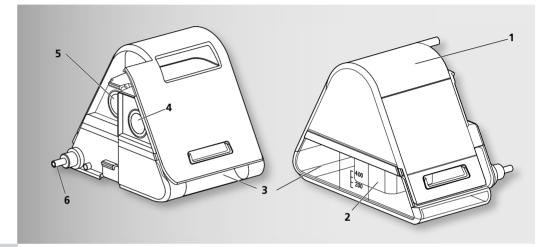
**DE** Gebrauchsanweisung **EN** Instructions for Use **FR** Mode d'emploi **NL** Gebruiksaanwijzing **IT** Istruzioni d'uso **TR** Kullanma Kılavuzu **ES** Manual de instrucciones



WM 68250e 06/2017 DE, EN, FR, NL, IT, TR, ES-MX

CE 0197

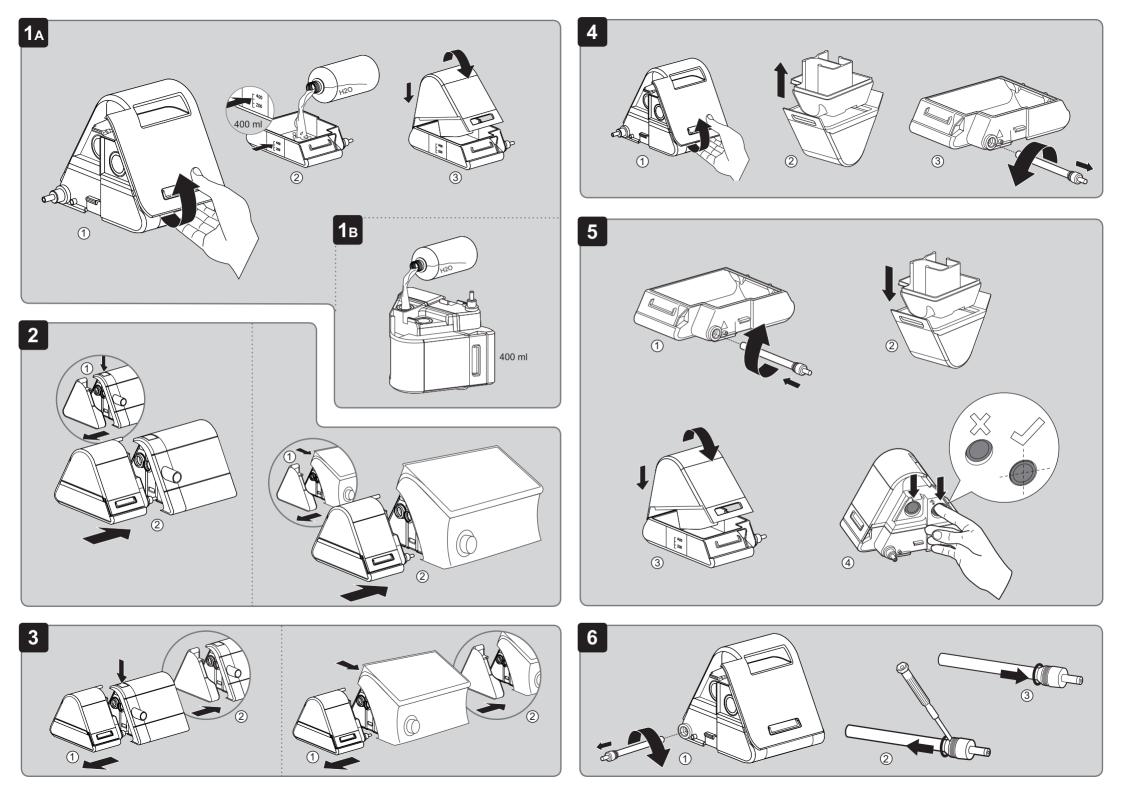
#### Löwenstein Medical Technology GmbH + Co. KG Kronsaalsweg 40 22525 Hamburg, Germany T: +49 40 54702-0 F: +49 40 54702-461 www.loewensteinmedical.de

# prismaAQUA Humidifier









)	
Power capacity	Max. 30 VA (only in combination with the approved device)
Classification to EN 60601-1-11: type of protection against electric shock	Protection class II
degree of protection against electric shock	Type BF
protection against damaging ingress of water and solids	IP22
Classification to DIN EN 60601-1: op- erating mode	Continuous duty
Electromagnetic compatibility (EMC) to DIN EN 60601-1-2	
radio interference suppression radio interference immunity (Test parameters and limit values can be obtained from the manufacturer on request)	PEN 55011 B IEC 61000-4 Parts 2 to 6, Part 11, Part 8 EN 61000-3 Parts 2 and 3
Heating of respiratory air	Max. +3 °C
Humidification system output to ISO 8185 at humidifier stage 7 without heatable tube at 23 °C	
- 5 hPa (12.2 l/min) - 10 hPa (18 l/min) - 20 hPa (25.9 l/min)	22 mg/l 23 mg/l 20 mg/l
Humidification system output to ISO 8185 at humidifier stage 7 with heatable tube at 23 °C	
- 5 hPa (12.2 l/min) - 10 hPa (18 l/min) - 20 hPa (25.9 l/min)	27 mg/l 28 mg/l 21 mg/l
Max. filling volume	400 ml
Pressure drop	Pressure drop does not increase as a result of combining therapy de- vice WM 100 TD with humidifier WM 100 TH.
Maximum flow	248 l/min
Max. permissible operating pressure	50 hPa
Gas leak at max. operating pressure	0.0 l/min
WM 100 TH can be combined with	WM 090 TD WM 100 TD WM 110 TD WM 120 TD

The right to make design modifications is reserved

For information about warranty conditions, see the Instructions for Use for your therapy device.

11 Warranty

12 Declaration of conformity

For information about the declaration of conformity, see the Instructions for Use for your therapy device.

#### **Operation/key** 1

See the figures for how to fill, connect and remove the humidifier:

- **1** Filling the humidifier
- **1**<sup>B</sup> Filling the humidifier (alternative to **1**<sub>A</sub>)
- 2 Connecting the humidifier
- 3 Removing the humidifier
- 4 Dismantling the humidifier
- 5 Assembling the humidifier
- 6 Replacing the heater rod seal

### Making humidifier settings on the therapy

**device:** operation differs depending on the therapy device used. Follow the Instructions for Use for your therapy device.

#### 2 Introduction

## 2.1 Intended use

Humidifier WM 100 TH warms and humidifies respiratory air and so prevents the mucous membranes in the respiratory tract from drying out. It can be used in clinical facilities and in the domestic sphere.

## 2.2 Description of function

The heatable humidifier operates in accordance with the "pass-over" principle. The air supplied is passed over the surface of warm water. This increases the relative humidity and the temperature of the air flow. Heating capacity can be set on the therapy device in stages.

## 2.3 Indications

Dry upper airways and respiratory air perceived to be too cold. prismaAQUA may only be used in accordance with a physician's recommendation.

## 2.4 Contraindications

The humidifier may not be used on patients whose upper airways have been bypassed.

## 2.5 Side effects

No side effects are known

#### Safetv 3

Please read these Instructions for Use carefully. They are a constituent part of the humidifier and must be available at all times. In accordance with Directive 93/ 42/EEC, observe the points below.

## Risk of infection from germs in stale water!

Germs and bacteria can easily colonize and multiply in stale water.

- $\Rightarrow$  Clean the humidifier regularly.
- $\Rightarrow$  Only use the humidifier with fresh water.

#### Risk of harm from operating the device outside the specified ambient conditions

Using the device outside the specified ambient conditions may lead to tolerances being exceeded and to device failure and harm the patient.

 $\Rightarrow$  Only operate the device within the specified ambient conditions (see "10 Technical data").

## Material damage from overfilling!

Escaping water may run into the device and damage it.

- $\Rightarrow$  Take the humidifier off the device before filling it.
- $\Rightarrow$  Only fill the humidifier up to the "max." mark.

### Material damage from hot water and aromatic additives!

Hot water or aromatic additives (such as eucalyptus oil) may damage the housing of the humidifier and the heater rod.

- $\Rightarrow$  Do not fill with hot water.
- $\Rightarrow$  Do not use any aromatic additives.

## 3.1 General information

- In the domestic sphere, sterile or boiled water need only be used in exceptional medical cases. Do not use distilled water intended for technical purposes as it may be microbiologically contaminated.
- To prevent infection, bacterial contamination or functional impairments, follow the instructions in the section entitled "Hygiene treatment" (see "5 Hygiene treatment").
- ٠ If third-party items are used, functional failures and restricted fitness for use may result. Biocompatibility requirements may also not be met. In such cases, please be aware that any claim under warranty and liability will be void if neither the accessories nor the genuine replacement parts recommended in the Instructions for Use are used.

Ц WM 68250e 06/2017

## EN

# 4 Product description

## 4.1 Overview

A diagram of the individual parts can be found on the fold-out page.

### Key

- 1. Upper part of humidifier
- 2. Humidifier insert
- 3. Lower part of humidifier
- 4. Inlet opening
- 5. Outlet opening
- 6. Heater rod

## 4.2 Marks and symbols

Position	Symbol	Description
4		Fill with water.
6		Humidifier is heating. Do not touch heater rod.

## 4.3 Symbols on the device ID plate

X	Do not dispose of device in domestic waste
C€ 0197	CE symbol (confirms that the product con- forms to the applicable European direc- tives).
32 V DC	32 V direct voltage
Ŕ	Application part type BF
IP22	IP protection class Degree of protection against solid foreign bodies. Device is pro- tected against drips.
>PC<	Material designation: polycarbonate
M	Date of manufacture (month/year)
Type: WM100TH	Type designation: Device of the WM 100 TH type
	Follow Instructions for Use.
SN	Serial number

## 5 Hygiene treatment

Clean - or in the clinical sphere disinfect - the humidifier weekly. If necessary, descale the humidifier (see "5.1 Descaling the humidifier"). Replace housing parts if they are in poor condition (cracked). If the therapy device or the humidifier have been used without a bacteria filter, the specialist dealer must perform a professional hygiene treatment on change of patient.

# **WARNING**

## Risk of injury from hot heater rod!

During and shortly after operation, the heater rod is hot and touching it can lead to burns.  $\Rightarrow$  Allow the heater rod to cool down completely.

- 1. Dismantling the humidifier (Fig. 4).
- Subject the humidifier to a hygiene treatment in accordance with the table below. Sterilizing is not permitted.

Part	Cleaning	Disinfecting	
Lower part of humidifier	With hot water and deter- gent. Recommended: wash weekly in the top basket of a dishwasher (max.	Disinfect by immersion (recommended: gigasept FF <sup>®</sup> ) / boil for 5 minutes	
Humidifier insert	65 °C). If necessary: descale (see 5.1)	Boil for 5 minutes	
Upper part of humidifier	Wipe down: use water or mild detergent; do not use microfiber cloth	Disinfect by wiping (recommended: terralin <sup>®</sup> protect / perform advanced Alcohol EP)	
Heater rod	If necessary: descale (see 5.1)	Disinfect by im- mersion (recommended: gigasept FF <sup>®</sup> ) Disinfect by spraying (recommended: perform advanced) or boil for 5 minutes	
Rinse off parts with clean water and dry.			

- Rinse off parts with clean water a
  Perform a visual inspection.
- 5. If necessary: replace damaged parts.
- 6. Assembling the humidifier (Fig. 6).

## 5.1 Descaling the humidifier

- Remove the humidifier from the therapy device (Fig. 4).
- 2. Dismantle the humidifier (Fig. 4).
- 3. Pour 300 ml pure household vinegar (5 % solution without additives) into the lower part of the humidifier.
- Put the humidifier insert in bowl of pure household vinegar (5 % solution without additives). Humidifier insert must be completely covered with vinegar.
- 5. Leave vinegar to take effect for 1 hour.
- 6. Rinse off the lower part of the humidifier, the heater rod and the humidifier insert with clean water.
- 7. Carefully dry the lower part of the humidifier, the heater rod and the humidifier insert.
- 8. Assemble the humidifier (see Fig. 5)

# 5.2 Replacing the heater rod seal (Fig. 6)

- 1. If necessary: allow the heater rod to cool down completely.
- 2. Unscrew the heater rod.
- 3. Replace the sealing ring.
- 4. Put the heater rod back in.

## 6 Function check

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

- 1. Check housing parts for cracks and damage. If necessary: replace damaged parts.
- Fill humidifier with water up to the mark (see Fig.
  or 1B)
- 3. Check whether the humidifier has any leaks. If necessary: replace damaged parts.
- 4. Fill humidifier with 200 ml water.
- 5. Connect the humidifier to the therapy device and switch on.
- 6. Set heating capacity to the highest stage.
- 7. Check whether the humidifier is heating up.
- 8. If the humidifier does not heat up slightly after 10 minutes: contact your specialist dealer.

# Troubleshooting

Fault	Cause	Remedy
Humidifier does not	Humidifier stage switched off.	Set humidifier stage.
warm up.	Humidifier is faulty.	Have humidifier repaired.
	Heater rod seal is faulty.	Replace seal (see 5.2).
Humidifier is	Humidifier insert is not inserted correctly.	Insert humidifier insert correctly.
leaking.	Humidifier insert is faulty.	Replace humidifier insert.
	Cracks in lower part of humidifier.	Replace lower part of humidifier.
Humidifier switches off.	Humidifier is empty.	Fill humidifier with water.

# 8 Servicing

If used in accordance with purpose (see "2.1 Intended use") the humidifier requires no servicing.

# 9 Scope of supply

prismaAQUA, black - WM 29680 prismaAQUA, white - WM 29490

# 9.1 Accessories and replacement parts

You can order accessories and replacement parts separately if necessary. You can order a current list on the Internet or via your specialist dealer.

## 10 Technical data

Product class to 93/42/EEC	lla
Dimensions W x H x D in cm	14 x 13.5 x 18
Weight (without water)	0.6 kg
Temperature range operation storage Permitted humidity for operation and storage	+5 °C to +37 °C -25 °C to +70 °C 15 % to 93 %, no condensation
Air pressure range	600 hPa - 1100 hPa, corresponds to an alti- tude of 4000 m above MSL