

User Manual for Breas HA 20 Humidifier

BREAS



Manufacturer:
Breas Medical AB
Företagsvägen 1
SE-435 33 Mölnlycke
SWEDEN
Phone: +46 31 86 88 00
Fax: +46 31 86 88 10
E-mail: breas@breas.com
Web: www.breas.com

CE 0123

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1 Intended use of the HA 20 Humidifier



- Read this manual thoroughly so that you completely understand how the HA 20 Humidifier is operated and maintained before taking it into use, to ensure correct usage, maximum performance and serviceability.
- Also read the Breas breathing therapy equipment manual, before you install the HA 20 Humidifier.



Breas Medical AB reserves the right to make changes to this product without any prior notification.

1.1 What is the HA 20 Humidifier?

The Breas HA 20 is an integrated humidifier intended to increase the breathing comfort for patients using Breas breathing therapy equipment. It is connected to the Breas iSleep or Vivo device through a smooth click-on design.

Under normal conditions, the nose and the airways keep the air we breathe in sufficiently humid. When using a CPAP device or ventilator, the normal humidification may not be sufficient. When the air you breathe in is too dry, you may suffer from dryness of the nose, throat or mouth, and from mucus build up, which in turn may cause pain, irritation or infection. Humidified air may relieve these symptoms of dry airways.

1.2 Indications for Use

The HA 20 Humidifier is intended to humidify the patient air during breathing therapy. It is intended for non-invasive use only.

The HA 20 Humidifier can only be used together with the following breathing therapy equipment:

- Breas CPAP devices: iSleep 20, iSleep 20+, iSleep 20i, iSleep 22, and iSleep 25
- Breas Bilevel ventilators: Vivo 30 and Vivo 40

It must always be prescribed by a licensed physician.



For complete instructions on how to set up the humidifier, refer to the Breas breathing therapy equipment manual.

1.3 Contraindications

The HA 20 Humidifier must not be used with patients whose supraglottic airways have been bypassed.



Refer to the Breas breathing therapy equipment manual for a complete list of contraindications associated with breathing therapy.

1.4 About this Manual

Icons

In this manual, icons are used to highlight specific information. The meaning of each icon is explained in the table below.

ICON	EXPLANATION
	Warning! Risk of serious personal injury.
	Caution! Risk of minor or moderate injury. Risk of equipment damage, loss of data, extra work, or unexpected results.
	Note Information that may be valuable but is not of critical importance, tips.
	Reference Reference to other manuals with additional information on a specific topic.

2 Safety Information

2.1 General User Precautions



- The HA 20 Humidifier must only be used:
 - for the intended treatment in accordance with this manual and with the instructions given by the responsible clinical personnel;
 - in accordance with the operating conditions specified in this manual;
 - in original and unmodified shape and only with accessories specified or approved by Breas Medical AB.
- Do not use the HA 20 Humidifier if the patient's upper (supraglottic) airways have been bypassed.
- Never operate the HA 20 Humidifier if it is not working properly, if any part of the humidifier has been dropped or damaged, or the heating unit has been submerged in water. In the event of suspected damage to the HA 20 Humidifier, do not use the humidifier and contact the responsible care provider or service provider for an inspection.
- The installed HA 20 Humidifier must be located below the patient and on a flat surface. This is to prevent personal injury from accidental spillage or from excess water or condensation flowing down the patient tube and into the patient's mask. Extra cautions should be taken for patients who are unable to guard their airways or cannot pull off the mask.
- Periodically check for moisture in the patient circuit. When present, remove the moisture. Before attempting to dry the circuit, disconnect it from the HA 20 Humidifier to ensure no water back-flow into the humidifier. The frequency at which these checks must be performed will depend on the patient's own condition and the device used. This should be assessed on an individual basis in accordance with the patient's needs.
- If the condensation in the patient circuit is excessive, the use of a heated humidifier may require the installation of a water trap in the circuit. The water trap prevents any condensation in the patient circuit from running into the patient airways and causing personal injury.
- Do not connect any filter to the HA 20 Humidifier.



- Handle the HA 20 Humidifier with care.
- To avoid burn injury, be careful not to touch the heater plate or the heated water in the water chamber when the HA 20 Humidifier is switched on or has not yet cooled down. Wait ten minutes for the heater plate and water to cool.
- Before transportation of the Breas breathing therapy equipment with the installed HA 20 Humidifier, always disconnect the water chamber from the heating unit.
- Do not place the Breas breathing therapy equipment with the HA 20 Humidifier in a bag when the water chamber is attached.
- Do not use aromatic additives (such as scented oil or perfume) with the water, as they may reduce the humidification effect and cause deterioration of the water chamber.

2.2 Electrical Safety



When handling the HA 20 heating unit, always turn off and disconnect the Breas breathing therapy equipment from any power source.

2.3 Environmental Conditions



- The performance of the HA 20 Humidifier may deteriorate at:
 - ambient temperatures below 5°C (41°F) and above 40°C (104°F).
 - ambient relative humidity below 10% RH (room humidity) and above 95% RH.
 - atmosphere pressure below 700 mbar and above 1060 mbar. At normal atmospheric pressure, 700 mbar = ~3000 metres above sea level, 1060 mbar = ~375 metres below sea level.
- The HA 20 heating unit, water chamber and any replaced parts must be disposed of in accordance with the local environmental regulations regarding the disposal of used equipment and waste.

2.4 Cleaning and Maintenance



- The HA 20 heating unit and water chamber shall be cleaned and maintained in accordance with this manual.
- Do not under any circumstances attempt to service or repair the HA 20 Humidifier yourself. If you do so, the manufacturer will no longer be responsible for the performance and safety of the humidifier.



HA 20 Heating Unit

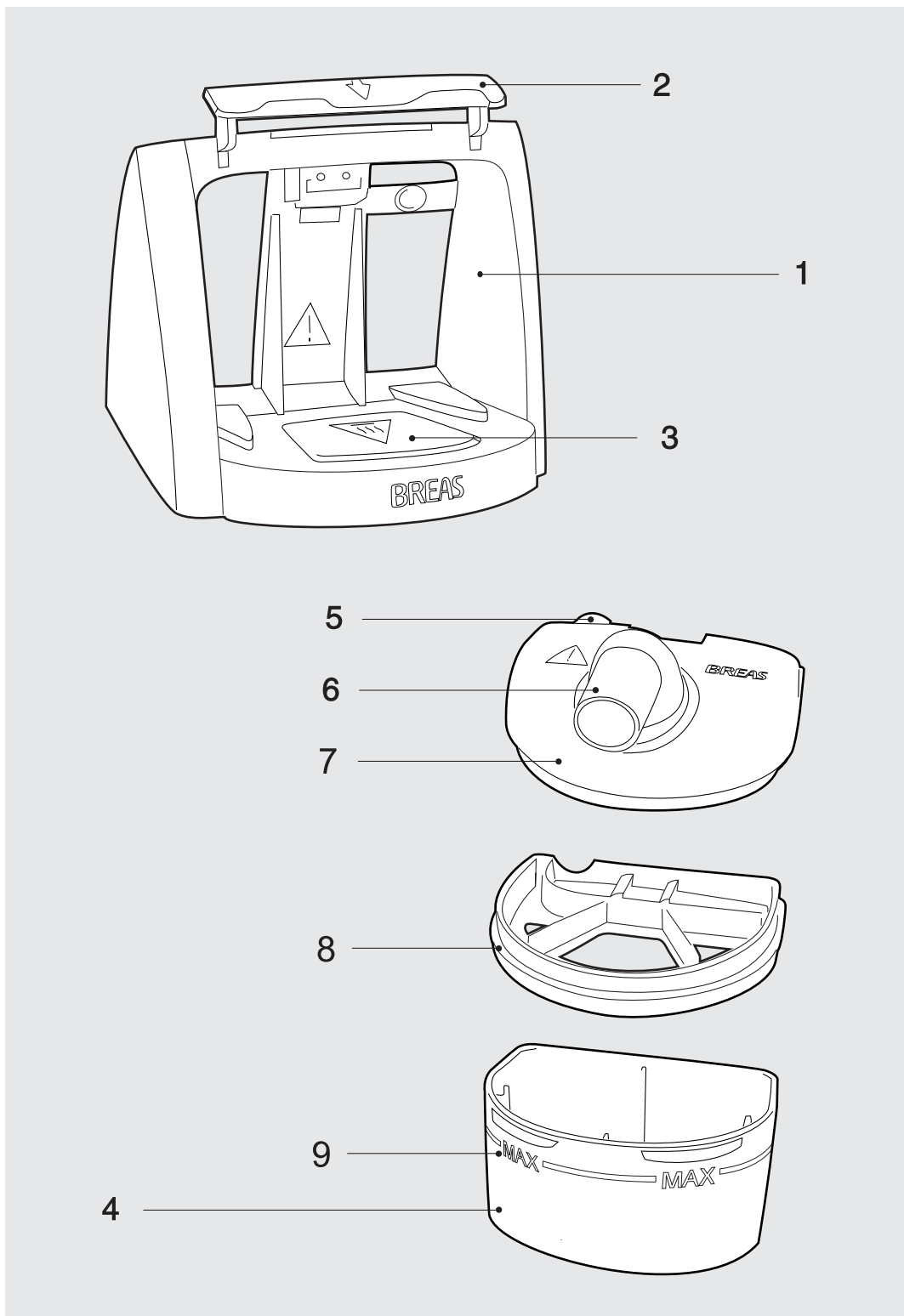
- Do not place or drop the HA 20 heating unit into water or other liquid.
- Do not attempt to autoclave or sterilise the HA 20 heating unit.

HA 20 Water Chamber

- The recommended maximum usage period of the HA 20 water chamber is 12 months. Deficient cleaning may lead to impaired performance.
- Do not attempt to autoclave the HA 20 water chamber.

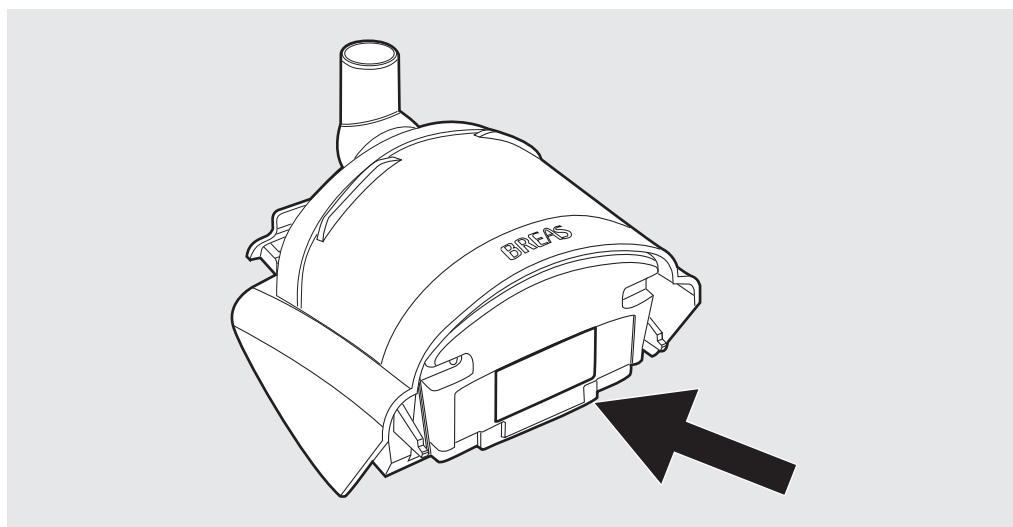
3 Product Description

3.1 Components



No.	COMPONENT	FUNCTION
1	HA 20 heating unit	Used for docking the water chamber to the Breas CPAP or ventilator. Contains the electric heater.
2	Locking mechanism	Locks the water chamber to the heating unit.
3	Heater plate 	Heats the water in the water chamber. Risk of burn during operation and up to ten minutes after use.
4	HA 20 water chamber	Contains water used for humidifying the patient's air.
5	Air inlet	From the Breas CPAP or ventilator to the humidifier's water chamber.
6	Swivel	Connects the water chamber to the patient circuit.
7	Cover	Covers the water chamber.
8	Cover seal	Used for sealing the cover and water chamber. Prevents leaks.
9	Max 	Marking the maximum level of water.

3.2 Equipment Designation and Safety Label



SYMBOL	EXPLANATION
	Model designation
	Serial number (the last six alphanumeric characters)
	Class II electrical equipment; dual isolation
	Body floating (Type BF, Isolated Applied Part according to IEC 60601-1)
	Read the user manual thoroughly before connecting the HA 20 Humidifier to the patient.
	CE marking applies in accordance with the directive MDD 93/42/EEC.
	The unit may be returned to Breas Medical AB for scrap- ping and should not be discarded with the household waste.

4 Installing the HA 20 Heating Unit

If installing the HA 20 Humidifier for the first time, check that all the humidifier components have been delivered and that they are in good condition (refer to the packing note or the invoice, if available).

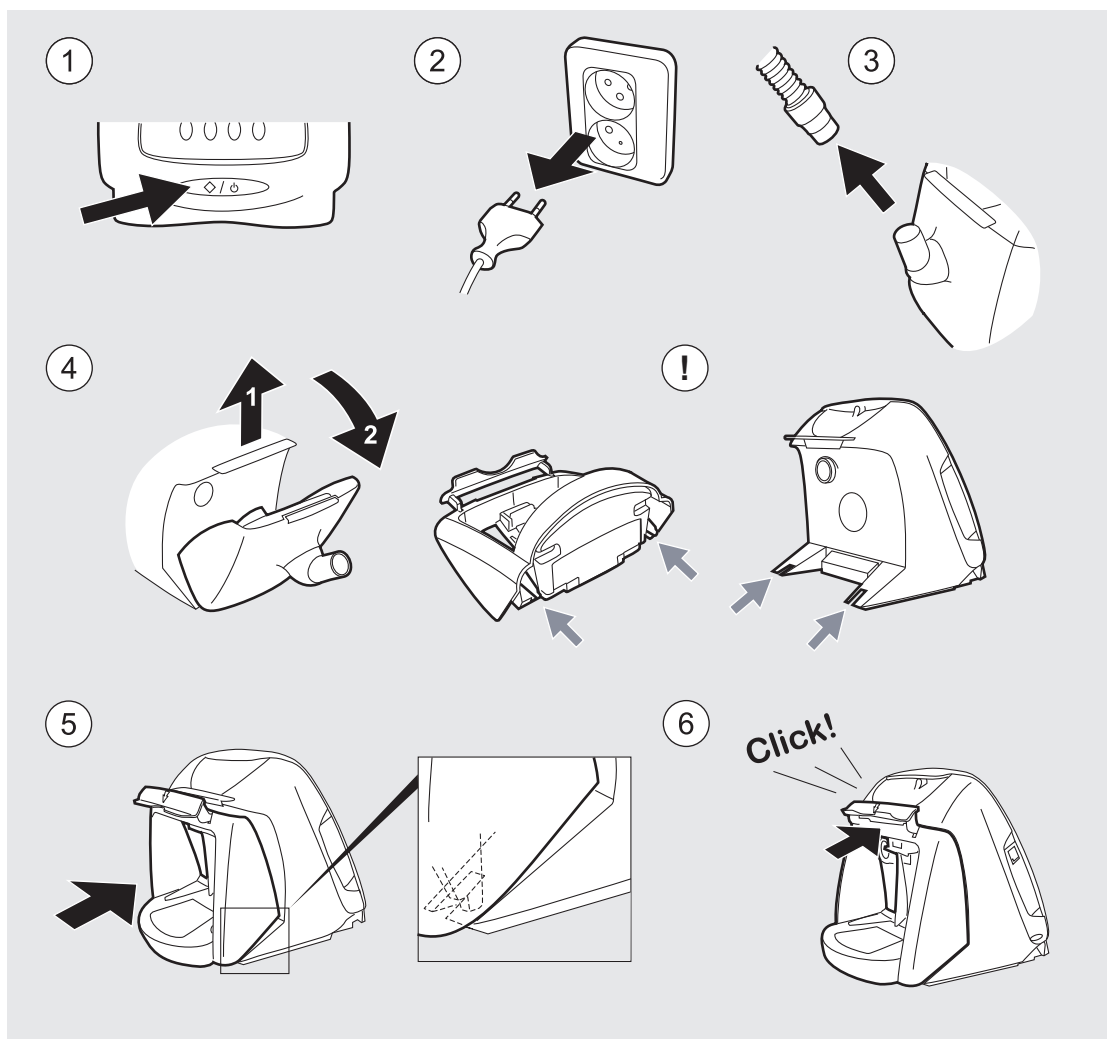


- Always turn off the Breas breathing therapy equipment and disconnect the mains supply before attaching or detaching the HA 20 heating unit.
- Do not switch on the HA 20 Humidifier without a filled water chamber connected to the heating unit, in order to avoid burn or damage to the humidifier's electronics.

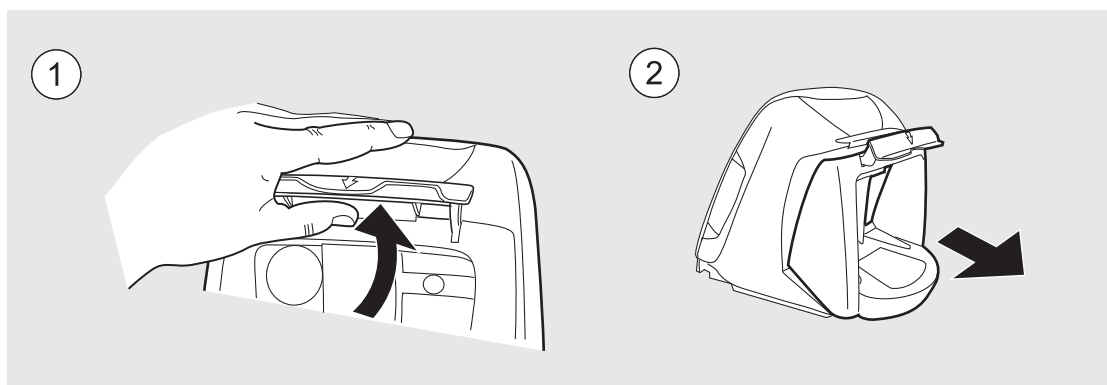


- Always make sure the HA 20 heating unit is in correct position after installation and before use.
- It is recommended to keep the HA 20 heating unit attached to the Breas breathing therapy equipment on permanent basis – also during transportation – to avoid extra strain to the equipment. Do not frequently attach and detach the heating unit from the Breas CPAP or ventilator, to maximize the lifetime of the humidifier.

Follow the instructions in the illustration below to connect the HA 20 heating unit to the Breas breathing therapy equipment.



To disconnect the heating unit, make sure you press up the inner locking mechanism on the rear of the Breas CPAP or ventilator. Do not press the outer locking mechanism of the HA 20.



5 Using the HA 20 Humidifier



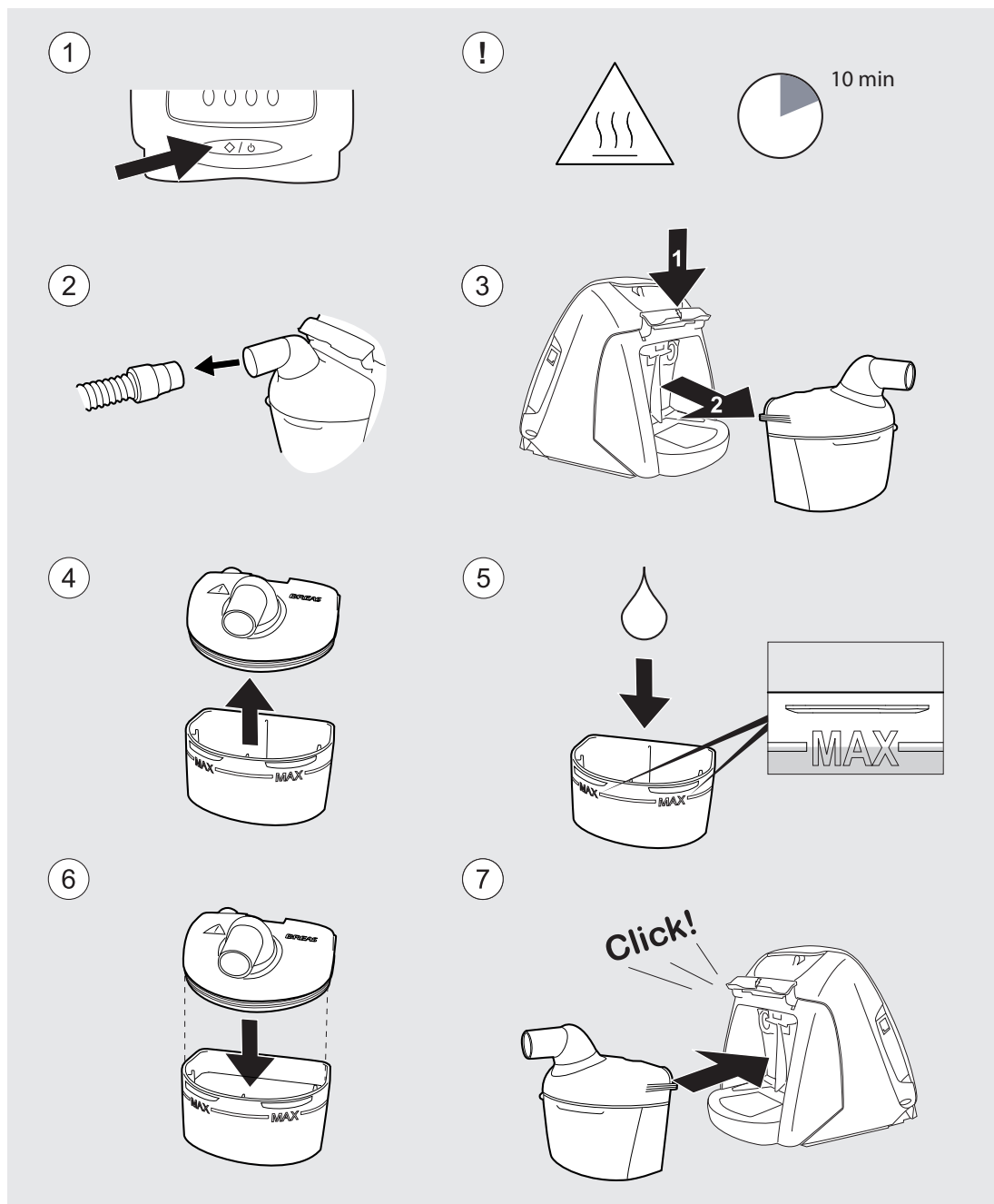
- Always turn off the Breas breathing therapy equipment before detaching or attaching the HA 20 water chamber.
- Prevent water from entering the Breas breathing therapy equipment. Make sure the Breas CPAP or ventilator with the installed humidifier is placed lower than the patient and on a flat surface. This is to prevent personal injury from accidental spillage or from excess water or condensation flowing down the patient tube and into the patient's mask.
- Never add or pour out water from the HA 20 Humidifier when it is attached to the Breas breathing therapy equipment.
- Make sure all parts are dry before the Breas breathing therapy equipment is put into operation. If there is water outside of the HA 20 Humidifier after filling, dry the chamber using a lint-free cloth before reconnecting it to the Breas CPAP or ventilator.
- To avoid burn injury, be careful not to touch the heater plate or the heated water in the water chamber when the HA 20 Humidifier is switched on or has not yet cooled down. Wait ten minutes for the heater plate and water to cool.

5.1 Adding Water to the HA 20 Water Chamber

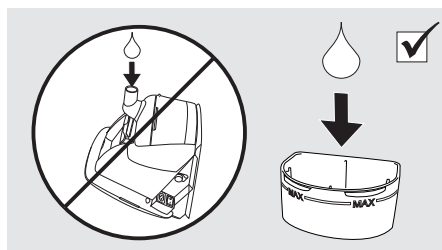


- Use only distilled or sterilised water or boiled, chilled tap water in the HA 20 water chamber. This is to reduce mineral deposits and maximize the life of the water chamber.
- Do not fill the water chamber with hot water.
- Do not overfill the HA 20 Humidifier. Fill only the water chamber to the indicated maximum level.
- Always ensure the cover with seal is properly connected after filling and reassembling the water chamber. Also check that the water chamber is correctly docked in place and locked to the heating unit.
- Avoid to remove the seal from the cover at normal, daily usage.
- Make sure all parts are dry before the Breas CPAP or ventilator is connected to the mains and put into operation.

Follow the instruction in the illustration below to add water to the HA 20 Humidifier. Use the same procedure when emptying water from the water chamber. A water chamber filled to the maximum level contains approximately 300 ml.



Never add water to the HA 20 Humidifier when it is attached to the Breas breathing therapy equipment.



6 Setting up the HA 20 Humidifier

After installation, you set up the integrated HA 20 Humidifier from the menu on the front panel of the Breas breathing therapy equipment.

The HA 20 Humidifier must always be installed in order to access and navigate to the humidifier setting on the iSleep or Vivo menu.

If the humidifier is disconnected and reconnected after usage according to the instructions in this manual, the Breas breathing therapy equipment will remember the humidity setting used.



Always set up the HA 20 Humidifier in accordance with the instructions given by the responsible clinical personnel.



For complete instructions on how to set up the humidifier, refer to the Breas breathing therapy equipment manual.



The most ideal setting is dependant on the ambient temperature and humidity. This implies that the ideal setting may vary due to seasonal temperature changes. If the room temperature gets very cold during the night, a lower setting may be necessary to prevent condensation in the tubes. If the overnight temperature remains high, a higher setting may be more comfortable.

A HA 20 Humidifier filled to the maximum level will be able to humidify the air for 12 hours with the following settings and conditions:

SETTING	CPAP	BILEVEL
Humidifier setting	7	7
CPAP	10 mbar	–
EPAP	–	8 mbar
IPAP	–	20 mbar
Breath Rate	–	15
Ambient temperature	20°C (68°F)	20°C (68°F)
Altitude	Sea level	Sea level

7 Cleaning

Clean the HA 20 water chamber and heating unit regularly to ensure correct operation of the HA 20 Humidifier. Deficient cleaning may lead to impaired performance.



- Always be careful when cleaning the HA 20 Humidifier, so not to damage any equipment.
- Always ensure all parts are properly put in place after cleaning.
- Make sure all parts are dry before the Breas breathing therapy equipment is connected to the mains and put into operation.
- Fluid must not be allowed to enter into the Breas CPAP or ventilator.
- Always make sure the two corresponding heater surfaces under the water chamber and on the heating unit are free from dirt. Any deposits may deteriorate the heating effect.

7.1 Cleaning and Disinfecting the HA 20 Water Chamber

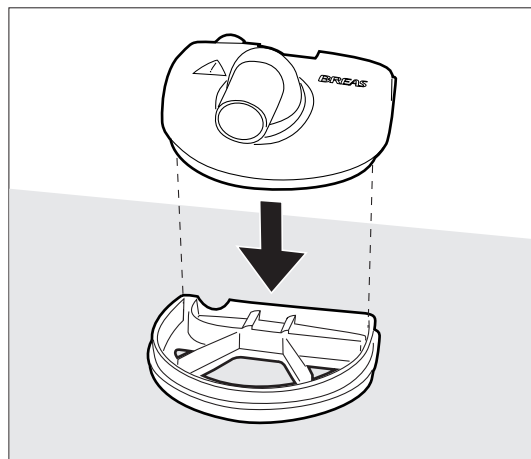
Clean the water chamber regularly. The required frequency is depending on the usage and water quality.

- 1 Switch off the Breas breathing therapy equipment and remove the patient circuit.
- 2 Allow the humidifier to cool down for ten minutes.
- 3 Disconnect the water chamber from the heating unit and remove the cover with seal.
- 4 Clean the water chamber and cover by hand with hot water and a mild detergent or in a dishwasher without dishwasher detergent at max 70°C (158°F). Rinse carefully and allow to dry.
- 5 Reconnect the water chamber.



Avoid to remove the seal from the cover at daily, normal cleaning.

After removal, e.g. for dishwasher cleaning, put the seal on a flat surface and press the cover in place from above. Always make sure the seal is properly attached to the cover and its edges.



In case of mineral deposits in the water chamber, you may do as follows for removal: Fill the water chamber to the maximum water level with 300 ml warm water and 15 g of citric acid. Leave the solution in the water chamber to penetrate the deposits for 30 minutes. Discard the solution and clean the water chamber as usual.

Disinfection

The HA 20 water chamber can be disinfected by the following solutions, provided that they are used according to the manufacturer's instructions:

- Virkon[®], for 10 minutes up to 20 cycles
- Steranios, for 60 minutes up to 20 cycles
- Sporox II[®], for 60 minutes up to 20 cycles
- Aniosyme (0.5%), 5 minutes up to 20 cycles

The HA 20 water chamber can be disinfected in a washer disinfector at max 94°C (201°F) for at least 20 times.

Sterilization

It is possible to sterilize the HA 20 water chamber with Sterrad[®] system using hydrogen peroxide at least 20 times.



Do not attempt to autoclave the HA 20 water chamber.

7.2 Cleaning the HA 20 Heating Unit

Clean the HA 20 heating unit on regular basis when cleaning the Breas breathing therapy equipment. At normal usage, there is no need to remove the heating unit from the Breas CPAP or ventilator for cleaning.

- 1 Switch off the Breas breathing therapy equipment and disconnect the mains supply.
- 2 Allow the humidifier to cool down for ten minutes. Remove the patient circuit and the water chamber.
- 3 Clean the outside of the heating unit using a lint-free cloth and a mild soap solution.
- 4 Reconnect the water chamber. Reconnect the patient circuit and cables.

Disinfection

The surface of the HA 20 heating unit can be disinfected by the following solutions: Virkon[®], Steranios, Sporox II[®], and Aniosyme.



- Do not clean the HA 20 heating unit in a dishwasher.
- Do not attempt to sterilise or autoclave the HA 20 heating unit.

7.3 Change of Patient

If the HA 20 Humidifier is to be used by a new patient, do as follows:

- 1 Replace the HA 20 water chamber with a new one.
- 2 Remove the HA 20 heating unit from the Breas CPAP or ventilator and clean the heating unit in accordance with the instructions above (7.3).
- 3 Always use a new patient circuit when the HA 20 Humidifier is used by a new patient.

8 Maintenance

To ensure correct operation of the HA 20 Humidifier, do as follows:

- Regularly check the water chamber and heating unit for deterioration and damage. In case of damage or leakage, contact the responsible care provider or service provider. Replace the water chamber or the whole humidifier with heating unit, if necessary.
- Replace the water chamber at regular intervals, depending on the usage and wear. The recommended maximum usage period of the HA 20 water chamber is 12 months.



Do not under any circumstances attempt to service or repair the HA 20 Humidifier yourself. If you do so, the manufacturer will no longer be responsible for the performance and safety of the humidifier.

8.1 Storage

Empty, clean and dry the HA 20 Humidifier before storage. Store the humidifier in a dry, clean place at a temperature from -20 to +60°C (-4 to +140°F).

8.2 Disposal

The HA 20 heating unit and water chamber and any replaced parts must be disposed of and recycled in accordance with the local environmental regulations regarding the disposal of used equipment and waste.

8.3 Troubleshooting

If the HA 20 Humidifier does not work properly, try to identify the problem in the table below. Check the possible causes and carry out the suggested remedial action.



The display of the Breas breathing therapy equipment connected to the HA 20 Humidifier will show any error indication of the humidifier. A complete list of all error codes is found in the Service Manual for the Breas CPAP or ventilator.

PROBLEM / POSSIBLE CAUSE	REMEDIAL ACTION
The HA 20 does not heat the water.	
There is no power.	• Check the power cord of the Breas CPAP or ventilator. • Check the connection at the rear of the ventilator and at the power inlet.
The HA 20 heating unit is not connected correctly.	Check that the heating unit is properly attached to the Breas CPAP or ventilator.
The HA 20 has been overheated.	Contact the care provider or service provider.
The heat element of the HA 20 is broken.	Contact the care provider or service provider.
The HA 20 water chamber is leaking.	
The water chamber has been overfilled.	Check the water level and remove the surplus water if necessary.
The cover is not attached correctly.	Check the cover and the seal.
The water chamber is damaged or cracked.	Contact the care provider or service provider for a replacement.

PROBLEM / POSSIBLE CAUSE	REMEDIAL ACTION
There is water in the patient tube.	
The setting of the HA 20 is too high.	Decrease the humidity setting on the Breas CPAP or ventilator.
The HA 20 water chamber has been overfilled.	Check the water level and remove the surplus water if necessary.
The patient air is too moist.	
- The setting of the HA 20 is too high. - High relative humidity in the room.	Decrease the humidity setting on the Breas CPAP or ventilator.
The patient air does not feel moist.	
The setting of the HA 20 is too low.	Increase the humidity setting on the Breas CPAP or ventilator.
The HA 20 is not working.	- Check that the heating unit and water chamber are properly connected to the Breas CPAP or ventilator. - Check that the CPAP or ventilator is operating. - Contact the care provider or service provider.
The patient breaths through the mouth.	Contact the care provider for a change of mask.

9 Technical Specifications

9.1 Data

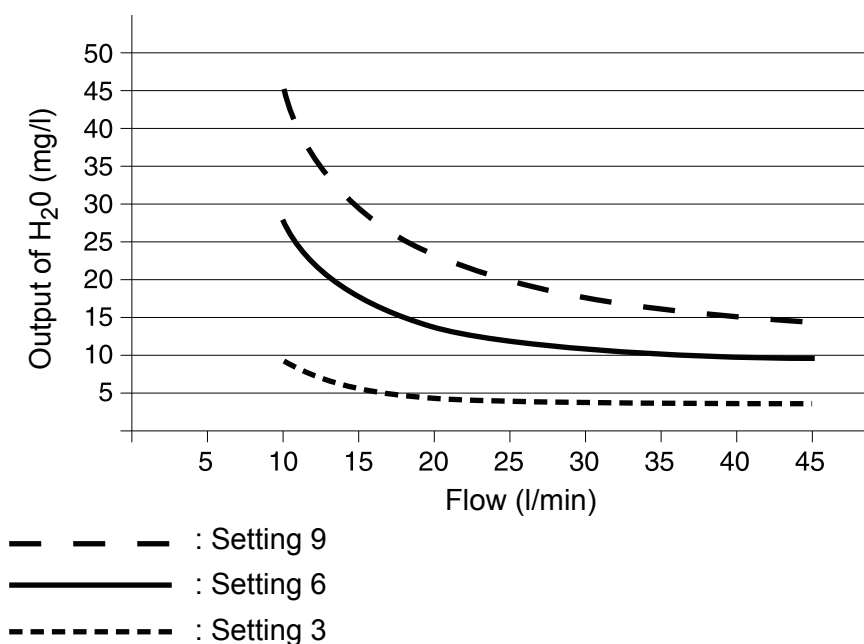
POWER SUPPLIES	SPECIFICATION
Power supply	10 to 30 V DC, max 40 W
ENVIRONMENTAL CONDITIONS	SPECIFICATION
Operating temperature range	5 to 40°C (41 to 104°F)
Storage and transport temperature	-20 to +60°C (-4 to +140°F)
Ambient pressure range	700 to 1060 mbar, corresponding to ~3000 metres above sea level to ~375 metres below sea level, at normal atmospheric pressure
Humidity	10% to 95%, non-condensing
DIMENSIONS, COMPLETE ASSEMBLY	SPECIFICATIONS
Width × height × depth	150 × 140 × 100 mm
Weight	425 g
Maximum volume, water chamber	300 ml
Air outlet	22 mm conical standard connector
PERFORMANCE	SPECIFICATIONS
Gas leakage at maximum operating pressure	< 5 ml/min
Maximum delivered gas temperature	43°C (109°F)

REPLACEMENT PARTS	PART NUMBER
HA 20 Humidifier (heating unit + water chamber)	• 004859: Silver colour • 004927: White colour
HA 20 water chamber	004861



The HA 20 Humidifier and its packaging do not contain any natural rubber latex.

The diagram below shows the output of the HA 20 Humidifier at the patient end of the tube:



The warm-up time for the delivered patient air to reach the set temperature from a starting temperature of 20 to 25°C (68 to 77°F) is less than 60 minutes when the HA 20 Humidifier is operated according to Breas' instructions.

The humidity settings of the HA 20 correspond to the following final water temperatures, at 10 mbar and 25 l/min:

HUMIDITY SETTING	WATER TEMPERATURE
3	35°C (95°F)
6	43°C (109°F)
9	50°C (122°F)

9.2 Compliance of Standards

STANDARD	SPECIFICATIONS
IEC 60601-1 (1988) A1 (1991) A2 (1995)	Medical electrical equipment – Part 1: General requirements for safety.
IEC 60601-1-1 (2000)	Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems.
IEC 60601-1-2 (2001)	Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests.
IEC 60601-1-6 (2004)	Medical electrical equipment – Part 1-6: General requirements for safety – Collateral standard: Usability.
ISO 8185 (2007)	Respiratory tract humidifiers for medical use – Particular requirements for respiratory humidification systems.

CLASSIFICATIONS	SPECIFICATIONS
Class IIa	Classification according to the European Medical Device Directive 93/42/EEC.
Type BF	Body floating (isolated) applied part according to IEC 60601-1.
IPX0	Degree of protection provided by enclosure.