**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

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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 5).

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 40). 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 46).

⇒ 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 46).

### 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 36) 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 5) 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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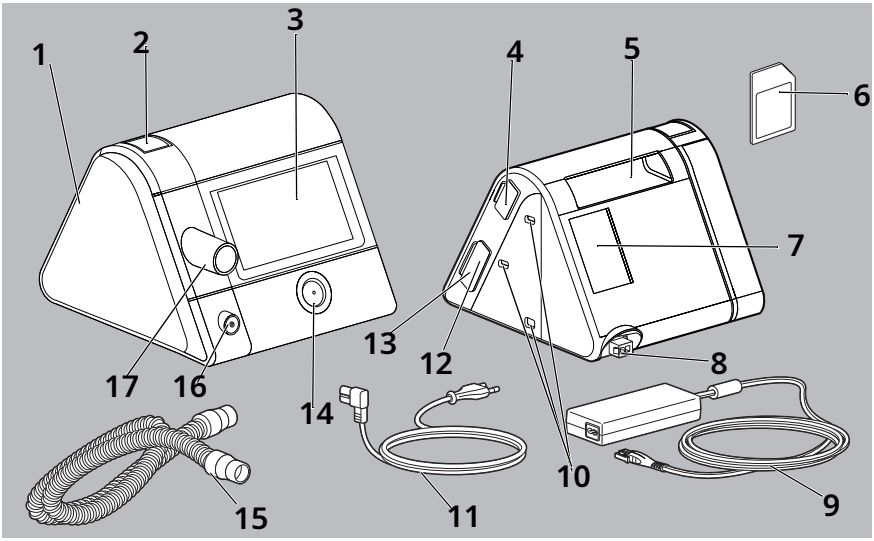
# 3 Product description

## 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.<br>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.<br>Switches the therapy device to Standby mode.<br>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.<br>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.<br>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:<br>The connected modem has been detected. |
| | Wireless icon flashing green:<br>The connected modem is making a connection. |
| | The connected modem is in flight mode. No wireless signals transmitted. |
| | The connected modem is transmitting data.<br>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.<br>Symbol flashes: Data is being saved to the SD card or read from the SD card. |
| | Humidifier is connected and switched off.<br>smartAQUAcontrol climate control is switched on. |
| | Humidifier is connected and switched on.<br>smartAQUAcontrol climate control is switched off.<br>The set humidifier stage is displayed.<br>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:<br>• Arrow pointing upward: inspiration<br>• Arrow pointing downward: exhalation<br>• Green arrow: spontaneous respiration<br>• 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.<br>Shows the remaining time in seconds. |
| | Switches the softSTART on and off. Shows the set or remaining softSTART time in minutes.<br>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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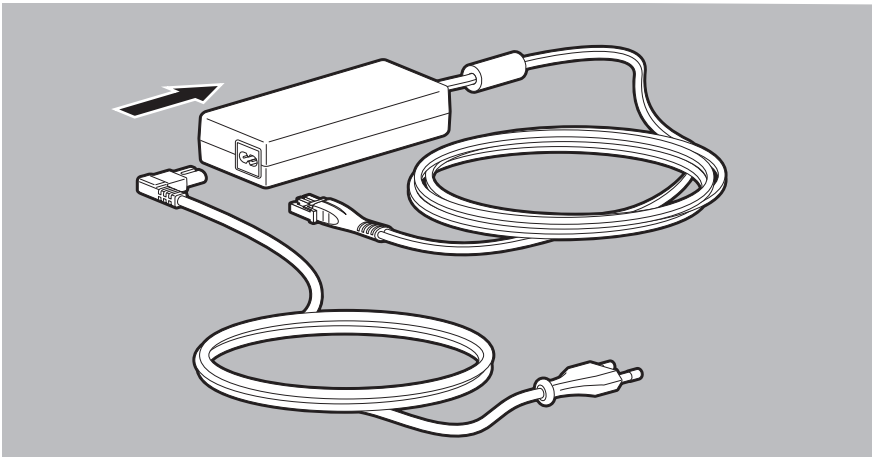
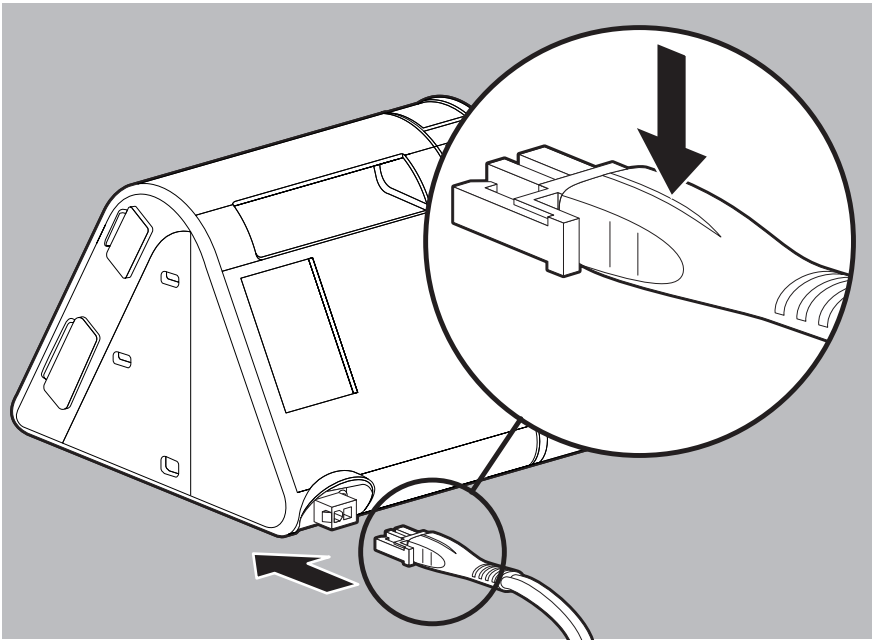


1. Connect the power cord to the power supply unit.



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.

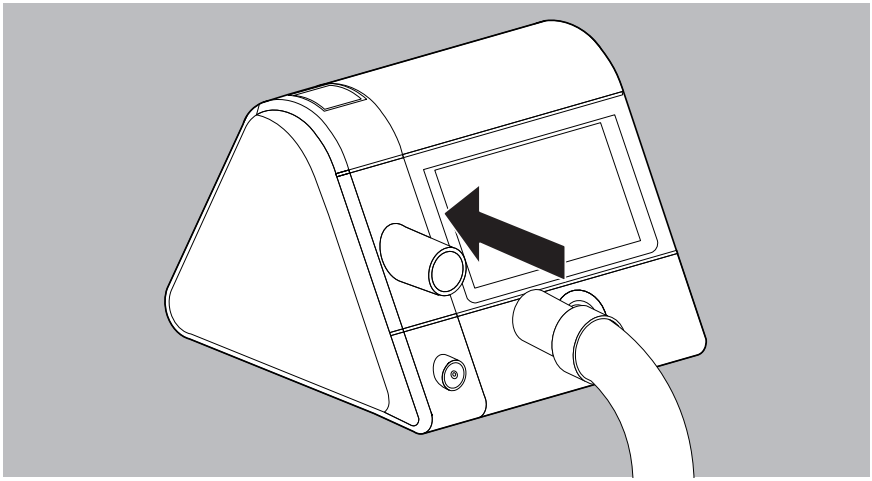
## 4.3 Connecting breathing tube

**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 39).

1. To achieve the correct therapy pressure, set tube diameter in the device (see „6.2 Setting accessory parameters“, page 34).



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.

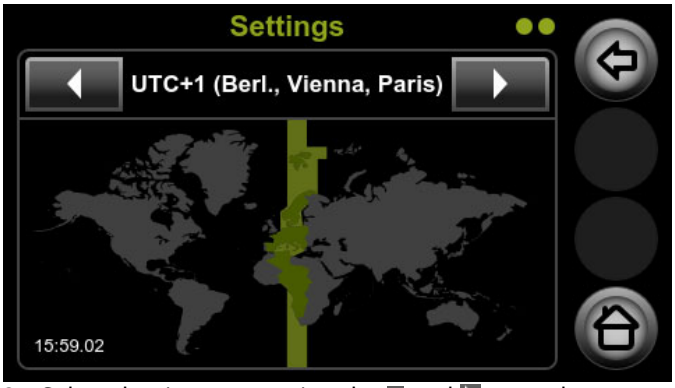
# 5 Operation

## 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 18).
2. Select language.




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



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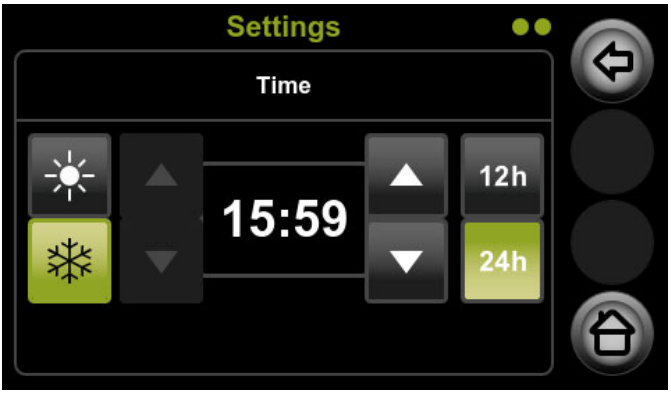


4. Setting the time:
   - Select summer time or winter time .
   - Set the minutes using the right arrow keys.
   - Select hour format: 24 h (0 to 24 hours) or 12 h (0 to 12 hours)
   - To set the hours: Select a different time zone.
5. Confirm set time using the key.

## 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 ⏻.<br>**or**<br>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 ⏻.<br>**or**<br>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.<br>**or**<br>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 33).

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.

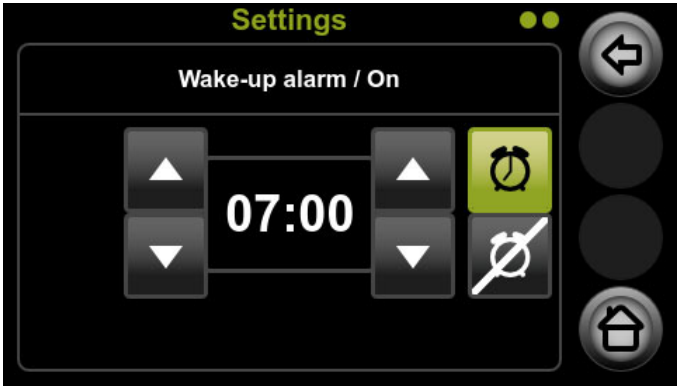
## 5.6 Setting the alarm

### 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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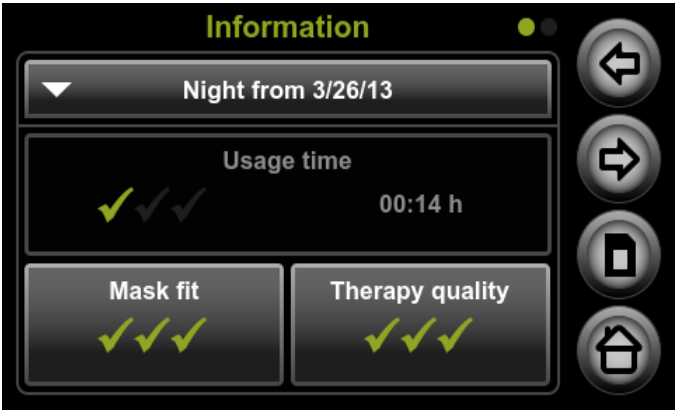



2. If necessary, To view therapy data from a night other than the previous night, select the desired date in the list .
3. To view the device information, navigate to the next screen using the and arrow keys.

## 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.

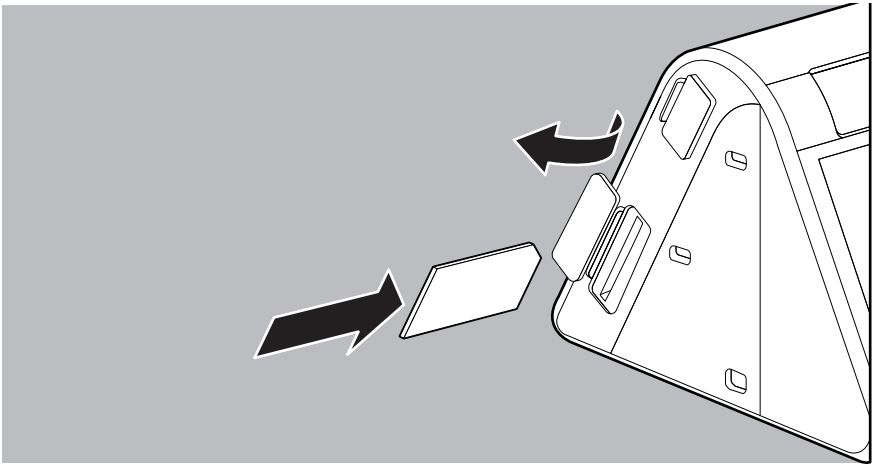
**NOTICE**
Loss of data as a result of incorrect SD card!
Functionality may be restricted or data may be lost in the case of SD cards not purchased from the manufacturer.
⇒ Only use SD cards from brand manufacturers which comply with the specifications (see „13 Technical data“, page 46).
⇒ Do not use 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.

### 5.8.2 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 29).



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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 28).

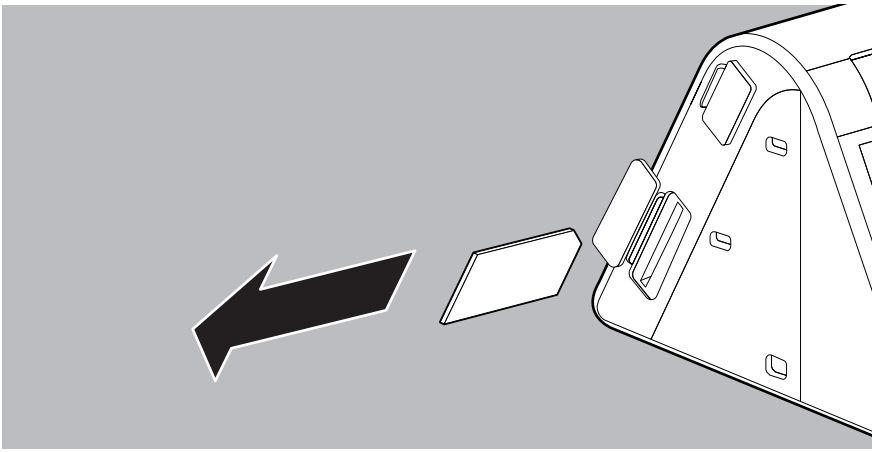
1. To save all the therapy data to the SD card, press the SD card key .
2. Press the **Save all data** field and confirm with the **OK** field.

### 5.8.3 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.

### 5.8.4 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 29).
   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<br>Off | With the automatic on feature activated, you can switch on the therapy device by taking a breath. |
| autoSTOP | On<br>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<br>1<br>2<br>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.<br>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.<br>This function is only available in CPAP and APAP mode. |
| smartAQUAcontrol | On<br>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<br>19-22 mm | Select the diameter of the tube type used here. |
| Air filter Change | Changed<br>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<br>2<br>3 | Level 1: dark<br>Level 2: medium<br>Level 3: bright |
| Leak alert | Off<br>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.<br>If this function cannot be selected, it needs to be enabled by your physician or specialist dealer. |
| Energy saving | Off<br>On | Here you can activate or deactivate whether the therapy device automatically switches to **Energy saving** mode 15 minutes after the therapy has finished.<br>You save electricity if the therapy device is in **Energy saving** mode during the day. |
| Key tone volume<br>Alarm Volume | Off<br>1<br>2<br>3 | Level 1: quiet<br>Level 2: medium<br>Level 3: loud |
| Alarm volume | 1<br>2<br>3 | Level 1: quiet<br>Level 2: medium<br>Level 3: loud |
| Therapy indicator | Off<br>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 37) |
| | Clean breathing tube (see „7.6 Hygiene treatment for breathing tube“, page 39) |
| | Clean humidifier<br>In the clinical sphere: Disinfect humidifier |
| Monthly | Clean air filter (see „7.4 Cleaning air filter (gray filter)“, page 38) |
| | If present: Replace pollen filter (optional) (see „7.5 Replacing optional pollen filter (white filter)“, page 38) |
| Every 6 months | Replace air filter |
| Annually | Replace breathing tube |
| As required | Descale the humidifier.<br>In the clinical sphere: Disinfect breathing tube.<br>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

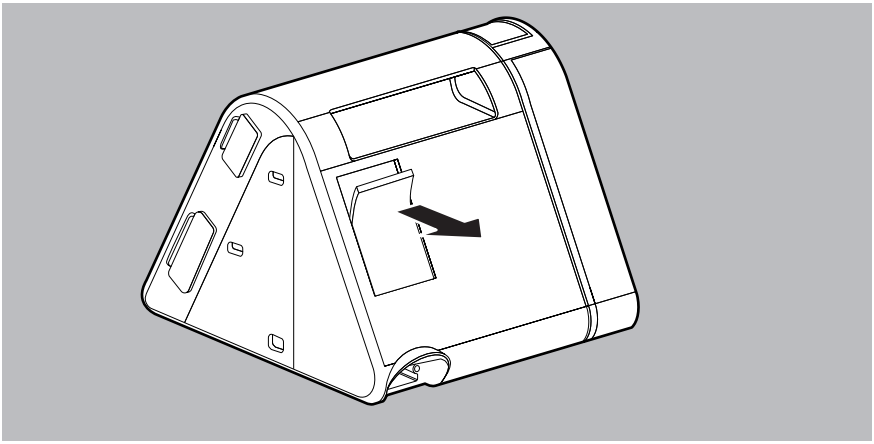
**CAUTION**
Risk of injury from electric shock!
Penetration of fluids may lead to a short circuit, injure the user, and damage the therapy device.
⇒ Disconnect the therapy device from the power supply before the hygiene treatment.
⇒ Do not immerse the therapy device or its components in liquids.
⇒ Do 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 24).
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 40).

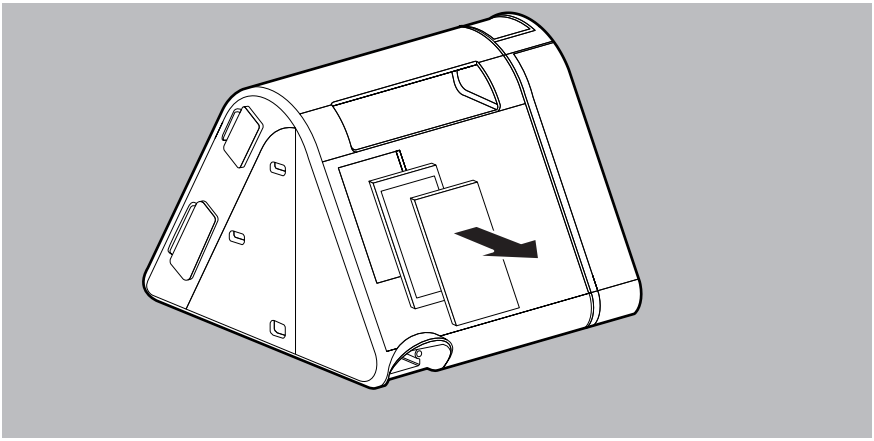
## 7.4 Cleaning air filter (gray filter)



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 22).
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 20). |
| ⚠ 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 35).

## 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 5.8.3, p. 31), disconnect the device from the power supply, reconnect it, and switch it back on.<br>If the device can be switched on: Replace SD card.<br>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. 33). |
| | 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. 33). |
| | 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 36). |
| | Breathing mask leaking. | Adjust headbands so that the mask is tight.<br>If necessary, replace faulty mask. |
| <br>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.<br>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.<br>Error occurs relatively frequently: Select a location with better reception.<br>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.<br>If the message persists, contact an authorized specialist dealer and have device and humidifier checked. |
| 702 | Device outlet port blocked. /<br>Water in the therapy device. | Ensure that breathing tube and device outlet port are not blocked.<br>If the fault persists:<br>• 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.<br>• If water comes out: Wait until all the water has drained.<br>• Allow the device to dry until the message is no longer displayed. In future, do not transport the device with water in the humidifier.<br>• 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. 18).<br>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 46).

# 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<br>- Operation<br>- Transport and storage | <br>+5°C to +40°C<br>-25 °C to +70 °C<br>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,<br>corresponds to an altitude of 3000 m above mean sea level<br>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<br>Max. 10 VA |
| Current consumption in operation (therapy)<br>240 V AC<br>100 V AC<br><br>on standby<br>240 V AC<br>100 V AC | <br>0.11 A<br>0.25 A<br><br>0.035 A<br>0.022 A |
| Classification to DIN EN 60601-1-11:<br>Protection class against electric shock<br><br>Degree of protection against electric shock<br><br>Protection against damaging ingress of water and solids | <br>Protection class II<br><br>Type BF<br><br>IP21 |
| Classification to IEC 60601-1:<br>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**<br>Disconnection, high leak<br><br>prisma30ST, prismaLAB<br>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<br>≥ 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<br>when using the 19 mm tube<br>when using the 15 mm tube, bacteria filter | <br>$\Delta p \leq 0.25$ hPa<br>$\Delta p \leq 0.25$ 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<br>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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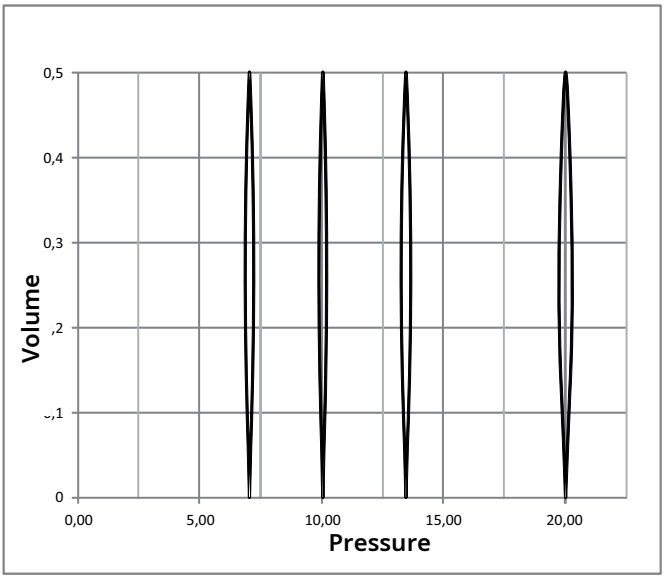
The power supply unit is part of the devices of type WM100TD.

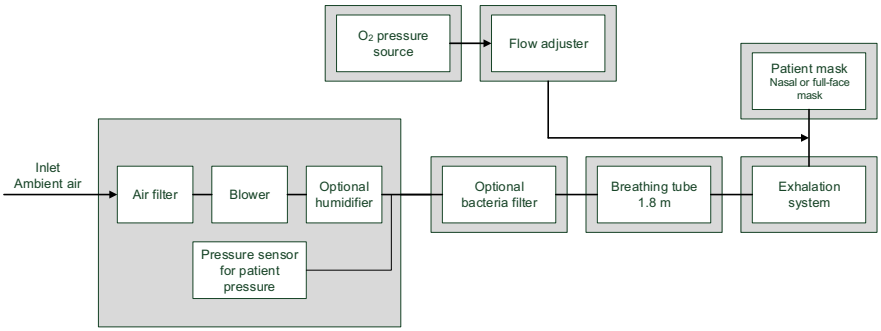
# 14 Annex

## 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*<br><br>* 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<br>± 15 kV air |
| Radiated RF EM fields IEC 61000-4-3 | 10 V/m<br>80 MHz to 2.7 GHz |
| Proximity fields from RF wireless communications equipment IEC 61000-4-3 | 9 to 28 V/m*<br>385 MHz to 5.785 GHz*<br>* Tested in accordance with IEC 60601-1-2:2020 Table 9 |
| | 27 to 84 V/m*<br>385 MHz to 5.785 GHz*<br><br>* 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<br>± 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<br>150 kHz to 80 MHz<br>6 Vrms<br>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<br>0 % UT; 1 cycle<br>70 % UT; 25/30 cycles<br>0 % UT; 250/300 cycles |
| Proximity magnetic fields IEC 61000-4-39 | 8 A/m at 30 kHz<br>65 A/m at 134.2 kHz<br>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 |
| 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 |
| 4G modem WM110MW EU | LMT 31831 |
| 4G modem WM110MW Japan | LMT 31832 |



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| Part | Article number |
|---|---|
| 4G modem WM110MW Canada | LMT 31833 |
| 4G modem WM110MW WW | LMT 31837 |
| 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 |

### 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 |
| 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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