EN Service and repair manual for type WM 100 TD and WM 100 TH devices

prisma20C
prisma20A
prismaCR
prisma25S
prisma30ST
prisma25S-C
prisma25ST
prismaLAB
prismaAQUA
prisma30ST-C

Sleep therapy devices

LÖWENSTEIN
medical

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1 Introduction

1.1 About this document

The aim of this service and repair manual is to familiarize you with the device in terms of function, technology, maintenance and repairs. This enables you to:

- provide instructions for customers
- rectify faults
- perform function checks
- carry out repairs

However, please observe the following:

- **You are responsible for all repairs carried out by yourself and for the repair warranty!**
- **Only use original spare parts from Löwenstein Medical.**
- **Please observe the accompanying documentation (instructions for use).**

If you have any queries or feedback, please contact our Technical Service team:

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1.2 Navigation in this document

The buttons below provide a quick way to navigate through this document:

- To view the last page you looked at, click the Back button.

  Example: If you are on page 30 and the last page you viewed was page 20, clicking the Back button will take you back to page 20.

- To return to the page you were viewing prior to clicking the Back button, click the Forward button.

  Example: If you were on page 20 and you clicked the Back button to skip back to page 10, clicking the Forward button would return you to page 20.

- Click the Contents button to go to the Table of Contents.
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1.3 Function

1.3.1 WM 100 TD therapy device

The fan in the therapy device sucks ambient air in through a filter, compresses it, and routes it to the device outlet.

From here, the air flows through the hose system and the mask to the patient. The exhalation system in front of the mask or optionally integrated in the mask prevents CO_2-enriched exhaled air from collecting in the hose system. The therapy device determines and analyzes the pressure and respiratory flow signal. This allows respiratory events to be recognized.

The pressure sensor is connected to the device outlet via a hose, allowing measurement of the pressure close to the device.

The flow sensor is connected to a flow element directly via 2 seals. The flow element contains many lamellae, which create a laminar flow. The laminar flow results in a pressure drop. The flow sensor calculates the resulting differential pressure. With the aid of additional state parameters, such as the absolute pressure, the flow sensor can also determine the flow rate.

The device can function with one pressure level (CPAP) or with two or three pressure levels (BILevel or inspiratory pressure, expiratory pressure, and end-expiratory pressure). Depending on the version employed, the pressure levels can be set automatically by the device within preset limits, or they can be set manually. Depending on the mode, the pressure can be continually applied at one level, or triggered by the patient or applied with time controls. Pressure signals, respiratory flow signals, and respiratory events can be saved and/or can be output in analog form on a PSG system.

The therapy data are saved in the device and on an SD card for therapy control.

The device is operated via an On/Off button and a touchscreen.

The prismaTS therapy software can be used to control the therapy device remotely from a PC.

In the case of a power failure, the settings are retained and the therapy is continued once the power supply is restored.

Mainboard

The mainboard forms the core of the therapy device. It contains important components such as the flow and pressure sensors, memory module, and controller. The controller is programmed with the respective device firmware, which includes the whole algorithm for device control.

In addition, the mainboard is also responsible for all the energy management of the therapy device.

Touchscreen

The touchscreen is used to display all the information and, at the same time, for operating and setting the therapy device. It is a resistive touchscreen.

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Fan

The fan is a centrifugal fan with a precision-balanced fanwheel and a 3-phase motor with Hall effect sensors for continuous speed measurement. The fan is controlled from the mainboard, and the fan speed depends on the current pressure requirements and the current leakage.

1.3.2 WM 100 TH respiratory air humidifier

The heatable respiratory air humidifier functions on the so-called pass-over principle. The air coming from the therapy device is routed across the surface of a preheated water reservoir. This increases the relative humidity and temperature of the air flow.
The humidifier level can be set individually using the buttons on the therapy device.

The power of the heating element, and consequently the temperature of the water in the humidifier chamber, is controlled electronically via the therapy device.
The transparent window of the humidifier chamber makes it possible to check the water level at any time.

1.4 Warnings in this document

Warnings are used to flag up safety-relevant information.

You will find a warning preceding any action that entails a hazard for persons or equipment.

Warnings consist of

- the warning symbol (pictogram),
- a signal word designating the hazard level,
- information about the hazard
- instructions for avoiding the hazard.

The warnings appear in three hazard levels, depending on the degree of danger:

⚠ DANGER	**Danger!** Designates an extremely dangerous situation. Failure to observe this warning will lead to serious, irreversible injury, or death.
⚠ WARNING	**Warning!** Designates an extremely dangerous situation. Failure to observe this warning may lead to serious, irreversible, or fatal injury.
⚠ CAUTION	**Caution!** Designates a dangerous situation. Failure to observe this warning may lead to minor or moderately serious injury.
NOTICE	**Notice!** Indicates a harmful situation. Failure to observe this warning may lead to damage to equipment.
i	Designates useful information relating to a particular action.

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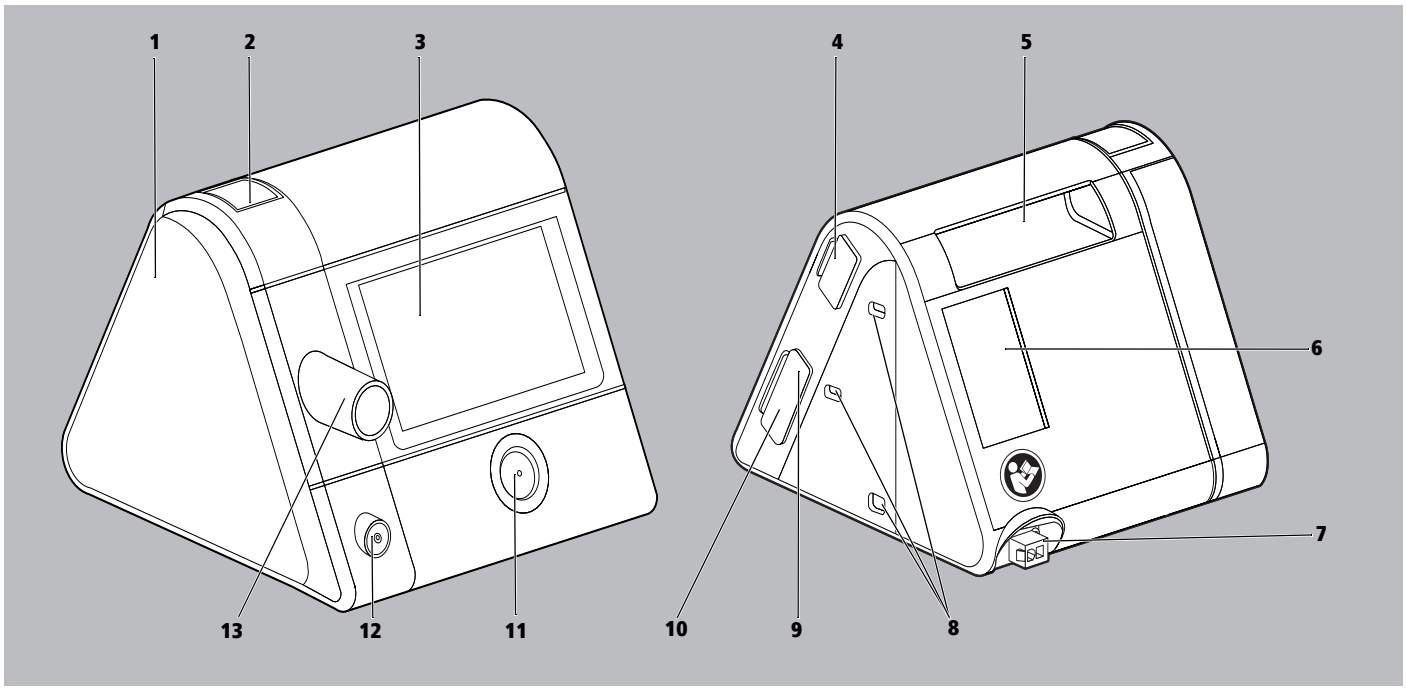
2 Product description

2.1 Therapy device overview



2-1 Therapy device

No.	Designation	Description
1	Cover	Covers the humidifier connection when no respiratory air humidifier is connected.
2	Unlocking button	Allows the cover to be removed for connecting the humidifier prismaAQUA.
3	Display	Allows operation of the therapy device and the respiratory air humidifier. Displays settings and current values.
4	System interface	Connects the therapy device to modules.
5	Handle	Allows lifting and transporting of the therapy device.
6	Filter compartment in suction section	Houses the air filter and, where applicable, the pollen filter. The respiratory air is sucked in here and the dust particles are filtered out.
7	Power input	Connects the therapy device to the power supply unit.
8	Mounting holes	For attaching and securing a module to the therapy device.
9	SD card slot	For inserting an SD card. The symbol on the display indicates the communication between the SD card and the therapy device.
10	Micro USB port	Used for point-to-point connection with a PC on which prismaTS is installed. Allows settings to be changed on the therapy device and data to be exported.
11	On/Off button	Switches the therapy device on and off. Switches the therapy device to standby mode. Starts and stops the therapy.
12	Hose heater connection	Electrical power supply connection for a heatable hose (only applies to devices as of serial number 5.000).
13	Device output	Connection for the breathing tube, through which the patient is supplied with respiratory air.

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2.2 Display

The information shown on the display depends on the current status of the therapy device:

- **Standby** mode (no therapy in progress)

  The clock is shown, as is the wake-up time if the alarm clock is set.

- **Therapy** mode (therapy in progress)

  Therapy is in progress (see "2.2.2 Display in patient sector (Start screen in Therapy mode)", page 8).

- **Energy-saving** mode

  The therapy device is supplied with a very low level of power; nothing is shown on the display. You can return to Standby mode by pressing the On/Off button ⏻.

2.2.1 Display in patient sector (Start screen in Standby mode)

2-2 Start screen in Standby mode

No.	Designation	Description
1	Info menu button	Provides access to the info menu.
2	Alarm clock with wake-up time	Alarm clock is set. Displays the set wake-up time.
3	Menu button	Provides access to the settings menus.
4	Dimmer button	Dims the display.
5	Clock	Displays the current time.

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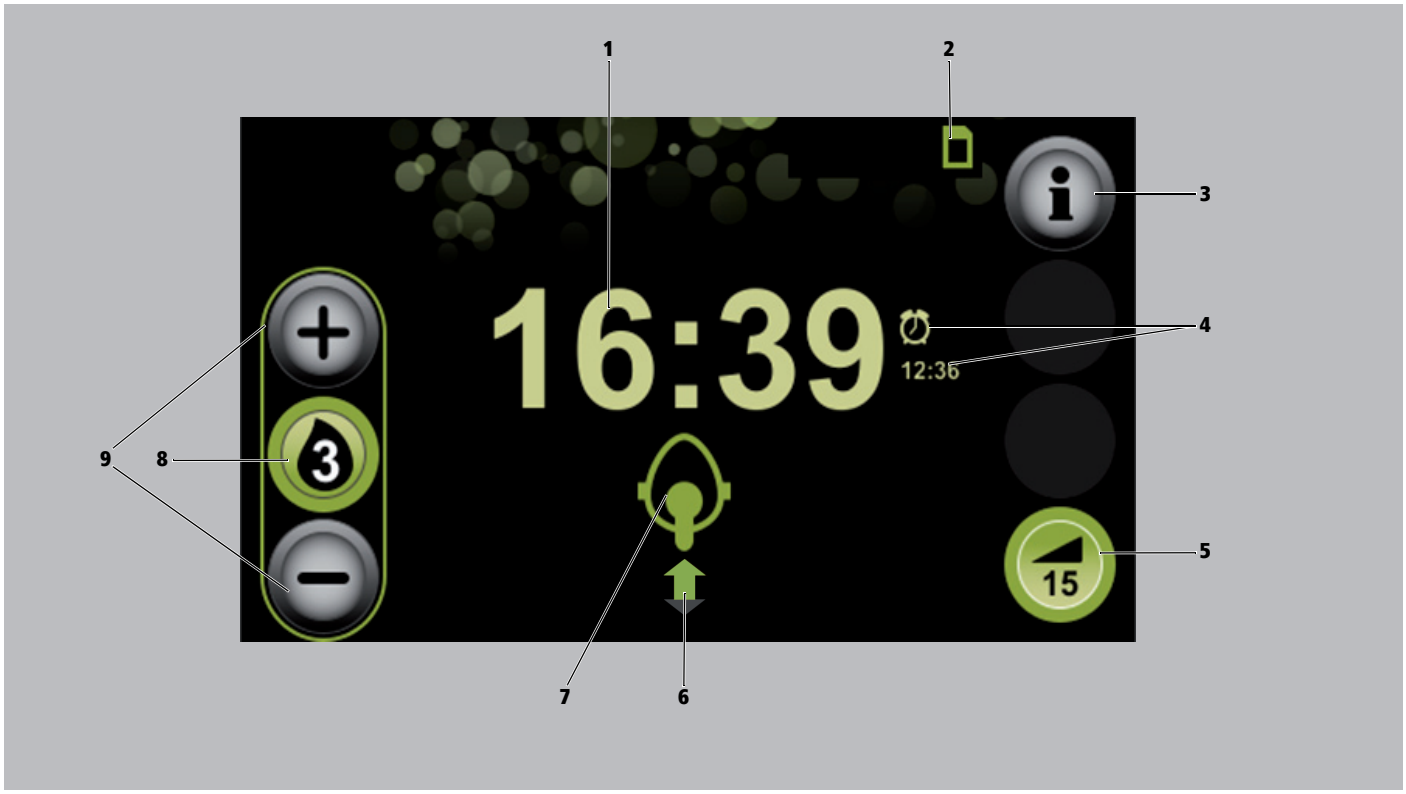
2.2.2 Display in patient sector (Start screen in Therapy mode)



2-3 Start screen in Therapy mode

No.	Designation	Description
1	Clock	Displays the current time.
2	SD card symbol	The SD card is in the therapy device.
3	Info button	Provides access to the info screen with detailed information on the therapy currently in progress.
4	Alarm clock with wake-up time	Alarm clock is set. Displays the set wake-up time.
5	softSTART button	Switches the softSTART function on or off. Displays the time remaining. If the softSTART is off, the set softSTART period is displayed. If there is no softSTART button, the physician or authorized dealer has disabled this function.
6	Respiration status symbol	Indicates the current respiration status.
7	Mask status symbol with leak indicator	Indicates how well the respiratory mask is positioned.
8	Humidifier button for respiratory air humidifier prismaAQUA	Indicates that the respiratory air humidifier is connected and switched on. Shows the set humidifier level of the respiratory air humidifier.
9	Function buttons for the respiratory air humidifier	Allow the humidifier level to be increased/decreased.

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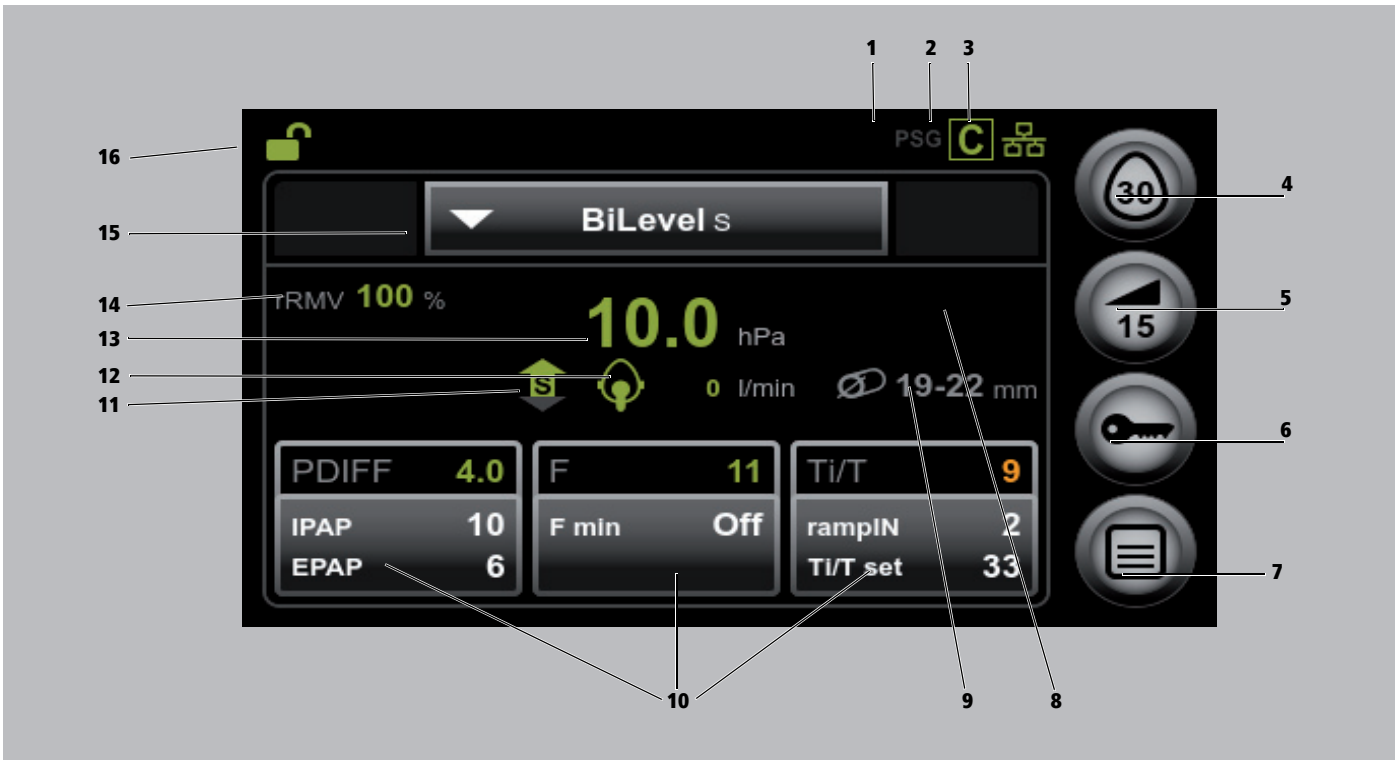
2.2.3 Display in the expert sector

Please note that the screens may differ slightly depending on the set ventilation mode and device mode.



2-4 Display in expert sector (screen in BILevel ST mode in Therapy device mode)

No.	Designation	Description
1	PSG symbol	prismaPSG module is not plugged in or there is no connection.
2	CONNECT symbol	prismaCONNECT is plugged in.
3	Network symbol	Network connection available.
4	Mask test button	Starts the mask test and stops it prematurely. Shows the remaining time in seconds.
5	softSTART button	Switches the softSTART on and off. Shows the set/remaining softSTART time in minutes.
6	Lock button	Exits the settings menus and locks the parameter setting function.
7	Menu button	Gives access to the settings menus (only available after login).
8	VT display	Displays the tidal volume. Please note that if an oxygen supply unit is used, the supplied quantity of oxygen is not taken into consideration.
9	Hose diameter display	Displays the diameter of the breathing tube used.
10	Info fields	Display the set therapy parameters. (They can be changed here following login).
11	Respiration status symbol	Indicates the current respiration status.
12	Mask status symbol with leak indicator	Displays how well the respiratory mask is positioned and the extent of any leak.
13	Actual pressure display	Shows the actual pressure.
14	rAMV display / MV display	Shows the relative or absolute respiratory minute volume (not available in CPAP or APAP mode).
15	Ventilation mode display	Displays the set ventilation mode. Allows selection of another ventilation mode.
16	Expert sector symbol	Shows that the expert sector is open and it is possible to set the parameters.

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2.3 Symbols on the display

Symbol	Designation	Description
Device status symbols (shown on the top line of the display)		
	Access symbol	The expert sector is open and the parameters can be set.
		The expert sector is open and the settings are locked. It is **not** possible to configure parameter settings.
	Bacteria filter symbol	Bacteria filter is connected and active.
	Filter change symbol	Air filter replacement required. (Symbol only appears when air filter replacement is active).
	Maintenance symbol	Maintenance required (symbol only appears when maintenance function is active).
	USB symbol	USB connection
	Connect symbol	prismaCONNECT module is plugged in.
	(Green symbol) prisma2CLOUD symbol	prisma2CLOUD module is plugged in.
	(Gray symbol)	No connection to prisma2CLOUD module established.
PSG	PSG symbol	prismaPSG module is plugged in.
PSG		No connection to prismaPSG module established.
	Network symbol	Network connection available.
		No network connection available.
	SD card symbol	SD card in SD card slot.
		Symbol flashes: Data is being saved to the SD card.
	Respiratory air humidifier symbol	Respiratory air humidifier is connected and switched off. The last set humidifier level is displayed.
		Respiratory air humidifier is connected and switched on. The currently set humidifier level is displayed.
		Respiratory air humidifier is connected and empty of water.

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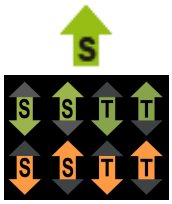
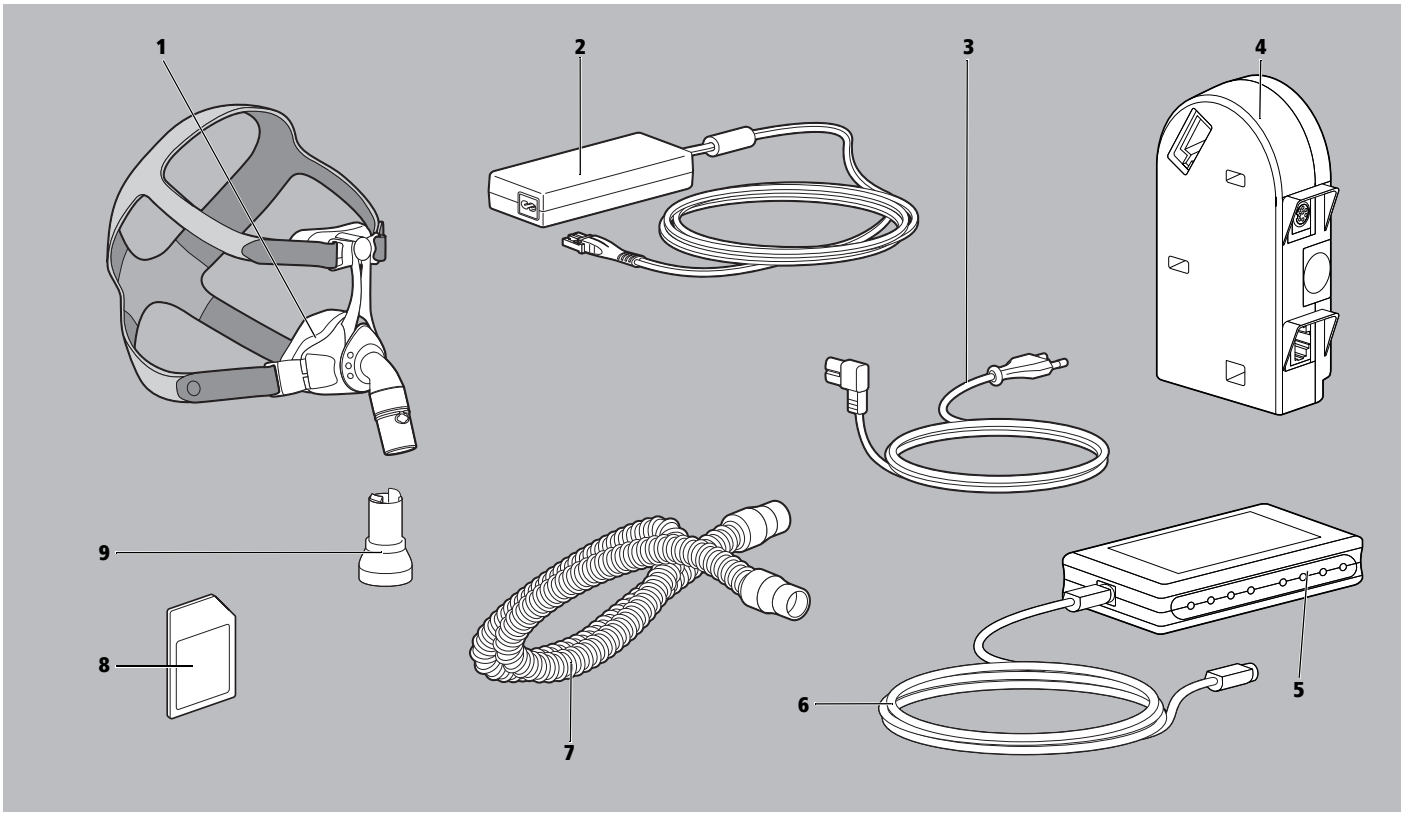
Symbol	Designation	Description
	Alarm clock symbol	Alarm clock is set. If no alarm clock symbol is shown: the alarm clock is off.
	Respiration status symbol	Displays the respiration status: S=spontaneous T=timed Arrow pointing upward: Inspiration Arrow pointing downward: Expiration
		Apnea
	Mask status symbol with leak indicator symbol	Mask position is good, no leaks
		Mask is not well positioned, considerable leaks, the efficacy of the therapy is not guaranteed
	Hose diameter symbol	Indicates the diameter of the hose in mm.
	Menu level symbol	Shows the menu level that you are currently in: The more green dots, the deeper you are in the menu structure.
Alarm window		
	Alarm symbol	Low-priority alarm triggered.
	(Black symbol) Mute symbol (Orange symbol)	Indicates that the acoustic signal for an alarm can be muted.
		Acoustic signal for alarm is muted.

2.4 Components



2-5 Components

No.	Designation	Description
1	Respiratory mask	Supplies the respiratory air to the patient.
2	Power supply unit with connection cable	Supplies power to the device. Connects the power supply unit to the therapy device.
3	Power supply cable	Connects the power supply unit to the power socket.
4	prismaCONNECT module	Creates the connection between the therapy device and PC and between the therapy device and prismaPSG module.
5	prismaPSG module	Used to convert digital signals from the therapy device into analog data.
6	PSG connection cable	Connects the therapy device to the prismaPSG module.
7	Breathing tube with 19 mm diameter	Connects the therapy device to the respiratory mask.
8	SD card	Records therapy data.
9	Exhalation system	If the mask does not feature an integrated expiratory system, the exhaled air escapes here during the therapy.

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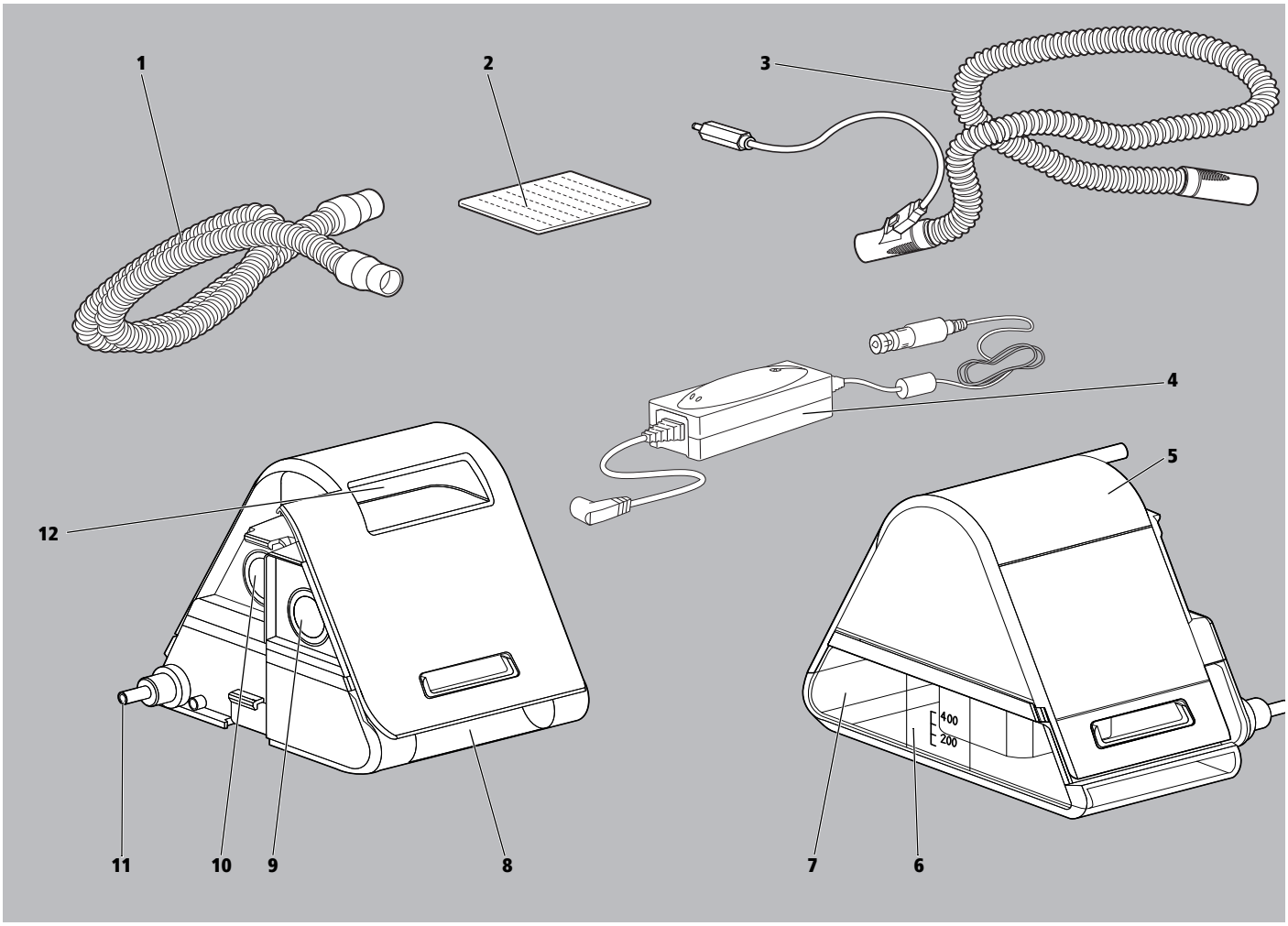
2.5 Accessories



2-6 Accessories

No.	Designation	Description
1	Breathing tube with 15 mm diameter	Connects the therapy device to the respiratory mask.
2	Pollen filter (white filter)	Filters the suctioned respiratory air and prevents the ingress of fine dust particles, pollen and fungal spores. Recommended for patients with allergies.
3	Heatable hose	Avoids condensation in the breathing tube (only applies to devices as of serial number 5.000).
4	Inverter	Enables operation of the device via a DC power socket (12 V/24 V).
	Respiratory air humidifier prismaAQUA	
5	Top of humidifier	Seals the respiratory air humidifier.
6	Humidifier insert	Prevents water from escaping.
7	Base of humidifier	Holds the water for humidifying the respiratory air.
8	Lower grip recess	For opening the respiratory air humidifier.
9	Input	Connects the therapy device to the respiratory air humidifier.
10	Output	Connects the respiratory air humidifier to the device output.
11	Heating element	Heats the water in the respiratory air humidifier.
12	Upper grip recess	For lifting and transporting the respiratory air humidifier.

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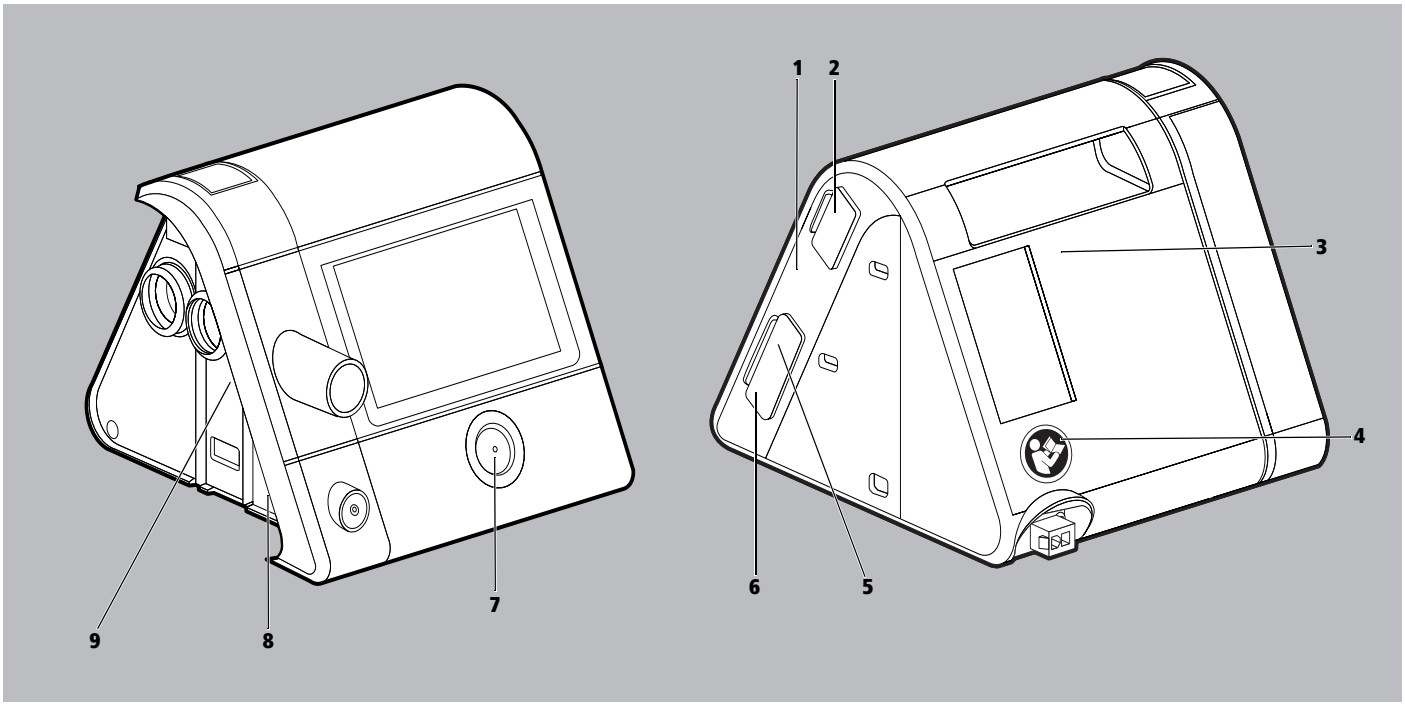
2.6 Labels and symbols

2.6.1 Labels on the therapy device



2-7 Labels on the therapy device

No.	Symbol	Description
Type plate on the right side of the therapy device		
1	SN	Serial number of the therapy device
		Year of manufacture
Labels and symbols on the therapy device		
2 , 8		Consult instructions for use
3		Device inlet: inlet for room air at ambient temperature
4		Follow the instructions for use
5		Slot for SD card
6		USB port
7		Indicates the On/Off button
9		Device output: Outlet for room air at 4 hPa to 30 hPa (depending on type of device)

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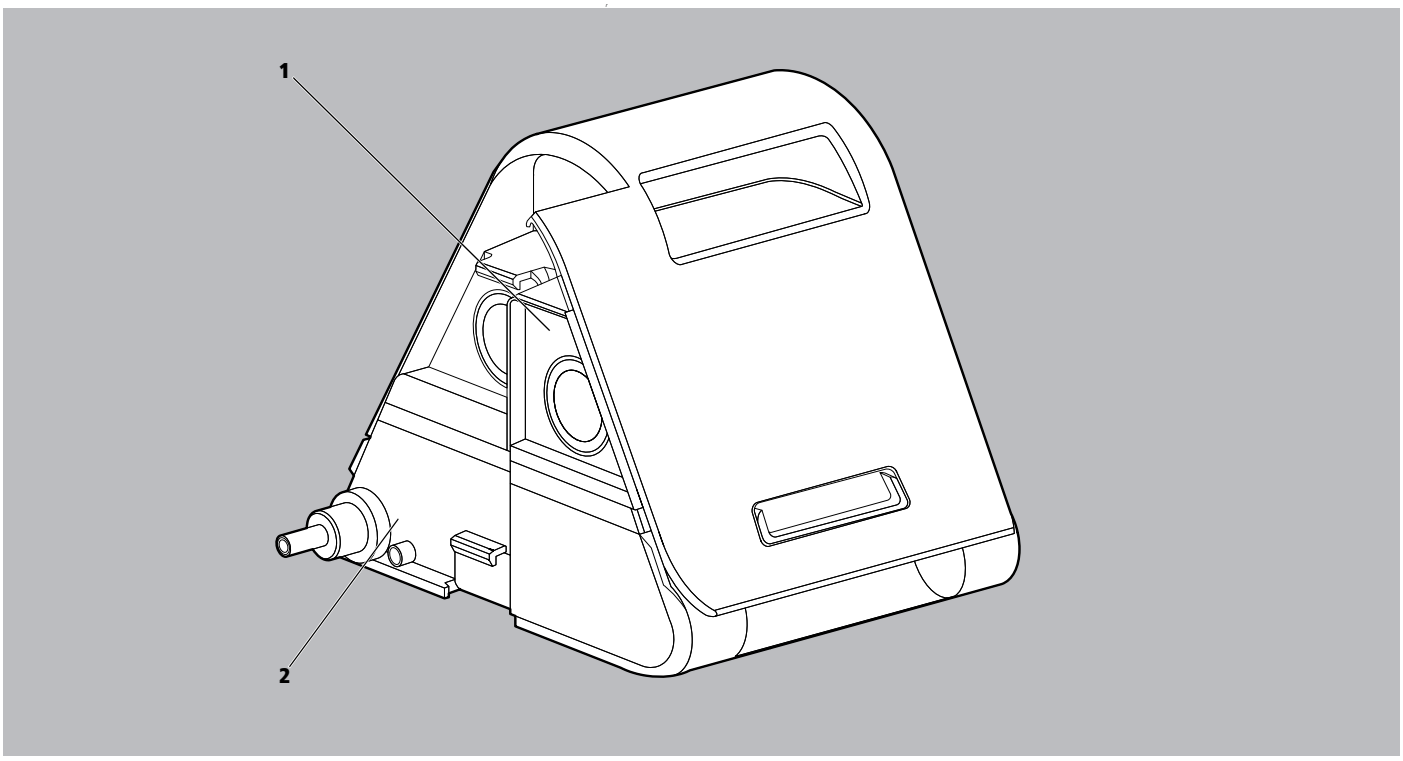
No.	Symbol	Description
Type plate on the underside of the therapy device		
	TYPE: WM 100 TD	Type designation of the therapy device
	37V ⎓	37 V DC
	IP21	IP protection class: Degree of protection against ingress of dangerous parts and solid foreign bodies. The device is protected against dripping water.
		Degree of protection against electric shock: Protection class II device
		Do not dispose of device in household waste
		Suitable for use in airplanes. Complies with RTCA/DO-160G chapter 21, Category M.
		Degree of protection against electric shock: Type BF device
		Manufacturer
	CE 0197	CE mark (confirms that the product complies with the applicable European directives)

2.6.2 Labels on the respiratory air humidifier



2-8 Labels on the respiratory air humidifier

No.	Symbol	Description
1		Fill with water

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No.	Symbol	Description
2		Respiratory air humidifier is heated. Do not touch the element!
Labels and symbols on the underside		
		Do not dispose of device in household waste
	CE 0197	CE mark (confirms that the product complies with the applicable European directives)
	32 V DC	32-volt direct current
		Degree of protection against electric shock: Type BF device
	IP21	IP protection class: Degree of protection against ingress of dangerous parts and solid foreign bodies. The device is protected against dripping water.
	>PC<	Material designation: Polycarbonate
		Date of manufacture (month/year)
	Type: WM100TH	Type designation: Device in the WM 100 TH series
		Consult instructions for use
	SN	Serial number

2.6.3 Labels on the type plate of the power supply unit

Symbol	Description
Input: 100-240 V, 50-400 Hz, 1.5 A	Input voltage: 100-240 V, 50-400 Hz, 1.5 A
Output: 37 V ⎓ 2.43 A	Output voltage 37 V DC 2.43 A
	GOST-R certification (confirms that the product complies with the applicable Russian directives)
	China RoHS label (confirms that the product does not emit toxic substances for the number of years indicated)
	PSE mark (confirms that the product complies with the applicable Japanese directives)
	Only intended for indoor use.
	Degree of protection against electric shock: Protection class II device
	Do not dispose of device in household waste
	CE mark (confirms that the product complies with the applicable European directives)
IP21	IP protection class: Degree of protection against ingress of dangerous parts and solid foreign bodies. The device is protected against dripping water.
29657#XXXX	Serial number

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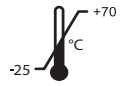
2.6.4 Labels on the therapy device packaging

Symbol	Description
	Permissible storage temperature: -25°C to +70°C
	Permissible storage humidity: 15% to 93% relative humidity

2.6.5 Labels on the breathing tube packaging

Symbol	Description
	For use on one patient only!

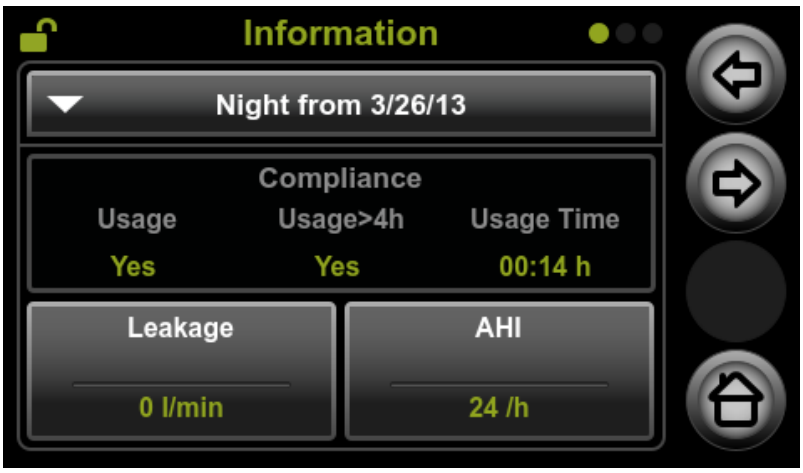
2.6.6 Viewing the therapy data and device information in the Expert Info menu

In the Expert Info menu you can view information about the therapy quality (compliance, leaks, AHI, pressure statistics in ventilation modes with automatic pressure adaptation) of a selectable period of time, the required pressure, and general information about the device and network.

Requirement

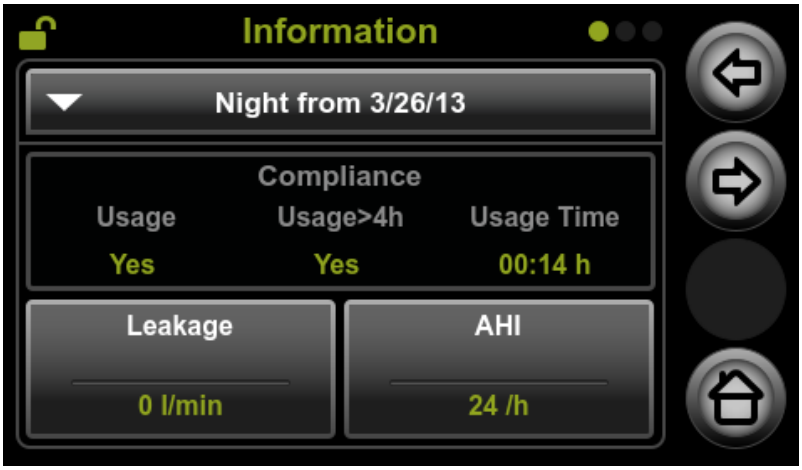
- The therapy device is in **Standby** mode.
- The expert sector is open.

1. Press the info button .

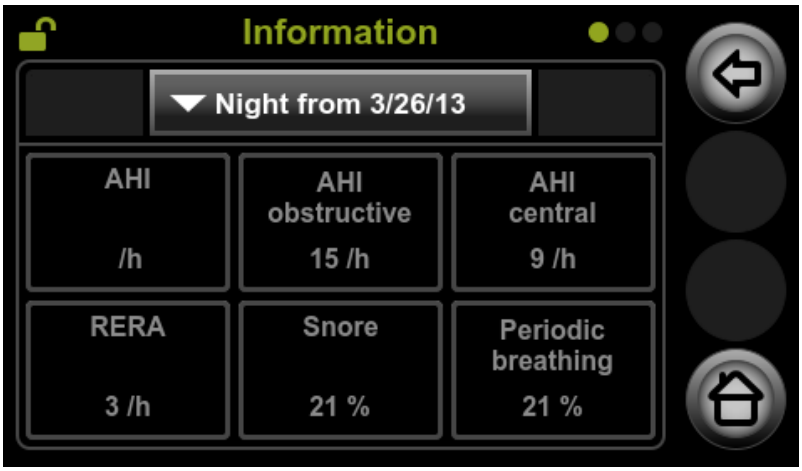


2. If necessary: To view therapy data from a night other than the previous night, select the desired date in the list .
3. If necessary: To view a longer period of time, navigate to the second screen .

4. Select the required period.
5. Navigate back with the ◀ arrow key.



6. To view detailed information about the leakage, press the **Leakage** field.
7. To view detailed information about the apnea–hypopnea index (AHI) and respiratory parameters, press the **AHI** field.



8. In some modes there are also additional pages displaying the required pressures and statistical parameters on respiratory rate and volume. If present: Use ▶2 to navigate to the second and third screens.
9. To view the device information, navigate using the arrow keys ▶ and ◀ and press the **Device** field.

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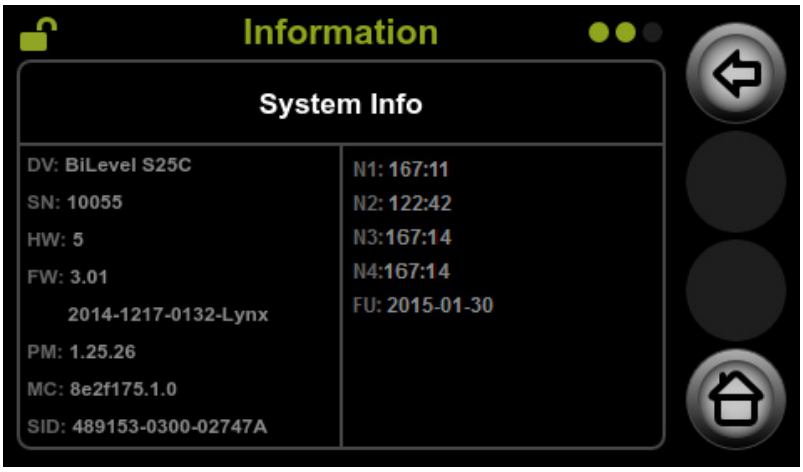


Abbreviation	Description
DV	Device version
SN	Serial number
HW	Hardware version
FW	Firmware version
PM	Not relevant, internal developer information
MC	Not relevant, internal developer information
SID	System identification of the device
N1	Therapy hours without artifacts or open mask. This counter is reset when therapy data in the device are deleted or the device is reset to the factory settings.
N2	Therapy hours with respiratory air humidifier (without artifacts or open mask). This counter is reset when therapy data in the device are deleted or the device is reset to the factory settings.
N3	Patient operating hours: Period of use including artifacts and open mask. This counter is reset when therapy data in the device are deleted or the device is reset to the factory settings.
N4	Fan running time. Determines the age of the device and cannot be reset.
FU	Date of first therapy. In combination with the current counter readings, you can use this to determine the compliance, for example the daily usage. This is especially important when therapy data in the device have been deleted since the last compliance check. In this case, you can see the date of the first therapy after the data were deleted and can reconstruct the compliance as of this date.

10.To exit the info menu, press the Home button .

Result The therapy data and device information are called up.

3 Maintenance

3.1 General information

Maintenance, safety checks, inspections and repairs must only be carried out by the manufacturer or a technician specifically authorized by the manufacturer.

3.2 Intervals

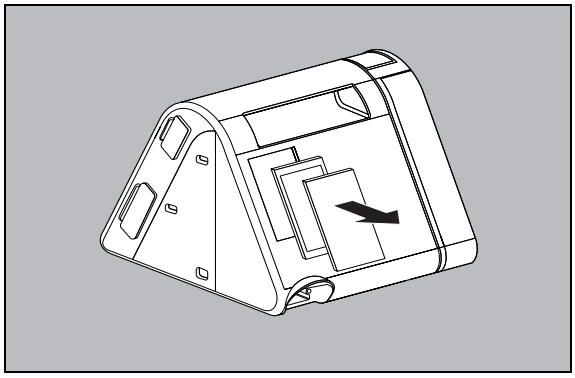
The therapy device is designed to have a useful service life of 6 years.

Once these 6 years have elapsed, a complete final test must be performed (see "5 Final test", page 29).

If the therapy device is used for its intended purpose, in accordance with the instructions for use, it does not require any maintenance.

If the respiratory air humidifier is used for its intended purpose, in accordance with the instructions for use, it does not require any maintenance.

3.3 Changing the filter



1. Remove the air filter WM 29651.
2. If present: Remove the pollen filter WM 29652.
3. Insert new pollen filter WM 29652.
4. Insert new air filter WM 29651.

Resetting the filter change interval

You need to set the filter change interval to zero if you have changed the air filter and the reminder for the air filter change is active.

1. Switch on the therapy device.
2. To open the expert sector, hold the info button down for > 4 seconds.
3. Press the menu button.
4. Press the **Reset** field.
5. Press **Reset air filter**.
6. Press **Changed**.

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Resetting the maintenance counter

Only applies if the maintenance counter is active: You need to reset the maintenance counter after every service and every hygienic preparation in order to return the hour counter to zero.

1. Switch on the therapy device.
2. To open the expert sector, hold the info button down for > 4 seconds.
3. Press the menu button .
4. Press the **Reset** field.
5. Press **Reset maintenance counter**.
6. Press **Reset**.
7. Press **OK**.

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4 Hygienic preparation

4.1 General information

- **This product may contain disposable items. Disposable items are intended to be used only once.** Use these items only once and do **not** reprocess them. Reprocessing disposable items may impair the functionality and safety of the product and lead to unforeseeable reactions as a result of aging, embrittlement, wear, thermal load, the effects of chemical processes, etc.
- Wear suitable protective equipment for disinfection work.
- Please refer to the instructions for use supplied with the disinfectant used.
- Also observe the respective instructions for use of the device, the components, and the accessories.
- As an alternative to the disinfection procedure described here, you can disinfect the device for a patient change up to 5 times using the Keredusy procedure. Please follow the manufacturer's procedure instructions. It is not necessary to exchange the components as per the patient change set WM 29973 in this case. However, the air filter WM 29651 and the pollen filter (if present) must be replaced.

4.2 Hygienic preparation of the therapy device

4.2.1 Hygienic preparation during use

Please observe the instructions for use of the therapy device.

4.2.2 Hygienic preparation for repairs

1. Wipe-disinfect the exterior of the housing and the power supply cable.
2. Clean or replace (depending on their condition) the following parts in accordance with the instructions for use:
   - Breathing tube WM 24445
   - Respiratory mask with headband
3. Open the therapy device.
4. Clean points which are extremely dirty.
5. Change the filter (see "3.3 Changing the filter", page 20).
6. Close the therapy device (see "7.3 Closing the therapy device", page 43).

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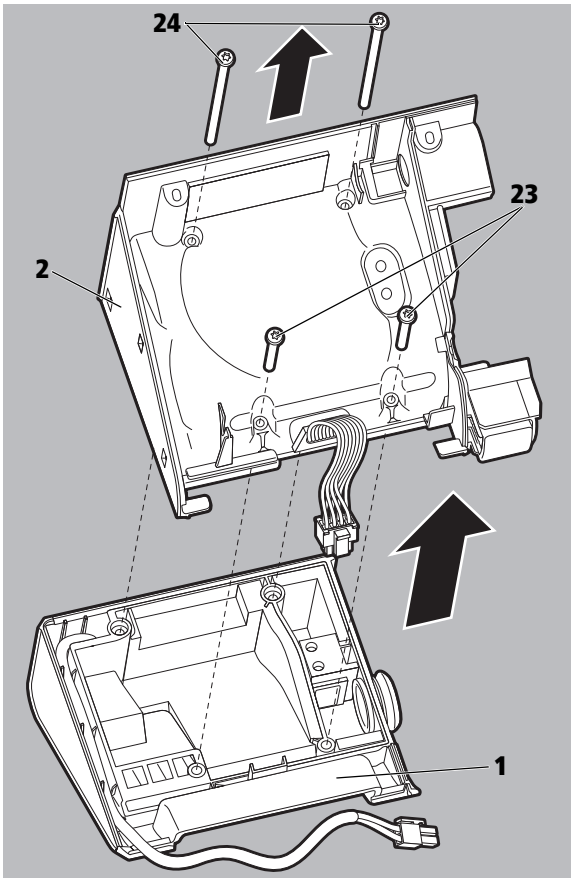
4.2.3 Hygienic preparation during patient change

1. Wipe-disinfect the following parts:
- Housing
- Power supply cable
- Power supply unit
2. Replace the following parts:
- Breathing tube WM 24445
- Respiratory mask with headband
- Transport case prismaBAG basic WM 29659 / prismaBAG premium WM 29977
- Patient change set WM 29973
3. Open the therapy device (see "7.2 Opening the therapy device", page 41).
4. Place the therapy device on a table on its rear.
5. Undo and remove 2 screws **23**.
6. Undo and remove 2 screws **24**.
7. Lift the central part of the housing **2** off the rear of the housing **1**.



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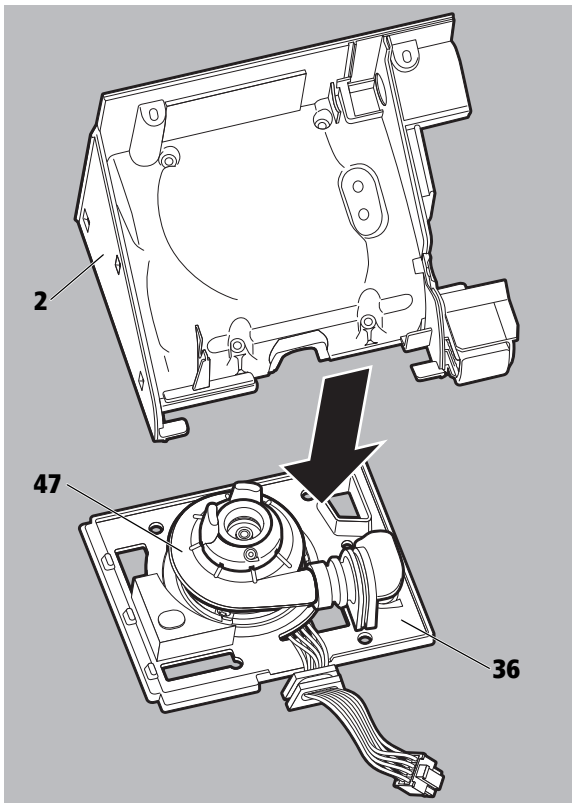
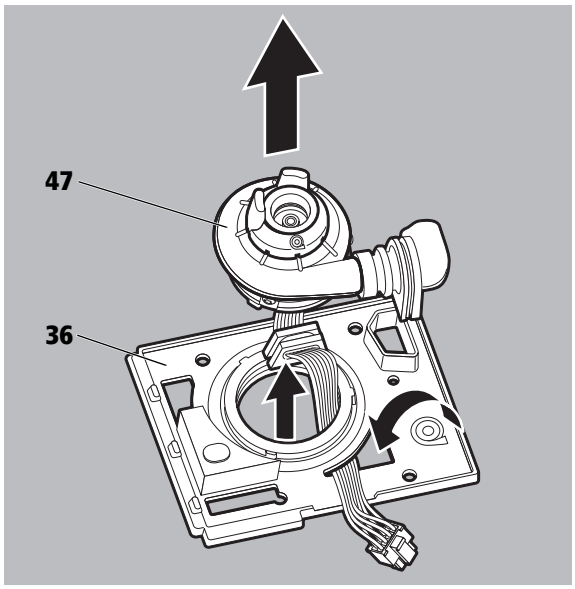
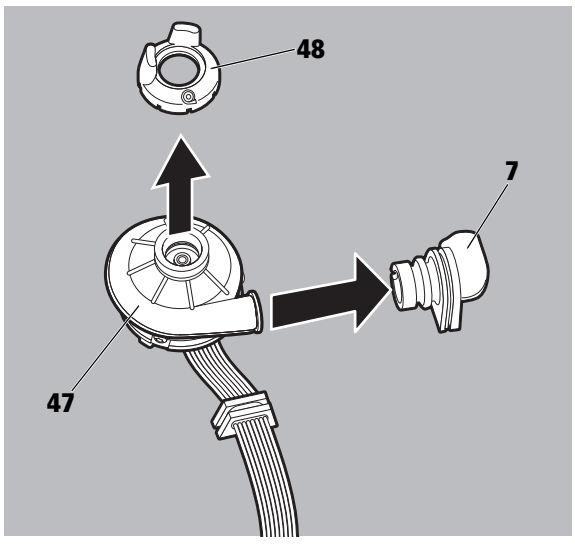


8. Pull out the fan **47** together with the membrane **36** from the central part of the housing **2**.



9. Remove the fan **47** from the membrane **36**.



10. Detach the decoupling hose **7** and spacer **48** from the fan **47**.

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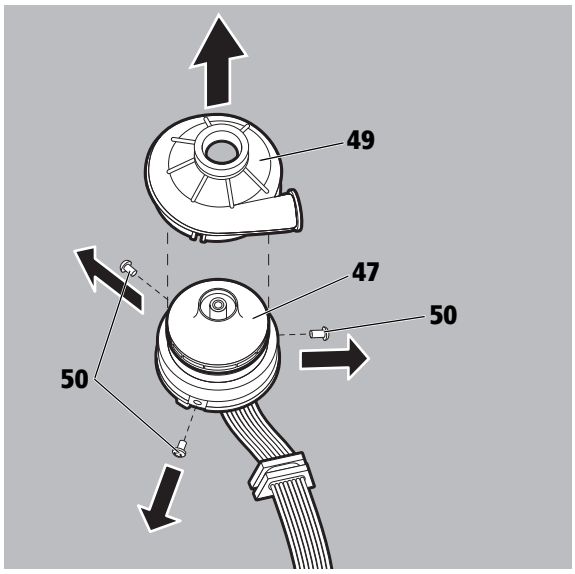
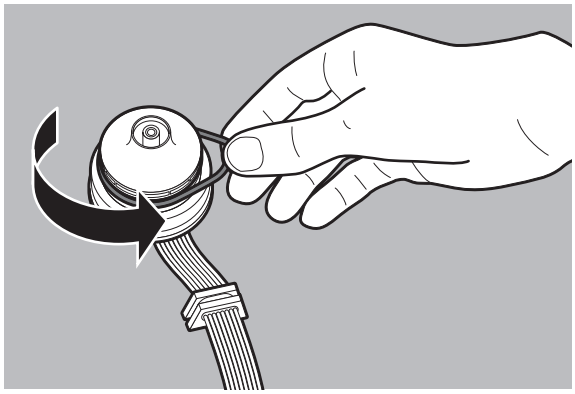
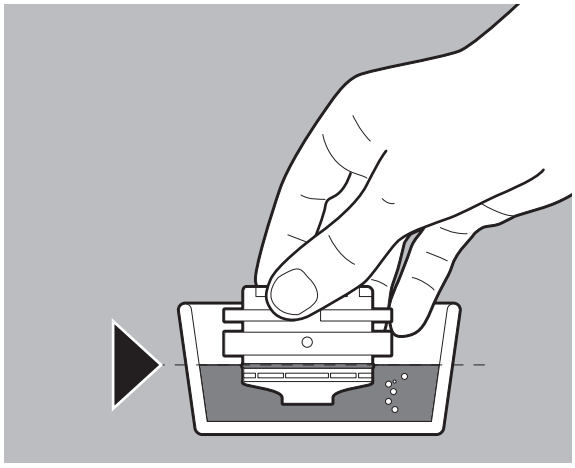


11. Undo and remove 3 screws **50** on the fan **47**.
12. Remove the fan cap **49** from the fan **47**.
13. Wipe-disinfect the following parts:
    - Fan body
    - Fan cable



14. Immerse the fan in disinfectant **47**:
    - Take the O-ring supplied in the service set and carefully pull it over the fanwheel, positioning it carefully between the fanwheel and the fan body. Ensure that the circumferential gap is completely sealed and the O-ring is not twisted.



- Place the fan with the fanwheel in a suitable container.
- Fill the container with disinfectant solution to the level of the O-ring.
- Lift and lower the fan gently a number of times so that the air escapes from the blade outlets of the fanwheel, and the outlets fill completely with disinfectant.
- Allow an exposure time of 15 minutes.
- Rinse the fanwheel with water in the same way.
- Remove the O-ring carefully.

15. Immerse or spray-disinfect the fan cap.

NOTICE

Risk of damage when tightening the screws against the fan cap.
There is a risk of damaging the fan cap when tightening the screws.
⇒ Only tighten the screws gently against the fan cap.

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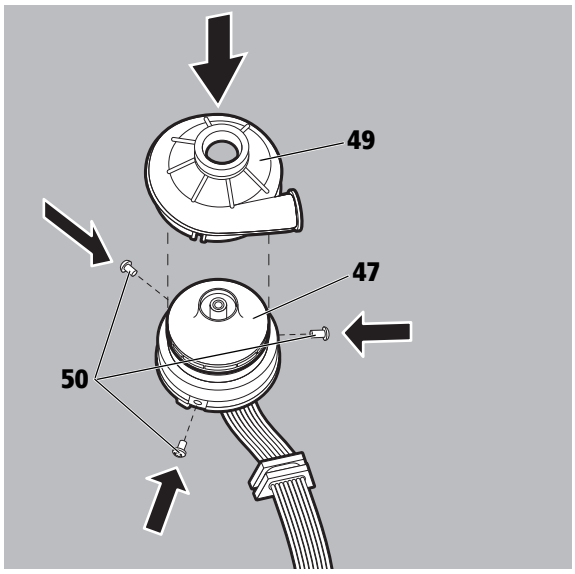
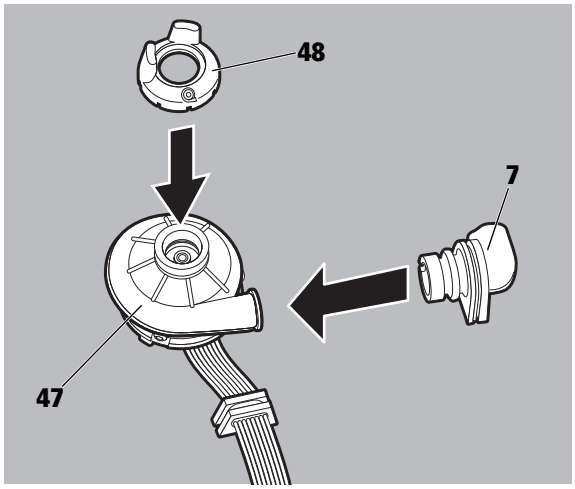
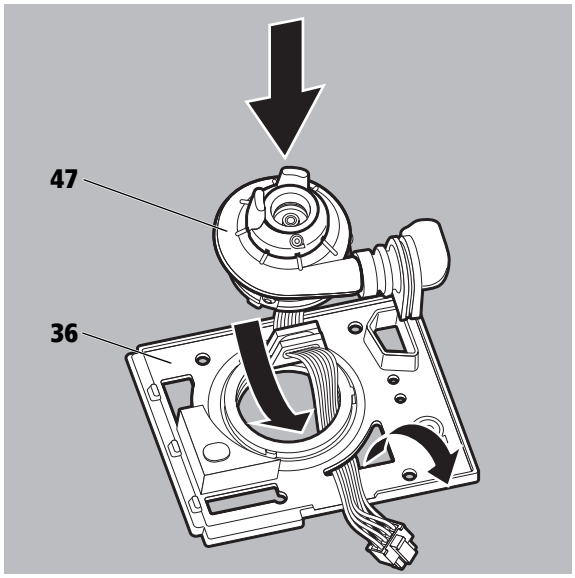


16. Replace the fan cap on the fan **47**.
    When doing so, pay attention to the correct positioning.
17. Secure the fan cap **49** in position with the 3 new screws **50**.



18. Secure the new decoupling hose **7** and new spacer **48** on the disinfected fan **47**.
    When doing so, pay attention to the correct positioning.



19. Insert the fan **47** in the membrane **36**.
    Note: The marks on the membrane must be aligned with the screws on the fan.

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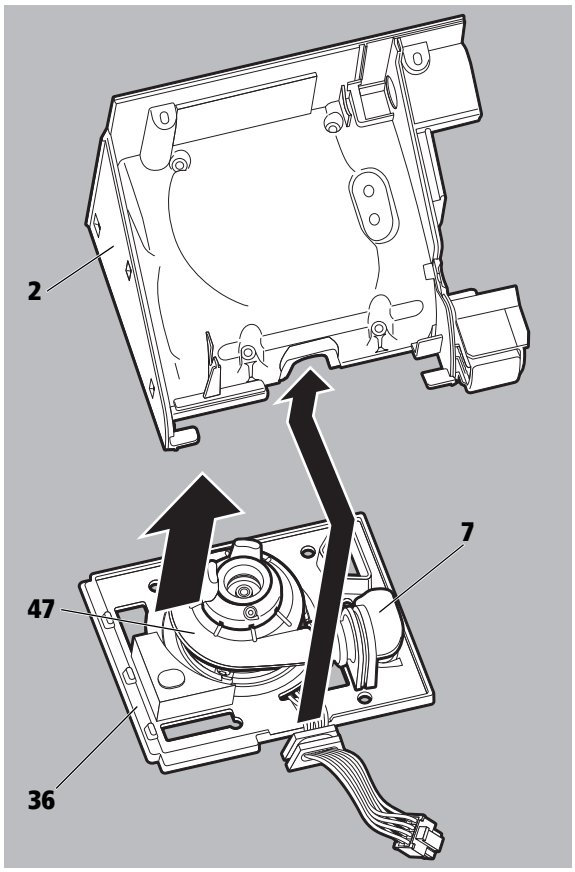
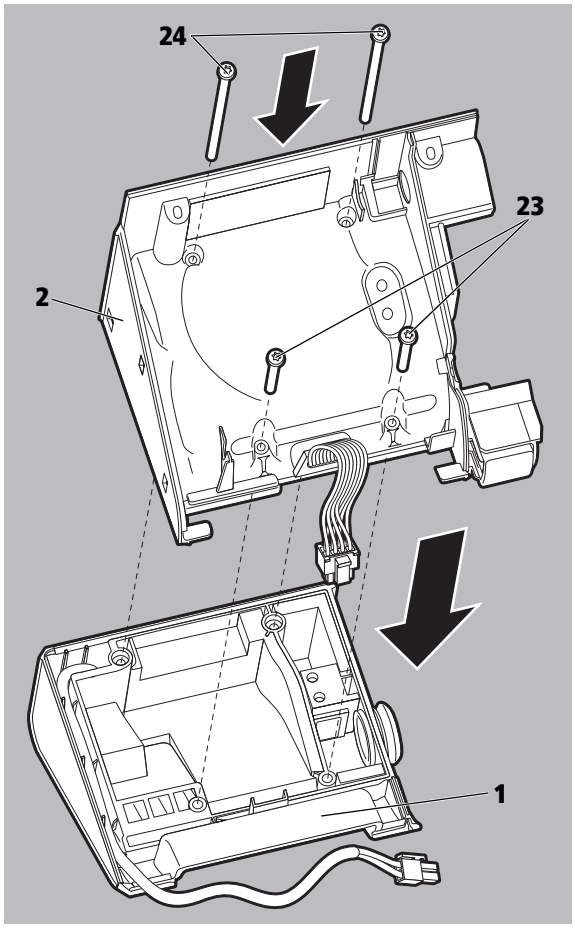


20. Insert the fan **47** with the membrane **36** into the central part of the housing **2**.
21. Insert the decoupling hose **7** and the cable bushing into the central part of the housing **2**.
    Note: The decoupling hose must not be kinked or trapped.



22. Place the central part of the housing **2** on the rear of the housing **1**.
    Note:
    - The connection cable for the power supply unit must be installed and correctly routed.
    - The membrane between the parts of the housing must be positioned correctly.
23. Secure the central part of the housing **2** in place with the 4 screws **23** and **24**.
24. Close the therapy device (see "7.3 Closing the therapy device", page 43).
25. Replace the air filter and pollen filter (if present) (see "3.3 Changing the filter", page 20).
26. Insert the new seal for the device outlet **40** and the new device outlet **51**.
27. Reset therapy device to factory settings.
28. Test the therapy device (see "5 Final test", page 29).

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4.3 Hygienic preparation of the respiratory air humidifier

4.3.1 Hygienic preparation during use

Please observe the instructions for use of the therapy device.

4.3.2 Hygienic preparation during patient change

Requirement The therapy device was used without a bacteria filter previously.

- Check the plastic components and replace if they display damage (e.g., cracks).
- If the plastic components and heating element display considerable limescale. Offer a new device.
- Use the patient change set WM 29974 for hygienic preparation.

1. Remove the top of the humidifier.
2. Remove the humidifier insert,
3. Unscrew the heating element out of the base of the humidifier.
4. Remove the O-ring from the heating element.
5. Wipe-disinfect the heating element and the top of the humidifier.
6. Place the new O-ring on the heating element.
7. Screw the heating element back into the new base of the humidifier.
8. Insert the new humidifier insert into the top of the humidifier.
9. Close the respiratory air humidifier.

4.3.3 Hygienic preparation during patient change, when using with a bacteria filter

Please observe the instructions for use of the therapy device.

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5 Final test

5.1 General information

The therapy device has a programmed step-by-step test to simplify the test procedure. This is available when the Service mode is active (see " Perform the step-by-step test", page 33).

The step-by-step test includes all the test steps which are necessary for checking the proper functioning of the therapy device.

The test procedure is not dependent on the current settings of the therapy device, i.e., the patient parameters are retained unaltered.

In addition, other service functions are available in Service mode (see "5.2 Service mode", page 29).

- Perform a final test:
  - Following every maintenance
  - Following every repair/service
  - Following every hygienic preparation
- During the final test, fill out the test record (see "13 Test record", page 72).
- If you discover any defects or deviations from the specified values during the final test, you must not use the therapy device again until they have been rectified.
- You should also use the final test to locate faults. You will find an overview of possible faults in the chapter "Error messages" (see "6 Faults", page 37).
- You will find the necessary auxiliary equipment in the chapter "Required auxiliary equipment" (see "11 Required auxiliary equipment", page 64).

5.2 Service mode

The therapy device has a Service mode, which can be activated with the service connector WM 29917, which is available for the trained service technician.

The Service mode is activated by connecting the service connector to the system interface. The Service menu appears after approx. 5 seconds. The Service menu is only available in English and contains the following functions:

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Function	Tab	Parameter	Description	Settings option
Versions, types	SNs, types	Device type	Shows which modes are available	
		Device serial number	Shows the serial number of the therapy device.	One-off input of serial number if current serial number is "0".
		Mainboard serial number	Shows the serial number of the mainboard.	One-off input of serial number if current serial number is "0".
		Blower index	Blower version index	Currently "0"
		Startup logo	Shows the activated startup logo.	
	Versions	Mainboard HW version	Shows the HW version of the mainboard.	Performed automatically
		Display HW version	Shows the HW version of the display.	Performed automatically
Display, touchscreen		Display test	For testing the color rendering of the display and any pixel errors.	Service for test purposes only; selection of different color tones.
		Recalibrate touchscreen	Calibration of the touchscreen	
		Power LED status	Check of On/Off button illumination	
		Start test for touchscreen	Check of touchscreen reaction	
		Display brightness test	Check of display brightness	
Beeper control			Check of beeper at 3 different volume settings	
Motor, humidifier	Motor & pressure control	Flow, l/min	Display of current flow	
		Ambient pressure	Display of current ambient pressure	
		Mask pressure	Display of current mask pressure	
		Device pressure	Display of current pressure at device outlet	
		Motor speed	For checking the flow/pressure depending on the set blower speed.	For test purposes only; motor speed
		Mask pressure	For checking the flow/pressure depending on a specific pressure.	For test purposes only; setpoint pressure
	Humidifier and hose heater control	Humidifier current	Shows the current consumption of the heating element.	
		Humidifier voltage	For checking the current voltage supply of the heating element.	For test purposes only; different voltages
		Hose heater connection	Shows whether a heatable hose is connected.	
		Hose heater	For activating the hose heater.	
	Voltages	Operating voltage	Shows the current operating voltage of the therapy device.	
		Humidifier voltage	Shows the current supply voltage of the heating element.	
		External modules voltage	Shows the current supply voltage of the system interface.	
		Motor voltage	Shows the current supply voltage of the blower.	
		RTC battery status	Shows whether the internal clock is supplied with power by the battery.	

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Function	Tab	Parameter	Description	Settings option
Date, time reminders	Date, time	RTC current date/ time (UTC)	Shows the current setting of the real time clock.	Date, time
		Time zone	Shows the current setting of the time zone.	Time zone
		Daylight saving time	Summer/winter time changeover	Press the On/Off button.
		Local date/time	Current local time	
	Using time/service dates	Device operating hours	Shows the total operating hours of the therapy device.	Current operating hours, if currently < 10
		Next device service	Indicates the date when the next service is due.	Resetting the maintenance counter
		Device service reminder	Optional activation of the service reminder	Press the On/Off button.
		Device service period	Specification of service interval, if service reminder is active.	Setting of interval between 1 and 4 years
		Filter change reminder	Optional activation of the filter change display	Press the On/Off button.
External interfaces		SD card test status	Check of SD card	Test of card access
		PSG UART test status	Check of PSG UART	Test of communication PSG UART
		Second MCU UART test status	Check of second MCU UART	Test of second MCU UART
		I2C test status	Check of I2C communication with the Zubehörteil module	Test of I2C communication, Zubehörteil must be connected
		Com. module on USB	Check of communication with Zubehörteil	
		USB mass storage cable	Connection of USB cable	Check of USB connection.
		SD card	Check of card reader	
		Power key status	Status of On/Off key	Check of function of On/Off key.
Service files			Error memory	Erasing of error memory.
Clear, copy, format		Clear user compliance	Clearing of patient usage times.	
		Format SD card	Erasing of SD card.	Erase SD card.
		Factory settings	Reset to factory settings.	
		Copy data on SD card	Copy data to SD card.	Start transfer.
		Import compliance & config from SD card	Take over settings and data from the SD card.	Start transfer.
Step by step test			Programmed test procedure	

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5.3 Preparation for testing

1. Connect the power supply unit to the therapy device and switch on the power supply (see instructions for use for the therapy device).
2. Connect up the breathing tube.
3. Connect up the respiratory mask.

5.3.1 Checking the housing

1. Check the general state of the housing (visual inspection).
2. If the housing is damaged or defective: Replace the housing (see "7.7 Replacing the parts of the housing", page 55).

5.3.2 Checking the power supply cable

1. Inspect the power supply cable.

   Requirement:

   - The insulation is OK.
   - The cable shows no signs of damage.
   - There are no loose contacts.

2. If any of the requirements are not fulfilled: Replace the power supply cable.

5.3.3 Checking the power supply unit.

1. Inspect the power supply unit for external damage.
2. Connect the power supply unit to the power supply.

   Requirement: The LED in the power supply unit lights up.

3. If the requirement is not fulfilled: Replace the power supply unit.

5.4 Performing a function check

5.4.1 Checking the therapy device

Requirement

- The therapy device is disconnected from the patient.
- The therapy device is connected to the power supply.
- The therapy device is in **Standby** mode.

1. Inspect the therapy device for external damage.
   If damaged: Do not use the therapy device.
2. Inspect the plug and cable for external damage.
   If damaged: Replace parts.

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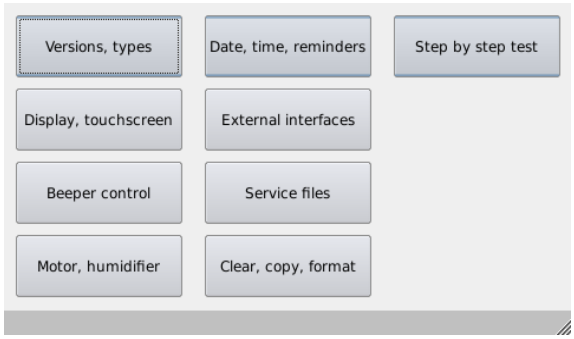
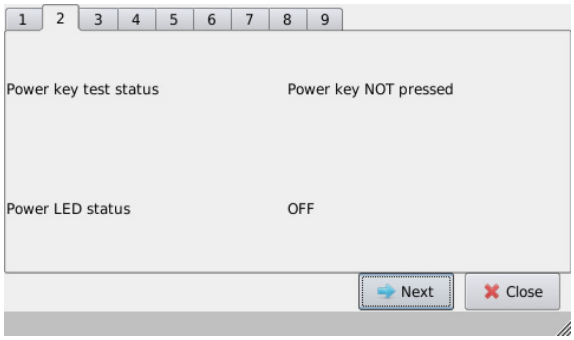
Perform the step-by-step test

1. Activate the Service mode: Connect the service connector WM 29917 to the system interface.
   The Service menu opens after approximately 5 seconds.
2. Press the **Step-by-step test** field.



3. **Step 1**: Compare the date and time with a reference clock.

   Requirement:
   The date and time are correct.
   If not, correct them.
4. Press **Next**.



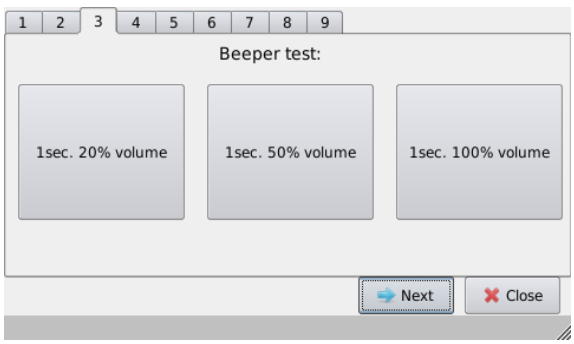
5. **Step 2**: Test the On/Off button.

   Requirement:

   - Display: **Power key test status -> Power key NOT pressed**
   - Display: **Power LED status -> OFF**
6. Press the On/Off button.

   Requirement:

   - Display: **Power key test status -> Power key pressed**
   - Display: **Power LED status -> ON**
   - On/Off button lights up green.
7. Press **Next**.



8. **Step 3**: Check alarm beeper.
9. Press the 3 buttons for the different volume levels one after the other.

   Requirement:
   Audible signals are emitted with three different volumes.
10. Press **Next**.

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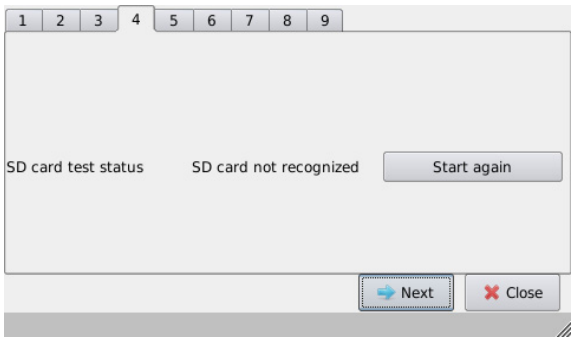


11. **Step 4**: Checking the SD card.

    Requirement:

    - Display: **SD card test status -> Passed** (if SD card is in the device)

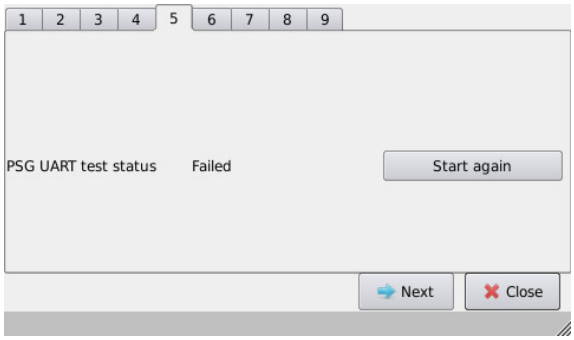
    or

    - Display: **SD card test status -> SD card not recognized** (if no SD card is in the device)

12. If no SD card is in the device:
    Insert SD card and press **Start again**.

    Requirement:
    Display: **SD card test status -> Passed**

13. Press **Next**.

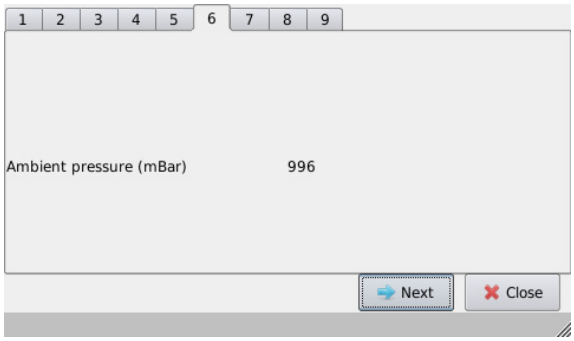


14. **Step 5**: Check PSG/system interface.

    Requirement:
    Display: **PSG UART test status -> Passed**
    (UART = Universal Asynchronous Receiver Transmitter)

15. If the display is **PSG UART test status -> Failed**:
    Press **Start again**.

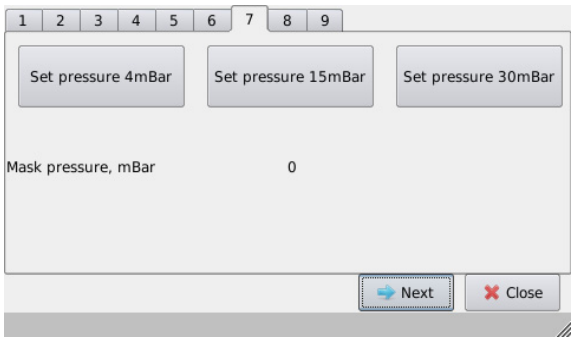
16. Press **Next**.



17. **Step 6:** Check the ambient pressure sensor.

    Requirement:
    The ambient pressure displayed corresponds to the current air pressure. The deviation must not be more than 20 mbar.

18. Press **Next**.



19. **Step 7**: Check the pressure settings.

20. Insert the pressure measurement adapter on the device outlet and close.

21. Connect the side port of the pressure measurement adapter to a pressure measurement device.

22. Press the 3 buttons for the different pressure values one after the other and compare the pressure displayed by the therapy device and by the pressure measurement device in each case.

    Requirement:
    The difference between the measured pressure and the pressure displayed by the therapy device is within the tolerance specified in the test record.

23. Remove the pressure measurement adapter from the device outlet.

24. Press **Next**.

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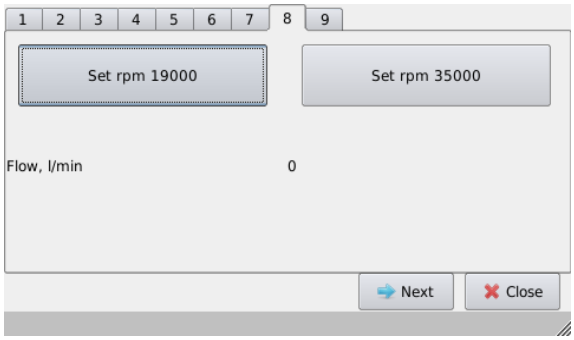

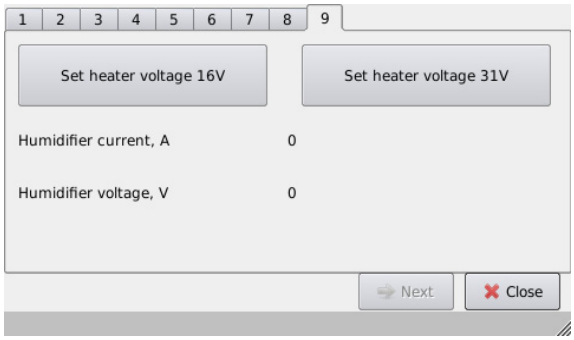

25. **Step 8**: Check the flow values
26. Press the 2 buttons for the different speeds one after the other and read off the displayed flow.

    Requirement:
    The displayed flow values are within the tolerance specified in the test record.
27. Press **Next**.

28. **Step 9**: Check the humidifier interface (heating element)
29. Connect up the respiratory air humidifier.

    or
30. Remove the side cover and connect the individual heating element to the port on the therapy device.
31. Press the 2 buttons for the different voltages one after the other.

    Requirement:
    The voltage and current consumption displayed are each within the tolerance specified in the test record.
32. Press **Close**.
33. Remove the service connector from the therapy device to exit the Service menu.

Result The function check is complete.

5.4.2 Checking the respiratory air humidifier

Requirement

- The therapy device is disconnected from the patient.
- The therapy device is connected to the power supply.
- The therapy device is in **Standby** mode.

1. Inspect the housing for cracks, damage, and heavy soiling.
2. If there are cracks, damage, or soiling: Replace housing parts or humidifier insert.
3. Fill the respiratory air humidifier to the line with water.
4. Check whether the respiratory air humidifier has any leaks.
   If the respiratory air humidifier does have leaks: Replace damaged parts.
5. Pour out the water.
6. Fill the respiratory air humidifier with 200 ml of water.
7. Connect the respiratory air humidifier to the therapy device.
8. Switch on the respiratory air humidifier.
9. Set humidifier heating level 7 on the therapy device.
10. Check whether the respiratory air humidifier warms up.
    If the respiratory air humidifier is not slightly warm after 10 minutes: Replace the heating element or mainboard (see "7.4 Replacing the mainboard", page 44).

Result The function check is complete.

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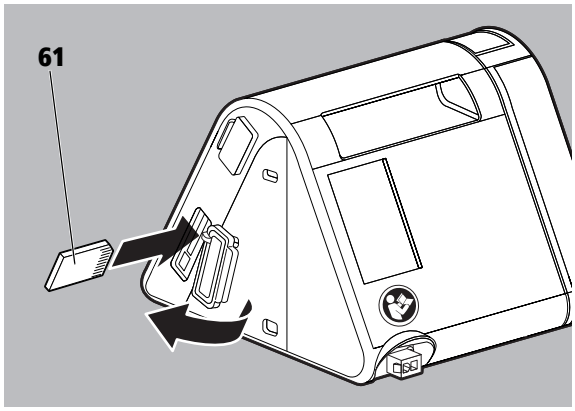
5.5 Checking the display and the function of the keys

1. Connect the therapy device to the power supply.
2. Switch the therapy device on with the On/Off button ⏻.

5.6 Checking the SD card



1. Insert the SD card **61** into the SD card slot.

   Requirement:
   The SD card symbol is shown on the display.
2. If the requirement is not fulfilled: Replace SD card.
3. If the error persists: Replace mainboard (see "7.4 Replacing the mainboard", page 44).

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6 Faults

If you are unable to eliminate faults immediately with the help of the table, contact the manufacturer. To avoid exacerbating the damage, do not continue operating the device.

Fault	Cause	Rectification
No running noise, no information on the display.	No power supply.	Check that the power supply cable is connected properly. Check the function of the socket-outlet. Check line voltage with another device (e.g., a lamp). If necessary: Replace power supply cable.
	Fuse is defective.	Replace mainboard (see 7.4, p. 44).
No running noise when display lights up.	Fan not running.	Replace mainboard (see 7.4, p. 44).
		Replace fan (see 7.6, p. 51).
It is not possible to start therapy with a breath. The therapy device does not switch off after approx. 5 seconds when the mask is removed.	autoSTART-STOP function is not active.	Activate the autoSTART-STOP function (see 6.1, p. 37).
	autoSTART-STOP function can be impaired by accessories with a high level of resistance.	Contact your authorized dealer.
softSTART cannot be switched on.	softSTART function is locked.	Contact the physician to determine whether the function can be enabled.
Therapy device does not reach the lower pressure limit	Air filter is dirty.	Clean the air filter. If necessary: Replace filter (see "4 Hygienic preparation", page 22).
	Respiratory mask is leaking.	Adjust the headband until the mask fits tightly. If necessary, replace defective mask.
Touchscreen not working, buttons do not work or only work imprecisely.	Touchscreen not calibrated.	Recalibrate touchscreen (see "7.5 Replacing the display", page 49).

6.1 Respiratory air humidifier faults

Fault	Cause	Remedy
The respiratory air humidifier is not warming up	Humidifier level switched off.	Set the humidifier level.
	Respiratory air humidifier is defective.	Have therapy device repaired.
Respiratory air humidifier is leaking.	Seal on the heating element is defective.	Replace seal.
	Humidifier insert is not inserted correctly.	Insert the humidifier insert correctly.
	Humidifier insert is defective.	Replace humidifier insert.
	Cracks in the base of the humidifier.	Replace base of humidifier.
Respiratory air humidifier switches off	No water in the respiratory air humidifier.	Fill the respiratory air humidifier with water.

6.2 Display messages

If the message Error (xxx): Please follow the instructions in the Instructions for use appears on the display, look for the displayed error code in the table (see "6.3.1 Opening/deleting the error memory", page 38). Rectify the error as described.

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6.3 Error memory

The therapy device has an internal error memory with space for up to 100 error entries. Once the maximum number of entries is reached, the oldest entry is overwritten.

6.3.1 Opening/deleting the error memory

1. Activate Service menu (see 5.2)
2. Press **Service files**.
3. Press **Delete all**.
4. Confirm the prompt with **Yes**.

   or

5. To cancel, press **No**.

The causes of the individual errors are shown in the following table:

Error number	Error memory designation	Description	Cause	Remedy
101	PressureSensorLinesLow		Mainboard defective	Replace mainboard
102	NoPressureSensor	Sensor error	Mainboard defective	Replace mainboard
103	PressureSensorZeroBalanceOutOfRange	Sensor error	Mainboard defective	Replace mainboard
			Device outlet fitted incorrectly	Check fitting of device outlet
104	FlowSensorLinesLow	Sensor error	Mainboard defective	Replace mainboard
105	NoFlowSensor	Sensor error	Mainboard defective	Replace mainboard
106	NoBarometerSensor	Sensor error	Mainboard defective	Replace mainboard
107	NoBarometerOutOfRange	Sensor error	Mainboard defective	Replace mainboard
108	RealTimeClockNotSet	Real time clock error	Clock not set	Set the date and time
			Battery on mainboard empty	Replace battery on mainboard
			Mainboard defective	Replace mainboard
109	RealTimeClockNotOscillating	Real time clock error	Mainboard defective	Replace mainboard
110	RealTimeClockNotInitFailed	Real time clock error	Mainboard defective	Replace mainboard
111	RealTimeClockSetByLcFailed	Real time clock error	Mainboard defective	Replace mainboard
112	MainCrystalNotOscillating	Hardware error	Mainboard defective	Replace mainboard
113	SelftestDoneWithErrors	Hardware error	Mainboard defective	Replace mainboard
			Cover or respiratory air humidifier fitted incorrectly	Check fitting of cover and respiratory air humidifier.
		Time deleted / RTC error	New mainboard	Reset time.
114	VoltageControlReferenceVoltageLow	Voltage supply error	Mainboard defective	Replace mainboard
201	FunctionCheckMotorFailed	Fan speed error	Mainboard defective	Replace mainboard
			Fan defective	Replace fan
202	ControlBlowerNotRunningForLongTimeError	Fan speed error	Mainboard defective	Replace mainboard
			Fan defective	Replace fan
203	ControlPressureSensorHighError	Sensor error	Mainboard defective	Replace mainboard
			Pressure-measurement hose kinked/blocked	Check position of pressure-measurement hose / remove blockage, replace hose
204	ControlHumidifierError	Humidifier error	Mainboard defective	Replace mainboard
			Heating element defective	Replace heating element
205	SystemControlSupplyVoltageFailure	Voltage supply error	Mainboard defective	Replace mainboard
			Power supply unit defective	Replace power supply unit
206	SlabModuleChecksumError	Module error	prismaCONNECT module defective	Replace prismaCONNECT module

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Error number	Error memory designation	Description	Cause	Remedy
500	ERR_MC_DONT_STARTS_IN_GIVEN_TIME	Controller error	Mainboard defective	Replace mainboard
501	ERR_MC_BOOTLOADER_ERROR	Controller error	Mainboard defective	Replace mainboard
502	ERR_COULD_NOT_START_APPLICATION	Initialization error	Further investigation necessary	Send therapy device to the manufacturer or replace mainboard
503	ERR_CLEAN_AND_PREPARE_UBI_CONFIG_DATA_MASSTORAGE	Initialization error	Further investigation necessary	Send therapy device to the manufacturer or replace mainboard
504	ERR_MOUNT_CONFIG_DATA	Initialization error	Further investigation necessary	Send therapy device to the manufacturer or replace mainboard
505	ERR_DEVICE_WARCHER_INIT	Initialization error	Further investigation necessary	Send therapy device to the manufacturer or replace mainboard
506	ERR_TOUCH_SCREEN_INIT	Initialization error	Further investigation necessary	Send therapy device to the manufacturer or replace mainboard
507	No Backup-Volume	Initialization error	Further investigation necessary	Send therapy device to the manufacturer or replace mainboard
601	sdWriteError	SD card error	SD card defective	Replace SD card
602	configurationSdCardFull	SD card error	SD card configuration defective	Clear SD card
603	SdCardFull	SD card error	SD card memory full	Clear SD card
604	sdRemovedWhileWritingError	SD card error	SD card removed during saving	Insert SD card in the therapy device
605	UpdateFileError	SD card error	Defective update file on SD card	Remove card and resave update file
620	MS FW update failed	Error in connection with prisma2CLOUD	prisma2CLOUD update failed	Contact your service provider
621	MS HW defective	Error in connection with prisma2CLOUD	prisma2CLOUD module defective	If this recurs, send module to the manufacturer
622	MSNotConfigured	Error in connection with prisma2CLOUD	prisma2CLOUD configuration error	Contact your service provider
623	MS no GSM connection	Error in connection with prisma2CLOUD	No mobile connection possible	Select location with mobile radio connection for therapy device/module
624	MS no server connection	Error in connection with prisma2CLOUD	No server connection possible	If this recurs, contact your service provider
625	MS sim suspension	Error in connection with prisma2CLOUD	SIM card locked	Contact your service provider
626	MS SIM no roaming	Error in connection with prisma2CLOUD	No mobile roaming possible	Contact your service provider
627	MS Server refused connection	Error in connection with prisma2CLOUD	Connection rejected by server.	Contact your service provider
628	MS device is not compatible please remove it	Error in connection with prisma2CLOUD	Module not compatible	Disconnect the module from the therapy device and reconnect. If the error persists: Send module to the manufacturer

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Error number	Error memory designation	Description	Cause	Remedy
701	ControlPressureSensorLowError	Error in pressure measurement line	Respiratory air humidifier or cover not correctly connected	Connect respiratory air humidifier or cover correctly
			Mainboard defective	Replace mainboard
			Pressure-measurement hose not connected	Connect pressure-measurement hose
			Pressure-measurement hose kinked/blocked	Check position of pressure-measurement hose / remove blockage, replace hose
702	ControlBlockedFlowError	Error in flow line	Breathing tube kinked	Check position of breathing tube or replace breathing tube
			Device outlet blocked	Remove blockage at device outlet
			Mainboard defective	Replace mainboard
			Fitting error	Check fitting of flow line
			Restrictor defective	Replace restrictor
703	ControlPneumaticPowerHighError	Error in flow line	Suction area blocked	Remove blockage in suction area or replace air filter
			Fan defective	Replace fan
704	SlabModuleDevConflict		Two identical modules connected	Remove second module.

The error entries are shown as follows:

Date - Time - Number of error message - Description

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7 Repairs

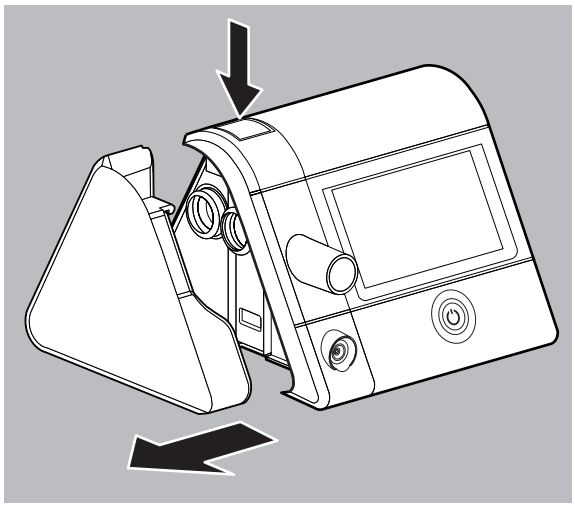
7.1 General information

- When carrying out repairs, please refer to the instructions for use and the service and repair manual. In particular, you should observe the safety information contained in the instructions for use.
- Repairs should only be carried out at an ESD workstation!
- Always ensure that the workstation is kept clean and tidy.
- Only carry out repairs that are described in this service and repair manual.
- Always carry out a final test after each repair job (see chapter "Final test".
- Only use original spare parts.
- You will find the necessary auxiliary equipment in the chapter "Required auxiliary equipment".
- The item numbers in this chapter are identical to the item numbers in the chapter "Replacement parts".
- Use a container with compartments for the screws and washers.

7.2 Opening the therapy device

⚠ CAUTION

Risk of injury from electric shock!
Opening the therapy device when it is connected to the power supply can result in electric shocks.
⇒ Unplug the device before opening it.
⇒ Remove the power supply cable from the therapy device before opening it.



1. Press the locking button and remove the cover/respiratory air humidifier sideways from the therapy device.

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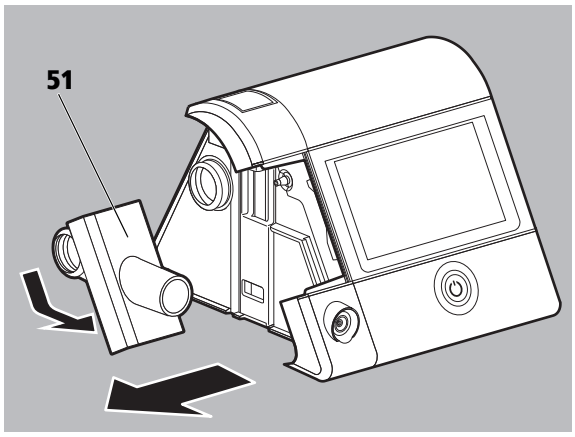
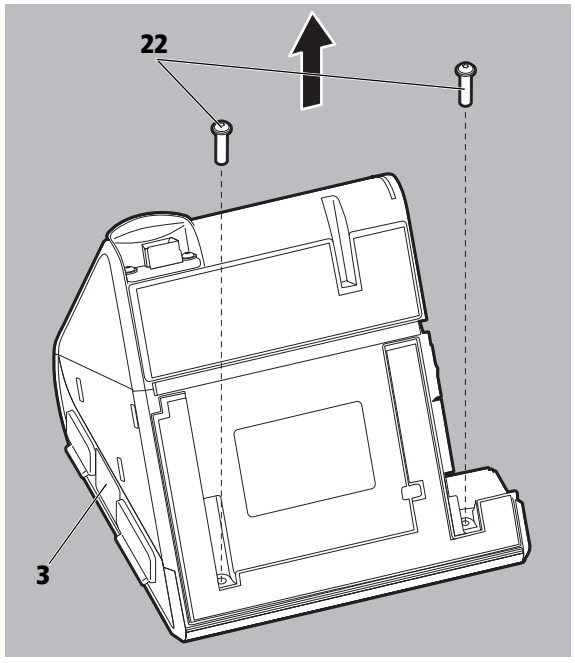
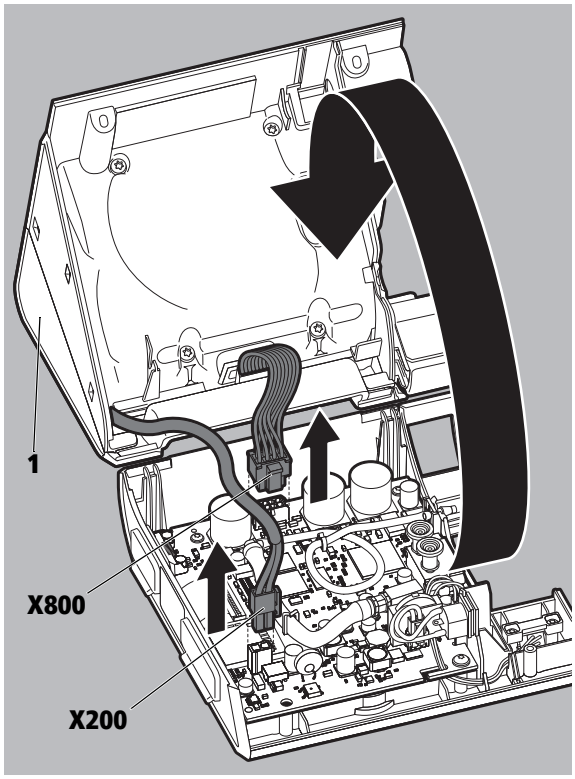


2. Pull off the device outlet **60**.



3. Place the therapy device on its front **3** on a table, and unscrew the 2 screws **22**.



4. Fold up the back of the housing **1** and place it on the table carefully.
5. Undo the connections **X800** and **X200**.

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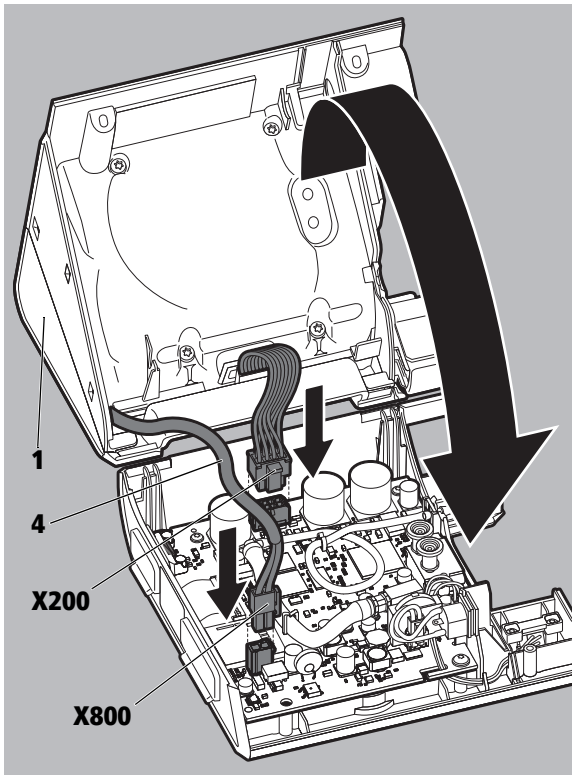
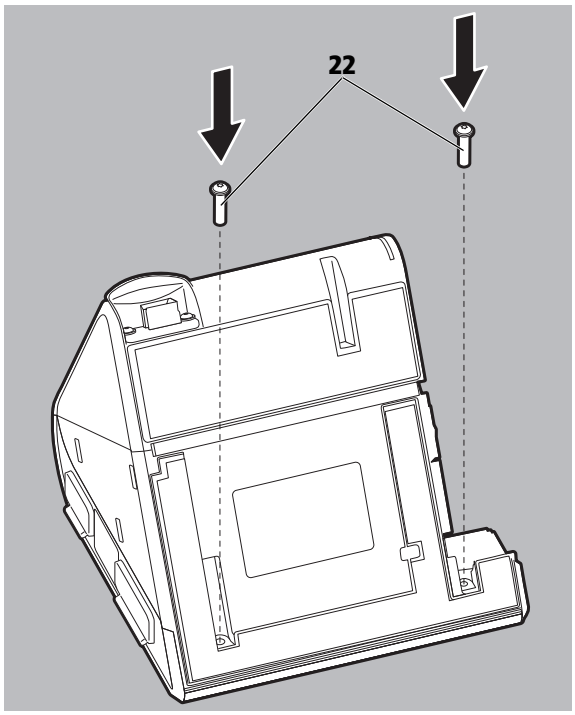
7.3 Closing the therapy device



1. Place the front of the housing **3** on the top edge of the fan box.
   Note: The recesses must face downwards and the display **20** backwards.
2. Connect the fan connector to connection **X200**.
3. Connect the connection cable of the power supply unit **4** to connection **X800** on the mainboard.
4. Fold the back of the housing **1** down into place.
   Note:
   - Insert the connection cable of the power supply unit **4** into the recess provided.
   - Hook the recesses into the fan box correctly.
5. Press the connection cable of the power supply unit **4** down gently (approx. 90°).



6. Insert and tighten 2 screws **22**.

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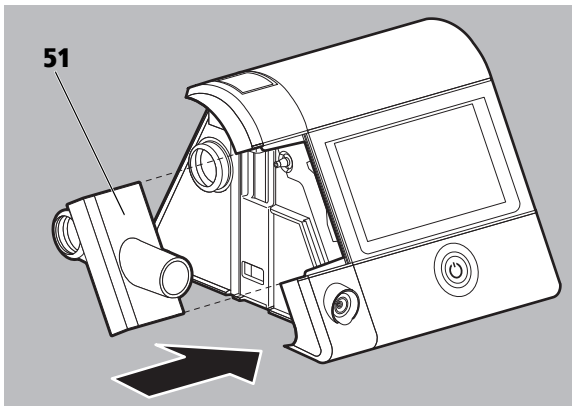
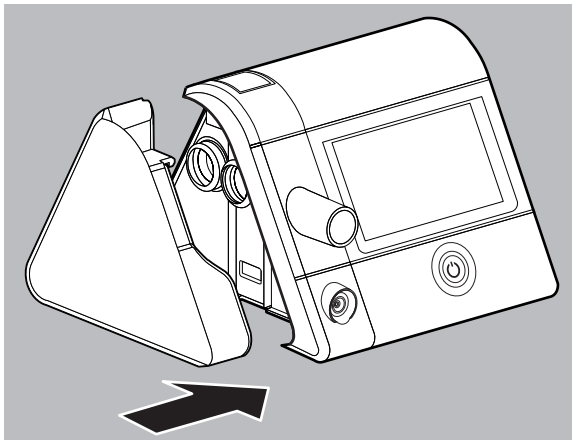


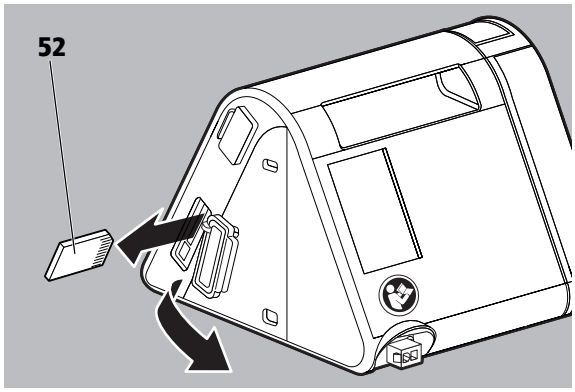
7. Insert device outlet **60** in the therapy device.



8. Insert the cover/respiratory air humidifier.

7.4 Replacing the mainboard

7.4.1 Removing the mainboard



1. Remove the SD card **61** from the SD card slot.

2. Open the therapy device (see "7.2 Opening the therapy device", page 41)

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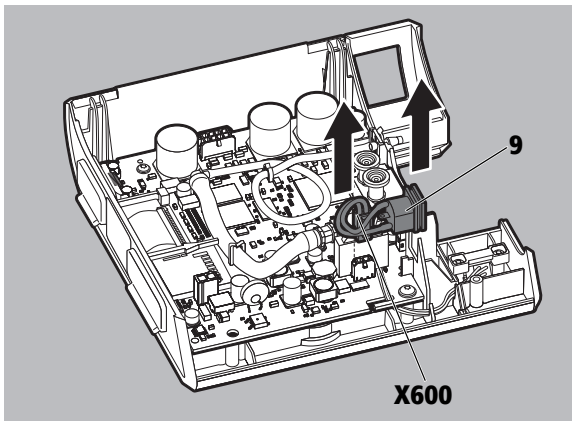
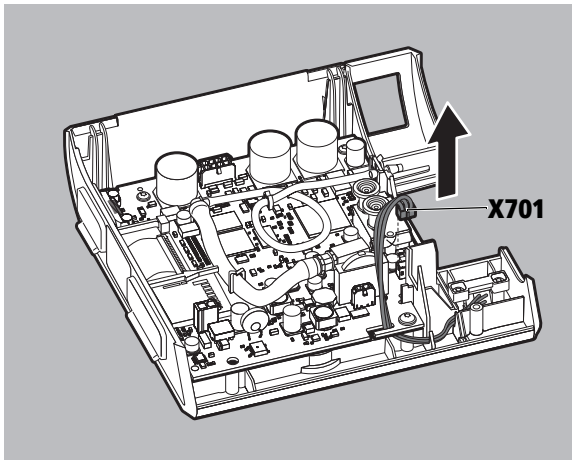
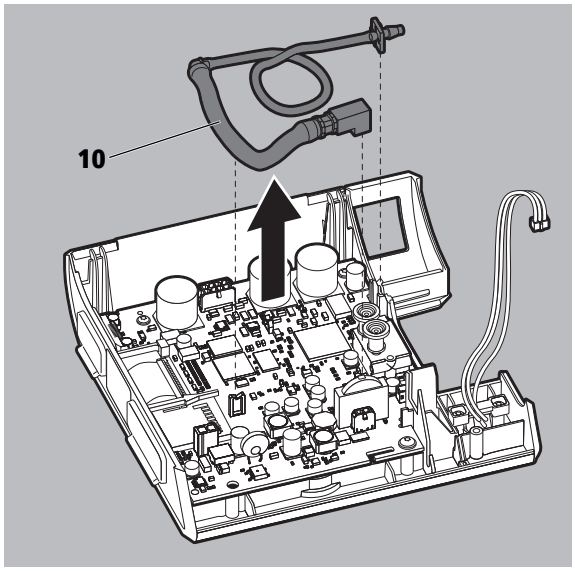


3. Remove the connection cable of the respiratory air humidifier **9** from the holding bracket.
4. Disconnect the connection **X600** from the mainboard.



5. Disconnect the connection **X701**.



6. Remove the pressure-measurement hose **10** with the elbow from the connection on the pressure sensor.

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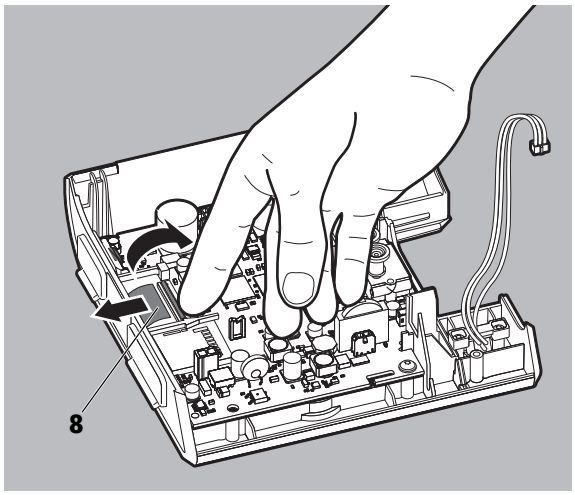
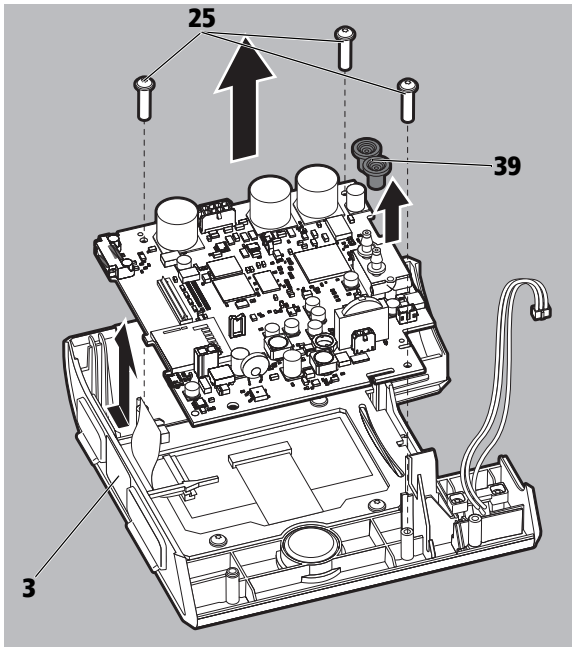
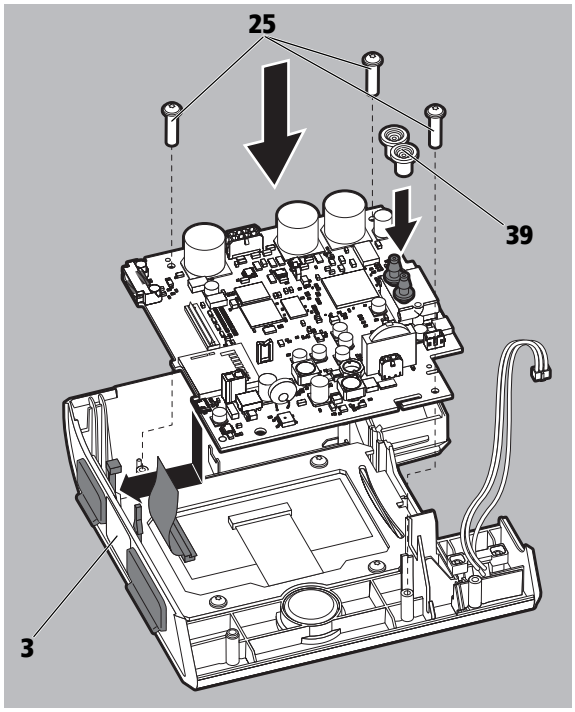


7. Undo the lock on the ribbon cable for the display **8**.
   Note: The black clip must be clicked upwards.
8. Remove the ribbon cable for the display **8**.



9. Unscrew the 3 screws **25**.
10. Remove the mainboard from the front of the housing **3** by lifting the mainboard slightly on one side and then pulling it out diagonally upwards.
11. Remove the 2 seals **39** from the connections on the flow sensor.

7.4.2 Installing the mainboard



1. Place the 2 seals **39** on the connections of the flow sensor.
2. Insert the mainboard in the front of the housing **3** at an angle.
   Note:
   - The connections on the mainboard must first be introduced into the openings provided.
   - The ribbon cable for the display must be passed around the edge of the mainboard.
   - The cover for the system interface must be inserted.
3. Secure the mainboard in place with the 3 screws **25**.

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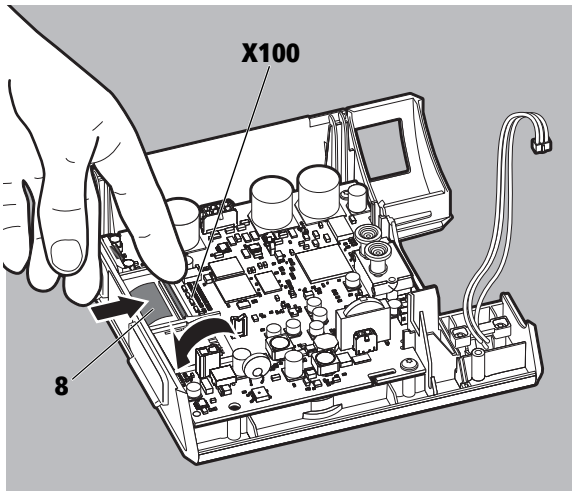
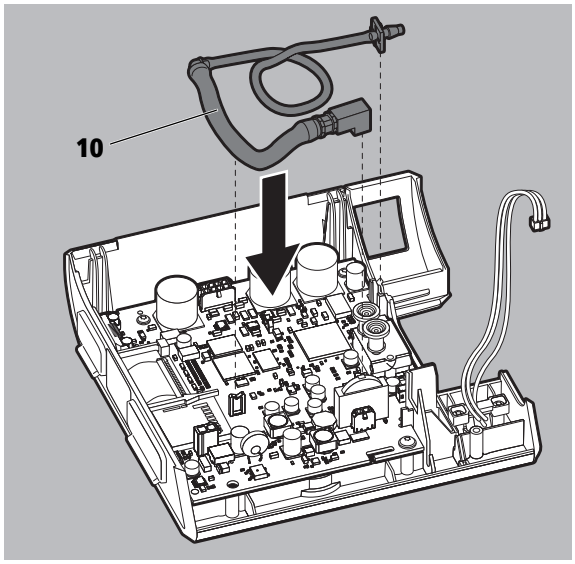
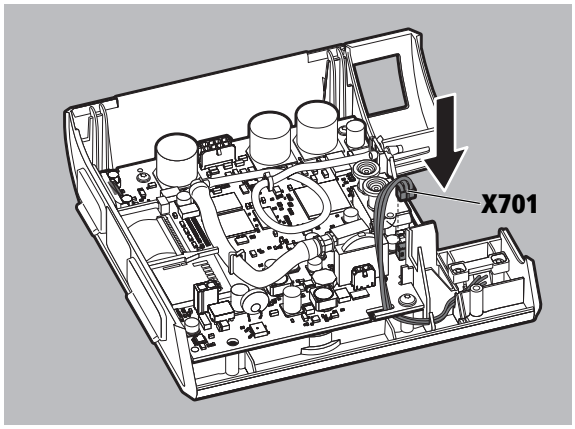


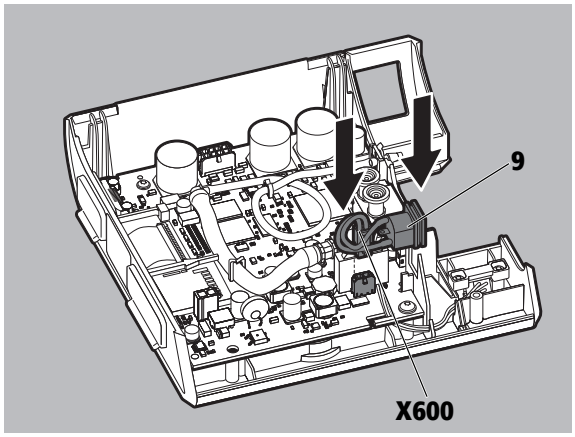
4. Insert the ribbon cable for the display **8** in the recess **X100** and secure it in place.
   Note:
   - The blue stripe must point upwards.
   - The black clip must be clicked downwards.



5. Secure the elbow of the pressure-measurement hose **10** in place on the pressure sensor.
6. Introduce the pressure-measurement hose **10** into the holding brackets provided.
   Note: Route the pressure-measurement hose correctly.



7. Connect up the connection **X701**.



8. Connect the connection cable for the respiratory air humidifier **9** to connection **X600**.
   Note: The red cable must point upwards.

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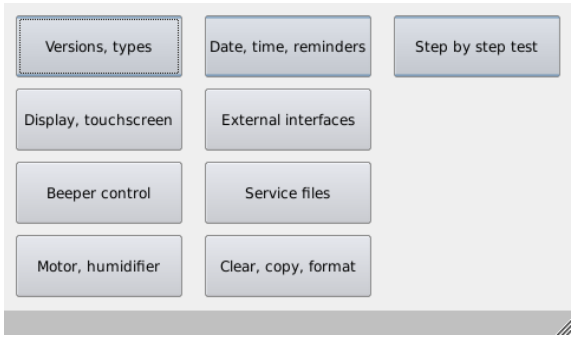
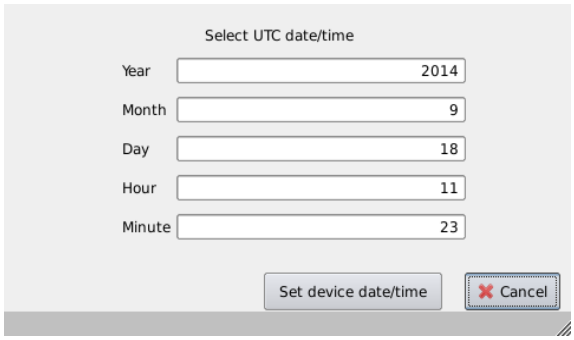
9. Close the therapy device (see "7.3 Closing the therapy device", page 43)

If necessary If the message **Code 113** appears on the therapy device after the mainboard has been changed, the following steps must be taken:

1. Activate the Service mode: Connect the service connector WM 29917 to the system interface.
2. Connect the power supply unit to the therapy device and switch on the power supply.
   The Service menu opens after approximately 5 seconds.



3. Press the **Date, time, reminders** field.



4. Press the **Set other** field.
5. Set the date and time.
6. Press the **Set device data/time** field.
7. Disconnect the power supply unit from the therapy device.
8. Remove the service connector from the therapy device to exit the Service menu.
9. Connect the power supply unit to the therapy device.

Result The message **Code 113** is no longer displayed.

7.4.3 Entering the serial number of the device.

1. Connect the power supply unit to the device and switch on the power supply.
2. Activating the Service mode (see "5.2 Service mode", page 29).
3. Press the **Versions, Types** field
4. Read the serial number off the sticker on the side of the device and enter it under **Device serial number**.

7.4.4 Taking over configuration and usage times

Once the mainboard has been exchanged, the saved configuration and usage times can be taken over from the previous mainboard.

1. Remove the SD card from the old mainboard and insert it in the new mainboard.
2. Press **Clear, copy, format**.
3. Press **Import compliance&config from SD card**.
4. **Done** appears

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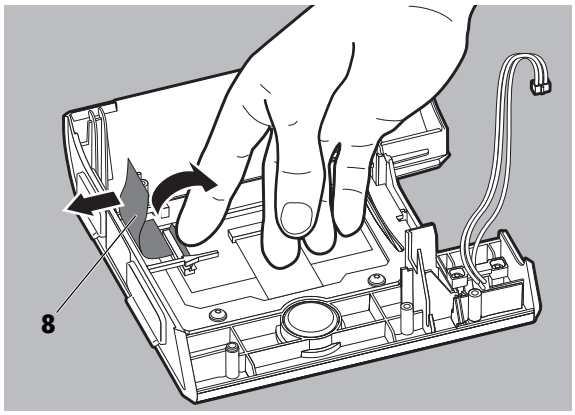
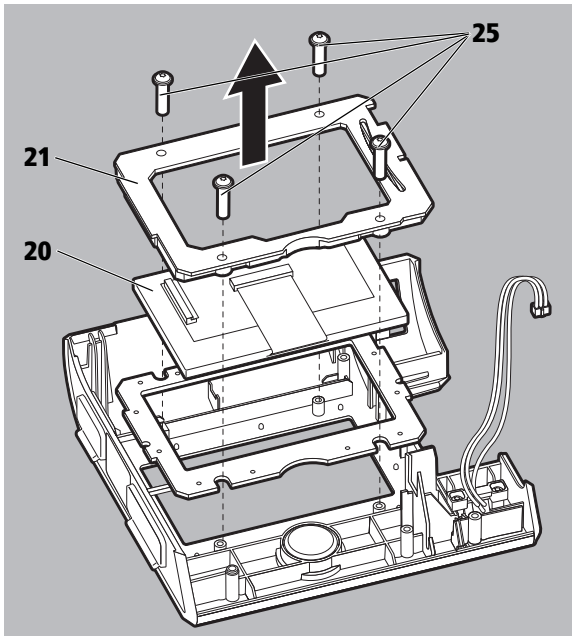
7.5 Replacing the display

7.5.1 Removing the display

1. Open the therapy device (see "7.2 Opening the therapy device", page 41).
2. Remove the mainboard (see "7.4.1 Removing the mainboard", page 44).



3. Undo the lock on the ribbon cable for the display **8**.
   Note: The brown clip must be clicked upwards.



4. Unscrew the 4 screws **25**.
5. Remove the display frame **21**.
6. Remove the display **20**.
7. Check the state of the display seal. Replace if necessary.

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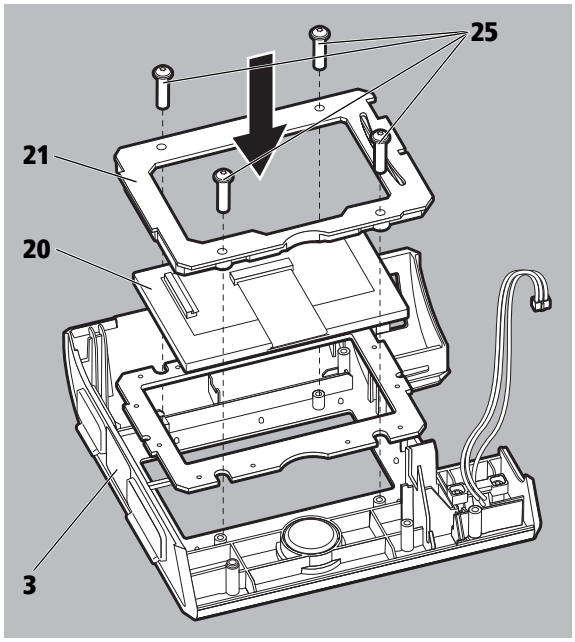
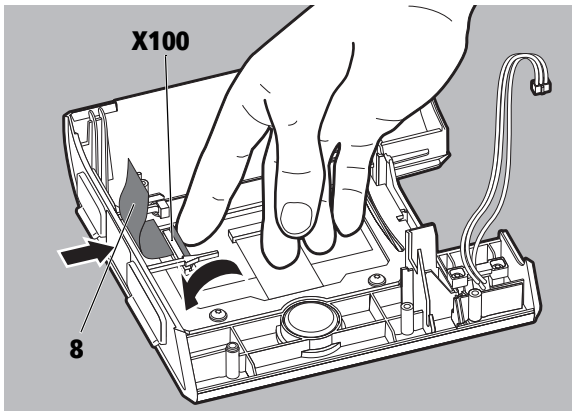
7.5.2 Installing the display



1. Insert the new display **20** in the display frame **21**.
2. Insert the display frame **21** with the new display **20** in the front of the housing **3**.
3. Secure the display frame **21** in place with the 4 screws **25**.



4. Insert the ribbon cable for the display **8** in the recess **X100** and secure it in place.
   Note:
   - The blue stripe must point upwards.
   - The black clip must be clicked downwards.
5. Install the mainboard (see "7.4.2 Installing the mainboard", page 46)
6. Close the therapy device (see "7.3 Closing the therapy device", page 43)

If necessary: If the touchscreen doesn't work after the display has been replaced, it is necessary to recalibrate the touchscreen.

1. Insert service connector.
2. Press the On/Off button for 3 seconds until the recalibration screen appears.
3. Press the center of the crosshair with a pen.
   The display then closes automatically and the Service menu appears.
4. Remove the service connector.

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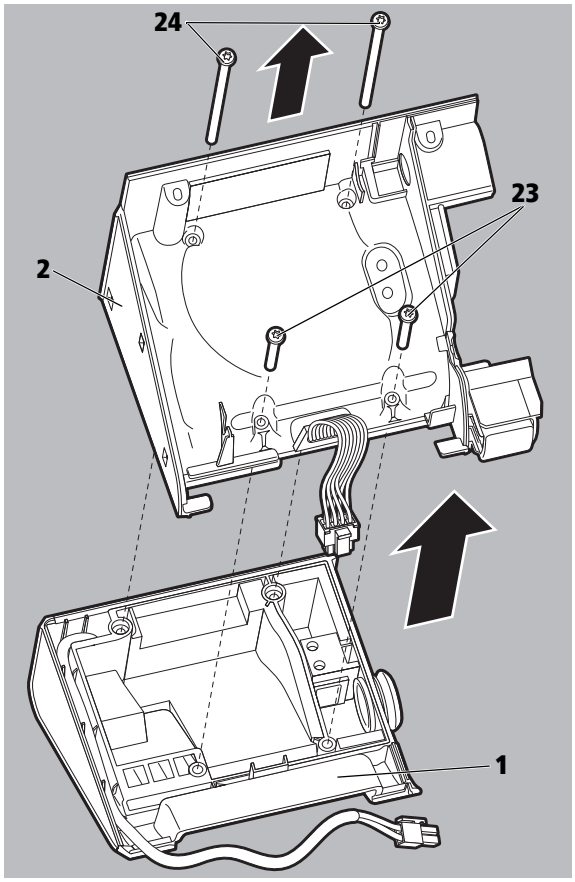
7.6 Replacing the fan

7.6.1 Removing the fan



1. Open the therapy device (see "7.2 Opening the therapy device", page 41).
2. Place the therapy device on its back on a table.
3. Undo and remove 2 screws **23**.
4. Undo and remove 2 screws **24**.
5. Lift the central part of the housing **2** off the back of the housing **1**.

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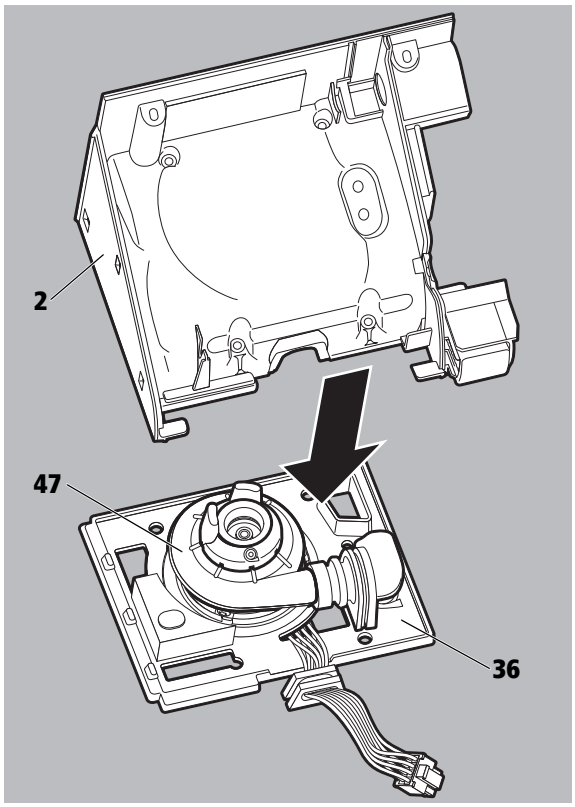
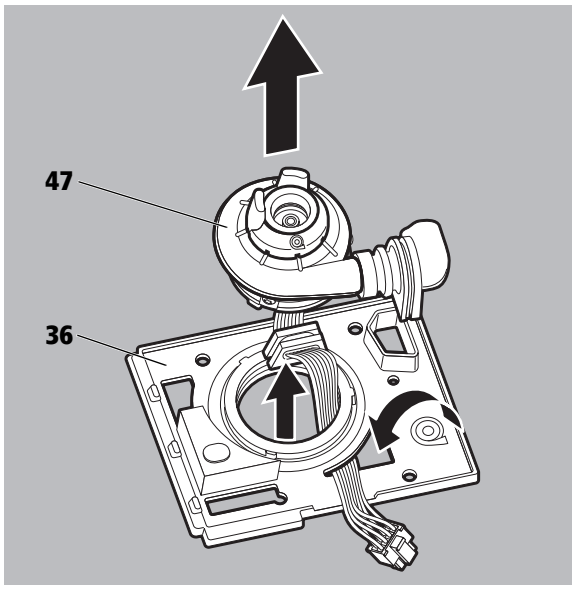
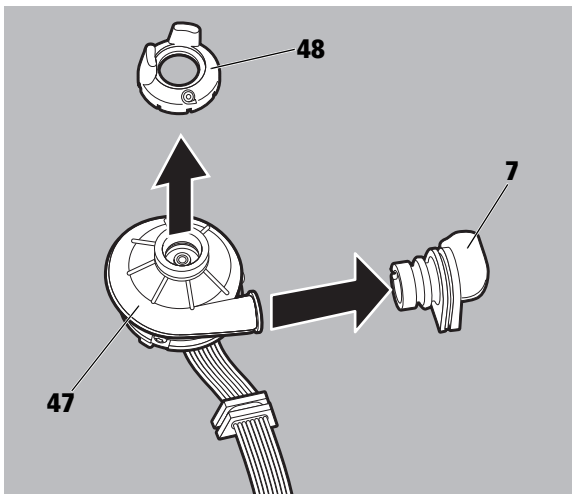


6. Pull out the fan **47** together with the membrane **36** from the central part of the housing **2**.



7. Remove the fan **47** from the membrane **36**.



8. Detach the decoupling hose **7** and spacer **48** from the fan **47**.

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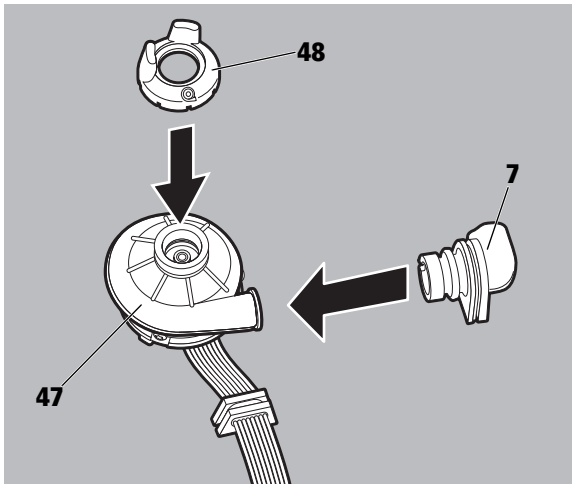
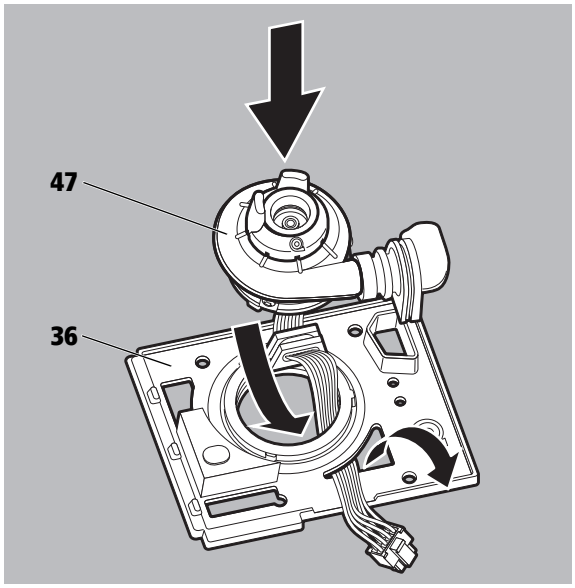
7.6.2 Installing the fan



1. Secure the new decoupling hose **7** and new spacer **44** on the new fan **47**.
   When doing so, pay attention to the correct positioning.



2. Insert the fan **47** in the membrane **36**.
   Note: The marks on the membrane must be aligned with the screws on the fan.

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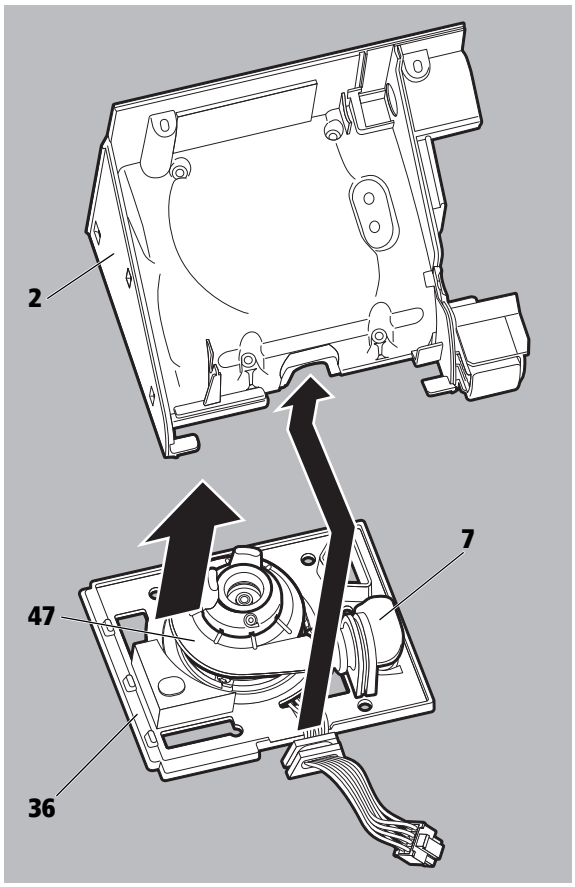
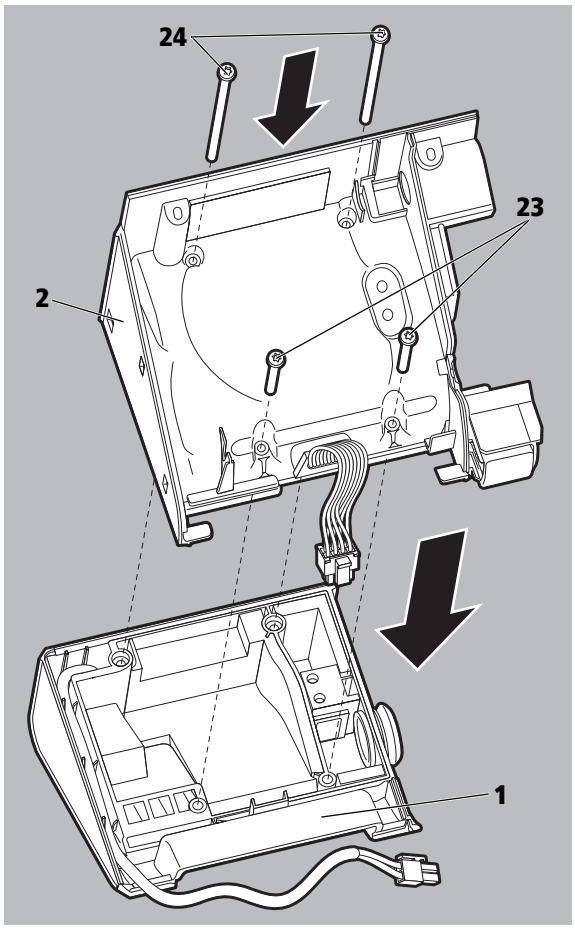


3. Insert the fan **47** with the membrane **36** into the central part of the housing **2**.
4. Insert the decoupling hose **7** and the cable bushing into the central part of the housing **2**.
   Note: The decoupling hose must not be kinked or trapped.



5. Place the central part of the housing **2** on the rear of the housing **1**.
   Note:
   - The connection cable for the power supply unit must be correctly routed.
   - The membrane between the parts of the housing must be positioned correctly.
6. Secure the central part of the housing **2** in place with the 4 screws **23** and **24**.
7. Close the therapy device (see "7.3 Closing the therapy device", page 43)

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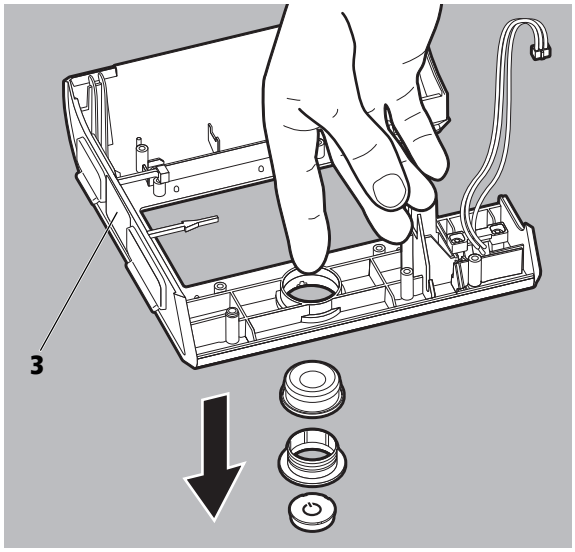
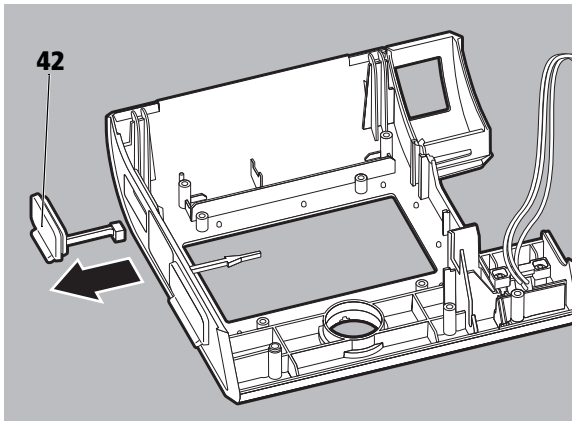
7.7 Replacing the parts of the housing

7.7.1 Replacing the front of the housing

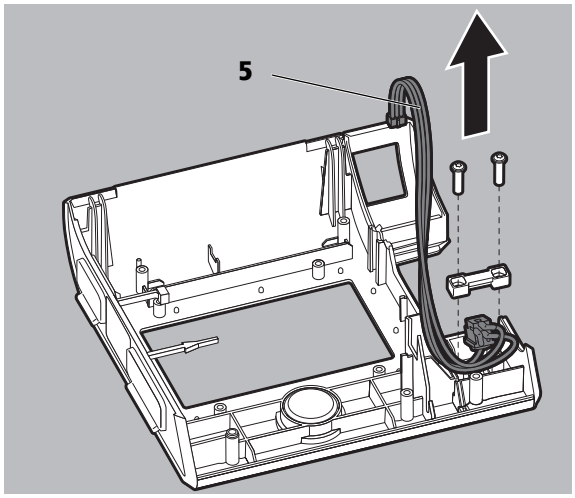
1. Open the therapy device (see "7.2 Opening the therapy device", page 41).
2. Remove the mainboard (see "7.4.1 Removing the mainboard", page 44).
3. Remove the display (see "7.5.1 Removing the display", page 49).
4. Press the On/Off button out of the front of the housing **3** from the back.



5. Remove the seal for the system interface **42**.



6. Detach and remove the connection cable for the hose heater **5**. (only applies to devices as of serial number 5.000).



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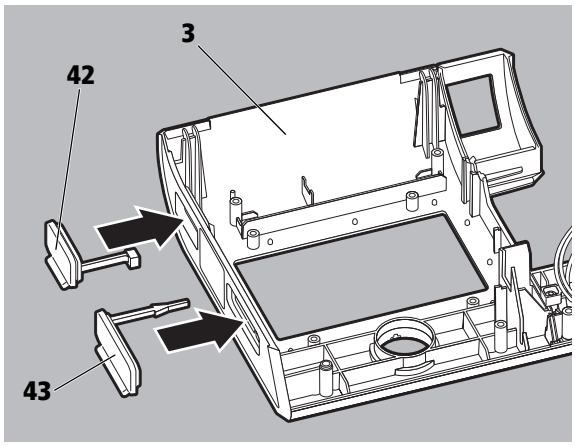
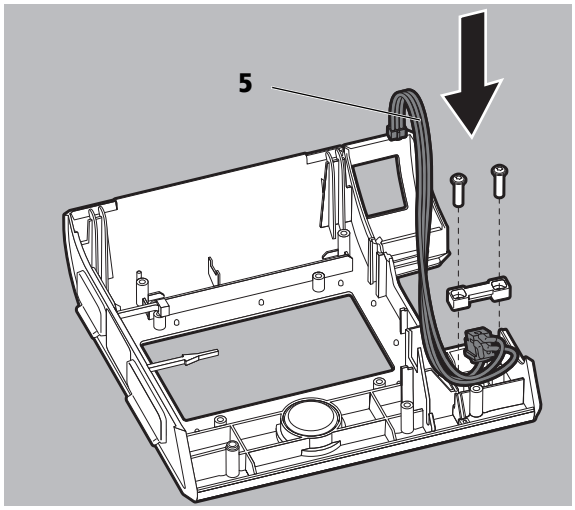
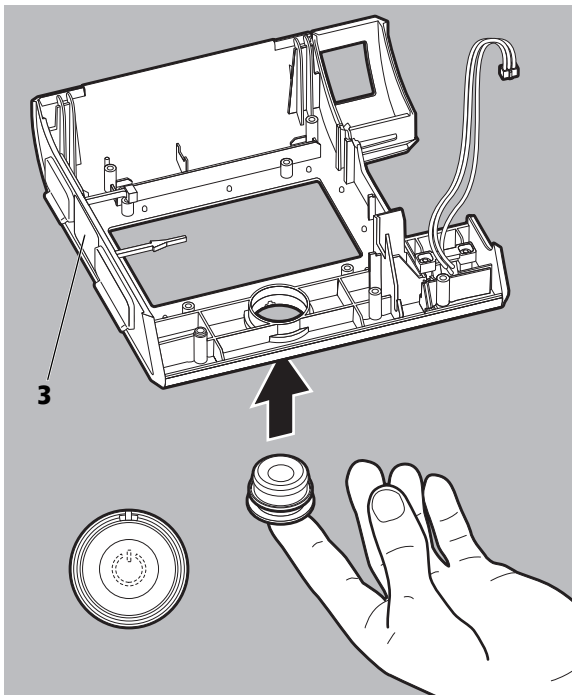


7. Insert the seal for the system interface **42** into the new front of the housing **3**.
8. Insert the new seal for the SD card slot **43** into the new front of the housing **3**.



9. Insert the new connection cable for the hose heater **5** into the new front of the housing **3**
(only applies to devices as of serial number 5.000).



10. Press the On/Off button into the front of the housing **3** from the front.
Note: The upper edge of the silicone seal must fit completely in the groove on the ring.

11. Install the display (see "7.5.2 Installing the display", page 50).
12. Install the mainboard (see "7.4.2 Installing the mainboard", page 46).
13. Close the therapy device (see "7.3 Closing the therapy device", page 43).

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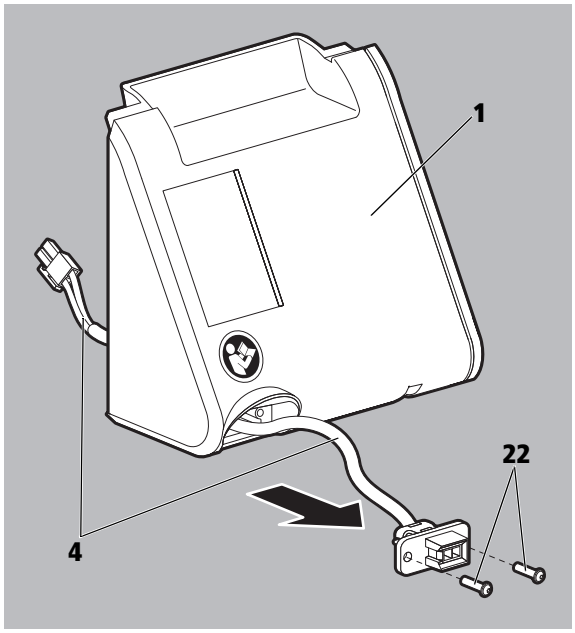
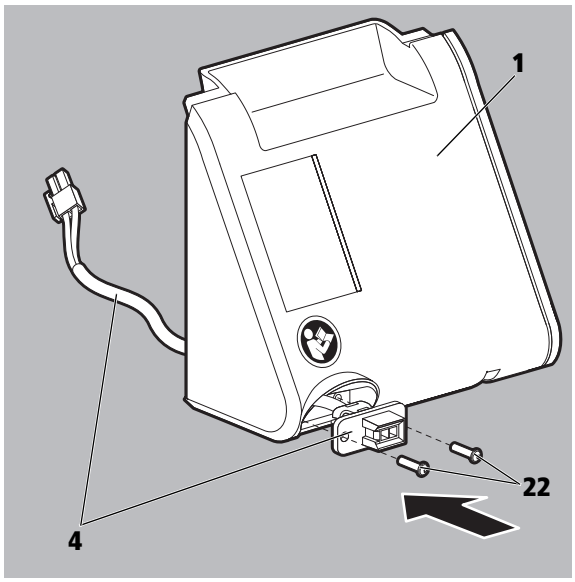
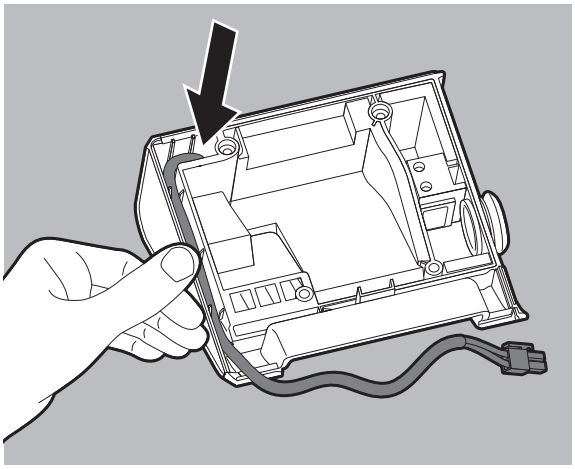
7.7.2 Replacing the central part and back of the housing

1. Remove the fan (see "7.6.1 Removing the fan", page 51).
2. Unscrew and remove the 2 screws **22** of the connection cable for the power supply unit **4** on the back of the housing **1**.
3. Pull the connection cable for the power supply unit **4** out of the back of the housing **1**.



4. Take the new central part of the housing **2** and the new back of the housing **1**.
5. Insert the connection cable for the power supply unit **4** in the new back of the housing **1** and secure in place with the 2 screws **22**.





Note: The connection cable for the power supply unit must sit in the channel.

6. Install the fan in the new central part of the housing (see "7.6.2 Installing the fan", page 53).
7. Close the therapy device (see "7.3 Closing the therapy device", page 43).

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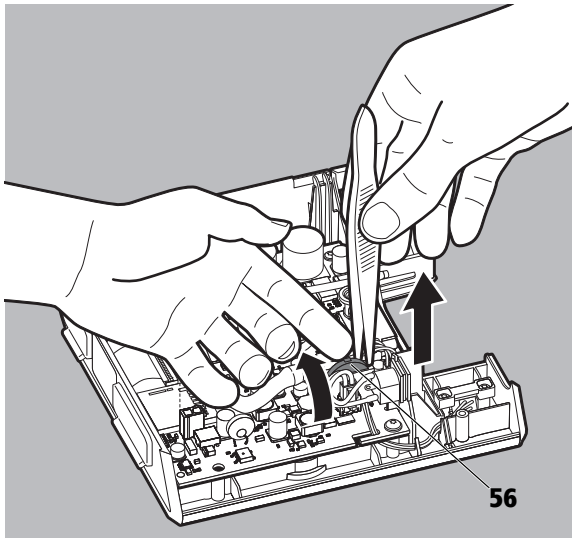
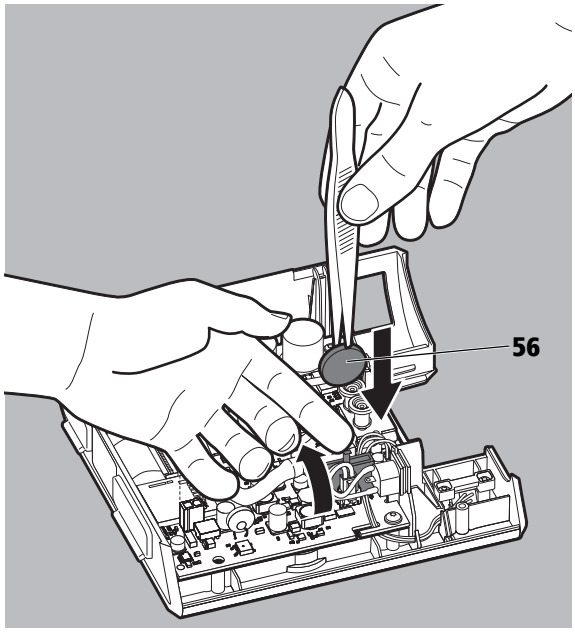
7.8 Replacing the battery on the mainboard

1. Open the therapy device (see "7.2 Opening the therapy device", page 41).
2. Depress the contact tab of the battery holder and remove the battery **56** with the help of plastic pliers or tweezers.



3. Insert the new battery **65**.
   Note: The writing on the battery must face the contact tab.



4. Close the therapy device (see "7.3 Closing the therapy device", page 43).

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8 Storage and disposal

8.1 Storage

8.1.1 General information

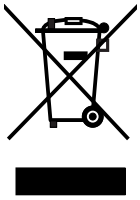
Store the device under the specified ambient conditions (see chapter "Technical data").

8.1.2 Storing the therapy device

1. Switch off the therapy device.
2. Disconnect the therapy device from the power supply.
3. Clean the therapy device, components, and accessories.
4. Store the therapy device, components, and accessories in a dry place.

Result The therapy device, components, and accessories are kept dry.

8.2 Disposal



Do not dispose of the product in the household waste. Consult an authorized, certified electronic waste recycling company for proper disposal. You can find out their address from your environmental officer or from your local council.
The device packaging (cardboard box and inserts) can be disposed of as waste paper.

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9 Replacement parts

9.1 Replacement parts list

The item numbers in this chapter are identical to the item numbers in the chapters "Hygienic preparation" and "Repairs".

Item	Designation	Article number
Housing		
1	Rear of housing, pre-assembled	WM 29698
2	Central part of housing, pre-assembled	WM 29697
3	Front of housing, pre-assembled up to SN 4.999 Front of housing, pre-assembled as of SN 5.000	WM 29692 WM 29946
Cables / connections / hoses		
4	Connection cable for power supply unit, complete	WM 29615
5	Connection cable for hose heater (only applies to devices as of SN 5.000)	WM 29944
6	Holder for connection cable for hose heater (only applies to devices as of SN 5.000)	WM 29912
7	Decoupling hose	WM 29646
8	Ribbon cable for display	WM 29634
9	Connection cable for respiratory air humidifier	WM 29637
10	Pressure-measurement hose, comprising: Angle nozzle Hose nozzle Hose, silicone, 4/7 105 Angle nozzle Hose, silicone, 1.5X0.7 200 B Hose nozzle	WM 29694 WM 24664 WM 29964 WM 29939 WM 29937 WM 29938 WM 29968
PCBs		
11	prisma20A mainboard	WM 35015
12	Zubehörteil mainboard	WM 35016
13	prismaLAB mainboard	WM 35017
14	prisma20C mainboard	WM 35018
15	prisma25S mainboard	WM 35025
16	prisma25S-C mainboard	WM 35026
17	prisma25ST mainboard	WM 35027
18	prisma30ST mainboard	WM 35028
19	prisma30ST-C mainboard	WM 35029
Display		
20	Display	WM 29633
21	Display frame	WM 29635
Screws/nuts/washers		
22	Screw EJOT DELTA PT 30X14 WN 5451	WM 50572
23	Screw EJOT DELTA PT 40X25 WN 5452	WM 50563
24	Screw EJOT DELTA PT 40X70 WN 1452	WM 50557
25	Screw EJOT DELTA PT 25X8 WN 5451	WM 50564
Buttons		
26	On/Off button, complete, prisma20A	WM 29916
27	On/Off button, complete, Zubehörteil	WM 29915

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Item	Designation	Article number
28	On/Off button, complete, prisma20C	WM 29913
29	On/Off button, complete, prismaLAB	WM 29914
30	On/Off button, complete, prisma25S	WM 29903
31	On/Off button, complete, prisma25S-C	WM 29909
32	On/Off button, complete, prisma25ST	WM 29923
33	On/off button, complete, prisma30ST	WM 29926
34	On/off button, complete, prisma30ST-C	WM 29943
Seals		
35	Sealing ring for rear of housing	WM 29658
36	Membrane	WM 29644
37	Noise insulation	WM 29606
38	Seal for flow element	WM 29677
39	Seal for flow sensor	WM 29678
40	Seal for device outlet	WM 29653
41	Seal for display	WM 29636
42	Seal for system interface	WM 29656
43	Seal for SD card slot	WM 29648
Miscellaneous		
44	Cover, assembled	WM 29622
45	Spacer for noise insulation	WM 29613
46	Flow element	WM 29676
47	Fan, complete	WM 29643
48	Spacer for fan	WM 29604
49	Fan cap	WM 29607
50	Oval-head screw M3X4 for fan cap	WM 53017
51	Device outlet	WM 29631
52	SD card	WM 29794
53	Set, 2 air filters (includes air filter WM 29651)	WM 29928
54	Power supply unit 36 V	WM 29657
55	Power supply cable	WM 24133
56	3 V battery	WM 40089

9.2 Service sets

Item	Designation	Article number
WM 100 TD patient change set		**WM 29973**
57	Seal for device outlet	WM 29653
58	Device outlet	WM 29631
59	Rear of device, pre-assembled	WM 29698
60	Sealing ring	WM 29658
61	Seal for flow element	WM 29677
62	Flow element	WM 29676
63	Label, instructions for use	WM 77063
64	Central part of housing, pre-assembled	WM 29697
65	Decoupling hose	WM 29646
66	Membrane	WM 29644
67	Spacer	WM 29613
68	Noise insulation	WM 29606
69	Label, devices	WM 76822
70	Cover, assembled	WM 29622

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Item	Designation	Article number
WM 100 TD patient change set		**WM 29973**
71	Air filter	WM 29651
72	Spacer	WM 29604
73	Label, patient change set	WM 77160
74	O-Ring 37x3	WM 1145/14
WM 100 TH patient change set		**WM 29974**
75	Humidifier insert	WM 29683
76	Base of humidifier	WM 29682
77	O-ring 8-1.5	WM 1145/190
78	Label, patient change set	WM 77161

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10 Components and accessories

Designation	Article number
Breathing tube with 19 mm diameter	WM 24445
Breathing tube with 19 mm, autoclavable	WM 24667
Breathing tube with 15 mm diameter	WM 29988
Bacteria filter	WM 24476
Set, 12 pollen filters	WM 29652
prismaBAG basic	WM 29659
prismaBAG premium	WM 29977
prismaBAG butler	WM 29978
prismaCONNECT, communication module	WM 29670
prismaPSG, PSG module	WM 29690
prismaAQUA	WM 29680
SD card	WM 29791
prismaTS, therapy software, complete with USB data cable	WM 93335

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11 Required auxiliary equipment

11.1 Tools

- Torx screwdriver Size T 20
- Torx screwdriver Size T 9
- Torx screwdriver Size T 8
- ESD workstation

11.2 Test equipment

- Portable pressure measuring device
  Measuring range 0-40 hPa
- Ambient pressure measuring device / barometer
- prisma therapy software
- ESD workstation
- Pressure measurement adapter (WM 23456)
- Sound absorber (WM 23685)
- Service connector (WM 29917)

11.3 Disinfectant

terralin® protect

and

gigasept FF® (new)

Can be obtained from:
Schülke & Mayr GmbH
Robert-Koch-Str. 2
22851 Norderstedt, Germany
Tel.: +49 40 52100 - 0
Fax: +49 40 52100 - 318
Internet: www.schuelkemayr.de

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12 Technical data

12.1 Technical data of therapy device

Specification	Therapy device
Product class according to 93/42/EEC	IIa
Dimensions W x H x D in cm	17 x 13.5 x 18
Weight	1.4 kg
Temperature range Operation Storage	 +5°C to +40°C -25°C to +70°C
Permissible humidity during operation and storage	Rel. humidity 15% to 93%, non-condensing
Air pressure range	700 hPa to 1060 hPa, corresponds to a height of 3000 m above sea level
Connection diameter of breathing tube (mask end) in mm	19.5 (to fit standard cone)
Electrical power	Maximum 40 VA
System interface	12 V DC Maximum 10 VA
Current consumption during operation 230 V 115 V in standby mode (Standby) 230 V 115 V	 0.11 A 0.22 A 0.036 A 0.019 A
Classification as per DIN EN 60601-11: Protection class against elec. shock Degree of protection against elec. shock Protection against harmful ingress of water and solid particles	 Protection class II Type BF IP21
Classification as per DIN EN 60601-1: Operating mode	Continuous operation
Applied part	Respiratory mask
Electromagnetic compatibility (EMC) acc. to EN 60601-1-2 Radio interference suppression Radio interference immunity	Test parameters and limit values can be requested from the manufacturer if required. EN55011 B IEC61000-4 Parts 2 to 6, Part 11, Part 8 IEC61000-3 Parts 2 and 3
Average sound pressure level in operation as per ISO 60601-2-70	Approx. 26.5 dB(A) at 10 hPa (corresponds to a sound power level of 34.5 dB(A)
Average sound pressure level in operation as per ISO 60601-2-70 with respiratory air humidifier	Approx. 27.5 dB(A) at 10 hPa (corresponds to a sound power level of 35.5 dB(A)
Sound pressure level of alarm beeper	at least 58 db(A)
Alarms (optional)	**All device types** Disconnection, severe leakage (optional) **prisma30ST, prisma30ST-C, prismaLAB** Apnea, low minute volume, low Tidal volume
Alarms	Disconnection, leak (optional)
Alarm output	Optical and acoustic
CPAP operating pressure range	4 hPa to 20 hPa
AcSV pressure range	4 hPa to 30 hPa
BILevel pressure range	4 hPa to 25 hPa

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Specification	Therapy device
Pressure accuracy	≤ 20 hPa: ± 0.6 hPa >20 hPa: ± 0.8 hPa
P Lim_{max} (maximum pressure in case of error)	≤ 40 hPa
Target volume in AcSV mode	It is not possible to set a target volume for the AcSV mode. The pressure control stabilizes the volume at the respective current level.
Automatic backup frequency in AcSV mode	The automatic backup frequency in AcSV mode is continuously adapted between 10 bpm and 20 bpm depending on the filtered spontaneous rate and the relative respiratory minute volume of the patient.
prisma25S-C	
- Inspiratory positive airway pressure (IPAP)	4 hPa to 25 hPa
- Expiratory positive airway pressure (EPAP)	4 hPa to 25 hPa
- Relative inspiration duration Ti/Tset	25% to 67%
- Trigger	Auto, can be set to 3 levels
- Pressure rise rate	Can be set to 3 levels
- Available modes	CPAP, S
prisma25S	
- Inspiratory positive airway pressure (IPAP)	4 hPa to 25 hPa
- Expiratory positive airway pressure (EPAP)	4 hPa to 25 hPa
- Relative inspiration duration Ti/Tset	25% to 67%
- Trigger	Auto, can be set to 3 levels
- Pressure rise rate	Can be set to 3 levels
- Available modes	CPAP, APAP, S, autoS
prisma25ST	
- Inspiratory positive airway pressure (IPAP)	4 hPa to 25 hPa
- Expiratory positive airway pressure (EPAP)	4 hPa to 25 hPa
- Relative inspiration duration Ti/Tset	25% to 67%
- Trigger	Auto, can be set to 3 levels
- Pressure rise rate	Can be set to 3 levels
- Backup frequency	0 bpm to 35 bpm
- Available modes	CPAP, APAP, S, autoS, autoS/T, S/T, T
prisma30ST	
- Inspiratory positive airway pressure (IPAP)	4 hPa to 30 hPa
- Expiratory positive airway pressure (EPAP)	4 hPa to 25 hPa
- Relative inspiration duration Ti/Tset	20% to 67%
- Ti	500 ms to 4000 ms
- Trigger inspiration	Auto, can be set to 3 levels
- Trigger expiration	Auto, can be set to 3 levels
- Pressure rise rate	Can be set to 4 levels
- Pressure drop rate	Can be set to 3 levels
- Backup frequency	Auto, 0 bpm to 35 bpm
- Target volume	300 ml to 2000 ml
- Pressure adjustment	Can be set to 3 levels
- Available modes	CPAP, APAP, autoS/T, S, S/T, T, aPCV
prisma30ST-C	
- Inspiratory positive airway pressure (IPAP)	4 hPa to 30 hPa
- Expiratory positive airway pressure (EPAP)	4 hPa to 25 hPa
- Relative inspiration duration Ti/Tset	20% to 67%
- Ti	500 ms to 4000 ms
- Trigger inspiration	Auto, can be set to 3 levels
- Trigger expiration	Auto, can be set to 3 levels
- Pressure rise rate	Can be set to 4 levels
- Backup frequency	0 bpm to 35 bpm
- Available modes	CPAP, S, S/T, T, aPCV

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Specification	**Therapy device**	
Peak flow as per ISO 80601-2-70	Pressure measured at the patient connection opening at a flow of 40 l/min	Average flow at the patient connection opening [l/min]
CPAP and APAP mode		
Test pressures:		
4 hPa	4.0 hPa	235 l/min
8 hPa	8.0 hPa	230 l/min
12 hPa	11.9 hPa	220 l/min
16 hPa	15.9 hPa	215 l/min
20 hPa	19.9 hPa	210 l/min
AcSV mode		
Test pressures:		
4 hPa	4.0 hPa	235 l/min
10.5 hPa	10.4 hPa	225 l/min
17 hPa	17.0 hPa	215 l/min
23.5 hPa	23.5 hPa	200 l/min
25 hPa	25 hPa	195 l/min
30.0 hPa	30.0 hPa	190 l/min
Warming of respiratory air	Maximum +3°C	
Stability of the dynamic pressure (short-term accuracy) for 10 breaths/min as per ISO 17510-1:2007 when using the 19 mm hose.		
7 hPa	$\Delta p \leq 0.24$ hPa	
10 hPa	$\Delta p \leq 0.28$ hPa	
13.5 hPa	$\Delta p \leq 0.3$ hPa	
20 hPa	$\Delta p \leq 0.4$ hPa	
Stability of the dynamic pressure (short-term accuracy) for 15 breaths/min as per ISO 17510-1:2007 when using the 19 mm hose.		
7 hPa	$\Delta p \leq 0.24$ hPa	
10 hPa	$\Delta p \leq 0.32$ hPa	
13.5 hPa	$\Delta p \leq 0.4$ hPa	
20 hPa	$\Delta p \leq 0.48$ hPa	
Stability of the dynamic pressure (short-term accuracy) for 20 breaths/min as per ISO 17510-1:2007 when using the 19 mm hose.		
7 hPa	$\Delta p \leq 0.4$ hPa	
10 hPa	$\Delta p \leq 0.32$ hPa	
13.5 hPa	$\Delta p \leq 0.46$ hPa	
20 hPa	$\Delta p \leq 0.56$ hPa	

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Specification	Therapy device
Stability of the dynamic pressure (short-term accuracy) as per ISO 80601-2-70 in CPAP and APAP mode - when using the 19 mm hose 4 hPa 8 hPa 12 hPa 16 hPa 20 hPa - when using the 15 mm hose, bacteria filter, and oxygen safety valve 4 hPa 8 hPa 12 hPa 16 hPa 20 hPa	 $\Delta p \leq 0.68$ hPa $\Delta p \leq 0.58$ hPa $\Delta p \leq 0.52$ hPa $\Delta p \leq 0.44$ hPa $\Delta p \leq 0.64$ hPa $\Delta p \leq 1.06$ hPa $\Delta p \leq 1$ hPa $\Delta p \leq 1.08$ hPa $\Delta p \leq 1.02$ hPa $\Delta p \leq 0.96$ hPa
Stability of the dynamic pressure (short-term accuracy) as per ISO 80601-2-70 in modes with 2 pressure levels at 10 bpm inspiratory at 15 bpm inspiratory at 20 bpm inspiratory at 10 bpm expiratory at 15 bpm expiratory at 20 bpm expiratory	 $\Delta p = 0.8$ hPa $\Delta p = 1.4$ hPa $\Delta p = 2.4$ hPa $\Delta p = 0.6$ hPa $\Delta p = 0.6$ hPa $\Delta p = 0.6$ hPa
Stability of the static pressure (long-term accuracy) as per ISO 80601-2-70 - when using the 19 mm hose - when using the 15 mm hose, bacteria filter, and oxygen safety valve	 $\Delta p = 0.15$ hPa $\Delta p = 0.19$ hPa
Pressure drop via the oxygen valve at 90 l/min at 60 l/min at 30 l/min	 0.5 hPa 0.25 hPa 0 hPa
Recommended maximum additional oxygen	15 l/min
Accuracy of volume measurement at 20 °C	±20 %
Filter and smoothing techniques	• Target volume that can be set: In the "slow" level, the device checks after every 8 breaths if the target volume has been reached and changes the pressure by 0.5 hPa. If the pressure reaches a corridor around the target volume, the device switches to exact regulation. In the "medium" level, the device checks after every 5 breaths if the target volume has been reached and changes the pressure by 1.0 hPa. If the pressure reaches a corridor around the target volume, the device switches to exact regulation. In the "fast" level, the device checks after every breath if the target volume has been reached and changes the pressure by 1.5 hPa. If the pressure reaches a corridor around the target volume, the device switches to exact regulation. • Alarms: The "low minute volume" and "low tidal volume" alarms are triggered if at least three of the last five breaths were below the alarm limit. The alarms are reset automatically as soon as the corresponding alarm limit is exceeded again with at least three of the five breaths. If a target volume is activated, the "low tidal volume" alarm is only triggered once IPAPmax or PDIFFmax has also been attained. The "Apnea" alarm is triggered if apnea is identified which is longer than the set alarm limit. The alarm is reset automatically as soon as the end of the apnea is identified.

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Specification	Therapy device
Pollen filter down to 1 µm down to 0.3 µm	Filter class E10 ≥ 99.5% ≥ 85%
Service life of pollen filter	Approx. 250 hours
SD card	Memory sizes of 256 MB to 8 GB can be used, interface compatible with SD physical layer version 2.0

Tolerances for measurements

Pressure:	± 0.75% of measurement or ± 0.1 hPa
Flow:	± 4 l/min
Temperature:	± 1.5°C
Sound pressure level and sound power level	± 2dB(A)

The right to make design modifications is reserved.
All flow values are determined under STPD conditions.
All the parts of the therapy device are free from latex.

12.2 Technical data of power supply unit

Specification	Power supply unit
Max. output	90 W
Input voltage	100 V - 240 V
Frequency	50 Hz - 60 Hz
Input voltage for use in airplanes	115 V
Frequency for use in airplanes	400 Hz

12.3 Technical data of respiratory air humidifier

Specification	prismaAQUA
Product class according to 93/42/EEC	IIa
Dimensions W x H x D in cm	14 x 13.5 x 18
Weight (without water)	0.6 kg
Temperature range Operation Storage	 +5 °C to +37 °C -25 °C to +70 °C
Permissible humidity during operation and storage	15% to 93%, non-condensing
Air pressure range	700 hPa to 1060 hPa, corresponds to a height of 3000 m above sea level
Electrical power	Maximum 30 VA (only in combination with the permitted device)
Classification as per DIN EN 60601-11: Type of protection against elec. shock Degree of protection against elec. shock Protection against harmful ingress of water and solid particles	 Protection class II Type BF IP21

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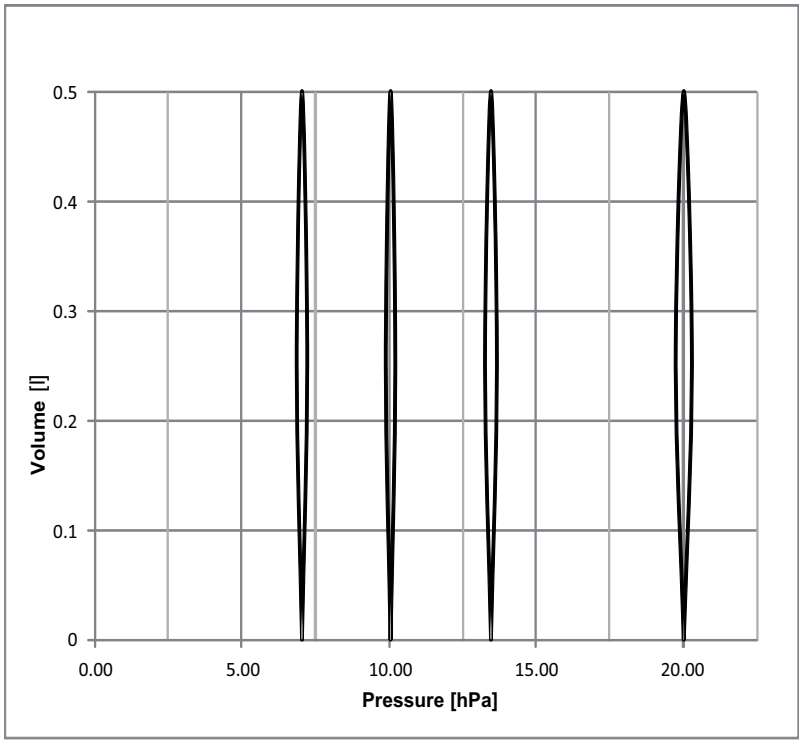
Specification	prismaAQUA
Classification as per DIN EN 60601-1: Operating mode	 Continuous operation
 Electromagnetic compatibility (EMC) acc. to DIN EN 60601-1-2: Radio interference suppression Radio interference immunity	Test parameters and limit values can be requested from the manufacturer if required. EN 55011 B IEC 61000-4 Parts 2 to 6, Part 11, Part 8 IEC 61000-3 Parts 2 and 3
Warming of respiratory air	Maximum +3°C
Maximum filling volume	400 ml
Pressure drop at a flow of (with 400 ml of water):	The pressure drop across the device combination of WM 100 TD therapy device and WM 100 TH respiratory air humidifier does not increase.
Maximum flow	248 l/min
Maximum permitted operating pressure	40 hPa

12.4 Pressure volume curve

pV curve at RV=0.5 l and f=20/min



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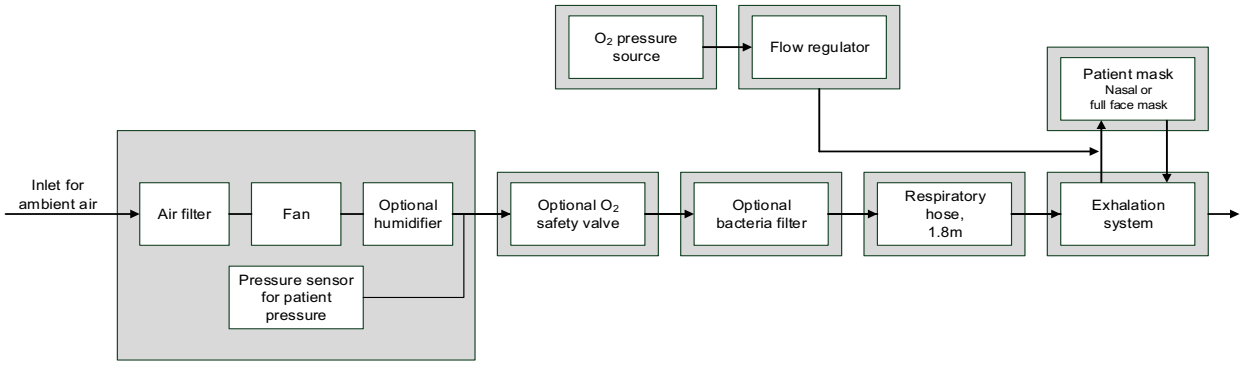
12.5 Pneumatic system diagram



12.6 Separation distances

Recommended separation distances between portable and mobile RF telecommunication devices (e.g., cell phones) and the therapy device.				
Rated maximum output power of the RF device in W	**Separation distance according to frequency of transmitter in m**			
	150 kHz-80 MHz outside the ISM bands	**150 kHz-80 MHz in the ISM bands**	**80 MHz-800 MHz**	**800 MHz-2.5 GHz**
0.01	0.04	0.12	0.12	0.23
0.1	0.11	0.38	0.38	0.73
1	0.35	1.20	1.20	2.30
10	1.10	3.80	3.80	7.27
100	3.50	12.00	12.00	23.00

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13 Test record

You can find a blank template for the test record on the following pages.

The headings in the test record correspond to the headings in the chapter "Final test".

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Test record

as per Service and Repair Manual WM 67971

	Device type:	☐ prisma20C	☐ prismaCR
		☐ prisma20A	☐ prismaLAB
		☐ prisma25S	☐ prisma25S-C
		☐ prisma25ST	☐ prisma30ST
		☐ prisma30ST-C	
	Device description:	Sleep apnea therapy device	
	Serial no.:		
	Manufacturer:	Löwenstein Medical Technology GmbH + Co. KG	
	Date of manufacture:		
	Operator:		
	Patient:		

5.	**Final test** (as per Service and Repair Manual WM 67971)		
5.3	**Preparation for testing**	OK	Not OK
5.3.1	Check housing: Housing is free from damage and defects.	☐	☐
5.3.2	Check the power supply cable		
	• The insulation is OK.	☐	☐
	• The cable shows no signs of damage.	☐	☐
	• There are no loose contacts.	☐	☐
5.3.3	Check the power supply unit.		
	The LED in the power supply unit lights up.	☐	☐
5.4	**Performing a function check**	OK	Not OK
5.4.1	Perform the step-by-step test		
	Step 1: Check the date and time • The date and time are correct.	☐	☐
	Step 2: Check the On/Off button • On/Off button not pressed: Display: Power key test status -> Power key NOT pressed Display: Power LED -> OFF • On/Off button pressed: Display: Power key status -> Power key pressed Display: Power LED status -> OFF	☐	☐
	Step 3: Check alarm beeper • Signal tones are emitted in three different volumes.	☐	☐
	Step 4: Check the SD card. • SD card present, display: SD card status -> Passed • SD card not present, display: SD card status -> SD card not recognized	☐	☐
	Step 5: Check PSG/system interface • Display: PSG UART test status -> passed	☐	☐
	Step 6: Check the ambient pressure sensor. • The ambient pressure displayed corresponds to the current air pressure. The deviation must not be more than 20 mbar.	☐	☐
	Step 7: Check the pressure settings		
	• The maximum difference between the setting and measured values is within the tolerance.	☐	☐

Setting	Measurement	Tolerance
4		+/-0.4 mbar
15		+/-0.6 mbar
30		+/-0.8 mbar

	Step 8: Check the flow values		
	• The displayed flow values are within the tolerance.	☐	☐

Speed	Setting
19,000 rpm	80-140 l/min
35,000 rpm	150-280 l/min

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	Step 9: Check the humidifier interface (heating element)					
	• The voltage and current consumption displayed are within the tolerance specified.	Voltage setting	Actual current	Actual voltage	☐	☐
		16 V	> 0 A	15 - 17 V		
		31 V	> 0 A	30 - 31 V		
5.4.2	**Checking the respiratory air humidifier**				OK	Not OK
	Device is used with the respiratory air humidifier.					
	No ☐	Yes ⇩				
		• The housing has no cracks, damage or heavy soiling.			☐	☐
		• The respiratory air humidifier has no leaks.			☐	☐
		• The respiratory air humidifier warms up.			☐	☐
5.5	**Checking the display and the function of the keys**				OK	Not OK
	• The therapy device can be switched on and off.				☐	☐
5.6	**Checking the SD card**				OK	Not OK
	• The SD card symbol is shown in the display.				☐	☐

	Record of tasks performed
	☐ Maintenance performed ☐ Hygienic preparation performed during patient change ☐ Repair performed ☐ Testing performed
	Date Signature

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