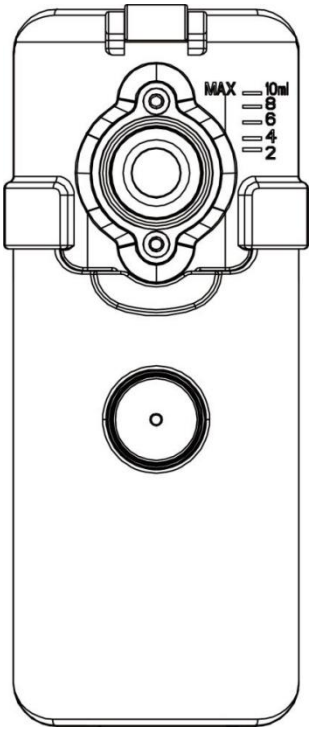
HEAL™ Ultrasonic Mesh Nebuliser
H-NEB02

Instructions for Use



Catalogue

1.Product introduction

1.1 Product characteristics

The Heal Ultrasonic Mesh Nebuliser (hereinafter referred to as nebuliser) is the use of ultrasonic oscillations to break the drug solution into microscopic droplets. It is safe and efficient to deliver medication to the upper respiratory tract. This device is conveniently portable. It can be used to treat the family in a prophylactic capacity, or for treatment of active upper respiratory diseases and infections.

1.2 Working principle

The Heal Ultrasonic Mesh Nebuliser is mainly composed of piezoelectric components, through which the electrical energy is converted into mechanical energy and ultrasonic vibration is generated. The vibration wave forces the liquid in the liquid medicine cup, so that the liquid can be atomized.

1.3 Intended use

The Heal Ultrasonic Mesh Nebuliser is intended to deliver the prescribed medication solution to treat patient respiratory disorders, such as asthma, allergies and bronchitis. The nebuliser converts the medication solution into an aerosolized mist which is inhaled by the patient through the mouth piece or mask. The nebuliser is ideal for home use by human patients of any age; from infants to elderly patients. The nebuliser may be used by the patient at home or by a medical practitioner administering care in a hospital or clinic, frail care, or doctors practice.

1.4 Contraindication

No contraindication.

1.5 Main technical parameters

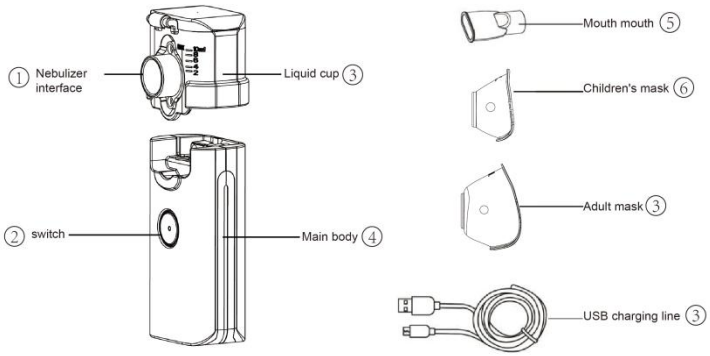
Model	H-NEB02

Power supply	Built-in lithium battery:DC3.7V,1200mAh, Charging mode DC 5 V; 1A
Lithium battery use Number of times	1000
Ultrasonic working frequency	103kHz±10%
Nebuliser rate	Speed 1 (Low grade nebulising rate): 0.15 0.30mL/min Speed 2 (High grade nebulising rate): ≥0.3 mL/min
Particle size	Particle size less than 5um accounts for 60% above
Maximum noise	≤40dB A)
MMAD	3+/-25% um
Liquid cup capacity	2~10 ml
Weight (including batteries)	0.088kg
Shape dimension (mm)	117*46*43
Child mask size (mm)	100*70*53
Adult mask size (mm)	116*83*62
Mouth piece size (mm)	64.5*33
Operating conditions	Temperature: +5 °C ~ +35 , humidity ≤ 93%RH Atmospheric pressure 700hPa~1060 hPa.
Life of products and accessories	3 years
Battery life	3 years
Shelf-life	No limit

Degree of safety in the presence of flammable anesthetics or oxygen
—No AP/APG (not suitable for use in the presence of flammable anesthetics or oxygen)
Mode of operation—Continuous
IP22—prevent solid objects greater than 12mm from intruding into the product and drops falling within a vertical range of 15" have no harmful effects.

1.6 Product structure composition

The Heal Ultrasonic Mesh Nebuliser is mainly composed of main engine, liquid cup, mouth piece and masks, as shown in the following figure:



1.7 Package contents

number	name	quantity	remarks
1	Main Body	1	Detachable
2	Liquid Cup	1	
3	Mouth Piece	1	Accessory
4	Adult Mask	1	
5	Pediatric Mask	1	
6	USB Charger Cable	1	5VDC 1A
7	Instruction Manual	1	
8	Pouch Bag	1	

2. Operation instructions

2.1 Preparation before use

- Remove all packaging materials and confirm that all accessories or accessories are complete.
- Please clean and disinfect this product for the first time (refer to Chapter 4).

2.1.1 Charging the nebuliser

a. This product has built-in lithium battery, the USB end of the charging cable is connected to the USB interface of the mesh nebuliser, the other end is connected to the adapter (not included), and then the adapter can be plugged into the network power supply to charge, or directly connected to the USB interface. The end installation charge connector and the adapter must comply with IEC 60601-1 standard requirements.
b. The light blue light flashes during charging.
c. Once the battery is charged, the light blue light will stay on.
d. Once charged, the mesh nebuliser can work for 60 minutes.
e. If the product is not used for a long time, it should be charged every six months.

CAUTION:

- If there is insufficient power, the blue or green indicator light will start flashing. Please charge as per instructions in 2.1.1
- Whilst charging, please make sure that there is no medication or liquid in the liquid cup, to avoid leaking during charging.
- Ensure that the nebuliser is not placed close to any heat source during charging.

2.2 Assembling the nebuliser

There are two options for nebulising, the first being the mouth piece and the second being a mask. Both an adult and paediatric size mask is included.

2.2.1 Using the mouth piece

a. Attach the mouth piece onto the nebuliser liquid cup as shown in figure 5.
b. Hold the mouth piece in your mouth and keep the nebuliser as vertical as possible whist doing so.
c. When you inhale medication whilst using a mouth piece, a small amount of

drugs will remain on the inner wall. Please clean the mouth piece after use.

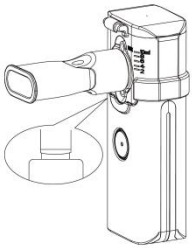


figure 5

2.3.2 Using the mask

a. Select the appropriate size mask for the patient (adult or paediatric)

b. Connect the mask to the nebuliser liquid cup as shown in figure 6.

c. Gently place the mask over the patient's mouth and nose.

d. Take slow, deep breathes in slowly through the nose or mouth.

e. The mask should be cleaned in a timely manner after each use (please refer to "cleaning, disinfection and maintenance")

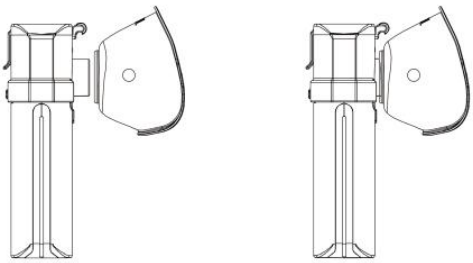


figure 6

CAUTION:

- The amount of liquid inhaled is greater when using the mask than when the mouth piece is used;
- Accessories (masks, mouth piece) that are in direct contact with patients must not be shared to avoid cross-infection.

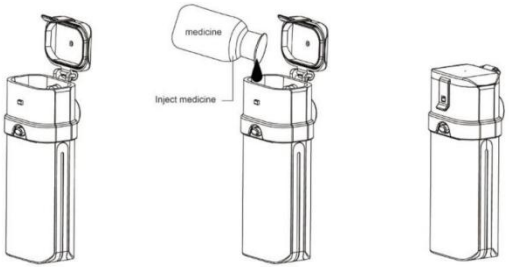
2.3 How to operate the nebuliser

2.3.1 Adding medication to the liquid cup

a. Open the lid of the liquid cup.

b. Pour the medication into the liquid cup.

c. Close the lid of the medicine cup and fasten the clip.



Warning:

a. The maximum liquid capacity of the cup is 10ml. It is suggested that be 2-10ml of medication be added.

b. Once the medication has been poured into the liquid cup, it is necessary to clip the cover of the liquid cup closed.

c. Please follow the doctor's instructions as to what type of medicine to use and the correct dosage thereof.

d. Do not use high viscosity or volatile drugs, as they may cause damage to the nebuliser diaphragm.

e. Only saline diluted drugs can be inhaled, otherwise bronchospasm may occurs

f. Do not use oil based medications in the nebuliser.

g. The inhalation time for each nebulisation session should not exceed 25 minutes.

2.3.2 Start nebulising treatment

a. Press the switch button once, and a solid green indicator light will display, and the nebulising mist will start. A green light indicates Speed 1, which is a normal speed mist.

b. Press the switch button a second time, and a solid blue indicator light will display, indicating Speed 2, which is a faster speed mist.

c. Once the liquid medicine is consumed, the main unit will stop automatically, and no mist will appear. At this time, press the switch button to shut down, the indicator light will go off.

Warning:

a. The nebuliser must be operated according to the method specified in this manual.

b. Prolonged contact with mask or mouthpiece maybe may cause skin irritations or allergies.

d. Not intended for use with flammable agents or anesthetics.

e. This product can only use parts or accessories manufactured by the original factory. The use of parts not included in the original packaging will result in the warranty becoming invalid.

f. No modification of this equipment is allowed.

g. The USB Connector for charging only, the end installation connector must comply with IEC 60601-1 standard requirements.

h. Do not use in dusty or dark places.

i. Degraded sensors and electrodes, or loose electrodes, can degrade performance. If this problem occurs, it should be dealt with by a professional maintenance personnel.

j. Replacing lithium batteries by untrained personnel can be dangerous.

k. Follow the instruction of your medical practitioner to operate this unit.

l. This product is a nebuliser for the inhalation of medical aerosols and is suitable for patient used solutions. Use only the type and amount of medication prescribed by patient's doctor. The dosage of drugs must be within the scope of the EU rules and regulations.

m. This product is intended for aerosol therapy only and any other use is not

recommended.

n. Please store out of reach from infants, young children, and mentally ill patients.

o. Do not to touch the connector/ electrode/ mesh whilst nebulising.

p. Hold the nebuliser as vertically upright as possible during use. Do not tilt the unit more than 45 degrees during use.

q. Ensure medicine in the liquid cup is disposed of after each use.

r. Do not use this product near high frequency electromagnetic transmitters. Electromagnetic interference exceeding the requirements of IEC 60601 may affect the performance of nebuliser.

s. Please keep it in a clean and dry place and avoid direct sunlight during use and storage;

t. If the equipment is stored in an overheated or supercooled environment before use, the equipment shall be placed in a normal temperature environment 2 hours in advance to make it consistent with the indoor temperature during use before reuse.

u. The nebuliser is not suitable for respiratory anesthesia and artificial respiration system.

v. If the patient has diabetes or other diseases, consult a doctor before using this product.

w. If the patient has contusion, burn, inflammation, trauma or sensitive site, please do not use this product.

x. If the patient is not feeling well during use, please stop using it and consult your doctor immediately.

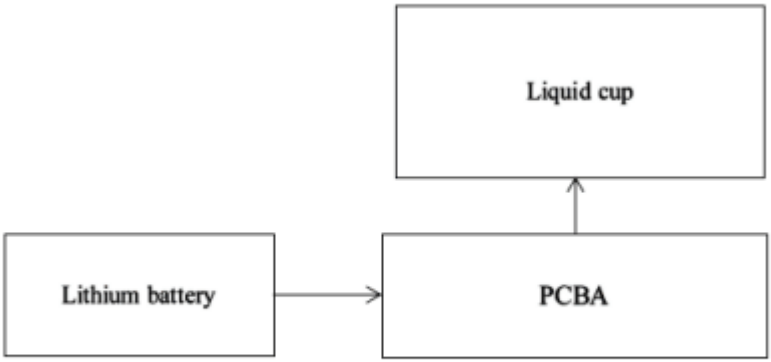
y. The use of suspended or high concentration liquid is prohibited.

z. The Nebuliser unit can be used by many people, but components which come into direct contact with the human body (mouth piece, mask) should only be used by one person to prevent cross-infection between patients.

3. Fault analysis and troubleshooting

This product is a medical device, and to ensure the safety of the product and patients, please strictly follow the operation steps in this manual or under the guidance of the doctor.

Some common problems and troubleshooting methods in the use of the product are shown in the following table. If it still cannot be solved, please contact the retailer from whom the device was purchased. Only authorized personnel shall make repairs to this product



Working principle diagram

The part list for repair.

Item	Part	Spec./model	Remark
1	Lithium battery	1200mAh, 3.7V DC	Replacement shall be with original factory parts
2	PCBA	MU452	Replacement shall be with original factory parts
3	Liquid cup	160A	Replacement shall be with original factory parts

Item	Failure phenomenon / problem	Analysis of causes	Exclusion method

1	No mist	1. The handheld is not the right way up. 2. Nebuliser is too tilted. 3. The liquid cup is not ready. 3.The drug is not suitable	1.Re-attached the liquid cup and its components 2.Too few drugs or modified drugs are not suitable for the use of this product (please consult your doctor for which drugs to use) 3.Keep nebuliser upright 4. Contact the retailer who will contact the manufacturer
2	Small mist	1.Insufficient battery power 2.Nebuliser sheet wear 3.The drug is not suitable	1.After charging the battery, retry. Too little medication liquid or modified drugs are not suitable for the use of this product (please consult your doctor for which drugs to use) 2. Contact the retailer who will contact the manufacturer
3	Which drugs are suitable for nebuliser.	Consult a doctor	It is recommended to seek advice from a medical practitioner
4	Why, after each use, there are some drug residues	When the device is automatically turned off, you stop inhaling the potion immediately.	This is normal.
5	Does everyone have to use accessories alone?	It is necessary to practice safe hygiene	It is recommended that each patient use their own accessories

Warning:

Incorrectly replace components by inadequately trained personnel could result in components short circuit (such as excessive temperatures, fire or explosion).

4. Cleaning, disinfection, and maintenance

4.1 Cleaning

Thoroughly clean all components to remove medication residuals and possible impurities after each treatment.

Use a soft and dry cloth with non-abrasive cleaners to clean the main unit.

Make sure that the internal parts of the device are not in contact with liquids

and that the power switch is off.

Before and after each use of the product, please clean the liquid cup and accessories.

a. Remove the liquid cup and accessories before cleaning.
b. The main unit is not waterproof, therefore do not immerse in water. Simply wipe with a soft cloth.
c. To clean the accessories (mouth piece or mask), clean with warm soapy water (not exceeding 80) and then rinse thoroughly with tap water.
d. To clean the liquid cup, pour about 8ml warm distilled water (50 ~ 60 °C) into the liquid cup. Turn on the device and nebulise the distilled water for 1-2 minutes.
e. After cleaning, place all the accessories on a towel and allow to air dry.

CAUTION:

- Do not use microwave oven and other high temperature equipment to dry products and accessories.
- Do not use fabric or cloth to clean the nebuliser mesh in the liquid cup to avoid affecting the atomization effect.

4.2 Disinfection

4.2.1 Before the nebuliser can be used by a different patient, it is necessary to disinfect the liquid cup.

4.2.2 Remove the liquid cup and pour about 2-5ml alcohol (75%) into the liquid cup and close the lid Leave the alcohol in the liquid cup for at least 10 minutes. To allow the alcohol to have maximum disinfecting action, gently swirl the unit with the lid closed. Pour the alcohol out the liquid cap. Then use distilled water to repeat the cleaning process outlined above.

CAUTION:

- The accessories are only for single patient use, otherwise there is a risk of

cross-infection.

● Rinse thoroughly with pure water and dry in a ventilated area before storing

4.3 Maintenance

1. If not used for a long time, the operator is recommended to clean the machine when it is used again. There is no need to disinfect the main unit.
2. Full charge the device before use.

CAUTION:

● The cleaning and maintenance of the nebuliser unit shall be carried out whilst the product is switched off, and no cleaning or maintenance shall be carried out during use.

5.Conditions of transport and storage

5.1 Transport

Ensure that the product is not exposed to rain or sun during transportation.

5.2 The storage

The packed nebuliser should be stored in a room with a temperature of -20 °C ~ +60 , Relative humidity ≤93%, a non-corrosive gas and a good ventilation, Atmospheric pressure : 700 1060hpa.

6.Waste disposal

Disposal Correct Disposal of this product (Waste Electrical & Electronic Equipment)

This marking shown on the product or its literature, indicates that it should not be disposed of with other household wastes at the end of its working life. To prevent possible harm to the environment or human health from uncontrolled waste

disposal, please separate this from other types of wastes and recycle it responsibly to promote the sustainable reuse of material resources.

Household users should contact either the retailer where they purchased this product, or their local government office, for details of where and how they can take this item for environmentally safe recycling.

7. Safety symbols and their meanings used on this device

Symbol	Meaning	Symbol	Meaning
	Type BF Equipment Mask and mouthpiece are Type BF applied parts		Caution
	Please read the instruction before use		It shall not be discarded as ordinary garbage
IP22	Protection against insertion of fingers and against From vertical tilt to 15 degrees dripping water		Charging source
	Date of manufacture		Serial number
	Fragile ,handle with care		Up
	Stack height		Keep dry

8.Important information regarding Electro Magnetic Compatibility (EMC)

1* WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such

use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally."

2* WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."

3* WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the BR-MN199, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result."

Table 1

declaration - electromagnetic emission	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Not applicable
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable

Table 2

declaration - electromagnetic immunity		
Immunity test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air

Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	Not applicable
Surge IEC 61000-4-5	± 0.5kV, ± 1 kV line(s) to lines	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m
NOTE: UT is the AC mains voltage prior to application of the test level.		

Table 3

declaration - electromagnetic immunity					
declaration - IMMUNITY to proximity fields from RF wireless communications equipment					
Immunity test	IEC 60601 test level		Compliance level		
Conducted RF IEC 61000-4-6	IEC60601 test level Test frequency	3 V 0.15 MHz to 80 MHz 6 V in ISM and amateur bands between 0.15 MHz and 80 MHz	Modulation	3 V 0.15 MHz to 80 MHz 6 V in ISM and amateur bands between 0.15 MHz and 80 MHz	Maximum power	Immunity level	Compliance level
Radiated RF IEC IEC 61000-4-3	385 MHz	10V/m 80 MHz to 2.7 GHz	Modulation: 18Hz 4 Pulse	1.8W 10V/m	27 V/m	27 V/m	

Table 4

61000-4-3	450 MHz	*FM+ 5Hz deviation: 1kHz sine	2 W	28 V/m	28 V/m
	710 MHz 745 MHz 780 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m
	810 MHz 870 MHz 930 MHz	**Pulse Modulation: 18Hz	2 W	28 V/m	28 V/m
	1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	2450 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m
Note* - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case. Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.					

Applicant:
Taga Medical
Unit 2 & 3 Mirabel Industrial Park,
Cnr Maple & Mirabel Roads,
Pomona, Kempton Park, 1619
www.tagamed.com

Date of publication: 17 May 2022