



**FRESENIUS
MEDICAL CARE**



Peritoneal Dialysis

sleep•safe harmony
Patient Guide 3.x

sleep-safe harmony cycler

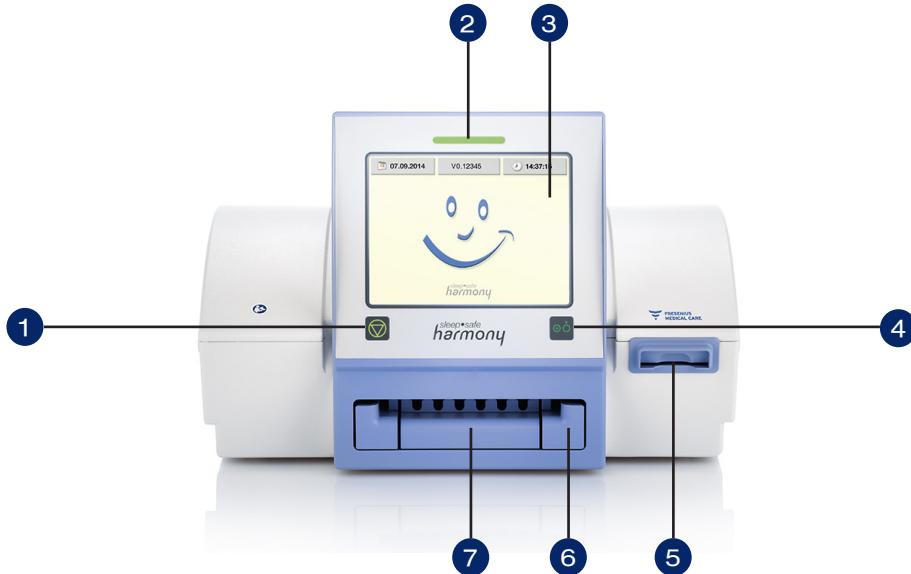


The *sleep-safe harmony* is an automated peritoneal dialysis cycler. This device has been designed to offer you maximum safety and ease of use. The advantage of using the *sleep-safe harmony* cycler is that your peritoneal dialysis treatment will be done during the night while you are sleeping.

This Patient Guide is intended as a support tool to help you operate the *sleep-safe harmony* cycler and does not replace the operating manual and the judgment or experience of your physician and nurse. The peritoneal dialysis treatment as well as the decisions concerning specific treatments for patients are the sole responsibility of your physician and nurse. This Patient Guide is valid for *sleep-safe harmony* software version 3.x.

The warnings in the operating manual should be carefully reviewed prior to your treatment.

sleep-safe harmony overview



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 Touch Screen

4 On/Off key

This key is used to turn the *sleep-safe harmony* on or off.

5 Card slot

Card slot for the PatientCard^{Plus}.

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.

Main power switch (not shown) is located on the back of the cycler.

Equipment required for treatment



- 1 sleep-safe harmony Cycler
- 2 PatientCard^{Plus}
- 3 sleep-safe Set
- 4 Solution Bags
- 5 Drain Line
- 6 Drain Bag

- 7 Disinfection Cap
- 8 Organizer
- 9 Organizer Clip
- 10 Face Mask
- 11 Liquid Soap
- 12 Hand Disinfectant

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Important symbols and icons

Patient Guide Symbols



Information



Caution

Damage to equipment or problems with treatment may occur



Warning

Hazardous situation that could result in illness or injury

Cycler Touch Screen Icons



Repeat animation



Confirm



Skip to next step



Return to previous step



Back



Repeat

For a complete list of touchscreen icons, see Appendix A.

Warnings and cautions

General warnings

In order for the *sleep-safe harmony* to read from the PatientCard^{Plus}, the card must be inserted before the cycler is turned on.

Check the treatment settings loaded from the *sleep-safe harmony* PatientCard^{Plus} for accuracy and compliance with your dialysis center's prescription before proceeding with treatment. Do not remove the PatientCard^{Plus} from the cycler while treatment is in progress.

Speak with your doctor or nurse if you have any questions or concerns about the treatment parameters set by your dialysis center.

It is important that you continue to follow the individually prescribed peritoneal dialysis therapy as taught to you by your health care team. Any deviation from this prescribed therapy must be discussed beforehand with your health care team, as it may cause serious injury or death.

Do not modify the parameters for your therapy unless directed by your Health Care Practitioners. Using incorrect parameters can cause you to receive inadequate or inappropriate dialysis. This can lead to serious injury or death.

Repeated reduction of the dwell duration and/or the inflow volume may result in inadequate treatment and uremia. This can lead to serious injury or death. If you have not completed your treatment as prescribed, please contact your dialysis center.

Contact Fresenius Medical Care Technical Services and/or your dialysis center if you are having difficulty troubleshooting any alarm.

Warnings and cautions

Risk of infection

Infection is a known risk of any peritoneal dialysis treatment. The following warnings are intended to reduce your risk of infection related to peritoneal dialysis treatment. Infection can lead to illness, serious injury or death.

Peritonitis is generally considered to be the most serious type of infection related to peritoneal dialysis. The signs and symptoms of peritonitis include:

- cloudy PD fluid
- abdominal pain
- nausea and/or vomiting
- diarrhea

If you are experiencing any of the above symptoms, contact your dialysis center immediately.

Follow your dialysis center's guidelines for aseptic technique and hand hygiene when handling dialysis equipment and accessories, during setup, and during patient connection and disconnection.

Do not remove single use items or consumables from their overwrap before being prompted to do so by the *sleep-safe harmony*.

Do not use accessories or solutions if:

- the overwrap is damaged.
- the expiration date has passed.
- the protective caps and/or closing caps have come off.
- there are leaks in the dialysis solution bags
- the dialysis solution is not clear

Care must be taken to avoid touching the solution bag connectors and the connector ends of the *sleep-safe* set. If you believe you may have contaminated the connectors, discard the bag and/or set and begin again.

If you feel that you are at risk of infection due to contamination, please contact your dialysis center immediately.

The connection and disconnection procedures in this guide are intended for right-handed patients. If you are left-handed, the ideal placement of the catheter extension and disinfection cap in the organizer would be reversed. Please consult with your training unit for further instruction.

Warnings and cautions

Increased Intraperitoneal Volume (IIPV)

IIPV is an inherent risk of peritoneal dialysis treatment. It occurs when the total intraperitoneal volume exceeds the intended target intraperitoneal volume. IIPV could result in a feeling of abdominal discomfort, serious injury, or death.

In rare cases IIPV may be associated with serious adverse effects that are difficult to predict and prevent, including:

- Feeling full, bloated, or overfull
- Abdominal pain or discomfort
- Expanded or tense abdomen
- Vomiting
- Localized swelling around the PD catheter exit site, belly button, or genital area
- Leakage of fluid from the PD catheter exit site
- Difficulty breathing
- Unexpected increase in blood pressure

Causes of Increased Intraperitoneal Volume

IIPV can occur if your treatment settings are incorrect or if you're inappropriately bypassing during an outflow phase. Always check that your name appears on the screen at the beginning of your treatment, and contact your health care team if you have any questions or concerns regarding your treatment settings.

IIPV may also occur if you terminate the initial outflow phase prematurely. At the end of the initial outflow you will be prompted to confirm that there is no fluid left in your peritoneal cavity. If you think there may be, press the  key to continue the outflow. **Do not press the  key** unless there is definitely no fluid left in your peritoneal cavity. If you are not certain whether your peritoneal cavity is empty, contact your dialysis center before proceeding.

What to do if you suspect that you have IIPV

If you suspect that you have increased intraperitoneal volume during a treatment, you should immediately perform a manual outflow and inform your dialysis center. A manual outflow can be performed at any time during the treatment. If for any reason a manual outflow is not possible, please contact your dialysis center immediately to discuss further options.

If you are experiencing symptoms of IIPV such as severe abdominal pain, vomiting or difficulty breathing, dial 911 for emergency assistance.

Warnings and cautions

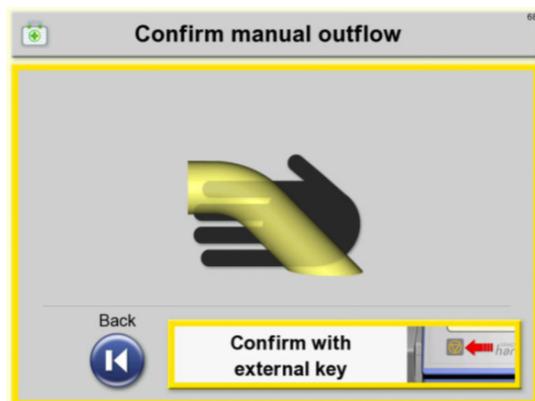
Increased Intraperitoneal Volume (IIPV)

Procedure for performing a manual outflow

Press 



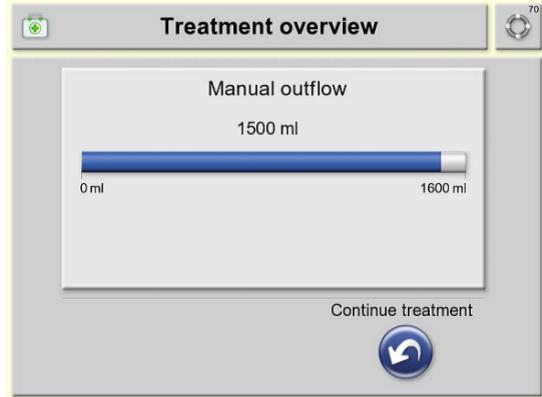
Select **Manual outflow**.



Confirm manual outflow by pressing the  key.

Warnings and cautions

Increased Intraperitoneal Volume (IIPV)



The manual outflow will begin.

If desired, treatment can be resumed at any time by pressing the  key.



Once the manual outflow is complete, you can choose to **Continue treatment** or **Terminate treatment**.

For further assistance performing a manual outflow, contact Fresenius Medical Care Technical Services at 1.888.709.4411.

If you are experiencing symptoms of IIPV such as severe abdominal pain, vomiting or difficulty breathing, dial 911 for emergency assistance.

1

**Prior to
your first
treatment**

Prior to your first treatment

Cycler placement



Cycler placement: Place the *sleep-safe harmony* at the same level as patient's bed. If not possible, place cycler lower to a maximum of 1 meter below.

Changes to the patient level outside this range during outflow may lead to a reduction in the outflow rate and even outflow interruptions.



Maximum to 1 meter below patient's bed.



Remove the *sleep-safe harmony* from the transport case and place it on a **flat, stable surface**. Ensure the cycler is horizontal. The maximum incline allowed is less than 5°.



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

Prior to your first treatment

Performing an Extended System Test



Variations in temperature during transport may cause water condensation on electrical parts. Allow at least 1 hour for the device to return to room temperature before turning on the power.

An Extended System Test is required when the *sleep-safe harmony* is first installed or if it has been transported to a destination outside of your home.



- Connect the *sleep-safe harmony* to the power supply.
- Insert the PatientCard^{Plus}.



- Press the power switch (circled in green at left) to turn the *sleep-safe harmony* on.
- Press the key when it lights up (this takes approximately one minute).



- **Touch the smiley face** to move to the next step.

Prior to your first treatment

Performing an Extended System Test



Press the key to move to the next step.

The *sleep-safe harmony* will perform internal tests. The loading tray will open and an audible alarm will sound. The status indicator will be red.

Do not place a *sleep-safe* set in the open loading tray.



Caution

Do not use the *sleep-safe harmony* if the audible alarm does not sound and/or the status indicator does not turn red during the internal test. If this occurs please contact Fresenius Medical Care Technical Services at 1.888.709.4411.



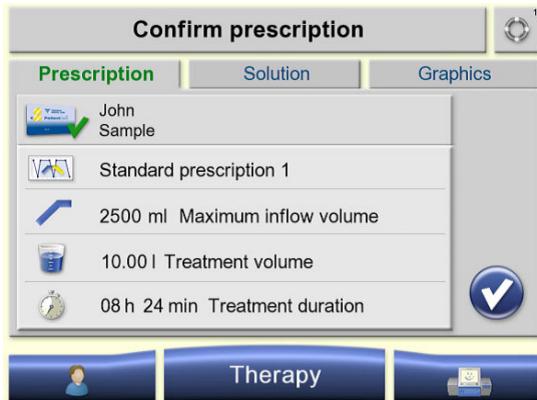
- Press the key.
- Press the key.

If the Extended System Test was **successful**, the loading tray will close and the machine will shut off automatically. The cycler is ready for use.

If the Extended System Test was **unsuccessful**, an error message will be displayed. In this case, do not use the device and contact Technical Services for assistance.

Prior to your first treatment

Selecting the cycler language



Select the  key.



Use the  and/or  key to highlight **Language**.

Press **Language** to display the languages available.

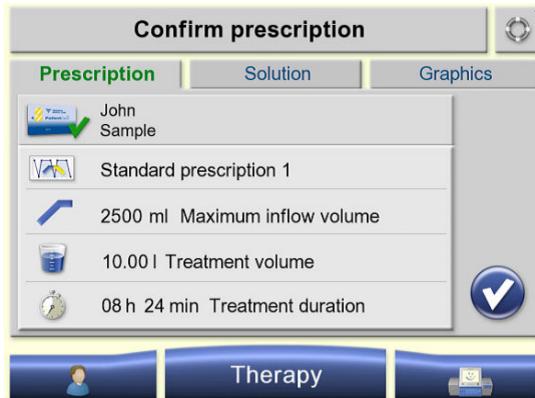


Select the desired language.

Pressing the  key will return you to the previous screen.

Prior to your first treatment

Setting the date and time



Select the  key.

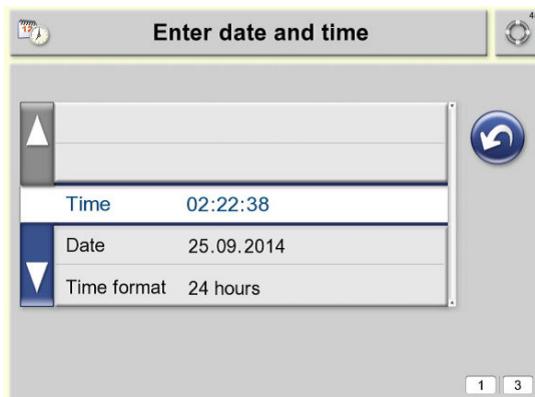
Note: The date and time can only be set when no treatment is being performed.



Use the  and/or  key to highlight **Date and time**.

Touch **Date and time** to display the time and date settings.

Pressing the  key will return you to the previous screen.



Use the  and/or  key to highlight **Time**, **Date** or **Time Format**.

Select the setting you wish to adjust and make the changes.

Press the  key to confirm your change.

Prior to your first treatment

Setting screen brightness

The brightness of the cycler screen, status indicator light and button backlight can be adjusted. There are 20 levels, and the default setting is 20, or 100% brightness.



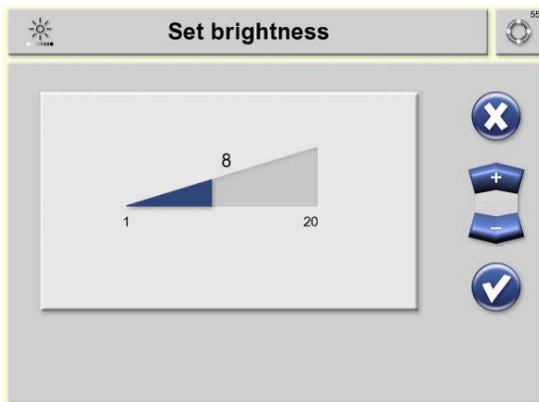
If the status indicator light turns red during an alarm situation, it cannot be adjusted and will remain on the maximum brightness.



Use the and/or key to highlight **Brightness**.

Touch **Brightness** to display the Set brightness screen.

Pressing the key will return you to the previous screen.



Use the and/or key to increase or decrease the brightness setting.

Press the key to confirm your change.

Prior to your first treatment

Adjusting screen saver settings



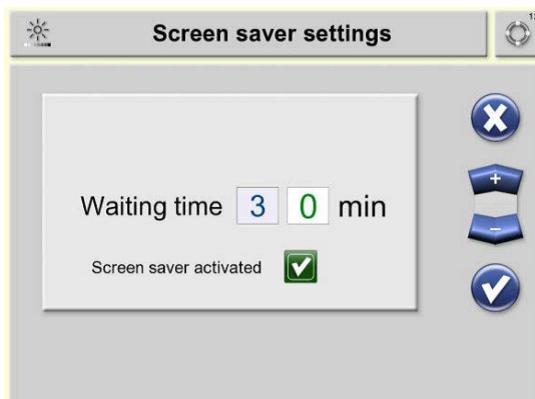
Select the key.



Use the and/or key to highlight **Screen saver**.

Touch **Screen saver** to display the Screen saver settings screen.

Pressing the key will return you to the previous screen.



Use the and/or key to increase or decrease the waiting time before the screen saver appears.

Enable the screen saver function by checking the box labeled *Screen saver activated*.

Press the key to confirm your settings.

Prior to your first treatment

Setting the sound volume



The volume for all sounds, including cautions, wake up melody and key clicks, can be adjusted. There are 10 levels, and the default setting is 10, or 100% volume.

Select the  key.



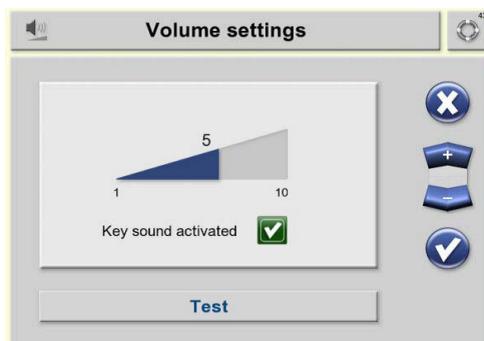
Changing the sound volume also changes the volume of the wake up melody. You may not hear the wake up melody at a sound volume below "7".



Use the  and/or  key to highlight **Volume**.

Touch **Volume** to display the Volume settings screen.

Pressing the  key will return you to the previous screen.



Use keys  and/or  to increase or decrease volume. Enable key sounds by checking the box labeled **Key sound activated**.

Check volume setting by selecting the **Test** button.

Press  to confirm settings.

2

**Preparing
for your
treatment**

Preparing for your treatment

2

Turning the cycler on

Press the  key. The *sleep-safe harmony* is ready for use as soon as the screen below is displayed.



Preparing for your treatment

Getting ready

- Close all doors and windows, and turn off your air conditioning or fan to prevent drafts.
- Take off your wristwatch and jewelry.
- Remove your catheter from your clothing.
- **Put on a face mask and wash your hands.**
- Gather the necessary supplies.



Warning

Risk of Infection

Do not remove single use items or consumables from their overwrap before being prompted to do so by the *sleep·safe harmony*.

Do not use single use items or consumables if:

- the overwrap is damaged.
- the expiration date has passed.
- the protective caps and/or closing caps have come off.

Preparing for your treatment

Confirming your prescription

2



Prescription tab shows:

- 1 Patient name
- 2 Prescription name
- 3 Maximum inflow volume
- 4 Total treatment volume
- 5 Expected treatment duration



For a pediatric treatment

The screen will display a pediatric treatment. The pediatrics icon “Teddy” appears next to the prescription name and in the top right screen corner.

The *sleep-safe harmony* can store up to 9 prescriptions. The cycler will default to the prescription set by your dialysis centre. For instructions on how to select another prescription, see page 24.

Press the key. The loading tray will open automatically after the internal test is complete.



Warning The treatment settings loaded from the *sleep-safe harmony* PatientCard^{Plus} must be checked for accuracy and compliance with your dialysis centre's prescription before proceeding with treatment.

Preparing for your treatment

Selecting a prescription

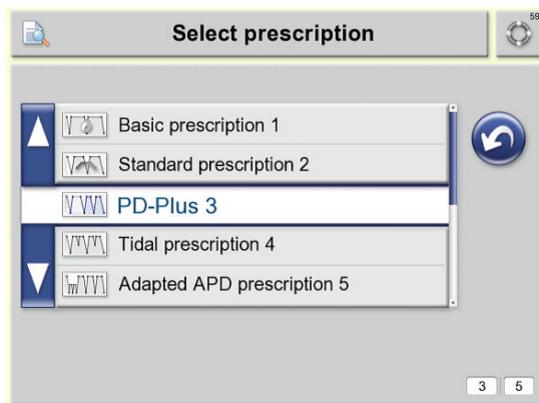


Select **Therapy** menu.



Use the **▼** and/or **▲** key to highlight **Select prescription**.

Touch **Select prescription** to display the prescriptions available.



Use the **▼** and/or **▲** key to highlight the desired prescription.

Touch the selected prescription name.

The **Confirm prescription** screen will reappear with the newly selected prescription name.

Preparing for your treatment

Inserting the *sleep-safe* set

2



Caution

Do not use the *sleep-safe harmony* if the audible alarm does not sound and/or the status indicator does not turn red during the internal test. If this occurs please contact Fresenius Medical Care Technical Services at 1.888.709.4411.



Warning

To reduce the risk of infection, avoid touching the connector ends of the *sleep-safe* set. If you believe you may have contaminated the connectors, discard the set and begin again.



Open the overwrap of the *sleep-safe* set and remove it from the wrapper.

Place the ***sleep-safe* set** in the open loading tray.

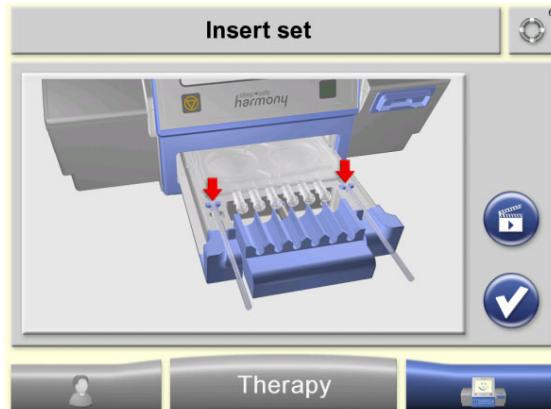


In pediatric mode

For a pediatric treatment, you will be requested to insert a ***sleep-safe Set Paed***, identified by the packaging with the "Teddy" icon.

Preparing for your treatment

Inserting the *sleep·safe* set



Push lines on the left and right into line clips, and then guide them into the grooves provided.

Insert the patient connector in the organizer clip.

Press the  key to confirm that the *sleep·safe* set is positioned correctly.



Caution

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.

If this occurs, discard the damaged set and use a new *sleep·safe* set for the treatment.

Preparing for your treatment

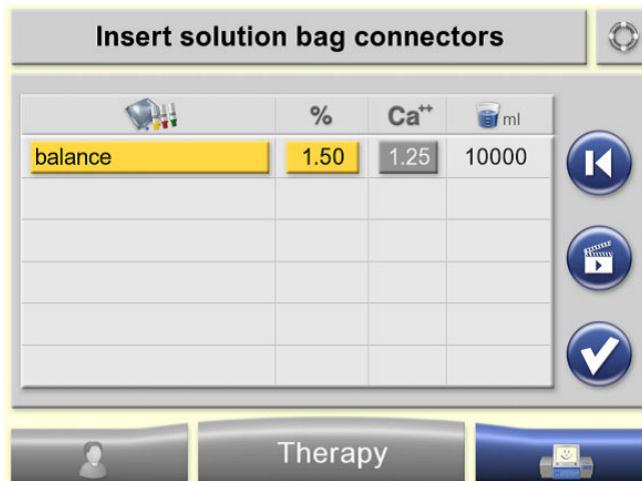
Checking and preparing the solution bags

2



Warning

To reduce the risk of infection, avoid touching the solution bag connectors and the connector ends of the *sleep-safe* set. If you believe you may have contaminated the connectors, discard the bag and/or set and begin again.



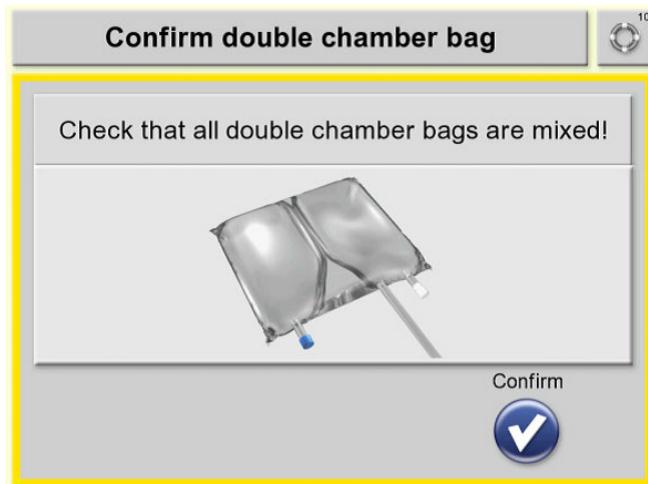
The solution bags required for the treatment are listed on the screen.

The color coding indicates which solution bags need to be connected.

- Remove the overwrap of the solution bags.
- Check the solution bags for leakage, clarity, and expiry date before use. Mix the solution; see Appendix C for detailed instructions.
- Uncoil the solution bag line.
- **Disinfect your hands.**
- Carefully remove the coloured cap of the solution bag connector.
- Place the connectors of the solution bags in the connector rail and push down until it snaps into place, as demonstrated in the onscreen animation. Pull back gently on the solution bag line to position the bar code correctly.
- Press the key. The loading tray will close.
- The cycler confirms that you have connected the correct solution bags.

Preparing for your treatment

Connecting the solution bags

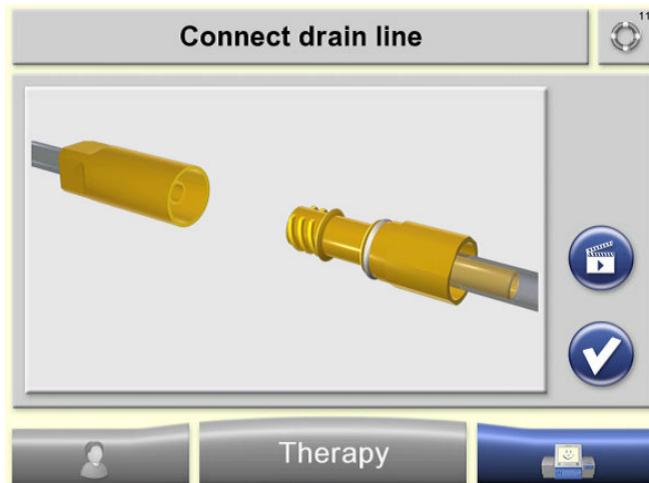


Press the key.

Preparing for your treatment

Connecting the drain line

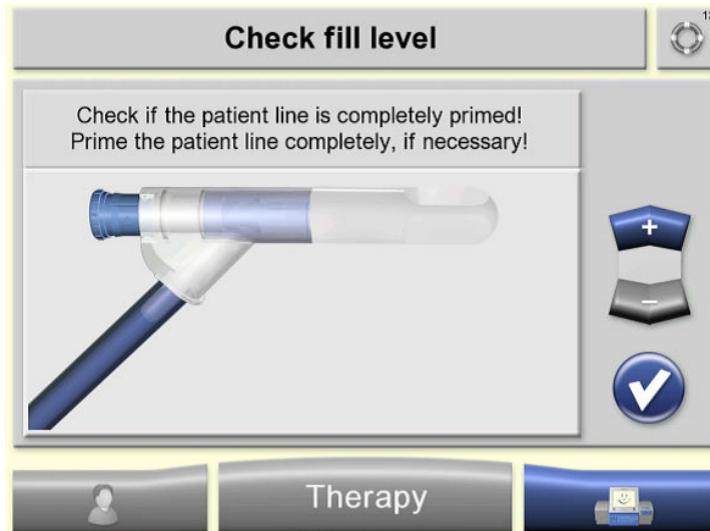
2



- After connecting the solution bags, connect the drain line to a drain line extension or drain bag.
- Uncoil the drain line on the *sleep-safe* set.
- Connect the yellow connector of the *sleep-safe* set drain line to the drain line extension or drain bag, as demonstrated in the onscreen animation.
- If using the drain line extension, ensure the line is placed into a suitable receptacle to dispose of the fluid. If using the drain bag, ensure that both clamps on the bags are closed. Ensure the clamp on the line that connects to the drain line on the *sleep-safe* set is open.
- Press the key.

Preparing for your treatment

Checking the fill level in the patient line



If priming has been completed, but the patient line is not yet fully primed, press the key to increase the fill level. If necessary, this step can be repeated until the line is completely filled.

Press the key.

Preparing for your treatment

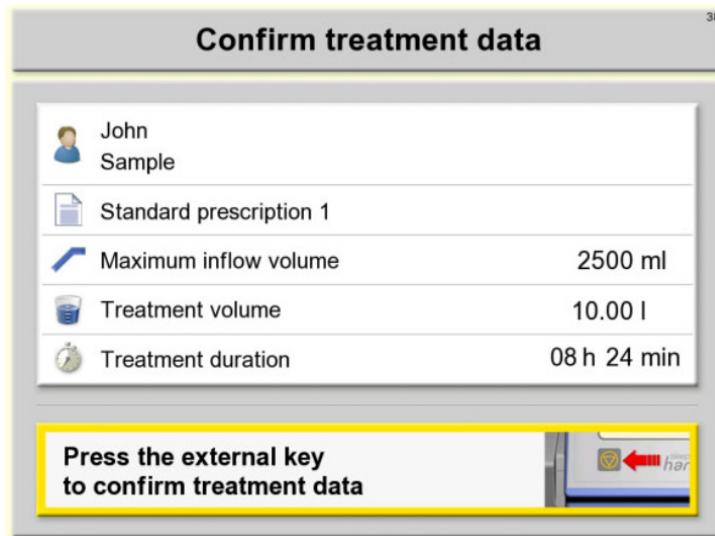
Confirming treatment data

2



Warning

Check the treatment data for accuracy before starting the treatment.



Press the  key to confirm the treatment data.

3

Starting your treatment

Starting your treatment

Connecting yourself to the *sleep-safe harmony*

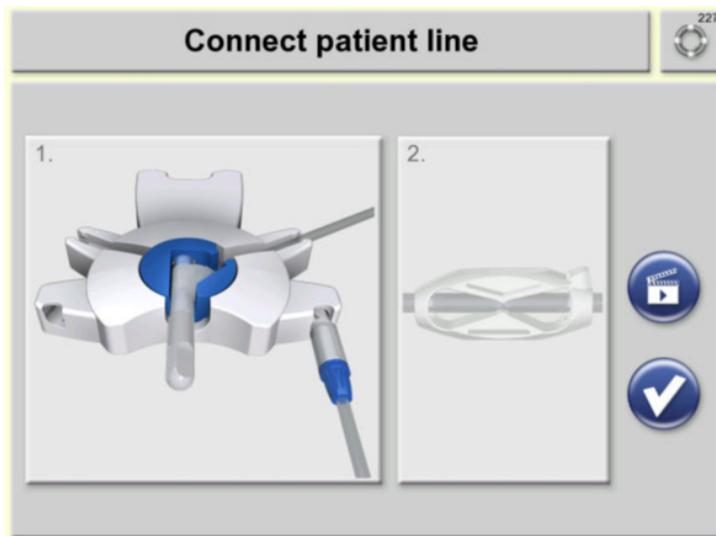
3



Warning

Risk of Infection

Follow your dialysis center's guidelines for aseptic technique when handling sterile items and during patient connection.



Once priming is complete, **connect yourself to the cycler immediately**, as demonstrated in the animation and/or as described below.

Starting your treatment

Connecting yourself to the *sleep·safe* harmony



- Ensure that your face mask is in place.
- **Wash hands if required.**
- Place your catheter extension into the right side of the organizer.



- **Disinfect your hands.**



- Unscrew and discard the protective cap of the *sleep·safe* set patient connector.

Starting your treatment

Connecting yourself to the *sleep-safe* harmony

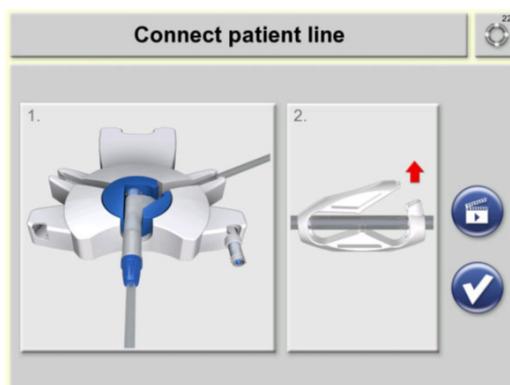
3



- Unscrew your catheter extension from the disinfection cap.



- Screw your catheter extension directly onto the patient connector of the *sleep-safe* set.
- **Open the white clamp on your catheter extension.**

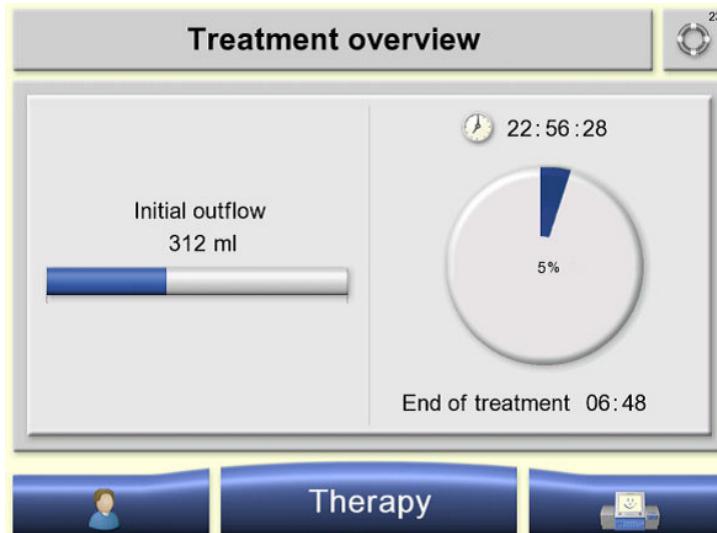


- Press the  key to confirm connection.
- The patient's name will be displayed on the next screen.
- Press the external  key to confirm connection and start treatment.

Starting your treatment

Initial outflow

The treatment will always begin with an initial outflow.



i

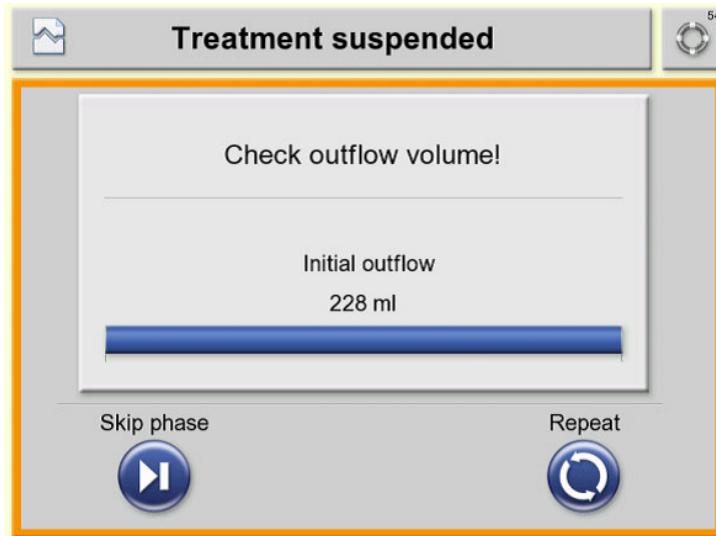
For safety reasons, the *sleep-safe harmony* will alarm at the end of the initial outflow. This allows you to check that you have completely emptied your peritoneal cavity.

Press the  icon to silence the audible signal.

Starting your treatment

3

Initial outflow



The initial outflow volume achieved will be displayed.

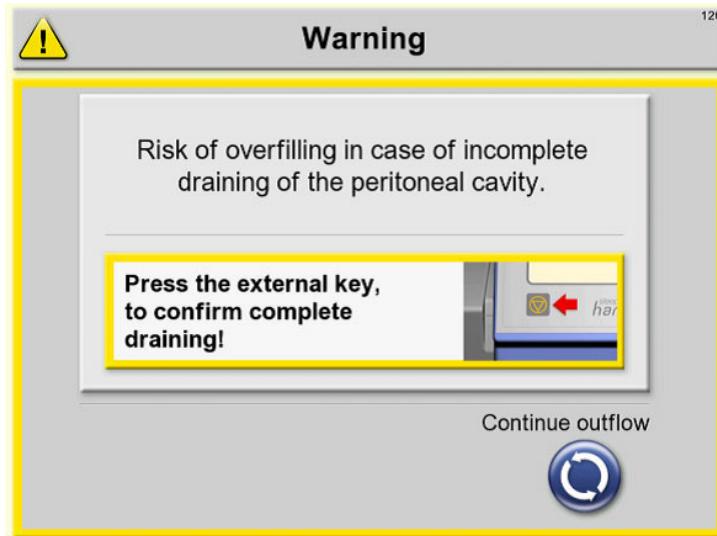
- **If the volume of fluid drained is less than you expected**, press the  key to repeat the initial outflow.

OR

- **If the volume of fluid drained is what you expected**, press the  key to proceed.

Starting your treatment

Initial outflow



A warning will appear asking you to confirm that your peritoneal cavity is completely empty.



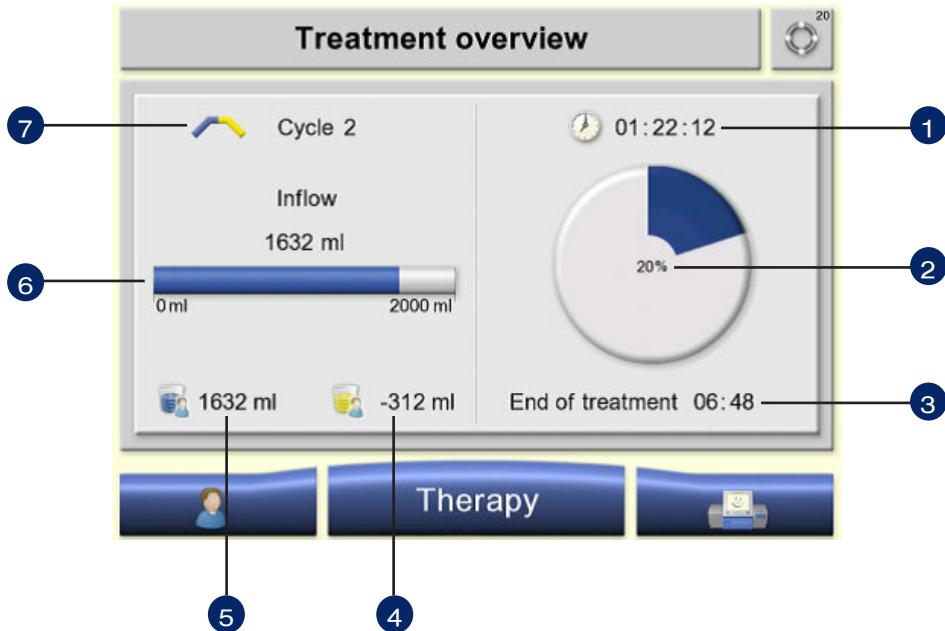
Do not press the  key unless there is definitely no fluid left in the peritoneal cavity. If you are not certain that your peritoneal cavity is empty, contact your dialysis unit before proceeding.

- If you think that you may have fluid remaining in your peritoneal cavity, press the  key to repeat the initial outflow.
- If you're certain that there is no fluid remaining, press the  key to start the initial inflow.

Starting your treatment

3

Treatment overview



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

- 1 Current time
- 2 Treatment progress in percentage (%)
- 3 Expected time at end of treatment
- 4 Current total volume balance
- 5 Volume of PD fluid in your abdomen
- 6 Progress of the current treatment phase
- 7 Current treatment cycle

4

During your
treatment

During your treatment

Accessing therapy options



To access the therapy options:

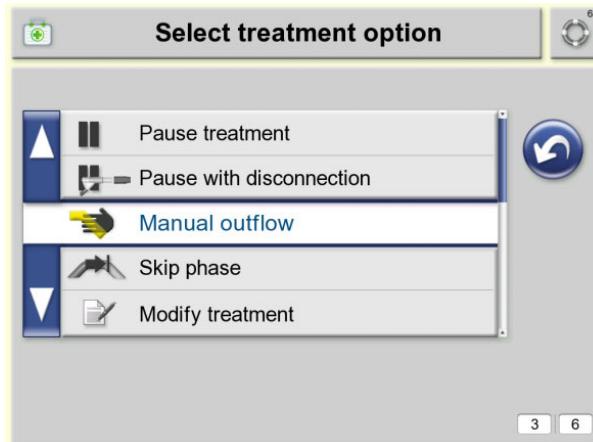
- Press the  key on the cycler.



- The **Select treatment option** screen will display.
- To return to the previous screen, press the  key.

During your treatment

Therapy options available



The following therapy options are available:

- **Pause treatment**
The treatment will be paused.
- **Pause with disconnection**
The treatment will be paused and prompt you to disconnect yourself and then reconnect yourself.
- **Manual outflow**
An outflow will commence immediately.
- **Skip phase**
The cycler will move to the next phase.
- **Modify treatment**
Allows you to change the dwell duration or the inflow volume.
- **Terminate treatment**
Ends the therapy immediately.
- **Treatment report**
A report of treatment results is shown.

Choose the appropriate option and follow the onscreen prompts.

Press the key to return to the previous screen.

During your treatment

Temporary disconnection during treatment

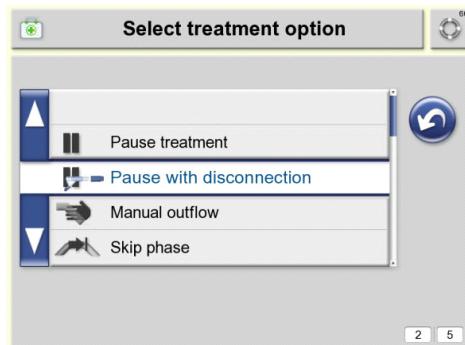
If you need to disconnect from your cycler during treatment, the disposable PIN Reload device can help you to do that quickly and easily.

Before you disconnect from the system make sure that you are in the **dwell phase** and have the following ready:

- PIN Reload device
- Disinfection cap
- Face mask
- Hand disinfectant

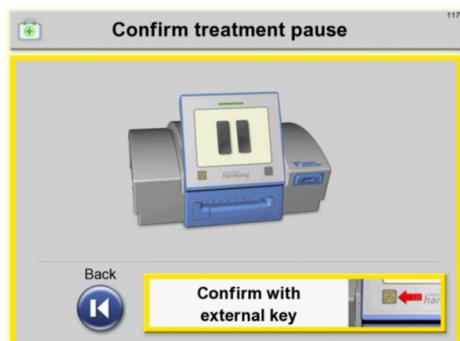
Disconnection during treatment

Press the  key.



Use the  and/or  key to highlight **Pause with disconnection**.

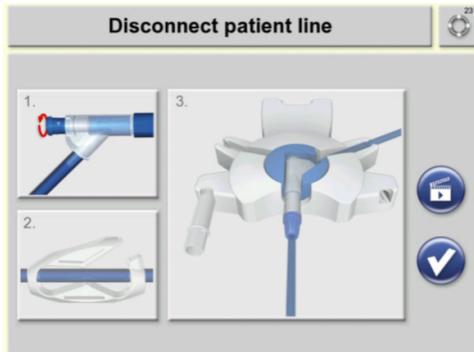
Touch **Pause with disconnection**.



Press the external  key to confirm that you want to pause your treatment.

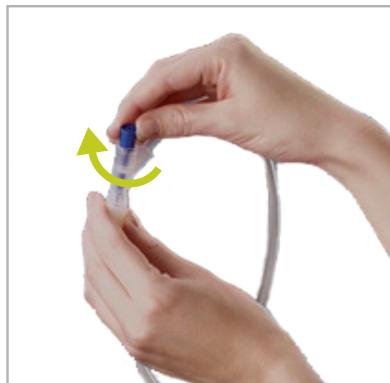
During your treatment

Temporary disconnection during treatment



The **Disconnect patient line** screen will appear.

Follow the steps outlined in the animation or as described in this section to disconnect.



Turn the blue button on the patient connector clockwise.

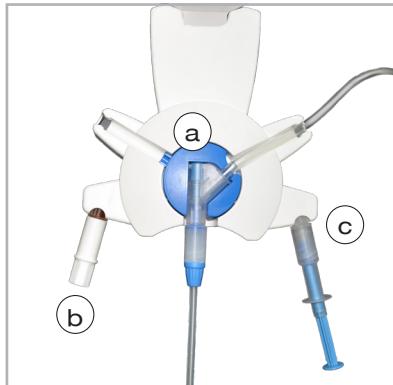


- ⓐ Firmly push the blue button all the way into the patient connector.
- ⓑ Close the white clamp on your catheter extension.

During your treatment

Temporary disconnection during treatment

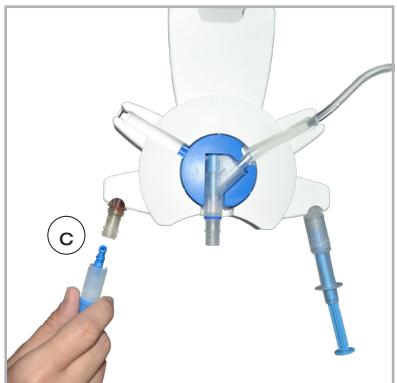
4



- Ⓐ Place the patient connector into the organizer.
- Ⓑ Place a new disinfection cap into the left hand side of the organizer.
- Ⓒ Place a PIN Reload device into the right hand side of the organizer.

Important

Use a face mask for the next steps, and disinfect your hands, drying them thoroughly.



- Ⓐ Unscrew the protective cover from a new disinfection cap.
- Ⓑ Unscrew your catheter extension from the patient connector of the set.
- Ⓒ Securely screw your catheter extension with PIN onto the new disinfection cap.



Unscrew the PIN Reload device from its protective cover and screw it onto the patient connector.

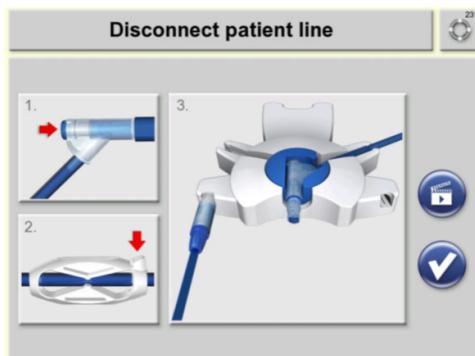
During your treatment

Temporary disconnection during treatment

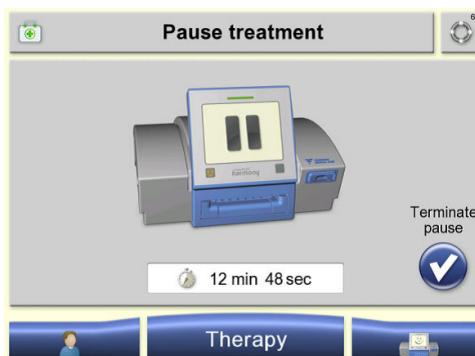


Remove your catheter extension from the organizer (pull toward you without turning).

Ensure the disinfection cap is firmly in place.



- Press the key to confirm that all disconnection steps have been carried out correctly.
- Press the external key to confirm disconnection.

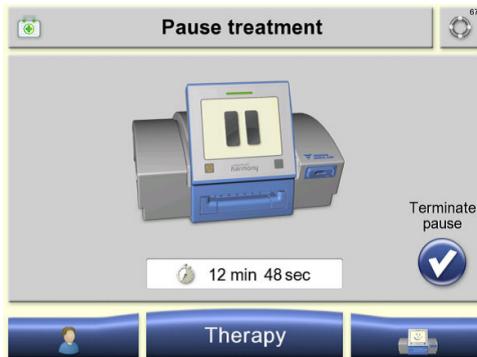


The Pause treatment screen will appear. A timer will display the duration of the pause.

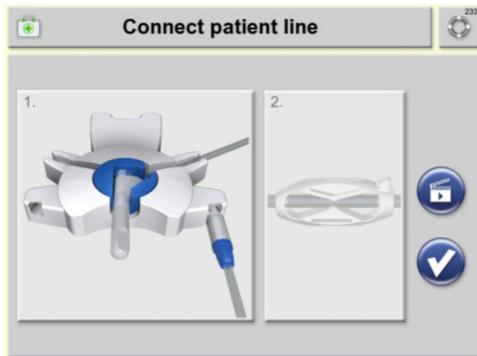
During your treatment

Temporary disconnection during treatment

Reconnection after treatment pause



Touch the key to terminate your treatment pause and reconnect.



The **Connect patient line** screen will appear.

Follow the steps outlined in the animation or as described in this section to reconnect.

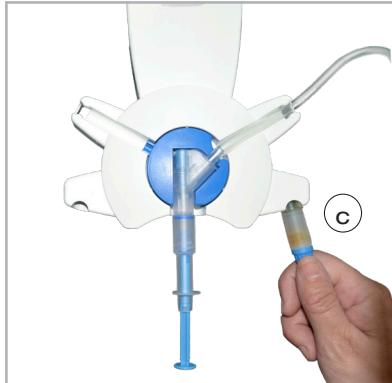
During your treatment

Temporary disconnection during treatment

Reconnection after treatment pause

Important

Put on your face mask; wash and dry your hands thoroughly, following the guidelines given to you by your renal unit.



- ⓐ Ensure that the patient connector is still secured in the organizer and the PIN Reload device is still screwed to the patient connector.
- ⓑ Remove your catheter extension from your clothing.
- ⓒ Place your catheter extension into the right hand side of the organizer.

Important

Ensure that your face mask is in place and disinfect your hands, drying them thoroughly.



Press the plunger firmly to the end to release the PIN into the patient connector.

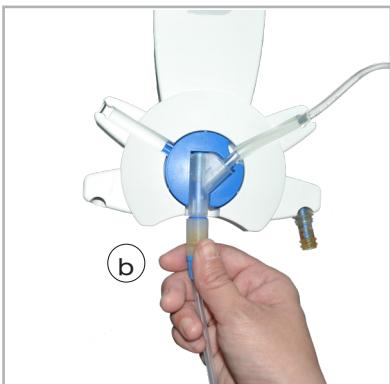
During your treatment

Temporary disconnection during treatment

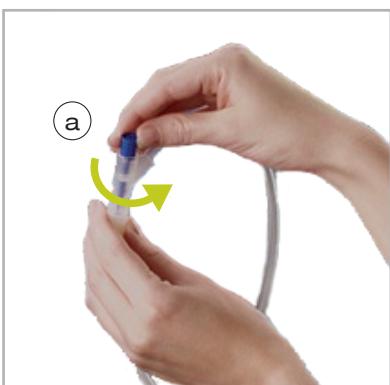
4



- ① a Unscrew the empty PIN Reload device from the patient connector and discard it.
- ② b Confirm that PIN was reloaded into patient connector. If not, repeat with new PIN Reload device.



- ① a Unscrew your catheter extension from the old disinfection cap.
- ② b Screw your catheter extension onto the patient connector.
- ③ c Open the white clamp on your catheter extension.
- ④ d Remove the patient connector from the organizer.



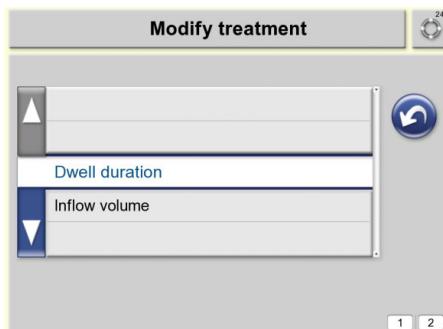
- ① a Turn the blue button counter-clockwise to prevent accidental release of the PIN.
- ② b Press the key to confirm connection.
- ③ c Press the key to resume your treatment.

During your treatment

Modify treatment


Warning

Do not modify the parameters for your therapy unless directed by your Health Care Practitioners. Using incorrect parameters can cause you to receive inadequate or inappropriate dialysis. This can lead to serious injury or death.



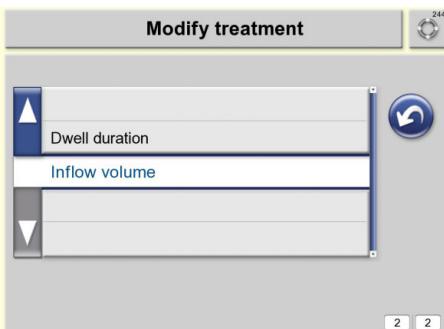
Select **Dwell duration** to change the total dwell duration.



Press the key.

Select **Modify treatment** to change the dwell duration or inflow volume. This option is only available if your nurse has provided you with editing rights.

To return to the previous screen, press the key.



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

If the dwell duration or the inflow volume was changed, then the screen on the left will be displayed with before and after change values.

Touch the key to confirm data entered.

Press the key to confirm modifications.

5

Ending your treatment

Ending your treatment

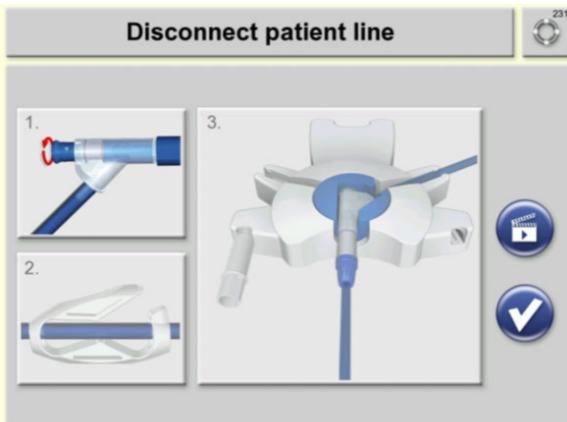
Disconnecting yourself



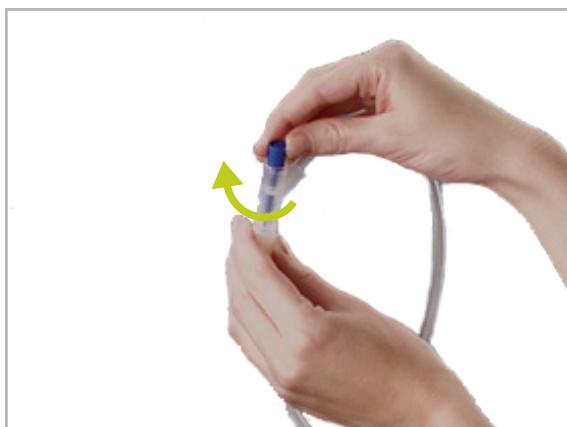
Warning

Risk of Infection

Follow your dialysis center's guidelines for aseptic technique when handling the patient connector.



Perform the steps for disconnection as demonstrated in the animation and/or as described below.



Turn the blue knob on the patient connector to which you are attached clockwise.

Ending your treatment

Disconnecting yourself



- Push the blue button on the patient connector to which you are attached all the way in. This will automatically insert the PIN into the catheter extension.
- **Close the white clamp on your catheter extension.**



- Open the overwrap of a new disinfection cap.
- Place the new disinfection cap in the left holder of the organizer.
- **Apply mask and disinfect hands.**
- Insert the patient connector into the blue clip of the organizer.
- Unscrew and discard the cover of the new disinfection cap.



- Unscrew your catheter extension from the *sleep-safe* set and screw it immediately onto the new disinfection cap.

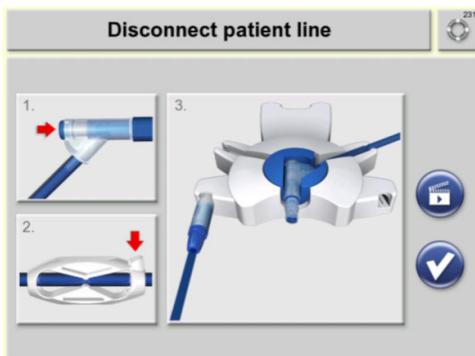
Ending your treatment

Disconnecting yourself

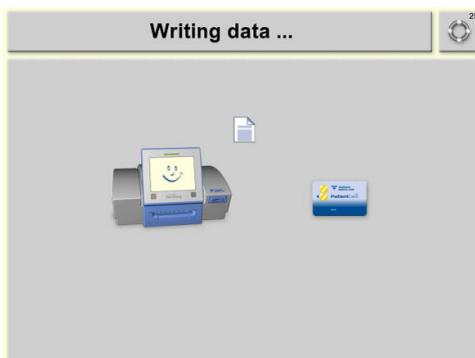
5



- Remove the catheter extension from the organizer (pull toward you without turning).
- Ensure the disinfection cap is firmly in place.



- Press the  key to confirm that all disconnection steps have been carried out correctly.
- Press the  key to confirm disconnection.

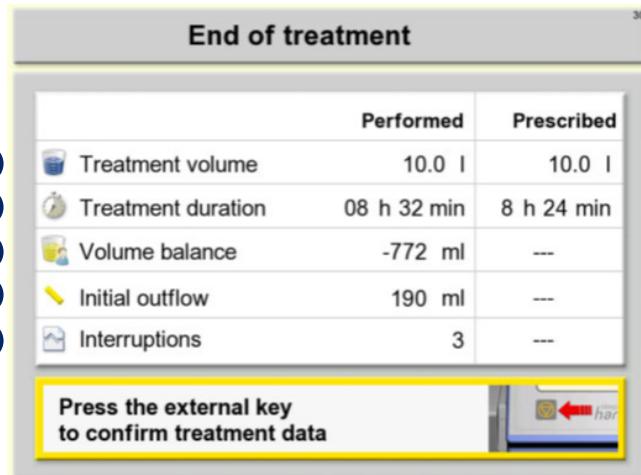


Your treatment results will be saved to the PatientCard^{Plus}.

Ending your treatment

Treatment summary

Once your treatment results have been saved to the PatientCard^{Plus}, the following screen will appear:



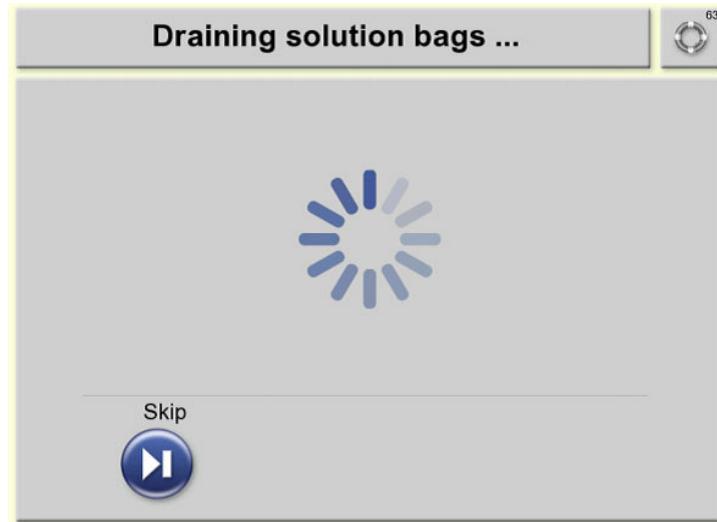
1. Total of all inflow volumes during treatment, including last inflow.
2. Total treatment duration.
3. Volume balance not including last inflow nor initial outflow.
 - Negative value indicates that you have removed fluid.
 - Positive value indicates that you have retained fluid.
4. Volume of the initial outflow.
5. Number of interruptions.

Press the  key to exit the **End of treatment** screen and to begin draining any remaining fluid in the bags and *sleep-safe* set.



Warning

Repeated reduction of the treatment duration and/or the treatment volume may result in inadequate treatment. If you have any concerns about these values, please contact your dialysis center.



- The cycler will automatically drain the solution bags and the *sleep-safe* set.
- If required, the  key can be used to skip draining.
- The loading tray will open automatically when draining is complete, or if the draining phase was skipped.

Ending your treatment

Removing the *sleep-safe* set



- Gently pull both the patient line and the drain line upward to remove the lines from the line holders. Remove the *sleep-safe* set from the loading tray, as demonstrated in the onscreen animation.
- Touch the  key to confirm the removal of the set.
- Dispose of the *sleep-safe* set, the solution bags and the drain line or drain bag. If using a drain bag, ensure that it is emptied prior to disposal.

**Caution**

Consumables must be discarded after the treatment according to the instructions provided by your dialysis center.

6

Alarms and troubleshooting

Alarms and troubleshooting

Color identification of screen messages

Screen messages are organized into three categories which can be identified by their frame color.



Yellow frame: Information

- Instructions which you must observe and follow as necessary.
- Treatment can be continued.



Orange frame: Caution

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



Red frame: Alarm - Device fault

- Device error which affects only the *sleep-safe harmony* cycler.
- Depending on the alarm type and instructions given, treatment may continue or it may stop.

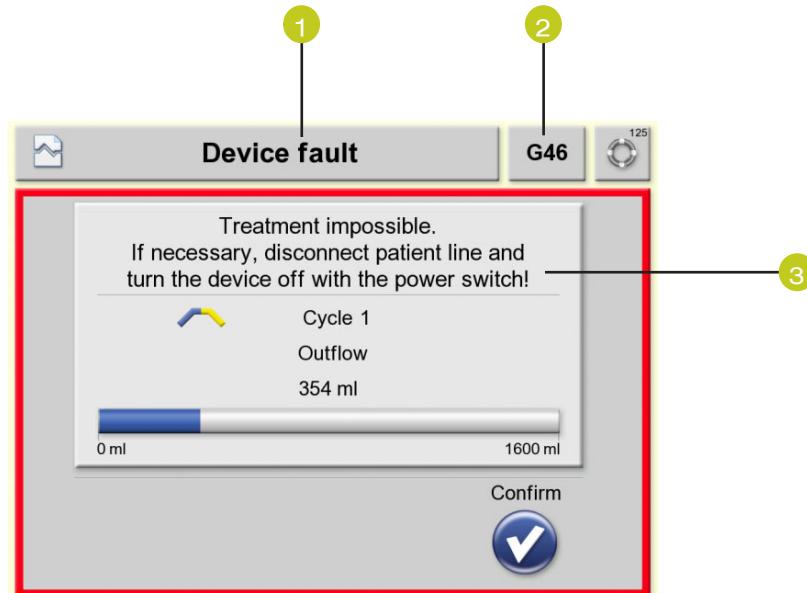


Red frame: Alarm - system error

- System errors affect the entire system, including line set, solution bags and drainage.
- Depending on the alarm type and instructions given, treatment may continue, or it may stop.

Alarms and troubleshooting

Screen layout



1 Screen message title

2 Screen message number

The screen message number provides the contact in your dialysis center or the Fresenius Medical Care technologist with additional troubleshooting information.

3 Information text

The following buttons may be displayed on an alarm screen:

Confirm key for confirming the screen message.

Repeat key to repeat the current step.

Skip phase key to terminate the current treatment phase and to switch to the next treatment phase.

Alarms and troubleshooting

6

Resetting the audible alarm



If an alarm sounds, it can be silenced for 6 minutes by pressing the screen.



If an alarm sounds and the above screen is not displayed, the alarm can be silenced by pressing the  key.

Alarms and troubleshooting

Common alarms

**Caution**

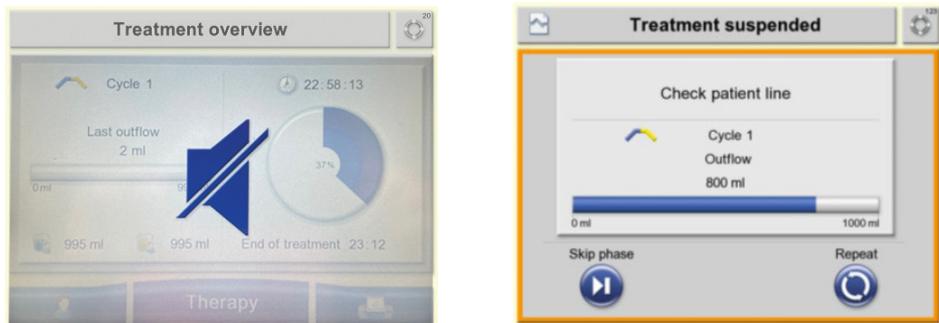
Please contact Fresenius Medical Care Technical Services at 1.888.709.4411 and/or your dialysis center if you are having difficulty troubleshooting any alarm.

Wake-up melody

If your outflow is interrupted (e.g. by a kinked patient line) before your permitted residual volume is reached, the *sleep-safe harmony* will play a wake up melody to rouse you and encourage you to move.

It takes the *sleep-safe harmony* approximately 60-120 seconds to detect a kinked patient line. Once the wake up melody starts, it will increase in volume until flow is resumed, and will then turn off. The wakeup melody can be muted at any time by touching the cycler screen.

If the problem does not resolve within approximately 3 minutes of occurring, a **Check patient line** caution will be triggered; this caution requires resetting.



Alarms and troubleshooting

6

Common alarms

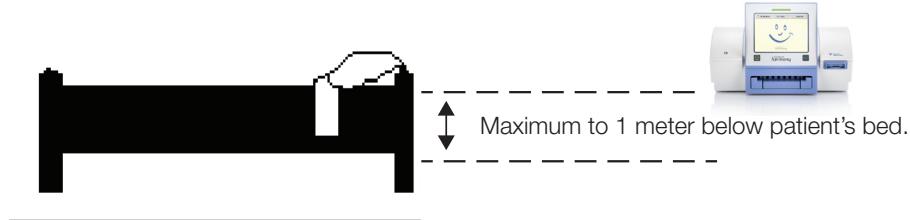
G93 Pressure in patient line too high



Action required:

- Check patient line for kinks.
- Check patient line for correct positioning.
- Check catheter extension for kinks and closed clamp.

- Check cyler placement. Place the *sleep-safe harmony* at the same level as patient's bed. If not possible, place cyler lower to a maximum of 1 meter below.

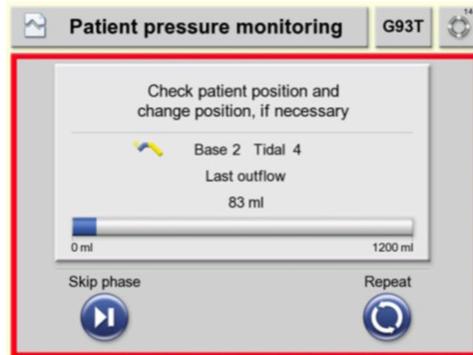


- Press  to continue treatment phase. If not possible, restart device.

Alarms and troubleshooting

Common alarms

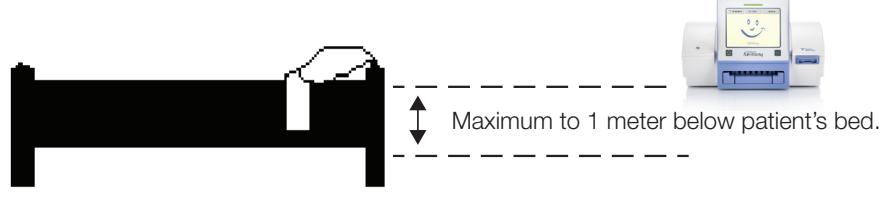
G93T Patient pressure monitoring



Action required:

- Check patient line for kinks.
- Check patient line for correct positioning.
- Check catheter extension for kinks and closed clamp.

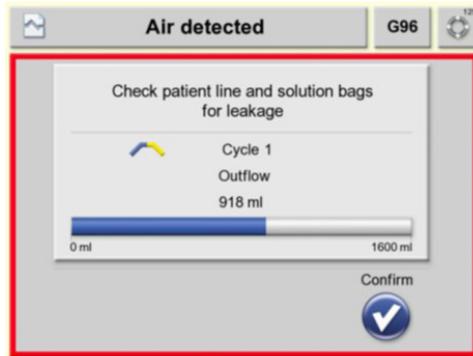
- Check cycler placement. Place the *sleep-safe harmony* at the same level as patient's bed. If not possible, place cycler lower to a maximum of 1 meter below.



- Change position. Press  to continue treatment phase.
- If a G93T error occurs multiple times in a phase, terminate the treatment and disconnect patient from the device.

Common alarms

G96 Air detected



Action required:

Error occurs during **outflow phase**:

- Check patient line for leakage.
- Ensure tight and correct patient connection.
- Check if patient line is completely primed after preparation.

Error occurs during **inflow phase**:

- Check bag line for leakage.
- Ensure proper positioning of solution bags to avoid air in tubing lines.
- Suspend the solution bag with the solution bag line pointing down.
- Ensure tight and correct connection of polyglucose bag (if using polyglucose bag).
- Press  to confirm the error message and continue. Otherwise, terminate the treatment and disconnect patient from the device.
- Restart the device.
- If error appears again contact Technical Service.

Alarms and troubleshooting

Common alarms

G100 Device has been inactive for several minutes



Action required:

- The treatment has been interrupted for more than 10 minutes, e.g. due to missing user interaction on caution screen.

- Press  to confirm error message and continue the treatment.
- Respond to caution in case of missing user interaction to caution screen.
- This alarm is not a device fault. Treatment can be continued by pressing the  key.

Alarms and troubleshooting

6

Error messages

**Caution**

Please contact Fresenius Medical Care Technical Services at 1.888.709.4411 and/or your dialysis center if you are having difficulty troubleshooting any alarm.

Error	Cause	Action Required
A001	Device fault	<ul style="list-style-type: none">• Confirm error message. Device will shut down.• Restart treatment.• If error appears again contact service.
A002	Power failure	<ul style="list-style-type: none">• Ensure device is connected to power supply.• Confirm error message. Treatment can be continued.
G12T	Temperature test error	<ul style="list-style-type: none">• Press . Continue if possible.• If not possible, try to restart device after heating elements have cooled.• Ensure device is not exposed to direct sunlight.• Ensure device is being operated within specified operating conditions (IFU chapter 9.2).• If error appears again contact service.
G41T	Barcode scanner error	<ul style="list-style-type: none">• Press . Continue if possible.• If not possible, try to restart device.• Ensure proper positioning of bag connectors in connector rail of the device.• Avoid exposing connector rail to direct sunlight.• If error appears again contact service.
G41	Invalid solution	<ul style="list-style-type: none">• Press . Continue if possible.• If not possible, try to restart device.• If error appears again contact service.

Alarms and troubleshooting

Error messages

G43	Device fault	<ul style="list-style-type: none">• Confirm error message. Device will shut down.• Restart device.• If error appears again contact service.
G44	Sensor fault	<ul style="list-style-type: none">• Press  . Continue if possible.• If not possible, try to restart device.• If error appears again contact service.
G55T	Heater test error	<ul style="list-style-type: none">• Press  . Continue if possible.• If not possible, try to restart device after heating elements have cooled.• Ensure device is not exposed to direct sunlight.• Ensure device is being operated within specified operating conditions (IFU chapter 9.2).• If error appears again contact service.
G61T	Hydraulic sensor error	<ul style="list-style-type: none">• Press  . Continue if possible.• If not possible, try to restart device.• Ensure device is adjusted to ambient temperature (IFU chapter 9.2).• Perform extended system test (IFU chapter 9.5.3).• If error appears again contact service.
G62T	Length sensor error	<ul style="list-style-type: none">• Press  . Continue if possible.• If not possible, try to restart device.• Ensure device is adjusted to ambient temperature (IFU chapter 9.2).• Ensure device is being operated within specified operating conditions (IFU chapter 9.2).• If error appears again contact service.

Alarms and troubleshooting

Error messages

G72T	Valve test error	<ul style="list-style-type: none">• Press  . Continue if possible.• If not possible, try to restart treatment with new <i>sleep·safe</i> set and new solution bags.• Check patient line and catheter extension for kinks and/or closed clamps.• Ensure that double chamber bags are mixed.• If error appears again contact service.
G93T	Patient Pressure Monitoring	<ul style="list-style-type: none">• Press  . Continue if possible.• If not possible, restart device.• Check patient line and catheter extension for kinks.• Check patient line for correct positioning.• Ensure device is positioned at (or < 100 cm below) patient level. (IFU chapter 9.3)
G93	Pressure in patient line too high	<ul style="list-style-type: none">• Press  . Continue if possible.• If not possible, restart device.• Check patient line and catheter extension for kinks.• Check patient line for correct positioning.• Ensure device is positioned at (or < 100 cm below) patient level. (IFU chapter 9.3)
G94	Temperature not in operating range	<ul style="list-style-type: none">• Press  . Continue if possible.• If not possible, try to restart device.• Ensure device is being operated within specified operating conditions (IFU chapter 9.2).• Ensure proper positioning of solution bags to avoid air in tubing lines.• If error appears again contact service.

Alarms and troubleshooting

Error messages

G96	Air detected	<ul style="list-style-type: none">• Press  . Continue if possible.• If not possible, try to restart device.• Ensure tight connection.• Ensure proper positioning of solution bags to avoid air in tubing lines.• If error appears again contact service.
G99	Device fault	<ul style="list-style-type: none">• Confirm error message. Device will shut down.• Restart device.• If error appears again contact service.
G100	Device inactive	<ul style="list-style-type: none">• Press  . Continue if possible.• If not possible, try to restart device.• Respond to caution, in case of missing user interaction with caution screen.
G109T	Patient safety clamp error	<ul style="list-style-type: none">• Press  . Continue if possible.• If not possible, try to restart device.• Ensure patient line is correctly positioned in line guide of the loading tray.• Ensure proper positioning of solution bags to avoid air in tubing lines.• If error appears again contact service.
G110T	Heater relay error	<ul style="list-style-type: none">• Press  . Continue if possible.• If not possible, try to restart device after heating elements have cooled.• Ensure device is not exposed to direct sunlight.• Ensure device is being operated within specified operating conditions (IFU chapter 9.2).• If error appears again contact service.

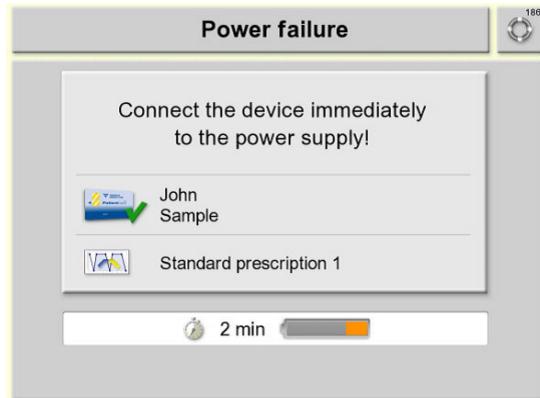
Alarms and troubleshooting

Error messages

G134T	Drain pressure monitoring	<ul style="list-style-type: none">• Check drain line for kinking.• Ensure outlet of drain line is within +/- 200 cm of cycler height (IFU chapter 9.3).• Press  . Continue if possible.• If not possible, try to restart device.• If error appears again contact service.
G155	Potentially insufficient treatment detected	<ul style="list-style-type: none">• The treatment was not performed as prescribed.• Press the  key to confirm the error message and disconnect the patient if necessary.• Contact the PD clinic as needed.

Alarms and troubleshooting

Power failure



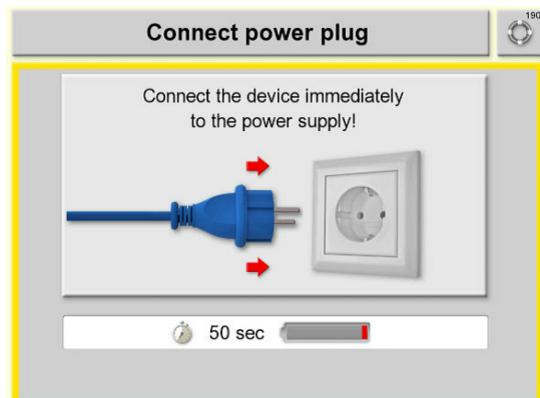
This screen will be displayed if the power supply for the *sleep-safe harmony* has failed.

The time remaining until the *sleep-safe harmony* will shut down is displayed on the bottom of the screen. If possible, restore power to the device.

If the power is not restored within 10 minutes, an alarm will sound.



Press the  key to mute the alarm.



If power cannot be restored in time, the treatment must be stopped. Disconnect yourself from the cycler.

Alarms and troubleshooting

Emergency shutdown

If the *sleep-safe harmony* is no longer responding 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.

Alarms and troubleshooting

Removing the *sleep-safe* set after premature termination of a treatment

Press the  key.



If the *sleep-safe* set is still in the *sleep-safe harmony* after a treatment has been prematurely terminated, press the  key in the lower right corner of the screen to open the loading tray.



Press the  key to move to the next step.

Alarms and troubleshooting

Removing the *sleep-safe* set after premature termination of a treatment



Gently pull both the patient line and the drain line upward to remove the lines from the line holders. Remove the *sleep-safe* set from the loading tray, as demonstrated in the onscreen animation.

Press the key to confirm removal of the set.

Dispose of the *sleep-safe* set, the solution bags and the drain line or drain bag. If using a drain bag, ensure that it is emptied prior to disposal.



Caution

Consumables must be discarded after the treatment according to the instructions provided by your dialysis center.

Appendices:

- A Icon list**
- B Glossary**
- C Handling solution bags**
- D Connecting polyglucose
(icodextrin) solution**
- E Cleaning / disinfection**
- F Contacts**

Appendix A

Icon list

	On / Off key		External key
	Start icon		Open loading tray
	Service login		Repeat animation
	Confirm input		Discard input
	Skip step		Return to previous step
	Repeat		Go to higher level screen
	Patient options menu		Device options
	Move selection up		Move selection down
	Increase value		Decrease value
	Audible signal off		Safety message
	Time		Treatment duration
	Patient volume		Volume balance
	Treatment progress		Patient card inserted
	Total treatment volume		Pediatric treatment

Appendix A

Icon list

	Inflow		Outflow
	Dwell duration		Cycle (inflow/dwell/outflow)
	Standard prescription		Adapted APD prescription
	Tidal prescription		Basic prescription
	PD-Plus prescription		Unknown prescription
	Parameter not profiled		Parameter profiled
	Calcium value		Solution (dialysate)
	Glucose concentration		Battery capacity
	Manual outflow		Please wait

Appendix B

Glossary

Aseptic technique: Actions intended to minimize the risk of infection due to touch contamination.

Catheter extension: A tube attached to your peritoneal catheter to allow connection to peritoneal dialysis equipment.

Consumable: An item that is discarded after use.

Contamination: The introduction of bacteria to an item or area that should remain sterile.

Dialysis solution: Fluid used in peritoneal dialysis to clear waste and excess fluid from the body.

Disinfection: The use of various chemicals to clean a device, surface, or hands.

Double chamber bag: A dialysis solution bag separated into two compartments by a seam.

Dwell: The phase of the treatment cycle during which your peritoneal cavity is full of dialysis fluid. The process of waste and fluid removal occurs during this phase.

Infection: An illness caused by harmful bacteria.

Inflow: The phase of the treatment cycle during which your peritoneal cavity is filled with fresh dialysis fluid.

Initial outflow: The drainage of peritoneal dialysis fluid from the peritoneal cavity at the start of your treatment.

Last inflow: The last inflow of dialysis fluid into the peritoneal cavity prior to disconnection.

Outflow: The phase of the treatment cycle during which fluid is drained from the peritoneum.

Patient connector: The end of the cycler set that connects to your catheter extension.

Appendix B

Glossary

Peritoneal cavity: The space between the layers of the peritoneum in the abdominal cavity.

Peritoneal dialysis: Dialysis using the peritoneal membrane to filter waste products and excess fluid.

PIN: A protective pin inserted into the catheter extension before disconnecting from the cycler set.

Prescription: The settings for your cycler therapy as determined by your dialysis center.

Priming: Procedure to fill the *sleep-safe* set with dialysis fluid before starting your treatment.

Sterile: Free of ALL bacteria.

Treatment cycle: A treatment cycle that includes three phases: inflow, dwell and outflow.

Volume balance: The amount of excess fluid that has been removed from your body during treatment. This is also known as ultrafiltration (UF).

Appendix C

Handling the solution bags

Check the following on each solution bag:



- The name of the dialysis solution matches that in the prescription.
- The glucose concentration and the calcium concentration match your prescription.
- The dialysis solution has not expired.
- The overwrap is not damaged.
- There are no leaks.
- The dialysis solution is clear.

Handling 5 litre double chamber bags



- Before using the bags, check that both PEEL seams are intact.
- Peel open the overwrap and remove the top layer. Leave the bag on the bottom layer to ensure that the bag and connector remain clean while you are mixing the solution.
- Unfold the small chamber and bag connector from underneath the bag.
- Roll the solution bag starting from the upper corner, diagonally opposite the bag connector, until the PEEL seam opens.
- Continue rolling the solution bag until the PEEL seam of the small chamber opens completely.

All PEEL seams should now be open.

- Mix the dialysis solution and confirm that there are no leaks.



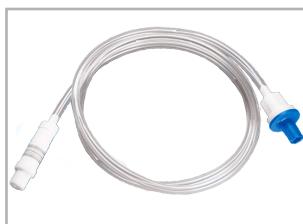
Warning

The double chamber bags should be connected to the cycler no later than 24 hours after mixing the dialysis solution.

Appendix D

Connecting polyglucose (icodextrin) solution

1. Uncoil and stretch/straighten the line attached to the Luer-Lock connector



2. Lay the PD bag on a table

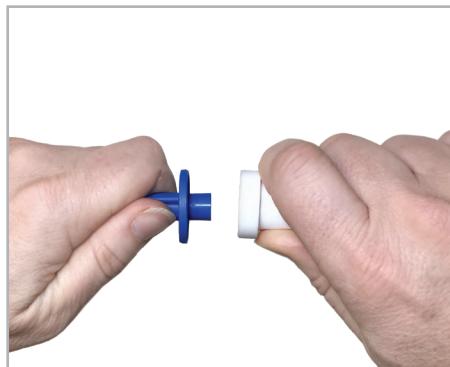


Important

Put on a face mask, disinfect your hands and then perform the following steps:



Remove the cap from the PD bag connector



Remove the blue cap from the Luer-Lock set

Appendix D

Connecting polyglucose (icodextrin) solution



Securely screw both connectors together



If necessary, break the cone (frangible) in the PD bag's tube



Tighten the Luer-Lock connection to ensure that it remains secure.

The bag is now ready to be connected to the *sleep·safe* cycler.

Just prior to priming a screen will appear to remind you to confirm that the cone is broken and the connection is secure.

Appendix E

Cleaning / Disinfection



Caution

Caution

- Do not submerge the *sleep-safe harmony*.
- Do not use solvent-based chemical cleaning agents.
- Use only a damp (not dripping) cloth for cleaning.
- Disconnect the *sleep-safe harmony* from the power supply before cleaning.

Cleaning interval

- As required (in case of contamination) or at least once a week

Parts to be cleaned

- Surfaces (housing, screen, loading tray)

Contacts



Customer Service



Technical Services



Doctor



Dialysis Center



Emergency Services



Other



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