sleep•safe harmony

Instructions for Use

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FRESENIUS MEDICAL CARE

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2 Important information

2.1 How to use the Instructions for Use

Identification

The document can be identified by the following information on the title page and on the labels, if any:
– Device software version
– Technical document edition
– Technical 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, for example, 3A-2014 refers to edition 3A released in 2014
– The page identification, e.g., 1-3 refers to chapter 1, page 3

Organization of the chapters

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

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

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

Changes

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

Reproduction

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

2.2 Significance of warnings

Warning

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

2.3 Significance of notes

Note

Advises the operator that failure to observe this information can result in the following:
– Damage to the device
– Required functions will not be executed at all or 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 fluid is infused and drained by a so-called cycler.

The *sleep•safe harmony* technology

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

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

– Automatic detection and connection of bags.

– Automatic inline flow heating of the dialysate to body temperature directly during the inflow phase.

– Options for profiling treatment parameters, 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 offers the possibility of performing CCPD, IPD, NIPD, Tidal Dialysis 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 with a body weight of 20 kg and more, irrespective of their age, under consideration of the specified technical data of the *sleep•safe harmony* (e.g., volume, delivery rates).
– Continuous treatments of up to 24 hours, with a typical overnight treatment duration of 7–10 hours.
– Operation in rooms that are suitable for peritoneal dialysis located in professional health care institutions, or for the home healthcare environment.

2.6.3   Side effects

Peritoneal dialysis therapy carries the risk of an inflammation of the peritoneum (peritonitis). In general, a lower incidence of peritonitis has been observed in APD therapy compared with CAPD therapy. Furthermore, infections of the catheter exit site may occur, which often progress to tunnel infections and, eventually, to peritonitis.

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

2.6.4   Contraindications

None known.

2.6.5   Interactions with other systems

None known.

2.6.6   Therapy restrictions

None known.

2.6.7   Target group

Warning

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.

2.7   Considerations for working on the device

Warning

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

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

For information on installation, refer to the appropriate chapter (see Chapter 9 on page 9-1).

For information on the Technical Safety Checks and maintenance procedures, refer to the appropriate chapter (see Chapter 11 on page 11-1).

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

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

2.8   Expected service life

If the Technical Safety Checks are performed to the full extent specified and at the prescribed intervals, the safe operation of the device in the time between TSC procedures is guaranteed.
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

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.

2.10 Operator responsibility

Warning

The following must be observed when entering parameters:

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

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

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

Warning

The treatment parameters loaded from the *sleep•safe harmony* patient card must be checked by the operator for plausibility and compliance with the physician's prescription before being used.

For reasons of data protection, the operator is responsible for the safekeeping of the patient card.

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

2.11 Disclaimer of liability

Warning

The device has been approved for use with certain consumables and accessories (see Chapter 8 on page 8-1). Should the responsible organization wish to use other consumables and accessories than those listed in the relevant chapter, their suitability must be verified beforehand by obtaining the appropriate information from the manufacturers.
The applicable legal regulations must be complied with.

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

2.12 Warnings

2.12.1 Warnings, hygiene

Warning

Risk of infection

➤ Use aseptic technique when connecting the patient connector.

➤ 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.

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

The attending physician is responsible for proper patient training.

2.12.2 Warnings, therapy

Warning

Risk of injury through damaged line set.

Risk of infection

➢ When inserting the line set (*sleep•safe* Set and the connected solution bags), make sure there is no risk of damage by sharp-edged objects or by pets.

Warning

Patients suffering from severe ascites are critically ill patients who require medical supervision during treatment according to their particular clinical picture.
If these patients lose large amounts of ascitic fluid with their outflow, the appropriate therapeutic measures must be taken to counteract the possibility of a fall in blood pressure or hemodynamic instability.

2.12.3 Warnings, system

Warning

If the device is used outside the specified storage and operating conditions, the safe function of the device cannot be guaranteed.

This may result in damage to patients, operators or the environment.

Warning

Risk of injury through defective device.

Do not use the device, and terminate a therapy in progress, if any of the following defects are detected:

– Mechanical damage
– Defective power cable
– Other defects
– The device does not react as expected
– The performance characteristics deteriorate

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

➢ The device must be taken out of service.

➢ Inform the responsible organization or service support.

Warning

Risk of injury through swallowing small parts.

Choking hazard due to small parts.

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

Warning

Strangulation hazard.

➢ Make sure the cables and lines do not present a hazard for children.

2.12.4 Warnings, electrical

Warning

Risk of injury from electrical currents.

Electric shock

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

Warning

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

Warning

➢ Operators must not simultaneously touch the patient and the contacts of the plugs or sockets of the device. This can cause a patient leakage current.

2.12.5 Warnings, consumables and accessories

Warning

➢ The *sleep•safe* Set and the *sleep•safe* Set Plus are single use items. The sets are specially designed for the *sleep•safe harmony*. Only these sets must be used.

Warning

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

2.13 Addresses

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

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

Local service support

Fresenius Medical Care   *sleep•safe harmony*   IFU-EN   7A-2015

3 Design

3.1 Views

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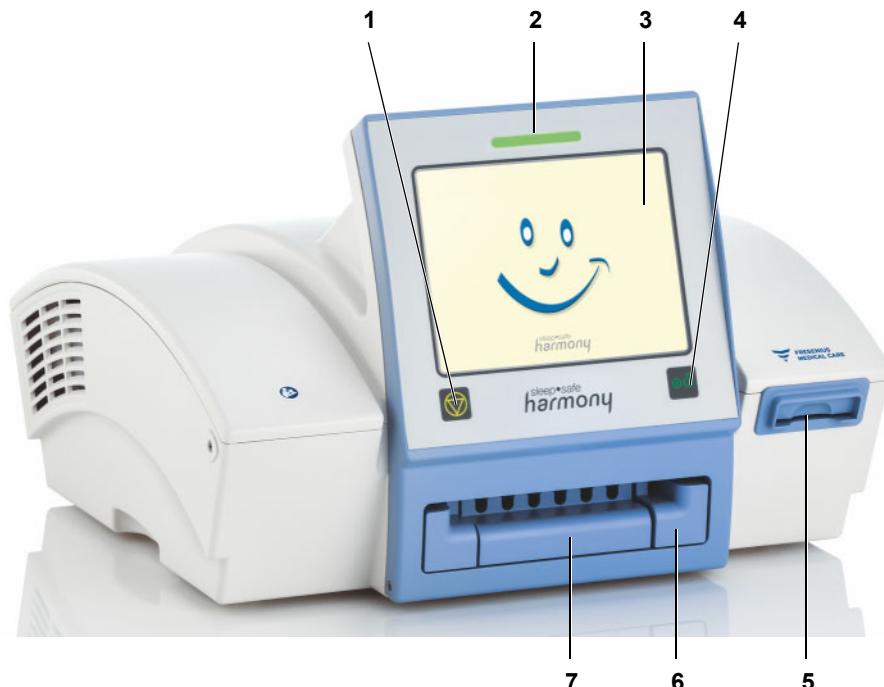
1 External key ⬇
This key is used to confirm the connection or disconnection of the patient as well as certain screen messages.

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

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

4   On/Off key ⌐o⌐

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 contains the patient's individual prescriptions and treatment data.

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.

2   LAN interface

Interface for data exchange. Here, optional device extensions can be connected.

3 **Identification label**

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

4 **Power cable**

The power cable 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
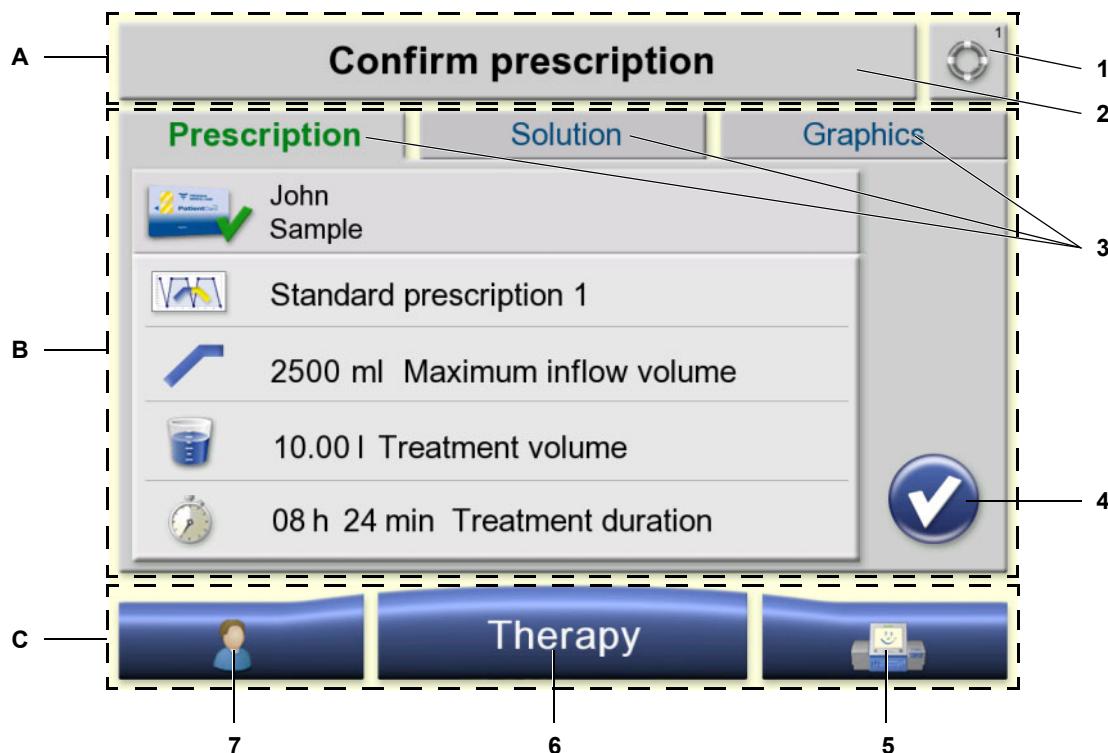
A **Status bar**

1 Help

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

B **Options panel**

3 Tabs

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 colors

● **Color of control elements**

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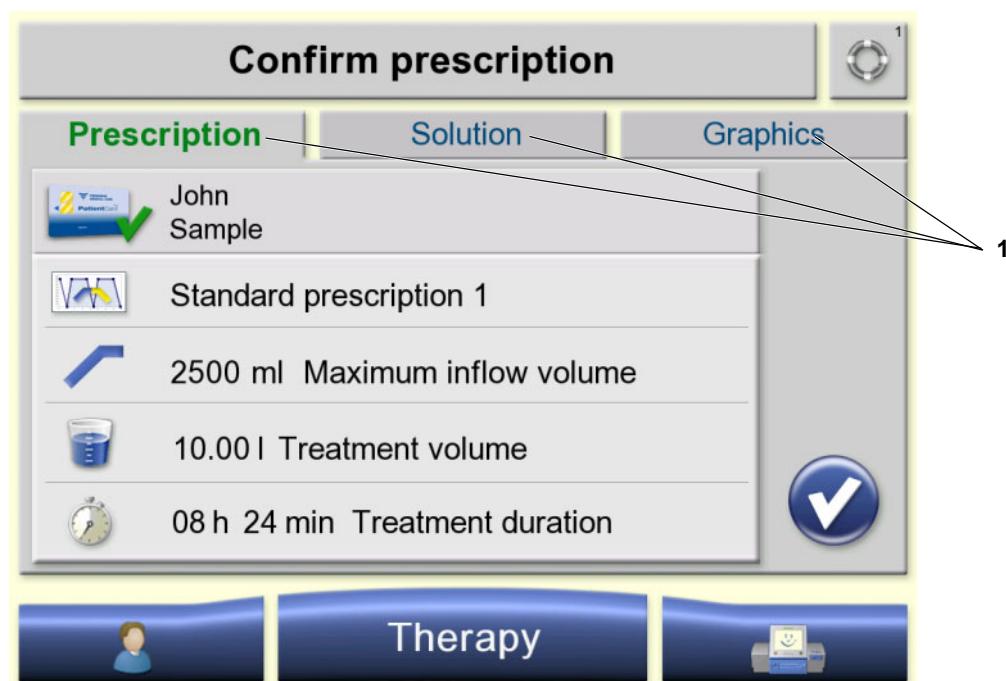
1 Tabs
green:
Tab selected.
The data for the selected tab will be displayed.
blue:
Tab not selected.
This tab can be selected.

3.3 General procedure for entering parameters

3.3.1 Entering text
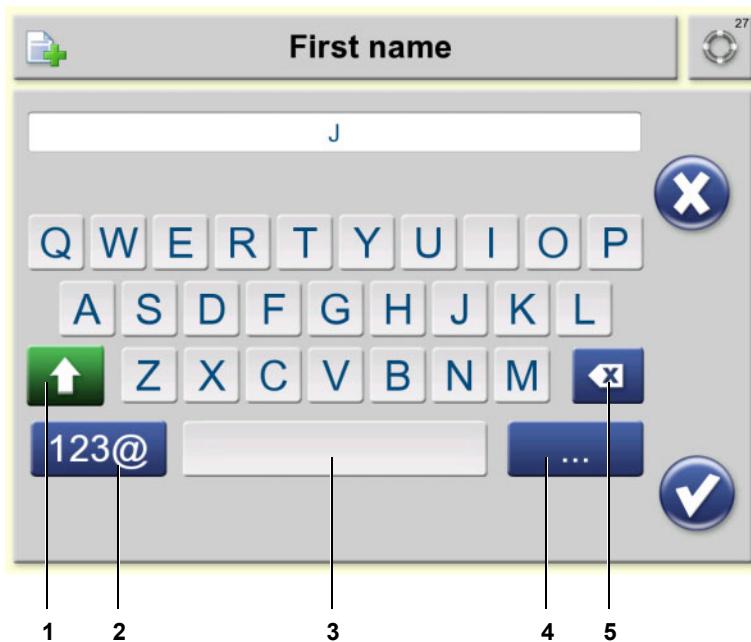
➢ Use the keyboard displayed to enter the required text.

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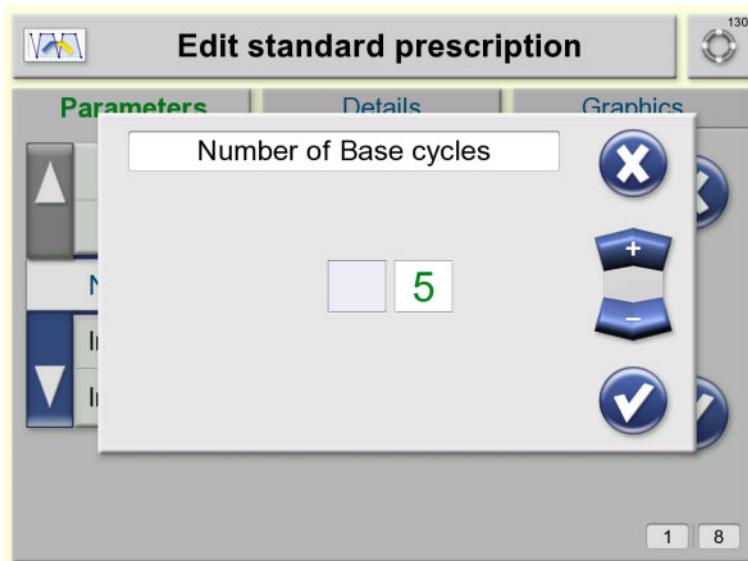
➢ Select the digit to be edited. The selected digit is shown in green.

➢ 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
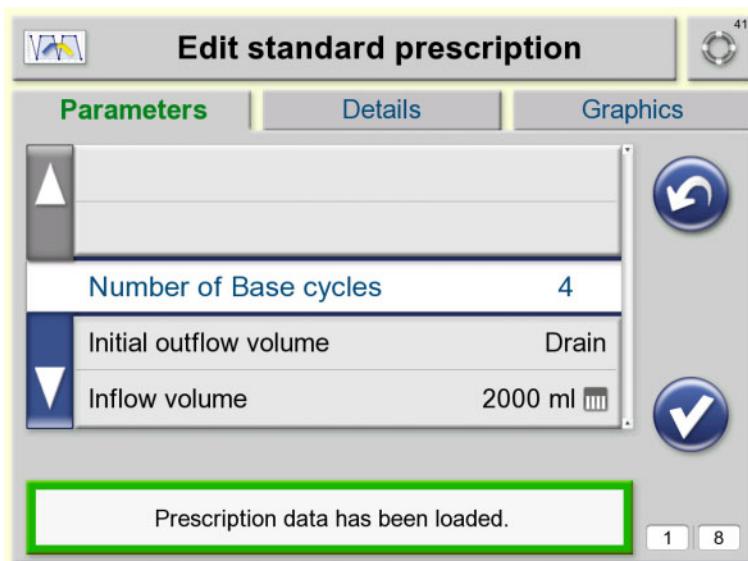
➢ Press the ✕ button to discard the change.
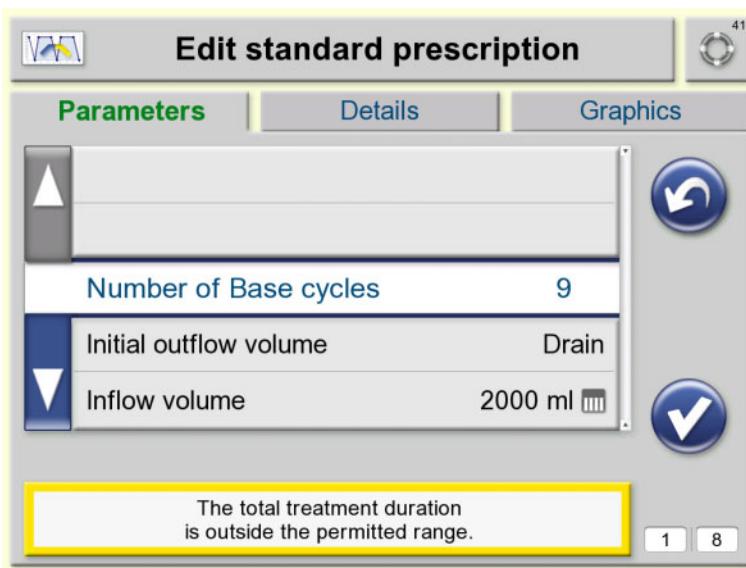
If the value entered is outside the range which can be set by the *sleep•safe harmony*, the value entered will be rejected.

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.

Select therapy option

163

▲ Create prescription

Select prescription

Edit prescription

Delete prescription

▼ Show treatment reports

3 6
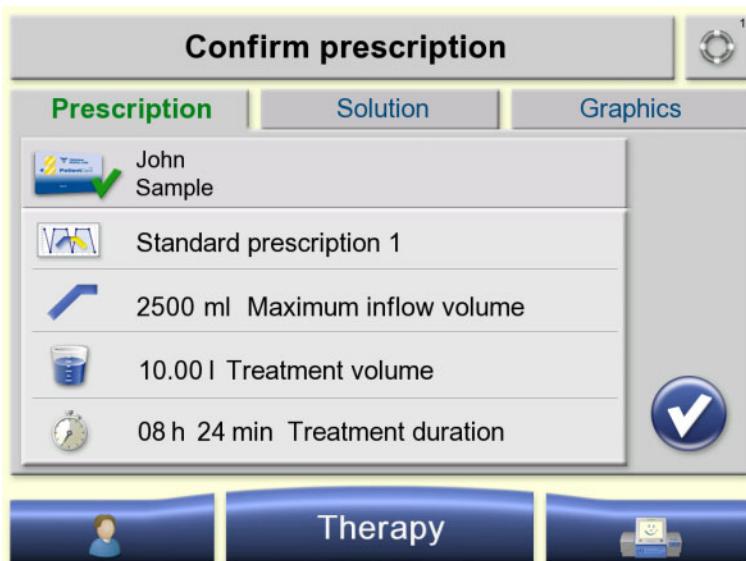
Therapy

➢ 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.

Edit standard prescription

41

Parameters | Details | Graphics

▲

Number of Base cycles   5

Initial outflow volume   Drain

▼ Inflow volume   2000 ml

1 8

1 2
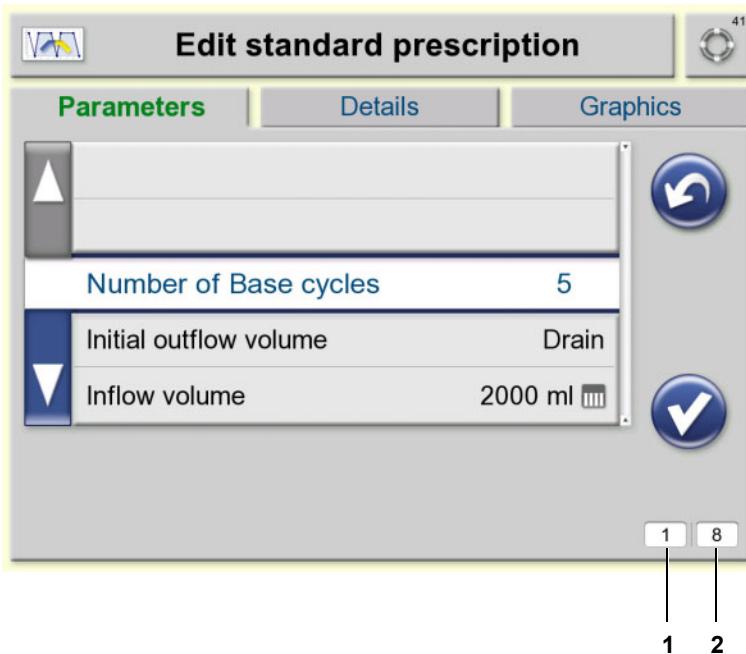
➢ Use the ▼ and ▲ buttons to move the required parameter to the highlighted line in the center. Press on this line to select the parameter.

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.
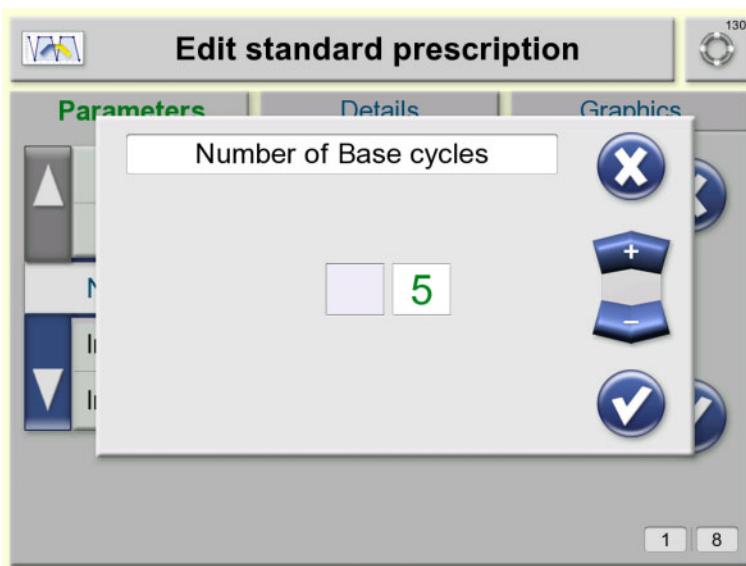
> ➢ Enter the required value (see Chapter 3.3.2 on page 3-7).

> ➢ Press the ✓ button to confirm the input

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
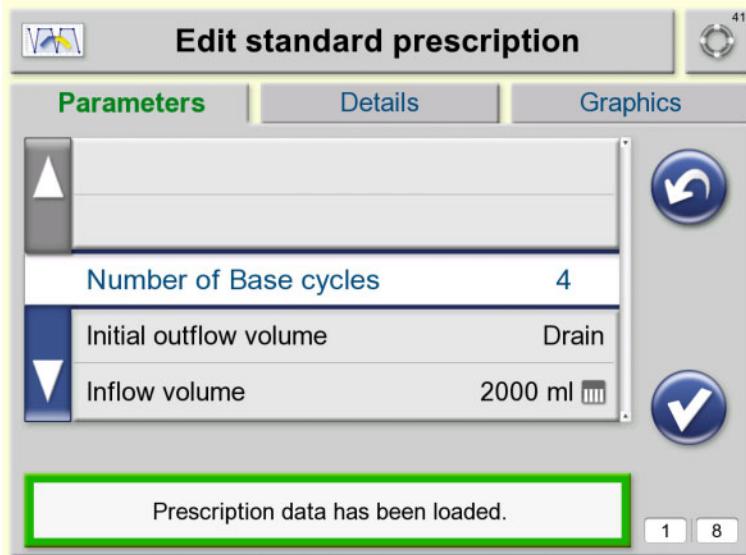
> ➢ Press the ✗ button to discard the change.

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.

3.4.1 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.

Confirm prescription

Prescription	Solution	Graphics

John Sample

Standard prescription 1

2500 ml Maximum inflow volume

10.00 l Treatment volume

08 h 24 min Treatment duration

Therapy

➢ Press the **Therapy** button.

Select therapy option

Create prescription

Select prescription

Edit prescription

Delete prescription

Show treatment reports

3 6

Therapy

➢ 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.

Edit standard prescription		41

Parameters | Details | Graphics

Initial outflow volume	700 ml
Inflow volume	2000 ml
Solution	balance 1.50 % Ca++ 1.75 mmol/l
Dwell duration	90 min
Last inflow volume	1200 ml

4 8
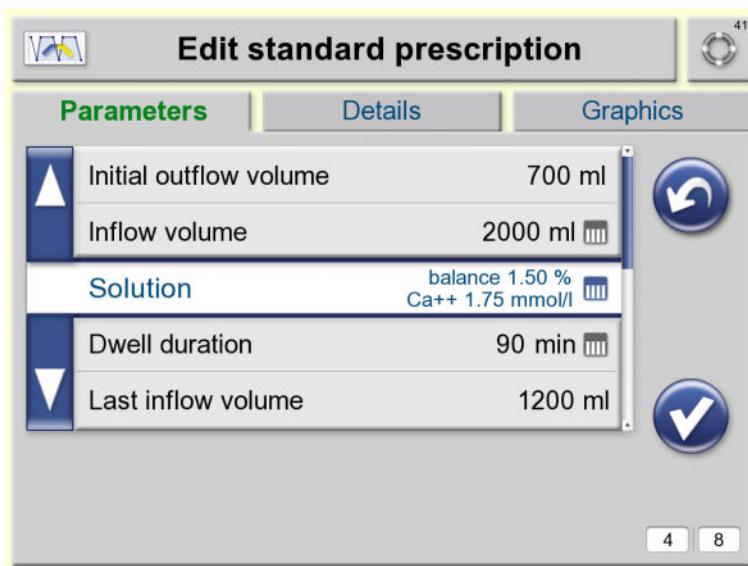
➢ Use the ▼ and ▲ buttons to move the parameter **Solution** to the highlighted line in the center. Press on this line to select the parameter.

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

● **Selecting the solution directly**

Select solution		137

	%	Ca⁺⁺
All	All	All

CAPD/DPCA	1.50	1.75
CAPD/DPCA	4.25	1.75
CAPD/DPCA	2.30	1.75
CAPD/DPCA	1.50	1.25

2 27
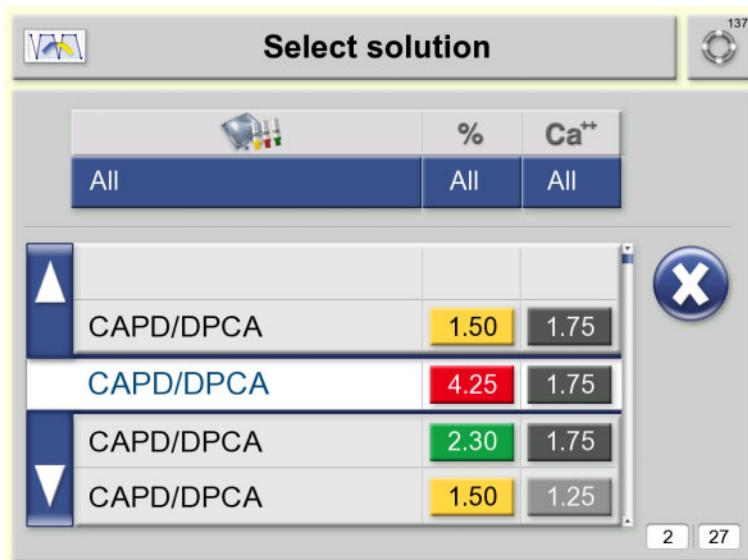
➢ Use the ▼ and ▲ button to move the required solution to the highlighted line in the center. Press on this line to select the parameter.

➢ Press the ✕ button to discard the change.

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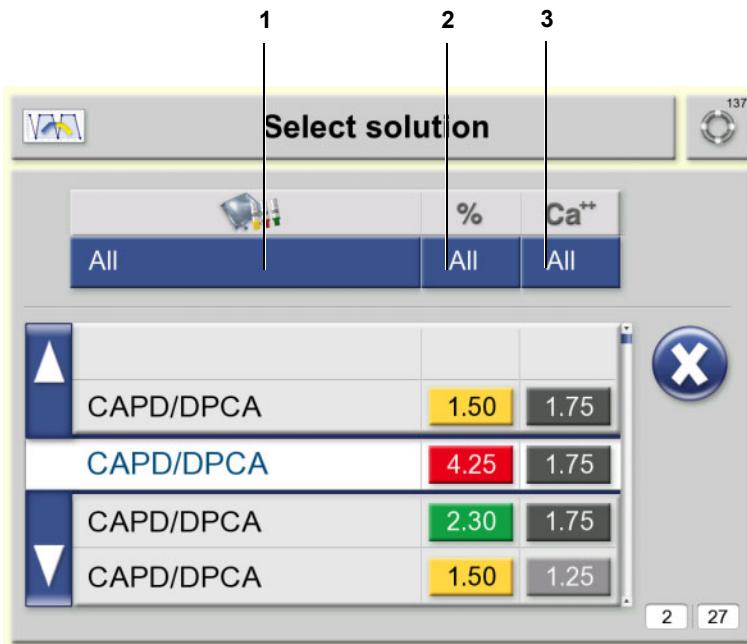
The buttons 1, 2 or 3 can be used to restrict the selection of the solutions.

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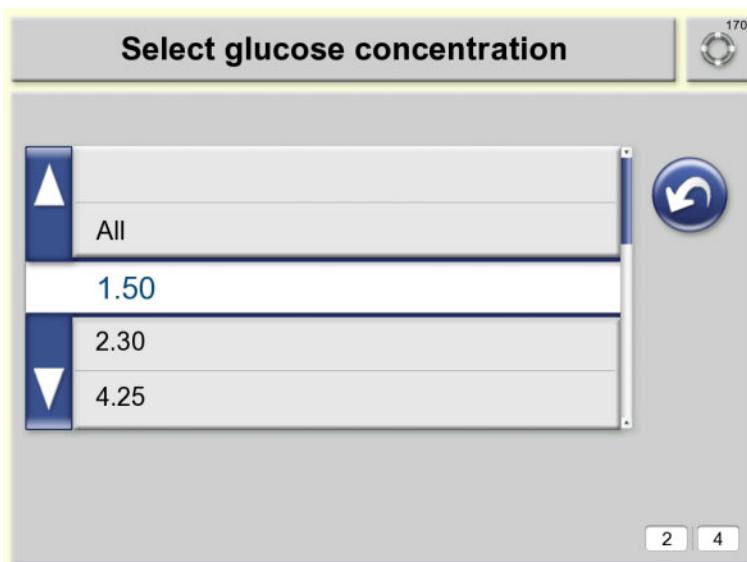
➢ Use the ▼ and ▲ buttons to move the required parameter to the highlighted line in the center. Press on this line to select the parameter.

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

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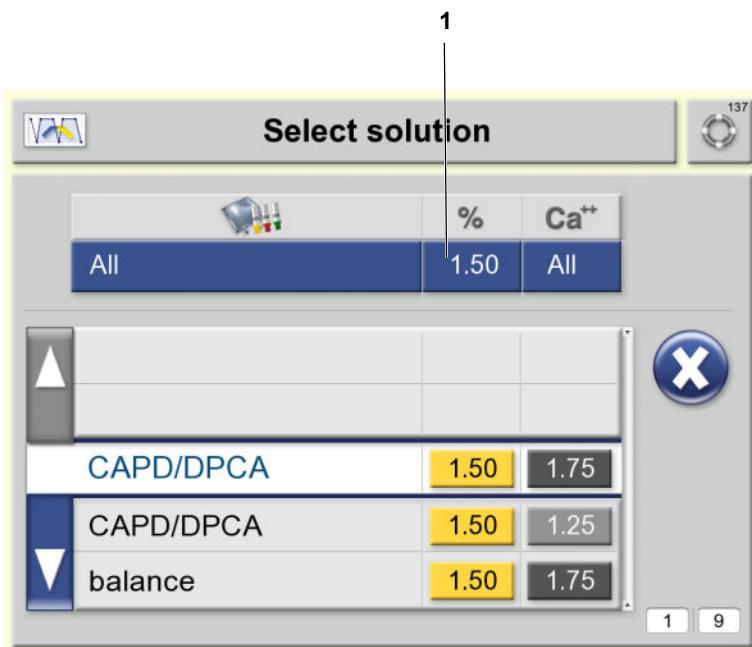
The selected parameter is displayed in the appropriate field (1).

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

➢ Press the [x] 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.

3.5   Profiling

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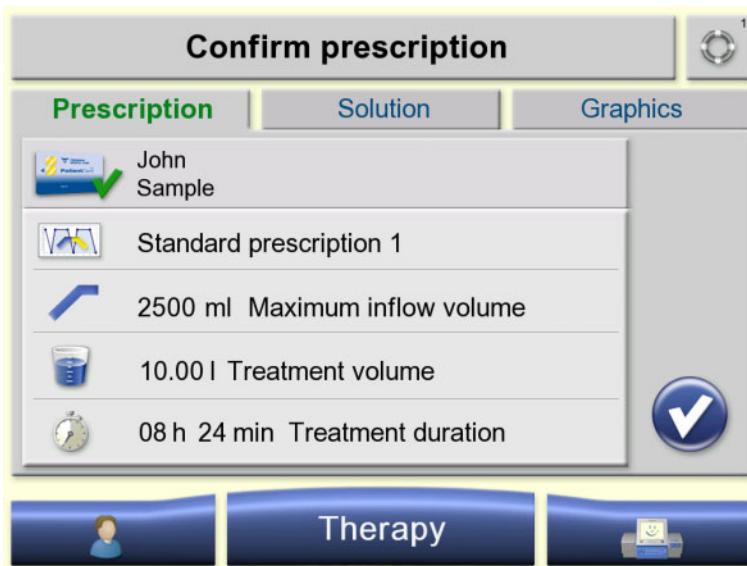
➢ Press the **Therapy** button.

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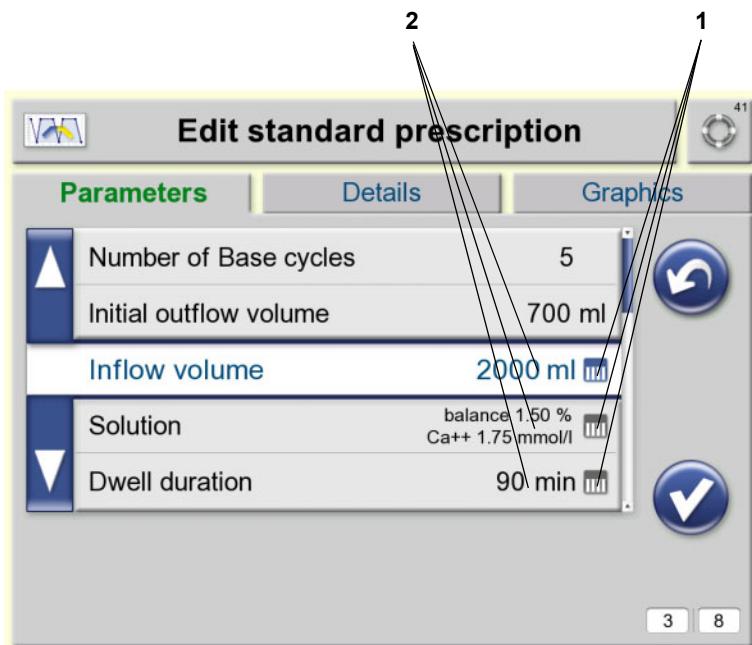
The icon (1) next to the parameters indicates which parameter can be profiled.

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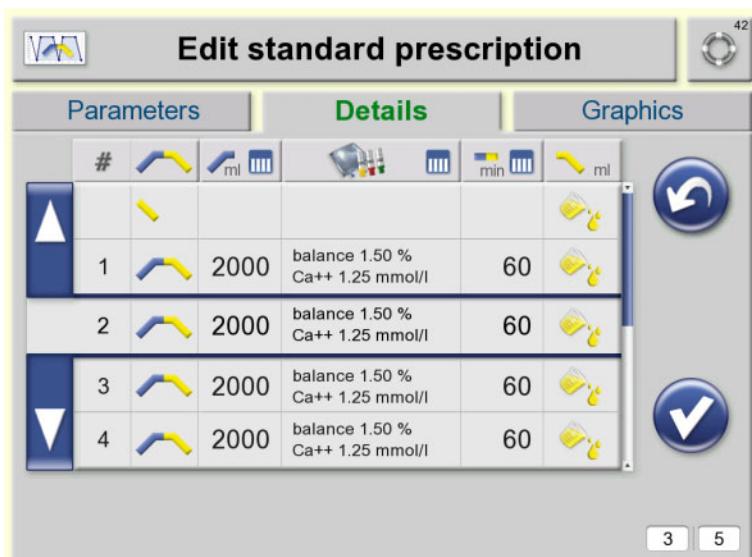
The following three parameters can be profiled:
– Inflow volume
– Solution
– Dwell duration

➢ Press the appropriate 🔢 button to profile the required parameter.

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

Select profile option

▢ Not profiled

▦ Profiled

➢ 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.

1   2

Edit standard prescription

| Parameters | Details | Graphics |

#						
1		2000	balance 1.50 % Ca++ 1.25 mmol/l	60	
2		2000	balance 1.50 % Ca++ 1.25 mmol/l	60	
3		2000	balance 1.50 % Ca++ 1.25 mmol/l	60	
4		2000	balance 1.50 % Ca++ 1.25 mmol/l	60	

Prescription data has been loaded.

3 5
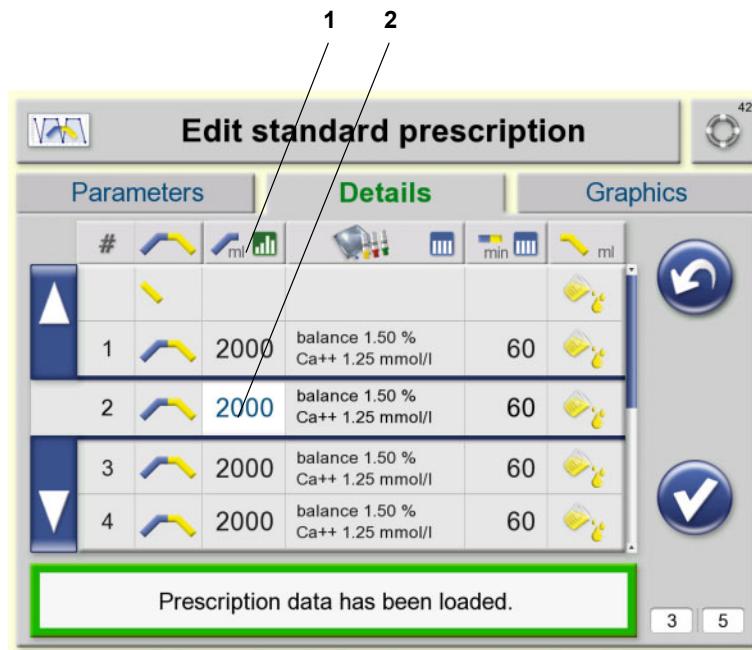
Parameters that can be profiled are identified by the icon ▦ (1).

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.
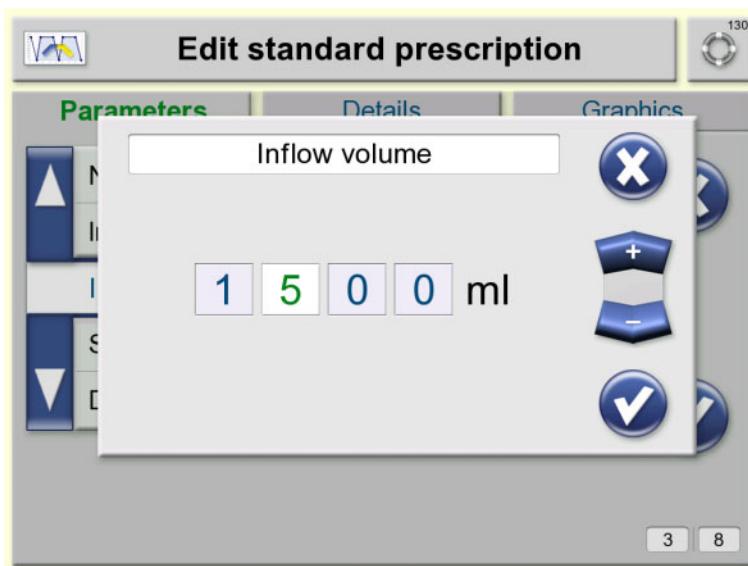
➢ Enter the required value (see Chapter 3.3.2   on page 3-7).

➢ Press the ✓ button to confirm the input

or

➢ Press the ✗ button to discard the change.
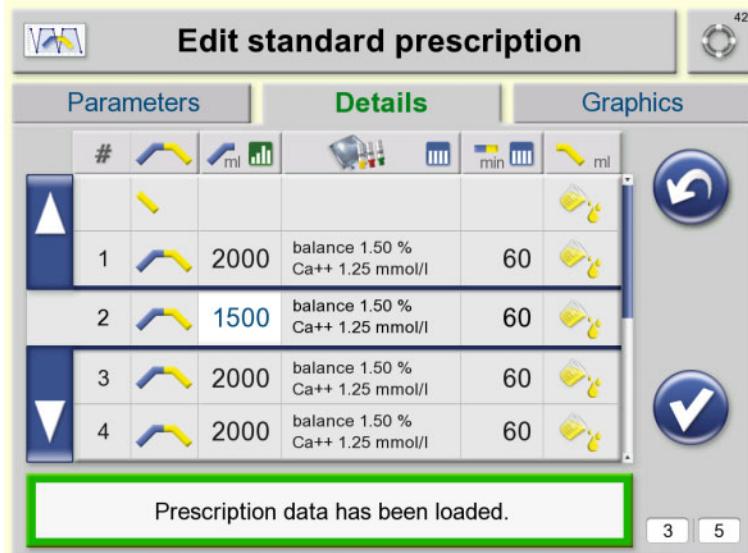
The changed value for this treatment cycle will be displayed.

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.
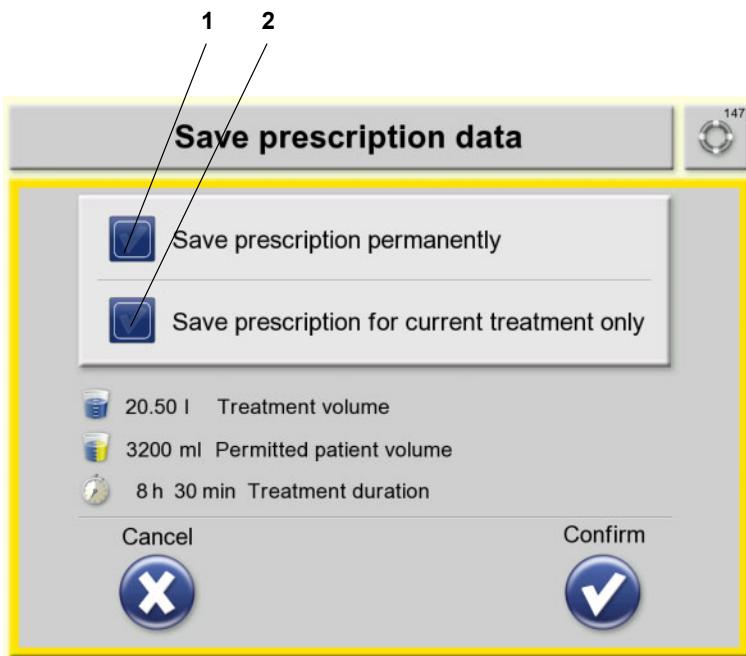
1   2

Save prescription data
147

Save prescription permanently

Save prescription for current treatment only

20.50 l   Treatment volume

3200 ml Permitted patient volume

8 h 30 min Treatment duration

Cancel   Confirm

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.

4 Operation

4.1 Preparing the device

This chapter describes how to prepare the *sleep•safe harmony* for treatment.

Note

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

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.

4.1.1 Functional test

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

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

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.

Warning

➢ Only the patient card approved by Fresenius Medical Care and intended for use with the *sleep•safe harmony* may be used in conjunction with the *sleep•safe harmony*.

If the *sleep•safe harmony* is operated without a patient card, the treatment data stored in the *sleep•safe harmony* will be used for the treatment. On completion of the treatment, the treatment results will be saved in the *sleep•safe harmony*.

If the patient card was inserted into the *sleep•safe harmony* before the device was switched on, the treatment data stored on the patient card will be used for the next treatment. On completion of the treatment, the treatment results will be saved to the patient card.

➢ Do not remove the patient card from the *sleep•safe harmony* while treatment is in progress.
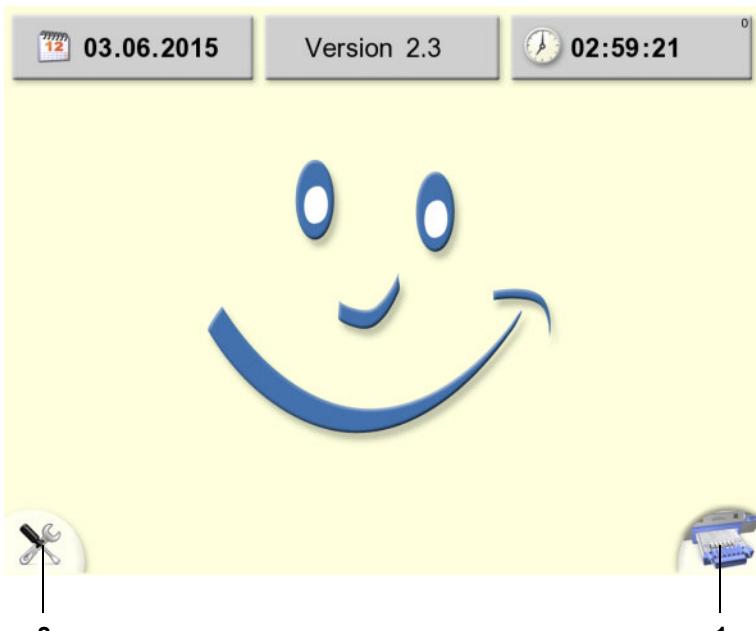
The *sleep•safe harmony* is ready for operation as soon as the screen shown on the left is displayed.

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).

4.2   Preparing for treatment

4.2.1   Preparing the supplies

Warning

Risk of infection

➢ Use aseptic technique when connecting the patient connector.

➢ 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.

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

➢ Do not remove the single use items or consumables from their overwrap before this operating step is displayed by the *sleep•safe harmony*.

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

The attending physician is responsible for proper patient training.

➢ Close windows and doors.

➢ Take off wrist watch and jewellery.

➢ Prepare the necessary supplies:

1. *sleep•safe harmony*

2. Patient card

3. Solution bags in overwrap

4. *sleep•safe* Set

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 bags used must have a temperature of 15–35 °C.

Warning

➢ Do not use the single use items or consumables if
– The overwrap is damaged.
– They are past their "use by" date
– The protective caps and closing caps have come off

➢ 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 leakage potential
– The dialysis solution is clear

● **Handling 5 liter 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.

➢ 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 liter 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
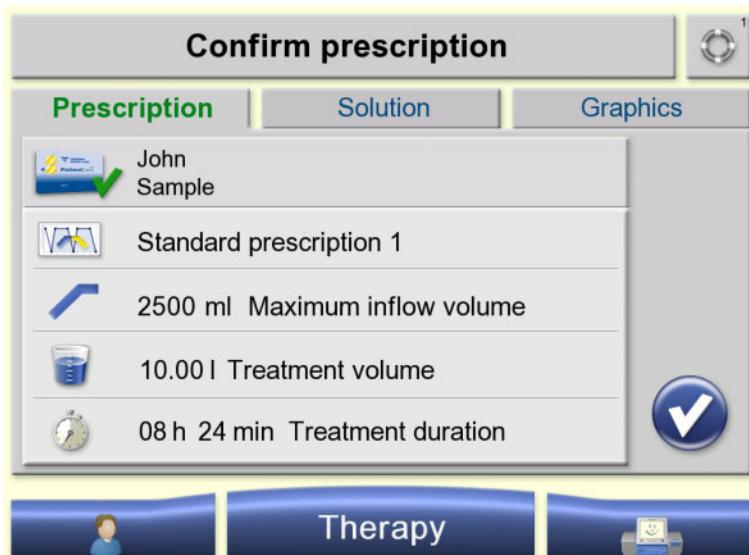
The **Prescription** tab shows the following information:
– Patient name
– Prescription name
– Maximum inflow volume
– Total treatment volume
– Expected treatment duration

➢ Select the **Solution** tab

or

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

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

– 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.
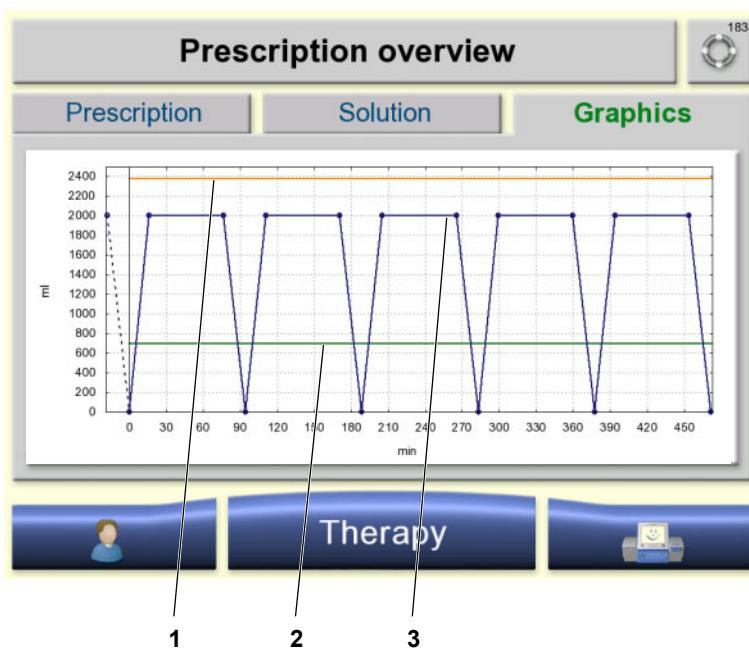
The **Graphics** tab shows a schematic of the prescription.

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 7-9)

2. Permitted residual volume in ml (green) (see Chapter 7.3.1.2 on page 7-9)

3. Prescribed volume curve (blue)

➤ select the **Prescription** tab.

4.2.3 Inserting the *sleep•safe* Set

⚠️ **Warning**

The treatment parameters loaded from the *sleep•safe harmony* patient card must be checked by the operator for plausibility and compliance with the physician's prescription before being used.

Confirm prescription

| Prescription | Solution | Graphics |

John
Sample

Standard prescription 1

2500 ml Maximum inflow volume

10.00 l Treatment volume

08 h 24 min Treatment duration

Therapy
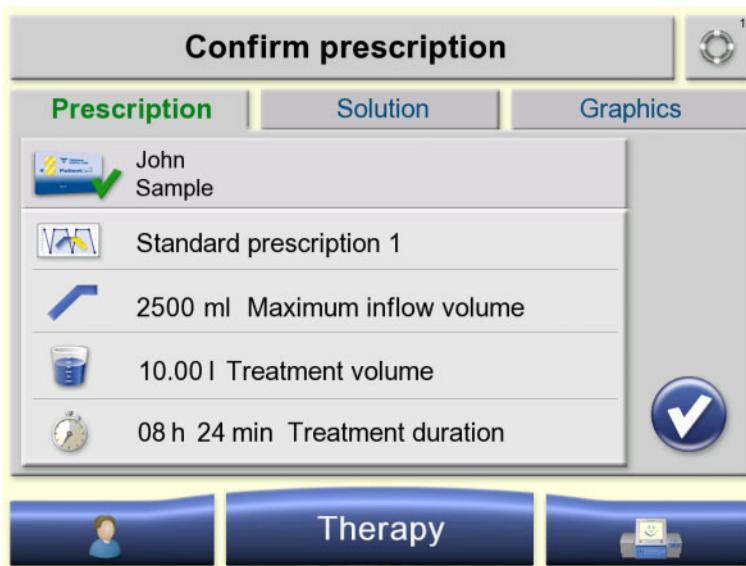
➢ Press the ✓ button to confirm the prescription.

Opening loading tray ...
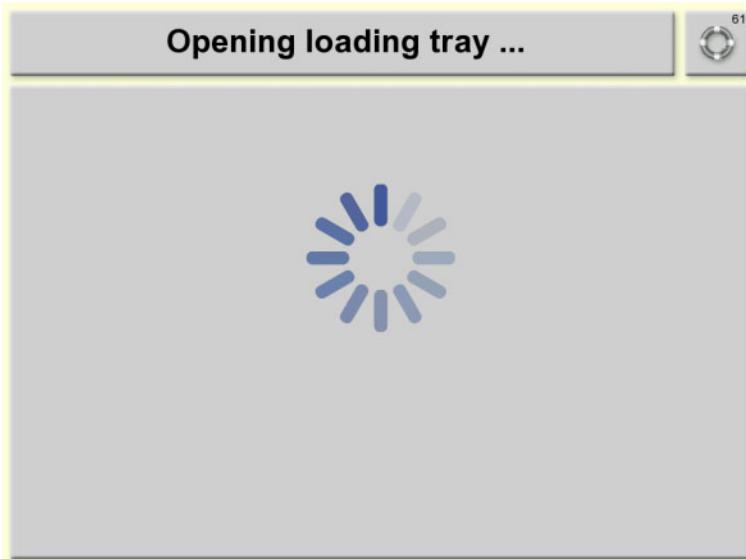
The *sleep•safe harmony* will perform internal tests.

The loading tray opens.
During the test an 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**

➢ Do not use the *sleep•safe harmony* if the audible alarm is not heard or the status indicator is not lit during the internal test.

➢ Call service support.

⚠ **Warning**

➢ 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.

> Push the lines on the left and right into the line locators provided for this purpose.

> Place the lines in the line guides.

> The ⬤ button can be used to replay the screen animation.

Warning

> 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.

> 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

➢ 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.

🗑️	%	Ca⁺⁺	🥤 ml
balance	1.50	1.25	10000

Insert solution bag connectors

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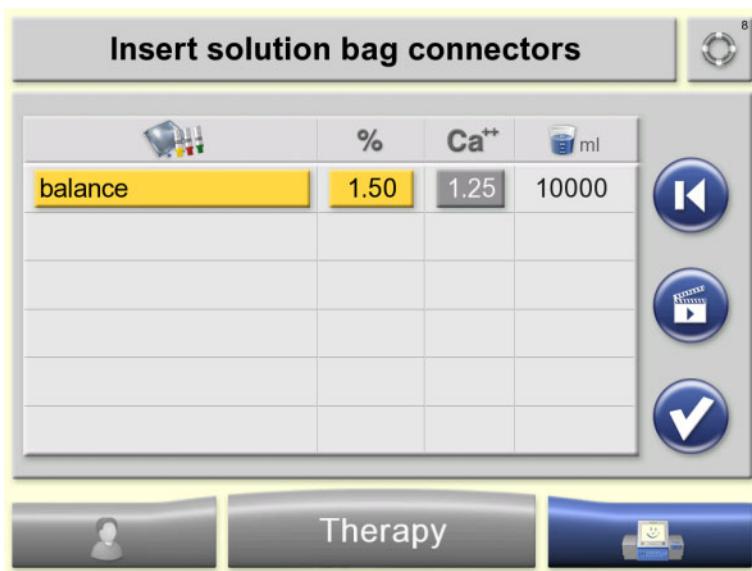
The solution bags required for the treatment are shown on the screen. The color coding facilitates the correct selection of the solution bags.

➢ 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.

➢ Place the connectors of the solution bags in a free tray port in front of the *sleep•safe* Set and push 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 4-16).

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

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

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

Closing loading tray ...	The loading tray closes.
	The next screen message will be displayed automatically.

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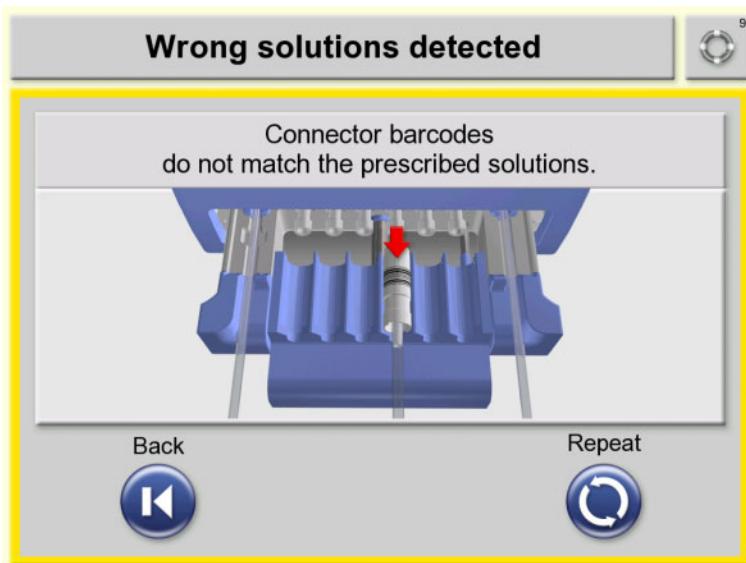
The loading tray will be opened if the connected solution bags do not match the prescription. The incorrect solution bags are identified by a red arrow.

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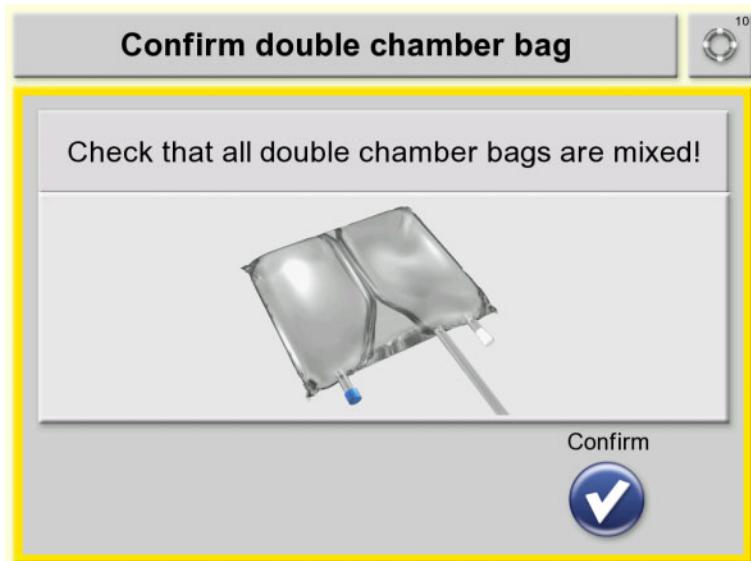
If a single chamber dialysis solution bag is used, this screen will not be displayed.

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

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

Warning

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

Confirm Polyglucose 7.5 % ⚠ ◌ 51

Make sure that the 7.5% Polyglucose solution bag
is correctly connected to the Luer-Lock adapter!

Break the cone on the solution bag!

Confirm
✓
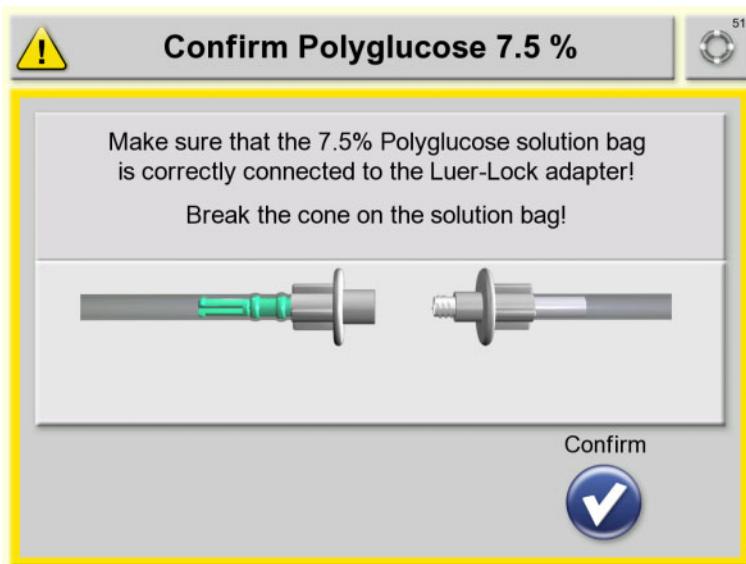
➢ When connecting a 7.5 %
polyglucose solution bag, make
sure you have the Luer lock
adapter and the 7.5 % polyglucose
solution bag ready to hand.

➢ Before breaking the cone of the
7.5 % polyglucose solution bag,
make sure the Luer lock adapter is
correctly connected.

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

Connecting solution bags ... ◌ 60
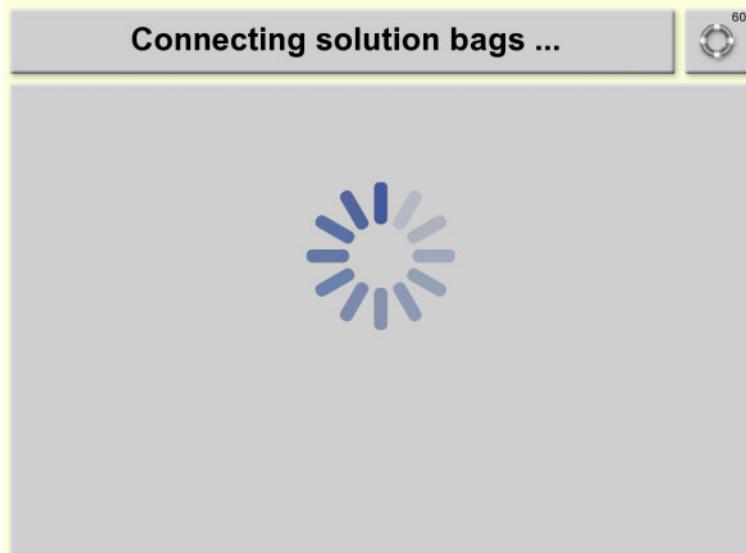
The connector rail will close when all
the required connectors have been
correctly inserted.

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 liters or
6 liters 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 meters below or above the *sleep•safe harmony*.

Connect drain line

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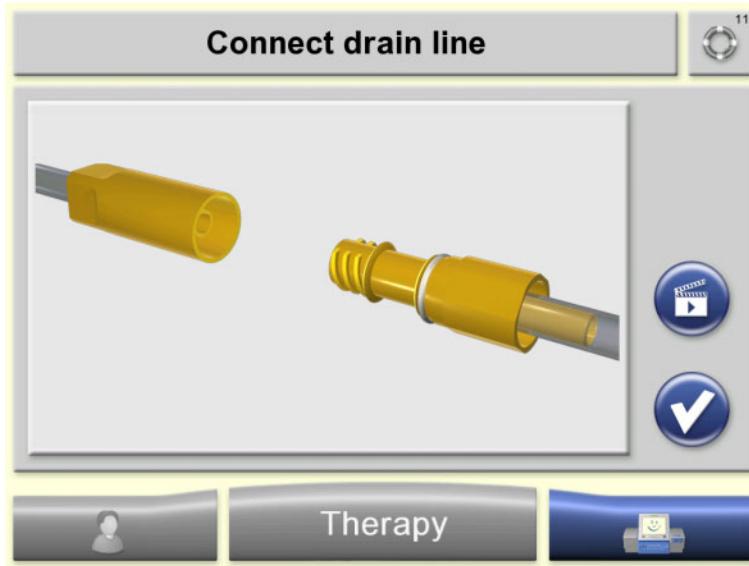
➢ After connecting the solution bags, connect the drain line.

➢ 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 line set.

➢ When using the drain line set, make sure that the clamp of the drain line is open and that the clamps of the emptying lines on the drain line 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
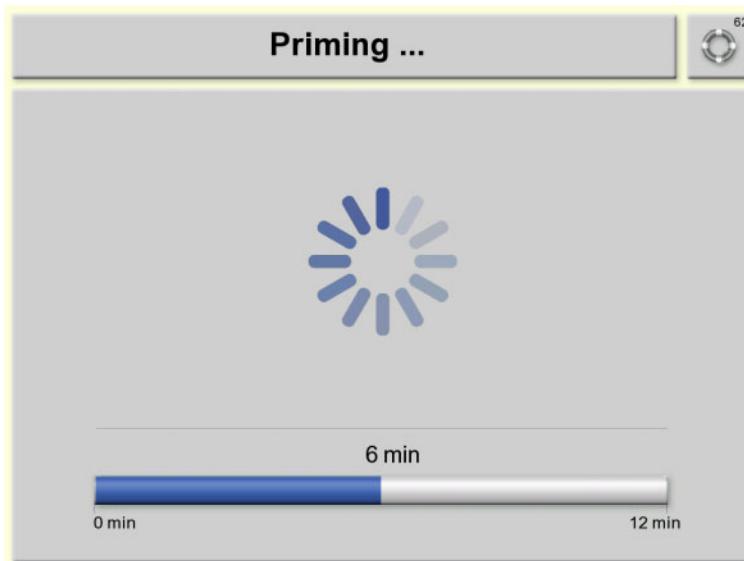
The *sleep•safe* Set, the patient line and the drain line will be primed automatically.

The next screen message will be displayed automatically.

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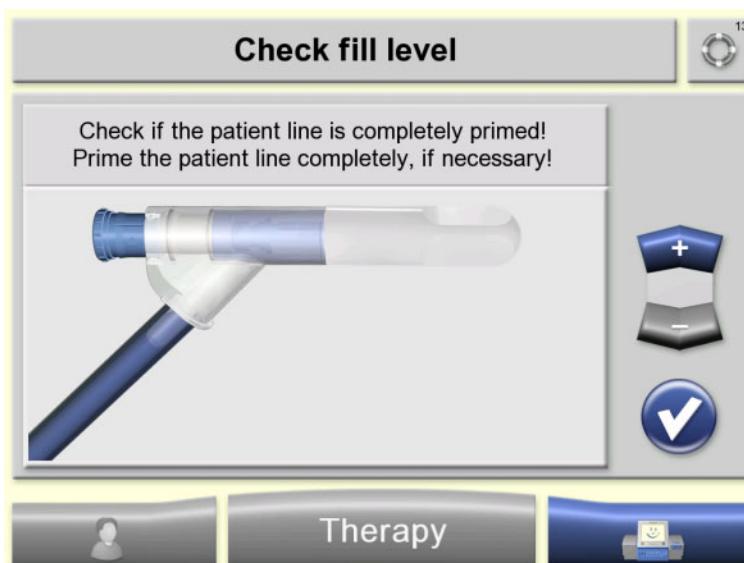
➢ If priming has been completed, but the patient line is not yet fully primed, it can be filled up with dialysis solution by pressing the ⬠ button.

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

4.2.7   Confirming treatment data

⚠️

Warning

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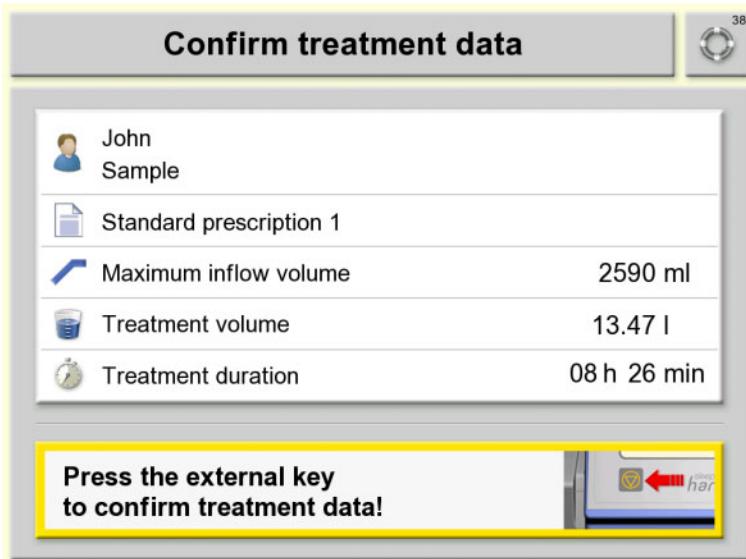
Check the treatment data for plausibility.

➢ Press the 🔽 key to confirm the treatment data.

4.3   Starting the treatment

4.3.1   Connecting the patient

Warning

Risk of infection

➢ Use aseptic technique when connecting the patient connector.

➢ 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.

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

The attending physician is responsible for proper patient training.

Warning

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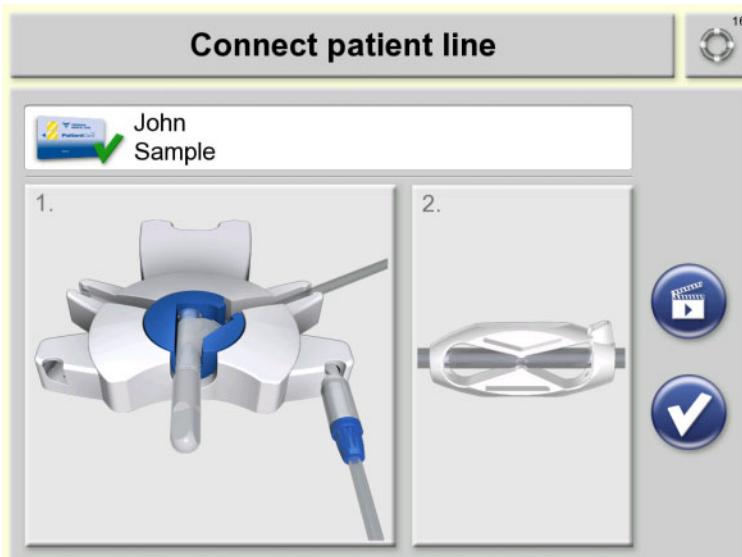
➢ Once priming is complete, the patient should be connected immediately.

The patient's name will be displayed.

➢ 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 in the clip.

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

➢ Put on the face mask.

➢ Disinfect your hands and dry them carefully.

➢ Unscrew and discard the protective cap of the *sleep•safe* 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.

Warning

➢ Only the patient whose name is displayed on the screen must be connected to the *sleep•safe harmony*.
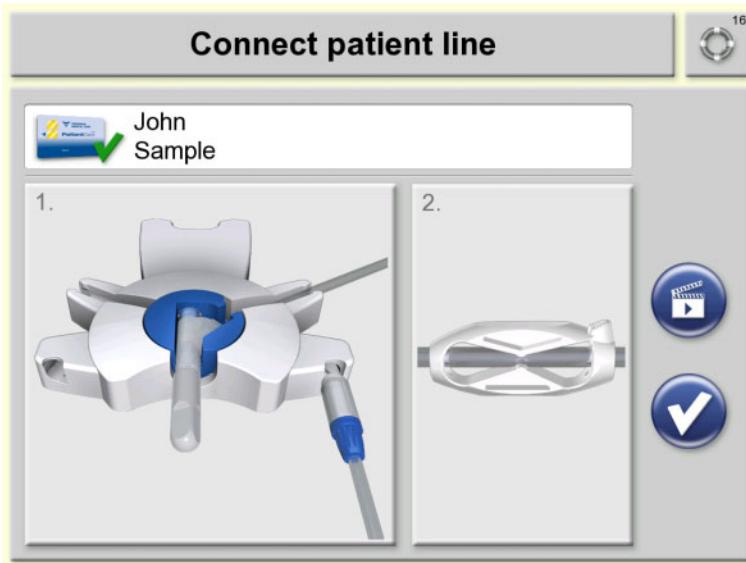
➢ Press the ✓ button to confirm the connection and to start the treatment.

4.3.2   Starting the treatment

Treatment is started.

The treatment will start with an initial outflow.

4.3.3   Terminating the initial outflow

Warning

After the initial outflow has been completed normally and the alarm has been confirmed by the operator, the *sleep•safe harmony* assumes that the draining of the peritoneal cavity has been completed. Volume monitoring will be restarted.

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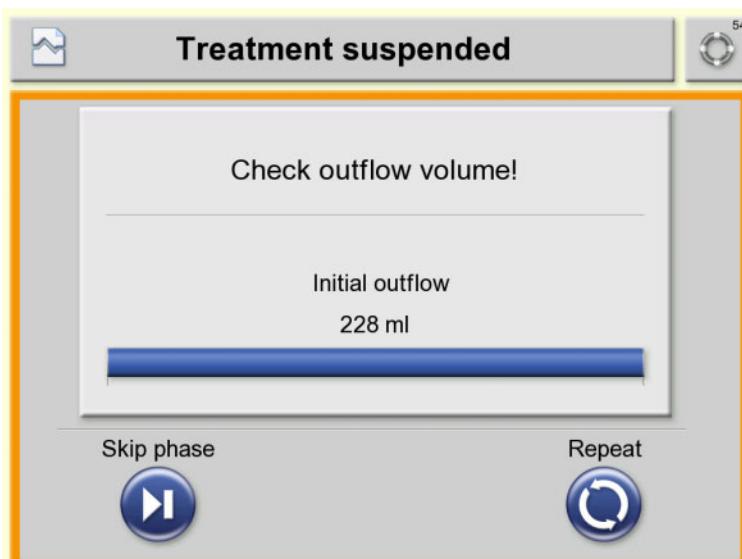
The initial outflow volume achieved and the initial outflow target volume will be displayed.

➢ 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 126

Risk of overfilling in case of incomplete draining of the peritoneal cavity.

Press the external key, to confirm complete draining!
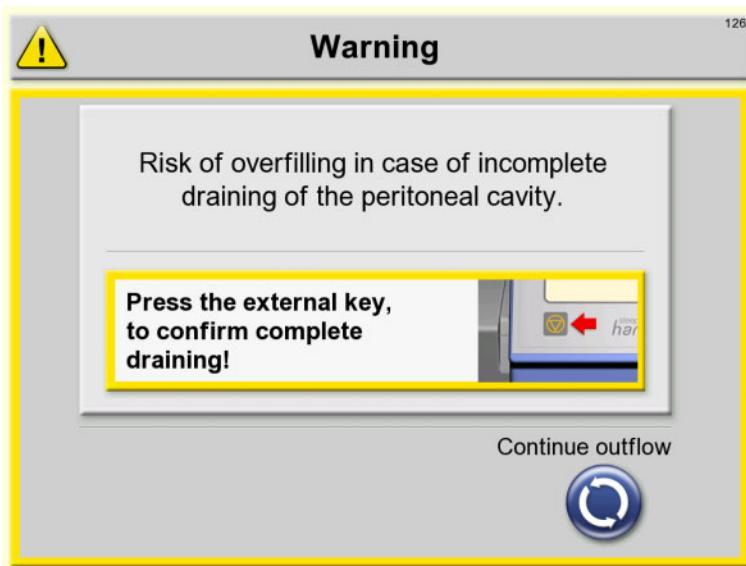
Continue outflow

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.

➢ Press the 🔄 button to continue the initial outflow.

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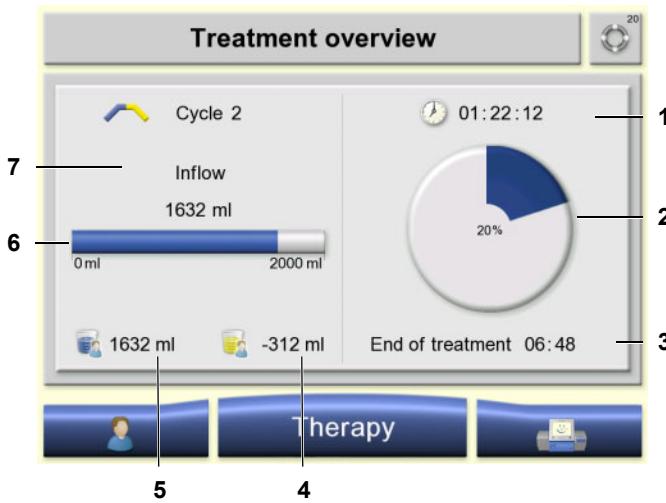
During the treatment, the following parameters will be displayed on the treatment overview screen:

1. Current time

2. Treatment progress in %

3. Expected end of treatment

4. Current total volume balance

5. Volume in patient

6. Progress of the current treatment phase

7. Treatment cycle

Negative values describe a weight loss (ultrafiltrate has been generated). Positive values describe a weight gain (resorption).

4.4 Terminating the treatment

4.4.1 Disconnecting the patient

⚠️ **Warning**

Risk of infection

➢ Use aseptic technique when disconnecting the patient connector.

➢ Wearing a face mask and hand disinfection is recommended.

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

The attending physician is responsible for proper patient training.
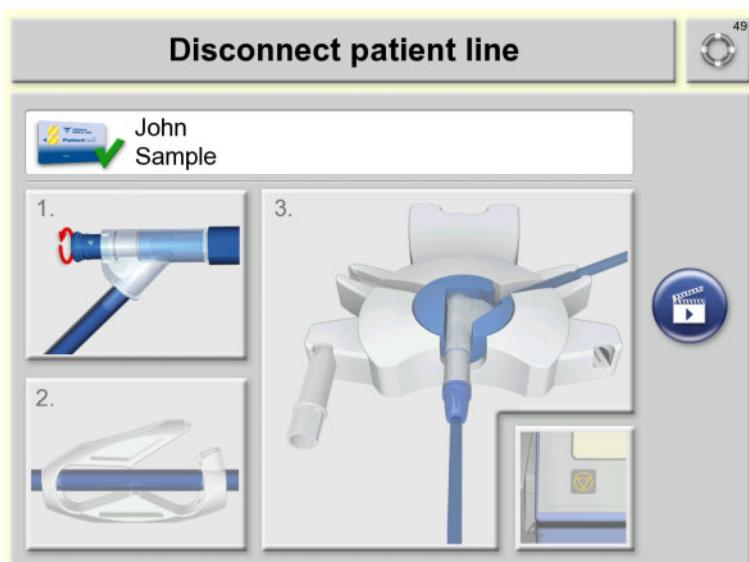
Perform the steps for disconnection as detailed below.

1. Release the PIN

2. Close the clamp

3. Disconnection

4. Confirmation

➢ The 🔘 button can be used to replay the screen animation.
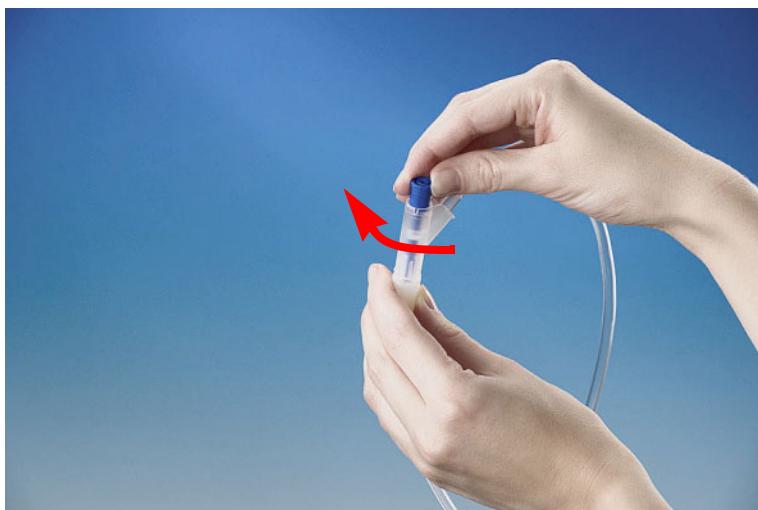
➢ Turn the blue knob on the patient connector one quarter of a turn clockwise.

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

➢ Insert the patient connector into the clip of the organizer.

➢ 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 screw the catheter extension with the PIN immediately onto the new disinfection cap.

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

➢ Press the 🛑 key to confirm the disconnection.

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

End of treatment			🔘30
1	🗑	20.5 l	Treatment volume
2	📋	-1835 ml	Volume balance
3	⏱	07 h 25 min	Treatment duration
4	📈	4	Interruptions
5	🔋	22 min	Reduced dwell duration
6	📉	113 ml	Reduced inflow volume
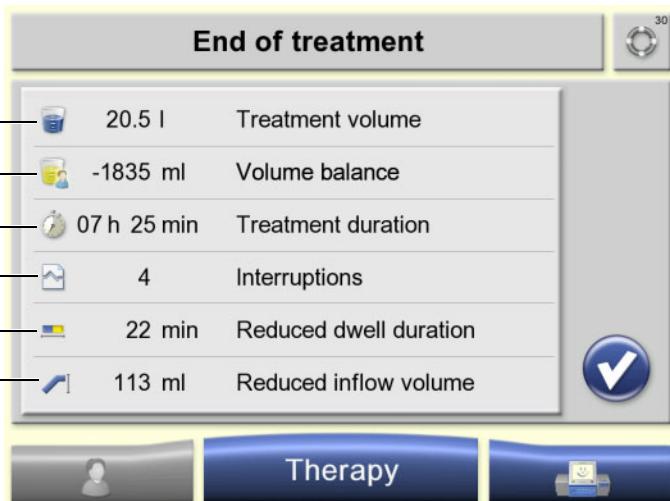
Therapy

Select the **Therapy** menu to display the treatment report or press the ✅ button to terminate the treatment.

The results of the last treatment will be displayed.

1. Total of all inflow volumes plus last inflow

2. 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).

3. Total treatment duration

4. Number of interruptions

5. Reduction of the dwell duration of the total treatment (as reduced automatically within the permitted limits) (see Chapter 7.3.2   on page 7-10).

6. Reduction of the inflow volume of the total treatment (as reduced automatically within the permitted limits) (see Chapter 7.3.1.3   on page 7-10).

➢ Press the ✅ button to exit the **Treatment complete** screen and to move to **Draining**.

Warning

A repeated reduction of the dwell duration or of the inflow volume may result in an inadequate treatment.

In this case, please inform the physician.

➢ Select the **Treatment report** option.

➢ Pressing the 🔄 button will display the higher-level screen.
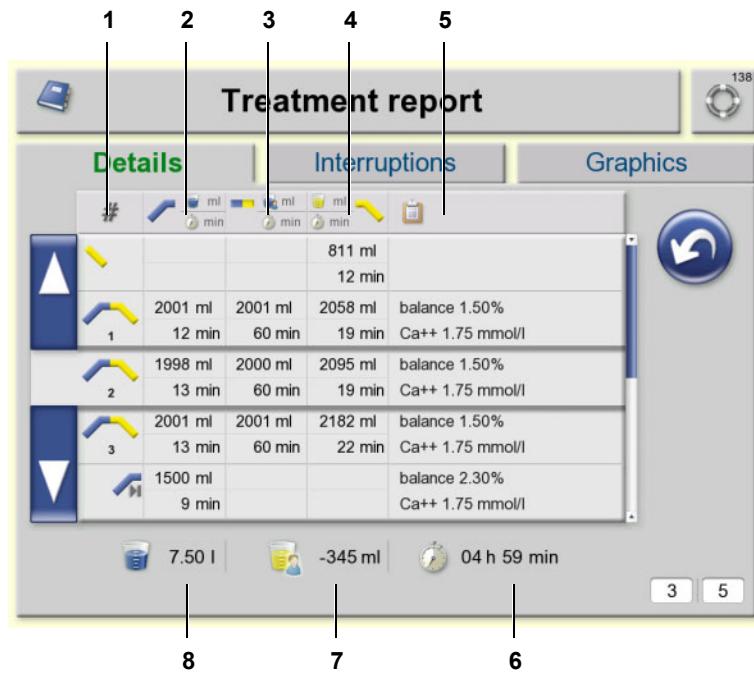
The **Details** tab shows the results of the treatment cycles and the total treatment results.

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. Balance in ml

8. Total treatment volume in liters

➢ Select the **Interruptions** tab

or

➢ Pressing the 🔄 button will display the higher-level screen.
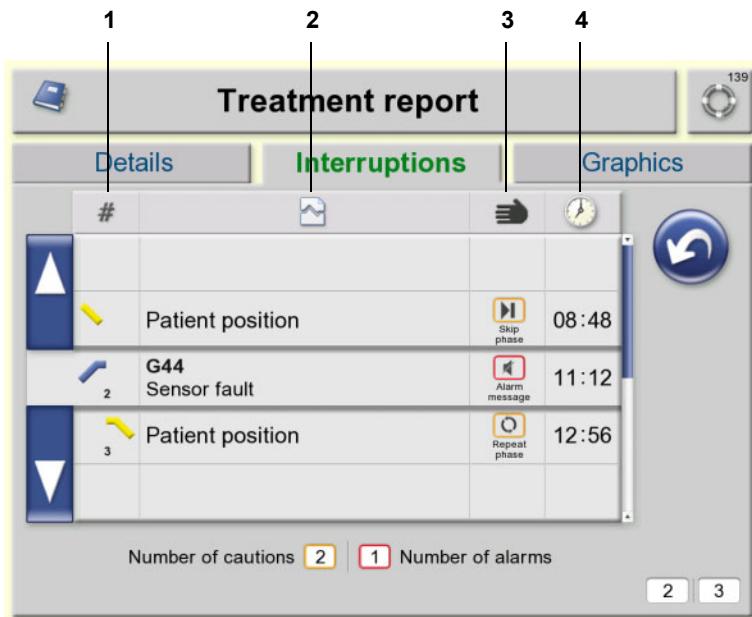
The **Interruptions** tab shows all the cautions and alarms, the time that they occurred, and the treatment phase during which they occurred.

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 5-1).

➢ Select the **Graphics** tab

or

➢ Pressing the ⟲ button will display the higher-level screen.
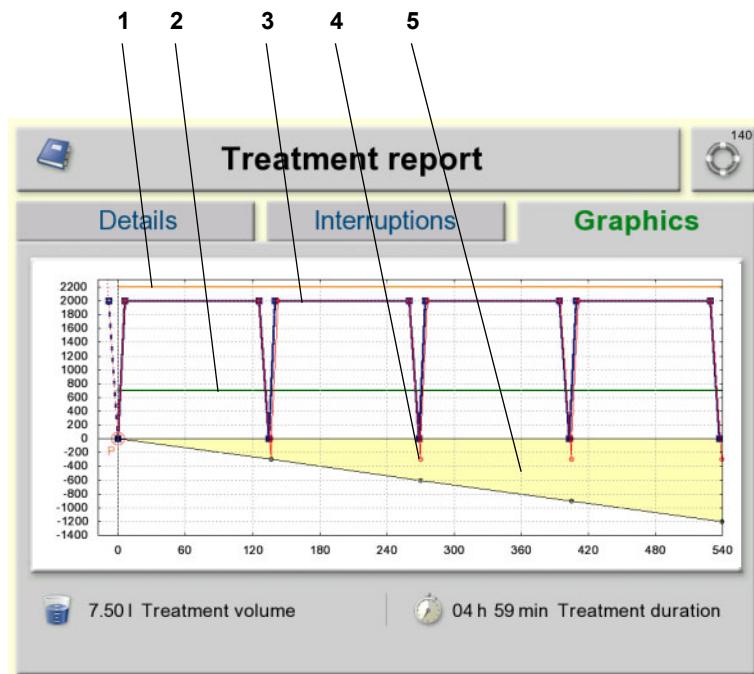
The **Graphics** tab shows a schematic of the treatment results.

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 7-9)

2. Permitted residual volume in ml (green) (see Chapter 7.3.1.2   on page 7-9)

3. Prescribed volume curve (blue)

4. Actual volume curve (red)

5. Volume removed curve (yellow) (Example as shown: -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.

Draining solution bags ...
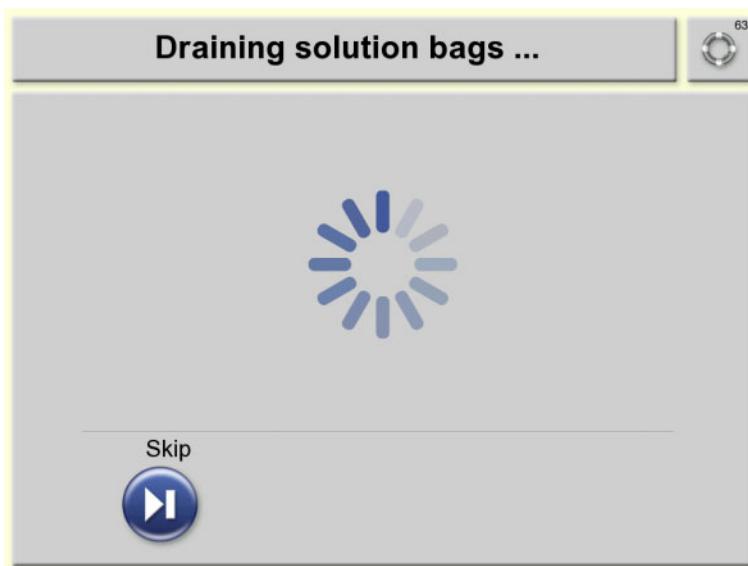
Skip

The solution bags and the line set are drained automatically.

The *sleep•safe harmony* prepares for unloading 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

Note

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

Remove set

Therapy

➢ 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.

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

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

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

Closing loading tray ... ⊙⁶¹	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.
Device can be turned off ⊙¹⁴²	➢ Dispose of the *sleep•safe* Set, the solution bags and the drain line system.
Goodbye	
👤 Therapy 🖥️	

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

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

When the *sleep•safe harmony* is used for the first time for a patient, the device or the patient card must be configured for the patient.
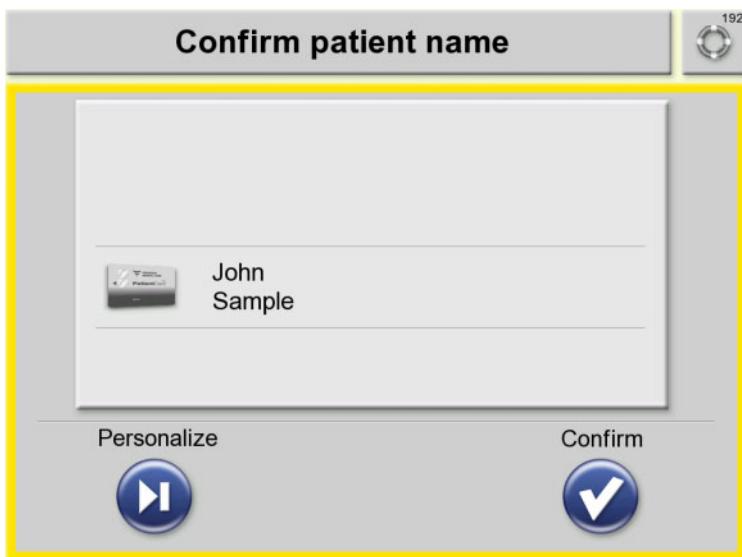
➢ Press the ⏭ button.
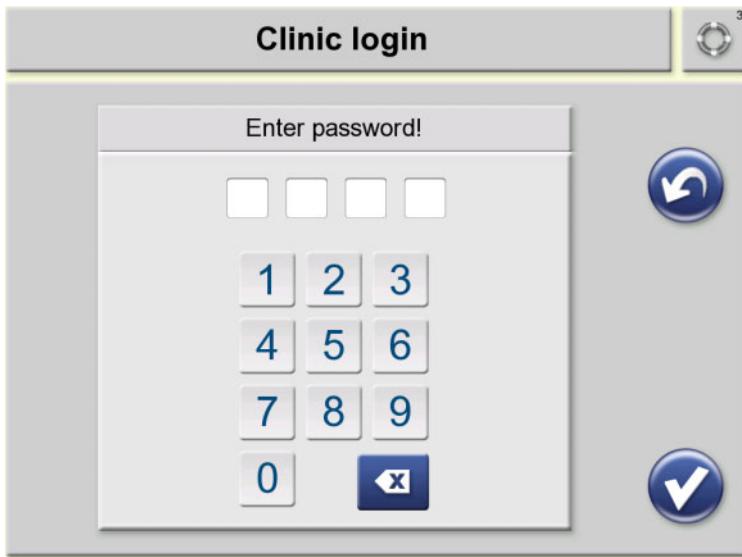
➢ Enter the password.

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

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

Select language	201	➢ Press the **Select language** button.

Personalize - step 1 of 5

Select language

🇬🇧 English

Back   Confirm
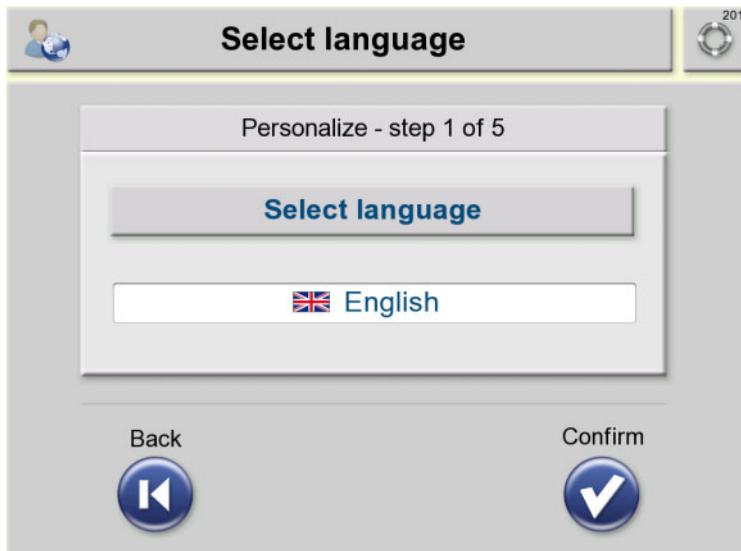
➢ Press the **Select language** button.

➢ 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.

Create patient data   202

Personalize - step 2 of 5

Enter first name

John

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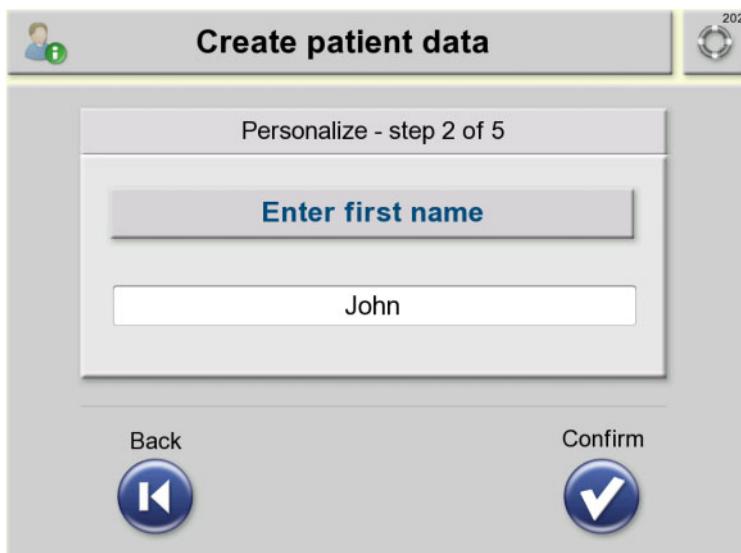
➢ Press the **Enter first name** button.

➢ 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.
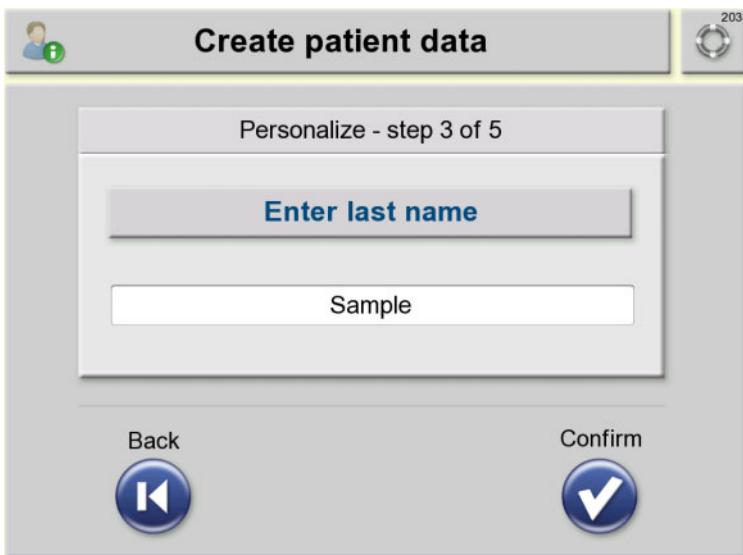
Create patient data 203	➢ Press the **Enter last name** button.
Personalize - step 3 of 5	➢ Enter the last name.
Enter last name	➢ Press the ✓ button to confirm the input and to move to the next operating step.
Sample	➢ Press the ⏮ button to return to the previous operating step.
Back Confirm	
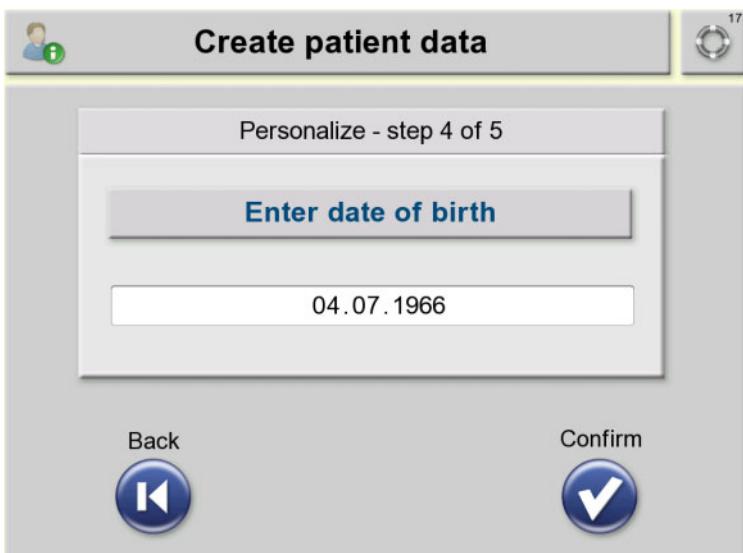
Create patient data 17	➢ Press the **Enter date of birth** button.
Personalize - step 4 of 5	➢ Enter the date of birth.
Enter date of birth	➢ Press the ✓ button to confirm the input and to move to the next operating step.
04.07.1966	➢ Press the ⏮ button to return to the previous operating step.
Back Confirm	
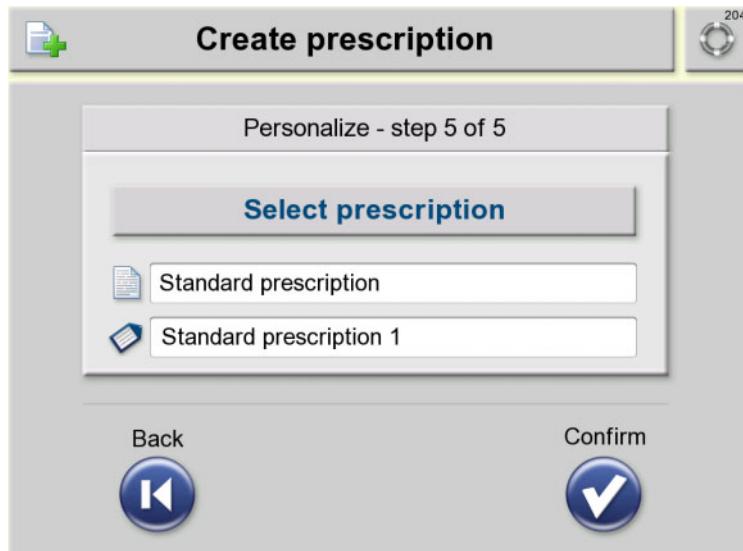
➢ Press the **Select prescription** button.

➢ 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.
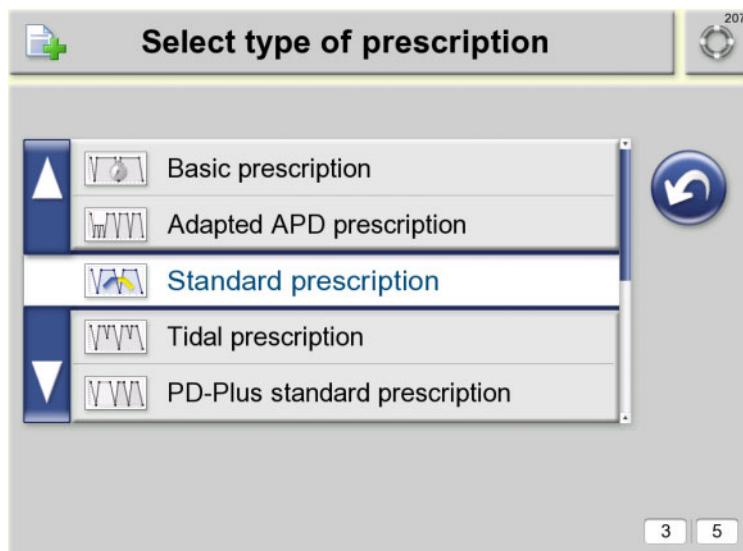
➢ Select the required prescription type and enter a name for this prescription.
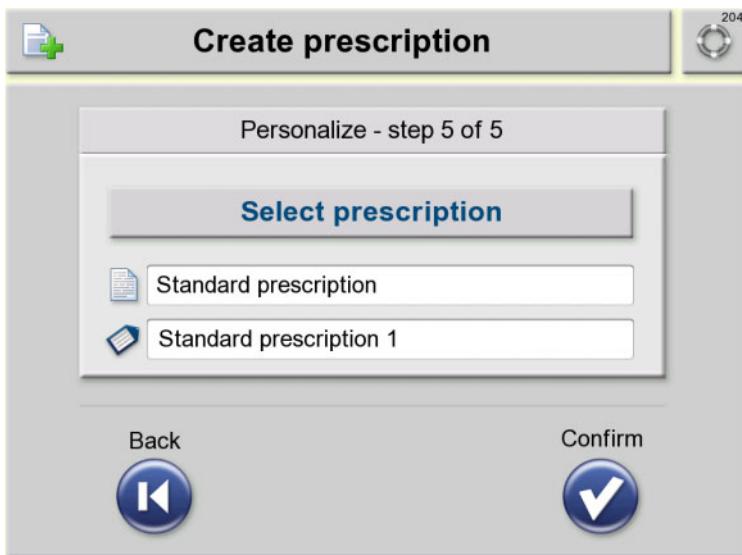
➢ Pressing the ↩ button will display the higher-level screen.

Create prescription   204

Personalize - step 5 of 5

Select prescription

Standard prescription

Standard prescription 1

Back   Confirm

➢ 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.

Create patient card   205

John

Sample

04.07.1966

Standard prescription

Standard prescription 1

Back   Confirm
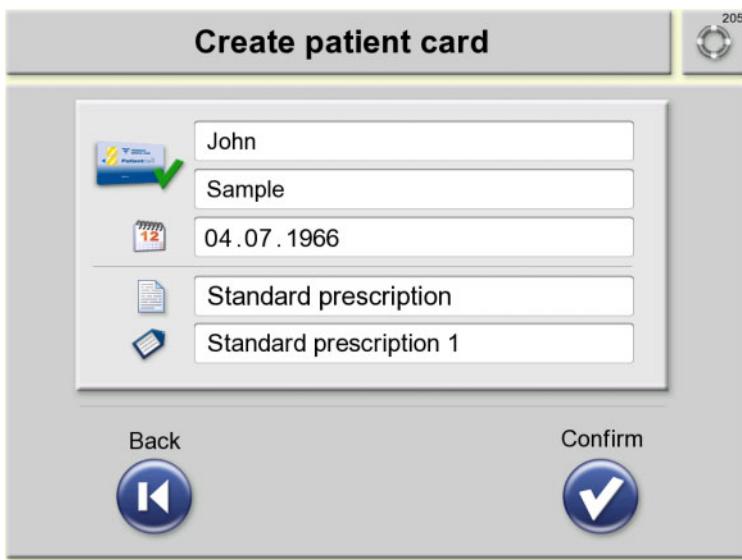
➢ Check all data entered.

➢ Once the data has been confirmed, the personalization is complete and the patient card is assigned to the patient. The first name, surname 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.

Personalization complete

Patient parameters and prescription
data contain default values.
Adapt default values to match the patient!

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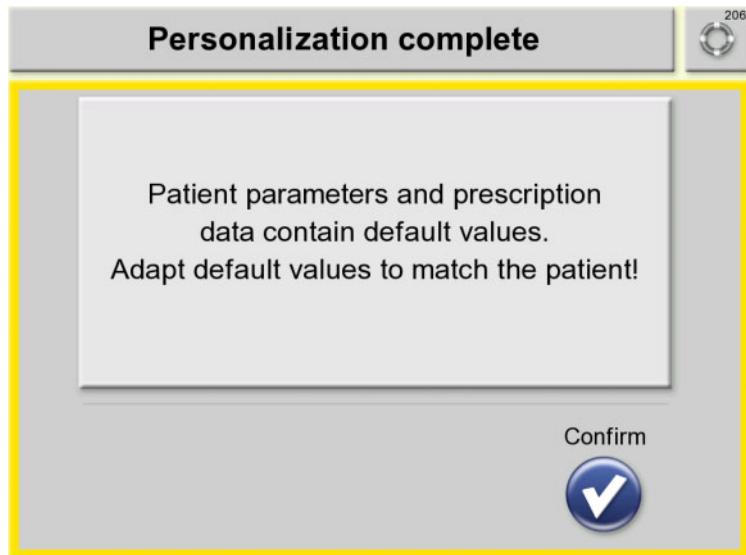
➢ Check and edit the patient
parameters and the prescription
data, if necessary.

Editing the patient parameters (see
Chapter 4.6.1.3 on page 4-54).

Editing the prescription data (see
Chapter 4.6.2.3 on page 4-65).

➢ Press the ✓ button to create a
patient card.

Confirm prescription

Prescription	Solution	Graphics

John
Sample

Standard prescription 1

2500 ml Maximum inflow volume

10.00 l Treatment volume

08 h 24 min Treatment duration

Therapy

➢ 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
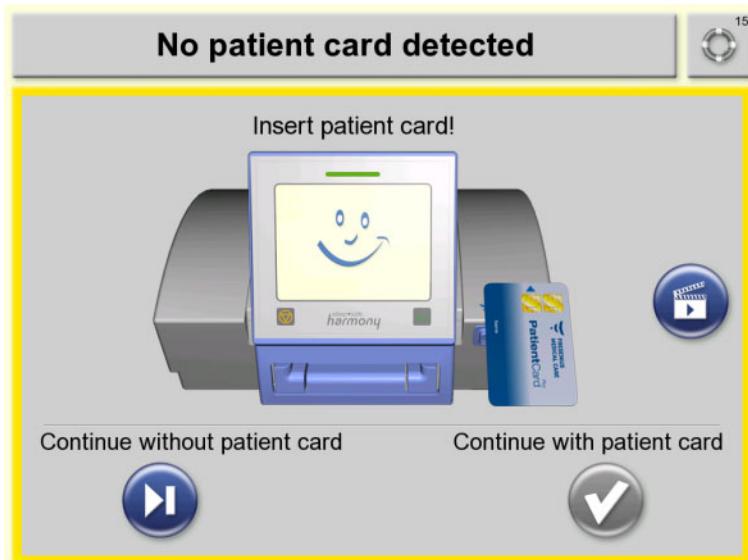
No patient card detected 15

Insert patient card!

Continue without patient card   Continue with 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**

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.

Confirm patient name 192

John
Sample

Personalize   Confirm

➢ Press the ▶ button only if you need to personalize the *sleep•safe harmony*.
This will create a patient card with standard values (see Chapter 4.5.1 on page 4-39).

➢ Press the ✓ button to confirm the patient name displayed.

4.5.3   Removing the *sleep•safe* Set after premature termination of a treatment
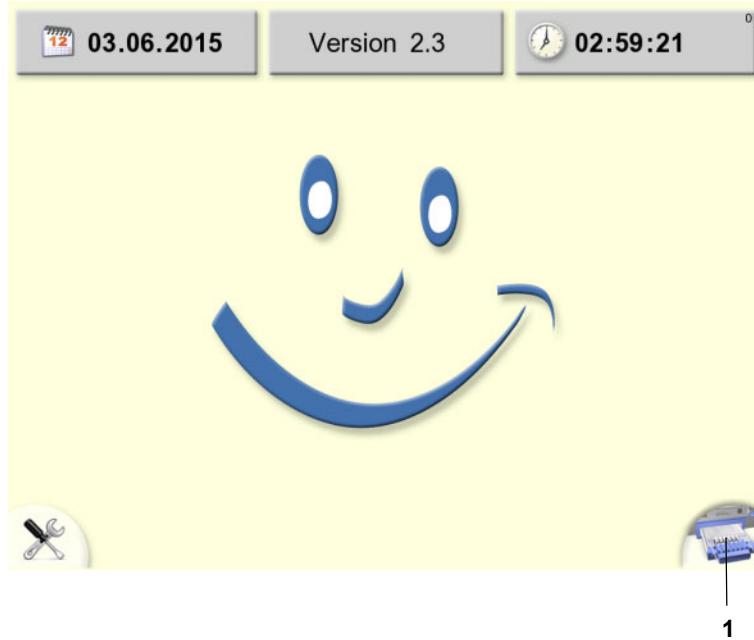
➢ Press the button (1) on the right at the bottom of the screen to open the loading tray.

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

Note

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

Remove set

Close loading tray!

Device will be turned off when
loading tray has closed.

Confirm

➢ 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**

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

4.5.4   Disconnection after premature termination of a treatment

⚠ **Warning**

Risk of infection

➢ Use aseptic technique when disconnecting the patient
connector.

➢ Wearing a face mask and hand disinfection is
recommended.

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

The attending physician is responsible for proper patient
training.

Disconnect patient line

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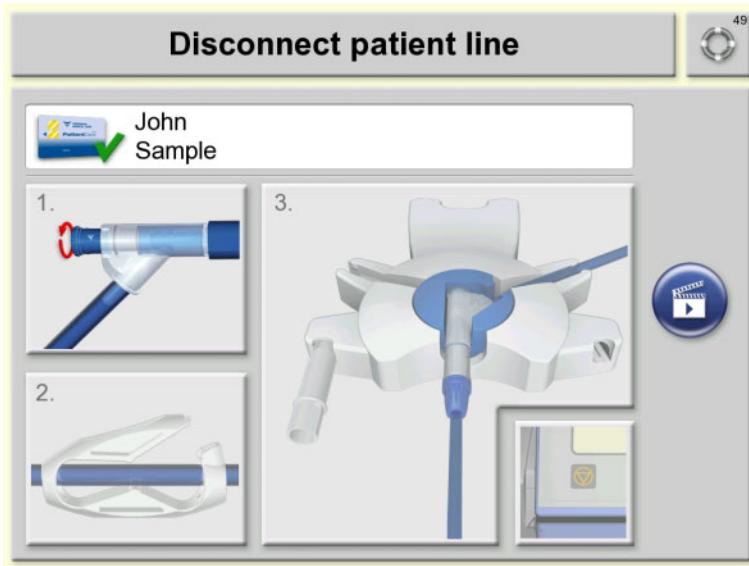
This screen message will only be displayed if treatment has been prematurely terminated and the patient has not been disconnected.

Perform the steps for disconnection

1. Release the PIN

2. Close the clamp

3. Disconnection

4. Confirmation

as detailed below.

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

➢ Insert the patient connector into the clip of the organizer.

➢ 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 screw the catheter extension with the PIN immediately onto the new disinfection cap.

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

➢ Press the ⬇ key to confirm the disconnection.

4.5.4.1 Switching the *sleep•safe harmony* off

> ➢ Press the ⌈o⌐o⌐⌉ key.

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

4.6 Options / changing data prior to treatment

4.6.1 Patient options

4.6.1.1 Selecting the language
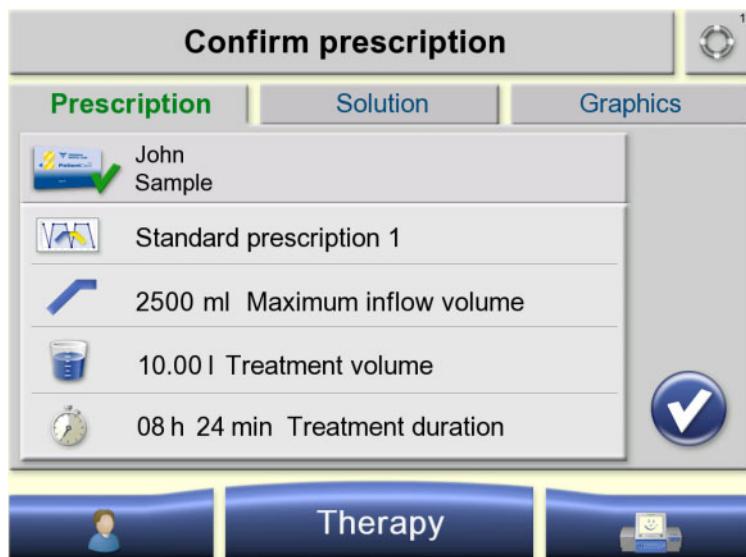
➢ Select the [icon] menu.

➢ Select **Language**.

➢ Pressing the [icon] 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 patient option

Personal data
Patient parameters
Language

Therapy
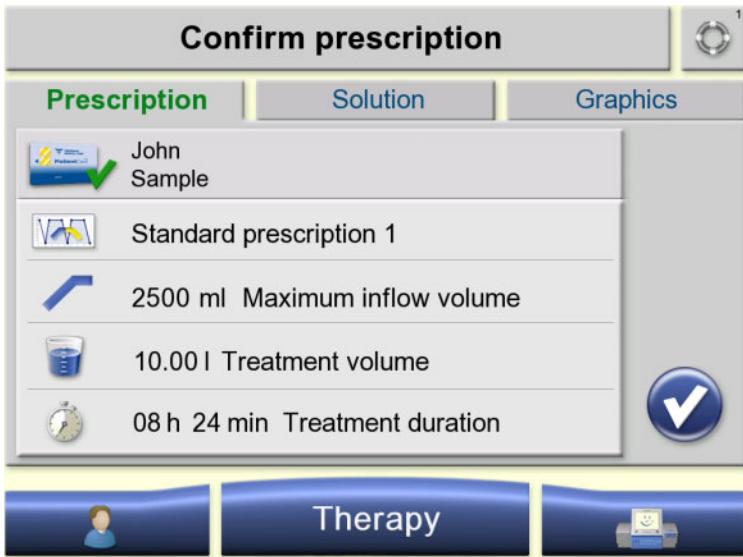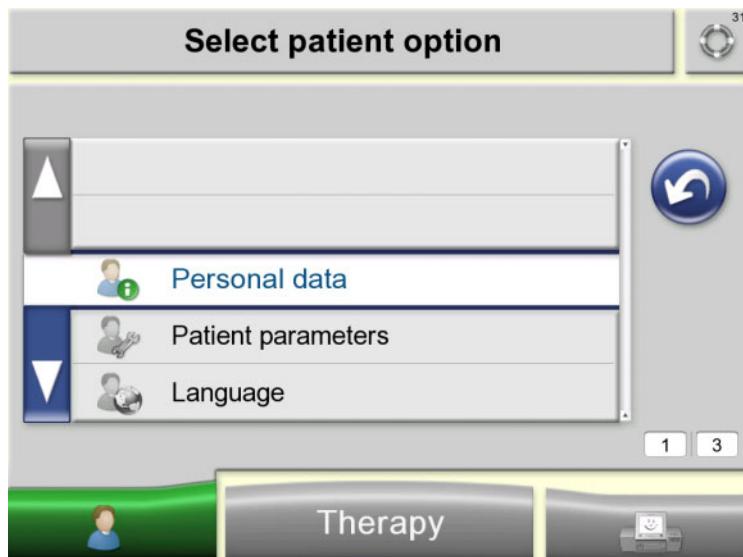
➢ Select **Personal data**.

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

Personal data

First name	John
Last name	Sample
Date of birth	04.11.1965
Gender	Male
Weight	80.0 kg

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.

⚠️ **Warning**

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

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

Warning

The maximum parameters (e.g., maximum inflow volume) represent the limits for all prescriptions.
A change of the maximum parameters may influence existing prescriptions.

When changing the maximum parameters, these must be checked for compliance with the 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 7-9)
– Permitted residual volume
  (see Chapter 7.3.1.2   on page 7-9)
– Permitted dwell duration reduction
  (see Chapter 7.3.2.1   on page 7-10)
– Permitted inflow volume reduction
  (see Chapter 7.3.1.3   on page 7-10)
– Catheter performance
  (see Chapter 7.3.2.2   on page 7-11)
– Set type (function cannot be selected)
– Additional outflow
– Access level
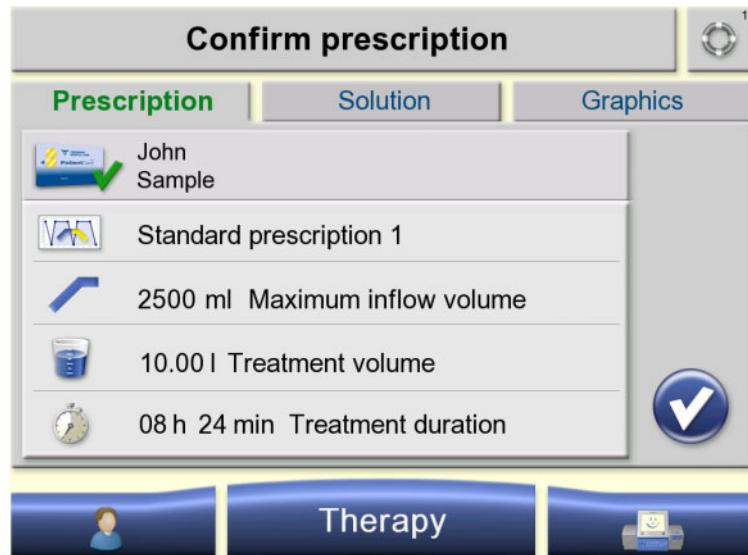
Confirm prescription

| Prescription | Solution | Graphics |

John
Sample

Standard prescription 1

2500 ml Maximum inflow volume

10.00 l Treatment volume

08 h 24 min Treatment duration

Therapy

➢ Select the ▬▬ menu.

Select patient option

Personal data

Patient parameters

Language

Therapy

➢ Select **Patient parameters**.

➢ Pressing the ↻ button will display the higher-level screen.
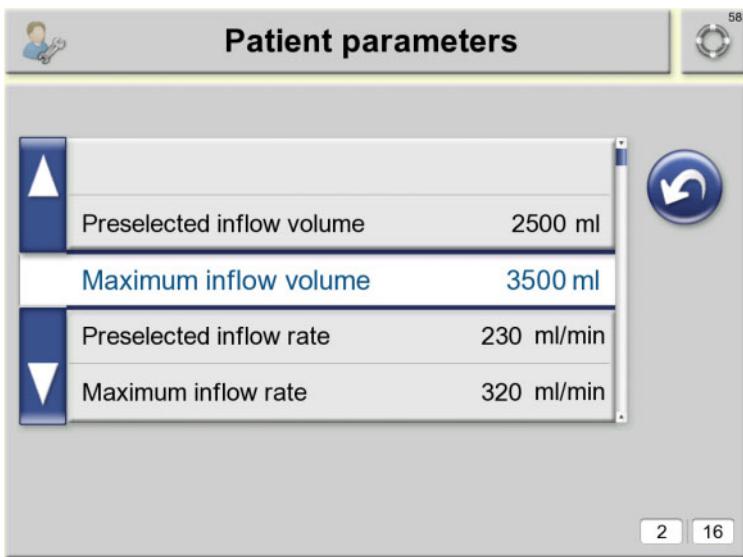
The preselected and maximum **Patient parameters** can be selected and edited.

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

4.6.1.4 Changing the additional outflow
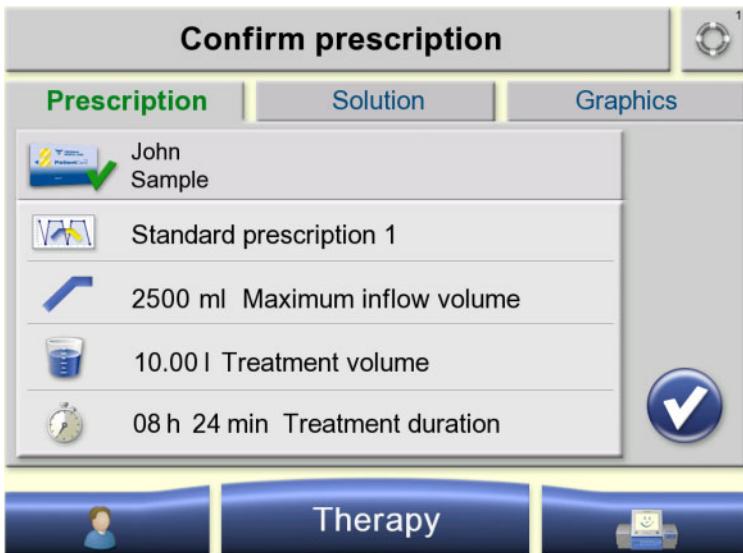
➢ Select the 👤 menu.

Select patient option	31

➢ Select **Patient parameters**.

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

- Personal data
- Patient parameters
- Language

| 2 | 3 |

Therapy

Patient parameters	58
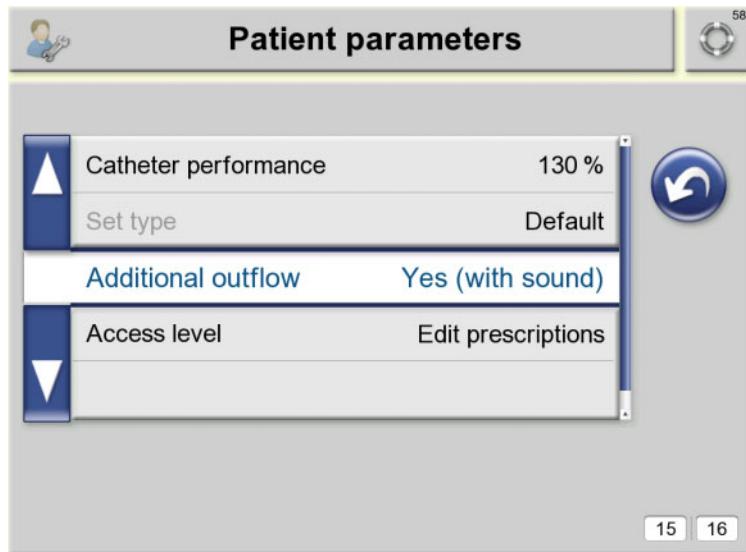
➢ Select **Additional outflow**.

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

Catheter performance	130 %
Set type	Default
Additional outflow	Yes (with sound)
Access level	Edit prescriptions

| 15 | 16 |

Select additional outflow option 178

▲

No

Yes (with sound)

Yes (without sound)

▼

2 3
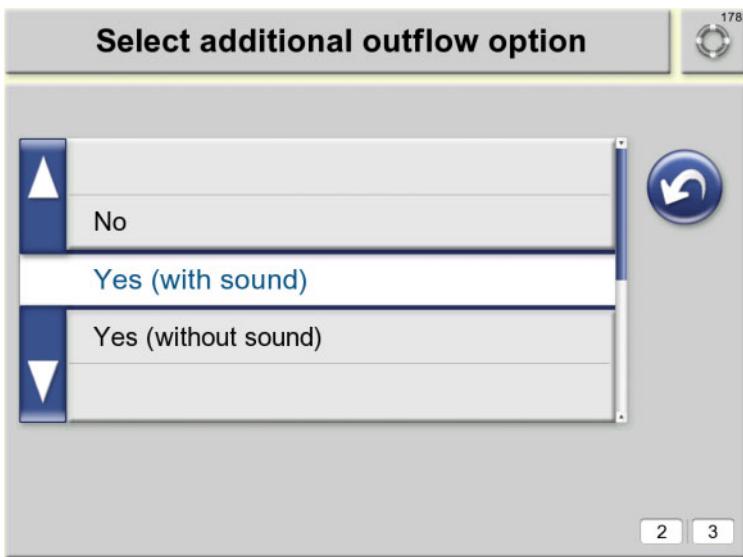
➢ The additional outflow option can be set as follows:
– No
– Yes (with sound)
– Yes (without sound)

Selecting the option Yes (without sound) initiates a treatment pause. Confirming the treatment pause continues the treatment.

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

4.6.1.5 Access levels
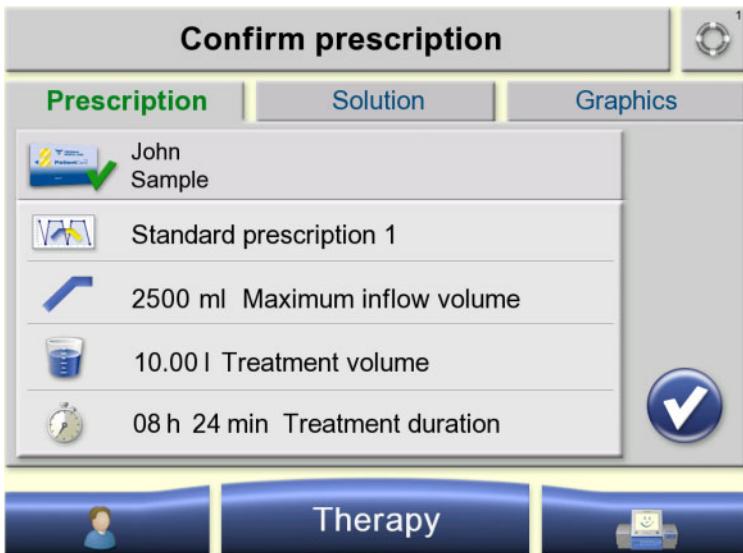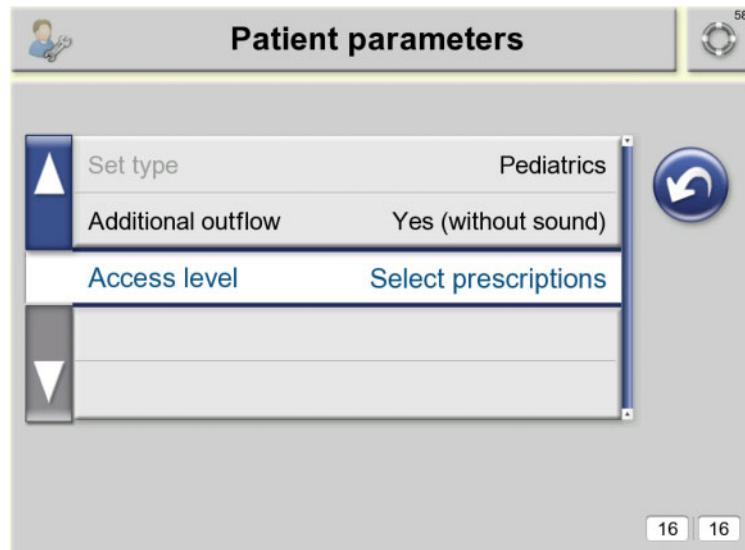
Confirm prescription 1

| Prescription | Solution | Graphics |

John Sample

Standard prescription 1

2500 ml Maximum inflow volume

10.00 l Treatment volume

08 h 24 min Treatment duration

Therapy

➢ Select the 👤 menu.

Select patient option 31	➢ Select **Patient parameters**.
▲	➢ Pressing the button will display the higher-level screen.
Personal data	
Patient parameters	
Language	
▼	
2 3	
Therapy	

Patient parameters 58	➢ Select **Access level**.
▲ Set type	Pediatrics
Additional outflow	Yes (without sound)
Access level	Select prescriptions
▼	
16 16	

➢ Select **Access level**.

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

Access level	
No changes	
Select prescription	
Edit prescriptions	
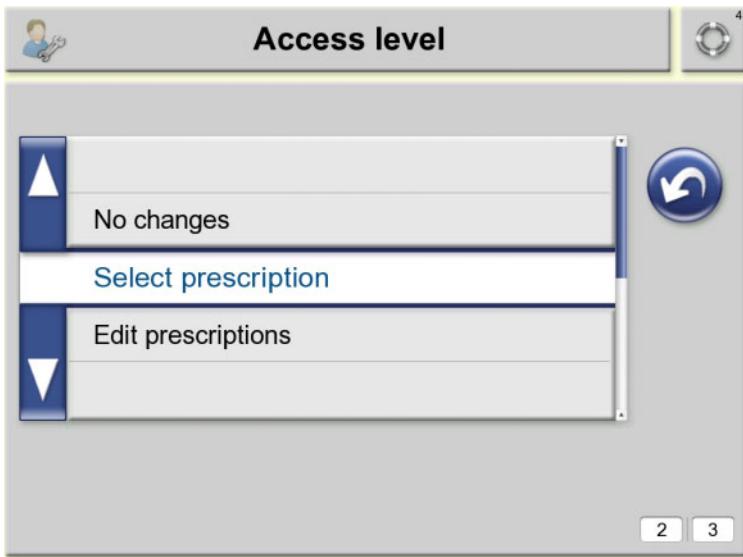
➢ The following **access levels** can be selected:
– No changes
– Select prescription
– Edit prescription

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

4.6.2 Therapy options

4.6.2.1 Creating a prescription

Confirm prescription

Prescription	Solution	Graphics

John Sample

Standard prescription 1

2500 ml Maximum inflow volume

10.00 l Treatment volume

08 h 24 min Treatment duration

Therapy

➢ Select the **Therapy** menu.

Select therapy option 163

- Create prescription
- Select prescription
- Edit prescription

1 6
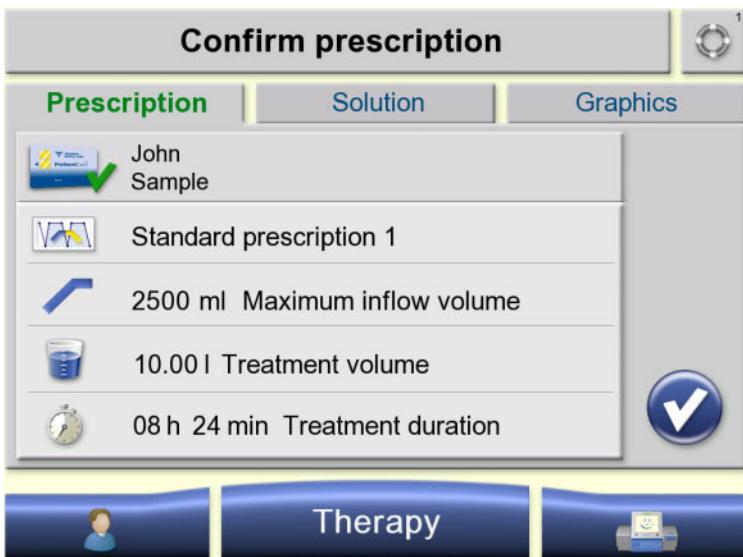
Therapy

➢ 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.

Create prescription 33

- Basic prescription
- Adapted APD prescription
- Standard prescription
- Tidal prescription
- PD-Plus standard prescription

3 5
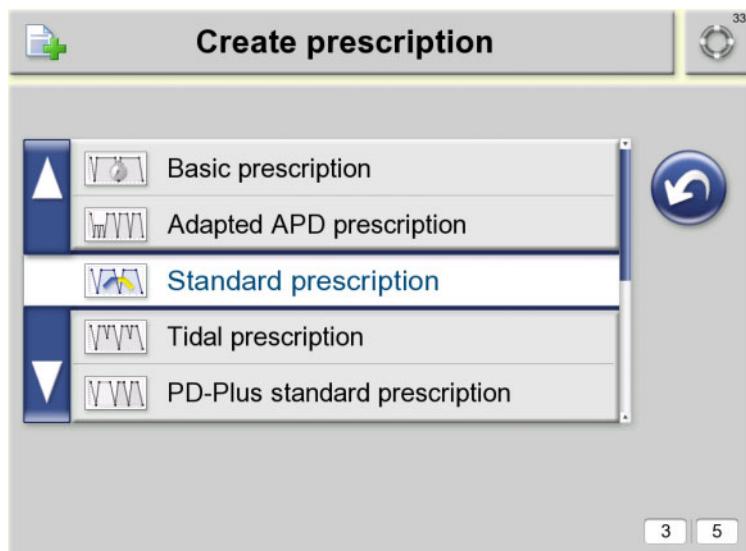
➢ Select the prescription to be created.

➢ Pressing the ⟲ button will display the higher-level screen.
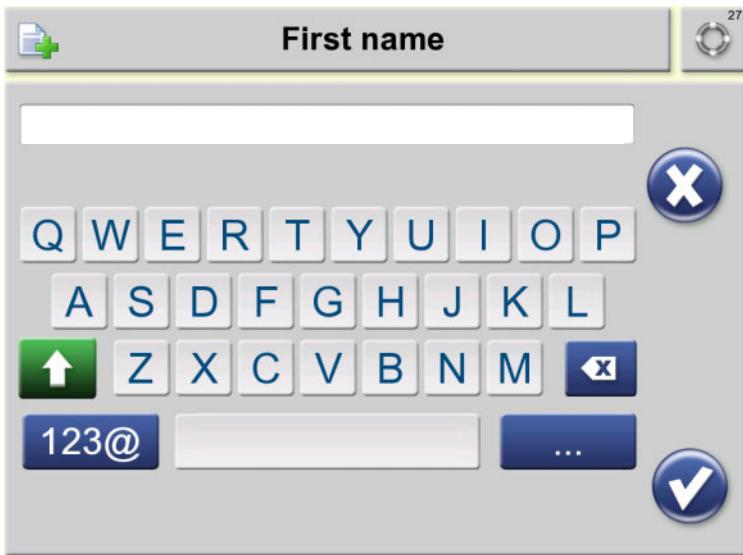
➢ Enter the name for the prescription.

➢ Press the ✓ button to confirm the change.

➢ Press the ✗ button to discard the change.
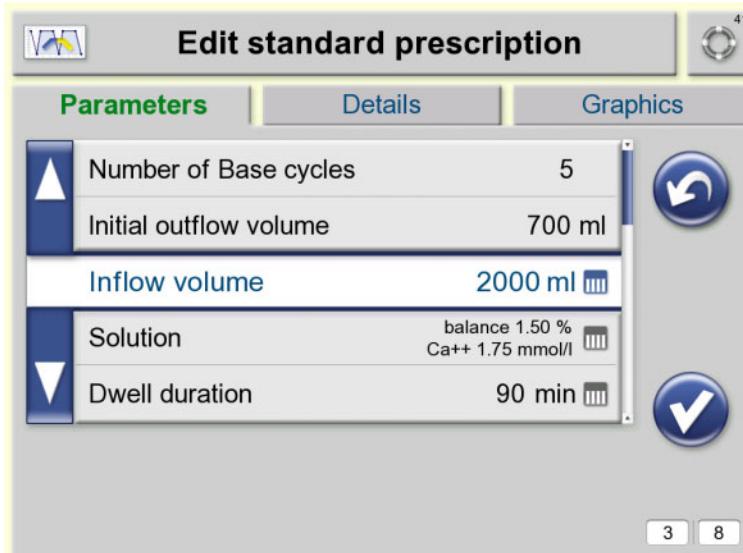
➢ Enter the parameters for the new prescription you have created.

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.
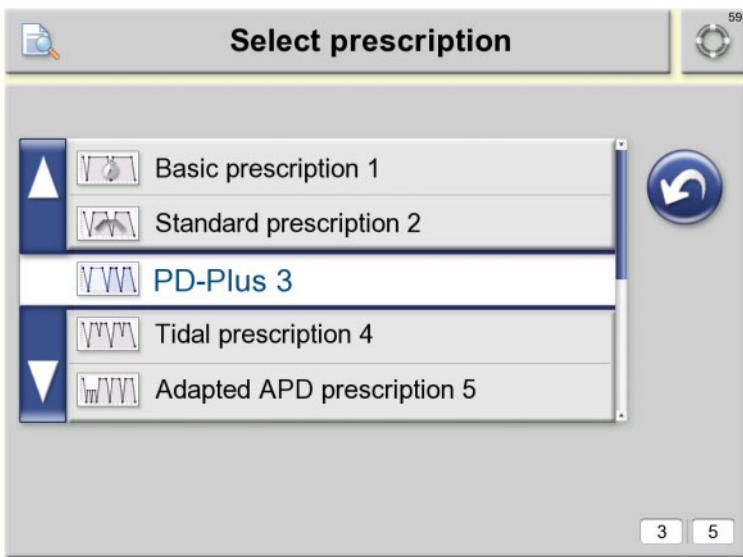
➢ Select the required prescription.

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

4.6.2.3 Editing a prescription

➢ Select the **Therapy** menu.

Select therapy option	163

- Create prescription
- Select prescription
- **Edit prescription**
- Delete prescription
- Show treatment reports

3 6

Therapy

➤ Select **Edit prescription**.

➤ Pressing the ⟲ button will display the higher-level screen.

Edit standard prescription	41

| Parameters | Details | Graphics |

Number of Base cycles	5
Initial outflow volume	700 ml
Inflow volume	**2000 ml**
Solution	balance 1.50 % Ca++ 1.75 mmol/l
Dwell duration	90 min

3 8
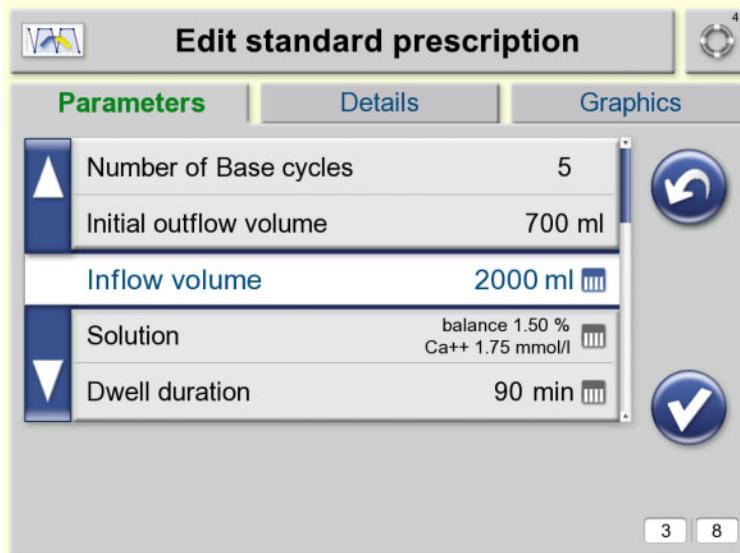
➤ Enter the parameters for the prescription to be edited.

4.6.2.4 Deleting a prescription
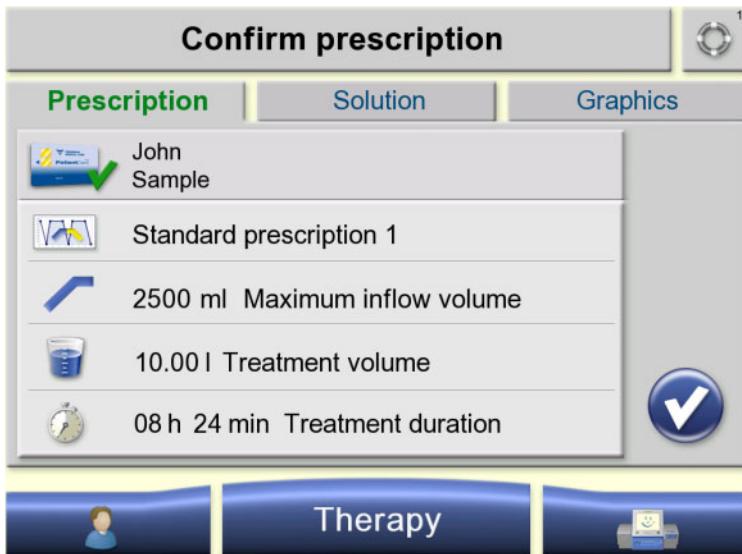
➢ Select the **Therapy** menu.

➢ Select **Delete prescription**.

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

| Delete prescription | 135 |

Basic prescription 1
Standard prescription 2
PD-Plus 3
Tidal prescription 4
Adapted APD prescription 5

| Mon | Tue | Wed | Thu | Fri | Sat ✔ | Sun ✔ | Default | 3 | 5 |
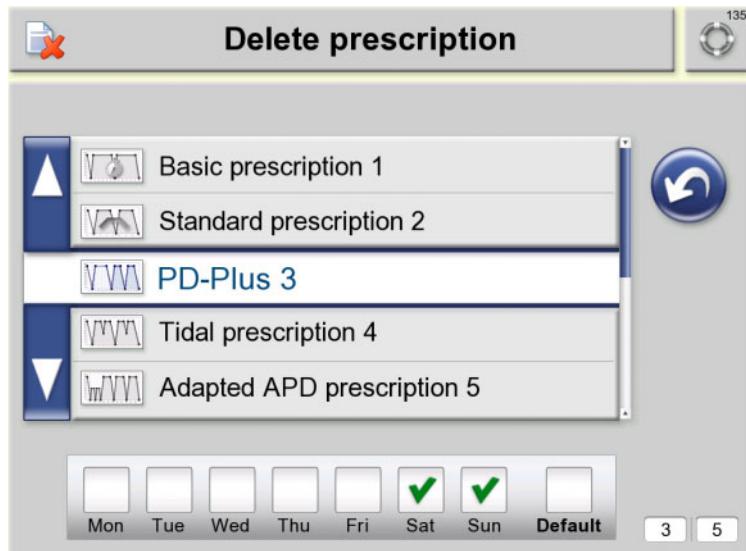
➢ Select the prescription to be deleted.

➢ Press the selected prescription to delete this prescription.

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

4.6.2.5 Displaying treatment reports

| Select therapy option | 163 |

Edit prescription
Delete prescription
Show treatment reports
Edit prescription schedule

| 5 | 6 |

Therapy

➢ Select **Show treatment reports**.

➢ Pressing the ⟲ button will display the higher-level screen.
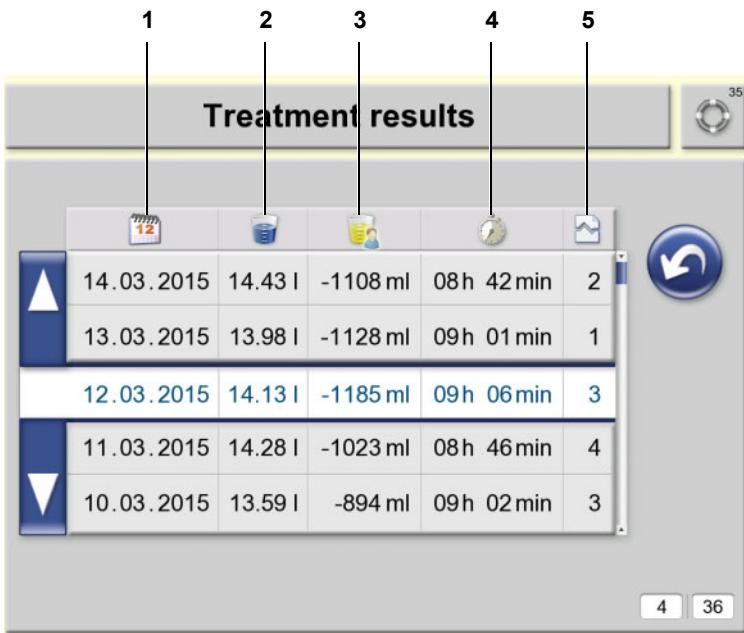
A list of the last treatments is displayed.

1. Start of treatment date

2. Total of all inflow volumes plus last inflow

3. Volume balance
If treatment is terminated prematurely, this value does not show the actual volume balance of the patient, but only the volume removed within the treatment time. (Example as shown: -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.

➢ Details of a selected treatment report (see Chapter 4.4.2 on page 4-32).

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

4.6.2.6   Editing the prescription schedule
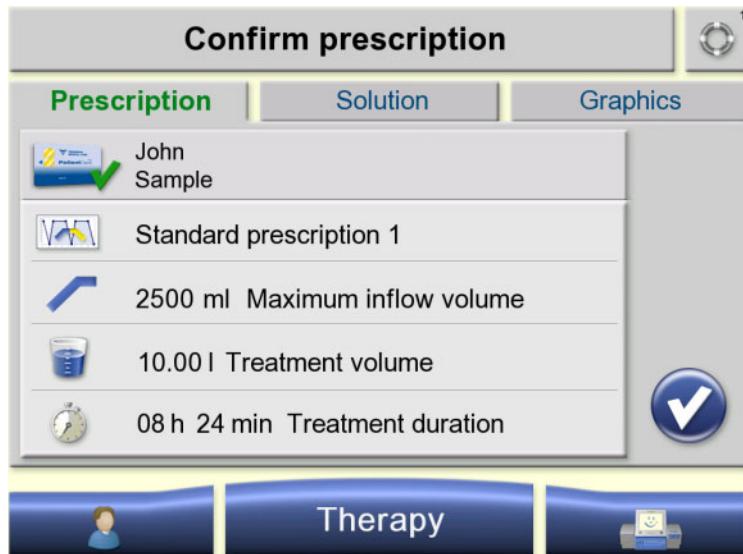
➢ Select the **Therapy** menu.

➢ Select **Edit prescription schedule**.

➢ Pressing the ⟲ button will display the higher-level screen.
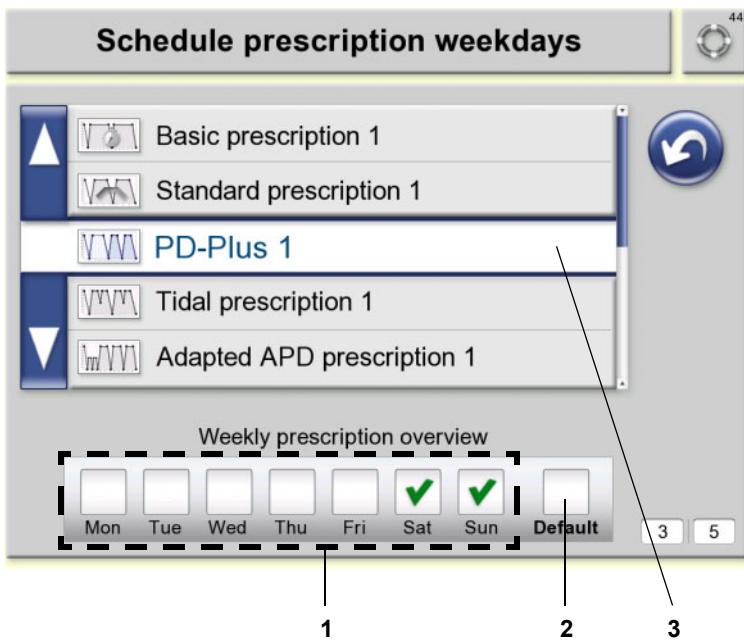
The treatment days of the prescription in the highlighted line in the center (3) are indicated by a green checkmark in the weekly overview (1).

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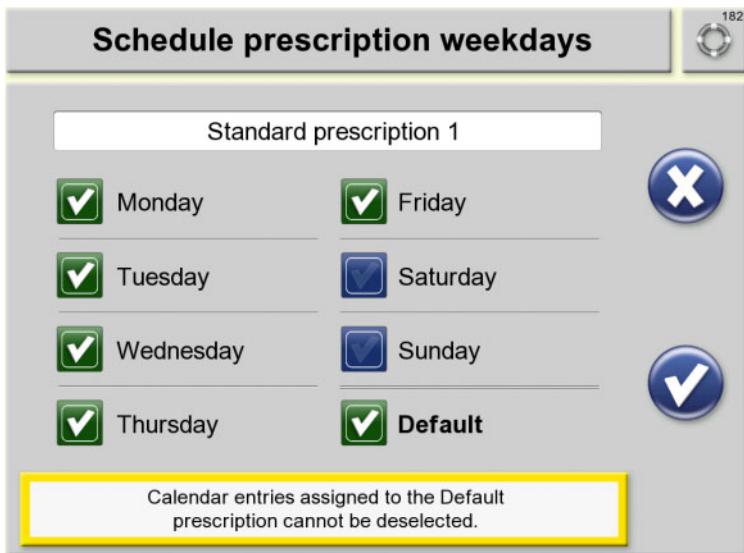
➢ Select the days of the week on which the selected prescription is to be performed.

➢ 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.

Confirm prescription

Prescription	Solution	Graphics

John
Sample

Standard prescription 1

2500 ml Maximum inflow volume

10.00 l Treatment volume

08 h 24 min Treatment duration

Therapy

➢ Select the ▭ menu.

Select device options

Date and time

Device information

Volume

1 9

Therapy
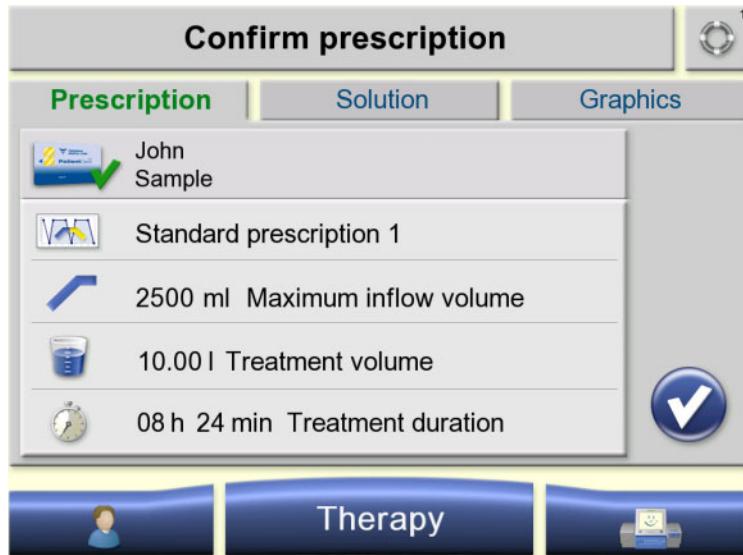
➢ Select **Date and time**.

➢ Pressing the ↺ button will display the higher-level screen.
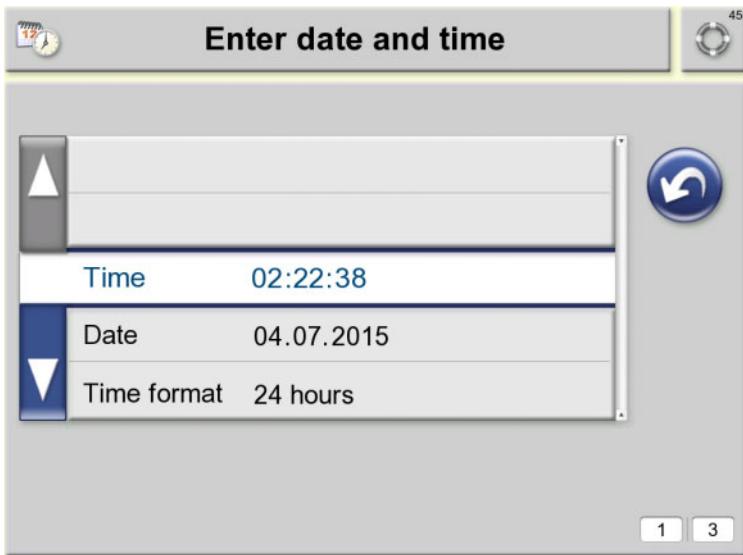
> ➢ Select **Date**, **Time** or **Time format** and set the date, the time or the time format.

> ➢ Press the ✓ button to confirm the change.

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

4.6.3.2 LAN setup data
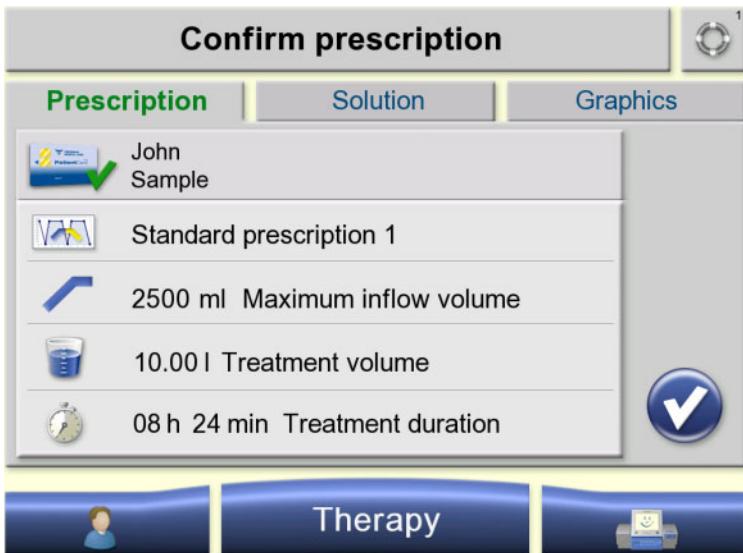
> ➢ Select the 🖨 menu.

Select device options	➢ Select **LAN setup data**.
Brightness	
Screen saver	➢ Pressing the ↺ button will display
LAN setup data	the higher-level screen.
Clinic login	
Service login	
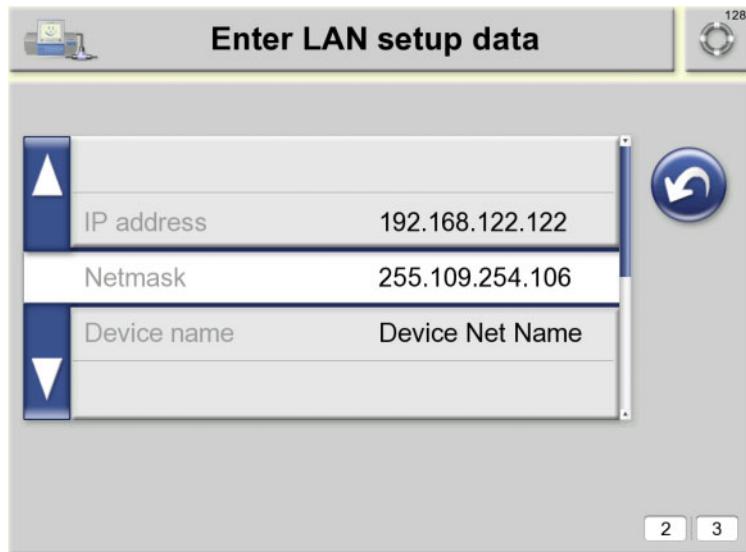
Enter LAN setup data	➢ Select **IP address**, **Netmask** and
IP address 192.168.122.122	**Device name** and enter the data.
Netmask 255.109.254.106	
Device name Device Net Name	➢ Pressing the ↺ button will display
	the higher-level screen.

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

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. This allows the preparation of the device and the treatment of the patient to take place in different rooms.

Note

The **Relocate device** function is only possible with a *sleep•safe* Set Plus.
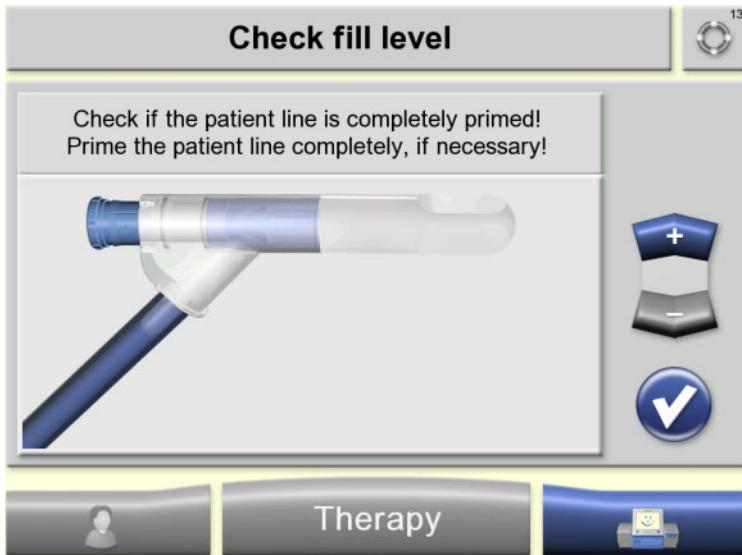
➢ Select the ▭ menu.

➢ Select **Relocate device**.

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

Relocate device 185

➢ Press the ✓ button to confirm relocation.

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

Back / Confirm

⚠ **Warning**

➢ The patient line must be sealed using aseptic technique.

Prepare for relocation 187

Close patient line!

Back / Confirm
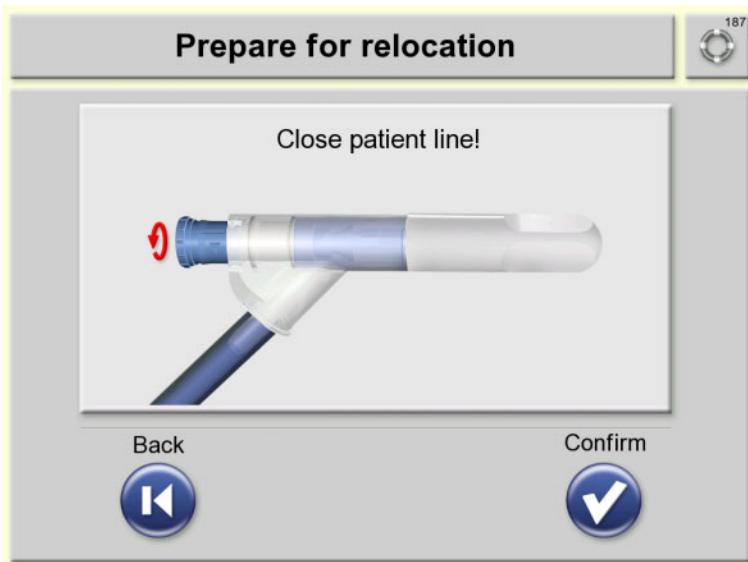
➢ Seal the patient line.

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

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

Disconnect power plug 189

Disconnect the device from the power supply!

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

Relocate device 186

Device can be relocated, after relocation reconnect the device to the power supply!

John
Sample

Standard prescription 1

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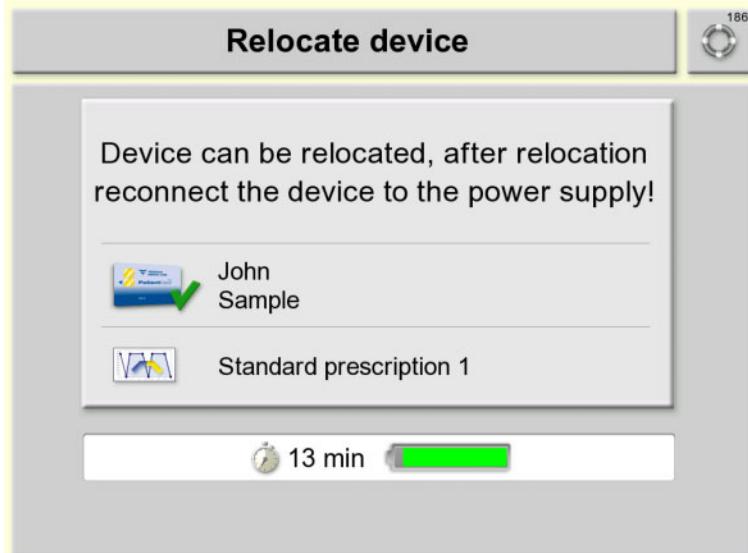
➢ The *sleep•safe harmony* can now be moved to a different location.

➢ After a maximum of 15 minutes, the *sleep•safe harmony* must be reconnected to the power supply.

The remaining time is displayed on the bottom of the screen.
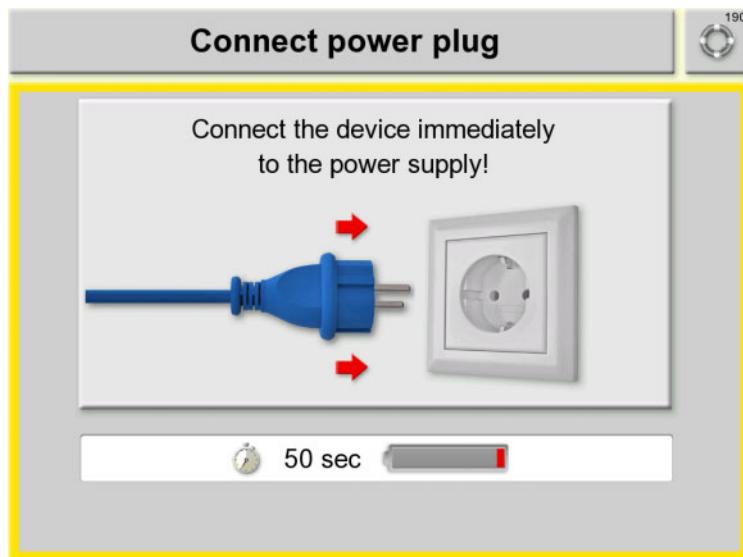
Connect power plug 190	If the *sleep•safe harmony* has not been reconnected to the power supply, the screen on the left will be displayed.
Connect the device immediately to the power supply!	➢ The *sleep•safe harmony* must now be connected to the power supply immediately, as the *sleep•safe harmony* will otherwise shut down.
50 sec	

Continue preparation for treatment 191	Preparation for treatment can be continued.
John Sample	➢ Press the ✔ button to confirm the patient name and the prescription.
Standard prescription 1	
Confirm ✔	

4.6.3.4   Setting the volume
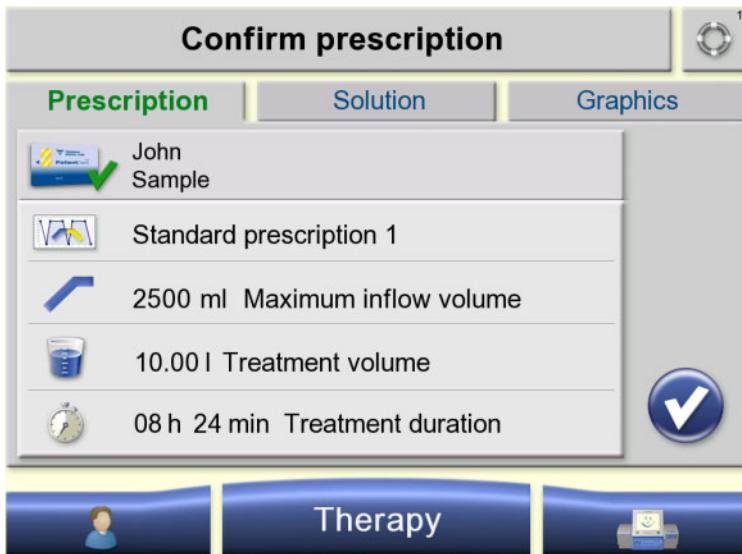
➢ Select the [icon] menu.

➢ Select **Volume**.

➢ Pressing the [icon] button will display the higher-level screen.
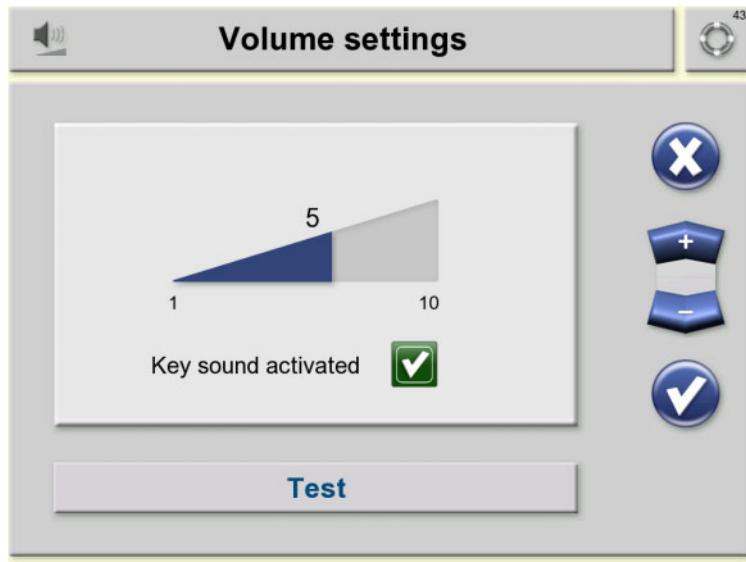
➢ Select the required volume for all the sounds (except audible alarms).

➢ 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.

4.6.3.5 Setting the brightness

➢ Select the 🖳 menu.

Select device options	⟳ 47	

▲ Device information	
🔊 Volume	↺
☼ **Brightness**	
Screen saver	
▼ LAN setup data	

4 9

👤 | Therapy | 🖥
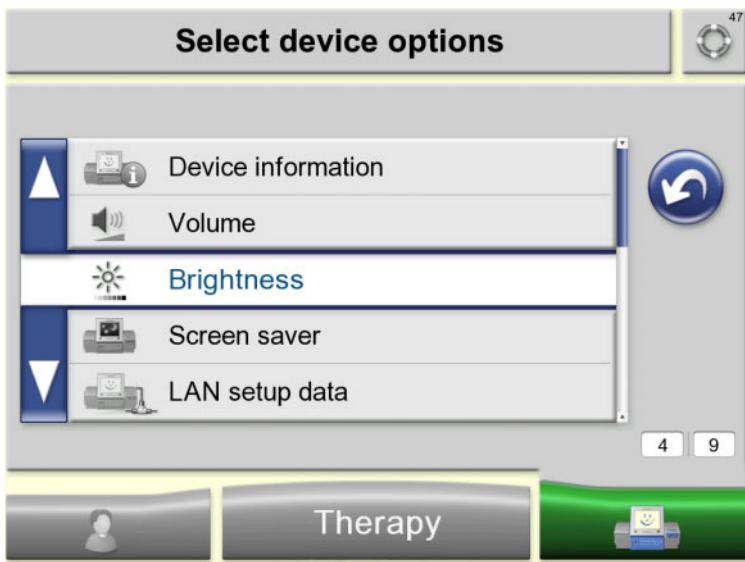
➢ Select **Brightness**.

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

☼ **Set brightness**	⟳ 55

8

1   20

❌

＋
－

✔

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.

4.6.3.6 Setting the screen saver

➢ Select the [icon] menu.

➢ Select **Screen saver**.

➢ Pressing the [icon] button will display the higher-level screen.
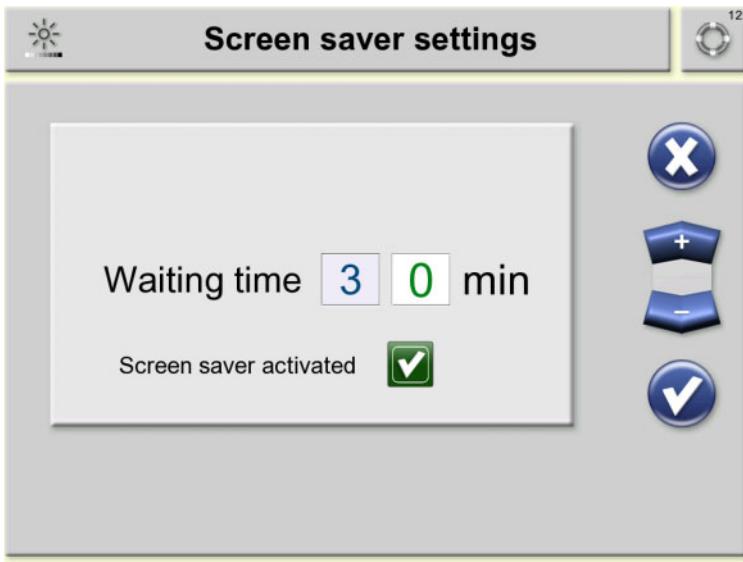
> ➢ Set the screen saver timeout ("Waiting time").

> ➢ 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.

4.6.3.7   Displaying device information

> ➢ Select the 🖳 menu.

Select device options

🗓	Date and time
💻ℹ	Device information
🔊	Volume
☼	Brightness

2 9

Therapy
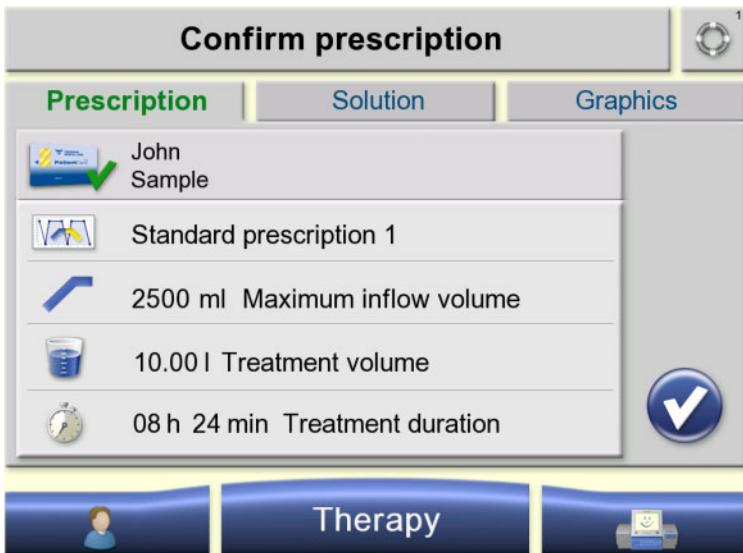
➢ Select **Device information**.

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

Device information

		Pump 1	Pump 2
Pressure sensor	mbar	27	-59
Static patient pressure	mbar	-79	-77
Pressure sensor offset	mbar	-10	0
Maximum position	µm	31648	30897
Minimum position	µm	13337	13095
Specified flow rate	ml/min	230	
Air detection	%	40.1	
Inflow volume	ml	0.0 - 2000.0	
Outflow volume	ml	34.4 - 2147483.6	

Device information is displayed over several pages.

➢ Pressing the ⏭ button will display the next page.

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

Device information

PWM heater	0.0 %
Bag line solution temperature T1	27.6 °C
Patient line solution temperature T2	27.5 °C
Patient line solution temperature T3	27.4 °C
Heater temperature T4	27.6 °C
Heater temperature T5	27.7 °C

Device information is displayed over several pages.

➢ Pressing the 🔘 button will display the next page.

➢ Pressing the 🔘 button will display the previous page.

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

Device information

Pneumatic pressure	1951 mbar
Air cushion pressure	1910 mbar

Connector barcode

197	197	197	197	197	197
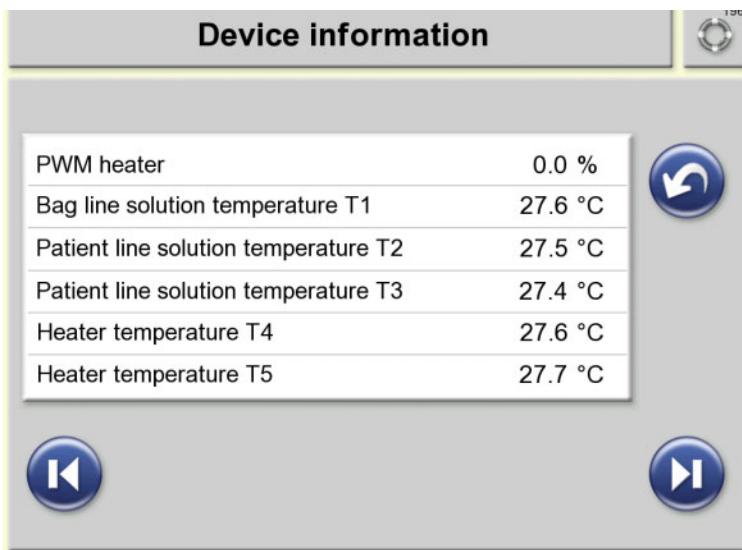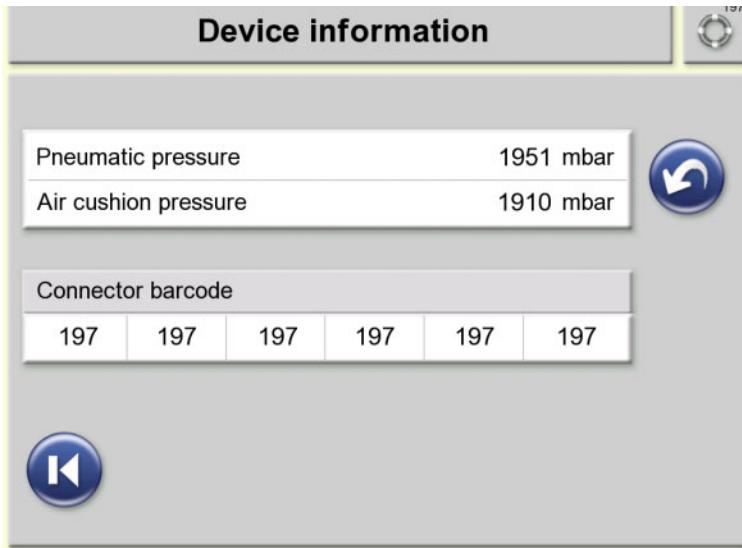
Device information is displayed over several pages.

➢ Pressing the 🔘 button will display the previous page.

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

4.6.3.8 Clinic login

This function can only be accessed by the clinical staff.

Confirm prescription

| Prescription | Solution | Graphics |

John
Sample

Standard prescription 1

2500 ml Maximum inflow volume

10.00 l Treatment volume

08 h 24 min Treatment duration

Therapy

➢ Select the [icon] menu.

Select device options

Screen saver

LAN setup data

Clinic login

Service login

Log out

7   9

Therapy

➢ Select **Clinic login**.

➢ Pressing the [icon] button will display the higher-level screen.
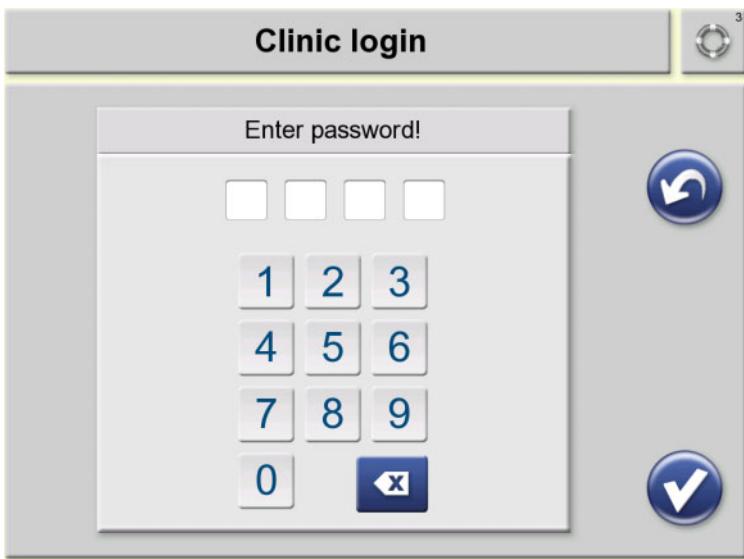
> ➤ Enter the password.

> ➤ Press the ✓ button to confirm the input and to move to the next operating step.

> ➤ Pressing the ↺ button will display the higher-level screen.

4.6.3.9 Service login

This function can only be accessed by service support.

> ➤ Select the 🖨 menu.

Select device options 47

- LAN setup data
- Clinic login
- Service login
- Log out

8 9

Therapy
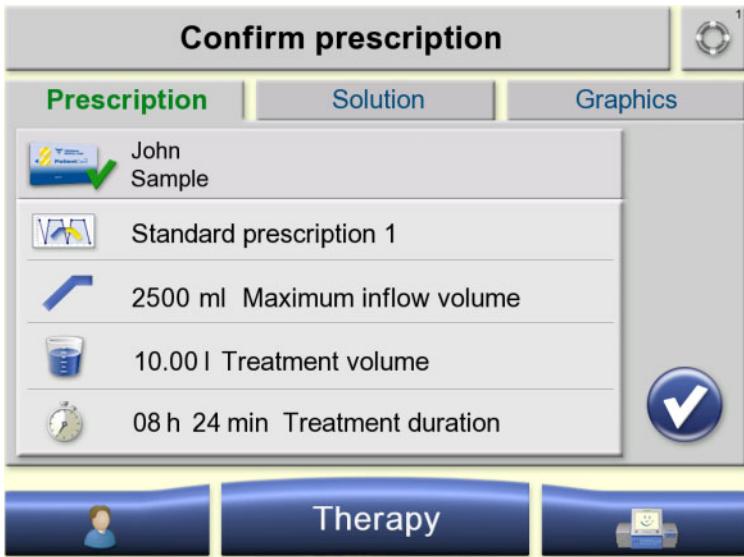
➢ Select **Service login**.

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

Service login 5

Enter password!

□ □ □ □

1	2	3
4	5	6
7	8	9
0	⌫

➢ 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.

4.6.3.10 Clinic / Service logout
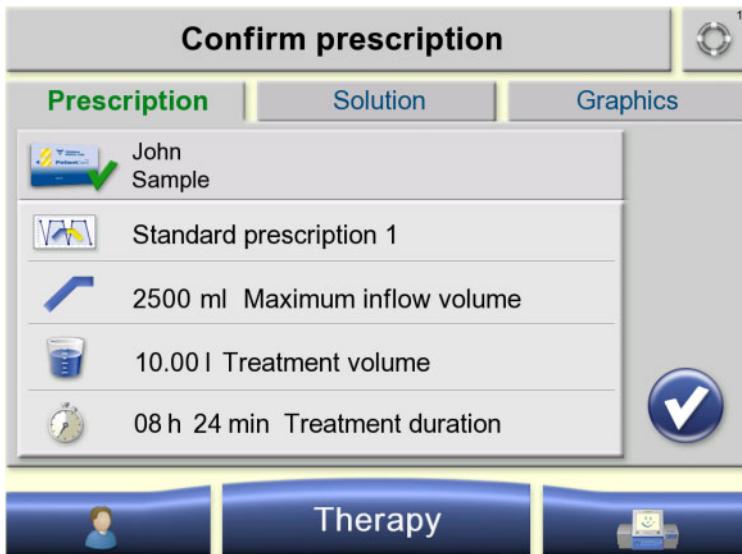
➢ Select the [icon] menu.
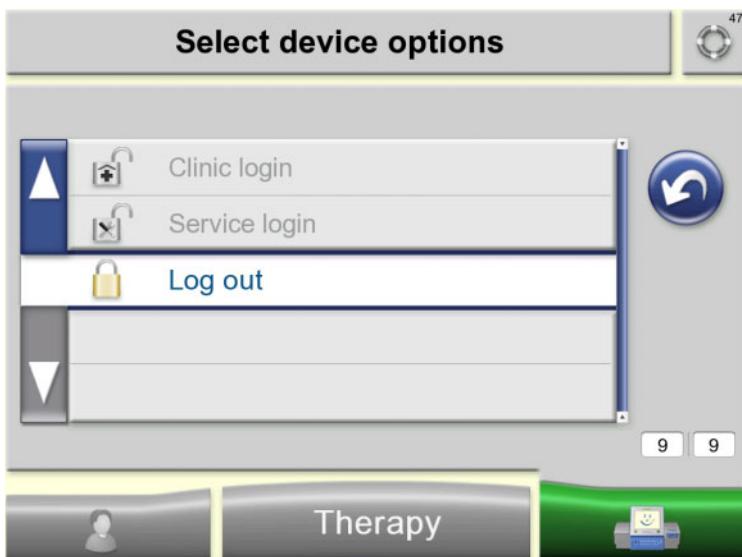
➢ Select **Log out**.

➢ Pressing the [icon] button will display the higher-level screen.

Confirm logout

All rights are reset to the
previous access level!

Cancel

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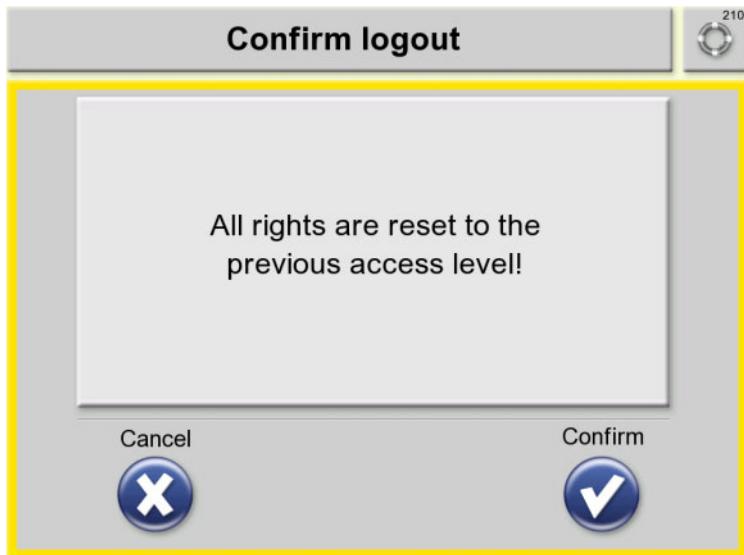
➢ Press the ✓ button to log out the clinical or service support staff currently logged in.

➢ Press the ✗ button to discard the change.

4.7 Therapy options during treatment
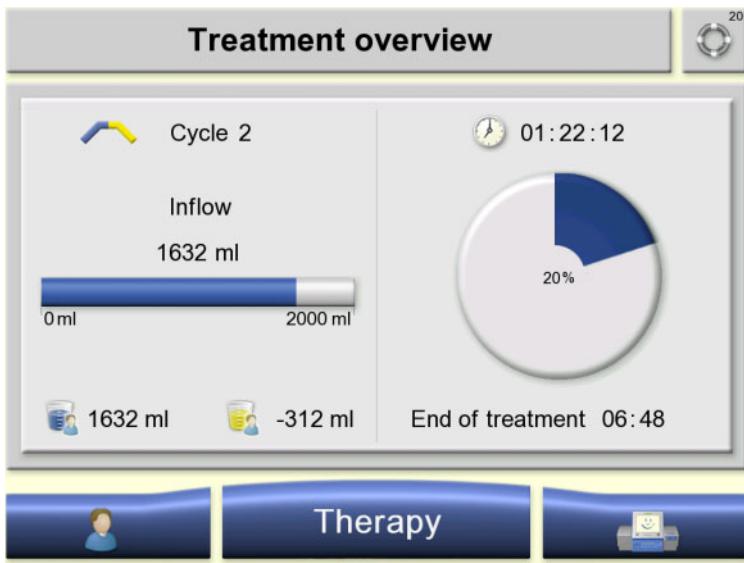
There are two ways to select the therapy options.

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

The following therapy options are available.

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

4.7.1 Pause treatment
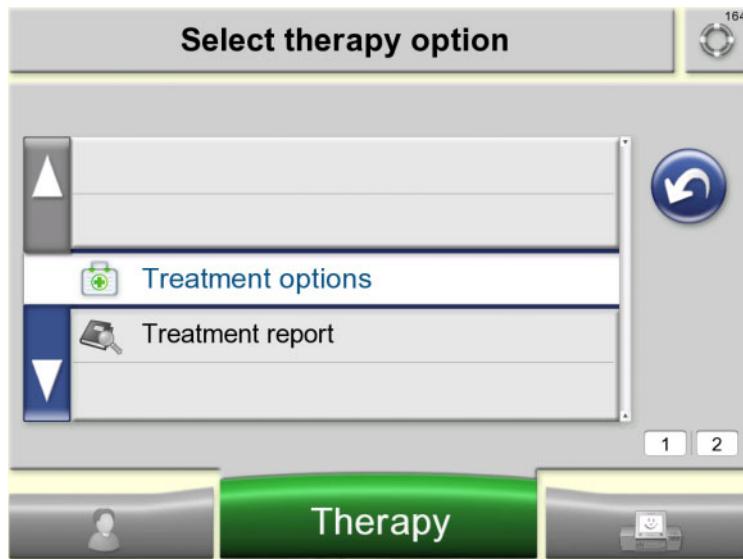
Select therapy option 164

Treatment options

Treatment report

1 2

Therapy

➢ Select **Treatment options**.

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

Select treatment option 66

Pause treatment

Pause with disconnection

Manual outflow

1 5
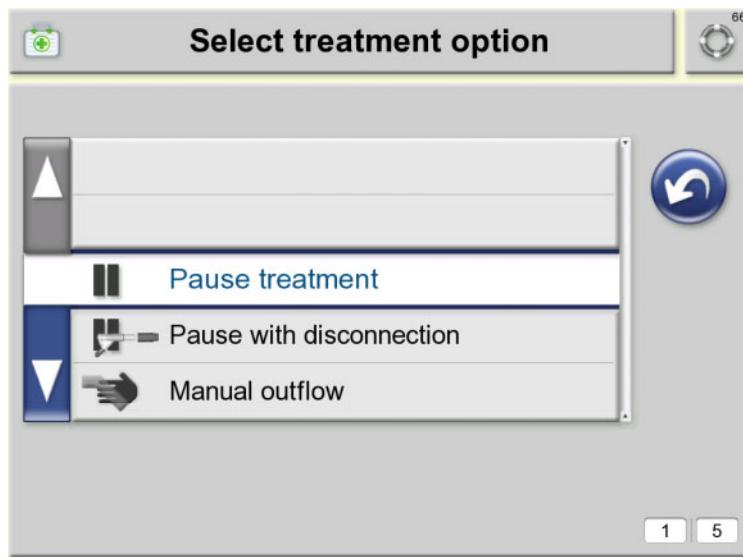
➢ Select **Pause treatment** to interrupt the treatment (pause) for a short period of time.

➢ Pressing the button will display the higher-level screen.
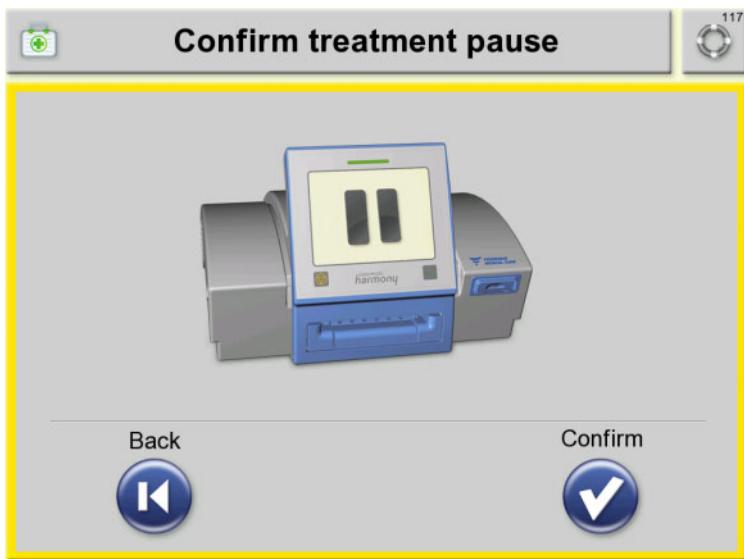
➢ Press the ✓ button to confirm the treatment pause.

➢ Pressing the ⏮ button will display the previous page.
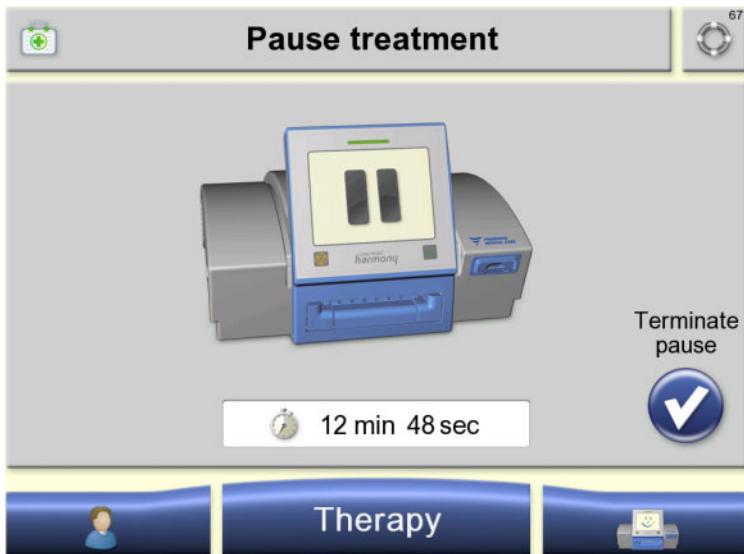
The duration of the pause will be displayed.

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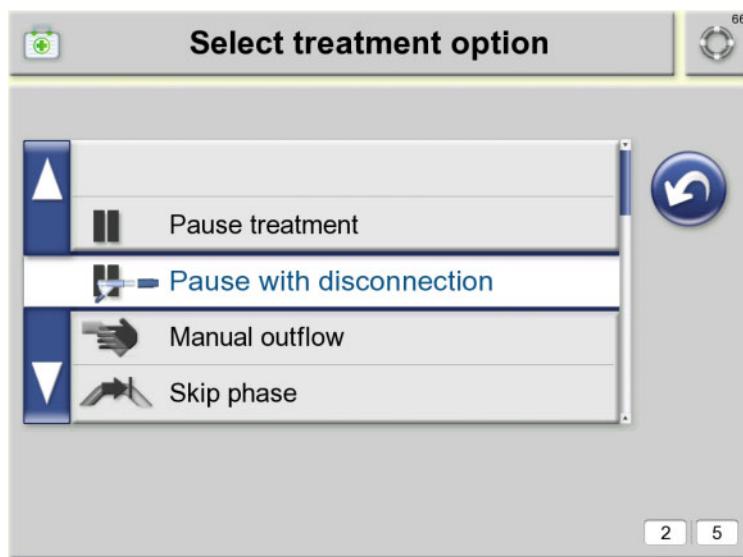
➢ Select **Pause with disconnection** to interrupt the treatment and to disconnect the patient line.

➢ After the pause, reconnect the patient line.
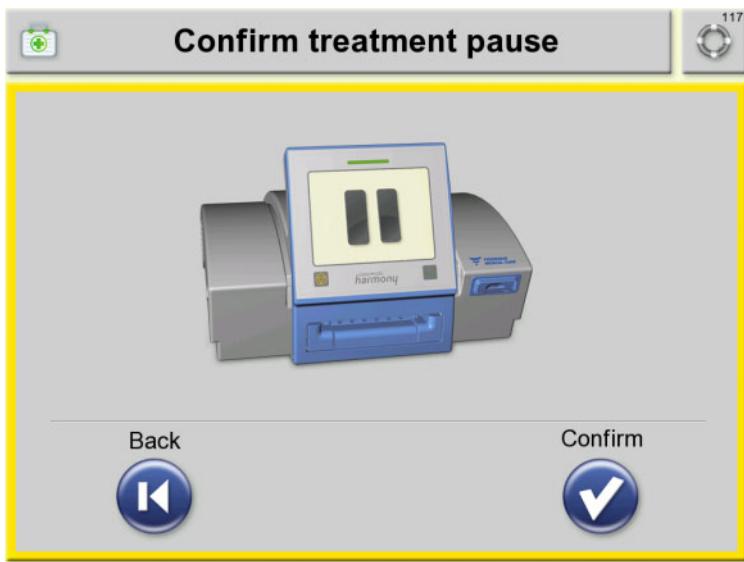
➢ Pressing the ⟳ button will display the higher-level screen.

Confirm treatment pause 117

➢ Press the ✓ button to confirm the treatment pause.

➢ Pressing the ◄ button will display the previous page.

Back   Confirm

● **Disconnecting the patient line**

⚠ **Warning**

➢ The patient line must be sealed using aseptic technique.

Disconnect patient line 49

John Sample

1.

2.

3.
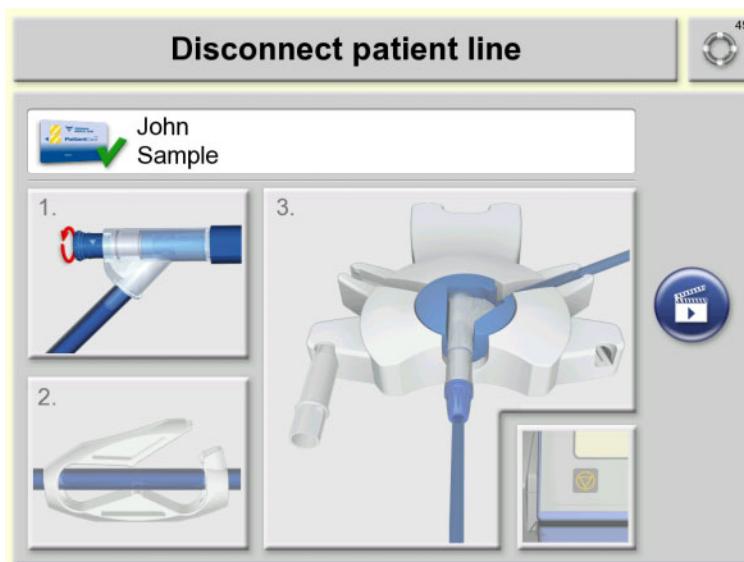
➢ Disconnect the patient line as shown in the screen animation (see Chapter 4.4.1   on page 4-28).

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

● **Connecting the patient line**

	Pause treatment	
		67

Pause treatment

harmony

Terminate
pause

⏱ 12 min 48 sec

Therapy
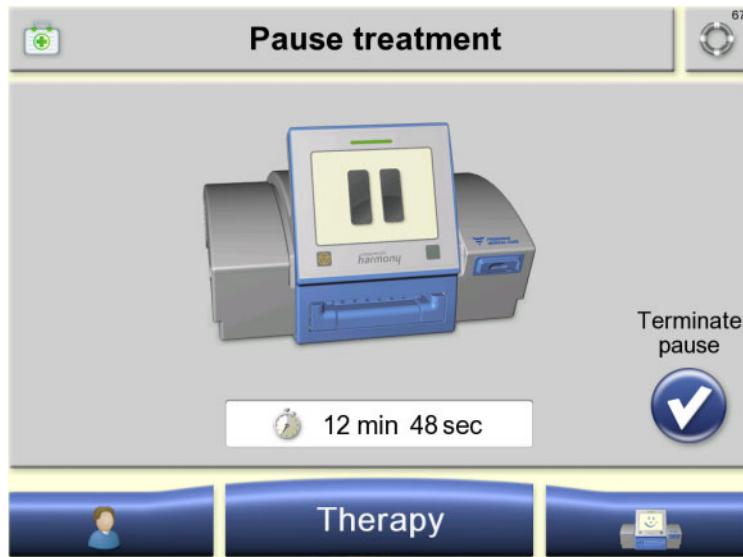
The duration of the pause will be displayed.

➢ Press the ✓ button to continue the treatment.

⚠ **Warning**

Risk of infection

➢ Use aseptic technique when connecting the patient connector.

➢ 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.

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

The attending physician is responsible for proper patient training.
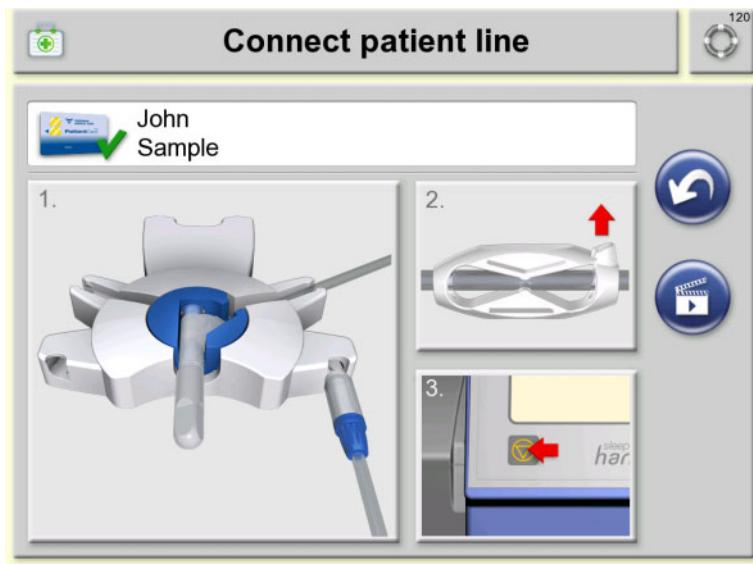
➢ Connect the patient line as shown in the screen animation (see Chapter 4.3.1 on page 4-21).

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

4.7.3 Manual outflow
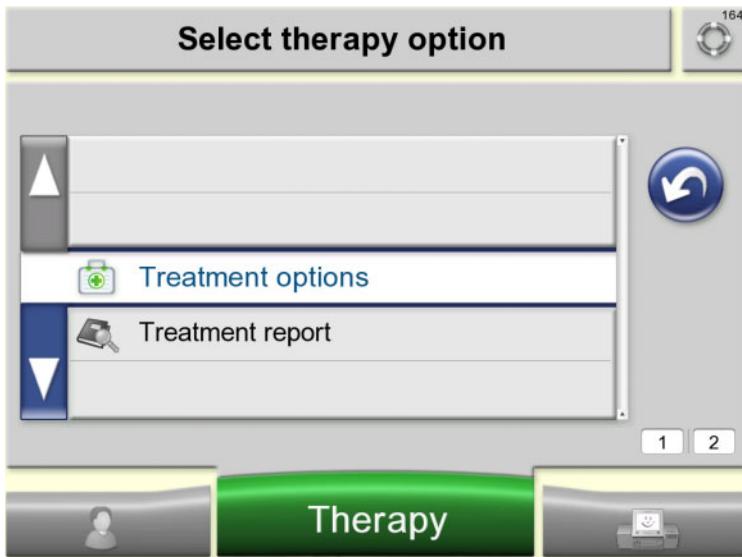
➢ Select **Treatment options**.

➢ Pressing the 🔘 button will display the higher-level screen.
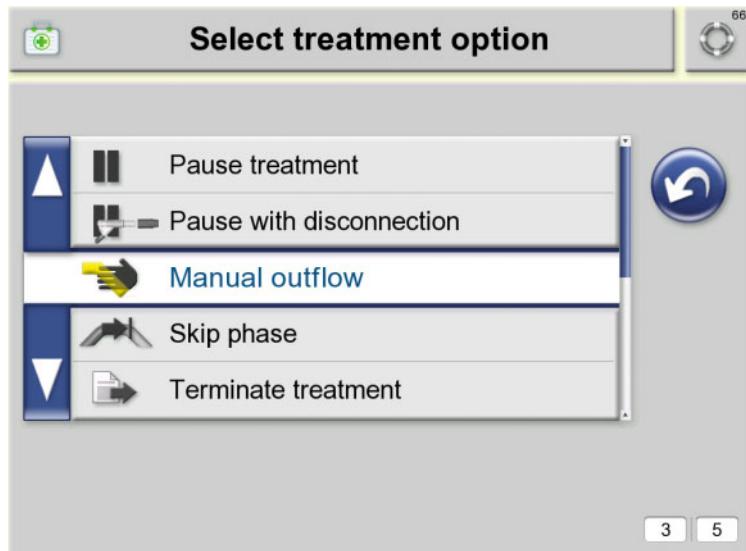
➢ Select **Manual outflow** to initiate a manual outflow.

➢ 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.
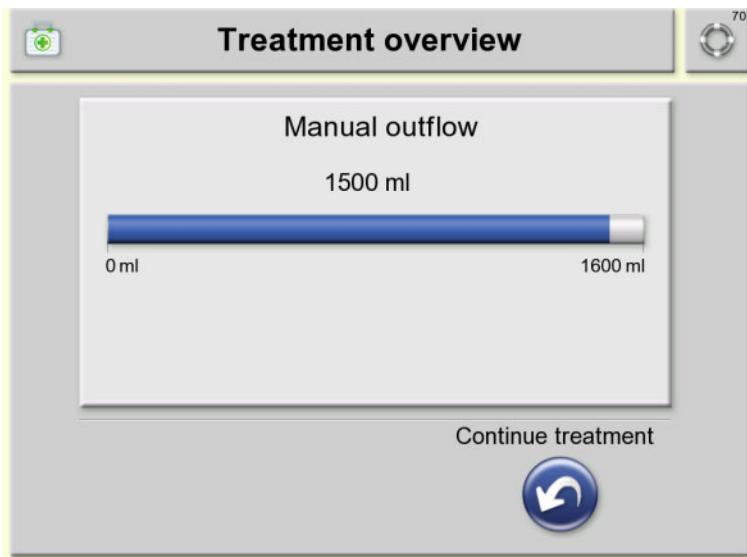
The manual outflow will be performed.

➢ The 🔄 button continues the treatment.

The manual outflow is interrupted.

➢ Touch the screen to confirm the interruption.

Treatment suspended

Check patient line!

Cycle 1
Outflow
800 ml

0 ml   1000 ml

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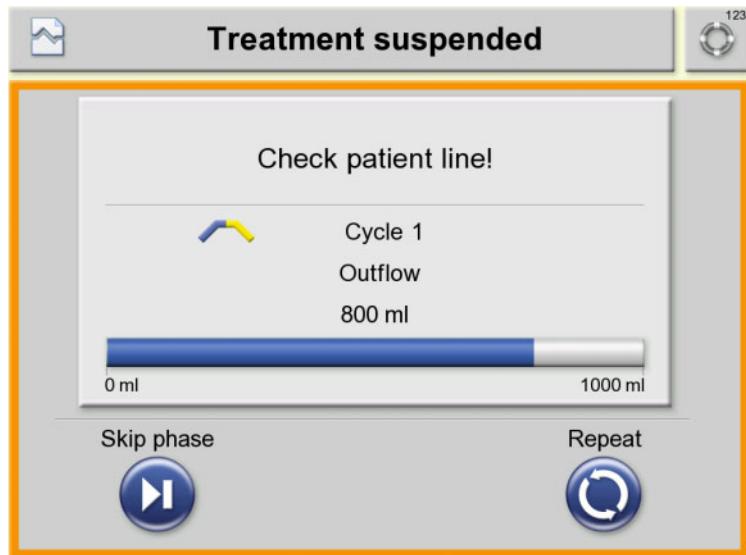
When the manual outflow is complete, the following screen will be displayed.

➢ Press the ⟳ button to continue the manual outflow.

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

Manual outflow completed

Continue treatment

Terminate treatment
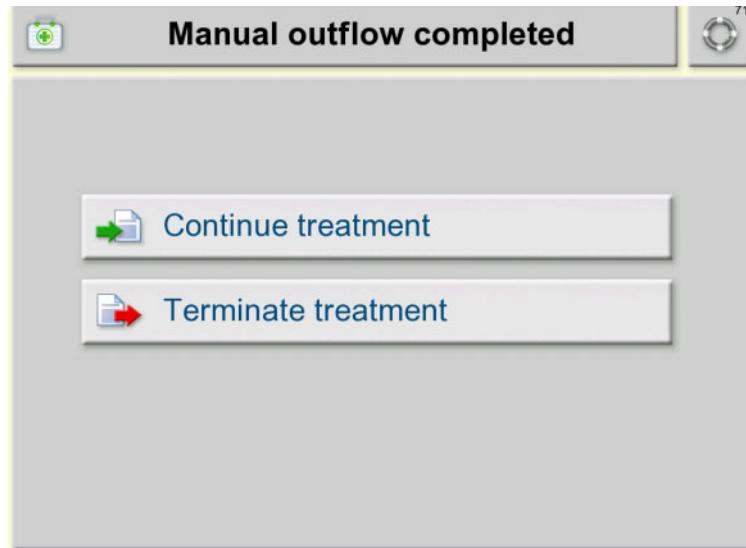
The manual outflow is complete.

➢ Press the **Continue treatment** button or the **Terminate treatment** button (see Chapter 4.4.1 on page 4-28).

4.7.4 Skip phase

➢ Select **Treatment options**.

➢ Pressing the ↺ button will display the higher-level screen.
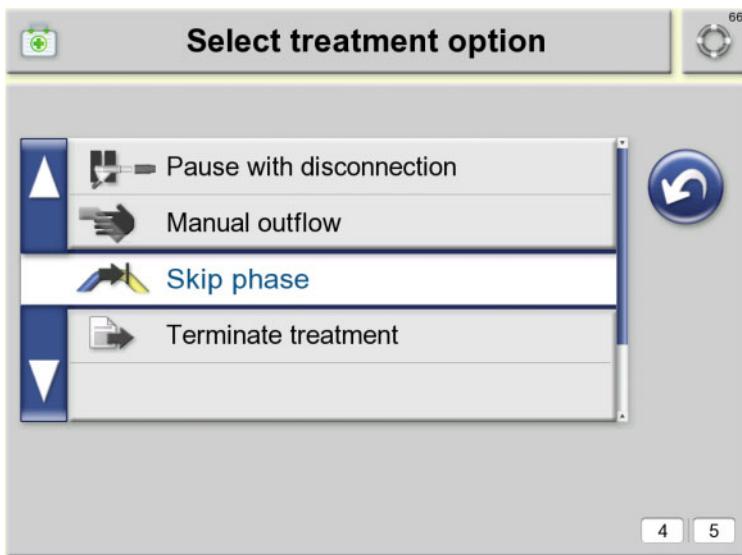
➢ Select **Skip phase** to skip the current treatment phase.

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

Skip treatment phase

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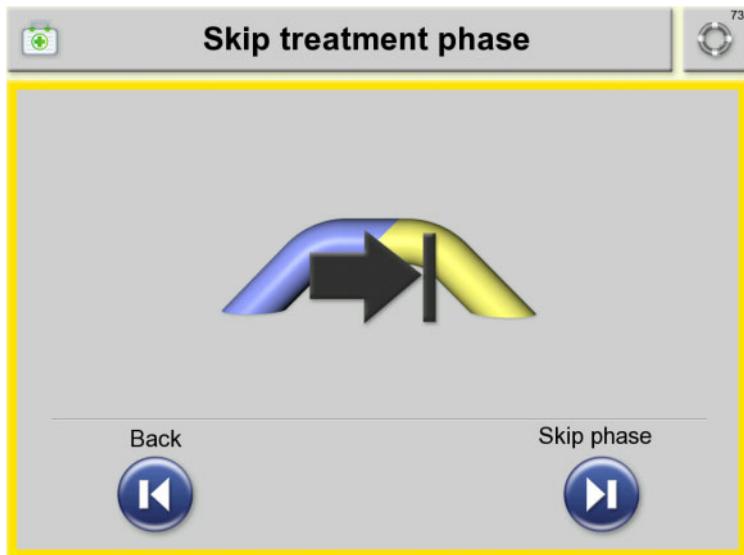
➢ Press the ⏭ button to skip the current treatment phase and to start the next treatment phase.

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

4.7.5 Terminating the treatment

Select therapy option

🔲 Treatment options
🔍 Treatment report

1 2

Therapy

➢ 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.
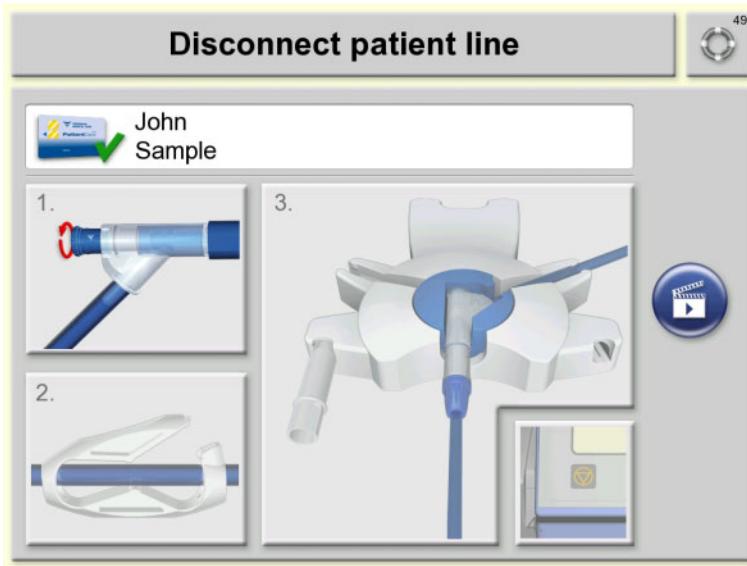
➢ Perform the steps for disconnection

1. Release the PIN

2. Close the clamp

3. Disconnection

4. Confirmation

as detailed below (see Chapter 4.4.1 on page 4-28).

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

4.7.6 Displaying the treatment report

➢ Select **Treatment report** (see Chapter 4.4.2 on page 4-32).

➢ 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 4-21).

4.8.2 Starting the PD-Plus cycle
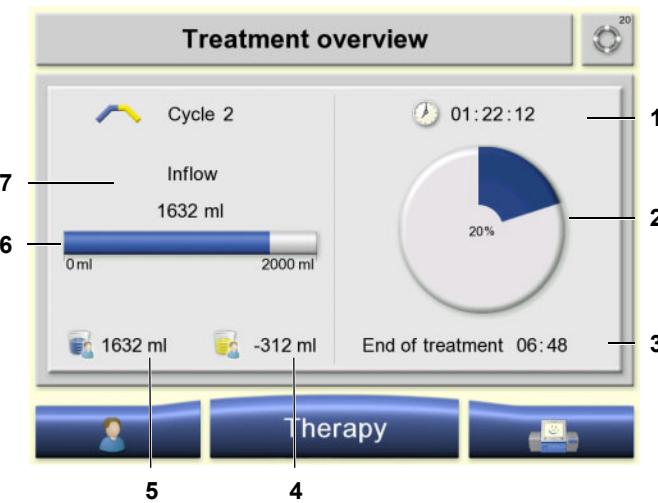
During the treatment, the following parameters will be displayed on the treatment overview screen:

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

4.8.2.1 Stopping the initial outflow

⚠ **Warning**

After the initial outflow has been completed normally and the alarm has been confirmed by the operator, the *sleep•safe harmony* assumes that the draining of the peritoneal cavity has been completed. Volume monitoring will be restarted.

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.
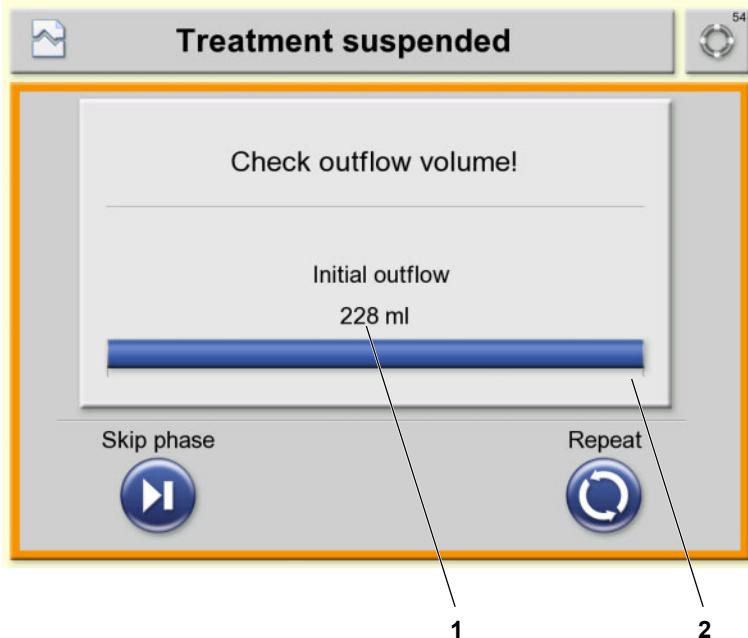
The outflow volume achieved (1) and the target volume (2) will be displayed.

➢ Press the ⟳ button to repeat the initial outflow.

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

> Press the ⟳ button to repeat the initial outflow.

Warning 126

⚠

Risk of overfilling in case of incomplete draining of the peritoneal cavity.

Press the external key, to confirm complete draining!

Continue outflow

⟳

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

PD-Plus pause 18

John
Sample

🕐 16:44:58

Terminate pause

✓

PD-Plus pause ends

🕐 18:12
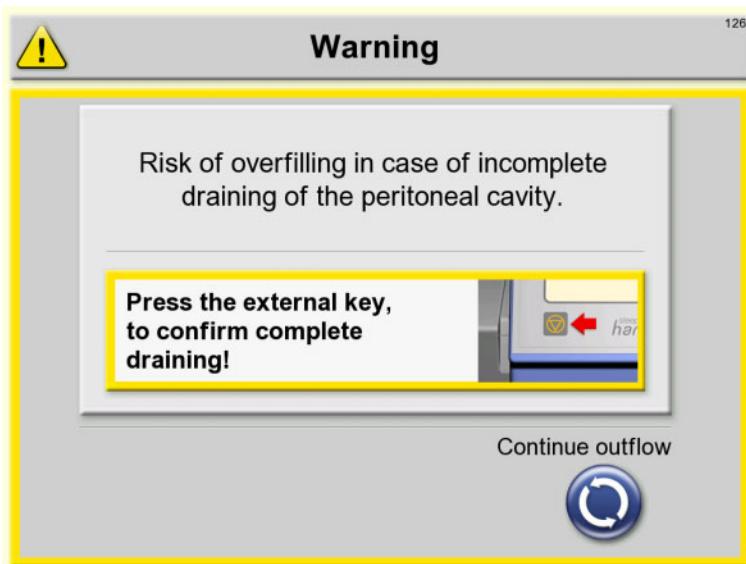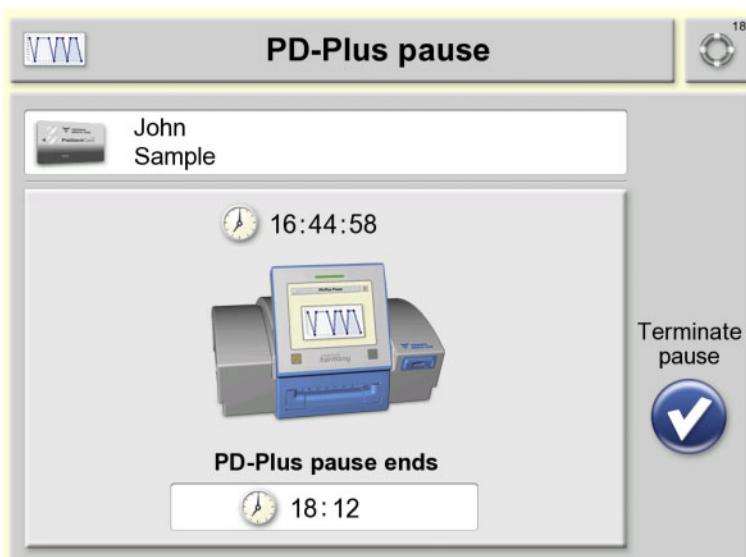
The PD-Plus inflow is followed by the PD-Plus dwell duration during which the *sleep•safe harmony* treatment is paused.

> Disconnect the patient (see Chapter 4.4.1 on page 4-28).

> Press the ✓ button to terminate the treatment pause.

⚠️ **Warning**

In the time before treatment is started, 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.).

4.8.3   Connecting the patient for nighttime treatment

Connect the patient (see Chapter 4.3.1   on page 4-21).

5   Alarm processing

5.1   Screen layout
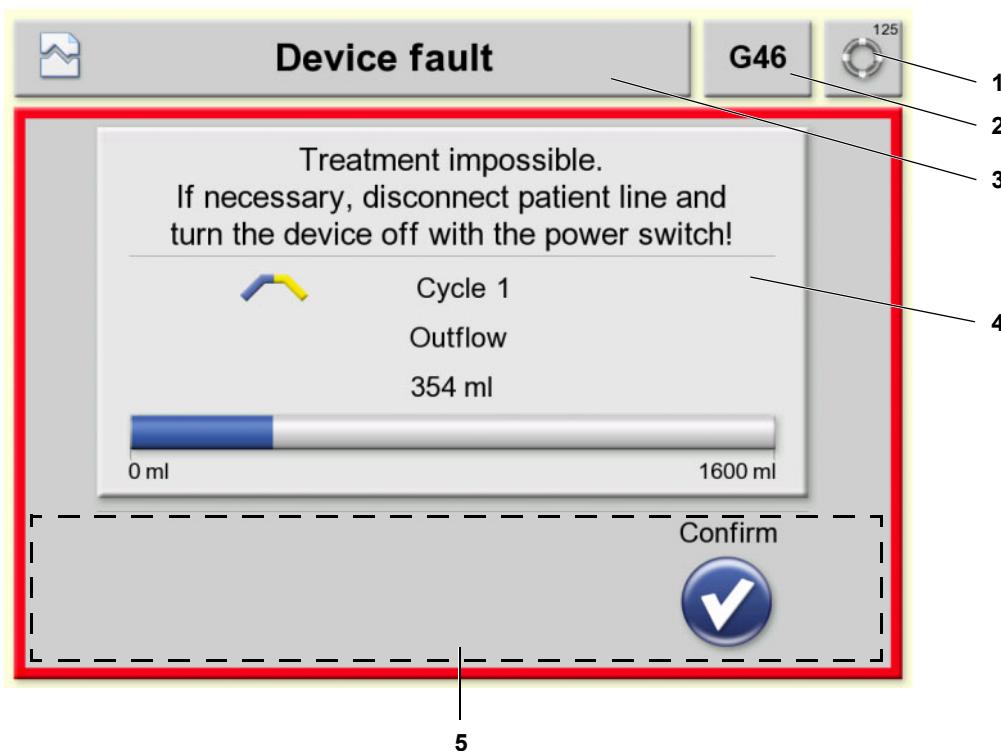
- **1**   **Help** button (function currently not available.)

- **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**   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 Color identification of the screen messages

The messages are organized in three categories which can be identified by their frame color.

Yellow frame, information (example)
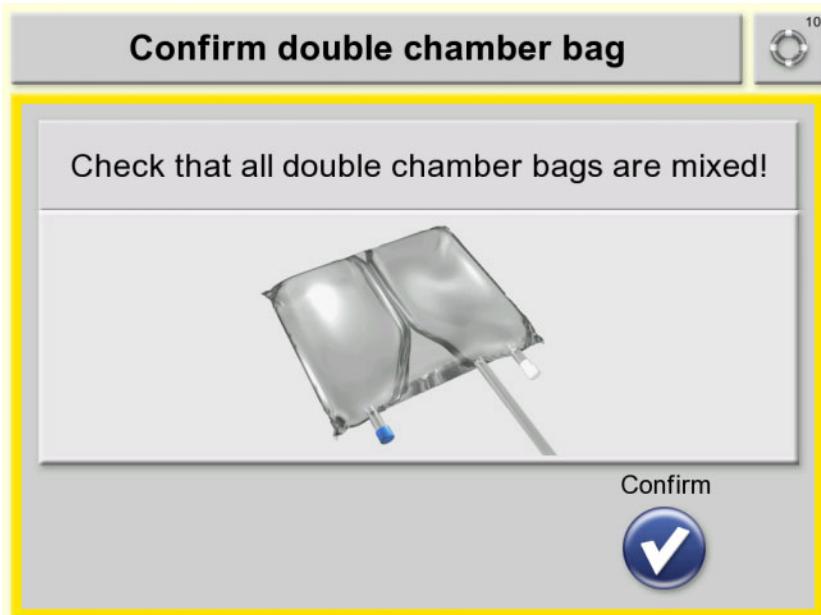
– Information and treatment-related assistance which the operator must always observe and follow as necessary.
– Treatment can be continued.

Orange frame, caution (example)
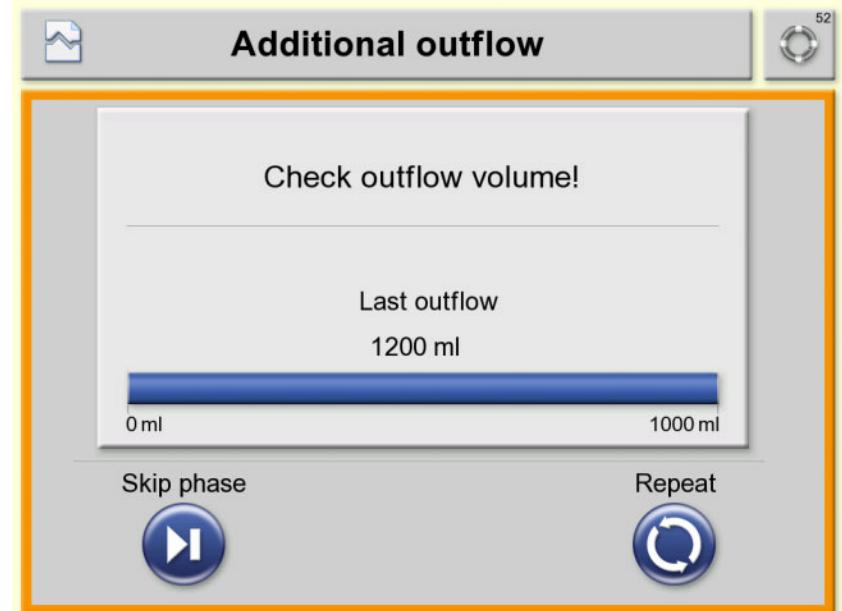
– The title bar contains a brief description of the cause of the problem. Follow the steps displayed on the screen to correct the problem.

– Treatment can be continued.

Red frame, alarm (system error / device fault)

Red frame, device fault (example)

– Faults which only affect the *sleep•safe harmony*.

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

Red frame, system error (example)

| | Device fault | G42 | ⊙ 125 |

Treatment impossible.
If necessary, disconnect patient line and
turn the device off with the power switch!

Cycle 1
Outflow
1455 ml

0 ml   1600 ml

Confirm
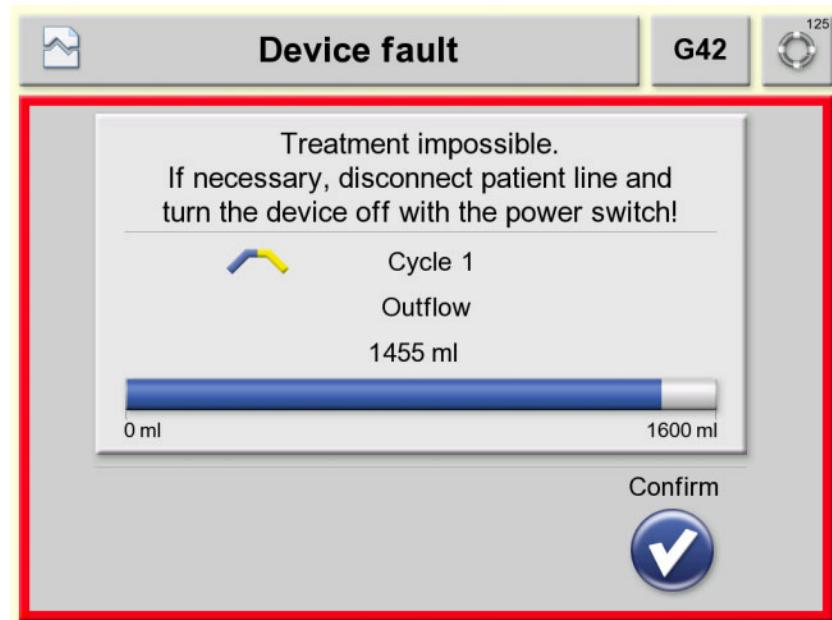
– Errors which affect the entire system, including lines, solution bags and drainage.

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

5.4   Screen messages

Message	Cause	Action required
A001	Internal error	– Disconnect the patient. – Terminate and restart the treatment, if necessary.
12T 55T 110	Heater error	– The *sleep•safe harmony* should not be exposed to direct sunlight. – The ambient temperature is too high. – Switch the *sleep•safe harmony* off with the power switch, allow the device to cool down for several minutes, then switch it on again.
61T	Error during the initial test	– Remove the *sleep•safe* Set by pressing the button on the right at the bottom of the screen (see Chapter 4.5.3 on page 4-46). Restart the *sleep•safe harmony*.
62T	Error during the initial test	– Device is running outside specified operating conditions, or time for adjustment to ambient temperature not observed (see Chapter 9.2 on page 9-2).
72T	Error during the initial test	– Check the patient line and the catheter extension for kinks and closed clamps. – Mix the solution in the double chamber bags. – Air detected in solution bag: Suspend the solution bag with the solution bag line pointing down and continue the treatment.
93	Pressure in patient line too high	– Check the patient line and the catheter extension for kinks and closed clamps. – Observe the patient position (see Chapter 9.3 on page 9-2). – Press the 🔘 button to terminate the current treatment phase and to switch to the next treatment phase.

Message	Cause	Action required
93T	Patient position monitoring	– Observe the patient position (see Chapter 9.3 on page 9-2). – 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.
94	Solution temperature too high	– Check patient line, catheter extension and solution bag lines for kinks and closed clamps. – The solution bags used must have a temperature of 15–35 °C. – The *sleep•safe harmony* should not be exposed to direct sunlight. – If the problem occurs repeatedly, terminate the treatment.
96	Air detected	– Outflow: Check the patient line for leakage. – Inflow: Check bag line for leakage. – Air detected in solution bag: Suspend the solution bag with the solution bag line pointing down and continue the treatment.
100	Pumps fail to deliver	– The treatment has been interrupted for more than 10 minutes. Press the "Continue" button to continue the treatment.
109	Patient safety clamp error	– Check that the patient line is correctly positioned in the line guide of the loading tray and replace the *sleep•safe* Set, if necessary.
134 134T	Pressure in drain line too high	– Check the drain line for kinks and closed clamps. – The outlet of the drain line must never be more than 2 meters below or above the *sleep•safe harmony*.

Warning

➢ 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 infection

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

➢ Use aseptic technique when disconnecting the patient connector.

➢ Wearing a face mask and hand disinfection is recommended.

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

The attending physician is responsible for proper patient training.

Additional screen layout information (see Chapter 5.1 on page 5-1).

Additional screen message information (see Chapter 5.4 on page 5-6).

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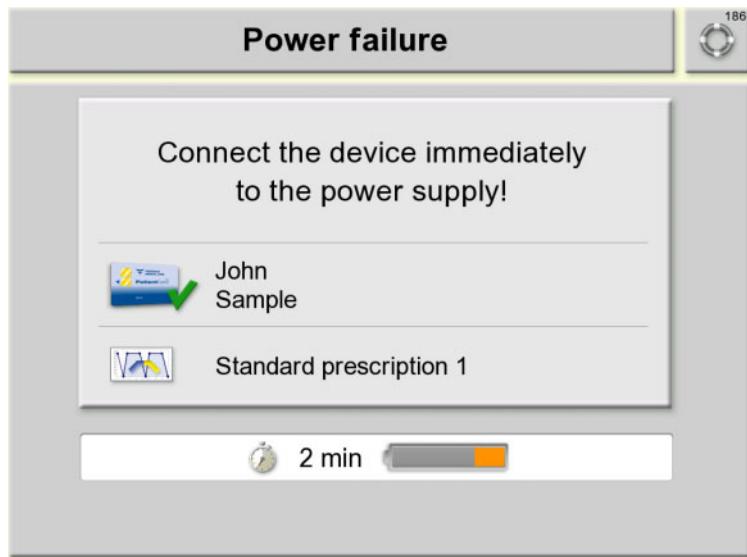
This screen will be displayed if the power supply for the *sleep•safe harmony* has failed.

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

Restore power.

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

➢ Press the ⬡ key to silence the audible signal.
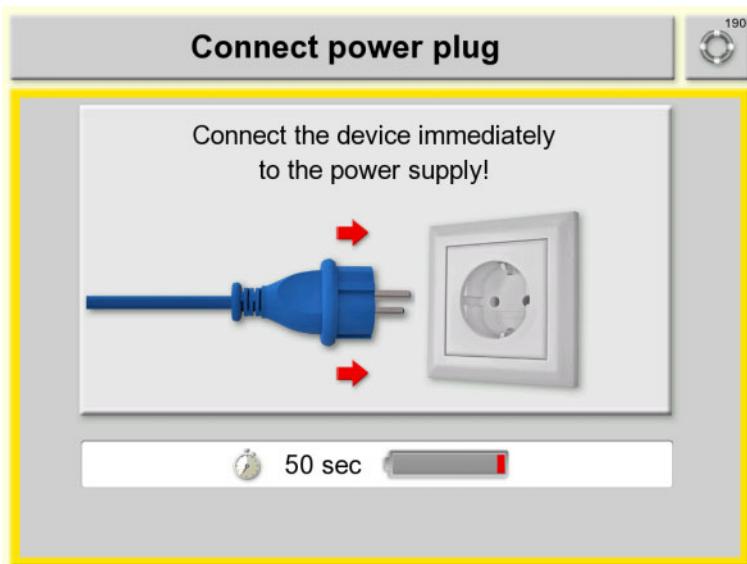
If power could not be restored in time, the treatment must be stopped.

➢ Disconnect the patient (see Chapter 4.4.1 on page 4-28) and remove the *sleep•safe* Set (see Chapter 4.5.3 on page 4-46).

5.8 Screen failure

Warning

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

➢ Use aseptic technique when disconnecting the patient connector.

➢ Wearing a face mask and hand disinfection is recommended.

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

The attending physician is responsible for proper patient training.

6   Cleaning / disinfection

6.1   Cleaning

⚠️

Warning

➢ 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)

Once the disinfectant and cleaning agent has completely evaporated, the *sleep•safe harmony* is 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 dialysate pumps
– High flow rates
– Automatic bag detection and connection
– 100 % PVC-free line sets made of Biofine®
– Inline flow heating (no need to preheat the solution bag)
– Graphic user guidance (color 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 through 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 a microprocessor. The *sleep•safe harmony* is provided with independent safety systems.

Further information material is available from the local service support organization 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.
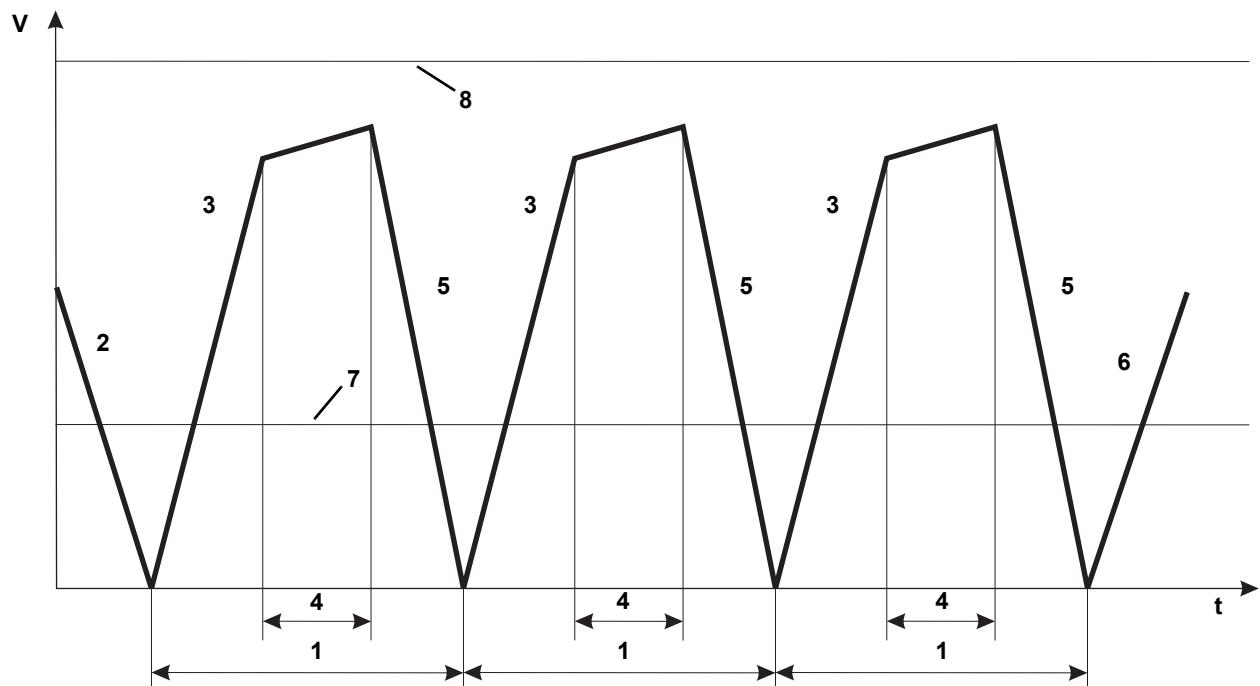
1	Treatment cycle
2	Initial outflow
3	Inflow volume
4	Dwell duration
5	Outflow volume
6	Last inflow
7	Permitted residual volume
8	Permitted patient volume

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.
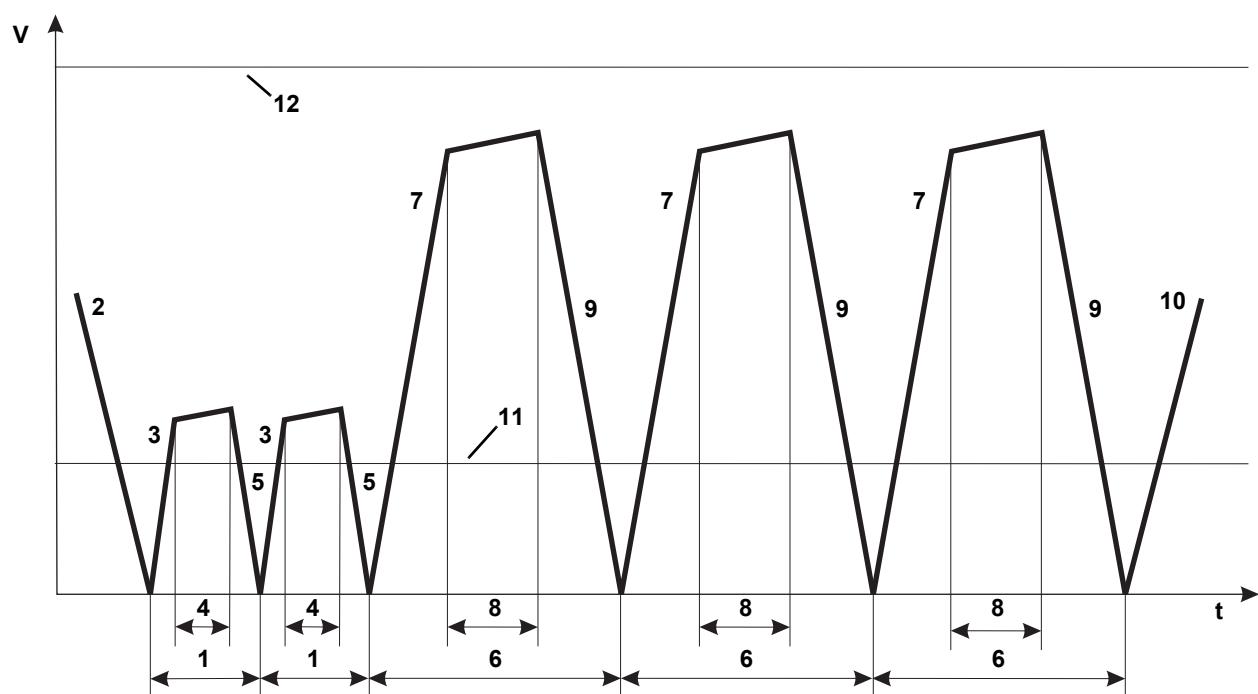
1	Cycle 1–2
2	Initial outflow
3	Cycle 1–2 inflow volume
4	Cycle 1–2 dwell duration
5	Cycle 1–2 outflow volume
6	Cycle 3-5

7   Cycle 3-5 inflow volume

8   Cycle 3-5 dwell duration

9   Cycle 3-5 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 1–2 inflow volume
– Cycle 1–2 solution
– Cycle 1–2 dwell duration
– Cycle 3-5 inflow volume
– Cycle 3-5 solution
– Cycle 3-5 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.
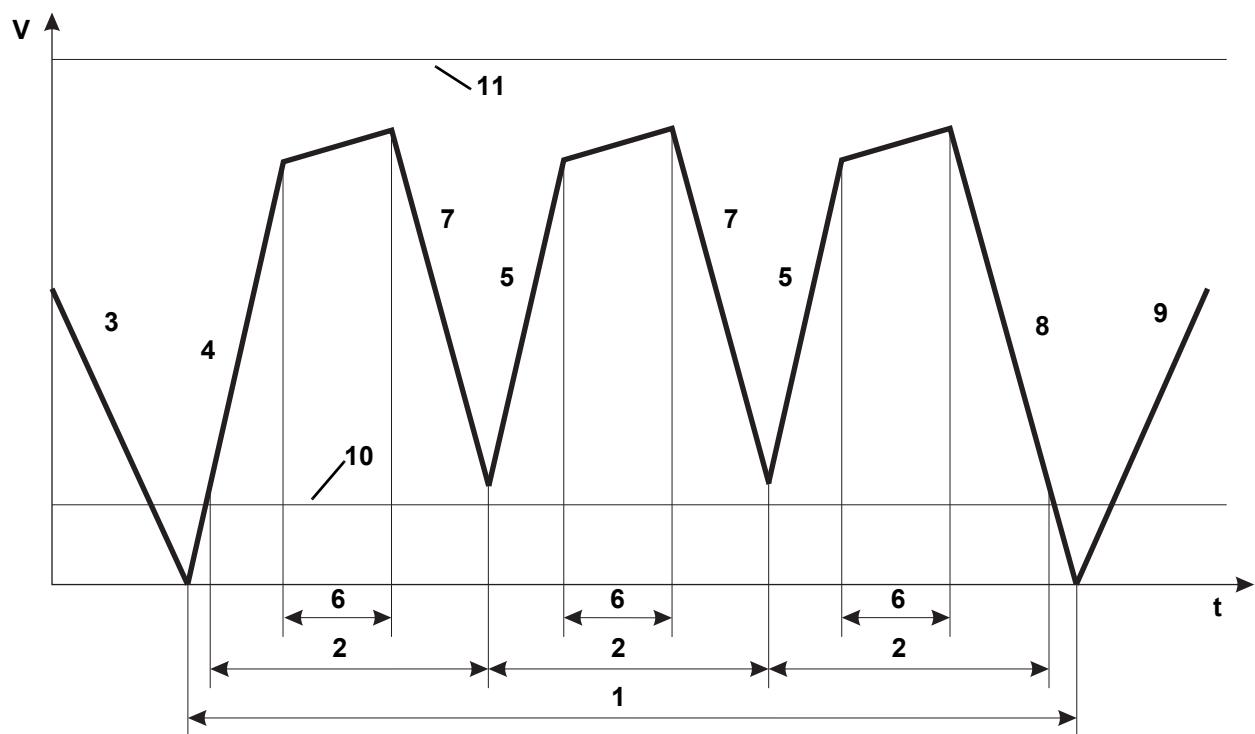
1   Base cycle

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
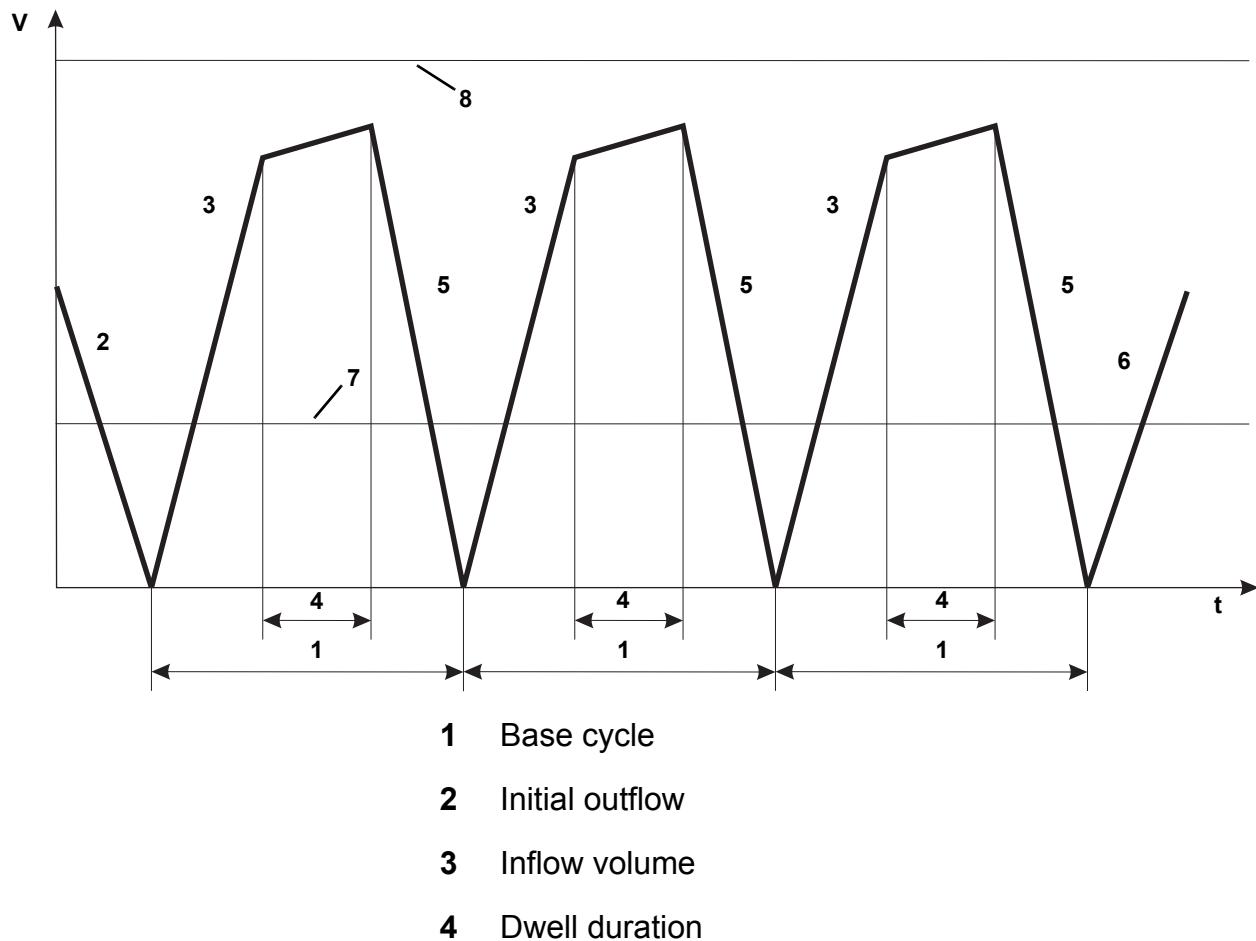
5 Outflow volume

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
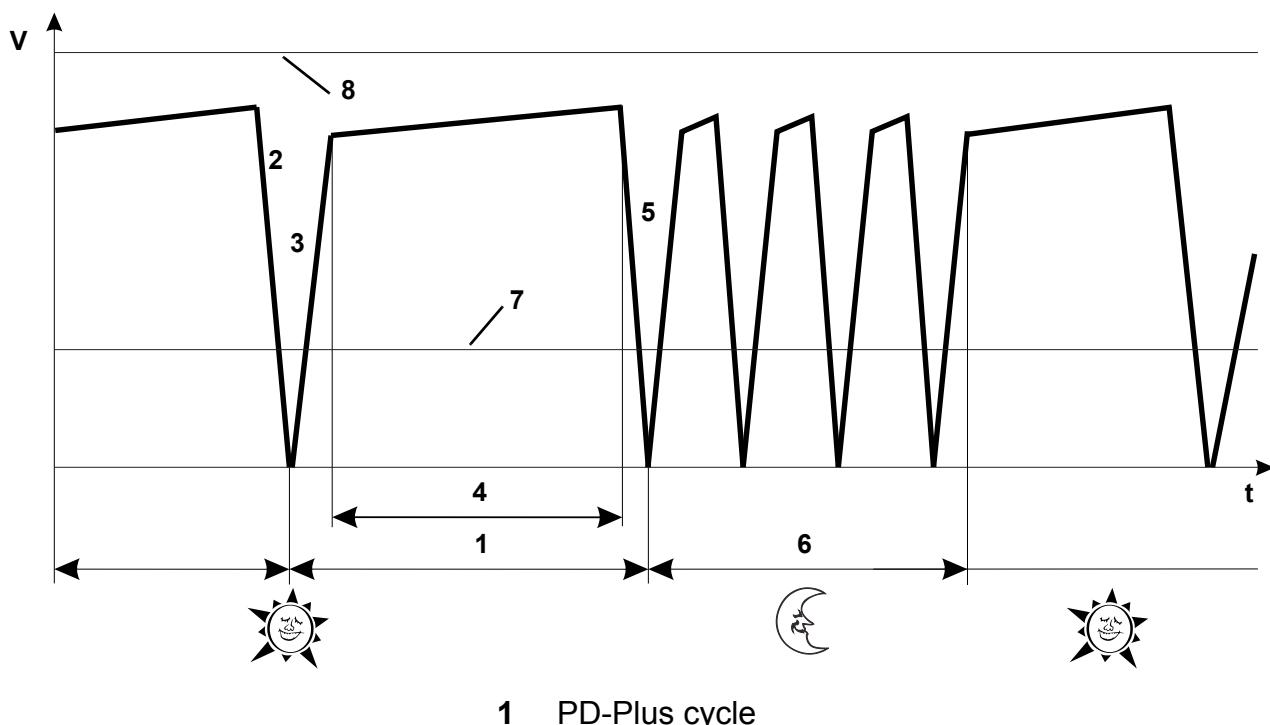
2   Initial outflow

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 alarm.

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

7.3.1.3   Permitted reduction of the inflow volume

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 10 % for the "permitted reduction of the inflow volume", the inflow volume may be reduced by up to 100 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 an alarm even if the originally prescribed treatment volume was not reached.

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 minutes and a factor of 15 % for the "permitted reduction of the dwell duration", this dwell duration may be reduced by 15 minutes.
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.

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.

8   Consumables, accessories, additional equipment

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

Warning

The device has been approved for use with certain consumables and accessories (see Chapter 8 on page 8-1). Should the responsible organization wish to use other consumables and accessories than those listed in the relevant chapter, their suitability must be verified beforehand by obtaining the appropriate information from the manufacturers.
The applicable legal regulations must be complied with.

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

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

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.

Warning

Observe the notes in the instructions for use of the consumables concerned.

Note

Consumables:

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

Single use item
Identified by the symbol:

②

Do not reuse.

Use by date
Identified by the symbol:

⧖

Use by:

8.1　Consumables

8.1.1　Dialysis solutions

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

Only dialysis solutions which are displayed on the screen under **Select solution** can be used for the treatment (see Chapter 3.4.1　on page 3-11).

8.1.2   Single use items

Product		Part number	Information
sleep•safe Set		501 692 1	Line set
sleep•safe Set Plus		501 693 1	Line set with second patient connector
Drainage Extension Line - 12 m Biofine®		F00001511	Drain line extension made of Biofine®, length 12 m
Drainage Extension Line - 12 m PVC		501 461 1	Drain line extension made of PVC, length 12 m
Safe•Lock® PD-NIGHT® Drainage Set		501 957 1	Drain line set with 2 drain bags
stay•safe® disinfection cap		284 509 1	Disinfection cap
APD sample bag		505 508 1	Sampling bag
sleep•safe Luer lock adapter		501 697 1	Only in combination with a 7.5 % polyglucose solution bag
Dialysis solution *sleep•safe balance* 5000 ml x 2	D, CH, A, GB, NL, E, P, GR, CY, F, B, I, S, FIN, N, DK	F 000 01 672	1.5 % glucose 1.25 mmol/L Ca
	RUS, LV, RO, LT, PL, EST, SLO, H, SK, HR+BiH, TR, CZ	F 000 00 437	

8.1.3 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

8.2 Accessories

Product	Part number	Information
sleep•safe harmony **Patient**Card*Plus*	M45 129 1	

8.3 Additional equipment

Product	Part number	Information
sleep•safe transport case	M39 023 1	

8.4 *sleep•safe harmony*

Product	Part number	Information
sleep•safe harmony	M20 600 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 cable   If the power cable needs to be replaced, use only the original power cable listed in the spare parts catalog.

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:
15 °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, 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 12-4).

9.3   Setting up the *sleep•safe harmony*

➢ Remove the *sleep•safe harmony* from its transport case and place it on a flat, stable 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, but no more than 1 meter below this.
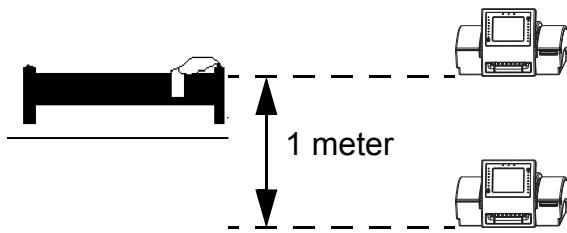
Note

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

9.4 Installation after shipment / transport outside of buildings

For storage, shipment and transporting the device outside of buildings, use the transport case provided (see Chapter 8.3 on page 8-4).

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

9.4.1 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 cable

➢ The device must be taken out of service.

➢ Inform the responsible organization or service support.

9.4.2 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.

9.4.3 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.

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1

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.

No patient card detected ◌ 15

Insert patient card!

harmony

Continue without patient card ▶❙

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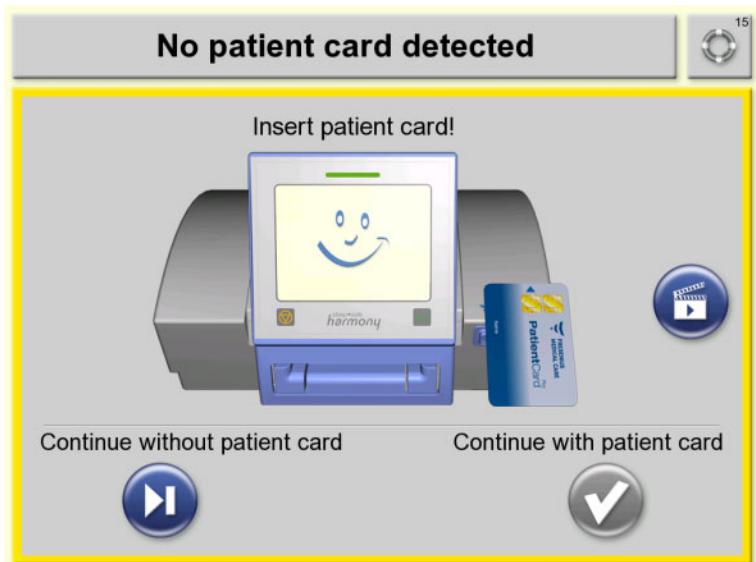
➢ Press the ✓ button to start the treatment with a patient card.

or

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

➢ The 🔄 button can be used to replay the screen animation.
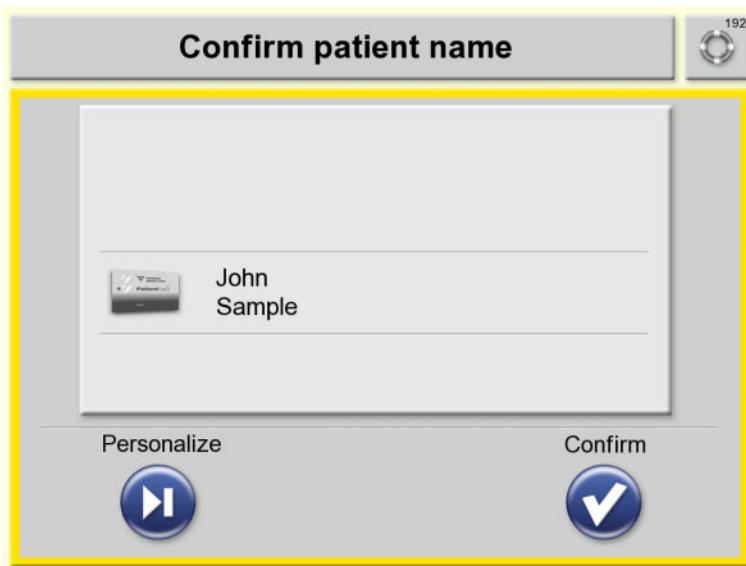
If the treatment was started without a patient card, the patient name must be confirmed.

➢ Press the ⏭ button only if you need to personalize 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 (shown here without time optimization)

➢ Press the ✓ button to move to the next operating step.
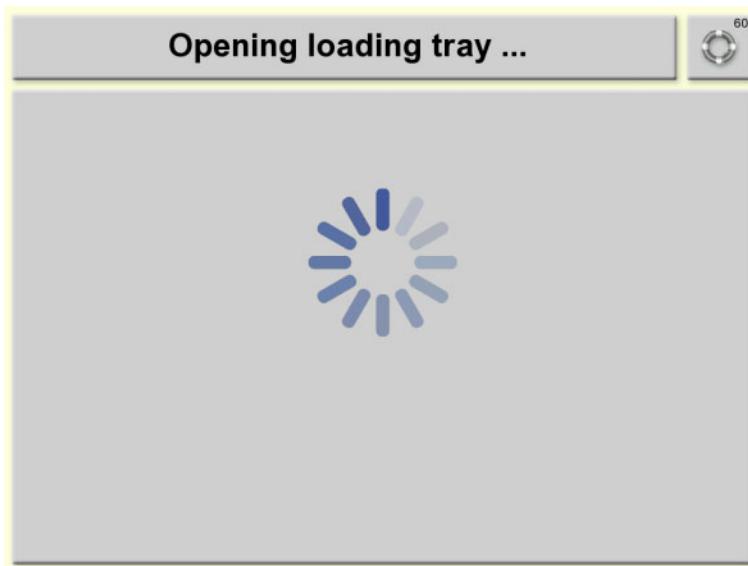
Opening loading tray ... ◎ 60

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

The loading tray opens.
During the test an audible alarm can be heard and the status indicator is red.

The next screen message will be displayed automatically.

Warning

➢ Do not use the *sleep•safe harmony* if the audible alarm is not heard or the status indicator is not lit during the internal test.

➢ Call service support.

Insert set ◎ 6
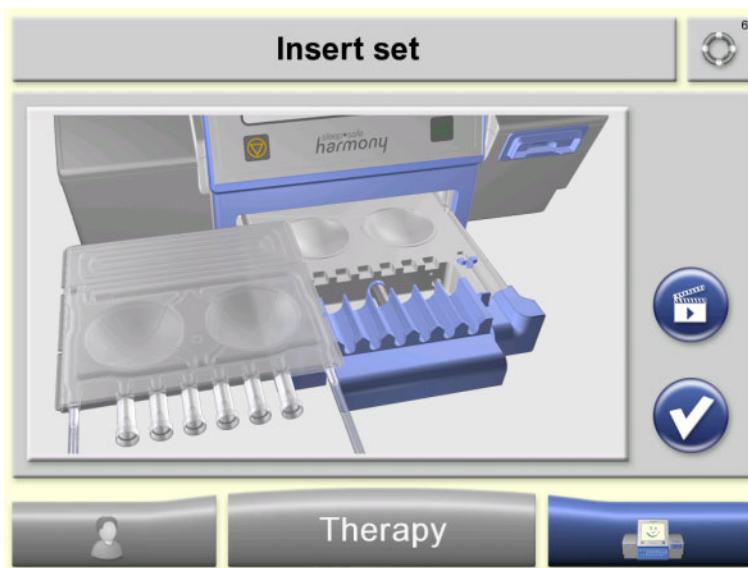
➢ **Do not** place a *sleep•safe* Set in the open loading tray.

➢ Press the ⊙⊙ key.

Therapy

Turn the device off	198

Back   Confirm

➢ Press the ✓ button.

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

Closing loading tray ...	60

The loading tray closes.

The next screen message will be displayed automatically.
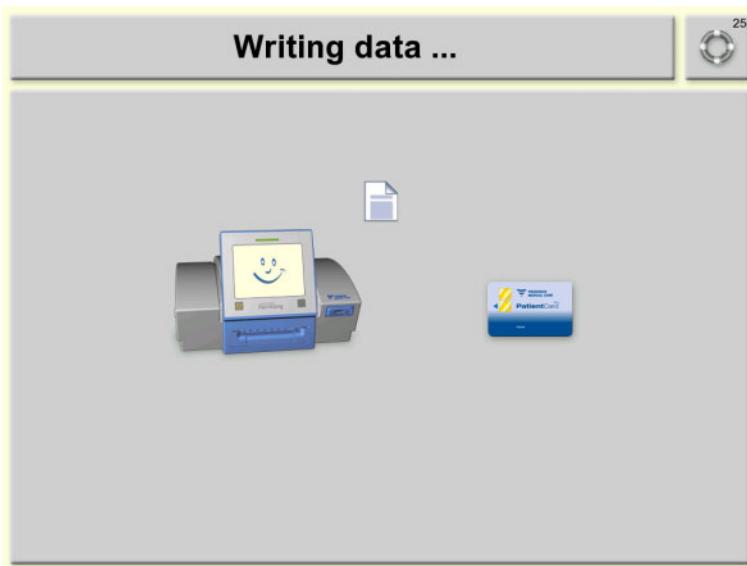
The *sleep•safe harmony* will shut down.

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

➢ If the "Extended system test" cannot be executed as described, do not perform a treatment.
Call service support.

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.

10.2 Shipment / transport outside of buildings

(see Chapter 9.4   on page 9-3)

10.3 Storage

The *sleep•safe harmony* must be stored in its 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

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 disposal, the responsible organization must ensure that all consumables attached to the device are removed and the device is disinfected as specified by the manufacturer (see Chapter 6 on page 6-1).

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

– There is a potential risk that the device is contaminated when it is returned. Suitable safety measures must be in place for dismantling the device, including the mandatory use of personal protective equipment.

– For information on the batteries and other materials used, consult the appropriate chapters of these instructions for use (see Chapter 12.10   on page 12-11) or (see Chapter 12.12   on page 12-14).

– 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 (MA)

The maintenance procedures (MA) are a recommendation of the manufacturer. The maintenance procedures help ensure trouble-free operation, and must be carried out for the first time before the end of the 24th month following initial start-up after delivery from the factory. All further maintenance procedures should be performed before the end of the 24th month following the last maintenance procedure performed.

Qualification requirements of testers

The checks must be performed by the 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 Technical Safety Checks (TSC), maintenance procedures 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	Approx. 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.
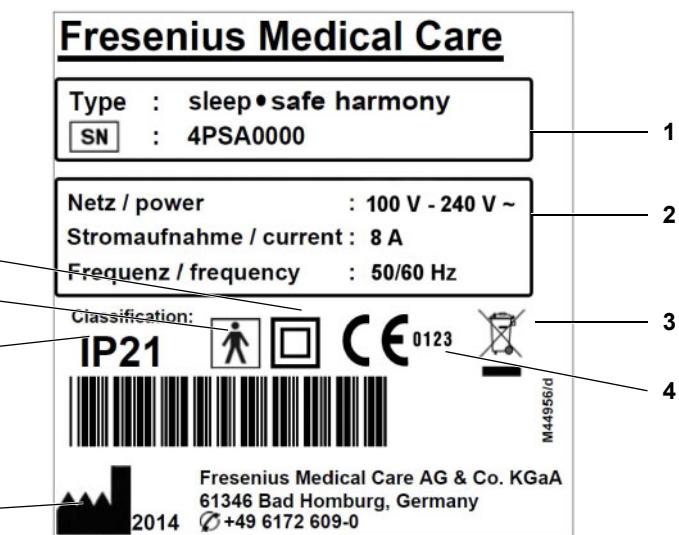
1   Type identification, serial number

2   Power requirements

3   Symbol for the marking of electrical and electronic equipment

4   CE mark

5   Manufacturer and year of manufacture

6   Protection against ingress of solid objects:
     protected against the ingress of foreign bodies larger
     than 12 mm in diameter; finger protection
     Protection against ingress of fluids:
     drip-proof

7   Degree of protection against electric shock: Type BF

8   Type of protection against electric shock:
     Protection class II

12.3 Electrical safety

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

Type of protection against electric shock	Protection class II, symbol: ▢
Degree of protection against electric shock	Type BF, symbol 立
Applied part	*sleep•safe* Set
Degree of protection against ingress of foreign bodies and liquids	IP21, symbol: **IP21** – protected against the ingress of foreign bodies larger than 12 mm in diameter; finger protection – drip-proof
Leakage currents	According to EN 60601-1

12.4 Electrical power supply

Line voltage	100–240 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.

Operating current 5 A (at 240 V AC)
8 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/ module	Item no.	Value
LP1365	F1	T 0.315 A / 305 VAC / 250 VDC
LP1365	F2	T 4.0 A / 305 VAC / 250 VDC
LP1365	F3	T 8.0 A / 250 VAC / 250 VDC
LP1365	F4	T 0.125 A / 305 VAC / 250 VDC
LP1366	F1	T 3.0 A
LP1366	F2	T 1.5 A
LP1366	F3	T 5.0 A
LP1366	F4	T 4.0 A
LP1366	F5	T 3.0 A
LP1366	F6	T 1.0 A
LP1367	F1	F 1 A / 125 V
LP1367	F2	F 1 A / 125 V
LP1367	F3	F 1 A / 125 V
LP1367	F4	F 1 A / 125 V
LP1367	F5	F 1 A / 125 V

PCB/ module	Item no.	Value
LP1367	F6	F 1 A / 125 V
LP1367	F7	0.160 A / 125 V
LP1367	F8	T 3.0 A / 125 V

12.6 Information on electromagnetic compatibility

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

Portable and mobile high-frequency RF communication equipment is a source of radiated electromagnetic interference that can affect medical electrical equipment. This can lead to device malfunctions.

For this reason, a certain minimum distance must be kept between such radiation sources and running medical electrical equipment.

Warning

Patient hazard due to device malfunctions

A device malfunction can be caused by high-frequency electromagnetic waves (radiated interference source).

➢ Observe the minimum required distances to radiated interference sources.

● **Minimum distances between radiation source and medical electrical equipment**

RF transmission technology employed	Minimum distance to medical electrical equipment, including all connecting cables	Radiated interference source (examples) (One device/interference source may use more than one RF transmission technology)
GSM (Global System for Mobile Communications) UMTS (Universal Mobile Telecommunications System) LTE (Long-Term Evolution)	1.0 m	Mobile, cell phone, smartphone, tablet computer
DECT (Digital Enhanced Cordless Telecommunications)	0.35 m	Cordless phone
WLAN (Wireless Local Area Network)	0.22 m	Laptop/notebook, desktop computer, E-book reader WLAN repeater, WLAN router, WLAN access point, WLAN print server
Bluetooth	0.07 m	Wireless keyboard, wireless mouse, wireless speakers
Radio	0.25 m	Radio remote control (except radio remote controls by FMC)

12.6.1 EMC guidance and manufacturer's declaration

Specifications refer to the requirements of
IEC 60601-1-2:2007.

● **Electromagnetic emissions**

Guidance and manufacturer's declaration – electromagnetic emissions		
The *sleep•safe harmony* is intended for use in the electromagnetic environment specified below. The customer or the user of the *sleep•safe harmony* should make sure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions according to CISPR 11	Group 1	The *sleep•safe harmony* uses RF energy solely for its for internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions according to CISPR 11	Class B	The *sleep•safe harmony* 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 according to IEC 61000-3-3	Compliant	

● **Electromagnetic immunity**

Guidance and manufacturer's declaration – electromagnetic immunity			
The *sleep•safe harmony* is intended for use in the electromagnetic environment specified below. The customer or the user of the *sleep•safe harmony* should make sure that it is used in such an environment.			
Immunity testing	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**

Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic materials, the relative humidity should be at least 30 %.
Electrical fast transient/burst according to IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Not applicable	The power supply quality should be that of a typical commercial and/or hospital environment.
Surges according to IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	The power supply quality should be that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage fluctuations on power supply lines according to IEC 61000-4-11	< 5% U_T (> 95 % dip in U_T) for 0.5 cycles 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 s	< 5% U_T (> 95 % dip in U_T) for 0.5 cycles 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 s	In the event of power supply interruptions, the battery of the *sleep•safe harmony* takes over the supply without delay.
Power frequency (50/60 Hz) magnetic field according to IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be within the limits characteristic of a typical commercial or hospital environment.
Note: U_T is the AC power supply voltage prior to the application of the test level			

			Portable and mobile RF communications equipment should be used no closer to any part of the *sleep•safe harmony*, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF according to IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms}	**Recommended separation distance** $d = 1.17 \sqrt{P}$ for 150 kHz to < 80 MHz
Radiated RF according to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m	$d = 0.35 \sqrt{P}$ for 80 MHz to < 800 MHz $d = 0.7 \sqrt{P}$ for 800 MHz to 2.5 GHz
			where P is the output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b].
			Interference may occur in the vicinity of equipment marked with the following symbol.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and by reflection from structures, objects and people.

a
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be theoretically predicted with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the *sleep•safe harmony* is used exceeds the applicable RF compliance level above, the *sleep•safe harmony* should be observed to verify normal operation. If any irregularities in performance are observed, additional measures may be necessary, such as reorienting or relocating the *sleep•safe harmony*.

b
Field strengths should be less than 3 V/m over the entire frequency band from 150 kHz to 80 MHz.

●   **Recommended separation distances between portable and mobile RF telecommunications equipment and the device**

Recommended separation distances between portable and mobile RF telecommunications equipment and the *sleep•safe harmony*			
The *sleep•safe harmony* is intended for use in an electromagnetic environment in which RF disturbances are controlled. The customer or the user of the *sleep•safe harmony* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *sleep•safe harmony* as recommended below, according to the maximum output power of the communications equipment.			
Nominal power of transmitter W	**Separation distance according to frequency of transmitter in m**		
	150 kHz to < 80 MHz $d = 1.17 \sqrt{P}$	80 MHz to < 800 MHz $d = 1.17 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.34 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and by reflection from structures, objects and people.

12.7 Operating conditions

Operating temperature range	+15 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 H5 and H6 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.

LAN	Intended for future use
Alarm output	Function currently not available: For connecting an external alarm indicator (nurse call). (Volt-free alarm output, alternating contact, maximum 24 V/24 W) Port: 3-pin diode plug via a shielded line.

12.10 Batteries

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

Batteries	ETX baseboard LP1450 / lithium CR 2032

Rechargeable battery   Lead-acid battery (maintenance-free)
12 V (2 x 6 V), 1.3 Ah

12.11 Parameters

STANDARD inflow volume *sleep•safe* set		Adjustment range	25–3500 ml
		Resolution	1 ml
		Tolerance	±5 %
TIDAL inflow volume *sleep•safe* set	base inflow volume	Adjustment range	50–3500 ml
		Resolution	1 ml
		Tolerance	±5 %
	Tidal inflow volume	Adjustment range	25-3475 ml
		Resolution	1 ml
		Tolerance	±5 %
	Tidal outflow volume	Adjustment range	25–3500 ml
		Resolution	1 ml
		Tolerance	±5 %
Dwell duration		Adjustment range	5–300 min
		Resolution	1 min
		Tolerance	±1 min
STANDARD number of cycles		Adjustment range	1-50
		Resolution	1
TIDAL number of cycles	Base cycles	Adjustment range	1-5
		Resolution	1
	Tidal cycles	Adjustment range	2-15
		Resolution	1
Inflow rate *sleep•safe* set		Adjustment range	50–350 ml/min
		Resolution	1 ml/min
Outflow rate *sleep•safe* set		Adjustment range	50-230 ml/min
		Resolution	1 ml/min

Inflow time	Depending on flow rate	
Outflow time	Depending on flow rate	
Dosing tolerance	±3 % if dialysis solution is free of air	
Balancing tolerance	±1 % if dialysis solution is free of air	
Heater	Fixed patient inflow temperature	37 °C
	Tolerance	-7 to +2 °C
Outflow pressure monitored by the safety system	Max. -100 mbar at patient access with closed patient line	
Technique and sensitivity of the safety system against infusion of air	Pressure / volume method 6 % air per pump chamber	
Technique and sensitivity of the safety system against overfilling	Volume balancing 10 % above maximum permitted inflow volume	
Audible signal silencing	The audible signal can be silenced for 6 minutes.	
Permitted patient volume	Adjustment range 100–120 % of the maximum prescribed inflow volume,	Default value 110 %
Permitted residual volume	Adjustment range 10–50 % of the maximum volume in the patient	Default value 35 %
Permitted reduction of the dwell duration	Adjustment range 0–30 % of the prescribed dwell duration	Default value 15 %
Permitted reduction of the inflow volume	Adjustment range 10–30 % of the prescribed inflow volume	Default value 10 %
Catheter performance	Adjustment range 100–130 % = High 131–160 % = Normal 161–200 % = Low	Default value 130 %

Temperature monitoring	The inflow temperature is monitored by a temperature sensor. The limit is set to 40 °C. This value has a tolerance of ±1 °C. In the event of an alarm situation, the alarm will be given after a maximum of 10 seconds.
Air detection	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.

12.12 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) Transport case, foam insert for 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 transport case
	Kapton film	Transformer/electromagnet
	Silicone	Loading tray and machine block coating, cable insulation, seals

Abbreviation	Material	Used in
	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 transport case
	Iron	Transformer/electromagnet, ferrite core
	Steel	Sockets, tubes, shielding plates
	Copper	Transformer/electromagnet, plug connectors, cables
	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	LP1450
	Lead-acid battery, 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
	Enamel: Alexit 346-18 Hardener: Alexit 345-39 Undercoating: 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 function block
	UNISILKON L 250 L	Special lubricating grease for function block
	Baysilone$^®$ MPH 1000	Oil for function block

12.13 Factory settings

Parameters	Factory setting	Selectable
Preselected inflow volume	2000 ml	25–3500 ml
Maximum inflow volume	3500 ml	25–3500 ml
Preselected inflow rate	350 ml/min	25–350 ml/min

Parameters	Factory setting	Selectable
Maximum inflow rate	350 ml/min	25–350 ml/min
Preselected outflow rate	230 ml/min	25-230 ml/min
Maximum outflow rate	230 ml/min	25-230 ml/min
Preselected dwell duration	120 min	5–300 min
Maximum dwell duration	300 min	5–300 min
Permitted patient volume	110 %	100–120 %
Permitted residual volume	35 %	10-50 %
Permitted dwell duration reduction	15 %	0-30 %
Permitted inflow volume reduction	10 %	10-30 %
Catheter performance	130 %	100-200 %
Set type	Standard	---
Additional outflow	Yes (with sound)	No Yes (without sound) Yes (with sound)
Access level	Select prescription	No changes Select prescription Edit prescription
Screen saver	5 min	---
Volume	100 %	---
Brightness	100 %	---

13 Definitions

13.1 Definitions and terms

Aseptic	Sterile
Autoclave	To sterilize by subjecting to high pressure saturated steam
CCPD	Continuous Cyclic Peritoneal Dialysis (continuous cyclic peritoneal dialysis)
Dialysate	The exchange fluid used for the treatment.
Hypokalemia	Potassium deficiency
Hypovolemia	Decreased blood volume
IPD	Intermittent Peritoneal Dialysis (intermittent peritoneal dialysis)
NIPD	Nightly Intermittent Peritoneal Dialysis (nightly intermittent peritoneal dialysis)
Pediatrics	Medical care of infants, children, and adolescents
Patient safe condition	Patient safety clamp closed. Dialysate flow from / to the patient stopped
Peritonitis	Inflammation of the peritoneum
Tidal	Cyclic inflow and outflow with permitted residual volume in patient's peritoneal cavity

13.2 Abbreviations

TSC	Technical Safety Checks
MA	Maintenance procedures

13.3 Symbols

⚠	Caution
IP21	Protection against ingress of solid objects: protected against the ingress of foreign bodies larger than 12 mm in diameter; finger protection
	Protection against ingress of fluids: drip-proof
🧍	Degree of protection against electric shock: Type BF
▢	Type of protection against electric shock: Protection class II
I/O	ON / OFF (power supply)
⊙⊘	On / Off (standby)
	10Base-T Ethernet port (LAN)
LOT	Batch code
REF	Reference number
	Date of manufacture
+5°C +30°C	Permitted storage temperature range
②	Do not reuse
LATEX	Latex-free
	Use by
STERILE	Sterile fluid path. Sterilized using steam or dry heat
	Quantity
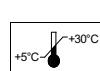
$C \epsilon$ 0123	The CE mark documents compliance with the MDD 93/42/EEC. (MDD: medical device directive) Notified body: TÜV PRODUCT SERVICE 0123
	Symbol for the marking of electrical and electronic equipment
max. 24V / 24W	Alarm output
YYY	Manufacturer and year of manufacture
SN	Serial number
	Follow instructions for use

13.4 Certificates

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

Fresenius Medical Care   *sleep•safe harmony*   IFU-EN   7A-2015

14 Options

Chapter without content.

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 patient card **inserted**
	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**
	Icon for **calcium value**		Icon for **solution** (dialysate)
	Icon for **glucose concentration**		Icon for **battery capacity**
	Icon for **manual outflow**		Icon for **please wait**

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 4-94).

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

➢ Turn the blue knob on the patient connector clockwise.

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

➢ Close the white clamp on the catheter extension.

➢ Insert the patient connector in the *sleep•safe harmony* clip.

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

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

➢ Put on the face mask.

➢ Disinfect your hands and dry them carefully.

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

➢ Unscrew the catheter extension from the patient connector of the *sleep•safe* set.

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

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

> ➢ Pull the catheter extension with the disinfection cap straight (without turning it) out of the organizer.

15.3 Connection with the PIN-Reload device

> ➢ Ensure that the patient connector is secured in the organizer and the PIN-Reload device is still screwed onto the patient connector.

> ➢ Remove the catheter extension from your clothing.

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

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

➢ Put on the face mask.

➢ Disinfect your hands.

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

➢ Unscrew the empty PIN-Reload device 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 from the disinfection cap.

➢ Screw the catheter extension directly onto the patient connector.

➢ Open the white clamp on the catheter extension.
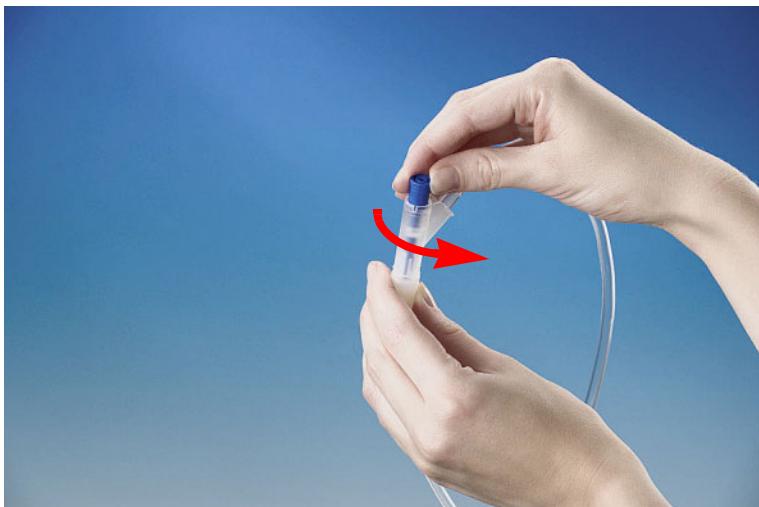
➢ Remove the patient connector from the organizer.

➢ 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

A. Peritoneal dialysis device – "Free software"

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

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

However, the privileges granted by copyright according to Section C. and the license texts contained therein, which relate to such free software, do not include the right to make modifications to the peritoneal dialysis device and subsequently continue use of the device with these modifications. On the contrary, the German Medical Devices Act prohibits any further operation of the peritoneal dialysis device once the software contained therein has been modified, because any medical device may only be operated in the form certified. For this reason, Section B. contains an appropriate note. In such a case, Fresenius Medical Care will

stop any further technical support for the device involved. In addition, such modifications and/or manipulations may result in the extinction of warranty claims against Fresenius Medical Care or other vendors of the peritoneal dialysis device in the event a claim has arisen or might arise in respect thereto. Any utilization of the free software contained in the peritoneal dialysis device in a manner other than that required during proper operation of the system will be solely at your own risk.

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

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

B. Note required according to German Medical Devices Act

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