CE 0123

LUVAR A/ LUVAR STA

Instructions for Use for patients

www.heyermedical.de

heyer

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heyer medical AG reserves the right to revise the contents of these instructions for use without prior notice or to replace them completely. Make sure that you always use the current version of the instructions for use. If you are unsure, contact your authorized dealer or find out more on the internet at www.heyermedical.de.

These instructions for use include 76 content pages.

The following documents are available in addition to these operating instructions for the LUVAR A/LUVAR STA are available:

- LUVAR A / LUVAR STA Instructions for Use for physicians and medical care staff
- Service manual

Table of contents

General Information

Read these instructions for use carefully before using the respiratory therapy device for the first time. Follow the important information provided in these instructions for use. Failure to do so may result in accidents as well as personal injury and damage to property. There are no known residual risks when using the respiratory therapy device beyond those stated in these instructions for use.

Keep these instructions for use near the device. Protect the instructions for use from loss or damage. They are part of the device being described and must be available at all times.

Use the device exclusively for the purpose defined in these instructions for use. Prior to use, instructions on how to use the device, known contraindications and any precautions to be taken must be provided by the prescribing physician or healthcare provider. The information contained in these instructions for use does not replace such instructions.

Safety information

Important information is specially marked in these instructions for use.

Marking	Description
⚠ **WARNING**	This symbol indicates hazardous situations which may result in injury to the user, operator or a third party.
CAUTION	This symbol indicates hazardous situations where damage to property may occur.
Note:	Notes identify useful information for how to use the device efficiently.

⚠ WARNING: Risk of injury if device is used outside the specified environmental conditions!

- Only use the device and humidifier in the intended environmental conditions (see “Environmental conditions” in “Technical data”). Use outside the prescribed environmental conditions may cause injury to the patient by impairing the quality of therapy as well as premature aging of device parts.

⚠ WARNING: Risk of injury due to incorrect device settings!

- Settings of the therapy parameters on the device may only be made by qualified, instructed medical staff under the supervision of a physician.

⚠ WARNING: Risk of infection due to contamination!

- The information in these instructions for use and the applicable regulations at the hospital or care facility must be observed in order to reprocess and clean the device hygienically.
- Replacement intervals for accessories and consumables must be observed.

⚠ WARNING: Risk of injury due to limited usability!

- If you notice inexplicable changes in the performance of the device, if it makes unusual or unpleasant noises, if the device or the power supply were dropped or otherwise mechanically damaged, if water has entered the device, or if the device is obviously damaged, stop operation and contact your healthcare provider. In case of water damage, immediately disconnect the device from the power supply.
- Any modification to the device may jeopardize its ability to be serviced and is not permitted.
- Do not perform any work on the device while it is in operation. This includes leaning and upkeep as well as maintenance, such as changing the air filter. Such work may cause damage to the device, which will affect its ability to be serviced.
- Using the respiratory therapy device together with incompatible equipment (e.g. humidifier, water tank or air filter) and accessories (e.g. tubes and masks) may reduce device performance. Therefore, only use this respiratory therapy device with the devices and accessories recommended in these instructions for use.

Electrical safety

⚠ WARNING: Risk of injury from electric shock!

Do not attempt to open the device or the power supply unit. Service and maintenance may only be carried out by persons authorized by heyer medical AG.

- Do not touch any exposed, live parts of the power cable or power supply unit.
  ⇨ Replace any defective power cable or power supply unit.
- The power supply unit is part of the respiratory therapy device. Only use the power supply unit supplied with delivery or genuine replacement power supply units.

⚠ WARNING: Risk of injury due to electromagnetic interference!

- The use of accessories, transducers and cables not specified or supplied by the manufacturer of this device may result in increased electromagnetic emissions from, or decreased electromagnetic immunity for, this device and may result in this or other devices not functioning correctly.
- Portable RF communication devices (including peripherals such as antenna cables and external antennas) should not be used closer than 30 cm to any part of the device, including the cables connected to the device. Otherwise, degradation of the performance of this device may result.
- Use of this device adjacent to or stacked with other equipment should be avoided as this may result in improper operation. If such use cannot be avoided, this device and the other devices should be monitored to ensure that they are functioning properly.
- Electrostatic discharge of the user via the device can impair the quality of respiratory therapy. Therefore, do not use electrically conductive or electrostatically chargeable patient tubes.

For detailed information on possible electromagnetic interference, refer to section „Electromagnetic compatibility “.

Transport and storage information

CAUTION: Risk of device damage due to improper transport and storage!

- Do not transport or tilt the device while the water tank is full, to prevent water getting into the device.
- Only transport and store the device and the humidifier in the intended environmental conditions (see “Environmental conditions” in “Technical data”).
- Only transport the device in the transport bag supplied, and store the device in the transport bag when not in use for prolonged periods to prevent dirt, dust and insects from getting in.

Scope of delivery

After unpacking, make sure everything is present and undamaged.

	LUVAR respiratory therapy device		H100 respiratory humidifier
	Power supply unit		SD card
	Power cable		Transport bag
	CPAP breathing tube		Patient instructions for use
	Air filter (set of 5)		Leaflet current instruction for use patients

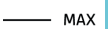
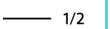
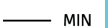
Accessories (optional)

The following accessories are available for use with the device. Contact your dealer for more information about the accessories.

	Air filter module (PM 2.5 – pollen filter) coarse/fine		Nasal mask
	Nasal pillow mask		

Symbols

Symbols on the device and humidifier

	„Humidifier“ sensor button
	„Ramp“ sensor button
	Observe instructions for use!
	Inlet (air inlet)
	Outlet (air outlet)
	SD card slot
	Maximum fill level
	Half fill level
	Minimum fill level
	Do not tilt
	Fill with water here
	Do not fill with water here
	Serial number
	Date of manufacture
	Medical Device
	Typ BF applied part
	Electrical protection class II
	Observe the instructions for use supplied!

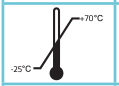
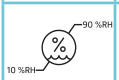
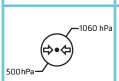
IP22	Protection against harmful ingress of: • solid foreign bodies with a diameter of 12.5 mm and above, and • falling dripping water when the housing is tilted by up to 15°.
	The device does not feature an alarm system
UDI	Unique Device Identifier
	Manufacturer
	The product contains electrical and electronic components. It must be disposed of in accordance with the appropriate local, state and federal regulations.
CE 0123	This device meets the requirements of Regulation (EU) 2017/745 or medical devices (MDR).
	Warning of hot surface – risk of burns!
	Do not touch!
Max:30W	30 watts maximum heating power

Symbols on the power supply unit

	Timescale during which hazardous substances are not expected to suddenly escape under normal operating conditions: 10 years
	Electrical protection class II
	For indoor use only
RoHS	Restrictions on the use of certain hazardous substances in electrical and electronic equipment
CE 0123	The device complies with the product-specific European directives.
IP22	Protection against harmful ingress: • of solid foreign bodies with a diameter of 12.5 mm and above • of falling dripping water when the housing is tilted by up to 15°.

	The product contains electrical and electronic components. It must be disposed of in accordance with the appropriate local, state and federal regulations.
	Observe the instructions for use supplied!

Symbols on the packaging

	This way up
	Fragile contents
	Keep dry
	Carton must not be rolled
	Permissible temperature range
	Permissible humidity range
	Permissible atmospheric pressure range
	Max. stacking quantity

Icons in the icon bar on the screen

	Go to home screen
	SD card in device is working properly
	SD card full or faulty
	In standby: Respiratory humidifier detected by device During therapy: Respiratory humidifier OFF (heat setting 0)

	In standby: Preheating function active on respiratory humidifier (30 minutes) During therapy: Respiratory humidifier active
	At least one wake-up alarm active
	Leakage detected
	Bacterial filter (activated pressure drop compensation)
	Filter life expired / change filter element
	Blower service cycle reached / service
	Electronic instruction for use

Terms

Apnea (A)

Apnea, in diagnostic terms, is a reduction in airway flow of more than 90 % for at least 10 s. This respiratory therapy device monitors airflow and can thus estimate when apnea has occurred.

Hypopnea (H)

Hypopnea, in diagnostic terms, is a reduction in airway flow of at least 30% for at least 10 s associated with a reduction in oxygen saturation of at least 3%. This respiratory therapy device monitors airflow and can thus estimate when hypopnea has occurred

Apnea-hypopnea-index (AHI)

In diagnostic terms, the apnea-hypopnea index is the average number of apnea and hypopnea events occurring per hour of sleep. This respiratory therapy device records the duration of therapy, as well as changes in respiratory airflow, which it evaluates as apnea or hypopnea events. These data are used by the device to calculate the average number of such events per hour of therapy.

Other terms

Terms	Meaning
Frequency (Freq)	Breaths per minute (bpm)
Tidal volume (VT)	Volume of air inhaled and exhaled during one breath in milliliters (ml)
Leakage	Volume of air escaping unused between device and patient in liters per minute (l/min).
Minute volume (MV)	Volume of air inhaled and exhaled over the course of one minute in liters (l/min).

Intended purpose

The CPAP and BiLevel system is intended as an active therapeutic medical device for the treatment of sleep-related breathing disorders or forms of respiratory insufficiency in patients weighing more than 30 kg.

The clinical benefit of CPAP and BiLevel therapy for obstructive sleep apnea is a reduction in apneas and hypopneas.

⚠ WARNING: Patient hazard due to use outside the intended purpose!

- **Sleep apnea respiratory therapy devices cannot be used for life-sustaining measures. They are generally not suitable for patients who require ventilator support or are dependent on a ventilator, or for patients who have had a tube inserted through the mouth or through an incision in the windpipe (endotracheal intubation or tracheostomy).**

This respiratory therapy device is intended for use and operation by a single untrained user at a time, under professional supervision, in health care facilities or unsupervised in home health care.

The expected service life, assuming average daily use of 8 hours, is 5 years.

Indications

The LUVAR series devices can be used for the following indications::

LUVAR A
- Obstruction sleep apnea syndrome (OSAS)

LUVAR STA
- Obstruction sleep apnea syndrome (OSAS)
- Respiratory failure

Contraindications

⚠ **WARNING: Risk of injury due to non-observance of contraindications!**
The use of respiratory therapy in conjunction with certain pre-existing conditions can lead to injuries to the patient. Please observe the following notes in this regard.

The respiratory therapy device must not be used under the following circumstances:
- **pneumothorax (accumulation of air between the lungs and chest wall),**
- **pneumocephalus (accumulation of air in the cranial cavity),**
- **pathologically low blood pressure,**
- **severe bullous lung disease (permanent air-filled spaces in lung tissue),**
- **dehydration (lack of body fluids).**

Side effects

The following side effects may occur while having therapy with LUVAR devices:

- Skin injury on the face, nose or bridge of the nose due to incorrect mask pressure or old mask cushion
- Skin irritation due to an allergic reaction to the mask
- Eye irritation, swollen eyes due to leakage from the mask
- Patient feels claustrophobic due to face mask being too large and finding difficulty putting it on
- Stomach becomes bloated due to therapy pressure being too high, or swallowing air
- Dry mouth/throat due to breathing air being too dry or insufficiently humidified, or sleeping with mouth open
- Ear or sinus trouble
- Nosebleeds, runny nose, sneezing and colds
- Chest pain (discomfort)

Note: Using the H100 humidifier and/or a more appropriate respiratory mask may reduce side effects that occur, such as dry mouth, nose and throat, nose-bleeds,runny nose, sneezing and colds.

An irregular sleep pattern, alcohol consumption, obesity, sleeping pills or sedatives may make your symptoms worse. Contact your physician if the symptoms of sleep apnea recur or if you have any questions about your therapy.

User training

The LUVAR respiratory therapy device is used in home health care settings by untrained users without direct professional supervision, as well as in professional health care settings. The device may only be used on the instructions of a physician.

The parameters for respiratory therapy may only be set by and under the supervision of medical personnel who have been trained in the operation and handling of the device by heyer medical AG or authorized dealers. These people must be familiar with how to operate the device and must have read and understood the instructions for use in full before starting up the device. They must instruct patients in how to operate and handle the device.

The patient is an intended user, can use all device functions and can operate and maintain the device in accordance with these instructions for use. The user must have attended school for at least 8 years, possess basic word and number reading skills, and be familiar with operating electronic equipment.

Principle of operation

The microcontroller-controlled blower installed in LUVAR series respiratory therapy devices draws in filtered ambient air, generates a positive pressure between 4 hPa and 20 hPa (BiLevel: 4 hPa and 25 hPa) and channels this to the air outlet. Air flows from the outlet into the patient through a tube and a breathing mask and, as positive airway pressure, keeps the patient's airways open. Depending on how it is set up, the LUVAR respiratory therapy device can respond to specific events by adapting the airway pressure.

The LUVAR A is a respiratory therapy device that maintains a certain continuous pressure level (“continuous positive airway pressure”, or “CPAP” for short).

The LUVAR STA is a respiratory therapy device that alternates between different pressure levels for inhalation and exhalation (BiLevel). This change between pressure levels can be controlled by the patient's breathing pattern or by time.

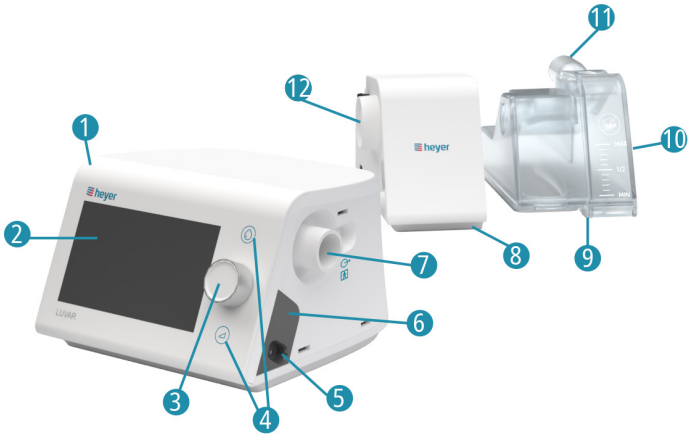
The pressure levels are set to specific values by the physician in the standard modes. Alternatively, it is possible for the physician to specify upper and lower pressure limits in the "Auto" modes, when the device sets the pressure according to events.

Note: On the following pages, all pressures are specified in hPa. Use the following table to convert to mbar and cmH_2O:

Pressure	hPa	mbar	cmH_2O
1 hPa	-	1	1,02
1 mbar	1	-	1,02
1 cmH_2O	0,98	0,98	-

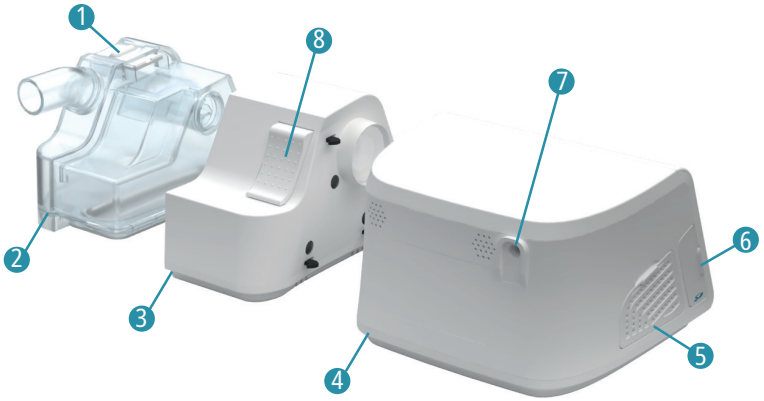
Product description

Front of device



1	LUVAR respiratory therapy device
2	Touch Screen Displays device information, selection and navigation within the menus and sets parameters by touching the screen
3	Rotary knob Selection and navigation within the menus and setting parameters
4	Sensor keys for humidifier and ramp function
5	Power supply connector for humidifier Supplies electrical voltage to the humidifier
6	IR data interface Used for communication between the respiratory therapy device and humidifier
7	Device air outlet Connection for the breathing tube system or the respiratory humidifier
8	Humidifier housing
9	Water tank
10	Fill level markings
11	Humidifier air outlet Connection for the breathing tube system
12	Humidifier air inlet

Rear of device



1	Water tank release button
2	Water tank
3	Humidifier housing
4	LUVAR respiratory therapy device
5	Filter cover
6	SD card cover
7	Respiratory therapy device power supply connection Supplies electrical voltage to the respiratory therapy device
8	Humidifier release button

Electronic slots

An SD card slot and a slot for electronic accessory modules are located under the SD card cover on the left side of the respiratory therapy device. These slots are intended to be used

- by patients and medical staff
- with the SD cards and accessory modules provided by heyer medical AG.

The slots are not intended for controlling the operation of any other medical device or accessory.

Using for the first time

Before using this respiratory therapy device for the first time, check for obvious damage. Do not operate the device if the housing or any cables on the device or power supply unit are damaged.

If the respiratory therapy device has been exposed to unusually high or low ambient temperatures, give the device time to adjust to room temperature before use – up to 2 hours, depending on the temperature difference.

Report any serious incidents that occur in relation to the device to the manufacturer and the competent authority.

If you need assistance with operating the device for the first time, or using or cleaning it or wish to report unexpected operation or incidents, please contact the specialist dealer who supplied the device. If they cannot be contacted, you can also contact heyer medical AG directly.

Setting up the device

⚠ WARNING: Risk of injury due to restricted air supply!

- **The device must not be covered or positioned in such a way that the air flow to the device is completely or partially blocked, in order to avoid reduced performance and the device overheating.**
  - **⇨ Do not place the device near curtains.**
  - **⇨ Make sure the area where the device is placed is dry, clean and free of bedding, clothing or other objects that may block the air intake.**

⚠ WARNING: Risk of fire and burns!

- **Oxygen sources must be more than 1 m away from the device to avoid the risk of fire and burns.**

CAUTION: Risk of damage to device due to water ingress!

- **Make sure that the device is protected from water when used outdoors.**

Place the device on a firm, level surface next to the bed (e.g. on a bedside table).

Make sure that the device is securely positioned and cannot be knocked by anything. The position must allow sufficient space for the device itself as well as the component parts connected during operation.

The device draws in dry ambient air for respiratory therapy through the air filter on the left side of the device. To avoid obstructing the air supply, the device should be at least 20 cm away from walls and other objects at all times. Avoid placing near radiators and room humidifiers. To avoid the material aging prematurely, the device should not be placed anywhere exposed to direct sunlight at any part of the day.

Connecting the power supply

1. Connect the power cable to the power supply unit.

Note: The power cable serves as a device for quickly and fully disconnecting the respiratory therapy device from the power supply at any time. Therefore, always position the power cable so that you can easily disconnect it from the power outlet or the power supply unit.

2. Insert the angled DC plug on the power supply unit into the power supply connection on the respiratory therapy device.
3. Lay the power cable so that no one can trip over it and insert the power plug into the mains socket (100-240 VAC, 50/60 Hz).

The device will start up automatically. The flash screen showing the heyer logo is displayed for around 20 seconds. The display then switches to the home screen and the device is ready for operation.

Inserting the air filter

Note: The air filter prevents particles 10 µm and above from getting in. Never operate the device without the air filter. Only use the air filters recommended by heyer medical AG.

1. On the left of the device, remove the filter cover from the device inlet opening.
2. Remove a white air filter from its packaging and place it in the device inlet opening.
3. Replace the filter cover. It should click into place under slight pressure.

Connecting the breathing tube system

1. Ensure that all parts and accessories used for connection to the patient are compatible with each other and with the respiratory therapy device and, if applicable, the humidifier.

⚠ WARNING: Risk of injury due to incorrect accessories!

- **Do not attach any additional parts or accessories to the device or the humidifier that are not listed in these instructions for use, as otherwise the device or the humidifier may not function properly. This may reduce the quality of the therapy or cause injury to the patient.**
- **Only use breathing tubes that comply with ISO 5367 and ISO 80601-2-74 to prevent the tube from coming loose during therapy and to prevent the tube from being adversely affected by heat emitted from the humidifier.**

⚠ WARNING: Risk of suffocation if exhalation system is not used!

- **Failure to use a mask or an accessory that minimizes the rebreathing of CO_2 or enables spontaneous breathing can lead to suffocation.**

  ⇨ Use only masks with an integrated exhalation system, such as those listed in these instructions for use under "Accessories" or use an exhalation system between the mask and the breathing tube.

2. Connect one end of the tube to the air outlet on the respiratory therapy device. If using the humidifier, connect the end to the air outlet on the humidifier.
3. Connect the other end of the breathing tube to the mask.

Note: Mask materials coming into contact with the skin may cause a rash, soreness or itching in people who are allergic. To avoid allergic reactions wherever possible, we recommend the use of the masks listed under "Accessories".

⚠ WARNING: Risk of injury due to therapy air being too hot!

- **Covering the breathing tubes with a blanket and heating them with a heater can impair the quality of the therapy or cause injuries to the patient.**

4. Run a mask check every time the breathing tube system is changed or a new mask is being used. For instructions, refer to the “Patient settings” section under “Mask calibration”.

Note: When using the tube and mask, follow the manufacturer’s specifications in the relevant instructions for use.

⚠ WARNING: Risk of injury from breathing tube system and cables!

- Incorrect routing of the breathing tube system or long cables can lead to injury or suffocation
  - ⇨ **Lay the tube system and cables carefully so that they cannot wrap around the neck and tighten**
  - ⇨ **Do not use any small parts that can be inhaled or swallowed to fix the tube system or cables.**

5. Arrange the breathing tube so that you can move around during therapy without the tube pulling on the mask.

Operation with the H100 respiratory humidifier

To humidify the respiratory air, the device can be operated using the easily integrated H100 respiratory air humidifier. The humidifier has a heater that warms the humidifier water. Before using the humidifier, be sure to read the safety and cleaning instructions in these instructions for use.

The LUVAR respiratory therapy device is needed in order to use the H100 humidifier. When operating the respiratory air humidifier, use only the accessories supplied or recommended for this respiratory therapy device.

Note: Humidifier output ranges from > 12.5 mg/l up to the maximum therapy pressure, as per ISO 80601-2-74.

Note: The humidifier requires a sufficient amount of water in the water tank to function correctly, (fill level between the “MIN” and “MAX” markings).

Connecting the respiratory humidifier

1. Make sure that the respiratory therapy device is placed on a level surface. There must be enough space to the right of the device to easily disconnect and reconnect the humidifier or its water tank.

Note: The respiratory therapy device should be positioned so that it is lower than the patient when lying down. This allows condensation to flow back into the humidifier and not collect in the breathing tube and mask

2. Bring the humidifier towards the respiratory therapy device from the right and line up the device and humidifier housings side by side.

3. Press the humidifier gently against the device until it clicks into place.
4. Fill the water tank as described in section “Filling the water tank”.

Filling the water tank

The water tank has a capacity of 300 ml. This is sufficient to operate for 8 hours at the maximum heating level. Proceed as follows to fill the water tank:

1. Press the release button on the water tank and pull it out sideways.

2. Turn the humidifier air outlet upwards for filling.

3. Hold the water tank horizontally and fill it up to the MAX mark. If possible, use cold and soft water of drinking quality.

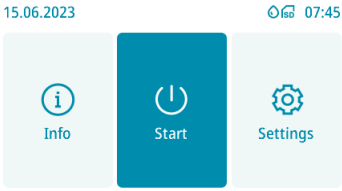
Note: Do not use any additives, such as fragrance oils or perfumes, as these can reduce the humidifier output and damage the water tank material.

4. Push the water tank sideways into the humidifier until it clicks into place.
5. Connect the breathing tube and mask as described in section "Connecting the breathing tube system"

Preheating the respiratory humidifier

In order for the humidifier to deliver full performance right from the start of therapy, it can be activated before the therapy starts. Preheating time is 30 minutes.

1. Connect the humidifier and fill the water tank as described above.
2. Connect the device to the power supply and wait until it displays the home screen.



   At the top right of the screen, an empty water droplet symbol next to the time indicates that the humidifier has been detected by the respiratory therapy device.
3. Press and hold the sensor button above the rotary knob for approximately one second. The water droplet symbol on the screen fills up, indicating that the humidifier is heating up.

   The preheating process can be stopped at any time by pressing and holding the sensor button above the rotary knob again for about a second.

Using an SD card

An SD card is included in the scope of delivery for the respiratory therapy device. When the SD card is inserted, the data recorded during therapy are written to the SD card. Your physician can read out and evaluate the data from the SD card to monitor therapy.

Note: No SD card is needed for the device to operate. The device has an internal memory for therapy data and settings.

Inserting the SD card

Only insert the SD card with the device switched off or in standby mode. The slot for the SD card is located on the left side of the device behind the SD card cover.

1. Remove the SD card cover.
2. Push the card into the slot. The “missing corner” of the SD card should face upwards and towards the device. Push the SD card in all the way until you hear a soft click from the slot lock.

3. Replace the SD card cover.

If there are already recorded therapy data on the respiratory therapy device, these will be written to the SD card – once the SD card has been successfully scanned. After inserting an SD card, it can therefore take several minutes until the device is ready for operation again.

Saving therapy data on the SD card

The therapy data are automatically saved on the SD card. The save process runs

- after therapy is complete
- and after inserting a new SD card in standby mode.

Removing the SD card

Only remove the card with the device switched off or in standby mode to avoid corrupt data on the SD card.

1. Remove the SD card cover on the left side of the device.
2. Press the SD card momentarily, until you hear a soft click from the slot lock. The SD card then slightly protrudes from the slot.
3. Remove the SD card.
4. Replace the SD card cover.

Controls

Individual menus are navigated and relevant parameters selected using the touch-sensitive display or alternatively the rotary knob.
Note: If the controls are not used for 30 seconds, the screen changes to the home screen or, if therapy is in progress, to the therapy screen.

Touch control

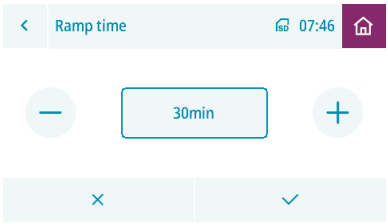
The touch-sensitive display makes it possible to access the various screens and menus and make settings by touching displayed objects.

To return to the menu level above, touch the back button ‹ in the upper left corner of the screen.

To return directly to the home screen, touch the home screen button in the upper right corner of the screen.

Setting a parameter

To change the setting of a parameter, call up the parameter by touching it in the relevant menu – in our example, the “Ramp time” parameter in the “Settings” > “Comfort” menu.



1. Change the setting by touching the plus or minus button repeatedly until the desired value is reached.

2. Touch the check mark button to apply the new value and exit the parameter screen. Alternatively, touch the cancel button with the cross to exit the parameter screen without accepting the new value.

Rotary knob control

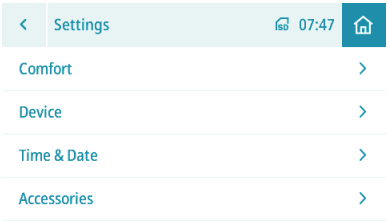
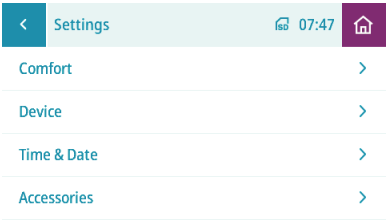
When operating the device via the rotary knob, objects are selected on the display by turning the knob left/right. The currently selected object is highlighted in color. Pressing the knob activates the selected object.

Object color	Meaning
	Not selected
	Selected

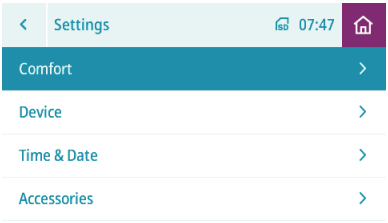
The following icons are used in the description of the action steps below.

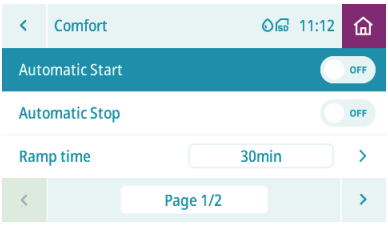
Icon	Meaning	Device response
	Turning the knob to the left (counterclockwise))	Selects the object to the left of the current selection/changes to the line above
	Turning the knob to the right (clockwise)	Selects the object to the right of the current selection/changes to the line below
	Pressing the knob	Activates the selected object

Selection in the icon bar

 Home button (top right) is selected	 Pressing the rotary button takes you back to the home screen.
	Turning to the left selects the back button.
 Back button (top left) is selected	 Pressing the rotary button takes you back to the previous screen.

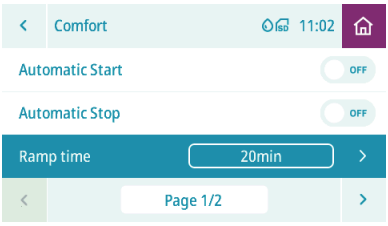
Selecting from a list

 “Comfort” menu is selected	 Turning the knob to the right/left selects the respective menu items from the list. Pressing the rotary knob confirms the menu item selection, in this case “Comfort”.



"Comfort" menu is displayed

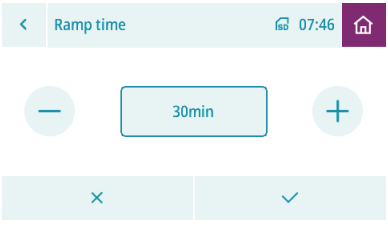
Turn the knob to the right in the "Comfort" menu until the "Ramp time" menu item is selected.



"Ramp time" is selected

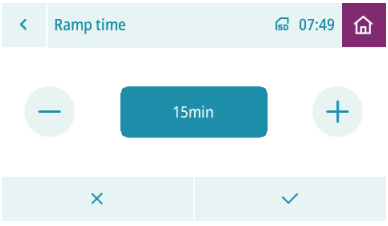
Pressing the rotary knob selects the settings screen for the selected parameter.

Setting a parameter



Parameter window

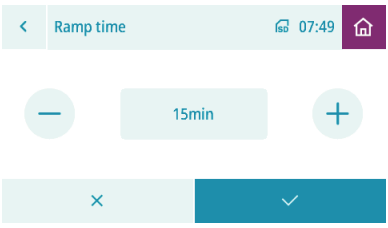
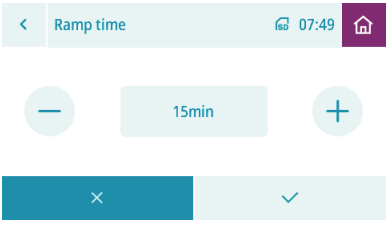
Pressing the rotary knob enables you to change the parameter.



Changed parameter value

Turning the knob to the left/right changes the displayed value.

Pressing the rotary knob takes you to the choice between "cancel" and "apply" the setting.

 Apply is selected	 Pressing the rotary knob applies the set value and exits the menu.
	Turning the knob to the left selects the cancel button.
 Cancel is selected	 Pressing the rotary knob discards the set value and exits the menu item.

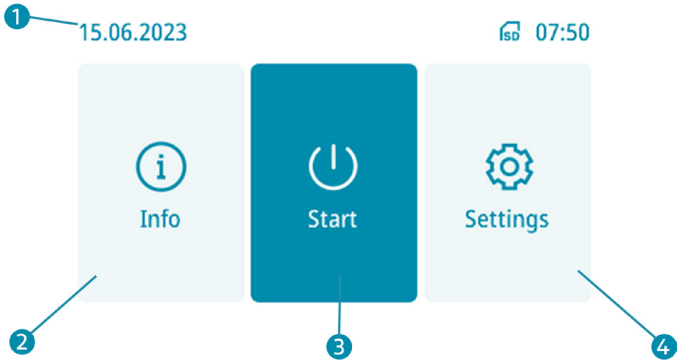
Sensor buttons

The sensor buttons above and below the rotary knob provide quick access to specific functions or settings.

Icon	Meaning	Device response
	Humidifier	• Pressing for approximately 1 second in standby mode: Activate/deactivate preheating for the respiratory humidifier. • Pressing for approximately 1 second during therapy: Switch to next heating level. • Pressing for more than 3 seconds during therapy: Cycle through all heating levels (until the sensor button is released). • The setting of the heating levels via the sensor key only applies to the current therapy. When the next therapy is started, the heating level set via the comfort settings or the accessory parameters is used again.
	Ramp	• Pressing for approximately 1 second during therapy: Restart the ramp (ramp time begins again). • Pressing for approximately 3 seconds during therapy: Cancel the ramp (switch to full therapy pressure).

Screens

Home screen

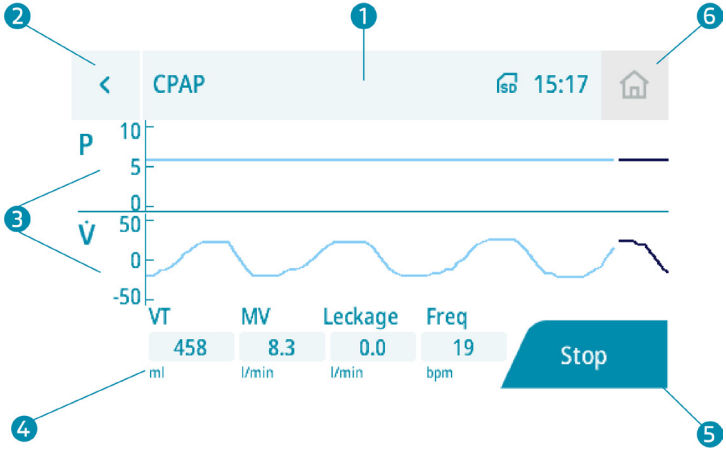


1	Icon bar Date | Icons (see page 14) | Time
2	“Info” button Access to the information menu
3	“Start“ button Starts the predefined therapy
4	“Settings” button Access to the patient settings menu

Therapy screen (standard)

1	Icon bar Mode indicator | Icons (see page 14) | Time
2	“Advanced therapy screen” button takes you to the advanced therapy screen during current therapy session
3	Reading display Tidal volume and leakage
4	“Comfort settings” button Shortcut to the settings for heating level and ramp time
5	Reading display Airway pressure
6	“Stop” button ends the current therapy session
7	Comfort value display Current heating level and remaining ramp time
8	“Home screen” button (deactivated) takes you back to the home screen after therapy is finished

Therapy screen (advanced)



1	Icon bar Mode indicator | Icons (see page 14) | Time
2	“Back“ button switches back to the standard therapy screen
3	Reading display graphic Pressure curve (“P“, depending on setting in hPa, mbar or cmH_2O) and flow curve (“$\dot{V}$“, in l/min)
4	Numeric display reading Tidal volume, minute volume, leakage and breathing frequency
5	“Stop“ button ends the current therapy session
6	“Home Screen“ button (deactivated) takes you back to the home screen after therapy is finished

Info screen

From the home screen, you can access the information area. This is where you can display analyses of the recorded data of your therapy for a selectable time period.

Information	Description
Valid Days	This value indicates the number of days when therapy was active for at least 4 hours.
Therapy	This value shows you how long you were treated with the device.
Leakage	Average leakage.
IPAP 95*	The value indicates the result of the statistical calculation of the 95th percentile from inspiratory positive airway pressure.
IPAP 50*	The value indicates the result of the statistical calculation of the 50th percentile from inspiratory positive airway pressure.
IPAP 5*	The value indicates the result of the statistical calculation of the 5th percentile from inspiratory positive airway pressure.
EPAP 95*	The value indicates the result of the statistical calculation of the 95th percentile from expiratory positive airway pressure.
EPAP 50*	The value indicates the result of the statistical calculation of the 50th percentile from expiratory positive airway pressure.
EPAP 5*	The value indicates the result of the statistical calculation of the 5th percentile from expiratory positive airway pressure..
MV 95*	The value indicates the result of the statistical calculation of the 95th percentile from the minute volume.
MV 50*	The value indicates the result of the statistical calculation of the 50th percentile from the minute volume.
MV 5*	The value indicates the result of the statistical calculation of the 5th percentile from the minute volume.
VT 95*	The value indicates the result of the statistical calculation of the 95th percentile of tidal volume.
VT 50*	The value indicates the result of the statistical calculation of the 50th percentile of tidal volume.
VT 5*	The value indicates the result of the statistical calculation of the 5th percentile of tidal volume.

Freq 95*	The value indicates the result of the statistical calculation of the 95th percentile from respiratory rate.
Freq 50*	The value indicates the result of the statistical calculation of the 50th percentile from respiratory rate.
Freq 5*	The value indicates the result of the statistical calculation of the 5th percentile from respiratory rate..
AHI (Apnea/ Hypopnea Index)	This value shows you the average number of apnea and hypopnea events during one hour of sleep.
AI (Apnea Index)	This value shows you the average number of apnea events during one hour of sleep.
HI (Hypopnea Index)	This value shows you the average number of hypopnea events during one hour of sleep
CAI (Central Apnea Index)	This value shows you the average number of central apnea events during one hour of sleep.
OAI (Obstructive Apnea Index)	This value shows you the average number of obstructive apnea events during one hour of sleep.
MAI (Mixed Apnea Index)	This value shows you the average number of mixed apnea events during one hour of sleep.
SNI (Snore Index)	This value shows you the average number of snoring events during one hour of sleep.

** These data are only displayed on the LUVAR STA depending on the selected mode.*
Note: The data displayed always refer to the selected time period as shown below.

Parameter	Setting range **Standard**	Description
Time period	**Last night** 1 week 1 month 2 month 3 month 6 month 1 year	This is where you can select the time period for which you want to display the information.

Starting the therapy

1. Make sure that all components are connected and the device is connected to the power supply. The device should be in standby mode and display the home screen.
2. Put the mask on. Correct positioning and location of mask on the face is crucial for correct device function. Note the mask's instructions for use.
3. Press the "Start" button or, if the "Automatic Start" function is activated (see "Setting a comfort parameter"), breathe in and out with the mask on in order to start the therapy.

Note: The device is operated either via the touch screen or via the rotary knob (turn to select, press the knob to confirm). For detailed information on how to operate, refer to section„Controls".

Note: Check the mask for correct positioning. It is normal for a small amount of air to escape. If larger amounts of air escape, the mask fit should be corrected following the specifications in the relevant instructions for use.

Note: The display automatically goes dark after 1 minute. The therapy continues as normal. Whenever you touch the display or operate the rotary knob, the therapy screen is displayed again. The automatic screen timeout can be deactivated (see "Setting device parameters"). We recommend leaving the automatic screen timeout on so that you can sleep undisturbed.

During therapy, you can switch to the advanced therapy screen or make changes to the ramp time and heating level. For more information on the therapy screen, see section "Therapy screen (standard)".

In the event of a power failure, the respiratory therapy device informs you with a brief audible signal. All settings are retained. Once the power supply returns, the therapy can be restarted as usual.

Terminating the therapy

In order to terminate the therapy, press and hold the "Stop" button while 3 seconds are counted down as shown on the screen.

If the "Automatic Stop" function is activated (see "Setting a comfort parameter"), simply take off the mask. The therapy will then be terminated automatically after approx. 5 seconds.

Switching off the device

Once therapy is complete, the device goes into standby mode again. If the automatic screen timeout is activated, the screen switches off after 5 minutes. The device can remain in this operating mode continuously without any danger.

To switch off the device completely, you can disconnect the power plug from the socket or the angled DC plug from the respiratory therapy device.

Patient settings

From the home screen, you can access the patient settings menu, where you will find submenus for comfort parameters, device parameters, time and date and accessory parameters.

Setting a comfort parameter

On the home screen, select the "Settings" button and navigate to the "Comfort" item in the "Settings" screen.

Parameter	Setting range ***Standard***	Description
Automatic Start	***ON*** OFF	Activate or deactivate automatic switch-on here. If this function is activated, therapy begins as soon as you inhale and exhale. If this function is deactivated, you must start therapy using the “Start” button.
Automatic Stop	ON ***OFF***	Activate or deactivate automatic switch-off here. If this function is activated, therapy ends 5 seconds after taking off the mask. Therapy will also end if the mask slips off your face or there is leakage that cannot be compensated for. If this function is deactivated, you must end the therapy using the “Stop” button.
Ramp time	5 … ***30*** … 60 min	The ramp function makes it easier to get used to the therapy pressure while going to sleep. This is where you can set the time over which the pressure increases from the start pressure (ramp start pressure) to the therapy pressure. If the ramp time is switched off, therapy starts immediately with the prescribed therapy pressure. *Note: The start pressure is set by your physician between 4 hPa and the prescribed therapy pressure.*

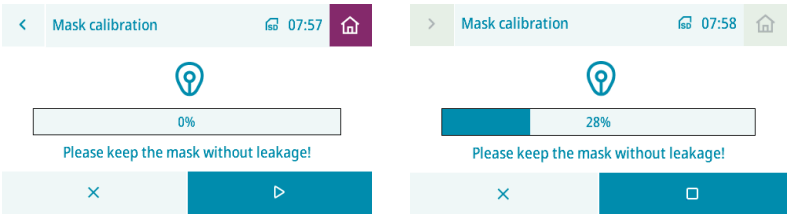
Parameter	Setting range ***Standard***	Description
breasyflex breasyflex in breasyflex ex	 OFF 1 ***2*** 3 OFF 1 ***2*** 3	For a description of this function, see the "Comfort functions". *Note: The function is only available in the CPAP and Auto CPAP modes.* You can set the degree of reduction here. (3 increments of 1 hPa each). *Note: Changing the level is only possible if the function has been enabled in the clinic menu.*
Mask calibration	Start	For a description of this function, refer to section "Mask calibration" (see below).

Mask calibration

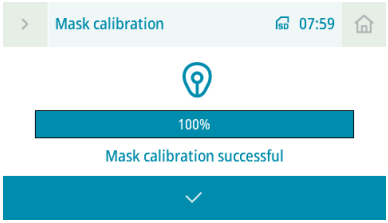
Mask calibration calculates the unavoidable leakage from the respiratory system under the best possible conditions. The leakage from the respiratory system determined during calibration is stored and will be subtracted from the leakage reading during future respiratory therapy sessions so that the respiratory therapy device only takes into account the additional leakage that can be influenced by the user.

Calibrate the mask each time the breathing tube system and breathing mask are replaced, as follows.

1. Select the "Mask Calibration" list item in the "Comfort" menu.
2. Seal the breathing mask completely, as if it were fitting perfectly on your face.
3. In the calibration screen, select the start button with the triangle pointing to the right. The device then applies pressure to the breathing system and measures the leakage. The calibration can be cancelled at any time using the stop button with the square and then restarted.



4. After the mask has been successfully calibrated, the apply button with the check mark takes you back to the “Comfort” menu.



Setting device parameters

On the home screen, select the “Settings” button and navigate to the “Device” item in the “Settings” screen.

Parameter	Setting range ***Standard***	Description
Display timeout	***ON*** OFF	Activate or deactivate automatic screen timeout here. If this function is activated, the display switches off after 5 minutes in standby mode and after 1 minute during therapy. If the function is deactivated, the display remains permanently active.

Parameter	Setting range ***Standard***	Description
Language	Български Hrvatski ***English*** Français Deutsch Ελληνική Magyar Italiano Lietuvių Nederlands Polski Portuguesa Românesc Español Türkçe	Select the language for the user interface here.
Pressure unit	***hPa*** mbar cmH_2O	Choose between the pressure units to be displayed here.

Parameter	Setting range ***Standard***	Description
Device info	electronic instructions for use for patients	Here you will find the link to download the current instructions for use as a PDF.
	Serial number	device serial number
	Software version	software version
	GUILIB Ver.	graphics library version
	MOT Ver.	motor firmware version
	HUMI Ver.	humidifier firmware version

Changing the device language

If your national language is not set, you can change the device language as follows.

1. In the home screen, touch the right button (“Settings”) or select it with the rotary knob.
2. In the “Settings” menu, touch the second line (“Device”) or select it with the rotary knob.
3. In the “Device” menu, touch the second line (“Language”) or select it with the rotary knob.
4. Select the desired language using the arrows or the rotary knob and confirm the selection.

Setting the time parameters

From the home screen, select the “Settings” button and navigate to “Time & Date” on the “Settings” screen.

Setting an alarm clock

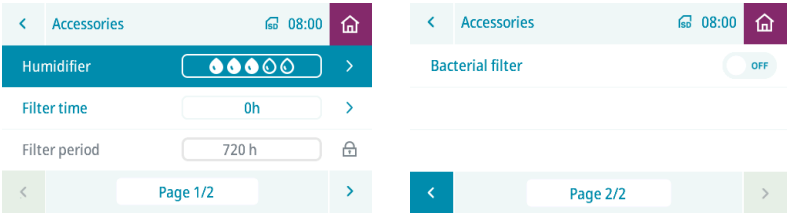
On the “Time & Date” screen, select the “Alarm Clock” menu item. You can set up to four alarm times here. You can choose from one of four preset names for each alarm time.

Note: When an alarm time is active, the alarm clock icon is displayed in the icon bar.

Function	Parameter	Setting range ***Standard***	Description
Alarm clock	Mode	***Off*** Once Every day	The wake-up alarm is disabled. The alarm will go off once at this time. The alarm will go off every day at this time.
	Label	Alarm clock Wake-up Going to sleep Tablets	You can assign a name to the alarm time here.
	Hours	00 ... ***08*** ... 23 12am ... 11pm	You can set the alarm time here.
	Minutes	***00*** ... 59	
Time	Time format Hours Minutes	12 hours 24 hours 00 ... 23 12am ... 11pm 00 ... 59	You can define the time format here and set the clock.
Date	Date format	Month/Day/Year Year/Month/Day Day/Month/Year ***Day.Month.Year*** 01 ... 31 01 ... 12 2000 ... 2099	You can define the date format here and set the date.

Setting accessories parameters

On the home screen, select the “Settings” button and navigate to the “Accessories” item in the “Settings” screen.



Parameter	Setting range ***Standard***	Description
Humidifier	Off 1 2 ***3*** 4 5	You can regulate the humidifier output in increments here.
Filter time	Reset	Total therapy time since the air filter was last changed is displayed here. *Note: For information on changing the filter, refer to section “Replace air filter”.*
Filter period	 -- h 240 h 480 h ***720 h*** 1440 h	The total therapy time set in hours between filter changes is displayed here. no filter period set equals approx. 1 month equals approx. 2 months equals approx. 3 months equals approx. 6 months
Bacterial filter	***OFF***, ON	If the device is used with a bacterial filter, this must be set to “ON”. This compensates for the pressure drop across the bacterial filter. *Note: For information on how to use the bacterial filter, refer to section "Bacterial filter".*

Comfort functions

Ramp

The ramp function makes it easier to get used to the prescribed pressure while falling asleep. It allows the pressure to increase steadily over the adjustable ramp time starting from a start pressure (ramp start pressure) up to the prescribed pressure. The start pressure can be set by the physician between 4 hPa and the prescribed pressure.

The ramp time can be set between 0 and 60 minutes in increments of 5 minutes. This is set using the sensor button (see section “Sensor buttons”) or the “Comfort” menu (see section “Setting a comfort parameter”). If the ramp time is zero, therapy starts immediately with the prescribed therapy pressure.

breasyflex

breasyflex is a comfort function that facilitates easier breathing for the patient when using the respiratory therapy device in CPAP and Auto CPAP mode.

breasyflex in is increase in pressure during inhalation proportional to the flow.

breasyflex ex is a decrease in pressure during exhalation proportional to the flow.

Note: Being the only function under clinical settings, breasyflex can be passed to the patient for setting if desired. To do this, the “breasyflex patient” parameter must be set to “ON” in the clinic section. In the “Comfort” menu under the patient section, the breasyflex settings are then no longer grayed out.

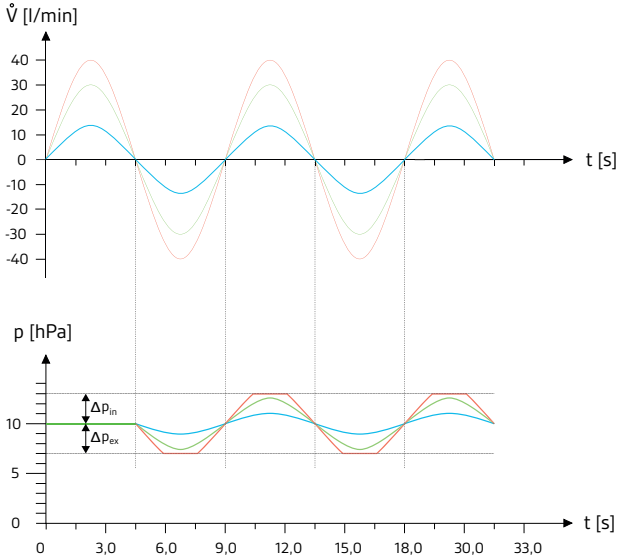
The breasyflex function levels can be set separately in 3 gain levels for in and for ex or switched off. Pressure support is lowest at level 1 and highest at level 3.

breasyflex in:

Level	1	2	3
max. pressure support	1 hPa	2 hPa	3 hPa

breasyflex ex:

Level	1	2	3
max. pressure support	-1 hPa	-2 hPa	-3 hPa



Flow proportional pressure increase or decrease exemplarily shown with level 3 of the function breasyflex in and breasyflex ex at different strong respiratory flow curves

- Pressure increase and decrease by 1hPa with low respiratory flow
- Pressure increase and decrease by 2.5hPa with higher respiratory flow
- Pressure increase and decrease by 3hPa (limitation) with very high respiratory flow

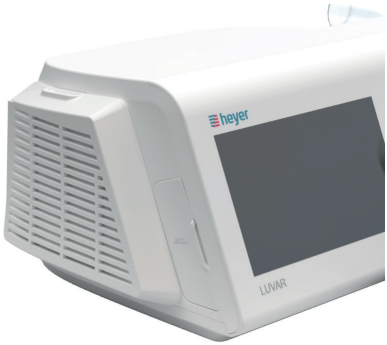
Air filter modul

The PM2.5 air filter module is available as an optional accessory. The filter module prevents the penetration of particles down to a size of 2.5 µm.

Using the PM2.5 air filter module

1. On the left of the device, remove the filter cover from the device inlet opening.
2. Remove the white filter insert from the intake opening.
3. Remove the filter module from the packaging.

4. Insert the filter module in place of the filter cover. It should click into place when pushed gently.



Warnings and troubleshooting

CAUTION: Potentially worse damage to device!

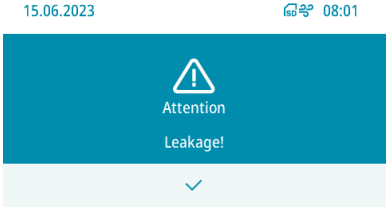
- If

  ⇨ you notice unexplained changes in the performance of the device,
  ⇨ it makes unusual or worrying noises,
  ⇨ the device or the power supply has been dropped or not used correctly,
  ⇨ water has got into the unit, or
  ⇨ the device is obviously defective

  and you cannot correct the fault using the charts, do not continue to operate the device, but stop operation to avoid major damage. Contact your specialist dealer to have the device checked.

Warnings

While using the device, it may happen that the device displays various warning and information messages, e.g. leakage.



Warning	Cause	Remedy
Leakage	Your physician has activated the optional “leakage Warning” for you and substantial leakage (> 50 l/min) occurs during therapy.	Eliminate the leakage by checking the components of the breathing tube system (tube and breathing mask).
VT Min Warning	Your physician has activated the optional “VT Min Warning” for you. It occurs when the respiratory volume of the patient is less than 90% of the set minimum volume over 3 breaths.	Contact your physician.

Warning	Cause	Remedy
Change filter	The service life for the current air filter has been exceeded.	Replace air filter and reset filter life.
SD card full	No free memory on SD card.	Replace SD card or delete data.
SD card access	Read or write error when accessing the SD card.	Re-insert SD card or replace if necessary.
Service	The defined blower service life has been exceeded.	Contact your specialist dealer and have the device checked.
System error	A bug in the operating system.	Restart the device. If the error occurs again, make a note of the error code and contact your specialist dealer to have the device checked.

Troubleshooting

The following charts list common problems that may occur while using the device along with possible solutions.

Device malfunctions

Malfunctions	Possible cause	Remedy
Device cannot be operated after booting.	The SD card is being read.	Wait a moment until the device has read the SD card.
Therapy does not start.	The device is faulty.	Contact your specialist dealer.
Therapy cannot be started by taking a breath.	The “Automatic start” comfort function is not activated.	Activate the “Automatic start” function.
Therapy is not terminated after the mask has been taken off.	The “Automatic stop” comfort function is not activated.	Activate the “Automatic stop” function.

Malfunctions	Possible cause	Remedy
Display is blank.	The screen timeout function is active.	Touch the display or operate the rotary knob.
	The power supply is not connected properly.	Check the connections between the power outlet and power cable, power cable and power supply unit, and power supply unit and device.
	You cannot find any cause.	Contact your specialist dealer.
Device delivers minimal air flow.	The device air inlet is blocked.	Replace the air filter and clean the air inlet. Make sure that the air inlet is not clogged.
	If the ramp function is activated, it takes some time for the initial pressure to rise to the therapy pressure. This is normal.	If necessary, deactivate the ramp function or set a shorter ramp time.
Device delivers incorrect therapy pressure.	The therapy pressure has been changed by mistake.	Contact your physician.

Problems during therapy

Problem	Possible cause	Remedy
Dry, cold, runny or stuffy nose	Irritation of nasal mucosa due to cold, dry therapy air.	Increase the heating level of the humidifier. Consult your physician and continue treatment unless the physician suggests otherwise.
Dry mouth and throat	The therapy air escapes through the open mouth.	Contact your physician. Use a chin strap to prevent the mouth from opening during sleep or use a full-face mask.

Problem	Possible cause	Remedy
Skin irritation or rash where the mask makes contact	Allergic reaction to the mask material, e.g. silicone allergy	Contact your physician. Use a fabric mask or a mask cushion.
	Dirty mask	Clean the mask daily.
	Dirty face	Adjust the head strap so that the mask fits tightly.
Pressure marks in the mask area	Wrong mask size	Contact your physician.
	Incorrectly adjusted mask (head strap too tight and presses heavily on the face)	Adjust the head strap so that the mask fits tightly.
	Mask worn out	Check the mask regularly for cracks, breaks, stiffening and the like. Replace the worn mask.
Water in the mask	If the room temperature is low and the humidifier is used, the humidifier air tends to condense in the tube and mask.	Reduce the heating level or increase the room temperature.
The air discharged from the unit is abnormally hot.	The air inlet on the unit is clogged or blocked.	Replace the air filter and clean the air inlet. Make sure that the air inlet is not blocked. Make sure that the device is at least 20 centimeters away from walls, curtains or other objects.
The device is too noisy.	The tube is not connected properly.	Connect the tube properly.

Cleaning and disinfection

Important information on cleaning and disinfection

⚠ WARNING: Risk of infection due to inadequate cleaning and disinfection!

- Compliance with the cycles for cleaning and disinfecting the device and accessories is necessary to prevent respiratory infections.

⚠ WARNING: Risk of injury from cleaning agents and disinfectants!

- Do not use bleach, chlorine or ammonia-based solutions or aggressive scouring agents or cleaning agents such as acetone to clean and disinfect the device and its accessories. The use of such agents can lead to injuries to the person doing so, as well as damage to important safety labels or the device itself.
- Even suitable cleaning agents and disinfectants can have undesirable effects, such as irritation of the skin, eyes or respiratory tract, if used incorrectly. Note the information on correct use provided by the relevant manufacturer.

CAUTION: Risk of damage due to incorrect cleaning and disinfection!

- The device must be cleaned and disinfected according to the information in these instructions for use to avoid damage to the device.
  - ⇨ The respiratory therapy device, the humidifier and the accessories are not suitable for machine cleaning and disinfection procedures. Only use the manual reprocessing procedures described in these instructions for use. In particular, the use of non-compatible after market ozone devices is not permitted.
  - ⇨ Before cleaning, make sure that the device is disconnected from the power supply, and make sure that all parts are dry before reconnecting the device to the power supply after cleaning.
  - ⇨ Never immerse the respiratory therapy device, the humidifier, the power supply unit or the power cable in water or other liquids.
  - ⇨ Sterilization of the device and accessories is not necessary and not permitted.
  - ⇨ Follow all instructions from the relevant manufacturers for cleaning the accessories, such as mask and breathing tube, and for determining the frequency of cleaning.

Cleaning at home

If the respiratory therapy device is operated in a domestic setting without different patients, regularly cleaning the device and accessories is sufficient for hygienic reprocessing. The domestic setting also includes shared apartments, nursing homes and care facilities where the respiratory therapy device is operated without changing patients. The following cleaning cycles must be observed.

Cycle	Activity to be performed
Daily	Clean mask*
	Water change
Weekly	Clean respiratory therapy device
	Clean respiratory humidifier
	Disassemble and clean water tank
	Clean breathing tube or replace if “single use” type*
	Clean head strap
Every 3 months	Replace air filter (more frequently in case of heavy contamination)
Annually	Replace air filter (more frequently in case of heavy contamination)
	Replace mask and head strap*
If required	Descaling the water tank
	Replace water tank if in poor condition

** The cycles for accessories given in this table are recommendations from the German industry association SPECTARIS. If shorter cycles are specified in the instructions for use for the relevant accessories, these take precedence over the information given here.*

For cleaning instructions, refer to section “Cleaning instructions”.

Cleaning instructions

Cleaning the respiratory mask

For hygienic reasons, clean the mask daily and the head strap weekly, or if you notice any contamination. Follow the mask manufacturer's instructions for use when disassembling, cleaning and reassembling the mask.

1. Separate the mask from the breathing tube.
2. Disassemble the respiratory mask into its components.
3. Soak the head strap in warm, mild soapy water.
4. Clean the mask components with the soapy water and a soft brush. Make sure that you reach all cavities and recesses in the parts - for example, the holes for exhalation openings.
5. Rinse the head strap and the other mask parts thoroughly under running water.
6. Allow all parts to air dry completely. Avoid direct sunlight when doing so.

Check the mask and head strap for wear, damage or deformation after each cleaning. Damaged parts must be replaced. When used by a single patient, disinfecting the device and accessories is not required.

Cleaning the breathing tube

For hygienic reasons, clean the tube once a week. When doing so, follow the cleaning instructions in the instructions for use for the breathing tube.

1. Disconnect the breathing tube from the device and mask before cleaning
2. Wash the tube in warm water and use a mild detergent.
3. Rinse the tube thoroughly with drinking-quality water.
4. Hang the tube up to air dry. Make sure that the tube hangs so that all liquid can drain off. Avoid direct sunlight, otherwise the tube may harden over time and cracks may form.
5. Do not use the tube again until it is completely dry.

Check the tube for damage after each cleaning. Damaged tubes must be replaced. Slight discoloration is acceptable.

Cleaning the device

The surfaces of the respiratory therapy device, humidifier, power supply unit and power cable must be cleaned weekly.

1. Make sure that the device is disconnected from the power supply.
2. Disconnect the power cable from the power supply unit, the power supply unit from the respiratory therapy device and the humidifier from the respiratory therapy device.
3. Moisten a soft, lint-free cloth with drinking-quality water or with a mild soap solution until the cloth is damp but not dripping wet.
4. Wipe all surfaces with the cloth at least once, or until all contaminants are removed.

Cleaning the water tank

For hygienic reasons, change the water in the humidifier once a day and clean the water tank at least every 7 days.

Note: At least once a month during cleaning, check all water tank parts and especially the seal on the metal plate for wear or damage. If the seal is damaged or if the water tank has cracks, discoloration or deposits that cannot be removed by cleaning or descaling, the affected parts must be replaced.

Follow the following steps for cleaning.

⚠ WARNING: Danger of burns due to hot surface!

- **The metal plate on the humidifier reaches high temperatures when in use. After use, allow the humidifier to cool down for 10 minutes before disassembling for cleaning.**

1. Press the release button for the water tank and pull the tank out to the side.

2. Turn the water tank upside down

3. Remove the metal plate on the underside of the water tank by reaching into the recesses with your thumbs and gently forcing the metal plate upwards.

Note: The water tank is not dishwasher proof and should therefore only be cleaned by hand. The metal plate can also be washed in the dishwasher (gentle or glassware program).

4. Clean the water tank and the metal plate in warm water and use a mild detergent.
5. Thoroughly rinse the water tank and the metal plate with drinking-quality water.
6. After cleaning, wipe the surfaces on the water tank and the metal plate dry with a soft cloth or allow the parts to air dry, avoiding direct sunlight.
7. Reinsert the metal plate into the water tank while applying slight pressure.

8. Fill the water tank to the specified level mark.
9. Push the water tank sideways into the humidifier housing until it clicks into place.

Descaling the water tank

The water tank can be descaled if required.

1. To do so, disassemble the water tank as you would for cleaning and use, for example, a mild acetic acid solution consisting of one part household vinegar and ten parts water.
2. Allow the water tank to soak in the vinegar solution for about 20 minutes.
3. After descaling, rinse the water tank thoroughly several times to prevent the odor and taste of vinegar from settling.

Note: To avoid limescale, use soft water if possible. Boiled, purified or even distilled water, for instance.

Replace air filter

The air filter must be replaced regularly (see above). Depending on the actual environmental conditions, replacement may also be necessary more frequently than specified.

1. On the left of the device, remove the filter cover from the device inlet opening.
2. Remove the contaminated filter element.
3. Clean the filter cover and the intake opening with a dry soft cloth.
4. Remove a white air filter element from its packaging and place it in the intake opening on the device.
5. Replace the filter cover. It should click into place under slight pressure.

After the air filter has been replaced, the filter life must be reset in the unit. To do this, proceed as follows.

6. Switch on the device.
7. Select the “Settings” menu on the home screen.
8. Select the “Accessories” menu item.
9. Select the “Filter life” menu item.
10. Press the apply button with the check mark to reset the filter life to 0.

Appendix

Technical data

Environmental conditions

These environmental conditions apply to the device with or without respiratory humidifier.

	Operation	Transport and storage
Temperature	+ 5°C to +35°C	-25°C to +70°C
Relative humidity	10 % to 90 % non-condensing	10 % to 90 % non-condensing
Atmospheric pressure (altitude above sea level)	760 to 1060 hPa (approx. 2200 m to -300 m)	500 to 1060 hPa (approx. 5500 m to -300 m)

Classification of device and humidifier

Product class as per EU Regulation 2017/745 (MDR)	IIa
Electrical protection class (IEC 61140)	Protection class II (protective insulation)
Operating mode (IEC 60601-1)	Continuous operation
Protection against harmful ingress of water and solid particles (IEC 60529)	IP22 • IP2x means that the device is protected against the ingress of solid foreign bodies with a diameter ≥12.5 mm. • IPx2 means that the device, tilted up to 15°, is protected against the ingress of dripping water.
Suitability for operation in an oxygen-enriched environment (AP/APG, IEC 60601-1)	Not suitable

Applied part (IEC 60601-1)	Respiratory mask
Protection of applied part against electric shock	Typ BF
Humidifier classification (ISO 80601-2-74)	Category 2

Conformity of device and humidifier

The respiratory therapy device and humidifier comply with the requirements of the following standards:

- IEC 60601-1:2005/AMD2:2020 medical electrical equipment,
- IEC 60601-1-2:2014/AMD1:2020 General requirements for basic safety and essential performance,
- IEC 60601-1-11:2015/AMD2:2020 for medical electrical equipment and medical electrical systems used in the home healthcare environment,
- ISO 80601-2-70:2020 for sleep apnea breathing therapy equipment,
- ISO 80601-2-74:2017 for respiratory humidifying equipment

Tolerances for the specifications

All fluid volume, flow, and leakage specifications were determined under STPD ("standard temperature and pressure, dry", temperature of 20 °C and pressure of 1013 hPa) conditions. In accordance with ISO 80601-2-70:2020 and 80601-2-74:2017, the measurement uncertainty of the manufacturer's test equipment for measurements is as follows:

Pressure	± 0.75 % of the measured value or ± 0.1 hPa (the larger tolerance applies)
Flow	± 1.9 % of the measured value or ± 0.1 l/min (the larger tolerance applies)
Temperature	± 1.5 °C (type K)

Displayed values

Displayed value	Display range	Reading accuracy	Measurement accuracy
Airway pressure	0 to 25 hPa	0.1 hPa	±(0.4 hPa + 4% of the displayed value)
Tidal volume	0 to 3000 ml	1 ml	±20 %
Leakage	0 to 170 l/min	0.1 l/min	±12 l/min or 20 % of the measured value, whichever is greater, at 0 to 60 l/min
Minute volume	0 to 30 l/min	0.1 l/min	± 20 %
Frequency	0 to 99 bpm	1 bpm	±1.0 bpm

Technical data for LUVAR respiratory therapy device

Dimensions W x D x H	16 x 15 x 10 cm without humidifier 25 x 15 x 10 cm with humidifier
Weight	0.92 kg or 1.34 kg without humidifier
Air outlet port diameter	22 mm, conical (ISO 5356-1)
Input voltage	24 V DC
Max. power consumption	53 W
Air filter element material	Polyester foam
Air filter element performance	Separation rate > 80% for particles > 5 µm
Mean sound pressure level during operation as per ISO 80601-2-70	< 30 dB(A) at 10 hPa, with an uncertainty of 2dB(A)
Mean sound power level during operation as per ISO 80601-2-70	< 38 dB(A) at 10 hPa, with an uncertainty of 2dB(A)
CPAP/Auto CPAP pressure range	4 hPa to 20 hPa
BiLevel pressure range	4 hPa to 25 hPa
Max. pressure in case of malfunction (P_{LIMmax})	≤ 40 hPa
Safety frequency to be activated in S mode	10 bpm

Adjustable start pressure	min. 4 hPa
Adjustable ramp time	Off; 5, 10, 15 ... 60 minutes

Technical data for power supply unit

Model name	DA-80A24
Weight	0.34 kg
Electrical protection class	Protection class II
Input voltage	100 - 240 V AC
Input current	max. 2.0 A_{eff}
Input frequency	50 - 60 Hz
Output voltage	24 V DC ±1.2 V
Output current	max. 3.33 A

Technical data for respiratory humidifier H100

Dimensions W × D × H (integrated in device)	11.5 x 15 x 10 cm (10.5 x 15 x 10 cm)
Weight	0.42 kg
Air outlet port diameter	22 mm, conical (ISO 5356-1)
Input voltage	24 V DC
Max. power consumption	30 W
Max. temperature of gas delivered	43 °C
Heating level, adjustable	Off, 1 to 5
Water tank capacity	≤ 300 ml
Operating time between refills at heating level 5	8 hours
Humidifier output as per ISO 80601-2-74	>12.5 mg/l

Stability of static pressure (long-term accuracy) at 10 hPa as per ISO 80601-2-70

Maximum deviation from set pressure for LUVAR A/STA without and with humidifier, with unheated breathing tube: $\Delta p \leq 0.39$ hPa.

Stability of dynamic pressure (short-term accuracy) as per ISO 80601-2-70

CPAP mode

LUVAR A/STA with unheated breathing tube

Stability of dynamic pressure in CPAP and Auto CPAP mode	without humidifier	with humidifier
at 10 breaths/min		
4 hPa	Δp ≤ -0.21 hPa	Δp ≤ -0.27 hPa
8 hPa	Δp ≤ 0.30 hPa	Δp ≤ -0.33 hPa
12 hPa	Δp ≤ 0.37 hPa	Δp ≤ 0.33 hPa
16 hPa	Δp ≤ 0.39 hPa	Δp ≤ 0.38 hPa
20 hPa	Δp ≤ 0.47 hPa	Δp ≤ 0.46 hPa
at 15 breaths/min		
4 hPa	Δp ≤ -0.30 hPa	Δp ≤ -0.36 hPa
8 hPa	Δp ≤ 0.34 hPa	Δp ≤ -0.42 hPa
12 hPa	Δp ≤ 0.41 hPa	Δp ≤ -0.42 hPa
16 hPa	Δp ≤ 0.45 hPa	Δp ≤ 0.47 hPa
20 hPa	Δp ≤ 0.52 hPa	Δp ≤ 0.61 hPa
at 20 breaths/min		
4 hPa	Δp ≤-0.42 hPa	Δp ≤ -0.52 hPa
8 hPa	Δp ≤ 0.47 hPa	Δp ≤ -0.58 hPa
12 hPa	Δp ≤ 0.58 hPa	Δp ≤ 0.66 hPa
16 hPa	Δp ≤ 0.67 hPa	Δp ≤ 0.82 hPa
20 hPa	Δp ≤ 0.75 hPa	Δp ≤ 0.96 hPa

BiLevel mode

Deviation from the set pressure given as the mean value and standard deviation of the error between the set values and the supplied values in hPa.

LUVAR STA without or with humidifier with unheated breathing tube

IPAP

	8 hPa		11 hPa		17 hPa		22 hPa		25 hPa		
	Without	With	Without	With	Without	With	Without	With	Without	With	humidifier
10 bpm	0.054	0.061	0.061	0.066	0.077	0.077	0.097	0.095	0.109	0.104	mean deviation
	0.067	0.081	0.076	0.082	0.098	0.096	0.123	0.120	0.139	0.132	standard deviation
15 bpm	0.106	0.120	0.109	0.137	0.131	0.150	0.146	0.170	0.156	0.170	mean deviation
	0.124	0.142	0.130	0.159	0.162	0.182	0.179	0.207	0.192	0.206	standard deviation
20 bpm	0.196	0.229	0.197	0.236	0.219	0.256	0.237	0.287	0.261	0.297	mean deviation
	0.229	0.267	0.230	0.277	0.261	0.301	0.308	0.366	0.358	0.382	standard deviation

EPAP

	4 hPa		7 hPa		13 hPa		18 hPa		21 hPa		
	Without	With	Without	With	Without	With	Without	With	Without	With	humidifier
10 bpm	0.036	0.040	0.049	0.054	0.070	0.071	0.089	0.085	0.101	0.094	mean deviation
	0.045	0.050	0.062	0.068	0.089	0.090	0.112	0.107	0.127	0.118	standard deviation
15 bpm	0.072	0.078	0.071	0.078	0.090	0.096	0.107	0.115	0.120	0.126	mean deviation
	0.081	0.089	0.087	0.095	0.113	0.120	0.135	0.144	0.151	0.158	standard deviation

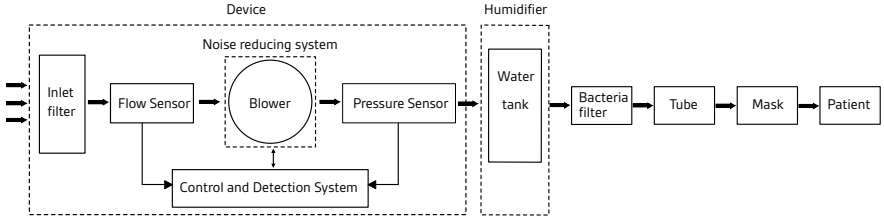
	4 hPa		7 hPa		13 hPa		18 hPa		21 hPa		
	Without	With	Without	With	Without	With	Without	With	Without	With	humidifier
20 bpm	0.142	0.155	0.125	0.137	0.123	0.136	0.137	0.144	0.143	0.156	mean deviation
	0.154	0.170	0.141	0.155	0.153	0.164	0.168	0.179	0.178	0.195	standard deviation

Note: The data in the tables were obtained between 60 and 85% during the inspiratory phase and between 65 and 90% during the expiratory phase. The data time windows begin immediately after initial settling and end at the point where the flow falls to an equivalent absolute value of its starting point, just before the end of the respiratory phases.

Maximum flow rate as per ISO 80601-2-70

Maximum flow in CPAP and Auto CPAP mode Test pressures:	Pressure at the patient connection port at a flow of 40 l/min	Flow rate at patient connection port
4 hPa	3.92 hPa	152 l/min
8 hPa	7.90 hPa	173 l/min
12 hPa	11.80 hPa	162 l/min
16 hPa	15.87 hPa	147 l/min
20 hPa	19.86 hPa	128 l/min

Pneumatic diagram



Accessories specifications

Breathing tube	
Length	180 cm
Inner diameter	19 mm
Complies with standard	ISO 5367 or ISO 80601-2-74
Bacterial filter	
Ports	22/15 mm conical
Resistance	< 0.9 hPa at 30 l/min
Weight	22 g
Internal volume	37 ml
Complies with standard	ISO 5376 and ISO 9360
SD card	
Storage space	min. 8 GByte, recommended 16 GByte

Consumables, accessories, and spare parts list

To order consumables, accessories and spare parts, please contact your healthcare provider, a heyer medical AG service partner or contact heyer medical AG directly.

Consumables

Item Item number	Image
Air filter, (set of 5) 521025	

Accessories

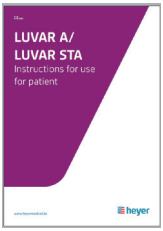
Item Item number	Image
PM2.5 air filter module 321012	
Nasal mask LuvON N10 Type 836 Size S: 323250 Size M: 323251 Size L: 323252	
Nasal mask LuvON N11 Typ 828 Size S: 323260 Size M: 323261 Size L: 323262	
Nasal pillow mask LuvON P10 101 Type 323350	

Item Item number	Image
Nasal pillow mask LuvON PR10 Typ Rolin™P 323340	
Bacterial filter 371006	
Instruction for use for physicians and medical care staff 320005	

Spare parts

Item Item number	Image
Power supply unit 321000	

Item Item number	Image
Power cable, Euro Standard C7 321002	
Power cord, UK Standard C7 331033	
SD card 321008	
Transport bag 321010	
CPAP breathing tube - Classic 19 White 320008	

Item Item number	Image
Patient instruction for use 320003	

Electromagnetic compatibility

The device meets the requirements of standard IEC 60601-1-2:2014/AMD1:2020 and is intended for use in the electromagnetic environment described below. Environmental conditions deviating from this could impair the performance of the device or lead to failure of the device.

⚠ WARNING: Risk of injury due to electromagnetic interference!

- **Replacing the components listed below may result in increased electromagnetic interference emissions or reduced electromagnetic interference immunity for the respiratory therapy device and lead to faulty operation:**

  ⇨ Power supply unit, DA-80A24

Electromagnetic interference emission

Guidelines and manufacturer's declaration – electromagnetic interference emission

The LUVAR respiratory therapy device with or without the H100 respiratory humidifier is intended for use in domestic settings as well as in appropriate clinical settings. Device users must ensure that it is used in such a setting. When used in a residential setting (for which Class B is typically required by CISPR 11), this device may not provide adequate protection from radio communication services. The user may need to take remedial action such as relocating or repositioning the device.

Interference emission	Compliance	Electromagnetic environment - guideline
RF emissions as per CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and unlikely to cause interference to nearby electronic equipment.
RF emissions as per CISPR 11	Class B	The device can be used in all facilities, including domestic facilities and facilities directly connected to the public power supply network.
Emissions of harmonics according to IEC 61000-3-2	Class A	
Emissions of voltage fluctuations/ flicker according to IEC 61000-3-3	Compliant	

Electromagnetic immunity

Guidelines and manufacturer's declaration – electromagnetic immunity

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Interference emission	IEC 60601 test level	Compliance level	Electromagnetic environment - guidelines
Electrostatic discharge (ESD) according to IEC61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	Floors should be made of wood, concrete or ceramic tiles. If floors are covered with synthetic material, the relative humidity must be at least 30%.
Radiated RF disturbance variable according to IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	10 V/m	Portable and mobile RF communications equipment (including the lines and antennas) should not be used at a distance from the device less than the recommended protective distance of 0.3 m. Interference may occur in the vicinity of equipment marked with the following symbol: 
	27 V/m 385 MHz PM: 18 Hz	27 V/m	
	28 V/m 450 MHz FM ± 5 Hz: 1 kHz sine	28 V/m	

Interference emission	IEC 60601 test level	Compliance level	Electromagnetic environment - guidelines
	9 V/m 710, 745, 780 MHz PM: 217Hz	9 V/m	
	28 V/m 810, 870, 930 MHz PM: 18Hz	28 V/m	
	28 V/m 1720, 1845, 1970 MHz PM: 217 Hz	28 V/m	
	28 V/m 2450 MHz PM: 217 Hz	28 V/m	
	9 V/m 5240, 5500, 5785 MHz PM: 217 Hz	9 V/m	
Fast transient electrical disturbances/ bursts according to IEC 61000-4-4	± 2 kV for power lines ± 1 kV for input and output lines	± 2 kV for power lines ± 1 kV for input and output lines	The quality of the supply voltage should correspond to that of a typical business or hospital setting.

Guidelines and manufacturer's declaration – electromagnetic immunity

The LUVAR respiratory therapy device with or without the H100 respiratory humidifier is intended for use in domestic settings as well as in appropriate clinical settings. Device users must ensure that it is used in such a setting. When used in a residential setting (for which Class B is typically required by CISPR 11), this device may not provide adequate protection from radio communication services. The user may need to take remedial action such as relocating or repositioning the device.

Interference resistance tests	IEC 60601 test level	Compliance level	Electromagnetic environment - guidelines
Surges in accordance with IEC 61000-4-5	± 1 kV line-to-linevoltage ± 2 kV line-to-ground voltage	± 1 kV line-to-linevoltage ± 2 kV line-to-ground voltage	The quality of the supply voltage should correspond to that of a typical business or hospital setting.
Conducted disturbances induced by high-frequency fields as per IEC 61000-4-6	3 V_{eff} 150 kHz – 80 MHz 6 V_{eff} in ISM and amateur frequency bands between 150 kHz – 80 MHz	3 V_{eff} 6 V_{eff}	Portable and mobile RF communications equipment (including the lines and antennas) should not be used at a distance from the device less than the recommended protective distance of 0.3 m. Interference may occur in the vicinity of equipment marked with the following symbol: 

Interference resistance tests	IEC 60601 test level	Compliance level	Electromagnetic environment - guidelines
Magnetic fields at supply frequency (50/60 Hz) as per IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields at the mains frequency should correspond to the typical values found in business and hospital settings.
Voltage dips, short-term interruptions, and voltage fluctuations of the power supply lines according to IEC 61000-4-11	Dip levels / duration: 30 %/500 ms 100 %/20 ms 100 %/10 ms at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 100 %/ 5000 ms	Dip levels /duration: 30 %/500 ms 100 %/20 ms 100 %/10 ms at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 100 %/ 5000 ms	The quality of the supply voltage should correspond to that of a typical business or hospital setting. If the device needs to continue operating uninterrupted in the event of a power failure, the device should be powered by an uninterruptible power supply or a battery.

Maintenance

The expected service life of the device is 5 years. Some components and accessories have a shorter service life: 2.5 years for the water tank and 12 months for the breathing tube and mask.

The device is maintenance-free within this period if used as intended in accordance with the instructions for use and if the cleaning and care instructions are observed. For use beyond this, we recommend an inspection by an authorized service company.

Disposal

Dispose of the device and packaging at the end of its service life in accordance with local laws and regulations. Proper disposal conserves natural resources and prevents harmful substances from entering the environment.

Packaging

The device packaging (cardboard box) will be taken back by the distributor. However, it can also be disposed of as waste paper.

Air filters

Used air filter elements can be disposed of with household waste.

Breathing tube, mask, bacterial filter

In the clinical setting, all parts potentially contaminated by the patient's breathing air must be disposed of following local regulations for used medical material.

The breathing tube, mask and bacterial filter from domestic use can be disposed of with the household waste by the patient at the end of their service life.

Device and power supply unit

The respiratory therapy device, the humidifier and the power supply unit with the power cable contain electrical and electronic parts and must therefore not be disposed of with household waste. For proper disposal, please contact your specialist dealer or ensure that all device components are disposed of in accordance with the relevant municipal, state and federal regulations. For more information, contact your local environmental authorities.

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This device meets the requirements of Regulation (EU) 2017/745 on medical devices (MDR).

heyer_LUVAR_UserManual_EN-4_CRev-2

heyer_LUVAR_UserManual_EN-4_CRev-2

HOMECARE

Scan the QR code for the current instructions for use to download as a PDF:

320003

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