

Humidifier

User Manual

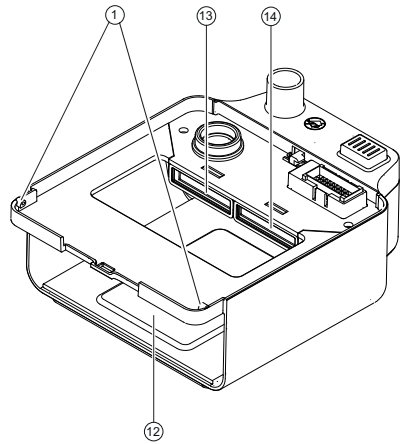
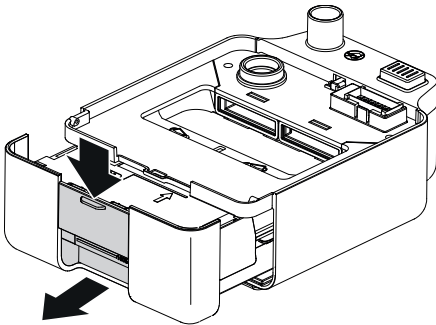
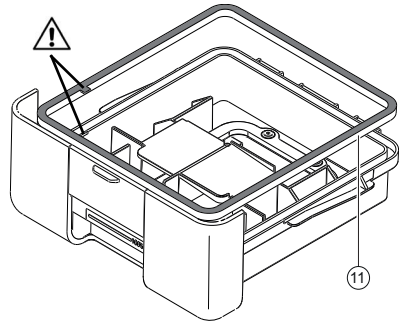
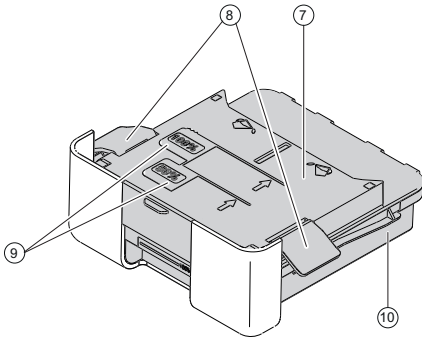
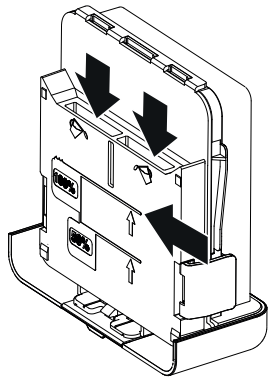
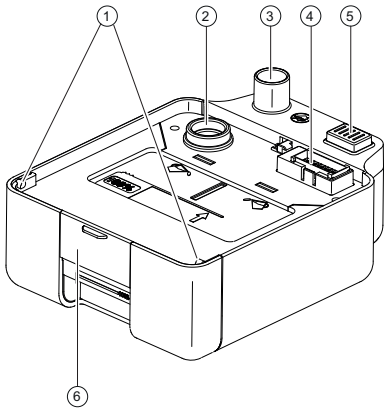


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1. INTRODUCTION

Please read the complete user manual carefully before using the Heated Humidifier as well as keep this manual for future reference.

The humidifier is compatible to use with the therapy device **Cube 30 ATV** which is validated with 28V humidifier from **JFR Medical**. All the function and setting instructions can be found in the manual of the therapy device.

Do not use the humidifier with any other therapy device.

1.1 Functionality

The humidifier is designed to moisten the air delivered from the therapy device through heated water, to increase patient comfort and compliance with the therapy. It can be operated by the patient and clinician in combination with a compatible therapy device. Please refer to the user manual of the therapy device for instructions.

1.2 Indications For Use

The humidifier is for use only as recommended by a physician to reduce the dryness of throat, nose and mouth. The humidifier cradle is multi-patient use provided that it is sterilized. **The humidifier water chamber is intended for single-patient use only.** This is to avoid the risk of cross-infection. The instructions from the clinician must be followed.

1.3 Contraindications

Classification:ISO 80601-2-74:Category II

The Heated Humidifier is **contraindicated for use with patients** whose upper airway has been bypassed.

Please refer to the instructions for use that accompanied your therapy device for any additional contraindications that may be specific to the use of that device.

Please contact with your clinician or healthcare provider for further question before using the humidifier.

2. IMPORTANT SAFEGUARDS

- Be sure to read and understand all safety instructions supplied with your therapy device.
- Replace the water chamber after **6 months** of use.
- The incompatible part can result in degraded performance of the humidifier.
- JFR Medical has no liability for the use of non-compliance with the safety instructions and the guarantee expires.
- The responsible organization is accountable for the compatibility of the device and all of the parts and accessories used to connect to the patient before use.



Danger

- Never open or remove parts from the humidifier cradle. There is a risk of electric shock.
- The equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.



Warning

- Do not use the humidifier if there is damage in any way.
- Do not add any attachments or accessories to the humidifier that are not listed in the instruction for use might not function correctly affecting the quality of the therapy or injuring the patient.
- Never block the air openings of the cradle or chamber. Do not insert any objects into any opening or tubes.
- Use the humidifier under the described operating conditions in the technical specification.
- Never operate the humidifier if any parts are damaged, if it is not working properly, or if the humidifier has been dropped or mishandled. Have any damaged parts replaced before continuing use.



Caution

- Do not place the device in or on any container that can collect or hold water.

- Repairs and adjustments must be performed by JFR Medical authorized service personnel only.
- Use only the respiratory tubing which applies to ISO 5367.
- Only use the water chamber from JFR Medical with your humidifier cradle. The use of other components may damage the device or interfere with the therapy.
- Use only the sealing gasket from JFR Medical.
- Please follow the hygiene guidelines of your physician or healthcare provider and use a bacterial filter if necessary which applies to DIN EN ISO 23328-1/23328-2 with your therapy.
- Do not move the device during operation.

3. PARTS OVERVIEW

The illustrations can be found at the beginning of this manual.

HUMIDIFIER CRADLE

1. Holding fence
2. Air inlet of the humidifier
3. Air outlet
4. Connection socket for the therapy device
5. Release button
6. Unlocking handle to the water chamber

WATER CHAMBER

7. Cover for water chamber
8. Locking clamps
9. Level indicator
10. Water bowl
11. Sealing gasket

BOTTOM OF HUMIDIFIER CRADLE

12. Heating plate
13. Air outlet of the water chamber
14. Air inlet of the water chamber

4. ASSEMBLY

Place the therapy device on the humidifier cradle as shown in the instructions of your therapy device.

Note!

Read and understand the entire manual of your therapy device before attempting to use this humidifier.

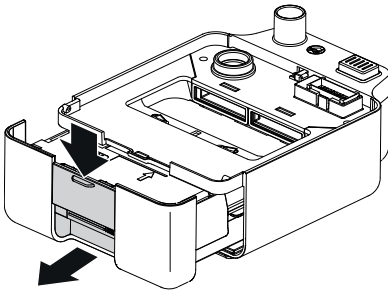
5. SET UP

The responsible organization is accountable for the compatibility of the device and all of the parts and accessories used to connect to the patient before use.

5.1 Filling The Chamber

Note!

Clean the water chamber before first use.



1.

Remove the water chamber from the humidifier cradle.

2.

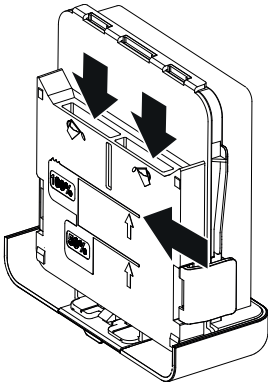
Hold the chamber upright and fill with distilled water to the maximum fill line 100%.

3.

Carefully tip the chamber water back to the level position. The water in the fill ports will flow into the chamber when it is tipped back to the level position.

4.

Slide the chamber back into the humidifier cradle. Ensure the chamber is fully engaged with the humidifier cradle and the unlocking handle to the water chamber in place when inserted.





Warning

- Do not fill the water chamber above the maximum fill line. If the water chamber is overfilled, water may leak into the therapy device, humidifier, or onto your furniture. Damage to the humidifier or therapy device may occur.
- Use only room temperature distilled water in the chamber. Do not put any chemicals or additives into the water. Possible airway irritation or damage to the water may result.
- Never touch the heating plate on the humidifier cradle. Never touch the heat transfer plate on the bottom of the water chamber. These plates can reach temperature as high as **65°C** during normal operation and **74°C** when a single failure occurs.
- The heating plate must be turned off from Humidifier Settings when the device is being used without water.
- Never place the device on a soft surface such as a bed or couch during operation. Do not position it where it may be stepped on when getting out of bed.
- The height of the system must always be lower than the interface mask during use to prevent water from getting into the mask.
- Covering breathing tubes with a blanket or heating them in an incubator or with an overhead heater can affect the quality of the therapy or injure the patient.

Caution

- Do not attempt to fill the water chamber while it is still inside the humidifier cradle.
- When installing the water chamber, do not allow any water to spill into the humidifier or therapy device.

Under normal condition, the humidification can last more than 8 hours with the setting of 10 hPa in CPAP mode, the heating level 5 and the water chamber filled.



5.2 Humidity Settings

The heating control and the status can be found on the display of the therapy device. Please refer to the relevant section in the user manual of your therapy device.

6. MAINTENANCE

Water Chamber

Clean the chamber daily.

Humidifier Cradle

The humidifier cradle should be cleaned weekly. Inspect the humidifier cradle for signs of wear or damage when cleaning.

6.1 Daily Cleaning

The humidifier is maintenance-free apart from cleaning.



Warning

- After turn off the heater or disconnect from power, allow the humidifier heat transfer plate and water to cool down for at least **10 minutes**. A burn may result from: touching the heat transfer plate, coming in contact with the heated water, or touching the heating plate.
- Clean the chamber daily. The chamber should be replaced according to the recommended schedule time of 6 months. Inspect the water chamber for signs of wear or damage when cleaning and replace if damaged.



Caution

- Do not clean the humidifier cradle in the dishwasher, thermal disinfectant or sterilizer! Damage to the device may occur. In addition to hand washing, the disassembled water chamber may also be washed in the dishwasher only on top shelf and in gentle or glass rinse cycle mode, the temperature should not more than 55°C with chemical detergents. Thermal disinfection is possible (e.g., cook for 5 minutes or steam disinfection).

1.

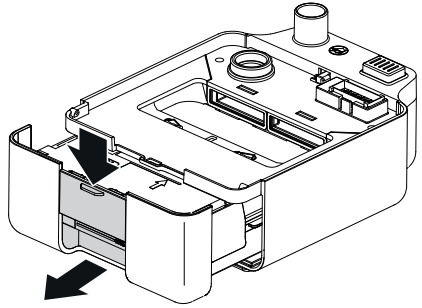
Turn off the heater.
(Allow the device to cool for at least 10 minutes.)

2.

Press down on the unlocking handle to the water chamber of the humidifier and remove the chamber from the cradle.

3.

Empty the water chamber and open the locking clamps on both sides and press the opening lever on the water chamber to separate both halves of the water chamber.



4.

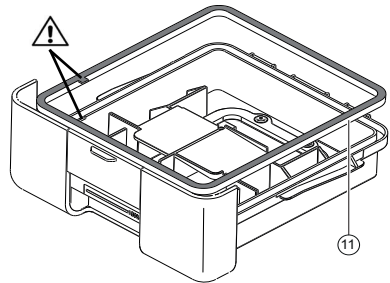
When required, the sealing gasket can be removed from the water bowl to the water chamber and washed by hand.

5.

Clean all parts of the water chamber with mild soapy water.

6.

Rinse all parts of the water chamber with clean water.



7.

Allow the individual parts to dry completely before reassembly.

8.

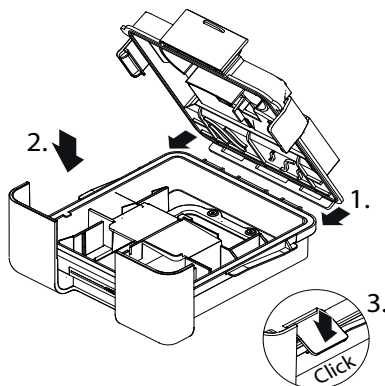
Insert the sealing gasket(11) into the groove on the water bowl. Inspect the fitting of the gasket to ensure it is fully in place and the sealing gasket handle is on the bottom left side.

9.

Snap the water bowl and cover together by inserting the tabs slightly on the bowl into the slots on the cover. Gently push down the cover and lock the water chamber with the clamps on both sides.

Note!

Inspect the sealing gasket(11) before each use to ensure that it is properly seated in the groove around the entire chamber and the sealing gasket handle is on the bottom left side.



Note! Use only mild soapy water to clean the components!



Warning

The humidifier must be hygienically prepared before used on another patient.

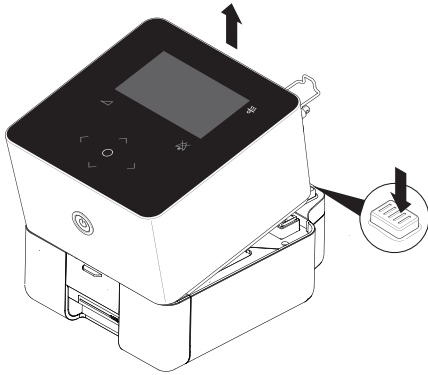


Caution

Do not use any solutions that contain bleach, chlorine, alcohol, scented oils or other aromatic-based ingredients to clean the humidifier components. These solutions may reduce the life of the product.

6.2 Weekly Cleaning

The humidifier cradle should be cleaned weekly.



1.

Turn off the heater.

(Allow the device to cool for at least 10 minutes.)

2.

Detach device from cradle, first remove water chamber then press therapy device release button.

3.

Wipe the cradle with clean and not much too damp cloth.

4.

Do not allow water to collect on the heating plate. Wipe it with a clean cloth if necessary.

5.

Put the therapy device back on the humidifier as soon as all parts dry.

Disinfecting

7. TRANSPORT

Note!

Do not move with the humidifier while the water chamber has water in it!

Disconnect the humidifier from the therapy device (if a therapy device is connected) and pack the humidifier and user manual in the carrying bag. The dry water chamber remains in the humidifier cradle during transport.

8. DISPOSAL

The **humidifier cradle** and the **water chamber** must not be disposed of with the household waste.

Please contact your authorised collection point or an authorised municipal authority waste disposal company for correct disposal or send the device back to your service partner.

The **packaging** can be disposed of with the normal household waste.

9. TROUBLESHOOTING



Caution

If you notice any unexplained changes in the performance of this device, if it is making unusual or harsh sounds, if it has been dropped or mishandled, or if the enclosure is broken, disconnect the mains cable from the therapy device and discontinue use. Contact your healthcare provider.

The table below lists some of the problems you may experience with your humidifier and possible solutions.

Problem	Possible Cause	Measure
The device reports a mask leak but my mask seems to be fitting well.	The humidifier chamber is not fully engaged or is missing.	Slide the humidifier chamber fully into the cradle. Verify the unlocking handle to the water chamber clicks into place.
	The silicone cover for air outlet is missing from the back of the device or not fully inserted.	Make sure the silicone cover for air outlet is fully inserted into the back of the device. Refer to Assembly in the manual of therapy device for instructions on system setup.
	The gasket seal between the two bowls of the water chamber is missing.	Insert the gasket seal into the water chamber. Follow the instructions for cleaning the water chamber.










The heater setting is not visible on the LCD display.	The therapy device is not fully seated onto the humidifier cradle.	Be sure the therapy device is properly placed on the humidifier. Refer to the instructions of therapy device in Assembly. If the problem continues, contact your healthcare provider.
Excessive condensation or water in tubing.	Humidification is too high.	Reduce humidifier heater setting.
	The humidifier is placed higher than the patient	Move unit to a lower position.
	Room temperature fluctuates from higher to lower levels through the night.	Increase room temperature.
	The humidifier chamber is overfilled.	Water level in chamber should not be above the maximum 100 % level.

Note!

For more information on troubleshooting your therapy device, see the manual included with your therapy device.

10. SYMBOL DEFINITION

Symbols on tape plate

Symbol	Meaning
	Manufacturer
	Date of manufacture
	Serial number
	Model number
	Alternating current
	Protection rating II
	Type BF - (Body Floating) In direct contact with patients for diagnosis, treatment or therapy. May NOT have direct contact with the heart.
IP21	Protection from: IP21 Protection against the ingress of solid foreign bodies ≥ 12.5 mm diameter and larger, and against vertically falling water droplets.
	CE declaration of conformity
	Medical device

Symbol	Meaning
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The product cannot be disposed of in domestic waste.

Symbols on the device

Symbol	Meaning
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Follow user instructions



Direct current

Symbols in the patient manual

Symbol	Meaning
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Danger

Urgent safety information for hazards that will cause serious injury or death.



Warning

Important safety information for hazards that might cause serious injury.



Caution

Information for preventing damage to the product.

Note!

Information to which you should pay special attention.

11. SCOPE OF DELIVERY

11.1 Standard scope of delivery

Part	Order number
Respiratory humidifier	P105
Water Chamber	P105E001

11.2 Spare Parts

Part	Order number
Sealing gasket	P105E002

12. TECHNICAL SPECIFICATIONS

Physical

Sizes, W x H x D:

168 mm x 100 mm x 217 mm

Weight:

440 g (Without water)

Operating conditions

Temperature range:

+ 5 °C to + 40 °C

Relative air humidity range:

15% to 90% non-condensing

Air pressure range:

790 hPa to 1060 hPa

Transport/storage conditions

Temperature range:

- 25 °C to + 70 °C

Relative air humidity range:

15% - 90% non-condensing

Air pressure range:

790 hPa to 1060 hPa

Heater power consumption:

28 W

Power supply:

Input range: 28 V

Maximum Recommended Pressure:

30 hPa

Maximum Pressure:

50 hPa

Water Capacity:	To maximum fill line 100%: 380 ml
Heater temperature:	Approximately + 40 °C to + 65 °C and + 74 °C when a single failure occurs
Maximum gas temperature:	+ 43 °C
Pressure Drop:	No pressure drop in humidifier.
Input air temperature:	+ 5 °C to + 40°C
Operating Mode:	Continuous operating
Product category in accordance with Regulation (EU) 2017/745 Annex VIII:	II a
Classification to IEC 60601-1:A2:2020 against electric shock:	BF type class II
IP protection class:	<p>IP 21 Protection from: IP 21 Protection against the ingress of solid foreign bodies \geq 12.5 mm diameter and larger, and against vertically falling water droplets.</p> <p>Note: <i>The IP 21 rating for the humidifier will only apply when it is used with the main device.</i></p>
<u>Guarantee</u>	
Humidifier cradle:	24 Months
Water Chamber:	6 Months
<u>Humidity Output</u>	
According to ISO 80601-2-74 on 23°C without heated tube:	- 5 hPa (12 l/min) = 18 mg/l - 10 hPa (18 l/min) = 15 mg/l - 20 hPa (28 l/min) = 13 mg/l
Expected operating life:	Humidifier cradle: 5 Years Water chamber: 6 months

The humidifier is validated to use with the Cube 30 ATV therapy device, which is compatible with the 28 V humidifier from JFR Medical.

Note! *Actual average power consumption will vary depending on factors such as temperature setting, set pressure, the use of accessories, height above sea level and ambient temperature.*



JFR Medical Instruments GmbH

Wasserwaage 8, 24226 Heikendorf, Germany
T: +49 431 - 7298 740-0, F: +49 431 - 7298 740-9
E: info@jfr-gmbh.de
Customer Service:

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