EN Instructions for Use for devices of type WM 110 TD and WM 120 TD

prisma VENT30
prisma VENT30-C
prisma VENT40
prisma VENT50
prisma VENT50-C

Ventilators

LÖWENSTEIN
medical

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1 Introduction

1.1 Intended use

WM 110 TD

Device WM 110 TD is for ventilating patients with an independent respiratory drive. It can be used on patients who weigh over 10 kg and have respiratory insufficiency. It can be used in both stationary and mobile applications in both domestic and clinical environments.

WM 120 TD

Device WM 120 TD is for ventilating patients with an independent respiratory drive. It can be used on patients who weigh over 10 kg and have respiratory insufficiency. It can be used in both stationary and mobile applications in both domestic and clinical environments.

1.2 Description of function

The device can be used with both non-invasive and invasive patient/ventilator interfaces.

A blower takes in ambient air through a filter and pumps it to the patient at therapy pressure through the breathing tube and the patient/ventilator interface. The blower is controlled to suit respiratory phases on the basis of the signals detected by the pressure and flow sensors.

The user interface is for displaying and setting the available parameters and alarms.

The device can be used with both a breathing tube with leakage ventilation and a breathing tube with patient valve (prisma VENT50 and prisma VENT50-C only). On the breathing tube with leakage ventilation, an exhalation system continuously flushes out the exhaled air containing CO_2. On the breathing tube with a patient valve (prisma VENT50 and prisma VENT50-C only), exhalation by the patient is controlled via the patient valve.

If the device has an integrated battery, it can continue to be operated without interruption in the event of a power outage.

Mode MPV is no ventilatory support mode within the scope of standard ISO 10651-6. As the corresponding interfaces are not closely and/or sealingly connected to the patient's airways, some specifications like detection of disconnection won't be applied.

Therapy data are saved on the SD card and can be evaluated using PC software.

prisma VENT50-C only

In High Flow mode (HFT mode), the device pumps the set flow rate to an external humidifier suitable for HFT. This conditions the respiratory gas in terms of temperature and humidity. The patient connection is made using accessories suitable for HFT.

1.3 User qualifications

The person operating the device is referred to in these Instructions for Use as the user. A patient is the person receiving the therapy.

As an owner/operator or user, you must be familiar with the operation of this medical device. The owner/operator is responsible for ensuring the compatibility of the device and of all the components or accessories connected to the patient before use.

The device is a medical device which may only be used by trained specialists as directed by a physician. Use the device only as directed by a physician or other medical staff.

When the device is handed over to the patient, the attending physician or hospital staff must instruct the patient in the function of the device.

1.4 Indications

Obstructive ventilation disorders (e.g. COPD), restrictive ventilation disorders (e.g. scolioses, deformities of the thorax), neurological, muscular, and neuromuscular disorders (e.g. pareses of the diaphragm), central respiratory regulation disorders, obstructive sleep apnea syndrome (OSAS), obesity hypoventilation syndrome (OHS), hypoxemic respiratory insufficiency.

1.5 Contraindications

The following contraindications are known - in the individual case, responsibility for deciding whether to use the device rests with the attending physician. Threatening situations have not ever been observed.

Cardiac decompensation, severe cardiac arrhythmias, severe hypotension, especially in combination with intravascular volume depletion, severe epistaxis, high risk of barotrauma, pneumothorax or pneumomediastinum, pneumoencephalus, head injury, status following brain surgery and following surgical procedures on the hypophysis or middle or inner ear, acute inflammation of the nasal sinuses (sinusitis), middle ear infection (otitis media) or perforated eardrum, dehydration.

1.6 Side effects

When using the device, the following undesired side effects may occur in short-term or long-term use: Pressure points from the mask and the forehead cushion on the face, reddening of the facial skin, dry throat, mouth, nose, feeling of pressure in the sinuses, irritated mucous membrane in the eyes, gastrointestinal insufflation of air ("bloating"), nosebleeds, muscular atrophy in the case of long-term ventilation.

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These are general side effects not attributable specifically to use of devices of type WM 110 TD/WM 120 TD.

2 Safety

2.1 Safety information

2.1.1 Handling the device, the components and the accessories

If the device is damaged or its function is restricted, people may be injured.

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

⇒ Perform a function check at regular intervals (see "7 Function check", page 34).

⇒ Only operate device within the specified ambient conditions (see "12.1 Technical data", page 44).

⇒ Do not use the device in an MRI environment or in a hyperbaric chamber.

⇒ Do not reuse disposables. Disposables may be contaminated and/or their function may be impaired.

⇒ Set the acoustic alarm volume high enough for the acoustic alarm to be heard.

⇒ Only use breathing tubes with an internal diameter of Ø 15 mm or more.

⇒ Only use accessory parts from the manufacturer. Third-party electrical connecting cables, in particular, may cause the device to malfunction.

⇒ Do not use antistatic or electrically-conductive tubes.

⇒ The device is subject to special precautions with regard to EMC (electromagnetic compatibility). 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, for example. Ignoring this requirement may lead to the device exhibiting reduced performance characteristics.

⇒ 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 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.

⇒ Regularly check bacteria filter for increased resistance and blockages. If necessary: Replace bacteria filter. Moistening with droplets or liquid can increase the resistance of bacteria filters and thus change the therapeutic pressure delivered.

2.1.2 Energy supply

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

⇒ Operate the device only at voltages from 100 V to 240 V.

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

⇒ Keep access to the power supply connector and the power supply free at all times.

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2.1.3 Handling oxygen

Supplying oxygen without a special safety device can lead to fire and injure people.

⇒ Follow the Instructions for Use for the oxygen supply system.

⇒ Set up oxygen sources at a distance of over 1 m from the device.

⇒ The oxygen rate supplied in l/min may not exceed the set HFT flow rate (prisma VENT50-C only).

⇒ At the end of therapy, shut off the oxygen supply and allow the device to run on briefly to flush residual oxygen out of the device.

2.1.4 Transport

Water and dirt in the device may damage the device.

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

⇒ Only transport the device with the cover fitted.

⇒ Transport or store the device in the associated carrying bag.

2.2 General information

- The use of third-party articles may lead to incompatibility with the device. In such cases, please be aware that any claim under warranty and liability will be void if genuine replacement parts are not used.
- Have measures such as repairs, servicing, and maintenance work, as well as modifications to the device, carried out exclusively by the manufacturer or by specialists expressly so authorized by the manufacturer.
- Connect only the devices and modules permitted 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.
- To prevent infection or bacterial contamination, follow the section about hygiene treatment (see "6 Hygiene treatment", page 30).
- In the event of a power outage, all settings including alarm settings are retained.
- The use of accessories in the respiratory flow (such as bacteria filters, for example) may make it necessary to reset device parameters. Be aware that pressure at the patient connection opening may rise during exhalation if you connect accessories.

2.3 Warnings in this document

Warnings indicate information relevant to safety in front of a step which contains a hazard to persons or objects.

There are three levels of warning depending on the degree of hazard:

⚠ WARNING	***Warning!*** Indicates an unusually significant hazardous situation. If you ignore this instruction, severe irreversible or fatal injuries may result.
⚠ CAUTION	***Caution!*** Indicates a hazard. If you do not follow this instruction, mild or moderate injuries may result
NOTICE	***Notice!*** Indicates a harmful situation. If you do not follow this instruction, material damage may result.
	Indicates useful information within procedures.

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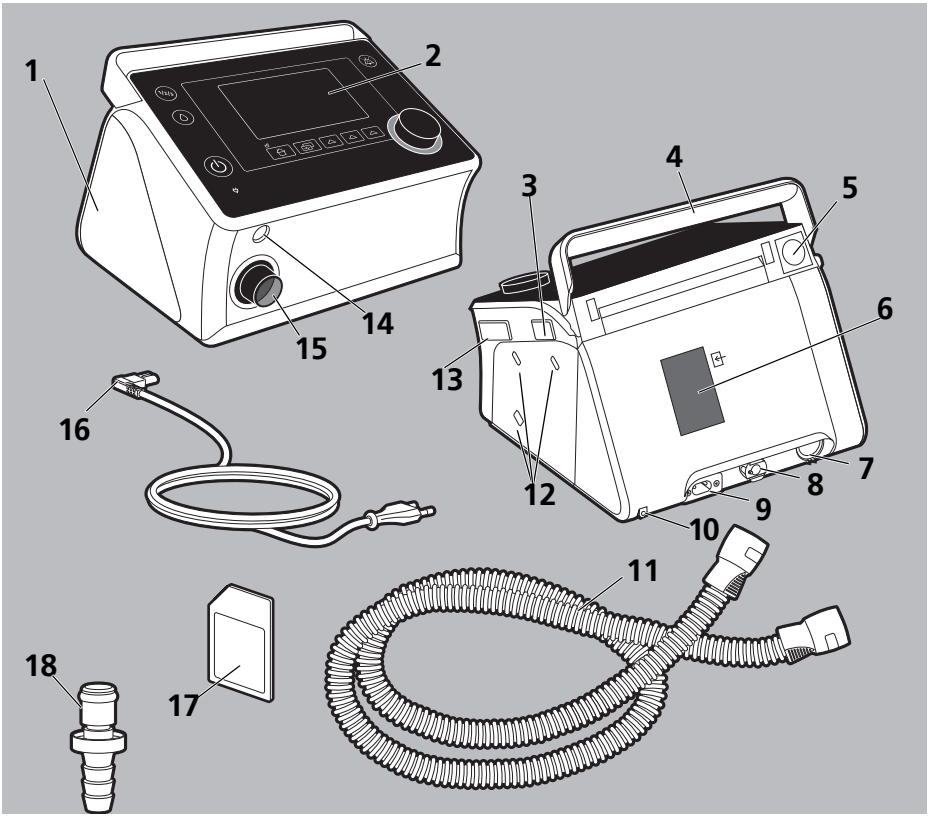
3 Product description

3.1 Overview

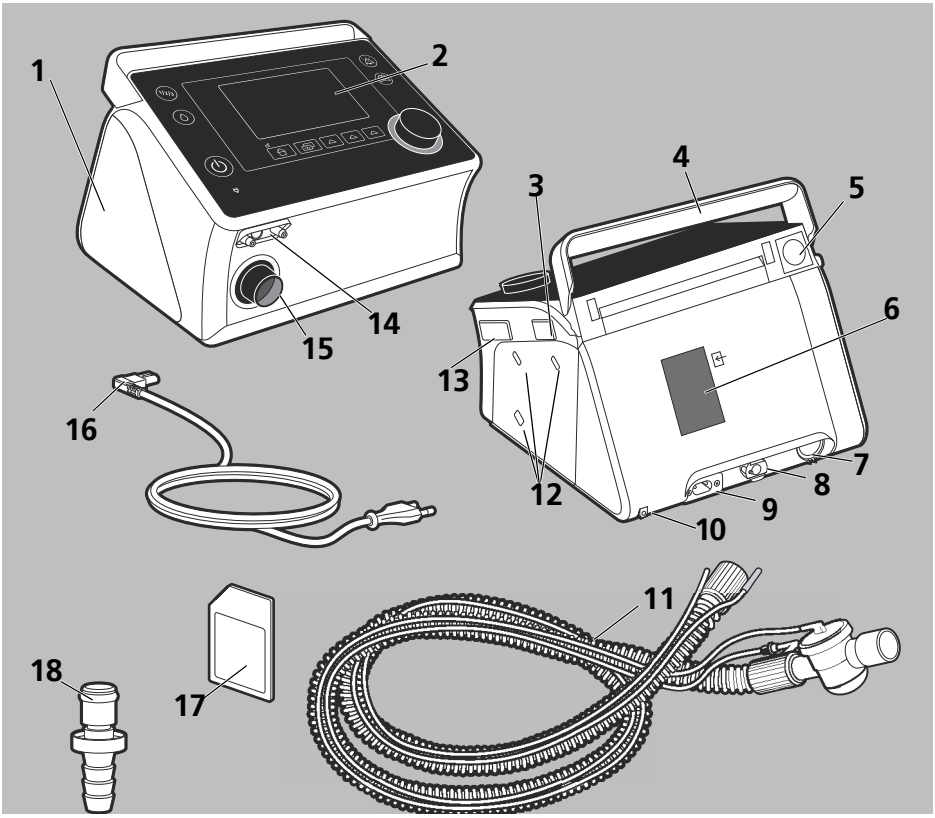
3.1.1 prisma VENT30, prisma VENT30-C, prisma VENT40



1 Humidifier connection with cover
2 Control panel with display
3 System interface for connecting modules
4 Handle
5 Release catch
6 Filter compartment with air filter and pollen filter
7 Sealing plug
8 O_2 supply

9 Connection for power supply cable
10 Strain relief for power supply cable
11 Breathing tube with connection for breathing mask
12 Latching bores for connecting modules
13 SD card slot
14 Connection for tube heater
15 Device outlet port
16 Power cord
17 SD card
18 O_2 connector

3.1.2 prisma VENT50, prisma VENT50-C



1 Humidifier connection with cover

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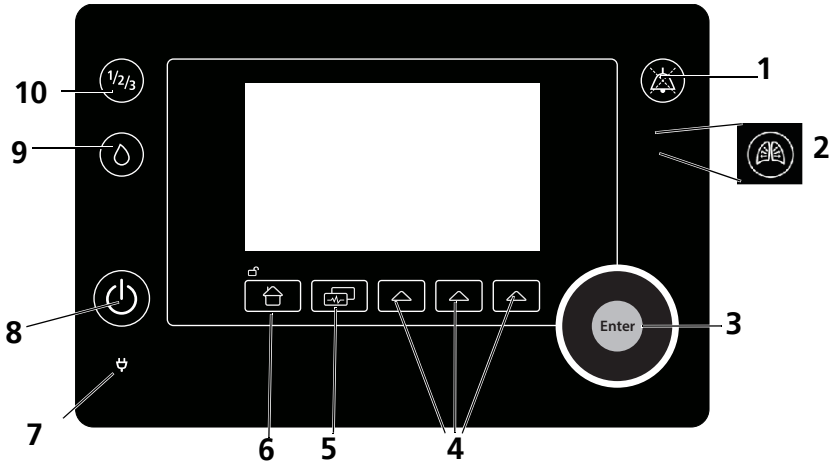
2 Control panel with display
3 System interface for connecting modules
4 Handle
5 Release catch
6 Filter compartment with air filter and pollen filter
7 Cooling air opening
8 O_2 supply
9 Connection for power supply cable
10 Strain relief for power supply cable
11 Breathing tube with active valve
12 Latching bores for connecting modules
13 SD card slot
14 Connection for tube heater, valve control tube and pressure measuring tube
15 Device outlet port
16 Power cord
17 SD card
18 O_2 connector

3.2 Operating states

- **On**: Therapy is running.
- **Standby**: Blower is off, but immediately operational if the on/off key is pressed briefly. Settings can be made on the device when it is in standby mode.
- **Off**: The device is switched off. No settings can be made and the display remains dark.

3.3 Control panel



1 Alarm acknowledgment key - mutes an alarm for 2 minutes

2 LIAM key (only present on prisma VENT50 and prisma VENT50-C)

3 Dial for navigating in the menu

4 Function keys for switching between the **System**, **softSTART/softSTOP**, **Ventilation** or **Report** menus and the **Back** function

5 Monitor key for switching between different screen views

6 Home key - switches the view back to the start screen, provides access to the expert area

7 Power supply indicator

8 On/off key

9 Humidifier key

10 Program key for selecting pre-configured programs

3.4 Symbols in the display

SYMBOL	DESCRIPTION
	Device in patient mode. Expert area disabled.
	Device in expert mode (device enabled)
	Breathing tube with leakage ventilation connected (prisma VENT50 and prisma VENT50-C only).
	Breathing tube with patient valve connected (prisma VENT50 and prisma VENT50-C only).

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SYMBOL	DESCRIPTION
	Device on standby. The blower is off.
	Air filter change required (only if filter function is activated).
	Servicing required (only if servicing function is activated).
	Humidifier connected but not active (gray symbol)
	Humidifier switched on (green symbol)
	Humidifier empty (orange symbol)
	Pulse rate (if pulsoximetry sensor connected)
	SpO_2 sensor connected
	prismaCONNECT module module connected
	prisma CHECK module connected
	prismaPSG module connected
	Network connection present.
	SD card inserted (flashes green if data are currently being written to the card).
	Indicates respiratory status: • Arrow pointing upward: Inspiration • Arrow pointing downward: Exhalation • S: Spontaneous breath • T: Mandatory breath
	Target volume switched on
	AirTrap Control switched on.
	LIAM activated.
	5 segments green: Battery capacity above 85 %
	4 segments green: Battery capacity above 65 %
	3 segments green: Battery capacity above 45 %
	2 segments green: Battery capacity above 25 %

SYMBOL	DESCRIPTION
	1 segment orange: Battery capacity below 25 %
	1 segment red: Battery capacity below 10 %
	0 segments: Battery capacity below 5 %
	Battery fault
	Low-priority alarm triggered.
	Medium-priority alarm triggered.
	High-priority alarm triggered.
	All physiological alarms have been deactivated.
	Acoustic signal for alarm paused.
	Acoustic signal for alarm deactivated.
	softSTART started with remaining time quoted in min:sec
	softSTOP started with remaining time for the ramp quoted in min:sec

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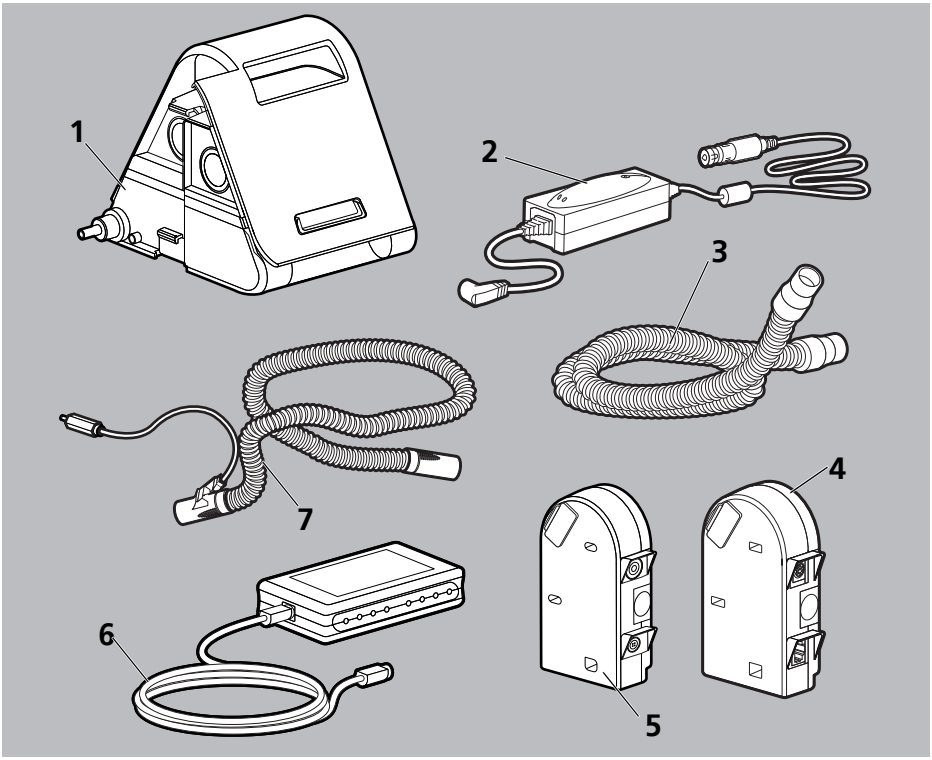
3.5 Accessories



1 Humidifier (not suitable for HFT mode and invasive use)

2 Inverter

3 Breathing tube with 15 mm/22 mm diameter

4 Communication module prismaCONNECT module - links the device and a PC or the PSG module.

5 SpO_2 and nurse call module prisma CHECK - links the device to a call system and determines SpO_2 and pulse frequency data.

6 prismaPSG - converts digital device signals into analog data. Is used in sleep laboratories.

7 prismaHYBERNITE heatable tube 15 mm/22 mm

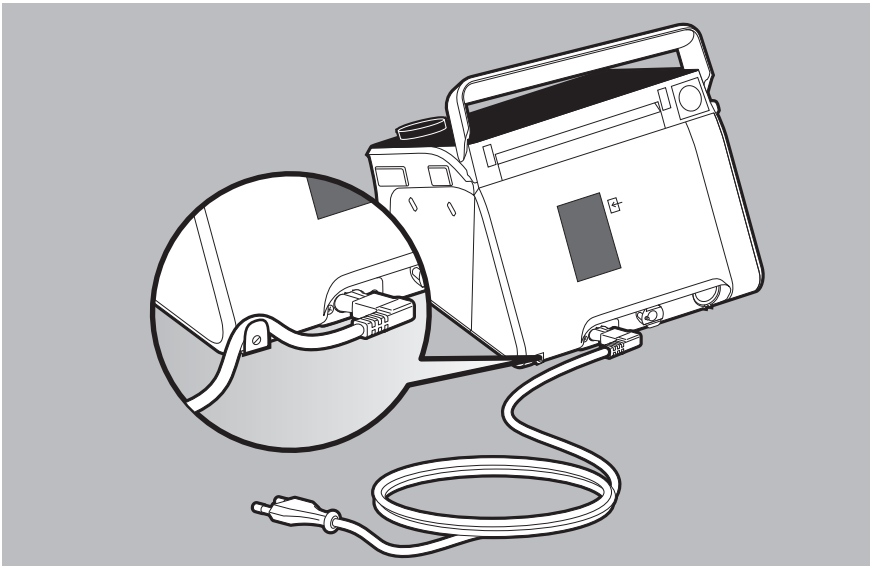
Follow the Instructions for Use for the accessories. Here you will find further information about operation and combining accessories with the device.

4 Preparation and operation

4.1 Set up the device

NOTICE

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



1. Connect the power cord to the therapy device and the power supply socket.

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4.2 Connect the breathing tube

⚠ WARNING

Risk of asphyxia if non-invasive or invasive patient/ventilator interfaces without an exhalation system are used!

If non-invasive or invasive patient/ventilator interfaces without an integrated exhalation system are used, CO_2 concentration may rise to critical values and put the patient at risk.

⇒ Use non-invasive or invasive patient/ventilator interfaces with an external exhalation system if there is no integrated exhalation system.

⇒ Follow the Instructions for Use for the exhalation system.

⚠ CAUTION

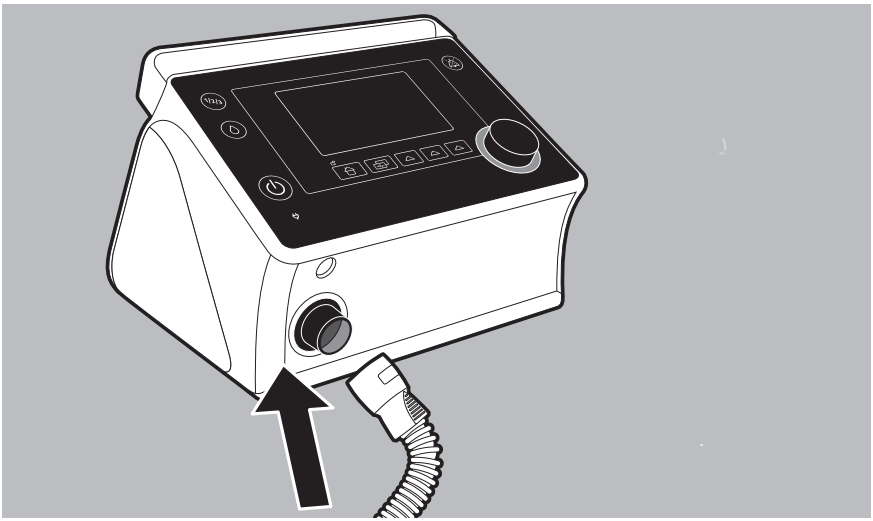
Risk of injury if breathing tube routed incorrectly!

An incorrectly routed breathing tube may injure the patient.

⇒ Never wrap the breathing tube around the neck.

⇒ Do not crush the breathing tube.

4.2.1 Connect breathing tube with leakage ventilation

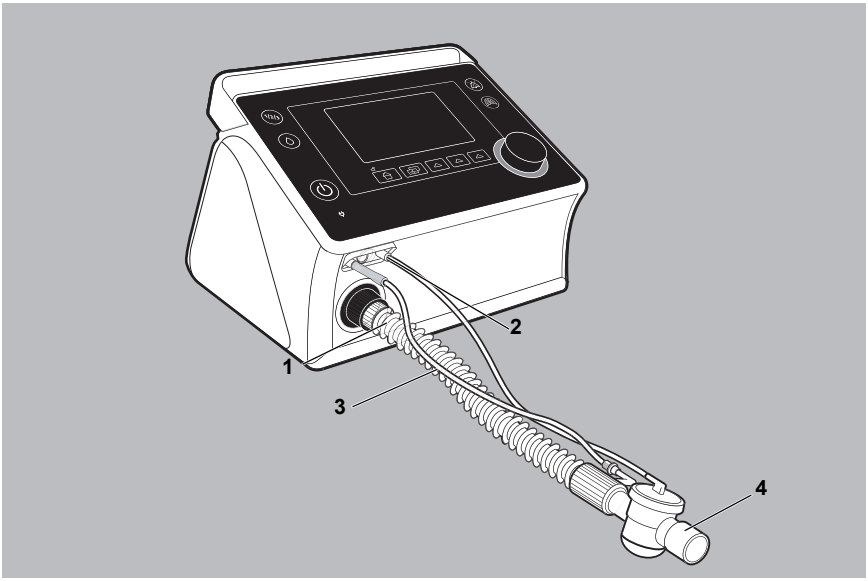


1. Push breathing tube onto the device outlet port.
2. Connect the non-invasive or invasive patient/ventilator interface to the breathing tube (see Instructions for Use for the patient/ventilator interface).

4.2.2 Connect breathing tube with patient valve (prisma VENT50 and prisma VENT50-C only)

⚠ WARNING

Risk of injury if patient valve is covered!
If the patient valve is covered, exhaled air can no longer be taken away and the patient will be put at risk.
⇒ Always keep the patient valve free.



1. Push the free end of breathing tube **1** onto the device outlet port.
2. Connect valve control tube **2** to connection .
3. Connect pressure measuring tube **3** to connection P.
4. Connect patient/ventilator interface (e.g. mask) to patient valve **4**.

NOTICE

The device can also be operated with valve ventilation without pressure being measured at the patient. In this case, the connection for the pressure measuring tube is unused (perform tube test).

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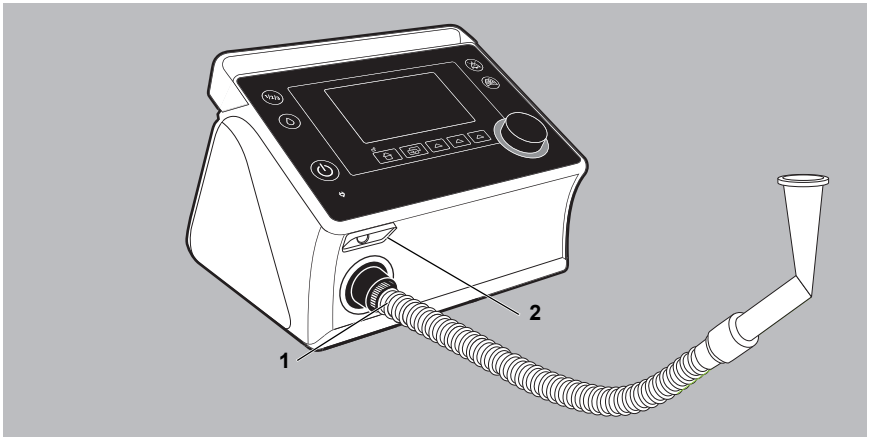
4.2.3 Connect patient circuit for mouthpiece ventilation (prisma VENT50 and prisma VENT50-C only)

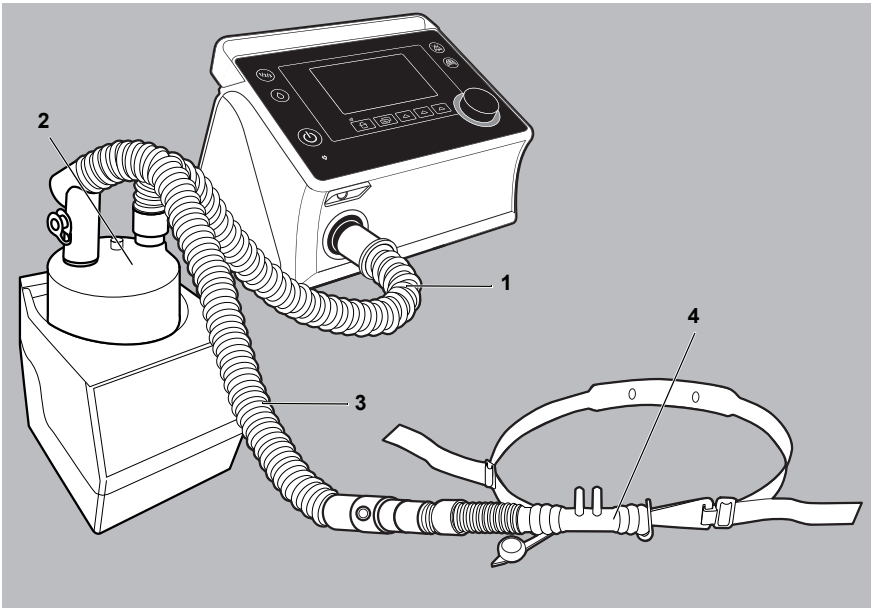


1. Push the free end of breathing tube **1** onto the device outlet port.
2. Connect mouthpiece **2** to the breathing tube (see Instructions for Use for the patient/ventilator interface).

NOTICE

As an alternative to leakage ventilation, it is also possible to use a breathing tube with patient valve for mouthpiece ventilation.

4.2.4 Connect HFT mode patient circuit (prisma VENT50-C only)



1. Push the free end of short breathing tube **1** onto the device outlet port.
2. Push the other end of short breathing tube **1** onto the connection for humidifier chamber **2** marked **In**.
3. Push long breathing tube **3** onto the connection for humidifier chamber **2** marked **Out**.
4. Connect High Flow interface **4** to long breathing tube **3**.
5. If necessary, connect the tube heater and temperature probe to breathing tube **3** (see Instructions for Use for external humidifier).

NOTICE

The prismaAQUA integrated humidifier is not suitable for High Flow therapy.

4.3 Before first use

The device must be configured before being used for the first time. If your specialist dealer has not yet done so, you must set language and time on the device.

If the device is equipped with an internal battery, leave the device connected to the power supply for at least 8 hours.

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4.4 Start therapy

Requirement

- Device is set up and connected (see "4.1 Set up the device", page 18).
- Patient/ventilator interface is connected (see Instructions for Use for patient/ventilator interface)

1. If the display is dark: Press on/off key briefly.
   The device switches to standby.
2. Press on/off key briefly.
   or
   If the Autostart function is activated: Breathe into the patient/ventilator interface.
   Therapy starts.
   If the softSTART function is activated in the selected program, therapy automatically starts with softSTART.

For more information on Autostart: See "5 Settings in the menus", page 27.

4.5 End therapy/switch off device

1. Press and hold on/off key until the **End therapy** display disappears.
   The device switches to standby.
   If the softSTOP function is activated, ventilation pressures and background frequency are continuously reduced. Remaining time is displayed in the button bar in minutes and seconds 0:40.
   Once the set softSTOP time has expired, the device continues running at an EPAP of 4 hPa and a background frequency of 5 bpm until it is switched to standby with a brief press of the on/off key.
   To interrupt softSTOP, briefly press the softSTART/softSTOP key (center function key **4**).
2. To switch off the device completely, press the on/off key until the message **Shutting down device** is no longer displayed and the display goes out.

4.6 Set humidifier

Requirement

Humidifier is connected and filled with water (see Instructions for Use for humidifier)

1. To switch the humidifier on or off, press humidifier key briefly.
   If the humidifier is active, the illuminated humidifier key goes out.
   The humidifier symbol in the display comes on.
2. To adjust humidifier stage, press and hold humidifier key.

The humidifier stage suitable for you depends on room temperature and humidity. 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.

4.7 Select a preconfigured program

Your physician can store up to three preconfigured programs in the device. If you need different ventilation settings during the day compared to during the night, for example, you can change the program.

⚠ CAUTION

Risk of injury from the use of incorrect ventilation programs
Use of ventilation programs which have not been configured for an individual can lead to incorrect therapy and put the patient at risk.

⇒ Only use ventilation programs if they have been configured for the patient in question.

1. Press the Program key (1/2/3).
2. Select and confirm the program using the dial.

4.8 LIAM (prisma VENT50 and prisma VENT50-C only)

LIAM (Lung Insufflation Assist Maneuver) supports the cough process or sigh ventilation.

Requirement

- Therapy is running,
- LIAM has been enabled by the physician.

1. Press the LIAM key.
   The device switches to LIAM mode and the process is started to synchronize with the next inspiration.
2. To interrupt LIAM: Press the LIAM key again.
   The process is canceled. The device switches back to the set ventilation mode.

4.9 Switching softSTART on and off (from firmware version 3.1.0008)

The softSTART function makes it easier to get used to ventilation pressure when falling asleep. A pressure and optionally also a pressure difference which deviate from those prescribed are set. The therapy device sets this softSTART pressure when it is switched on. After that, pressures gradually rise to therapy level within the specified time.

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This function is suitable for patients who find elevated pressures unpleasant when awake and are unable to fall asleep.

Requirement

- The softSTART function is activated by the physician or the specialist dealer.
- softSTART is supported by the selected ventilation mode (S, S/T, autoS/T, T, aPCV, PSV or PCV).
- A breathing tube with leakage ventilation is used.
- A softSTART time is set.

1. Start therapy (see "4.4 Start therapy", page 23).
   Therapy automatically starts with softSTART.
   Remaining time is displayed in the button bar in minutes and seconds 0:16.
2. Press the softSTART/softSTOP key (center function key **4**) to switch off softSTART.
3. softSTART can be interrupted or re-started at any time by pressing the softSTART/softSTOP key (center function key **4**).

If you press the softSTART/softSTOP key (center function key **4**) with the device on standby, the device switches to the patient menu and you can adjust softSTART time and softSTART EPAP within the value range configured by the physician or the specialist dealer or switch it off (softSTART time OFF) (see "5.5 softSTART/softSTOP menu (from firmware version 3.1.0008)", page 29).

4.10 Use SD card (optional)

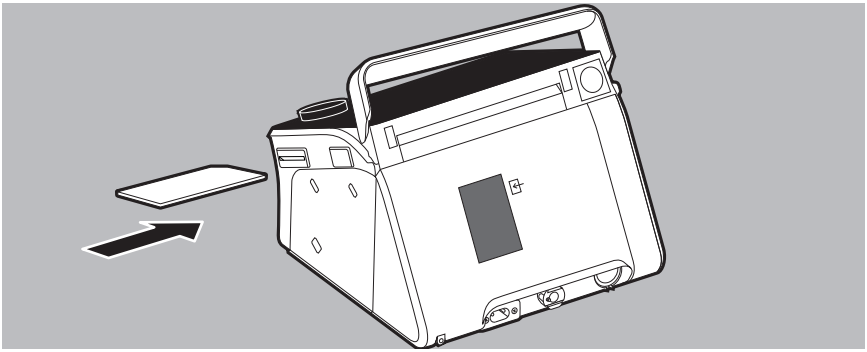
If an SD card is present, the device automatically saves the therapy data to the SD card. An SD card is not required to operate the device. Therapy data and settings are also stored inside the device (maximum 14 days).

NOTICE

Loss of data if power is interrupted!

If the device is disconnected from the power supply during the save process, data may be lost.

⇒ Leave the device connected to the power supply during the save process (SD card symbol flashing).



1. Push the SD card into the SD card slot until you hear it engage.
   The SD card symbol appears in the display.
2. To remove it, press the SD card briefly and remove the SD card.

If you wish to send away the SD card: Mark the SD card with name and date of birth to prevent confusion when it reaches the physician or specialist dealer.

4.11 Use battery (optional)

Your device can optionally be equipped with an internal battery. If the device is no longer connected to the power supply or there is a power outage, the battery automatically starts supplying the device.

4.11.1 General information

- Battery running time depends on ventilation settings and ambient temperature.
- When planning your time, take account of the fact that battery running time is considerably reduced at low or very high outdoor temperatures.
- When the **Battery capacity critical** alarm appears, only about 10 % capacity remains. When the **Battery capacity highly critical** alarm appears, the device will switch off in a few minutes' time (less than 5 % capacity remaining). Keep an alternative ventilation option to hand.
- If device and battery have been stored outside the quoted operating temperatures, the device can only be started up once it has warmed up to the permitted operating temperature.

4.11.2 Charge battery

The battery is charged automatically as soon as the device is connected to the power supply. The consecutively flashing segments of the battery indicator show the charging process. Once the battery indicator is displaying 5 segments and is no longer flashing, the battery is fully charged.

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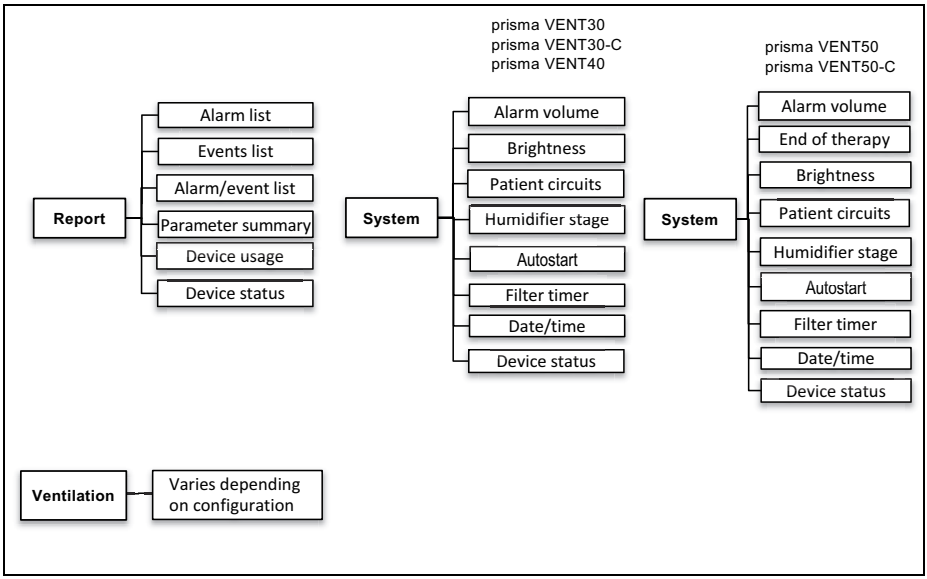
5 Settings in the menus

5.1 Navigating in the device

ACTION	RESULT	
	IN THE MENU	**WITHIN A MENU ITEM**
Press function key 	Function is displayed directly in the display via the key (e.g. **System**, **softSTART/softSTOP** or **Ventilation** or **Report** menus or **Back** menus).	
Turn dial to the left	Navigate upward	Reduce value
Turn dial to the right	Navigate downward	Increase value
Press the dial	Select menu item	Confirm set value
Press Home key 	Back to start screen	
Press Monitor key 	Switches between different screen views.	

5.2 Menu structure



5.3 System menu (device settings)

Information about the parameters in this menu can be found in the table below. For more information about navigating through the menu: See "5.1 Navigating in the device", page 27.

PARAMETER	DESCRIPTION
Alarm volume	You can set alarm volume here.
Brightness	You can change the brightness of the display here.
End of therapy (prisma VENT50 and prisma VENT50-C only)	Here you can see whether the alarm is activated/ deactivated at the end of therapy/at the start of softSTOP triggering.
Patient circuits	Here you can see which patient circuit is being used and perform the tube test.
	The O_2 supply must be switched off during the tube test. For the accuracy of therapy, it is recommended to conduct this test when changing tube, changing tube type or changing accessory (such as bacteria filter, for example). This process checks for resistance, compliance and leaks.
Humidifier stage	You can change the humidifier stage of the humidifier here. The setting suitable for you depends on room temperature and humidity. In the event of dry airways, increase the humidifier stage. If there is condensation in the breathing tube, reduce the humidifier stage
Autostart	You can switch Autostart on or off here. If Autostart is switched on, the device switches on when a breath is taken into the patient/ventilator interface.
Filter timer	You can reset the filter change reminder function here.
Date/time	You can set current time and date here.
Device status	The following information can be found here: • Device name • Serial number • Firmware version • Information about the battery (if present)

5.4 Ventilation menu (ventilation settings)

The Ventilation menu shows the settings for current ventilation parameters. The parameters displayed vary depending on the ventilation mode set. This menu can only be manipulated in the Expert area. The settings cannot be changed in Patient mode. If more than one preconfigured program is enabled in the device, the program can be selected here.

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5.5 softSTART/softSTOP menu (from firmware version 3.1.0008)

To call up the softSTART/softSTOP menu, the device must be on standby. If enabled by the physician or specialist dealer, the following parameters can be set here:

PARAMETER	ADJUSTABLE VALUES	DESCRIPTION
softSTART time **T**	5-minute increments within the framework specified by the physician or specialist dealer (e.g. 5 min. to a maximum of 45 min.).	Here you can set the time for which ventilation pressure rises to therapy pressure during softSTART. If this function cannot be selected, it needs to be enabled by your physician or specialist dealer.
softSTART EPAP pressure	0.2 hPa increments within the framework specified by the physician or specialist dealer (e.g. at least 4 hPa to 25 hPa).	Here you can set the pressure on exhalation with which softSTART will begin. If this function cannot be selected, it needs to be enabled by your physician or specialist dealer.
softSTOP time **T**	5-minute increments within the framework specified by the physician or specialist dealer (e.g. 5 min. to a maximum of 45 min.).	Here you can set the time period during which ventilation pressure is reduced within the softSTOP framework. If this function cannot be selected, it needs to be enabled by your physician or specialist dealer.

5.6 Report menu (usage data)

Information about the parameters in this menu can be found in the table below. For more information about navigating through the menu: See "5.1 Navigating in the device", page 27.

PARAMETER	DESCRIPTION
Alarm list	Lists the alarms which have occurred.
Events list	Lists the events which have occurred.
Alarms + events	Lists the alarms and events which have occurred in chronological order.
Parameter summary	Lists the parameters set for the ventilation programs.
Device usage	Lists the usage time of the device.
Device status	The following information can be found here: • Device name • Serial number • Firmware version • Information about the battery (if present)

6 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.

⇒ Do not reuse disposables.

⇒ Use of a bacteria filter is obligatory when the device is used for several patients.

⚠ WARNING

Risk of injury due to contaminated or infected patient circuit!
A contaminated or infected patient circuit may transmit contamination or infections to the next patient.

⇒ Do not reprocess disposable patient circuits.

⇒ Subject reusable patient circuits to the correct hygiene treatment.

6.1 General information

- Wear appropriate safety gear for the disinfecting process.
- Refer to the Instructions for Use for the disinfectant used.
- Following a hygiene treatment by the authorized specialist dealer, the device is suitable for using again with other patients.

6.2 Cleaning intervals

INTERVAL	ACTION
Weekly	Clean device (see "6.3 Hygiene treatment for device", page 31)
	Clean breathing tube with leakage ventilation (see "6.4 Hygiene treatment for breathing tube", page 33)
Monthly	Clean air filter (see "6.3.1 Clean air filter (gray filter)", page 32)
	Replace pollen filter (see "6.3.2 Replace pollen filter (white filter)", page 32)
Every 6 months	Replace air filter (see "6.3.1 Clean air filter (gray filter)", page 32).
Every 12 months	Replace breathing tube with leakage ventilation.
As required	In the clinical sphere: disinfect breathing tube (see "6.4 Hygiene treatment for breathing tube", page 33)

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INTERVAL	ACTION
On change of patient	Have specialist dealer perform a hygiene treatment on the device before using it again (see "6.3 Hygiene treatment for device", page 31). Reset device to factory settings.

6.3 Hygiene treatment for device

⚠ CAUTION

Risk of injury from electric shock!

Ingress of liquids may lead to a short-circuit, injure the user and damage the device.

⇒ Disconnect the device from the power supply before the hygiene treatment.

⇒ Do not immerse the device and components in liquids.

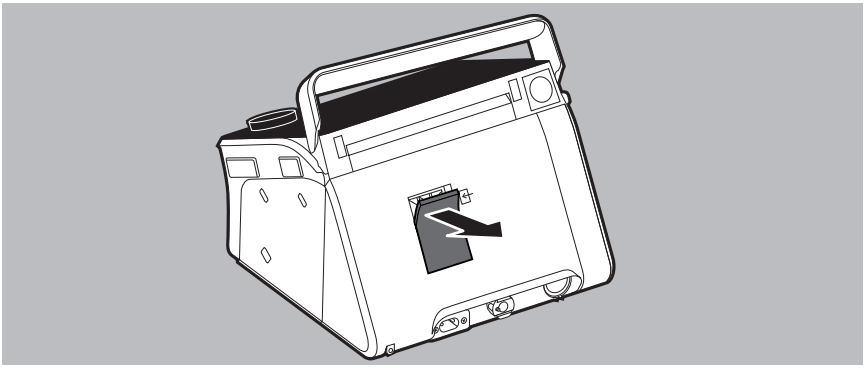
⇒ Do not pour liquids over the device and components.

1. Subject the device and components to a hygiene treatment in accordance with the table below.

PART	CLEANING	DISINFECTING ON CHANGE OF PATIENT	STERILIZING
Housing including device outlet port/ inlet	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 cloth.		
Power cord	Wipe down: Use water or mild detergent.		

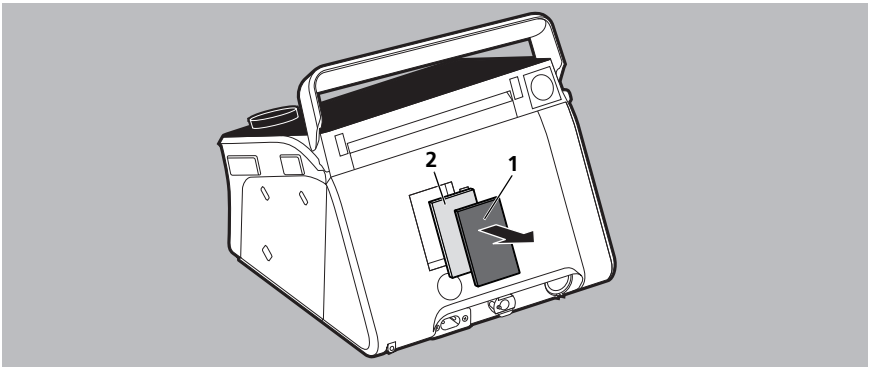
2. Replace mask, breathing tube, air filter, pollen filter, and bacteria filter.
3. Perform function check (see "7 Function check", page 34).

6.3.1 Clean air filter (gray filter)



1. Clean air filter under running water.
2. Allow air filter to dry.

6.3.2 Replace pollen filter (white filter)



1. Remove air filter **1**.
2. Replace white pollen filter **2**.
3. Replace air filter **1** in the holder.

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6.4 Hygiene treatment for breathing tube

NOTICE

Risk of 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.

If you use a heated breathing tube, see the Instructions for Use for the breathing tube.
If you are using a breathing tube with an active exhalation valve, follow the associated Instructions for Use.

6.4.1 Subject breathing tube with leakage ventilation to a hygiene treatment

1. Subject the breathing tube to a hygiene treatment in accordance with the table below.

CLEANING	DISINFECTING	STERILIZING
Use warm water and detergent.	Disinfect by immersion (recommended: gigasept FF®)	Not permitted

2. Rinse out breathing tube with clean water and shake out thoroughly.
3. Dry breathing tube.

6.4.2 Subject breathing tube with patient valve to a hygiene treatment (prisma VENT50 and prisma VENT50-C only)

Breathing tubes with patient valve are not suitable for reuse. Follow the associated Instructions for Use.

6.4.3 Subject breathing tube for mouthpiece ventilation to a hygiene treatment (prisma VENT50 and prisma VENT50-C only)

Breathing tubes for mouthpiece ventilation are not suitable for reuse. Follow the associated Instructions for Use.

7 Function check

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

1. Check device for external damage.
2. Check connectors and cables for external damage.
3. Check that components are correctly connected to the device.
4. Connect the device to the power supply (see "4.1 Set up the device", page 18).
5. Interrupt softSTART if necessary (see "4.9 Switching softSTART on and off (from firmware version 3.1.0008)", page 24).
6. Switch on device.
7. Seal off tube.
8. Compare the pressure shown in the display with the prescribed pressure.
9. To check the alarm function:

- When switching on, ensure that alarm acknowledgment key  comes on first yellow and then red.
- Take breathing tube off device.
  The disconnection alarm is triggered and an acoustic alarm sounds.

10. If there is an internal battery:

- Disconnect the device from the power supply.
  An alarm sounds. The battery takes over supplying power.
- Connect the device to the power supply.
  The power supply indicator is green.

11. If one of the items is not OK or pressure deviates by > 1 hPa: Do not use device and contact your specialist dealer.

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8 Alarms and faults

A distinction is made between two types of alarm: Physiological alarms relate to ventilation of the patient. Technical alarms relate to configuration of the device.

All physiological alarms are deactivated on delivery or when the device is reset. The technical alarms are active and cannot be configured.

8.1 Sequence for display of alarms

Alarms are divided into the three priority levels low  , medium  , and high  .

If several alarms are triggered simultaneously, the highest-priority alarm is always shown first.

The lower-priority alarm is retained and is displayed again once the higher-priority alarm has been rectified.

8.2 Deactivating physiological alarms

The attending physician can decide which physiological alarms to activate, deactivate, or mute.

If the symbol  appears in the status line, the attending physician has deactivated all the physiological alarms.

If the symbol  appears in the status line, the attending physician has muted all the physiological alarms.

8.3 Muting alarms

1. Mute alarm for 120 seconds: Press alarm acknowledgment key  .
   The fault continues to be displayed in the status line and the alarm acknowledgment key flashes until the fault has been rectified.
2. Mute all acoustic alarm signals for 2 minutes: Press and hold alarm acknowledgment key  .

8.4 Physiological alarms

DISPLAY	CAUSE	ACTION
Apnea 	No spontaneous breathing within set time.	Have settings checked by attending physician.
Pressure high 	Maximum pressure exceeded.	Have settings checked by attending physician.
Pressure low 	Minimum therapy pressure undershot.	Clean/change soiled filters.
	Patient/ventilator interface leaking.	Re-adjust patient/ventilator interface.
	Patient/ventilator interface defective.	Replace patient/ventilator interface.
	Settings implausible.	Have settings checked by attending physician.
Frequency high 	Maximum respiratory frequency exceeded.	Have settings checked by attending physician.
Frequency low 	Minimum respiratory frequency undershot.	Have settings checked by attending physician.
Leakage high 	Leak	Check connection from device to patient/ventilator interface at the patient via the breathing tube.
Minute volume high 	Maximum minute volume exceeded.	Have settings checked by attending physician.
Minute volume low 	Minimum minute volume undershot.	Have settings checked by attending physician.
Pulse high 	Ventilation parameter settings not suitable (maximum alarm setting for patient's pulse rate exceeded).	Have settings checked by attending physician.
	Alarm settings implausible.	
Pulse low 	Alarm settings implausible (minimum alarm setting for patient's pulse rate undershot).	Have settings checked by attending physician.
SpO_2 high 	Maximum alarm setting for patient's oxygen saturation exceeded.	Have settings checked by attending physician.

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DISPLAY	CAUSE	ACTION
SpO_2 low 	Patient/ventilator interface faulty or defective.	Check patient/ventilator interface and replace if necessary.
	Oxygen supply faulty or inadequate.	Have settings checked by attending physician.
	Ventilation parameter settings not suitable.	
	Alarm settings implausible (minimum alarm setting for patient's oxygen saturation undershot).	
Tidal volume high 	Leak in breathing tube.	Find and eliminate leak. If necessary: Replace breathing tube.
	Patient breathing as well.	Have settings checked by attending physician.
Tidal volume low 	Filter dirty.	Clean/change filter.
	Patient/ventilator interface leaking or defective.	Adjust headgear/headband so that the patient/ventilator interface seals. If necessary: Replace.
	Patient/ventilator interface defective.	Replace patient/ventilator interface.
	Settings implausible (minimum alarm setting for tidal volume exceeded).	Have settings checked by attending physician.
	Minimum volume is not reached within the specified time in MPVv mode.	Have settings checked by attending physician.
prisma VENT50 and prisma VENT50-C only		
ARP limit 	Patient and device asynchronous	Check device settings

8.5 Technical alarms

DISPLAY	CAUSE	ACTION
Service necessary. Please get in touch with your specialist dealer/contact.	Technical fault which can only be eliminated by an authorized specialist dealer.	Have device repaired.
Battery defective. Service necessary. 	Battery defective.	Have battery replaced.
	Device defective.	Have device repaired.
Battery not present. Service necessary. 	Battery defective.	Have device repaired.
	Unapproved battery in use.	
Battery capacity highly critical 	Battery discharged (less than 5 % capacity remaining).	Connect the device to the power supply.
Battery capacity critical 	Battery discharged (less than 10 % capacity remaining).	Connect the device to the power supply.
Battery switched off due to temperature 	Battery too hot.	Operate device at an ambient temperature of 5 °C to 40 °C.
Service life of battery ended. Have battery replaced. 	Service life of battery ended.	Have battery replaced.
Battery temperature high 	Battery too hot.	Operate device at an ambient temperature of 5 °C to 40 °C.
Battery not detected. Service necessary 	Battery defective.	Have battery replaced.
	Device defective.	Have device repaired.
Intake area covered. Please keep intake area free. 	Intake area covered.	Keep intake area free.

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DISPLAY	CAUSE	ACTION
Permanent disconnection; check breathing tube and patient connection 	Breathing tube is not connected to the device correctly or not connected at all.	Check connection from device to patient/ventilator interface at the patient via the breathing tube.
	Device operated with open patient/ventilator interface (mask not applied).	
Rebreathing 	Patient valve does not open in exhalation (medication has caused it to stick, for example).	Check patient circuit and replace if necessary
	Patient's reinhalation volume excessive at high frequency.	
Fault in patient circuit 	Valve control tube and pressure measurement tube switched.	Check tubes.
	Valve control tube kinked.	Check that valve control tube is not blocked.
Fault in patient circuit 	The valve control tube is incorrectly connected between the device and the patient valve.	Check valve control tube for damage. If necessary: Replace patient circuit.
		Connect valve control tube correctly.
	Valve control tube and pressure measurement tube switched.	Check tubes.
	Valve control tube kinked.	Check that valve control tube is not blocked.
Leakage low 	No leakage exhalation system present.	Connect leakage exhalation system.
Blower overheating 	Blower temperature too high. Cooling air filter blocked.	Check cooling air filter. If necessary: Have cooling air filter replaced by specialist dealer.
Therapy at an end 	Device is switched off.	Switch device back on.
	End of therapy with softSTOP, device switched off.	

DISPLAY	CAUSE	ACTION
Disconnection. Check breathing tube and patient connection 	Breathing tube is not connected to the device correctly or not connected at all.	Check connection from device to patient/ventilator interface at the patient via the breathing tube.
	Device operated with open patient/ventilator interface (mask not applied).	
Connect cover or humidifier. 	Leak due to missing or defective cover/humidifier.	Check connection of cover or humidifier to the device. If the alarm persists: Have device repaired.
Breathing tube or device outlet port blocked 	Breathing tube kinked or blocked.	Check that breathing tube and device outlet port are not blocked.
Fault in patient circuit 	Valve ventilation selected. No valve ventilation connected.	Check tubes. If necessary: Replace breathing tube.
		Change patient circuit.
		Have settings checked by attending physician.
	Leakage ventilation selected, valve ventilation connected.	Change patient circuit.
		Have settings checked by attending physician.
	Pressure measuring tube not correctly connected.	Check tubes.
SpO_2 measurement faulty 	SpO_2 sensor defective.	Replace SpO_2 sensor. If the alarm persists: Replace module.
	SpO_2 sensor not connected correctly.	Connect SpO_2 sensor correctly. If the alarm persists: Replace SpO_2 sensor.
SpO_2 sensor not connected 	No SpO_2 sensor connected.	Connect SpO_2 sensor. If the alarm persists: Replace module.
SpO_2 signal weak 	SpO_2 sensor not connected to the finger correctly.	Check connection to the finger.
	Signal interfered with by nail varnish or contaminants.	Remove nail varnish. Clean finger.

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DISPLAY	CAUSE	ACTION
Battery not charging due to excessive temperature 	Battery too hot.	Operate device at an ambient temperature of 5 °C to 40 °C.
Internal battery not charging - too cold 	Battery too cold.	Operate device at an ambient temperature of 5 °C to 40 °C.
Battery cannot be charged. Service necessary 	Battery defective.	Have battery replaced.
prismaCONNECT module defective. Please get in touch with your specialist dealer/contact 	prismaCONNECT module defective.	Have module replaced.
prisma CHECK module not present. 	prisma CHECK module defective or not connected.	Replace module or connect correctly.
Clock not set. 	Internal clock not set.	Have clock set by a specialist dealer so that course of therapy is recorded correctly.
Device in battery mode! 	Power supply failed.	Check that the power cord is securely connected. Check function of the socket.
	Device converted to battery operation.	Press alarm acknowledgment key. The device is in battery mode.
Display vanished. Acoustic and visual signal for at least 120 seconds, no display.	Power supply outage and battery (if present) discharged.	Check that the power cord is securely connected. Check function of the socket. If battery present: Connect device to power supply and charge battery.
	Device defective.	Have device repaired.

DISPLAY	CAUSE	ACTION
	HFT MODE ONLY	
Flow rate cannot be achieved. Check FiO_2, change flow rate setting or accessories. ⚠	Set flow rate cannot be used.	Upper flow limit: set a lower HFT flow rate and adjust O_2 supply or use accessories with lower resistance.
		Lower flow limit: set a higher HFT flow rate and adjust O_2 supply or use accessories with higher resistance.
prismaAQUA connected. Use a suitable external humidifier. ⚠	prismaAQUA not permitted in HFT mode.	Disconnect prismaAQUA from the therapy device and connect external humidifier suitable for HFT.

8.6 Troubleshooting

FAULT/FAULT MESSAGE	CAUSE	REMEDY
No running noise, nothing in the display.	No power supply.	Check that the power cord is securely connected. Check function of socket.
Therapy cannot be started by taking a breath.	Autostart function not activated.	Activate Autostart function.
Device does not reach the set target pressure.	Air filter dirty.	Clean air filter. If necessary: Replace filter (see "6 Hygiene treatment", page 30).
	Breathing mask leaking.	Adjust headgear so that the mask is tight. If necessary, replace faulty mask.

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9 Servicing

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

If used in accordance with the intended use, the device requires no servicing during this period.

If the device is used beyond this period, it needs checking by an authorized specialist dealer.

For Germany: In accordance with §6 of the German law governing the owners/operators of medical devices, the device must be subjected to a Technical Safety Check [Sicherheitstechnische Kontrolle (STK)] every 2 years. Country-specific requirements apply to all other countries.

If the device has a battery, this must be replaced every 4 years.

10 Transport and storage

Store and transport the device under the specified ambient conditions. Clean the device before storing it.

If the device has an internal battery that is always supposed to be ready for use, leave the device connected to the power supply. This ensures that the battery is always fully charged.

If the device is not connected to the power supply for an extended period, the battery will discharge. We recommend checking charge status regularly and recharging the battery with the aid of the device (if required).

11 Disposal

Do not dispose of the product or any batteries present with domestic waste. To dispose of properly, contact a licensed, certified electronic scrap 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.

12 Appendix

12.1 Technical data

12.1.1 Device

SPECIFICATION	DEVICE prisma VENT30, prisma VENT30-C, prisma VENT40	DEVICE prisma VENT50 prisma VENT50-C
Product class to 93/42/EEC	IIa	
Dimensions W x H x D in cm	21.8 x 17.5 x 21.8	
Weight	2.4 kg	2.5 kg
Weight of internal battery (if present)	0.63 kg	
Temperature range - operation - Transport and storage - Transport and storage at +70 °C - Transport and storage at -25 °C	 +5 °C to +40 °C -25 °C to +70 °C Allow to cool to room temperature for 4 h before starting up Allow to heat to room temperature for 4 h before starting up	
Permitted humidity for operation, transport and storage	Rel. humidity 10 % to 95 %, no condensation > +35 °C to +70 °C at a water vapor pressure up to 50 hPa	
Air pressure range	600 hPa to 1100 hPa, corresponds to an altitude of 4,000 m above MSL (keep leaks small below 700 hPa, as the device may no longer be able to compensate at very high ventilation pressures)	
Connection diameter for breathing tube	Standard 22 mm tapered connector to ISO 5356-1	
Maximum air flow at 20 hPa	> 220 l/min	
System interface	12 V DC Max. 10 VA	
Electrical rating	100-240 V AC, 50-60 Hz, tolerance -20 % - 10 %	
Mean power consumption at maximum load	At 100 V: 1.02 A At 240 V: 0.43 A	At 100 V: 1.12 A At 240 V: 0.5 A
Maximum electrical capacity	100 W	120 W

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SPECIFICATION	DEVICE prisma VENT30, prisma VENT30-C, prisma VENT40	DEVICE prisma VENT50 prisma VENT50-C
Internal battery (if present) - Type - Nominal capacity - Nominal voltage - Nominal power - Typical discharge cycles	Li-ion 2,900 mAh 39.6 V 107.8 Wh 600 charging cycles	
Service life of internal battery assuming following settings: T mode, f = 20/min, Ti = 1 s, PEEP = 4 hPa, Vt = 800 ml Passive lung: Resistance R = 5 hPa (l/s); Compliance C = 50 ml/hPa	> 12 hours	
Battery charging time	> 8 hours	
Classification to IEC 60601-1-11: Class of protection against electric shock Degree of protection against electric shock Protection against harmful ingress of solids and water	Protection class II Type BF IP22	
Classification to IEC 60601-1: Operating mode	Continuous duty	
Application part	Device outlet port, breathing mask, SpO_2 sensor	
Electromagnetic compatibility (EMC) to IEC 60601-1-2 Radio interference suppression Radio interference immunity	Electrical medical devices may only be installed and commissioned in a defined electromagnetic environment with regard to emission and immunity. More information, including test parameters and limit values, can be obtained from the manufacturer if required. EN 55011 B IEC 61000-4 Parts 2 to 6, Part 11, Part 8 IEC 61000-3 Parts 2 and 3	
Heating of respiratory air	Maximum +3 °C	

SPECIFICATION	**DEVICE** prisma VENT30, prisma VENT30-C, prisma VENT40	**DEVICE** prisma VENT50 prisma VENT50-C
Mean sound pressure level/operation to ISO 80601-2-70	Approx. 26 dB(A) at 10 hPa (corresponds to a sound power level of 34 dB(A))	Approx. 28 dB(A) at 10 hPa (corresponds to a sound power level of 36 dB(A))
Mean sound pressure level/operation to ISO 80601-2-70 with humidifier	Approx. 27 dB(A) at 10 hPa (corresponds to a sound power level of 35 dB(A))	Approx. 28 dB(A) at 10 hPa (corresponds to a sound power level of 36 dB(A))
Sound pressure level of acoustic alarm to IEC 60601-1-8 for all alarm conditions (high, medium, low priority)	Level 1: 50 dB(A) Level 2: 59 dB(A) Level 3: 61 dB(A) Level 4: 75 dB(A) ±5 dB(A)	
IPAP pressure range prisma VENT30 prisma VENT30-C prisma VENT40 prisma VENT50 prisma VENT50-C Tolerance	 4 hPa to 30 hPa 4 hPa to 30 hPa 4 hPa to 40 hPa 4 hPa to 50 hPa 4 hPa to 50 hPa ±1.2 hPa (±8 % of set value)	
PEEP pressure range Tolerance	4 hPa to 25 hPa ±1.2 hPa (±8 % of set value)	Leakage ventilation: 4 hPa to 25 hPa Valve ventilation: 0 hPa to 25 hPa ±1.2 hPa (±8 % of set value)
CPAP operating pressure range Tolerance	4 hPa to 20 hPa ±1.2 hPa (±8 % of set value)	
Pressure increment	0.2 hPa	
PLS min (minimum stable limit pressure) Minimum pressure in the event of a fault	0 hPa	
PLS max (maximum stable limit pressure) Maximum pressure in the event of a fault	≤ 60 hPa	
PWmax (maximum therapy pressure) prisma VENT30 prisma VENT30-C prisma VENT40 prisma VENT50 prisma VENT50-C	 30 hPa, pressure control 30 hPa, pressure control 40 hPa, pressure control 50 hPa, pressure control 50 hPa, pressure control	

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SPECIFICATION	DEVICE prisma VENT30, prisma VENT30-C, prisma VENT40	DEVICE prisma VENT50 prisma VENT50-C
PWmin (minimum therapy pressure)	Leakage ventilation: 4 hPa; pressure control Valve ventilation: 0 hPa	
Respiratory frequency Precision Increment	0 to 60 bpm ± 0.5 bpm 0.5 bpm	
Ti/Ti max Ti min, Ti max, Ti timed Precision Increment	0.5 s to 4 s 0,2 s to 4 s auto (Ti timed only) ± 0.1 s 0.1 s	
Target volume Precision Increment	100 ml to 2,000 ml ± 20 % 10 ml	
Trigger stage Inspiration Exhalation	1 (high sensitivity) to 8 (low sensitivity) 95 % to 5 % of maximum flow in 5 % increments	
Trigger device	The trigger on inspiration is triggered when the patient flow exceeds the trigger limit. The trigger on exhalation is triggered when the patient flow on inspiration drops to the percentage value of maximum patient flow on inspiration.	
Speed of pressure rise	Level 1: 100 hPa/s Level 2: 80 hPa/s Level 3: 50 hPa/s Level 4: 20 hPa/s	
Speed of pressure drop	Level 1: 100 hPa/s Level 2: 80 hPa/s Level 3: 50 hPa/s Level 4: 20 hPa/s	
Tidal volume Tolerance	100 ml to 2,000 ml ± 20 %	
Minute volume (averaged over previous 5 breaths) Tolerance	0 l/min to 99 l/min ± 20 % (conditions: Vt ≥ 100 ml)	
Maximum permitted flow rate for oxygen supply	15 l/min	

SPECIFICATION	DEVICE prisma VENT30, prisma VENT30-C, prisma VENT40	DEVICE prisma VENT50 prisma VENT50-C
HFT flow rate range	5 to 60 l/min Increment: 1 l/min	
Pollen filter up to 1 µm up to 0.3 µm	Filter class E10 ≥ 99.5 % ≥ 85 %	
Service life of pollen filter	approx. 250 h	
SD card	Memory size 256 MB to 8 GB can be used, interface compatible with SD physical layer version 2.0	
Filtering and smoothing techniques	The physiological alarms are triggered 3 breaths after the alarm limit is reached. Exception: The alarms **Pulse high**, **Pulse low**, **SpO_2 high** and **SpO_2 low** are triggered 3 seconds after the alarm limit is reached. The **Rebreathing** alarm is triggered 10 breaths after the alarm limit is reached. The ARP alarm limit occurs a max. of 20 breaths after the alarm limit is reached. The displays for pressure, flow and leakage have low-pass filters.	
Bacteria filter	Dead space: 26 ml Flow resistance: 2.0 cm H_2O at 60 l/min	

TOLERANCES FOR MEASURING DEVICES USED

Pressure:	± 0.75 % of measured value or ± 0.1 hPa
Flow:	± 2 % of actual value
Volume	± 3 % of actual value
Temperature:	± 0.3 °C
Time	± 0.05 Hz / ± 0.001 bpm

All physiological flow and volume values are displayed in BTPS (patient flow, target volume, breath volume, minute volume). All other flow and volume values are displayed in STPD.

The right to make design modifications is reserved.

All parts of the device are free from latex.

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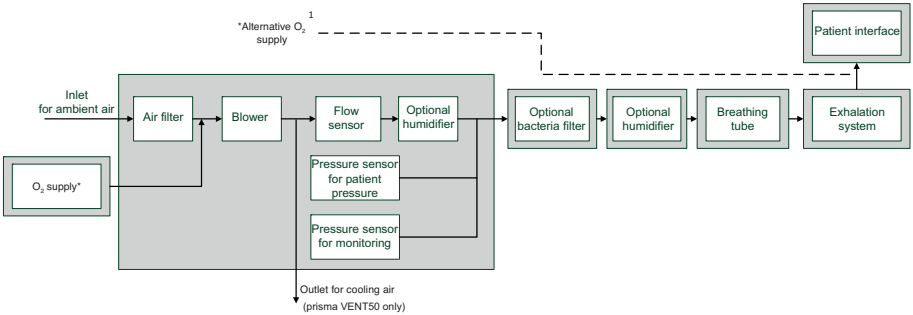
Standard applied: EN ISO 10651-6: Lung ventilators for medical use - particular requirements for basic safety and essential performance - Part 6: Home ventilation devices for respiratory support.

Devices of types WM 110 TD and WM 120 TD 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.

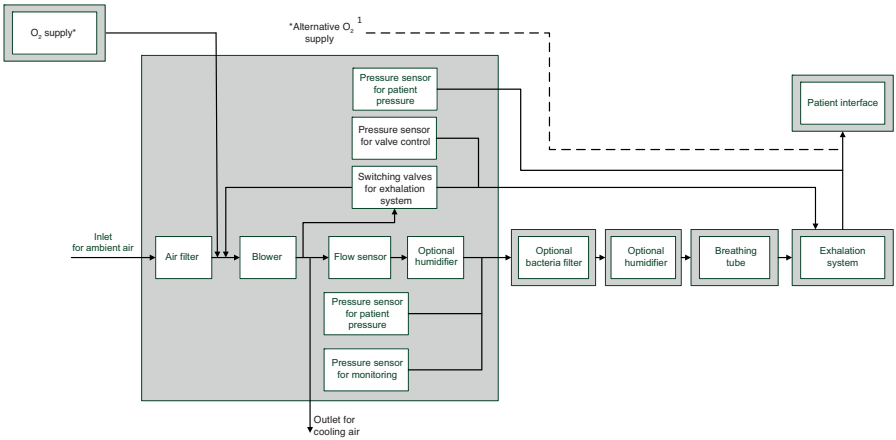
12.1.2 Pneumatic diagram

Breathing tube with leakage ventilation



[1] The O_2-supply must be switched off during the tube test.

Breathing tube with valve ventilation



[1] The O_2-supply must be switched off during the tube test.

12.1.3 System resistances

	prisma VENT30, prisma VENT30-C, prisma VENT40		prisma VENT50, prisma VENT50-C			
			Breathing tube with valve ventilation		Breathing tube with leakage ventilation	
Flow	**Exhalation**	**Inspiration**	**Exhalation**	**Inspiration**	**Exhalation**	**Inspiration**
Device with 22 mm breathing tube and humidifier						
15 l/min	0.3 hPa	0.4 hPa	0.1 hPa	0.2 hPa	0.3 hPa	0.3 hPa
30 l/min	0.91 hPa	1.1 hPa	0.4 hPa	0.6 hPa	0.9 hPa	1.0 hPa
60 l/min	2.98 hPa	3.44 hPa	1.4 hPa	5.1 hPa	2.7 hPa	3.1 hPa
Device with 22 mm breathing tube (no humidifier)						
15 l/min	0.32 hPa	0.42 hPa	0.2 hPa	0.2 hPa	0.4 hPa	0.3 hPa
30 l/min	0.98 hPa	1.17 hPa	0.5 hPa	0.7 hPa	1.0 hPa	1.0 hPa
60 l/min	3.19 hPa	3.62 hPa	1.4 hPa	5.7 hPa	3.0 hPa	3.3 hPa
Device with 15 mm breathing tube, humidifier, and bacteria filter						
15 l/min	0.44 hPa	0.51 hPa	-	-	-	-
30 l/min	1.26 hPa	1.35 hPa	-	-	-	-
60 l/min	3.77 hPa	4.05 hPa	-	-	-	-
Device with 15 mm breathing tube (no humidifier and bacteria filter)						
15 l/min	-	-	1.1 hPa	1.2 hPa	0.5 hPa	0.3 hPa
30 l/min	-	-	1.9 hPa	3.3 hPa	1.1 hPa	1.1 hPa
60 l/min	-	-	3.4 hPa	10.4 hPa	3.4 hPa	3.6 hPa

12.2 Emission of electromagnetic interference

GUIDELINES AND MANUFACTURER DECLARATION - EMISSION OF ELECTROMAGNETIC INTERFERENCE	
The device can be used in both static and mobile operation, in both domestic and appropriate hospital environments. In a domestic environment, the device may cause radio interference, possibly making it necessary to take suitable remedial measures, such as realigning the device, for example.	
MEASUREMENTS OF INTERFERENCE EMISSION	**COMPLIANCE**
HF emissions to CISPR 11	Group 1
HF emissions to CISPR 11	Class B
Emission of oscillations IEC 61000-3-2	Class A
Emission of voltage fluctuations/flicker to IEC 61000-3-3	Complies

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12.3 Electromagnetic interference immunity

GUIDELINES AND MANUFACTURER DECLARATION - ELECTROMAGNETIC INTERFERENCE IMMUNITY			
The device can be used in both static and mobile operation, in both domestic and appropriate hospital environments. In a domestic environment, the device may cause radio interference, possibly making it necessary to take suitable remedial measures, such as realigning the device, for example.			
INTERFERENCE IMMUNITY TESTS	**IEC 60601 TEST LEVEL**	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT GUIDELINE**
Discharge of static electricity (ESD) to IEC 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	Floors should be made of wood or concrete or have ceramic tiles laid on them. If the floor has a synthetic material laid on it, relative humidity must be at least 30 %.
Electrical fast transients/bursts to IEC 61000-4-4	± 2 kV for power supply cables ± 1 kV for input and output cables Connection duration ≥ 60 s Burst frequency: 100 kHz	± 2 kV for power supply cables ± 1 kV for input and output cables Connection duration ≥ 60 s Burst frequency: 100 kHz	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Surge immunity to IEC 61000-4:-5	Source impedance: 2 Ω, 18 µF: 0.5 kV, 1 kV Number of surges: 5 surges/ phase angle Phase angle: 0°, 90°, 180°, 270° Repetition rate: 60 s	Source impedance: 2 Ω, 18 µF: 0.5 kV, 1 kV Number of surges: 5 surges/phase angle Phase angle: 0°, 90°, 180°, 270° Repetition rate: 60 s	The quality of the supply voltage should correspond to that of a typical business or hospital environment.

GUIDELINES AND MANUFACTURER DECLARATION - ELECTROMAGNETIC INTERFERENCE IMMUNITY			
The device can be used in both static and mobile operation, in both domestic and appropriate hospital environments. In a domestic environment, the device may cause radio interference, possibly making it necessary to take suitable remedial measures, such as realigning the device, for example.			
Voltage dips, short interruptions and voltage variations in supply voltage to IEC 61000-4-11	Number of voltage drops: 3 drop levels/ duration: 30% / 500 ms 60% / 100 ms 100% / 20 ms 100% / 10 ms at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Number of voltage drops: 3 drop levels/ duration: 30% / 500 ms 60% / 100 ms 100% / 20 ms 100% / 10 ms at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	The quality of the supply voltage should correspond to that of a typical business or hospital environment. If the user of the device requires continued FUNCTION, even in the event of interruptions to the power supply, it is recommended that the device be supplied from an uninterruptible power supply or a battery.
Magnetic field at power frequency (50/60 Hz) to IEC 61000-4-8	30 A/m Duration: 30 s per axis Axes: x axis, y axis, z axis	30 A/m Duration: 30 s per axis Axes: x axis, y axis, z axis	Magnetic fields at power supply frequency should correspond to the values typical of those found in business and hospital environments.

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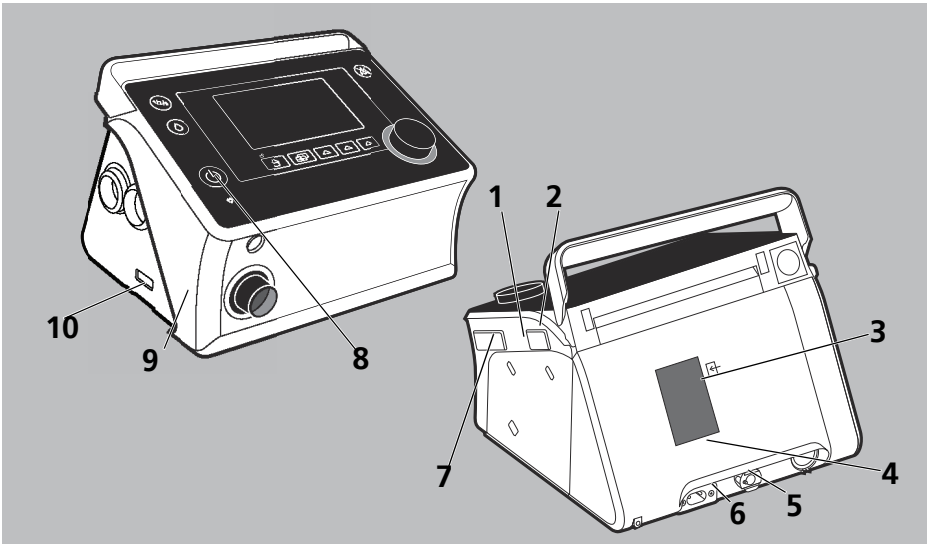
12.4 Electromagnetic interference immunity for ME equipment and ME systems

GUIDELINES AND MANUFACTURER DECLARATION - ELECTROMAGNETIC INTERFERENCE IMMUNITY		
The device can be used in both static and mobile operation, in both domestic and appropriate hospital environments. In a domestic environment, the device may cause radio interference, possibly making it necessary to take suitable remedial measures, such as realigning the device, for example.		
INTERFERENCE IMMUNITY TESTS	**IEC 60601 TEST LEVEL**	**COMPLIANCE LEVEL**
Conducted HF interference to IEC 61000-4:-6	10 $V_{effective\ value}$ 150 kHz to 80 MHz within ISM bands	10 V
Radiated HF interference to IEC 61000-4:-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 2 Hz	10 V/m
Magnetic field at power frequency (50/60 Hz) to IEC 61000-4-8	30 A/m	30 A/m

12.5 Markings and symbols

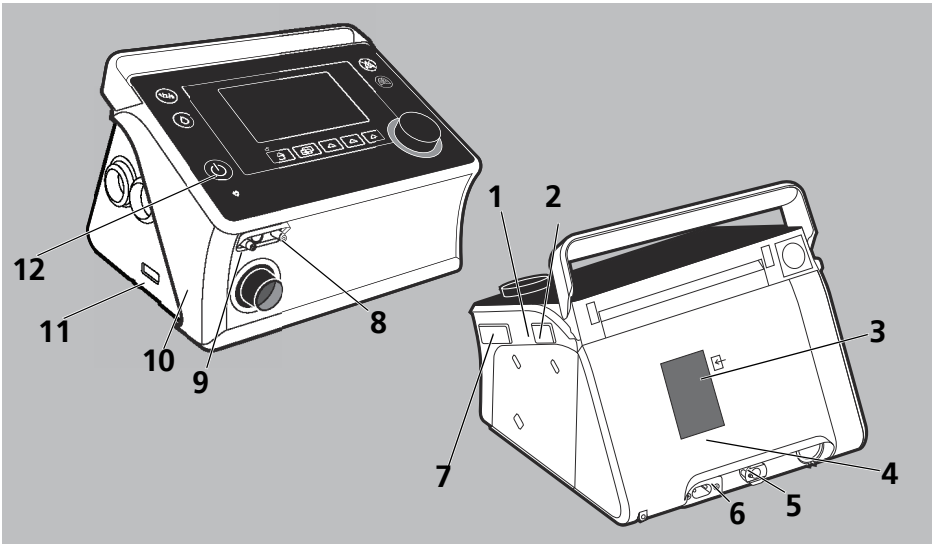
12.5.1 Markings on the device

prisma VENT30, prisma VENT30-C, prisma VENT40



NO.	SYMBOL	DESCRIPTION
1	SN	Serial number of the device
		Year of manufacture
2 , 10		Follow Instructions for Use.
3		Device inlet: ambient air inlet
4		Follow Instructions for Use.
5		Oxygen connection: maximum supply rate 15 l/min at < 1000 hPa
6		Electrical connection
7		Slot for SD card
8		On/off: Identifies the on/off key
9		Device outlet port for connecting the breathing tube.

prisma VENT50, prisma VENT50-C



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NO.	SYMBOL	DESCRIPTION
1	SN	Serial number of the device
		Year of manufacture
2 , 11		Follow Instructions for Use.
3		Device inlet: ambient air inlet
4		Follow Instructions for Use.
5		Oxygen connection: maximum supply rate 15 l/min at < 1000 hPa
6		Electrical connection
7		Slot for SD card
7		USB port (optional)
8		Connection for control tube for patient valve
9		Connection for pressure measuring tube (marked blue)
10		Device outlet port for connecting the breathing tube.
12		On/off: Identifies the on/off key

12.5.2 Device ID plate underneath the device

SYMBOL	DESCRIPTION
TYP	Type designation of the device
IP22	Degree of protection against solid foreign bodies. Device is protected against drips.
	Degree of protection against electric shock: Protection class II device
	Do not dispose of device in domestic waste.
	Suitable for use in aircraft. Meets RTCA/DO-160G Section 21, Category M.

	Application part type BF
	Manufacturer
CE 0197	CE symbol (confirms that the product conforms to the applicable European directives)

12.5.3 Markings on the packaging of the device and accessories

SYMBOL	DESCRIPTION
	Permitted temperature for transport and storage: -25 °C to +70 °C
	Permitted humidity for transport and storage: 10 % to 95 % relative humidity
	Use only for a single patient.

12.6 Scope of supply

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

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

PART	ITEM NUMBER
Basic device	Varies depending on device.
Breathing tube with leakage ventilation (prisma VENT30, prisma VENT30-C, prisma VENT40))	WM 23962
Breathing tube with valve ventilation (prisma VENT50, prisma VENT50-C)	WM 27181
Power cord	WM 24177
O_2 connector	WM 30669
Set, 12 pollen filters	WM 29652
Set, 2 air filters	WM 29928
Carrying bag	WM 29710
SD card	WM 29794
Instructions for Use	WM 68131

12.7 Accessories and replacement parts

A current list of accessories and replacement parts can be ordered on the internet site of the manufacturer or through your authorized specialist dealer.

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12.8 Warranty

Löwenstein Medical gives the customer a limited manufacturer warranty on a new genuine Löwenstein Medical product and on any replacement part fitted by Löwenstein Medical 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 website of the manufacturer. 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 quoted differently in the technical documentation), sensors, patient circuits	6 months
Disposable products	None

12.9 Declaration of conformity

Löwenstein Medical Technology GmbH + Co. KG, Kronsaalsweg 40, 22525 Hamburg, Germany, the manufacturer of the devices described in these Instructions for Use, hereby declares that the product complies with the respective regulations of Medical Devices Directive 93/42/EEC. The unabridged text of the Declaration of Conformity can be found on the manufacturer's website.

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CE 0197

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