sleep•safe harmony

Instructions for Use

Software version: 3.1
Edition: 13D-2023
Date of issue: 2024-05
Part no.: F50023448
CE 0123

FRESENIUS
MEDICAL CARE

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2 Important information

2.1 How to use the Instructions for Use

Identification

The document can be identified by the following information on the title page and on the labels, if any:
- Device software version
- 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, means Instructions for Use in English.
- The edition identification, for example, 13A-2022 refers to edition 13A released in 2022
- Page identification

Organization of the chapters

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

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** button
➢ Instruction	➢ Instructions are indicated by an arrow ➢. Instructions must be followed. ➢ Example: ➢ Carry out instruction.

Style	Description
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

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

Reproduction

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

2.2 Significance of warnings

Information alerting the operator that serious to life-threatening injuries can occur if the measures for averting the hazard are not observed.

Warning

Type and cause of the hazard

Potential consequences of the hazard.

➢ Measures for averting the hazard.

The warnings may deviate from the above example in the following cases:
– If a warning refers to multiple hazards.
– If no specific hazards can be assigned to a warning.

2.3 Significance of notes

Note

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

2.4 Significance of tips

Tip

Information providing useful tips for easy handling.

2.5 Brief description

Automated peritoneal dialysis (APD) is a treatment method normally performed overnight. Dialysis solution is infused and drained by what is known as a cycler.

The *sleep•safe harmony* technology

Important components of the *sleep•safe harmony* system are:

– Easy handling due to a clearly arranged colour screen (touchscreen) for displaying and entering data.

– Automatic detection and connection of bags.

– Automatic inline flow heating of the dialysis solution to body temperature directly during the inflow phase.
– Treatment profiling option: for example, different glucose concentrations, inflow volumes and dwell durations can be programmed.
– Adapted APD: short dwell durations with low inflow volumes and long dwell durations with high inflow volumes.
– 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.
– Patient connector with PIN technology reduces the risk of contamination during patient disconnection.

The *sleep•safe harmony* offers the possibility of performing CCPD, IPD, NIPD, Tidal Dialysis or PD-Plus therapies.

The device is classified as class IIb equipment (MDD).

2.6 Intended use

2.6.1 Intended purpose

The *sleep•safe harmony* has been designed for the treatment of patients suffering from renal insufficiency or terminal renal failure. It provides life support through the removal of excess fluids and detoxification. It offers the possibility of performing NIPD, CCPD, Tidal Dialysis, IPD or PD-Plus therapies. The therapies available on the device include fluid removal and detoxification.

2.6.2 Specification of use

The device has been specified by the manufacturer for
– the treatment of patients, irrespective of their age, taking into account the indicated Specifications of the *sleep•safe harmony* (e.g., minimum inflow volume of 100 ml).
– The device allows setting individual inflow volumes, dwell durations and glucose concentrations for each individual cycle.
– Continuous treatments of up to 24 hours, with a typical overnight treatment duration of 7 to 10 hours.
– Operation in rooms that are suitable for peritoneal dialysis located in professional health care institutions, or for the home health care environment.

2.6.3 Side effects

Peritoneal dialysis therapy carries the risk of an inflammation of the peritoneum (peritonitis). Furthermore, infections of the catheter exit site may occur, which often progress to tunnel infections and, eventually, to peritonitis.

Patients may experience pain during inflow and outflow. Distension and bloating (abdominal pain) may also occur in some patients. Shoulder pains and shortness of breath have also been observed, caused by an elevated diaphragm.

Depending on the dialysis solution used, a fluid-electrolyte imbalance can occur, e.g., potassium deficiency (hypokalemia). If too much fluid is removed during dialysis, this may result in a decreased blood volume (hypovolemia) with attendant diminished blood pressure.

In addition, the following side effects for APD have also been reported:
abdominal wall hernias, peritoneal leaks, and residual renal function (RRF) loss.

2.6.4 Contraindications

This device must not be used on patients with severe chronic inflammatory bowel diseases or large abdominal adhesions.

2.6.5 Interactions with other systems

None known.

2.6.6 Therapy restrictions

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

2.6.7 Target group

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 is not intended for use in an intensive care unit.

2.7 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.

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

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

For information on installation, (see chapter 9 on page 219).

For information on the Technical Safety Checks and maintenance procedures, refer to the appropriate chapter (see chapter 11 on page 237).

Use only spare parts approved by the manufacturer.

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

For information on transport and storage, (see chapter 10 on page 231).

2.8 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.

2.9 Duties of the responsible organization

Requirements

The responsible organization has the following duties:
- Compliance with the national or local regulations concerning the installation, operation, use, and maintenance of the device.
- Compliance with the accident prevention regulations.
- Ensuring the proper and safe condition of the device.
- Ensuring the permanent availability of the Instructions for Use.
- The device must only be operated under the operating conditions specified by the manufacturer (see chapter 12.7 on page 249).
- Patient cards must be kept in a safe place.
- The applicable data protection regulations (e.g., GDPR) must be observed.
- The measures to be taken for implementing data protection should be documented by the responsible organisation.
- When disposing of the device and patient card, disposal of the data storage devices in compliance with data protection law must be ensured.

Manufacturer’s notes on data protection (see chapter 2.14 on page 33).

Training and instruction

Before the responsible organization can begin to operate the device, the individual responsible for its operation must have received a certificate of instruction from the manufacturer on 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.

If you have any questions, please contact your local service support organization (see chapter 2.15 on page 37).

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 labelling ( ) and to the competent authority of the member state in which the user is established.

Data protection violation incidents may be subject to notification requirements in accordance with Art. 33, 34 of the DSGVO.

Ensure that the safety seal is undamaged. If the safety seal is missing, damaged or if it looks as if it has been removed and re-affixed, this may be a data protection violation subject to notification requirements, which must be handled in accordance with defined data protection processes.
In addition, the following points can be contacted:
– Responsible service support
– Manufacturer via the following e-mail address: DataProtectionOfficer@freseniusmedicalcare.com

Manufacturer’s notes on data protection (see chapter 2.14 on page 33).

2.10 User responsibility

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 following must be observed when entering parameters:

– The parameters entered must be verified by the user, i.e., the user 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.

Warning

Patient hazard from overfilling of peritoneal cavity

The use of incorrect prescription data can result in an incorrect treatment for the patient.

➢ 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 technical and organisational measures defined by the dialysis centre for compliance with data protection must be observed by the user. For the protection of any saved personal data, secure storage of the device, and of the patient card in particular, is recommended.

When using the device, personal data may be viewable and accessible to others via the device screen. Make sure that the device screen cannot be viewed by unauthorized persons.

Whenever the patient card is passed on, it is the duty of the responsible organisation to comply with the national or local data protection directives.

Manufacturer's notes on data protection (see chapter 2.14 on page 33).

2.11 Disclaimer of liability

Warning

Chapter 8 (see chapter 8 on page 215) 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 device manufacturer cannot make any statements regarding the safety and performance of the device when it is used with consumables and accessories other than those listed.

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.

2.12 Warnings

2.12.1 Hygiene warnings

Warning

Risk of contamination from non-compliance with hygiene measures

Improper handling during connection can lead to touching the opening of the patient connector.
Contamination can result.

➢ You are recommended to wear a face mask, wash your hands and the spaces between your fingers with medical grade handwash and then apply a hand disinfection rub.

➢ Use aseptic technique when connecting the patient.

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

Warning

Risk of contamination from non-compliance with hygiene measures

➢ The patient line must be sealed using aseptic technique.

Warning

Risk of contamination from non-compliance with hygiene measures

Improper handling during disconnection can lead to touching the opening of the patient connector.
Contamination can result.

➢ Wearing a face mask and hand disinfection is recommended.

➢ Use aseptic technique when disconnecting the patient connector.

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

2.12.2 Therapy warnings

Warning

Risk of contamination from a damaged *sleep•safe* Set

Microbes (pathogens) may enter the dialysis solution.

➢ Insert the line set (*sleep•safe* Set and the connected solution bags) in such a way as to ensure there is no risk of damage by sharp-edged objects or pets.

Warning

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

Overly rapid withdrawal of fluid can lead to circulatory disturbances.

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

To the trained Health Care Practitioners:

– The dialysis prescription given to the patients remains the full responsibility of the Health Care Practitioners.
– Only knowledgeable, educated clinicians or medical professionals may prescribe and set the therapy parameters.

To the Operators:

– Patients or users MUST talk to their doctors or nurses if they have any concerns or questions about the parameters set by the trained health care practitioners.
– It is important for you to continue to follow the individually prescribed peritoneal dialysis therapy as taught to you by your peritoneal dialysis team. Any deviations from this prescribed therapy need to be discussed beforehand with your Health Care Practitioners as it may cause you serious injury or death.
– Do not modify the parameters for your therapy unless directed by your Health Care Practitioners. Using incorrect parameters can cause you to receive inadequate or inappropriate dialysis. This can lead to serious injury or death.

Overfill/IIPV (Increased Intraperitoneal volume)

IIPV could result in a feeling of abdominal discomfort, serious injury, or death. Severity of the clinical course associated with overfill can be classified as follows:

1. Minor: asymptomatic or abdominal complaints, no medical evaluation at a clinic or hospital;
2. Moderate: respiratory complaints such as shortness of breath or abdominal complaints requiring medical evaluation at a clinic or hospital;
3. Major: complaints that are life-threatening, require hospitalization, or require surgical procedure; any hernia or peritoneal fluid leak; and
4. Death.

IIPV- when the total intra-peritoneal volume exceeds the intended target IP volume. IIPV appears to be under-diagnosed and under-reported. Increased Intraperitoneal volume (IIPV) can occur during automated peritoneal dialysis (APD).

Though uncommon, IIPV is potentially associated with serious adverse effects that are difficult to predict and prevent
– Feeling full, bloated, or overfull
– Abdominal pain or discomfort
– Expanded or tense abdomen
– Vomiting
– Localized swelling around the PD catheter exit site, belly button, groin region, or genital area
– Leakage of fluid from the PD catheter exit site
– Impaired breathing
– Unexpected increase in blood pressure

Causes of IIPV

IIPV can occur because of one or more of the following reasons:
– Incorrect or inappropriate setting of fill or drain parameters
– Incorrect or inappropriate setting of number of tidal PD base cycles
– Inappropriate bypassing during outflow phase

2.12.3 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 a treatment 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 organisation or service support.

A device defect is present in the following cases, for example:
– If there is mechanical damage
– If the power supply cord is damaged
– If the device reacts differently than expected
– If the performance characteristics of the device deteriorate

Warning

Choking hazard from small parts.

Children can swallow and choke on small parts.

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

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.

2.12.4 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

Suffocation hazard 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

A patient leakage current can arise from contact with the operator.

➢ Operators must not simultaneously touch the patient and the contacts of the plugs or sockets of the device.

2.12.5 Warnings regarding consumables and accessories

Warning

Risk of contamination from reuse of the *sleep•safe* Set

The products *sleep•safe* Set, *sleep•safe* Set Plus and *sleep•safe* Set Paed are single-use items. Reuse can lead to patient contamination.

➢ The *sleep•safe* Set, *sleep•safe* Set Plus and *sleep•safe* Set Paed are to be used only once.

Warning

Risk of contamination from contaminated consumables

Improper disposal can lead to the transmission of bacteria to third parties (cross-contamination).

➢ The line sets and drain line must be discarded after treatment in compliance with the local regulations for the disposal of potentially contaminated materials.

2.13 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

2.14 Data protection

2.14.1 Safely handling personal data

The responsible organisation or dialysis centre must disclose any data protection notices to the user or patient.

The manufacturer offers information on safely handling personal data. This is available at the following website.

https://www.freseniusmedicalcare.com/en/product-data-governance/product-privacy

2.14.2 Position and handling of the safety seal

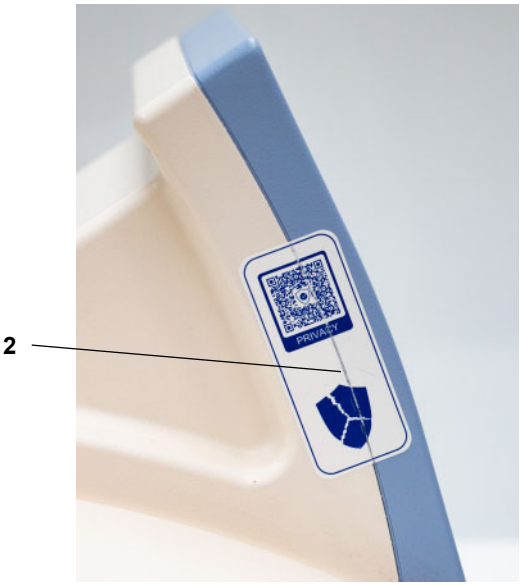
To recognise any unauthorised opening of the device, the device is equipped with a safety seal with a QR code. The QR code refers to the manufacturer's website.

The safety seal with a QR code is located on the left of the screen (1).

Ensure that the safety seal is undamaged. If the safety seal is missing, damaged or if it looks as if it has been removed and re-affixed (2), this should be reported to the relevant dialysis centre, clinic or attending physician in accordance with the applicable data protection directives.
In addition, the following points can be contacted:

– Responsible service support
– Manufacturer via the following e-mail address: DataProtectionOfficer@freseniusmedicalcare.com

They will take the necessary measures (see chapter 2.9 on page 22).



2.14.3 Processing personal data

When using the device and patient card, the following personal data is processed:

1. General personal data:
   – Name
   – First name
   – Date of birth
   – Weight (optional)
   – Gender (optional)
   – Device identification number
   – Patient identification number
   – User login information

For more information, (see chapter 4.5.1 on page 104) and (see chapter 4.6 on page 121)

2. Special categories of personal data (health data) in the course of treatment:
   – Prescription data
   – Treatment report data
   – Patient parameters

3. Technical device data is required by the manufacturer for processing any malfunctions or complaints and for providing information for reporting incidents, such as for the Medical Device Directive (MDD, 93/42/EEC) or the Medical Device Regulation (MDR, (EU) 2017/745).

For more information, (see chapter 2.9 on page 22) and (see chapter 2.10 on page 24)

2.14.4 Saving personal data

Personal data is required in the course of treatment. This data is entered into the device and then saved during the personalisation of the device when preparing treatment (see chapter 2.14.3 on page 35).

When using the patient card, personal data is imported from the card and then saved on the device.

When using the device, personal data may be viewable and accessible to others via the device screen. Make sure that the device screen cannot be viewed by unauthorized persons.

When using the patient card, the treatment report is saved along with personal data onto the patient card at the end of treatment (see chapter 4.4.1 on page 93).

2.15 Addresses

Manufacturer

Fresenius Medical Care AG
61346 Bad Homburg
GERMANY
Telephone: +49 6172 609-0
www.freseniusmedicalcare.com

International service support

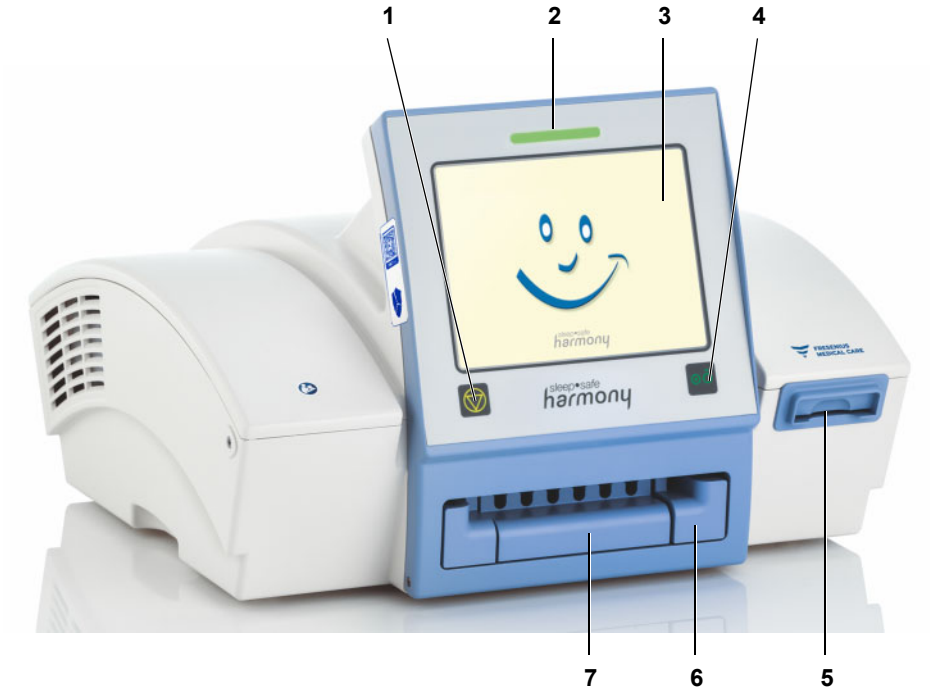
Fresenius Medical Care Deutschland GmbH
Global Technical Operations
Technical Coordination
Hafenstrasse 9
97424 Schweinfurt
GERMANY

Local service support

3 Design

3.1 Views

3.1.1 Front view



1 External key
This key is used to confirm the connection or disconnection of the patient as well as certain screen messages.

2 Status indicator
The indicator lights up red to indicate an alarm, and during the functional test.
The indicator lights up green to indicate alarm-free operation.

3 Screen with integrated touch function
The screen displays treatment information and buttons that can be pressed.

4 **On/Off** key
This key is used to switch the *sleep•safe harmony* on or off.

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

6 **Loading tray**
The loading tray holds the *sleep•safe* Set.

7 **Connector rail**
The connectors of the solution bags are inserted into the connector rail.

3.1.2 Rear view

1 **Alarm output**
Can be used to connect an external alarm indicator.
(Function currently not available.)

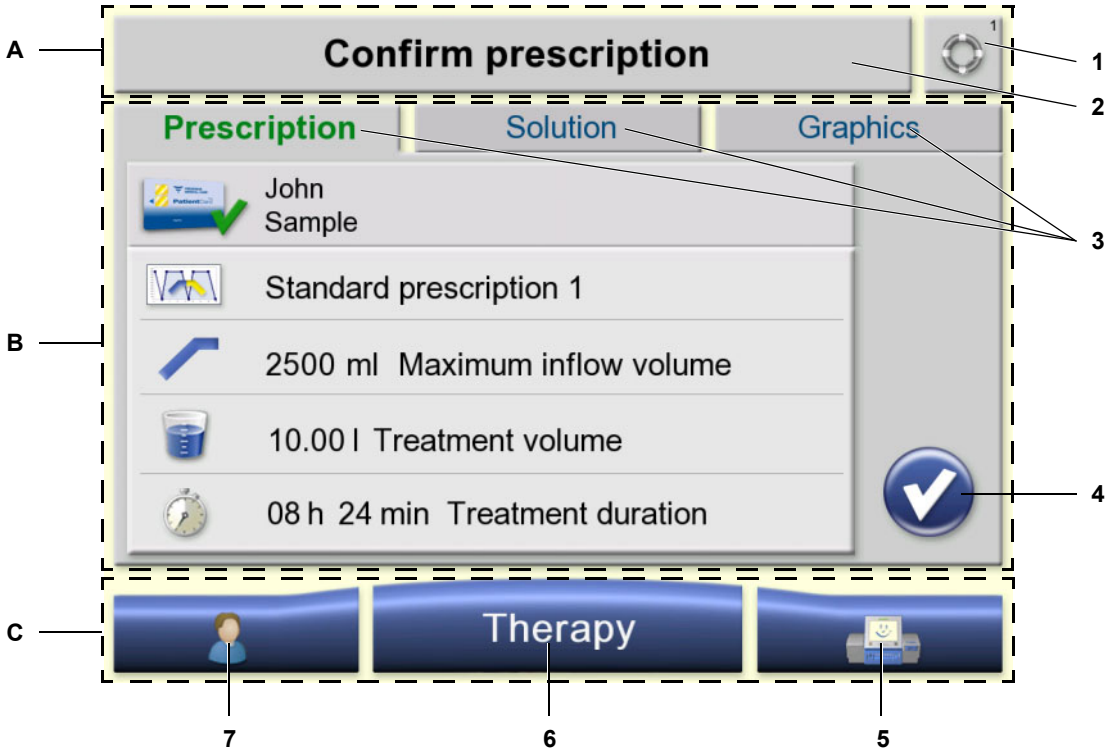
2 **LAN interface**
Interface for data exchange.
(Function currently only available for service support.)

3 Identification label
The identification label shows the *sleep•safe harmony* connection data.

4 Power supply cord
The power supply cord is used to connect the *sleep•safe harmony* to the power supply.

5 Power switch
The power switch is used to switch the electrical power on or off.

3.2 User interface



A Status bar

1 Help (button currently without function)

2 Title of the action to be performed or status of the *sleep•safe harmony*

B Options panel

3 Tab

4 Accept / Confirm button

C Menu bar

5 Device option menu
Depending on the treatment phase, you may not be able to select all of the device options.

6 Therapy option menu

7 Patient option menu

3.2.1 Screen colours

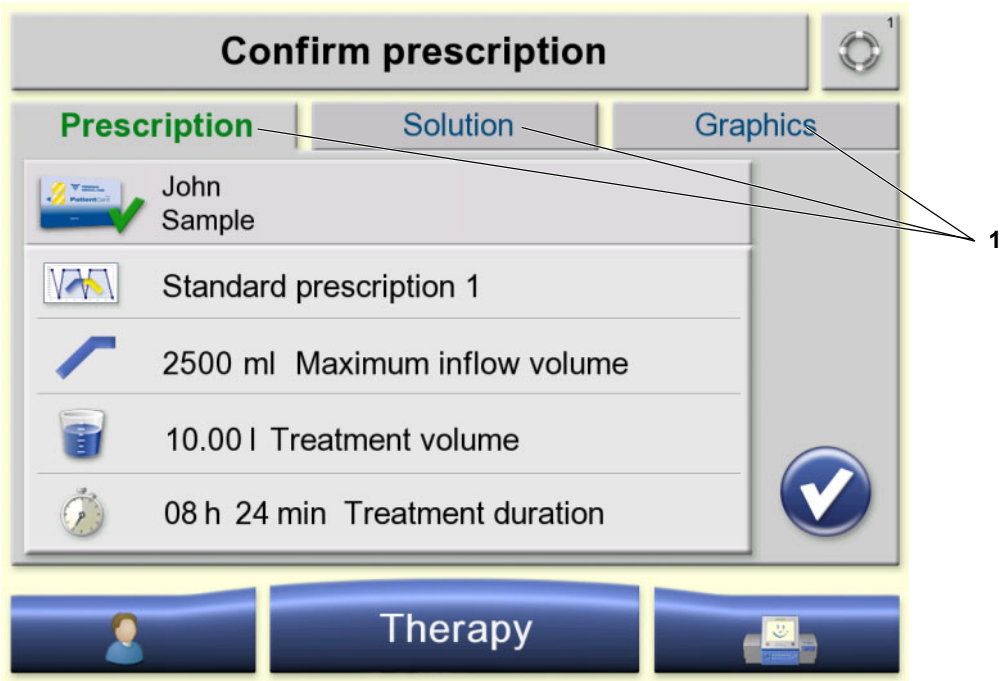
- **Colour of control elements**

The elements which can be selected (e.g., buttons, tabs) have a uniform operating concept.

blue: can be selected

green: active

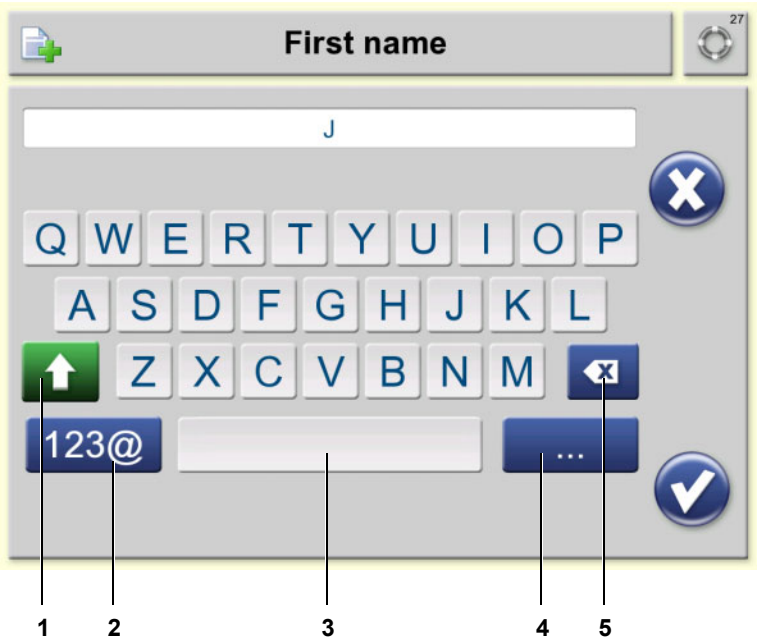
gray: not active / cannot be selected



1 Tab
green:
Tab selected.
The data for the selected tab will be displayed.
blue:
Tab not selected.
The tab can be selected.

3.3 General procedure for entering parameters

3.3.1 Entering text



➢ Use the keyboard displayed to enter the required text.

The other buttons have the following functions:

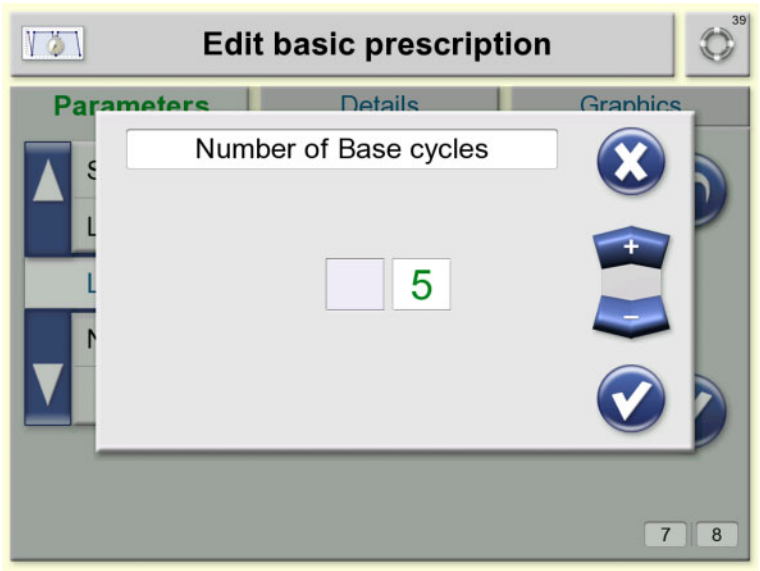
1. Shifts between upper case and lower case letters
2. Shifts between letters and digits
3. Space bar
4. Shows special characters
5. Deletes the last character

➢ When all the required parameters have been entered, press the button to confirm the data entered.

or

➢ Press the button to discard the change.

3.3.2 Entering numbers



➢ Select the digit to be edited. The selected digit is shown in green.

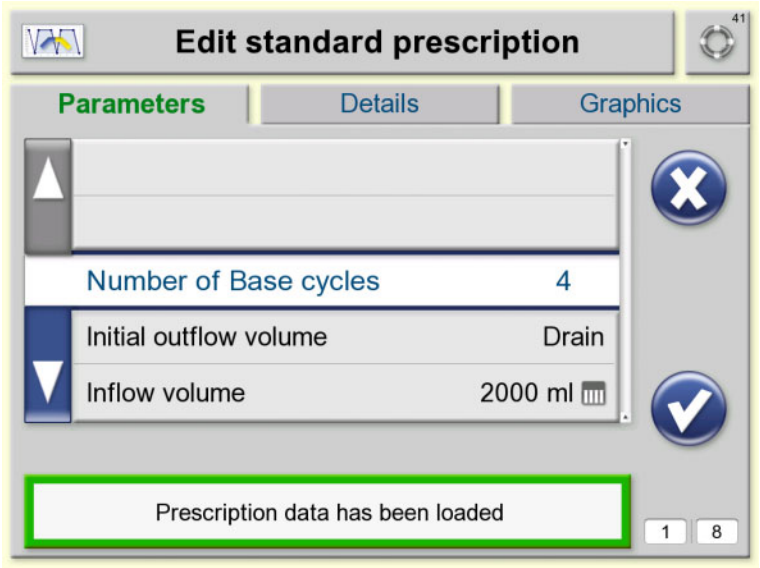
➢ Use the + and − buttons to increase or decrease the digit.

➢ If necessary, select and edit the next digit.

➢ When all the required parameters have been entered, press the ✓ button to confirm the data entered.

or

➢ Press the ✗ button to discard the change.



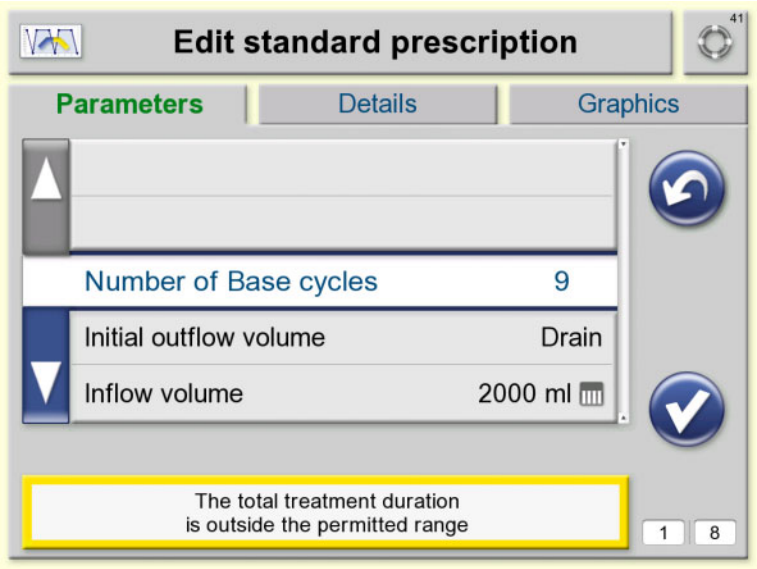
A screen message with a green frame confirms that the data has been saved.

If the value entered is outside the valid range, the *sleep•safe harmony* will adjust this value to the next possible, permitted value.

➢ When all the required parameters have been entered, press the ✓ button to confirm the data entered.

or

➢ Press the ✗ button to discard the change.



If the value entered is outside the range which can be set by the *sleep•safe harmony*, the value entered will be rejected.

An appropriate screen message with a yellow frame will be displayed at the bottom of the screen.

The value entered must be within the valid range.
In this example, either the number of base cycles or the dwell duration can be reduced.

➢ Press the button to confirm the input.

or

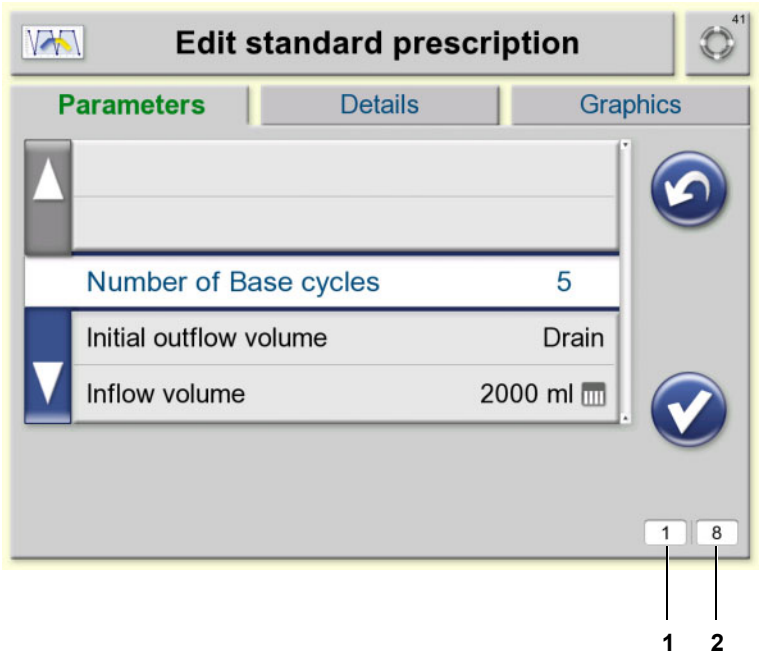
➢ Press the button to discard the change.

3.4 Selecting and editing options or parameters

➢ Press the **Therapy** button.

➢ Use the and buttons to move the required option to the highlighted line in the center. Press on this line to select the option.

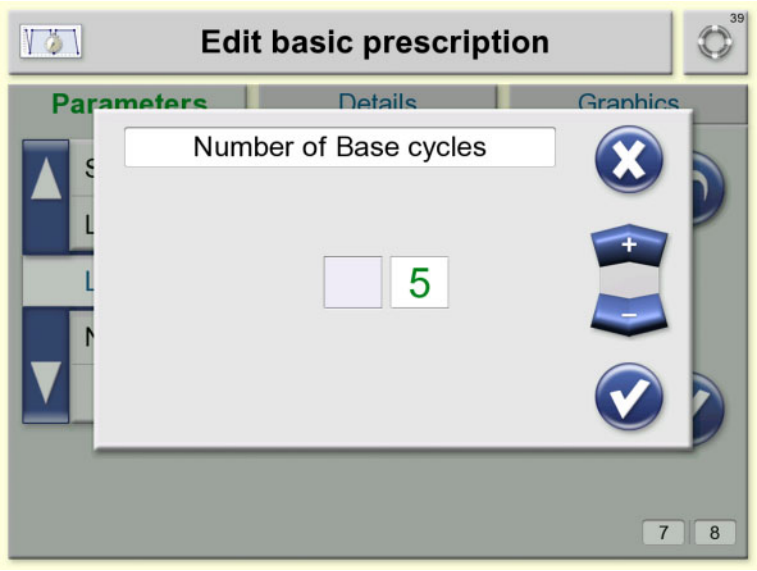
➢ Pressing the button will display the higher-level screen.



➢ Use the and buttons to move the required parameter to the highlighted line in the center. Press on this line to select the parameter.

The number of the selected list item (1) and the total number of list items (2) in this menu are displayed at the bottom of the screen on the right.

➢ Pressing the button will display the higher-level screen.



➢ Enter the required value (see chapter 3.3.2 on page 45).

➢ Press the ✓ button to confirm the input.

or

➢ Press the ✗ button to discard the change.

Warning

Patient hazard from overfilling of peritoneal cavity

Risk of circulatory disturbance due to balancing error

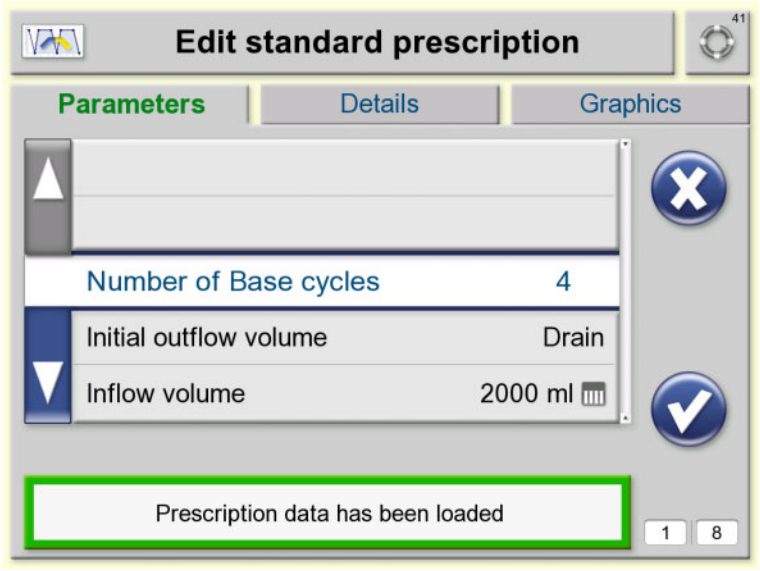
Patient hazard from glucose imbalance due to incorrectly entered parameters

The following must be observed when entering parameters:

– The parameters entered must be verified by the user, i.e., the user 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.



A screen message with a green frame confirms that the data has been saved.

If the value entered is outside the valid range, the *sleep•safe harmony* will adjust this value to the next possible, permitted value.

➢ When all the required parameters have been entered, press the button to confirm the data entered.

or

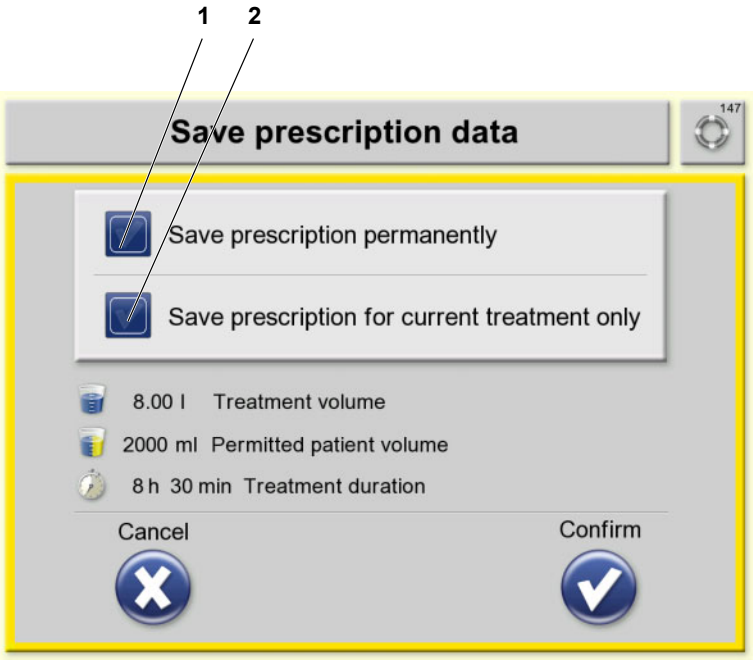
➢ Press the button to discard the change.

Warning

Patient hazard from overfilling of peritoneal cavity

The use of incorrect prescription data can result in an incorrect treatment for the patient.

➢ After editing, the operator must check the treatment data (treatment volume, permitted patient volume and treatment duration) for plausibility.



The prescription data can be saved in two ways.

The prescription data is saved permanently (1) and can be used for future treatments.

or

The prescription data is saved temporarily (2) and can only be used for the current treatment.

➢ Press the appropriate button.

➢ Press the button to confirm the input.

or

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

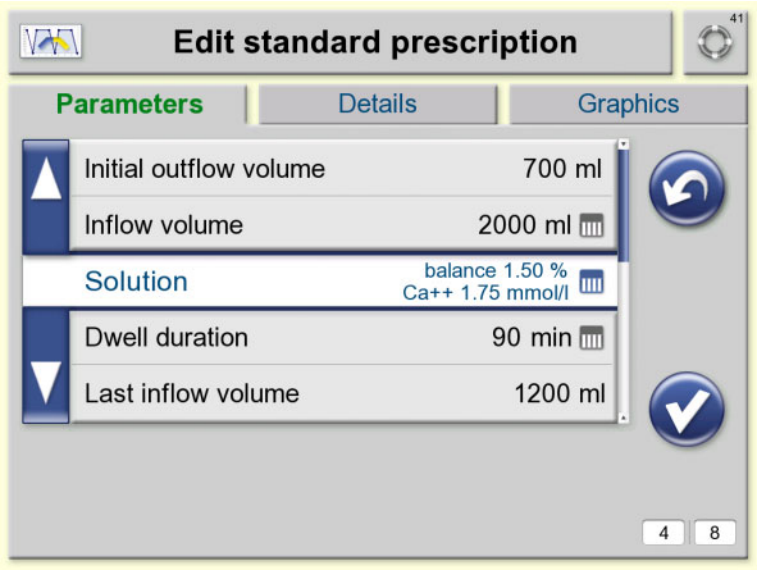
3.4.1 Selecting and editing the solution

There are two ways to select the solution:
– Selecting the solution directly from the list.
– Restricting the selection by selecting only a specific solution type, a specific glucose concentration, a specific calcium concentration (Ca^{++}) or a combination of these three selection options.

➢ Press the **Therapy** button.

➢ Use the and buttons to move the option **Edit prescription** to the highlighted line in the center. Press on this line to select the option.

➢ Pressing the button will display the higher-level screen.



➢ Use the and buttons to move the parameter **Solution** to the highlighted line in the center. Press on this line to select the parameter.

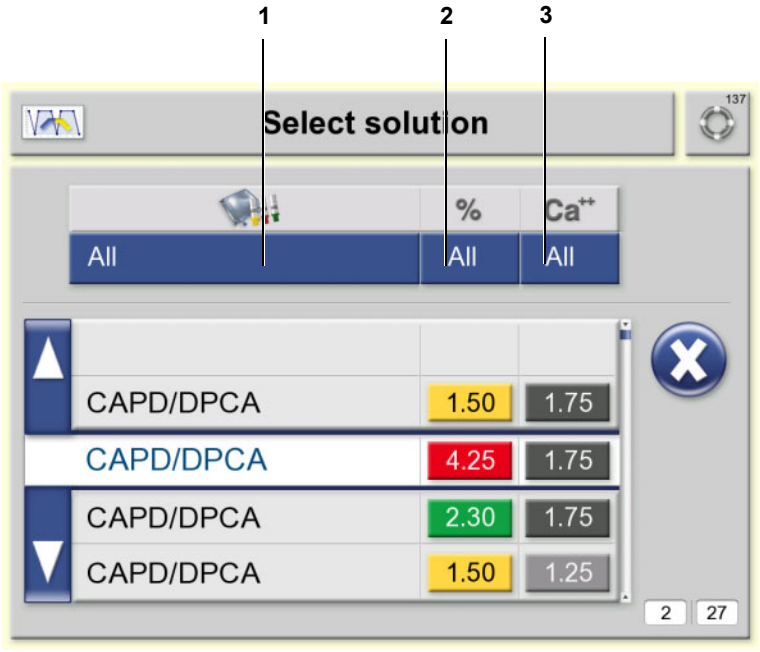
➢ Pressing the button will display the higher-level screen.

- **Selecting the solution directly**

➢ Use the and button to move the required solution to the highlighted line in the center. Press on this line to select the parameter.

➢ Press the button to discard the change.

Restricting the selection of solutions



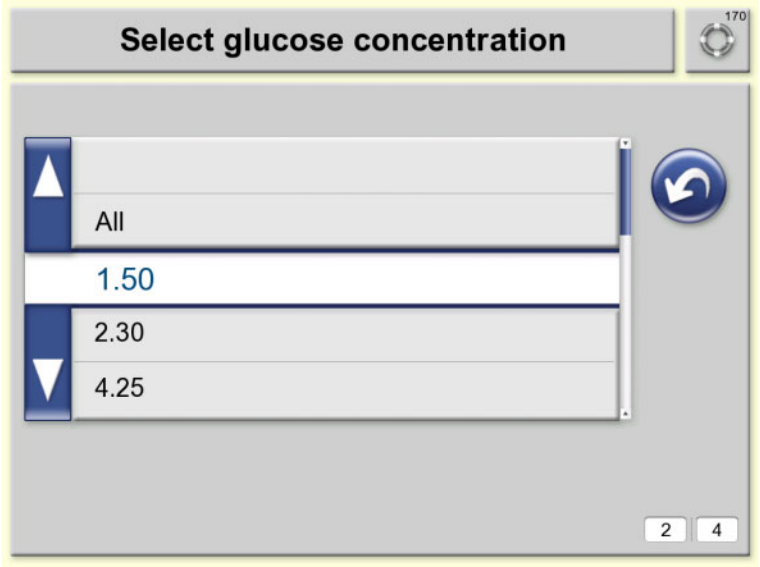
The buttons 1, 2 or 3 can be used to restrict the selection of the solutions.

1. Solution type
2. Glucose concentration
3. Calcium concentration

The procedure for restricting the selection is described using the glucose concentration as an example.

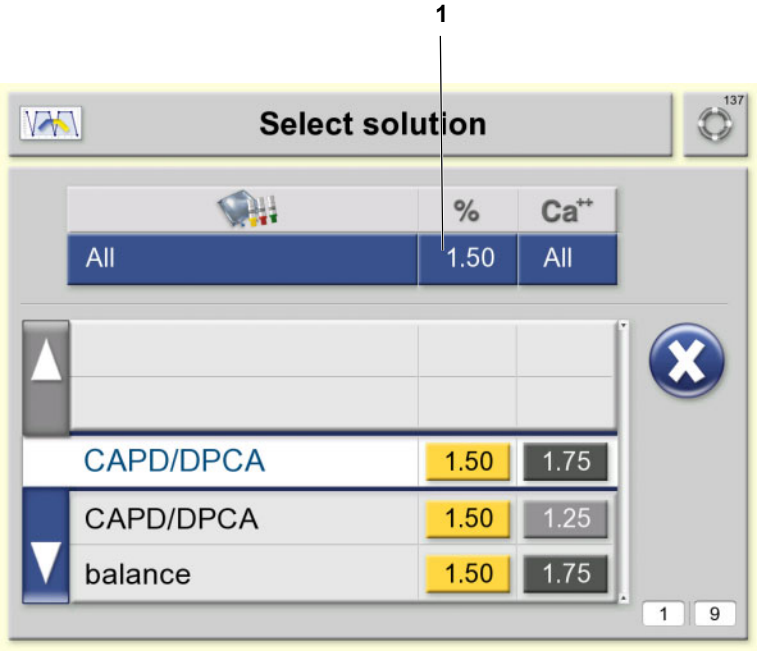
➢ Press button 2.

➢ Press the button to discard the change.



➢ Use the and buttons to move the required parameter to the highlighted line in the center. Press on this line to select the parameter.

➢ Pressing the button will display the higher-level screen.



The selected parameter is displayed in the appropriate field (1).

➢ In the restricted selection list, use the and buttons to move the required parameter to the highlighted line in the center. Press on this line to select the parameter.

➢ Press the button to discard the change.

Note

When restricting the selection of solutions in this way, certain parameter combinations may result in no matching solution being found.
In this case an appropriate message will be displayed on the screen.

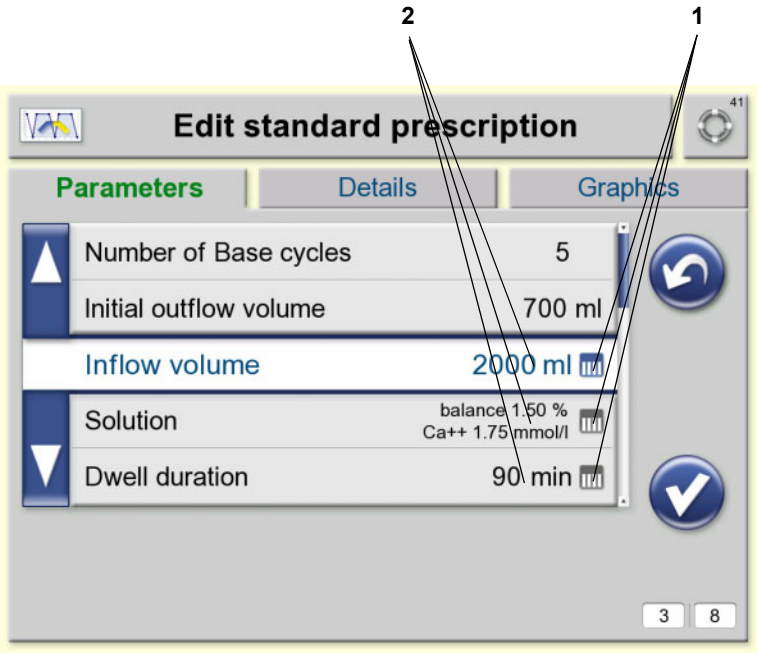
3.5 Profiling

Some types of prescriptions permit parameter profiling. Here, different parameter values can be set for the individual treatment cycles.

➢ Press the **Therapy** button.

➢ Use the and buttons to move the option **Edit prescription** to the highlighted line in the center. Press on this line to select the parameter.

➢ Pressing the button will display the higher-level screen.



The icon (1) next to the parameters indicates which parameter can be profiled.

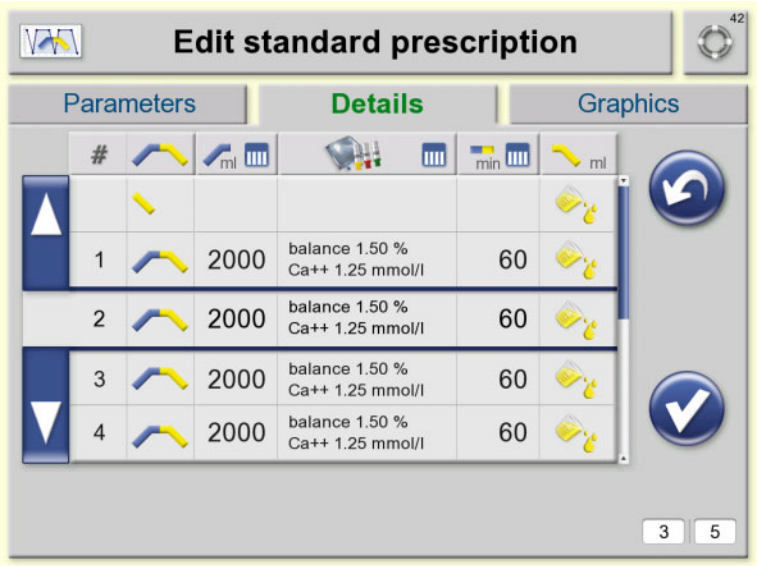
Parameter already profiled.

Parameter not yet profiled.

The parameters (2) are valid for a non-profiled prescription.
If a parameter is profiled, the respective parameter is not active and will be shown in gray.

➢ Select the **Details** tab.

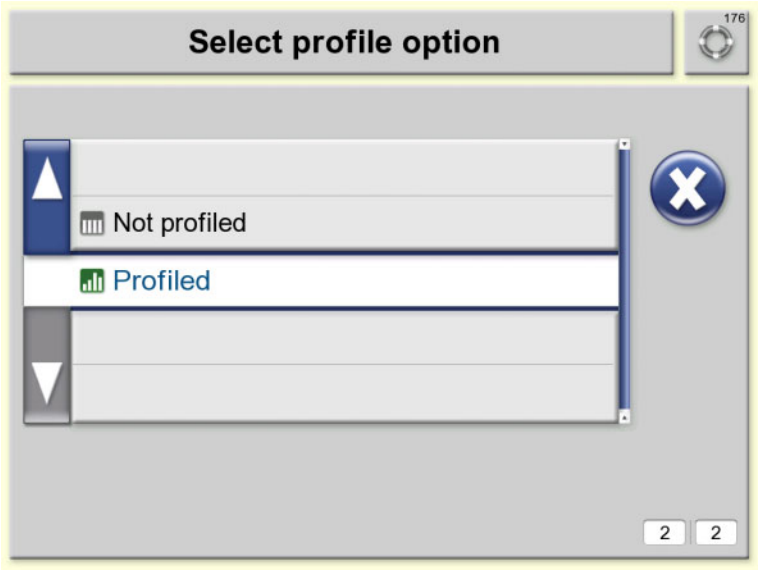
➢ Pressing the button will display the higher-level screen.



The following three parameters can be profiled:
– Inflow volume
– Solution
– Dwell duration

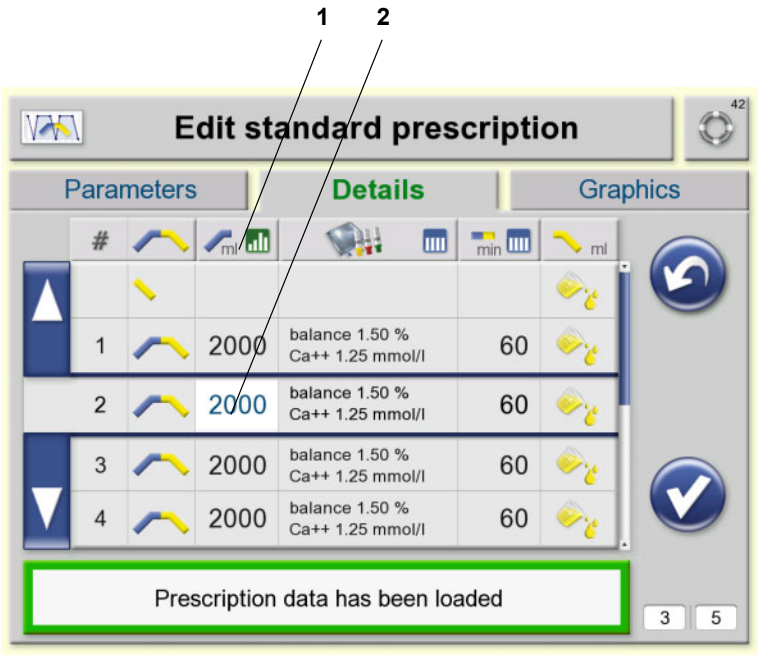
➢ Press the appropriate button to profile the required parameter.

➢ Pressing the button will display the higher-level screen.



➢ Use the and buttons to move the required profile type to the highlighted line in the center. Press on this line to select the parameter.

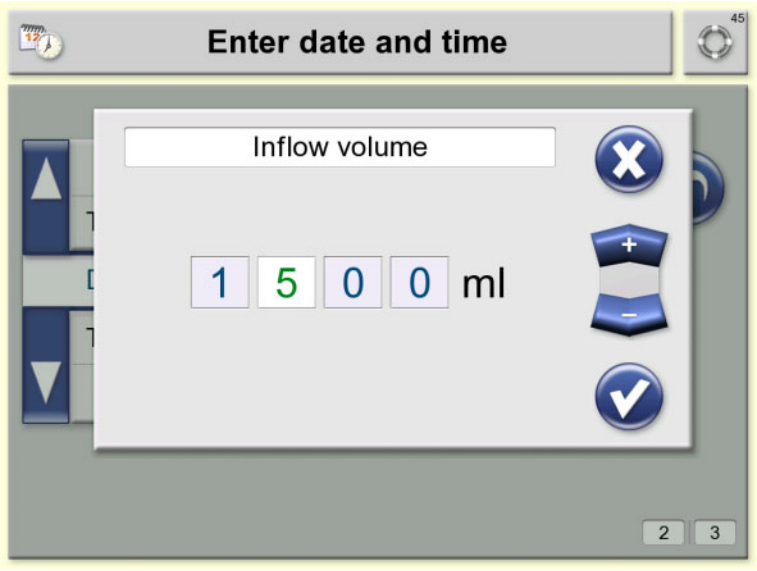
➢ The button cancels the profiling.



Parameters that can be profiled are identified by the icon (1).

The treatment cycle for which the parameter value can be changed is highlighted (2).

➢ Use the and buttons to move the treatment cycle for which the parameter is to be edited to the center. Press on the highlighted parameter field to open the screen for entering or selecting the required value.

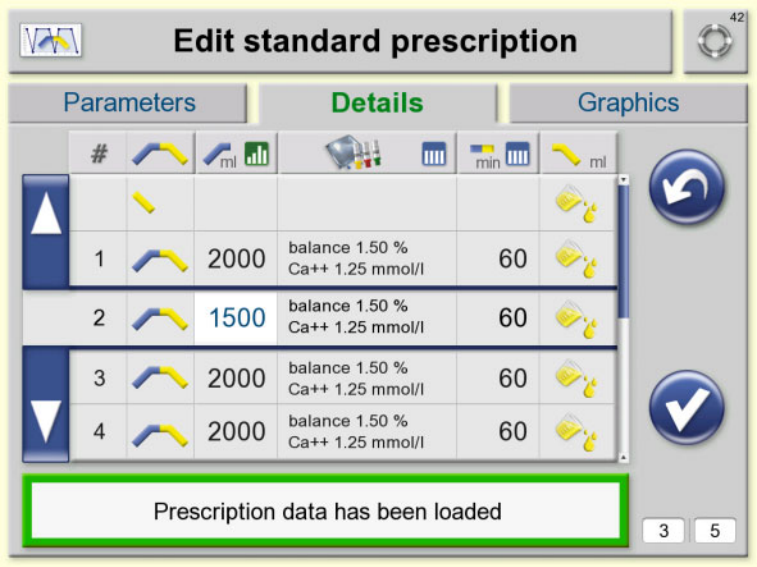


➢ Enter the required value (see chapter 3.3.2 on page 45).

➢ Press the button to confirm the input.

or

➢ Press the button to discard the change.



The changed value for this treatment cycle will be displayed.

A screen message with a green frame confirms that the data has been saved.

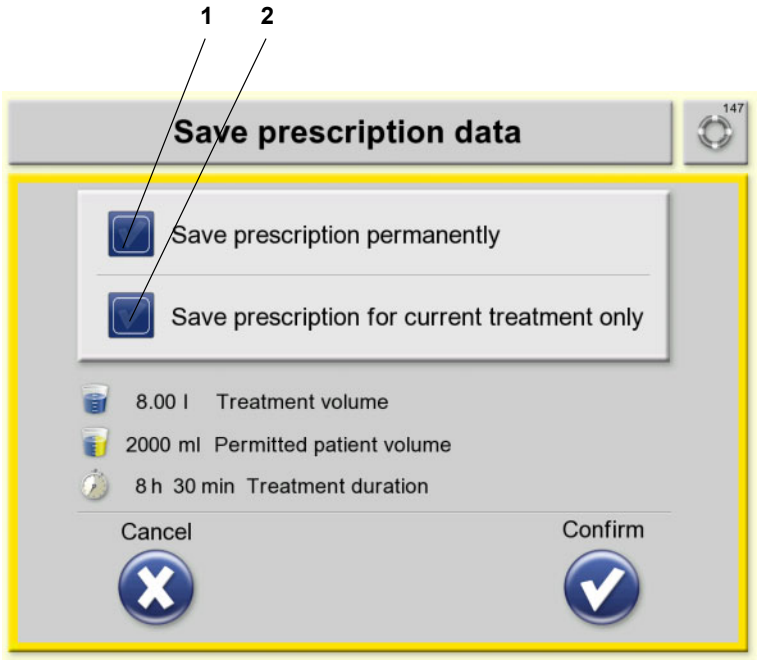
If the value entered is outside the valid range, the *sleep•safe harmony* will adjust this value to the next possible, permitted value.

An appropriate message will be displayed at the bottom of the screen.

➢ When all the required parameters have been entered, press the button to save the changes.

or

➢ Press the button to discard the change.



The prescription data can be saved in two ways.

The prescription data is saved permanently (1) and can be used for future treatments.

or

The prescription data is saved temporarily (2) and can only be used for the current treatment.

➢ Press the appropriate button.

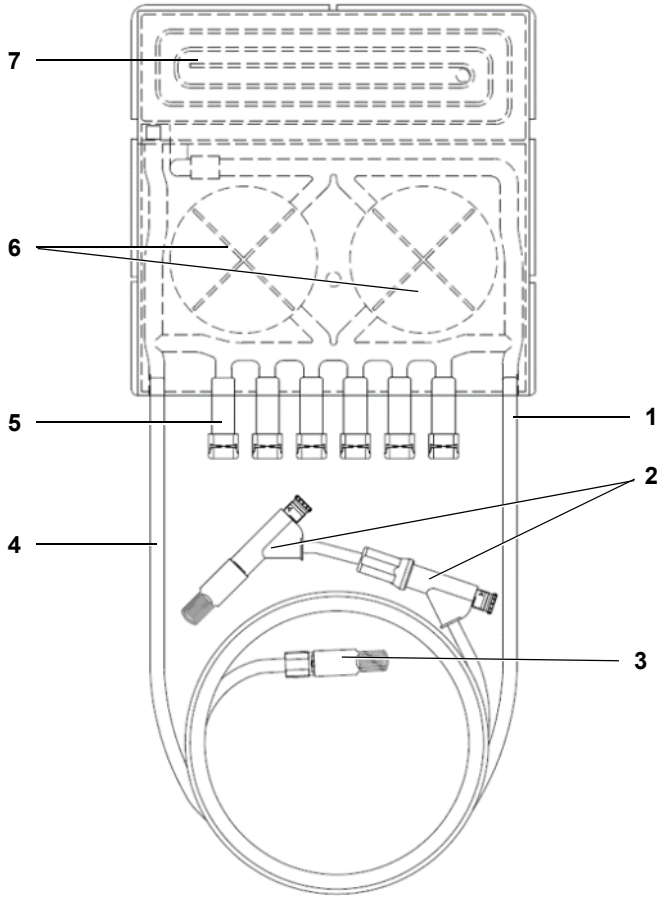
➢ Press the button to confirm the input.

or

➢ Press the button to discard the change.

3.6 Description of the tubing system

The *sleep•safe* Set Plus is used as an example for the tubing system shown.



1 Drain line

2 Patient connector
Optional: additional patient connectors with *sleep•safe* Set Plus and *sleep•safe* Set Paed

3 Connector for drain bag or drain line extension

4 Patient line

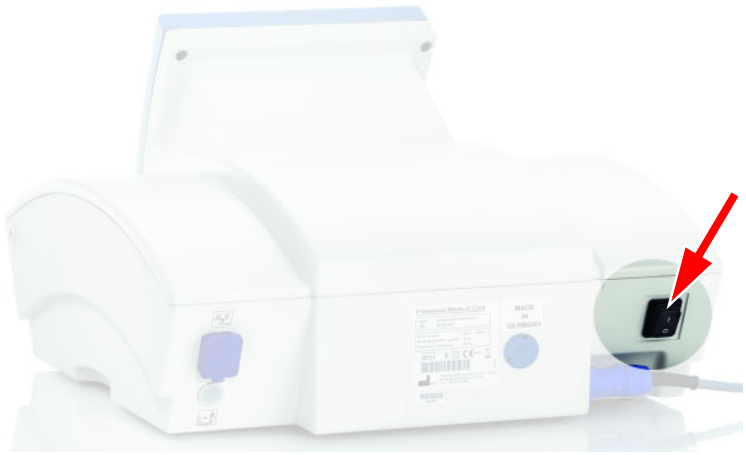
5 Connectors for solution bags

6 Pump chambers

7 Area for heating the dialysis solution

4 Operation

4.1 Switching on the device



➢ Connect the *sleep•safe harmony* to the power supply.

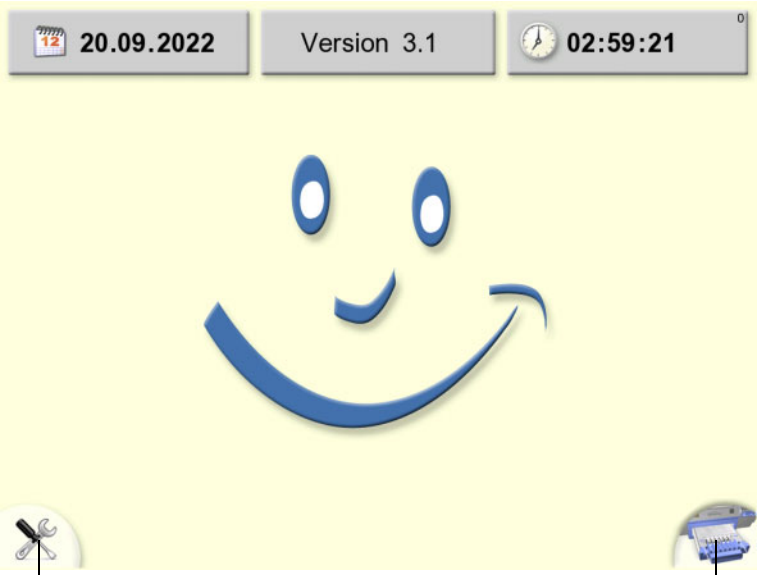
➢ Switch the *sleep•safe harmony* on with the power switch.

4.1.1 Functional test

After the power has been switched on, the device will first perform a functional test.

The key will light up after approx. 1 minute.

➢ Press the key as soon as it lights up.



The *sleep•safe harmony* is ready for operation as soon as the screen shown on the left is displayed.

The following information will be displayed:

– The current date
– The software version
– The current time

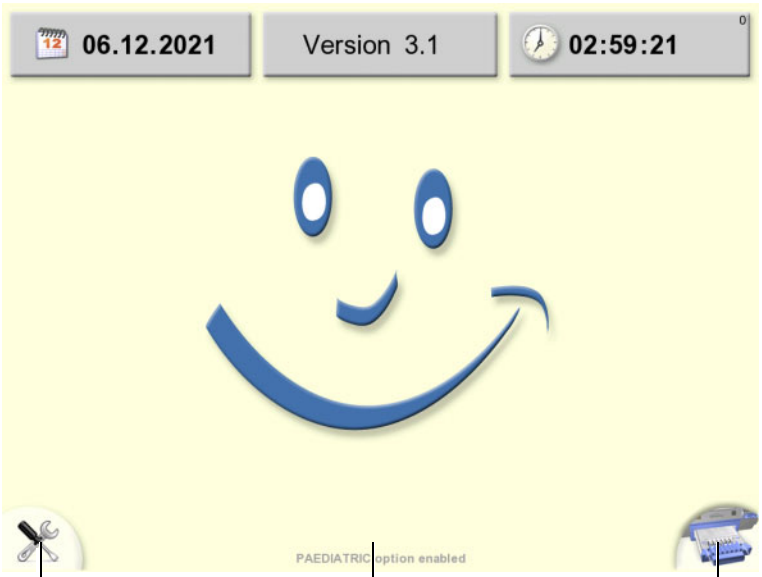
➢ Press the nose of the smiley to move to the next operating step.

➢ If the *sleep•safe* Set is still in the *sleep•safe harmony* after a treatment has been prematurely terminated, press the button (1) on the right at the bottom of the screen to open the loading tray.

➢ For Service login, press the button (2) on the left at the bottom of the screen (only available for service support).

Note

If bridging of the power supply for 15 minutes cannot be ensured, additional information will be displayed.



The device can also be optionally enabled for paediatric treatments.

In this case, the text “PAEDIATRIC option enabled” appears on the lower edge of the screen (3).

The data displayed correspond to the data from the previous screen message.

➢ Press the nose of the smiley to move to the next operating step.

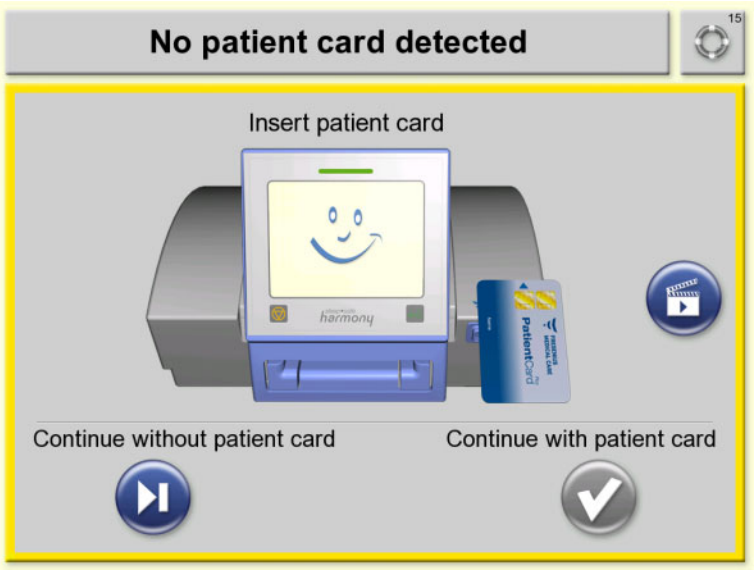
Warning

Chapter 8 (see chapter 8 on page 215) 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 device manufacturer cannot make any statements regarding the safety and performance of the device when it is used with consumables and accessories other than those listed.

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.



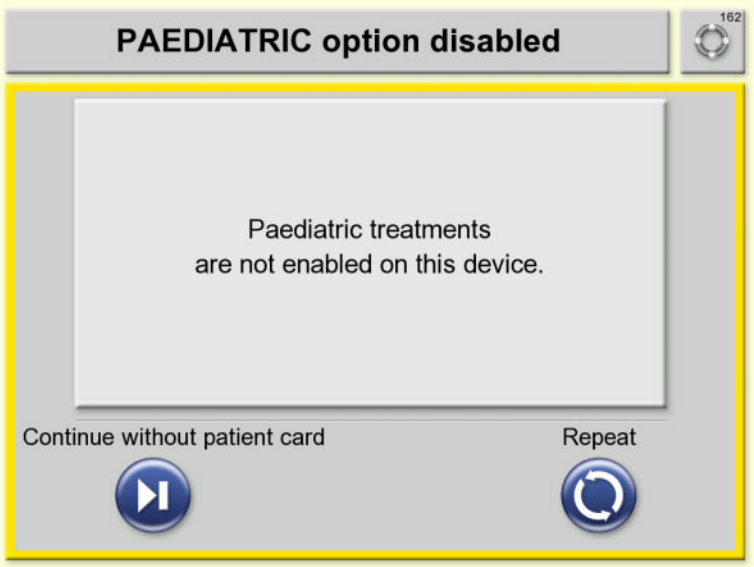
➢ Insert the patient card into the card slot.

➢ Press the button to start the treatment with a patient card.

or

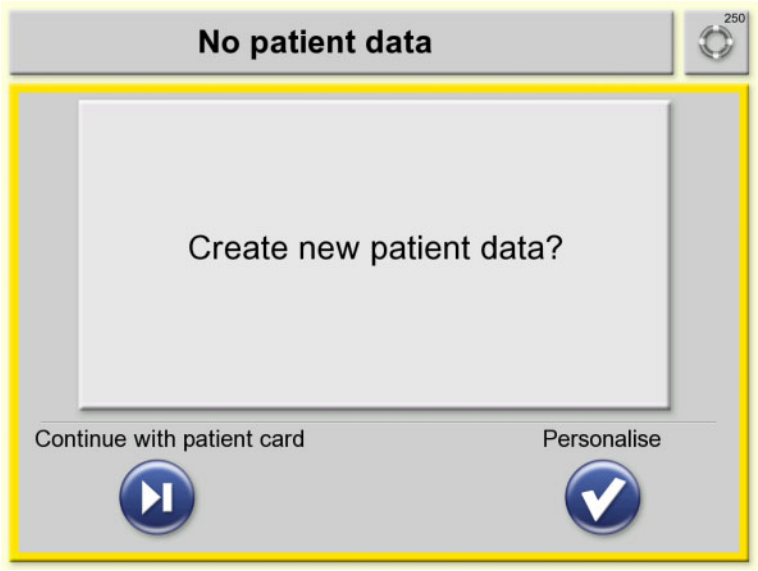
➢ Press the button to start the treatment without a patient card.

➢ The button can be used to replay the screen animation.



If the patient card is intended for a paediatric treatment, but the function is not enabled on the device, the screen on the left appears.

In this case, the device must first be enabled for the PAEDIATRIC option or treatment can only be started with a patient card that does not contain a paediatric prescription.



Alternatively, a treatment can be started without a patient card.

The treatment data are displayed. Additional information on the treatment can be called up via the **Solution** and **Graphics** tab.

The screen will optionally display a paediatric treatment. The “Teddy” paediatric symbol appears next to the patient name and in the top right corner of the screen instead of the **Help** key.

Further operating steps for a paediatric treatment can be identified by the “Teddy” paediatric symbol at the top right corner of the screen.

4.2 Preparing for treatment

4.2.1 Preparing materials and treatment environment

Note

Do not place solution bags on the *sleep•safe harmony* or above the *sleep•safe harmony*.

➢ Close any windows and doors of the treatment room.

➢ Take off wrist watch and jewellery.

➢ Prepare the necessary supplies:

1. *sleep•safe harmony*
2. Patient card
3. Peritoneal dialysis solution bags in overwrap
4. *sleep•safe* Set in overwrap
5. Drain line system
6. Organizer with clip
7. Disinfection cap

8. Face mask
9. Liquid soap (medical grade handwash)
10. Hand disinfectant

Note

The solution bag used, the *sleep•safe* Set used as well as the *sleep•safe harmony* must have a temperature of +15 to +35 °C for non-paediatric treatments and a temperature of +20 to +35 °C for paediatric treatments.

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 microbial contamination in single-use items and consumables

Microbes can be brought in through damage in the consumables or they can form there after the expiration date has elapsed.

➢ Use consumables only if the overwrap is undamaged beforehand.

➢ Check that the expiry date has not passed and that the protective and closing caps have not fallen off.

➢ Always make sure that the *sleep•safe* Set membrane is not dented or damaged (deformed, torn, etc.).

➢ Do not remove consumables from their overwrap before the corresponding operating step is displayed by the device.

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

➢ Check the following items on each solution bag:
– The name of the dialysis solution matches that in the prescription
– The glucose concentration and the calcium concentration match those specified in the prescription
– It is not yet past its "use by" date
– The overwrap is not damaged
– There is no potential leakage
– The dialysis solution is clear

● Handling 5 liter double chamber bags

➢ For double chamber bags, check before use that both PEEL seams are undamaged.

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

➢ Fold out the separating seam in the middle and the bag connector.

➢ Roll up the solution bag starting from the upper corner, which is diagonally opposite 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 is tight.

- **Handling 3 litre double chamber bags**

➢ Before using the bags, check 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 at the upper corner until the PEEL seam opens.

➢ Then roll up the solution bag starting from the upper edge until the PEEL seam of the lower triangular section opens completely.

All PEEL seams must now be open.

➢ Mix the dialysis solution and check that the bag is tight.

4.2.2 Confirming the prescription

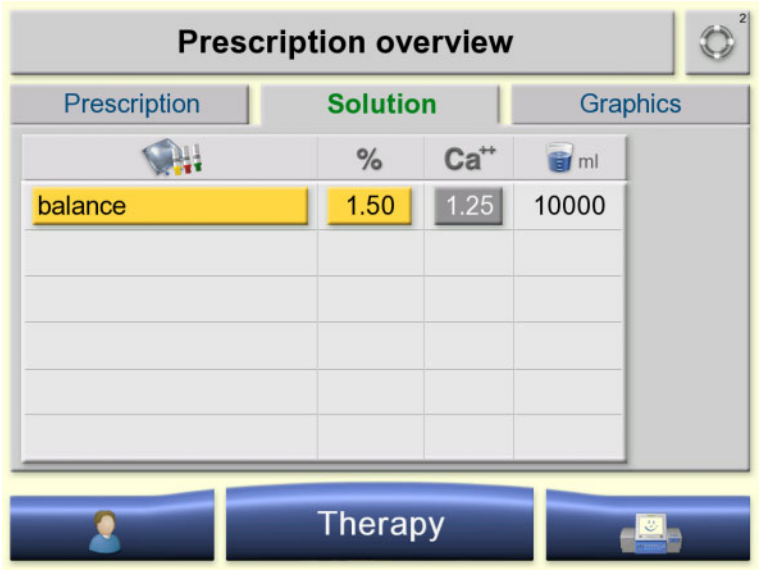
➢ The treatment data displayed in the **Prescription** tab must be checked for plausibility and must match the doctor's prescription.

– Patient name
– Prescription name
– Maximum inflow volume
– Total treatment volume
– Expected treatment duration

➢ Select the **Solution** tab.

or

➢ Press the button to move to the next operating step and to start preparation.



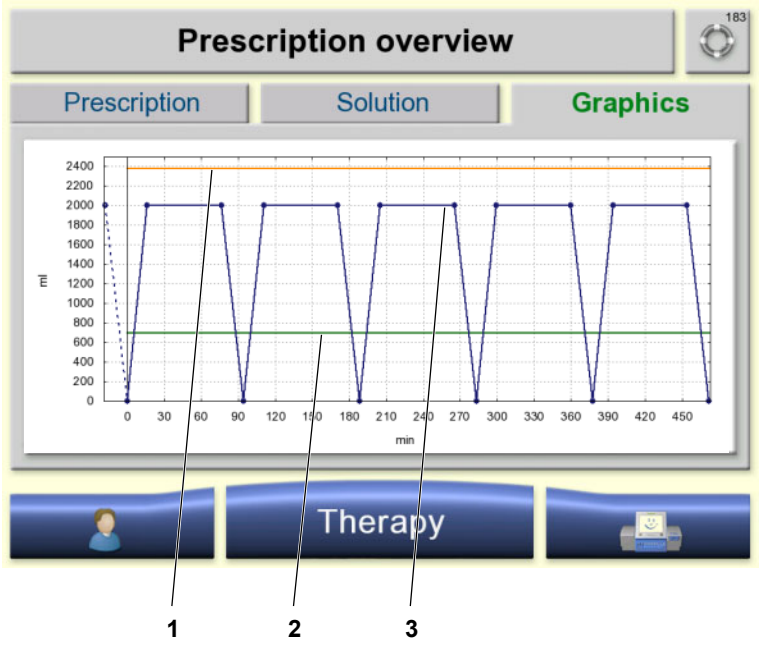
➢ The treatment data displayed in the **Solution** tab must be checked for plausibility and must match the doctor's prescription.

– Solution type
– Amount of glucose in %
– Amount of calcium in mmol/l
– Total solution volume in ml of the respective solution type

➢ Select the **Graphics** tab.

or

➢ Select the **Prescription** tab.

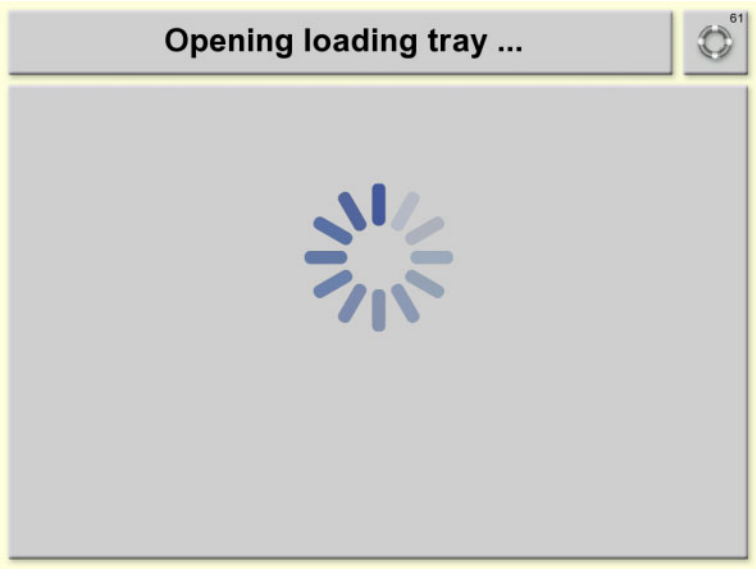


The **Graphics** tab shows a schematic of the prescription.
The vertical axis shows the volume in ml and the horizontal axis shows the time in minutes.

1. Permitted patient volume in ml (orange) (see chapter 7.3.1.1 on page 209)
2. Permitted residual volume in ml (green) (see chapter 7.3.1.2 on page 210)
3. Prescribed volume curve (blue)

➢ Select the **Prescription** tab.

4.2.3 Inserting the *sleep•safe* Set



The *sleep•safe harmony* will perform internal tests.

During the test the audible alarm can be heard and the status indicator is red. After about 5 seconds, first the connector rail, then the loading tray opens.

The opening of the loading tray can take some time depending on the progress of the internal tests.

The next screen message will be displayed automatically.

Warning

Patient hazard from not reaching 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 signalled during the treatment. This would prevent detection of any treatment interruptions, and it would not be possible to carry out the treatment as planned.

➢ The device must not be used.

➢ Call service support.

Warning

Risk of contamination from damage of consumables

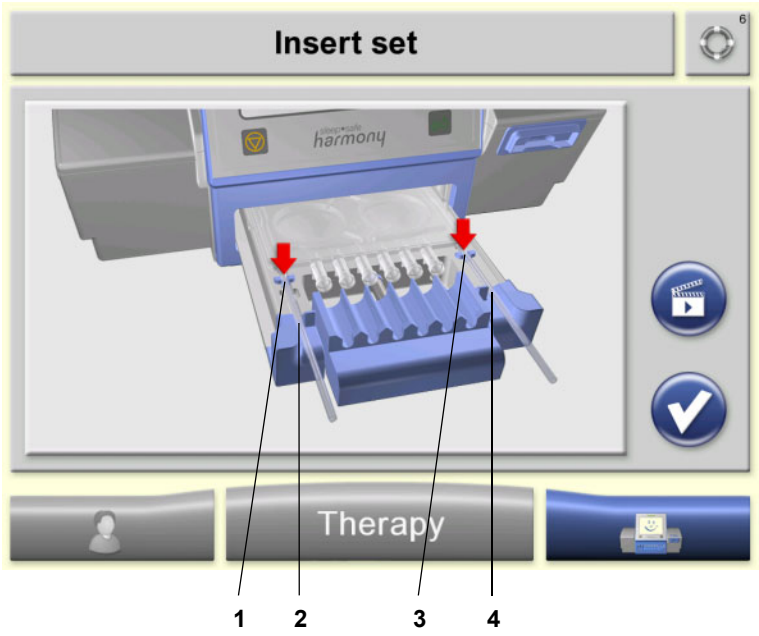
Objects that are placed on the *sleep•safe harmony* can damage the *sleep•safe* Set.

➢ Do not place any objects on the *sleep•safe* Set.

➢ Open the overwrap of the *sleep•safe* Set and remove the *sleep•safe* Set.

➢ Place the *sleep•safe* Set in the open loading tray.

➢ The button can be used to replay the screen animation.



➢ Push the lines on the left (1) and right (3) into the line locators provided for this purpose.

➢ Insert the lines in the left (2) and right (4) line guides.

➢ Insert the patient connector into the organiser.

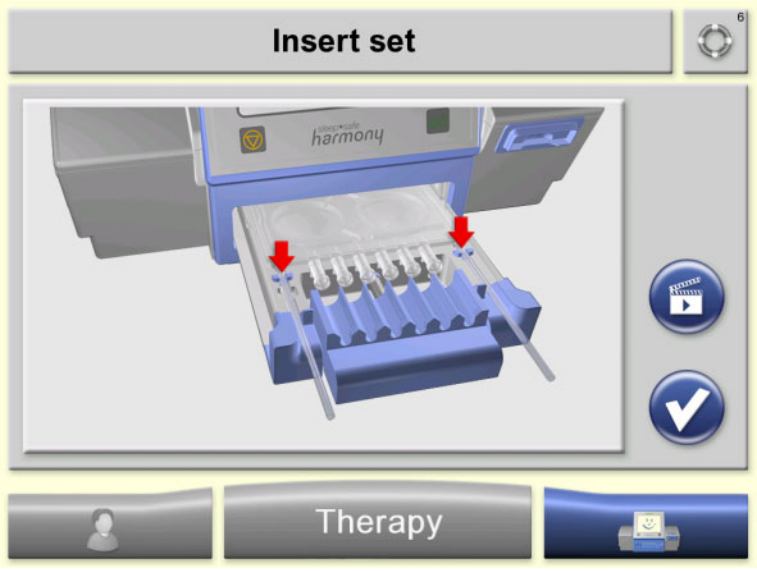
➢ Optionally the operator will be requested to insert a *sleep•safe* Set Paed, identifiable by the name “*sleep•safe* Set Paed”, as well as the “Teddy” paediatric symbol.

Warning

Patient hazard from air in the *sleep•safe* Set

If the *sleep•safe* Set gets jammed when the loading tray closes, preventing the tray from being closed properly, the *sleep•safe* Set can be damaged. Microbes may enter the dialysis solution.

➢ Use a new *sleep•safe* Set for the treatment.



➢ Press the button to confirm that the *sleep•safe* Set is positioned correctly and to move to the next operating step.

4.2.4 Connecting the solution bags

Warning

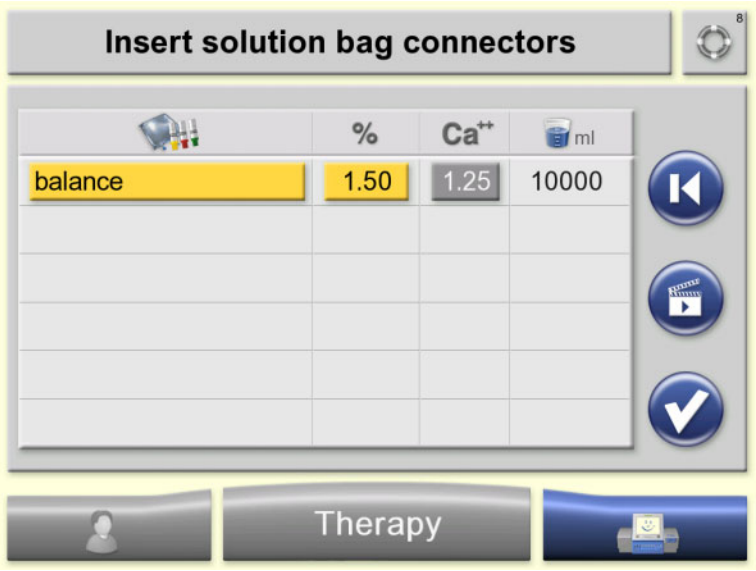
Risk of contamination from microbes in the dialysis solution

Non-compliance with hygienic conditions may lead to microbes entering the dialysis solution.

➢ For reasons of hygiene, the solution bag connectors and the connector ends of the *sleep•safe* Set must only be touched on the outside.

Note

To prevent errors when checking the solution bag connectors, protect the loading tray slot from direct light.



The solution bags required for the treatment are shown on the screen. The colour coding facilitates the correct selection of the solution bags.

➢ Take off the overwrap of the solution bags.

➢ If using a double chamber bag, mix the solution.

➢ Check the solution bags for leakage before use.

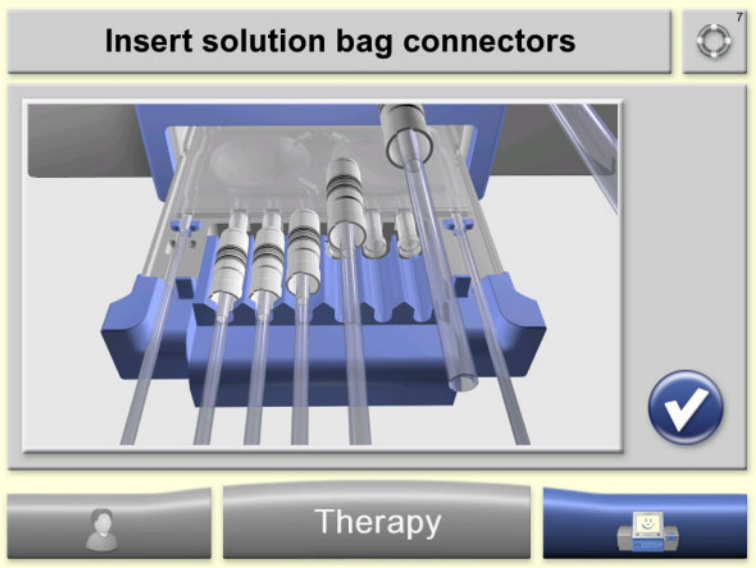
➢ Unroll the connecting line with the solution bag connector.

➢ Unscrew the closing cap of the solution bag connector.

➢ Press the button to return to the previous screen.

➢ The button can be used to replay the screen animation.

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

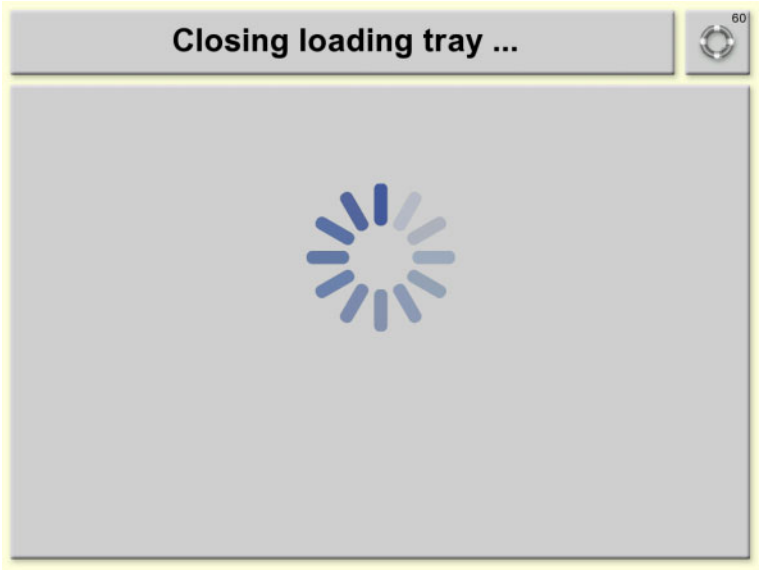


Place the solution bag connectors in a free tray port in front of the *sleep•safe* Set and push them down.

Make sure all of the connectors are firmly secured in the tray ports.

When using a 7.5 % polyglucose solution bag, handle the bag as shown in the operator training (see chapter 4.2.4.2 on page 79).

Press the button to move to the next operating step.



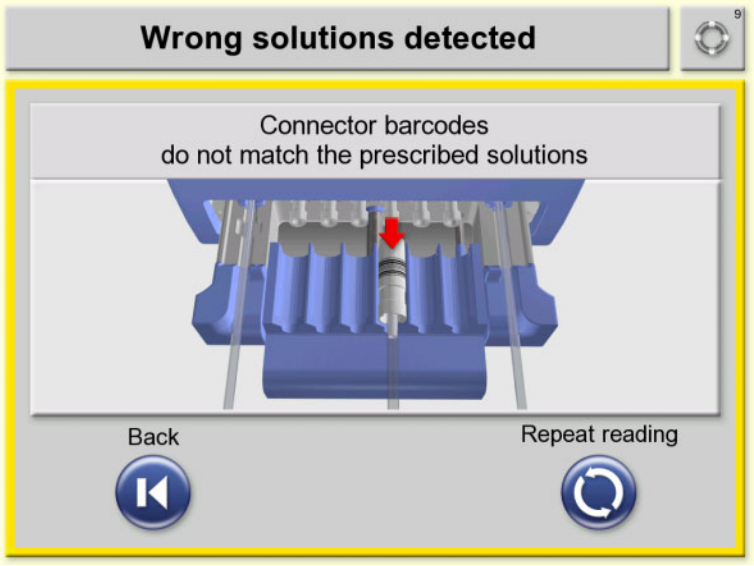
The loading tray closes.

The next screen message will be displayed automatically.

The volume and solution type of the inserted solution bags are compared with the prescription.

The next screen message will be displayed automatically.

4.2.4.1 Connected solution bags do not match the prescription



The loading tray will be opened if the connected solution bags do not match the prescription. The incorrect solution bags are identified by a red arrow.

➢ Check the solution bag and replace it as necessary.

➢ Press the button to return to the previous operating step.

or

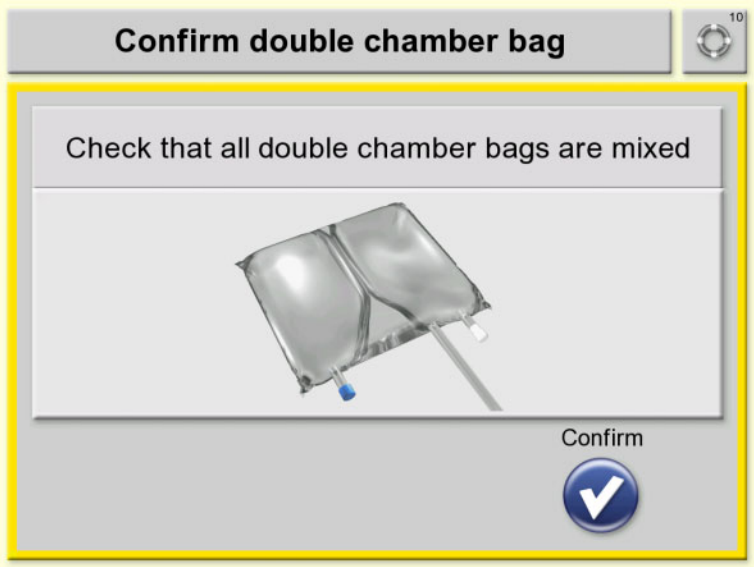
➢ Press the button to repeat the barcode reading.

The volume and solution type of the inserted solution bags are compared with the prescription.

The next screen message will be displayed automatically.

4.2.4.2 Continuing the connection of the solution bags

- **Confirming that double chamber bags have been mixed**



If a single chamber dialysis solution bag is used, this screen will not be displayed.

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

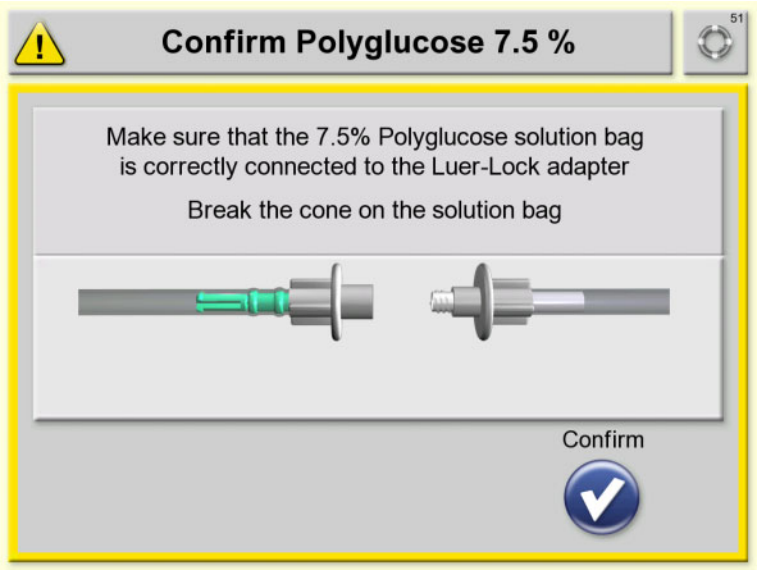
- **Connecting a 7.5 % polyglucose solution bag**

Warning

Patient hazard from not reaching the treatment goal

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

➢ The *sleep•safe* Luer lock adapter must only be used in combination with a 7.5 % polyglucose solution bag for the last inflow.



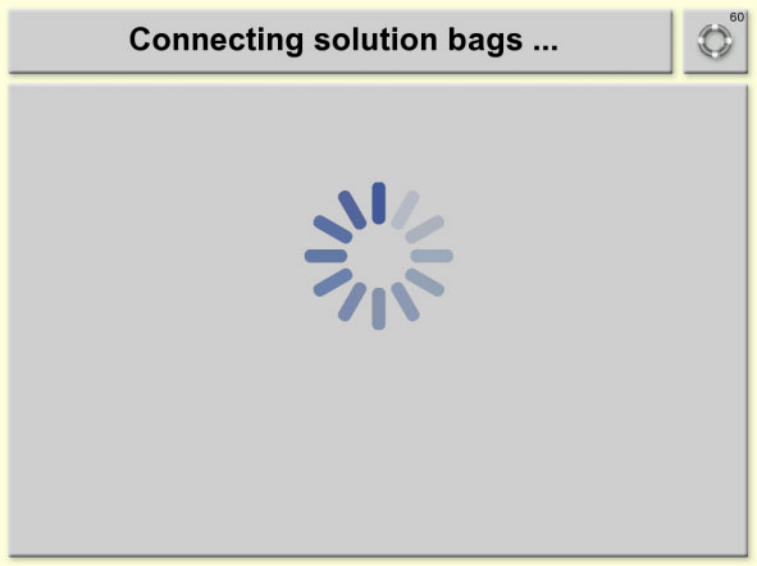
➢ If required for the treatment, have a 7.5 % polyglucose solution bag and a *sleep•safe* Luer lock adapter ready to hand.

➢ Then connect the 7.5 % polyglucose solution bag to the *sleep•safe* Luer lock adapter, making sure that the connection is secure.

➢ Break the cone of the solution bag connected.

➢ Prior to priming, check that the *sleep•safe* Luer lock adapter and the 7.5 % polyglucose solution bag are tightly screwed together.

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



The connector rail will close when all the required connectors have been correctly inserted.

The solution bags will then be connected to the *sleep•safe* Set automatically.

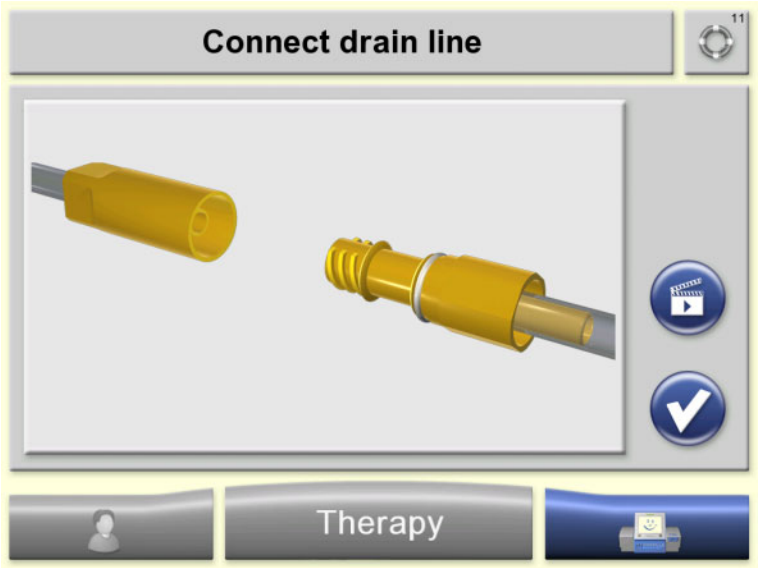
4.2.5 Connecting the drain line system

Note

The use of the *sleep•safe* drain line extension is recommended if 5 or 6 solution bags with 5 litres or 6 litres each are connected. The capacity of the drain line set is not sufficient for a treatment with 6 solution bags.

Note

The outlet of the drain line must never be more than 2 metres below or above the *sleep•safe harmony*.



➢ After connecting the solution bags, connect the drain line.

➢ Unroll the drain line on the right of the *sleep•safe* Set.

➢ Connect the yellow connector of the *sleep•safe* Set to the drain line or the drain set.

➢ When using the drain set, make sure that the clamp of the drain line is open and that the clamps of the emptying lines on the drain set are closed.

➢ The button can be used to replay the screen animation.

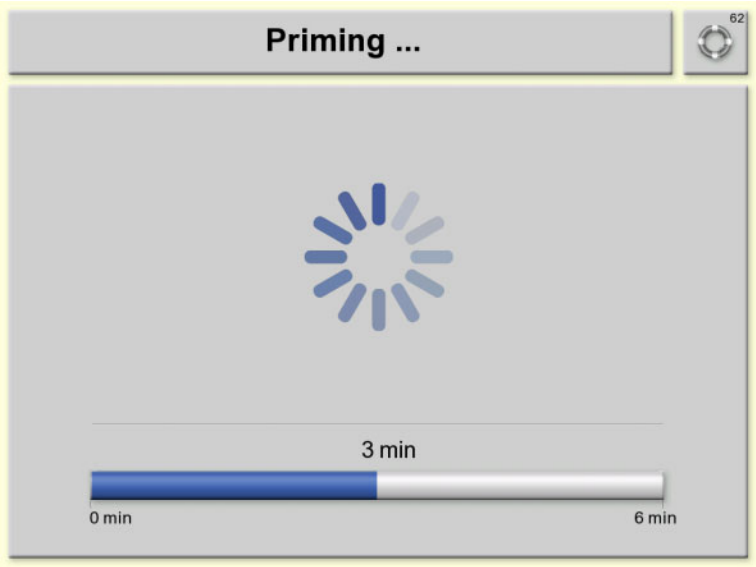
➢ Press the button to move to the next operating step.

4.2.6 Priming the line set

Note

If an interruption occurs while priming the line set, an appropriate caution is displayed. This can be confirmed. Subsequently, the priming process is resumed.

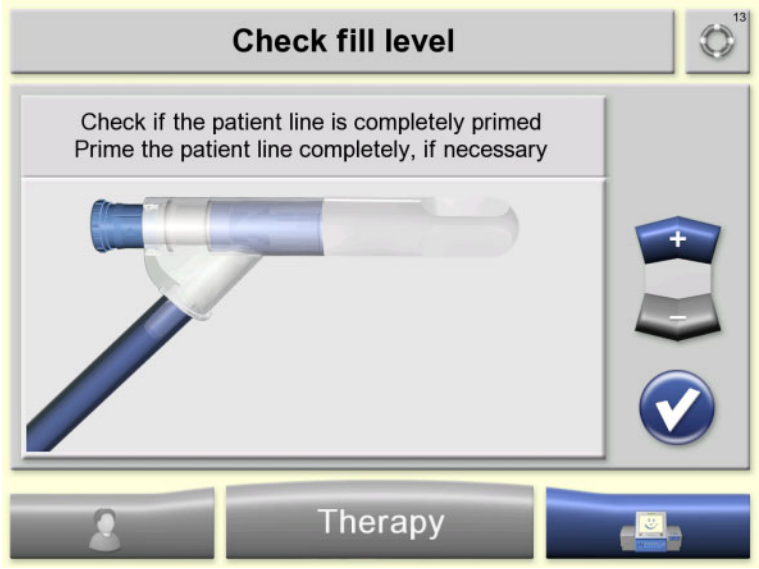
After completion of automatic priming of the *sleep•safe* Set, the patient line must be primed completely by the operator using the button.



The *sleep•safe* Set and the patient line will be primed automatically.

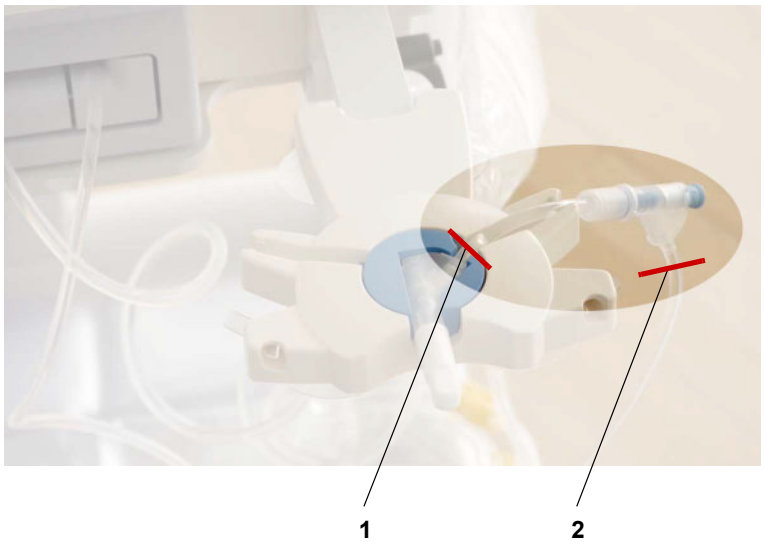
The next screen message will be displayed automatically.

4.2.6.1 Checking the fill level in the patient line



➢ If priming has been completed, but the patient line is not yet fully primed, it can be filled up with dialysis solution by pressing the button.

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



➢ After priming is complete, the fill level of the patient line should lie somewhere between (1) and (2).

4.2.7 Confirming treatment data

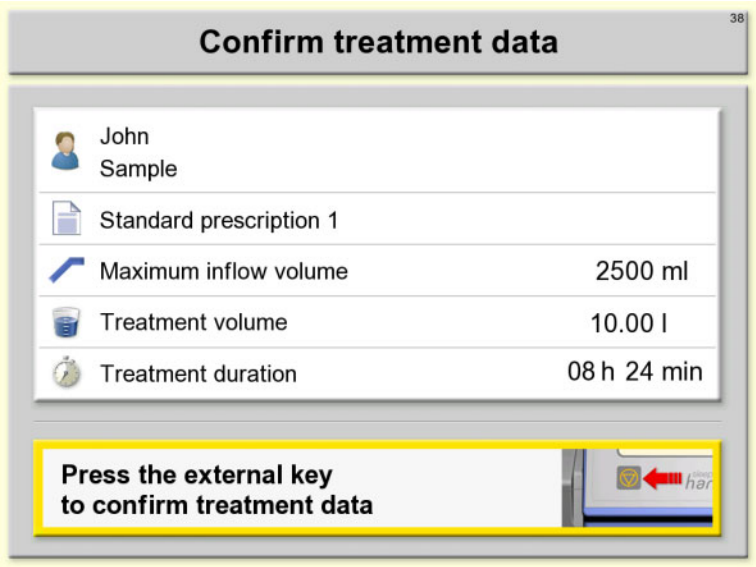
Warning

Patient hazard from overfilling of peritoneal cavity

The use of incorrect prescription data can result in an incorrect treatment for the patient.

➢ 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 the treatment data for plausibility.

➢ Press the ▽ key to confirm the treatment data.

4.3 Starting the treatment

4.3.1 Connecting the patient

Warning

Risk of contamination from non-compliance with hygiene measures

Improper handling during connection can lead to touching the opening of the patient connector.
Contamination can result.

➢ You are recommended to wear a face mask, wash your hands and the spaces between your fingers with medical grade handwash and then apply a hand disinfection rub.

➢ Use aseptic technique when connecting the patient.

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

Warning

Risk of contamination from open patient line

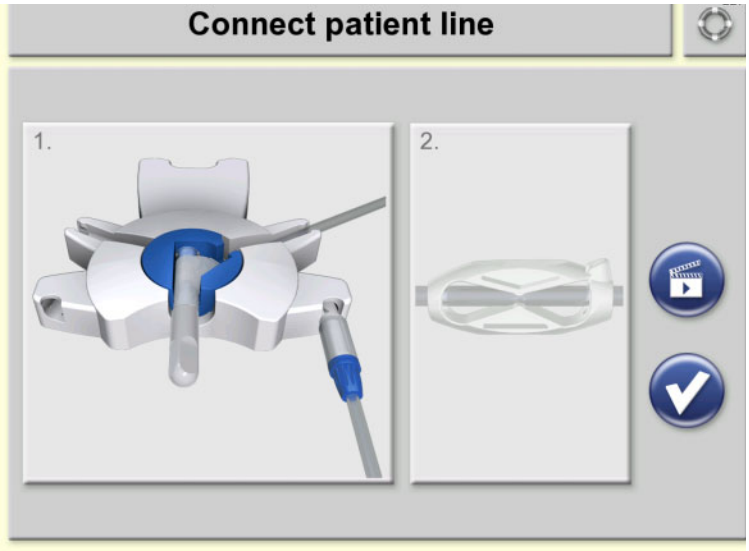
Microbes can enter the dialysis solution through the vent opening in the protective cap on the patient connector of the line set.

➢ Treatment should be performed immediately after priming is complete.

Warning

Risk of contamination from non-compliance with hygiene measures

➢ The patient line must be sealed using aseptic technique.



➢ Once priming is complete, the patient should be connected immediately.

➢ Connect the patient line as described below.

➢ The button can be used to replay the screen animation.

➢ Unroll the patient line on the left of the *sleep•safe* Set.

➢ Insert the patient connector into the organiser (if not already inserted when inserting the *sleep•safe* Set).

➢ Insert the catheter extension system connector into the right holder of the organiser (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 of the *sleep•safe* Set patient connector.

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

➢ Screw the catheter extension system connector directly onto the patient connector of the *sleep•safe* Set.

➢ Open the white clamp on the catheter extension.

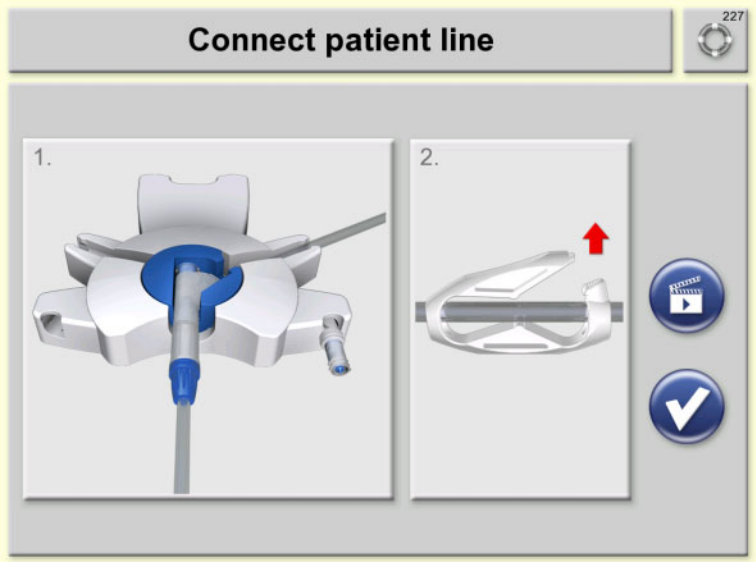
➢ Remove the patient connector from the organiser if all connection steps have been carried out correctly.

Warning

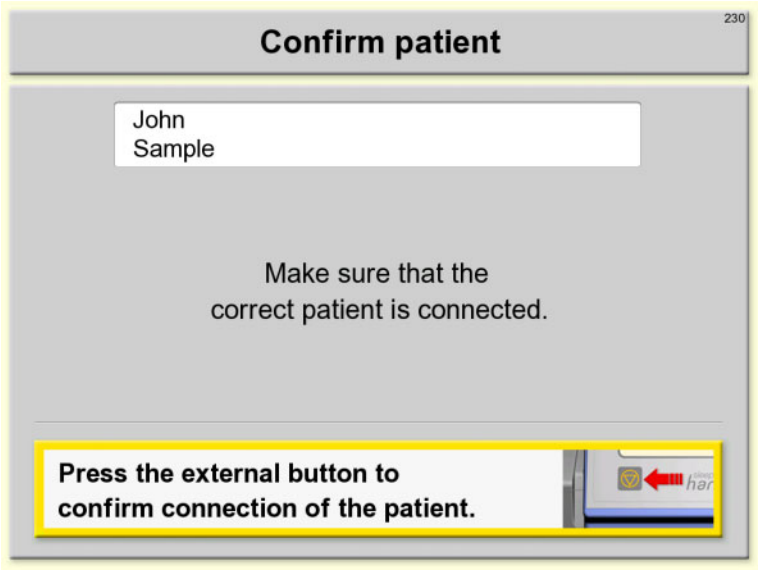
Patient hazard from overfilling of peritoneal cavity

The use of incorrect prescription data can result in an incorrect treatment for the patient.

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



➢ Press the button to confirm connection.



➢ The patient's name will be displayed.

➢ Press the ▽ button to confirm connection of the correct patient and to start the treatment.

4.3.2 Starting the treatment

Note

During outflow, the level difference between the *sleep•safe harmony* and the patient should not be significantly changed. A change between a lying and a sitting position does not have any negative effect.

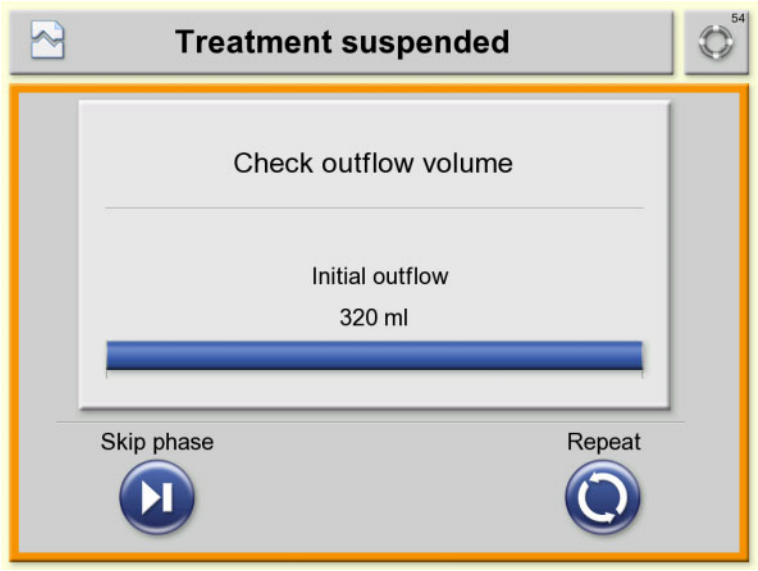
Treatment is started.

The treatment will start with an initial outflow.

4.3.3 Terminating the initial outflow

If an initial outflow has been set for the treatment, this message will be displayed when the device detects that the draining of the peritoneal cavity has been completed.

➢ Press the button to silence the audible signal.



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

➢ Press the button to repeat the initial outflow.

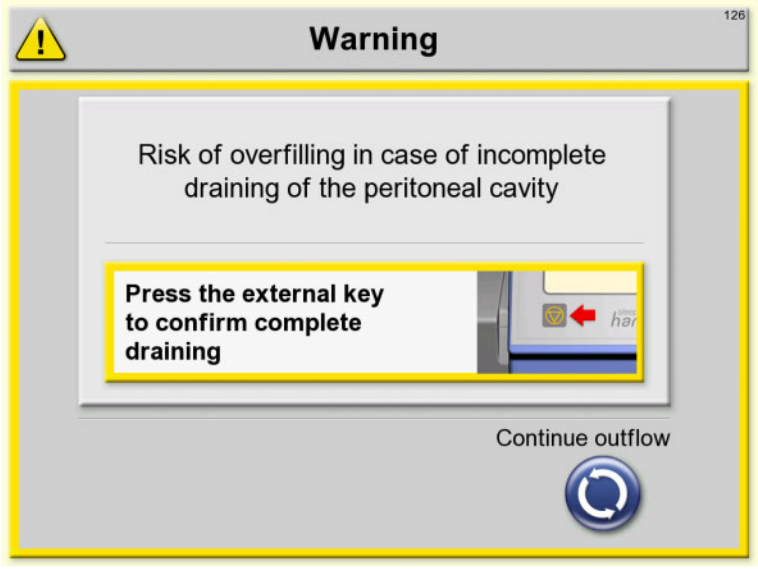
➢ Press the button only if you wish to end the initial outflow and start the subsequent inflow phase.

Warning

Patient hazard from overfilling of peritoneal cavity

Respiratory and circulatory disturbances can be caused by overfilling the peritoneal cavity with fluid.

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



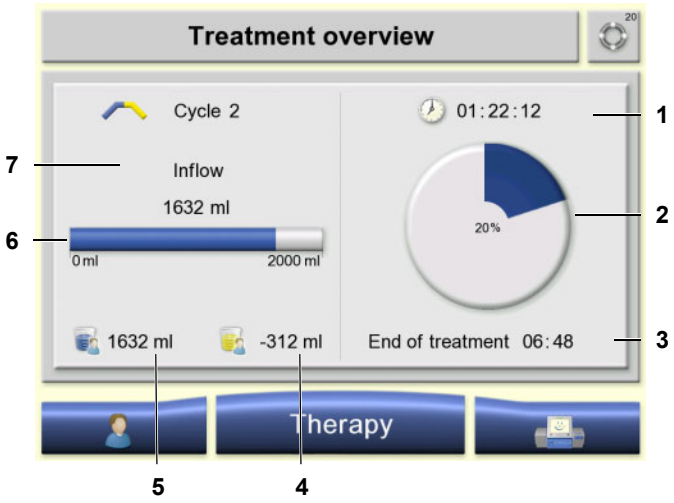
This warning appears when you end the initial outflow.

➢ Do not press the key unless there is definitely no fluid left in the peritoneal cavity.

The first inflow will be started after confirming.

➢ Press the button to continue the initial outflow.

4.3.4 Treatment overview



During the treatment, the following parameters will be displayed on the treatment overview screen:

1. Current time
2. Treatment progress in %
3. Expected end of treatment
4. Current total volume balance
   The device calculates the volume balance during treatment. Negative values describe a weight loss (ultrafiltrate has been generated). Positive values describe a weight gain (resorption).
5. Volume in patient
6. Progress of the current treatment phase
7. Treatment cycle

4.4 Terminating treatment

4.4.1 Disconnecting the patient

Warning

Risk of contamination from non-compliance with hygiene measures

Improper handling during disconnection can lead to touching the opening of the patient connector.
Contamination can result.

➢ Wearing a face mask and hand disinfection is recommended.

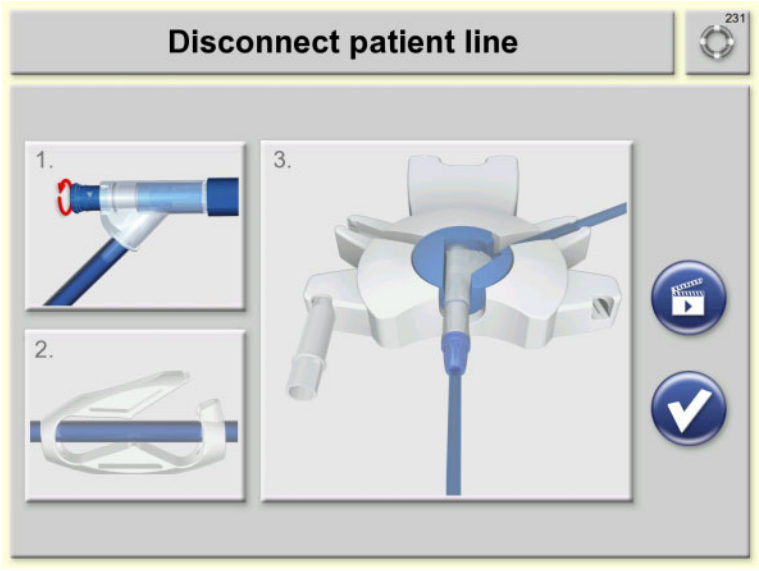
➢ Use aseptic technique when disconnecting the patient connector.

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

Warning

Risk of contamination from non-compliance with hygiene measures

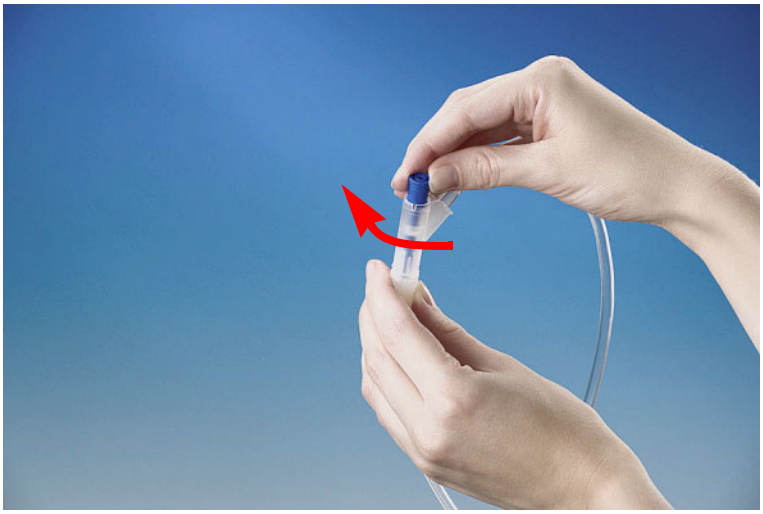
➢ The patient line must be sealed using aseptic technique.



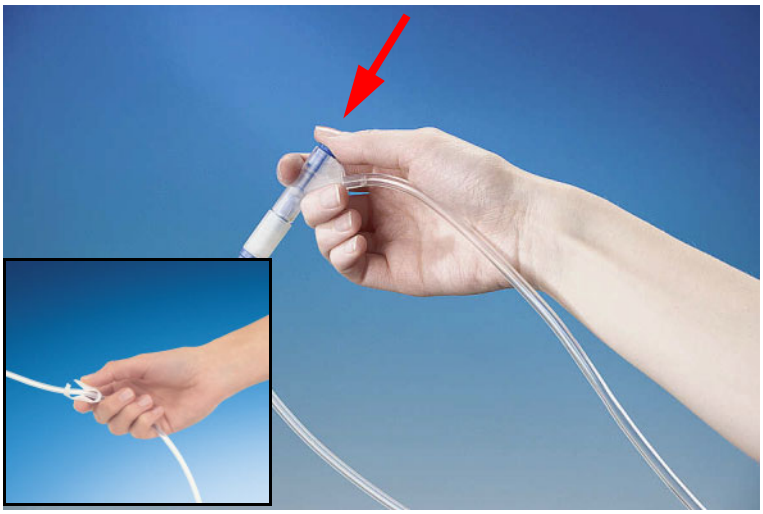
Perform the steps for disconnection as detailed below.

1. Release the PIN
2. Close the clamp
3. Disconnection

➢ The button can be used to replay the screen animation.



➢ Turn the blue knob on the patient connector one quarter of a 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 organiser (if left-handed, place the disinfection cap in the right holder).

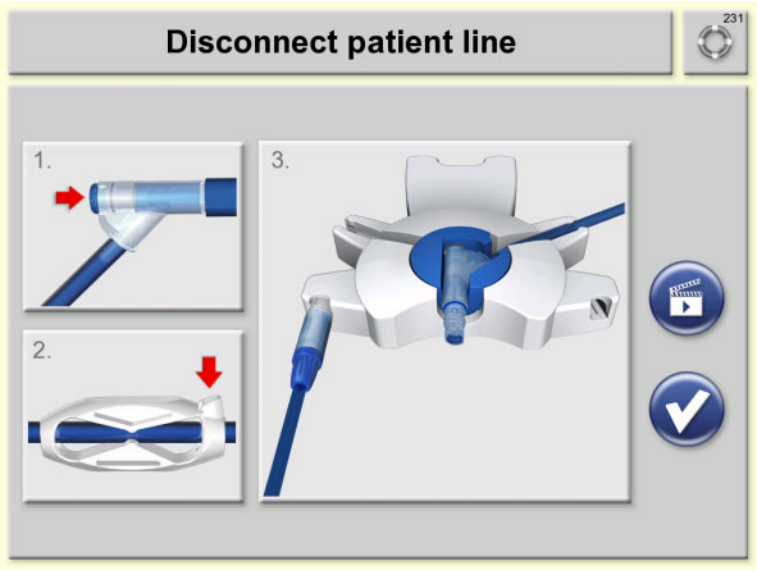
➢ Insert the patient connector into the organiser.

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

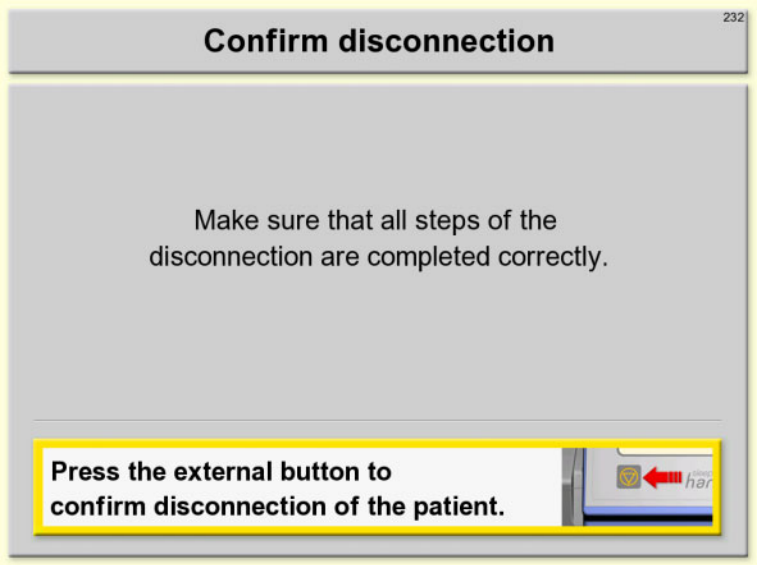
➢ Unscrew the catheter extension system connector from the patient connector on the line set.

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

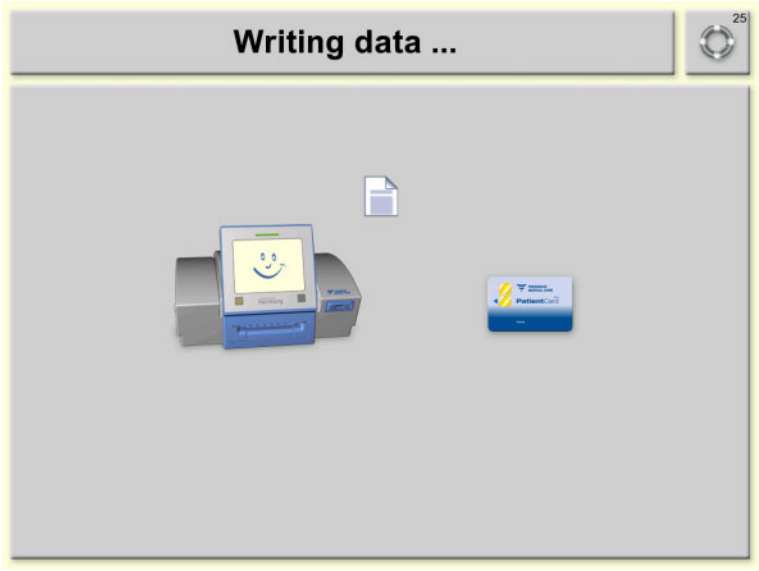
➢ Pull the closed catheter extension straight (without turning it) out of the organizer.



➢ Press the button to confirm that all disconnection steps have been carried out correctly.

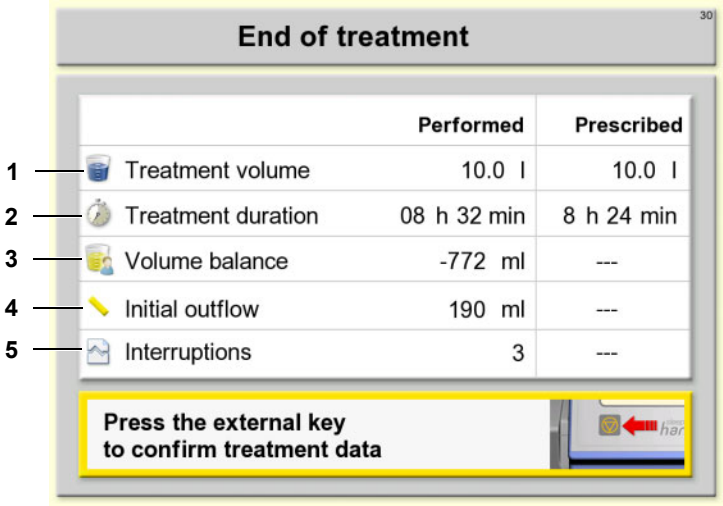


➢ Press the button to confirm the disconnection.



The treatment results will be saved to the patient card or in 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.

4.4.2 Treatment results



➢ The results of the treatment carried out and the prescribed treatment volume and duration are displayed.

1. Total of all inflow volumes plus last inflow
2. Total treatment duration
3. Volume balance without last inflow and without initial outflow
   Negative values describe a weight loss (ultrafiltrate has been generated). Positive values describe a weight gain (resorption).
4. Volume of the initial outflow
5. Number of interruptions

➢ Press the button to confirm the treatment data, to exit the **End of treatment** screen and to move to draining of the line set.

Warning

Patient hazard from insufficient detoxification

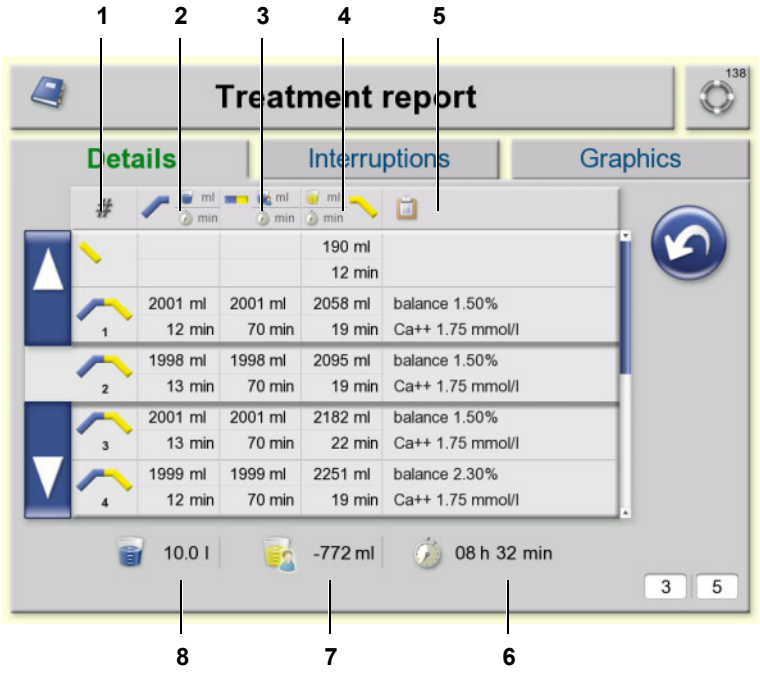
A repeated reduction of the treatment duration or the treatment volume may result in the desired treatment goal not being achieved.

➢ The attending physician must be informed.

➢ Select the **Therapy** menu after draining the line set to obtain more information on the treatment carried out.

➢ Select the **Treatment report** option.

➢ Pressing the button will display the higher-level screen.



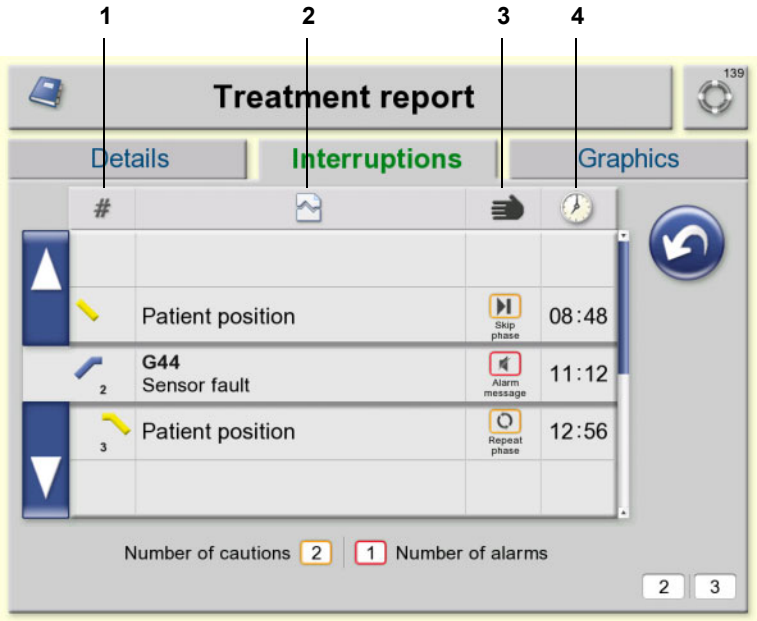
The **Details** tab shows the results of the treatment cycles and the total treatment results.

1. Treatment cycle
2. Inflow volume in ml and inflow duration in minutes
3. Patient volume in ml and dwell duration in minutes
4. Outflow volume in ml and outflow duration in minutes
5. Solutions
6. Total treatment duration in hours and minutes
7. Volume balance in ml
8. Total treatment volume in litres

➢ Select the **Interruptions** tab.

or

➢ Pressing the button will display the higher-level screen.



The **Interruptions** tab shows all the cautions and alarms, the time that they occurred, and the treatment phase during which they occurred.

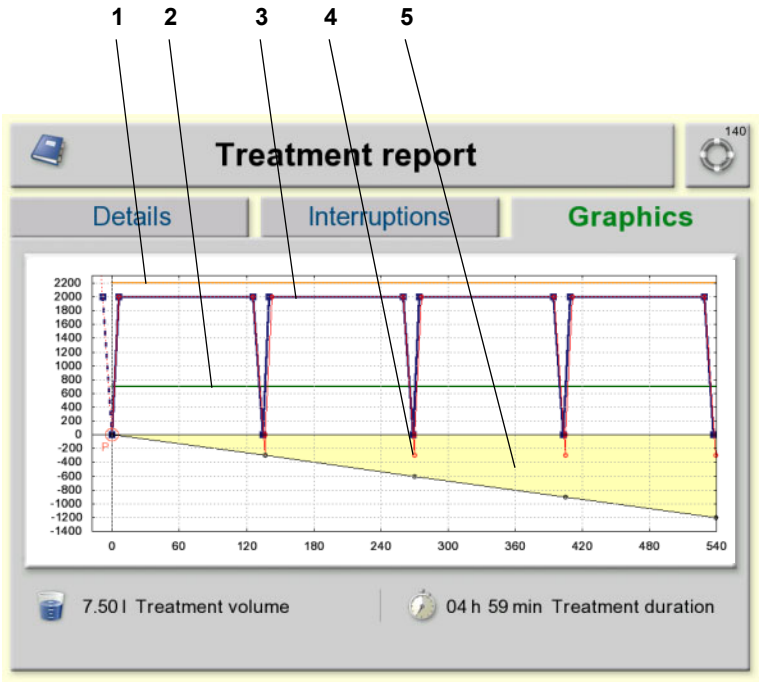
1. Treatment phase and cycle
2. Number and description of the interruption
3. Operator response to the interruption
4. Time when the interruption occurred

The significance of the interruptions is explained in a separate chapter (see chapter 5 on page 183).

➢ Select the **Graphics** tab.

or

➢ Pressing the button will display the higher-level screen.



The **Graphics** tab shows a schematic of the treatment results.

The vertical axis shows the volume in ml and the horizontal axis shows the time in minutes.

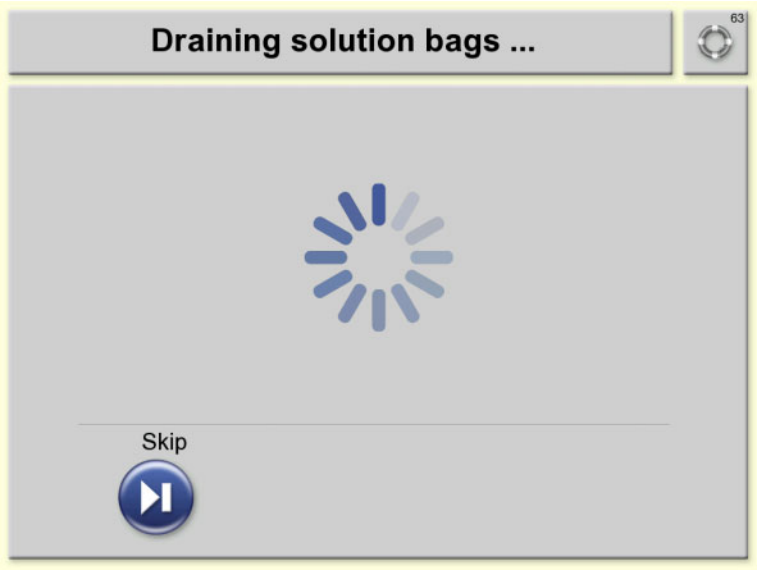
1. Permitted patient volume in ml (orange) (see chapter 7.3.1.1 on page 209)
2. Permitted residual volume in ml (green) (see chapter 7.3.1.2 on page 210)
3. Prescribed volume curve (blue)
4. Actual volume curve (red)
5. Volume removed curve (yellow) (Example of displayed value: -1200 ml indicates a total removed volume of 1200 ml).

➢ Select the **Interruptions** or the **Details** tab.

4.4.3 Draining the line set

Note

Do not place the solution bags above the level of the *sleep•safe harmony*, if draining has been prematurely stopped or has been skipped and there is still fluid left in the solution bags.



The solution bags and the line set are drained automatically.

The *sleep•safe harmony* prepares for removing the *sleep•safe* Set.

➢ The button can be used to skip draining.

The loading tray will open automatically when the automatic draining of the line set has been completed, or if draining was stopped manually.

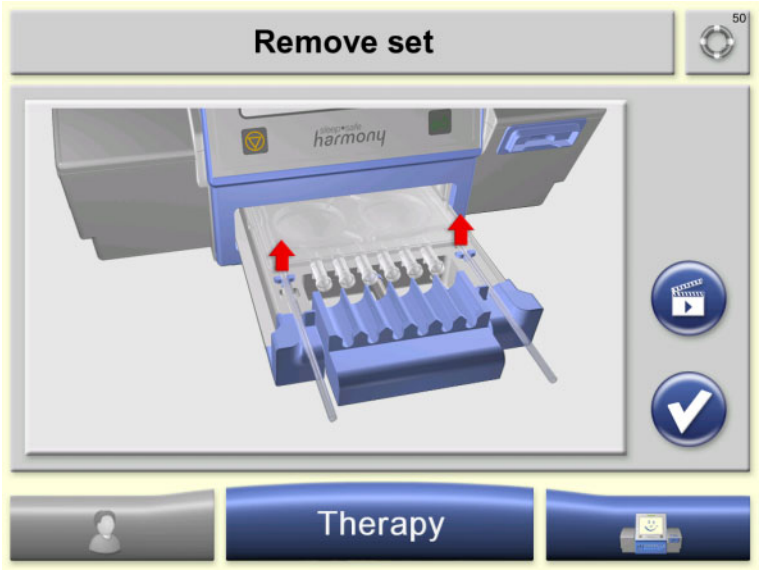
While the loading tray opens, a tone sequence can be heard.

4.4.4 Removing the *sleep•safe* Set

➢ Additional information on the treatment carried out can be called up (see chapter 4.4.2 on page 97).

Note

Do not pull on the solution bag connectors' line as this may damage the *sleep•safe* Set and cause a contamination of the *sleep•safe harmony* with dialysis solution.



➢ Remove the *sleep•safe* Set from the loading tray in a timely manner after draining the solution bags. Pull the patient line and the drain line simultaneously upwards until the lines come off the line holders.

➢ The button can be used to replay the screen animation.

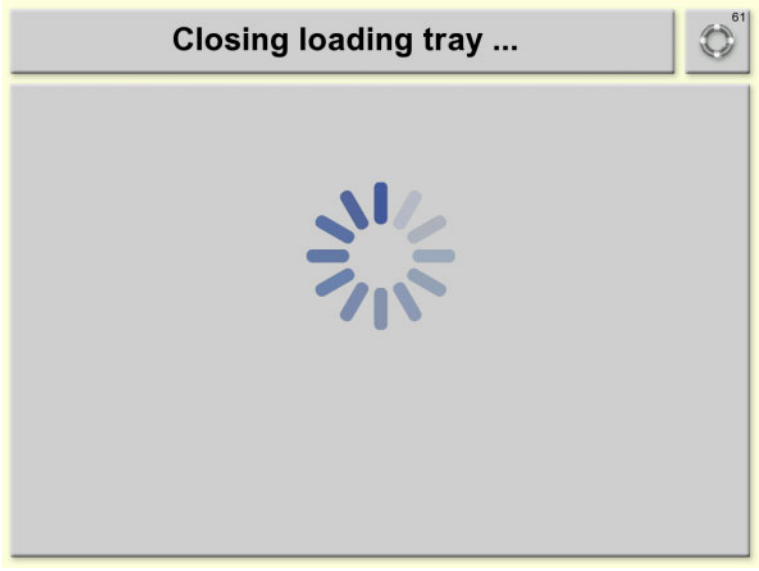
➢ Press the button to confirm the removal of the set.

Warning

Risk of contamination from contaminated consumables

Improper disposal can lead to the transmission of bacteria to third parties (cross-contamination).

➢ The line sets and drain line must be discarded after treatment in compliance with the local regulations for the disposal of potentially contaminated materials.



The loading tray closes.

The *sleep•safe harmony* is checked and switches to standby mode.

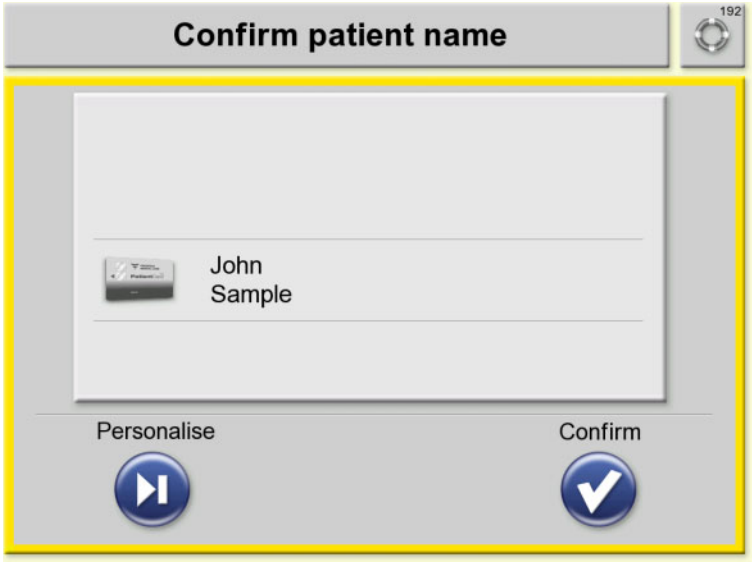
If necessary, the *sleep•safe harmony* can be switched off with the power switch.

➢ Dispose of the *sleep•safe* Set, the solution bags and the drain line system.

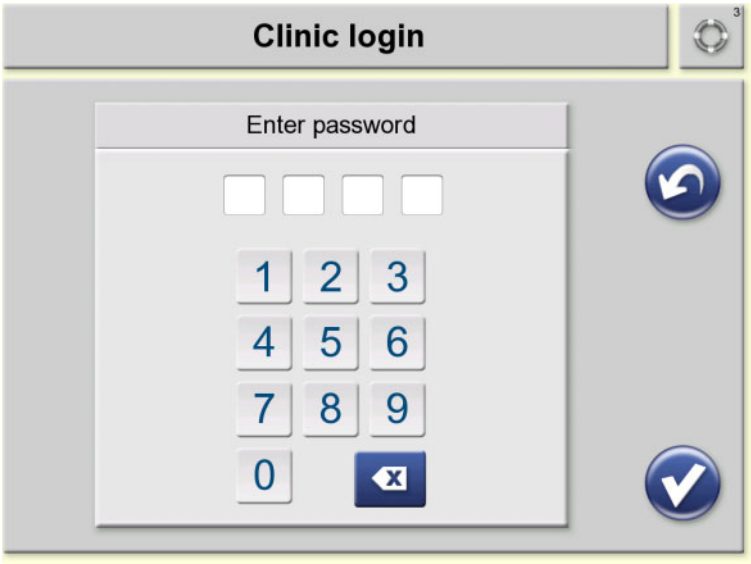
4.5 Special operational features of the *sleep•safe harmony*

4.5.1 Personalising the *sleep•safe harmony* for a patient

When the *sleep•safe harmony*, which has not been personalised, is used for the first time for a patient, the device or the unpersonalised patient card must be configured for the patient.



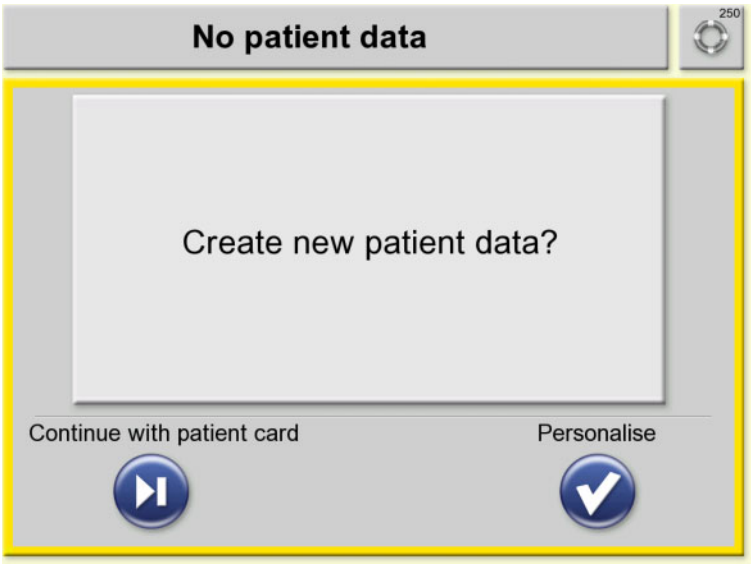
➢ Press the ⏭ button.



➢ Enter the password.

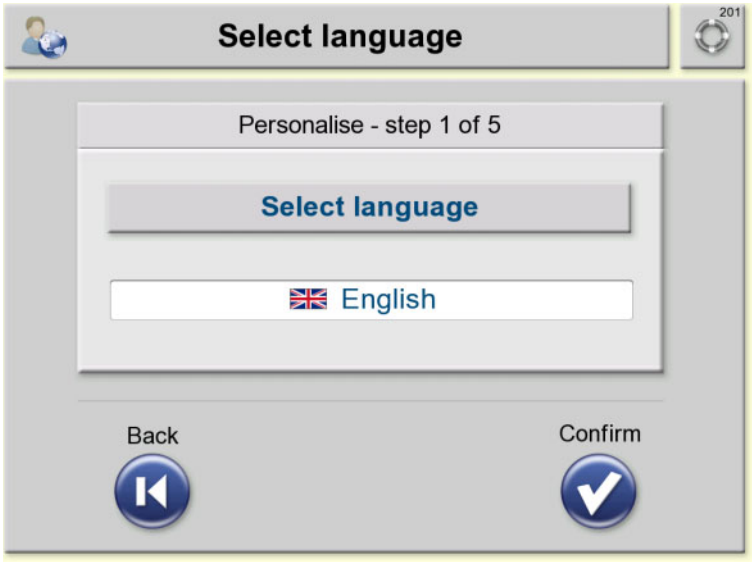
➢ Press the button to confirm the input and to move to the next operating step.

➢ Pressing the button will display the higher-level screen.



➢ Press the button to personalise an unpersonalised patient card.

➢ Press the button to personalise the device.



➢ Press the **Select language** button.

➢ Select the required language.

➢ Press the button to confirm the input and to move to the next operating step.

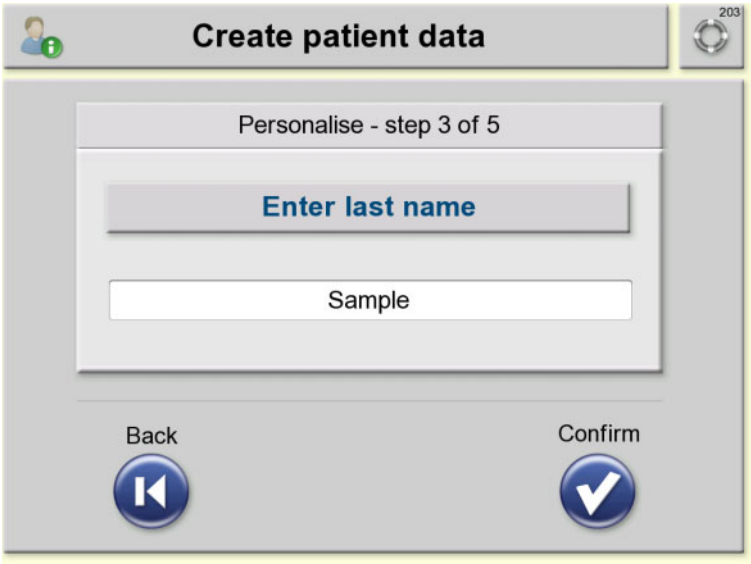
➢ Press the button to return to the previous operating step.

➢ Press the **Enter first name** button.

➢ Enter the first name.

➢ Press the button to confirm the input and to move to the next operating step.

➢ Press the button to return to the previous operating step.

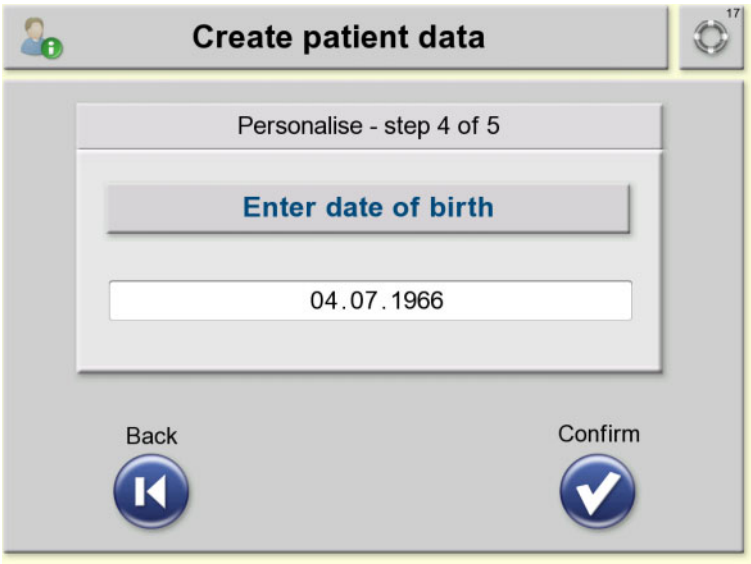


➢ Press the **Enter last name** button.

➢ Enter the last name.

➢ Press the button to confirm the input and to move to the next operating step.

➢ Press the button to return to the previous operating step.

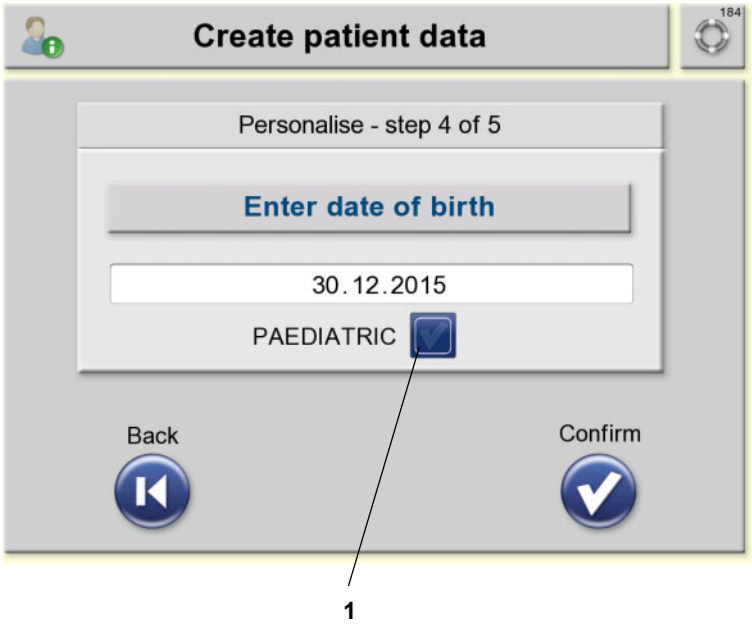


➢ Press the **Enter date of birth** button.

➢ Enter the date of birth.

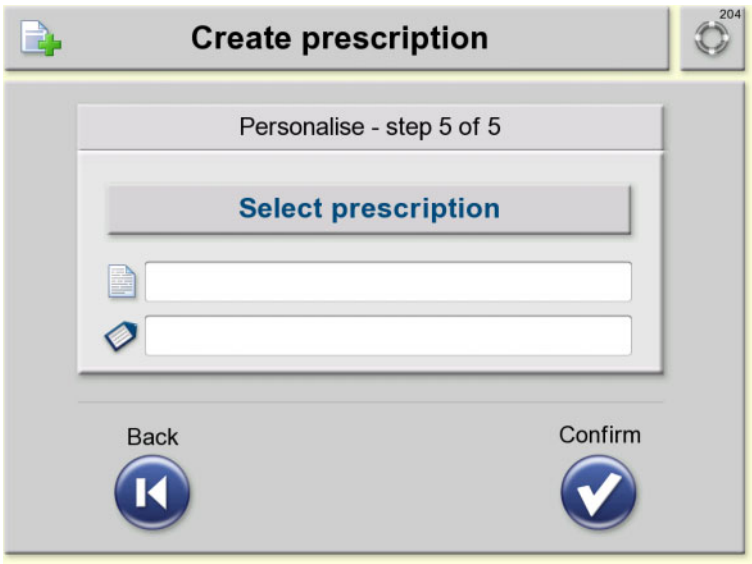
➢ Press the button to confirm the input and to move to the next operating step.

➢ Press the button to return to the previous operating step.



In addition to the date of birth, the option to select the paediatric therapy mode appears, provided that the device has been enabled for paediatric treatment.

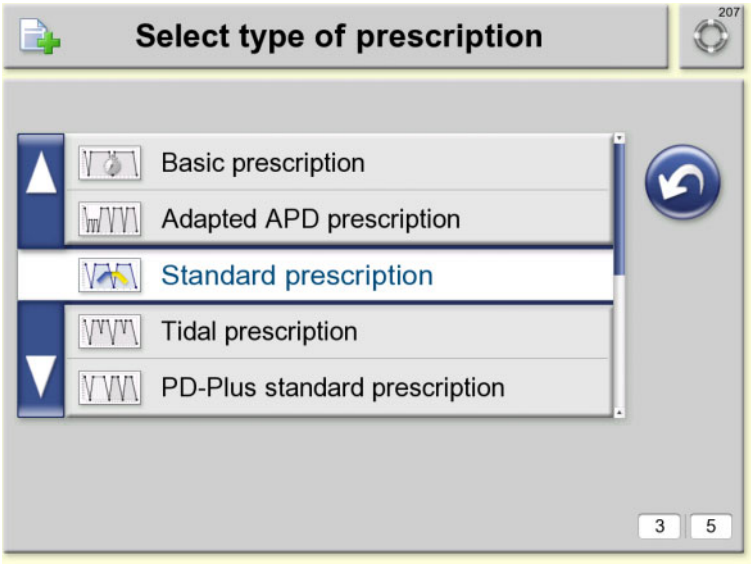
➢ Select **PAEDIATRIC** (1) to activate the paediatric treatment mode.



➢ Press the **Select prescription** button.

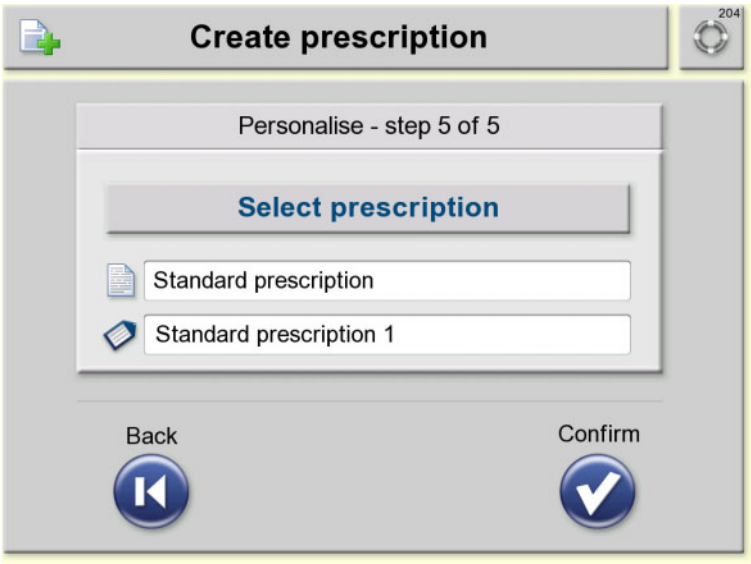
➢ Press the button to confirm the input and to move to the next operating step.

➢ Press the button to return to the previous operating step.



➢ Select the required prescription type.

➢ Pressing the button will display the higher-level screen.



➢ Enter a name for the prescription.

➢ Press the button to confirm the input and to move to the next operating step.

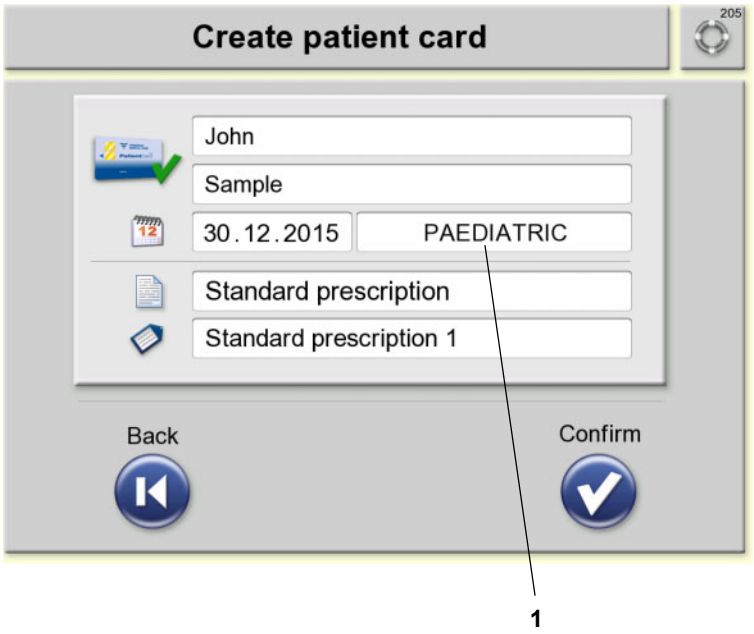
➢ Press the button to return to the previous operating step.

➢ Check all data entered.

➢ Once the data has been confirmed, the personalization is complete and the patient card is assigned to the patient. The first name, last name and date of birth can then no longer be edited on the *sleep•safe harmony*.

➢ Press the button to create a patient card.

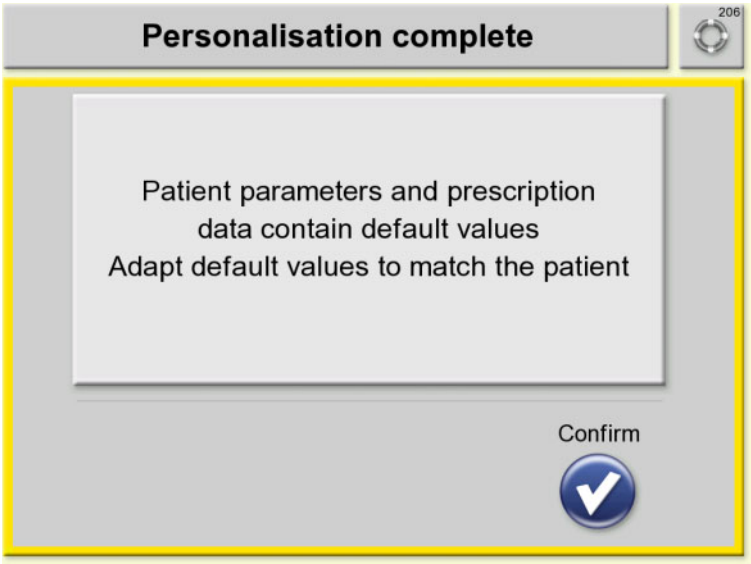
➢ Press the button to return to the previous operating step.



Optionally, if the paediatric therapy mode is selected then **PAEDIATRIC** (1) is displayed next to the date of birth.

➢ Press the button to create a patient card.

➢ Press the button to return to the previous operating step.



➢ Check and edit the patient parameters and the prescription data, if necessary.

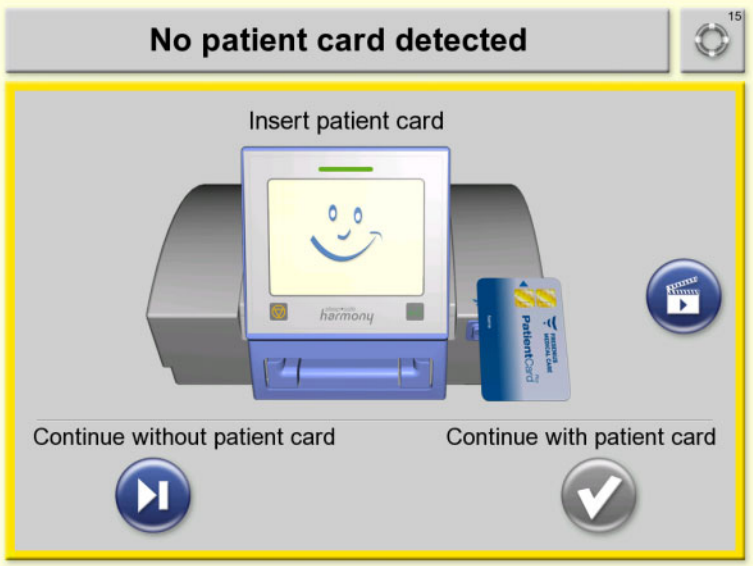
Editing the patient parameters (see chapter 4.6.1.3 on page 124).

Editing the prescription data (see chapter 4.6.2.3 on page 135).

➢ Press the button to create a patient card.

➢ On completion of the treatment or after switching the *sleep•safe harmony* off, the patient data and, depending on the selection, also the prescription data, will be saved to the patient card.

4.5.2 Preparing the *sleep•safe harmony* for a treatment without a patient card



➢ Press the button to start the treatment with a patient card.

or

➢ Press the button to start the treatment without a patient card.

➢ The button can be used to replay the screen animation.

Warning

Patient hazard from overfilling of peritoneal cavity

The use of an incorrect prescription can result in the treatment goal not being achieved.

➢ If the treatment was started without a patient card, the patient name must be confirmed.
If the patient name displayed is not the name of the patient to be treated, start personalization.

➢ Press the button only if you need to personalise the *sleep•safe harmony*.
This will create a patient card with standard values (see chapter 4.5.1 on page 104).

➢ Press the button to confirm the patient name displayed.

4.5.3 Removing the *sleep•safe* Set when starting the device

If the treatment was terminated prematurely or an alarm occurred (see chapter 5.4 on page 187) without removing the *sleep•safe* Set, the *sleep•safe* Set can be removed as described below after restarting the device.

➢ Press the button (1) on the right at the bottom of the screen to open the loading tray.

➢ Press the button to confirm the opening of the loading tray.

Note

Do not pull on the solution bag connectors' line as this may damage the *sleep•safe* Set and cause a contamination of the *sleep•safe harmony* with dialysis solution.

➢ Remove the *sleep•safe* Set from the loading tray. Pull the patient line and the drain line simultaneously upwards until the lines come off the line holders.

➢ Press the button to close the loading tray and to switch the *sleep•safe harmony* to standby mode.

Warning

Risk of contamination from contaminated consumables

Improper disposal can lead to the transmission of bacteria to third parties (cross-contamination).

➢ The line sets and drain line must be discarded after treatment in compliance with the local regulations for the disposal of potentially contaminated materials.

4.5.4 Disconnection after premature termination of a treatment

Warning

Risk of contamination from non-compliance with hygiene measures

Improper handling during disconnection can lead to touching the opening of the patient connector.
Contamination can result.

➢ Wearing a face mask and hand disinfection is recommended.

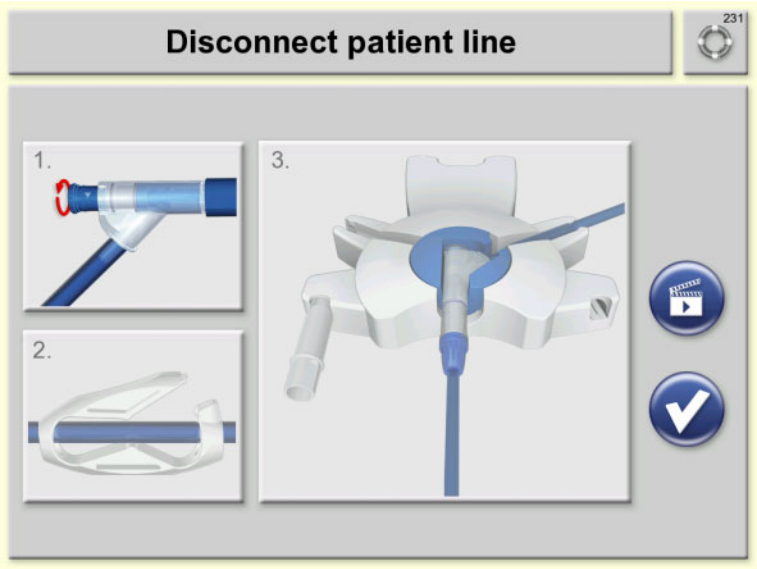
➢ Use aseptic technique when disconnecting the patient connector.

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

Warning

Risk of contamination from non-compliance with hygiene measures

➢ The patient line must be sealed using aseptic technique.

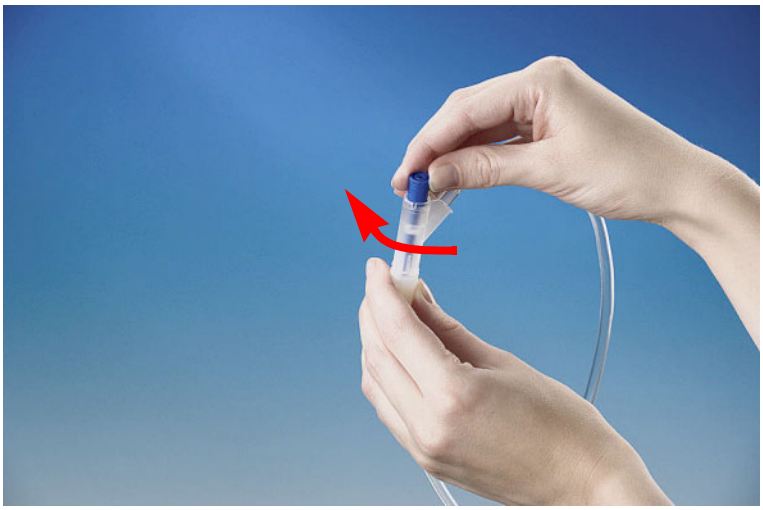


This screen message will only be displayed if treatment has been prematurely terminated and the patient has not been disconnected.

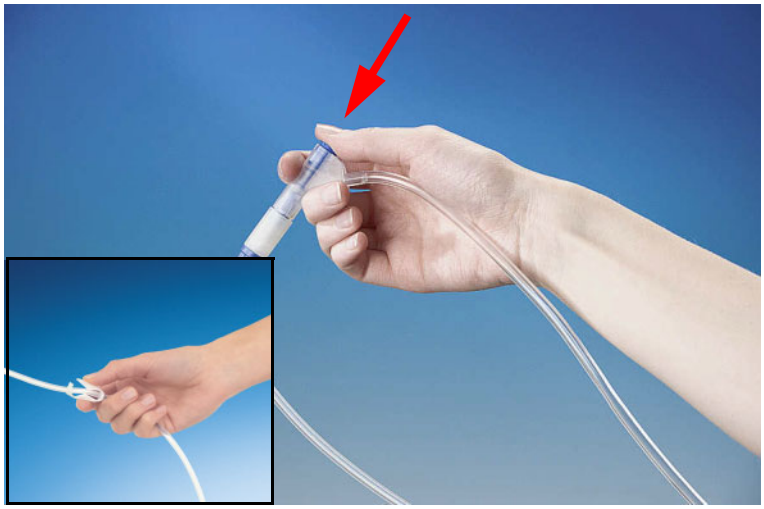
Perform the steps for disconnection as detailed below.

1. Release the PIN
2. Close the clamp
3. Disconnection

➢ The button can be used to replay the screen animation.



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



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

The catheter extension will automatically be closed by the PIN.

➢ Close the white clamp on the catheter extension.

➢ Open the overwrap of the new disinfection cap.

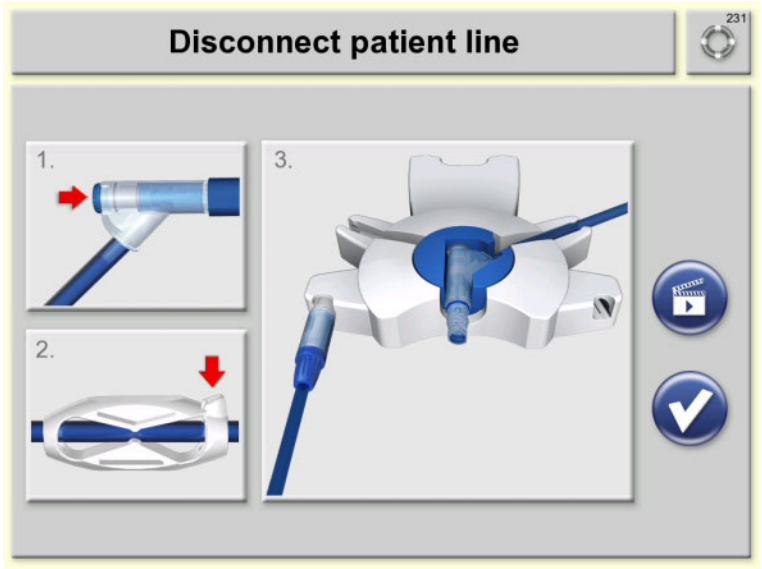
➢ Place the new disinfection cap in the left holder of the organiser (if left-handed, place the disinfection cap in the right holder).

➢ Insert the patient connector into the organiser.

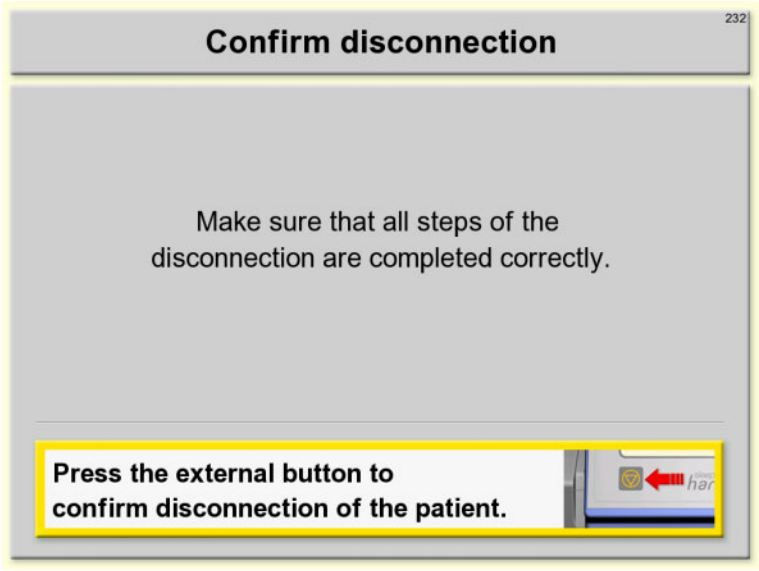
➢ Unscrew and discard the closing cap of the new disinfection cap.

➢ Unscrew the catheter extension from the patient connector of the *sleep•safe* Set and immediately screw the catheter extension with the PIN onto the new disinfection cap.

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



➢ Press the button to confirm that all disconnection steps have been correctly completed.



➢ Press the ▽ button to confirm the disconnection.

4.5.4.1 Turning the *sleep•safe harmony* off

➢ Press the ⏻ key.

The *sleep•safe harmony* will turn off after approx. 5 seconds.

4.6 Options / changing data prior to treatment

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 following must be observed when entering parameters:

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

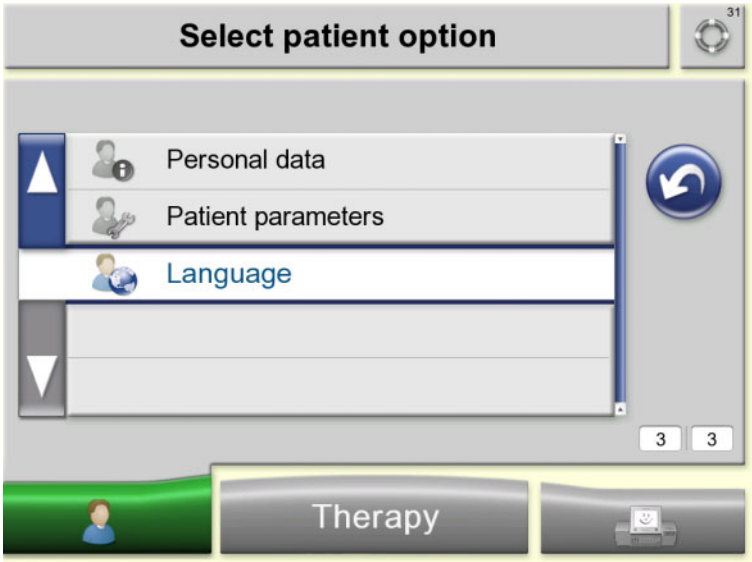
– If the check reveals a deviation between the required parameters and the parameters displayed on the device, the setting must be corrected before activating the function.

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

4.6.1 Patient options

4.6.1.1 Selecting the language

➢ Select the menu.



➢ Select **Language**.

➢ Pressing the button will display the higher-level screen.

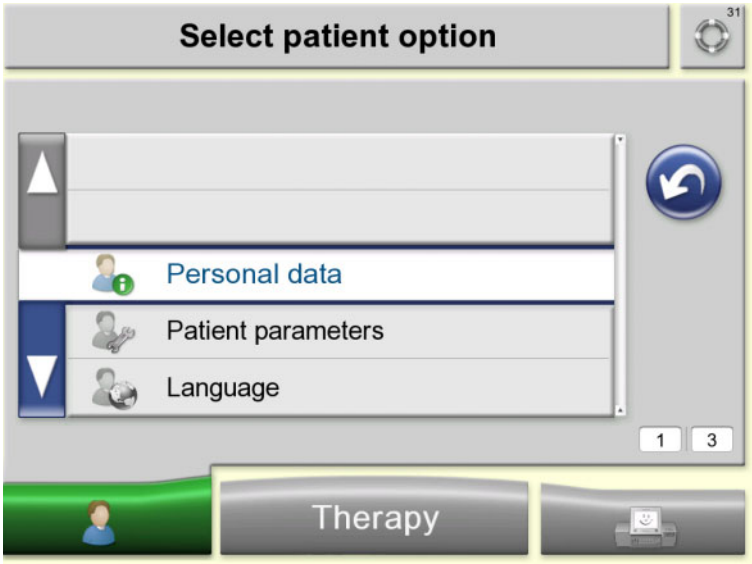
➢ Select the required language.

➢ Pressing the button will display the higher-level screen.

4.6.1.2 Editing personal data

This function can only be accessed by the clinical staff.

➢ Select the menu.



➢ Select **Personal data**.

➢ Pressing the button will display the higher-level screen.

The following **Personal data** will be displayed:
– First name
– Last name
– Date of birth

The following **Personal data** can be edited:
– Gender
– Weight

➢ Pressing the button will display the higher-level screen.

4.6.1.3 Editing patient parameters

This function can only be accessed by the clinical staff.

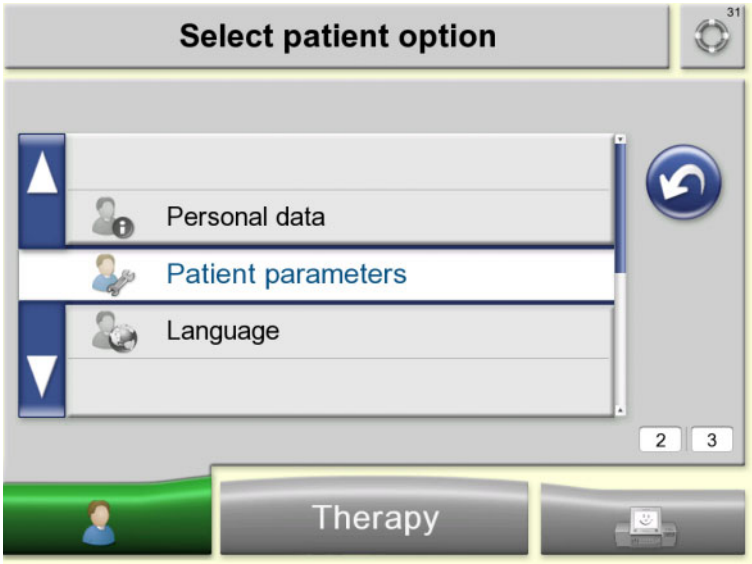
If patient parameters are restricted, the prescriptions will automatically be adapted to the new patient parameters.

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.

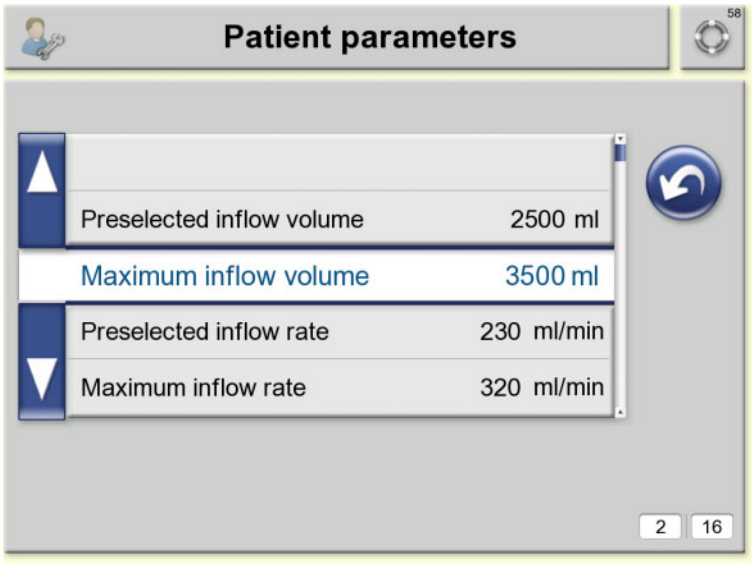
The following patient parameters can be set:
- Preselected inflow volume
- Maximum inflow volume
- Preselected inflow rate
- Maximum inflow rate
- Preselected outflow rate
- Maximum outflow rate
- Preselected dwell duration
- Maximum dwell duration
- Permitted patient volume (see chapter 7.3.1.1 on page 209)
- Permitted residual volume (see chapter 7.3.1.2 on page 210)
- Permitted dwell duration reduction (see chapter 7.3.2.1 on page 211)
- Permitted inflow volume reduction (see chapter 7.3.1.3 on page 210)
- Catheter performance (see chapter 7.3.2.2 on page 212)
- Therapy mode (see chapter 7.3.3 on page 212)
- Additional outflow (see chapter 7.3.4 on page 213)
- Access level

➢ Select the menu.



➢ Select **Patient parameters**.

➢ Pressing the button will display the higher-level screen.

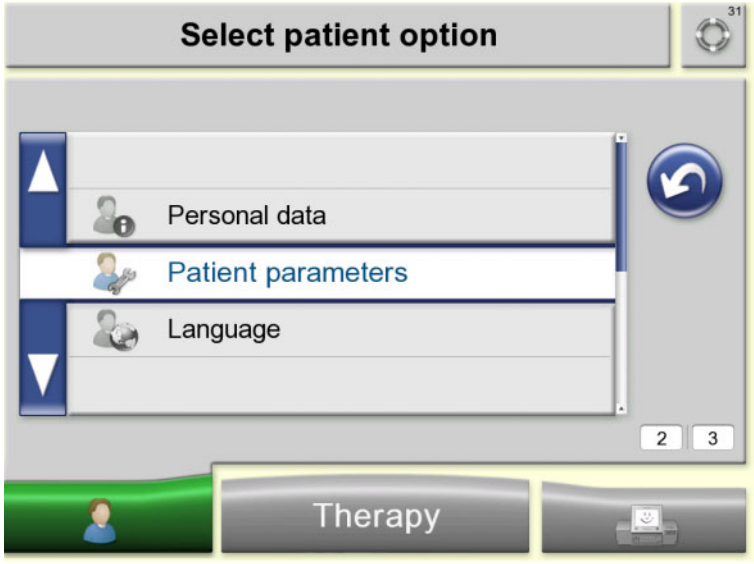


The preselected and maximum **Patient parameters** can be selected and edited.

➢ Pressing the button will display the higher-level screen.

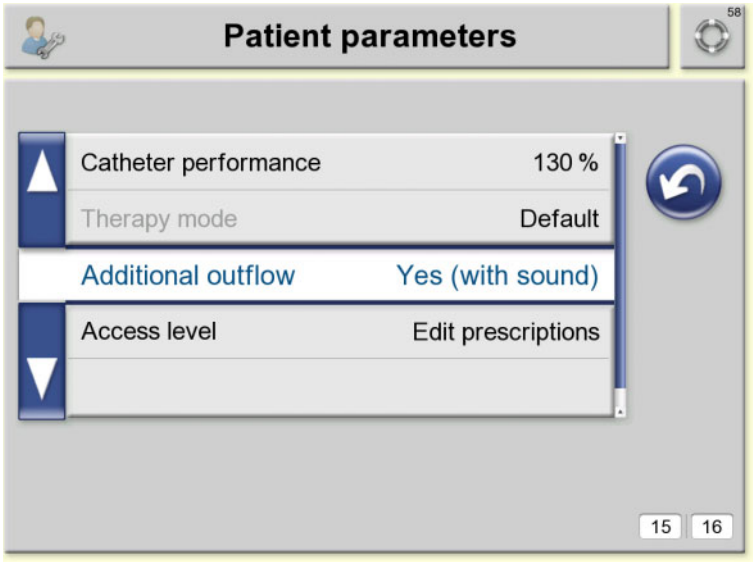
4.6.1.4 Changing the additional outflow

➢ Select the menu.



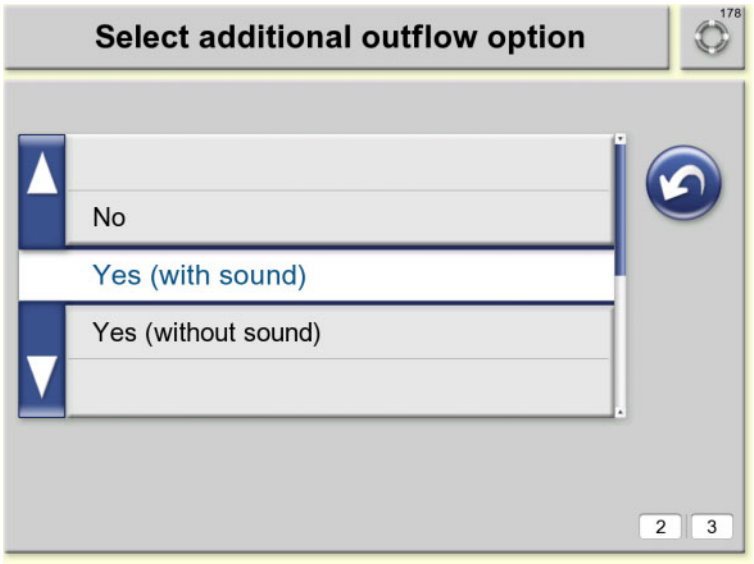
➢ Select **Patient parameters**.

➢ Pressing the button will display the higher-level screen.



➢ Select **Additional outflow**.

➢ Pressing the button will display the higher-level screen.



➢ The following options can be set for the last outflow:

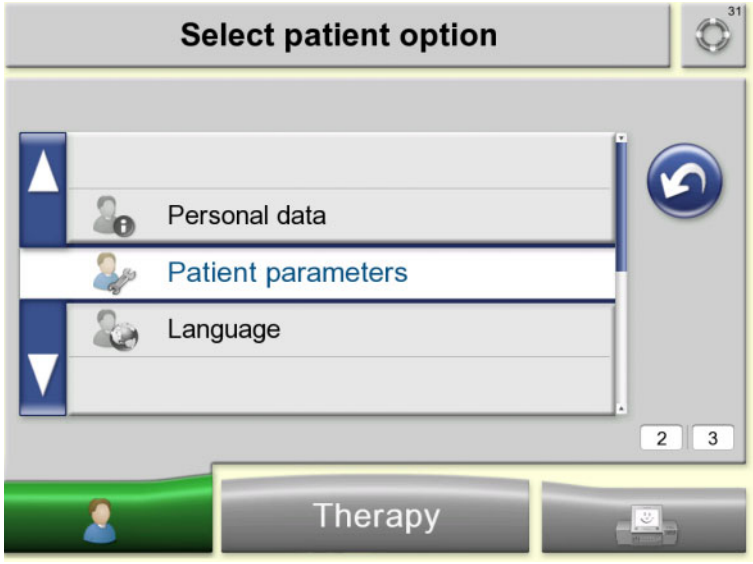
Additional outflow:
– No
– Yes (with sound)
– Yes (without sound)

Selecting the option Yes (without sound) initiates a treatment pause. Confirming the treatment pause continues the treatment.
Further information on the additional outflow is available (see chapter 7.3.4 on page 213).

➢ Pressing the button will display the higher-level screen.

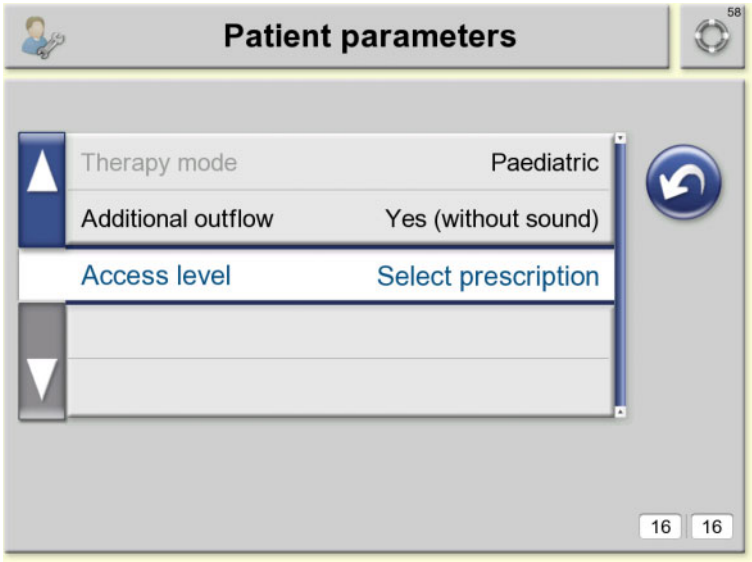
4.6.1.5 Access levels

➢ Select the menu.



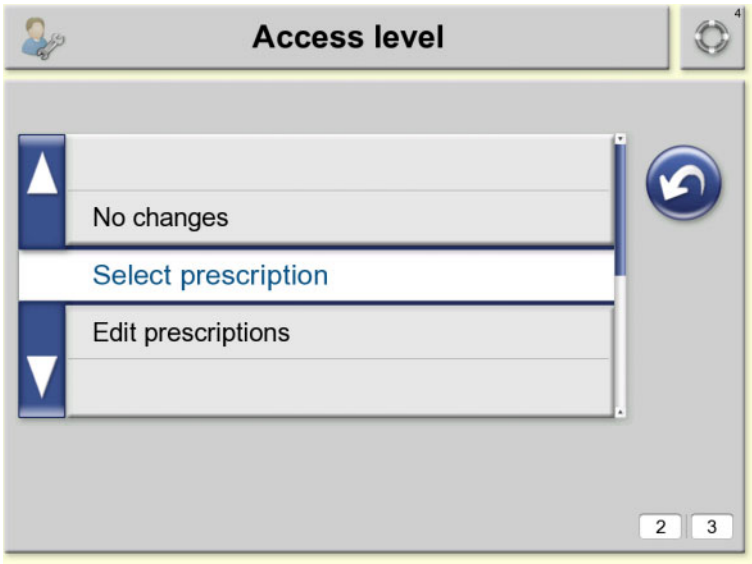
➢ Select **Patient parameters**.

➢ Pressing the button will display the higher-level screen.



➢ Select **Access level**.

➢ Pressing the button will display the higher-level screen.



➢ The following **Access levels** can be selected:
- No changes
- Select prescription
- Edit prescription

➢ Pressing the button will display the higher-level screen.

4.6.2 Therapy options

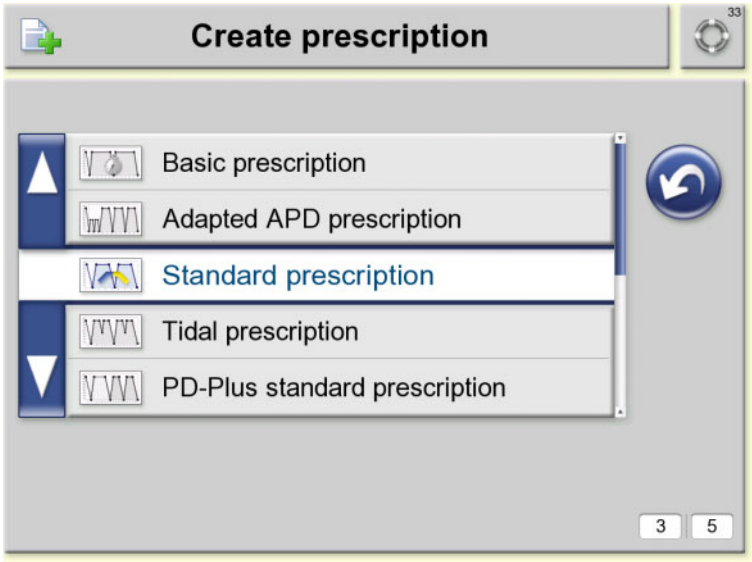
4.6.2.1 Creating a prescription

➢ Select the **Therapy** menu.

➢ Select **Create prescription**.

A maximum of nine prescriptions can be stored in the *sleep•safe harmony*. If this number is exceeded, an appropriate screen message will be displayed.

➢ Pressing the button will display the higher-level screen.



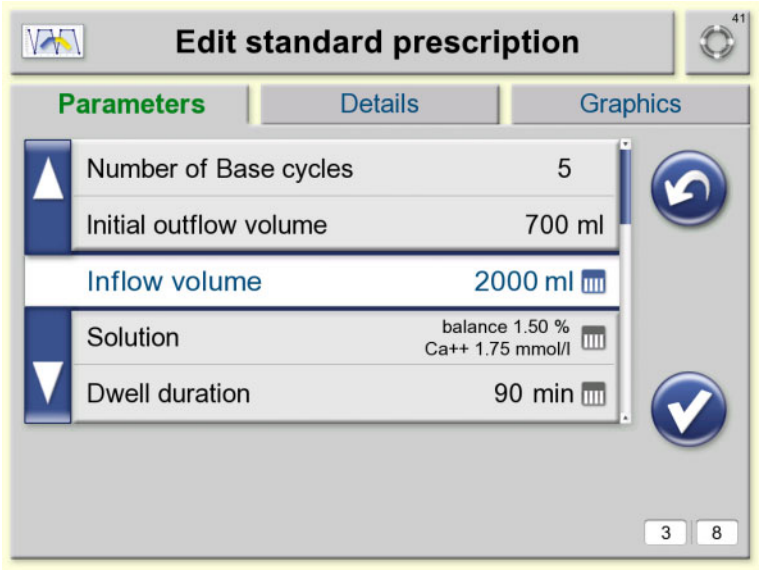
➢ Select the prescription to be created.

➢ Pressing the button will display the higher-level screen.

➢ Enter the name for the prescription.

➢ Press the button to confirm the change.

➢ Press the button to discard the change.



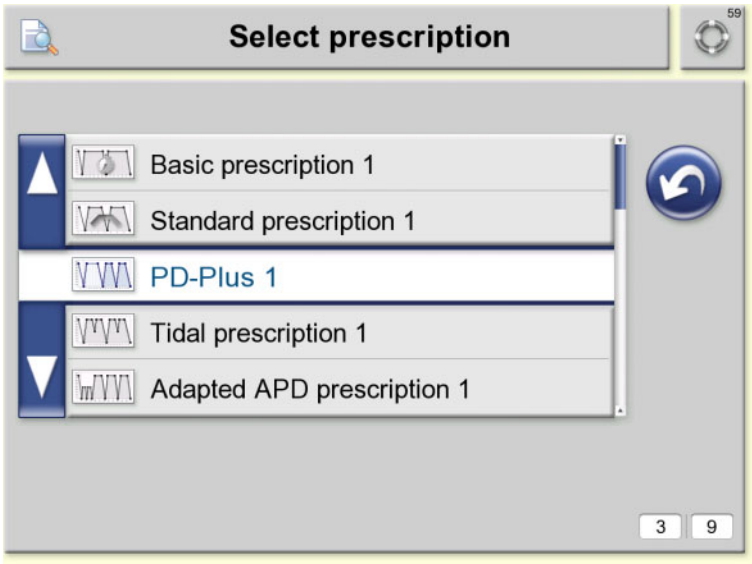
➢ Enter the parameters for the new prescription you have created.

4.6.2.2 Selecting a prescription

➢ Select the **Therapy** menu.

➢ Press **Select prescription** to display the prescriptions available for selection.

➢ Pressing the button will display the higher-level screen.



➢ Select the required prescription.

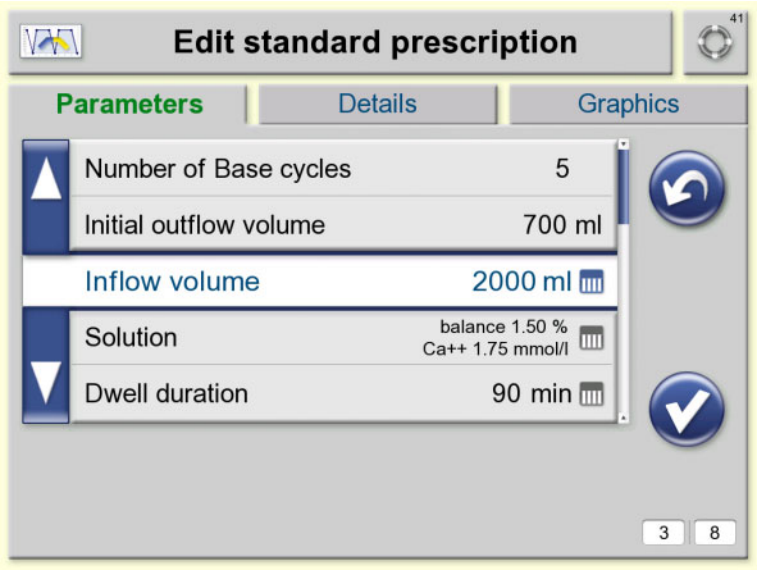
➢ Pressing the button will display the higher-level screen.

4.6.2.3 Editing a prescription

➢ Select the **Therapy** menu.

➢ Select **Edit prescription**.

➢ Pressing the button will display the higher-level screen.



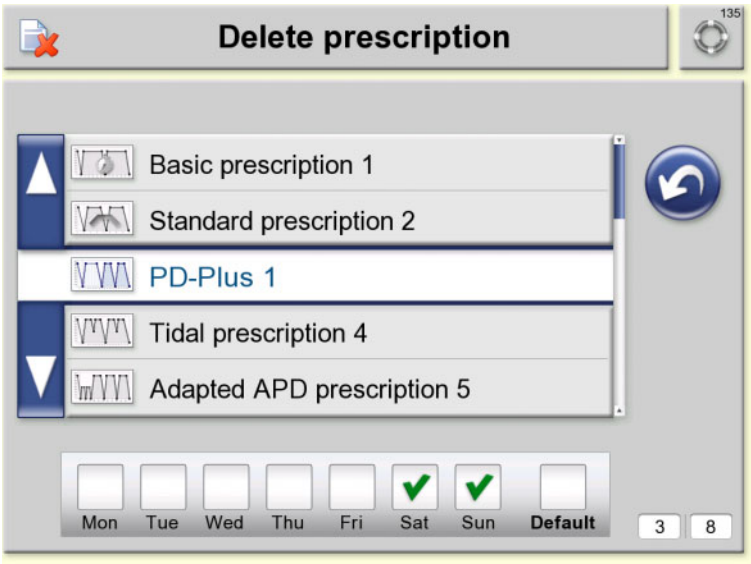
➢ Enter the parameters for the prescription to be edited (see chapter 3.4 on page 46).

4.6.2.4 Deleting a prescription

➢ Select the **Therapy** menu.

➢ Select **Delete prescription**.

➢ Pressing the button will display the higher-level screen.



➢ Select the prescription to be deleted.

➢ Press the selected prescription to delete this prescription.

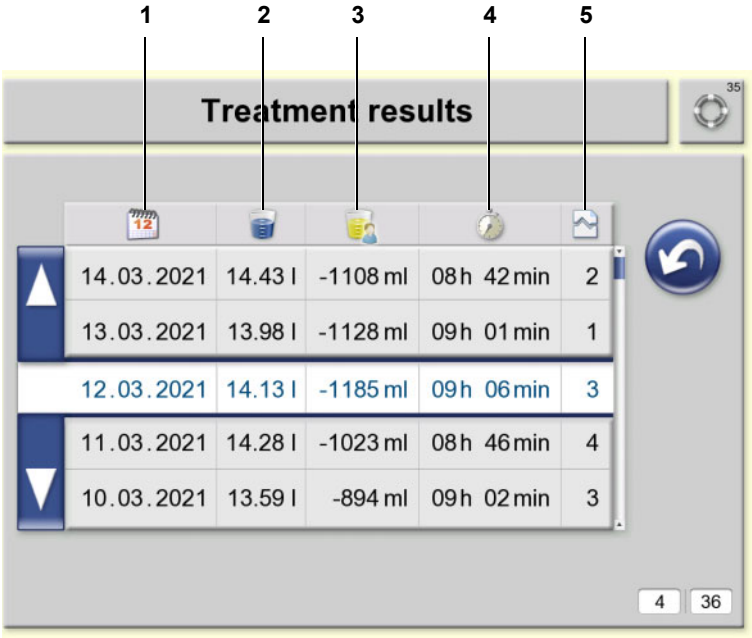
➢ Pressing the button will display the higher-level screen.

The currently selected prescription cannot be deleted.
The default prescription cannot be deleted.
In order to be able to delete this prescription, a different prescription must be selected as the default prescription.

4.6.2.5 Displaying treatment reports

➢ Select **Show treatment reports**.

➢ Pressing the button will display the higher-level screen.

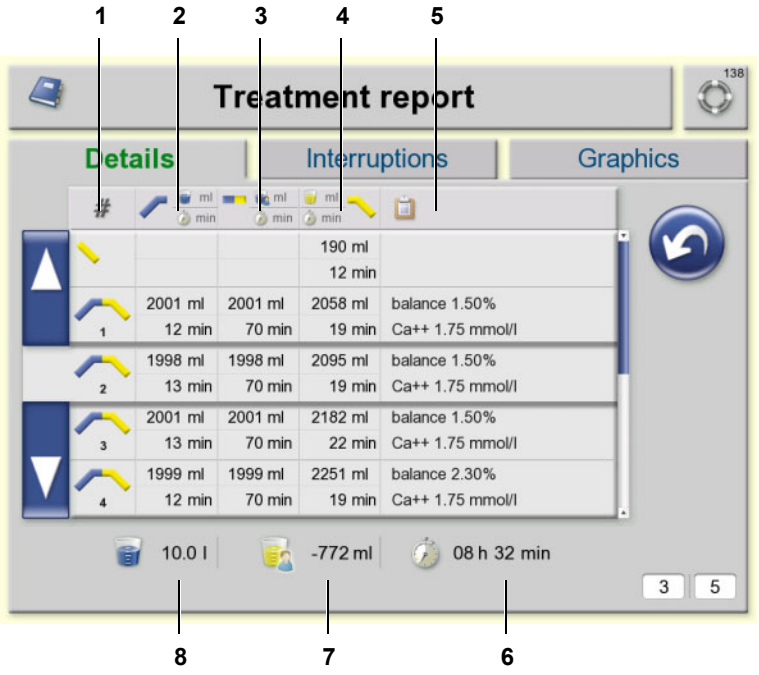


A list of the last treatments is displayed.

1. Start of treatment date
2. Total of all inflow volumes plus last inflow
3. Volume balance
   Volume balance without last inflow and initial outflow. Negative values describe a weight loss (ultrafiltrate has been generated). Positive values describe a weight gain (resorption).
   (Example of displayed value: -1000 ml indicates a total removed volume of 1000 ml).
4. Total treatment duration
5. Number of interruptions

➢ Select a treatment to view further details.

➢ Pressing the button will display the higher-level screen.



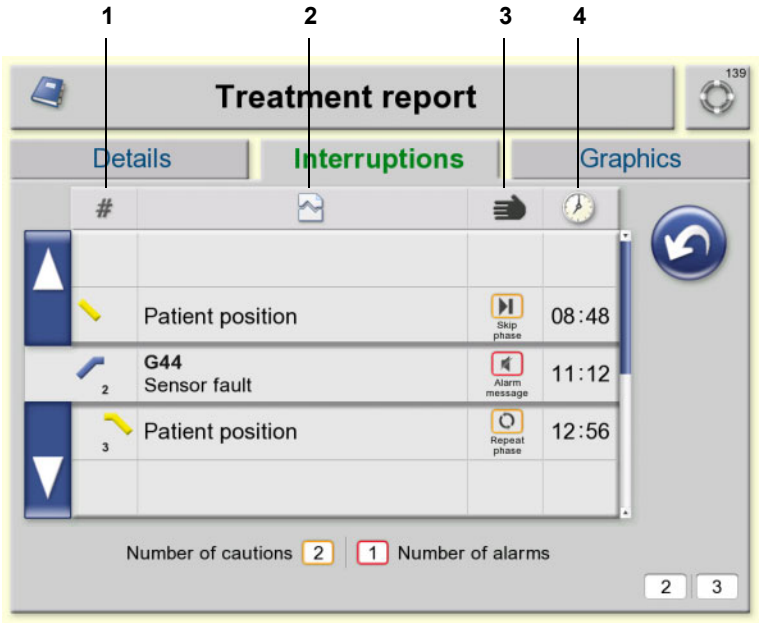
The **Details** tab shows the results of the treatment cycles and the total treatment results.

1. Treatment cycle
2. Inflow volume in ml and inflow duration in minutes
3. Patient volume in ml and dwell duration in minutes
4. Outflow volume in ml and outflow duration in minutes
5. Solutions
6. Total treatment duration in hours and minutes
7. Volume balance in ml
8. Total treatment volume in litres

➢ Select the **Interruptions** tab.

or

➢ Pressing the button will display the higher-level screen.



The **Interruptions** tab shows all the cautions and alarms, the time that they occurred, and the treatment phase during which they occurred.

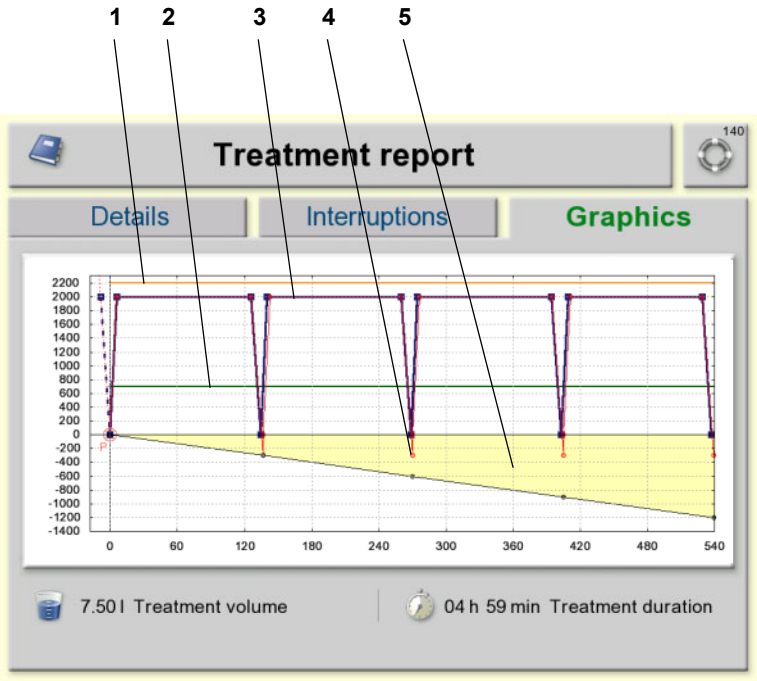
1. Treatment phase and cycle
2. Number and description of the interruption
3. Operator response to the interruption
4. Time when the interruption occurred

The significance of the interruptions is explained in a separate chapter (see chapter 5 on page 183).

➢ Select the **Graphics** tab.

or

➢ Pressing the button will display the higher-level screen.



The **Graphics** tab shows a schematic of the treatment results.

The vertical axis shows the volume in ml and the horizontal axis shows the time in minutes.

1. Permitted patient volume in ml (orange) (see chapter 7.3.1.1 on page 209)
2. Permitted residual volume in ml (green) (see chapter 7.3.1.2 on page 210)
3. Prescribed volume curve (blue)
4. Actual volume curve (red)
5. Volume removed curve (yellow) (Example of displayed value: -1200 ml indicates a total removed volume of 1200 ml).

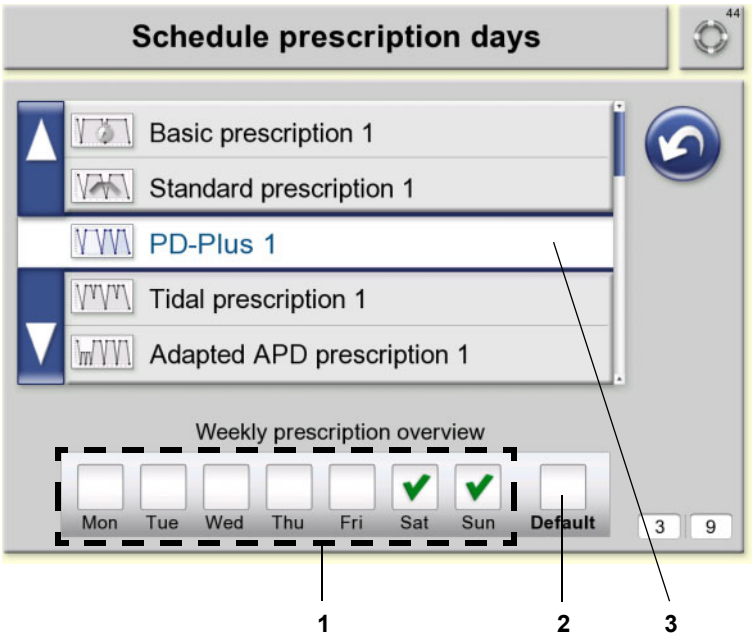
➢ Select the **Interruptions** or the **Details** tab.

4.6.2.6 Editing the prescription schedule

➢ Select the **Therapy** menu.

➢ Select **Edit prescription schedule**.

➢ Pressing the button will display the higher-level screen.



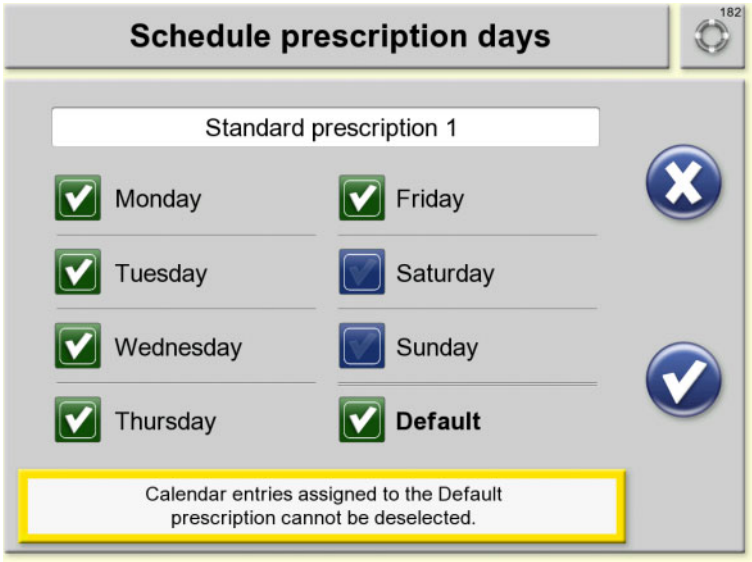
The treatment days of the prescription in the highlighted line in the center (3) are indicated by a green checkmark in the weekly overview (1).

If the standard prescription is selected, this is indicated in the Default field (2) by a green checkmark.

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

➢ Select the prescription for which the weekdays are to be defined.

➢ Pressing the button will display the higher-level screen.



➢ Select the days of the week on which the selected prescription is to be performed.

➢ If the selected prescription is to be used as the standard prescription, also select the **Default** check box.

➢ Press the button to confirm the data entered.

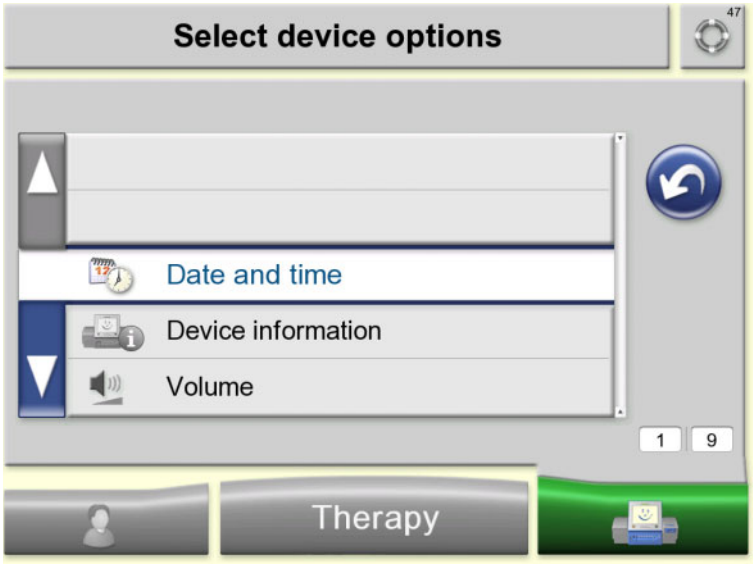
➢ Press the button to discard the change.

4.6.3 Device options

4.6.3.1 Setting the date and time

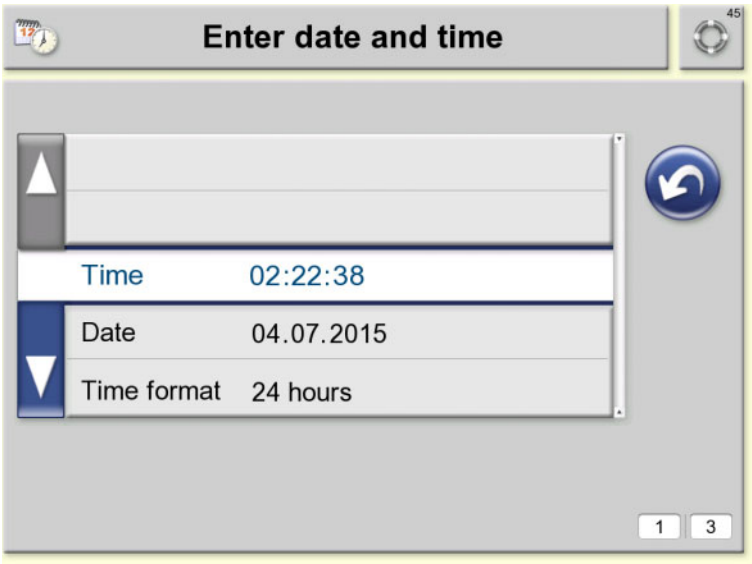
Date and time can only be set when no treatment is being performed.

➢ Select the menu.



➢ Select **Date and time**.

➢ Pressing the button will display the higher-level screen.



➢ Select **Date**, **Time** or **Time format** and set the date, the time or the time format.

➢ Press the button to confirm the change.

➢ Pressing the button will display the higher-level screen.

4.6.3.2 Relocating the *sleep•safe harmony* within a building

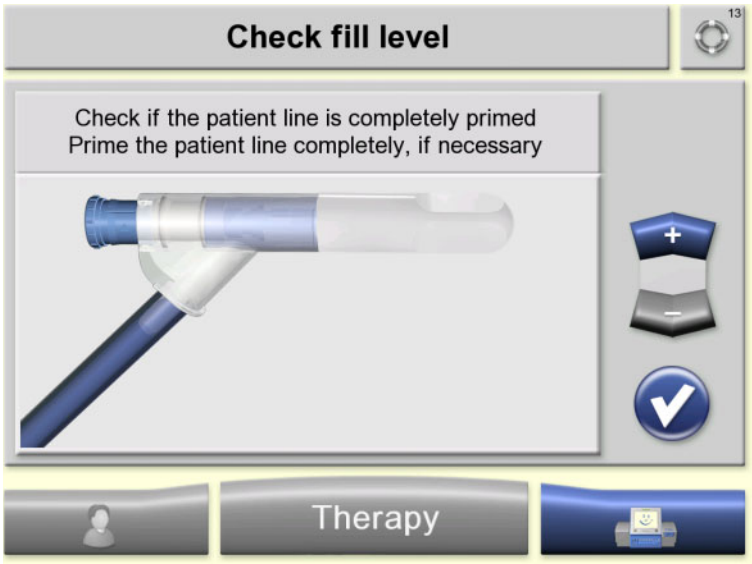
During preparation, after the line set has been automatically primed, the device can be set to relocation mode, to move the device to a different location. This allows the preparation of the device and the treatment of the patient to take place in different rooms (see chapter 10.1.2 on page 232).

Note

The **Relocate device** function is only possible with a *sleep•safe* Set Plus and *sleep•safe* Set Paed.

Note

The **Relocate device** function is only possible with the porter.

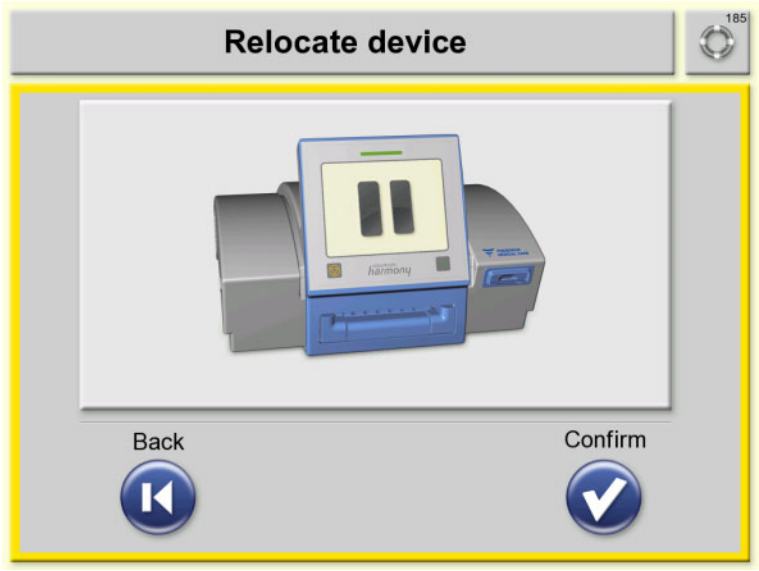


➢ Select the menu.

➢ Select **Relocate device**.

➢ Pressing the button will display the higher-level screen.

The Relocate device function can only be selected at this point.



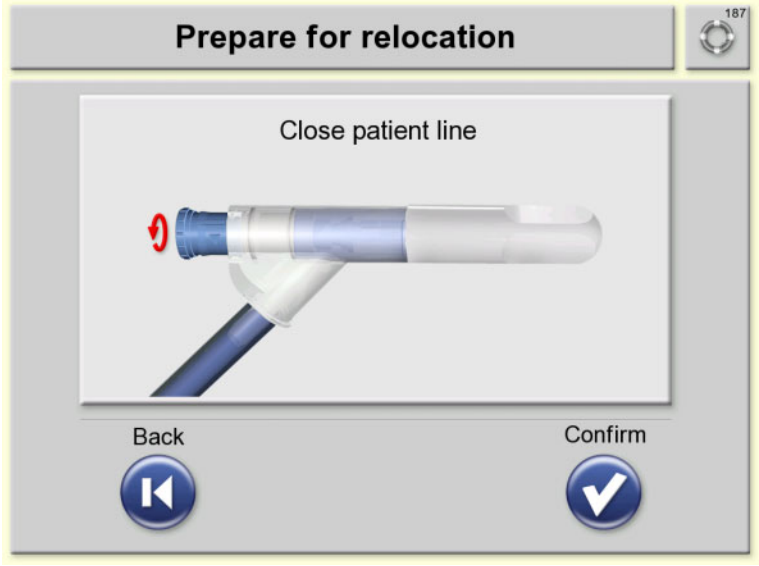
➢ Press the button to confirm relocation.

➢ Press the button to return to the previous operating step.

Warning

Risk of contamination from non-compliance with hygiene measures

➢ The patient line must be sealed using aseptic technique.

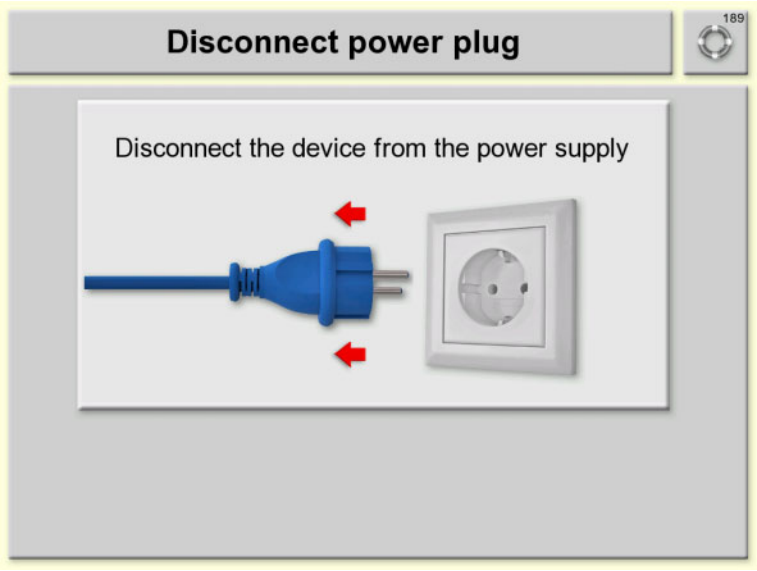


➢ Seal the patient line by releasing the PIN.

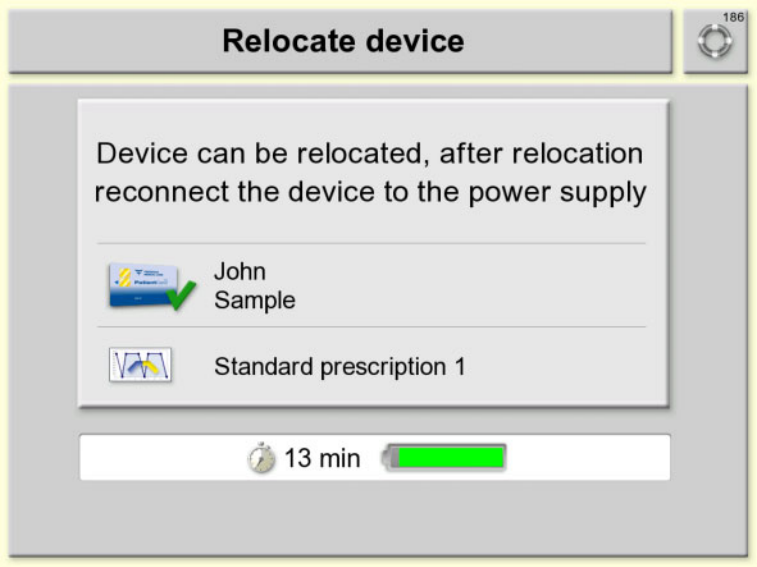
➢ Press the button to confirm that the patient line is sealed.

➢ Insert the unsealed patient connector into the organiser.

➢ Press the button to return to the previous operating step.



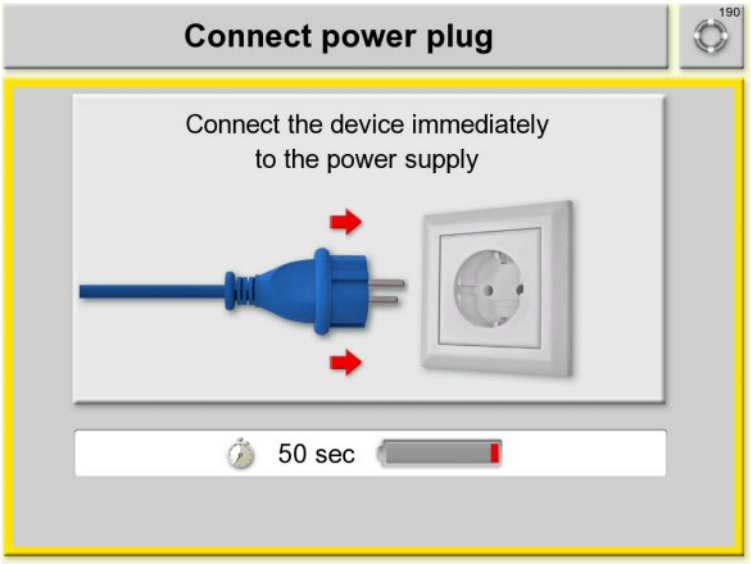
➢ Disconnect the *sleep•safe harmony* from the power supply.



➢ The *sleep•safe harmony* can now be moved to a different location.

➢ Depending on the charging status of the battery, but at the latest after 15 minutes, the *sleep•safe harmony* must be reconnected to the power supply.

The remaining time is displayed on the bottom of the screen.



If the *sleep•safe harmony* has not been reconnected to the power supply, the screen on the left will be displayed.

➢ The *sleep•safe harmony* must now be connected to the power supply immediately, as the *sleep•safe harmony* will otherwise shut down.

Preparation for treatment can be continued.

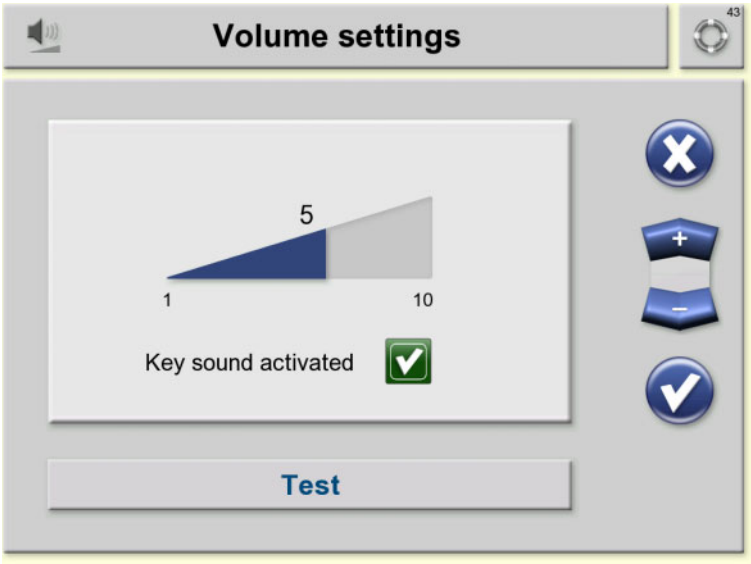
➢ Press the button to confirm the patient name and the prescription.

4.6.3.3 Setting the volume

➢ Select the menu.

➢ Select **Volume**.

➢ Pressing the button will display the higher-level screen.



➢ Select the required volume for all the sounds (except audible alarms).

➢ Press the **Test** button to test the sound volume you have set.

➢ If the **Key sound activated** option is selected, this is indicated by a checkmark. The device will then emit a tone each time a key or button is pressed.

➢ Press the button to confirm the input.

or

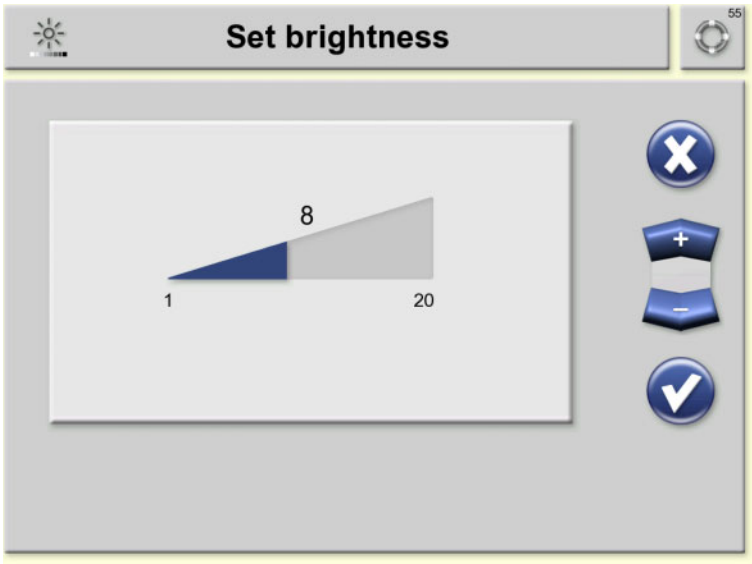
➢ Press the button to discard the change.

4.6.3.4 Setting the brightness

➢ Select the menu.

➢ Select **Brightness**.

➢ Pressing the button will display the higher-level screen.



Set the required brightness for the display and all indicator lights (except for the red light of the **status indicator**).

➢ Press the button to confirm the input.

or

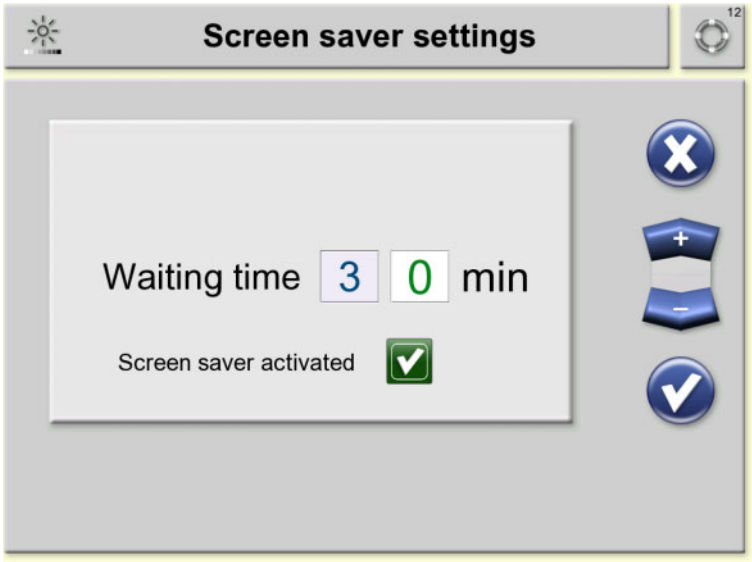
➢ Press the button to discard the change.

4.6.3.5 Setting the screen saver

➢ Select the menu.

➢ Select **Screen saver**.

➢ Pressing the button will display the higher-level screen.



➢ Set the screen saver timeout ("Waiting time").

➢ If the **Screen saver activated** option is selected, this is indicated by a checkmark. The screen saver function is then active.

➢ Press the button to confirm the input.

or

➢ Press the button to discard the change.

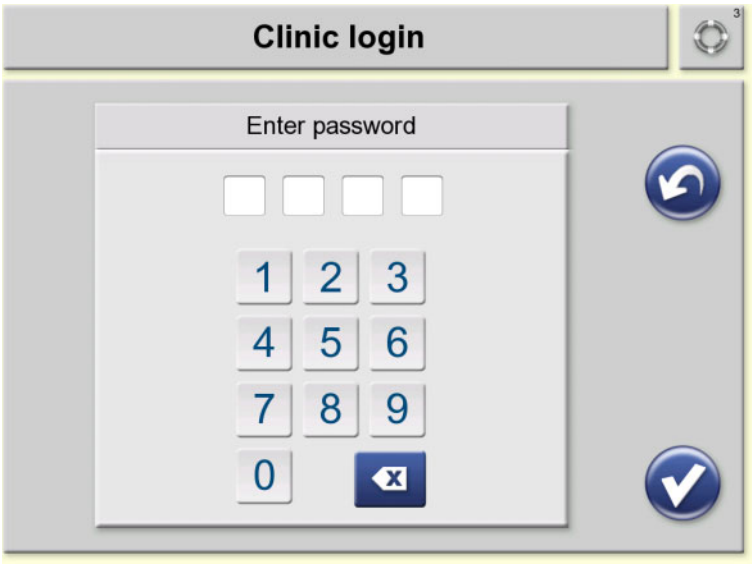
4.6.3.6 Clinic login

This function can only be accessed by the clinical staff.

➢ Select the menu.

➢ Select **Clinic login**.

➢ Pressing the button will display the higher-level screen.



➢ Enter the password.

➢ Press the button to confirm the input and to move to the next operating step.

➢ Pressing the button will display the higher-level screen.

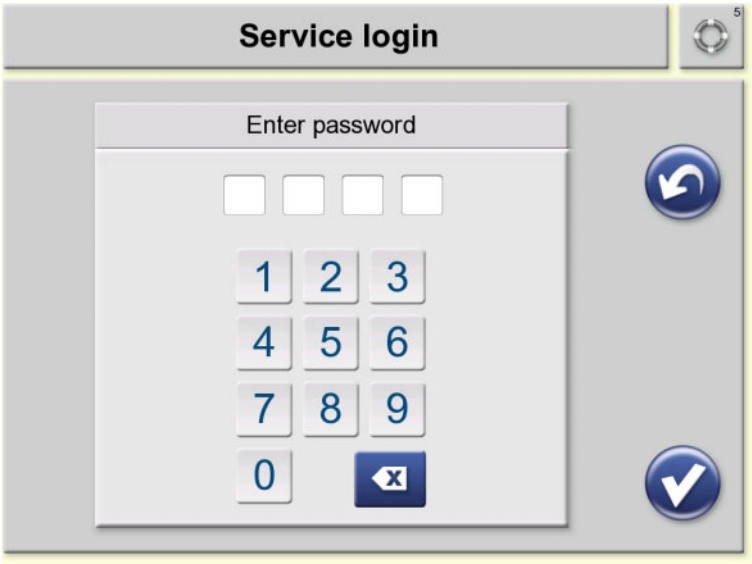
4.6.3.7 Service login

This function can only be accessed by service support.

➢ Select the menu.

➢ Select **Service login**.

➢ Pressing the button will display the higher-level screen.



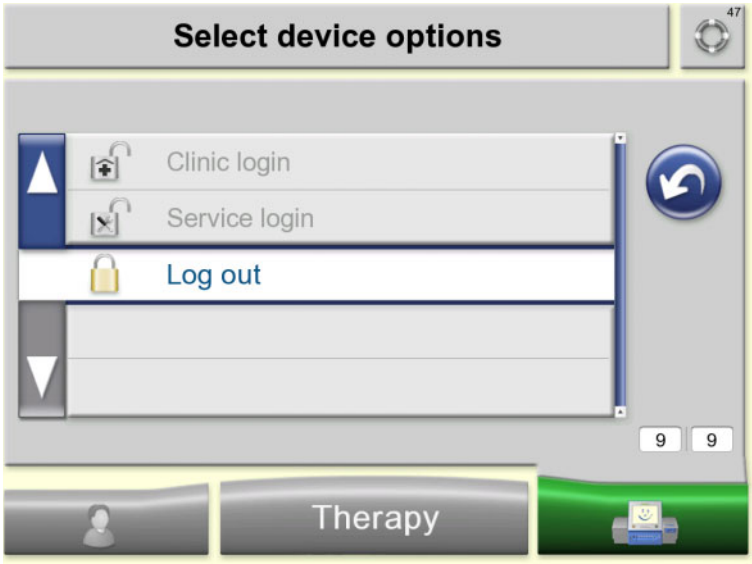
➢ Enter the password.

➢ Press the button to confirm the input and to move to the next operating step.

➢ Pressing the button will display the higher-level screen.

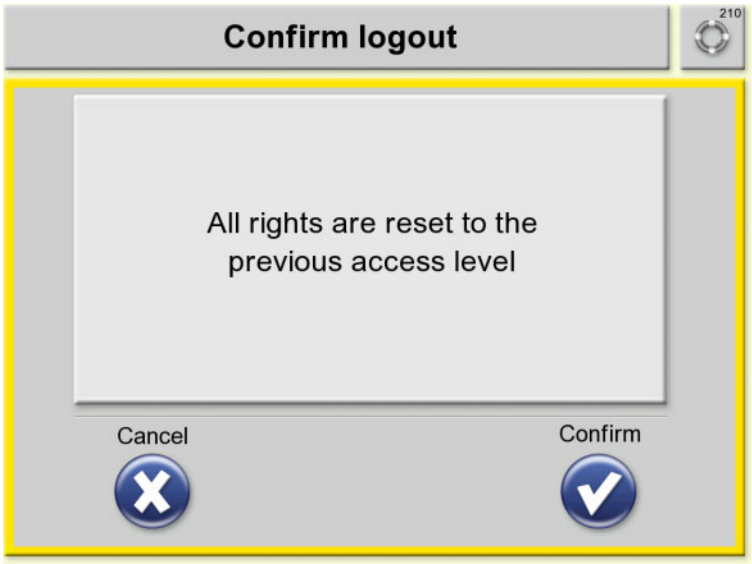
4.6.3.8 Clinic / Service logout

➢ Select the menu.



➢ Select **Log out**.

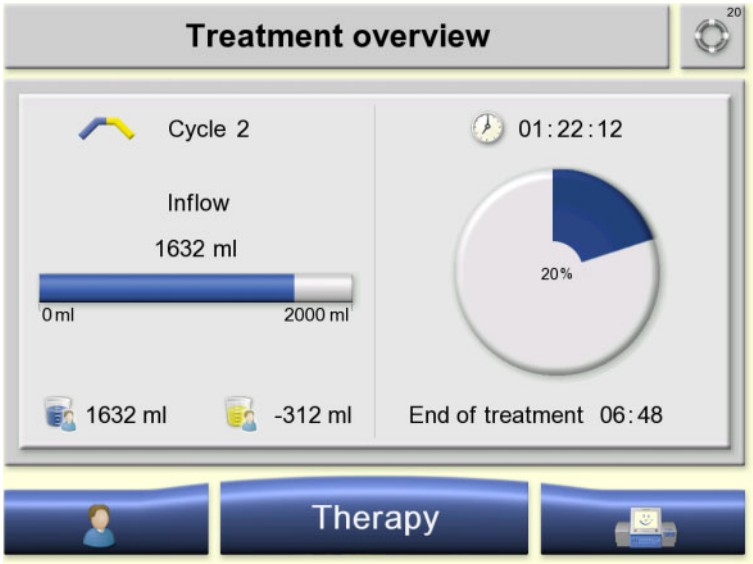
➢ Pressing the button will display the higher-level screen.



➢ Press the button to log out the clinical or service support staff currently logged in.

➢ Press the button to discard the change.

4.7 Therapy options during treatment



There are two ways to select the therapy options.

➢ Select the **Therapy** menu or press the ▽ button.

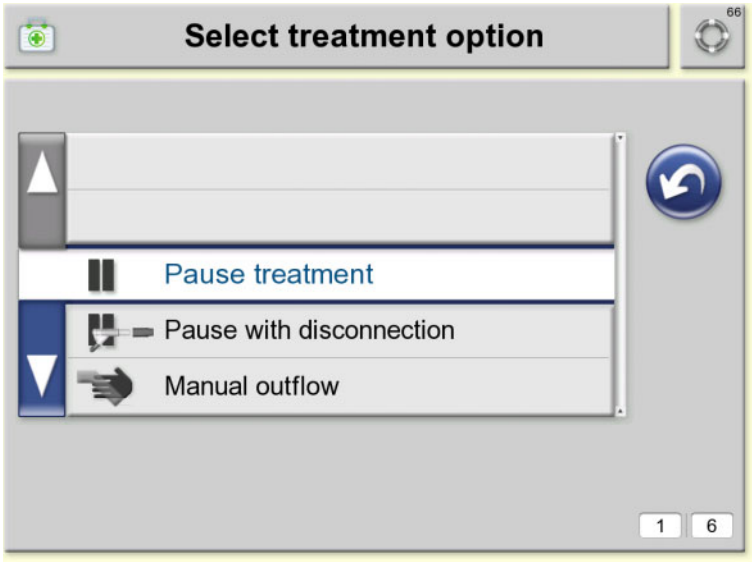
The following therapy options are available:

– Pause treatment
– Pause with disconnection
– Manual outflow
– Skip phase
– Modify treatment
– Terminate treatment
– Treatment report

4.7.1 Pause treatment

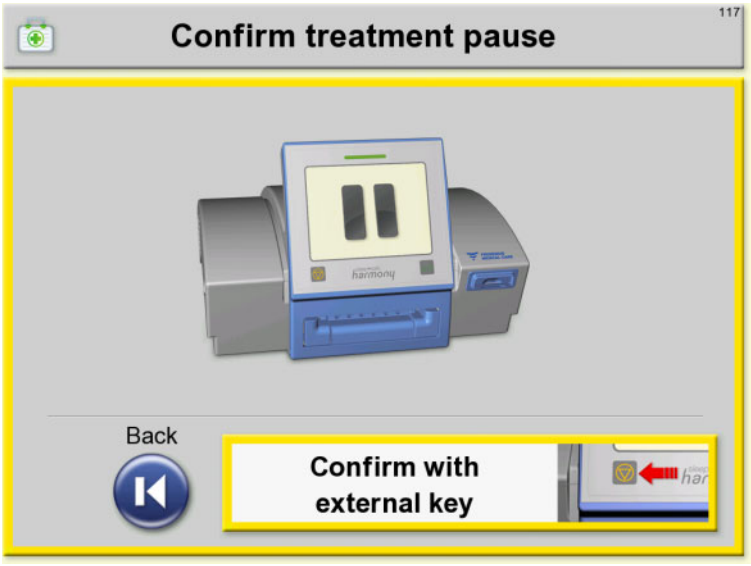
➢ Select **Treatment options**.

➢ Pressing the button will display the higher-level screen.



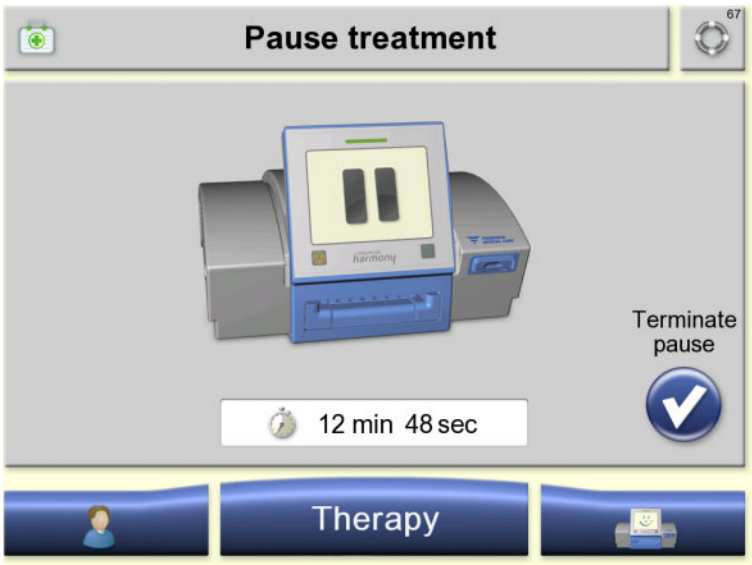
➢ Select **Pause treatment** to interrupt the treatment (pause) for a short period of time.

➢ Pressing the button will display the higher-level screen.



➢ Press the ▽ button to confirm the treatment pause.

➢ Pressing the ◀ button will display the previous page.



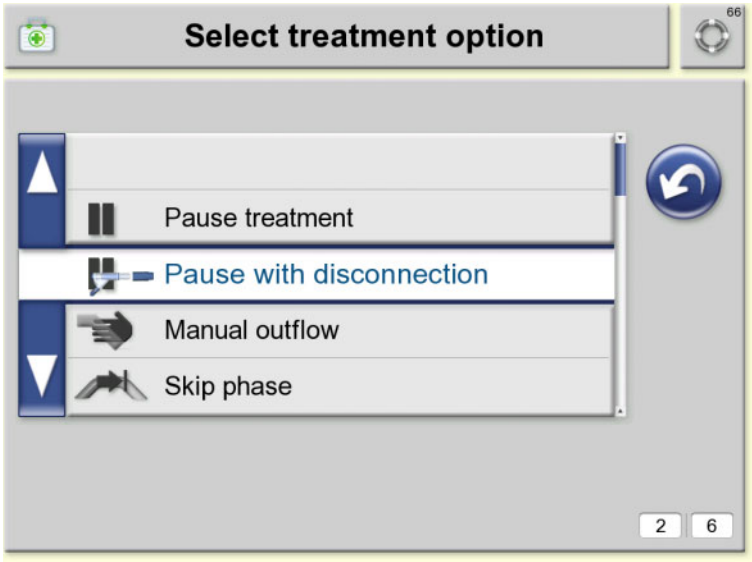
The duration of the pause will be displayed.

➢ Press the ✓ button to continue the treatment.

4.7.2 Pause with disconnection

➢ Select **Treatment options**.

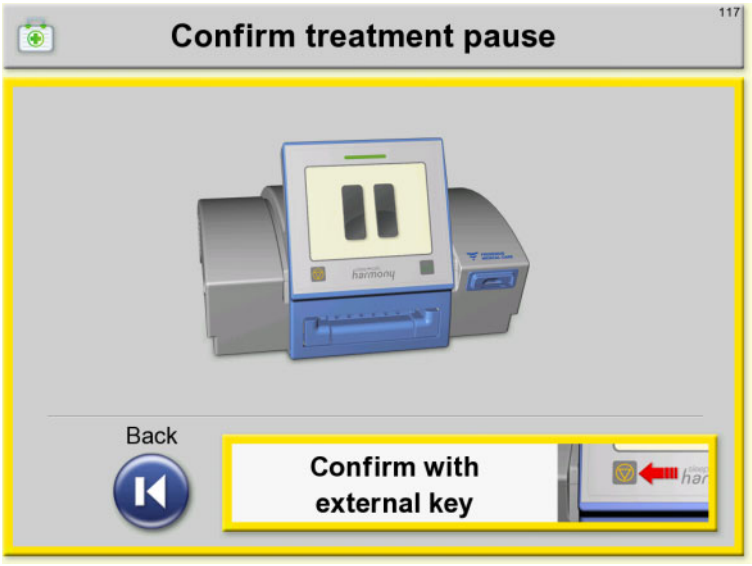
➢ Pressing the button will display the higher-level screen.



➢ Select **Pause with disconnection** to interrupt the treatment and to disconnect the patient line.

➢ After the pause, reconnect the patient line.

➢ Pressing the button will display the higher-level screen.



➢ Press the ▽ button to confirm the treatment pause.

➢ Pressing the ◀ button will display the previous page.

● Disconnecting the patient line

Warning

Risk of contamination from non-compliance with hygiene measures

Improper handling during disconnection can lead to touching the opening of the patient connector.
Contamination can result.

➢ Wearing a face mask and hand disinfection is recommended.

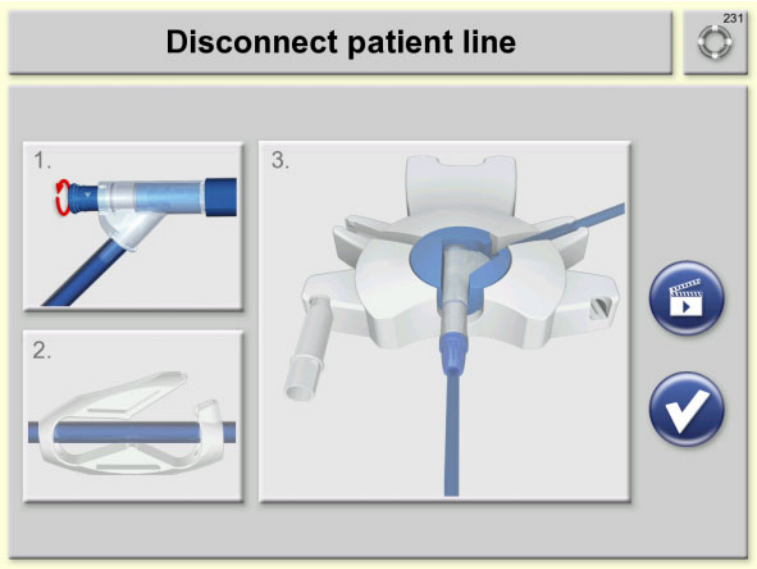
➢ Use aseptic technique when disconnecting the patient connector.

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

Warning

Risk of contamination from non-compliance with hygiene measures

➢ The patient line must be sealed using aseptic technique.



➢ Disconnect the patient line as shown in the screen animation (see chapter 4.4.1 on page 93).

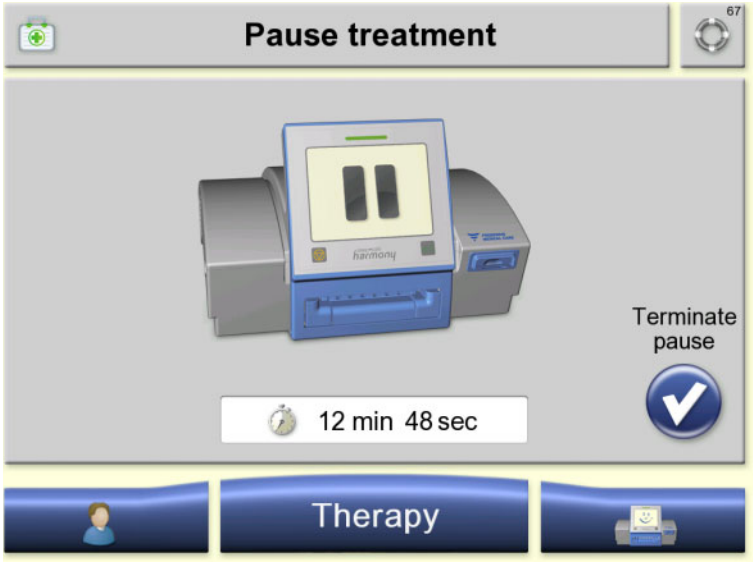
Connecting the patient line

Warning

Patient hazard from overfilling of peritoneal cavity

The use of incorrect prescription data can result in an incorrect treatment for the patient.

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



The duration of the pause will be displayed.

➢ Press the button to continue the treatment.

Warning

Risk of contamination from non-compliance with hygiene measures

Improper handling during connection can lead to touching the opening of the patient connector.
Contamination can result.

➢ You are recommended to wear a face mask, wash your hands and the spaces between your fingers with medical grade handwash and then apply a hand disinfection rub.

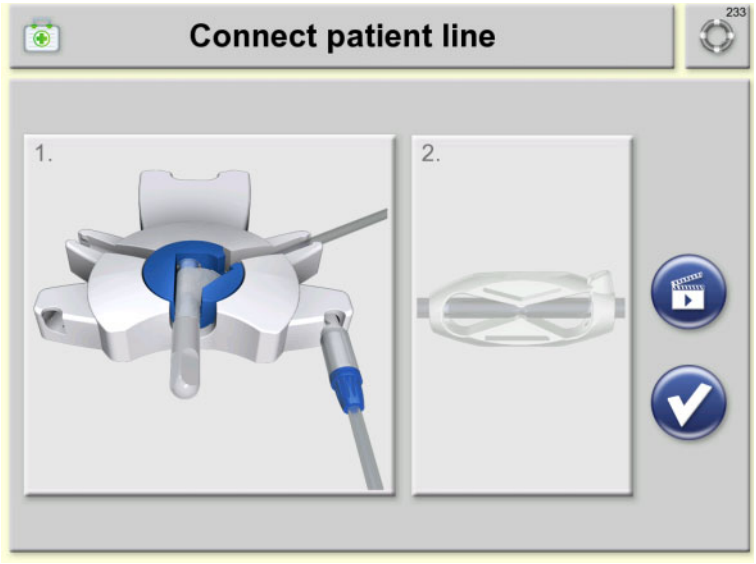
➢ Use aseptic technique when connecting the patient.

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

Warning

Risk of contamination from non-compliance with hygiene measures

➢ The patient line must be sealed using aseptic technique.

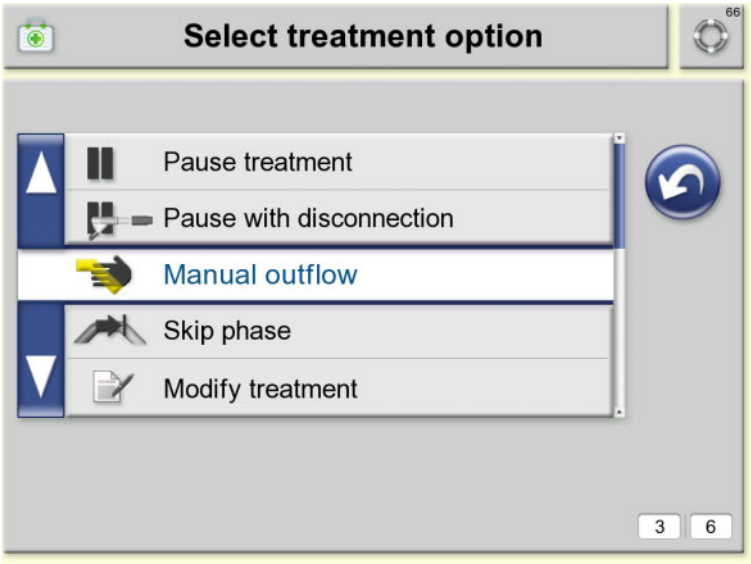


➢ Connect the patient line as shown in the screen animation (see chapter 4.3.1 on page 85).

4.7.3 Manual outflow

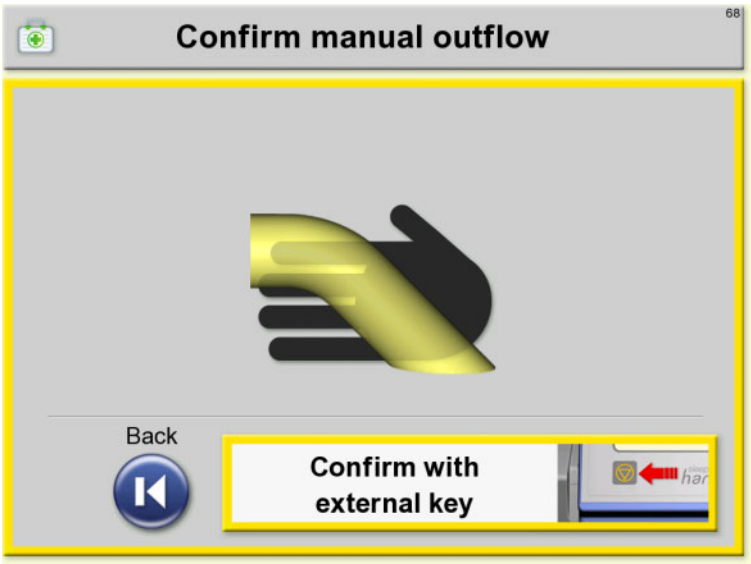
➢ Select **Treatment options**.

➢ Pressing the button will display the higher-level screen.



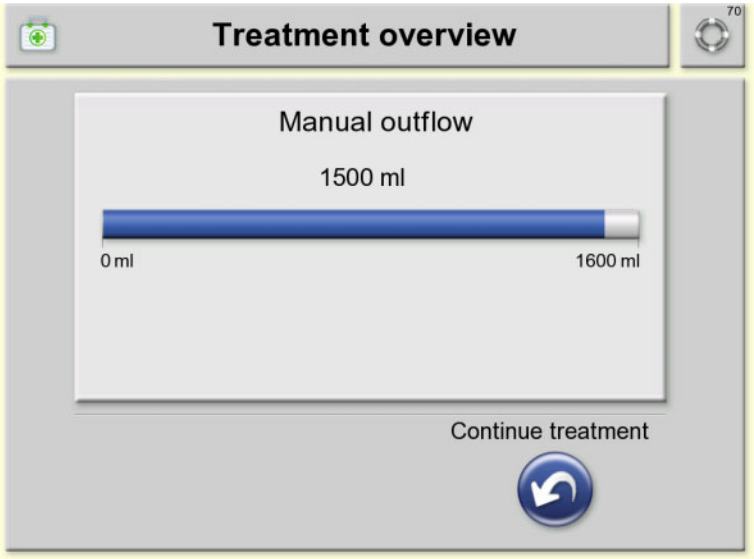
➢ Select **Manual outflow** to initiate a manual outflow.

➢ Pressing the button will display the higher-level screen.



➢ Press the button to start the manual outflow.

➢ Pressing the button will display the higher-level screen.

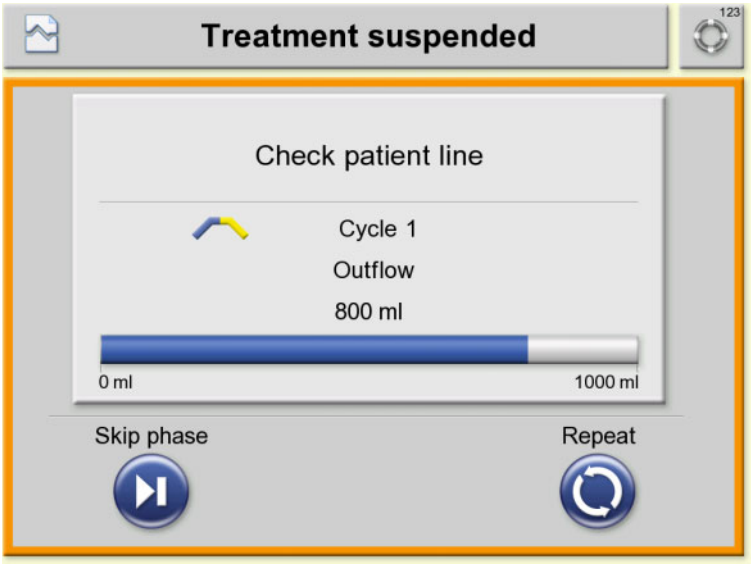


The manual outflow will be performed.

➢ The button continues the treatment.

The manual outflow is interrupted.

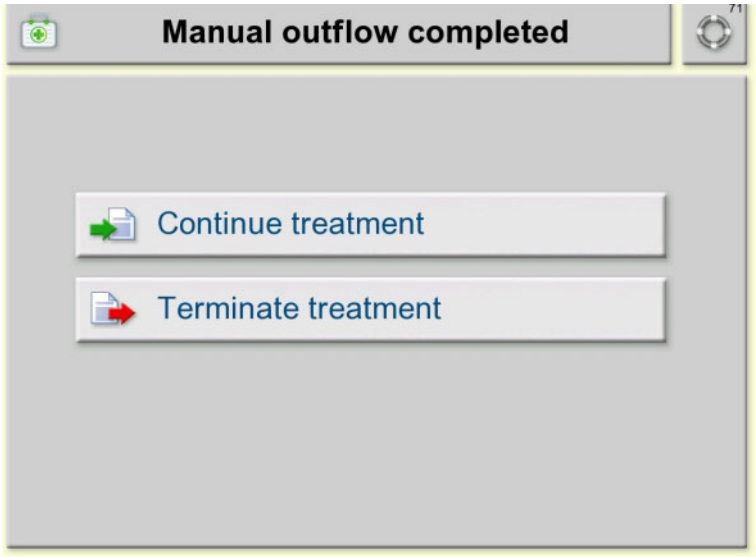
➢ Touch the screen to confirm the interruption.



When the manual outflow is complete, the following screen will be displayed.

➢ Press the button to continue the manual outflow.

➢ Press the button only if you wish to end the manual outflow.



The manual outflow is complete.

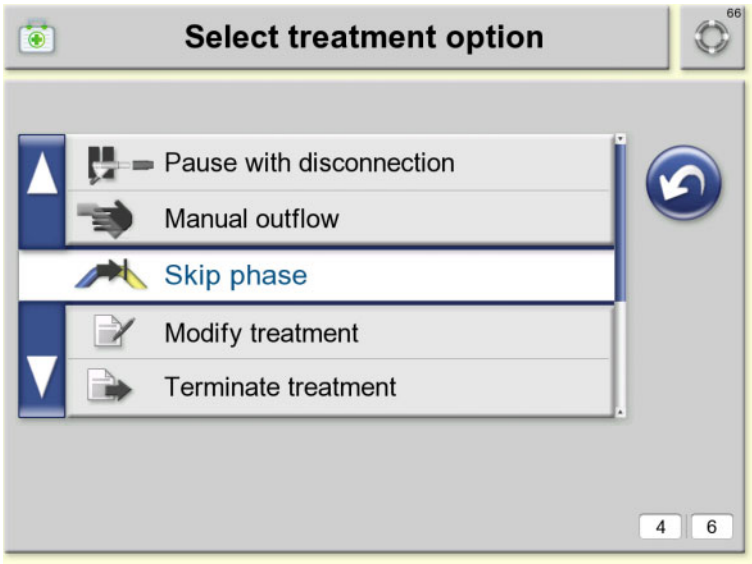
➢ Press the **Continue treatment** button or the **Terminate treatment** button (see chapter 4.4.1 on page 93).

4.7.4 Skip phase

The option is not available during the initial outflow.
The option is not available for the “No changes” access level.

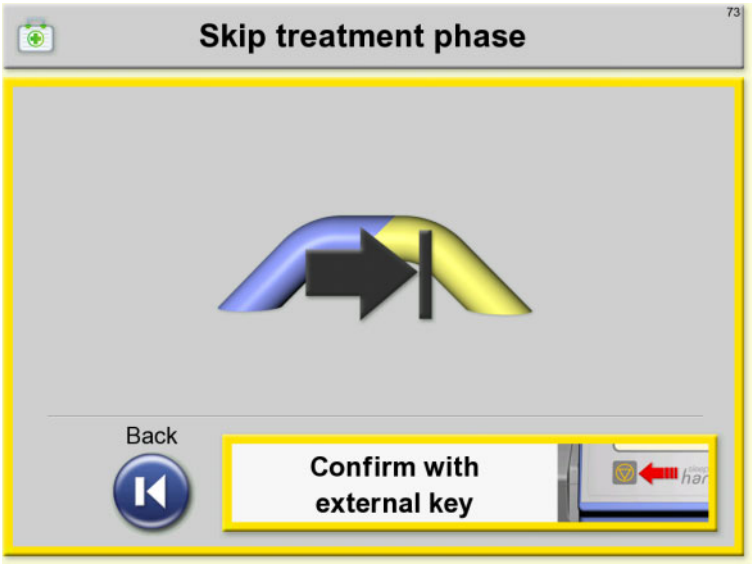
➢ Select **Treatment options**.

➢ Pressing the button will display the higher-level screen.



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

➢ Pressing the button will display the higher-level screen.



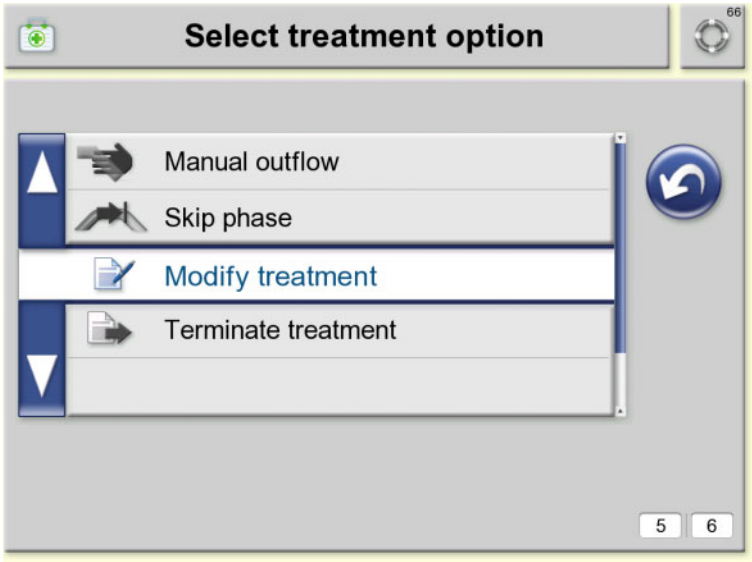
➢ Press the ▽ button to skip the current treatment phase and to start the next treatment phase.

➢ Pressing the ◀ button will display the higher-level screen.

4.7.5 Modify treatment

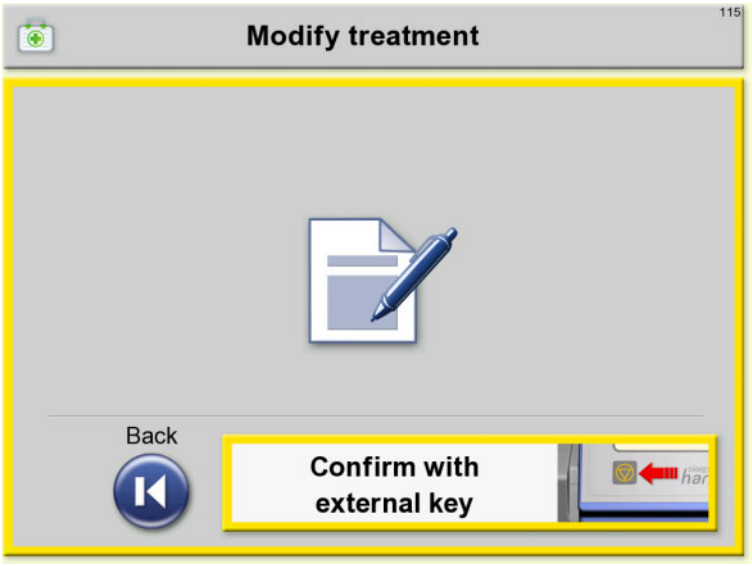
➢ Select **Treatment options**.

➢ Pressing the button will display the higher-level screen.



➢ Select **Modify treatment** to change the dwell duration or the in-flow volume.

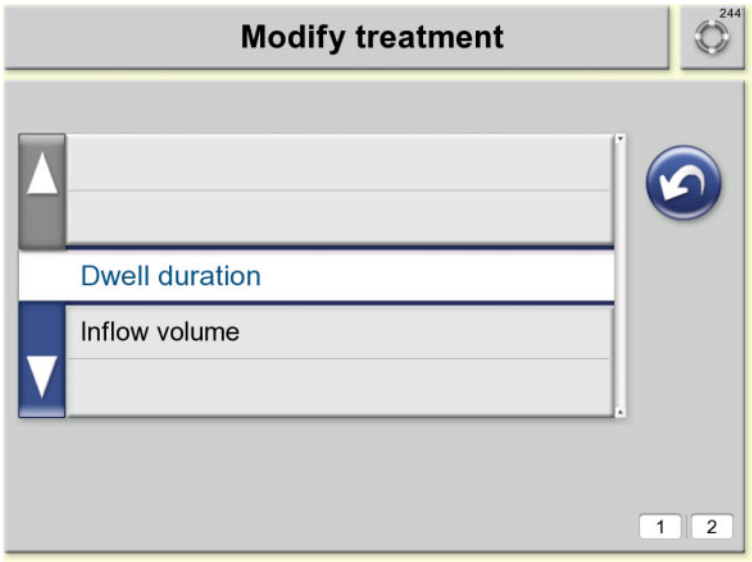
➢ Pressing the button will display the higher-level screen.



➢ Press the button to modify the treatment.

➢ Pressing the button will display the higher-level screen.

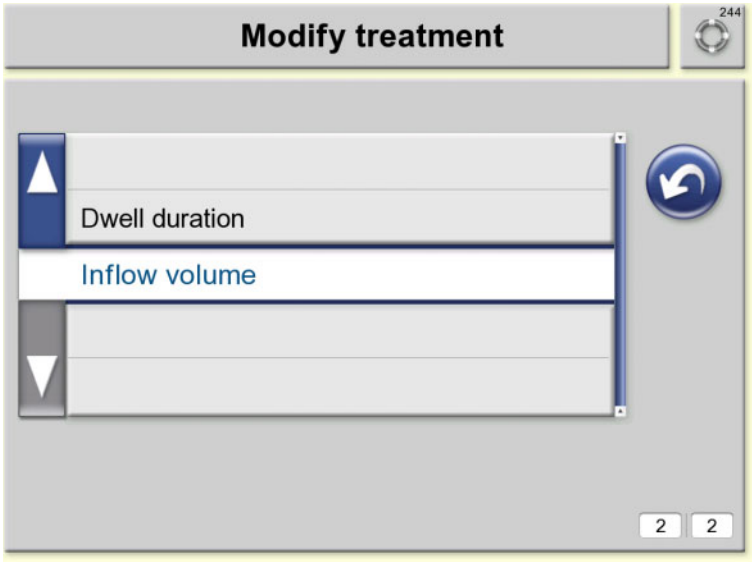
● Change dwell duration



➢ Select **Dwell duration** to change the total dwell duration.

➢ Pressing the button will display the higher-level screen.

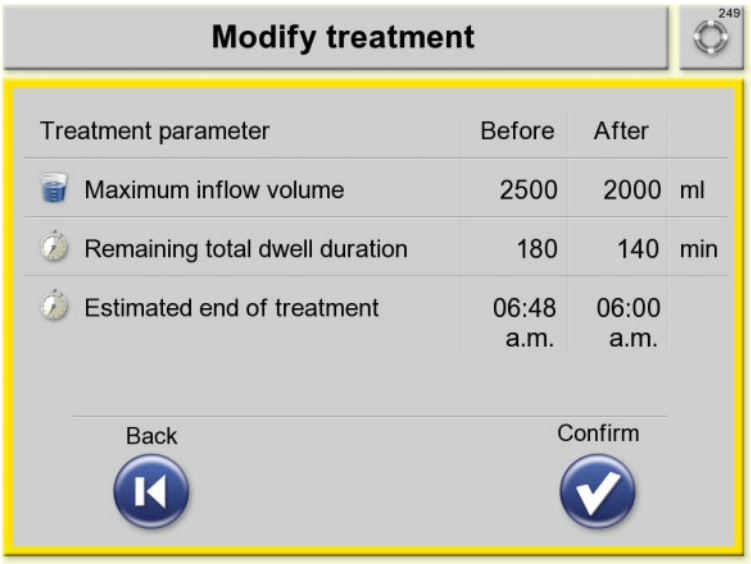
● Change the inflow volume



➢ Select **Inflow volume** to change the maximum inflow volume.

➢ Pressing the button will display the higher-level screen.

Confirm changes

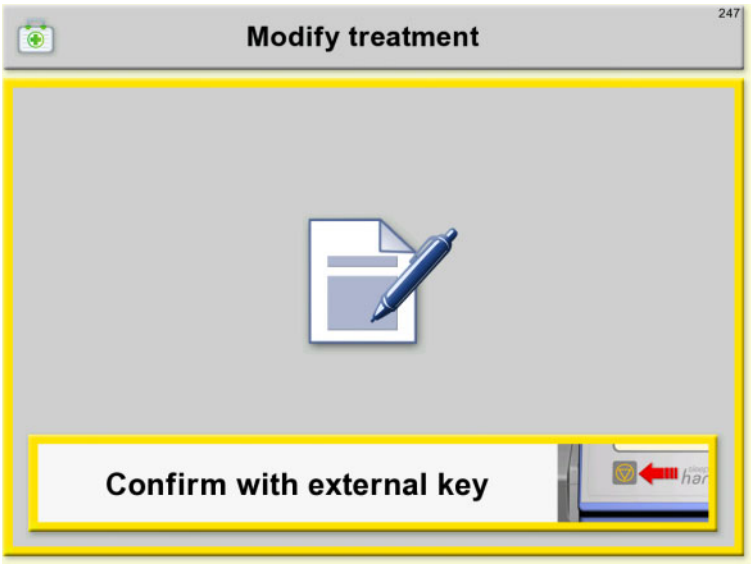


If the dwell duration or the inflow volume was changed, then the screen on the left will be displayed.

The values for the maximum inflow volume, the remaining total dwell duration and the estimated end of treatment are displayed on the screen both before and after the change.

➢ Press the button to confirm the data entered.

➢ Press the button to return to the previous screen.

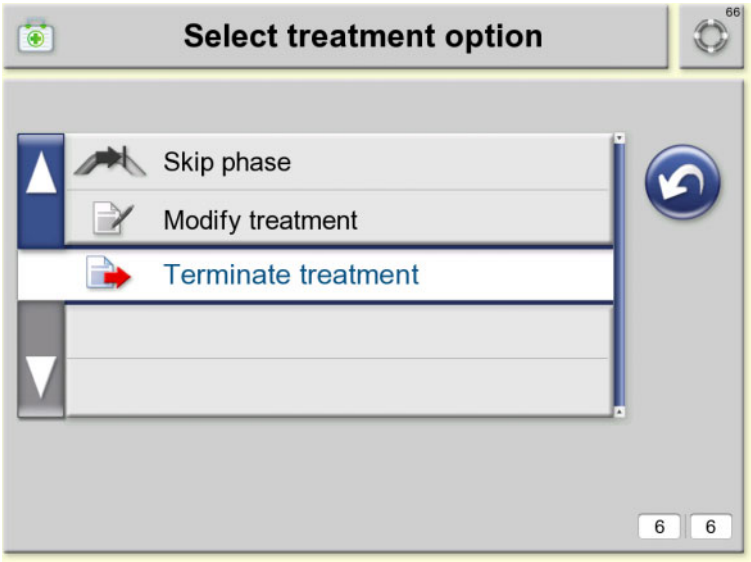


➢ Press the button to confirm the modifications.

4.7.6 Terminating the treatment

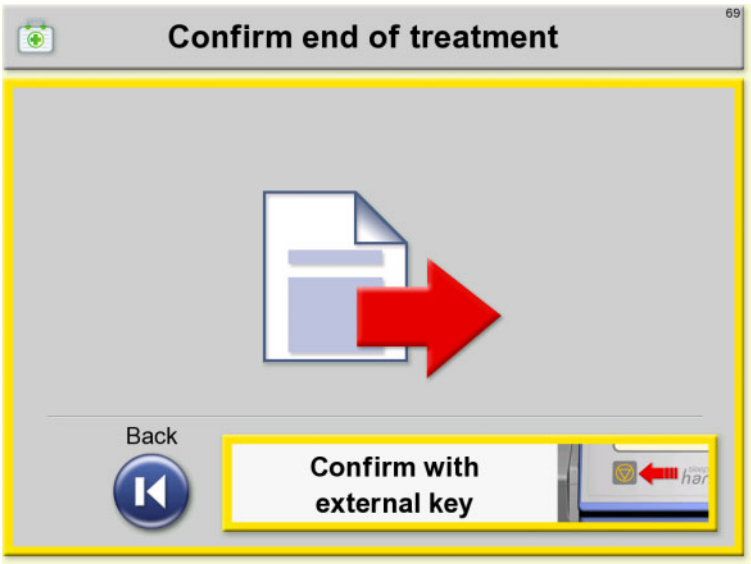
➢ Select **Treatment options**.

➢ Pressing the button will display the higher-level screen.



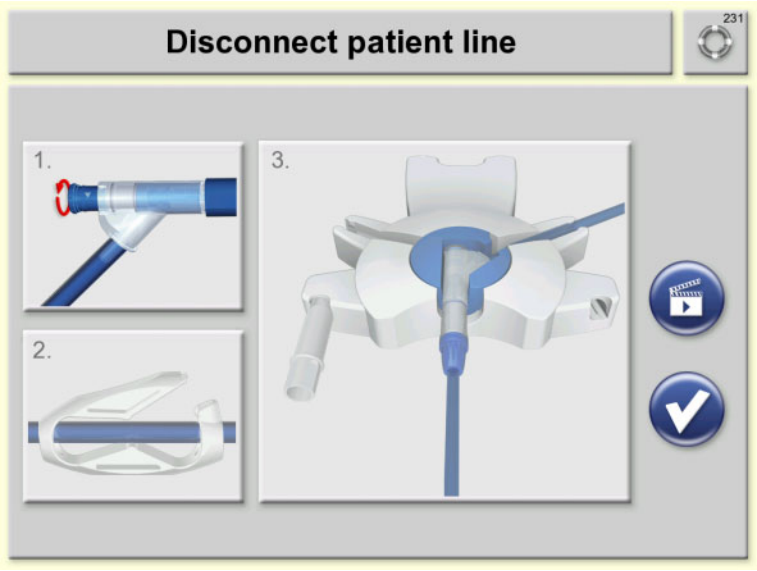
➢ Select **Terminate treatment** to terminate the current treatment immediately and to disconnect the patient line.

➢ Pressing the button will display the higher-level screen.



➢ Press the button to terminate the treatment.

➢ Pressing the button will display the higher-level screen.



Disconnect the patient line as shown in the screen animation
(see chapter 4.4.1 on page 93).

4.7.7 Displaying the treatment report

➢ Select **Treatment report**
(see chapter 4.6.2.5 on page 138).

➢ Pressing the button will display the higher-level screen.

4.8 Performing a PD-Plus treatment

4.8.1 Connecting the patient

Connect the patient (see chapter 4.3.1 on page 85).

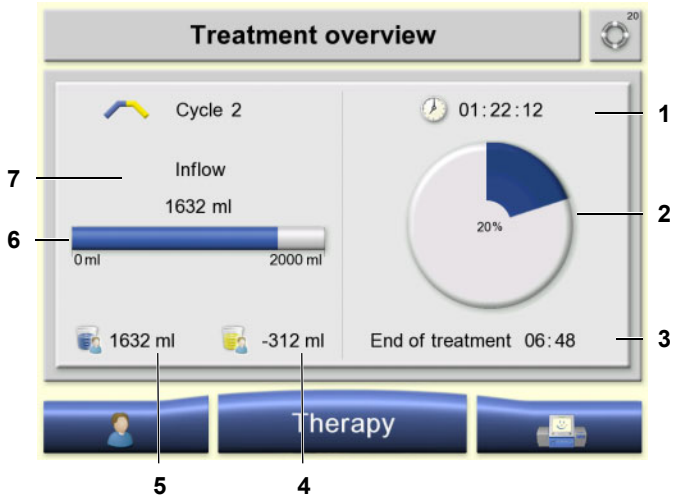
4.8.2 Starting a PD-Plus treatment

Treatment is started.

The treatment will start with an initial outflow.

Terminate the initial outflow
(see chapter 4.3.3 on page 90).

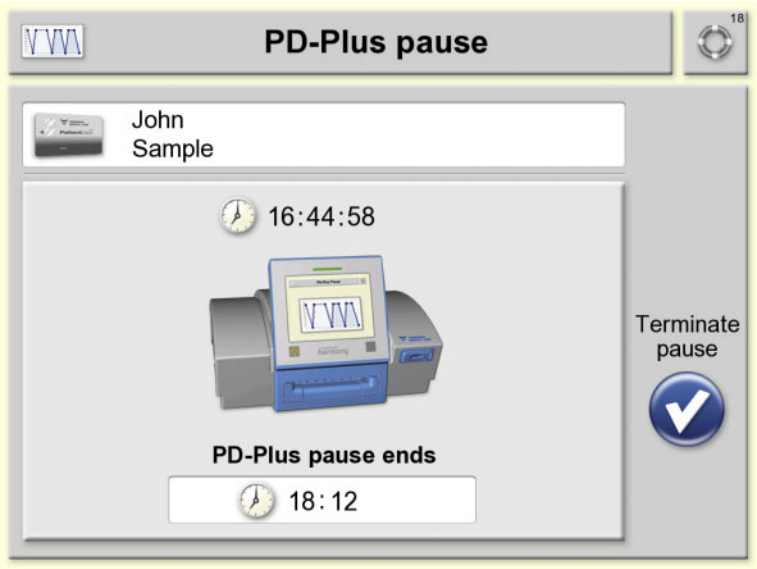
4.8.3 PD-Plus inflow



During the treatment, the following parameters will be displayed on the treatment overview screen:

1. Current time
2. Treatment progress in %
3. Expected end of treatment
4. Current total volume balance
5. Volume in patient
6. Progress of the current treatment phase
7. Treatment cycle

4.8.4 PD-Plus pause



The PD-Plus inflow is followed by the PD-Plus dwell duration during which the *sleep•safe harmony* treatment is paused.

➢ Disconnect the patient (see chapter 4.4.1 on page 93).

➢ Press the button to terminate the treatment pause.

Warning

Patient hazard from hot dialysis solution

The peritoneum can be damaged by dialysis solution that is too hot.

➢ During the treatment, make sure that the temperature of the fluid in the patient line does not rise above 40 °C due to external influences (exposure to sun, radiators, etc.).

4.8.5 Connecting the patient for nighttime treatment

Connect the patient (see chapter 4.3.1 on page 85).

4.9 Using the device with the porter

Do not place any sharp or pointed objects on the tray or the drain tray (optional).

Do not place the device or solution bags on the tray or the drain tray (optional) during the treatment.

➢ Apply the brakes prior to preparation and treatment.

➢ Clean the tray and the drain tray (optional) with the recommended disinfectant and cleaning agent prior to the treatment.

➢ The organiser must be checked to ensure it is positioned securely before connecting and disconnecting the patient and before relocating the device.

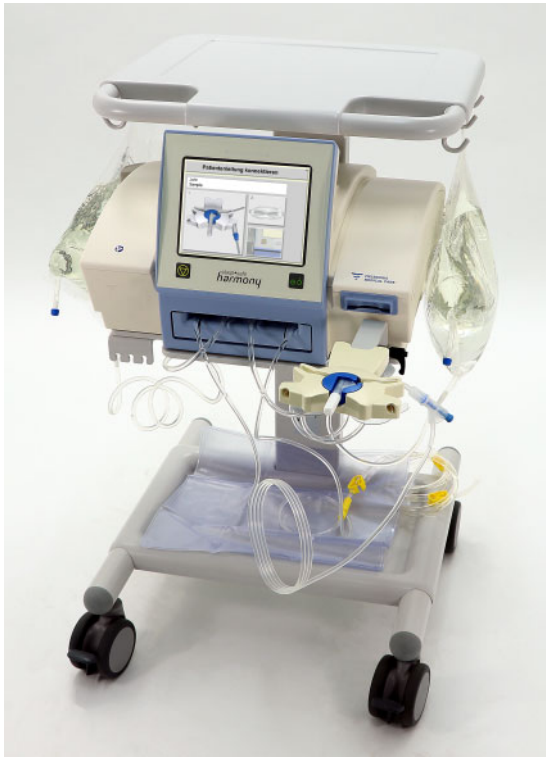
Only one bag may be hung on each hook of the solution bag holder.

➢ Hang the solution bags with the bag connector facing forwards.

The patient connector must not be inserted in the holder for the solution bag connectors.

➢ Do not completely unroll the patient line in order to avoid it being run over.

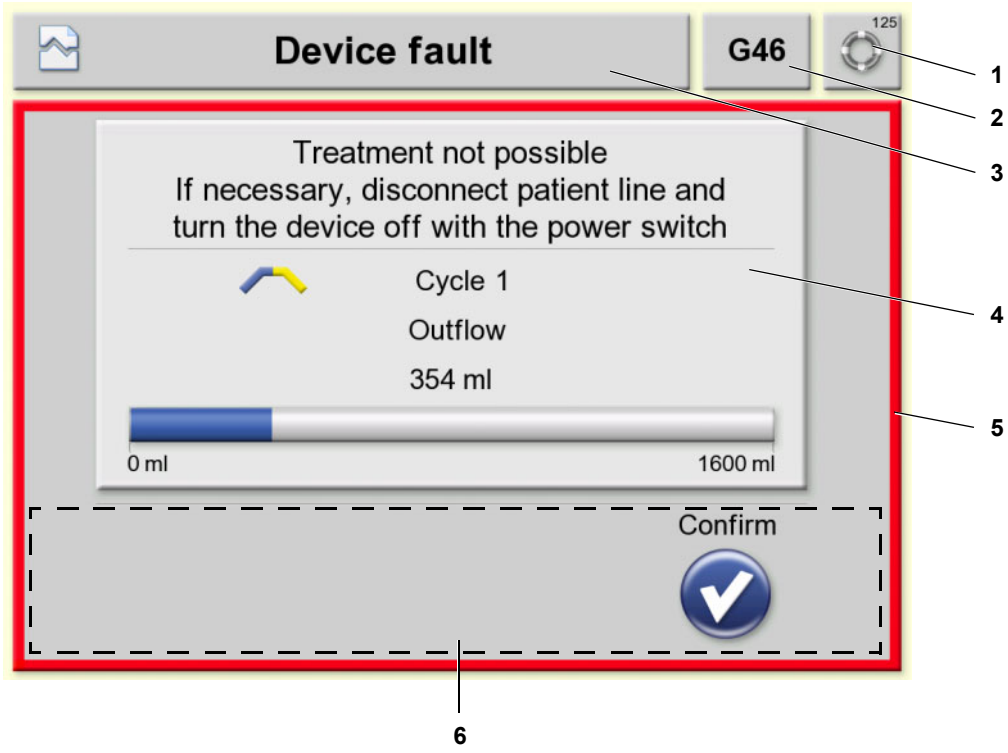
The image below shows the porter with a *sleep•safe harmony* that has been prepared for a treatment by way of example.



5 Alarm processing

5.1 Screen layout

The screen shown is used as an example.



1 **Help** button (function currently not available)

2 Screen message number
The screen message number permits an unambiguous analysis of the error and provides the contact in the dialysis center or the local service support organization with additional troubleshooting information.

3 Screen message title

4 Information text

5 Colour identification of the screen messages
The screen messages are divided into three categories (information, caution and alarm) that are denoted by the frame colour.

6 Options panel
The following buttons may be displayed on an alarm screen:

Confirm button
Button for confirming the screen message.

Repeat button
Button to repeat the current test step.

Skip phase button
Button for terminating the current treatment phase and switching to the next treatment phase.

Terminate treatment button
Button for terminating the treatment.

5.2 Resetting the audible alarm

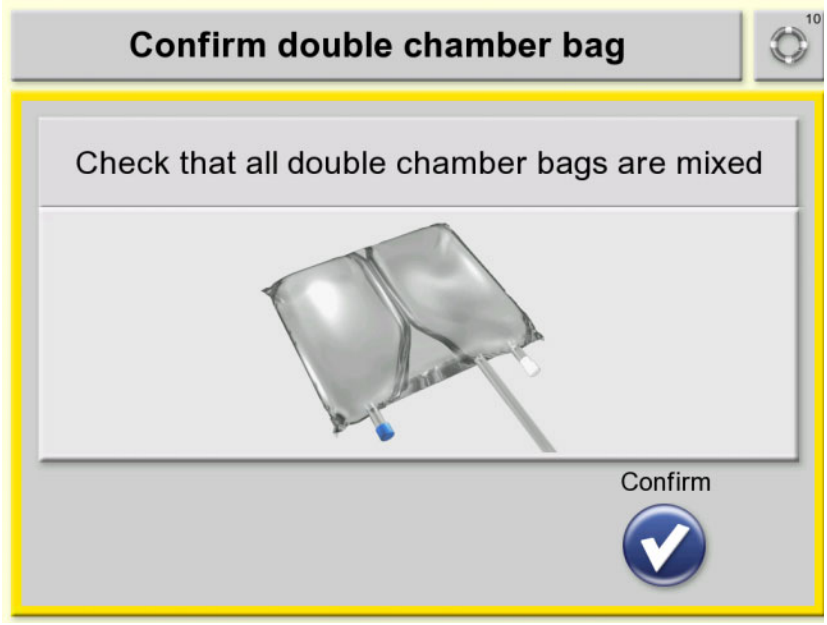
If an audible signal or an audible alarm is sounded, it can be silenced for 6 minutes by touching the screen.

➢ If an audible signal or an audible alarm is sounded and the "Reset audible alarm" screen is not displayed, it can be silenced by pressing the ▽ key.

5.3 Colour identification of the screen messages

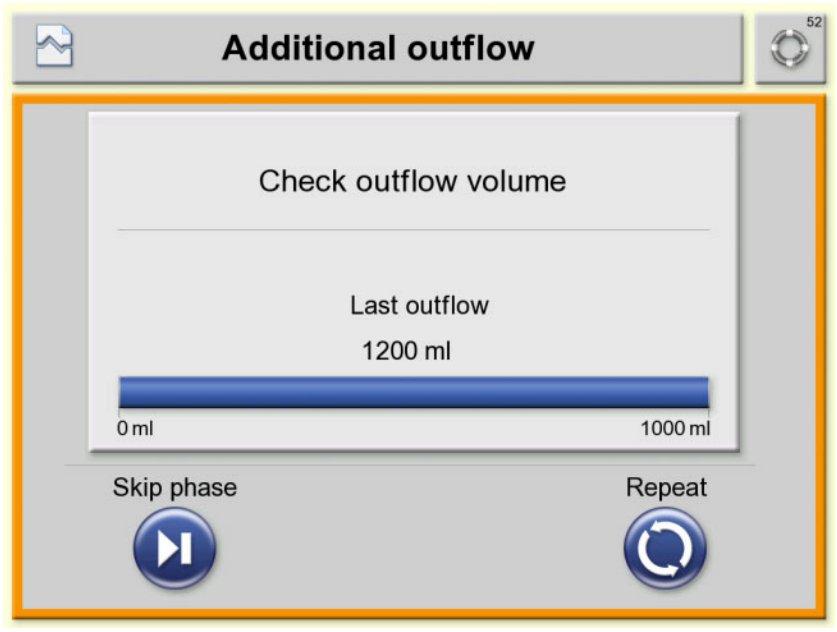
The screen messages are divided into three categories (information, caution and alarm) that are denoted by the frame colour. The screens shown serve as examples.

Yellow frame, information (example)



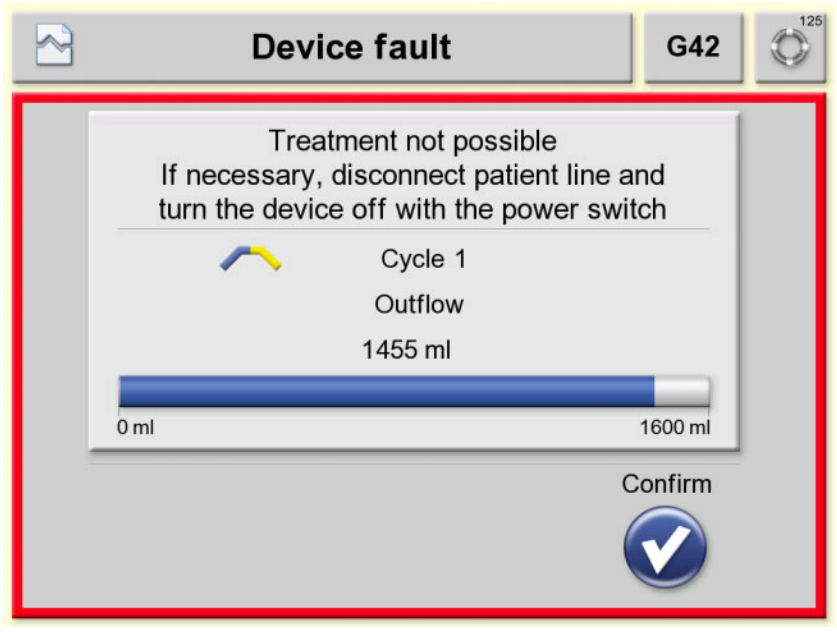
– Information and treatment-related assistance which the operator must always observe and follow as necessary.
– Treatment can be continued.

Orange frame, caution (example)



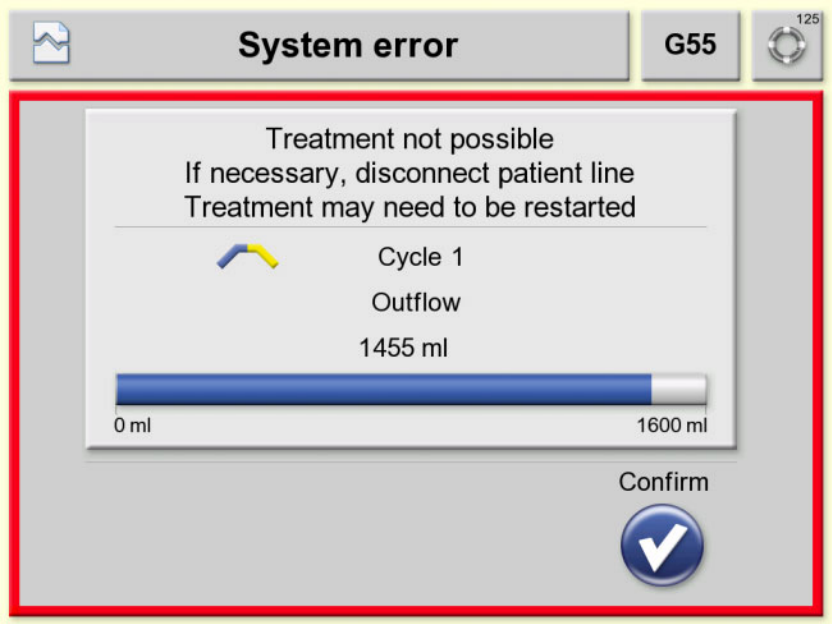
– The title bar contains a brief description of the cause of the problem. Follow the steps displayed on the screen to correct the problem.
– Treatment can be continued.

Red frame, alarm – device fault (example)



– Device faults affect the *sleep•safe harmony* device.
– Depending on the alarm situation, treatment can be continued or will be stopped.

Red frame alarm – system error (example)



– System errors affect the entire system, including line set, solution bags and drainage.

– Depending on the alarm situation, treatment can be continued or will be stopped.

5.4 Screen messages

Note

Any alarms and warnings which have occurred can be displayed on the device:

– Alarms and warnings for the current treatment (see chapter 4.4.2 on page 97)

– Alarms and warnings for previous treatments (see chapter 4.6.2.5 on page 138)

This list of possible alarms and warnings is not exhaustive.

Message	Cause	Measure
A001	Timeout during internal test	– Disconnect the patient if necessary. – Terminate and restart the treatment, if necessary. – If necessary, use the button on the right at the bottom of the screen on restart to remove the *sleep•safe* Set, (see chapter 4.5.3 on page 113). – Remove the *sleep•safe* Set in a timely manner at the end of the treatment after draining the solution bags. Press the ✓ button to confirm removal and to close the loading tray.
A002	Interruption of the power supply	– Ensure that the device is connected to the power supply. – As soon as the device has been connected to the power supply, the treatment can be resumed.
G12T	Error during self-test for monitoring the temperature sensor	– The device must not be exposed to direct sunlight. – Make sure that the device is being operated within the specified operating conditions. – Use the solution bags within the specified operating conditions. – Switch the device off with the power switch, allow it to cool down for several minutes, then switch it on again. – Press the ✓ button to confirm the error message and continue the treatment if possible.
G43	Error during the plausibility check of the pressure sensor	– Press the ✓ button to confirm the error message and disconnect the patient if necessary. – Switch off the device with the power switch after shutting it down. – Wait at least 10 seconds before switching the device on again.

Message	Cause	Measure
G44	Error during the plausibility check of the sensor signals	– Press the button to confirm the error message and continue the treatment if possible. –
G55T	Error during self-test for plausibility check of the actuators/sensors of the heating system	– The device must not be exposed to direct sunlight. – Make sure that the device is being operated within the specified operating conditions. – Use the solution bags within the specified operating conditions. – Switch the device off with the power switch, allow it to cool down for several minutes, then switch it on again. – Press the button and continue the treatment if possible.
G61T	Error during self-test for plausibility check of the pressure sensor of the pump system	– Press the button and continue the treatment if possible. – If necessary, use the button on the right at the bottom of the screen on restart to remove the *sleep•safe* Set, (see chapter 4.5.3 on page 113). Restart the device.
G62T	Error during self-test for plausibility check of the length sensor of the pump system	– Press the button and continue the treatment if possible. – The device may be running outside specified operating conditions, or the time for adjustment to ambient temperature was not observed (see chapter 9.2 on page 220). – If necessary, use the button on the right at the bottom of the screen on restart to remove the *sleep•safe* Set, (see chapter 4.5.3 on page 113). Restart the device.

Message	Cause	Measure
G72T	Error during self-test for plausibility check of the integrity of the valve control	– Check the patient line and the catheter extension for kinks and closed clamps. – Ensure that the double chamber bags are fully mixed. – Check the solution bags and lines for leakage. – Suspend or position the solution bags with the solution bag line pointing down. – Press the button and continue the treatment if possible.
G93	Error during patient pressure monitoring	– Check the patient line and the catheter extension for kinks and closed clamps. – Observe the patient position (see chapter 9.3 on page 220). – Press the button to terminate the current treatment phase and to switch to the next treatment phase.
G93T	Error during self-test for patient pressure monitoring	– Check the patient line and the catheter extension for kinks and closed clamps. – Observe the patient position (see chapter 9.3 on page 220). – Elevate the patient's upper torso and continue the treatment. – Press the button to terminate the current treatment phase and to switch to the next treatment phase.

Message	Cause	Measure
G94	Error during monitoring of the dialysis solution temperature	– Use the device and consumables within the operating conditions. – The device must not be exposed to direct sunlight. – Check patient line, catheter extension and solution bag lines for kinks and closed clamps. – Store the solution bags within the operating conditions of the device (see chapter 12.7 on page 249). – Suspend or position the solution bags with the solution bag line pointing down. – Press the button to confirm the error message and continue the treatment if possible. – If the problem occurs repeatedly, terminate the treatment.
G96	Monitoring for air during treatment has exceeded permitted limit	– During inflow: Suspend or position the solution bags with the solution bag line pointing down. Check bag line for leakage. – During outflow: Check the patient line for leakage. Ensure correct connection of the patient line. Ensure that the patient line is fully primed after preparation. – Press the button to confirm the error message and continue the treatment if possible.
G99	Error during the plausibility check of the time counter	– Press the button to confirm the error message and continue the treatment if possible.

Message	Cause	Measure
G100	Device has remained inactive for several minutes	– The device has remained inactive for several minutes. Press the button to confirm the error message and continue the treatment if possible.
G107	Error during monitoring of program execution synchronisation	– Press the button to confirm the error message and disconnect the patient if necessary. – Always use new solution bags and new consumables when starting a new treatment.
G109T	Error during the self-test of the patient safety clamp	– Check that the patient line is correctly positioned in the line guide of the loading tray and replace the *sleep•safe* Set, if necessary. – Suspend or position the solution bags with the solution bag line pointing down. – Comply with the operating conditions for the device, the *sleep•safe* Set and the solution bags used (see chapter 12.7 on page 249). – Press the button and continue the treatment if possible.
G110T	Error during the self-test of the heating system	– The device must not be exposed to direct sunlight. – Make sure that the device is being operated within the specified operating conditions. – Use the solution bags within the specified operating conditions. – Switch the device off with the power switch, allow it to cool down for several minutes, then switch it on again. – Press the button and continue the treatment if possible.

Message	Cause	Measure
G134 G134T	Error during drain pressure monitoring	– Check the drain line and the patient line for kinks and closed clamps. – The outlet of the drain line must never be more than 2 metres below or above the device. – Press the button to confirm the error message and continue the treatment if possible.
G155	Potentially insufficient treatment detected	– The therapy monitoring system has identified a deviation. – Press the button to confirm the error message and disconnect the patient if necessary. – Consult the responsible organisation or service support.

Warning

Patient hazard from a device malfunction

➢ If the treatment **cannot** be continued, the *sleep•safe harmony* must be switched off with the power switch.

5.5 Premature termination of a treatment after a system error / device fault

Warning

Risk of contamination from non-compliance with hygiene measures

Improper handling during disconnection can lead to touching the opening of the patient connector.
Contamination can result.

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

➢ Wearing a face mask and hand disinfection is recommended.

➢ Use aseptic technique when disconnecting the patient connector.

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

Warning

Risk of injury from a device defect

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

➢ Do not perform a treatment 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 organisation or service support.

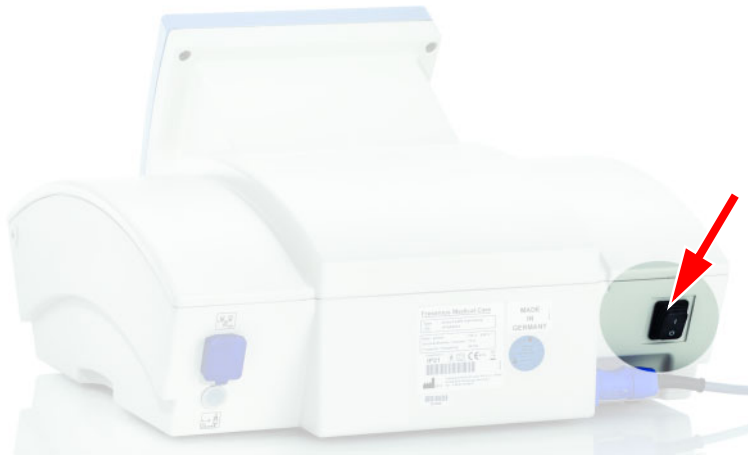
A device defect is present in the following cases, for example:
– If there is mechanical damage
– If the power supply cord is damaged
– If the device reacts differently than expected
– If the performance characteristics of the device deteriorate
– If the screen remains constantly dark when the device is switched on and there is no response from the device

Additional screen layout information (see chapter 5.1 on page 183).

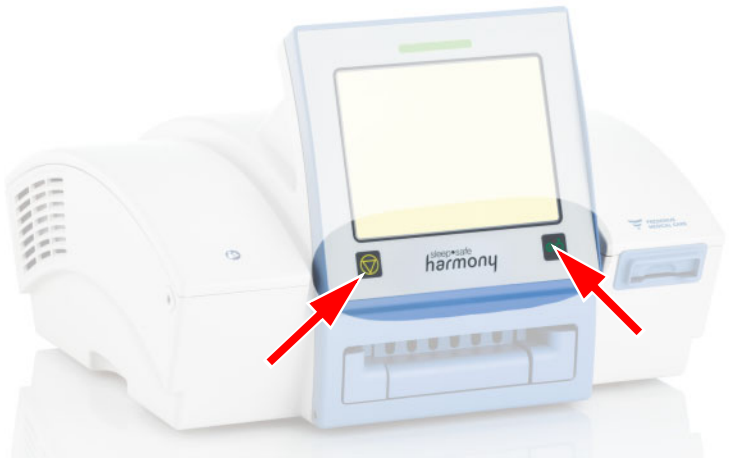
Additional screen message information (see chapter 5.4 on page 187).

5.6 Emergency shutdown

If the *sleep•safe harmony* no longer responds to screen commands, an emergency shutdown can be performed.



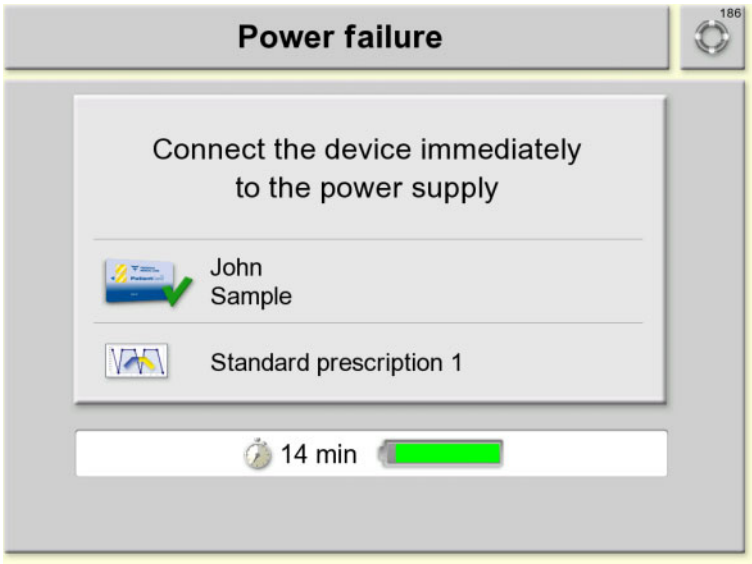
➢ To do this, first flip the power switch on the rear of the *sleep•safe harmony* to off (position "0").



➢ Then simultaneously press the ▽ and ⊙ keys for 5 seconds.

The *sleep•safe harmony* will shut down.

5.7 Power failure



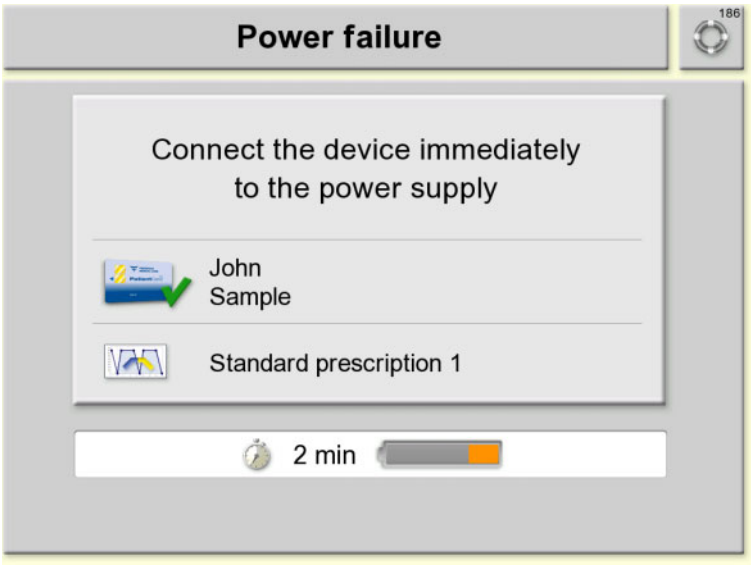
This screen will be displayed if the power supply for the *sleep•safe harmony* has failed.

The time remaining until the *sleep•safe harmony* will shut down is displayed at the bottom of the screen.

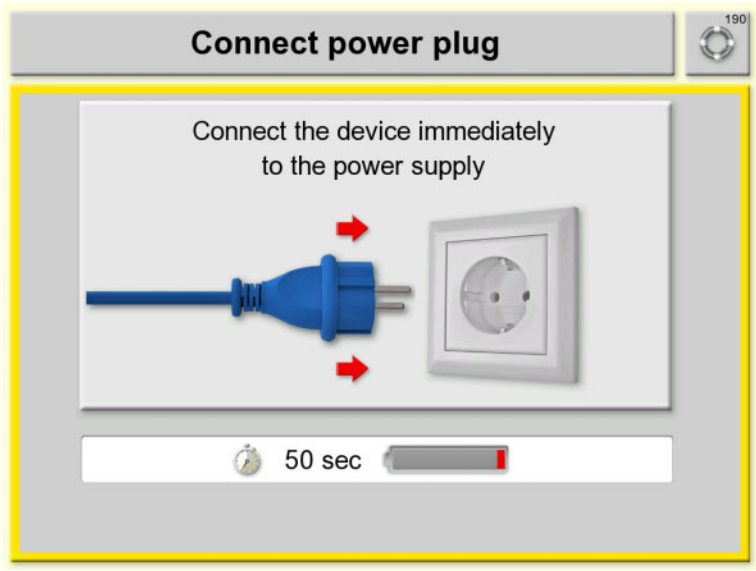
➢ Reconnect the device to the power supply.

If power is not restored within the following 10 minutes, an audible signal will be sounded.

➢ Press the ▽ key to silence the audible signal.



The device bridges the power failure for another 5 minutes.



If bridging of the power supply for more than one minute can no longer be ensured, the screen shown on the left will be displayed. If a connection with the power supply cannot be re-established during this time, the treatment must be stopped.

➢ The patient must be disconnected (see chapter 4.4.1 on page 93) and the *sleep•safe* Set removed (see chapter 4.5.3 on page 113).

5.8 Screen failure

Warning

Risk of contamination from non-compliance with hygiene measures

Improper handling during disconnection can lead to touching the opening of the patient connector.
Contamination can result.

➢ If the *sleep•safe harmony* can no longer be operated via the screen, follow the instructions of the attending physician.

➢ Wearing a face mask and hand disinfection is recommended.

➢ Use aseptic technique when disconnecting the patient connector.

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

6 Cleaning/disinfection

6.1 Cleaning

Warning

Risk of injury from a device defect

If unapproved cleaning agents/disinfectants are used, the housing material may be damaged or disinfection may be inadequate.

➢ Do not autoclave or submerge the *sleep•safe harmony*.

➢ Do not use solvent-based chemical cleaning agents.

➢ Disconnect the *sleep•safe harmony* from the power supply before cleaning.

➢ Use the recommended 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 Freka-NOL

Cleaning interval

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

Parts to be cleaned

– Surfaces (housing, screen, loading tray, porter)

Once the disinfectant and cleaning agent has completely evaporated, the *sleep•safe harmony* and the porter are ready for use again.

7 Functional description

7.1 Description of functional procedures

The *sleep•safe harmony* is a peritoneal dialysis device which has been designed to offer maximum safety and convenience for patients, physicians, nurses and technicians. It reflects the latest state of technology in the fields of electronics, mechanics and software.

The most important features of the *sleep•safe harmony* are:
– Active dialysis solution pump
– High flow rates
– Automatic bag detection and connection
– *sleep•safe* Set line set made of 100 % PVC-free Biofine®
– Inline flow heating (no need to preheat the solution bag)
– Graphic user guidance (colour touchscreen)
– Extremely quiet operation
– Integrated management system for patient and treatment data using a patient card

The *sleep•safe harmony* is an automated peritoneal dialysis device designed for use at home and in hospitals. The pumping action is enabled by a hydraulically-driven membrane piston pump.

The *sleep•safe* Set is a single-use item with semi-spherical chambers in which the hydraulic system either forces dialysis solution out or draws dialysis solution into the chamber using a membrane. A built-in heater warms the dialysis solution before it is infused into the patient. An automatic connecting system connects the solution bags to the line set.

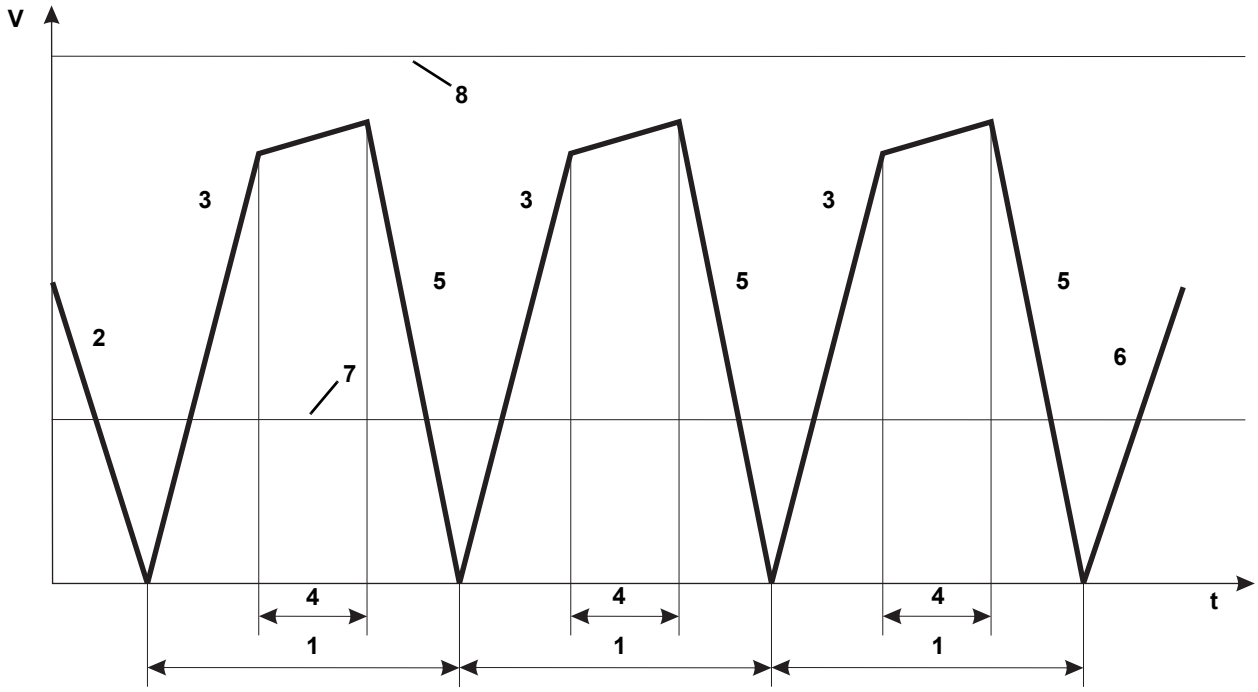
Several pressure sensors monitor the pressures. The *sleep•safe harmony* is controlled and monitored by microprocessors. The *sleep•safe harmony* is provided with independent safety systems.

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

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

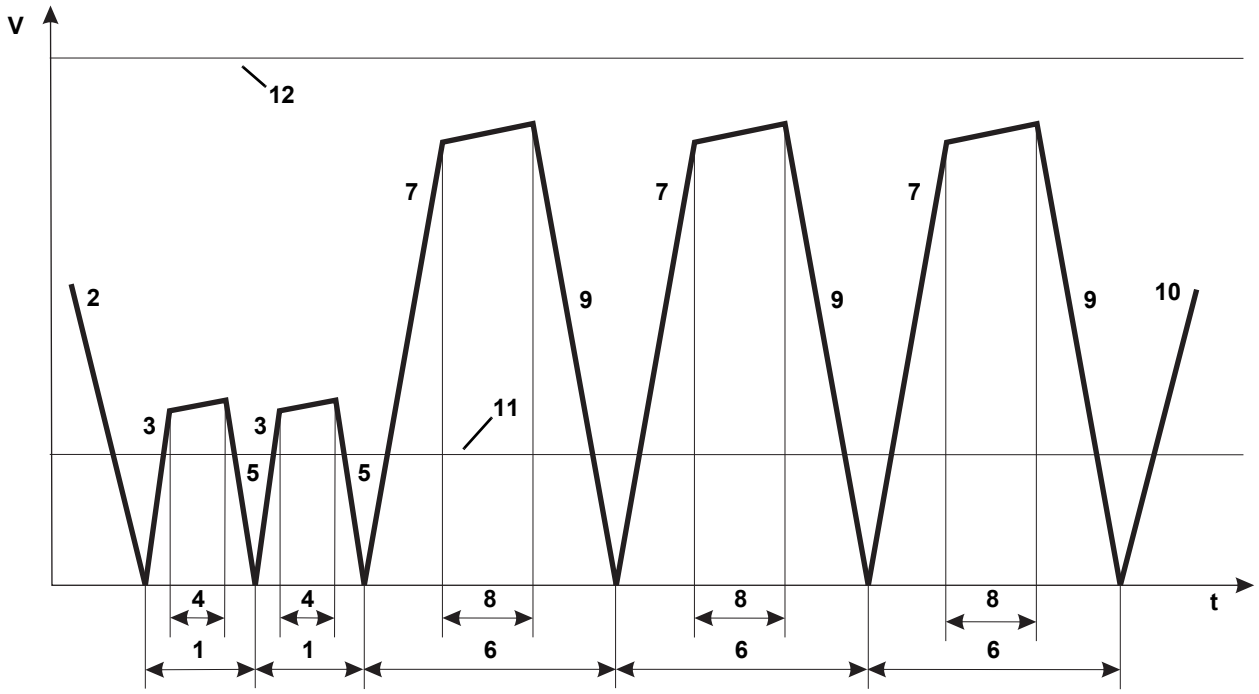
8 Permitted patient volume

The standard prescription consists of individual base cycles with the possibility of profiling the inflow volume, the solution and the dwell duration per cycle.

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

7.2.2 Adapted APD prescription

The following schematic shows the cycles of the adapted APD prescription:



1 Cycle 1 to 2

2 Initial outflow

3 Cycle 1 to 2 inflow volume

4 Cycle 1 to 2 dwell duration

5 Cycle 1 to 2 outflow volume

6 Cycle 3 to 5

7 Cycle 3 to 5 inflow volume

8 Cycle 3 to 5 dwell duration

9 Cycle 3 to 5 outflow volume

10 Last inflow

11 Permitted residual volume

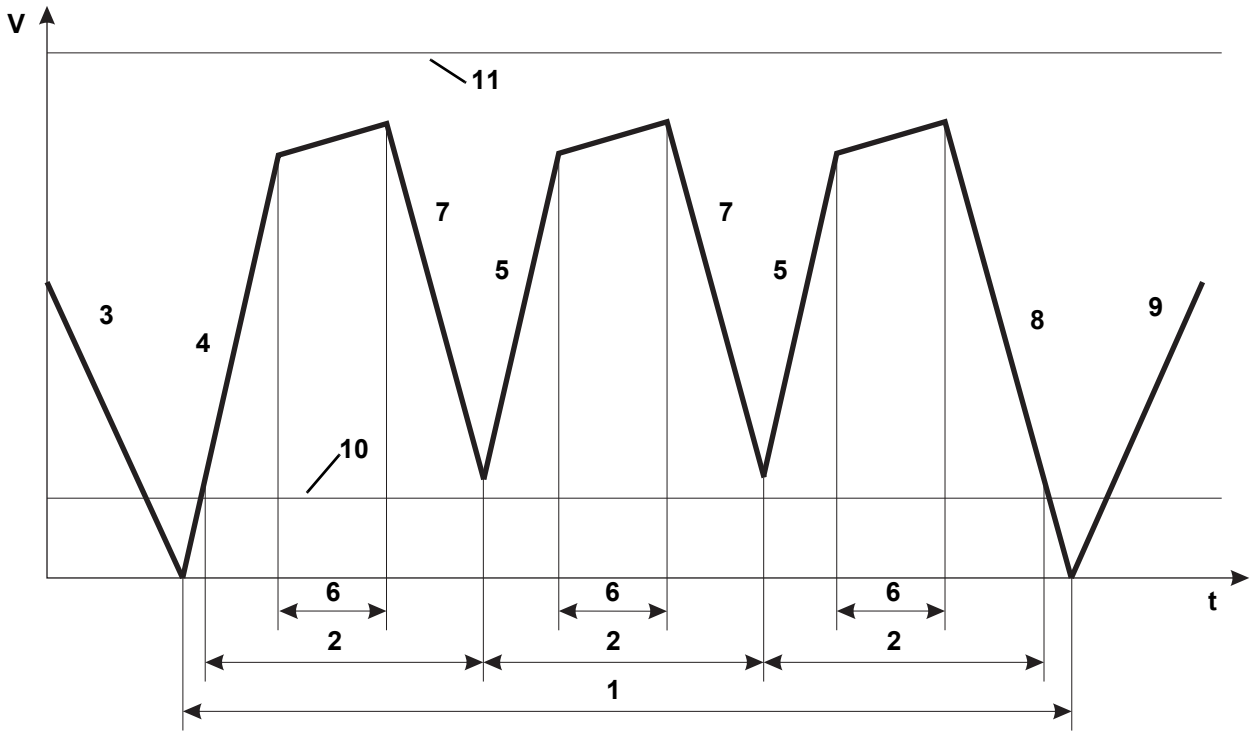
12 Permitted patient volume

The adapted APD prescription consists of two cycles with a low inflow volume and short dwell duration, and three cycles with a higher inflow volume and a longer dwell duration.

The following parameters can be set:
– Initial outflow volume
– Cycle 1 to 2 inflow volume
– Cycle 1 to 2 solution
– Cycle 1 to 2 dwell duration
– Cycle 3 to 5 inflow volume
– Cycle 3 to 5 solution
– Cycle 3 to 5 dwell duration
– Last inflow volume
– Last inflow solution
– Prescription name

7.2.3 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

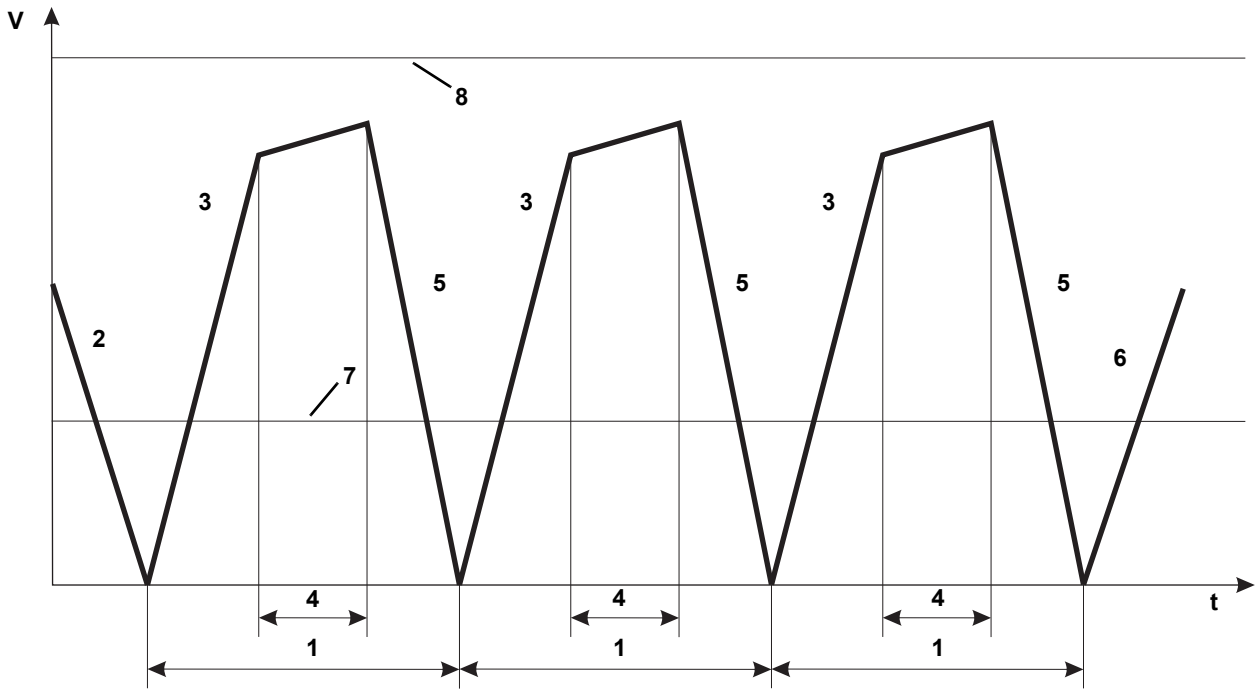
11 Permitted patient volume

The Tidal prescription consists of individual base cycles and Tidal cycles. The base inflow solution, the Tidal inflow solution and the dwell duration can be profiled.

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 (can be profiled)
– Dwell duration (can be profiled)
– Last inflow volume
– Last inflow solution
– Name

7.2.4 Basic prescription

The following schematic shows the cycles of a basic prescription:



1 Base cycle

2 Initial outflow

3 Inflow volume

4 Dwell duration

5 Outflow volume

6 Last inflow

7 Permitted residual volume

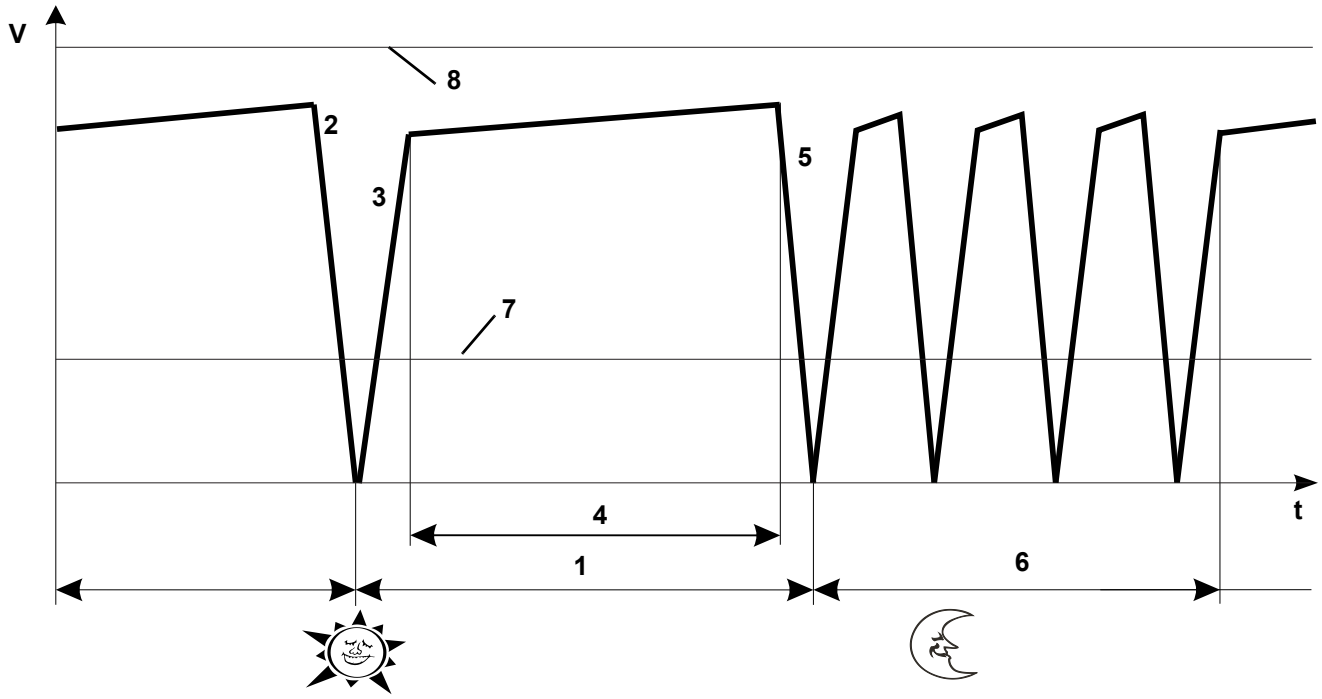
8 Permitted patient volume

The number of cycles of a base prescription depends on the maximum inflow volume, the treatment volume and the total treatment duration.

The following parameters can be set:
– Initial outflow volume
– Maximum inflow volume
– Treatment duration
– Treatment volume
– Base cycle solution
– Last inflow volume
– Last inflow solution
– Prescription name

7.2.5 PD-Plus prescription

The following schematic shows a PD-Plus prescription:



1 PD-Plus cycle

2 Initial outflow

3 PD-Plus inflow

4 PD-Plus pause duration

5 PD-Plus outflow

6 Normal night-time treatment

7 Permitted residual volume

8 Permitted patient volume

The PD-Plus prescription consists of the normal night-time treatment and an additional daytime outflow and inflow. Inflow volume, solution and dwell duration can be profiled.

The following parameters can be set:
– Initial outflow volume
– Number of base cycles of the nighttime treatment
– PD-Plus inflow volume
– PD-Plus solution
– PD-Plus pause duration
– Inflow volume (can be profiled)
– Solution (can be profiled)
– Dwell duration (can be profiled)
– Last inflow volume
– Last inflow solution
– Prescription 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. They influence the volume and time management of the treatment.

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 computed against the percentage factor of the "permitted patient volume", resulting in 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" described above.

The permitted residual volume describes the maximum residual volume which is allowed to remain in the patient's peritoneal cavity if the outflow was not fully completed before the device is permitted to switch to the next inflow without generating an error message.

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

Under certain circumstances, the prescribed total solution volume may not be available for the treatment (due to the solution volume required to prime the line set, for example). In such cases, the inflow volume will be slightly reduced.

Assuming an inflow volume of 1000 ml and a factor of 18 % for the “permitted reduction of the inflow volume”, the inflow volume may be reduced by up to 180 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 terminated without a caution message even if the originally prescribed treatment volume was not reached.

If a value less than or equal to 18 % was prescribed via the associated medical software application for the patient parameter “permitted reduction of the inflow volume”, this preset value is automatically adapted by the device to a value of 18 %.
If a value greater than or equal to 19 % was prescribed via the associated medical software application for the patient parameter “permitted reduction of the inflow volume”, this preset value is automatically adapted by the device to a value of 19 %.
The information on the patient card and the saved data on the device remain unchanged.

7.3.2 Time optimization

7.3.2.1 Permitted reduction of the dwell duration

The goal of the "permitted reduction of the dwell duration" 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 min and a factor of 15 % for the “permitted reduction of the dwell duration”, this dwell duration may be reduced by 15 min.

In case of frequent reductions of the dwell duration, the parameter **Catheter performance** can be used to influence the expected treatment duration. The **Catheter performance** parameter can be changed by specialized clinical staff.

If a value greater than 19 % was prescribed via the associated medical software application for the patient parameter “permitted reduction of the dwell duration”, this preset value is automatically adapted by the device to a value of 19 %.
The information on the patient card and the saved data on the device remain unchanged.

7.3.2.2 Catheter performance

The catheter performance describes the patient's outflow characteristics.
It can be set by specialized clinical staff in the **Patient parameters** menu.
The **catheter performance** influences the calculated outflow duration and thus the expected total treatment duration.

In case of frequent reductions of the dwell duration, the expected treatment duration can be adapted to the actual treatment duration using the parameter **Catheter performance**. Increasing this parameter will increase the expected treatment duration.

7.3.3 Therapy mode

The different therapy modes are "Default" and "Paediatric".

A patient card is configurable either in the "Default" therapy mode or the "Paediatric" therapy mode. This configuration can be defined only upon creating a new patient card and cannot be changed afterwards.

A treatment can only be performed with the patient card configured for this therapy mode. In the process, the patient parameters can be adjusted in a certain range corresponding to the therapy mode (see chapter 12.11 on page 251).

To carry out paediatric treatment, the patient card must be configured for the "Paediatric" therapy mode. The “Paediatric option” must also be enabled on the device.

7.3.4 Additional outflow

Three settings are possible for the “additional outflow” option:
– No additional outflow
  “No” is displayed on the screen
– Additional outflow with sound
  “Yes (with sound)” is displayed on the screen
– Additional outflow without sound
  “Yes (without sound)” is displayed on the screen

- **No additional outflow**

If the calculated patient volume is less than or equal to 0 ml at the end of the outflow, the last inflow is started automatically or the treatment is terminated if the last inflow has not been prescribed.

If the calculated patient volume is greater than 0 ml, a caution is displayed prompting the operator to check the patient line.

- **Additional outflow with sound**

If the calculated patient volume is below the permitted residual volume at the end of the outflow, a caution is displayed prompting the operator to check the outflow volume achieved.

If the calculated patient volume is greater than the permitted residual volume, a caution is displayed prompting the operator to check the patient line.

- **Additional outflow without sound**

If the calculated patient volume is below the permitted residual volume at the end of the outflow, a treatment pause is initiated.

If the calculated patient volume is greater than the permitted residual volume, a caution is displayed prompting the operator to check the patient line.

8 Consumables, accessories, additional equipment

8.1 To be observed in the "Consumables, accessories, additional equipment" chapter

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

Warning

Chapter 8 (see chapter 8 on page 215) 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 device manufacturer cannot make any statements regarding the safety and performance of the device when it is used with consumables and accessories other than those listed.

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.

Note

Various consumables are required to perform a treatment. When using dialysis solutions, make sure these solutions are used in accordance with the manufacturer's specifications.

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:

8.2 Consumables

8.2.1 Dialysis solutions

The following dialysis solutions are registered in Canada.

Dialysis Solution	Product Description	Product Codes	DIN
Balance 1.25 mmol/L Calcium	1.5 % glucose	F00006306	02261057
	2.3 % glucose	F00006307	02261073
	4.25 % glucose	F00006308	02261065
Balance 1.75 mmol/L Calcium	1.5 % glucose	Not currently marketed in Canada	02261022
	2.3 % glucose		02261049
	4.25 % glucose		02261030

8.2.2 Single use items

Product	Information
sleep•safe Set	Line set
sleep•safe Set Plus	Line set with second patient connector
sleep•safe Set Paed	Line set for paediatric treatment
Drainage Extension Line - 12 m Biofine®	Drain line extension made of Biofine®, length 12 m
Drainage Extension Line - 12 m PVC	Drain line extension made of PVC, length 12 m
Safe•Lock® PD-NIGHT® Drainage Set	Drain set with 2 drain bags
stay•safe® disinfection cap	Disinfection cap with povidone-iodine
stay•safe® closure cap	Closure cap without povidone-iodone
APD sample bag	Sampling bag
sleep•safe Luer lock adapter	Only in combination with a 7.5 % polyglucose solution bag
PIN Reload device	

8.2.3 Surface disinfection / surface cleaning

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

8.3 Accessories

No accessories are provided for this device.

8.4 Additional equipment

Product	Part number	Information
sleep•safe harmony **Patient**Card *Plus*	M45 129 1	Patient card
sleep•safe transport case	M39 023 1	
sleep•safe harmony porter with drain tray	M20 601 1	With drain tray
sleep•safe harmony porter	M20 602 1	Without drain tray

8.5 Device

Product	Part number	Information
sleep•safe harmony	M20 600 1	

8.5.1 Products in combination with the device

Products that can be used in combination with the device.

Product	Part number	Information
Organiser	284 256 1	
Clip for organiser	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)

9.1.2.1 General requirements

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

Power supply cord

If the power supply cord needs to be replaced, use only the power supply cord approved by the manufacturer and listed in the spare parts catalogue.

Rechargeable battery

Maintenance of the built-in rechargeable battery

Connect the *sleep•safe harmony* to the power supply every 6 months, use the power switch to switch the device on and leave on for 24 hours in Ready mode.

9.2 Installation requirements

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:
Non-paediatric treatment +15 °C to +35 °C
Paediatric treatment +20 °C to +35 °C

Atmospheric pressure:
750 hPa (approx. altitude 2500 m) up to 1060 hPa

Relative humidity:
30 % to 75 %, temporarily 95 % (non-condensing)

Electromagnetic radiation

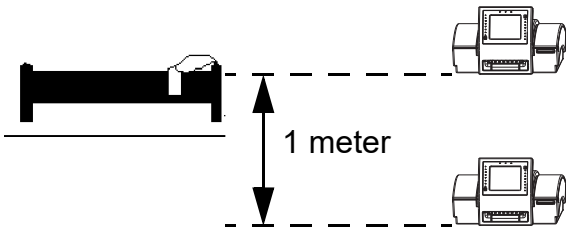
Do not use devices that emit any form of electromagnetic radiation (e.g., walkie-talkies, mobile phones or radio transmitters) in the vicinity of a *sleep•safe harmony* in operation. This may cause a malfunction of the *sleep•safe harmony* (see chapter 12.6 on page 242).

9.3 Setting up the *sleep•safe harmony*

➢ Remove the *sleep•safe harmony* from the *sleep•safe* transport case and place it on a stable, horizontal surface. Make sure the *sleep•safe harmony* is horizontal. The maximum incline allowed is less than 5°.

Note

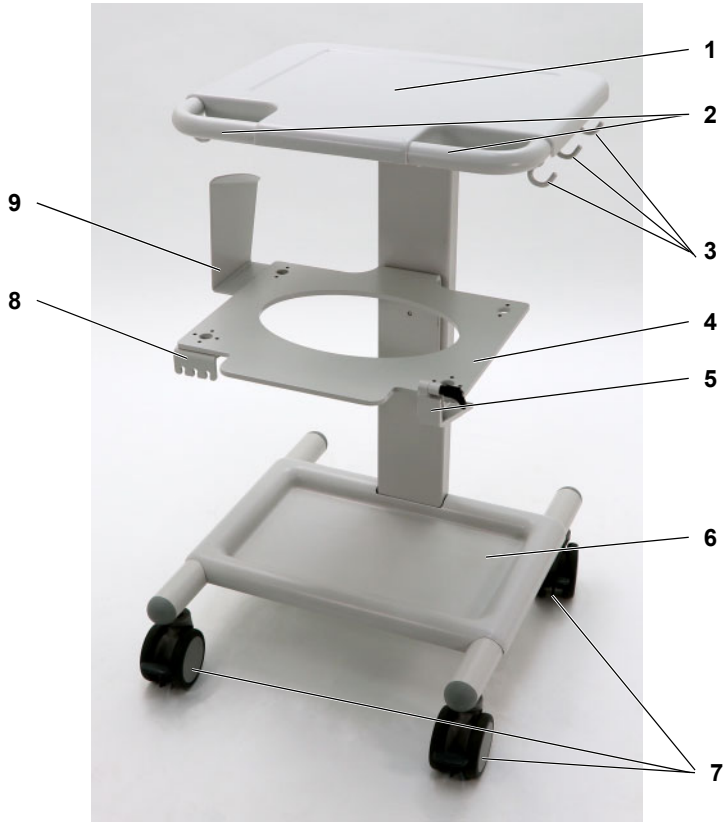
During treatment, the *sleep•safe harmony* should be positioned at the same level as the patient or a maximum of 1 metre below the patient.
Changes to the patient level outside this range during outflow may lead to a reduction in the outflow rate and even outflow interruptions.



Note

The outlet of the drain line must never be more than 2 metres below or above the *sleep•safe harmony*.

9.4 Mounting the porter



1 Tray

The tray can be placed on the porter frame in two positions so that the handles are on either the front or back of the porter.

Solution bags and single-use items (e.g., disinfection cap, disinfectant or face mask) can be placed on the tray prior to the treatment.

2 Handles

Only move the porter using the two handles.

3 Holder for solution bags

The solution bags can be attached here during preparation and treatment.

4 Shelf for the device

The shelf can be set at two different heights. To adjust the height, loosen the knob on the back of the porter and lift the shelf slightly to release it from its anchoring. Turn the shelf upside down and insert it back into its anchoring.

Fasten the anchoring in place by tightening the knob on the back of the porter.

5 Holder for organiser

The holder for the organiser is fastened in place with the wing screws on the underside of the device shelf. To adjust holder for the organiser, unscrew the lever, bring the holder into the required position and then screw the lever tight again.

The lever can be brought into the required screwing position by pulling and simultaneously turning it.

To fasten the organiser in place, push it onto the holder as far as it will go.

6 Drain tray (optional)

The tray for the drain line system is positioned on the porter frame.

The drain line system is placed on the drain tray.

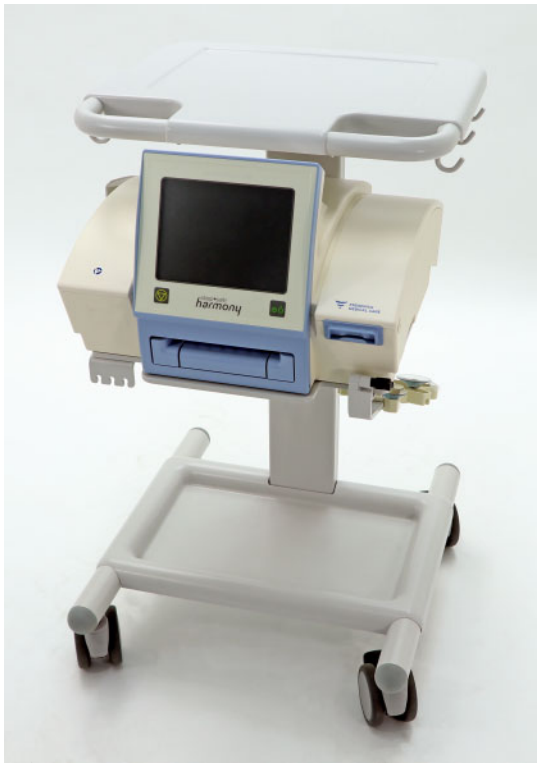
7 Wheels with brake

The four wheels can be locked individually.

8 Holder for the solution bag connectors
The holder is fastened in place with the wing screws on the underside of the device shelf.
The solution bag connectors' lines can be inserted here during preparation.

9 Spacer for ventilation grille
The spacer is fastened in place with the wing screws on the underside of the device shelf.
The space between the spacer and the device must be kept clear.

9.4.1 Positioning the *sleep•safe harmony* on the porter



➢ Apply the brakes.

➢ When placing the device on the shelf, make sure that the feet of the device are positioned in the openings on the shelf.

9.5 Installation after shipment / transport outside of buildings

For storage, shipment and transport of the device outside of buildings, use the designated *sleep•safe* transport case (see chapter 8.4 on page 218).

Follow the instructions below if the *sleep•safe harmony* is transported in its *sleep•safe* transport case, e.g., by car or railway, to a different location for operation.

9.5.1 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.

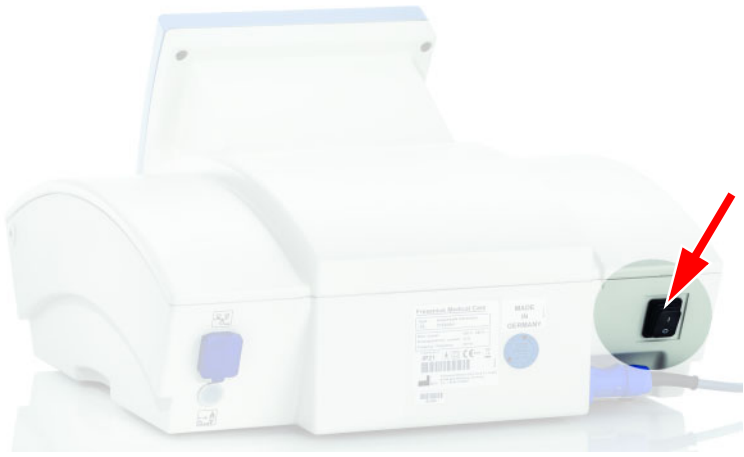
➢ Inform the responsible organization or service support.

9.5.2 System check

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.

9.5.3 Extended system test

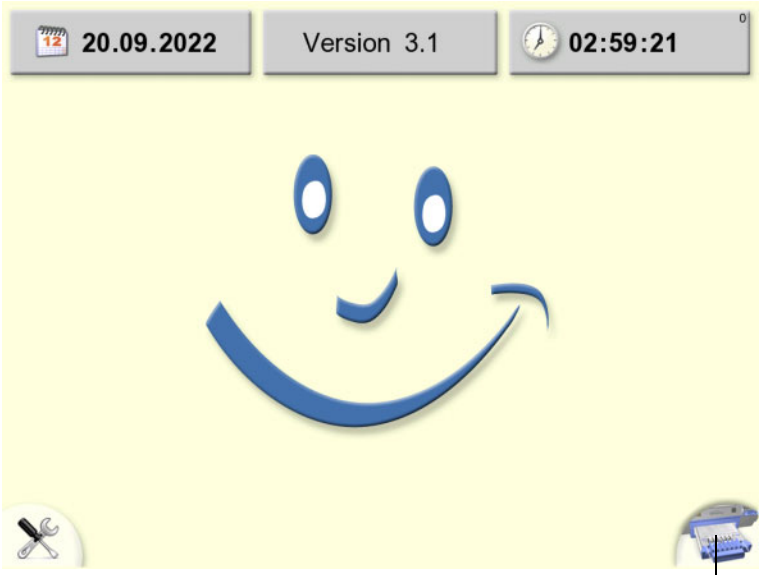


➢ Connect the *sleep•safe harmony* to the power supply.

➢ Switch the *sleep•safe harmony* on with the power switch.

➢ Press the key as soon as it lights up.

After the power has been switched on, the device will first perform a functional test as described in the following steps.



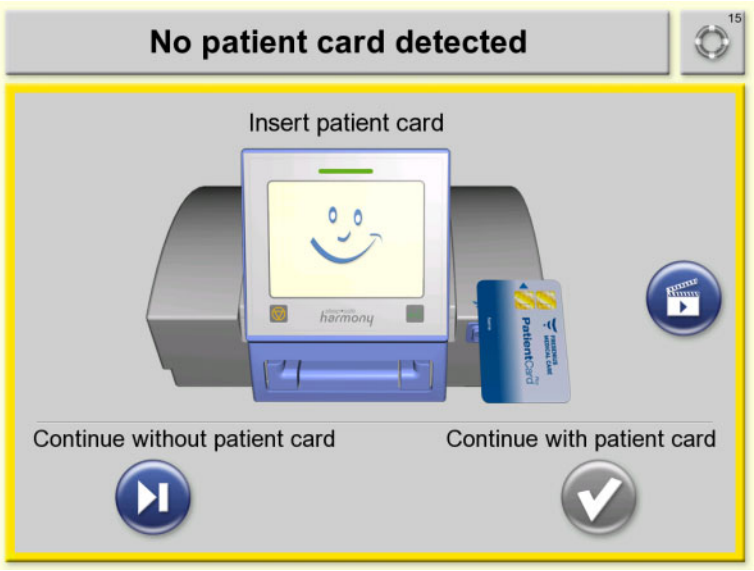
The *sleep•safe harmony* is ready for operation as soon as the screen shown on the left is displayed.

The following information will be displayed:

– The current date
– The software version
– The current time

➢ Press the nose of the smiley to move to the next operating step.

➢ If the *sleep•safe* Set is still in the *sleep•safe harmony* after a treatment has been prematurely terminated, press the button (1) on the right at the bottom of the screen to open the loading tray.

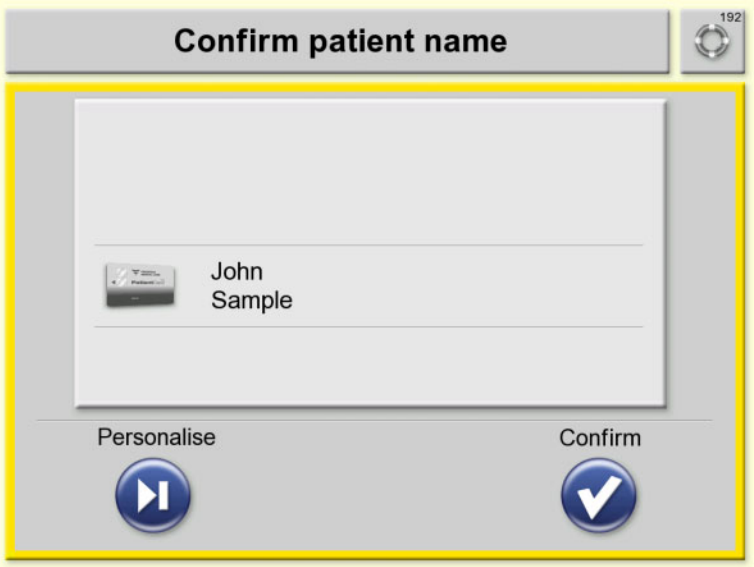


➢ Press the button to start the treatment with a patient card.

or

➢ Press the button only if you wish to start treatment without a patient card.

➢ The button can be used to re-play the screen animation.



If the treatment was started without a patient card, the patient name must be confirmed.

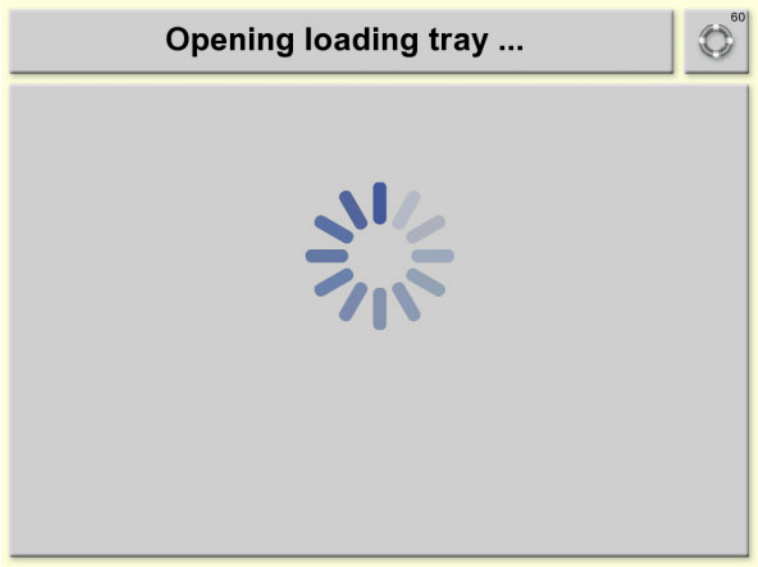
➢ Press the button only if you need to personalise the *sleep•safe harmony*.
This will create a patient card with standard values.

➢ Press the button to confirm the patient name.

The **Prescription** tab shows the following information:

– Patient name
– Prescription
– Maximum inflow volume
– Total treatment volume
– Expected treatment duration (without time optimisation here)

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



The *sleep•safe harmony* will perform internal tests.

During the test the audible alarm can be heard and the status indicator is red. After about 5 seconds, first the connector rail, then the loading tray opens.

The next screen message will be displayed automatically.

Warning

Patient hazard from not reaching 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 signalled during the treatment. This would prevent detection of any treatment interruptions, and it would not be possible to carry out the treatment as planned.

➢ The device must not be used.

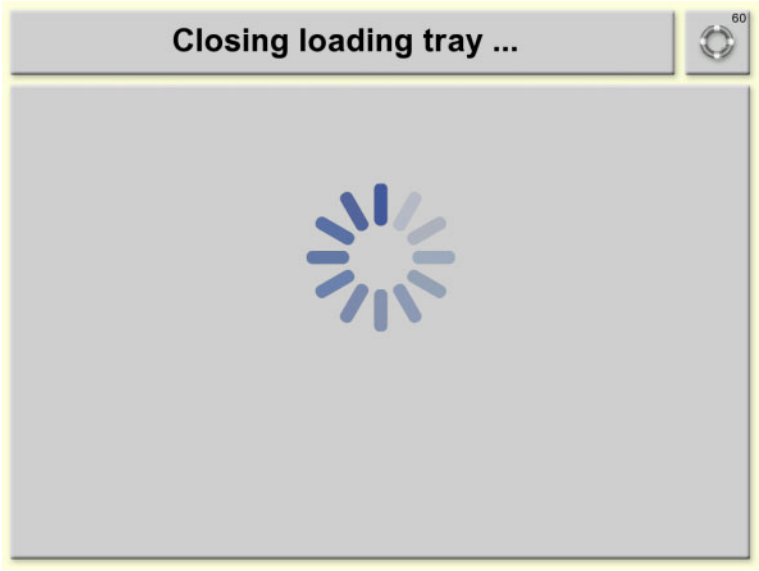
➢ Call service support.

➢ **Do not** insert a *sleep•safe* Set in the open loading tray.

➢ Press the key.

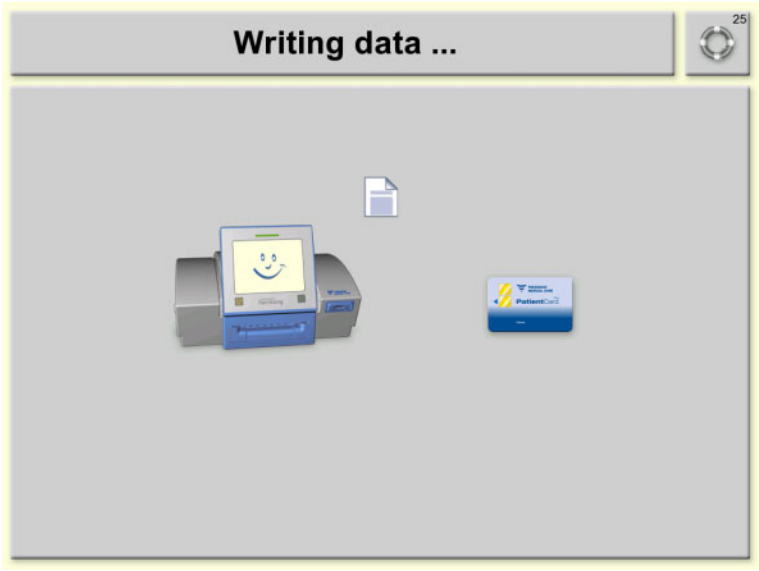
➢ Press the button.

➢ Press the button to return to the previous operating step.



The loading tray closes.

The next screen message will be displayed automatically.



The *sleep•safe harmony* will shut down.

➢ If the "Extended system test" has successfully completed, the *sleep•safe harmony* can be used for treatment.

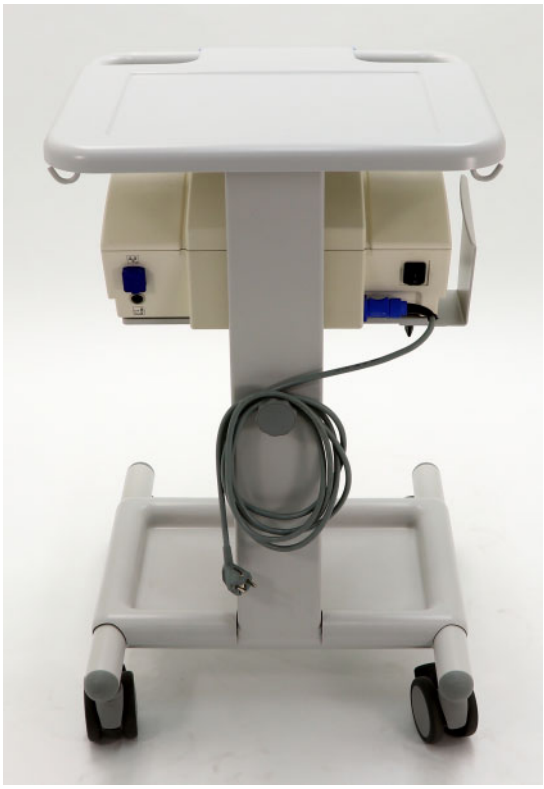
10 Transport/storage

10.1 Transport within buildings

The *sleep•safe harmony* can be put back into operation without any additional tests if it is only briefly disconnected from the power supply and moved to a different room within the same building.

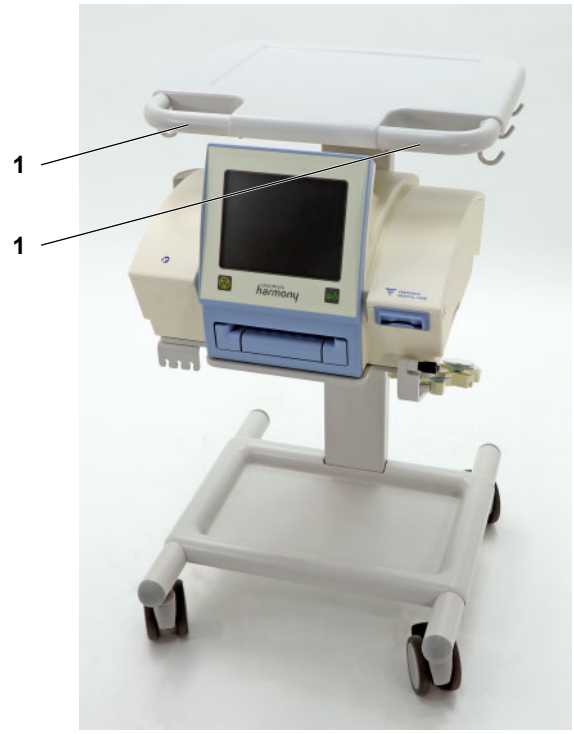
10.1.1 Transport prior to preparation

The porter can be used to transport the *sleep•safe harmony* within buildings.



➢ Disconnect the device from the power supply prior to transport.

➢ Wind up the power supply cord and place it on the knob on the back of the porter.



➢ Release all brakes.

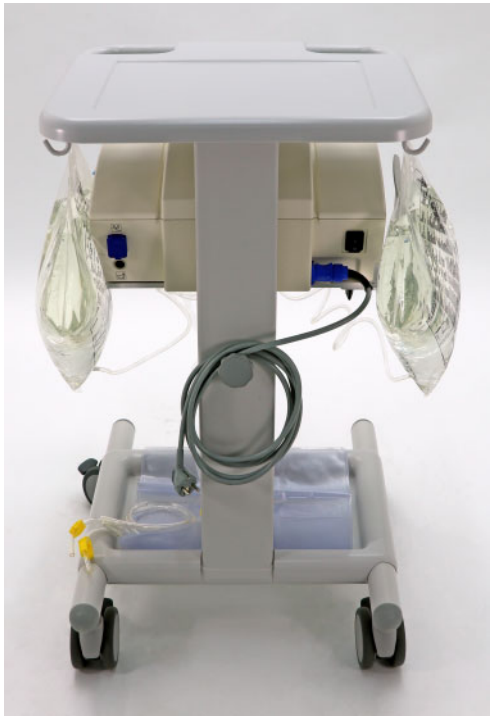
➢ Hold the porter by both handles (1) when pushing or pulling it. Watch out for obstacles.

➢ If you need to pull the device over an obstacle, hold the porter by the handles and pull it up to the obstacle.
Pull the porter from one side, holding onto either the right or left handle, and move it slowly over the obstacle one wheel at a time.

10.1.2 Transport during preparation with the Relocate device function

The porter can be used to transport the device within buildings.

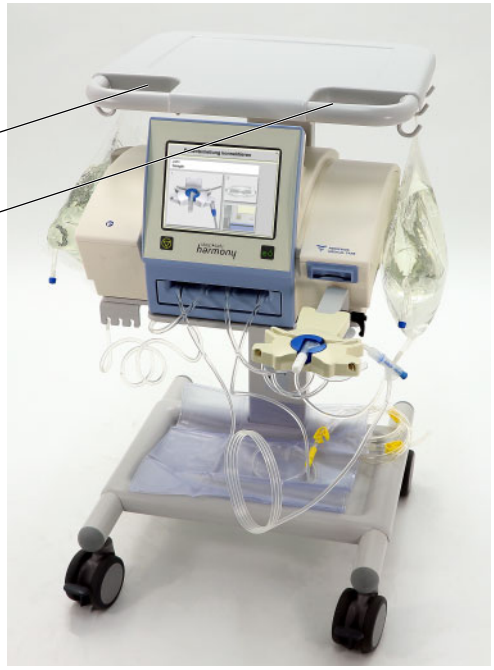
During preparation, after the line set has been completely primed, the device can be set to relocation mode, to move the device to a different location (see chapter 4.6.3.2 on page 145).



➢ Disconnect the device from the power supply prior to transport.

➢ Wind up the power supply cord and place it on the knob on the back of the porter.

➢ Leave the patient line rolled up to ensure that the porter does not roll over it.



➢ The organiser must be checked to ensure it is positioned securely before relocating the device.

➢ Release all brakes.

➢ Hold the porter by both handles (1) when pushing or pulling it. Watch out for obstacles.

➢ If you need to pull the device over an obstacle, hold the porter by the handles and pull it up to the obstacle.
Pull the porter from one side, holding onto either the right or left handle, and move it slowly over the obstacle one wheel at a time.

10.2 Shipment/transport outside of buildings

(see chapter 9.5 on page 223)

10.3 Storage

The *sleep•safe harmony* must be stored in its *sleep•safe* transport case on a stable, horizontal surface in a well ventilated room.

10.3.1 Storage conditions

Temperature	-10 to +60 °C
Relative humidity	30 % to 75 %, temporarily 95 % (non-condensing)
Atmospheric pressure	500 (approx. 5000 m) up to 1060 hPa
Maintenance of the built-in rechargeable battery	Connect the *sleep•safe harmony* to the power supply every 6 months, use the power switch to switch the device on and leave on for 24 hours in Ready mode.

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 organisation 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.

Within the EC member states, the device must be disposed of in accordance with the "Directive on waste electrical and electronic equipment" (WEEE directive). Please also observe the applicable local regulations.

Before the device is sent off for return or disposal, the responsible organisation must ensure that all consumables attached to the device are removed and the device is disinfected as specified by the manufacturer (see chapter 6 on page 199).

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

– For information on the batteries and other materials used, consult the appropriate chapters of these Instructions for Use (see chapter 12.10 on page 251) or (see chapter 12.15 on page 259).
– Batteries must be properly disposed of in accordance with the applicable national regulations.
– The *sleep•safe harmony* contains triacetin, a hydraulic fluid. Triacetin must not be disposed of with domestic refuse and must not enter the sewage system. The disposal options depend on the local, national regulations and requirements, which must be followed.
– The *sleep•safe harmony* has an 8.4" 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 on the technical safety checks / maintenance procedures

Technical safety checks (TSCs)

The first TSC is required before the end of the 24th month following initial start-up after delivery from the factory. All further TSCs are required before the end of the 24th month following the last TSC performed.

Maintenance procedures (MAs)

The maintenance procedures (MA) are a recommendation of the manufacturer. The maintenance procedures (MAs) 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 (MAs) should be performed before the end of the 24th month following the last maintenance procedure (MA) performed.

Qualification requirements of testers

The checks must be performed by the Fresenius Medical Care 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 TSCs and detailed explanations of how to perform them are described in the Service Manual.

Reports can be supplied on request.

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

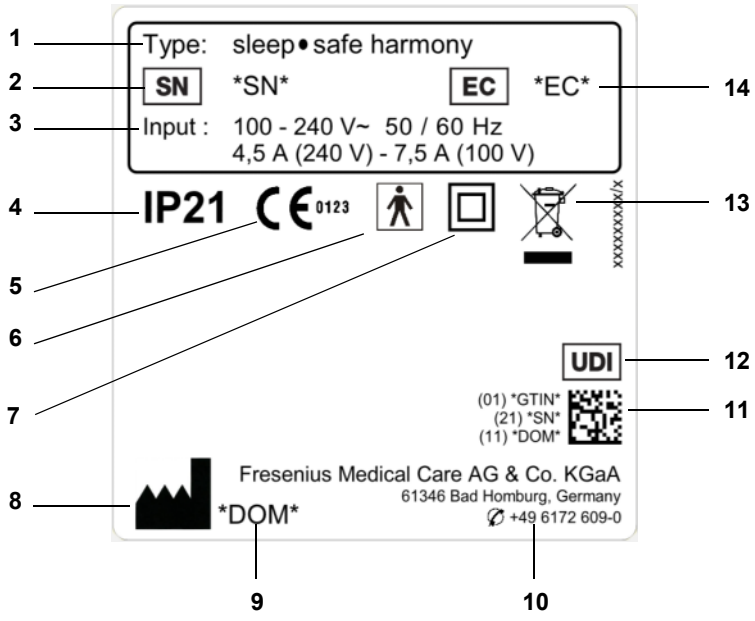
12 Specifications

12.1 Dimensions and weight

Dimensions	Height: 30.5 cm Width: 45.5 cm Depth: 42.5 cm
Weight without *sleep•safe* case	max. 20 kg

12.2 Identification label (*sleep•safe harmony* product marking)

The identification label shown is only an example. Always go by the information shown on the identification label affixed to the *sleep•safe harmony* device itself.



1 Type identification

2 Serial number

3 Power requirements

4 Degree of protection against ingress of foreign bodies and liquids
2: Protection against touch and foreign bodies with a diameter greater than 12.5 mm
1: Protection against vertically falling water drops

5 CE mark

6 Type of applied part BF (degree of patient protection)

7 Device protection against electric shock:
Protection class II

8 Manufacturer’s symbol

9 Date of manufacture

10 Manufacturer’s address

11 Datamatrix code

12 Unique Device Identifier

13 Separate waste disposal of electrical and electronic equipment.

14 Equipment code

12.3 Electrical safety

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

Device protection against electric shock	Protection class II, symbol: 
Type of applied part (Degree of patient protection)	Type BF, symbol 
Applied part	*sleep•safe* Set
Degree of protection against ingress of foreign bodies and liquids	IP21, Symbol: **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, 50/60 Hz (Always go by the line voltage, frequency and current consumption information specified on the identification label affixed to the *sleep•safe harmony* device itself.)
Power supply connection	According to local regulations for electrical power supply.
Power supply cord	Length 3.5 m, unshielded
Operating current	4.5 A (at 240 V AC) 7.5 A (at 100 V AC)
Power supply (internal)	+24 V ±5 %, 3 A, short-circuit-proof +12 V ±5 %, 0.5 A, short-circuit-proof +5 V ±5 %, 3 A, short-circuit-proof
Power switch	All-pole, simultaneous disconnection

12.5 Fuses

PCB/ assembly	Item no.	Value
PCB LP1365	F1	T 0.315 A / 305 VAC / 250 VDC
PCB LP1365	F2	T 4.0 A / 305 VAC / 250 VDC
PCB LP1365	F3	T 8.0 A / 250 VAC / 250 VDC
PCB LP1365	F4	T 0.125 A / 305 VAC / 250 VDC
PCB LP1366	F1	T 3.0 A
PCB LP1366	F2	T 1.5 A

PCB/ assembly	Item no.	Value
PCB LP1366	F3	T 5.0 A
PCB LP1366	F4	T 4.0 A
PCB LP1366	F5	T 3.0 A
PCB LP1366	F6	T 1.0 A
PCB LP1467	F1	F 1 A / 125 V
PCB LP1467	F2	F 1 A / 125 V
PCB LP1467	F3	F 1 A / 125 V
PCB LP1467	F4	F 1 A / 125 V
PCB LP1467	F5	F 1 A / 125 V
PCB LP1467	F6	F 1 A / 125 V
PCB LP1467	F7	0.160 A / 125 V
PCB LP1467	F8	T 2.5 A / 250 V

12.6 Information on electromagnetic compatibility

Specifications refer to the requirements of IEC 60601-1-2.

The device corresponded to an applicable edition of IEC 60601-1-2 at the time of production.

12.6.1 Minimum distances between radiation source and medical electrical equipment

Medical electrical devices are subject to special protective measures with regard to electromagnetic compatibility (EMC).

Warning

Patient hazard from a device malfunction

Portable RF communications equipment (radio equipment including its accessories such as antenna cables and external antennas) should not be used at a distance less than 30 cm (12 inches) from the device parts and cables 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):
mobile phone, smartphone, tablet PC, cordless phone, notebook/laptop, wireless keyboard, wireless mouse, wireless speaker, wireless remote control (The device-specific wireless remote control provided by the manufacturer is not affected.)

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 Guidance and manufacturer's declaration on EMC

- **Electromagnetic emissions**

Regardless of the following EMC specifications, the specification of use must be taken into account and followed.

Guidance and manufacturer's declaration – electromagnetic emissions		
The *sleep•safe harmony* device is intended for use in the electromagnetic environment specified below. The customer or the user of the *sleep•safe harmony* 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 *sleep•safe harmony* 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 *sleep•safe harmony* 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 *sleep•safe harmony* device is intended for use in the electromagnetic environment specified below. The customer or the user of the *sleep•safe harmony* device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, and ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, and ±15 kV air	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 100 kHz repetition rate	±2 kV for power supply lines ±1 kV for input / output lines 100 kHz repetition rate	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV and ±1 kV differential mode ±0.5 kV, ±1 kV, and ±2 kV common mode; line(s) to earth	±0.5 kV and ±1 kV differential mode ±0.5 kV, ±1 kV, and ±2 kV common mode; line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
The *sleep•safe harmony* device is intended for use in the electromagnetic environment specified below. The customer or the user of the *sleep•safe harmony* device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T for 0.5 cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0 % U_T for 1 cycle 70 % U_T for 25 cycles at 50 Hz or 30 cycles at 60 Hz 0 % U_T for 250 cycles at 50 Hz or 300 cycles at 60 Hz	0 % U_T for 0.5 cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0 % U_T for 1 cycle 70 % U_T for 25 cycles at 50 Hz or 30 cycles at 60 Hz 0 % U_T for 250 cycles at 50 Hz or 300 cycles at 60 Hz	In the event of power supply interruptions, the rechargeable batteries of the *sleep•safe harmony* device take over the supply without delay. Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 or 60 Hz	30 A/m 50 or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The *sleep•safe harmony* device is intended for use in the electromagnetic environment specified below. The customer or the user of the *sleep•safe harmony* device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz 80 % AM at 1 kHz 6 V_{rms} in ISM bands between 150 kHz and 80 MHz 80 % AM at 1 kHz	3 V_{rms} 150 kHz to 80 MHz 80 % AM at 1 kHz 6 V_{rms} in ISM bands between 150 kHz and 80 MHz 80 % AM at 1 kHz	Portable radio-frequency communications equipment (radio equipment including its accessories such as antenna cable and external antennas) should not be used at a distance less than 30 cm (12 inches) from the device. Failure to observe this information may have a negative impact on the performance characteristics of the device.

Guidance and manufacturer's declaration – electromagnetic immunity			
The *sleep•safe harmony* device is intended for use in the electromagnetic environment specified below. The customer or the user of the *sleep•safe harmony* device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz 9 V/m 704 to 787 MHz, 5100 to 5800 MHz Modulation: PM; 217 kHz 27 V/m 380 to 390 MHz Modulation: PM; 18 kHz 28 V/m 430 to 470 MHz Modulation: FM; 1 kHz sine 28 V/m 800 to 960 MHz Modulation: PM; 18 kHz 28 V/m 1700 to 1990 MHz 2400 to 2570 MHz Modulation: PM; 217 kHz	10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz 9 V/m 704 to 787 MHz, 5100 to 5800 MHz Modulation: PM; 217 kHz 27 V/m 380 to 390 MHz Modulation: PM; 18 kHz 28 V/m 430 to 470 MHz Modulation: FM; 1 kHz sine 28 V/m 800 to 960 MHz Modulation: PM; 18 kHz 28 V/m 1700 to 1990 MHz 2400 to 2570 MHz Modulation: PM; 217 kHz	Portable radio-frequency communications equipment (radio equipment including its accessories such as antenna cable and external antennas) should not be used at a distance less than 30 cm (12 inches) from the device. Failure to observe this information may have a negative impact on the performance characteristics of the device.

Guidance and manufacturer's declaration – electromagnetic immunity			
The *sleep•safe harmony* device is intended for use in the electromagnetic environment specified below. The customer or the user of the *sleep•safe harmony* device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Radiated fields in close proximity according to IEC 61000-4-39	30 kHz Modulation: CW, 8 A/m (for home care settings only) 134.2 kHz Modulation: PM; 2.1 kHz, 65 A/m 13.56 MHz Modulation: PM; 50 kHz, 7.5 A/m	30 kHz Modulation: CW, 8 A/m (for home care settings only) 134.2 kHz Modulation: PM; 2.1 kHz, 65 A/m 13.56 MHz Modulation: PM; 50 kHz, 7.5 A/m	The impact of radio equipment on magnetically sensitive components or circuits must not have a negative impact on the performance.
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

12.7 Operating conditions

Operating temperature range	Non-paediatric treatment +15 °C to +35 °C Paediatric treatment +20 °C to +35 °C
Atmospheric pressure	750 (approx. altitude 2500 m) up to 1060 hPa
Relative humidity	30 % to 75 %, temporarily 95 % (non-condensing)
Stability	Maximum incline allowed: 5°

12.8 Storage conditions

Temperature	-10 to +60 °C
Relative humidity	30 % to 75 %, temporarily 95 % (non-condensing)

Atmospheric pressure	500 (approx. 5000 m) up to 1060 hPa
Maintenance of the built-in rechargeable battery	Connect the *sleep•safe harmony* to the power supply every 6 months, use the power switch to switch the device on and leave on for 24 hours in Ready mode.

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 require 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.

Note

Additional devices may only be connected by the local service.

LAN

Interface for data exchange.
Electrically isolated by transformer.
Port: RJ 45
Length of network cable: 3 m
Network cable shielding: CAT5 or better

Alarm output

Function currently not available.

12.10 Batteries

The operator has no access to the batteries or the rechargeable battery.

Batteries

Lithium CR 2032 / PCB LP1452

Rechargeable battery

Lead-acid battery (maintenance-free)
12 V, 1.2 Ah

12.11 Parameters

12.11.1 Prescription parameters for the DEFAULT therapy mode

Inflow volume	Adjustment range	501 to 3500 ml
	Resolution	1 ml

TIDAL inflow volume	Base inflow volume	Adjustment range	501 to 3500 ml
		Resolution	1 ml
	Tidal inflow volume	Adjustment range	50 to 3450 ml
		Resolution	1 ml
	Tidal outflow volume	Adjustment range	50 to 3450 ml
		Resolution	1 ml
Dwell duration		Adjustment range	5 to 300 min
		Resolution	1 min
		Tolerance	±1 min
Number of cycles		Adjustment range	1 to 50
		Resolution	1
TIDAL number of cycles	Base cycles	Adjustment range	1 to 5
		Resolution	1
	Tidal cycles	Adjustment range	2 to 15
		Resolution	1
Initial outflow		Adjustment range	50 to 3450 ml
		Resolution	1 ml
Last inflow		Adjustment range	50 to 3500 ml
		Resolution	1 ml
Target inflow rate		Adjustment range	50 to 350 ml/min
		Resolution	1 ml/min
Target outflow rate		Adjustment range	50 to 230 ml/min
		Resolution	1 ml/min
Dialysis solution flow into the patient*		Depends on the set maximum inflow rate	0 to 350 ml/min
Dialysis solution flow out of the patient*		Depends on the set maximum outflow rate	0 to 230 ml/min

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

12.11.2 Prescription parameters for the PAEDIATRIC therapy mode

Inflow volume		Adjustment range	100 to 500 ml
		Resolution	1 ml
TIDAL inflow volume	Base inflow volume	Adjustment range	100 to 500 ml
		Resolution	1 ml
	Tidal inflow volume	Adjustment range	50 to 450 ml
		Resolution	1 ml
	Tidal outflow volume	Adjustment range	50 to 450 ml
		Resolution	1 ml
Dwell duration		Adjustment range	5 to 300 min
		Resolution	1 min
		Tolerance	±1 min
Number of cycles		Adjustment range	1 to 50
		Resolution	1
TIDAL number of cycles	Base cycles	Adjustment range	1 to 5
		Resolution	1
	Tidal cycles	Adjustment range	2 to 15
		Resolution	1
Initial outflow		Adjustment range	50 to 450 ml
		Resolution	1 ml
Last inflow		Adjustment range	50 to 500 ml
		Resolution	1 ml
Target inflow rate		Adjustment range	50 to 150 ml/min
		Resolution	1 ml/min
Target outflow rate		Adjustment range	50 to 100 ml/min
		Resolution	1 ml/min
Dialysis solution flow into the patient*		Depends on the set maximum inflow rate	0 to 150 ml/min
Dialysis solution flow out of the patient*		Depends on the set maximum outflow rate	0 to 100 ml/min

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

12.11.3 General device parameters

Dosing tolerance	±15 ml (if dialysis solution is free of air) From 50 ml to 100 ml inflow volume. ±15 % (if dialysis solution is free of air) From 100 ml to 500 ml inflow volume. ±3 % (if dialysis solution is free of air) From 500 ml inflow volume.	
Balancing tolerance *	+2 ml / -10 ml for each cycle (if dialysis solution is free of air) from 50 ml to 500 ml inflow volume. +1% / -5% for each cycle and the complete treatment (if dialysis solution is free of air) from 500 ml inflow volume.	
Inflow time	Depending on flow rate	
Outflow time	Depending on flow rate	
Heater *	Fixed patient inflow temperature	37 °C
	Tolerance	-7 to +2 °C
Temperature monitoring	A maximum limit of less than 41 °C at the patient connector has been defined. When an alarm occurs, this is audibly signalled after a maximum 120 seconds.	
Outflow pressure monitored by the safety system	At patient access with closed patient line DEFAULT therapy mode	Maximum -100 mbar
	At patient access with closed patient line PAEDIATRIC therapy mode	Maximum -80 mbar

Technique and sensitivity of the safety system against infusion of air	Pressure/volume method 2.5 % air per pump chamber Continuous air detection during each cycle. Larger amounts of air in the inflow phase will be diverted to the drain. The operator will be alerted if air is drawn in directly.
Technique and sensitivity of the safety system against overfilling	Volume balancing is a maximum of 10 % above the permitted patient volume
Audible signal silencing	The audible signal can be silenced for 6 minutes.

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

12.11.4 Patient parameters

Permitted patient volume	Adjustment range: 100 to 120 % of the maximum prescribed inflow volume	Default value 110 %
Permitted residual volume	Adjustment range: 10 to 50 % of the maximum volume in the patient	Default value 35 %

Permitted reduction of the dwell duration	Adjustment range: 0 to 19 % The device adapts the value for the current treatment if necessary. The data on the patient card will remain unchanged (see chapter 7.3.2.1 on page 211).	Default value 15 %
Permitted reduction of the inflow volume	Adjustment range: 18 to 19 % The device adapts the value for the current treatment if necessary. The data on the patient card will remain unchanged (see chapter 7.3.1.3 on page 210).	Default value 18 %
Catheter performance	Adjustment range: 100 to 130 % = High 131 to 160 % = Normal 161 to 200 % = Low	Default value 130 %

12.12 Factory settings

Parameters		Factory setting
Inflow volume DEFAULT therapy mode		2000 ml
Inflow volume PAEDIATRIC therapy mode		100 ml
TIDAL inflow volume DEFAULT therapy mode	Base inflow volume	2000 ml
	Tidal inflow volume	1000 ml
	Tidal outflow volume	1000 ml
TIDAL inflow volume PAEDIATRIC therapy mode	Base inflow volume	100 ml
	Tidal inflow volume	50 ml
	Tidal outflow volume	50 ml
Dwell duration DEFAULT therapy mode		120 min
Dwell duration PAEDIATRIC therapy mode		60 min
Target inflow rate DEFAULT therapy mode		350 ml/min

Parameters	Factory setting
Target inflow rate PAEDIATRIC therapy mode	150 ml/min
Target outflow rate DEFAULT therapy mode	230 ml/min
Target outflow rate PAEDIATRIC therapy mode	100 ml/min
Permitted patient volume	Default value 110 %
Permitted residual volume	Default value 35 %
Permitted reduction of the dwell duration	Default value 15 %
Permitted reduction of the inflow volume	Default value 18 %
Catheter performance	Default value 130 %
Therapy mode	DEFAULT
Additional outflow	Yes (with sound)
Access level	Select prescription
Screen saver	5 min
Volume	100 %
Brightness	100 %

12.13 Porter

12.13.1 Dimensions and weight of the porter

Dimensions

Height: 94 cm
Width: 55 cm
Depth: 60 cm

Weight

24 kg

12.13.2 Permissible loads

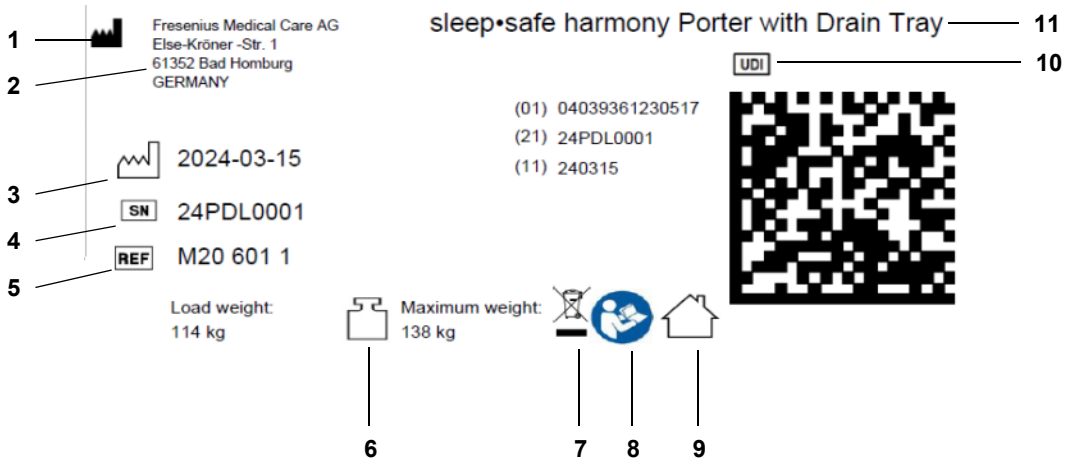
Loading of solution bag holder

Maximum: 1 solution bag per hook

Maximum load capacity of tray	20 kg
Maximum load capacity of drain tray	20 kg
Maximum load capacity of device shelf	25 kg

12.14 Identification label (porter marking)

The identification label shown is only an example. Always go by the information shown on the identification label affixed to the porter itself.



1 Manufacturer’s symbol

2 Manufacturer’s address

3 Date of manufacture

4 Serial number

5 Order number

6 Maximum total weight

7 Separate waste disposal of electrical and electronic equipment.

8 Follow Instructions for Use

9 Only for indoor use

10 Unique Device Identification

11 Type identification

12.15 Materials used

- **Plastics and elastomers**

Abbreviation	Material	Used in
ABS	ABS (TSG) Rotec	Housing
ZK/CR	Cellular rubber	Sound insulation
POM	Delrin	Hydraulic pump housing
PA (PA6.6)	Polyamide	Barcode scanner holder
PE	Polyethylene	Container (hydraulic pump) *sleep•safe* transport case, foam insert for *sleep•safe* transport case
PES	Polyethersulfone	Heater frame
EPDM	Ethylene propylene diene monomer	Seals, air cushion
PTFE	Polytetrafluoroethylene	Slide bushings
PVC	Polyvinyl chloride	Cable insulation
PP	Polypropylene	Wheels of *sleep•safe* transport case
	Kapton film	Transformer/electromagnet
	Silicone	Loading tray and machine block coating, cable insulation, seals
	Butyl rubber	Dome membrane
	Epoxy fiberglass	Printed circuit boards, insulating boards
	Keratherm® - Softtherm®	Heat conductor pad for ETX CPU

- **Metals**

Abbreviation	Material	Usage
	Aluminum	Loading tray Machine block, function block and PSU chassis Compressor retaining plate Telescopic handle for *sleep•safe* transport case
	Iron	Transformer/electromagnet, ferrite core
	Steel	Sockets, tubes, shielding plates
	Copper	Transformer/electromagnet, plug connectors, cords
	Tin	Plug connectors

- **Glass/ceramics**

Abbreviation	Material	Usage
	Borosilicate glass	Glass cylinder of hydraulic pump, screen plate of display panel
	Ceramics (aluminum oxide, Al2O3)	Supports for heating conductors
	Ceramics (aluminum nitride AlN)	Mounting plate for heating element

- **Batteries**

Abbreviation	Material	Usage
	Lithium battery CR2032	PCB LP1450
	Lead-acid battery 12 V (2 x 6 V), 1.3 Ah	Rechargeable battery

● Auxiliary materials

Abbreviation	Material	Usage
	Loctite 648, 243, 406, 603, 2701, 595, 5366 UHU-Plus Endfest 300	Bonding adhesive for screws/bolts, drive sprockets, holding frames, temperature sensors
	Top coat: Alexit 346-18 Hardener: Alexit 345-39 Primer: Alexit 343-67 Hardener: Alexit 345-67	Coating system for base enclosure of the housing, lid, display panel, card slot
	Triacetin	Hydraulic fluid
	POLYLUB® GLY 151	Special lubricating grease for loading tray
	Barrierta L55/1	Special lubricating grease for machine block
	UNISILKON L 250 L	Special lubricating grease for loading tray
	Silicone oil	Oil for assembling dome membrane

13 Definitions

13.1 Definitions and terms

Aseptic	Sterile
Autoclave	To sterilize by subjecting to high pressure saturated steam
Dialysis solution	The exchange fluid used for the treatment.
Hypokalemia	Potassium deficiency
Hypovolemia	Decreased blood volume
Patient safe condition	Patient safety clamp closed. Dialysis solution flow from/to the patient stopped.
Pediatrics	Medical care of infants, children, and adolescents
Peritonitis	Inflammation of the peritoneum
Tidal	Cyclic inflow and outflow with permitted residual volume in patient's peritoneal cavity

13.2 Abbreviations

CCPD	Continuous Cyclic Peritoneal Dialysis
IPD	Intermittent Peritoneal Dialysis
MA	Maintenance procedures
NIPD	Nightly Intermittent Peritoneal Dialysis
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SVHC	Substance of Very High Concern

TSC	Technical Safety Checks

13.3 Symbols

Symbol	Description
	General warning
IP21	Degree of protection against ingress of foreign bodies 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
I/O	ON/OFF (power supply)
	On/Off (standby)
	10Base-T Ethernet port (LAN)
CE 0123	The CE mark documents compliance with the MDD 93/42/EEC. (MDD: medical device directive) Notified body: TÜV PRODUCT SERVICE 0123
	Separate waste disposal of electrical and electronic equipment.
	Alarm output
	Manufacturer’s symbol
	Serial number

Symbol	Description
	Equipment code
	Unique Device Identification
	Follow Instructions for Use
	Importer
	Safety seal

13.4 Certificates

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

14 Options

14.1 Paediatric option

Canadian Association of Paediatric Nephrologists (CAPN) recommends that in paediatrics the exchange volume be scaled to the patient's body surface area.

Further information on the Paediatric option is found in the following chapters.

14.1.1 Intended use

14.1.1.1 Intended purpose

(see chapter 2.6 on page 18)

14.1.1.2 Specification of use

(see chapter 2.6 on page 18)

14.1.1.3 Side effects

Peritoneal dialysis therapy carries the risk of an inflammation of the peritoneum (peritonitis). Furthermore, infections of the catheter exit site may occur, which often progress to tunnel infections and, eventually, to peritonitis.

Patients may experience pain during inflow and outflow. Distension and bloating (abdominal pain) may also occur in some patients. Shoulder pains and shortness of breath have also been observed, caused by an elevated diaphragm.

Depending on the dialysis solution used, a fluid-electrolyte imbalance can occur, e.g., potassium deficiency (hypokalemia). If too much fluid is removed during dialysis, this may result in a decreased blood volume (hypovolemia) with attendant diminished blood pressure.

In addition, the following side effects for APD have also been reported:
abdominal wall hernias, peritoneal leaks, and residual renal function (RRF) loss.

The following side effects have been reported in paediatric populations:
Infection-specifically peritonitis and catheter exit –site or tunnel infections; dialysis leakage; pain; hernia; hydrothorax and sclerosing encapsulating peritonitis.

14.1.1.4 Contraindications

This device must not be used on patients with severe chronic inflammatory bowel diseases or large abdominal adhesions.

This device should not be used in paediatric patients with omphalocele, gastroschisis, bladder extrophy, diaphragmatic hernia, or an obliterated peritoneal cavity.

14.1.1.5 Interactions with other systems

(see chapter 2.6 on page 18)

14.1.1.6 Therapy restrictions

(see chapter 2.6 on page 18)

14.1.1.7 Target group

(see chapter 2.6 on page 18)

14.1.2 Operating conditions

(see chapter 9.2 on page 220)

14.1.3 Parameters

(see chapter 12.11 on page 251).

14.1.4 Factory settings

(see chapter 12.12 on page 256)

15 Appendix

15.1 *sleep•safe harmony* icons list

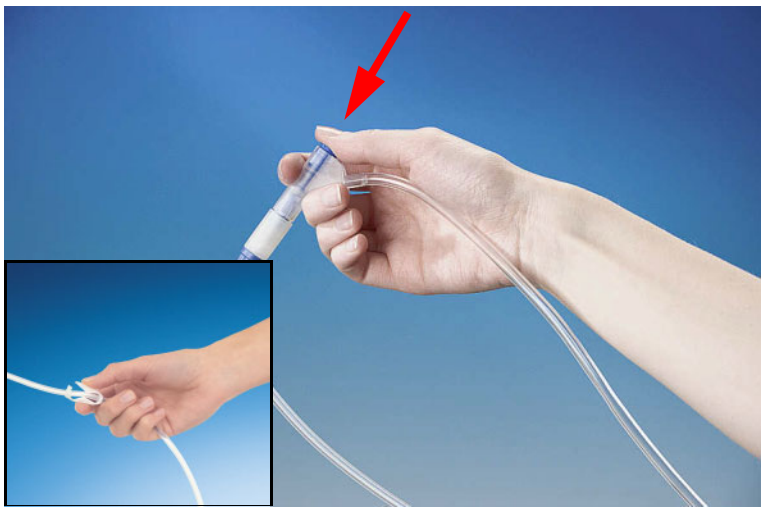
	**On / Off** key		External key for confirming actions
	Start icon		**Open loading tray** button
	**Service login** button		**Repeat animation** button
	**Confirm input** button		**Discard input** button
	**Skip operating step** button		**Return to previous operating step** button
	**Repeat** button		**Return to higher-level screen** button
	Patient options menu		Device options menu
	**Move selection up** button		**Move selection down** button
	**Increase value** button		**Reduce value** button
	Icon for **Audible signal Off**		Icon for **safety-relevant message**
	Icon for **time**		Icon for **treatment duration**
	Icon for **patient volume**		Icon for **volume balance**

	Icon for **treatment progress**		**Help** button
	Icon for **total treatment volume**		Icon for **please wait**
	Icon for **inflow**		Icon for **outflow**
	Icon for **dwell duration**		Icon for **cycle** (inflow – dwell duration – outflow)
	Icon for **standard prescription**		Icon for **adapted APD prescription**
	Icon for **Tidal prescription**		Icon for **basic prescription**
	Icon for **PD-Plus prescription**		Icon for **unknown prescription**
	Icon for parameter **not profiled**		Icon for parameter **profiled**
Ca++	Icon for **calcium value**		Icon for **solution** (Dialysis solution)
%	Icon for **glucose concentration**		Icon for **battery capacity**
	Icon for **manual outflow**		Icon for **patient card inserted**
	Teddy icon for **paediatric treatment**		Teddy icon with patient card for **patient card inserted with paediatric treatment**

15.2 Disconnection with the PIN Reload device

PIN Reload should be used in combination with the "Pause with disconnection" option (see chapter 4.7.2 on page 162).

➢ 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 into the organiser.

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

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

➢ 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 *sleep•safe* set.

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

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

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

15.3 Connection with the PIN Reload device

➢ Ensure that the patient connector (1) sits firmly in the organiser 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 organiser.

➢ Put on the face mask.

➢ Disinfect your hands.

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

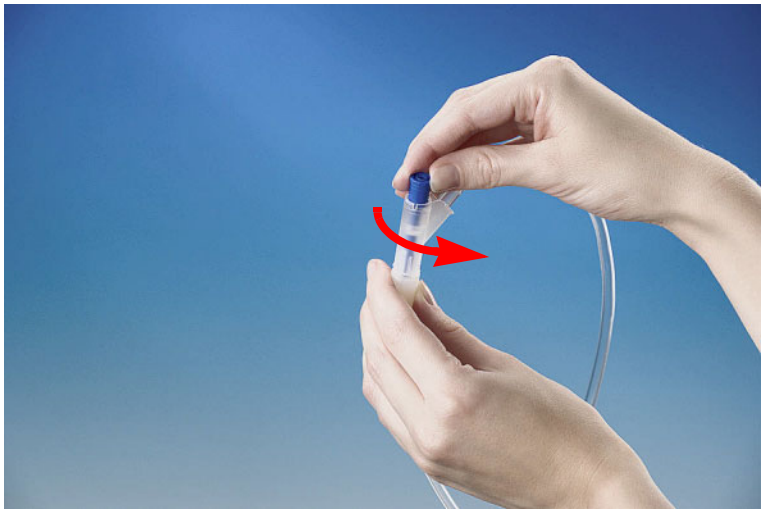
➢ Unscrew the empty PIN Reload from the patient connector and discard.

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

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

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

➢ Open the white clamp on the catheter extension.



➢ Remove the patient connector from the organizer.

➢ Turn the blue knob counterclockwise to avoid an unintended release of the PIN.

➢ Continue your treatment.

15.4 Instructions on the use of "free software"

Contents

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C. Information and remarks on the free software contained in the peritoneal dialysis device

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base-files
GPLv2

base-passwd
GPLv2

bash
GPLv2

busybox
GPLv2 & bzip2
Copyright (C) 1996-2010 Julian R Seward (libbzip2)

bzip2
bzip2
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ca-certificates
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2003 Fumitoshi UKAI <ukai@debian.or.jp>
2009 Philipp Kern <pkern@debian.org>
2011 Michael Shuler <michael@pbandjelly.org>

cairo
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u-boot
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Julian Seward, jseward@bzip.org
bzip2/libbzip2 version 1.0.6 of 6 September 2010

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GCC RUNTIME LIBRARY EXCEPTION
Version 3.1, 31 March 2009

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(For example, a function in a library to compute square roots has a purpose that is entirely well-defined independent of the application. Therefore, Subsection 2d requires that any application-supplied function or table used by this function must be optional: if the application does not supply it, the square root function must still compute square roots.)

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[The licence continues]

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```
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15.5 Training Record

Scope, purpose

The responsible organisation is responsible for proper user training. Training is based on the Instructions for Use and, if present, the enclosed Additional Sheets. The manufacturer recommends using this Training Record to document the operator instruction performed.

Significance of the warnings

Observing all warnings in the Instructions for Use is essential for using the device safely. Instruction must be given on all warnings in the Instructions for Use.

- **Explanations on the Training Record report**

General information

– The report heading records the circumstances of user training.
– The report footer records the trainer and participants.
– The chapters of the Instructions for Use are listed on separate lines up to the second level.

Y/N/NA

– ❑/–/– Chapter required for proper training.
– ❑/❑/– Chapter recommended for proper training.
– ❑/–/❑ If option is available: Chapter required for proper training.
– ❑/❑/❑ If option is available: Chapter recommended for proper training.

➢ Record the instruction of the relevant content and warnings completed by marking ✔ in field **Y**.

➢ Record chapters or options that have not been instructed with ✔ in field **N**.

➢ Record unavailable options with ✔ in field **NA**.

FRESENIUS MEDICAL CARE	**Training Record**	***sleep•safe harmony***
Customer name:		Start date:
Address:		End date:
		Software version: 3.1
		Serial number:

Description		**Y/N/NA**
1	**Index**	
2	**Important information**	
2.1	How to use the Instructions for Use	❑/❑/–
2.2	Significance of warnings	❑/❑/–

Description		Y/N/NA
2.3	Significance of notes	❑/❑/–
2.4	Significance of tips	❑/❑/–
2.5	Brief description	❑/❑/–
2.6	Intended use	❑/–/–
2.7	Considerations for working on the device	❑/–/–
2.8	Expected service life	❑/❑/–
2.9	Duties of the responsible organization	❑/–/–
2.10	User responsibility	❑/–/–
2.11	Disclaimer of liability	❑/–/–
2.12	Warnings	❑/–/–
2.13	SVHC (REACH)	❑/❑/–
2.14	Data protection	❑/–/–
2.15	Addresses	❑/❑/–
3	**Design**	
3.1	Views	❑/–/–
3.2	User interface	❑/–/–
3.3	General procedure for entering parameters	❑/–/–
3.4	Selecting and editing options or parameters	❑/–/–
3.5	Profiling	❑/–/–
3.6	Description of the tubing system	❑/–/–
4	**Operation**	
4.1	Switching on the device	❑/–/–
4.2	Preparing for treatment	❑/–/–
4.3	Starting the treatment	❑/–/–
4.4	Terminating treatment	❑/–/–
4.5	Special operational features of the sleep•safe harmony	❑/–/–
4.6	Options / changing data prior to treatment	❑/–/–
4.7	Therapy options during treatment	❑/–/–
4.8	Performing a PD-Plus treatment	❑/–/–
4.9	Using the device with the porter	❑/–/–
5	**Alarm processing**	
5.1	Screen layout	❑/–/–
5.2	Resetting the audible alarm	❑/–/–
5.3	Colour identification of the screen messages	❑/–/–
5.4	Screen messages	❑/–/–
5.5	Premature termination of a treatment after a system error / device fault	❑/–/–
5.6	Emergency shutdown	❑/–/–
5.7	Power failure	❑/–/–
5.8	Screen failure	❑/–/–
6	**Cleaning/disinfection**	
6.1	Cleaning	❑/–/–
7	**Functional description**	
7.1	Description of functional procedures	❑/❑/–
7.2	Therapy types	❑/❑/–
7.3	Therapy options	❑/❑/–
8	**Consumables, accessories, additional equipment**	
8.1	To be observed in the "Consumables, accessories, additional equipment" chapter	❑/–/–
8.2	Consumables	❑/–/–
8.3	Accessories	❑/–/–
8.4	Additional equipment	❑/❑/–
8.5	Device	❑/❑/–
9	**Installation**	
9.1	Connection requirements	❑/❑/–
9.2	Installation requirements	❑/–/–
9.3	Setting up the sleep•safe harmony	❑/–/–
9.4	Mounting the porter	❑/–/–
9.5	Installation after shipment / transport outside of buildings	❑/–/–
10	**Transport/storage**	
10.1	Transport within buildings	❑/–/–
10.2	Shipment/transport outside of buildings	❑/❑/–
10.3	Storage	❑/–/–
10.4	Environmental compatibility/disposal	❑/–/–
11	**Technical safety checks/maintenance procedures**	
11.1	Important information on the technical safety checks / maintenance procedures	❑/–/–
12	**Specifications**	
12.1	Dimensions and weight	❑/❑/–

Description		Y/N/NA
12.2	Identification label (sleep•safe harmony product marking)	❑/❑/–
12.3	Electrical safety	❑/❑/–
12.4	Electrical power supply	❑/❑/–
12.5	Fuses	❑/❑/–
12.6	Information on electromagnetic compatibility	❑/–/–
12.7	Operating conditions	❑/–/–
12.8	Storage conditions	❑/–/–
12.9	External connection options	❑/–/–
12.10	Batteries	❑/❑/–
12.11	Parameters	❑/❑/–
12.12	Factory settings	❑/❑/–
12.13	Porter	❑/❑/–
12.14	Identification label (porter marking)	❑/❑/–
12.15	Materials used	❑/❑/–
13	**Definitions**	
13.1	Definitions and terms	❑/❑/–
13.2	Abbreviations	❑/❑/–
13.3	Symbols	❑/❑/–
13.4	Certificates	❑/❑/–
14	**Options**	
14.1	Paediatric option	❑/–/❑
15	**Appendix**	
15.1	sleep•safe harmony icons list	❑/❑/–
15.2	Disconnection with the PIN Reload device	❑/❑/–
15.3	Connection with the PIN Reload device	❑/❑/–
15.4	Instructions on the use of "free software"	❑/❑/–
15.5	Training Record	❑/❑/–

Comments:

Trainer		
Date	**Name**	**Signature**

Participant			
Date	**Function**	**Name**	**Signature**