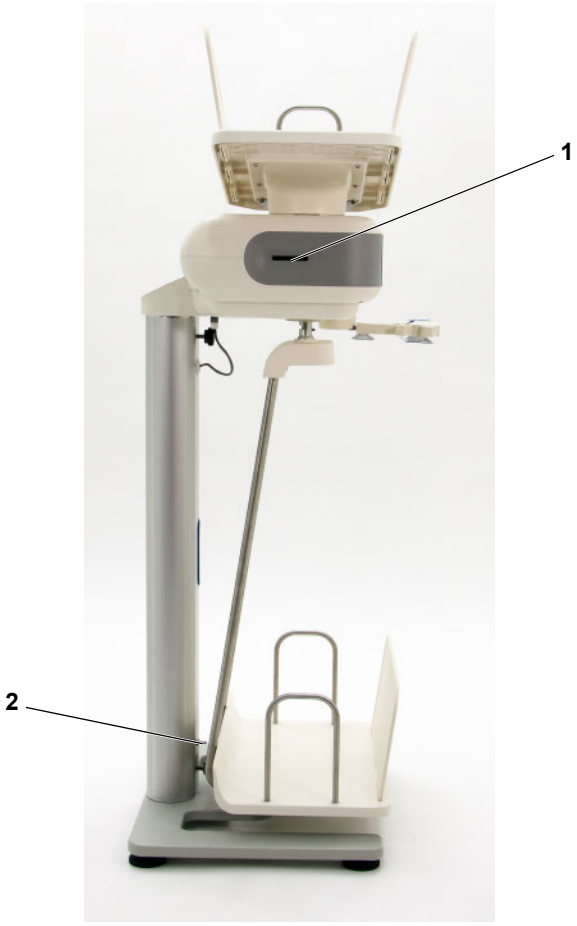
10 Drain tray suspension

11 Display and control elements
(see Chapter 3.2 on page 38)

12 Base unit

13 Tray side panels
Side panels on the heating tray and drain tray.
The side panels keep the solution and drainage bags from sliding.

3.1.2 Side view



1 Card slot
Card slot for the patient card.
The patient card stores the patient's individual prescriptions and treatment reports.

2 Pin to check electrical safety
Only the service support may use the pin to perform the electrical safety measurement.

3.2 Display and control elements

1 **Button** △
Move selection up button
Increase value button

2 **Button** ✓
Confirm selection button

3 **Button** ▽
Move selection down button
Reduce value button

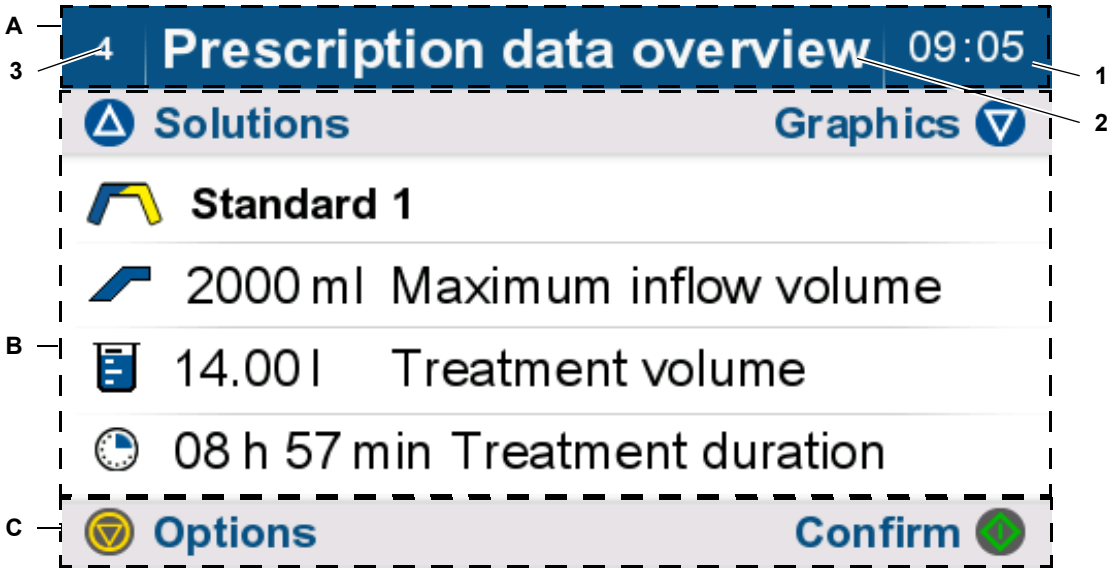
4 **Button**
On/Off button
Confirm input button

5 **Display**
Treatment information is shown on the display.

6 **Button**
Back button
Special functions button

7 **Status indicator**
The indicator lights up red to indicate an alarm, and during the functional test.
The indicator lights up green to indicate correct operation.

3.3 Screen layout



A **Status bar**

1 Time

2 Title of the operating step or status of the device

3 Screen number

B **Main screen**
Displays information about the current and other necessary operating steps.

C **Options bar**
Displays buttons that are enabled for the current operating step.

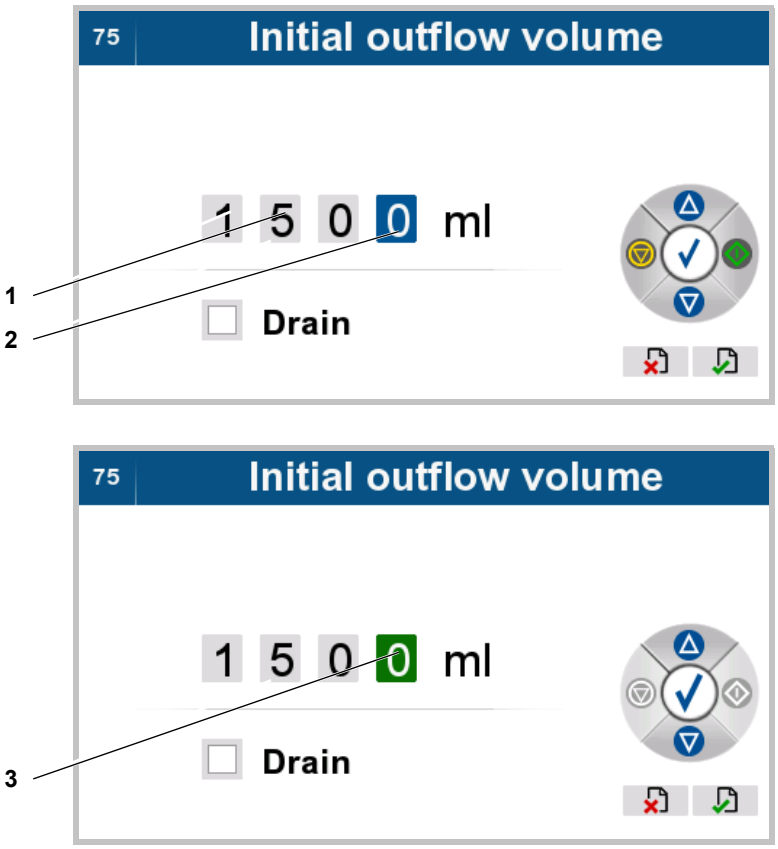
3.3.1 Color of display elements

The display elements have a uniform design concept.

gray: not currently selected (1)

blue: currently selected (2)

green: can be changed (3)

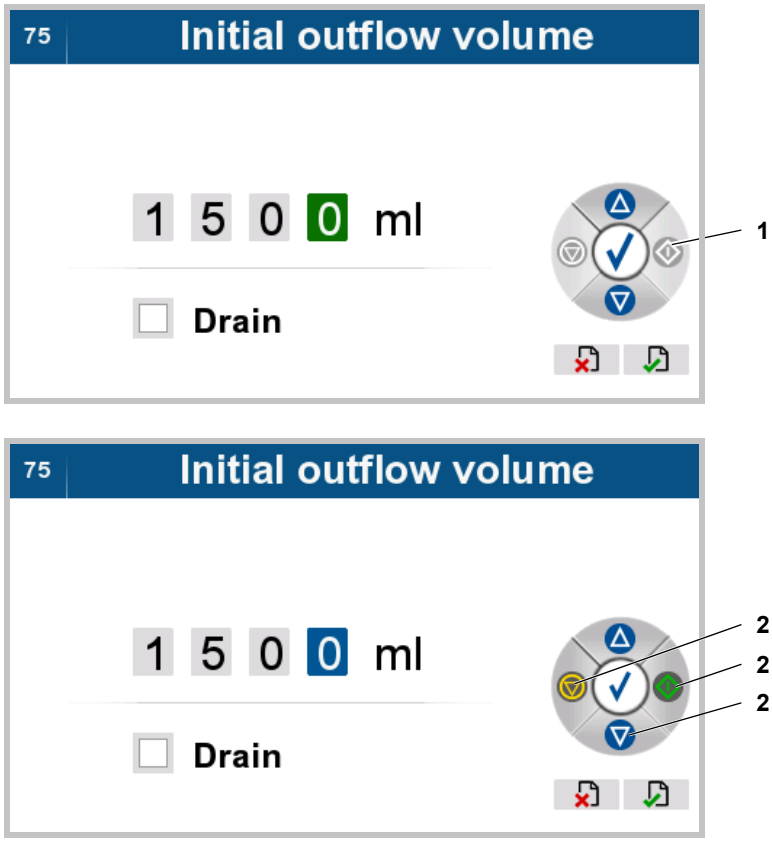


3.3.2 Color of control elements

The control elements have a uniform operating concept.

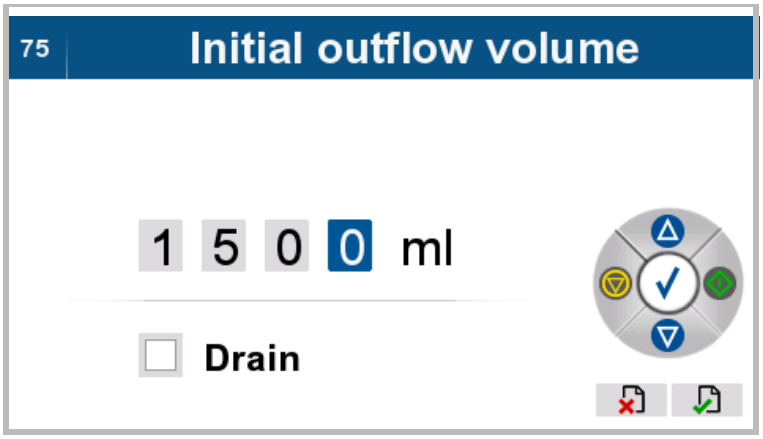
gray: disabled control elements (1)

blue, green, yellow: enabled control elements (2)



3.4 General procedure for entering parameters

3.4.1 Entering numbers



The selected number is highlighted blue.

The device is in selection mode.

The buttons can be used to move the selection field as described below.

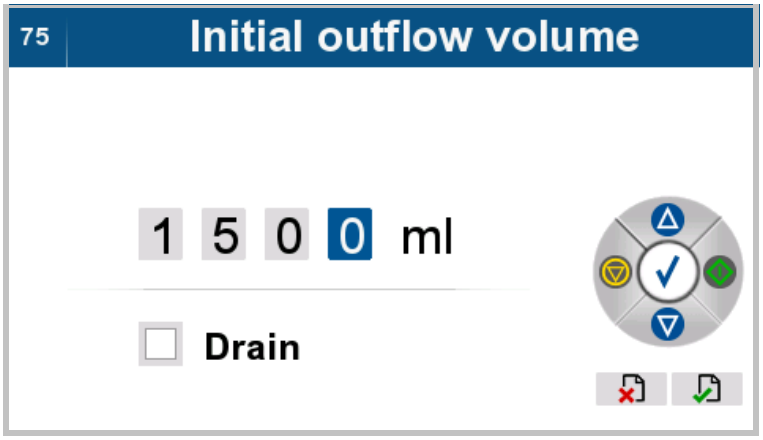
right

left

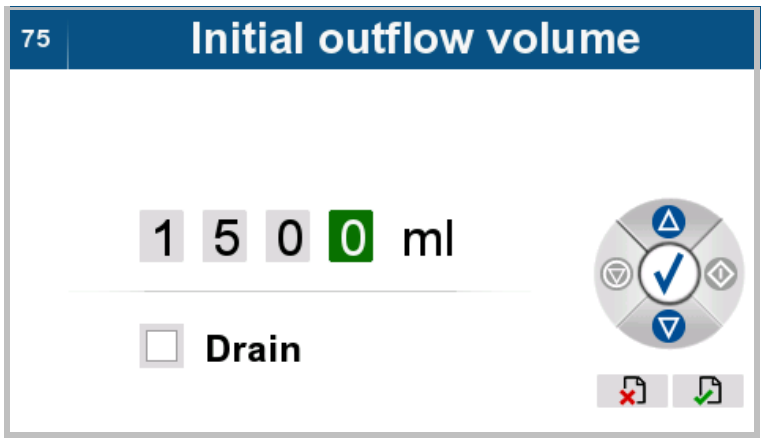
up

down

➢ Select the digit (e.g., 0) to be edited.

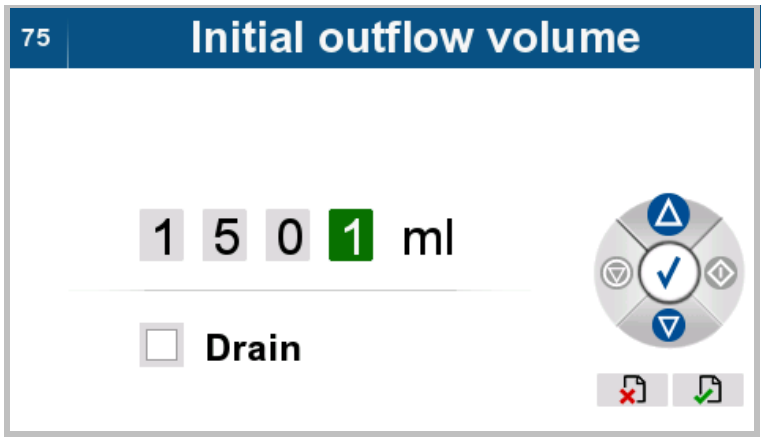


➢ Press the ✓ button to allow the number to be changed.



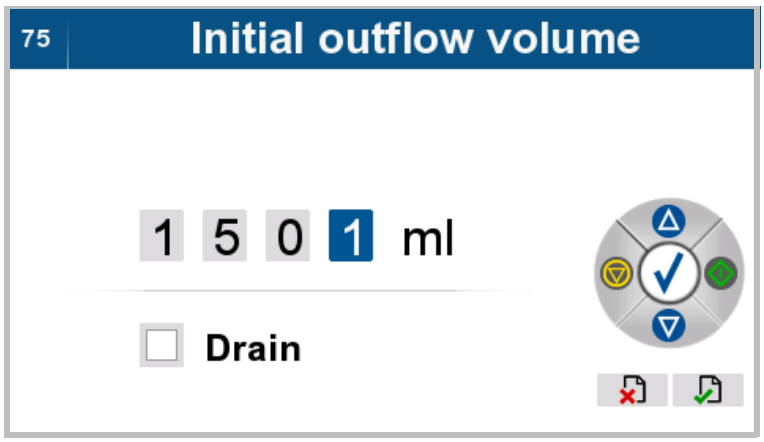
The selected digit is highlighted green.

The device switches to input mode.



➢ Use the △ and ▽ buttons to increase or decrease the digit.

➢ Press the ✓ button to confirm the entry.

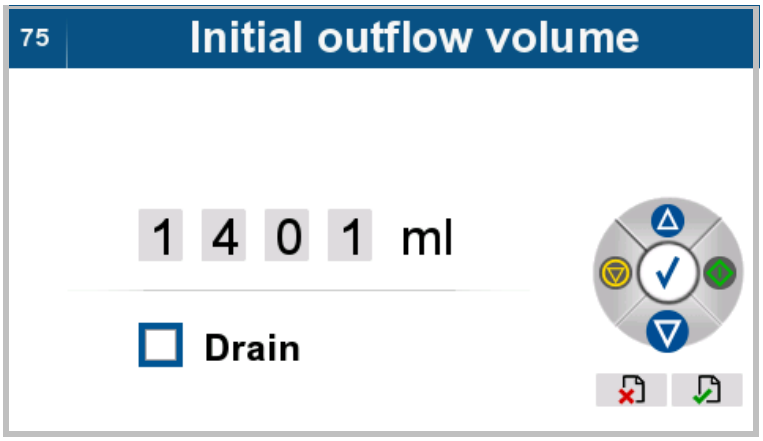


The selected digit is highlighted blue.

The device switches to selection mode.

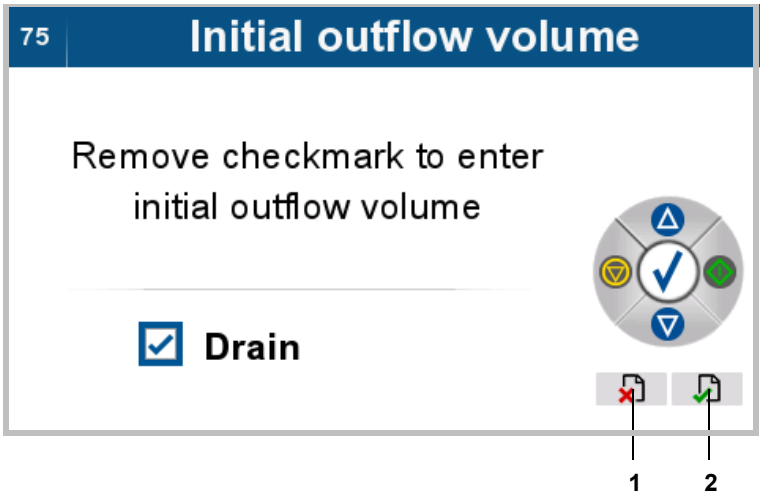
➢ If necessary, select and edit the next digit.

3.4.2 Selecting checkboxes

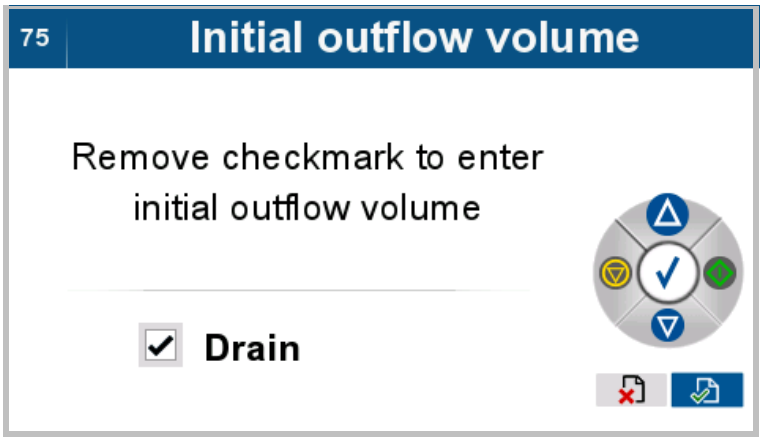


➢ Use the △ and ▽ buttons to select the checkbox.

➢ Press the ✓ button to confirm the entry.



➢ Press the △ or ▽ button, to select the **Save entry** (2) or **Cancel entry** (1) key.

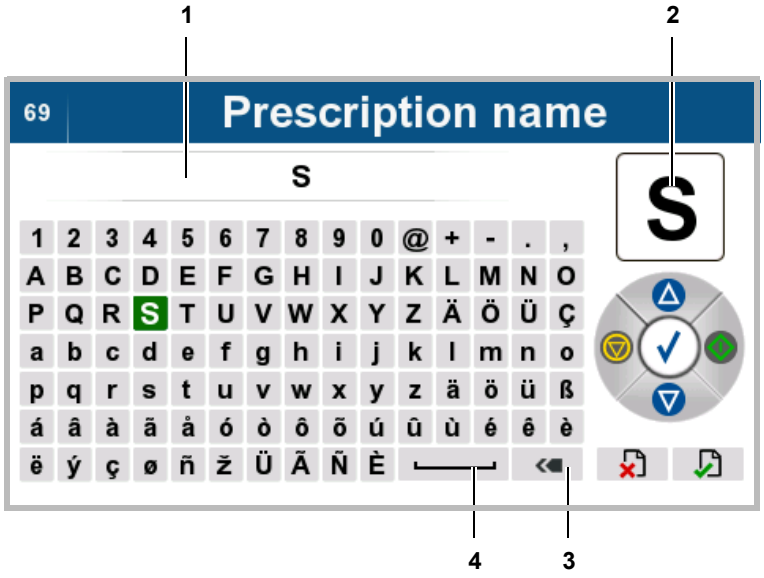


The selected symbol is highlighted blue.

➢ Use the ◇ and ▽ buttons to select the desired symbol.

➢ Press the ✓ button to confirm the selection and switch to the higher-level menu.

3.4.3 Entering text



You can enter the desired text and numerical values with the character palette shown.

The selected character is highlighted blue, and a larger version is displayed at the top right corner (2) of the screen.

The buttons can be used to move the selection field as described below:

- right
- left
- up
- down

The space character (4) can be used to insert a blank space in the text field. The backspace character (3) deletes the last character.

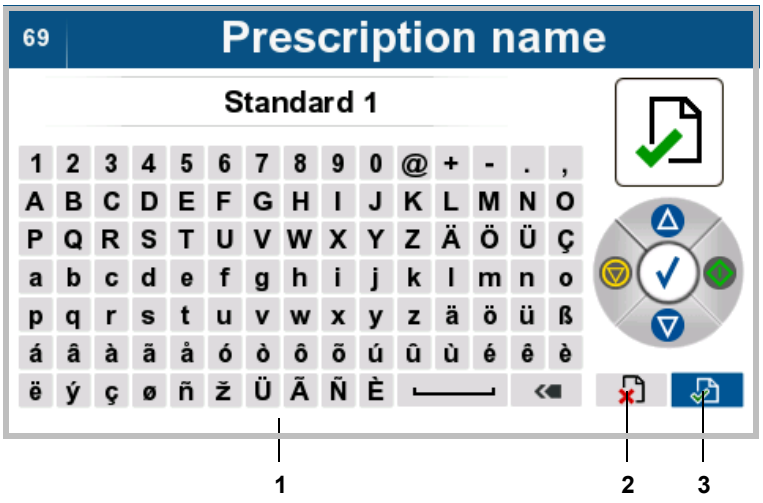
➢ Select the desired characters.

➢ Press the ✓ button to confirm the entry.

The selected character appears in the text field (1).

➢ Select the next character as needed.

3.4.4 Saving the entry



If the cursor is moved above or below the character palette (1) using the △ or ▽ button, the **Save entry** (3) and **Cancel entry** (2) key can be selected.

The selected symbol is highlighted blue.

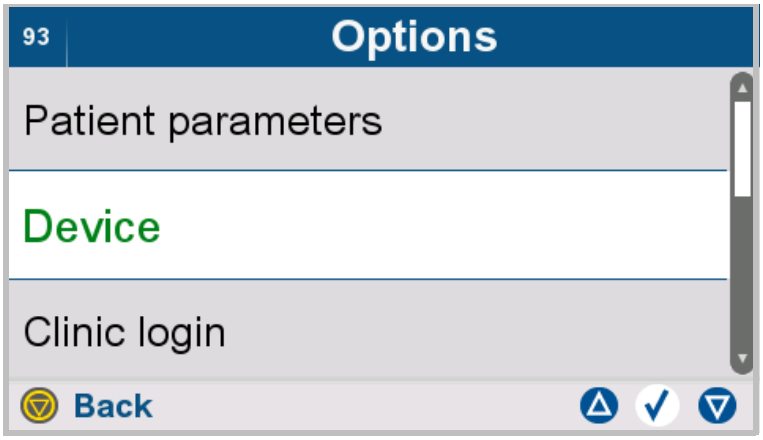
➢ Use the ◁ and ▽ buttons to select the desired symbol.

➢ Press the ✓ button to confirm the selection and switch to the higher-level menu.

If you do not wish to save the selection and instead would like to enter more text, use the △ or ▽ button to move the cursor back to the character palette.

3.4.5 Selecting options or parameters

The following step describes how to select parameters from a list.



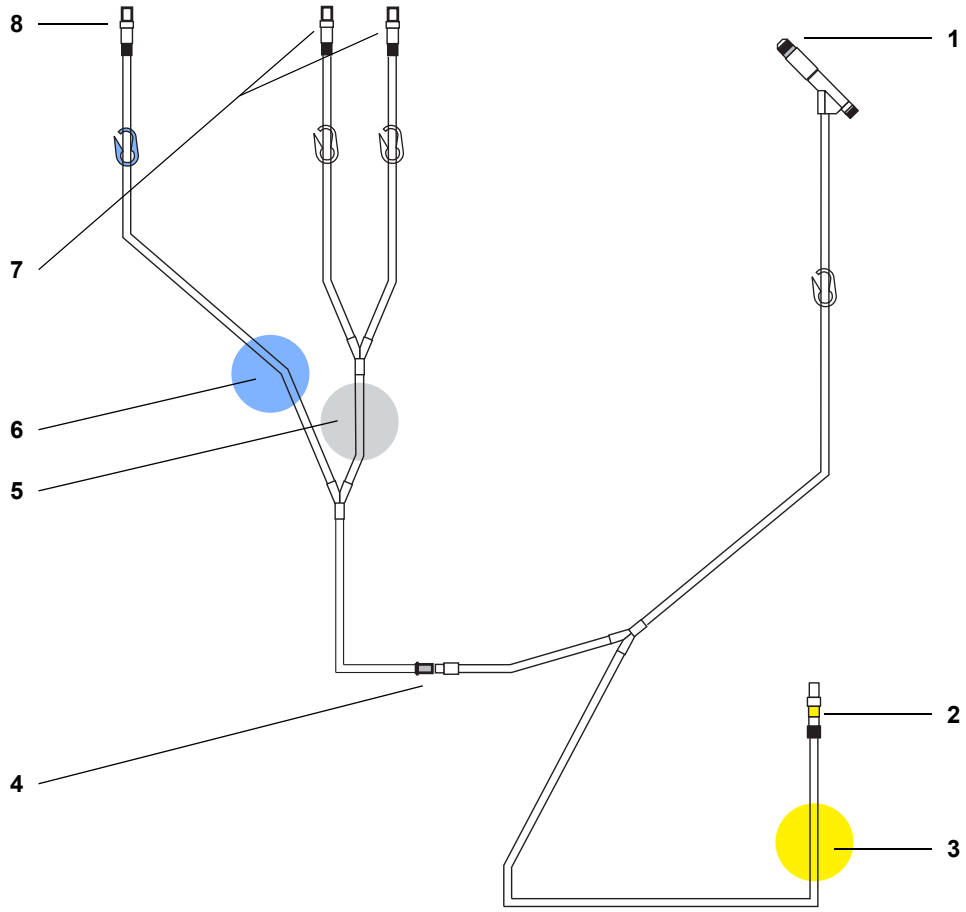
➢ Use the △ and ▽ buttons to move the desired option to the brightly highlighted line in the center.

➢ Press the ✓ button to select the option or parameter.

➢ Press the ▽ button to return to the higher-level menu.

3.5 Description of the tubing system

3.5.1 Tubing system



The illustrated tubing system is merely an example and may differ from the original equipment.

1 Patient connector

2 Connector for drainage bag

3 Position of drain valve on device (yellow)

4 Vario-Connector
After the treatment, the Vario-Connector is separated by breaking it apart, so that the empty solution bags can be used as drainage bags for the next treatment.

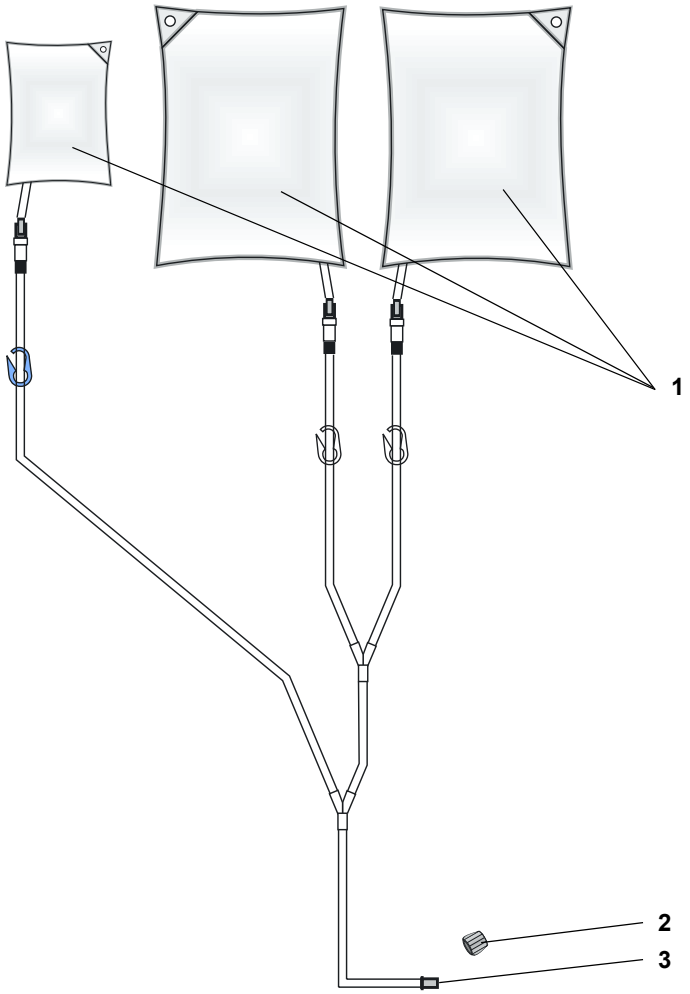
5. Position of inflow valve on device (white)

6. Position of inflow valve on device (blue)

7. Connectors for solution bags
8. Connector for optional "last bag"

3.5.2 Drain system

The empty solution bags are used as drainage bags for the next treatment. For this purpose, the tubing system is broken apart at the Vario-Connector, and the drainage bags are connected to the drain line of the tubing system (see Chapter 4.5.3 on page 100).



The illustrated drain system is merely an example and may differ from the original equipment.

1 Empty solution bags from the previous treatment are used as drainage bags for the next treatment.

2 Closing cap for sealing the drain system that will be stored until the next treatment (included with every tubing system).

3 Vario-Connector
The Vario-Connector has been broken apart following treatment so that the empty solution bags and the connected section of the tubing system can be used as a drain system for the next treatment.

4 Operation

4.1 Switching the device on

Warning

Patient hazard as a result of a failure to achieve the treatment goal

If no audible signal sounds during the initial internal test, or if the status indicator does not light up, no visual or audible alarm can be signaled.

➢ The device must not be used.

➢ Call service support.

- **Connecting the device to the power supply**

The device will automatically power on after it has been connected to the power supply.

The **SILENCIA** product logo is displayed on the screen as the device boots up, which takes approx. 1.5 minutes.

The **status indicator** lights up red for the duration of the initial test.

The screen shown to the left appears.

The **status indicator** lights up red.

The screen shown to the left appears.

The **status indicator** lights up green.

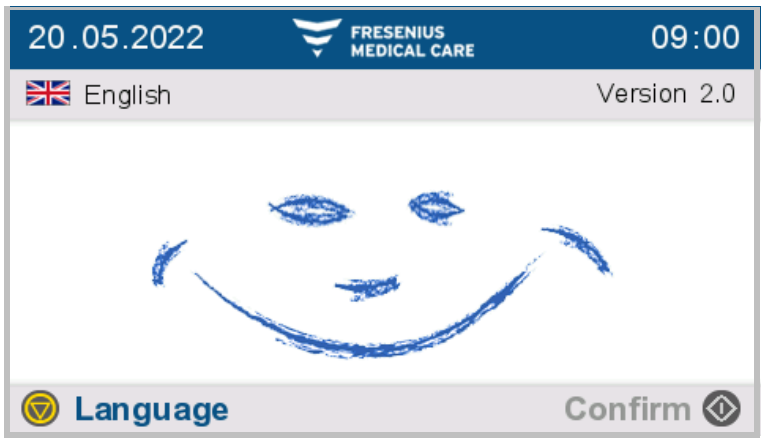
The device is ready for operation.

- **Switching the device on with the On/Off button**

Press the button to switch on the device.

The **SILENCIA** product logo is displayed on the screen as the device boots up, which takes approx. 1.5 minutes.

The **status indicator** lights up red for the duration of the initial test.



The screen shown to the left appears.

The **status indicator** lights up red.

The screen shown to the left appears.

The **status indicator** lights up green.

The device is ready for operation.

4.1.1 Functional test

Warning

Patient hazard as a result of a failure to achieve the treatment goal

If no audible signal sounds during the initial internal test, or if the status indicator does not light up, no visual or audible alarm can be signaled.

➢ The device must not be used.

➢ Call service support.

The following information will be displayed:

– The current date
– The current time
– The language selected
– The software version

➢ Press the button to move to the next operating step.

The audible signal sounds.

➢ Press the button to set the language.

The patient data is then loaded.

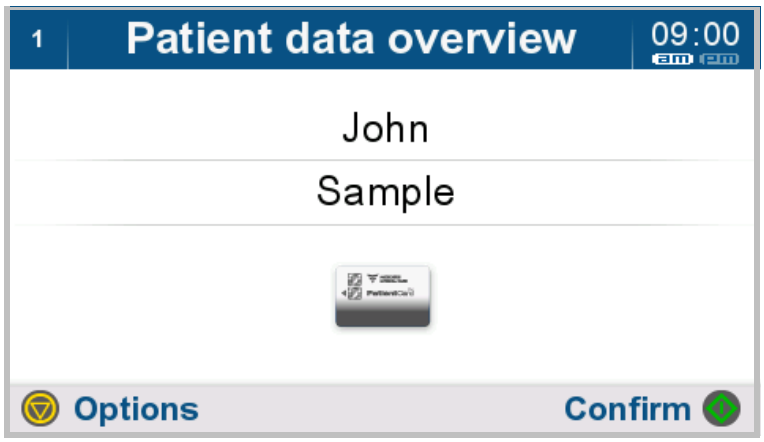
Warning

Risk of overfilling the peritoneal cavity

The use of incorrect treatment data may result in an incorrect patient prescription.

➢ Only the patient whose name is displayed on the screen must be connected to the device.

➢ The operator must check the treatment data (maximum inflow volume, treatment volume, and treatment duration) for plausibility before starting the treatment.



The patient's name is displayed.

A patient card icon displayed in color with a green check mark indicates that the inserted patient card contains patient data (i.e., is personalized) for the patient displayed.

If there is no patient card in the device, this will be indicated by a patient card icon displayed in gray. The last data used that are stored on the device will be loaded.

Press the button to accept the displayed patient data and move to the next operating step.

Press the button to open the patient card options. This is where the system can be personalized for the patient if necessary.

If the patient name shown does not match the patient being treated, the patient card must be changed or the device personalized for the patient in this operating step. The patient card must be inserted into the card slot with the contact surfaces facing up.

When the patient card is removed from the device, three beeps will sound. When the patient card is inserted in the device, a single beep will sound.

4.2 Preparing for treatment

4.2.1 Preparing the materials and treatment environment

Warning

Choking hazard from small parts

Children can swallow and choke on small parts.

➢ Keep loose small parts out of the reach of children.

➢ Close all windows and doors in the treatment room.

➢ Take off any wristwatches and jewelry.

➢ Prepare the necessary supplies:

1. SILENCIA APD cycler
2. Patient card
3. Peritoneal solution bags in overwrap
4. Tubing system (SILENCIA Vario system) in overwrap
5. Drain system
6. Organizer with clip
7. Disinfection cap
8. Face mask
9. Liquid soap
10. Hand disinfectant

Note

➢ The solution bags used as well as the tubing system must be at a temperature of 15 to 35 °C.

Warning

Risk of contamination from introduction of microbes to consumables

Microbes can be introduced into the consumables as a result of damage and can form in the consumables after their expiration date.

➢ Only use consumables if the overwrap has not been damaged.

➢ Make sure that items have not expired, and that the protective cap and closing cap have not fallen off.

➢ Do not remove consumables from their overwrap until required to do so by the corresponding operating step.

➢ Observe the hygiene practices of the dialysis center and the hygiene regulations in force.

Warning

Patient hazard as a result of a failure to achieve the treatment goal

The use of a non-prescribed solution can result in damage to the patient.

➢ Check the following for each solution bag:
- The name of the dialysis solution matches the name in the prescription.
- The glucose concentration matches that specified in the prescription.
- The calcium concentration matches that specified in the prescription.

➢ Also check each solution bag for the following points:
– It is not yet past its "use by" date.
– The overwrap is not damaged.
– There are no potential leaks.
– The dialysis solution is clear.

- **Handling the 5-liter/6-liter double chamber bags**

Warning

Risk of poisoning from incorrect dialysis solution composition

An insufficiently mixed dialysis solution in a double chamber bag can result in poisoning.

➢ All PEEL seams must be completely opened.

➢ Thoroughly mix the dialysis solution.

➢ Before using double chamber bags, check to make sure that both PEEL seams are intact.

➢ Open the overwrap and leave the bag on the lower part of the overwrap.

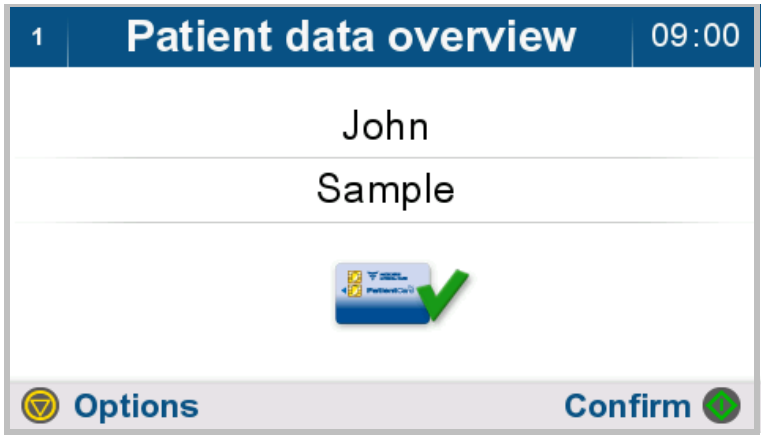
➢ Roll up the solution bag, starting from the upper corner diagonally opposite from the bag connector, until the PEEL seam opens.

➢ Continue rolling up the solution bag until the PEEL seam of the small chamber opens completely.

All PEEL seams must now be open.

➢ Mix the dialysis solution and check that the bag has no leaks.

4.2.2 Confirming the prescription

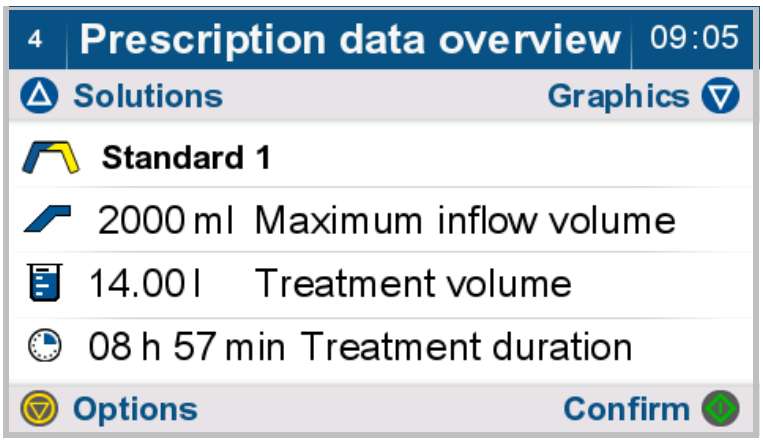


The patient's name is displayed.

➢ Press the button to move to the next operating step.

➢ Press the button to display options.

The treatment data is then loaded.



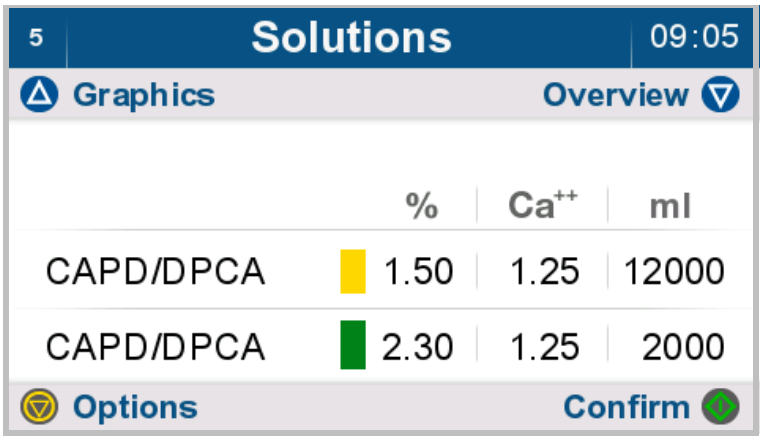
The following are shown in the prescription overview:
– Prescription name
– Maximum inflow volume
– Total treatment volume
– Expected treatment duration

➢ Press the button to move to the next operating step.

➢ Press the button to display options.

➢ Press the button to display the solution overview.

➢ Press the button to display the graphics overview.



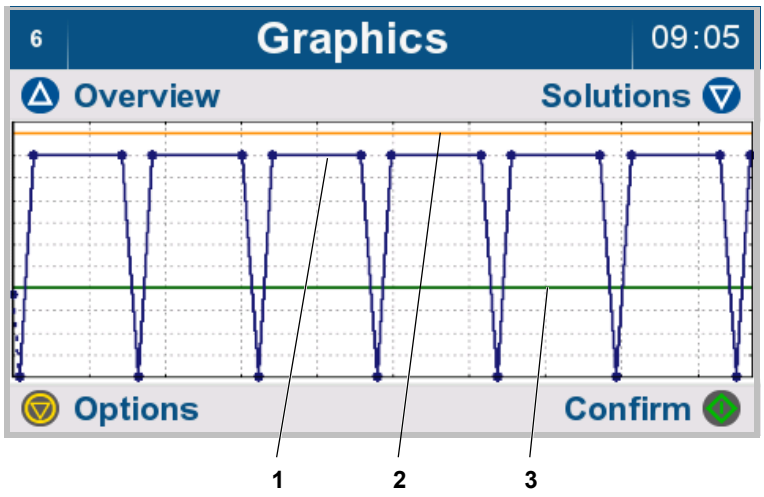
The following are shown in the solution overview:
– Solution type
– Glucose concentration in %
– Calcium concentration in mmol/L
– Total solution volume in ml for each solution type

➢ Press the button to move to the next operating step.

➢ Press the button to display options.

➢ Press the button to display the graphics overview.

➢ Press the button to display the prescription overview.



The following are shown in the graphics overview:

1. Prescribed volume curve (blue)
2. Permitted patient volume (orange) (see Chapter 7.3.1.1 on page 182)
3. Permitted residual volume (green) (see Chapter 7.3.1.2 on page 182)

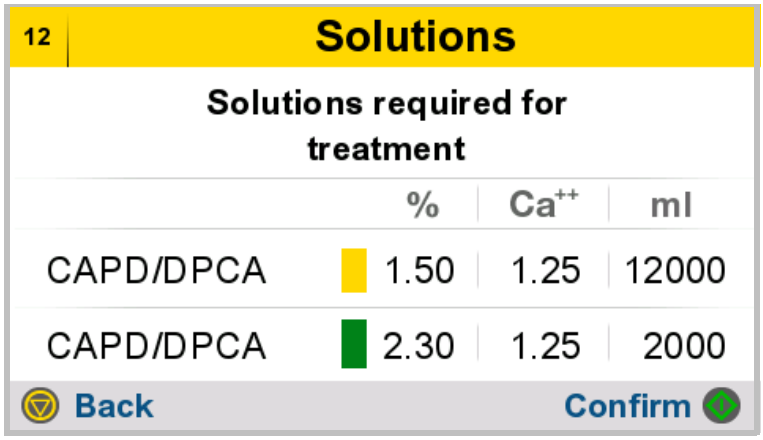
The vertical axis shows the volume and the horizontal axis shows the time.

➢ Press the button to move to the next operating step.

➢ Press the to display options.

➢ Press the button to display the prescription overview.

➢ Press the button to display the solution overview.



The volume of each solution required for the treatment is displayed.

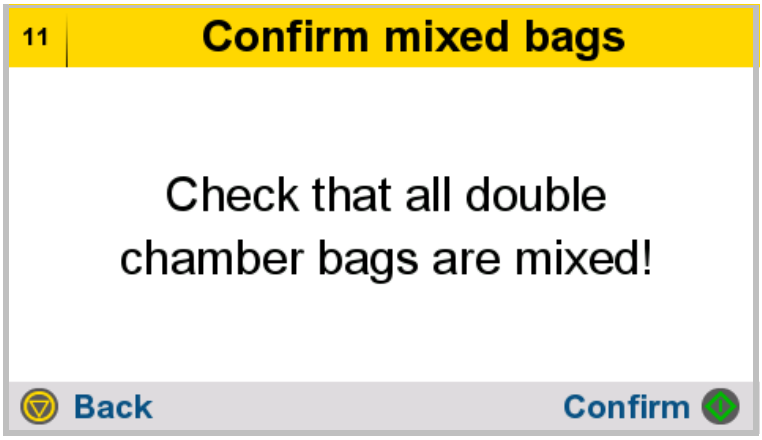
➢ Remove the solution bags from their overwrap.

➢ If using a double chamber bag, mix the solution (see Chapter 4.2.1 on page 56).

➢ Check the solution bags for leakage before use.

➢ Press the button to move to the next operating step.

➢ Press the button to return to the previous screen.

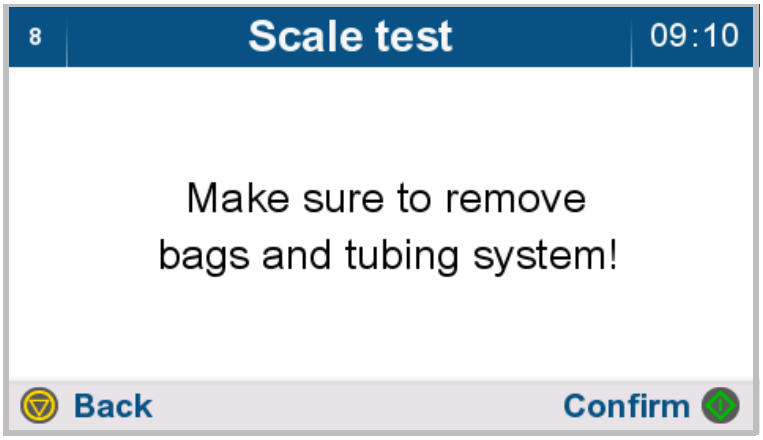


If the prescription calls for double chamber bags, these must be mixed before continuing.

➢ Press the button to confirm that the double chamber bags have been mixed and proceed to the next operating step.

➢ Press the button to return to the previous screen.

4.2.3 Positioning the solution bag



Make sure that all objects have been removed from the device.

➢ Press the button to confirm completion of the current operating step and proceed to the next step.

➢ Press the button to return to the previous screen.

Note

Solution bags must be aligned so that the bag connector points to the display side (front) of the device and must be connected to the tubing system that is inserted in the inflow valve – white.

If a last bag is required for the treatment, this bag must be aligned so that the bag connector points to the device rear side and must be connected to the tubing system that is inserted in the inflow valve – blue. The last bag should be placed last on the heating tray in the top position.

➢ Place the solution bags on the heating tray according to the on-screen instructions.
Solution bags must be positioned in such a way that the heating surface is as fully covered as possible.

The positioned bag is checked for validity.

If a valid solution bag is detected, an audible signal sounds.

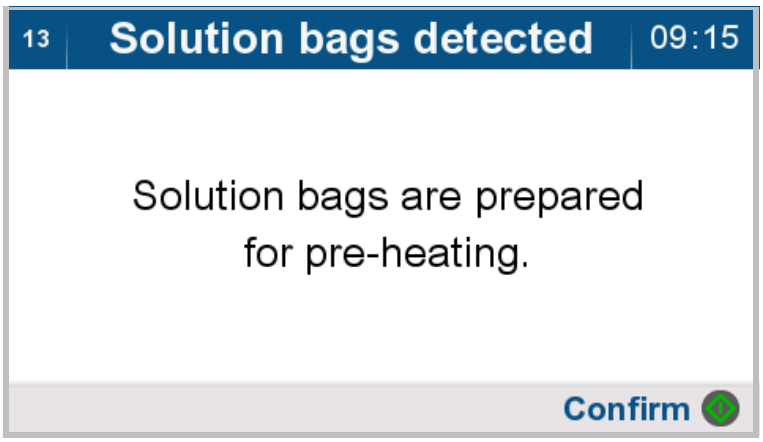
If an invalid solution bag is detected, a signal sounds 3 times with instructions to remove the last positioned solution bag.

If the prescription calls for an additional solution bag, this will be indicated on the screen (solution bag icon with number).

➢ Position the required solution bag.

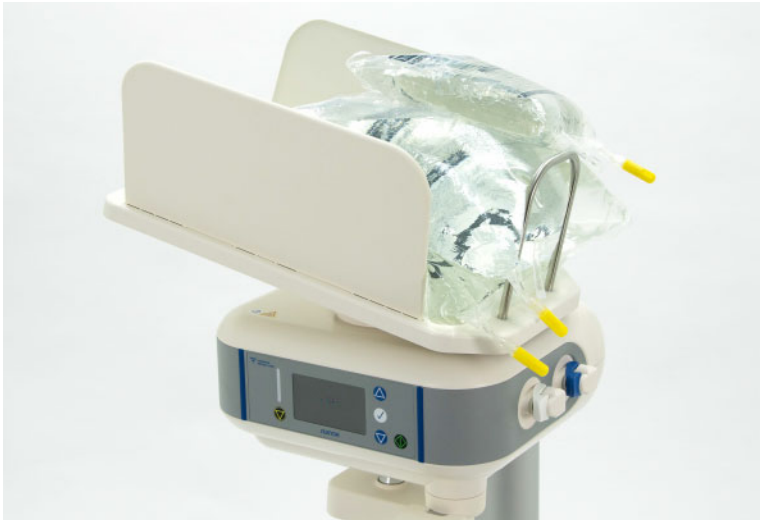
Once the positioned solution bags match the prescription, treatment preparation continues.

➢ Press the button to stop the procedure and switch to the prescription overview.



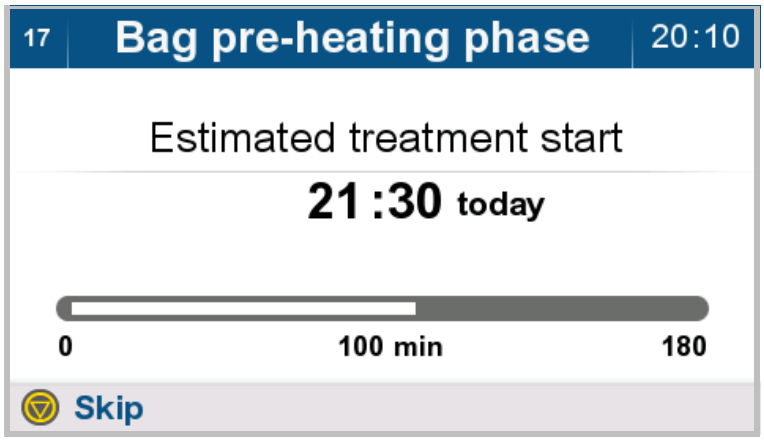
The solution bags are ready for pre-heating.

➢ Press the button to confirm completion of the current operating step and proceed to the next step.



The image shows an example of a solution bag arrangement on the heating tray.

4.2.4 Pre-heating solution bags without the treatment timer



If the treatment timer has not been activated, the solution bags are heated immediately.

The display shows the following:
– Expected treatment start
– Elapsed pre-heating time
– Total pre-heating time

Once the pre-heating phase is complete, the device automatically proceeds to the next operating step.

➢ Press the button to stop preheating and begin the next operating step.

4.2.5 Pre-heating solution bags with the treatment timer activated

➢ Press the button to confirm the set time for the treatment timer (see Chapter 4.7.3.1 on page 135).

The treatment timer has been activated.

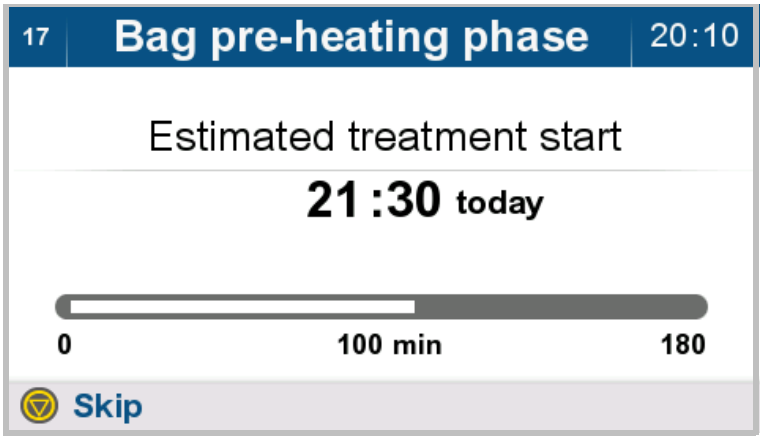
The selected treatment start is displayed.

The device automatically enters the pre-heating phase at the set time.

➢ Press the button to skip the wait time and begin the next operating step.

Note

After the time for the timer has expired, the device performs an internal test, during which the status indicator briefly lights up red. The device cannot be operated during this test. Once the test is complete, the device begins the pre-heating phase.



The device automatically begins pre-heating.

The display shows the following:
– Expected treatment start
– Elapsed pre-heating time
– Total pre-heating time

➢ Press the button to stop preheating and proceed to the next step.

4.2.6 Inserting the tubing system

Warning

Risk of contamination from introduction of microbes to consumables

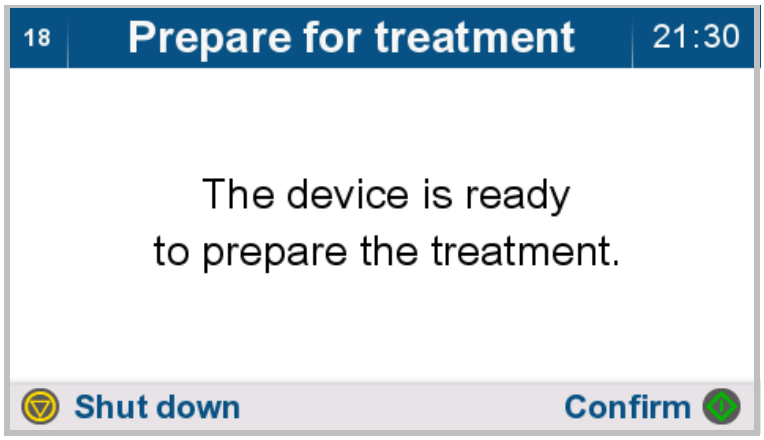
Microbes can be introduced into the consumables as a result of damage and can form in the consumables after their expiration date.

➢ Only use consumables if the overwrap has not been damaged.

➢ Make sure that items have not expired, and that the protective cap and closing cap have not fallen off.

➢ Do not remove consumables from their overwrap until required to do so by the corresponding operating step.

➢ Observe the hygiene practices of the dialysis center and the hygiene regulations in force.



The solution bags are pre-heated, and treatment preparation can be continued.

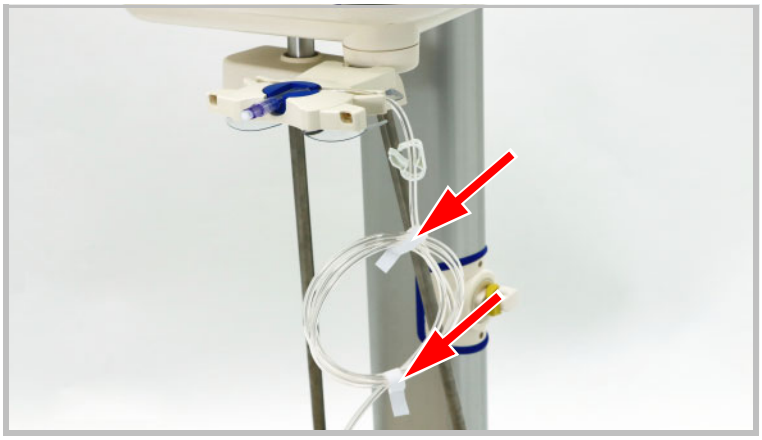
The tubing system can be inserted.

➢ Press the button to move to the next operating step.

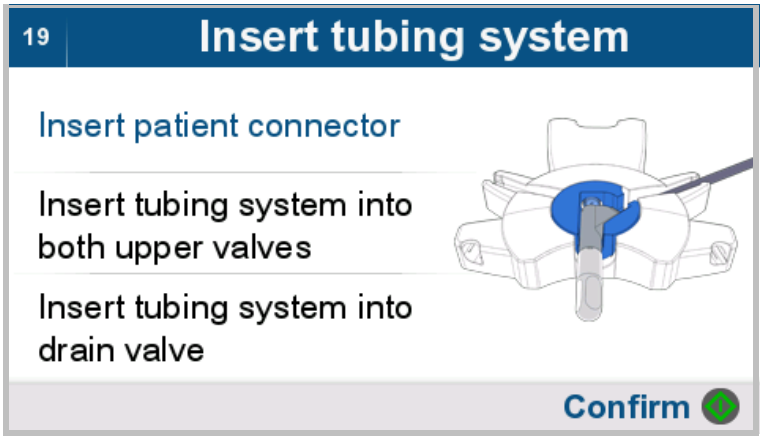
➢ The device can be switched off by pressing the button. Treatment preparation will be stopped.

Note

The paper bands on the tubing system must only be removed once priming is complete.



Leave the paper bands on the tubing system.



This image sequence is displayed automatically and in a repeating cycle. The instructions for inserting the tubing system are shown one after another with an accompanying image.

➢ Remove the tubing system from the overwrap.

➢ Insert the tubing system as described below.

➢ Insert the patient connector in the organizer.

Warning

Patient hazard from overfilling of peritoneal cavity

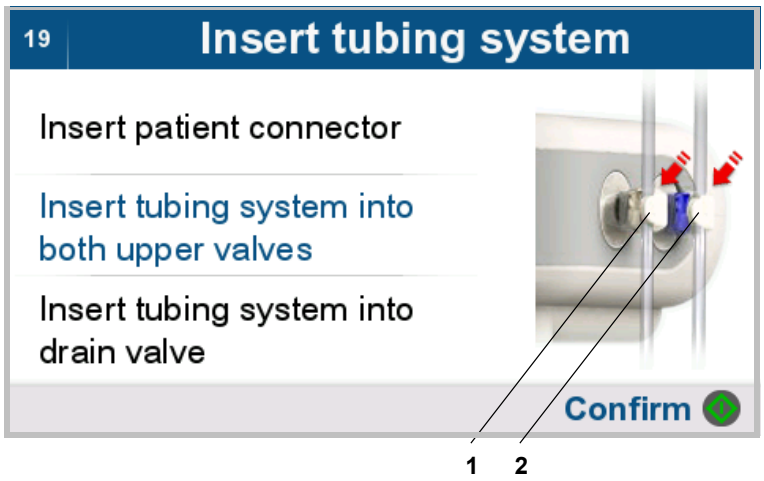
Patient hazard from insufficient detoxification

Risk of circulatory disturbance due to balancing error

Air infusion due to insufficient priming of the patient line

Uncontrolled flow of the dialysis solution can pose a patient hazard.

➢ Insert the tubing system correctly into the valves.

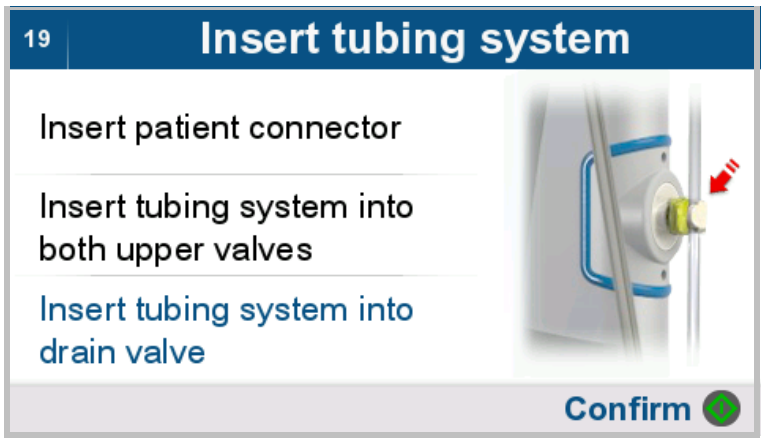


➢ Insert the tubing system with the white clamps into the inflow valve – white (1).
If the tubing system connectors are not both being used, make sure that the white tube clamp is closed on the connector that will not be in use.

➢ Insert the tubing system with the blue clamps (if present) into the inflow valve – blue (2).
If the prescription does not call for a last inflow, the tubing system must still be inserted into the inflow valve – blue (2). In this case, close the blue clamp on the tubing system.

Note

If the prescription does not call for a last inflow, the tubing system must still be inserted into the inflow valve – blue. In this case, close the blue clamp on the tubing system.



➢ Insert the drain line, identified by the yellow connector, into the drain valve – yellow.

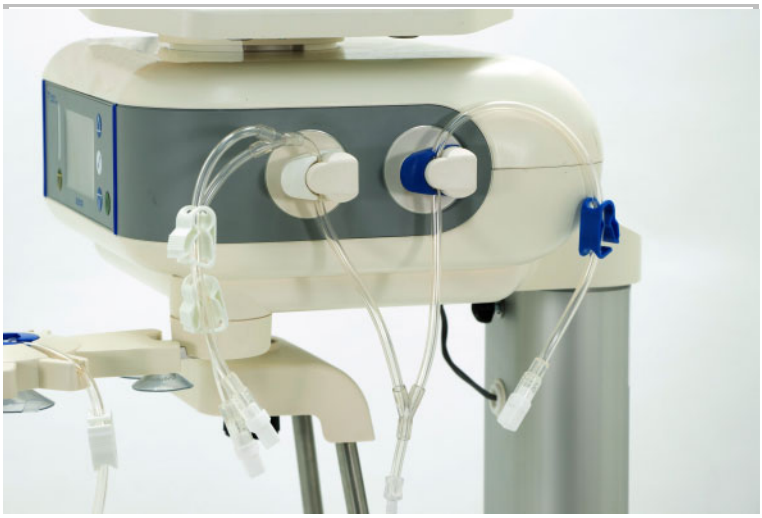
➢ Press the button to confirm that the tubing system has been inserted and to proceed to the next operating step.

➢ Keep the closing cap contained in the overwrap for use with the drain system.

The following images depict the insertion of the tubing system as described in the previous screen sequence.

Insert the patient connector in the organizer.

Leave the clamp on the patient line open.



➢ Insert the tubing system with the white clamps into the inflow valve – white (1).
If the tubing system connectors are not both being used, make sure that the white tube clamp is closed on the connector that will not be in use.

➢ Insert the tubing system with the blue clamps into the inflow valve – blue (2).
If the prescription does not call for a last inflow, the tubing system must still be inserted into the inflow valve – blue (2). In this case, close the blue clamp on the tubing system.

Insert the drain line of the tubing system with the yellow connector into the drain valve – yellow.

4.2.7 Connecting the drain system

Warning

Risk of contamination from non-compliance with hygiene measures

Improper handling can result in contact with the opening of the solution bag connector, the tubing system or the drain system.
This may lead to microbial contamination.

➢ We recommend wearing a face mask, washing your hands and the spaces between your fingers with medical-grade hand wash, and then applying hand sanitizer.

➢ Use aseptic technique when connecting the solution bag connectors.

➢ Observe the hygiene practices of the dialysis center and the hygiene regulations in force.

Warning

Risk of contamination from introduction of microbes to consumables

Microbes can be introduced into the consumables as a result of damage and can form in the consumables after their expiration date.

➢ Only use consumables if the overwrap has not been damaged.

➢ Make sure that items have not expired, and that the protective cap and closing cap have not fallen off.

➢ Do not remove consumables from their overwrap until required to do so by the corresponding operating step.

➢ Observe the hygiene practices of the dialysis center and the hygiene regulations in force.

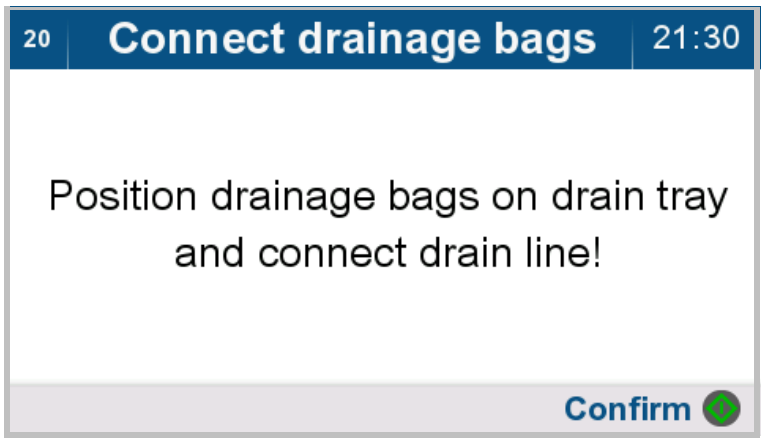
Warning

Risk of contamination from reuse of the SILENCIA Vario system

The SILENCIA Vario system is a single-use item.
Reuse can lead to patient contamination.

➢ Only use the SILENCIA Vario system once to supply the patient with dialysis fluid.

➢ Only use the empty solution bags as a drain system once.

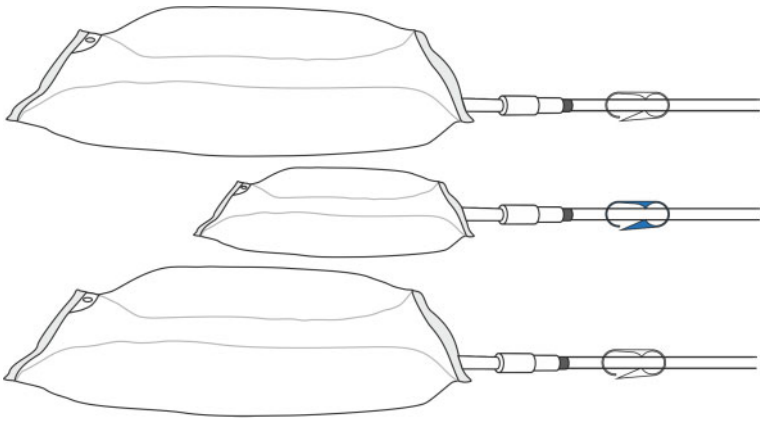


➢ Place the drainage bag on the drain tray.
The drainage bags must be aligned so that the solution bag connector points to the display side (front) of the device.

➢ Remove the protective cap from the drain line of the tubing system and the closing cap from the drain system.

➢ Connect the drain line of the tubing system to the drain system.
Make sure that the tubes of the drain system do not touch the floor.

➢ Press the button to move to the next operating step.



➢ If a last bag is used in the drain system, we recommend positioning this bag as the second bag on the drain tray.

Example: When using two 6-liter bags and one 2-liter bag in the drain system, position the 2-liter bag between the two 6-liter bags.

4.2.8 Connecting the solution bags

Warning

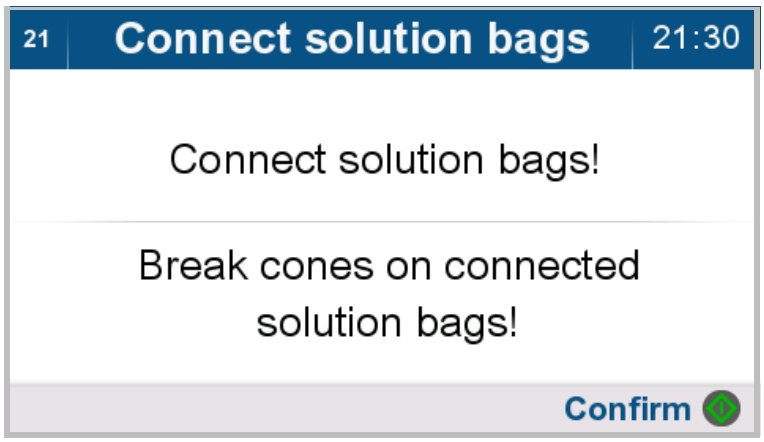
Risk of contamination from non-compliance with hygiene measures

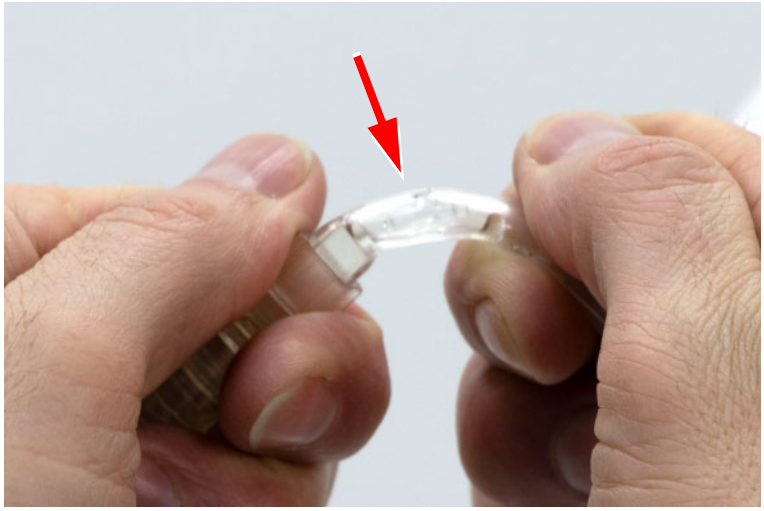
Improper handling can result in contact with the opening of the solution bag connector, the tubing system or the drain system.
This may lead to microbial contamination.

➢ We recommend wearing a face mask, washing your hands and the spaces between your fingers with medical-grade hand wash, and then applying hand sanitizer.

➢ Use aseptic technique when connecting the solution bag connectors.

➢ Observe the hygiene practices of the dialysis center and the hygiene regulations in force.





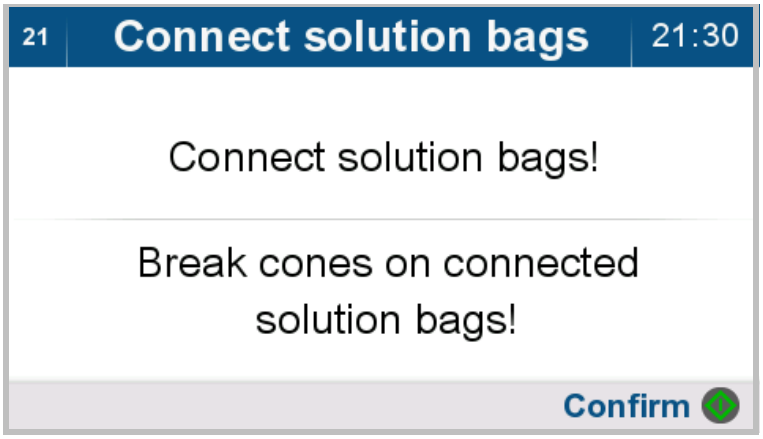
➢ Connect the solution bags.

➢ Break the cones on the connected solution bags.

➢ Press the button to move to the next operating step.

● Connecting a 7.5 % polyglucose solution bag

➢ If required for the treatment, make sure you have a 7.5 % polyglucose solution bag and a Safe•Lock® APD Luer lock connector ready to hand.



➢ When using a 7.5 % polyglucose solution bag, connect the Safe•Lock® APD Luer lock connector to the connector for optional last bag of the SILENCIA Vario system 2+1.
Then connect the 7.5 % polyglucose solution bag with the Safe•Lock® APD Luer lock connector, making sure that the connection is secure.

➢ Make sure that the tubing system is inserted into the inflow valve – blue (1) as shown.

➢ Break the cones on the connected solution bags.

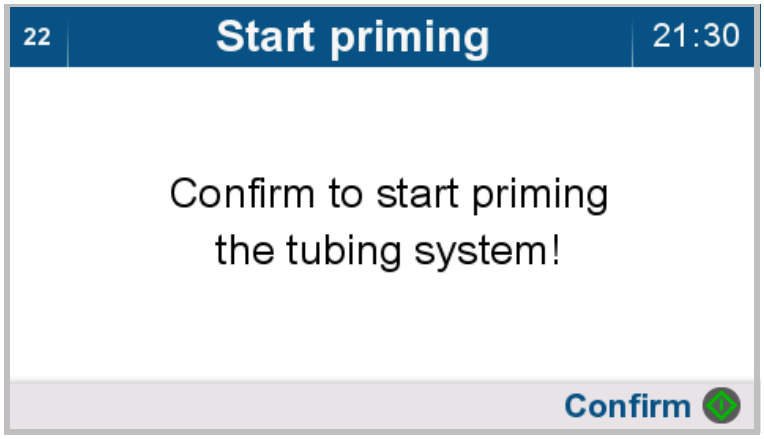
➢ Before starting filling, check that the connection between the Safe•Lock® APD Luer lock connector and the 7.5 % polyglucose solution bag is screwed correctly.

➢ Press the button to move to the next operating step.

4.2.9 Priming the tubing system

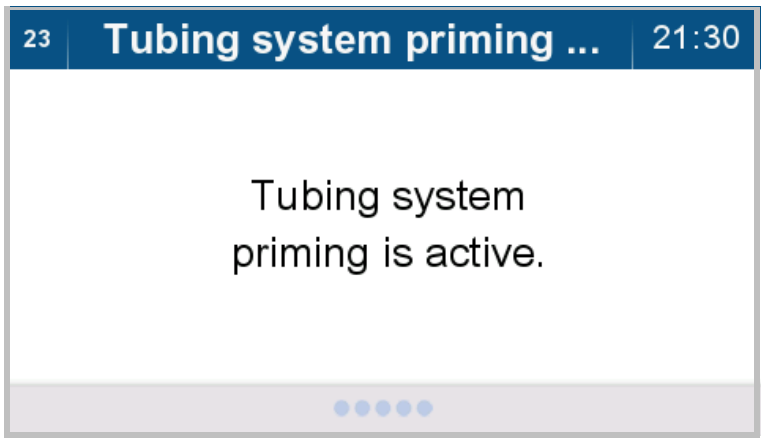
Note

Check for the following before priming the tubing system:
- The organizer along with the inserted patient connector has been fitted onto the organizer mount on the base unit.
- The cones are broken on all connected solution bags.
- All tube clamps on the solution bag lines are open.
- All tube clamps on the drain system are open.
- All tube clamps not in use are closed.

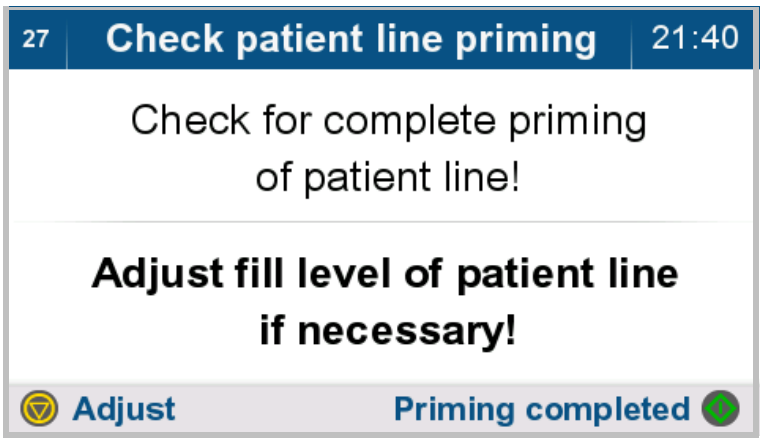


The tubing system is ready to be primed.

➢ Press the button to start the priming process.



The tubing system is then primed automatically.



➢ Check the fluid level in the patient line.

➢ Press the button to continue priming the patient line.

➢ Press the button if the patient line has been fully primed.
The device advances to the next operating step.

If priming fails, check for the following:
– The cones are broken on all connected solution bags.
– All tube clamps on the solution bag lines are open.
– The tubing system has been inserted into all valves.

➢ Press the button to repeat the priming process.

Note

Priming can be repeated a maximum of three times.

4.3 Performing a treatment

4.3.1 Confirming treatment data

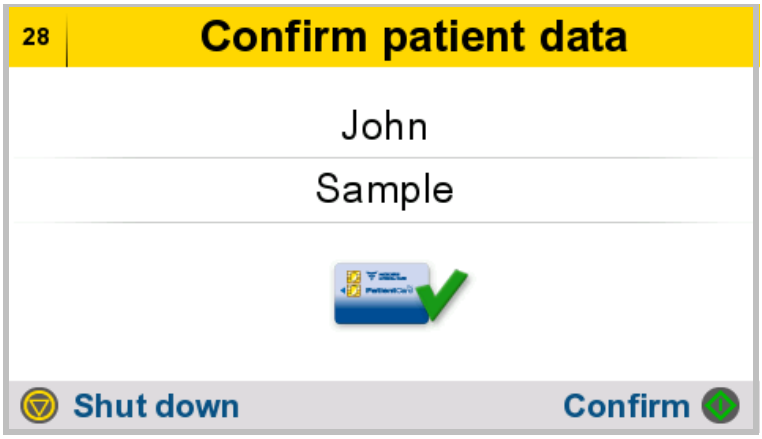
Warning

Patient hazard from overfilling of peritoneal cavity

The use of incorrect treatment data may result in an incorrect patient prescription.

➢ Only the patient whose name is displayed on the screen must be connected to the device.

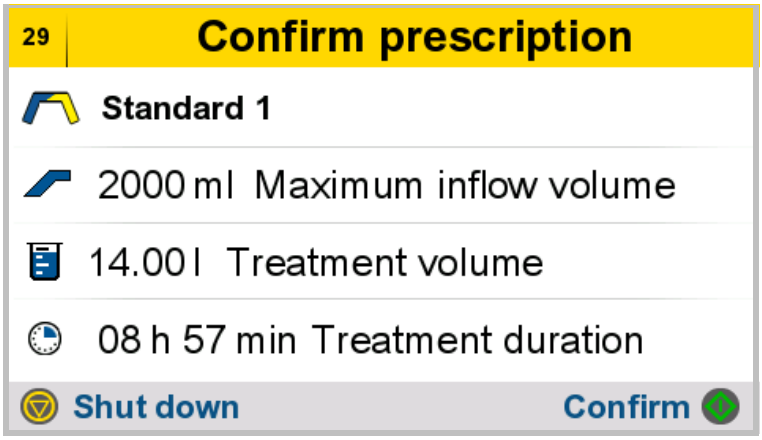
➢ The operator must check the treatment data (maximum inflow volume, treatment volume, and treatment duration) for plausibility before starting the treatment.



➢ Check patient data for plausibility and confirm.

➢ Press the button to move to the next operating step.

➢ The device can be switched off by pressing the button.



➢ Check treatment data for plausibility and confirm.

➢ Press the button to move to the next operating step.

➢ The device can be switched off by pressing the button.

4.3.2 Connecting the patient

Warning

Risk of contamination from non-compliance with hygiene measures

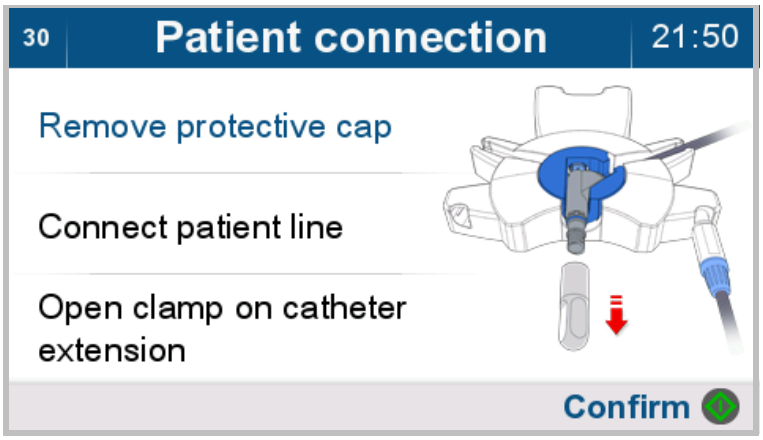
Improper handling during connection can lead to contact with the opening of the patient connector.
This may lead to microbial contamination.

➢ We recommend wearing a face mask, washing your hands and the spaces between your fingers with medical-grade hand wash, and then applying hand sanitizer.

➢ Use aseptic technique when connecting the patient.

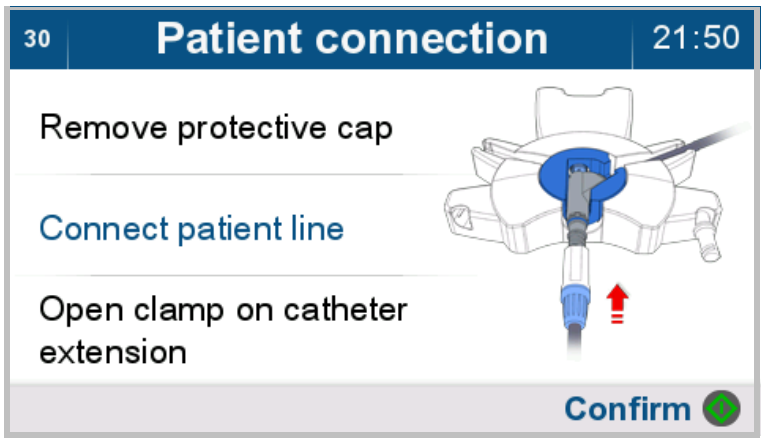
➢ The patient line must be tightly sealed.

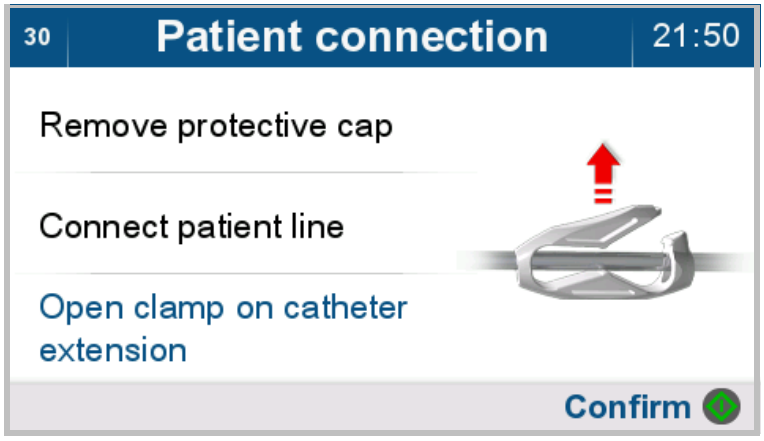
➢ Observe the hygiene practices of the dialysis center and the hygiene regulations in force.



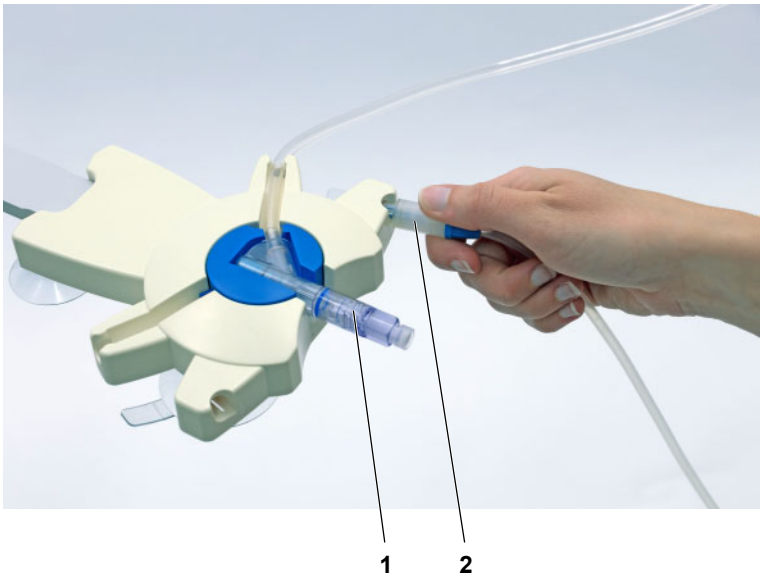
The patient should be connected immediately after priming of the tubing system and patient line.

This image sequence is displayed automatically and in a repeating cycle. Connection instructions are shown one after another with the associated image.





➢ Connect the patient line as described below.

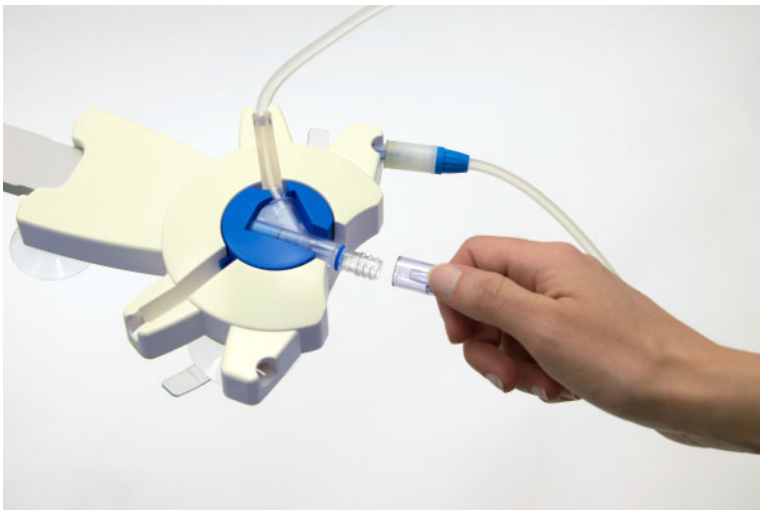


In order to connect the patient, the patient connector (1) must be inserted into the organizer.

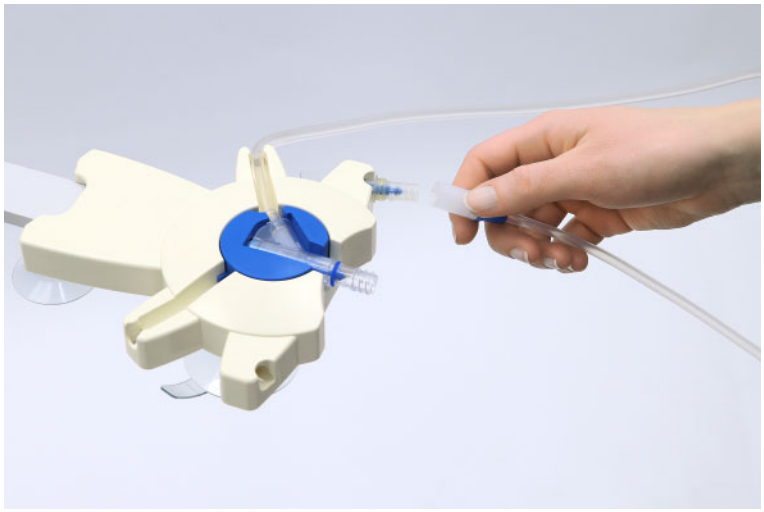
➢ Place the system connector (2) of the catheter extension in the right holder of the organizer (if left-handed, place in the left holder).

➢ Put on the face mask.

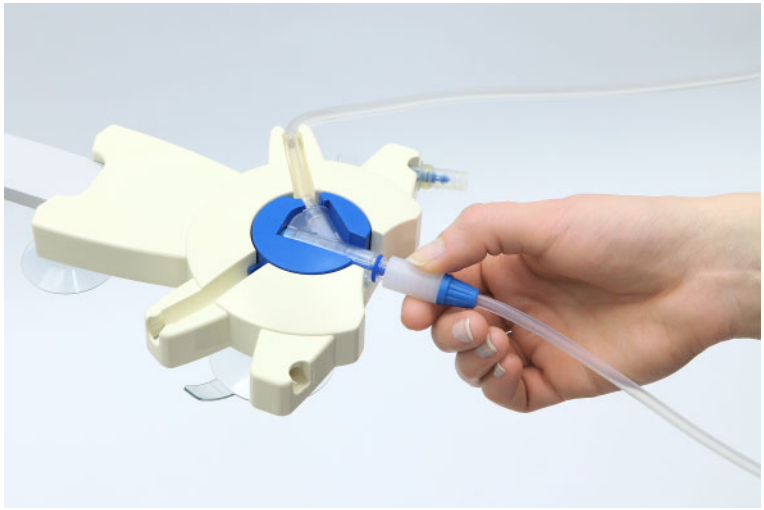
➢ Disinfect your hands and dry them carefully.



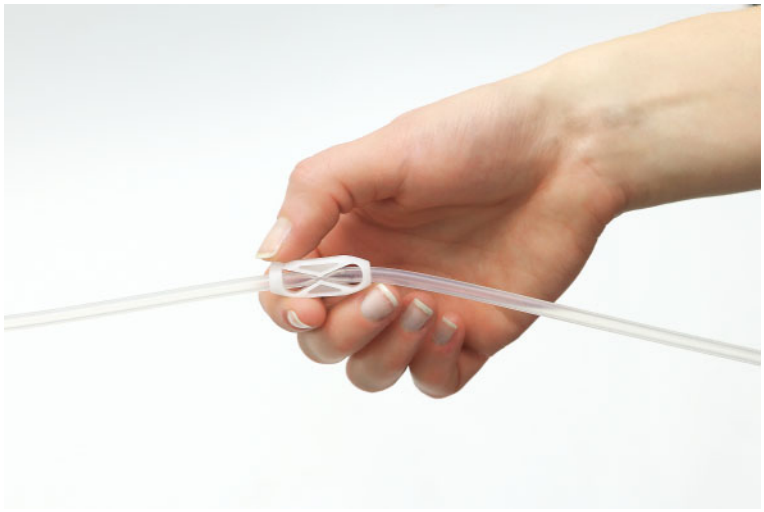
➢ Unscrew and discard the protective cap from the patient connector on the tubing system.



➢ Unscrew the system connector of the catheter extension from the disinfection cap.



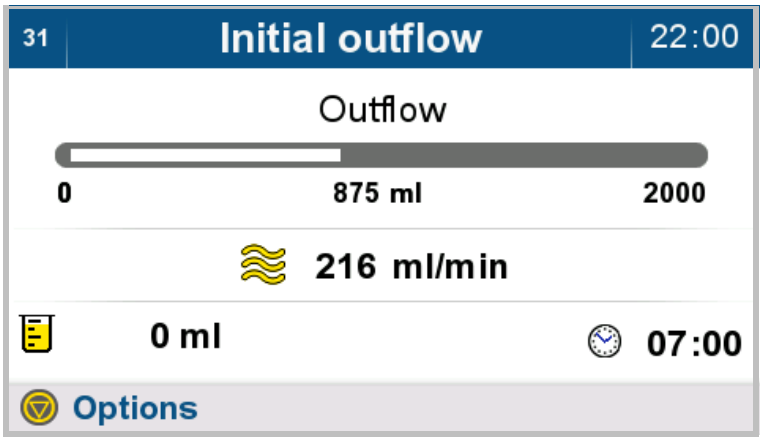
➢ Screw the catheter extension system connector directly onto the patient connector on the tubing system.



➢ Open the white clamp on the catheter extension.

➢ Press the button to confirm the connection and to start the treatment.

4.3.3 Starting the treatment



Treatment is started.

The treatment will start with an initial outflow.

If the prescription specifies a defined target volume for the initial outflow, this volume is displayed.

➢ Press the to display options.

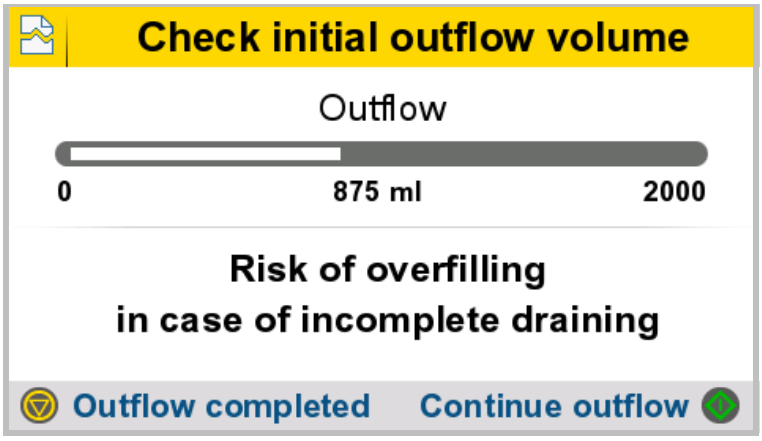
4.3.4 Terminating the initial outflow

Warning

Patient hazard from overfilling of peritoneal cavity

Breathing and circulatory problems can result if the peritoneal cavity is filled with too much fluid.

➢ Ensure that the peritoneal cavity is completely empty at the end of the initial outflow.



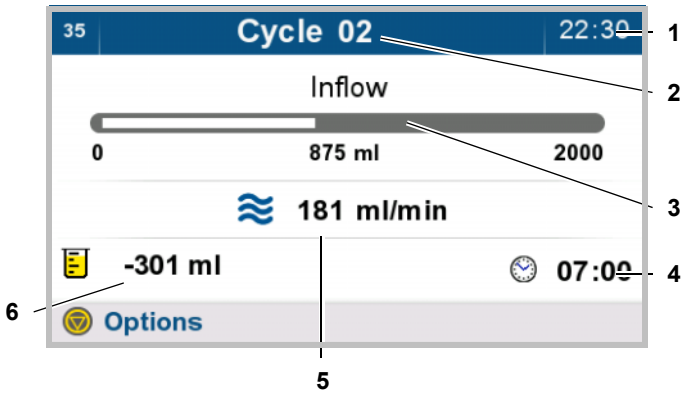
The initial outflow volume achieved and the initial outflow target volume will be displayed.

➢ Press the button to continue the initial outflow.

➢ Only press the button if the peritoneal cavity has been completely drained. The initial outflow is ended so that the next inflow phase can begin.

4.3.5 During treatment

- **Inflow**

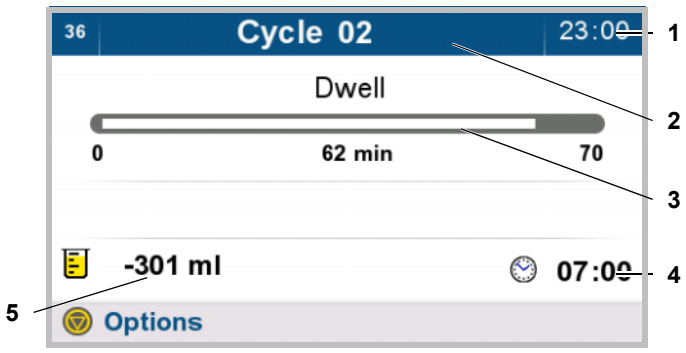


During the inflow process, the following parameters will be displayed in the treatment overview screen:

1. Current time
2. Treatment cycle
3. Progress of the current treatment phase
4. Expected treatment end time
5. Flow rate
6. Current total volume balance

➢ Press the to display options.

- **Dwell**

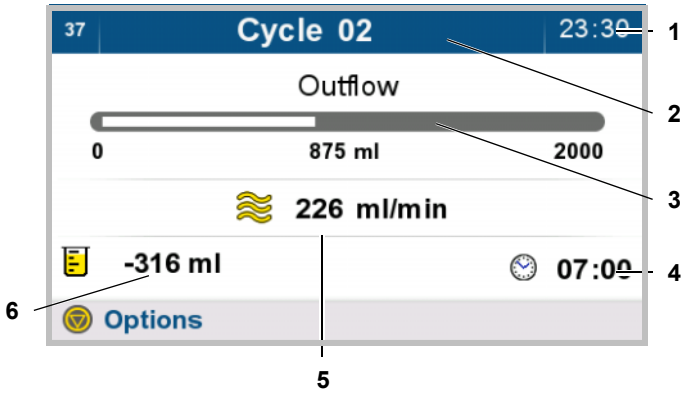


During the dwell process, the following parameters will be displayed in the treatment overview screen:

1. Current time
2. Treatment cycle
3. Progress of the current treatment phase
4. Expected treatment end time
5. Current total volume balance

➢ Press the to display options.

- **Outflow**

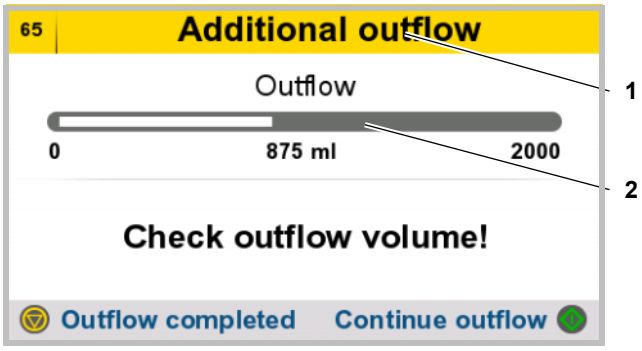


During the outflow process, the following parameters will be displayed in the treatment overview screen:

1. Current time
2. Treatment cycle
3. Progress of the current treatment phase
4. Expected treatment end time
5. Flow rate
6. Current total volume balance

➢ Press the ▽ to display options.

4.3.6 Additional outflow



If the prescription calls for an additional outflow, this outflow is performed.

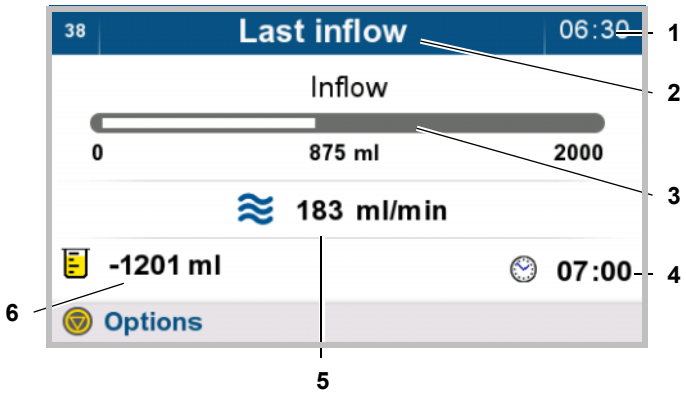
During the outflow process, the following parameters will be displayed in the treatment overview screen:

1. Treatment cycle
2. Progress of the current treatment phase

➢ Press the ◇ button to continue the outflow.

➢ Only press the ▽ button if the outflow is complete.
The device advances to the next operating step.

4.3.7 Last inflow



If the prescription calls for a last inflow, this inflow is performed.

During the inflow process, the following parameters will be displayed in the treatment overview screen:

1. Current time
2. Treatment cycle
3. Progress of the current treatment phase
4. Expected treatment end time
5. Current flow rate during last inflow
6. Current total volume balance

➢ Press the to display options.

4.4 Ending the treatment

4.4.1 Disconnecting the patient

Warning

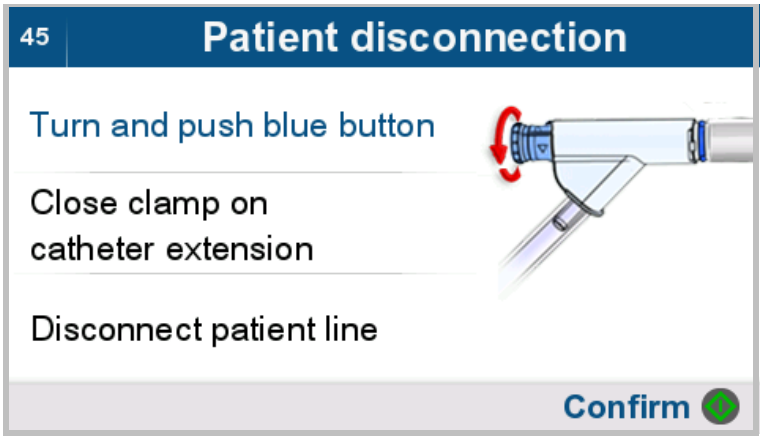
Risk of contamination from non-compliance with hygiene measures

Improper handling during disconnection can lead to contact with the opening of the patient connector or the Vario-Connector.
This may lead to microbial contamination.

➢ We recommend wearing a face mask and using hand sanitizer.

➢ Use aseptic techniques when disconnecting the patient.

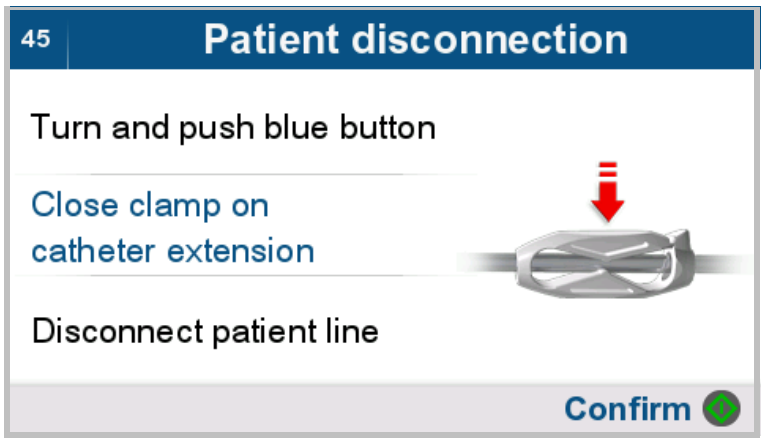
➢ Observe the hygiene practices of the dialysis center and the hygiene regulations in force.



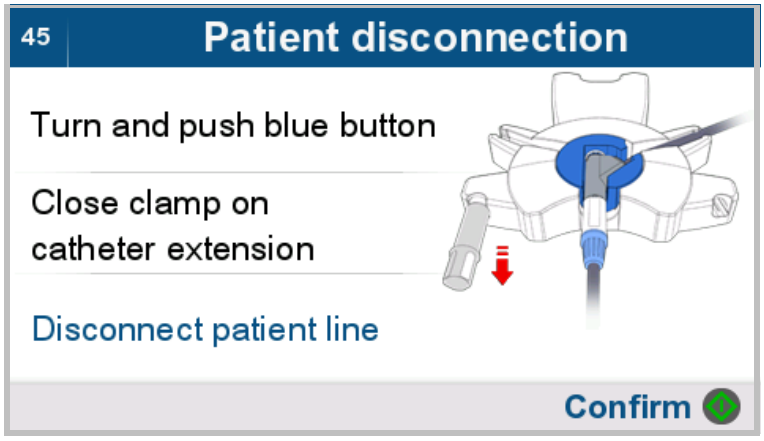
This image sequence is displayed automatically and in a repeating cycle. Disconnection instructions are shown one after another with the associated image.

➢ Turn the blue knob on the patient connector a quarter turn clockwise.

➢ Push the blue knob on the patient connector fully in.

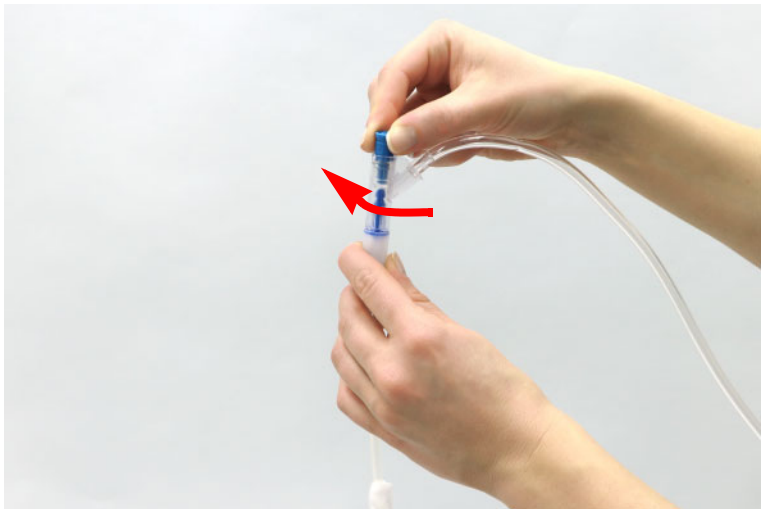


➢ Close the white clamp on the catheter extension.

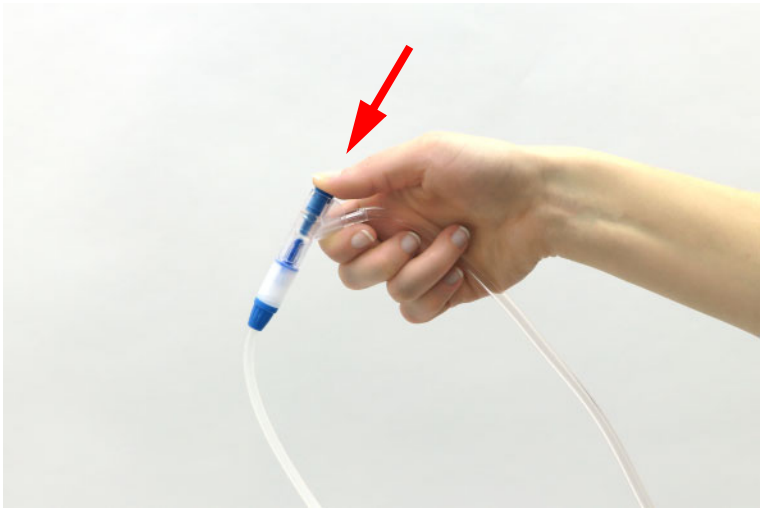


Disconnect the patient line.

➢ Perform the disconnection as described below.

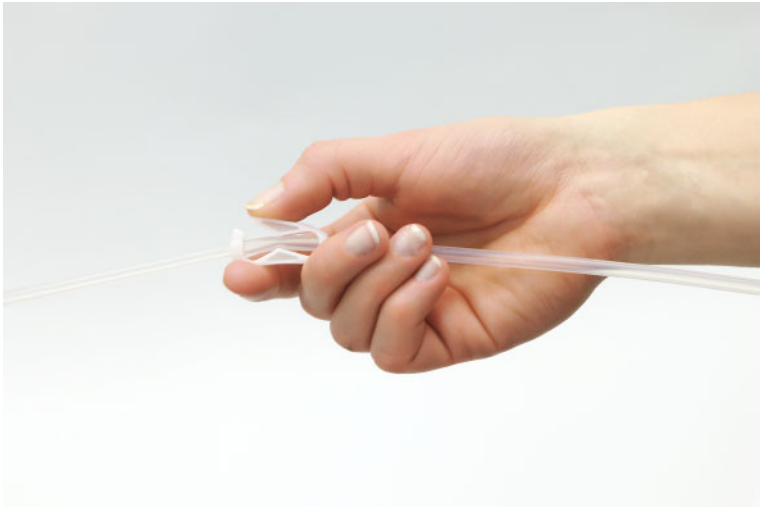


➢ Turn the blue knob on the patient connector a quarter turn clockwise.

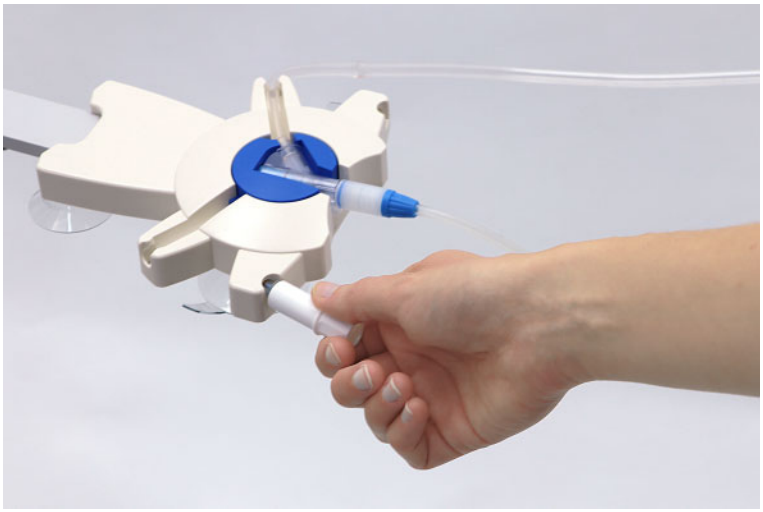


➢ Push the blue knob on the patient connector fully in.

This will automatically close the catheter extension with the PIN.



➢ Close the white clamp on the catheter extension.

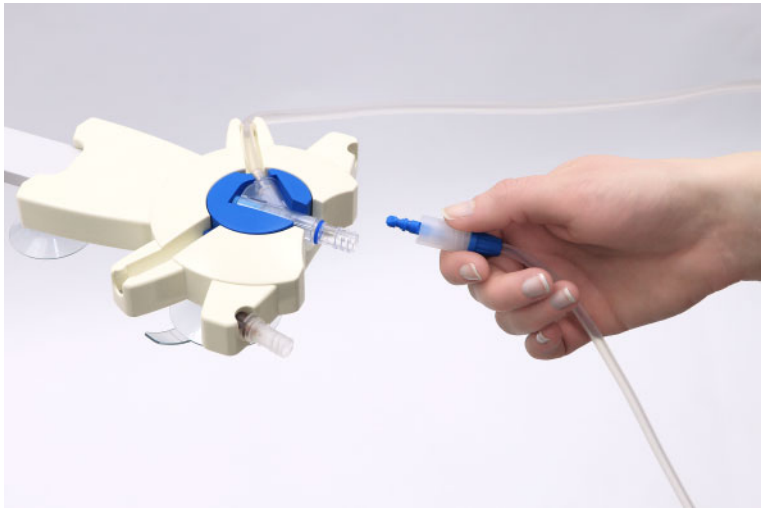


➢ Open the overwrap of the new disinfection cap.

➢ Place the new disinfection cap in the left holder of the organizer (if left-handed, place the disinfection cap in the right holder).

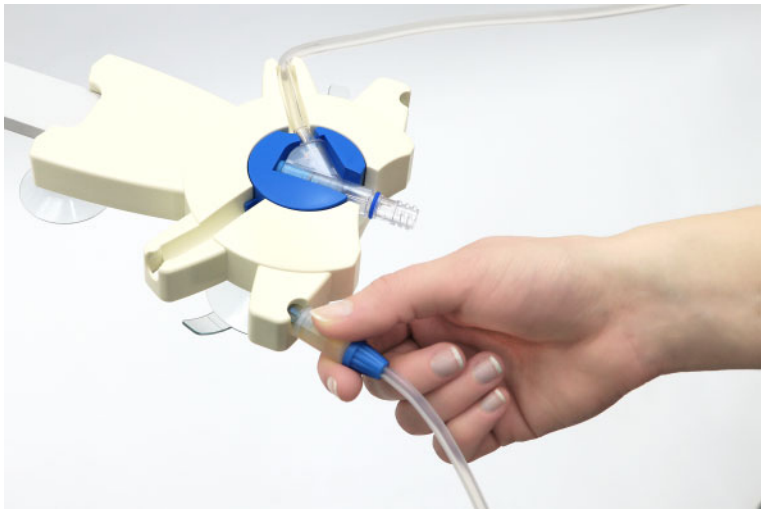
➢ Insert the patient connector into the organizer.

➢ Unscrew and discard the closing cap of the new disinfection cap.



➢ Unscrew the catheter extension system connector from the patient connector on the tubing system.

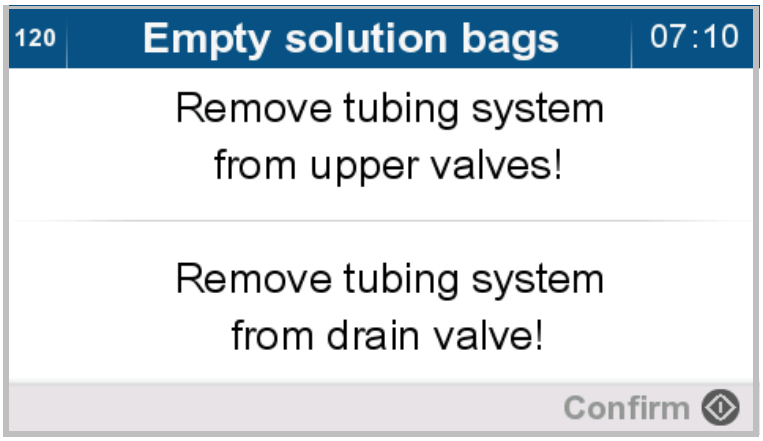
➢ Screw the catheter extension system connector with the PIN firmly onto the new disinfection cap.



➢ Pull the closed catheter extension straight (without turning it) out of the organizer.

➢ Press the key to confirm the disconnection.

4.4.2 Draining the solution bag and tubing system



➢ Remove the tubing system from the upper valves.

➢ Remove the tubing system from the drain valve.

➢ Press the button to move to the next operating step.

Leave the tubing system on the device during the draining procedure to ensure that the solution bags are fully drained.

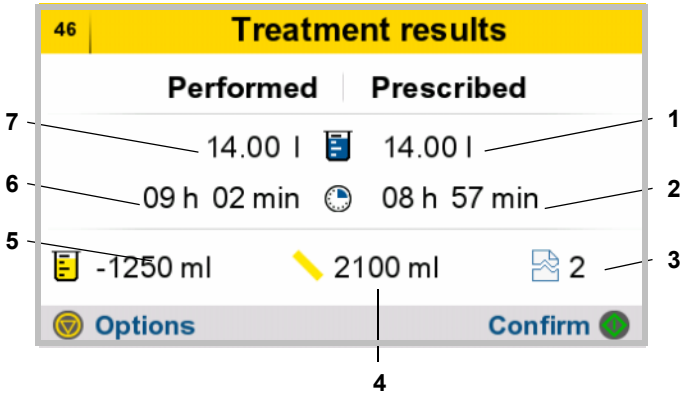
4.4.3 Treatment results

Warning

Patient hazard from insufficient detoxification

A repeated reduction of the treatment duration or the treatment volume may result in the desired treatment goal not being achieved.

➢ The attending physician must be informed.



The results of the last treatment will be displayed:

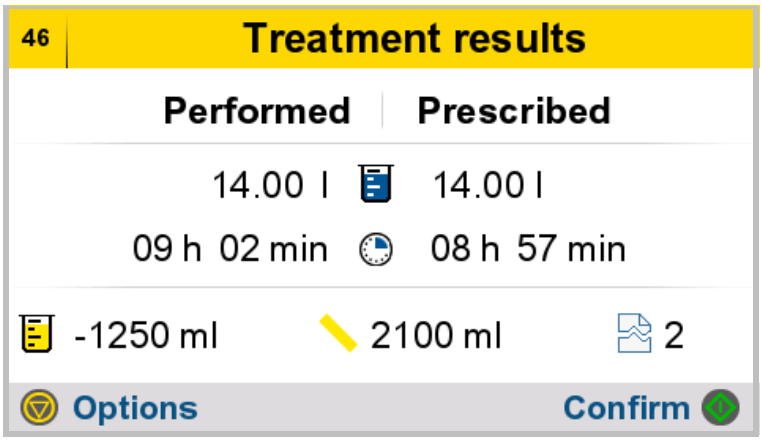
1. Prescribed treatment volume
2. Prescribed treatment duration
3. Number of interruptions
4. Initial outflow volume
5. Volume balance without last inflow and without initial outflow. Negative values describe a withdrawal of fluid from the patient (ultrafiltrate has been generated). Positive values describe an uptake of fluid in the patient (resorption).
6. Actual treatment duration
7. Actual treatment volume

Press the button to display additional treatment report information (graphics and interruptions),

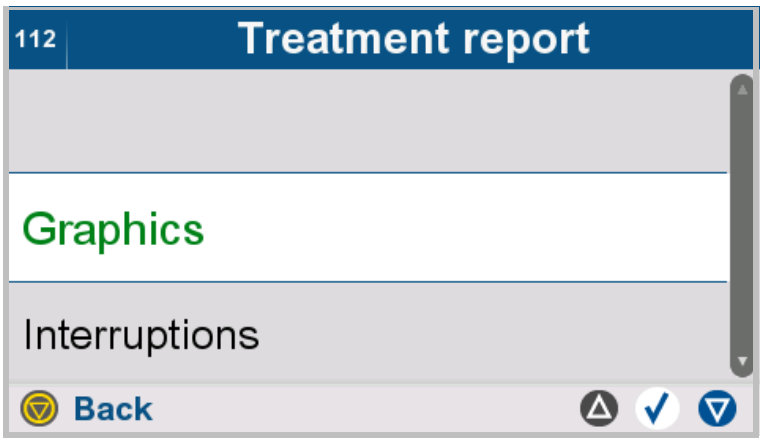
or

Press the button to end the treatment.

4.4.4 Displaying graphics

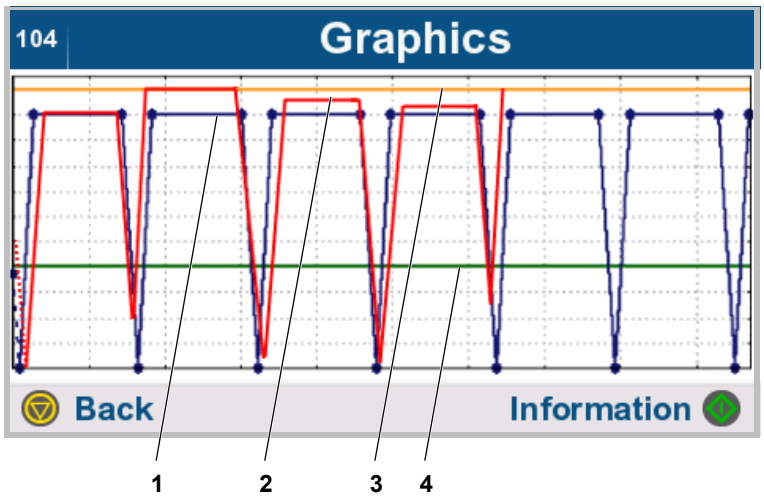


➢ Press the button to display additional treatment report information.



➢ Select **Graphics**.

➢ Press the button to return to the higher-level menu.

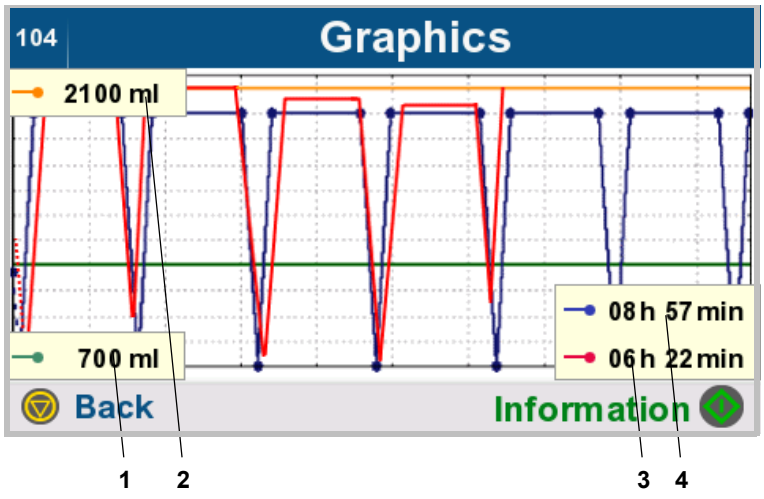


Treatment progress is displayed in graphical form.

1. Prescribed treatment progress (blue)
2. Actual treatment progress (red)
3. Permitted patient volume in ml (orange) (see Chapter 7.3.1.1 on page 182)
4. Permitted residual volume in ml (green) (see Chapter 7.3.1.2 on page 182)

➢ Press the button to display additional information.

➢ Press the button to return to the higher-level menu.



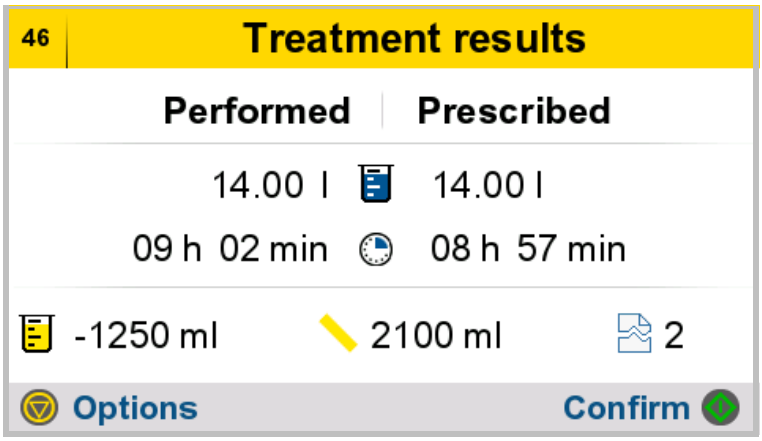
Treatment progress is shown in graphical form, and additional information can also be displayed:

1. Permitted residual volume in ml (green) (see Chapter 7.3.1.2 on page 182)
2. Permitted patient volume in ml (orange) (see Chapter 7.3.1.1 on page 182)
3. Actual treatment duration (red)
4. Prescribed treatment duration (blue)

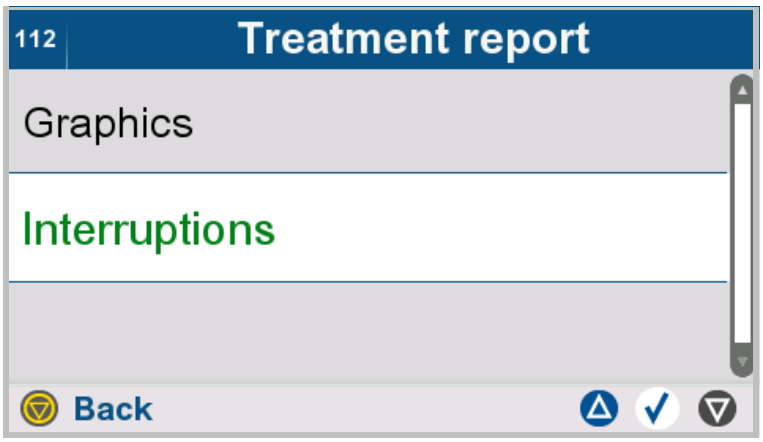
➢ Press the button to hide the additional information.

➢ Press the button to return to the higher-level menu.

4.4.5 Viewing interruptions

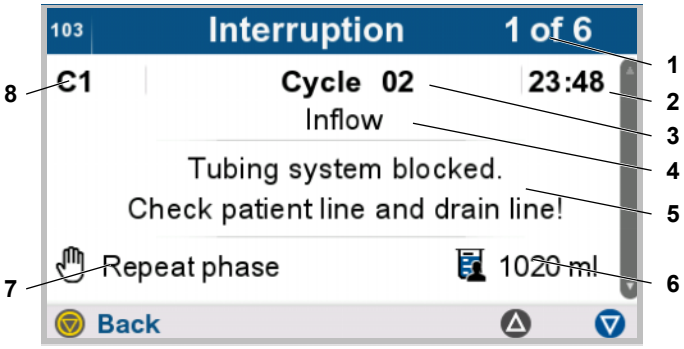


➢ Press the button to display additional treatment report information.



➢ Select **Interruptions**.

➢ Press the button to return to the higher-level menu.



The interruptions for the selected treatment are displayed:

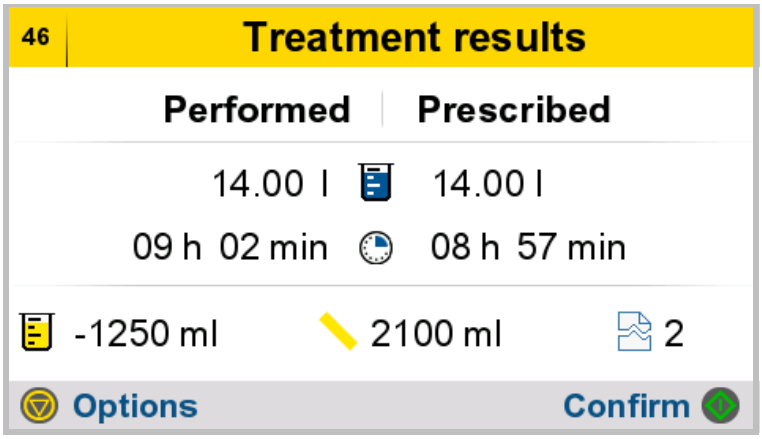
1. Number of the currently selected interruption (interruption 1 of 6)
2. Time of interruption
3. Treatment cycle
4. Treatment phase
5. Description of interruption
6. Quantity of dialysis solution in peritoneal cavity when interruption occurred
7. Type of interruption acknowledgment
8. Identification number

➢ Use the △ and ▽ buttons to scroll through the pages.

➢ Press the ▽ button to return to the higher-level menu.

4.5 Treatment post-processing

4.5.1 Saving treatment results



➢ Press the button to move to the next operating step.

The treatment data are stored.

The treatment data are written to the patient card. If a patient card is not being used, or if the patient card cannot be accessed momentarily, the data are stored internally on the device.

If the patient card needs to be removed, e.g., for visiting a physician, this must only be done after the device has been switched off.

4.5.2 Removing the tubing system

Warning

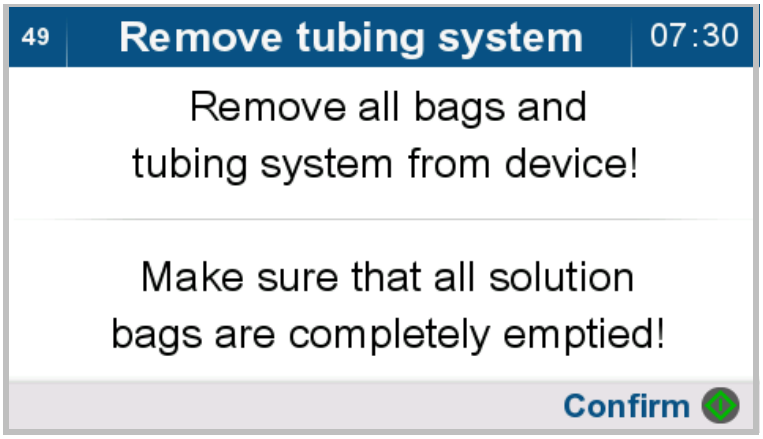
Risk of cross-contamination as a result of contaminated consumables

Improper disposal may lead to the transmission of microbes to third parties (cross-contamination).

➢ After treatment, dispose of the tubing system and drainage bag in compliance with local regulations for handling potentially contaminated materials.

Note

The solution bags must be fully drained before the tubing system is removed.



Remove the solution bags, the drainage bag, and the tubing system from the device.

➢ Press the button to confirm removal.

4.5.3 Preparing the drainage bag for the next treatment

Warning

Risk of contamination from non-compliance with hygiene measures

Improper handling during disconnection can lead to contact with the opening of the patient connector or the Vario-Connector.
This may lead to microbial contamination.

➢ We recommend wearing a face mask and using hand sanitizer.

➢ Use aseptic techniques when disconnecting the patient.

➢ Observe the hygiene practices of the dialysis center and the hygiene regulations in force.

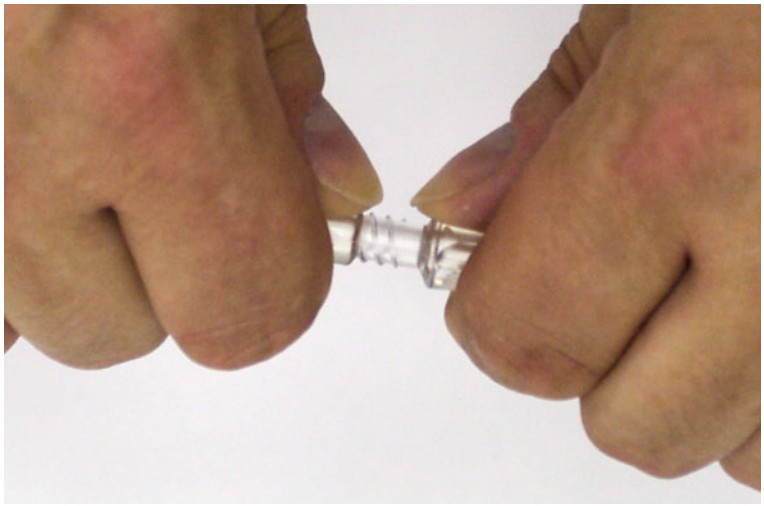
Warning

Patient hazard as a result of a failure to achieve the treatment goal

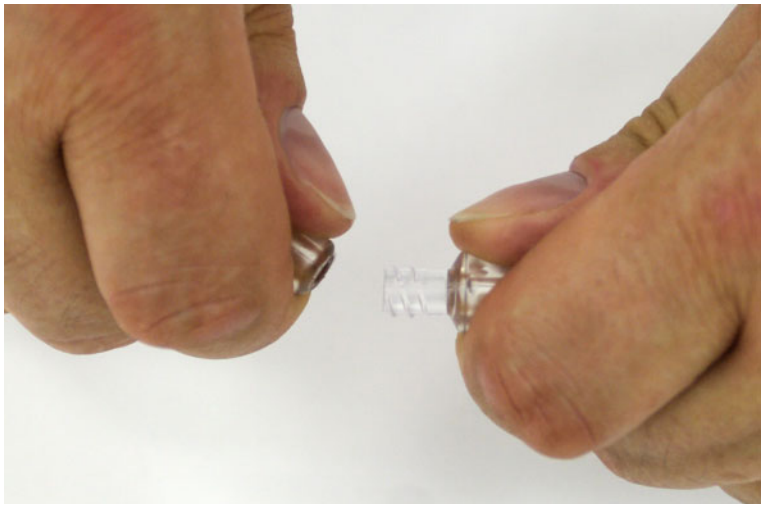
If solution bags are not completely drained, the dialysate from the next treatment cannot be stored.

➢ Fully drain the solution bags from the completed treatment.

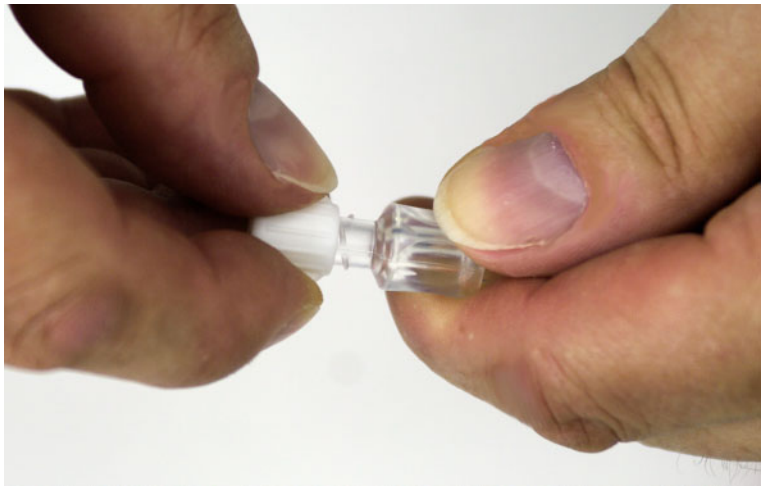
➢ Keep the fully emptied solution bags of the completed treatment at hand as a drainage system for the next treatment.



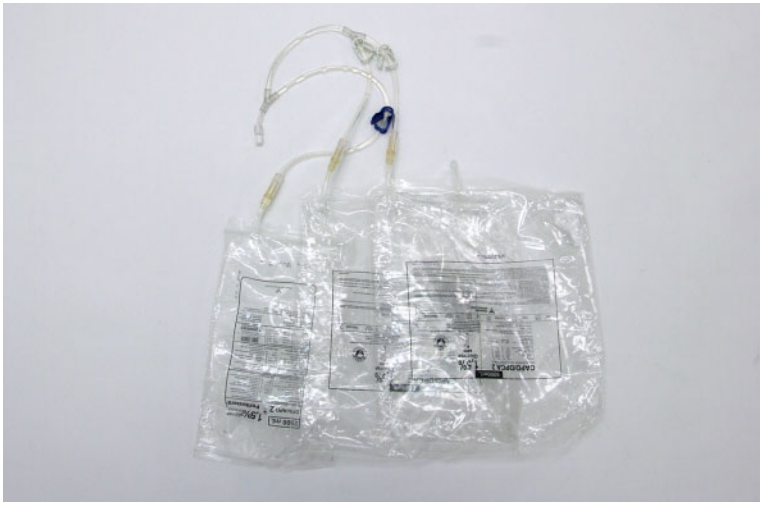
➢ Hold both sides of the Vario-Connector on the tubing system from the completed treatment.



➢ Break apart the Vario-Connector at the separation point.

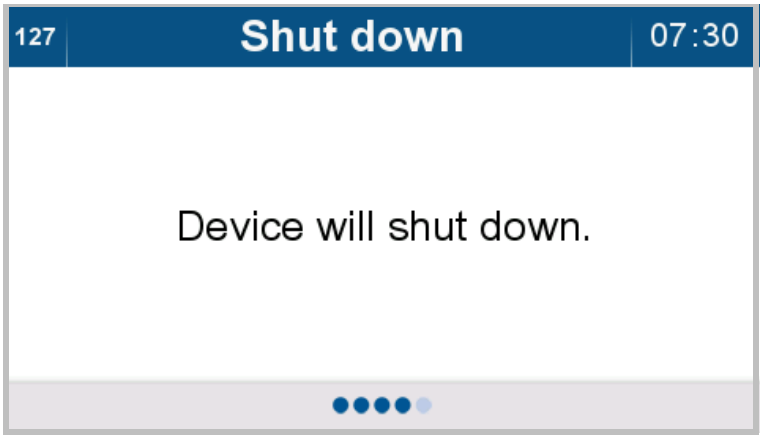


➢ Screw the protective cap supplied with the tubing system onto the Vario-Connector.



➢ Keep the empty solution bags and the separated tubing segment to use as a drain system for the next treatment.

4.5.4 Powering down the device

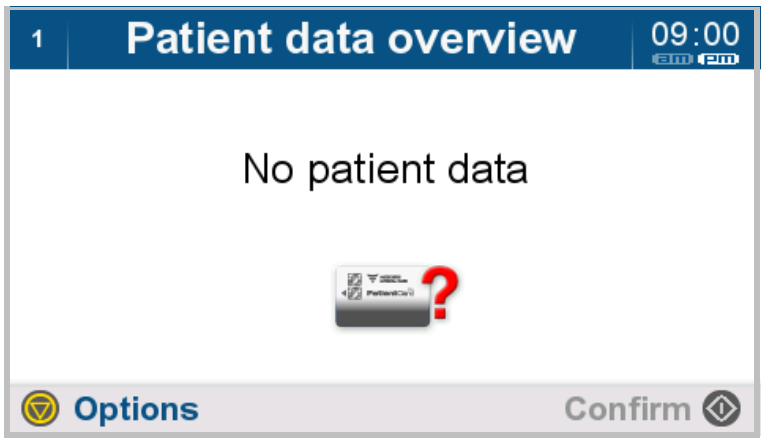


The device switches off automatically.

4.6 Personalizing

4.6.1 Personalizing the device/patient card

These functions can only be accessed by the clinical staff.

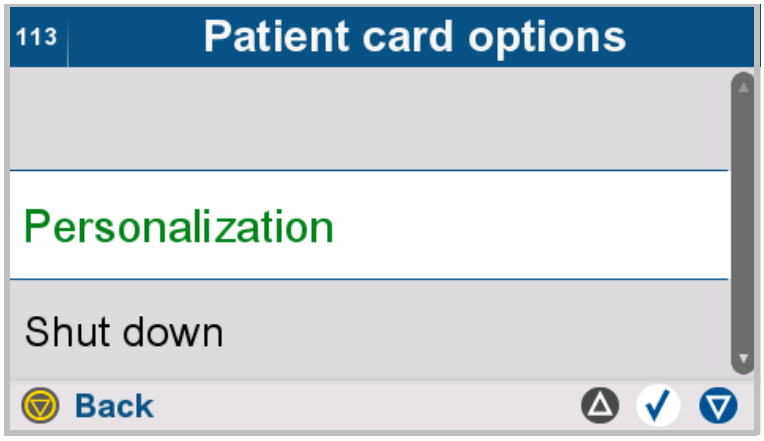


If no patient card has been inserted, or if the patient card is not recognized, a gray card icon is displayed on the screen.

If the system is not personalized, a red question mark will appear on the screen.

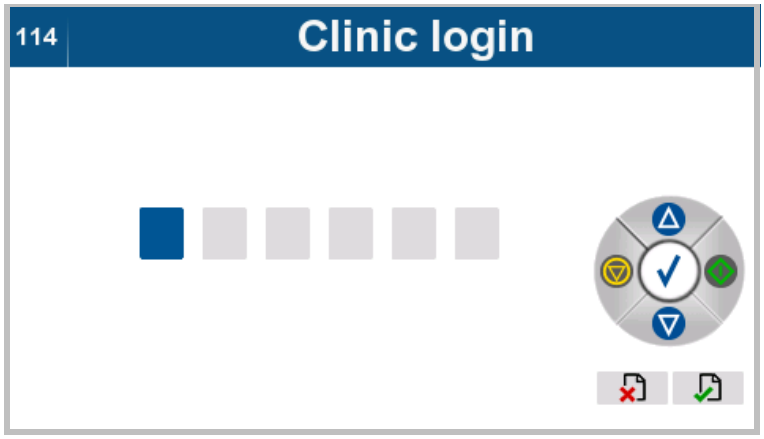
A treatment can only be performed if the system is adjusted (personalized) for the patient.

➢ Press the button to access the options.



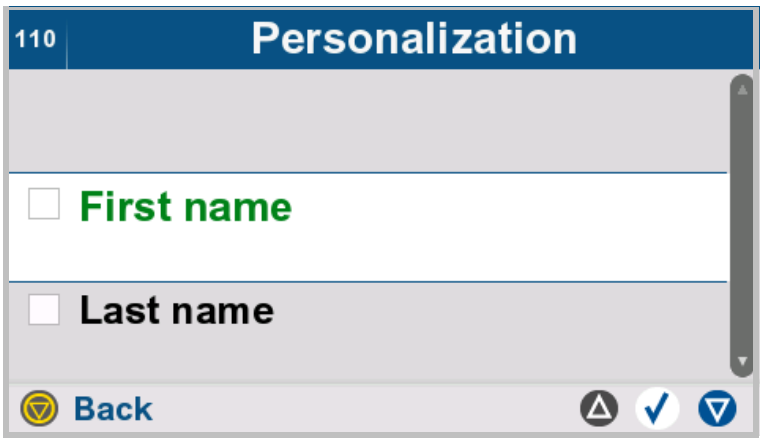
➢ Select **Personalization**.

➢ Press the button to return to the higher-level menu.



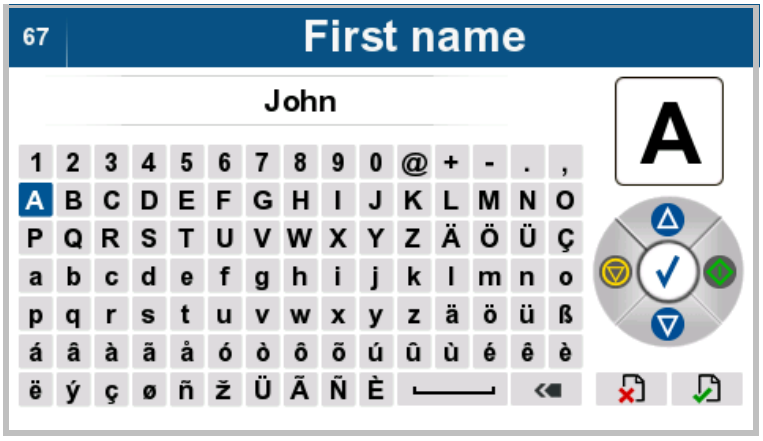
➢ If no clinic login has occurred, the screen shown here is displayed.

➢ Enter the access code for the clinic login using the buttons shown below.

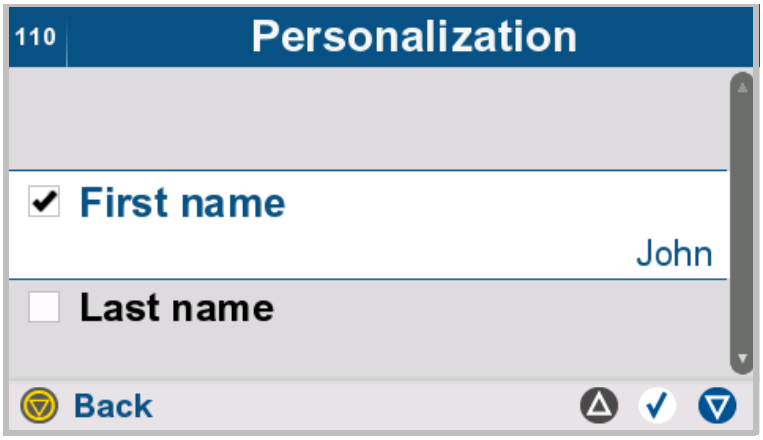


➢ Select **First name**.

➢ Press the button to return to the higher-level menu.

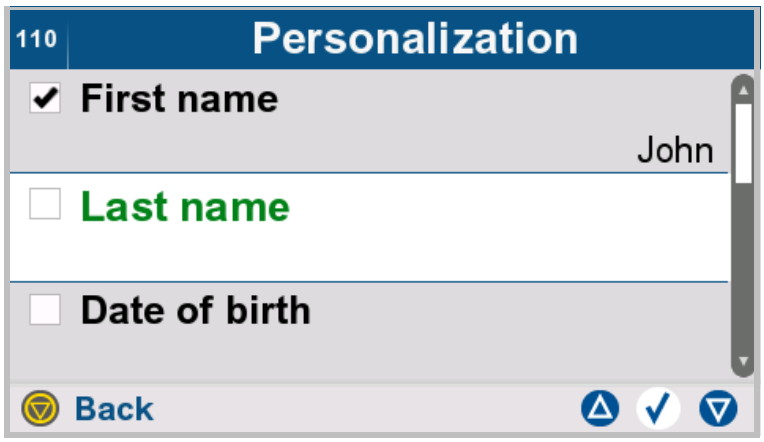


➢ Enter the patient's first name.



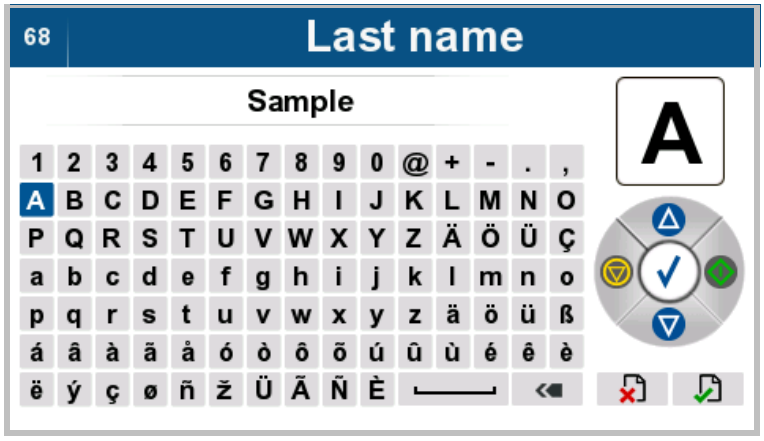
The entered first name is displayed.

The **First name** box is checked.

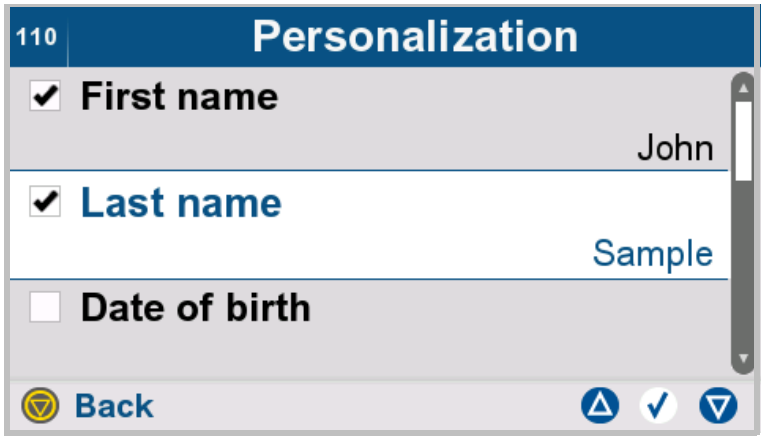


➢ Select **Last name**.

➢ Press the button to return to the higher-level menu.

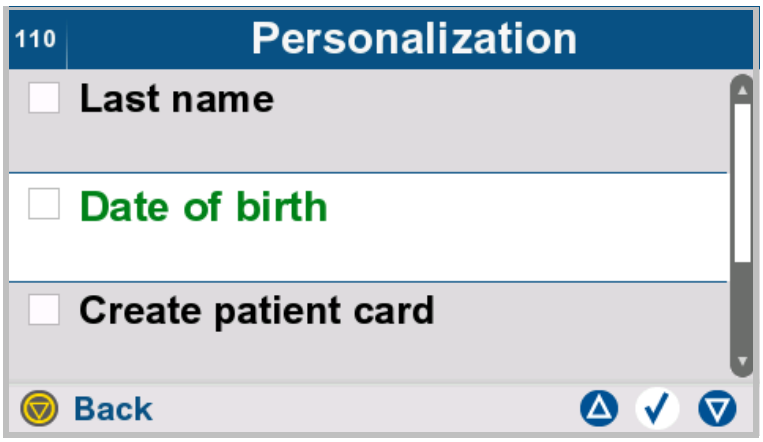


➢ Enter the patient's last name.



The entered last name is displayed.

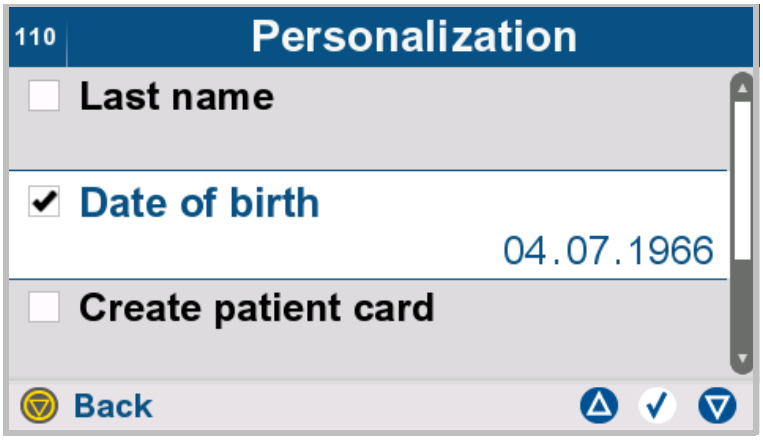
The **Last name** box is checked.



➢ Select **Date of birth**.

➢ Press the button to return to the higher-level menu.

➢ Enter the patient's date of birth.



The entered date of birth is displayed.

The **Date of birth** box is checked.

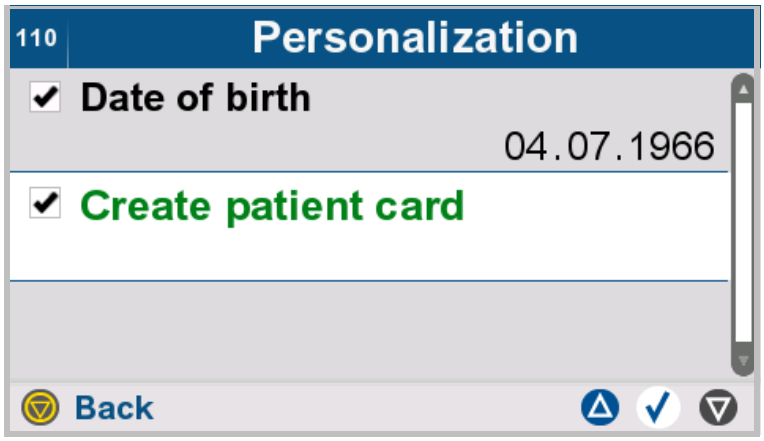
Warning

Patient hazard from overfilling of peritoneal cavity

Risk of circulatory disturbance due to balancing error

Patient hazard from glucose imbalance due to incorrectly entered parameters

➢ The entered parameters must be checked for plausibility by the operator.



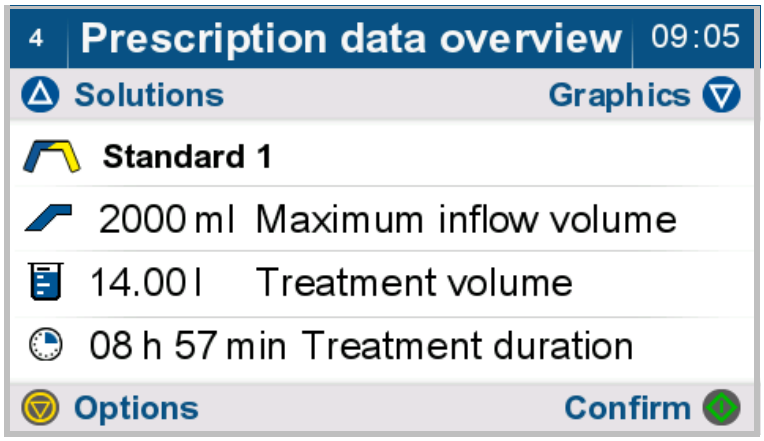
➢ Select **Create patient card** to create a patient card.

➢ Press the ✓ button to create a patient card.

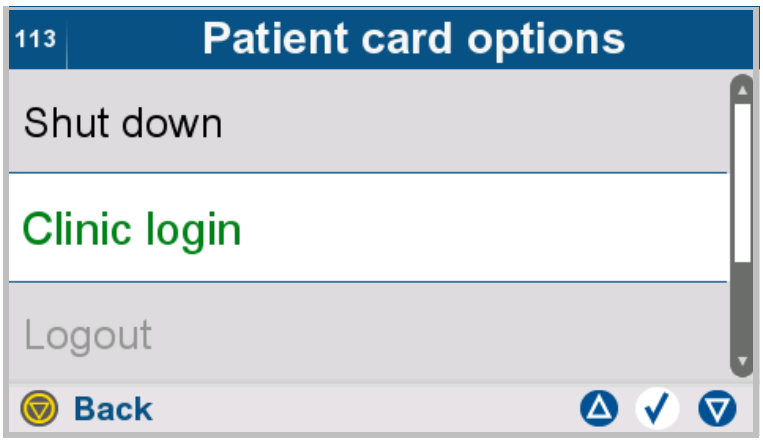
➢ Press the button to return to the higher-level menu.

4.6.2 Clinic login

The "clinic login" function allows patient data, patient parameters and prescription data to be entered and modified. This function can only be accessed by clinical staff.

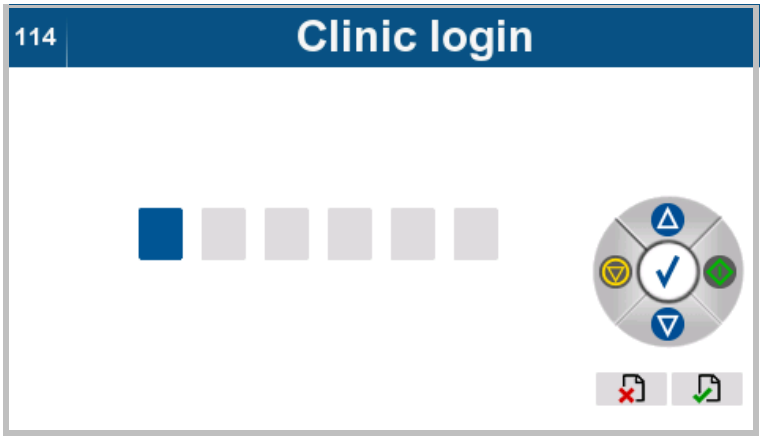


Press the button to access the options.



➢ Select **Clinic login**.

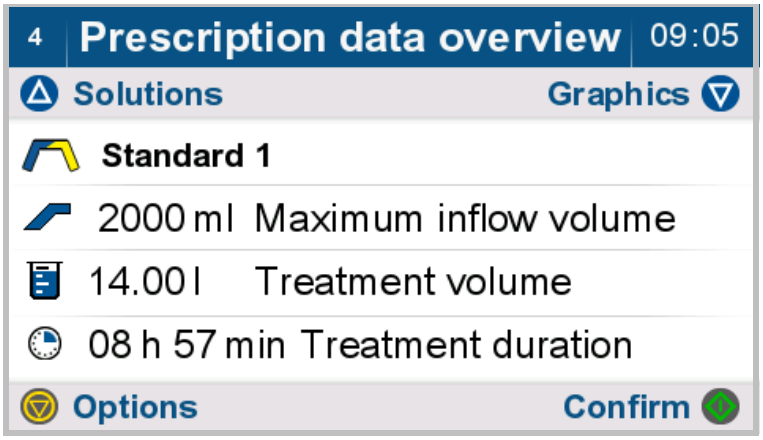
➢ Press the button to return to the higher-level menu.



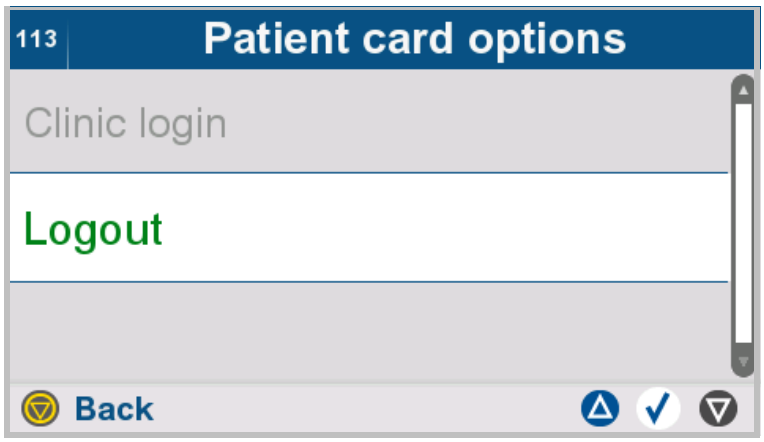
➢ Enter the access code for the clinic login using the buttons shown below.

4.6.3 Clinic logout

This function can only be accessed by the clinical staff.



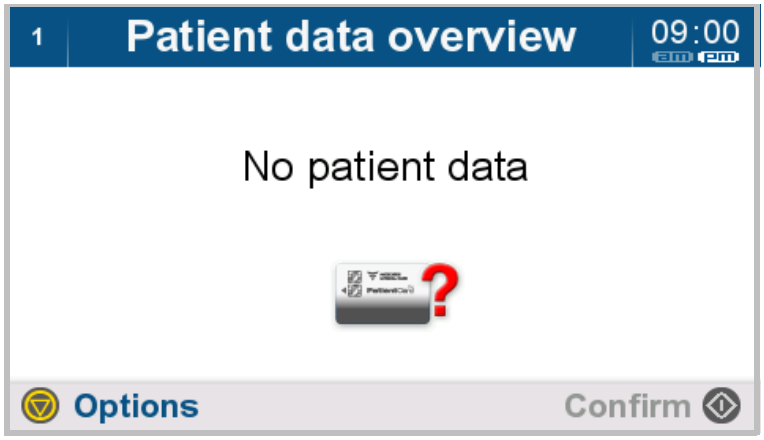
Press the button to access the options.



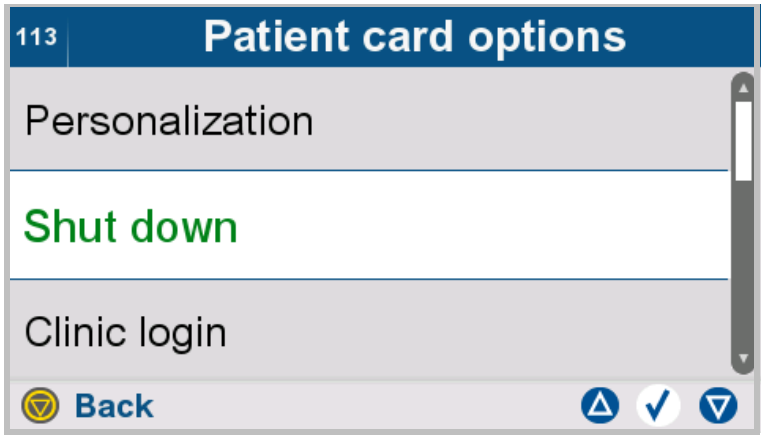
➢ Select **Logout**.
The "clinic login" access level is reset. The original access level for the patient is activated.

➢ Press the button to return to the higher-level menu.

4.6.4 Canceling personalization

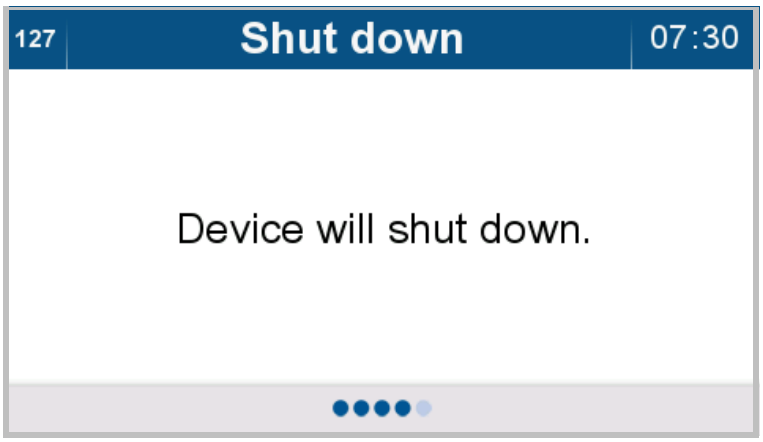


Press the button to access the options.



➢ Select **Shut down**.

➢ Press the button to return to the higher-level menu.



The device switches off automatically.

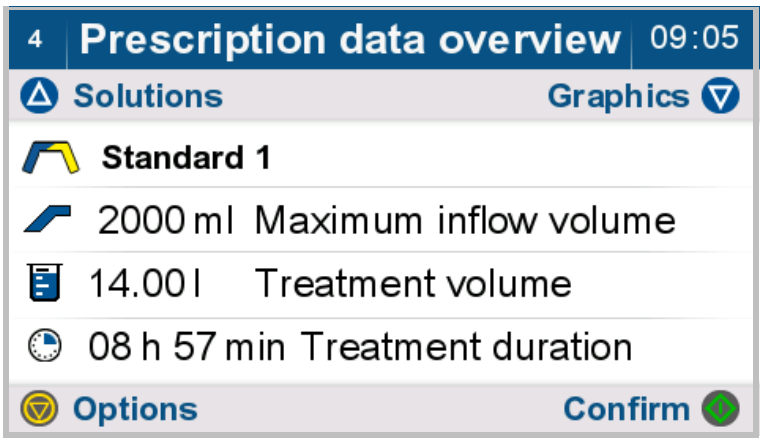
4.7 Options/Modifying data prior to treatment

The following options are available before the start of treatment:

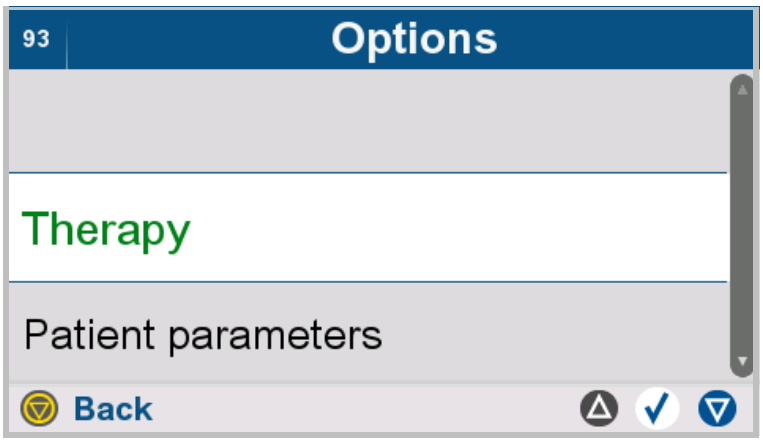
- Therapy options:
  creating, selecting, modifying and deleting prescriptions (depends on access level)
- Modifying patient parameters (only with clinic login)
- Device options:
  setting device-specific data such as the treatment timer, brightness, idle screen, sound volume, date and time
- Clinic login
- Clinic logout
- Switching off the device

4.7.1 Therapy options

4.7.1.1 Selecting a prescription

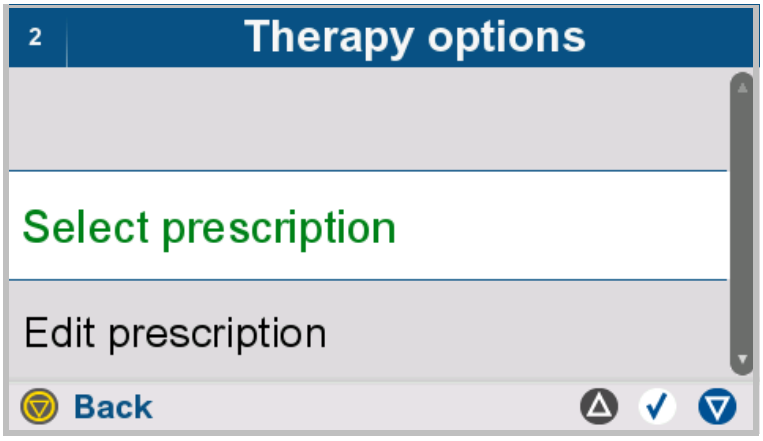


Press the ▽ button to access the options.



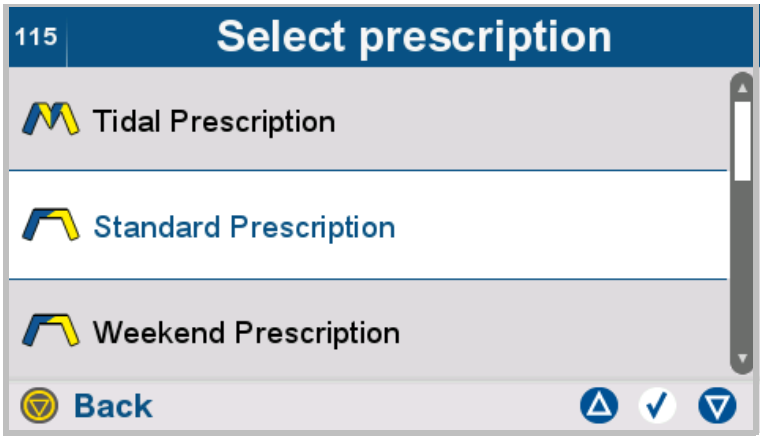
➢ Select **Therapy**.

➢ Press the button to return to the higher-level menu.



➢ Select **Select prescription**.

➢ Press the button to return to the higher-level menu.



When the list is opened, the brightly highlighted line shows the prescription that is currently selected.

➢ Use the and buttons to move the desired prescription to the brightly highlighted line in the center.

➢ Press the button to select the desired prescription.

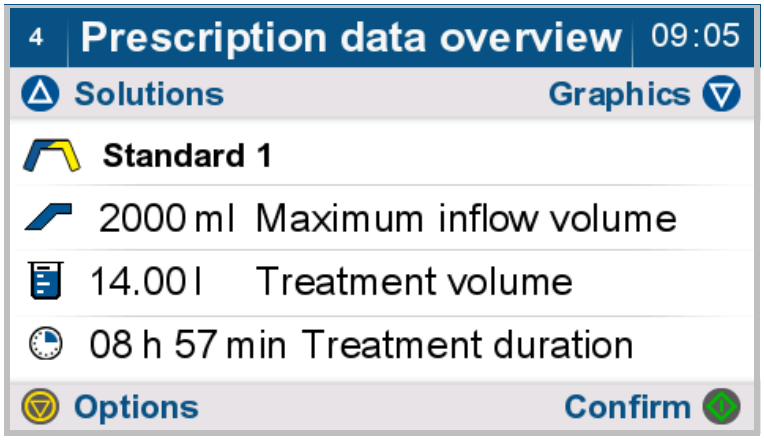
➢ Press the button to return to the higher-level menu.

4.7.1.2 Editing a prescription

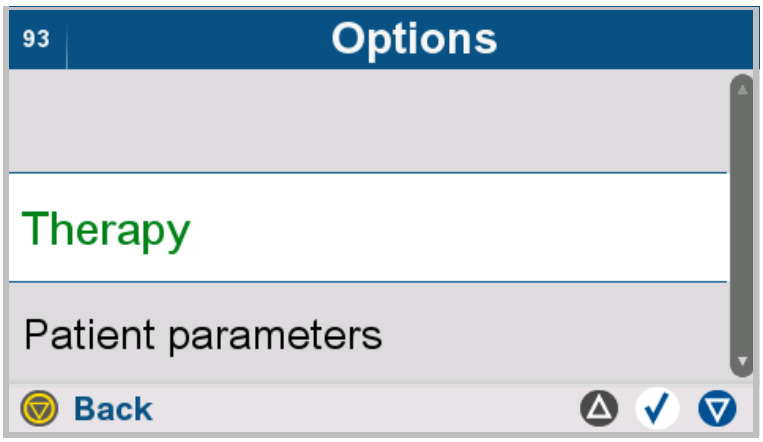
The treatment parameters listed below can be adjusted.

Standard treatment:
- Prescription name
- Initial outflow volume
- Number of cycles
- Inflow volume
- Solution
- Dwell duration
- Last inflow volume
- Last inflow solution

Tidal treatment:
- Prescription name
- Initial outflow volume
- Number of base cycles
- Base inflow volume
- Number of Tidal cycles
- Tidal inflow volume
- Tidal outflow volume
- Solution
- Dwell duration
- Last inflow volume
- Last inflow solution

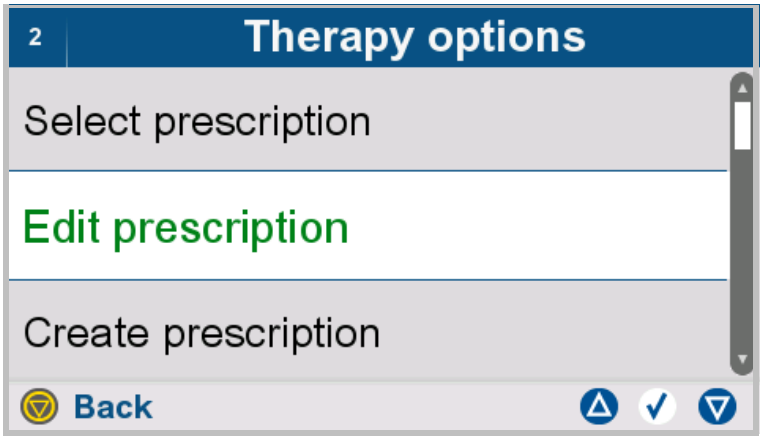


Press the ▽ button to access the options.



➢ Select **Therapy**.

➢ Press the button to return to the higher-level menu.



➢ Select **Edit prescription**.

➢ Press the button to return to the higher-level menu.

Warning

Patient hazard from overfilling of peritoneal cavity

Risk of circulatory disturbance due to balancing error

Patient hazard from glucose imbalance due to incorrectly entered parameters

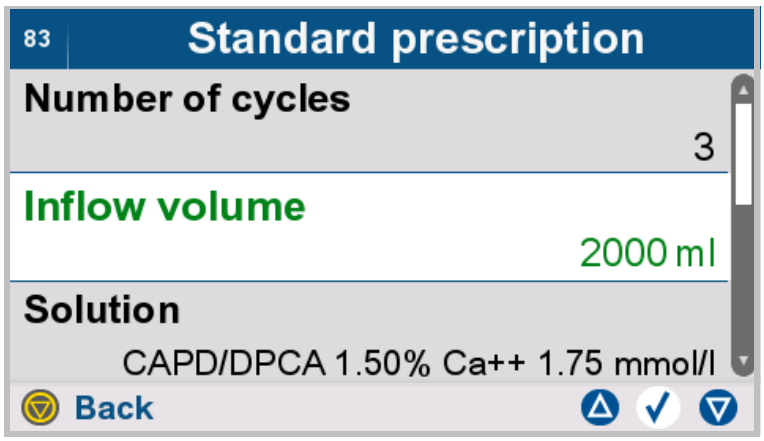
Patient hazard from insufficient detoxification

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 the 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.

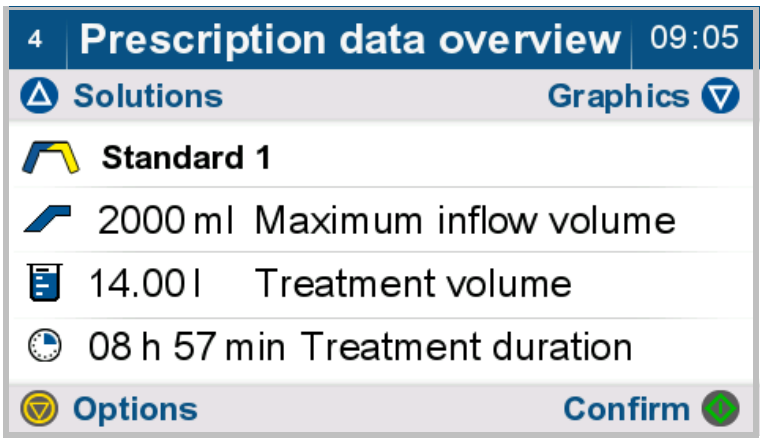


➢ Select and modify the desired prescription parameters.

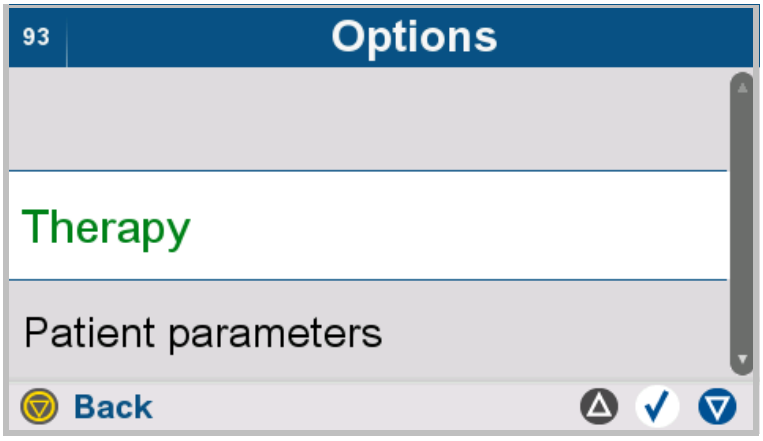
➢ Press the button to return to the higher-level menu.

- **Selecting a solution**

The following steps describe how to select solutions from a list.



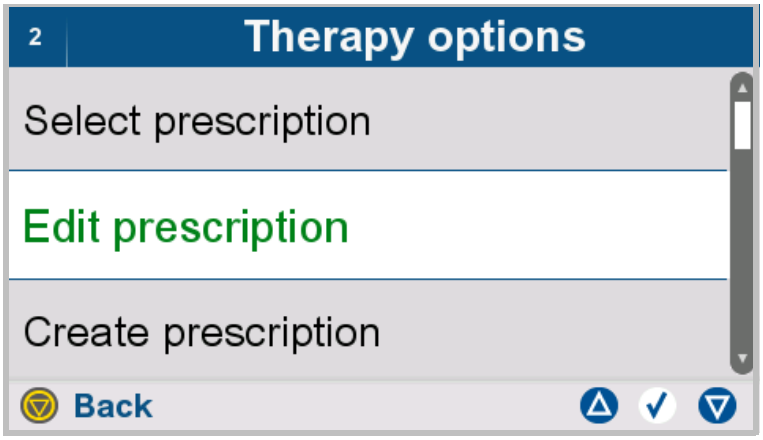
Press the button to access the options.



➢ Use the and buttons to move **Therapy** to the brightly highlighted line in the center.

➢ Press the button to select **Therapy**.

➢ Press the button to return to the higher-level menu.

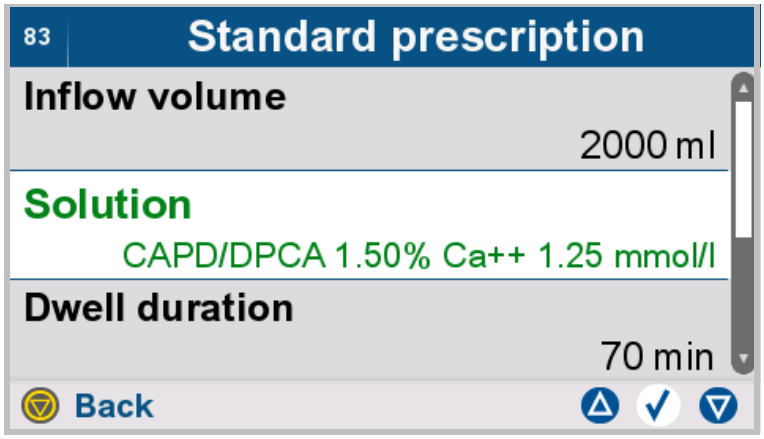


➢ Use the and buttons to move **Edit prescription** to the brightly highlighted line in the center.

➢ Press the button to select **Edit prescription**.

➢ Press the button to return to the higher-level menu.

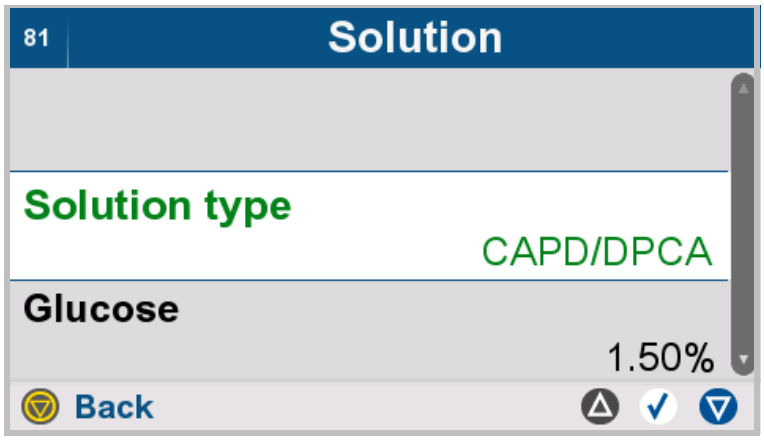
Selecting a solution type



➢ Use the △ and ▽ buttons to move **Solution** to the brightly highlighted line in the center.

➢ Press the ✓ button to select **Solution**.

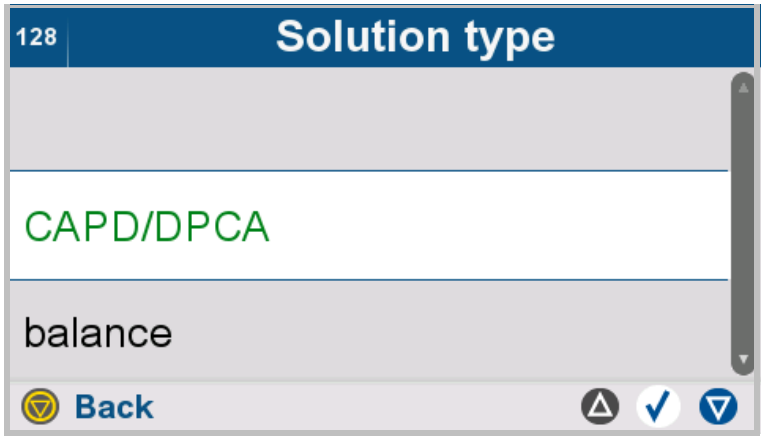
➢ Press the ▽ button to return to the higher-level menu.



➢ Use the △ and ▽ buttons to move **Solution type** to the brightly highlighted line in the center.

➢ Press the ✓ button to select **Solution type**.

➢ Press the ▽ button to return to the higher-level menu.

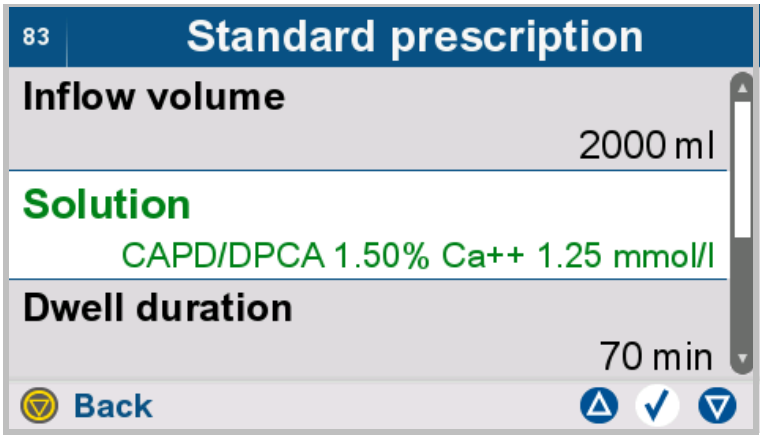


➢ Use the △ and ▽ buttons to move the desired solution type to the brightly highlighted line in the center.

➢ Press the ✓ button to select the desired solution type.

➢ Press the ▽ button to return to the higher-level menu.

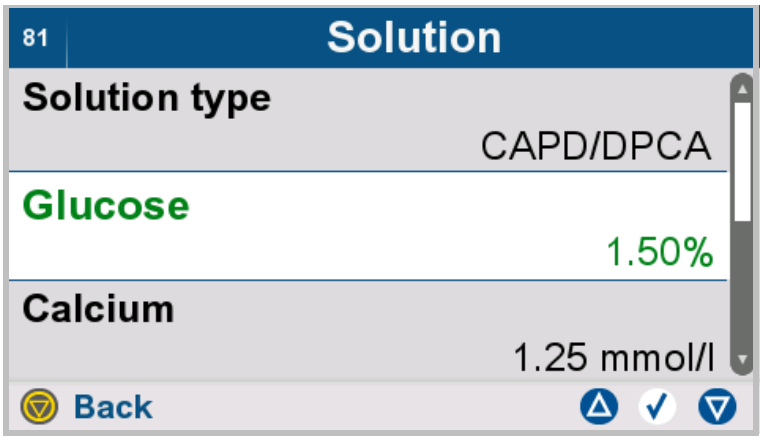
Selecting a glucose concentration



➢ Use the △ and ▽ buttons to move **Solution** to the brightly highlighted line in the center.

➢ Press the ✓ button to select **Solution**.

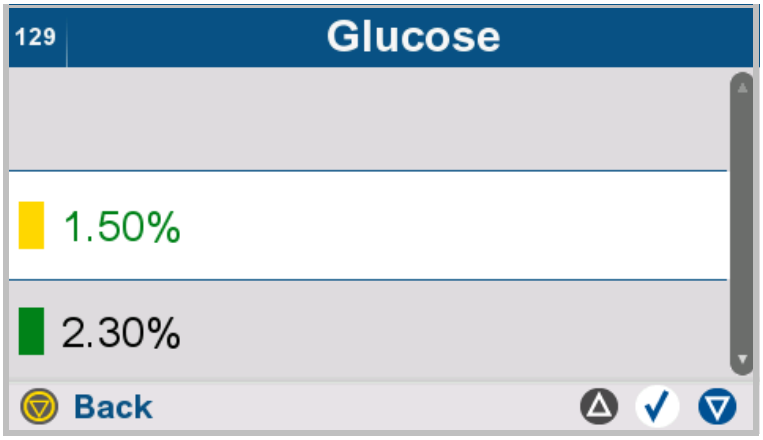
➢ Press the ▽ button to return to the higher-level menu.



➢ Use the △ and ▽ buttons to move **Glucose** to the brightly highlighted line in the center.

➢ Press the ✓ button to select **Glucose**.

➢ Press the ▽ button to return to the higher-level menu.

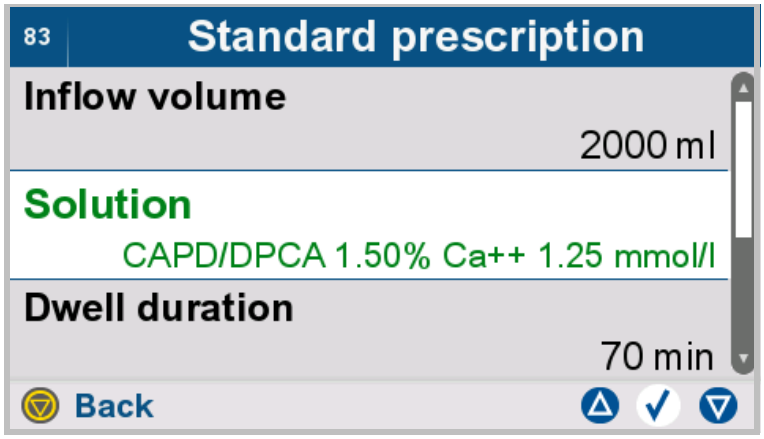


➢ Use the △ and ▽ buttons to move the desired glucose concentration to the brightly highlighted line in the center.

➢ Press the ✓ button to select the desired glucose concentration.

➢ Press the ▽ button to return to the higher-level menu.

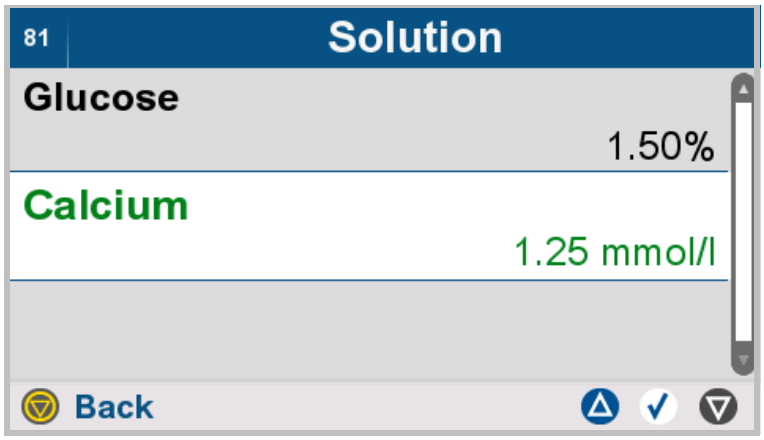
- **Selecting a calcium concentration**



➢ Use the △ and ▽ buttons to move **Solution** to the brightly highlighted line in the center.

➢ Press the ✓ button to select **Solution**.

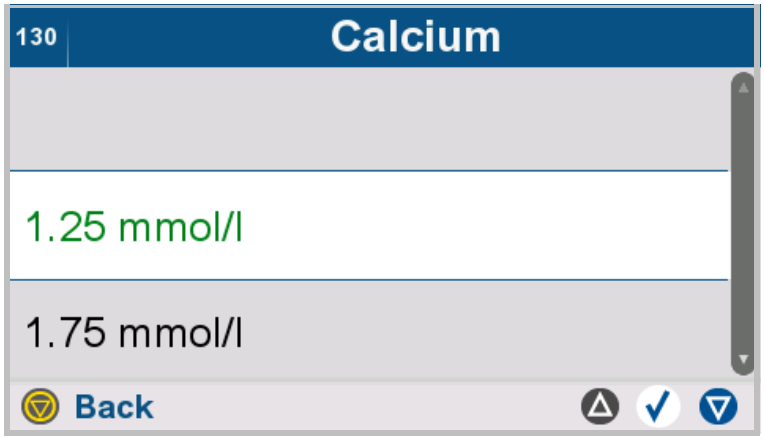
➢ Press the ▽ button to return to the higher-level menu.



➢ Use the △ and ▽ buttons to move **Calcium** to the brightly highlighted line in the center.

➢ Press the ✓ button to select **Calcium**.

➢ Press the ▽ button to return to the higher-level menu.

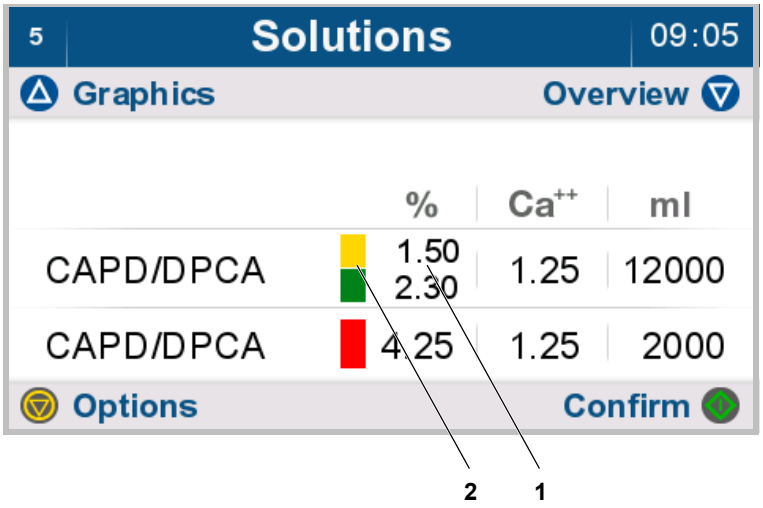


➢ Use the △ and ▽ buttons to move the desired calcium concentration to the brightly highlighted line in the center.

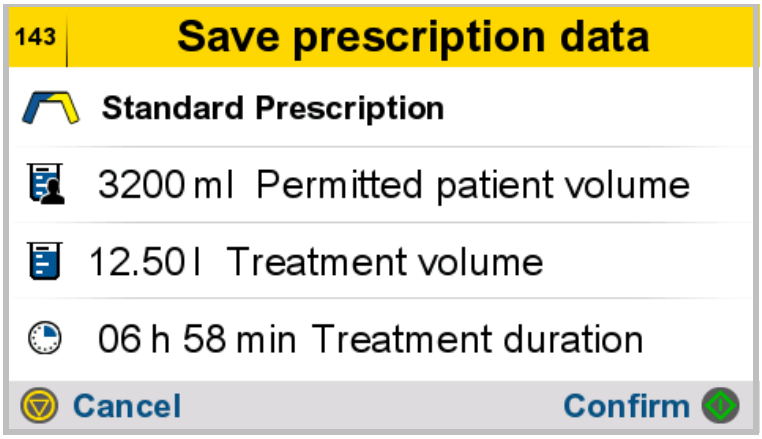
➢ Press the ✓ button to select the desired calcium concentration.

➢ Press the ▽ button to return to the higher-level menu.

- **Combined solutions**



➢ If the prescription calls for different glucose concentrations (1) on the inflow valve – white, the concentrations will be displayed in a vertical list.
Both color codes (2) for the solutions will also be shown.

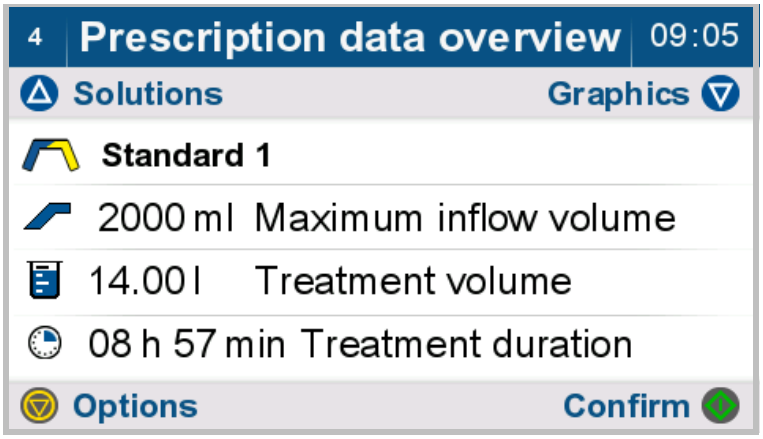


➢ Press the button to confirm the input

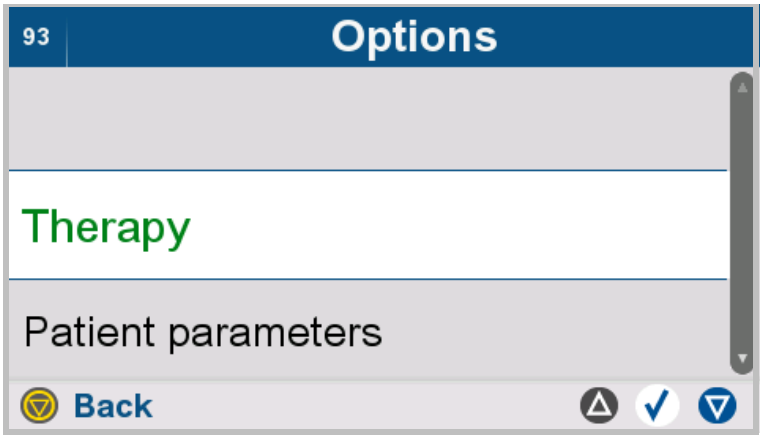
or

➢ Press the button to discard the data entered and to return to the previous screen.

4.7.1.3 Creating a prescription

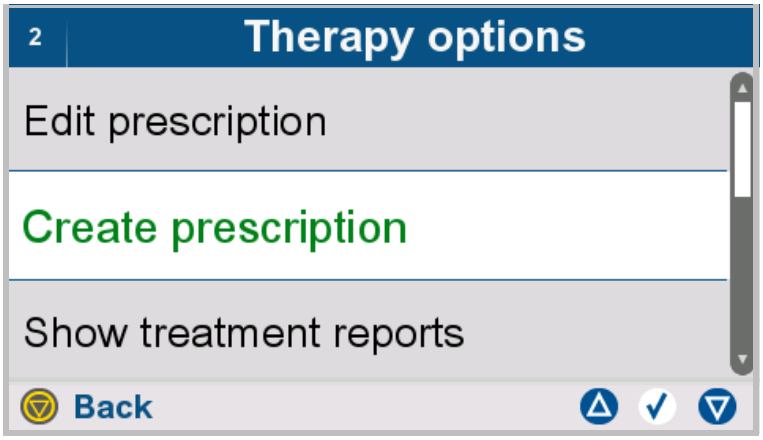


➢ Press the button to access the options.



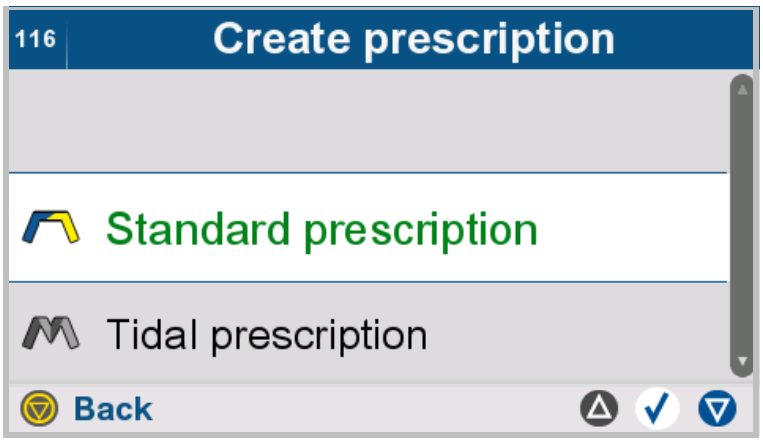
➢ Select **Therapy**.

➢ Press the button to return to the higher-level menu.



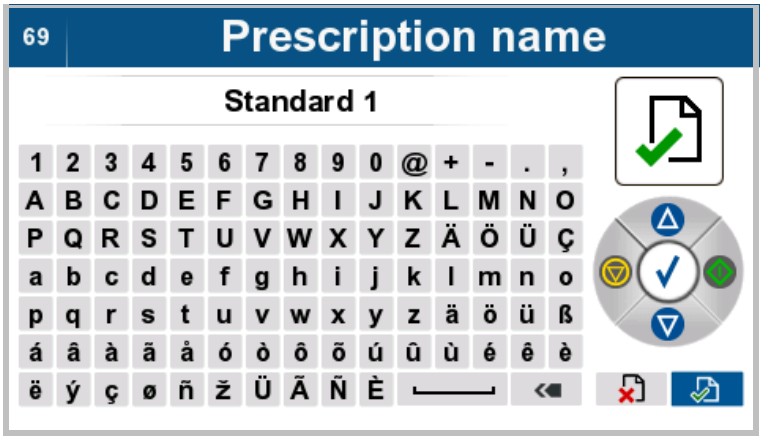
➢ Select **Create prescription**.

➢ Press the button to return to the higher-level menu.

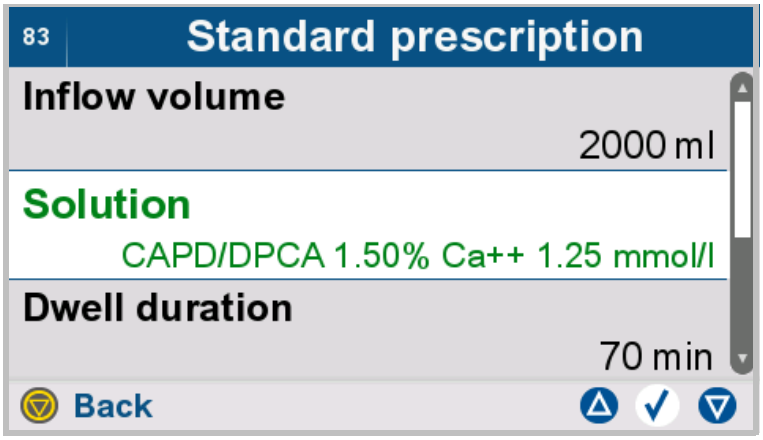


➢ Select the treatment type for the prescription being created.

➢ Press the button to return to the higher-level menu.



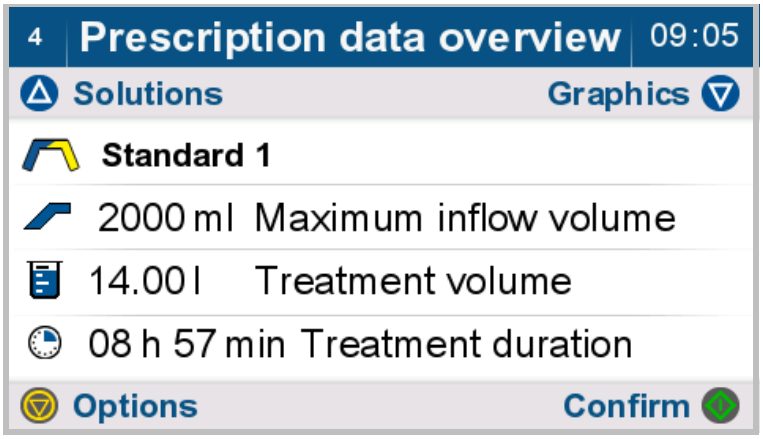
➢ Enter the name of the prescription.



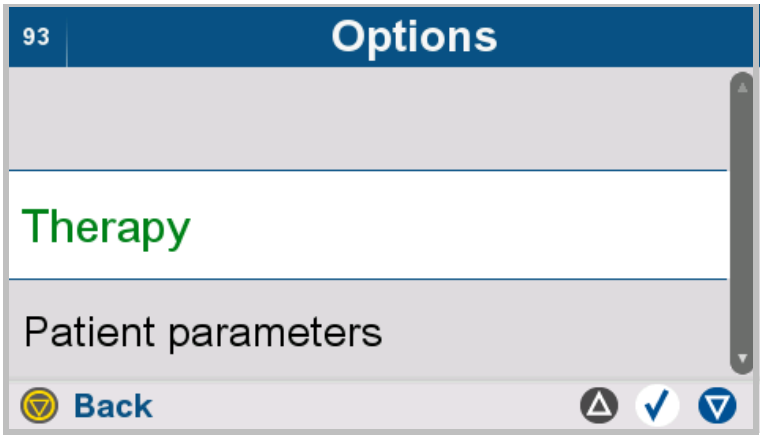
➢ Select and enter the desired prescription parameters.

➢ Press the button to return to the higher-level menu.

4.7.1.4 Displaying treatment reports

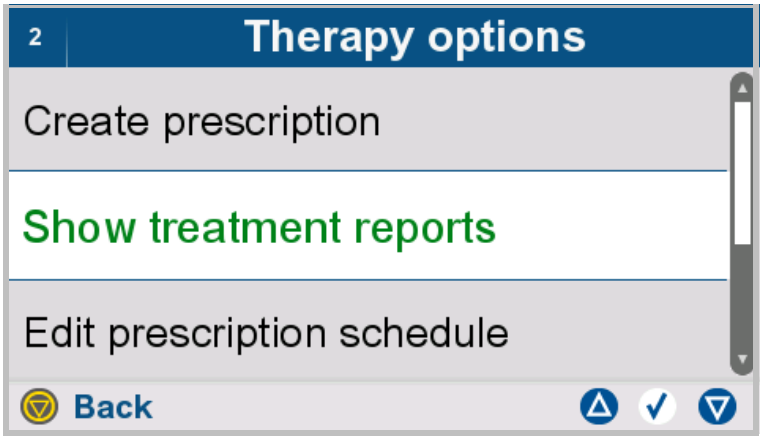


Press the button to access the options.



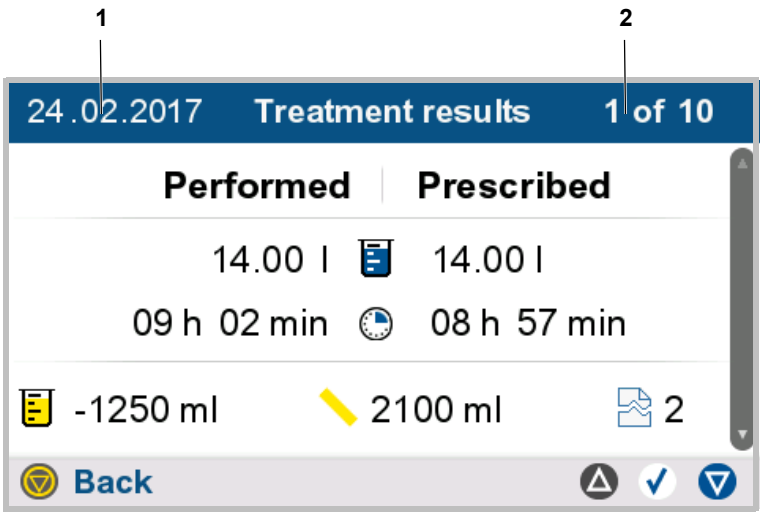
➢ Select **Therapy**.

➢ Press the button to return to the higher-level menu.



➢ Select **Show treatment reports**.

➢ Press the button to return to the higher-level menu.



The results of the selected treatment are displayed:

1. Date of the selected treatment.
2. Number of treatment in the saved treatment list.

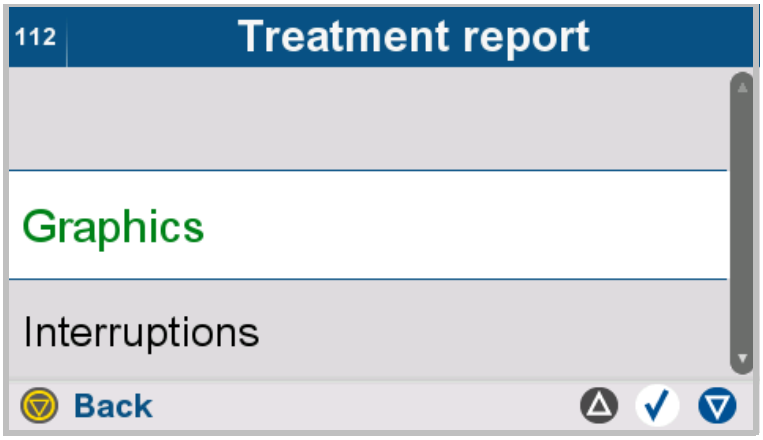
➢ Use the △ and ▽ buttons to select the desired treatment.

➢ Press the ✓ button to confirm the selection. This will display the results of the selected treatment in chart form and also show any interruptions that occurred.

➢ Press the ✓ button to obtain detailed information about the treatment progress (graphics and interruptions) for the displayed treatment.

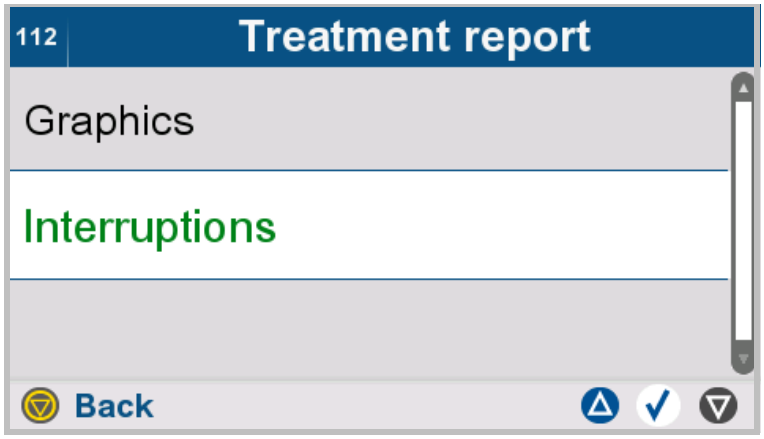
➢ Press the ▽ button to return to the higher-level menu.

- **Graphics**



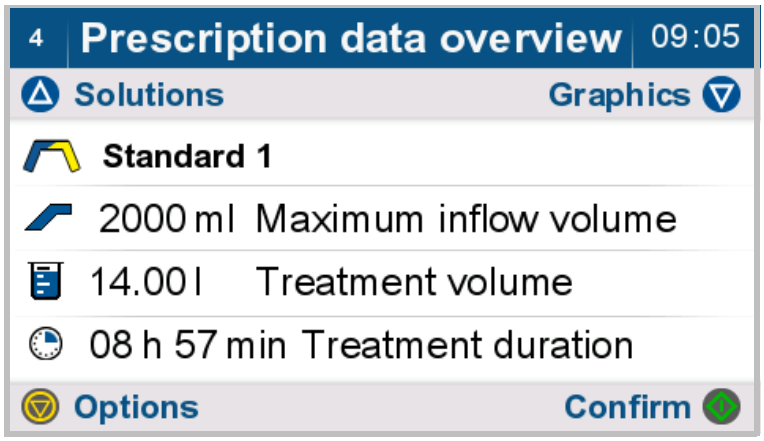
(see Chapter 4.4.4 on page 94)

- **Interruptions**

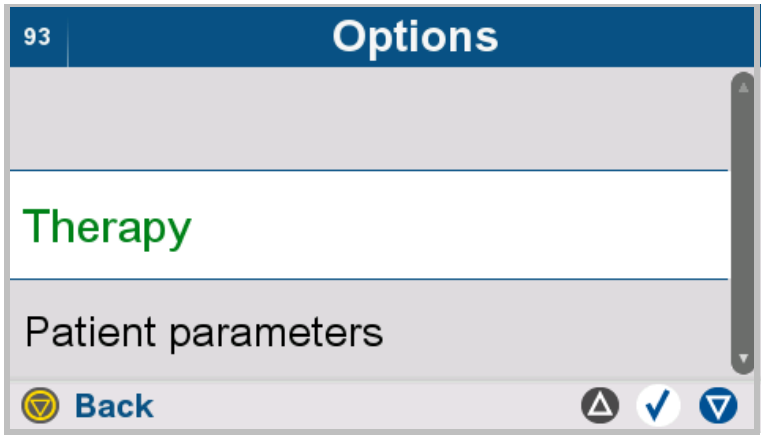


(see Chapter 4.4.5 on page 96)

4.7.1.5 Editing the prescription schedule

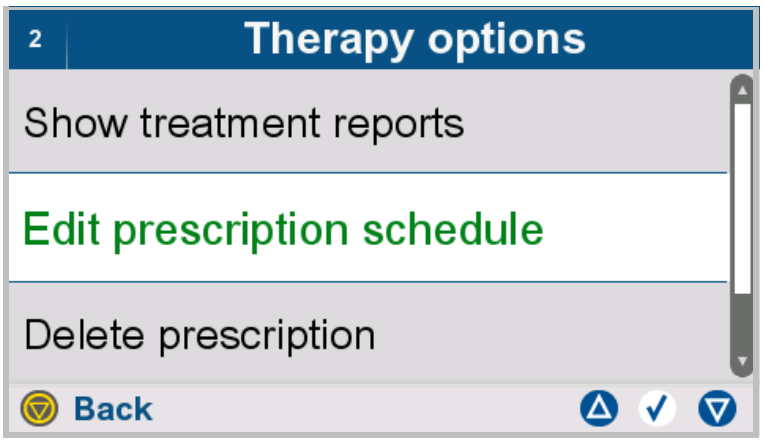


Press the button to access the options.



➢ Select **Therapy**.

➢ Press the button to return to the higher-level menu.



➢ Select **Edit prescription schedule**.

➢ Press the button to return to the higher-level menu.

Warning

Patient hazard from overfilling of peritoneal cavity

Risk of circulatory disturbance due to balancing error

Patient hazard from glucose imbalance due to incorrectly entered parameters

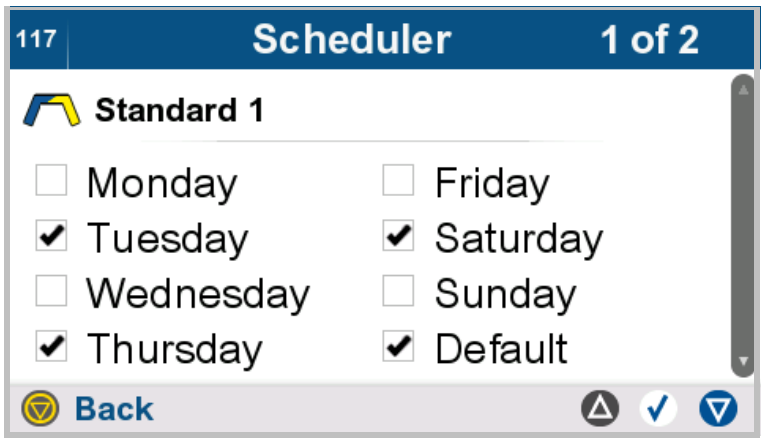
Patient hazard from insufficient detoxification

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 the 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.



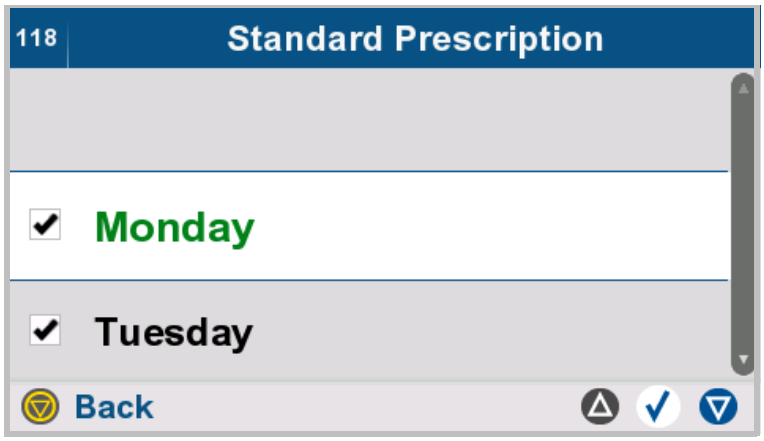
The weekly overview indicates the days of the week for which the selected prescription is scheduled.

If no prescription is selected for a day of the week, the standard prescription will automatically be used.

➢ Press the button to return to the higher-level menu.

➢ Use the and buttons to select a prescription.

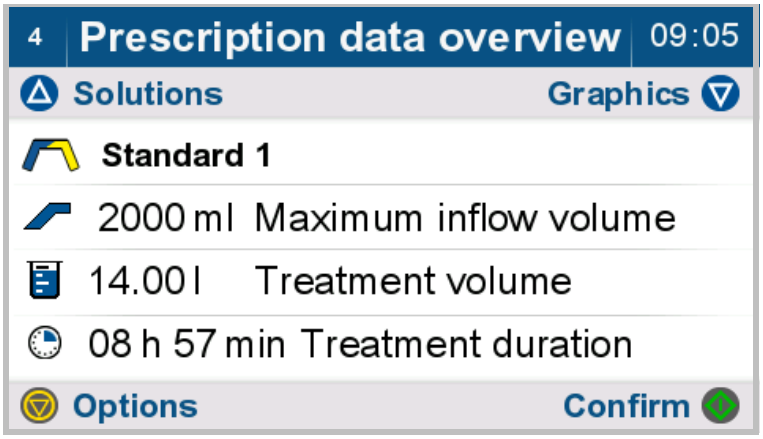
➢ Press the ✓ button to change the assignment of the days to the selected prescription.



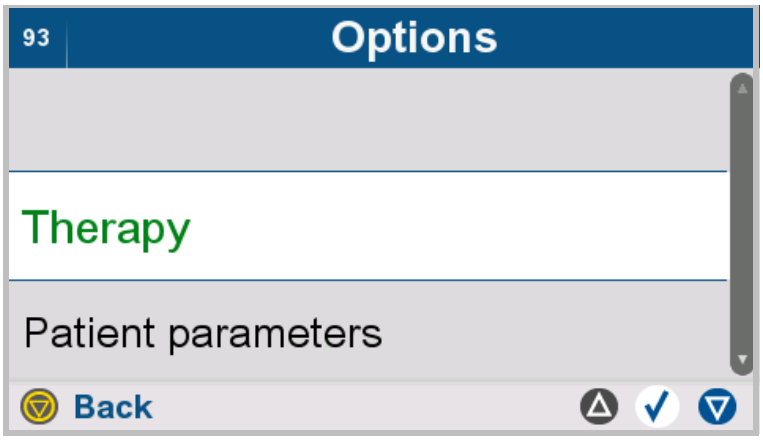
➢ From the list, select the days of the week on which the selected prescription is to be performed.

➢ Press the button to return to the higher-level menu.

4.7.1.6 Deleting a prescription

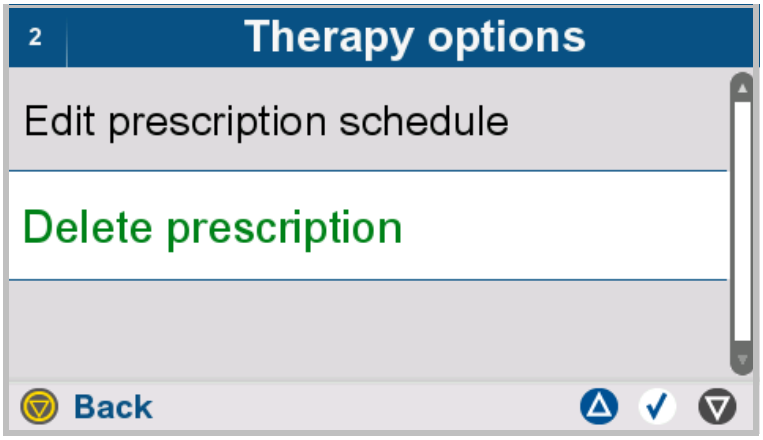


Press the button to access the options.



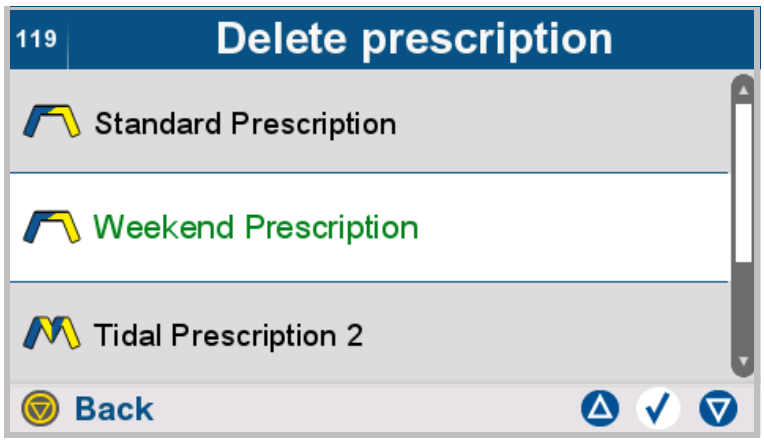
➢ Select **Therapy**.

➢ Press the button to return to the higher-level menu.



➢ Select **Delete prescription**.

➢ Press the button to return to the higher-level menu.



As a rule, it is not possible to delete the currently selected prescription and the standard prescription.

➢ Select the prescription to be deleted.

➢ Press the ✓ button to delete the selected prescription.

➢ Press the button to return to the higher-level menu.

4.7.2 Editing patient parameters

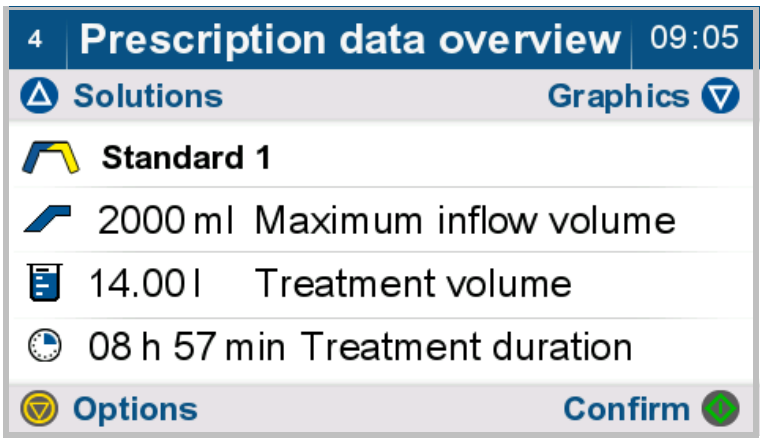
This function can only be accessed by the clinical staff.

If patient parameters are restricted, the prescriptions will automatically be adapted to the new patient parameters.

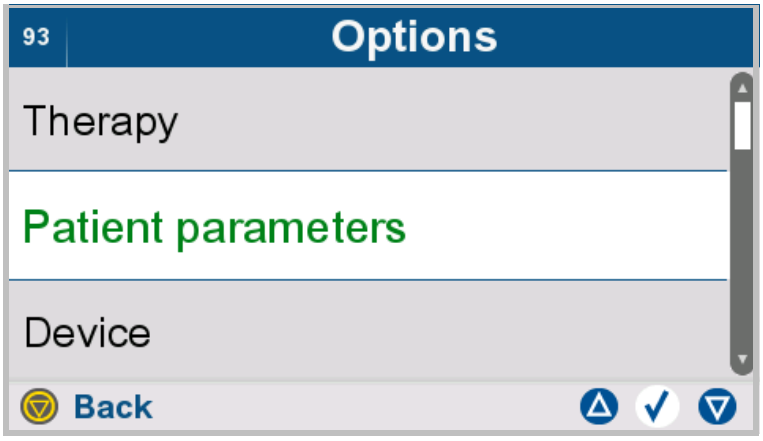
The preselected parameters (e.g., preselected inflow volume) will be used when creating a new prescription.

Patient parameters can only be edited by the attending physician.

The following patient parameters can be set:
– Permitted patient volume
– Maximum inflow volume
– Permitted residual volume
(see Chapter 7.3.1.2 on page 182)
– Permitted dwell duration reduction
(see Chapter 7.3.2.1 on page 183)
– Additional outflow
– Access level
– Preselected inflow volume
– Preselected dwell duration



Press the button to access the options.



➢ Select **Patient parameters**.

➢ Press the button to return to the higher-level menu.

Warning

Patient hazard from overfilling of peritoneal cavity

Risk of circulatory disturbance due to balancing error

Patient hazard from glucose imbalance due to incorrectly entered parameters

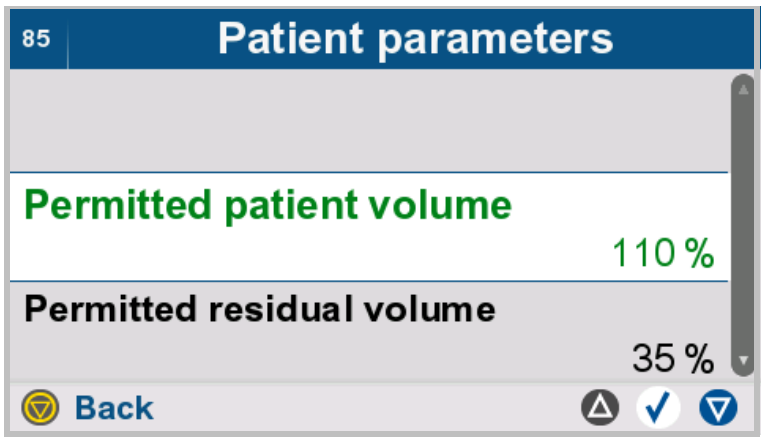
Patient hazard from insufficient detoxification

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.

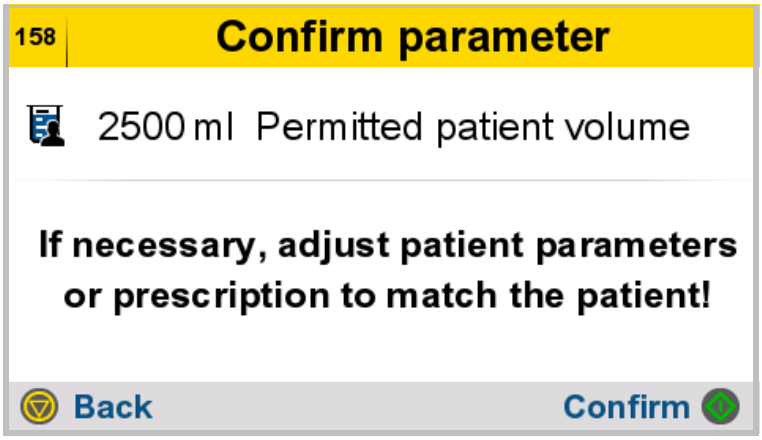
➢ If the check reveals a deviation between the required parameters and the parameters displayed on the device, the setting must be corrected before activating the function.

➢ The actual values displayed must be compared with the prescribed target values.



➢ Select and modify the desired patient parameters.

➢ Press the button to return to the higher-level menu.



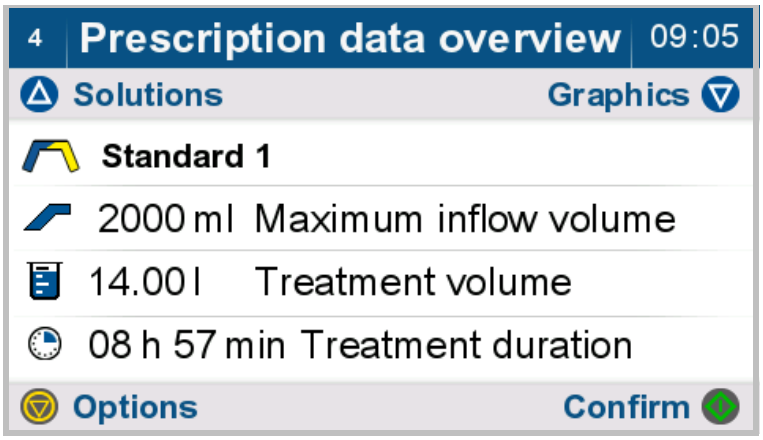
➢ Description: The permitted patient volume in ml is calculated from the permitted patient volume in % and the maximum prescribed inflow volume.

➢ Press the button to confirm the input

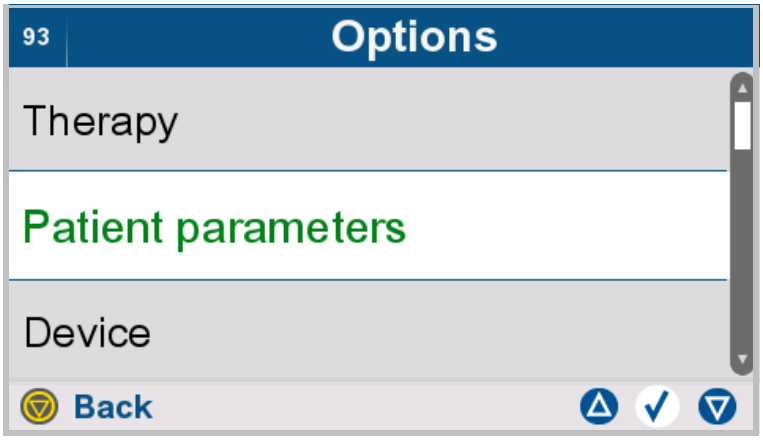
or

➢ Press the button to discard the data entered and to return to the previous screen.

4.7.2.1 Changing the additional outflow

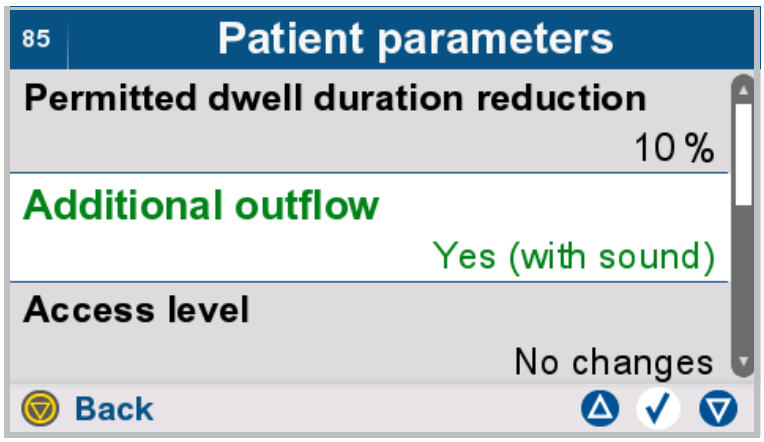


Press the button to access the options.



➢ Select **Patient parameters**.

➢ Press the button to return to the higher-level menu.



➢ Select **Additional outflow**.

➢ The following options are available for the last outflow:
– **No**
– **Yes (with sound)**
– **Yes (without sound)**

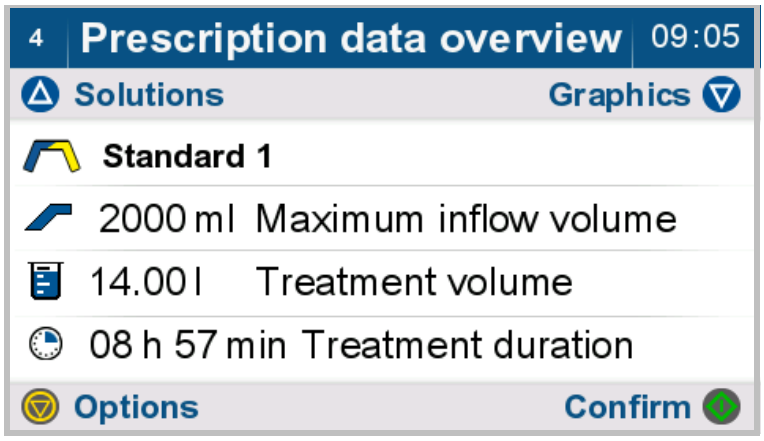
With the "No" option, the treatment is continued or ended without any additional outflow.

In the "Yes (with sound)" option, the patient receives audible and visual notification at the end of the last outflow and can perform an additional outflow.

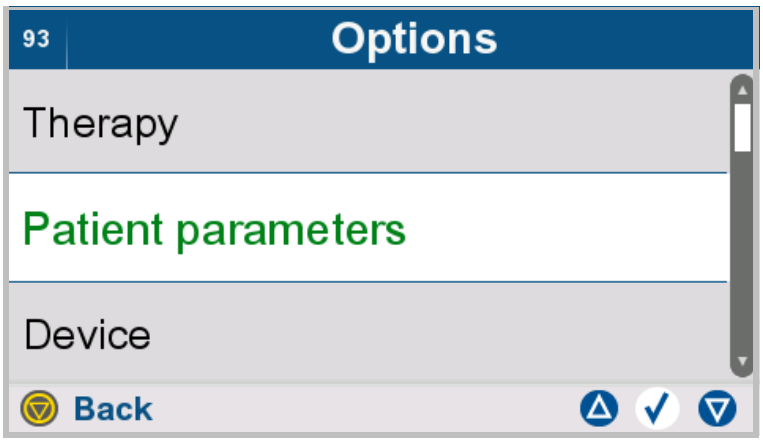
With the "Yes (without sound)" option, a treatment pause is initiated at the end of the last outflow.

➢ Press the button to return to the higher-level menu.

4.7.2.2 Access level

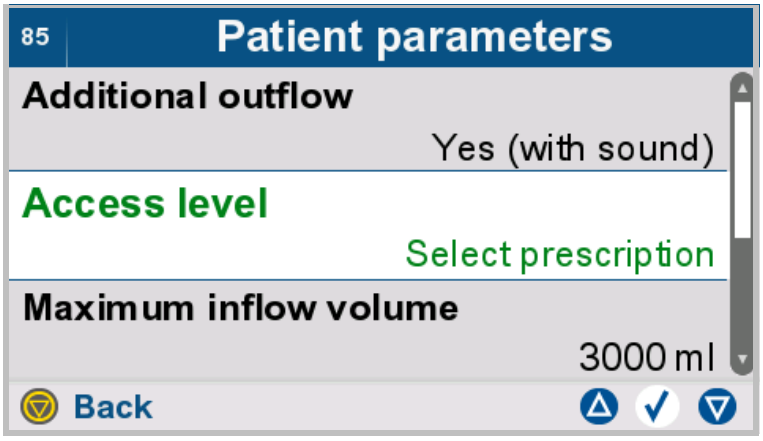


Press the button to access the options.



➢ Select **Patient parameters**.

➢ Press the button to return to the higher-level menu.



➢ Select **Access level**.

➢ The following access levels can be selected.
– No changes
– Selecting a prescription
– Editing a prescription

➢ Press the button to return to the higher-level menu.

4.7.3 Device options

Warning

Patient hazard from overfilling of peritoneal cavity

Risk of circulatory disturbance due to balancing error

Patient hazard from glucose imbalance due to incorrectly entered parameters

Patient hazard from insufficient detoxification

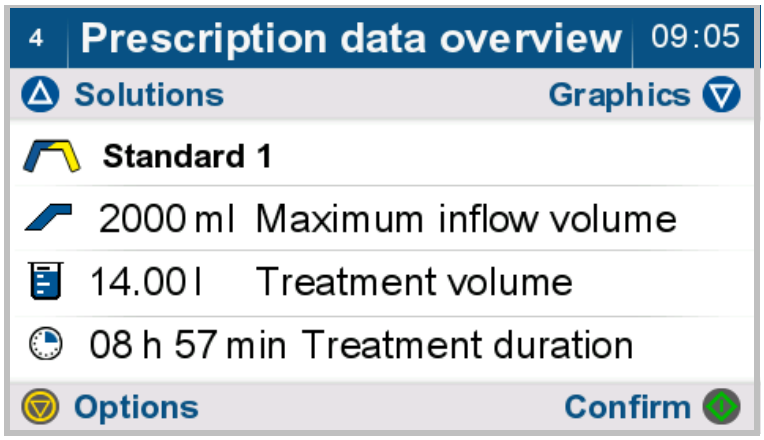
The following must be observed when entering parameters:

➢ The parameters entered must be verified by the operator, i.e., the operator must check that the values entered are correct.

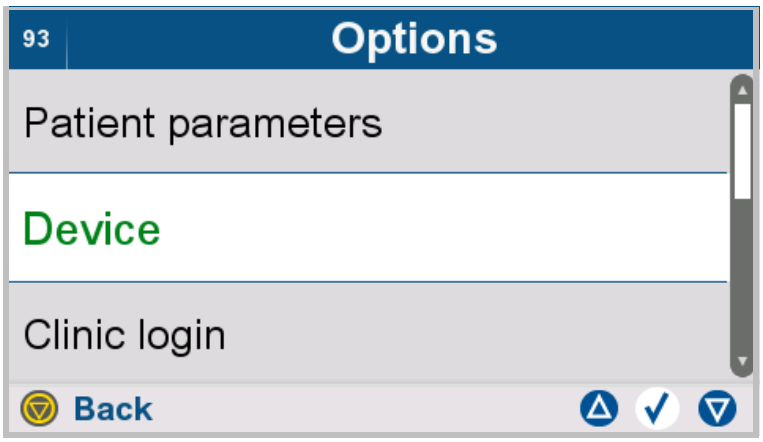
➢ If the check reveals a deviation between the required parameters and the parameters displayed on the device, the setting must be corrected before activating the function.

➢ The actual values displayed must be compared with the prescribed target values.

4.7.3.1 Treatment timer

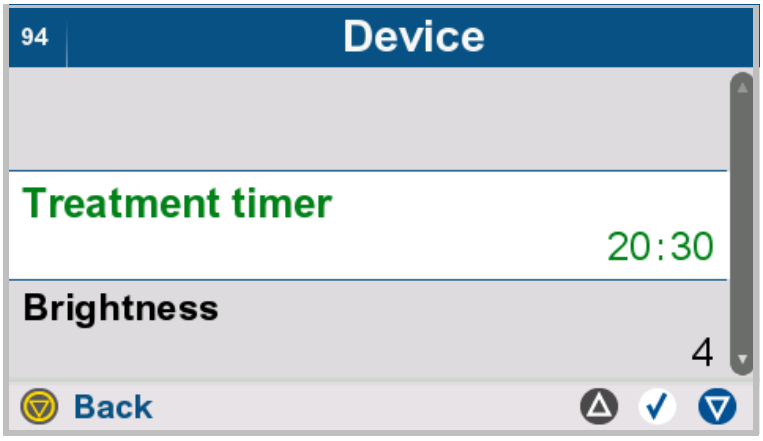


Press the ▽ button to access the options.



➢ Select **Device**.

➢ Press the button to return to the higher-level menu.



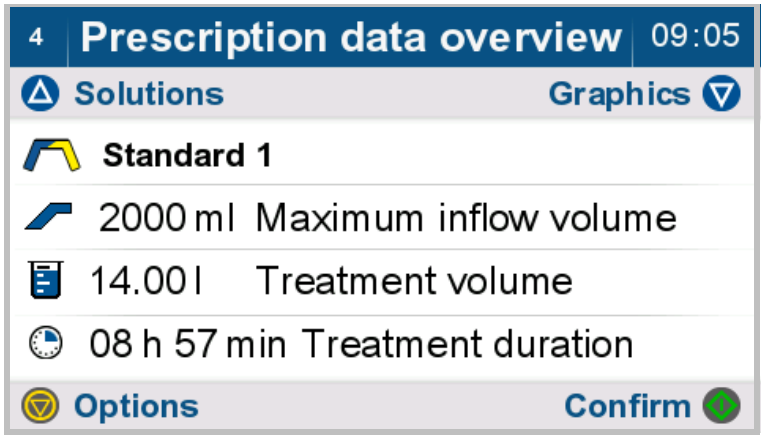
➢ Select **Treatment timer**.

➢ Press the button to return to the higher-level menu.

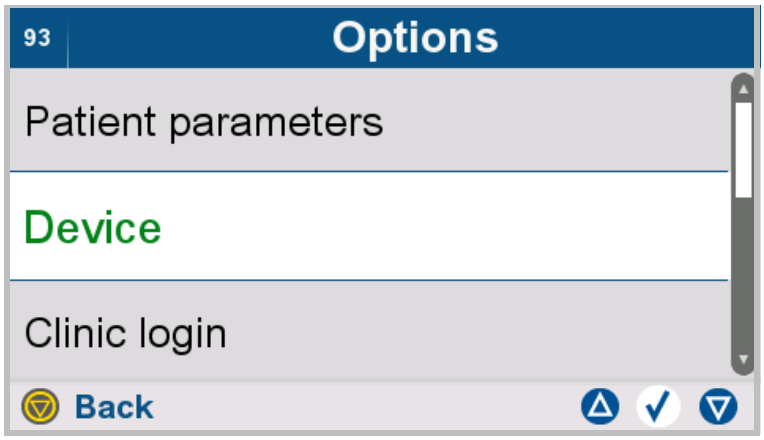
➢ Enter the planned treatment start time.

➢ Check the **Inactive** box to deactivate the treatment timer.

4.7.3.2 Setting the brightness

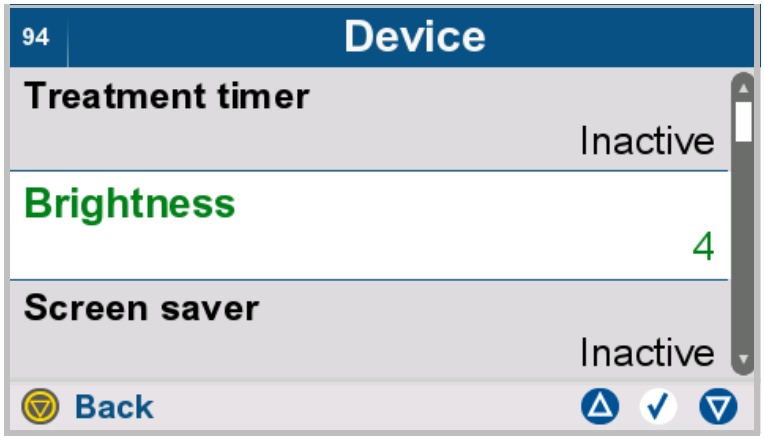


Press the button to access the options.



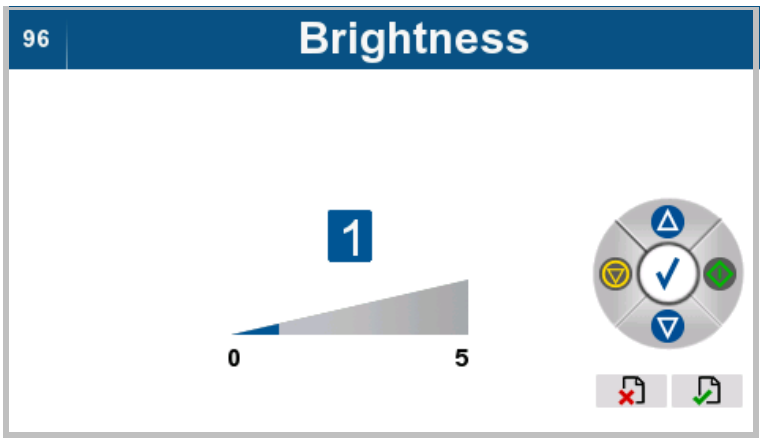
➢ Select **Device**.

➢ Press the button to return to the higher-level menu.



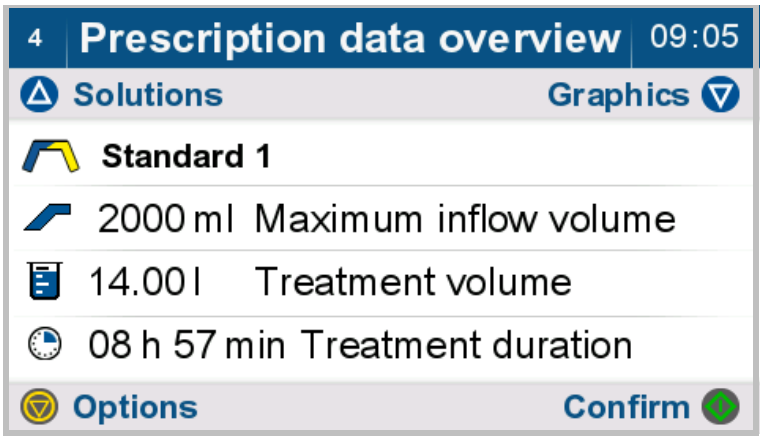
➢ Select **Brightness**.

➢ Press the button to return to the higher-level menu.

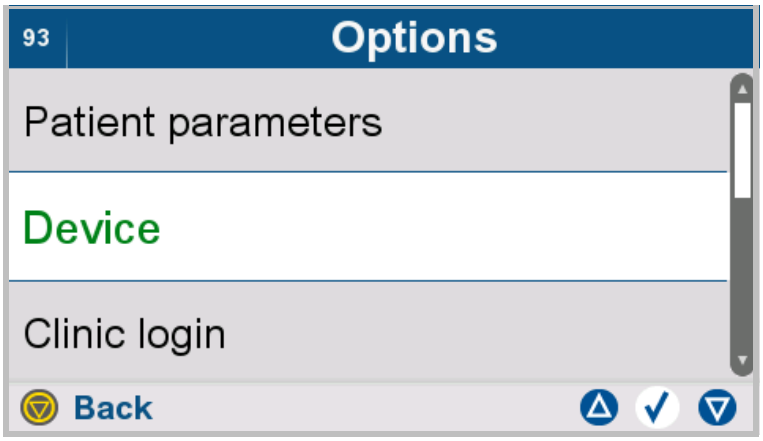


➢ Set the desired screen brightness.

4.7.3.3 Setting the screen saver

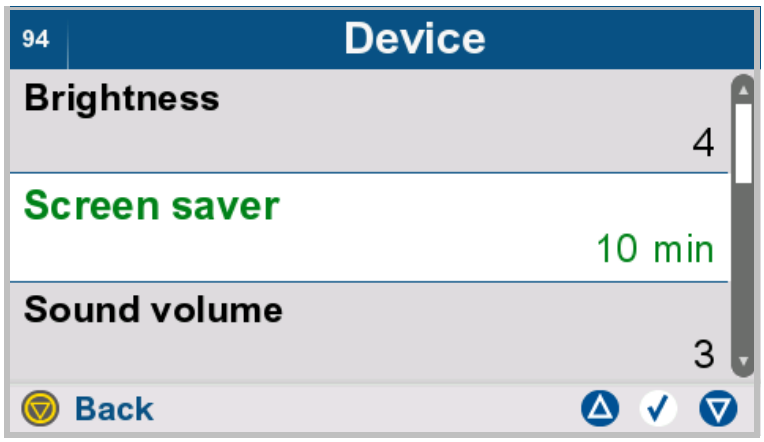


Press the ▽ button to access the options.



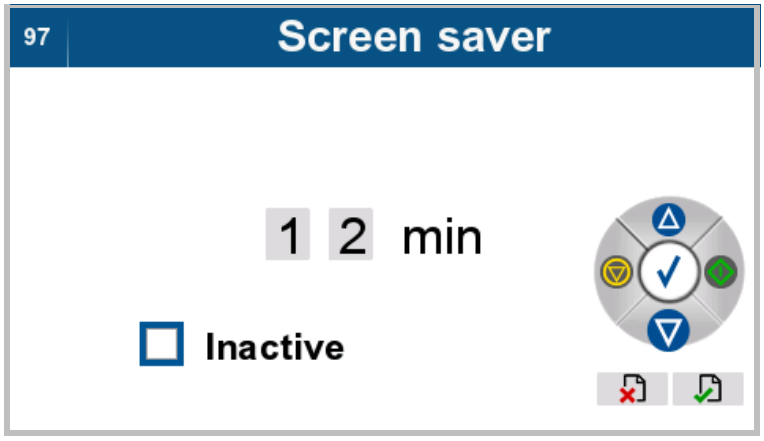
➢ Select **Device**.

➢ Press the ▽ button to return to the higher-level menu.



➢ Select **Screen saver**.

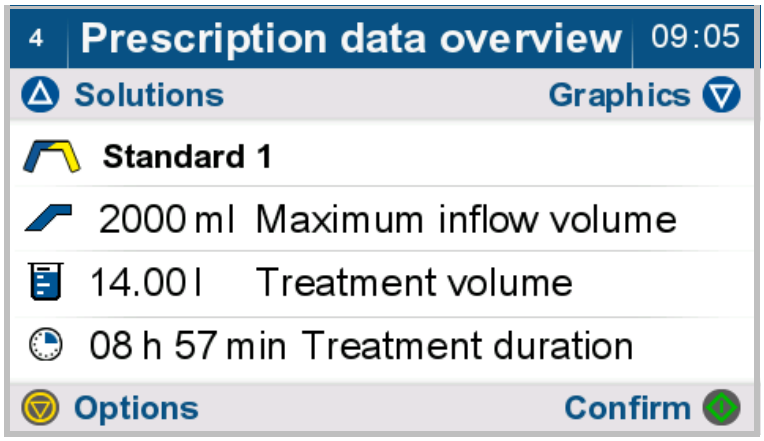
➢ Press the button to return to the higher-level menu.



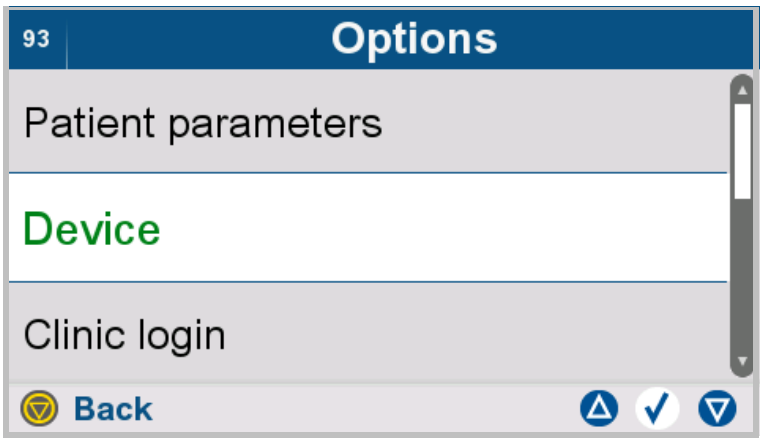
➢ Set the screen saver timeout (wait time).

➢ Check the **Inactive** box to deactivate the screen saver.

4.7.3.4 Setting the sound volume

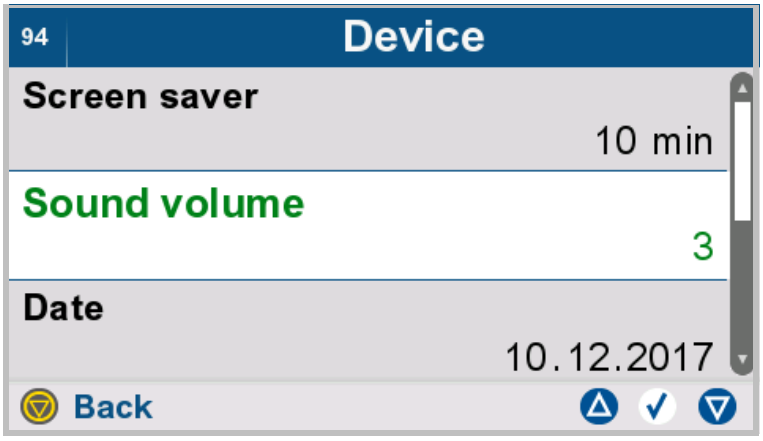


Press the button to access the options.



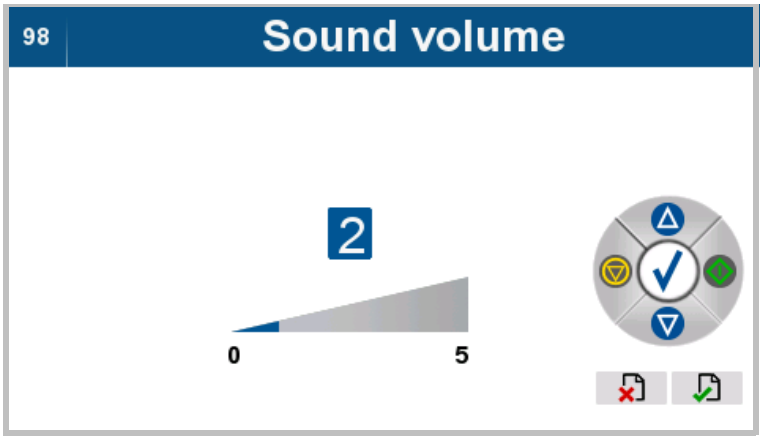
➢ Select **Device**.

➢ Press the button to return to the higher-level menu.



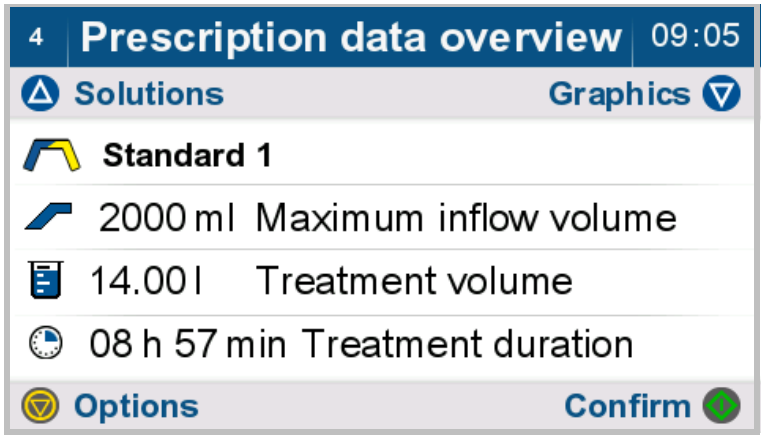
➢ Select **Sound volume**.

➢ Press the button to return to the higher-level menu.

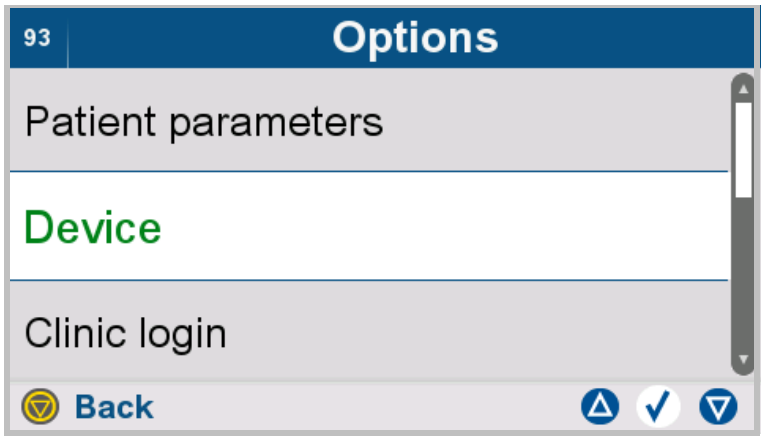


➢ Set the desired sound volume for audible signals.

4.7.3.5 Setting the date

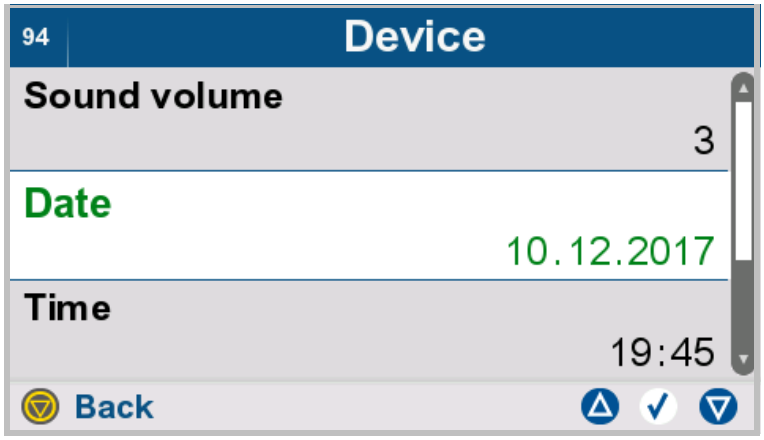


Press the button to access the options.



➢ Select **Device**.

➢ Press the button to return to the higher-level menu.

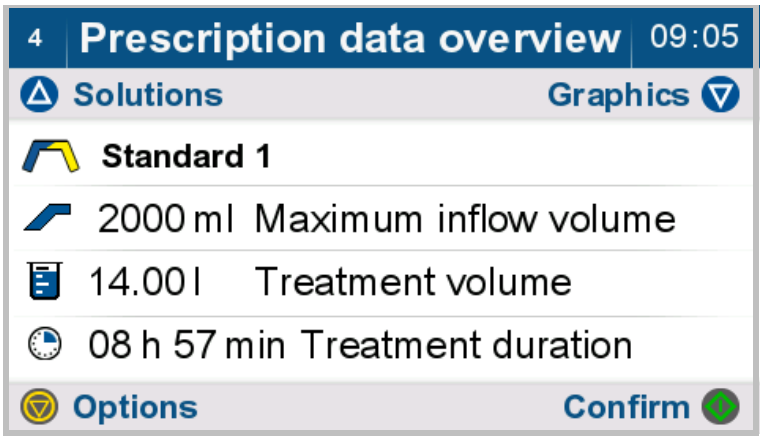


➢ Select **Date**.

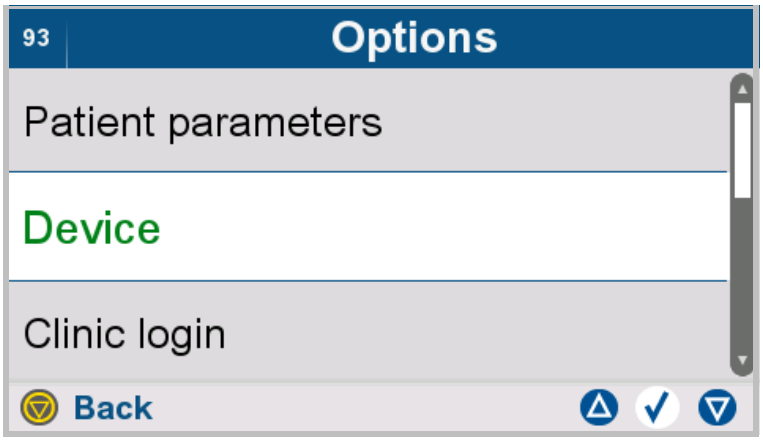
➢ Press the button to return to the higher-level menu.

➢ Set the current date.

4.7.3.6 Setting the time

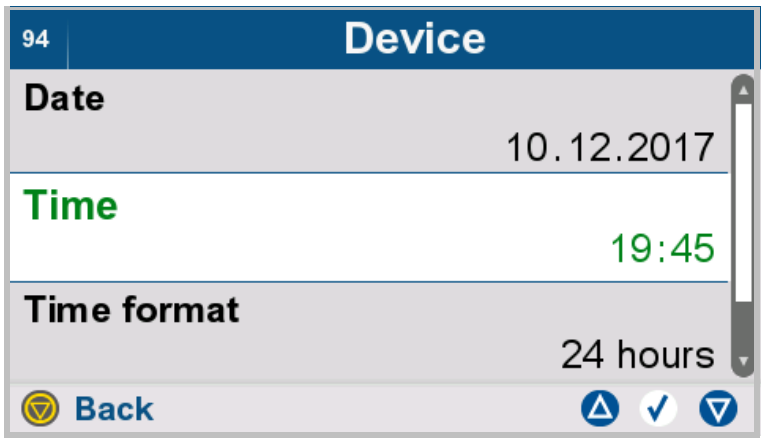


Press the ▽ button to access the options.



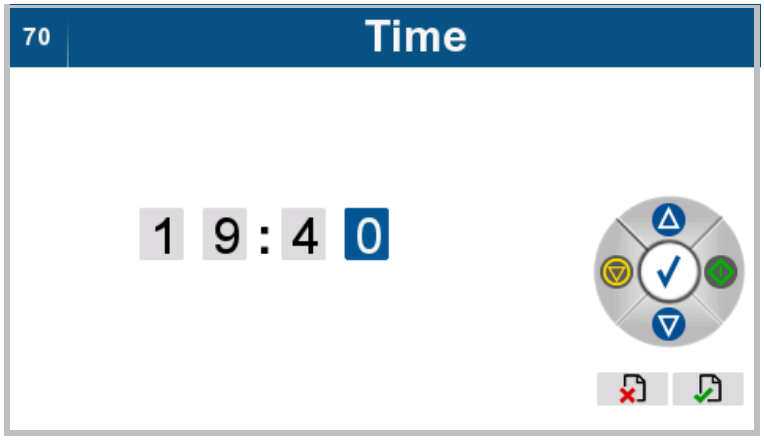
➢ Select **Device**.

➢ Press the ▽ button to return to the higher-level menu.

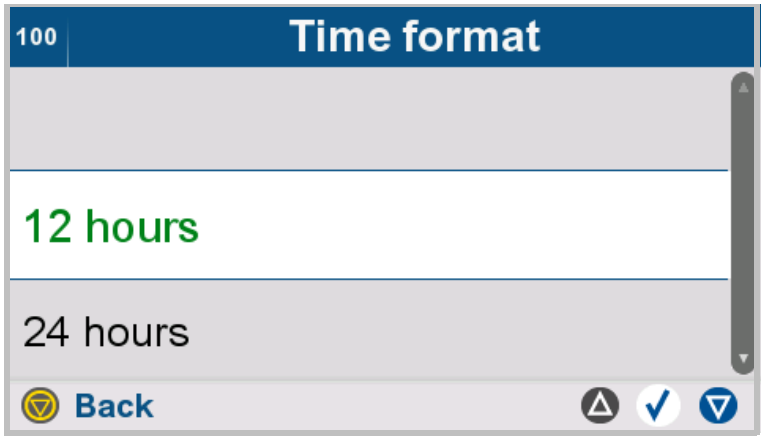


Select **Time**.

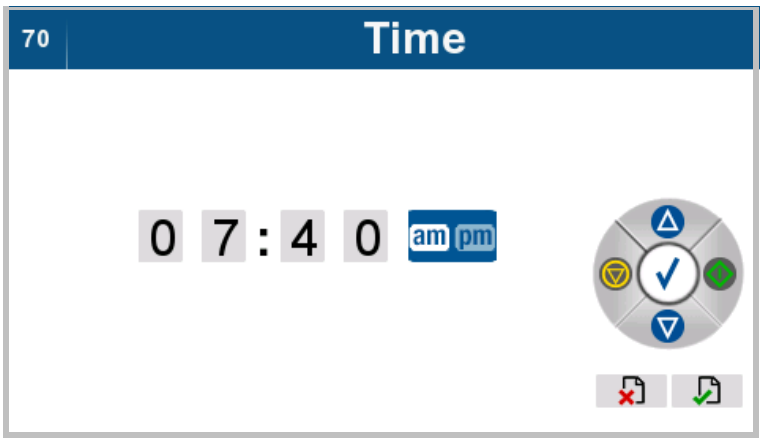
➢ Press the button to return to the higher-level menu.



➢ Set the current time.



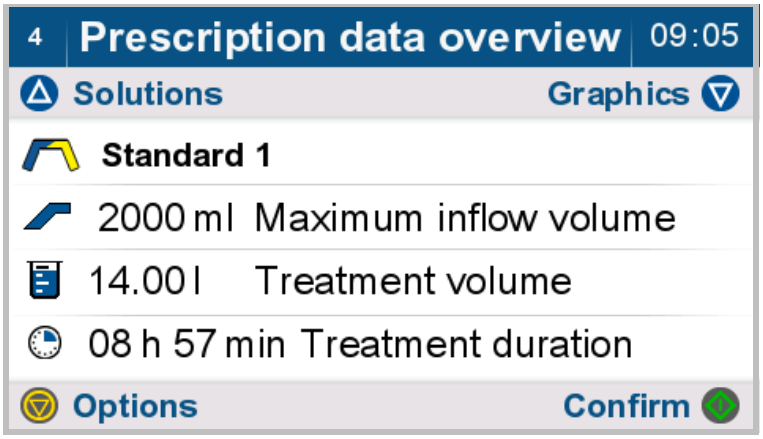
➢ Select **12 hours** or **Yes (with sound)** as the time format.



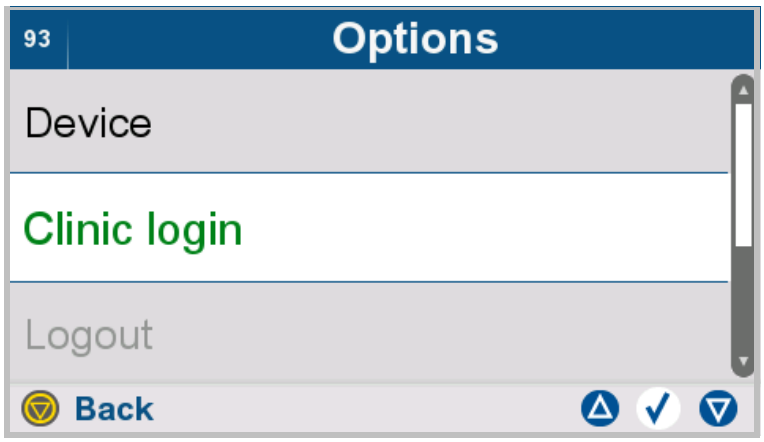
➢ When using the 12-hour format, select **am** or **pm**.

4.7.4 Clinic login

The "clinic login" function allows patient data, patient parameters and prescription data to be entered and modified. This function can only be accessed by clinical staff.

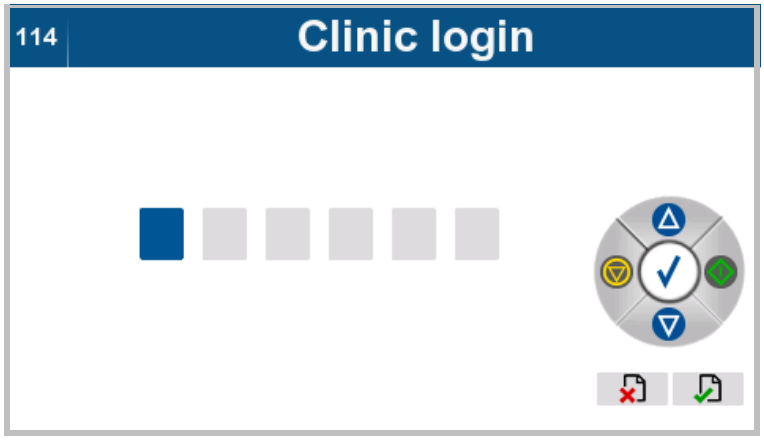


Press the ▽ button to access the options.



➢ Select **Clinic login**.

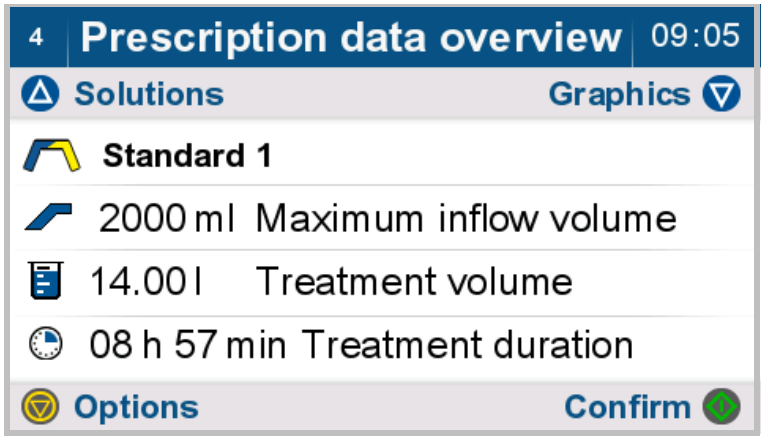
➢ Press the button to return to the higher-level menu.



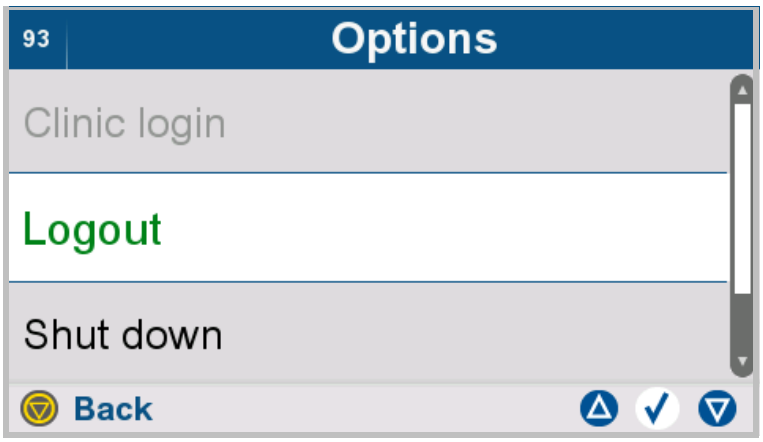
➢ Enter the access code for the clinic login using the buttons shown below.

4.7.5 Clinic logout

This function can only be accessed by the clinical staff.



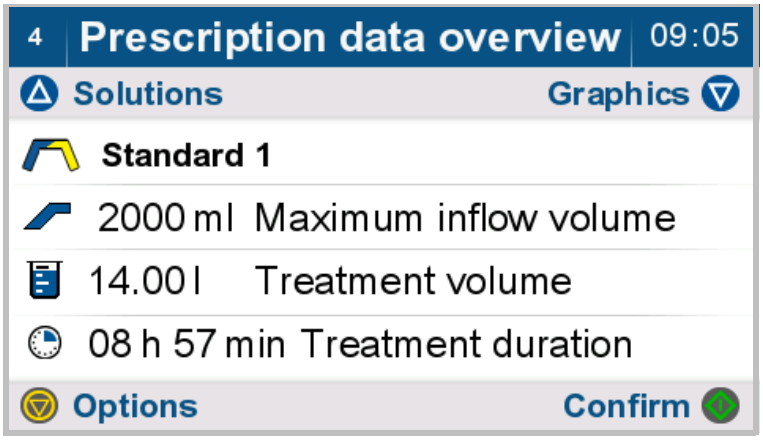
Press the button to access the options.



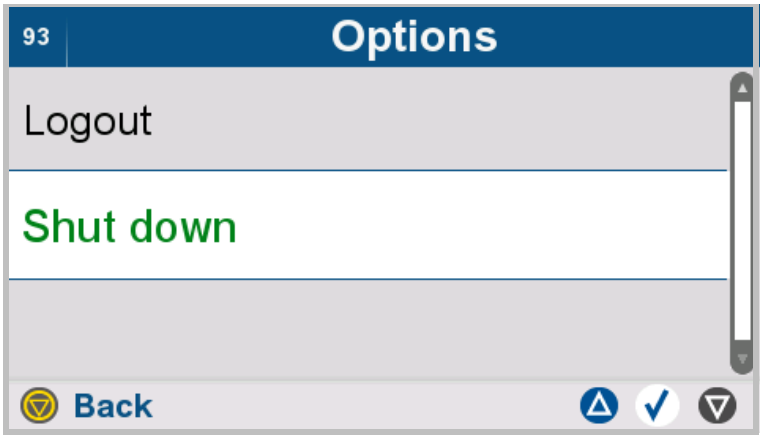
➢ Select **Logout**.
The "clinic login" access level is reset. The original access level for the patient is activated.

➢ Press the button to return to the higher-level menu.

4.7.6 Switching off the device

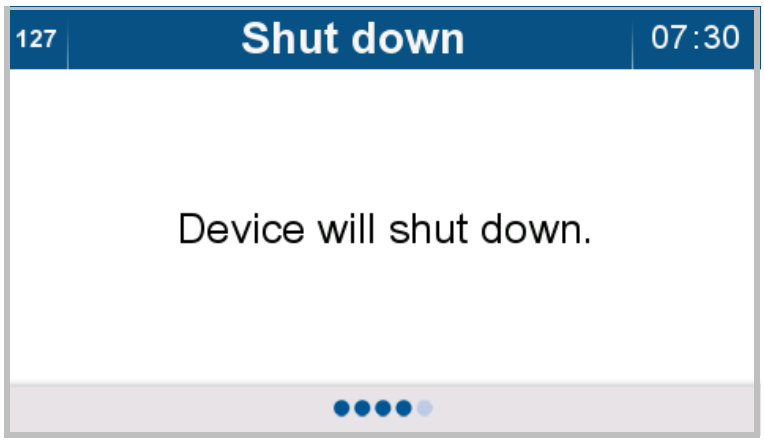


Press the button to access the options.



➢ Select **Shut down**.

➢ Press the button to return to the higher-level menu.

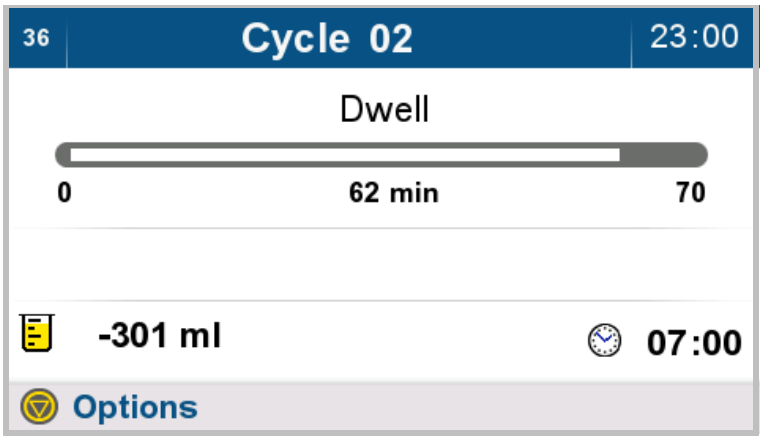


The device switches off automatically.

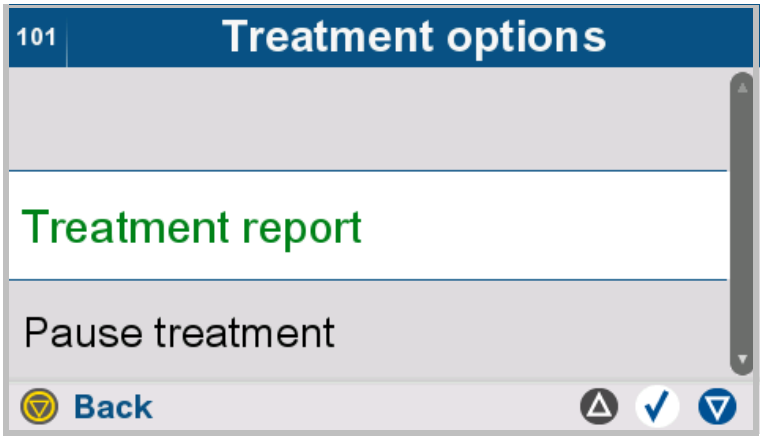
4.8 Therapy options during treatment

The following options are available during treatment:
– Viewing the treatment report
– Pausing treatment
– Manual outflow
– Skipping a phase
– Ending the treatment

4.8.1 Viewing the treatment report



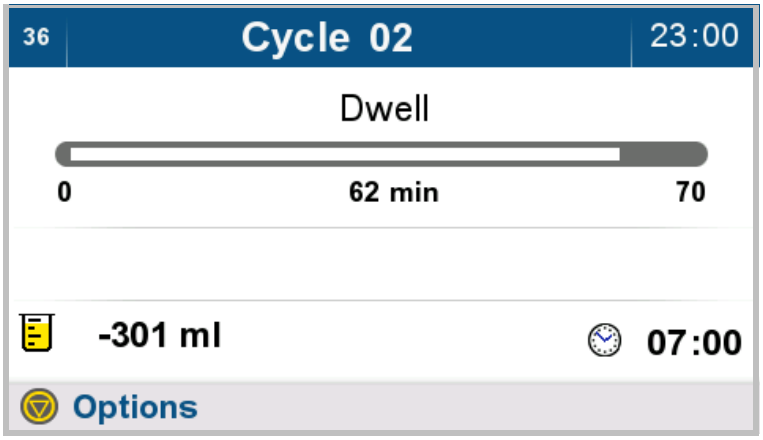
Press the button to access the options.



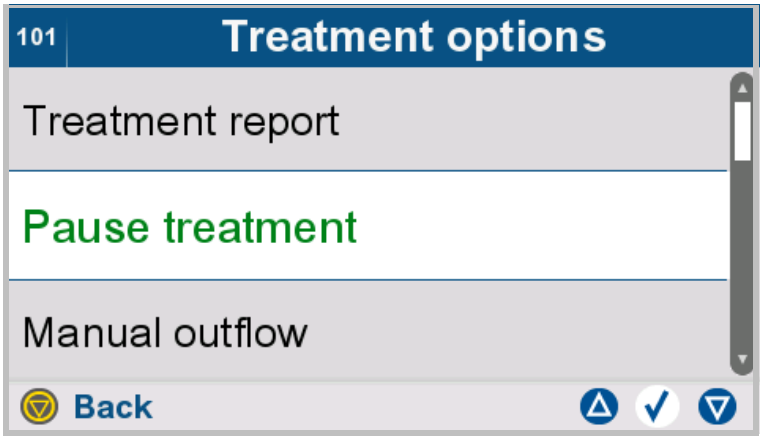
➢ Select **Treatment report**.
(see Chapter 4.4.4 on page 94)

➢ Press the button to return to the higher-level menu.

4.8.2 Pausing treatment



Press the button to access the options.

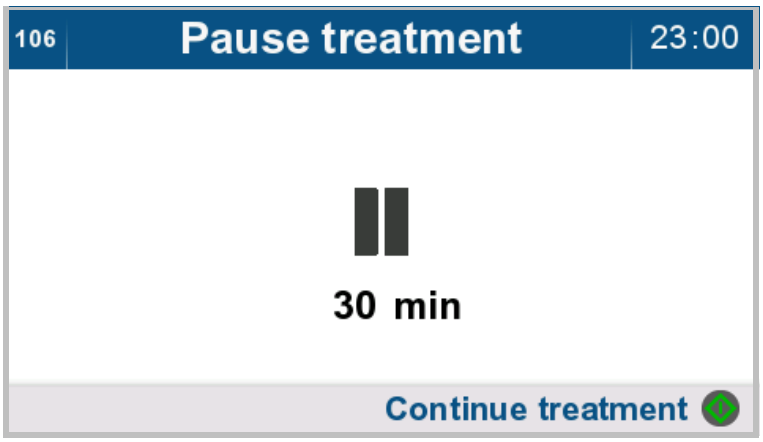


➢ Select **Pause treatment**.

➢ Press the button to return to the higher-level menu.

➢ Press the button to confirm the treatment pause.

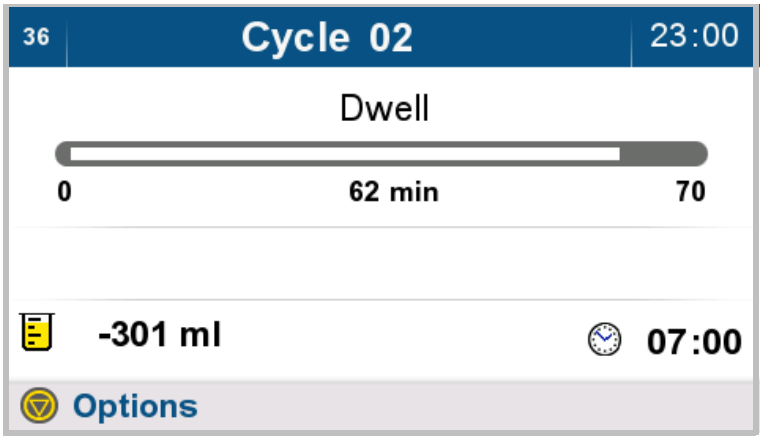
➢ Press the button to return to the higher-level menu.



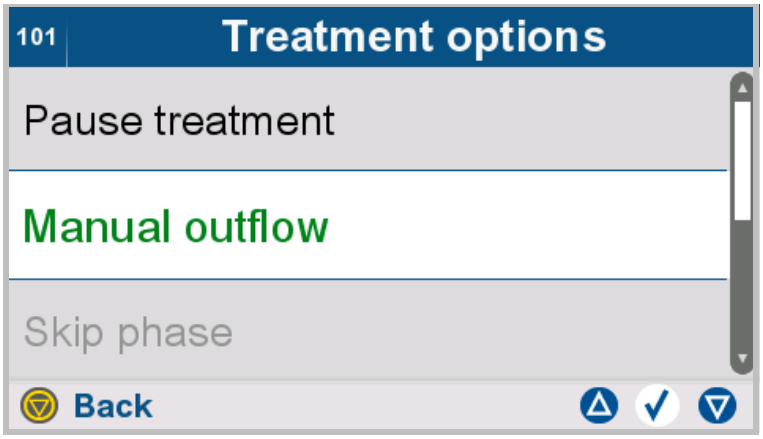
The elapsed pause time is displayed.

➢ Press the button to continue the treatment.

4.8.3 Manual outflow

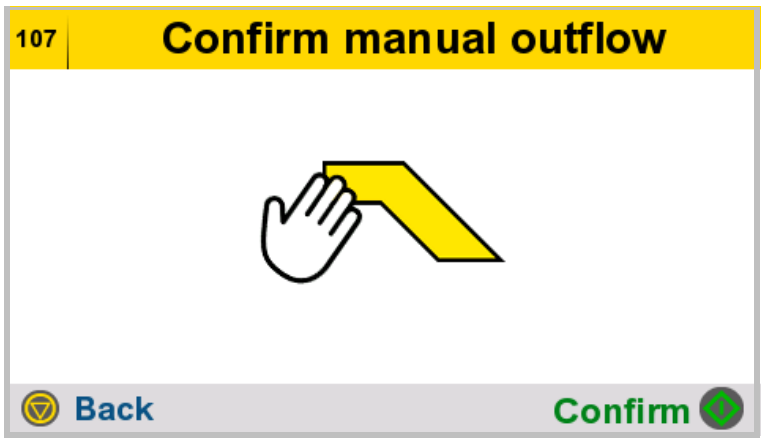


Press the button to access the options.



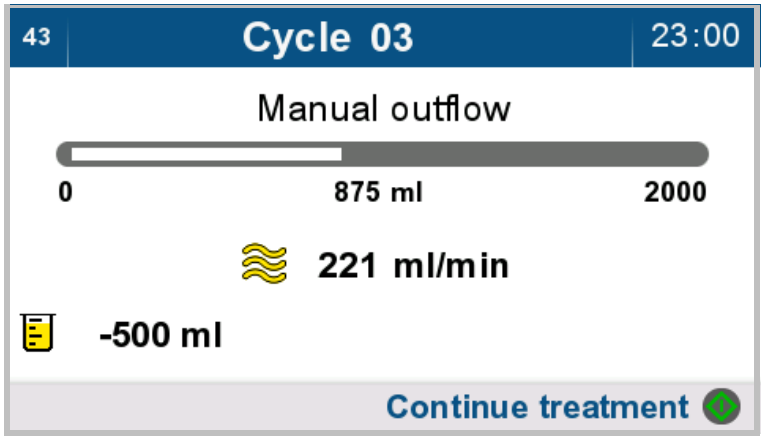
➢ Select **Manual outflow**.

➢ Press the button to return to the higher-level menu.



➢ Press the button to confirm the manual outflow.

➢ Press the button to return to the higher-level menu.



➢ The manual outflow will be performed.

➢ Press the button to end manual outflow and continue the treatment.

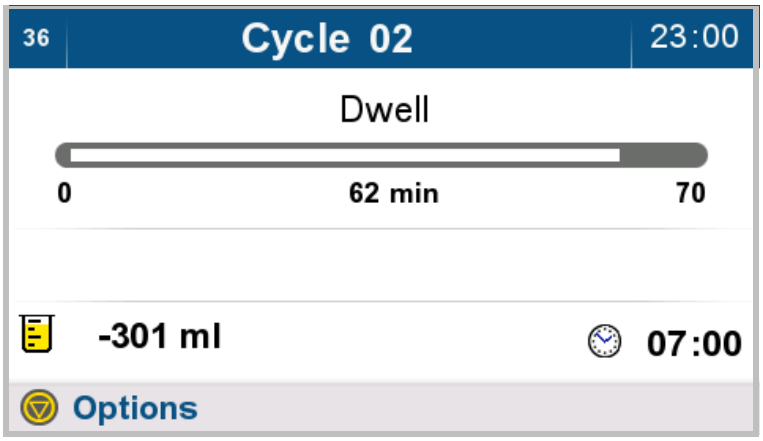
The manual outflow is complete.

➢ Press the button to end the treatment (see Chapter 4.4.1 on page 88).

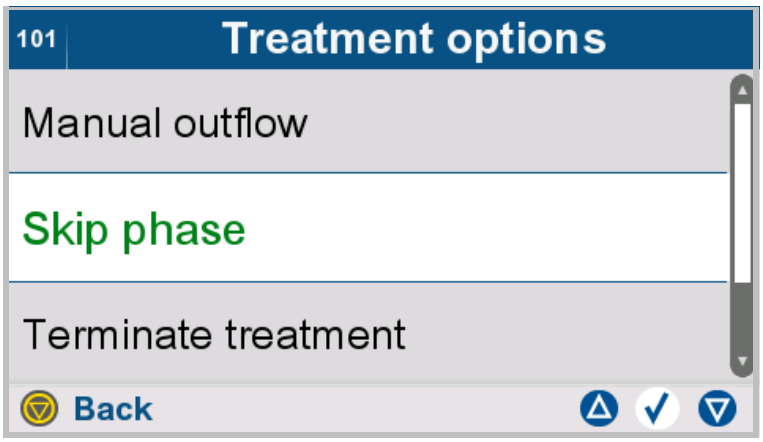
or

➢ Press the button to continue the treatment.

4.8.4 Skipping a phase



Press the button to access the options.



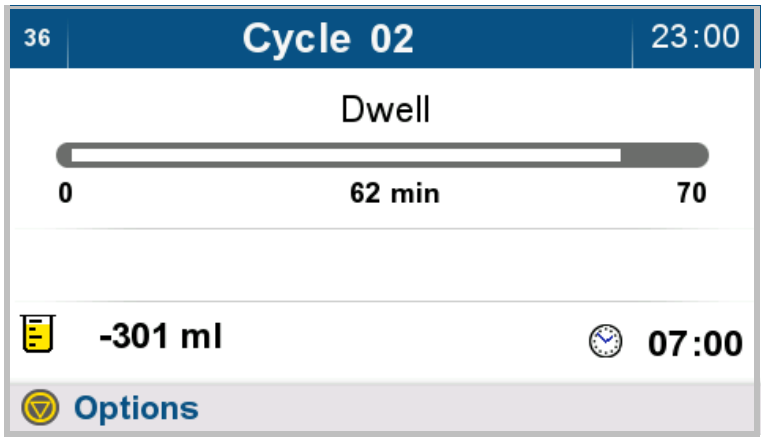
➢ Select **Skip phase** to skip the current treatment phase.

➢ Press the button to return to the higher-level menu.

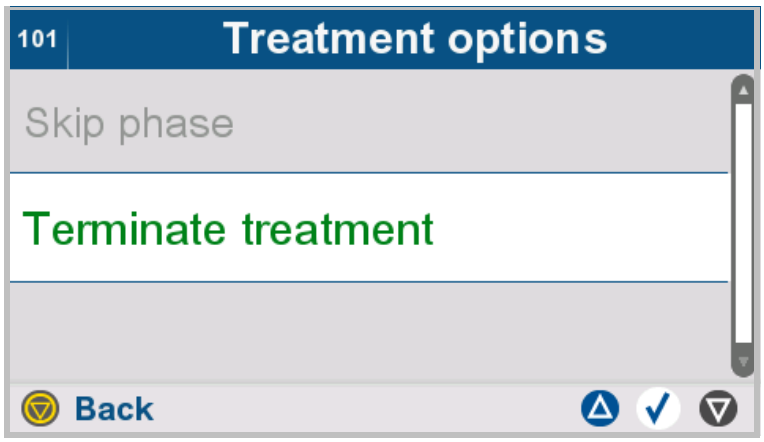
➢ Press the button to skip the current treatment phase and start the next treatment phase.

➢ Press the button to return to the higher-level menu.

4.8.5 Terminating treatment

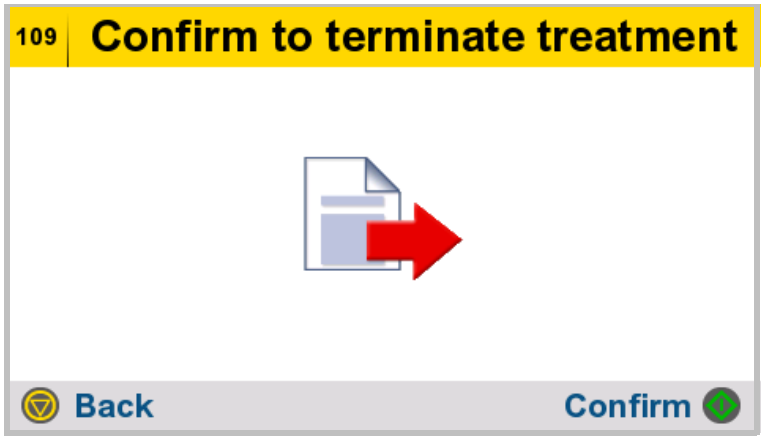


Press the button to access the options.



➢ Select **Terminate treatment**.

➢ Press the button to return to the higher-level menu.



➢ Press the button to end the treatment (see Chapter 4.4.1 on page 88).

➢ Press the button to return to the higher-level menu.

5 Alarms

Warning

Risk of injury from a device defect

A treatment cannot be performed properly and safely with a defective device.

➢ Do not perform treatments with a defective device.

➢ Take the device out of service and disconnect it from the power supply.

➢ If the treatment is stopped due to an alarm (system error/device fault), follow the instructions of the attending physician.

➢ Inform the responsible organization or service support.

A device defect is present in the following cases, for example:
– Mechanical damage
– Damaged power supply cord
– Unexpected device responses
– Deteriorated device performance

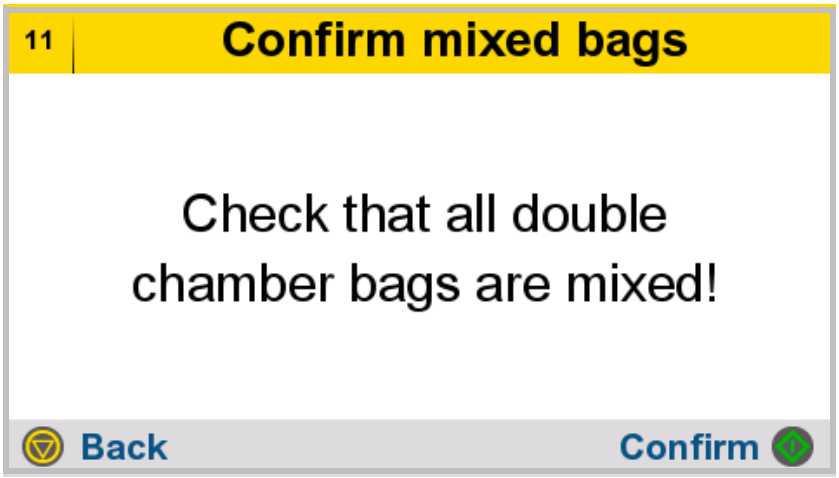
5.1 Information

5.1.1 Definition of "Information"

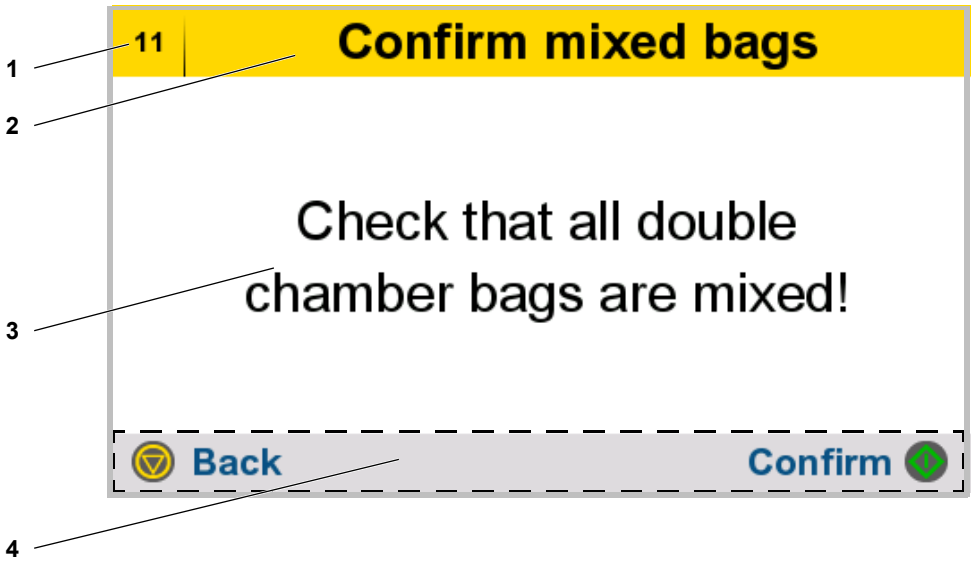
Information messages are screen messages that provide the operator with assistance while using the device during normal operation.
This can take the form of notes about specific work steps when performing treatment, or information notifying the operator of system-relevant aspects for using the device.
Screen messages providing assistance with specific work steps have a unique screen identification number.
Information messages concerning system-relevant aspects have a general screen identification number (121).

5.1.2 Color identification for "Information" screen messages

“Information" screen messages are indicated by a yellow header.
The screen shown is used as an example.



5.1.3 Layout of "Information" screen messages



1 Screen message number
The screen message number allows the message to be uniquely assigned to the related operating step.

2 Screen message title

3 Screen message description and instructions

4 Options panel
Displays buttons that are enabled for the current operating step.

5.2 Caution

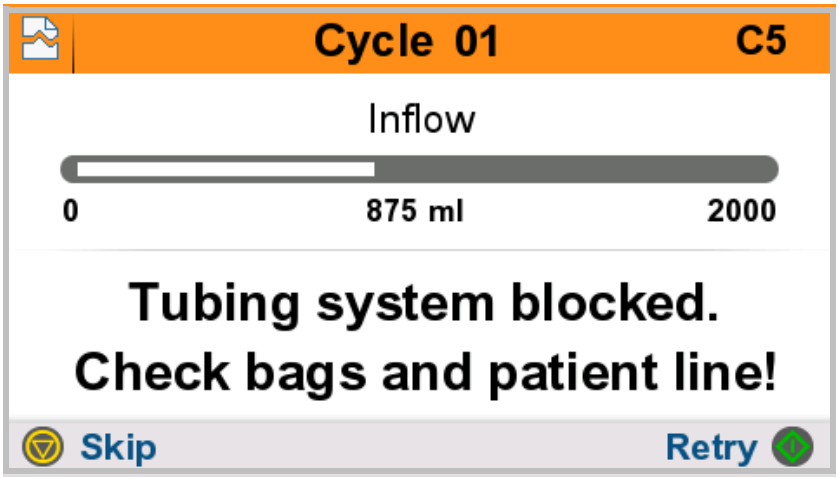
5.2.1 Caution requiring operator action on device

5.2.1.1 Definition of "Caution requiring operator action on device"

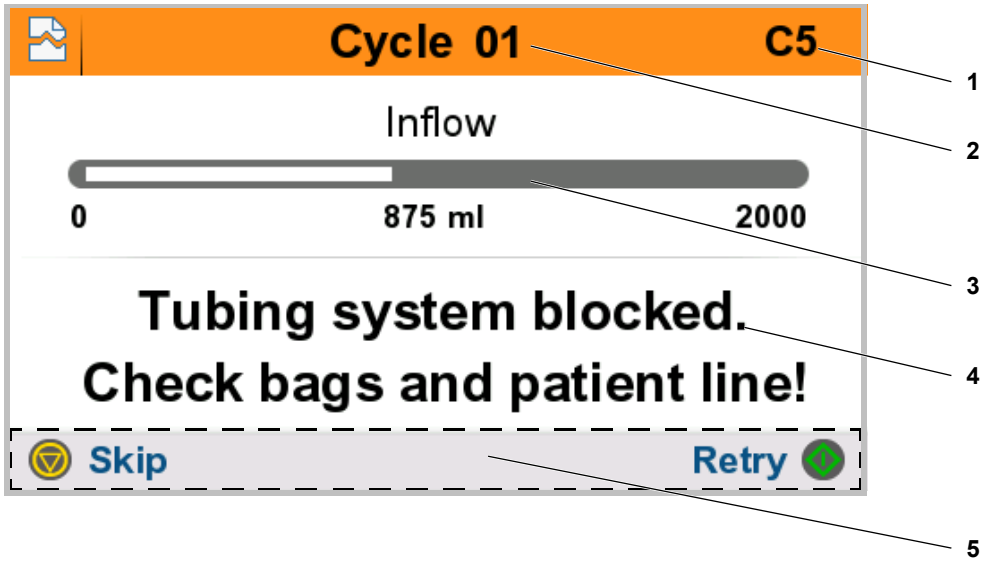
"Caution requiring operator action on device" refers to treatment interruptions that require both operator intervention to eliminate the cause of the problem and an operator action on the device.
Once the cause has been eliminated, treatment can be continued as usual.
"Cautions requiring operator action on device" have a unique identification code (C###).

5.2.1.2 Color-coding of screen message "Caution requiring operator action on device"

The "Caution requiring operator action on device" screen message is indicated by an orange header.
The screen shown is used as an example.



5.2.1.3 Layout of "Caution requiring operator action on device" screen message



1 Identification number of "Caution requiring operator action on device"
The screen message number allows a clear analysis of the error and provides the contact person at the dialysis center or local service support organization with additional troubleshooting information.

2 Current treatment cycle when "Caution requiring operator action on device" occurs

3 Current treatment phase and progress when "Caution requiring operator action on device" occurs

4 Description of "Caution requiring operator action on device" and instructions

5 Options panel
Displays buttons that are enabled for the current operating step.

5.2.2 Caution not requiring operator action on device

5.2.2.1 Definition of "Caution not requiring operator action on device"

"Caution not requiring operator action on device" refers to treatment interruptions that require operator intervention in order to eliminate the cause of the problem, but do not require an operator action on the device. A reduced flow rate or a blocked patient line (inflow or outflow) will cause such a "Caution not requiring operator action on device".

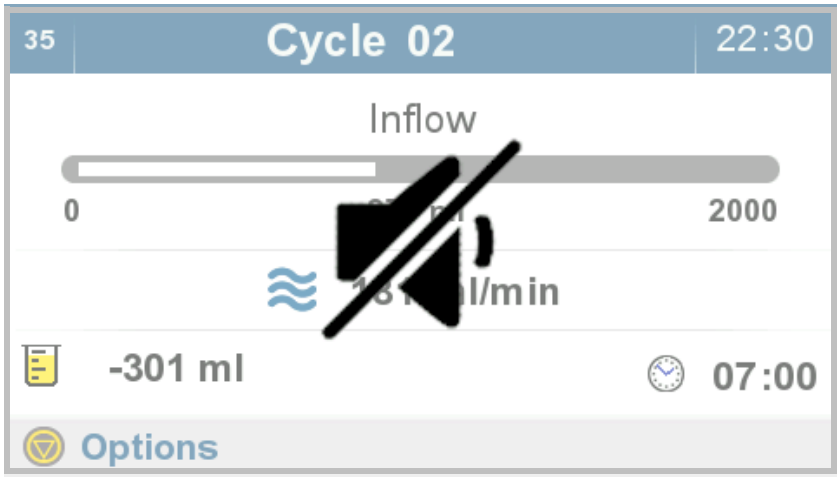
A tone sequence is played to tell the patient to change their position. Changing the position will often achieve an acceptable flow rate again, in turn allowing the inflow or outflow to continue. As soon as the reduced flow rate or blocked patient line is remedied, the tone sequence stops automatically without any further operator action required by the operator.

If the screensaver is active, it remains activated during "Caution not requiring operator action on device". Pressing any button will deactivate the screensaver. If the screen is active, the tone sequence can be muted by pressing any button.

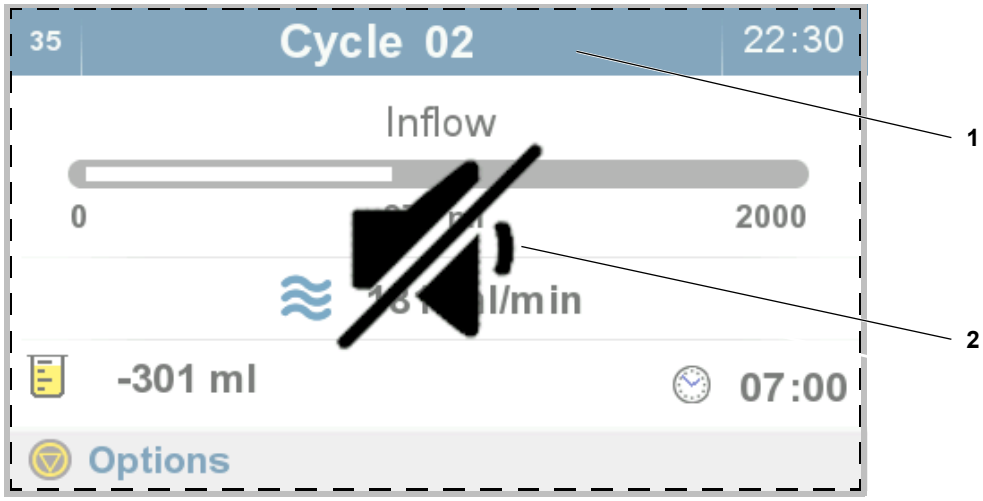
If "Caution not requiring operator action on device" is not resolved within 4 minutes, the device switches to "Caution requiring operator action on device".

5.2.2.2 Color-coding of screen message "Caution not requiring operator action on device"

The "Caution not requiring operator action on device" screen message is indicated by a treatment overview with a crossed-out speaker icon superimposed on it.
The screen shown is used as an example.



5.2.2.3 Layout of "Caution not requiring operator action on device" screen message



When a "Caution not requiring operator action on device" occurs, the parameters below are displayed.

1 Treatment overview

2 Symbol indicates that the tone sequence can be muted with any button.

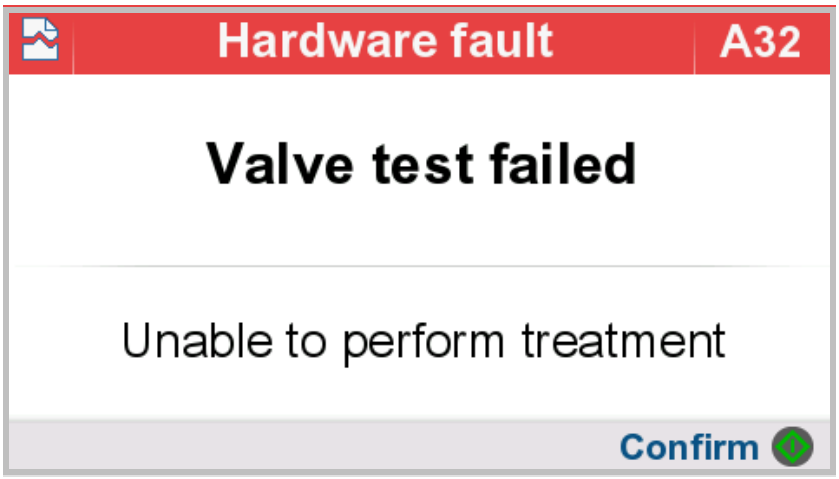
5.3 Alarm

5.3.1 Definition of "Alarm"

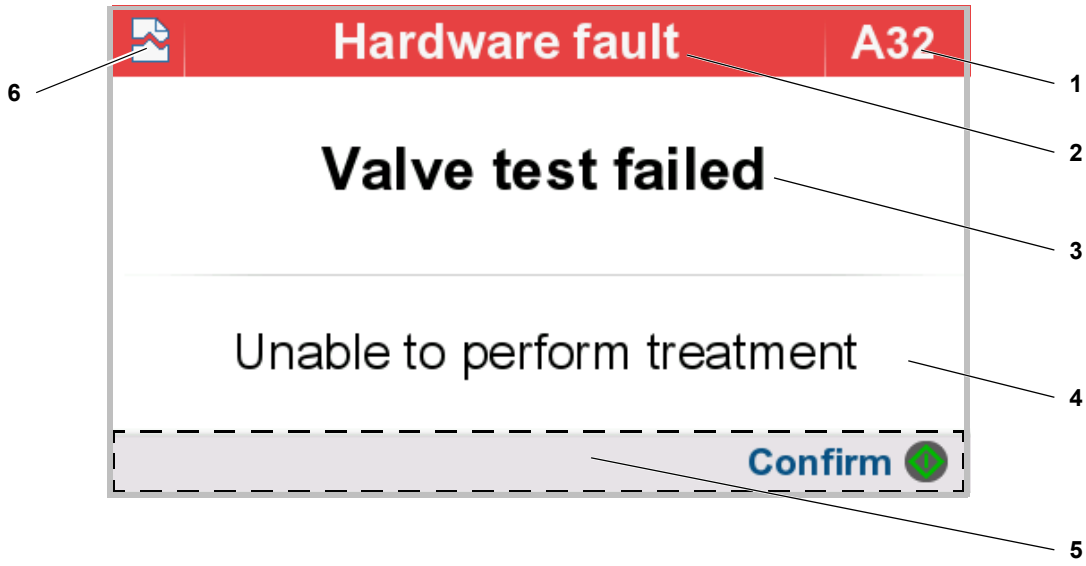
Alarms are system or device faults that typically result in treatment being discontinued or the device switching off. Alarms have a unique identification code (A###).

5.3.2 Color identification for "Alarm" screen messages

“Alarm" screen messages are indicated by a red header. The screen shown is used as an example.



5.3.3 Layout of "Alarm" screen message



1 Alarm identification number
The screen message number allows a clear analysis of the error and provides the contact person at the dialysis center or local service support organization with additional troubleshooting information.

2 Screen message information

3 Description of alarm or cause of failure

4 Information about how to proceed

5 Options panel
Displays buttons that are enabled for the current operating step.

6 Interruption icon

5.4 Resetting the audible alarm

➢ If an audible signal or alarm occurs, the sound can be muted by pressing any button.

5.5 Screen messages

5.5.1 Overview of caution messages

Message ID	Screen message, possible cause	Measure
Failure during scale test.	**Failure during scale test.** The scale test prior to positioning the solution bags has failed. This can be caused by objects on the heating tray or drain tray, or by a malfunction of the scale itself.	– Make sure that there are no objects on the heating tray or the drain tray. – If the scale test fails again, please contact the service support organization.
Failure during priming.	**Failure during priming.** The device cannot detect a properly prepared tubing system	Ensure the following during priming: – The cones are broken on all connected solution bags. – All used tube clamps are open. – The tubing system has been inserted into all valves.

Message ID	Screen message, possible cause	Measure
Failure during priming.	**Failure during priming.** The device could not detect a stable weight to prime the tubing system.	– Make sure that the heating tray and the drain tray are not moved during priming.
C1	**Tubing system blocked. Check patient line and drain line!** No flow is detected by the device during the outflow phase.	– Inspect the tubing system for kinks. – Make sure that all clamps for the drainage bags are open. – Make sure that the clamps on the catheter extension and patient line are open.
C2	**Verify completion of initial outflow!** No flow is detected by the device during initial outflow.	– Make sure that the peritoneal cavity is completely drained at the end of the initial outflow, and end the initial outflow. If the outflow has not finished: – Make sure that all clamps to the drainage bags are open. – Make sure that the clamps on the catheter extension and patient line are open. – Inspect the tubing system for kinks.
C3	**Verify completion of last outflow!** No flow is detected by the device during the last outflow.	– Make sure that the peritoneal cavity is completely drained at the end of the last outflow, and end the last outflow. If the outflow has not finished: – Make sure that all clamps to the drainage bags are open. – Make sure that the clamps on the catheter extension and patient line are open. – Inspect the tubing system for kinks.

Message ID	Screen message, possible cause	Measure
C4	**Abrupt weight change. Check for scale interferences!** An abrupt change in the weight on the scale has caused the treatment to be interrupted. This can be caused by objects on the heating tray or drain tray, or by incorrectly positioned solution bags.	– Make sure that there are no objects on the heating tray or the drain tray. – Make sure that all bags are properly positioned on the heating tray and drain tray.
C5	**Tubing system blocked. Check bags and patient line!** No flow is detected by the device during the inflow phase.	– Inspect the tubing system for kinks. – Make sure that all clamps for the solution bags are open and that all solution bag cones have been properly broken. – Make sure that the clamps on the catheter extension and patient line are open. – Make sure that all double chamber bags have been mixed.
C6	**Verify completion of manual outflow!** No flow is detected by the device during manual outflow.	– Make sure that the desired outflow volume is reached and stop the manual outflow. If the outflow has not finished: – Make sure that all clamps to the drainage bags are open. – Make sure that the clamps on the catheter extension and patient line are open. – Inspect the tubing system for kinks.

5.5.2 Overview of alarm messages

Message ID	Screen message, possible cause	Measure
A32	**Valve test failed**	– Confirm alarm message. The device switches off. – Make sure that the plug is properly connected at the bottom of the base unit. – Restart the device. – If the problem occurs repeatedly, please contact the service support organization.
A33	**Valve test failed**	– Confirm alarm message. The device switches off. – Make sure that the plug is properly connected at the bottom of the base unit. – Restart the device. – If the problem occurs repeatedly, please contact the service support organization.
A48	**Heater temperature exceeded** This error can occur, for example, when the solution bags are removed from the heating tray during pre-heating.	– Confirm alarm message. The device switches off. – Make sure that the device is being operated within the specified operating conditions (see Chapter 9.2 on page 190). – Make sure that the solution bags are within the specified temperature range (for this information, please refer to the printed label on the solution bags). – If necessary, allow the device to cool down before restarting. – If the problem occurs repeatedly, please contact the service support organization.

Message ID	Screen message, possible cause	Measure
A50	**Valve monitoring timeout**	– Confirm alarm message. The device switches off. – Make sure that the plug is properly connected at the bottom of the base unit. – Restart the device. – If the problem occurs repeatedly, please contact the service support organization.
A51	**Patient volume monitoring** The patient volume monitoring has identified a deviation.	– Confirm alarm message. The device switches off. – Disconnect from the device; if necessary, drain the patient manually and speak to the responsible organization if necessary.
A53	**Temperature sensor discrepancy**	– Confirm alarm message. The device switches off. – If necessary, allow the device to cool down before restarting. – If the problem occurs repeatedly, please contact the service support organization.
A54	**Weighing cell discrepancy** This alarm can occur if the device is subjected to strong vibrations.	– Confirm the alarm message and restart the device. – If the problem occurs repeatedly, please contact the service support organization.

Message ID	Screen message, possible cause	Measure
A55	**Invalid weight change**	– Confirm alarm message. The device switches off. – Make sure that all connections to the solution bags, drain system and catheter extension are tightly secured. – Check solution bags and drainage bags for leakages. – Restart the device. – If the problem occurs repeatedly, please contact the service support organization. – Make sure that the tubing system is properly inserted into the valves.
A56	**Valve status error** The alarm may occur if a clamp was opened outside of treatment while the patient was connected.	– Confirm alarm message. The device switches off. – Restart the device. – If the problem occurs repeatedly, please contact the service support organization.
A58	**Heater temperature too low**	– Confirm alarm message. The device switches off. – Make sure that the device is being operated within the specified operating conditions (see Chapter 9.2 on page 190). – Make sure that the solution bags are within the specified temperature range. – If necessary, allow the device to adjust to the ambient temperature before restarting. – If the problem occurs repeatedly, please contact the service support organization.

Message ID	Screen message, possible cause	Measure
A59	**Treatment parameter implausible**	– Confirm alarm message. The device switches off. – Restart the device. – If the problem occurs repeatedly, please contact the service support organization.
A61	**Maximum weight exceeded at start of treatment**	– Confirm alarm message. The device switches off. – Make sure that the positioned solution bags do not exceed the maximum permitted weight (see Chapter 12.1 on page 223). – Make sure that the drain system is completely empty before it is positioned on the drain tray. – Make sure that there are no objects on the heating tray or the drain tray. – Restart the device. – If the problem occurs repeatedly, please contact the service support organization.
A70 to A81	**Inconsistent program monitoring state**	– Confirm alarm message. The device switches off. – Restart the device. – If the problem occurs repeatedly, please contact the service support organization.
A118	**Unexpected low value on temperature sensor**	– Confirm alarm message. The device switches off. – Restart the device. – If the problem occurs repeatedly, please contact the service support organization.

Message ID	Screen message, possible cause	Measure
A119	**Unexpected high value on temperature sensor**	– Confirm alarm message. The device switches off. – Restart the device. – If the problem occurs repeatedly, please contact the service support organization.
A140	**Corrupt volume balancing information**	– Confirm alarm message. The device switches off. – Restart the device. – If the problem occurs repeatedly, please contact the service support organization.
A150	**Valve malfunction**	– Confirm alarm message. The device switches off. – Restart the device. – If the problem occurs repeatedly, please contact the service support organization.
A200	**Treatment data invalid** This alarm can occur if, after a restart following a power failure, the current weight and last stored weight do not match.	– Confirm alarm message. The device switches off. – Restart the device. – If the problem occurs repeatedly, please contact the service support organization.
A202	**Treatment data invalid after power failure**	– Confirm alarm message. The device switches off. – Restart the device. – If the problem occurs repeatedly, please contact the service support organization.
A203	**Treatment data invalid after power failure**	– Confirm alarm message. The device switches off. – Restart the device. – If the problem occurs repeatedly, please contact the service support organization.

Message ID	Screen message, possible cause	Measure
A208	**Software status error**	– Confirm alarm message. The device switches off. – Restart the device. – If the problem occurs repeatedly, please contact the service support organization.
A214	**Inconsistent safety-relevant information displayed**	– The monitoring has detected a deviation in the displayed values. – Consult the responsible organization or the service support organization.
A215	**Internal communication error**	– Confirm alarm message. The device switches off. – Restart the device. – If the problem occurs repeatedly, please contact the service support organization.
A216	**Inconsistent treatment results**	– The therapy monitoring system has identified a deviation. – Consult the responsible organization or the service support organization.
A219	**Priming of patient line not possible** This alarm may occur if priming fails more than three times, e.g., if the tubing system is incorrectly inserted, the tube clamps are closed, the solution bag cones are not broken, or the heating tray and drain tray are constantly moving.	– Confirm alarm message. The device switches off. – Restart the device. Ensure the following before priming: – The cones are broken on all connected solution bags. – All used tube clamps are open. – The tubing system has been inserted into all valves. – Make sure that the heating tray and the drain tray are not moved during priming.

After an alarm occurs, the device should be restarted and a functional test should be performed (see Chapter 4.1 on page 51).

If the functional test cannot be completed successfully, please contact the service support organization.

5.6 Terminating treatment after an alarm

Warning

Risk of contamination from non-compliance with hygiene measures

Patient hazard from overfilling of peritoneal cavity

Risk of circulatory disturbance due to balancing error

Patient hazard from insufficient detoxification

Improper handling during disconnection can lead to contact with the opening of the patient connector.
This may lead to microbial contamination.

➢ If treatment is terminated due to an alarm, follow the instructions of the attending physician.

➢ We recommend wearing a face mask and using hand sanitizer.

➢ Use aseptic techniques when disconnecting the patient.

➢ Observe the hygiene practices of the dialysis center and the hygiene regulations in force.

For additional screen layout information, please refer to the appropriate chapter (see Chapter 5.1 on page 156).

For additional screen message information, please refer to the appropriate chapter (see Chapter 5.5 on page 164).

5.7 Emergency shutdown

If the device no longer responds to button commands, an emergency shutdown can be performed.

To perform an emergency shutdown, press and hold the button for approximately 10 seconds or unplug the power plug.

5.8 Power failure

The device automatically switches on and will continue operation in the relevant phase as soon as the power supply is available again.

Depending on the length of the power failure, an additional solution bag pre-heating may be performed if necessary.

5.9 Failure of display, buttons or status indicator

Warning

Patient hazard from overfilling of peritoneal cavity or insufficient detoxification

If it is no longer possible to operate the device, breathing and circulatory problems can result if the peritoneal cavity is filled with too much fluid.

➢ If the device can no longer be operated, disconnect the patient and follow the instructions of the attending physician.

➢ We recommend wearing a face mask and using hand sanitizer.

➢ Use aseptic techniques when disconnecting the patient.

➢ Comply with the hygiene practices of the dialysis center and all applicable hygiene regulations.

6 Cleaning/Disinfection

6.1 Cleaning

Warning

Risk of injury from a device defect

Risk of cross-contamination from inadequate cleaning of device surface

The use of unapproved cleaning agents or disinfectants can damage the device's housing material or inscriptions and may result in inadequate disinfection.

➢ Do not autoclave or submerge the device in fluid.

➢ Do not use solvent-based chemical cleaning agents.

➢ Disconnect the device from the power supply system before cleaning.

➢ Use the approved disinfectant and cleaning agent.

The test procedure by which the efficiency of each required disinfection has been verified is available on request.

Approved disinfectants

– Fresenius ClearSurf
– Fresenius ClearSurf Wipes
– Fresenius Freka-NOL

Cleaning interval

– As necessary (in case of contamination) but at least once a week

Parts to be cleaned

– Surfaces (housing, display, heating tray, drain tray, organizer)

Once the disinfectant and cleaning agent has completely evaporated, the device is ready for use again.

7 Functional description

7.1 Description of functional procedures

The SILENCIA is a peritoneal dialysis cycler which has been designed to offer maximum safety and convenience for patients, physicians, nurses, and service staff. It reflects the latest state of technology in the fields of electronics, mechanics, and software.

The most important features of the device are:
– Therapy management (volume, time management)
– Timer operation
– Ease of use
– Graphical user guidance
– Virtually noiseless operation
– Integrated management system for patient and treatment data using a patient card

The SILENCIA is an automated peritoneal dialysis device designed for use at home and in hospitals.

Further information material is available from the local service support organization in the form of manuals, posters, etc.

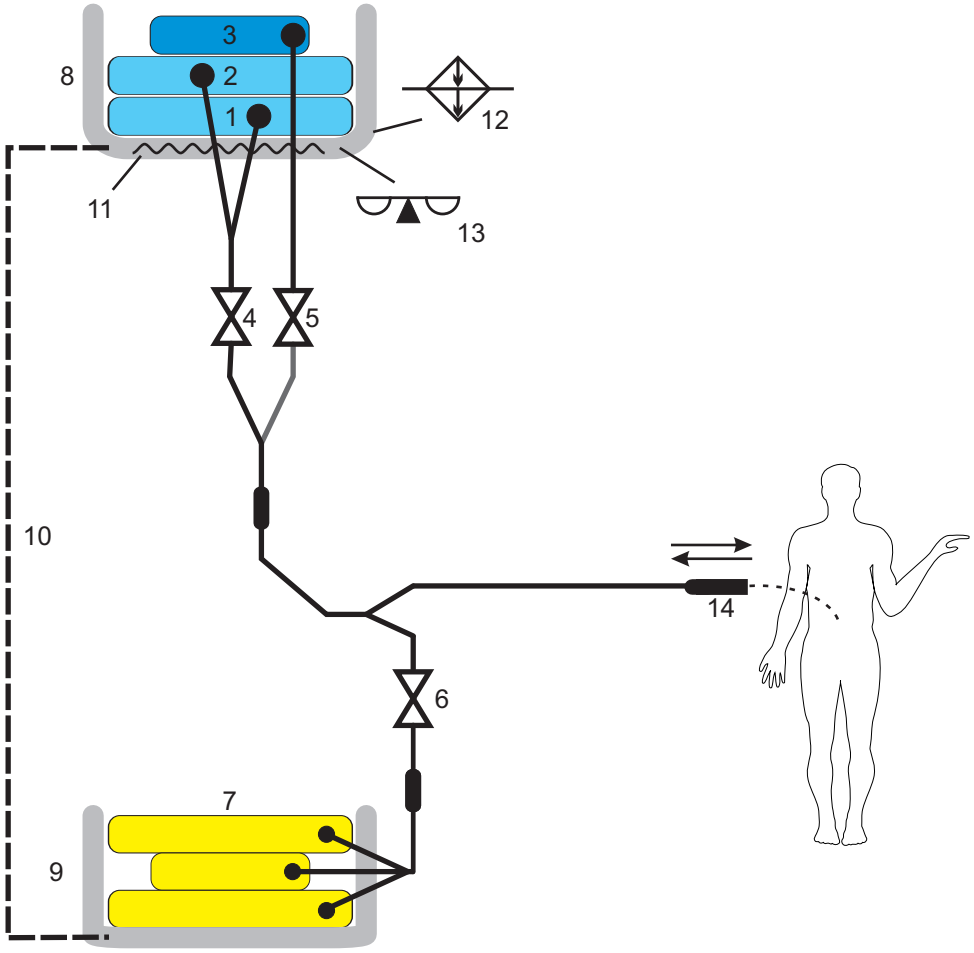
7.1.1 Flow diagram

The inflow of new peritoneal dialysis solution into the patient’s peritoneal cavity as well as the outflow out of the patient both occur through hydrostatic pressure.

Three tube valves control the flow paths of the new and used dialysis solution within the tubing system.

Fluid balancing is performed using an integrated scale to which the heating tray is connected on the inflow side and to which the drain tray is attached on the outflow side.

On the heating tray, the new dialysis solution is heated before inflow.



1 Solution bag

2 Solution bag

3 "Last inflow" solution bag

4 Inflow valve – white

5 Inflow valve – blue

6 Drain valve

7 Drainage bag

8 Tray for peritoneal dialysis solution

9 Drain tray

10 Mechanical coupling of trays

11 Heater for solution bags

12 Temperature regulation for heating tray

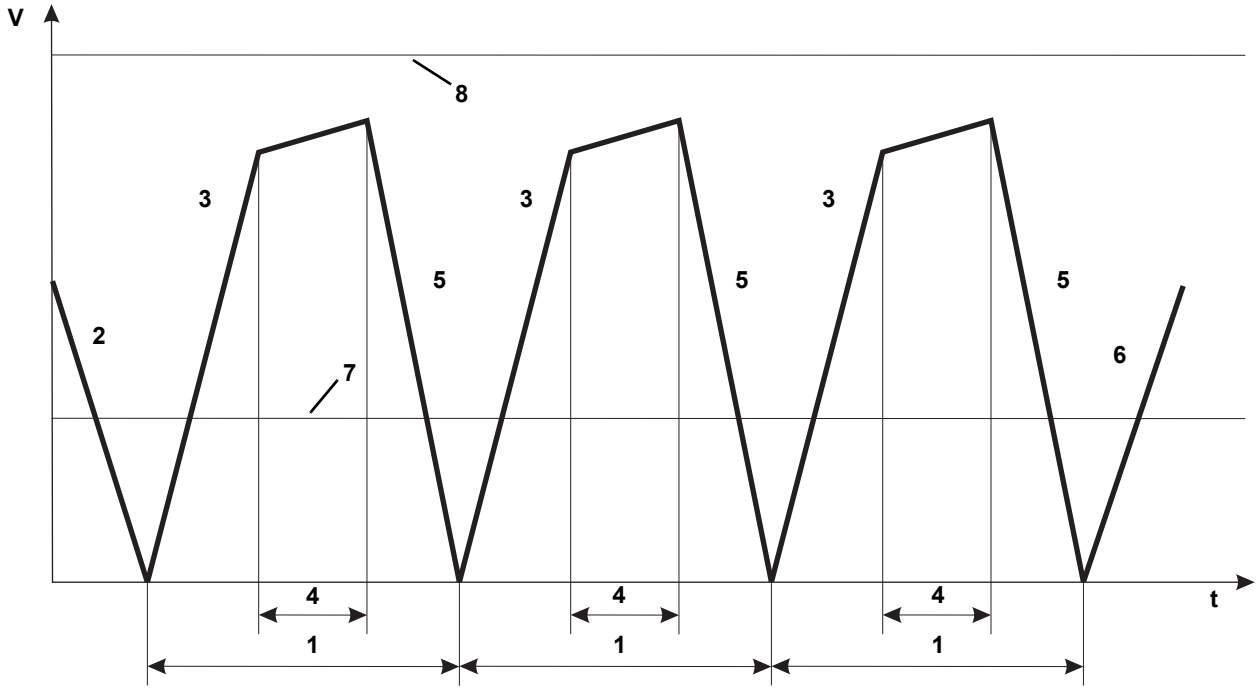
13 Scale

14 Patient connector

7.2 Therapy types

7.2.1 Standard prescription

The following schematic shows the cycles of a standard prescription.



1 Treatment cycle

2 Initial outflow

3 Inflow volume

4 Dwell duration

5 Outflow volume

6 Last inflow

7 Permitted residual volume

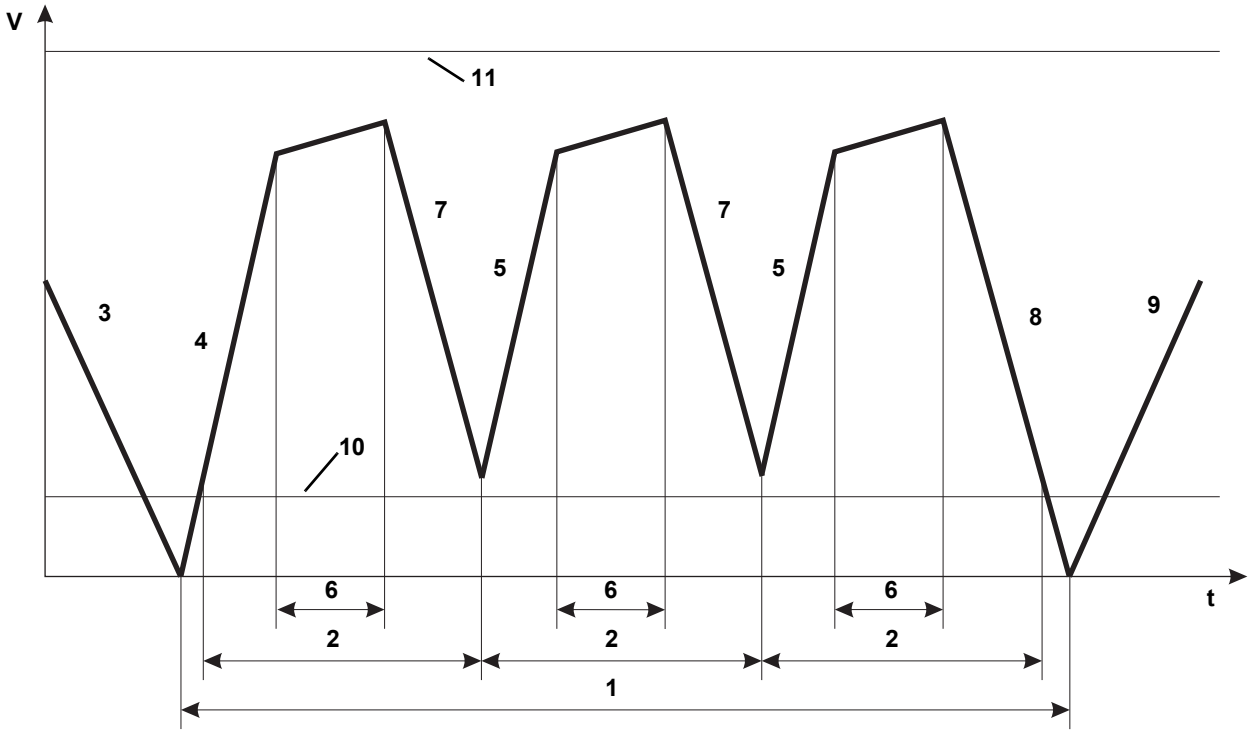
8 Permitted patient volume

The standard prescription consists of individual Base cycles for which the inflow volume, solution, and dwell duration can be set.

The following parameters can be set:
– Initial outflow volume
– Number of Base cycles
– Inflow volume
– Solution
– Dwell duration
– Last inflow volume
– Last inflow solution
– Prescription name

7.2.2 Tidal prescription

The following schematic shows the cycles of a Tidal prescription.



1 Base cycle

2 Tidal cycles

3 Initial outflow

4 Base inflow volume including first Tidal inflow volume

5 Tidal inflow volume

6 Dwell duration

7 Tidal outflow volume

8 Base outflow volume including last Tidal outflow volume

9 Last inflow

10 Permitted residual volume

11 Permitted patient volume

The Tidal prescription consists of individual Base cycles and Tidal cycles. The solution for the base inflow and the dwell duration can be set.

The following parameters can be set:
– Initial outflow volume
– Number of Base cycles
– Base inflow volume
– Number of Tidal cycles
– Tidal inflow volume
– Tidal outflow volume
– Solution
– Dwell duration
– Last inflow volume
– Last inflow solution
– Name

7.3 Therapy options

The following options must be individually adapted to the respective patient and can be set by specialized medical staff in the Patient options menu.

7.3.1 Volume optimization

7.3.1.1 Permitted patient volume

Due to individual patient-related circumstances, an outflow may occasionally not be fully completed. As a consequence, a certain residual volume will remain in the peritoneal cavity. In such cases, the "permitted patient volume" option will be applied.

The permitted patient volume restricts the maximum volume which is allowed to be in the patient's peritoneal cavity over the entire treatment.

The maximum inflow volume of a prescription is multiplied by the percentage factor for "permitted patient volume" to determine the permitted patient volume for the entire treatment. Assuming a maximum inflow volume of 2000 ml and a factor of 110 % for the "permitted patient volume", the permitted patient volume would be 2200 ml.

The goal of this option is to attain the inflow volume prescribed by the physician as closely as possible, to ensure the efficacy of the dialysis treatment.

7.3.1.2 Permitted residual volume

The "permitted residual volume" is closely related to the "permitted patient volume" option described above.

The permitted residual volume describes the maximum residual volume allowed to remain in the patient's peritoneal cavity in the case of an incomplete outflow before the device can switch to the next inflow without generating an alarm.

The goal of this option is to adapt the device to the individual catheter performance of the patient.

7.3.1.3 Permitted reduction of the inflow volume

In special cases, the prescribed solution volume is not fully available for treatment. In such cases, the inflow volume will be slightly reduced.

Assuming an inflow volume of 2000 ml and a factor of 15 % for the "permitted reduction of the inflow volume", the inflow volume may be reduced by up to 300 ml, as required. The volume will only be reduced as required and within this specified limit, and the reduction is performed automatically by the device. This ensures that the treatment can be ended without an alarm even if the originally prescribed treatment volume was not reached.
At the present time, this parameter cannot be changed on the device.

7.3.2 Time optimization

7.3.2.1 Permitted dwell duration reduction

The goal of the "permitted dwell duration reduction" option is to keep to the prescribed total treatment duration as precisely as possible. This is achieved by a dynamic adaption of the dwell duration over the remaining cycles. Assuming a dwell duration of 100 minutes and a factor of 15 % for the "permitted dwell duration reduction", this dwell duration may be reduced by 15 minutes.

8 Consumables, accessories, additional equipment

The peritoneal dialysis solutions required for the treatment must comply with the German Medicinal Products Act (Arzneimittelgesetz, AMG).

Warning

Chapter 8 (see Chapter 8 on page 185) contains a list of consumables and accessories that are suitable for use with this device and can be used safely with it.

The manufacturer cannot vouch for any other consumables and accessories than those listed in this chapter being suitable for use with this device. The manufacturer can also not make any assertions that the safety and performance of the device will remain unimpaired if consumables and accessories other than those listed in this chapter are used.

If other consumables and accessories are used, their suitability must be verified beforehand. This can be performed using the information in the instructions for use for the relevant consumables and accessories, for example.

The manufacturer accepts no liability for damage to the device resulting from the use of unsuitable consumables or accessories.

On request, the local service support organization will provide information on further accessories, consumables and other additional equipment.

Warning

Patient hazard from improper use of consumables

If consumables are used improperly, a treatment cannot be carried out properly and safely.

➢ Follow the instructions for use of the consumables used.

Warning

Risk of contamination from reuse of the SILENCIA Vario system

The SILENCIA Vario system is a single-use item.
Reuse can lead to patient contamination.

➢ Only use the SILENCIA Vario system once to supply the patient with dialysis fluid.

➢ Only use the empty solution bags as a drain system once.

Note

Consumables:
When using consumables, it is important to take note of the following symbols:

Single-use item
Identified by the symbol:

Do not reuse.

Use-by date
Identified by the symbol:

Use by:

8.1 Consumables

8.1.1 Peritoneal dialysis solutions

For detailed information on the dialysis solutions, refer to the Fresenius Medical Care product range.

Only those peritoneal dialysis solutions which are displayed on the device can be used for treatment.

8.1.2 Single-use items

Product	Part number	Information
SILENCIA Vario system 2	F00006957	Tubing system
SILENCIA Vario system 2+1	F00006794	Tubing system
stay•safe® disinfection cap	284 509 1	Disinfection cap
Dialysis solution (example): CAPD/DPCA 2 6L SAFE.LOCK	F00000577	1.5 % glucose 1.75 mmol/L calcium
PIN Reload	501 700 1	(see Chapter 15.1 on page 249)
Safe•Lock® APD Luer lock connector	284 960 1	Only use the connector in combination with a 7.5 % polyglucose solution bag.

8.1.3 Surface disinfection/surface cleaning

Product	Information
Fresenius Medical Care ClearSurf	Disinfectant for wipe disinfection Active substance: cationic surfactants
Fresenius Medical Care ClearSurf Wipes	Ready-to-use disinfection wipes, soaked with 1 % ClearSurf Active substance: cationic surfactants
Fresenius Medical Care Freka-NOL	Quick-acting disinfectant for wipe disinfection in combination with Freka-Wipes single-use wipes Active substance: 45 % ethanol

8.2 Accessories

No accessories are provided for this device.

8.3 Additional equipment

Product	Part number	Information
PatientCard *Plus*	M45 129 1	Patient card
SILENCIA “Main Unit” box 1/2	F40014828	With base unit
SILENCIA “Stand” box 2/2	F40014829	With pedestal and mounting stand

8.4 Device

Product	Part number	Information
SILENCIA	M20 700 1	–

8.4.1 Products in combination with the device

Products that can be used in combination with the device.

Product	Part number	Information
Organizer	284 256 1	–
Clip for organizer	M20 048 1	–

9 Installation

9.1 Connection requirements

9.1.1 Environment

The manufacturer has specified the device for operation in rooms that are suitable for peritoneal dialysis located in professional health care institutions, or for the home healthcare environment.

9.1.2 Power supply (electrical power network)

Warning

Risk of suffocation from smoke inhalation

An overload of electrical extension cords can lead to overheating with the formation of smoke.

➢ The use of power strips and extension cords is prohibited.

Warning

Risk of injury from electric shock

Contact with a damaged power supply cord can cause electric shocks.

➢ The power supply cord must be laid so as to ensure that it cannot be damaged by sharp-edged objects or by pets.

The national standards and regulations must be observed when connecting the device to the power supply.

Power plug

When setting up the device, it must be ensured that the power plug is accessible at all times.

Power supply cord

If the power supply cord needs to be replaced, use only the original power supply cord listed in the Spare Parts Catalog.

9.2 Installation requirements

Warning

Patient hazard from a device malfunction

If the device is used outside the specified storage and operating conditions, the device may not operate safely.

➢ The specified storage and operating conditions must be followed.

Note

Variations in temperature during transport may cause water condensation on electrical parts. In the event of major variations in temperature, allow 3 hours for the device to adjust to the ambient temperature with the power switched off.

Operating conditions

Operating temperature range:
+15 to +35 °C

Relative humidity:
10 to 90 %

Atmospheric pressure:
700 to 1100 hPa
(approx. 3000 to -425 m altitude)

Electromagnetic radiation

Do not use devices that emit any form of electromagnetic radiation (e.g., walkie-talkies, cordless/cell phones or radio transmitters) in the vicinity of a SILENCIA in operation. This may cause a malfunction of the SILENCIA
(see Chapter 12.6 on page 227).

9.3 Installation after shipment/transport outside of buildings

9.3.1 Visual check after transport

Do not use the device if any of the following defects are detected:
– Mechanical damage to the housing
– Mechanical damage to the screen
– Mechanical damage to the card slot
– Defective power supply cord

➢ The device must be taken out of service.

➢ Inform the responsible organization or service support.

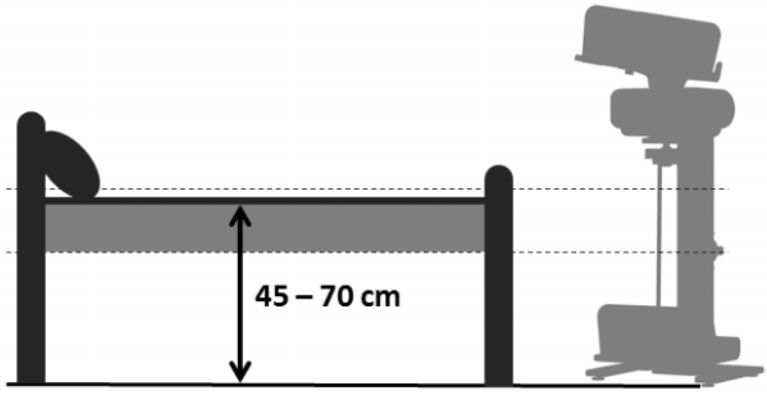
9.3.2 Acclimation time

Note

Variations in temperature during transport may cause water condensation on electrical parts. In the event of major variations in temperature, allow 3 hours for the device to adjust to the ambient temperature with the power switched off.

9.3.3 Permitted patient positioning

During treatment, the permissible patient position is 45 to 70 cm above the floor.



9.4 Assembling the device

9.4.1 Preparing for assembly

Before assembling the device, open both boxes and check the contents for completeness and any transport damage. If device components are missing or damaged, contact the local service support organization.

Remove the Instructions for Use from the "base unit" box, and proceed with assembly according to the instructions.

Contents of the "base unit" box (small box):
– Instructions for Use
– Base unit
– Side panels
– Bag rest
– Organizer

Contents of the "pedestal and drain tray" box (large box):
– Mounting stand
– Pedestal
– Side panel
– Drain tray suspension
– Drain tray
– Bag rests (screws in separate package)

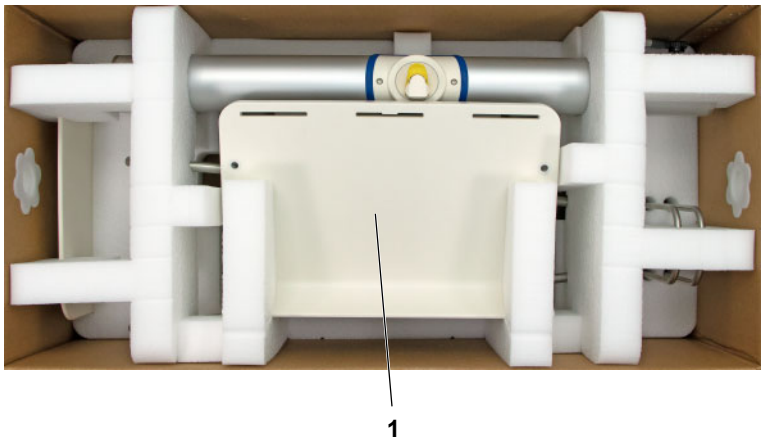
Warning

Risk of injury as a result of improper assembly

An incorrectly assembled device can cause injury to patients, operators or third parties.

➢ Each individual step described in the assembly instructions must be carried out completely and correctly.

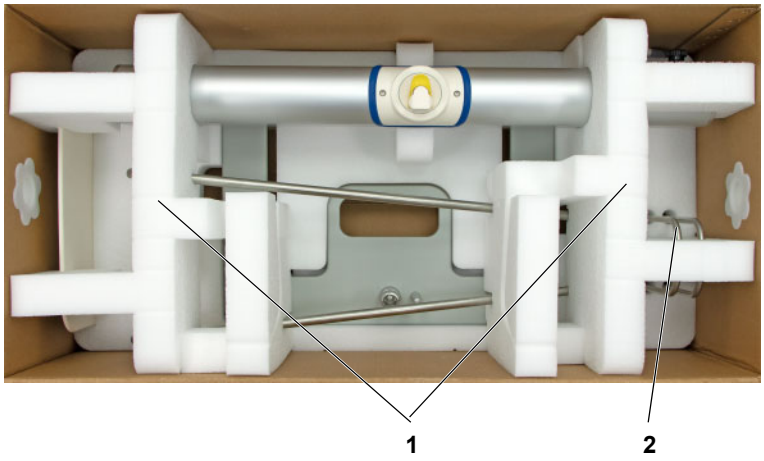
9.4.2 Assembling the pedestal and drain tray



All device components for assembling the pedestal and drain tray are contained in the larger of the two boxes.

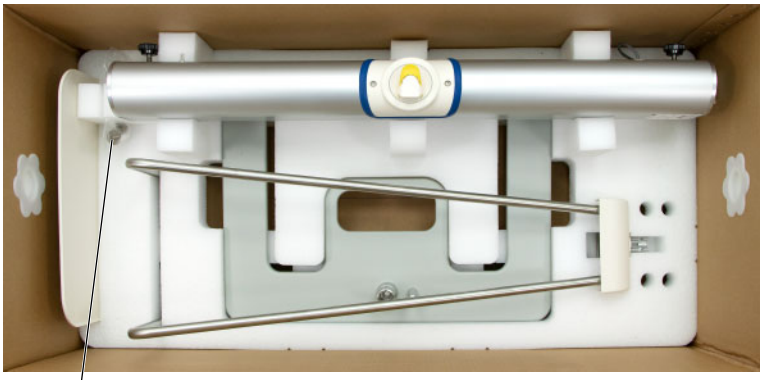
➢ Open the larger of the two boxes.

➢ Remove the drain tray (1) from the foam inserts.



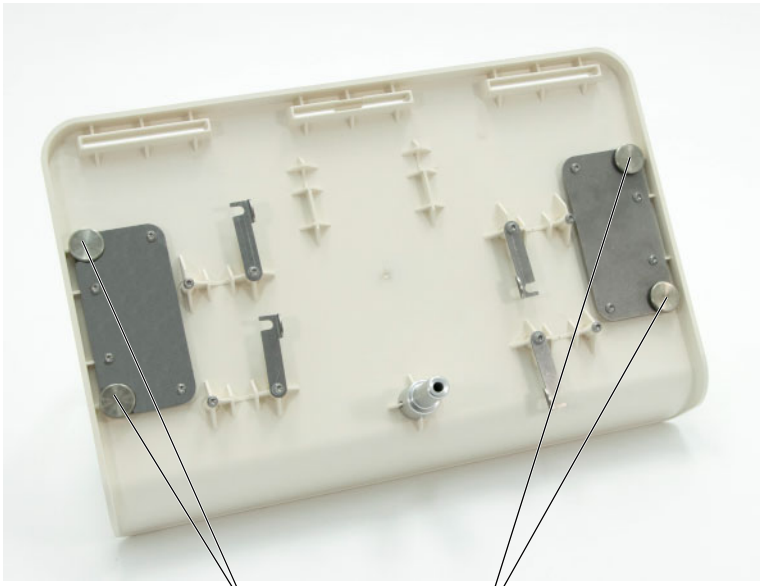
➢ Remove the two bag rests (2) from the foam insert on the right side.

➢ Remove the two foam inserts (1).



➢ Remove the bag rest screws (1) from the foam insert.

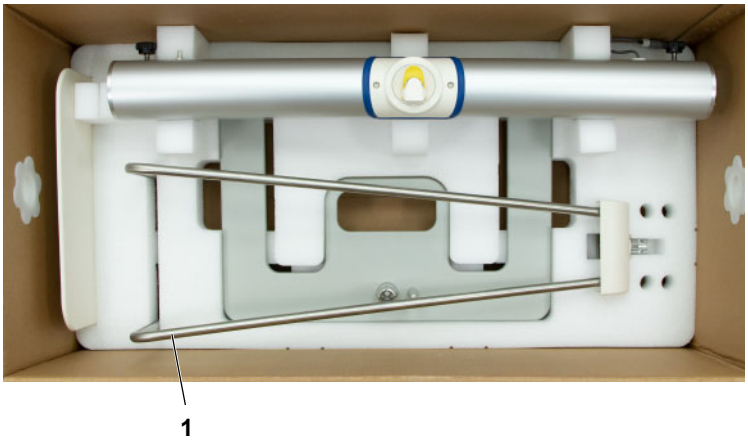
➢ Insert one of the two bag rests into the drain tray.



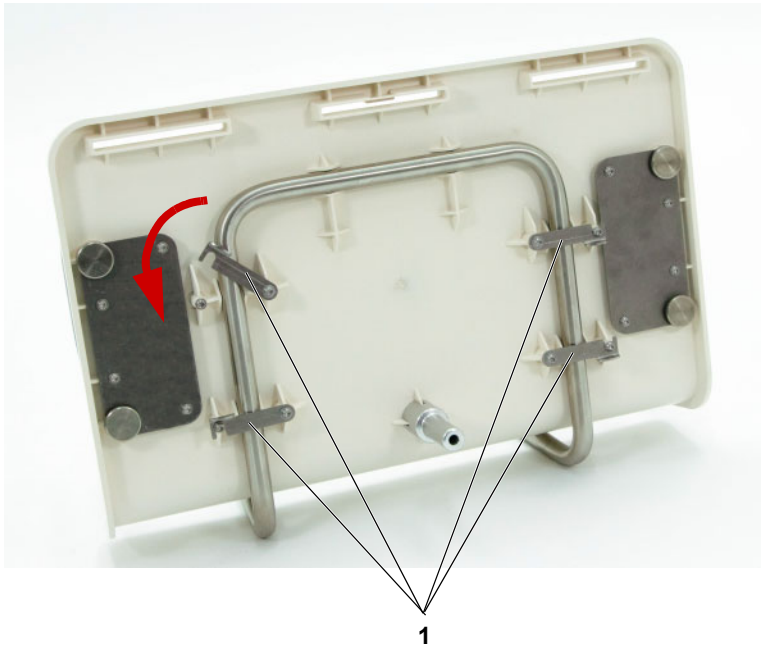
➢ Secure the bag rest using two screws (1).

➢ Insert the second bag rest into the drain tray.

➢ Secure the second bag rest using two screws (2).



➢ Remove the drain tray suspension (1) from the foam insert.

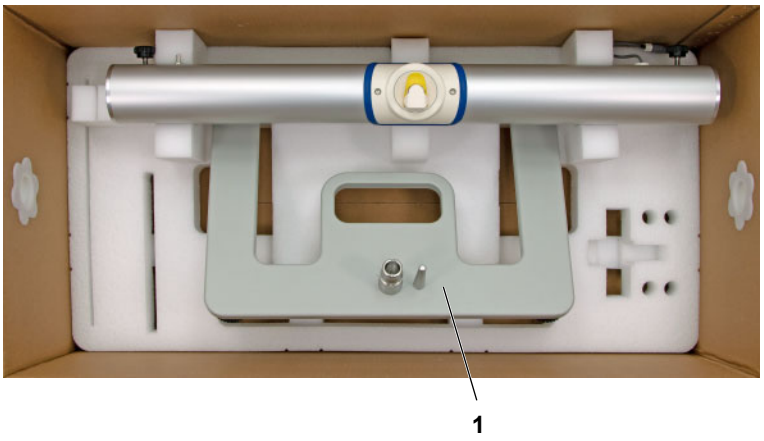


➢ Position the drain tray on the drain tray suspension and close the four locking levers (1).

➢ Remove the side panel (1) from the foam insert.

➢ Insert the side panel in the drain tray with the peripheral edge facing inwards.

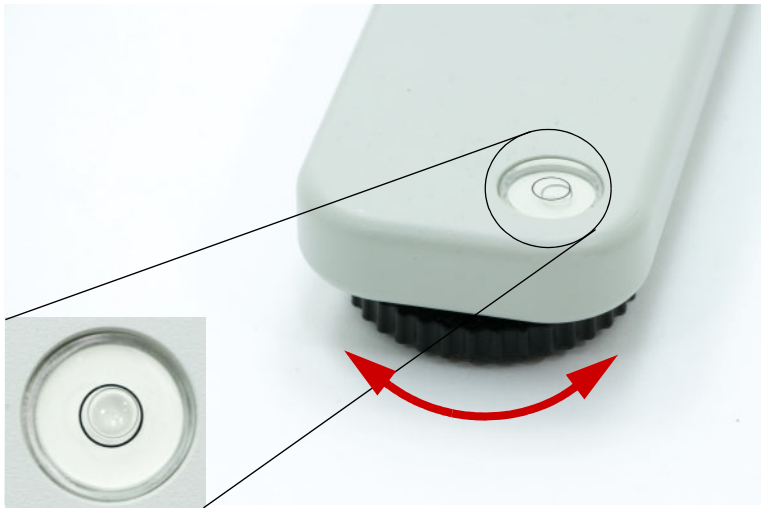
➢ Set aside the assembled drain tray suspension.



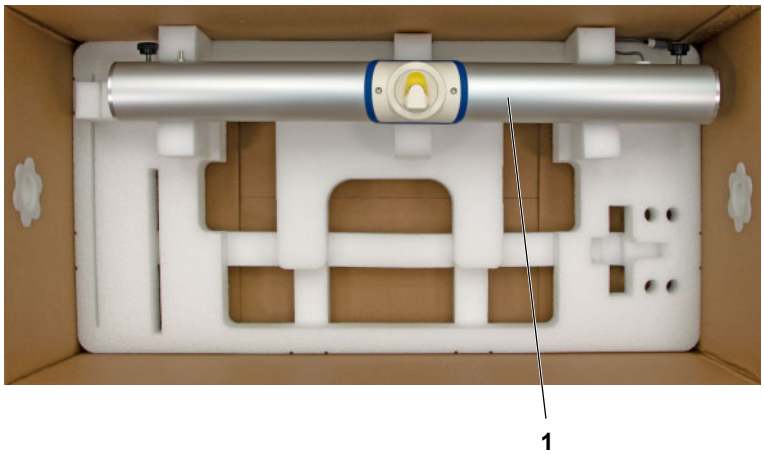
➢ Lift the pedestal (1) up and slide it forward as shown to remove it from the foam insert.

Do not let the pedestal touch the mounting stand.

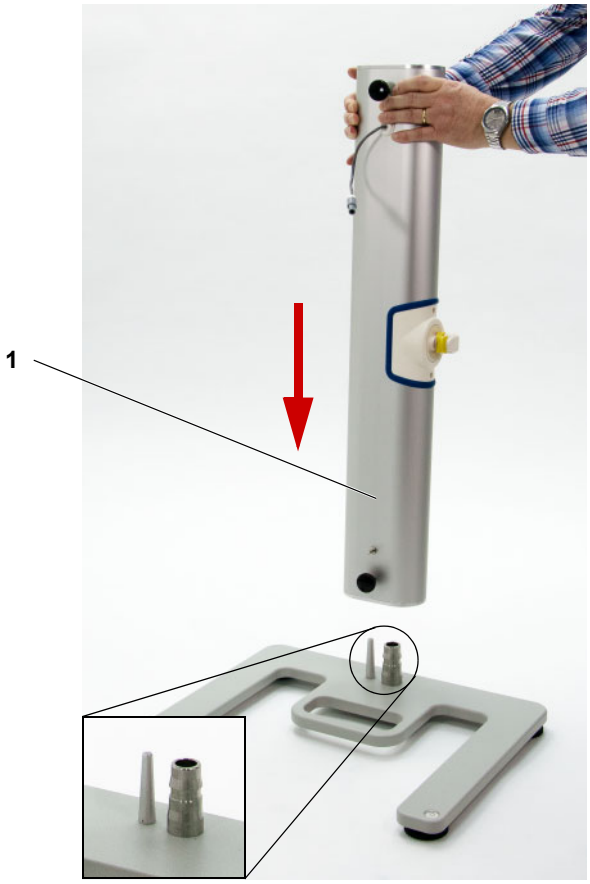
➢ Place the pedestal on a level surface at the treatment location.



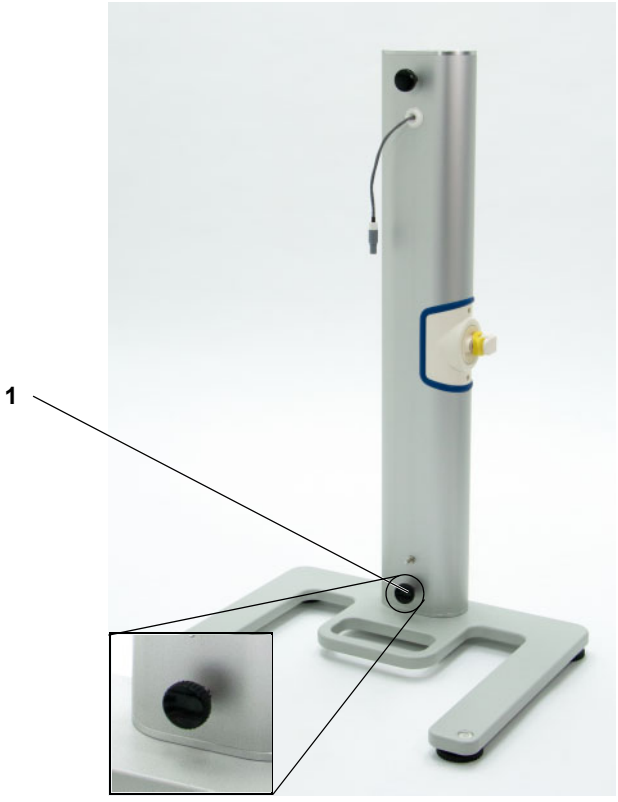
➢ Turn the leveling feet located on the bottom of the pedestal to horizontally compensate for any uneven surfaces. The pedestal is level when the bubble is located at the center of the indicator.



➢ Remove the mounting stand (1) from the foam insert.

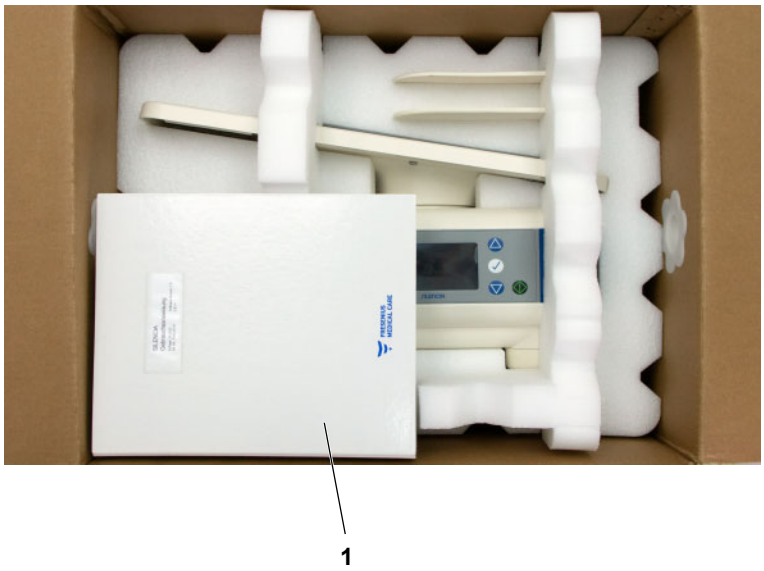


➢ Insert the mounting stand (1) into the pedestal from above as shown in the image.
Ensure that the mounting stand is the right way round. The plug on the mounting stand must be at the top.



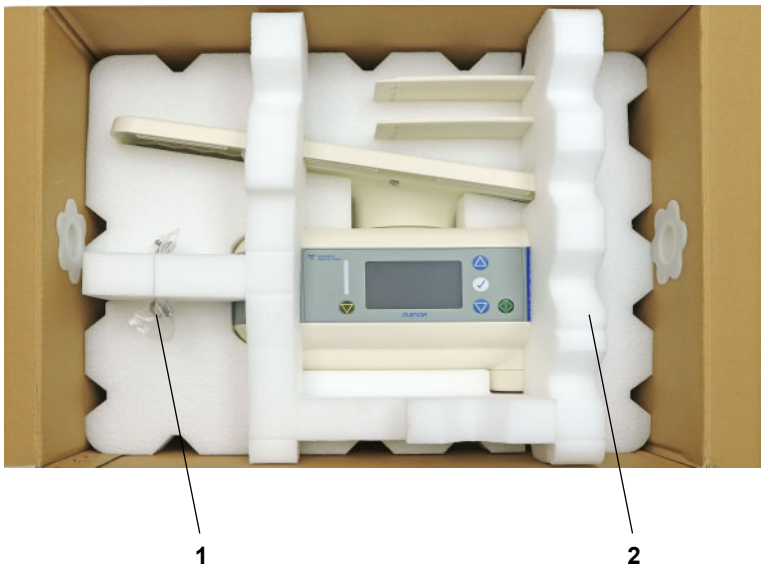
➢ Secure the mounting stand to the pedestal by tightening the screw (1).

9.4.3 Assembling the base unit



➢ All device components for assembling the base unit are contained in the smaller of the two boxes.

➢ Remove the Instructions for Use (1).

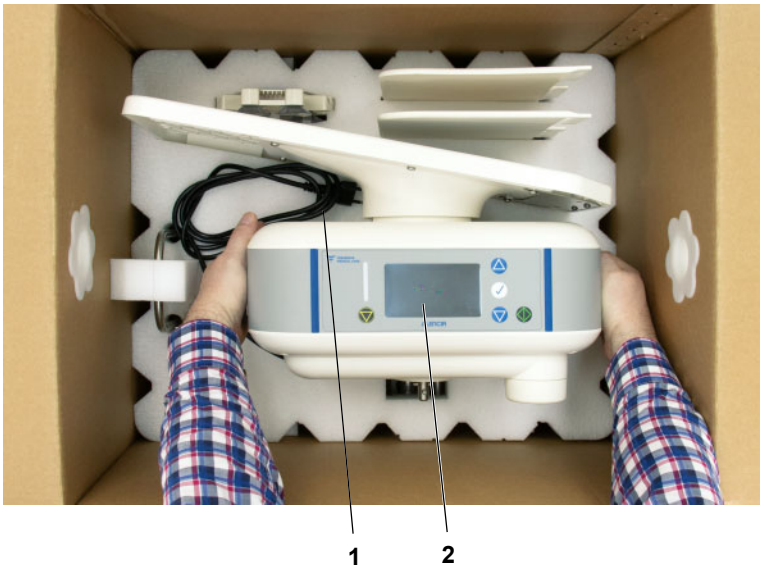


➢ Remove the bag rest screws (1) from the foam insert.

➢ Remove the foam insert (2).

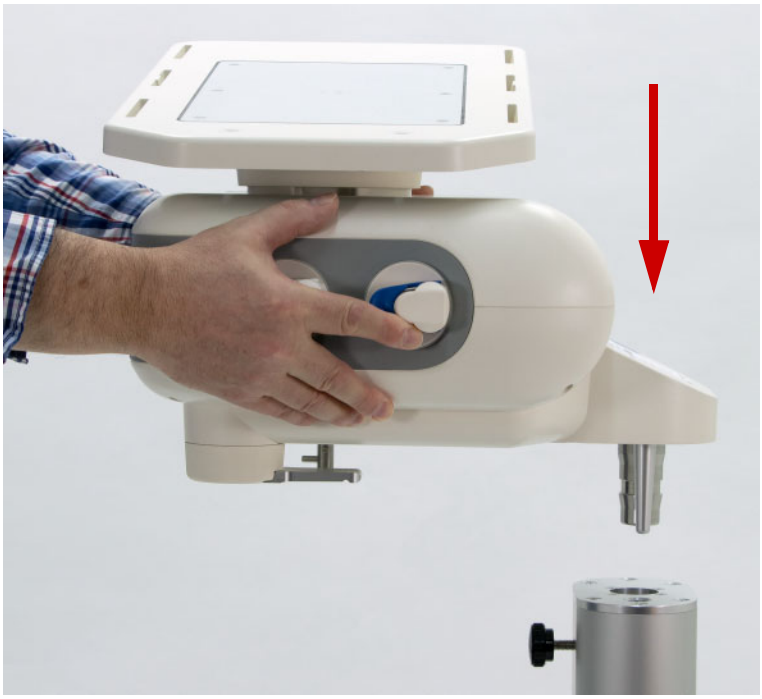
Note

Do not use the heating tray to lift the base unit.



➢ Pull the power supply cord (1) out of the foam insert and place it on the foam insert.

➢ Remove the base unit (2) from the foam insert.

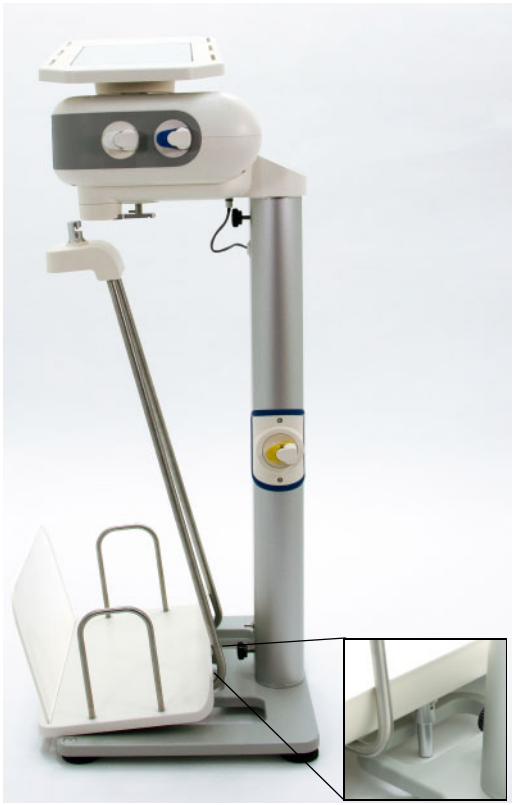


➢ Hold base unit firmly at the sides. Do not hold the base unit by the heating tray during this step.

➢ Insert the base unit into the mounting stand as shown.

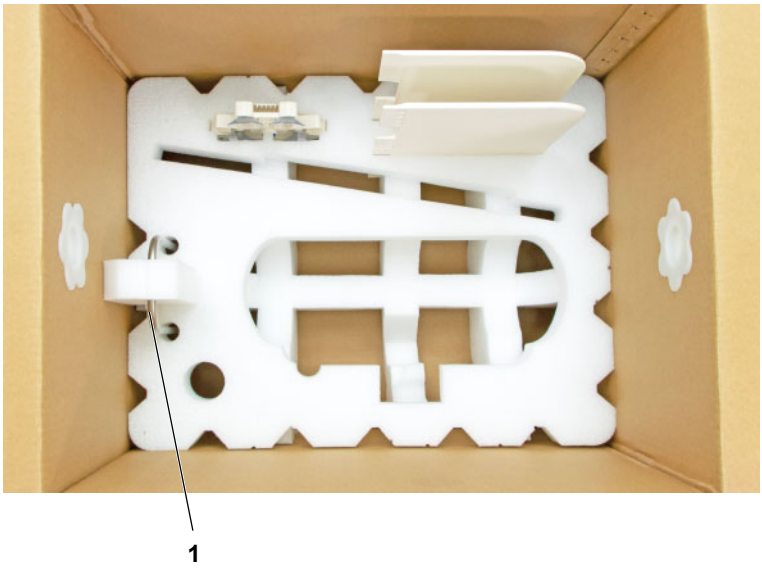
➢ Secure the base unit to the mounting stand by tightening the screw (1).

➢ Insert the mounting stand plug (2) into the socket on the bottom of the base unit.
Make sure that the plug clicks into place in the socket.

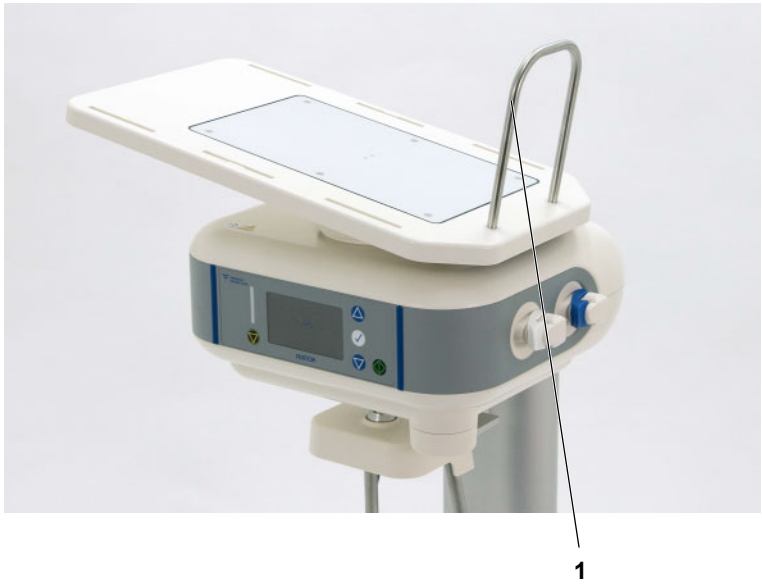


➢ Position the drain tray suspension beneath the base unit.
Place the pin located on the bottom of the drain tray into the rectangular opening in the pedestal.

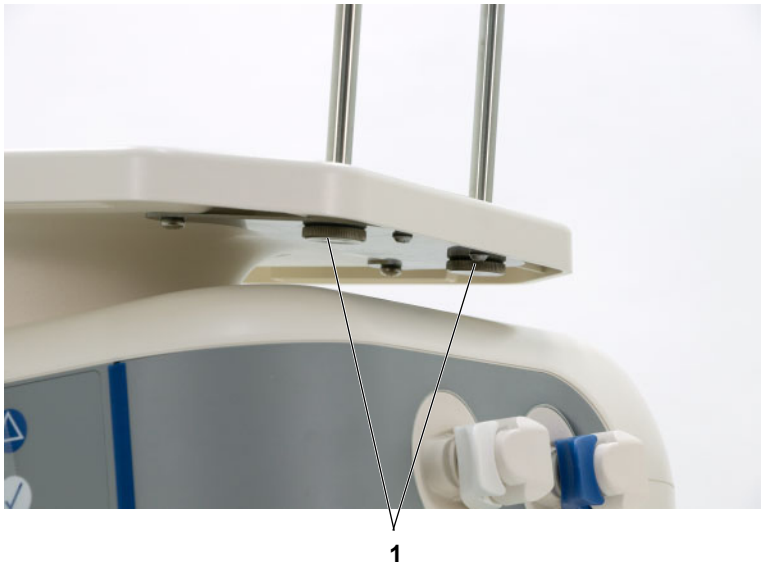
➢ Fix the drain tray (1) to the holder on the underside of the base unit. Make sure that the pin on the underside of the drain tray is placed in the rectangular opening in the pedestal.



➢ Remove the bag rest (1) from the foam insert.

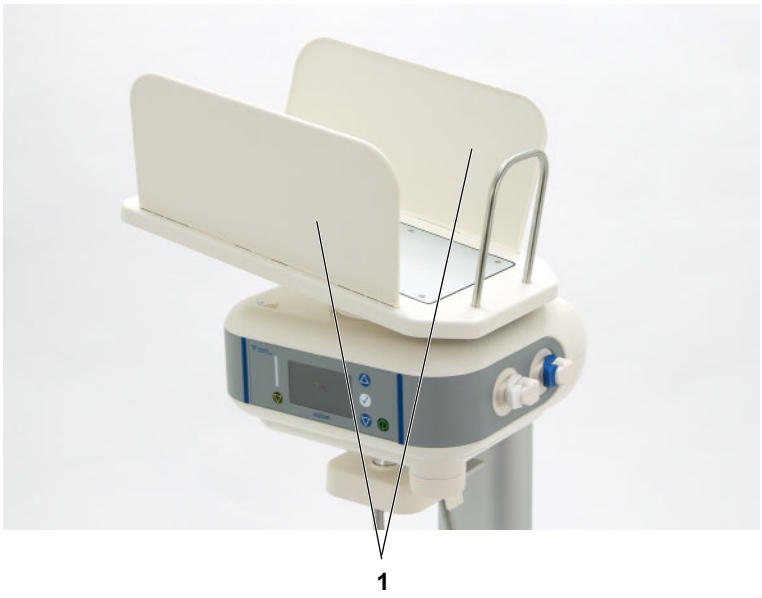


➢ Insert the bag rest (1) into the heating tray.



➢ Secure the bag rest using the two enclosed screws (1).

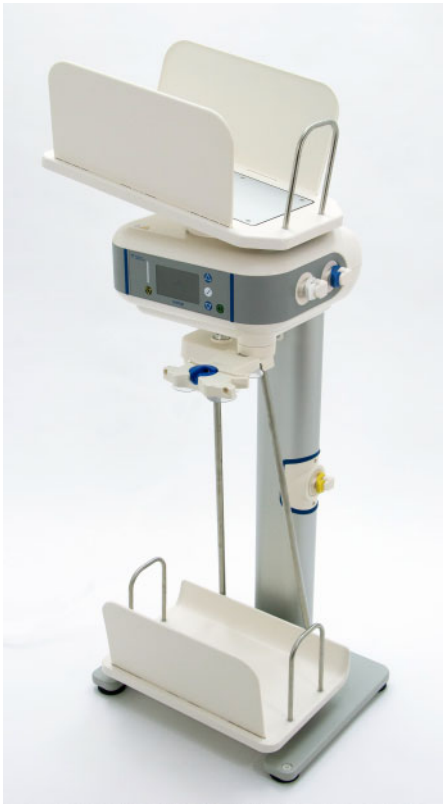
➢ Remove the side panels (1) from the foam insert.



➢ Insert the side panels (1) into the heating tray with the peripheral edge facing inwards.

➢ Remove the organizer (1) from the foam insert.

➢ Fit the organizer (1) onto the mount.



➢ The device is now fully assembled.

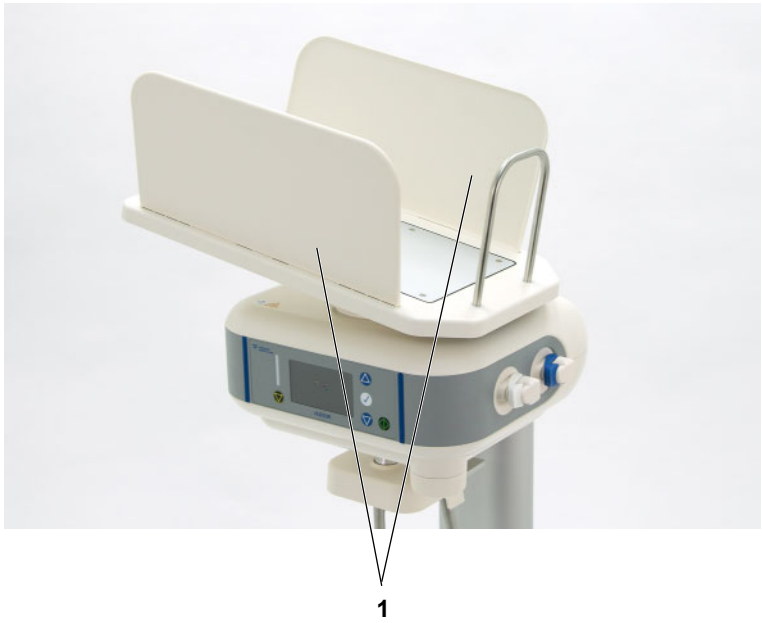
9.5 Disassembling and packaging the device

1

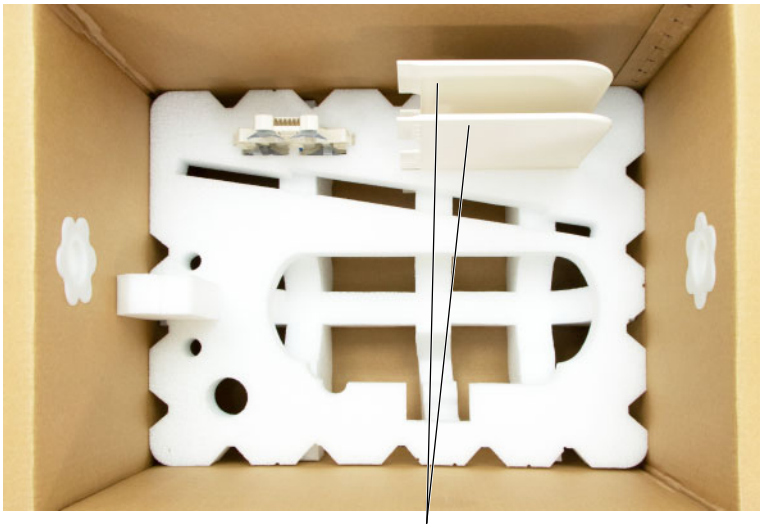
➢ Unplug the power plug before disassembling the device.

➢ Remove the organizer (1) from the mount and pivot the mount counterclockwise beneath the base unit.

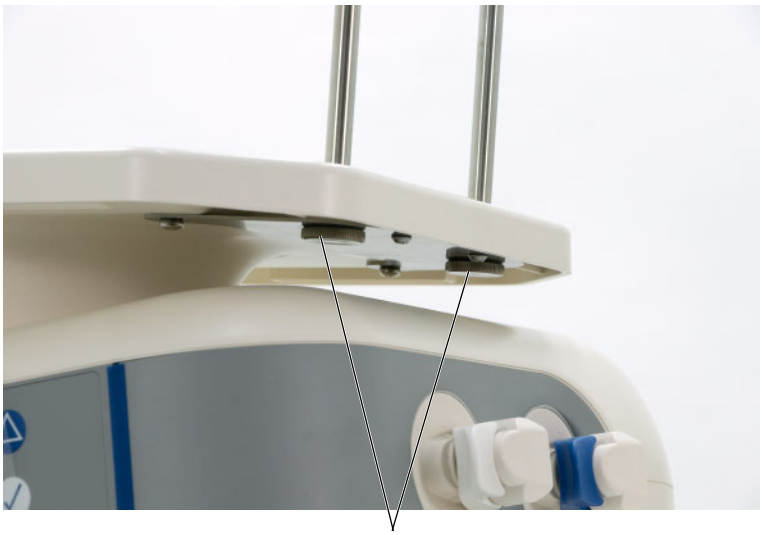
➢ Place the organizer (1) in the foam insert.



➢ Remove the side panels (1) from the heating tray.

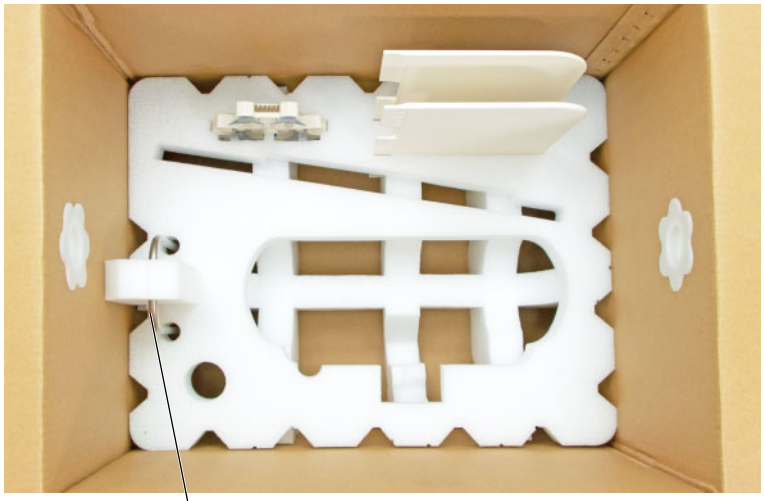


➢ Place the side panels (1) in the foam insert.



➢ Loosen the screws (1) on the bag rest and remove the bag rest.

➢ Store the screws in the plastic bag provided.



➢ Secure the bag rest (1) in the foam insert.

➢ Remove the drain tray from the holder on the underside of the base unit.

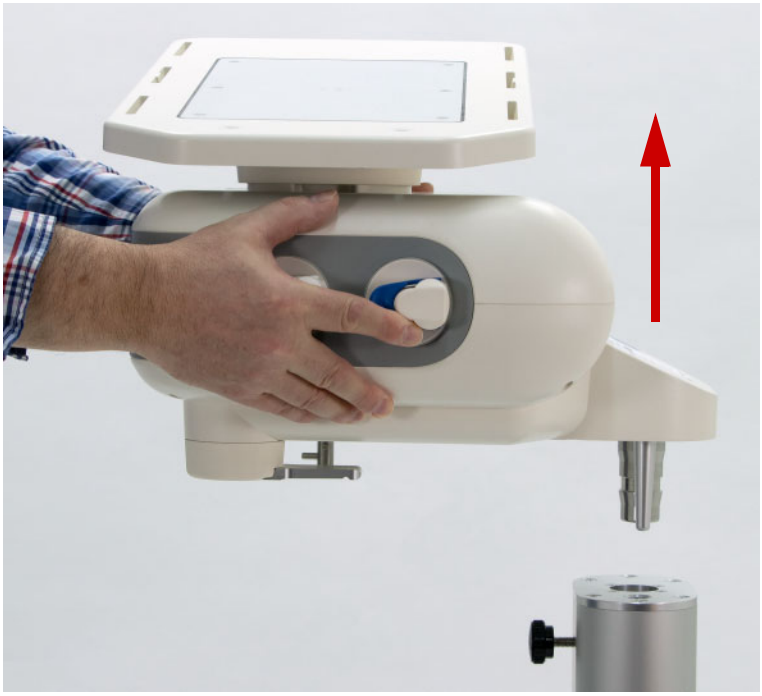
➢ Set the drain tray aside.

➢ Disconnect the mounting stand plug (1).

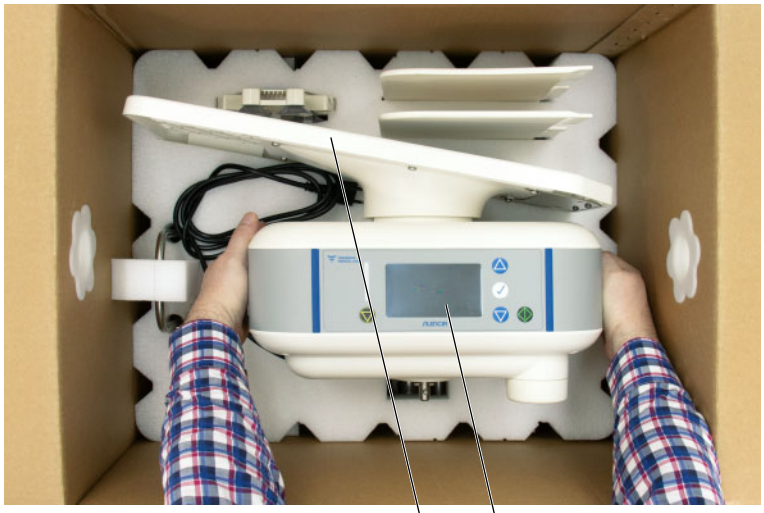
➢ Loosen the screw on the mounting stand (2).

Note

Do not use the heating tray to lift the base unit.



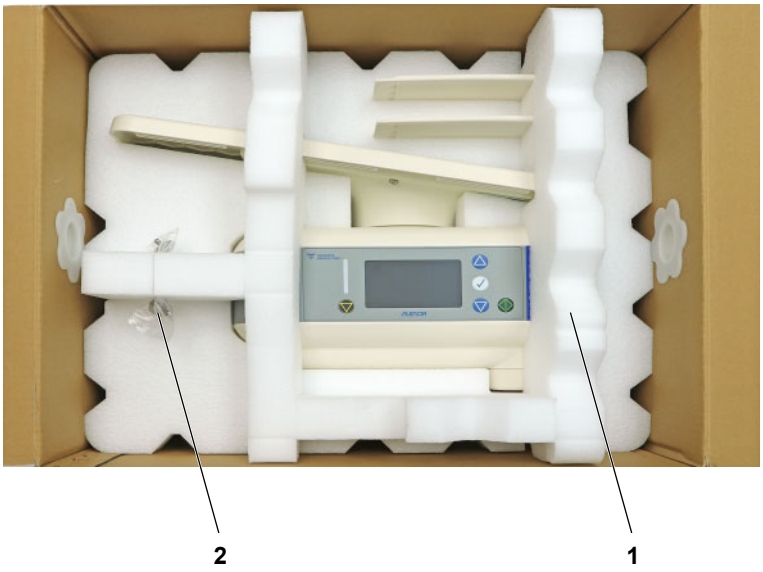
➢ Hold the base unit by the sides and remove it from the mounting stand as shown in the image.



➢ Place the base unit (1) in the foam insert.

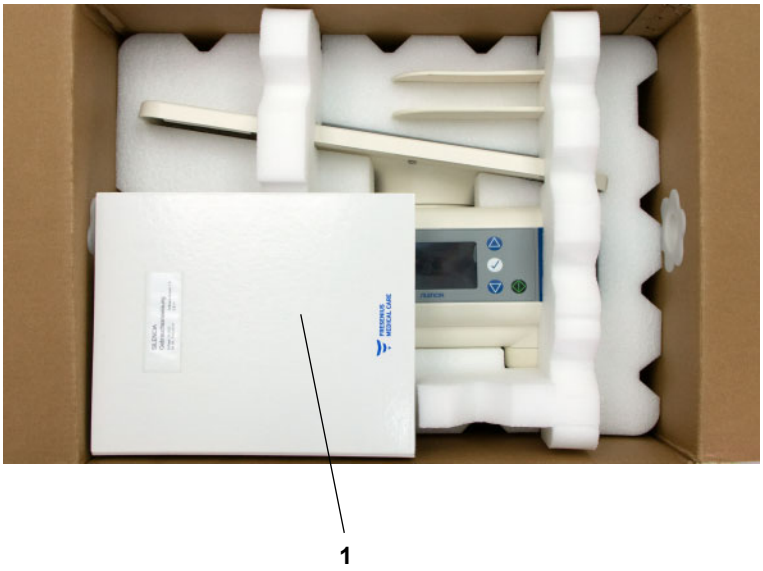
Do not use the heating tray (2) to place the base unit in the packaging.

➢ Roll up the power supply cord (1) and secure it in the foam insert.



➢ Position the foam insert (1).

➢ Secure the screws (2) of the bag rest at the location provided in the foam insert.

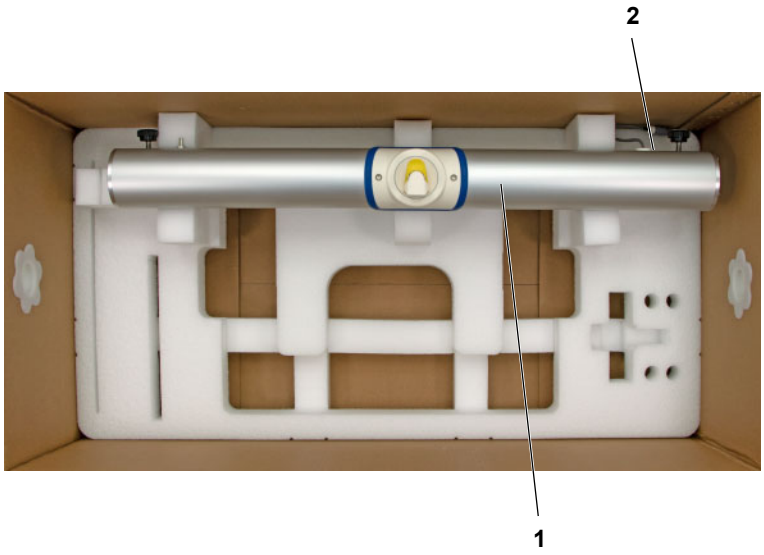


➢ Lay the Instructions for Use (1) on the foam insert.

➢ Close the box.

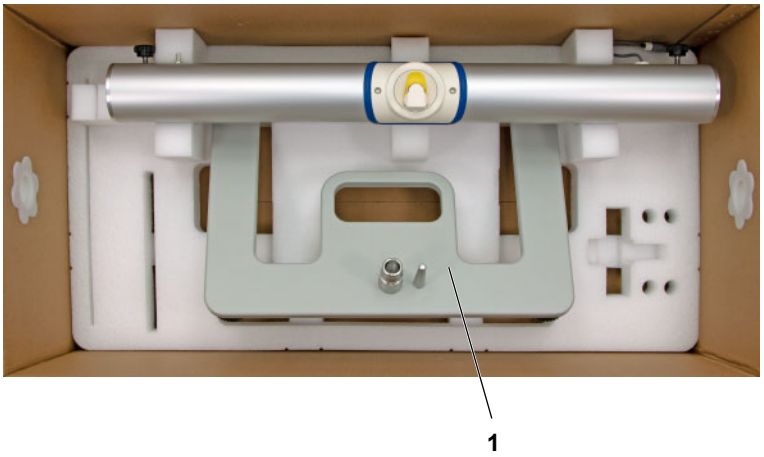
➢ Loosen the screw (1).

➢ Lift the mounting stand and unhook it from the pedestal.



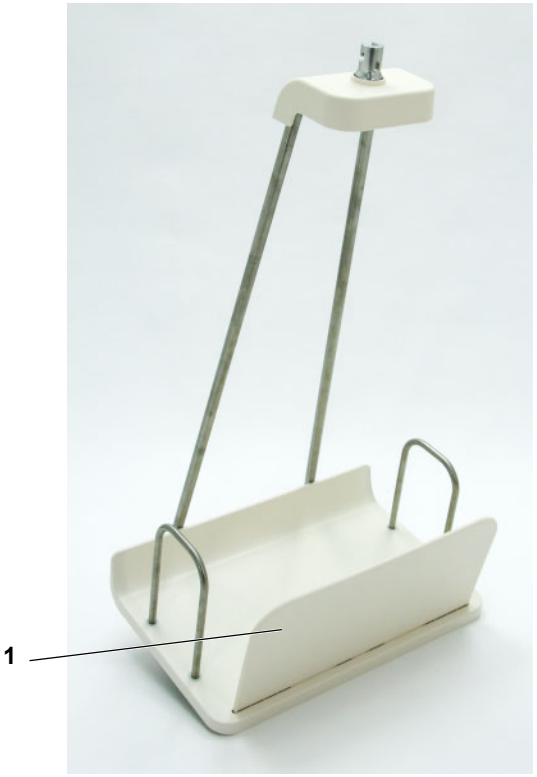
➢ Place the mounting stand (1) in the foam insert.

The end of the mounting stand with the cable (2) must be positioned on the right side.



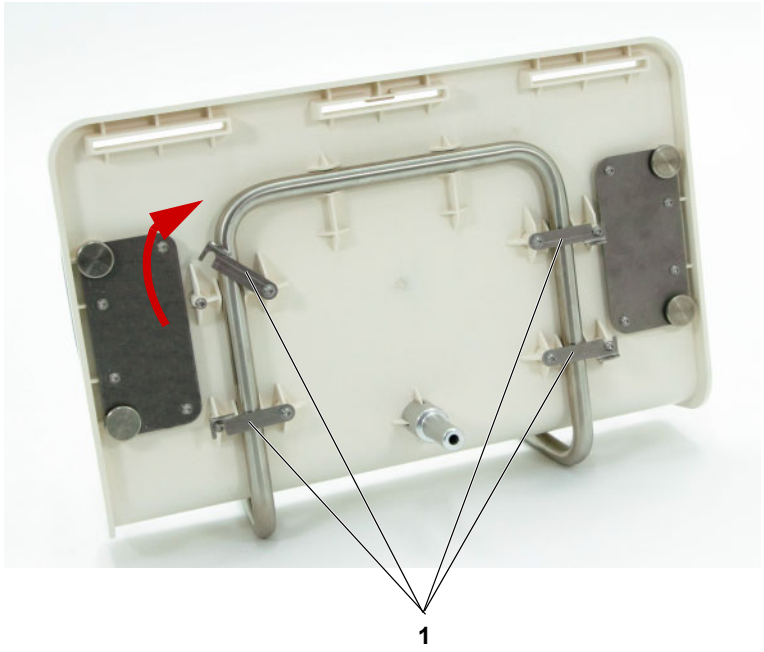
➢ Place the pedestal (1) in the foam insert from the front as shown.

Do not let the pedestal touch the mounting stand.

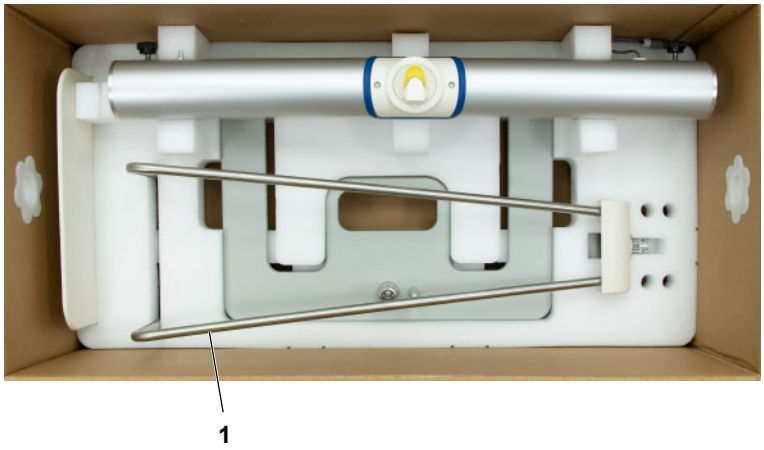


➢ Remove the side panel (1) from the drain tray.

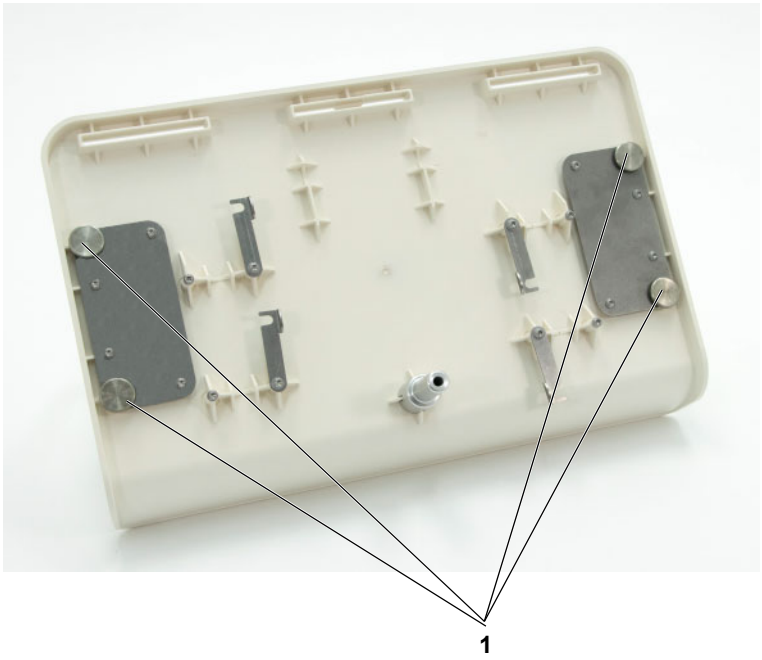
➢ Place the side panel (1) in the foam insert.



➢ Open the four locking levers (1) on the drain tray and detach the drain tray from the mount.

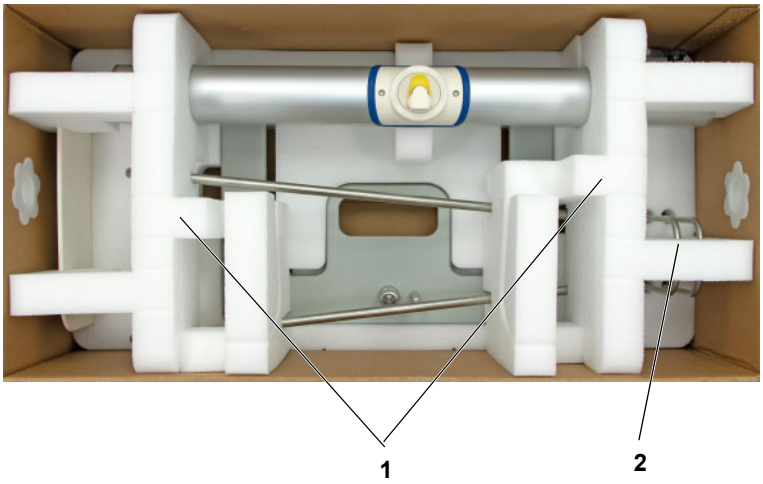


➢ Place the drain tray suspension (1) in the foam insert.



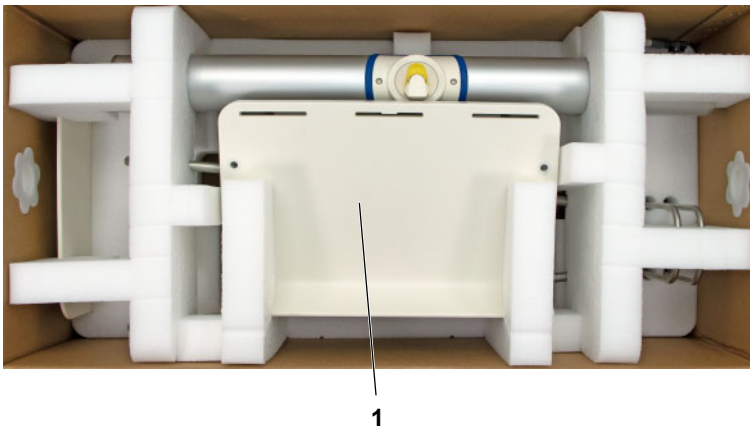
➢ Loosen the screws (1) on the bag rests and remove the bag rests.

➢ Store the screws (1) in the plastic bag provided and secure it to the foam insert.



➢ Position the foam inserts (1).

➢ Secure the bag rests to the foam insert (2).



➢ Place the drain tray (1) in the foam inserts.

➢ Close the box.

10 Transport/storage

10.1 Transport within buildings

The device must be disassembled for transport within buildings (see Chapter 9.5 on page 206).

10.2 Shipment/Transport outside of buildings

The device must be disassembled for transport outside buildings (see Chapter 9.5 on page 206).

10.3 Storage

Warning

Patient hazard from a device malfunction

If the device is used outside the specified storage and operating conditions, the device may not operate safely.

➢ The specified storage and operating conditions must be followed.

- **Transport and storage conditions**

Temperature	-15 to +60 °C
Relative humidity	10 to 90 %
Atmospheric pressure	500 to 1100 hPa

10.4 Environmental compatibility/disposal

Warning

Risk of contamination from non-compliance with hygiene measures

There is a potential risk that the device is contaminated when it is returned.

➢ The responsible organization must notify the disposal company responsible for the disassembly and disposal of the device before beginning disposal actions that suitable precautions must be observed, such as wearing personal protective equipment when dismantling the unit.

In EU member states, the device can be returned in accordance with the "Directive on waste electrical and electronic equipment" (WEEE Directive). Please also observe the applicable local regulations.

Before the device is sent off for disposal, the responsible organization must ensure that all consumables attached to the device are removed and the device is disinfected as specified by the manufacturer (see Chapter 6.1 on page 175).

Moreover, the responsible organization must ensure that the waste disposal company is informed of the following facts before the dismantling process is begun:

– Information on the batteries and other materials used can be found in the appropriate chapters of these Instructions for Use (see Chapter 12.13 on page 238).

– Batteries and rechargeable batteries must be disposed of properly in accordance with local legal regulations.

– The device has a 4.3" TFT LC display.

– More information will be made available by the manufacturer to waste disposal services on request.

11 Technical Safety Checks/maintenance procedures

11.1 Important information about 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 further 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 (MA) 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 further maintenance procedures (MA) should be performed before the end of the 24th month following the last maintenance procedure performed.

Qualification requirements of testers

The checks must be performed by the manufacturer’s service support organization or a person authorized by them.

The checks must be performed by personnel qualified to perform them correctly, based on their education, training, knowledge and experience. Furthermore, the persons performing the checks must be permitted to do so independently and without outside interference.

Specifications

The information contained in the Specifications chapter must be observed.

Documentation

The TSC and detailed explanations of how to perform them are described in the Service Manual.

Reports can be supplied on request.

The completion of the TSC must be entered in the Medical Device Register.

12 Specifications

12.1 Dimensions and weight

Dimensions

Height: 132.5 cm
Width: 57 cm
Depth: 44 cm

Weight

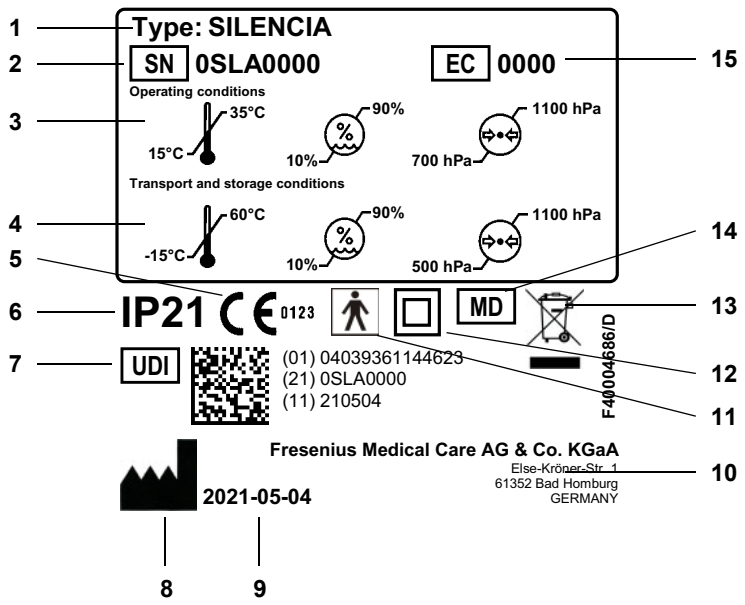
30.0 kg

Safe working load: 17 kg
Maximum total weight: 47 kg

12.2 Identification labels

12.2.1 Identification label of the device

The identification labels shown are only examples. Always go by the information shown on the identification labels affixed to the device itself.



1 Type identification

2 Serial number

3 Operating conditions (temperature range, atmospheric pressure, relative humidity)

4 Storage conditions (temperature range, atmospheric pressure, relative humidity)

5 CE marking

6 IP rating 21
2: Protection against touch and foreign bodies with a diameter greater than 12.5 mm
1: Protection against vertically falling water drops

7 Unique Device Identification

8 Manufacturer symbol

9 Date of manufacture

10 Manufacturer address

11 Type of applied part (degree of patient protection): Type BF

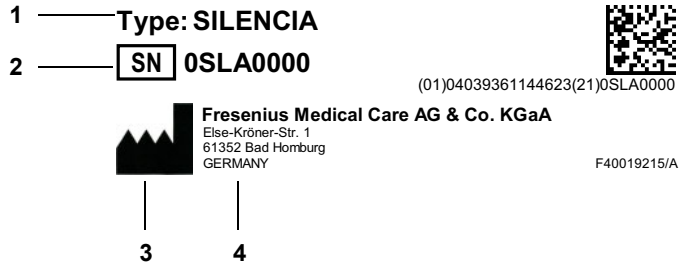
12 Device protection against electric shock: Protection class II

13 Symbol for the marking of electrical and electronic equipment

14 Medical Device

15 Equipment code (EC)

12.2.2 Mounting stand identification label



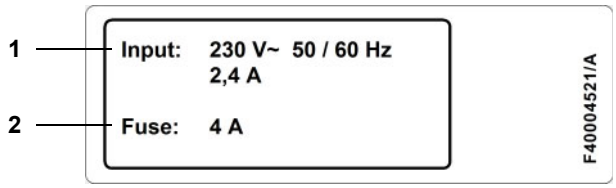
1 Type identification

2 Serial number

3 Manufacturer symbol

4 Manufacturer address

12.2.3 Power requirements label



1 Power requirements

2 Fuses

12.3 Electrical safety

Classification according to EN 60601-1, IEC 60601-1

Device protection against electric shock	Protection class II
Type of applied part (degree of patient protection)	Type BF
Applied part	The applied part consists of the tubing system and, when combined with the solution bags, forms the dialysis system.
Degree of protection against ingress of foreign objects and liquids	IP21 **2**: Protection against touch and foreign bodies with a diameter greater than 12.5 mm **1**: Protection against vertically falling water drops
Leakage currents	According to EN 60601-1

12.4 Electrical power supply

Line voltage	100 to 240 V AC, 50 to 60 Hz (Always go by the line voltage, frequency and current consumption information specified on the power requirements label affixed to the device itself.)
Power supply connection	According to local regulations for electrical power supply.
Current consumption	2.3 A at 253 V (230 V +10 %) at maximum heat output 4.5 A at 121 V (110 V +10 %) at maximum heat output
Power supply (internal)	+24 V ±3 %, 3.15 A, short circuit-proof 60 W total output power

12.5 Fuses

PCB	Remark	Rating for 230 V operating voltage	Rating for 110 V operating voltage	Fuse protection for:
Power supply	F1 Not replaceable	T 3.15 A	T 3.15 A	Power input fuse
Power supply	F2 Not replaceable	T 3.15 A	T 3.15 A	Power input fuse
Main board (MainPCB)	Fuse holder X200	T 4 A	T 6.3 A	Entire device
Main board (MainPCB)	Fuse holder X201	T 3.15 A	T 3.15 A	Power supply
Main board (MainPCB)	Fuse holder X202	F 3.15 A	F 5 A	Heater

12.6 Information on electromagnetic compatibility

12.6.1 Minimum distances between radiation source and medical electrical equipment

Medical electrical equipment is subject to special precautions with respect to electromagnetic compatibility (EMC).

Warning

Patient hazard from a device malfunction

Portable and mobile RF communication devices (radio devices including their accessories, such as antenna cables and external antennas) should not be used at a distance of less than 30 cm (12 inches) to the parts and lines of the device designated by the manufacturer. Failure to observe this information may have a negative impact on the performance characteristics of the device.

➢ Always maintain a distance of at least 30 cm between portable and mobile RF communication devices and the device.

Portable RF communications equipment may include the following radiation sources (examples):
cell phone, smartphone, tablet PC, cordless phone, notebook/laptop, wireless keyboard, wireless mouse, wireless speaker, wireless remote control.

Warning

Patient hazard from a device malfunction

The use of electrical accessories and cables other than those specified in the Instructions for Use can lead to an increase in electromagnetic emissions or a reduction in electromagnetic immunity of the device.

➢ Only use accessories and cables approved by the manufacturer.

Warning

Patient hazard from electromagnetic incompatibility between devices

The electromagnetic radiation of another device may cause the device to malfunction.

➢ Do not use the device directly next to or stacked with other devices.

If operation of the device near or stacked with other devices is required:

➢ Monitor the device to check for normal operation.

12.6.2 EMC guidance and manufacturer's declaration

- **Electromagnetic emissions**

Guidance and manufacturer's declaration – electromagnetic emissions		
The SILENCIA device is intended for use in the electromagnetic environment specified below. The customer or the user of the SILENCIA device should assure that it is used in such an environment.		
Emissions test	**Compliance**	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1, Class B	The SILENCIA device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The SILENCIA device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

- **Electromagnetic immunity**

Guidance and manufacturer's declaration – electromagnetic immunity			
The SILENCIA device is intended for use in the electromagnetic environment specified below. The customer or the user of the SILENCIA device should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines +1 kV for input / output lines	±2 kV for power supply lines +1 kV for input / output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV voltage, line to line ±2 kV line(s) to earth	±1 kV voltage, line to line Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T for 0.5 cycles at 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0 % U_T for 1 cycle 70 % U_T for 25 cycles 0 % U_T for 250 cycles (5 s)	0 % U_T for 0.5 cycles at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0 % U_T for 1 cycle 70 % U_T for 25 cycles 0 % U_T for 250 cycles (5 s)	In the event of a power supply interruption, the device returns to the treatment mode when the power is restored.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
The SILENCIA device is intended for use in the electromagnetic environment specified below. The customer or the user of the SILENCIA device should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Note: U_T is the a.c. mains voltage prior to application of the test level.			
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz 6 V_{rms} in ISM and amateur radio bands between 150 kHz and 80 MHz	3 V_{rms} 6 V_{rms} in ISM and amateur radio bands	N/A
Radiated fields in close proximity in accordance with IEC 61000-4-39	8 A/m 30 kHz CW 65 A/m 134.2 kHz PM 2.1 kHz 7.5 A/m 13.56 MHz PM 50 kHz	8 A/m 30 kHz CW 65 A/m 134.2 kHz PM 2.1 kHz 7.5 A/m 13.56 MHz PM 50 kHz	N/A
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	N/A
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

- **Test specifications for IMMUNITY of COVERINGS against high-frequency wireless communication devices**

Test frequency	Frequency band	Radio-frequency communication service	Modulation	Maximum power	Distance	Immunity test level
[MHz]	[MHz]			[W]	[m]	[V/m]
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 to 470	GMRS 460, FRS 460	FM ±5 kHz 1 kHz sine or Pulse modulation 18 Hz	2	0.3	28
710	704 to 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 to 960	GMS 800/900 TETRA 800 IDEN 820 CDMA 850 LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700 to 1990	GMS 1800 CDMA 1900 GMS 1900 DECT LTE Band 1, 3, 4, 25 UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400 to 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28

Test frequency	Frequency band	Radio-frequency communication service	Modulation	Maximum power	Distance	Immunity test level
[MHz]	[MHz]			[W]	[m]	[V/m]
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

12.7 Operating conditions

Operating temperature range +15 to +35 °C

Relative humidity 10 to 90 %

Atmospheric pressure 700 to 1100 hPa
(approx. 3000 to -425 m altitude)

Stability Maximum incline allowed: 5°

Stability during operation Maximum incline allowed: 3°

12.8 Transport and storage conditions

Temperature -15 to +60 °C

Relative humidity 10 to 90 %

Atmospheric pressure 500 to 1100 hPa

12.9 External connection options

Any additional equipment connected to this device must comply with the relevant IEC or ISO standards (e.g., IEC 60950-1 for information technology equipment).

Furthermore, all device configurations must comply with the requirements for medical electrical systems (see EN 60601-1:2006 section 16 and annex I).

Connecting the device to an IT network that contains components not installed and validated by the device manufacturer can introduce unknown risks for patients, operators or third parties. These risks must be identified, analyzed, evaluated and monitored by the responsible organization. For assistance, consult IEC 80001-1:2010 and annexes H6 and H7 of EN 60601-1:2006.

Any modification to an IT network that has been installed and validated by the device manufacturer can introduce new risks and therefore requires a repeat analysis. Especially problematic activities:

– Changes to the IT network configuration
– Connecting additional components and devices to the IT network
– Removing components and devices from the IT network
– Updating or upgrading 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 organization.

LAN

The LAN port is not accessible to the operator.

Interface for data exchange.

12.10 Battery

Battery	The battery is not accessible to the operator. Lithium CR 1220/real-time clock (on carrier board)

12.11 Parameters

Inflow volume		Adjustment range	250 to 3000 ml
		Resolution	1 ml
		Tolerance	< 5 % or 15 g whichever is larger
Tidal inflow volume	Base Inflow volume	Adjustment range	500 to 3000 ml
		Tolerance	< 5 % or 15 g whichever is larger
	Tidal Inflow volume	Adjustment range	250 to 2750 ml
		Tolerance	< 5 % or 15 g whichever is larger
	Tidal Outflow volume	Adjustment range	250 to 3000 ml
		Tolerance	< 5 % or 15 g whichever is larger
Dwell duration*		Adjustment range	5 to 300 min
		Resolution	1 min
		Tolerance	±20 s
Number of STANDARD cycles		Adjustment range	1 to 15
		Resolution	1
Number of TIDAL cycles	Base cycles	Adjustment range	1 to 5
		Resolution	1
	Tidal cycles	Adjustment range	2 to 15
		Resolution	1
Inflow time		Depending on flow rate	–
Outflow time		Depending on flow rate	–
Dosing tolerance		< 5 % or 15 g whichever is larger	–
Balancing tolerance*		< 1 % or 10 g whichever is larger	–

Temperature*	Fixed patient inflow temperature	37 °C after 3 h pre-heating time
	Tolerance	28 to 39 °C
Technique and sensitivity of the safety system against overfilling	Volume balancing 10 % over maximum permitted inflow volume +30 ml	–
Audible signal silencing	The signal can be interrupted for 6 minutes.	–
Permitted patient volume	Adjustment range is 100 % to 120 % of the maximum prescribed inflow volume	Default value 110 %
Permitted residual volume	Adjustment range is 10 % to 50 % of maximum volume in patient	Default value 40 %
Permitted dwell duration reduction	Adjustment range is 0 % to 30 % of the prescribed dwell duration	Default value 15 %
Permitted reduction of the inflow volume	Not adjustable	15 % of the last prescribed cycle volume
Screen saver	Adjustment range	5 to 99 min

(* = essential performance for IEC 60601-2-39)

Temperature monitoring

A maximum limit of less than 41 °C at the patient connector has been defined.

When an alarm occurs, this is audibly signaled after a maximum of 60 seconds.

Scale

Max. load capacity: 35 kg
Weighing range: 0 to 17 kg
Resolution: 1 g
Tolerance: ±5 g

12.12 Factory settings

Parameters	Factory setting
Preselected inflow volume	2000 ml
Maximum inflow volume	3000 ml
Preselected dwell duration	60 min
Permitted patient volume	110 %
Permitted residual volume	40 %
Permitted dwell duration reduction	15 %
Permitted reduction of the inflow volume	15 %
Additional outflow	Yes (with sound)
Access level	Selecting a prescription Other setting options: – No changes – Editing a prescription
Screen saver	5 min
Sound volume	Level 3 of 5
Brightness	Level 3 of 5

12.13 Materials used

- **Plastics and elastomers**

Abbreviation	Material	Usage
ABS	Rotec ABS 1001 FR V 04	Housing (injection molding)
PA	Frianyl B63 FK 1020 PA 6	Housing (injection molding)
DP180	DuroBest	Assembly blocks, mechanical protection (milled parts)
EPDM	Ethylene propylene diene monomer	Seals
–	Silicone	Seal
–	Silicone	Heating field
–	Epoxy fiberglass	PCBs
NR	Natural rubber	Elastomer bumpers

- **Metals**

Abbreviation	Material	Usage
–	1.0037 S235JR (stainless steel, structural steel)	Bent metal sheets
–	EN AW 5083 (aluminum)	Assembly blocks/plates, pedestal, sleeve
–	EN AW 6060 (aluminum)	Extruded profile/mount
–	1.4301 (stainless steel)	Tubular frame
–	Steel	Binding for elastomer bumpers
–	1.4034 (stainless steel)	Torsion spring

- **Batteries**

Abbreviation	Material	Usage
–	Lithium battery	

- **Auxiliary materials**

Abbreviation	Material	Usage
–	Loctite 243, 2701, 406	Thread locker
–	Thermal paste	Silicone heating field contacts

13 Definitions

13.1 Definitions and terms

Abdomen	Area of the torso between the chest and the pelvis
Acidosis	An overload of acids in the blood
Action system	System for controlling relevant device functions (e.g., heater, flow control, treatment progress, etc.)
Adhesion	Scar-like tissue adhesions, e.g., between bowel loops
Alkalosis	An excess of bases in the blood
Ascites	Accumulation of fluid in the peritoneal cavity due to illness
Aseptic	Sterile
Autoclave	To sterilize by subjecting to high pressure saturated steam
Bladder exstrophy	A congenital deformity that occurs when the bladder does not form as a hollow organ and is exposed on the abdominal wall
CCPD	Continuous cyclic peritoneal dialysis
Colostomy	An artificial relocation of the large intestine that attaches it to the skin surface
Cystic kidney	Pouches of fluid that form in the kidney
Diaphragmatic hernia	The abdominal organs are displaced to the chest cavity through a gap in the diaphragm
Dyspnoea	A subjective feeling of breathlessness or difficulty breathing
Edema	Swelling that occurs when a body part swells because fluid has collected in the tissue

Electrolyte disturbance	A deviation in the concentration of one or several ions dissolved in the blood (electrolytes, such as potassium, sodium, calcium, and phosphate) from the normal range
Encapsulating peritoneal sclerosis (EPS)	A rare and often severe disease of the peritoneum. It most frequently occurs as a late complication after PD and features thickening of the peritoneum as a result of scarring.
Exit-site infection	Reddening, inflammation, hardening, and/or tenderness around the site where the catheter exits the skin, mostly because of bacteria
Fibrosis	Hardening of an organ or tissue as a result of the formation of new connective tissue
Gastroschisis	A deformity in the anterior abdominal wall in which the abdomen is not completely closed and causes a prolapse of bowel loops
Hernia	A hernia occurs through a weak area in the abdominal wall, e.g., an inguinal hernia
Hydrothorax	Pathological collection of fluid in the thoracic cavity
Hyperlipidemia	An increase in the concentration of certain fats in the blood
Hypersensitivity reaction	Strong allergic reaction
Hyperthermia	Abnormally high body temperature
Hypervolemia	An increase in the volume of the blood in the circulatory system
Hypoalbuminemia	A decrease in the level of albumin in the blood
Hypokalemia	Potassium deficiency
Hypoproteinemia	A low concentration of total protein in the blood plasma
Hypotension	Blood pressure is too low

Hypovitaminosis	Diseases and disorders caused by a deficiency of vitamins
Hypovolemia	Lack of volume in the circulatory system, e.g., due to loss of blood
Ileal conduit	A surgical procedure during which an artificial urinary outlet is created
Ileostomy	A surgical procedure that relocates the small intestine and attaches it to the skin surface
Ischemic colitis	Damage to the large intestine (colon) caused by disrupted blood circulation
Malignant disease	The presence of cancer cells that could spread to other sites in the body (metastasize) or invade nearby (locally) and destroy tissues
Necrotizing enteritis	A severe inflammatory disease that affects the intestine
NIPD	Nightly intermittent peritoneal dialysis
Obliteration	The adhesion (atrophy) or closing of a vessel, a hollow organ, or a body cavity
Omphalocele	A congenital defect in the abdominal wall in which the abdominal organs are in a thin sack or a membrane protruding in front of the abdominal wall
Osmotic agent	Osmotically active substance that provokes removal of excess fluid, e.g., glucose, during PD
Peritoneum	A smooth tissue that forms the lining of the abdominal cavity
Peritonitis	Inflammation of the peritoneum
Pneumoperitoneum	An abdominal cavity filled with air or gas
Reflux	Return of acidic content from the stomach into the esophagus

Residual renal function (RRF)	The kidney function left after the patient has started dialysis treatment
Safety system	System for monitoring relevant parameters (e.g., temperature, weight, treatment progress, etc.)
Tachycardia	The condition when the heart rate exceeds 100 beats per minute for a prolonged time
Tunnel infection	Reddening, hardening with stretching, and/or tenderness from the site where the catheter exits from the skin and along the subcutaneous tunnel of the tunneled catheter
Ultrafiltration (UF)	Excess fluid in the body that is removed from the patient during PD

13.2 Abbreviations

MA	Maintenance procedures
TSC	Technical Safety Checks

13.3 Symbols

Symbol	Description
IP21	Degree of protection against ingress of foreign objects and liquids **2**: Protection against touch and foreign bodies with a diameter greater than 12.5 mm **1**: Protection against vertically falling water drops
	Type of applied part (degree of patient protection) Type BF
	Device protection against electric shock: Protection class II
CE 0123	The CE marking documents compliance with the current European medical device regulations. Notified body: TÜV SÜD Product Service GmbH (0123)

Symbol	Description
	Identification of electrical and electronic devices (Do not dispose of the device with household waste.)
	Manufacturer symbol
	Serial number
	Medical Device
 2	Unique Device Identification
	Follow Instructions for Use
	Warning: Tipping hazard when pushing or leaning against the device
	Temperature limitation (operating conditions)
	Atmospheric pressure limits (operating conditions)
	Relative humidity limits (operating conditions)

13.4 Certificates

The device is approved according to the Medical Device Regulation (MDR) as a class IIb medical device in the European Union (EU).

The current versions of the EC certificates will be provided by your local service support organization on request.

14 Options

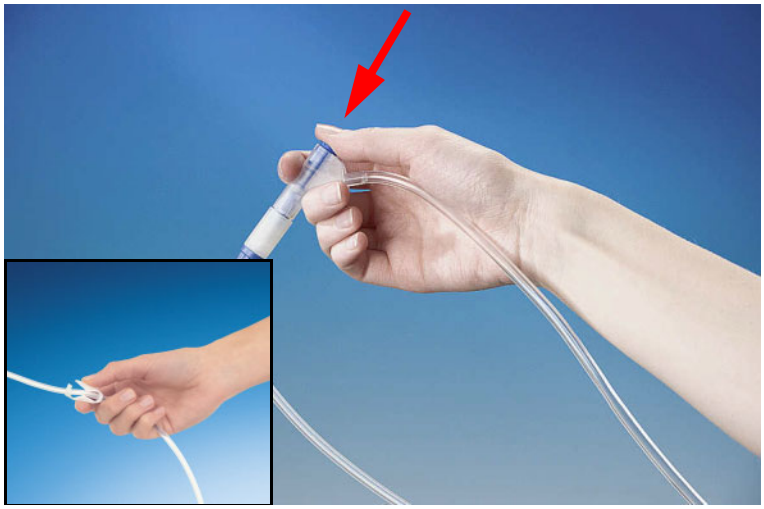
Chapter without content.

15 Appendix

15.1 Disconnection with PIN Reload

PIN Reload should be used in combination with the "Pause treatment" option (see Chapter 4.8.2 on page 149).

➢ Before disconnecting from the device have the following ready:
– Disinfection cap
– PIN Reload
– Face mask
– Hand disinfectant



➢ Turn the blue knob on the patient connector clockwise.

➢ Then firmly push the blue knob into the patient connector.

➢ Close the white clamp on the catheter extension.

➢ Insert the patient connector in the organizer.

➢ Place a new disinfection cap into the holder of the organizer.

➢ Place the PIN Reload into the other holder of the organizer.

➢ Put on the face mask.

➢ Disinfect your hands and dry them carefully.

➢ Unscrew and discard the closing cap of the new disinfection cap.

➢ Unscrew the catheter extension system connector from the patient connector on the tubing system.

➢ Screw the catheter extension system connector with the PIN firmly onto the new disinfection cap.

➢ Unscrew the PIN Reload and screw it onto the patient connector.

➢ Pull the closed catheter extension straight (without turning it) out of the organizer.

15.2 Connection with PIN Reload

➢ Ensure that the patient connector (1) sits firmly in the organizer and that it is securely closed with the PIN Reload (2).

➢ Remove the catheter extension from your clothing.

➢ Wash and dry your hands thoroughly according to the instructions of the PD center.

➢ Place the catheter extension into the holder of the organizer.

➢ Put on the face mask.

➢ Disinfect your hands.

➢ Push the syringe plunger in fully to place the PIN into the patient connector.

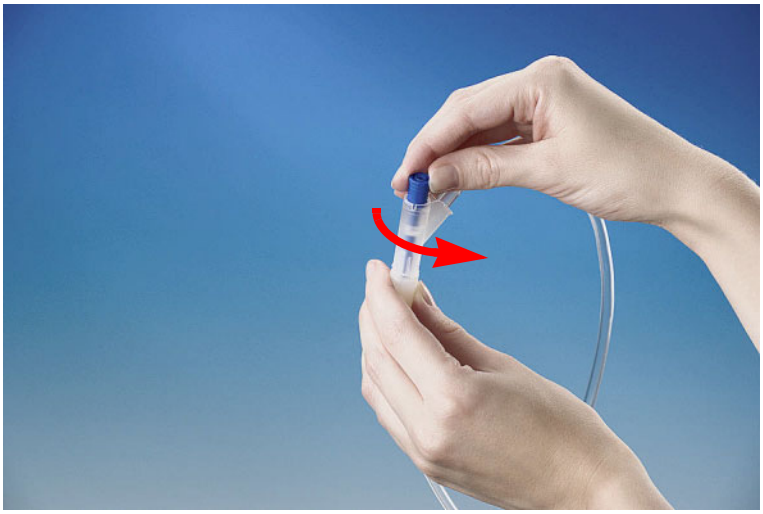
➢ Unscrew the empty PIN Reload from the patient connector and discard it.

➢ Visually check that the PIN was released correctly. If not, repeat the procedure with a new PIN Reload.

➢ Unscrew the system connector of the catheter extension from the disinfection cap.

➢ Screw the catheter extension system connector directly onto the patient connector on the tubing system.

➢ Open the white clamp on the catheter extension.



➢ Remove the patient connector from the organizer.

➢ Turn the blue knob counterclockwise to prevent an accidental release of the PIN.

➢ Continue the treatment.

15.3 Instructions on the use of “Free software”

Contents

A. Peritoneal dialysis device – “Free software”

In addition to other software, the peritoneal dialysis device contains what is called “free software” which is subject to license conditions deviating from those of the proprietary software protected for Fresenius Medical Care and their licensors.

Some of the license conditions pertaining to such free software provide that Fresenius Medical Care is authorized to distribute the peritoneal dialysis device only if the accompanying documentation contains special information and notes, supplies license conditions and/or provides the source code of such free software. Fresenius Medical Care meets these requirements by providing the copyright notices, remarks and license texts contained in Section C. below. Please note that, if such information is printed in two languages, the English version has priority.

However, the privileges granted by copyright according to Section C. and the license texts contained therein, which relate to such free software, do not include the right to make modifications to the peritoneal dialysis device and subsequently continue use of the device with these modifications. On the contrary, the German Medical Devices Act prohibits any further operation of the peritoneal dialysis device once the software contained therein has been modified, because any medical device may only be operated in the form certified. For this reason, Section B. contains an appropriate note. In such a case, Fresenius Medical Care will stop any further technical support for the device involved. In addition, such modifications and/or manipulations may result in the extinction of warranty claims against Fresenius Medical Care or other vendors of the peritoneal dialysis device in the event a claim has arisen or might arise in respect thereto. Any utilization of the free software contained in the peritoneal dialysis device in a manner other than that required during proper operation of the system will be solely at your own risk.

Please also note that the powers listed in Section C. apply only to the “free software” mentioned therein. Any other software contained in the peritoneal dialysis device is protected by copyright for the benefit of Fresenius and their licensors and may be used only as intended for the peritoneal dialysis device.

Both the GNU General Public License (GPL) and the GNU Lesser General Public License (LGPL) are supplied with this device. You can also download these license conditions from the Internet.
For GPL, please refer to: http://www.gnu.org/copyleft/gpl.html
For LGPL, please refer to: http://www.gnu.org/copyleft/lesser.html

B. Note required according to German Medical Devices Act

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