EN Instructions for Use for patients for devices of type WM100TD

prisma20A
prisma20C
prismaCR
prisma25S
prisma25S-C
prisma25ST
prismaLAB
prisma30ST

Sleep therapy device

LÖWENSTEIN
medical

Contents

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1 Introduction

1.1 Intended use

The WM100TD devices are pressure-controlled, non-invasive, non-life-sustaining therapy devices for the treatment of sleep-related breathing disorders by means of a mask.

The WM100TD devices can be used on persons weighing above 30 kg. The CPAP mode can be used on persons above the age of 3 years, irrespective of their weight. The WM100TD devices may only be used on the instruction of a physician.

The WM100TD devices are used in clinical and domestic environments. In domestic environments, the WM100TD devices are also taken on trips.

1.2 Description of function

The blower in the therapy device draws in ambient air through a filter, compresses the air, and delivers it to the device outlet port.

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

The device can operate 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 variant, the device can automatically specify the pressure levels in preset limits or settings can also be made manually. Depending on the mode, the pressure can be triggered continuously at one level or triggered by the patient or applied at certain times. Pressure signals, respiratory flow signals, and respiratory events can be saved and/or output to a PSG system.

The therapy data are stored in the device and on an SD card for monitoring therapy.

The device is operated by an on/off key and a touchscreen.

The device can be controlled remotely via the therapy software prismaTS and prisma CLOUD.

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

1.3 User qualifications

The person operating the device is referred to in these instructions for use as the user. A patient, on the other hand, is the person receiving the therapy. Always follow all operating steps according to these instructions for use.

Notice for blind or partially-sighted users

An electronic version of the instructions for use is also available on the website.

1.4 Indications

Patients with sleep-related breathing disorders.

1.5 Contraindications

The therapy devices must not be used in the case of:

No spontaneous breathing or in the case of acute respiratory failure, unconsciousness, somnolence or coma, pneumothorax or pneumomediastinum, pneumocephalus or CSF fistula, severe injuries to the head or face, severe epistaxis, high risk of a barotrauma, blocked airways, compromised ability to cough, middle ear infection (otitis media) or perforated eardrum, other acute intolerance, elevated pressure in the upper respiratory tract.

The therapy devices must only be used with caution and following assessment by a physician in the case of:

Acute cardiac decompensation, acute cardiac infarction, severe arrhythmia, severe hypotension, particularly in combination with intravascular volume depletion, severe cardiac insufficiency, dehydration, acute sinus infection (sinusitis) or infection of the upper respiratory tract, chronic infection of the respiratory tract or of the middle ear (otitis media).

prismaCR

Symptomatic chronic systolic cardiac insufficiency (NYHA 2-4) with reduced left-ventricular ejection fraction (LVEF ≤ 45%) and moderate to severe predominantly central sleep apnea (AHI ≥ 15/h, CAHI / AHI ≥ 50% and CAI ≥ 10/h).

1.6 Side effects

The following side effects may be caused by the overpressure generated by the therapy device and the respiration support:

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Experiencing the therapeutic pressure as unpleasant, especially in the upper respiratory tract or in the ribcage, aerophagia, flatulence, headache, earache, otitis, aspiration, fatigue, anxiety, feeling of dependence on the therapy device, tinnitus, gagging, periodic leg movements, hypoventilation, episodes of prolonged oxygen desaturation.

If the following side effects occur, they may be reduced by using a humidifier and/or a perfectly suited breathing mask:

Feeling of dryness in the mouth, throat or upper respiratory tract, (allergic) rhinitis, rhinorrhea, sinusitis, epistaxis.

If the following side effects occur, they may be reduced by using comfort functions on the therapy device or by optimizing therapy settings:

Increased effort to exhale, feeling of dyspnea, central sleep apnea, disturbed sleep, insomnia.

Other side effects may be caused by the use of accessory components such as breathing mask or humidifier. Follow the instructions for use for the accessories.

1.7 Clinical benefit

Correction of the breathing pattern during sleep, improved sleep quality, reduced daytime sleepiness, improvement in quality of life, reduction in blood pressure (hypertensive patients).

2 Safety

Read these instructions for use carefully. They are a constituent part of the devices described and must be available at all times.

Use the device exclusively for the purpose described (see „1.1 Intended use“, page 4).

For your own safety and the safety of your patients and in accordance with the requirements of (EU) Regulation 2017/745, follow the safety information below.

2.1 Safety information

2.1.1 Handling the therapy device, the components, and the accessories

A damaged device or damaged components may injure the patient, the user, and bystanders.

⇒ Only operate the device and its components if they are externally undamaged.

⇒ Perform a function check before every use (see „8 Function check“, page 39). Only operate the device and its components if a function check has been completed successfully.

⇒ Only operate the device if the display is functional.

2.1.2 Ambient conditions

Using the device outside the specified ambient conditions may lead to tolerances being exceeded and to device failure, injuring the patient. Dirt entering the device can impair the success of the therapy and damage the device.

⇒ Only operate the device within the specified ambient conditions (see „13 Technical data“, page 45).

⇒ Use the gray air filter.

⇒ Use the white pollen filter (optional accessory) if required.

⇒ Keep therapy device and accessories away from children and pets.

2.1.3 Patients with limited cardiac function

The cardiac output may be reduced under therapy for patients with limited cardiac function. A notable drop in blood pressure during the therapy or feeling unwell (dizziness, etc.) is indicative of decreased cardiac output. In this case stop the therapy immediately. The patient is not suitable for the therapy.

⇒ Perform a blood pressure test when setting the device for the first time:

1. Measure the blood pressure before performing overpressure therapy.

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2. Measure the blood pressure after 20 minutes of therapy with the expected medium pressure (e.g., 7 hPa).
3. Measure the blood pressure after 20 minutes of therapy with maximum pressure (e.g., 15 hPa).

2.1.4 USB connection

If the USB connection is connected, the PC can cause a higher leakage current. The therapy device cannot detect a USB cable connected to a switched-off PC and an increased leakage current.

⇒ Do not connect a USB cable to a switched-off PC when operating the therapy device.

2.1.5 Oxygen

Oxygen in combination with flammable substances can result in spontaneous explosions. In cases of insufficient ventilation, oxygen in the surrounding area (e.g., clothes, hair, bedclothes) can become enriched and cause fires and thus injuries to the patient, user, and others in the immediate vicinity.

⇒ Do not smoke.
⇒ Do not use naked flame.
⇒ Ensure adequate ventilation.
⇒ Keep the device and screwed unions free from oil and grease.
⇒ Always replace splashguards immediately after use.
⇒ Observe the instructions for use for the oxygen supply unit.
⇒ Set up oxygen sources at a distance of over 1 m from the device.
⇒ Only switch off the oxygen supply at the end of therapy. Allow the device to run on briefly to flush residual oxygen out of the device.
⇒ Define oxygen dosage in consultation with a doctor.
⇒ Observe the maximum oxygen flow (see „13 Technical data“, page 45).

2.1.6 Highly concentrated oxygen

Highly concentrated oxygen can poison the patient if administered for too long and depending on the patient's age.

⇒ Do not ventilate the patient for too long with highly concentrated oxygen.
⇒ Adapt the oxygen flow to suit the patient's age.
⇒ The prescribed flow must only be set by the physician or specialist dealer.

2.1.7 Cleaning

Ozone may attack and damage the materials of the devices.

⇒ Only clean the device, its accessories, and the mask in accordance with the associated instructions for use.
⇒ Do not use over-the-counter ozone cleaning equipment.

2.1.8 Disposables

Disposables are intended to be used only once. Reused disposables may be contaminated and/or their function impaired, causing injury to the patient.

⇒ Do not reuse disposables.

⇒ Follow the section on hygiene treatment (see „7 Hygiene treatment“, page 35) to avoid infection or bacterial contamination.

2.1.9 Change of patient

If the therapy device is used by several patients, infections may be transmitted to the next patient.

⇒ Use bacteria filter.

⇒ When reusing the device without a bacteria filter: Have the device subjected to hygiene treatment by the manufacturer or an authorized specialist dealer.

2.1.10 Energy supply

Operating the device outside the specified energy supply may injure the user and damage the device.

⇒ Operate the device only with the power supply unit provided on voltages from 100 V to 240 V.

⇒ Use the DC adapter for operation on voltages of 12 V or 24 V.

2.1.11 Transport

If the device is at an extreme angle, residual water from the humidifier may run into the device and damage it. Dirt which penetrates the device during transport may damage it.

⇒ Do not transport or tilt the device with the humidifier full.

⇒ Only transport the device with the cover fitted.

⇒ Store therapy device in carrying bag when not in use or being transported.

2.1.12 Tube heating

In combination with the device itself, the tube heating will generate a slightly higher temperature at the patient connection opening.

⇒ Follow the instructions for use for the tube heating.

2.1.13 Electromagnetic compatibility

The device is subject to special precautions with regard to EMC (electromagnetic compatibility). Ignoring this requirement may impair device performance.

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⇒ Maintain a minimum distance of 30 cm between the device and equipment that emits HF radiation (e.g., cell phones). This also applies to accessories such as antenna cables and external antennas.

⇒ Do not operate the device outside the EMC environment specified for this device (see „1.1 Intended use“, page 4) in order to prevent undesired events for the patient or owner/operator due to electromagnetic interference. Do not operate the device if the housing, cables, or other equipment for electromagnetic shielding are damaged.

⇒ Do not operate the device in the immediate vicinity of other devices or in a stacked arrangement, otherwise there may be malfunctions. If it is necessary to operate the device in the immediate vicinity of other devices or in a stacked arrangement, keep all the devices under observation to ensure that they are all operating properly.

2.2 General information

- In the EU: As a user and/or patient, you must report any serious incidents occurring in conjunction with the product to the manufacturer and to the responsible authority.
- If third-party articles are used, malfunctions and restricted fitness for use may result. Biocompatibility requirements may also fail to be met. In such cases, please be aware that any claim under warranty and liability will be void if neither the accessories nor the genuine replacement parts recommended in the instructions for use are used.
- Have measures such as repairs, servicing, modifications, and maintenance work carried out by the manufacturer or by specialists expressly so authorized by the manufacturer.
- Connect only the devices and modules approved in accordance with these instructions for use. The devices must meet the product standard applicable to them. Non-medical equipment should be positioned out of the patient's vicinity.
- The owner/operator is responsible for ensuring the compatibility of the therapy device and of all the components or accessories connected to the patient before use.
- Only use accessory parts from the manufacturer. Third-party electrical connecting cables, in particular, may cause the device to malfunction.
- The owner/operator is responsible for ensuring that the setting of the therapeutic pressure has been determined for each patient individually with the device configuration, including accessories, to be used.

- The owner/operator should regularly assess the effectiveness of the therapeutic settings.
- You should also follow the instructions for use of the therapy device, the components, and the accessories.
- The device is not suitable for patients requiring continuous support from the ventilation device.

2.3 Warnings in this document

DANGER
Indicates an unusually significant hazardous situation. If you ignore this instruction, severe irreversible injuries or death will result.

WARNING
Indicates an unusually significant hazardous situation. If you ignore this instruction, severe irreversible or fatal injuries may result.

CAUTION
Indicates a hazardous situation. If you ignore this instruction, mild or moderate injuries may result.

NOTICE
Indicates a harmful situation. If you ignore this instruction, material damage may result.

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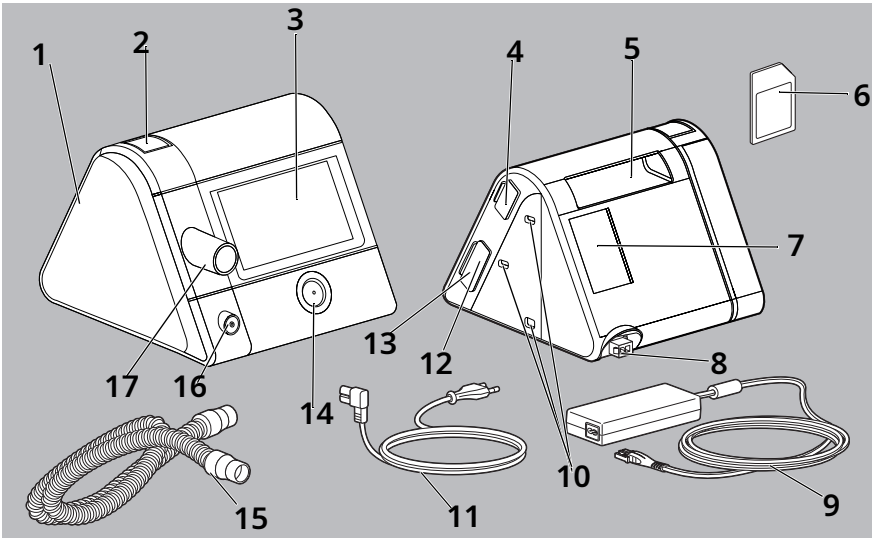
3 Product description

3.1 Overview of therapy device



No.	Designation	Description
1	Cover	Covers the humidifier connection if no humidifier is connected.
2	Unlocking button therapy device	Makes it possible to remove the cover in order to connect the humidifier.
3	Display	Allows operation of the therapy device and the humidifier. Displays settings and current values.
4	System interface	Connects the therapy device to modules.
5	Handle	Allows the therapy device to be lifted and transported.
6	SD card	Records therapy data.
7	Filter compartment in suction area	Houses the air filter and, where applicable, the pollen filter. The respiratory air is sucked in here and the dust particles filtered out.
8	Power input	Connects the therapy device to the power supply unit.
9	Power supply unit with connecting cable	Supplies the therapy device with power. Connects the power supply unit to the therapy device.
10	Mounting holes	Accept a module and secure it to the therapy device.
11	Power cord	Connects the power supply unit to the socket.
12	SD card slot	Takes an SD card. The symbol in the display indicates the communication between the SD card and the therapy device.

No.	Designation	Description
13	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.
14	On/off key	Switches the therapy device on and off. Switches the therapy device to Standby mode. Starts and stops the therapy.
15	Breathing tube	Connects the therapy device to the breathing mask
16	Connection for tube heater	Electrical power supply connection for a heatable tube.
17	Device outlet port	Connection for the breathing tube through which the patient is supplied with respiratory air.

3.1.1 Display in Standby mode (start screen)

No.	Designation	Description
1	Info menu key	Provides access to the Info menu.
2	Menu key	Provides access to the settings menus.
3	Dimmer key	If you want to end the therapy prematurely during the night, you can use the dimmer key on the start screen to turn the display dark and sleep undisturbed. The therapy device is still supplied with power and the alarm function remains activated. As soon as you touch the display, the start screen is shown in **Standby** mode again.
4	Time	Displays the current time.

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3.1.2 Symbols in display

Symbol	Description
	Expert area opens, allowing you to set the parameters.
	Expert area opens and the settings are locked. Parameter settings **cannot** be adjusted.
	Bacteria filter is connected and activated. If this symbol is displayed even though you are not using a bacteria filter, contact your specialist dealer.
	Air filter replacement required (symbol only appears if the authorized dealer has activated the reminder to change the air filter).
	Maintenance required (symbol only appears when maintenance function is active).
	USB port
	prismaCONNECT module is connected
	Wireless icon flashing white: The connected modem has been detected.
	Wireless icon flashing green: The connected modem is making a connection.
	The connected modem is in flight mode. No wireless signals transmitted.
	The connected modem is transmitting data. The number of green bars indicates signal strength.
	prismaPSG module is connected (green symbol)
	No connection to the prismaPSG module established (gray symbol)
	Network connection available (green symbol)

Symbol	Description
	No network connection available (gray symbol)
	SD card in SD card slot. Symbol flashes: Data is being saved to the SD card or read from the SD card.
	Humidifier is connected and switched off. smartAQUAcontrol climate control is switched on.
	Humidifier is connected and switched on. smartAQUAcontrol climate control is switched off. The set humidifier stage is displayed. The physician can restrict the selection of the humidifier levels 1-7.
	Humidifier is connected and empty of water.
	Alarm is set. The wake-up time is shown below the symbol.
	Indicates respiratory status: • Arrow pointing upward: inspiration • Arrow pointing downward: exhalation • Green arrow: spontaneous respiration • Orange arrow: assisted breathing
	Apnea
	Mask position is good, no leaks.
	Mask is not well positioned, severe leaks, the therapy efficacy is not guaranteed.
	Specifies the diameter of the tube in mm.
	The more green dots, the deeper you are in the menu structure.

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Symbol	Description
	Starts and stops the mask test prematurely. Shows the remaining time in seconds.
	Switches the softSTART on and off. Shows the set or remaining softSTART time in minutes. prisma30ST, prismaLAB: Switches off the current softSTOP. Shows the remaining softSTOP time in minutes.
Alarm window	
	Information signal triggered.
	Information signal paused for 2 minutes.
	Indicates that the acoustic signal for an information signal can be muted (black symbol)
	Acoustic signal for information signal is muted (orange symbol)

4 Preparation

4.1 Setting up the therapy device

NOTICE
Material damage from overheating!
Excessive temperatures may lead to the therapy device overheating and damage the device.
⇒ Do not cover therapy device and power supply unit with textiles (e.g., the blanket).
⇒ Do not operate therapy device in the vicinity of a radiator.
⇒ Do not expose therapy device to direct sunlight.
⇒ Do not operate therapy device in the carrying bag.

1. Place the therapy device on a level surface (e.g., a bedside table).
2. Keep the suction area of the therapy device uncovered.
3. Remove the protective film from the device.

4.2 Connecting power supply

WARNING
Risk of injury due to electric shock when connecting an incorrect power supply unit to the line power!
The power supply unit contains a safety device to prevent electric shock. Use of a non-genuine power supply unit may result in injury to the user and the patient.
⇒ Only operate the device on line power using the power supply unit recommended by the manufacturer.

CAUTION
Risk of injury due to inaccessible power supply connector!
An obstructed power supply connector cannot be pulled out in an emergency and can thus result in injury.
⇒ Keep access to the power supply connector and the power supply free at all times.

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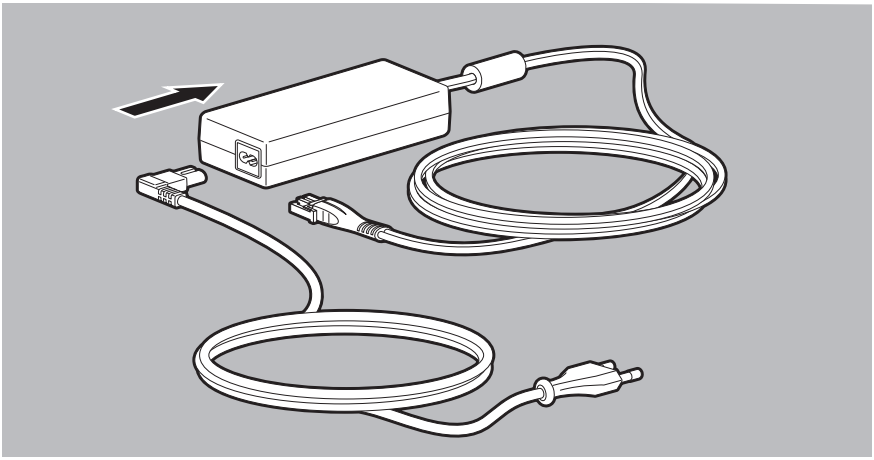
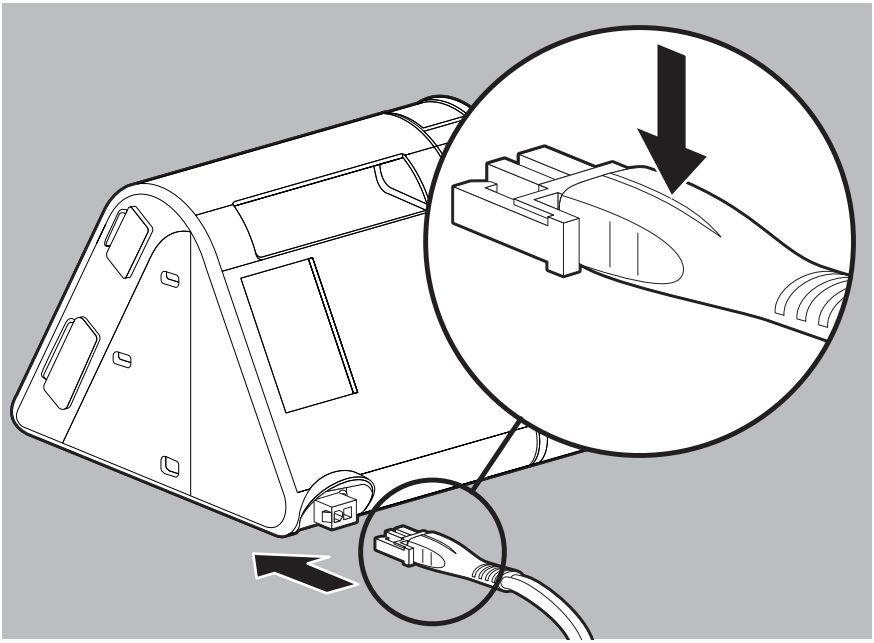


1. Connect the power cord to the power supply unit.



2. Plug the free plug on the power supply unit connecting cable into the power supply connection on the therapy device. Make sure the plug is aligned correctly.

If you want to operate the therapy device at 12 V or 24 V, connect the device to the optionally available inverter WM 24616 (12 V) or WM 24617 (24 V).

3. Plug the free end of the power cord in the power socket.
   The power supply unit adjusts to the power supply voltage automatically.
   The LED on the power supply unit lights up green.
4. If you want to disconnect the therapy device from the power supply, press the clip on the connector and pull the connector out. Do not pull on the power cord.

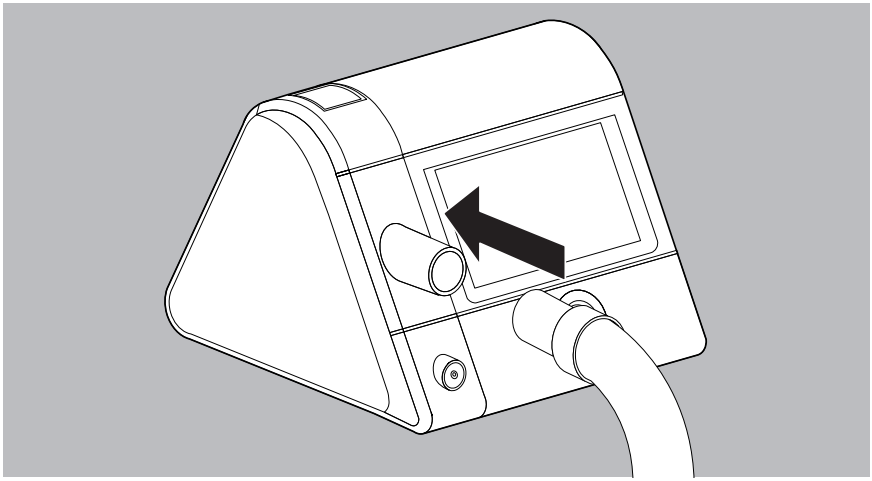
4.3 Connecting breathing tube

WARNING
Risk of injury due to contaminated or infected patient circuit!
A patient circuit contaminated or infected due to lack of or incorrectly performed hygiene treatment procedures can pass contamination or infection on to the next patient and cause injuries.

⇒ Do not reprocess disposable circuits.

⇒ Subject reusable patient circuits to the correct hygiene treatment (see „7.6 Hygiene treatment for breathing tube“, page 38).

1. To achieve the correct therapy pressure, set tube diameter in the device (see „6.2 Setting accessory parameters“, page 33).



2. Push breathing tube onto the device outlet port.

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CAUTION
Risk of suffocation if full-face masks without an exhalation system are used!
If full-face masks without an integrated exhalation system are used, the CO_2 concentration may rise to critical values and put the patient at risk.
⇒ Use full-face masks with an external exhalation system if there is no integrated exhalation system.

3. If not integrated: Insert the external exhalation system between the respiratory mask and the breathing tube (see instructions for use of the respiratory mask and the exhalation system).

CAUTION
Risk of injury if breathing tube routed incorrectly!
An incorrectly routed breathing tube may injure the patient.
⇒ Never wrap the breathing tube around the neck.
⇒ Do not use any small parts to fix the breathing tube in position as they might be accidentally swallowed.
⇒ Do not crush the breathing tube.

4. Connect the mask to the breathing tube.
5. Put on breathing mask.

The proper position and arrangement of the mask on the patient's face is critical for uniform use of the device.

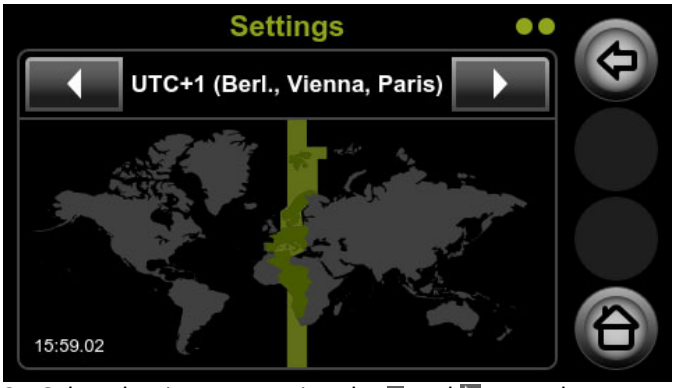
5 Operation

5.1 Switching on the therapy device for the first time

The therapy device must be configured before being used for the first therapy. If your specialist dealer has not yet done so, you must adjust the settings.

NOTICE
Material damage due to interruption of the power supply during configuration!
The configuration is not completed correctly if the power supply is interrupted prematurely.
⇒ Leave the therapy device connected to the power supply during the configuration.
⇒ Only interrupt the power supply once the message **Configuration successful** appears.

1. Provide a power supply (see „4.2 Connecting power supply“, page 17).
2. Select language.



3. Select the time zone using the ◀ and ▶ arrow keys.

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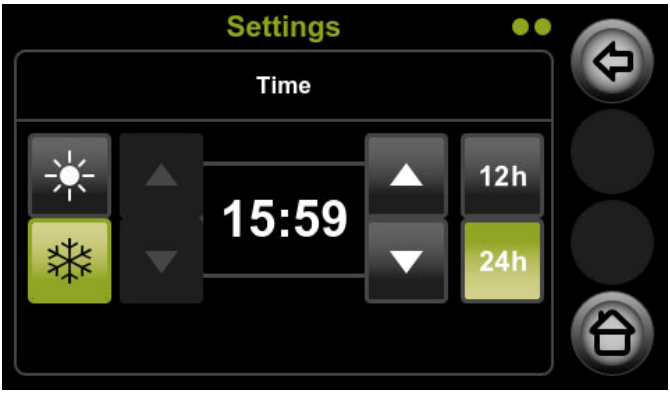

4. Setting the time:
   - Select summer time or winter time .
   - Set the minutes using the right arrow keys.
   - Select hour format: 24 h (0 to 24 hours) or 12 h (0 to 12 hours)
   - To set the hours: Select a different time zone.
5. Confirm set time using the key.

5.2 Navigating in the menu

You can adjust all settings in the menu via the display. Press the required field directly in the display.

Key	Description of function
	Scroll back one screen
	Scroll forward one screen
	Increase or decrease value
	Confirm value
	Discard value
	Return to the start screen (Standby or Therapy mode)

5.3 Switching device on and off / Starting and ending therapy

ACTION	Key or action	Result
Switching on the device	Press on/off key ⏻.	**Standby** mode. You can adjust the settings on the therapy device.
Starting therapy	Press on/off key ⏻. **or** If the autoSTART function is activated: Breathe into the mask.	**Therapy** mode. You can perform the mask test and start the softSTART sleep function.
End therapy	Press on/off key ⏻. **or** If the autoSTOP function is activated: Remove the mask. The therapy is automatically brought to an end after 5 seconds.	**Standby** mode. You can adjust the settings on the therapy device.
Switch off device	Press and hold on/off key ⏻ for 3 seconds. **or** If the automatic energy saving function is activated: Therapy device automatically switches to the **Energy saving** mode 15 minutes after the last action of the operator.	**Energy saving** mode. The therapy device is supplied with very low levels of power; nothing is shown on the display.

5.4 During therapy

If you would like to view detailed information on your therapy: Press Info key ⓘ.

To allow you to sleep undisturbed, the display automatically turns dark after 30 seconds . The therapy continues normally. As soon as you press the display, the start screen is shown in **Therapy** mode again.

5.4.1 Switching softSTART on and off

The softSTART function makes it easier to get used to ventilation pressure when falling asleep. You can set a pressure different to the prescribed therapy pressure. The therapy device sets this softSTART pressure when it is switched on. The pressure then increases slowly within the specified period, or drops to the therapy level after the specified period (maximum 45 minutes) has expired.

This function is suitable for patients who find a high or low pressure uncomfortable when awake and cannot fall asleep.

Requirement

- The softSTART function is activated by the physician or the specialist dealer.

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- A softSTART pressure is set (see „6.1 Setting comfort parameters“, page 32).

1. Start therapy.
2. If softSTART was activated during the last therapy: softSTART starts automatically when the therapy starts.
   or
   Press the softSTART key to switch on softSTART.
   The remaining time in minutes is shown.
3. Press the softSTART key to switch off softSTART.
   The set softSTART time in minutes is shown.

A mask test only interrupts a running softSTART. The softSTART is restarted after the mask test.

5.4.2 Performing the mask test

To minimize the risk of leaks and test the correct positioning of the mask even at higher pressures, you can perform a mask test before starting the therapy.
Requirement

- The mask test function was activated by the physician or specialist dealer.

1. Starting therapy.
2. Press the key.
3. To start the mask test, press the mask test key .
   The remaining time in seconds is shown.
4. Check the seal of the mask against what is shown on the display:

Symbol	Meaning
	Mask position is good, no leaks
	Mask is not well positioned, severe leaks, the therapy efficacy is not guaranteed

5. If necessary, adjust the mask headbands.
6. Wait until the therapy device automatically ends the mask test after 30 seconds.
   or
   To end the mask test prematurely, press the mask test key .

If you switch the softSTART on during the mask test, the mask test is automatically switched off.

5.4.3 Therapy result

The therapy data for the last therapy period is shown briefly after ending the therapy if the physician or specialist dealer has enabled this function. In all other cases, only the usage time is displayed.

The more green checks are shown (max. 3), the better the result.

5.5 Using the humidifier

You can activate smartAQUAcontrol climate control to keep humidification performance constant during therapy.

The smartAQUAcontrol function is activated in the menu *Main menu* | *Comfort* | *smartAQUAcontrol*.

5.5.1 Switching humidifier on and off

Requirement

- The therapy device is in **Standby** mode.
- The humidifier is filled with water.
- The humidifier is connected.

1. Press the humidifier key to preheat the humidifier. Please note that the humidifier will switch itself off again automatically after 30 minutes of preheating.
   or
   Starting therapy. The humidifier switches on automatically.

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2. The ⊕ or ⊖ keys can be used to increase or decrease the humidifier level.
   The humidifier levels 1-7 are available. The setting suitable for you depends on the room temperature and humidity. Humidifier level 4 is the standard setting. If you have dry airways in the morning, heating output is set too low. If condensation has formed in the breathing tube in the morning, heating output is set too high.
   The physician can restrict the selection of the humidifier levels 1-7.
   To reduce condensation in the breathing tube, we recommend using a tube heating system.
3. The humidifier automatically switches off if you bring the therapy to an end. Press the humidifier key (4) to switch off the humidifier during the therapy.

If there is no more water left in the humidifier, the humidifier switches off automatically. The humidifier key is orange.

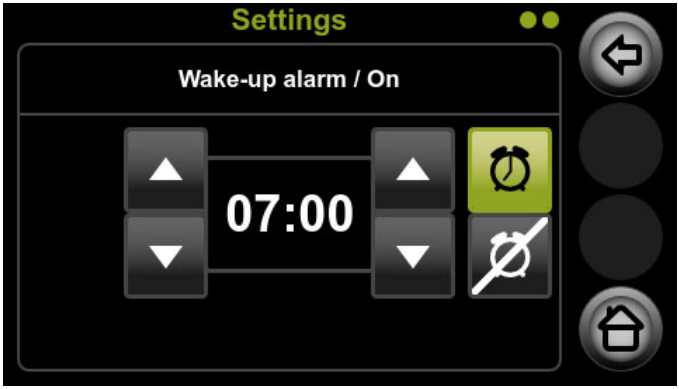
5.6 Setting the alarm

5.6.1 Setting, switching on, and deactivating wake-up time

Requirement

- The therapy device is in **Standby** mode.

1. Press the time on the start screen.
   or
   Press the menu key.
2. Press the **Time** field.
3. Press the **Wake-up time** field.
4. To switch the alarm on, press the alarm key. To deactivate the alarm, press the alarm clock key.



5. To set the wake-up time, use the left arrow keys to select the hours and the right arrow keys to select the minutes.
6. Confirm the settings with the key.

5.6.2 Switching off the alarm

Requirement

- The alarm is ringing.

1. To snooze the alarm for 5 minutes and set the alarm to ring again, press the **Pause** field.
2. To turn the alarm off for today, press the **Off** field.
   The alarm will go off the following day again at the set wake-up time.

5.7 Accessing therapy data and device information

In the info menu you can view information about the therapy (usage time, mask fit, therapy quality) within a selectable period of time and view general information about the device and network.
RequirementRequirement

- The therapy device is in **Standby** mode.

1. Press Info key .

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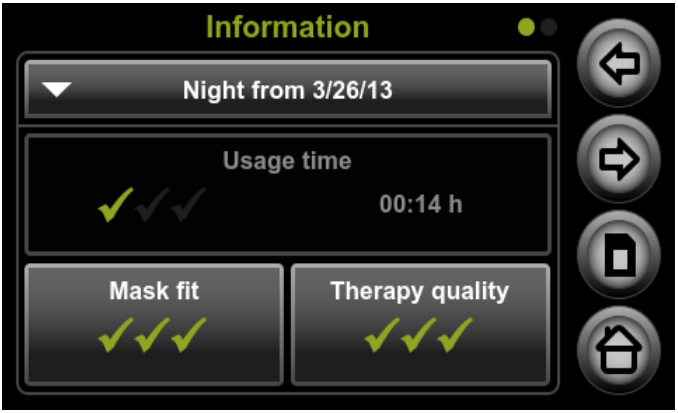


2. If necessary, To view therapy data from a night other than the previous night, select the desired date in the list .
3. To view the device information, navigate to the next screen using the and arrow keys.

5.8 Using the SD card

An SD card is not essential for operating the therapy device. Therapy data and settings are stored inside the device.

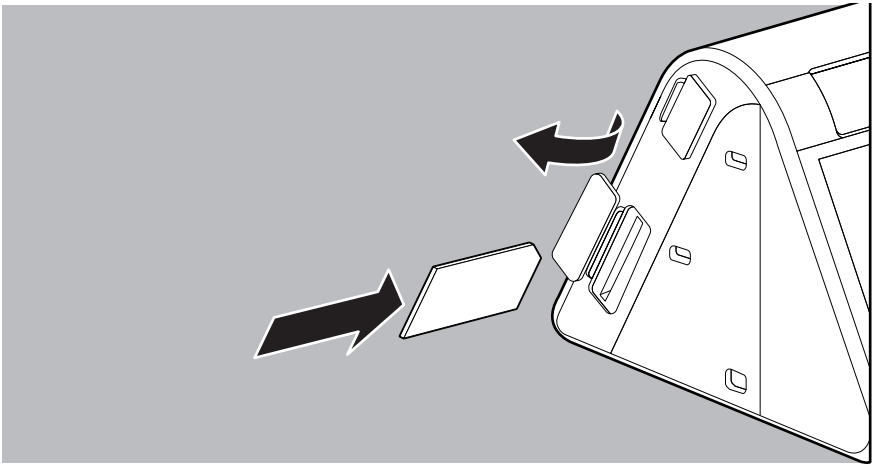
NOTICE
Loss of data as a result of incorrect SD card!
Functionality may be restricted or data may be lost in the case of SD cards not purchased from the manufacturer.
⇒ Only use SD cards from brand manufacturers which comply with the specifications (see „13 Technical data“, page 45).
⇒ Do not use SD card for third-party files.

5.8.1 Inserting the SD card

Requirement

- The therapy device is in **Standby** mode.

1. Open the SD card slot cover.



2. Push the SD card into the SD card slot until you hear it engage.
   In doing so, please note: The beveled corner of the SD card must be at the top and facing the device during insertion.
3. Close the SD card slot cover.

Saving therapy data to the SD card

NOTICE
Loss of data if power is interrupted!
If the therapy device is disconnected from the power supply during the save process, data may be lost.
⇒ Keep the therapy device connected to the power supply during the save process (SD card symbol flashes).

Autosave

The therapy device saves therapy data automatically in the cases below:

- Each time you end a therapy.
- Each time you insert an SD card. Only insert SD cards when the device is in **Standby** mode.
- When the therapy device is reconnected to the power supply after a saving process is interrupted.

Saving the therapy data manually

Requirement

- An SD card is inserted in the therapy device (see „5.8.1 Inserting the SD card“, page 28).

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- The info menu with the therapy data for the requested period is open (see „5.7 Accessing therapy data and device information“, page 27).

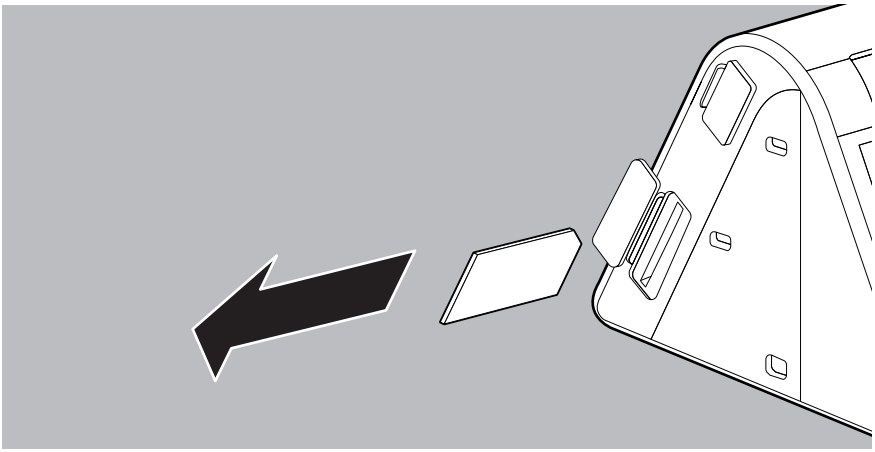
1. To save all the therapy data to the SD card, press the SD card key .
2. Press the **Save all data** field and confirm with the **OK** field.

5.8.2 Removing the SD card

Requirement

- The therapy device is in Standby mode.
- The SD card symbol is no longer flashing.

1. Open the SD card slot cover.
2. Briefly press in the SD card.
   The SD card is ejected slightly.



3. Remove the SD card.
4. Close the SD card slot cover.

5.8.3 Setting the device with the SD card

You can set the device with the help of an SD card provided by your physician or specialist dealer.

Requirement

- The therapy device is in Standby mode.

1. Insert the SD card with the saved device settings (see „5.8.1 Inserting the SD card“, page 28).
   The message **Configuration via SD card was successful** appears on the display. You can continue the therapy with the new settings.
   If the new settings for your device were not suitable or could not be read, the message **Configuration via SD card has failed** appears on the display. Contact your specialist dealer to obtain new settings.

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6 Settings in the menu

The settings menu lets you adjust the settings of the comfort, accessories and time parameters if the therapy device is in **Standby** mode.

Only applies to prisma30ST/prismaLAB: If the softSTOP function is activated, ventilation pressures and background frequency are continuously reduced. Remaining time is displayed in minutes on the softSTOP key. Once the set softSTOP time has elapsed, the device continues running at an EPAP of 4 hPa, an IPAP of 6 hPa and a background frequency of 5 bpm (softSTOP key flashes). Pressing the on/off key again switches the device to **Standby** mode. To cancel softSTOP, press the softSTOP key briefly.

6.1 Setting comfort parameters

Comfort parameters make using the therapy device and components easier for the patient and ensure a comfortable therapy.

Requirement

- The therapy device is in **Standby** mode.

1. Press the menu key  .
2. Press **Comfort**  field.
3. Configure the required settings and confirm.

Parameter	Adjustable values	Description
autoSTART	On Off	With the automatic on feature activated, you can switch on the therapy device by taking a breath.
autoSTOP	On Off	If you remove the breathing mask with the automatic off feature activated, therapy is automatically brought to an end after 5 seconds. Exception: If the **Disconnection** information signal has been activated, this function is locked.
softSTART Pressure[1]	Steps in units of 0.5 in the framework specified by the physician or specialist dealer	The softSTART function makes it easier to get used to ventilation pressure when falling asleep.
softSTART time[1]	5-minute steps in the framework specified by the physician or specialist dealer	Here you can set the time for which ventilation pressure rises to therapy pressure during softSTART.

Parameter	Adjustable values	Description
softPAP[1]	Off 1 2 3	Levels 1 and 2 (slight and normal breathing relief) of softPAP breathing relief are intended for patients who find it unpleasant to exhale against a high pressure. The breathing relief function reduces the pressure early during the transition to expiration, allowing you to breathe out more easily. Level 3 (breathing relief with inhalation assistance) is suitable for patients that experience a feeling of breathlessness at a low pressure. The pressure is raised slightly here during inspiration. This function is only available in CPAP and APAP mode.
smartAQUAcontrol	On Off	With climate control active, the device continuously adapts humidification performance to suit the current situation.
Mask test pressure	8 hPa-20 hPa (depending on your set therapy pressure)	Leaks due to a poorly fitted mask often only occur at relatively high pressures.

[1]This function must be enabled by your physician or specialist dealer.

6.2 Setting accessory parameters

These functions must be enabled by your physician or specialist dealer.

Requirement

- The therapy device is in **Standby** mode.

1. Press the menu key .
2. Press the **Accessories** field.
3. Configure the required settings and confirm.

Parameter	Adjustable values	Description
Tube type	15 mm 19-22 mm	Select the diameter of the tube type used here.
Air filter Change	Changed Cancel	Here you specify whether you have changed the air filter.

6.3 Setting time parameters

Requirement

- The therapy device is in **Standby** mode.

1. Press the menu key .
2. Press the **Time** field.

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3. Configure the required settings and confirm.

You can reset the time to the end of the last therapy at most.

6.4 Setting device parameters

Requirement

- The therapy device is in **Standby** mode.

1. Press the menu key .
2. Press the **Device** field.
3. Configure the required settings and confirm.

Parameter	Adjustable values	Description
Display Brightness	1 2 3	Level 1: dark Level 2: medium Level 3: bright
Leak alert	Off On	Here you can set whether an information signal should be triggered in case of a leak. This allows you to change the position of your mask at night. By doing so you avoid side effects or a reduced therapy quality due to high leaks. If this function cannot be selected, it needs to be enabled by your physician or specialist dealer.
Energy saving	Off On	Here you can activate or deactivate whether the therapy device automatically switches to **Energy saving** mode 15 minutes after the therapy has finished. You save electricity if the therapy device is in **Energy saving** mode during the day.
Key tone volume Alarm Volume	Off 1 2 3	Level 1: quiet Level 2: medium Level 3: loud
Alarm volume	1 2 3	Level 1: quiet Level 2: medium Level 3: loud
Therapy indicator	Off On	Here you can set whether the on/off key should be illuminated during therapy, even if the display darkens.

7 Hygiene treatment

WARNING
Risk of infection when the device is used again!
If the device is used by several patients, infections may be transmitted to the next patient.
⇒ If the device is used again: have the device subjected to a hygiene treatment by the manufacturer or the authorized specialist dealer.

7.1 General information

- **This product may contain disposables. Disposables are intended to be used only once.** Therefore, use these items only once and do **not** reprocess them. Reprocessing disposables may impair the functionality and safety of the product and lead to unforeseeable reactions due to aging, embrittlement, wear, thermal load, the effects of chemical processes, etc.
- Wear appropriate safety gear for the disinfecting process.
- Refer to the instructions for use for the disinfectant used.
- You should also follow the instructions for use of the therapy device, the components, and the accessories.
- Following hygiene treatment by the authorized specialist dealer, the therapy device is suitable for using again with other patients.

7.2 Cleaning intervals

Interval	Action
Weekly	Clean therapy device (see „7.3 Hygiene treatment for therapy device“, page 36)
	Clean breathing tube (see „7.6 Hygiene treatment for breathing tube“, page 38)
	Clean humidifier In the clinical sphere: Disinfect humidifier
Monthly	Clean air filter (see „7.4 Cleaning air filter (gray filter)“, page 37)
	If present: Replace pollen filter (optional) (see „7.5 Replacing optional pollen filter (white filter)“, page 37)
Every 6 months	Replace air filter
Annually	Replace breathing tube
As required	Descale the humidifier. In the clinical sphere: Disinfect breathing tube. For hygiene reasons: Replace parts of housing of the humidifier if they are in poor condition (e.g., cracked).

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Interval	Action
On change of patient	If the therapy device or humidifier has been used without a bacteria filter: Have professional hygiene treatment performed before using the device again. Send therapy device to specialist dealer.

7.3 Hygiene treatment for therapy device

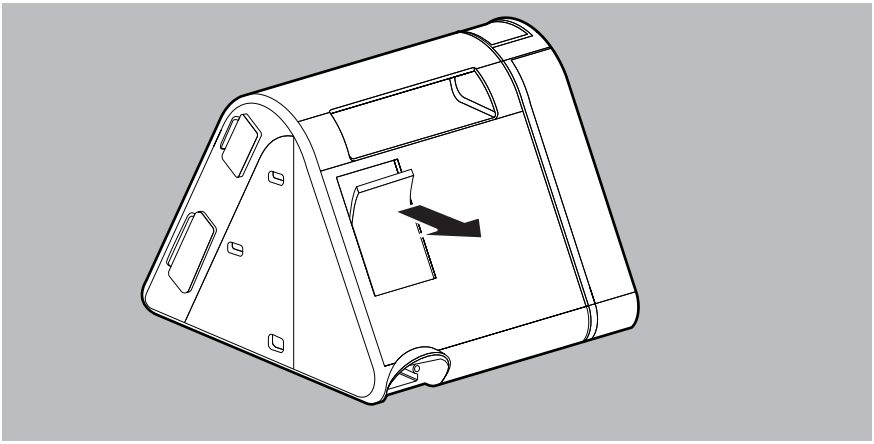
CAUTION
Risk of injury from electric shock!
Penetration of fluids may lead to a short circuit, injure the user, and damage the therapy device.
⇒ Disconnect the therapy device from the power supply before the hygiene treatment.
⇒ Do not immerse the therapy device or its components in liquids.
⇒ Do not pour liquids over the therapy device or its components.

1. Switch off therapy device (see „5.3 Switching device on and off / Starting and ending therapy“, page 23).
2. Disconnect the therapy device from the power supply.
3. If present: Remove the humidifier.
4. Subject the therapy device and its components to a hygiene treatment in accordance with the table below:

Part	Cleaning	Disinfection	Sterilization
Housing	Wipe down: Use water or mild detergent	Disinfect by wiping (recommended products: terralin® protect or perform advanced Alcohol EP)	Not permitted
High-gloss surfaces on the housing	Wipe down: Use water or mild detergent; do not use microfiber cloths		
Display	Wipe with a dry cloth: do not use water, mild detergent or microfiber cloths		
Power supply unit	Wipe down: Use water or mild detergent		
Power cord	Wipe down: Use water or mild detergent		

5. If present: Connect humidifier to the therapy device.
6. Restore power supply.
7. Perform a function check (see „8 Function check“, page 39).

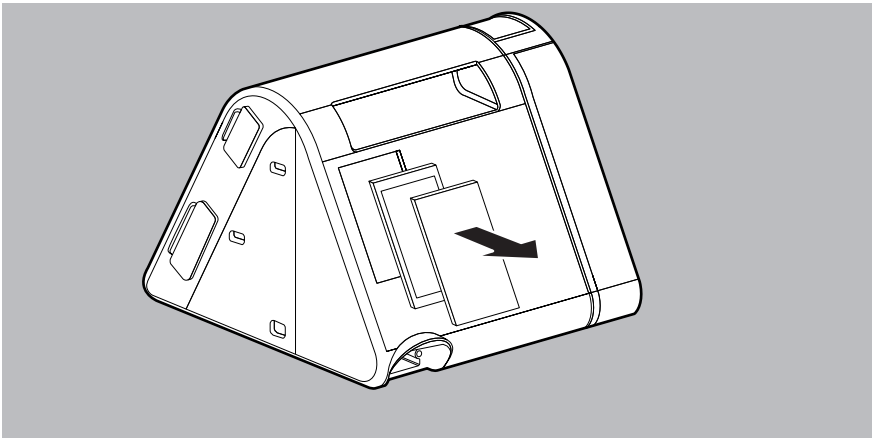
7.4 Cleaning air filter (gray filter)



1. Remove air filter.
2. Clean air filter under running water.
3. Allow air filter to dry.
4. Insert air filter in the holder.

7.5 Replacing optional pollen filter (white filter)

1. Remove air filter.



2. Remove pollen filter and dispose of it.
3. Insert new pollen filter in the holder.

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4. Insert air filter in the holder.

7.6 Hygiene treatment for breathing tube

NOTICE
Material damage as a result of ingress of liquids!
The device may be damaged by the ingress of liquids.
⇒ Use the breathing tube only when completely dry.

1. Subject the breathing tube to a hygiene treatment according to the information supplied by the manufacturer.

8 Function check

8.1 Intervals

Carry out a function check after every hygiene treatment and maintenance task, but at least every 6 months.

8.2 Checking therapy device

Requirement

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

1. Check therapy device for external damage.
   If damaged: Do not use therapy device.
2. Check connectors and cables for external damage.
   If damaged: Contact your specialist dealer and have parts replaced.
3. Check that components are correctly connected to the therapy device as per these instructions for use.
4. Switch on therapy device (see „5.1 Switching on the therapy device for the first time“, page 21).
5. If softSTART is active: press softSTART key to cancel softSTART.
6. Close the opening on the mask (using your knee, for example).
7. Press Info key .
8. Compare the pressure shown in the display with the prescribed pressure.
   If pressure deviation is > 1 hPa: Do not use the therapy device and contact your specialist dealer.

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9 Alarms and faults

If you are unable to remedy faults with the aid of the table, or in the event of unexpected operation or an incident, contact your authorized specialist dealer to have the device repaired. To avoid exacerbating the damage, do not continue operating the device.

9.1 Information signals

The messages designated as an "alarm" in the device are information signals.

Information signal	Cause	Remedy
⚠ Pressure build-up not possible! Please connect the mask and tube.	No breathing tube and / or no mask connected.	Connect the mask and breathing tube correctly (see „4.3 Connecting breathing tube“, page 19).
⚠ Severe leak! Please check the mask fit.	Mask has slipped or is not tight.	Reposition mask. Replace the mask if faulty.
⚠ Apnea! Please check the ventilation settings and the course of the breathing tube.	The respiratory volume output by the device is lower than the target value.	Check that the breathing tube is neither blocked nor kinked. Reposition the mask and breathe through it. If the information signal continues to show: Have settings checked by the attending physician.
⚠ Low tidal volume! Please check the ventilation settings and the course of the breathing tube.	The respiratory volume output by the device is lower than the target value.	Check that the breathing tube is neither blocked nor kinked. Reposition the mask and breathe through it. If the information signal continues to show: Have settings checked by the attending physician.
⚠ Low minute volume! Please check the ventilation settings and the course of the breathing tube.	The respiratory volume output by the device is lower than the target value.	Check that the breathing tube is neither blocked nor kinked. Reposition the mask and breathe through it. If the information signal continues to show: Have settings checked by the attending physician.

9.1.1 Muting information signals

If an information signal sounds, you can mute the audible alarm for 2 minutes.

Requirement

- An information signal is triggered.

1. Press the mute symbol  .
   The information signal is muted for 2 minutes. The symbol turns orange. After 2 minutes, the information signal sounds again.

9.1.2 Pausing information signals

If an information signal sounds, you can pause the it for 2 minutes to operate the device normally in the meantime.

RequirementRequirement

The **Apnea**, **Low minute volume** or **Low tidal volume** information signal has been triggered.

1. Press the **PAUSE** field.
   The information signal is paused for 2 minutes. The  symbol appears in the status line. After 2 minutes, the audible alarm sounds again.

If your physician has activated this function, you can also deactivate the **Severe leak** information signal permanently (see „6.4 Setting device parameters“, page 34).

9.2 Therapy device faults

Fault	Cause	Remedy
No running noise, nothing in the display.	No power supply.	Check that the power cord is securely connected. Check function of socket.
	SD card defective.	Remove the SD card (see 5.8.2, p. 30), disconnect the device from the power supply, reconnect it, and switch it back on. If the device can be switched on: Replace SD card. If the error persists: Contact your specialist dealer.
Therapy cannot be started by taking a breath.	autoSTART function not activated.	Activate autoSTART function (see 6.1, p. 32).
	autoSTART function may be restricted in the case of accessories with a high resistance.	Contact your specialist dealer.

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Fault	Cause	Remedy
Therapy device does not switch off after approx. 5 seconds once mask is removed.	autoSTOP function not activated.	Activate autoSTOP function (see 6.1, p. 32).
	autoSTOP function may be restricted in the case of accessories with a high resistance.	Contact your specialist dealer.
softSTART cannot be switched on.	softSTART function is locked.	Ask the physician whether the function can be enabled.
Therapy device does not reach lower pressure limit.	Air filter dirty.	Clean air filter. If necessary, replace filters (see „7 Hygiene treatment“, page 35).
	Breathing mask leaking.	Adjust headbands so that the mask is tight. If necessary, replace faulty mask.
 Bacteria filter symbol is shown on the display even though no bacteria filter is being used.	-	Contact your specialist dealer.

9.3 Display messages

If the message **Error (xxx)** appears in the display, **l**ook up the relevant error code in the table. Remedy the error in accordance with the description.

Error code	Cause	Remedy
108	Therapy device has lost the saved time.	Contact specialist dealer and have device repaired.
204	Humidifier not working properly.	Remove humidifier from therapy device and reconnect it. If the message persists, contact an authorized specialist dealer and have device and humidifier checked.
205	Power supply voltage is outside the permissible range.	Check that the correct power supply unit is connected (WM 29657). Contact your specialist dealer and have the device and power supply unit checked and repaired.
206	Fault in the prismaCONNECT module	Disconnect prismaCONNECT module and plug it back in. If the fault persists: Contact your specialist dealer and have the prismaCONNECT module replaced.
601	Faulty SD card	Remove and reinsert SD card. If the message persists, replace the SD card.
603	SD card full	Delete data from the SD card/Use new SD card.

Error code	Cause	Remedy
623	No mobile wireless network available	Try again later. Error occurs relatively frequently: Select a location with better reception. No remedy possible: Contact your specialist dealer.
629	Mobile wireless network not providing a data service	Try again later. No remedy: Contact your specialist dealer.
701	Leak on humidifier or at the cover on the side	Remove humidifier or side cover from device and re-connect. If the message persists, contact an authorized specialist dealer and have device and humidifier checked.
702	Device outlet port blocked. / Water in the therapy device.	Ensure that breathing tube and device outlet port are not blocked. If the fault persists: • Check whether there is water in the device. To do so, remove the humidifier and side part and tilt the device with the open side facing downward. • If water comes out: Wait until all the water has drained. • Allow the device to dry until the message is no longer displayed. In future, do not transport the device with water in the humidifier. • If water collects in the breathing tube: Reduce the humidifier level to avoid condensation.
All other error codes	Problems with the electronics	Disconnect the therapy device from the power supply and reconnect it (see 4.2, p. 17). If the message persists, contact an authorized specialist dealer and have device and humidifier checked

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10 Servicing

The therapy device is designed for a service life of 6 years.

If the therapy device is used as intended in accordance with the instructions for use, it does not require any maintenance within this period.

If the therapy device is used beyond this period, we recommend having it checked by an authorized specialist dealer.

11 Transport and storage

Transport and store the device under the specified ambient conditions (see „13 Technical data“, page 45).

12 Disposal

Do not dispose of the product in domestic waste. To dispose of properly, contact a licensed, certified electronic waste disposal merchant. This address is available from your Environment Officer or from your local authority.
The device packaging (cardboard and inserts) can be disposed of in paper recycling facilities.

13 Technical data

13.1 Technical data therapy device

Specification	Therapy device
Product class to MDR (EU) 2017/745	IIa
Dimensions Width x Height x Depth	17 x 13.5 x 18 cm
Weight	1.4 kg
Temperature range - Operation - Transport and storage	 +5°C to +40°C -25 °C to +70 °C Allow to cool or heat up to room temperature for 4 hours before starting up.
Permitted humidity for operation, transport, and storage	Rel. humidity 15% to 93%, no condensation
Air pressure range	700 hPa to 1060 hPa, corresponds to an altitude of 3000 m above mean sea level Adapts automatically to altitude
Connection diameter of circuit	Standard 22 mm tapered connector to ISO 5356-1
Power capacity humidifier interface	Max. 40 VA
System interface	12 V DC Max. 10 VA
Current consumption in operation (therapy) 240 V AC 100 V AC on standby 240 V AC 100 V AC	 0.11 A 0.25 A 0.035 A 0.022 A
Classification to DIN EN 60601-1-11: Protection class against electric shock Degree of protection against electric shock Protection against damaging ingress of water and solids	 Protection class II Type BF IP21
Classification to IEC 60601-1: Operating mode	Continuous duty
Applied part	Breathing mask
Mean sound pressure level/operation to ISO 80601-2-70	Approx. 26.5 dB(A) at 10 hPa
Mean sound pressure level/operation to ISO 80601-2-70 with humidifier	Approx. 27.5 dB(A) at 10 hPa

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Specification	Therapy device
Information signals (optional)	**All device types** Disconnection, high leak prisma30ST, prismaLAB Apnea, low minute volume, low tidal volume
CPAP operating pressure range	4 hPa to 20 hPa
AcSV pressure range	4 hPa to 30 hPa
BiLevel pressure range	4 hPa to 30 hPa
Pressure accuracy	< 20 hPa: ± 0.6 hPa ≥ 20 hPa: ± 0.8 hPa
P Lim_{max} (maximum pressure in the event of a fault)	≤ 40 hPa
Target volume in AcSV mode	AcSV mode does not have an adjustable target volume. Pressure control stabilizes the volume at the current level in each case.
Automatic background frequency in AcSV mode and autoS/T	The automatic background frequency is continuously adapted between 12 bpm and 20 bpm depending on the filtered spontaneous frequency and the patient's relative respiratory minute volume.
softSTART can be adjusted	0; 5-45 min
softSTART pressure	min. 4 hPa
Maximum additional oxygen flow rate	15 l/min
Precision of volume measurement at 20°C	±20%
SD card	Memory size 256 MB to 8 GB can be used, interface compatible with SD physical layer version 2.0
Stability of static pressure (long-term precision) to ISO 80601-2-70 when using the 19 mm tube when using the 15 mm tube, bacteria filter	 $\Delta p \leq 0.25$ hPa $\Delta p \leq 0.25$ hPa

Maximum flow rate to ISO 80601-2-70	Pressure measured at the patient connection opening at a flow rate of 40 l/min	Mean flow rate prevailing at the patient connection opening
when using the 19 mm tube Test pressures:		
4 hPa	4.0 hPa	221 l/min
8 hPa	7.9 hPa	224 l/min
12 hPa	11.9 hPa	218 l/min
16 hPa	15.9 hPa	213 l/min
20 hPa	19.9 hPa	207 l/min

Maximum flow rate to ISO 80601-2-70	Pressure measured at the patient connection opening at a flow rate of 40 l/min	Mean flow rate prevailing at the patient connection opening
when using the 15 mm tube		
Test pressures:		
4 hPa	4.0 hPa	204 l/min
8 hPa	7.9 hPa	202 l/min
12 hPa	11.9 hPa	201 l/min
16 hPa	15.9 hPa	198 l/min
20 hPa	19.9 hPa	193 l/min

Stability of dynamic pressure (short-term precision) to ISO 17510-1:2007	at 10 breaths/min	at 15 breaths/min	at 20 breaths/min
when using the 19 mm tube			
7 hPa	$\Delta p \leq 0.24$ hPa	$\Delta p \leq 0.24$ hPa	$\Delta p \leq 0.4$ hPa
10 hPa	$\Delta p \leq 0.28$ hPa	$\Delta p \leq 0.32$ hPa	$\Delta p \leq 0.32$ hPa
13,5 hPa	$\Delta p \leq 0.3$ hPa	$\Delta p \leq 0.4$ hPa	$\Delta p \leq 0.46$ hPa
20 hPa	$\Delta p \leq 0.4$ hPa	$\Delta p \leq 0.48$ hPa	$\Delta p \leq 0.56$ hPa

Stability of dynamic pressure (short-term precision) to ISO 80601-2-70	at 10 breaths/min	at 15 breaths/min	at 20 breaths/min
in CPAP and APAP mode			
when using the 19 mm tube			
4 hPa	$\Delta p \leq 0.3$ hPa	$\Delta p \leq 0.3$ hPa	$\Delta p \leq 0.7$ hPa
8 hPa	$\Delta p \leq 0.3$ hPa	$\Delta p \leq 0.3$ hPa	$\Delta p \leq 0.6$ hPa
12 hPa	$\Delta p \leq 0.3$ hPa	$\Delta p \leq 0.3$ hPa	$\Delta p \leq 0.6$ hPa
16 hPa	$\Delta p \leq 0.4$ hPa	$\Delta p \leq 0.4$ hPa	$\Delta p \leq 0.6$ hPa
20 hPa	$\Delta p \leq 0.5$ hPa	$\Delta p \leq 0.5$ hPa	$\Delta p \leq 0.7$ hPa
when using the 15 mm tube, bacterial filter			
4 hPa	$\Delta p \leq 0.5$ hPa	$\Delta p \leq 0.8$ hPa	$\Delta p \leq 1.1$ hPa
8 hPa	$\Delta p \leq 0.6$ hPa	$\Delta p \leq 0.8$ hPa	$\Delta p \leq 1.1$ hPa
12 hPa	$\Delta p \leq 0.7$ hPa	$\Delta p \leq 0.9$ hPa	$\Delta p \leq 1.1$ hPa
16 hPa	$\Delta p \leq 0.8$ hPa	$\Delta p \leq 1$ hPa	$\Delta p \leq 1.2$ hPa
20 hPa	$\Delta p \leq 0.9$ hPa	$\Delta p \leq 1$ hPa	$\Delta p \leq 1.3$ hPa
in modes with 2 pressure levels			
at 8 hPa on inspiration	$\Delta p \leq 0.6$ hPa	$\Delta p \leq 0.6$ hPa	$\Delta p \leq 0.6$ hPa
at 11 hPa on inspiration	$\Delta p \leq 0.8$ hPa	$\Delta p \leq 0.8$ hPa	$\Delta p \leq 0.8$ hPa
at 17 hPa on inspiration	$\Delta p \leq 0.8$ hPa	$\Delta p \leq 0.8$ hPa	$\Delta p \leq 0.8$ hPa
at 22 hPa on inspiration	$\Delta p \leq 1$ hPa	$\Delta p \leq 1$ hPa	$\Delta p \leq 1$ hPa
at 25 hPa on inspiration	$\Delta p \leq 1$ hPa	$\Delta p \leq 1$ hPa	$\Delta p \leq 1$ hPa
at 4 hPa on exspiration	$\Delta p \leq 1$ hPa	$\Delta p \leq 1$ hPa	$\Delta p \leq 1.2$ hPa
at 7 hPa on exspiration	$\Delta p \leq 1.2$ hPa	$\Delta p \leq 1.2$ hPa	$\Delta p \leq 1.3$ hPa
at 13 hPa on exspiration	$\Delta p \leq 1.4$ hPa	$\Delta p \leq 1.4$ hPa	$\Delta p \leq 1.5$ hPa
at 18 hPa on exspiration	$\Delta p \leq 1.6$ hPa	$\Delta p \leq 1.6$ hPa	$\Delta p \leq 1.7$ hPa
at 21 hPa on exspiration	$\Delta p \leq 1.7$ hPa	$\Delta p \leq 1.7$ hPa	$\Delta p \leq 1.8$ hPa

The right to make design modifications is reserved.

All flow rate and volume values determined under STPD conditions.

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No part of the therapy devices contains latex.

Therapy devices of the type WM100TD use the following open-source software: FreeRTOS.org

The software of this device contains code which is subject to the GPL. You can obtain the source code and the GPL on request.

13.2 BiLevel device variants

SPECIFICATION	prisma30ST	prisma25ST	prisma25S-C	prisma25S
Inspiratory positive airway pressure (IPAP)	4 hPa - 30 hPa	4 hPa - 25 hPa	4 hPa - 25 hPa	4 hPa - 25 hPa
Expiratory positive airway pressure (EPAP)	4 hPa - 25 hPa	4 hPa - 25 hPa	4 hPa - 25 hPa	4 hPa - 25 hPa
Available modes	CPAP, APAP, autoS/T, S, S/T, T, aPCV	CPAP, APAP, S, autoS, autoS/T, S/T, T	CPAP, S	CPAP, APAP, S, autoS
Relative duration of inspiration Ti/T set	-	25% to 67%	25% to 67%	25% to 67%
Trigger (prisma30ST: Trigger Inspiration/Trigger Expiration)	auto, can be adjusted in 3 stages			
Speed of pressure rise	Adjustable in 4 stages	Adjustable in 3 stages	Adjustable in 3 stages	Adjustable in 3 stages
Speed of pressure drop	Adjustable in 3 stages	-	-	-
Background frequency	auto, 0 bpm - 35 bpm	auto, 0 bpm - 35 bpm	-	-
Target volume	300 ml - 2000 ml			
Pressure adjustment	Adjustable in 3 stages			
Ti	500 ms - 4000 ms	-	-	-
Ti min	500 ms - 1700 ms	-	-	-
Ti max	500 ms - 1700 ms	-	-	-
Ti timed	auto, 500 ms - 1700 ms	-	-	-

13.3 Filters and smoothing techniques

Adjustable target volume:

In the "slow" stage, the device checks after 8 breaths whether 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 precise control.
In the "medium" stage, the device checks after 5 breaths whether 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 precise control.
In the "fast" stage, the device checks after each breath whether 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 precise control.

Information signals:

The "Low minute volume" and "Low tidal volume" information signals are triggered if the limit has been undershot in at least three of the previous five breaths. The information signals are automatically reset once the relevant limit has been exceeded again in at least three of the next five breaths.

Where the target volume has been activated, the "Low tidal volume" information signal is not triggered until IPAPmax or PDIFFmax has also been reached.

The "Apnea" information signal is triggered if apnea is detected that lasts longer than the set limit. The information signal is automatically reset once the end of the apnea has been detected.

13.4 Tolerances for measured values

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

13.5 Technical data for power supply unit

Specification	Power supply unit
Input voltage/maximum current	100 V - 240 V AC, 3 A - 1.5 A
Input frequency	50 Hz - 60 Hz
Output voltage/maximum current	37 V DC, 2.5 A

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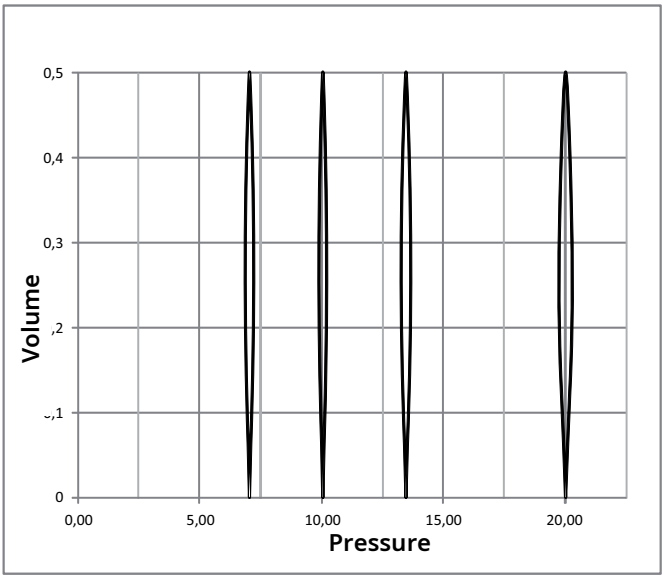
The power supply unit is part of the devices of type WM100TD.

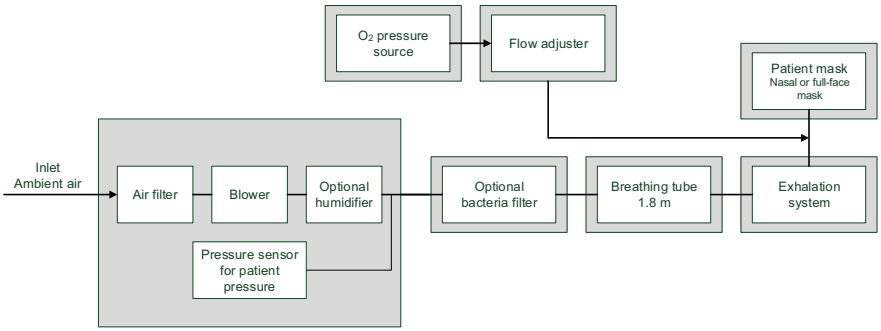
14 Annex

14.1 Pressure/volume curve

p/V curve at AV = 0.5 l and f = 20/min



14.2 Pneumatics diagram



14.3 Emission of electromagnetic interference

Interference emission test	Compliance

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Conducted and radiated RF emissions CISPR 11	Group 1 / Class B* * Radiated emissions Class A when operated in combination with accessories WM090MC, WM100MC or WM100MP
Harmonic distortion IEC 61000-3-2	Class A
Voltage fluctuations and flicker IEC 61000-3-3	Complies
Conducted and radiated RF emissions for airborne equipment RTCA DO-160G - Section 21, Category M	Complies

14.4 Electromagnetic interference immunity

Interference immunity test	Compliance level
Electrostatic discharge IEC 61000-4-2	± 8 kV contact ± 15 kV air
Radiated RF EM fields IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz
Proximity fields from RF wireless communications equipment IEC 61000-4-3	9 to 28 V/m* 385 MHz to 5.785 GHz* * Tested in accordance with IEC 60601-1-2:2020 Table 9
	27 to 84 V/m* 385 MHz to 5.785 GHz* * Tested in accordance with IEC 60601-1-2:2020 Table 9 with three times higher test levels. Corresponds to a distance of wireless communications equipment of 0.1 m.
Electrical fast transients/bursts IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input and output lines
Surges IEC 61000-4-5	± 1 kV line-to-line
Conducted disturbances induced by RF fields IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands between 150 kHz and 80 MHz
Power frequency magnetic fields (50/60 Hz) IEC 61000-4-8	30 A/m
Voltage dips and voltage interruptions IEC 61000-4-11	0 % UT; 0.5 cycle 0 % UT; 1 cycle 70 % UT; 25/30 cycles 0 % UT; 250/300 cycles
Proximity magnetic fields IEC 61000-4-39	8 A/m at 30 kHz 65 A/m at 134.2 kHz 7.5 A/m at 13.56 MHz

14.5 Markings and symbols

The following symbols may be applied to the device, the device ID plate, accessories, or packaging.

Symbol	Description
	Serial number
	Date of manufacture
	Follow the Instructions for Use
	Inlet
	Follow the Instructions for Use
	Slot for SD card
	USB port
	On/off key
	Outlet
	Direct current
IP21	Degree of protection against contact with a finger. Product is protected against vertically-falling drops of water.
	Degree of protection against electric shock: Protection class II product
	Do not dispose of the product in domestic waste.

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Symbol	Description
	Suitable for use in aircraft. Meets RTCA/DO-160G Section 21, Category M.
	Applied part type BF
	Manufacturer
	CE symbol (confirms that the product conforms to the applicable European directives/regulations)
	Alternating current
	China RoHS label (confirms that the product does not produce toxic substances during the indicated service life).
	Only intended for indoor use.
	Permitted temperature range for transport and storage
	Permitted humidity range for transport and storage
	Indicates the product is a medical device
	Unique device identifier
	Model number
	Fragile. Do not throw or drop.

Symbol	Description
	Protect from moisture
	Lot number
	Order number

14.6 Scope of supply

14.6.1 Standard scope of delivery

A current list of scopes of supply can be ordered on the manufacturer's website or through your specialist dealer.

The parts below are included in the standard scope of supply:

Part	Article number
Basic device	Varies depending on device variant
Breathing tube	WM 24445
Power supply unit	WM 29657
Power cord	Varies depending on country
Air filter/coarse dust filter (set of 2)	WM 29928
Pollen filter/fine filter (set of 12)	WM 29652 (not included in all device variants)
Carrying bag	Varies depending on device variant
Doming	WM 29899
SD card	WM 29794
Instructions for Use	Varies depending on language (see barcode on back cover for number of the current language)

14.6.2 Accessories

You can order accessories separately if required.

Part	Article number
prismaAQUA humidifier	WM 29680
SpO_2 module prisma CHECK	WM 29390
prismaCONNECT communication module	WM 29670
prisma HUB communication module	WM 31660
PSG module prismaPSG	WM 29690
2G modem WM110MW	WM 31240

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Part	Article number
3G modem WM110MW	WM 31770
4G modem WM110MW EU	LMT 31831
4G modem WM110MW Japan	LMT 31832
4G modem WM110MW Canada	LMT 31833
Cloud platform prisma CLOUD	WM 29610
Software prismaTS	WM 93335
Breathing tube 19 mm (22 mm)	WM 24445
Breathing tube 19 mm (22 mm), can be autoclaved	WM 24667
Breathing tube 15 mm	WM 29988
prismaHYBERNITE heatable breathing tube 19 mm (22 mm)	WM 29067
prismaHYBERNITE heatable breathing tube 15 mm	WM 29083
Exhalation system Silentflow 2	WM 23600
Bacteria filter	WM 24476
Pollen filter/fine filter (set of 12)	WM 29652
Air filter/coarse dust filter (set of 2)	WM 29928
SD card (set of 10)	WM 29793
Carrying bag prismaBAG basic	WM 29708
Carrying bag prismaBAG premium	WM 29709
Micro-USB connecting cable	WM 35130
Inverter 12 V	WM 24616
Inverter 24 V	WM 24617

14.6.3 Spare parts

You can order spare parts separately if necessary. A current list of spare parts can be obtained on the manufacturer's website or through your specialist dealer.

14.7 Warranty

Löwenstein Medical Technology gives the customer a limited manufacturer warranty on a new original Löwenstein Medical Technology product and on any replacement part fitted by Löwenstein Medical Technology in accordance with the warranty conditions applicable to the product in question and in accordance with the warranty periods from date of purchase listed below. The warranty conditions are available on the manufacturer's website. We will also send you the warranty conditions on request.
In the event of a claim under warranty, contact your specialist dealer.

Product	Warranty periods
Devices including accessories (except masks)	2 years

Product	Warranty periods
Masks including accessories, rechargeable batteries, batteries (unless stated otherwise in the technical documentation), sensors, patient circuits	6 months
Disposable products	None

14.8 Declaration of conformity

The manufacturer Löwenstein Medical Technology GmbH + Co. KG (Kronsaalsweg 40, 22525 Hamburg, Germany) hereby declares that the product complies with the relevant provisions of the Medical Device Regulation (EU) 2017/745. The unabridged text of the Declaration of Conformity can be found on the manufacturer's website.

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