

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

1 Intended Use of the Breas HA 01 Humidifier



Read this manual thoroughly so that you completely understand how the humidifier is operated and maintained before taking it into use, to ensure correct usage, maximum performance and serviceability.



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

The humidifier is intended to humidify the patient air.

1.1 Indications for Use

The humidifier can only be used together with Breas breathing therapy equipment, such as iSleep or Vivo.

It must always be prescribed by a licensed physician.







For complete instructions how to operate the humidifier, refer to the Breas breathing therapy equipment manual.

1.2 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 death and 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 humidifier should be located below the patient to prevent personal injury from accidental spillage.
- Periodically check for moisture in the patient circuit. When present, remove the moisture. Before attempting to dry the circuit, disconnect it from the 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 condensed water in the patient circuit from running into the patient airways and causing personal injury
- The 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 humidifier and contact your responsible care provider for an inspection in the event of suspected damage to the device.



- Handle the humidifier with care.
- The humidifier shall be disconnected from the Breas breathing therapy equipment during transportation.
- The Breas breathing therapy equipment shall not be placed in the bag with the humidifier attached.

2.2 Electrical Safety



- When handling the humidifier, disconnect the Breas breathing therapy equipment from any power source.
- Do not connect cables to the Breas breathing therapy equipment when there is water in the humidifier.

2.3 Environmental Conditions



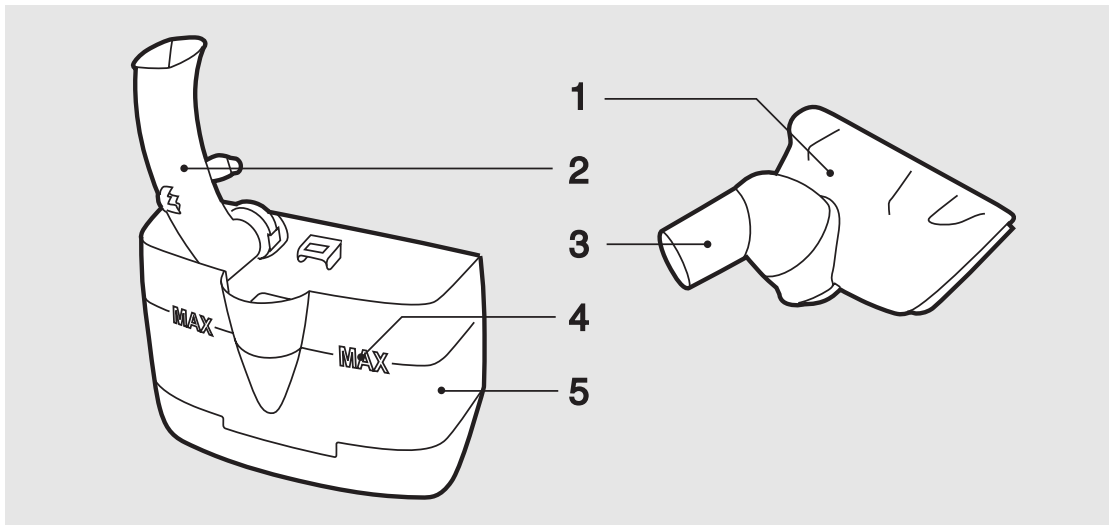
- The performance of the humidifier may deteriorate at:
 - ambient temperatures below 5°C (41°F) and above 40°C (104°F).
 - ambient relative humidity below 10% RH (room humidity) and above 95% RH.
 - atmosphere pressure below 700 mbar and above 1060 mbar.
- The humidifier, any accessories and all replaced 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



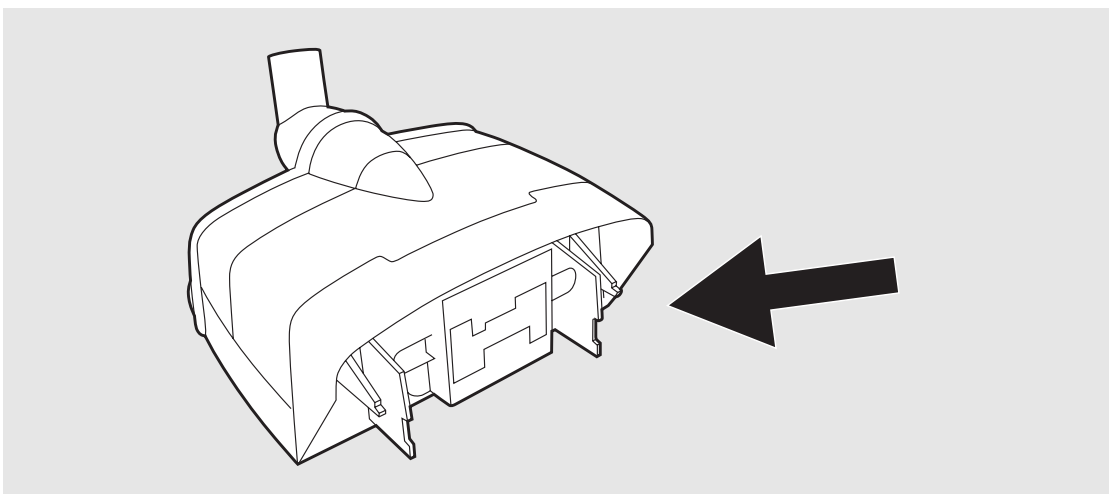
- The humidifier shall be cleaned and maintained in accordance with this manual.
- Do not attempt to autoclave or sterilise the humidifier.
- Recommended usage period of the humidifier: 12 months.
Maximum usage period: 24 months.
- Do not under any circumstances attempt to service or repair the humidifier yourself. If you do so, the manufacturer will no longer be responsible for the performance and safety of the humidifier.






3 Product Description



No.	COMPONENT	FUNCTION
1	Humidifier lid	Sealing the humidifier.
2	Internal pipe	To prevent water spillage into the Breas breathing therapy equipment.
3	Swivel	Patient tubing connector.
4	Max	Marking the maximum level of water.
5	Water container	Contains and heats water.

3.1 Equipment Designation and Safety Label



SYMBOL	EXPLANATION
	Model designation
	Serial number (the last six alphanumeric characters)
	Class II electrical equipment; dual isolation
	Body floating (IEC 60601-1 Type BF, Isolated Applied Part)
	Read the user manual thoroughly before connecting the 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 scrapping and should not be discarded with the household waste.

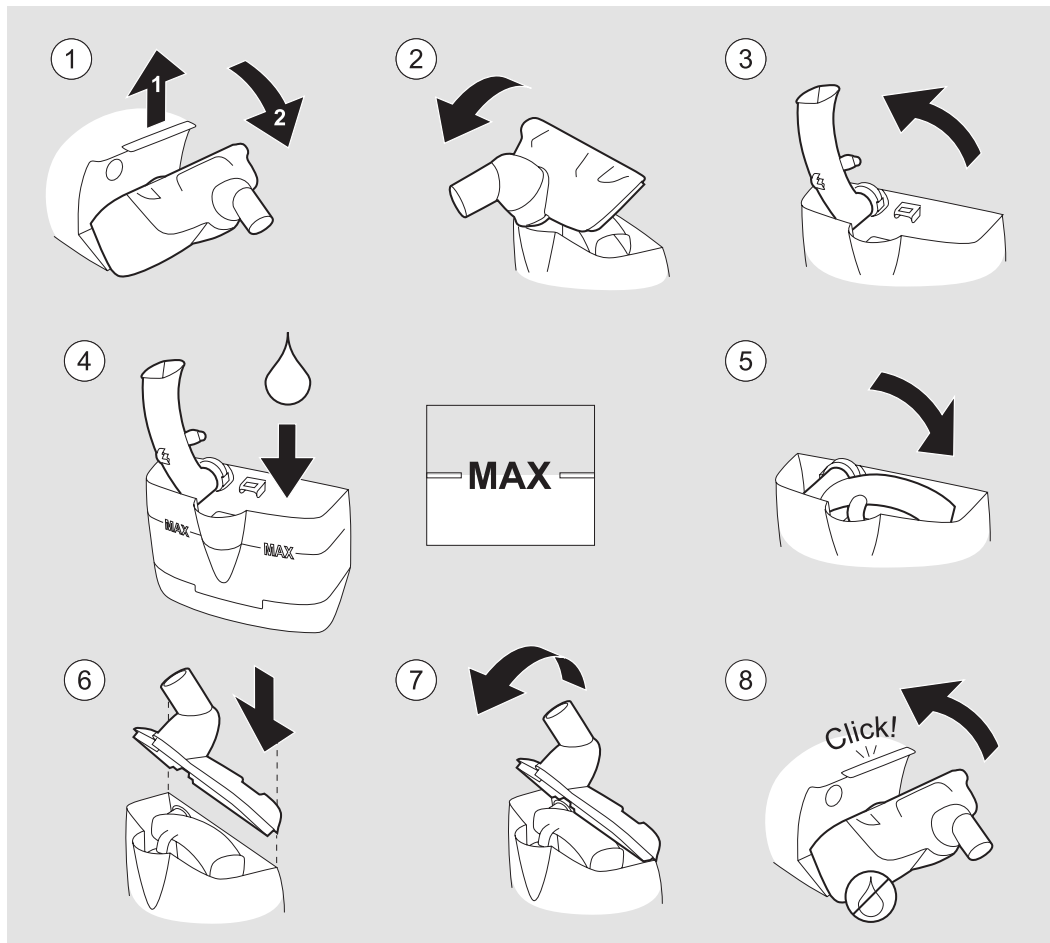
4 Using the Humidifier



- Never add or pour out water from the humidifier when attached to the Breas breathing therapy equipment.
- Prevent water from entering the Breas breathing therapy equipment.
- Always turn off the Breas breathing therapy equipment and disconnect the mains supply before removing the humidifier.
- Do not use the humidifier if the internal pipe in the water container is missing.
- Do not overfill the humidifier.
- If there is water outside of the humidifier after filling, dry the humidifier using a lint-free cloth before reconnecting it to the Breas breathing therapy equipment.

Adding Water to the Humidifier

Follow the instruction in the illustration below. Use the same procedure when emptying water from the humidifier.



i Add distilled water or boiled, chilled tap water to the humidifier until it reaches the marking “Max” on the humidifier. A full humidifier contains approximately 400 ml. Do not overfill the humidifier.

Cleaning the Humidifier

- Clean with hot water and a mild detergent or in a dishwasher without dishwasher detergent at max 70°C. Rinse carefully and allow to dry.
- The humidifier can be disinfected with Virkon® or Lysetol.®

Hand icon Do not attempt to autoclave the humidifier. Exposure to temperatures above 100°C causes irreparable damage.

4.1 Disposal

The humidifier, any accessories and all replaced parts must be disposed of and recycled in accordance with the local environmental regulations regarding the disposal of used equipment and waste.

5 Technical Specifications

5.1 Data

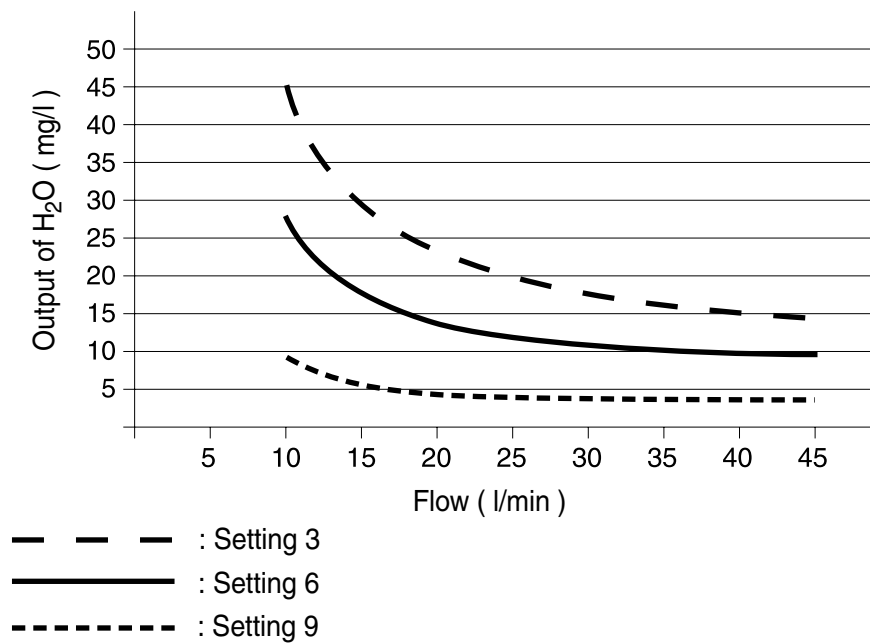
POWER SUPPLIES	SPECIFICATION
Power supply	12-30 V DC, max 40 W.

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
Humidity	10% to 95%, non-condensing

DIMENSIONS	SPECIFICATIONS
W × H × D	148 × 155 × 98 mm
Weight	260 g
Air outlet	22 mm conical standard connector

PERFORMANCE	SPECIFICATIONS
Gas leakage at max. operating pressure	< 5 ml/min

The diagram below shows the output of the humidifier at the patient end of the tube:



The warm-up time for the delivered gas temperature to reach the set temperature from a starting temperature of $23 \pm 2^\circ\text{C}$ is less than 60 minutes when operated according to Breas instructions.

5.2 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 60601-1-4 (2000)	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral Standard: Programmable electrical medical systems.
IEC 60601-1-6 (2004)	Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability.
ISO 8185 (1997) C1(2001)	Humidifiers for medical use - General requirements for humidification systems.

CLASSIFICATIONS	SPECIFICATIONS
Class IIa	Classification according to the European Medical Device Directive 93/42/EEC.
Class II	FDA classification
Class II (IEC 60601-1) Class II, Type BF	Electrical equipment with dual isolation and body floating (isolated) applied part according to IEC 60601-1.
IPX1	Degree of protection provided by enclosure.



The humidifier and its packaging do not contain any natural rubber latex.

