EN

prisma VENT AQUA respiratory humidifier

Instructions for use and technical description

LÖWENSTEIN
medical

Contents

1. Scope of use

The prisma VENT AQUA respiratory humidifier is a device for heating and humidifying respiratory gases such as medical oxygen and/or compressed air or room air during artificial respiration or respiratory therapy in both clinical and non-clinical settings.

The prisma VENT AQUA can be used in non-invasive respiration/respiratory therapy.

This device may only be operated by trained personnel. User training will be provided by Löwenstein Medical or Löwenstein Medical authorized agents.

The prisma VENT AQUA is always operated between the therapy device and patient. A tube system with a humidification chamber is always required for this connection. This tube system must be matched beforehand to the therapy device being used, suit the medical indication and the respective patient group.

The prisma VENT AQUA may only be connected to approved therapy devices (e.g. ventilators, bilevel and CPAP devices, etc.) if the safety of patients, users and the surrounding area is not compromised by this combination. If the the safety of the combination is not obvious, the user must confirm it e.g. by an inquiry to the manufacturers.

The respiratory gas is passed from the treatment device or oxygen source into the humidification chamber of the respiratory humidifier, where it is warmed and enriched with water vapor and then passed through the inspiratory breathing tube to the patient. Three different basic modes enable the humidification power to be set or adjusted optimally for each application.

The prisma VENT AQUA respiratory humidifier is neither suitable nor intended for the nebulization of medication.

2. Warnings, Cautions and Guidelines

2.1 Warnings

Warnings are indicated by the term WARNING. Warnings alert the user when potentially serious consequences for the patient or the user may occur, which can lead to injury with negative consequences including death.

WARNING

Before the patient is connected to the breathing tube system, a check must be made on whether the breathing gas is flowing unimpeded through the breathing tube system.

WARNING

To avoid penetration of any condensate in the breathing tube system and its flow to the patient, the humidifier should be positioned below the actual level of the patient.

WARNING

Risk of burns!
Under continuous operation, the heater and the humidifier chamber can reach temperatures of over 85°C. Before removing the humidification chamber from the humidifier, the humidification chamber must be allowed sufficient time to cool down.

WARNING

When using the temperature probe, the temperature sensor must be inserted so that the temperature of the respiratory gas is measured in the middle of the breathing tube. Failure to observe the temperature of the supplied respiratory gas can lead to exceedance of the critical temperature of 43°C.

WARNING

Do not cover the heated breathing tube system with any insulating material, such as towels or blankets, or other materials, because the filament inside the tube will then become overheated at the covered spot. This can lead to a deformation to the point of melting of the breathing tube.

WARNING

The prisma VENT AQUA respiratory humidifier may be connected to all conventional ventilators/therapy equipment, provided its connection is made such that any danger for the patient, user or environment can be avoided.

WARNING
Risk of burns!
Heated breathing tube systems must not touch the patient's skin.

WARNING
Keep in mind that, when using the machine near other electrical appliances, faulty operation could occur. If this separation from other equipment becomes necessary, it must be checked that the devices are functioning properly.

WARNING
The use of accessories and cables other than those specified by the manufacturer may result in an increased electromagnetic emission or a decreased electromagnetic compatibility of the humidifier.

WARNING
This device may not be altered without the manufacturer's permission.

WARNING
If used correctly, the heating plate and the chamber become hot.

WARNING
If the device is stored or transported at an ambient temperature of -25°C or +70°C, the device must then be acclimatized prior to operation at an ambient temperature of 18°C to 28°C for 30 minutes.

WARNING
Operating temperatures are different from storage and transport temperatures. The prisma VENT AQUA may only be operated at an ambient temperature of 18°C to 28°C.

WARNING
The prisma VENT AQUA respiratory humidifier is not to be operated in the vicinity of radiators and other heat sources. Solar radiation and bright light sources must be avoided.

WARNING
Please note that the ambient conditions change if a window is opened.

WARNING
Children and pets are to be supervised when the prisma VENT AQUA respiratory humidifier is being operated.

WARNING
Portable HF communications devices (radio equipment) (including their accessories, such as antenna cables and external antennae) should not be at a closer distance than 30 cm (or 12 inches) from the parts and lines of the prisma VENT AQUA indicated by the manufacturer. If this is not observed, it can lead to a reduction in the performance of the device.

WARNING
Small parts can be swallowed.

WARNING
This device may only be operated by trained personnel. User training will be provided by Löwenstein Medical or Löwenstein Medical authorized agents.

2.2 Precautions

Precautions are indicated by the term CAUTION. Precautions warn the user for special precautions to be observed in order to ensure safe and effective use of the prisma VENT AQUA respiratory humidifier.

CAUTION
Breathing tubes with a diameter of 15 mm may only be used as a **heated** system with temperature probe and heating wire adapter.

CAUTION
The use of accessories that are not approved by Löwenstein Medical may impair the operational reliability of the system.

CAUTION
The output power of the humidity can be affected if the device is operated outside of the specified range of operating temperatures.

CAUTION
To avoid overheating, a breathing gas flow of at least 5 l/min is constantly required in the breathing tube system. If the breathing gas supply is interrupted, the device must be turned off. For applications that require the patient's separation from the humidifier, the device needs to be switched to the "treatment interruption" mode.

CAUTION
The water used to fill the humidification chamber must not be warmer than the ambient temperature!

CAUTION
Before any maintenance, inspection or repair work, the device must be disconnected from the mains.

CAUTION
Every servicing of the device - including any maintenance and testing - must be performed by trained service technicians. For details, please refer to the additions to the technical specifications, and to the maintenance and service manual.

CAUTION
Defective humidifiers may not be used. Disconnect defective devices from the power and notify hospital maintenance technicians or the supplier.

CAUTION
Do not immerse the base unit or its accessories in liquids to sterilize them! Detailed instructions for cleaning and maintaining the device are included in the sections regarding maintenance and cleaning.

CAUTION
Before each use, check that the base unit, the supplied system parts and the accessories used are free from defects. If the prisma VENT AQUA humidifier is damaged or defective, it must not be used. In addition, in this situation, please notify the hospital maintenance technician or the customer service department. Sort out the damaged components of the system and do not use them!

CAUTION
The determination of the operational shutoff may only be performed by a physician or his/her authorized representatives.

CAUTION
This operation manual does not replace the medical prescription or the service requirements for the appropriate care of the patient. These requirements and service regulations take precedence over this user manual.

2.3 Guidelines

Guidelines are indicated by the term NOTE. Guidelines contain important information that should be respected.

NOTE
Before use, follow the instructions of the user manual of each accessory!

NOTE
A change in the room climate (for example, heating, ventilation) or the entry of new ventilation parameters can lead to increased condensation in the breathing tube system.

NOTE
The abbreviation "(i)" means inspiratory breathing.

NOTE
The prisma VENT AQUA humidifier and the humidification chamber are not inhalers and therefore are neither suitable nor intended for administration of drugs!

NOTE
Portable and mobile high frequency communication equipment (such as mobile phones) can affect the proper functioning of the prisma VENT AQUA humidifier. Further evidence is included in the manufacturer's EMC declaration in the Appendix.

NOTE
The maintenance and inspection of this equipment should be performed only by authorized and trained service engineers, in compliance with applicable regulations.

NOTE
The operating life of the device is limited to 8 years.

NOTE
Its operation in a potentially explosive and oxygen-rich environment is not allowed.

NOTE
If problems arise during commissioning, use or possibly servicing, or if an unexpected operating state or incident occurs, the representative should be contacted.

NOTE
The prisma VENT AQUA humidifier and the humidification chamber are not inhalers and therefore are neither suitable nor intended for administration of drugs, medical substances or human blood derivatives.

NOTE
Only Löwenstein Medical approved accessories and consumables may be used. Accessories and consumables from third party providers may affect the safety of the device.

NOTE
The anticipated operating lifetime of the device and of the jointly-supplied accessories is limited to 8 years. The anticipated operating lifetime of the consumables is shown in the user instructions for the consumables.

NOTE
The prisma VENT AQUA respiratory humidifier is suitable for reuse. Prior to reuse following a change of patient, cleaning and disinfection pursuant to chapter 11 must be carried out.

3. Side effects / Contraindications

There are no known adverse side effects.

4. Basic equipment and resources needed

4.1 Delivery and special accessories

- prisma VENT AQUA base unit (230V 100506, 115V 100507)
- Wire distribution cable for heating (i) (100.942)
- Temperature probe (160 cm 100910 or 180 cm 100909)*
- Power cord (country specific)
- User instructions (country specific)
- Quick Start Guide (country specific)

Base unit

Power cord

Heating wire distributor cable

Temperature probe

* The 180 cm temperature probe (100909) is a special accessory and must be ordered separately.

4.2 Consumables

Depending on the specific application, other accessory parts are required and available from Löwenstein Medical. For a full list of all available accessory parts, please contact the manufacturer. Examples of accessory parts and consumables are listed in the following table:

Item number	Accessory
271705	High-flow leakage tube, heated (i), auto-fill chamber, passive valve, connection for HFT nasal cannula (150cm + 60cm, 22mm Ø)
271707	Single-tube valve system, heated (i), with auto-fill chamber for prisma VENT AQUA or AIRcon (150cm + 60cm, 15mm Ø)
271708	Single-tube valve system, heated (i), with auto-fill chamber for prisma VENT AQUA or AIRcon (150cm + 60cm, 22mm Ø)
270822	Oxi Plus high-flow nasal cannula Size 2, retail pack = 15 items
270823	Oxi Plus high-flow nasal cannula Size 3, retail pack = 15 items
270824	Oxi Plus high-flow nasal cannula Size 4, retail pack = 15 items

Breathing tube system must be compatible with the treatment device used.

NOTE

Only Löwenstein Medical approved accessories and consumables may be used. Consumables from third party providers may affect the safety of the device

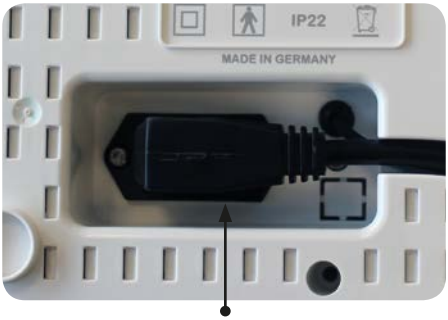
5. Installation and commissioning

5.1 Connecting components

The room thermometer is firmly connected to the basic unit. Its sensor has a plastic protector and is secured with an integrated clip on the power cord.

Clip Power cord

The power plug is connected under the machine.



Power plug

Connect the power cord to an AC outlet or power strip with allowable voltage. The connections for the wire distribution cable for heating and for the temperature sensor are mounted laterally on the device. These connectors are colored and mechanically coded, being marked with appropriate symbols.

When using a heated breathing tube system, the plug of the heating wire distributor cable is connected using the yellow connector (symbol).

When using a special accessory temperature probe, the temperature probe plug is connected using the blue connector (symbol). The temperature probe is a special accessory and must be ordered separately.

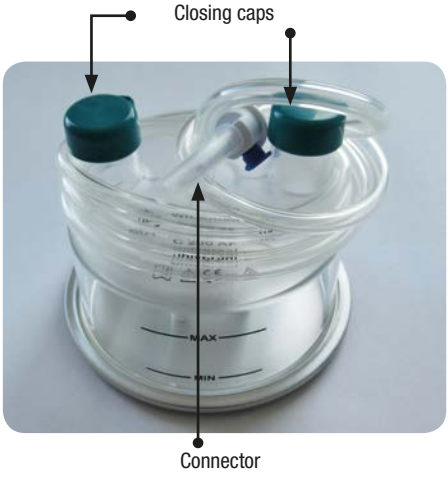
The plug of the heated breathing tube system is also color-marked (green) and mechanically coded.

5.2 Installation / Mounting the base unit

The prisma VENT AQUA device is equipped with silicone feet and can be placed on a flat, solid and level surface. Alternatively, the device can be suspended with the rear retaining tab in a suitable hook.

5.3 Installing the humidification chamber

Unpack the humidification chamber with automatic refill device (e.g., C200AF universal) and check it before use for any visible damage.



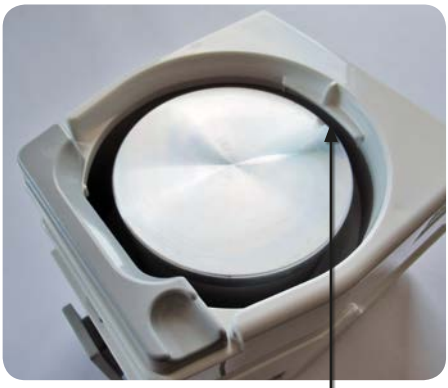
Attention: Use only proper quality humidification chambers!
Attention: The operating instructions for the respective humidification chamber must be followed!

Pull off the colored caps, dispose of them properly and connect the handle to the water bag.

Connect the therapy device output with the input of the humidification chamber - marked with the inscription "IN"; then connect the breathing tube (e.g. the disposable breathing tube system 27105) to the patient, using the output of the humidification chamber - marked "OUT". The humidification chamber should be oriented so that the MIN and MAX inscriptions on the chamber are easy to read from the front and the breathing tube system is not convoluted.

Out In

First slide the bottom edge of the humidification chamber under the front flap on the base unit



Front flap

and then fix it under the movable mounting bracket, until the bracket clicks into place.

Mounting bracket

Only with correct use of the humidification chamber is the full-surface heat transfer of the heating plate ensured.

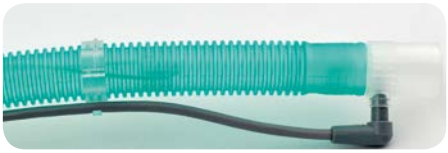
5.4 Connect the breathing tube system

If a temperature probe is connected, the T-sensor of the temperature probe must be inserted in the opening of the angle connector

T-sensor in the angle connector opening

and the sensor must be inserted at the end of the cable, into the opening nearest the patient at the end of the breathing tube system.

Both sensors must be firmly and securely inserted in the respective opening. The wiring of the temperature probe can be secured in the appropriate hook of the tubing clamps.



The green coupling of the heating wire supply is always connected to the green heating wire plug of the inspiration tube.

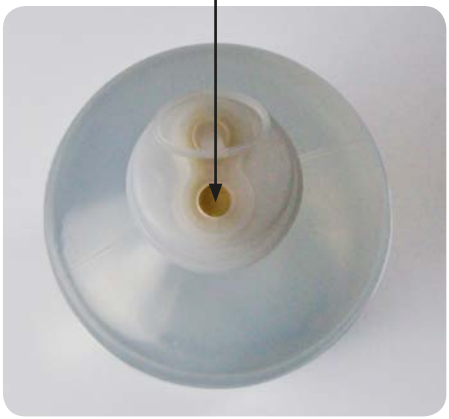
When using a heated breathing tube system, the prisma VENT AQUA base unit is only operational when the inspiration heating wire is connected. Cables need to be run in such a way that no one can get tangled in them.

Note: Tubing clamps and mounting clamps are to be used.

The use of sterile water is recommended. However, other water to a medical specification can be used. However, this water must not contain any mineral additives or drugs.

The automatic refill device works when the container filled with the water (e.g. WILAqua 500186) is suspended at least 0.5 m above the humidifier. After this, the seal plate is removed on the bottle neck of the container

Rubber membrane



and the perforator of the terminal handle is inserted in the rubber membrane.

Perforator

For water bottles, the blue vent cap on the perforator must be opened.

Venting cap

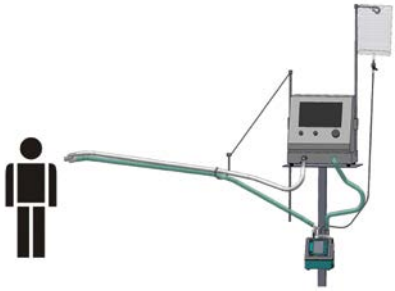
The water gradually fills the humidification chamber and maintains a constant level.

If the humidification chamber is filled manually, it must be ensured that the level of the humidification chamber does not exceed or fall short of the water level markings.

Do not use hot water when manually filling the humidification chamber. Manual filling of the chamber in conjunction with the HWC "heating wire without temperature probe" mode is not recommended.

Before the patient is connected to the breathing tube system, make sure that the treatment device is working properly, that the treatment parameters are set correctly and that the breathing gas flows freely out of the breathing tube system.

The following illustration shows the schematic set-up of the device:



5.5 Turn on the base unit

Turn on a humidifier with the lateral main switch only when the breathing tube system, the humidification chamber and the water reserve are connected, plugged or clamped correctly.

NOTE

The prisma VENT AQUA humidifier saves the last setting and uses it for a restart (for example, after a power failure).

NOTE

After switching on, the warm-up takes a maximum of 30 minutes (typically 15 minutes). After switching on, the heating and the water vapor saturation of the respiratory gas will steadily increase in order to achieve an optimum value.

The current intensity of humidification is indicated by an LED.

5.6 Turn off the base unit

The humidifier can be turned off using the power switch, after the end of the therapy. After switching off, the device should cool for at least 30 minutes before it is packed or transported.

6. Mode of operation

The device independently recognizes the connected equipment at the start, and will automatically begin the associated operational functions, without the need of additional setting being done by the operator. The device is set via a simple two-button operation. Thereby, the operation mode, the current state of the humidification intensity and the alarms are displayed via a light emitting diode. An Alarm Mute Key is used to temporarily interrupt the audible alarm. If the cause of the alarm is not resolved within 10 minutes, the unit switches to the "OFF" mode.

A detailed description of the controls and indicators can be found under Chapter

7. Operation
8. Representation of the operating mode
9. Representation of the Guidelines
10. Alarms

The device can be operated in three modes, which arise from the various combinations of features of the optional use of inspiratory heater wire and temperature probe. For dynamic adjustment of breathing gas conditioning to the ambient temperature, the device is equipped with a room thermometer that optimizes control.

6.1 Description of the operating modes

6.1.1 NHW

NHW "Non Heated Wire" means: without heating wire and without temperature probe.

In this mode, a simple, unheated breathing tube system is used. The heating plate temperature is adjusted to a desired value, which can be selected by the user via three settings.

The breathing gas is humidified and heated when passing through the humidification chamber, which means the respiratory gas temperature and its humidity intensity correlate. The respiratory gas that leaves the humidification chamber has a relative humidity of about 100%. Since no heated tube is used in this mode, the breathing gas cools more quickly on the way to the patient than with the use of a heated breathing tube system

In this operating mode, this inevitably results in increased condensation because the breathing gas cools to a temperature level below the dew point on its way to the patient.

To avoid excessive condensation at low ambient temperatures, the heating plate temperature is adjusted automatically. Should too much condensation build up in the breathing tube system, we recommend reducing the level of humidification.

6.1.2 HWC

HWC “Heated Wire Calculated” means: with heating wire but without a temperature probe.

As no temperature probe is used in this mode of operation, the output of the heating plate and the heating wire must be calculated. Based on the heating plate temperature, heating plate power and room temperature parameters, the machine selects the necessary settings, so that the required temperatures are reached.

In this mode, there is less condensation than in the operation without heating wire. The nominal value of the humidification intensity can be selected in three steps.

NOTE

During extended operation of the treatment device with a high flow rate, the value must not drop suddenly.

6.1.3 HWT

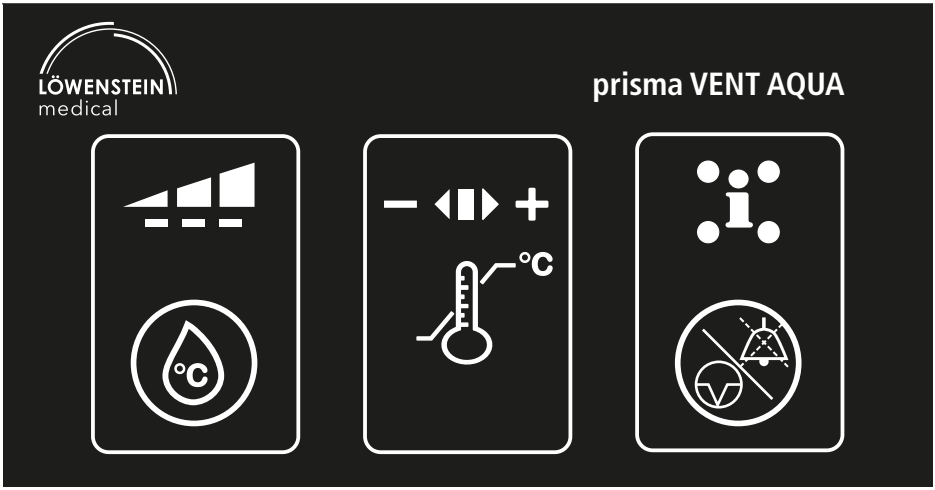
HWT "Heated Wire Temperature" means: with heating wire and with a temperature probe.

In this mode, both the temperature at the outlet of the humidification chamber and the temperature nearest the patient are regulated.

In operating mode with heating wire and with temperature probe, the humidity intensity and the breathing gas temperature are kept in a narrowly defined area, whereby the humidity intensity can be selected in three steps.

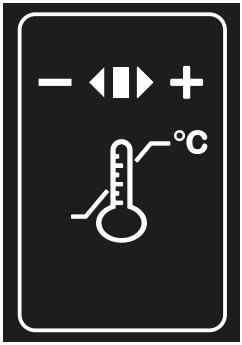
7. Operation

7.1 Representation of the operating controls



The following chapters explain the functions of the controls and the meaning of the display messages.

7.2 Status display of the current humidification



The LEDs in the central region show whether the breathing gas has reached the set humidification. The left and right orange LED indicate that the humidification is less than or greater than the set value. The middle green LED indicates that the set humidification is reached.

7.3 Configuration of humidification levels

By holding the button for three seconds, it is possible to select between humidification levels 1 (low), 2 (medium) and 3 (high). The Selected Humidification is displayed via .

7.4 The temperature ranges NHW, HWC and HWT

Operation mode	Level	Temperature near patient
NHW	1	approx. 23-25°C (1)
	2	approx. 25-28°C (1)
	3	approx. 28-31°C (1)
HWC	1	approx. 30-31°C (1)
	2	approx. 31-32°C (1)
	3	approx. 32-34°C (1)
HWT	1	31°C (2)
	2	33°C (2)
	3	36°C (2)

(1) these values apply at an ambient temperature of 23°C

(2) these values apply for all permitted operating temperatures (18 to 28°C)

7.5 Respiratory flow areas

Operating mode / tube diameter	Level	Respiratory flow area (l/min)
NHW /22 mm	1	5 to 50
	2	5 to 40
	3	5 to 30
HWT / 22 mm HWC / 22 mm	1	5 to 60
	2	5 to 60
	3	5 to 40

7.6 Impact on the performance

There are no known adverse reactions to the performance of the prisma VENT AQUA via impacts of electrocautery, electrosurgery, defibrillation, X-rays, infrared rays, switching pulses, magnetic fields and radio frequency interference.

7.7 Muting the alarm

The audible alarm can be muted by pressing the button for 120 seconds. Then the alarm sounds again. If the cause of the alarm is not resolved within 10 minutes, the unit switches to the "OFF" mode.

7.8 Treatment interruption

The treatment interruption may be carried out in normal operation, that is, if there is no alarm activated, by pressing the button for 3 seconds. The treatment interruption lasts 3 minutes and can be prematurely terminated at any time by pressing any key. During the treatment interruption, the heating plate and the heating wire (if connected) can be controlled with half of the power of normal operation.

During the treatment interruption, all 4 green LEDs of the matrix display will flash.

7.9 Warm-up time

During the warm-up time of 30 minutes, certain alarm messages are suppressed.

These alarms indicate a deviation of the actual temperature from that of the setpoint. The reason for this lies in the fact that the temperatures cannot be achieved immediately after switching on.

7.10 Alarm delay

Alarm messages are also suppressed for a certain time if the following conditions are present:

- After completion of treatment interruption, the alarm delay is activated for 3 minutes, because during the treatment interruption period no adjustment has been made. Only the heating power was reduced and the temperature cannot be immediately achieved after switching to the normal mode.
- After changing the humidification level, the alarm delay is activated for 3 minutes for the same reason.

8. Representation of the operating mode

After switching on, the device checks whether a temperature probe or a heating wire is connected and it starts automatically with the corresponding operating mode. If the temperature probe or the heating wire is removed during operation, an alarm sounds, provided that they were connected upon startup of unit.

Display	Term	Operation mode
	NHW	with neither heating wire, nor temperature probe
	HWC	with heating wire, but without temperature probe
	HWT	with both heating wire and temperature probe

9. Representation of the Guidelines

Display	Note
	The ambient temperature is too high in relation to the selected setting. This may result in reduced humidification.
	The ambient temperature is higher than the set value of the temperature at the connection nearest the patient. The temperature cannot be effectively controlled at the location. There will be no risk to the patient!
	Treatment interruption active. Reduction of the power of the heating plate and the heating wire (if connected) to half. The treatment interruption period ends automatically after 3 minutes or by pressing any button of the prisma VENT AQUA.

- filled circle means LED is lit
- filled circle with rays means LED is flashing

10. Alarms

When the device is switched on, there is an audible signal and a visual signal in the form of yellow glowing LEDs on the display  , which verify the functionality of the alarm system. All alarms are assigned to the middle priority.

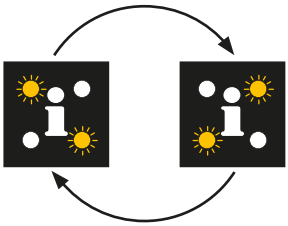
10.1 Causes and Solutions

No.	Display	Cause	Remedy
1		Temperature nearest the patient Error	○ Check the installation ○ Check the temperature probe ○ Check the flow
2		Internal hardware error	○ Check the installation ○ Shut off the device ○ Allow heating plate to cool before turning on again ○ Contact the supplier
3		Peripheral element Error	○ Connect or check the temperature probe ○ Connect or check the heating wire
4		Chamber/heating plate temperature Error	○ Check the installation ○ Check the temperature probe ○ Check the flow

 filled circle with rays means LED is flashing

10.2 Alarm "OFF" Status

If a sounding alarm is not rectified within 10 minutes or the heating plate temperature increases above 93°C, the forced shutdown of all heaters occurs. The device can be turned on again only by restarting it and after cooling the heating plate again. This status is indicated by diagonally-flashing LEDs (as shown below).



11. Cleaning

Before cleaning the humidifier with accessories, it must be ensured that the prisma VENT AQUA humidifier is switched off and the power cord disconnected from the mains. Furthermore, it should be ensured that the unit has cooled down.

Do not sterilize or immerse the base unit in liquids! Do not sterilize the temperature probe!

Base unit, temperature probe and heating wire distribution cable are to be cleaned weekly or when there is a change of patient.

The base unit, temperature probe and heating wire distribution cable can be cleaned with a mild detergent (e.g. WILAsil). Disinfection is performed by wiping it with any of the following disinfectants:

- Hydrogen peroxide (4%)
- Isopropanol (17%)
- CaviWipes®, METREX® RESEARCH
- Incidin® Plus, Ecolab Deutschland GmbH
- mikrozid® sensitive liquid, Schülke & Mayr GmbH
- perform®, Schülke & Mayr GmbH
- quartamon® med, Schülke & Mayr GmbH

It is important to ensure that only a damp cloth is used for cleaning! Do not allow any liquids to penetrate the housing. The disinfectant manufacturer's instructions shall be strictly followed. In particular, dilution, exposure times and change in the composition have a major impact on the cleaning process.

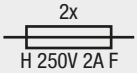
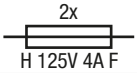
The respective user instructions must be followed when cleaning and disinfecting the accessories.

12. Maintenance

The prisma VENT AQUA humidifier does not need calibration. Every 12 months (hospital) or every 24 months (domestic use), an electrical safety check and a functional test must be performed on the prisma VENT AQUA unit. This is carried out using the maintenance and servicing manual.

13. Legend

	Application part, Type BF (B = Body; F = Floating applied part)
	Warning of a potential danger
REF 100.506	Symbol for Order No.
SN201500001	Manufacturer's serial number
CE 0197	CE mark with designated location
	Manufacturer
	Disposing of the appliance in accordance with the applicable regulations
	Protective insulation; Protection class II
IP22	Protection type
	Follow the instructions
	Warning - hot surface. Can cause burns.

	Connection for heating wire distribution cable (imprinted symbol on housing)
	Connection for temperature sensor cable (imprinted symbol on housing)
220-240V~	Operating voltage - 230V version
110-120V~	Operating voltage - 115V version
50/60Hz	Mains frequency
260VA	Volt Ampere electric power
	Fuse for 230V version
	Fuse for 115V version
	Changing of levels (humidification levels)
	Current humidification value
	Display of operating modes and alarms

Identification plates depending on the version

14. Technical specifications

Before commissioning, the correspondence of the voltage with the operating voltage specified on the identification plate must be checked.

Dimensions	○ Height: 142 mm ○ Width: 150 mm ○ Depth: 200 mm
Weight	prisma VENT AQUA humidifier: approx. 2.3kg approx. 2.5kg incl. delivery accessories

classification	○ Device (protection class under IEC 60601) Class II
	○ Application parts, Type BF:
	  ○ heated/unheated breathing tube system
	  ○ Temperature probe
	○ Protection by housing IP22 (protected against solid bodies with diameters greater than 12.5 mm, protected against finger access, protected against falling drip water, if the housing is inclined up to 15°.)

Electrical specifications	○ Operating voltage: prisma VENT AQUA 100506 220V~ – 240V~ prisma VENT AQUA 100507 110V~ – 120V~ ○ Mains frequency: 50Hz / 60Hz ○ Power consumption: 260VA max ○ Heating plate: 170W ○ Inspiratory tube heating: 22V~ , 30W

Operating data	○ Warm-up time:	max. 30min., regularly 10-15min
	○ Recommended flow rate:	5 to 60l/min
	○ Humidifier system output:	> 10mg/l in range 5 - 60l/min
	○ Maximum operating pressure:	200mbar(1)
	○ Continuous noise:	< 50dB (1m)
	○ Decibel level of alarms:	max. 65dB
	○ Max. volume of water:	200 ml
humidification system	○ Gas leakage at max. operating pressure:	< 10 ml/min(2)
	○ Gas leakage at 60mbar:	< 5 ml/min(2)
	○ Pressure drop:	< 0.02 (mbar*min)/l(2)
	○ Internal Compliance:	Minimum 1.0 ml/mbar(2) Maximum 2.0 ml/mbar(2)

Environment	○ Temperature	
	during operation:	+18°C – +28°C
	during storage and transport:	-25°C – +70°C
	○ Gas inlet temperature:	+18°C – +28°C[3]
	○ Humidity	
	during operation:	15 – 93% non-condensing
	during storage and transport:	15 – 93% non-condensing
	○ Atmospheric pressure	
	during operation:	700hPa – 1060hPa
	during storage and transport:	500hPa – 1200hPa

The humidification performance decreases if the therapy device delivers breathing gas at a higher temperature!

Measurement range	○ Temperature sensor:	9.5°C – 50°C (nearest the patient) 5°C – 80°C (humidification chamber)
Use area	○ Heated / unheated Breathing tube system	
	○ Temperature probe	

[1] Unless the instructions for use of the humidification chamber used require lower maximum pressures.

[2] Depending on the humidification chamber used and the breathing tube system used. Data refer to the heated 22 mm system with humidification chamber (271.705).

[3] The maximum gas output temperature of the therapy device at 23°C room temperature is 32°C.

15. Storage and disposal

- Clean unit before storing and store it in a plastic bag.
- Loosely wind up the temperature probe and heating wire adapter.
- The permissible storage temperature is from -25°C to + 70°C.
  Prior to use, the device must be acclimatized and may be put into operation only after reaching the ambient temperature.

To preserve and protect the environment, to prevent environmental pollution, and to enable recycling of raw materials, the European Commission has determined that electrical and electronic equipment shall be taken back by the manufacturer for their proper disposal. The devices with the symbol "Not for disposal in municipal waste" may not be disposed in the unsorted municipal waste.

16. Supplement to the technical description

The prisma VENT AQUA measures the breathing gas temperatures at the outlet of the humidification chamber and the output of the breathing tube system nearest the patient. (HWT mode)

The fuses on the primary side are accessible from the bottom of prisma VENT AQUA.

17. EMC proof

Guidance and manufacturer's declaration - electromagnetic emissions

The prisma VENT AQUA is intended for operation in an environment as specified below. The customer or user of the prisma VENT AQUA should ensure that it is operated in such an environment.

Emission measurements	Conformity	Electromagnetic environment - Guidelines
HF emissions according to CISPR 11	Group 1	The prisma VENT AQUA uses HF energy only for its internal functioning. Therefore, HF emissions are very low and it is unlikely that nearby electronic devices will be disturbed.
HF emissions according to CISPR 11	Class B	The prisma VENT AQUA is suitable for use in the residential area directly connected to a public supply grid that also supplies buildings used for residential purposes.
Harmonics according to IEC 61000-3-2	Satisfied	
Voltage fluctuations / flicker according to IEC 61000-3-3	Satisfied	

Guidance and manufacturer's declaration - electromagnetic immunity to interference

The prisma VENT AQUA is intended for operation in an environment as specified below.
The customer or user of the prisma VENT AQUA should ensure that it is operated in such an environment.

Checks for immunity to interference	IEC 60601 – test level	Conformity level	Electromagnetic environment - Guidelines
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 8kV contact discharge ± 15kV air discharge	± 6kV contact discharge ± 8kV air discharge	Floors should be made of wood, concrete or ceramic tile. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Fast transient electrical interferences / bursts according to IEC 61000-4-4	± 2kV for power lines 100kHz repeat frequency	± 2kV for power lines 100kHz repeat frequency	The quality of the supply voltage should be typical for business or hospital environment
Voltage fluctuations (Surges) according to IEC 61000-4-5	± 1kV Differential mode voltage ± 2kV Common mode voltage	± 1kV Differential mode voltage ± 2kV Common mode voltage	The quality of the supply voltage should be typical for a business or hospital environment.

Voltage dips, short interruptions and voltage variations according to IEC 61000-4-11	0% U_T; ½ period At 0, 45, 90, 135, 225, 270 and 315 degrees 0% U_T; 1 period and 70% U_T; 25/30 period Single-phase: at 0 degrees 0% U_T; 250/300 period	0% U_T; ½ period At 0, 45, 90, 135, 225, 270 and 315 degrees 0% U_T; 1 period and 70% U_T; 25/30 period Single-phase: at 0 degrees 0% U_T; 250/300 period	The quality of the supply voltage should be typical for business or hospital environment
Magnetic field with supply frequency (50/60 Hz) according to IEC 61000-4-8	30A/m	30A/m	Magnetic fields at the mains frequency should correspond to the typical values as they are found in a business and hospital environment,

Guidance and manufacturer's declaration - electromagnetic immunity to interference

The prisma VENT AQUA is intended for operation in an environment as specified below. The customer or user of the prisma VENT AQUA should ensure that it is operated in such an environment.

Radiation resistance	IEC 60601 – test level	Conformity levels	Electromagnetic environment - Guidelines
Conducted HF interference according to IEC 61000-4-6	$3V_{eff}$ 150 kHz to 80 MHz	3V	Portable and mobile radio equipment including cables should not be operated within a shorter distance to the prisma VENT AQUA than the recommended separation distance calculated according to that which applies to the transmission frequency. Recommended separation distance: $d = 3.5/3 \sqrt{P}$ $d = 3.5/3 \sqrt{P}$ 80 MHz to 800 MHz $d = 7/3 \sqrt{P}$ 800MHz to 2.5GHz where P is the rated power of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). The field strength of stationary radio transmitters should be less than the compliance level [b] at all frequencies in accordance with an on-site examination [a] . In the vicinity of equipment marked with the following symbol, interference is possible. 
	$6V_{eff}$ in ISM and amateur radio frequency bands between 0.15MHz and 80MHz	6V	
Radiated HF interference according to IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m 80 MHz to 2.7 GHz	
Radiated HF interference in the direct vicinity of wire-less communi-cations devices pursuant to IEC 61000-4-3	contained in Table 1	contained in Table 1	

Note 1: at 80 MHz and 800 MHz, the higher frequency range applies

Note 2: these guidelines may not always apply. The propagation of electromagnetic waves depends on the absorption and reflection of buildings, objects and people.

[a] The field strength of stationary transmitters, such as base stations of cordless telephones and land mobile radios, amateur radio, AM and FM radio transmitters and TV transmitters cannot be theoretically predicted with accuracy. To determine the electromagnetic environment of stationary transmitters, a study of the electromagnetic phenomena of the location should be considered. If the measured field strength at the site where the prisma VENT AQUA is used exceeds the above compliance level, the prisma VENT AQUA should be monitored to demonstrate proper function. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the prisma VENT AQUA.

[b] Over the frequency range 150 kHz to 90 MHz, the field strength should be less than 3V/m.

Table 1

Test frequency MHZ	Frequency band a MHz	Radio service a	Modulation b	Maximum power W	Distance m	Interference immunity test level
385	380 to 390	TETRA 400	Pulse modulation[b] 18Hz	1.8	0.3	27
450	430 to 470	GMRS 460, FRS 460	FM[c] ± 5kHz swing 1kHz sine	2	0.3	28
710 745 780	704 to 787	LTE Band 13, 17	Pulse modulation[b] 217Hz	0.2	0.3	9
810 870 930	800 to 960	GSM 800/900 TETRA 800, iDen 820, CDMA 850, LTE Band 5	Pulse modulation[b] 18Hz	2	0.3	28
1720 1845 1970	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3,4,25; UMTS	Pulse modulation[b] 217Hz	2	0.3	28

Test frequency MHZ	Frequency band a MHz	Radio service a	Modulation b	Maximum power W	Distance m	Interference immunity test level
2450	2400 to 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[b] 217Hz	2	0.3	28
5240 5500 5785	5100 to 5800	WLAN 802.11 a/n	Pulse modulation[b] 217Hz	0.2	0.3	9

NOTE

If necessary, to achieve the interference immunity test level the distance between the transmitter antenna and the ME device or ME system can be reduced to 1 m. The 1 m test distance is permitted under IEC 61000-4-3.

[a] For some radio services, only the frequencies for the radio connection from the communication device to the base unit (en: uplink) were included in the table.

[b] The carrier must be modulated with a square wave signal with 50% duty cycle.

[c] As an alternative to frequency modulation (FM), pulse modulation with 50% duty cycle with 18Hz can be used, since this, although not the actual modulation, would nevertheless represent the worst-case scenario.

Recommended separation distances between portable and mobile HF communications equipment and the prisma VENT AQUA.

The prisma VENT AQUA is intended for use in an electromagnetic environment in which HF disturbances are controlled. The customer or user of the prisma VENT AQUA can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile HF communications equipment (transmitters) and the prisma VENT AQUA - depending on the output of the communication device as indicated below.

Rated capacity of the transmitter W	Separation distance depending on frequency of transmitter in m		
	150 KHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For the transmitters whose nominal power is not specified in the above table, the distance can be determined using the equation for the respective column, where P is the nominal power of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: at 80MHz or 800MHz, respectively, the separation distance of the higher frequency range applies

Note 2: these guidelines may not always apply. The propagation of electromagnetic waves depends on the absorption and reflection of buildings, objects and people.

Additional notes

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