

User Manual

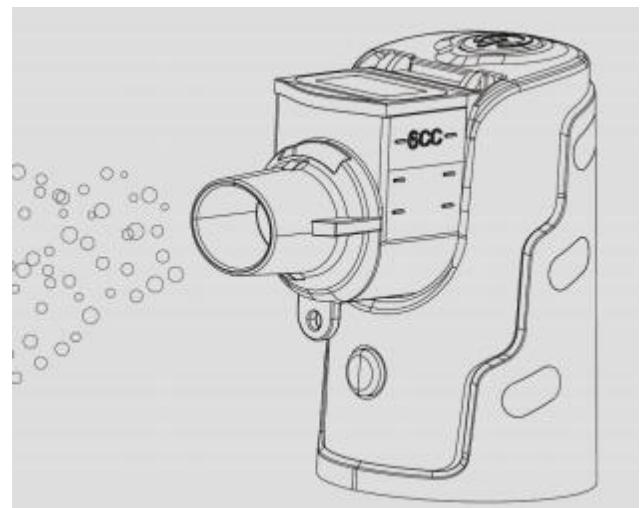
Mesh Nebulizer

Instruction For Use

MODEL: JLN-MB001

Revision: V1.3

Date: 21.12. 23



Read the instructions carefully before using the device

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1. INTRODUCTION

Thank you for purchasing the HOMED Mesh Nebulizer. It is a compact medical device designed to efficiently deliver physician prescribed medicine to the bronchial lung passages. With proper care and use, it will provide you with many years of reliable treatment. **The intended OPERATOR is also a PATIENT.**

Intended use/Indication for use

The mesh nebulizer is intended for use in the treatment of asthma, COPD and other respiratory ailments in which an aerosolized medicine is required during therapy. It is used for single patient and can be reusable. The device is for pediatric and adult population.

Your Homed Mesh Nebulizer should be used under the supervision of a licensed physician and/or a respiratory therapist. We encourage you to thoroughly read this guidebook to learn about the features of this product. Any use of this product other than its intended use should always be avoided.

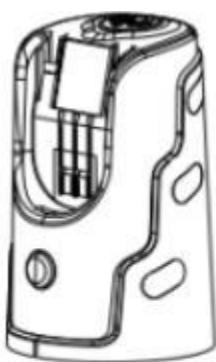
Note:

As the Mesh Nebulizers, models No.: JLN-MB002, JLN-MB003, JLN-MB004 have the same intended use, basic technique principle and basic technical specification, just different in color, so they can share the JLN-MB001's user manual.

2. PRODUCT IDENTIFICATION

Mesh Nebulizer mainly consists of main unit, medicine cup, mask (big or small), mouthpiece, and AC adapter, batteries (optional).

As power, you can also choose to use two AA 1.5V batteries



1.main unit

medicine cup



2.nebulizer part



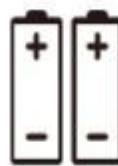
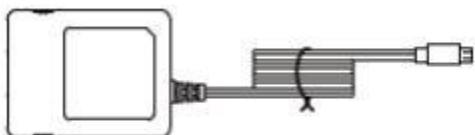
3.mask



4.mouthpiece

The mask or mouthpiece is the BF application part.

The mask is made of PVC and polyester fiber, and the mouthpiece is made of silicone
Adapter DC5V/1A, 100-240V, 50Hz, use micro-USB as connecting line



5. Or batteries (two AA alkaline 1.5V*2), people can buy them by himself on the market.

3. IMPORTANT SAFEGUARDS

Note: Read all instructions carefully before use.

The following basic precautions are needed when using an electrical product:

Caution: Failure to read and observe all precautions could result in personal injury or equipment damage.

Contraindication: Patients who are allergic to PVC and silicone materials should use with caution or under the guidance of a doctor.

⚠ Product cautions:

This machine, like any other machine, may not work because of power failure, battery depletion or other failures. We recommend that you have spare batteries or other spare machines available.

When using electrical products, always follow the basic electrical safety precautions. Such as any electrical equipment has a special care for children.

1. To avoid electrical shock:
 - Keep the unit away from water.
 - Do not immerse the power cord or the unit in liquid.
 - Do not use while bathing.
 - Do not reach for a unit that has fallen into water - immediately unplug the unit.
2. Never operate the unit if it has any damaged parts (including power cord), if it has been dropped or submersed in water. Promptly send it to a service center for examination and repair.
3. The unit should not be used where flammable gas, oxygen or aerosol spray products are being used.
4. Disconnect the unit from the electrical outlet before cleaning, filling and after each use.
5. Avoiding dropping the device otherwise it may not function normally.
6. Machine can be used by many people, but the attachment is disposable and single-patient-use.
7. Do not attempt to disassemble, repair or modify the machine.
8. Follow local laws and recycling plans regarding disposal or recycling of components, batteries and packaging.
9. The connecting tube and the power adapter cable may be necked. During charging, tighten the adapter cable or place it away from the human body.

10. Do not use other attachments unless recommended by manufacturer.

All accessories meet the requirements of ISO10993.

11. Not to position me equipment to make it difficult to operate the disconnection device.

Operating Cautions:

1. Connect this product to an appropriate voltage outlet for your model.
2. Do not run this product unattended.
3. Never operate the device if it has a damaged part, or dropped on the floor or into water, or else it will not work properly. Return it to a service center for repair.
4. If any abnormality occurs, discontinue use immediately until the unit has been examined and repaired.
5. Always unplug the product immediately after use.
6. The children should use the device under the supervision by adult.
7. Do not drop any liquid on the main machine or adapter, if the liquid splashes on it, please wipe it off immediately.
8. Non oily drugs that are soluble in water should be used.
9. Do not use the machine when it is close to the inflammable and explosive materials.
10. Do not use a cellular phone near the device. It may result in an operational failure.
11. Do not use extension cords. Plug the power cord directly into the electrical outlet.
12. For type, dose, and regime of medicine follow the instructions of your licensed physician and/or respiratory therapist.
13. Do not add more than 6ml of medicine to the medicine cup.
14. Do not plug in or unplug the Adapter from the electrical outlet with wet hands.
15. Using a solution, suspension, or emulsion different from that recommended by the manufacturer, in particular, a suspension and/or high-viscosity solution, can alter the particle size distribution curve, the mass median aerodynamic diameter (MMAD), aerosol output, and/or aerosol output rate, which can then be different from those disclosed by the manufacturer.
16. The mesh nebulizer and the accessories are designed for single-patient reuse, do not reuse them among different people to avoid cross-contamination.
17. The mesh nebulizer is not suitable for use in an aesthetic breathing system or a ventilator breathing system.
18. Patients who are allergic to PVC and silicone materials should use with caution or under the guidance of a doctor
19. Aging of the electrode sheet will cause adverse contact between the host and the medicine cup, which will affect the use of the product. Do not use the product in a high temperature and high humidity environment, or store the product in environmental conditions beyond the instructions.

Storage Cautions:

1. Keep the device away from direct sunlight, excessive heat or cold to avoid damaging the batteries.

2. Keep the unit out of reach of small children and infant or mental disease patients.

3. Always keep the unit unplugged while not in use.

4. Keep the unit out of reach of small children and infant or mental disease patients.

5. Do not place the device in a place where pollutants or smoke are present.

Cleaning Cautions:

1. Do not immerse the unit in water. It may damage the unit.
2. Disconnect the unit from the electrical outlet before cleaning.
3. Clean all necessary parts after each use as instructed in this guidebook.
4. Don't try to clean the grid with any object, it will damage the grid.

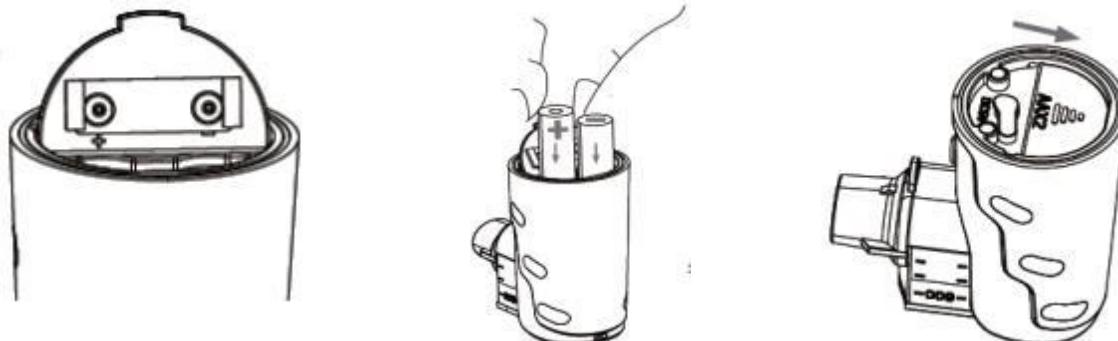
4. OPERATING YOUR MESH NEBULIZER

Note: Prior to initial operation, the nebulizer should be thoroughly cleaned.

Note: The device cannot be maintained or serviced while a patient is in use

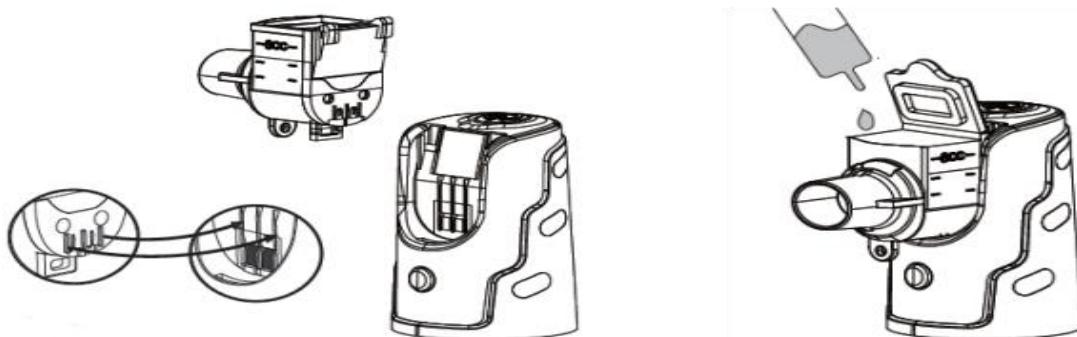
4.1 How to operate with batteries

1. Insert the batteries.
 - Turn the machine upside down.
 - Push back and pull up the battery cover to open it.
 - Insert two AA alkaline (1.5 V*2) according to the battery polarity indicated inside the battery compartment.
 - Push down and push forward the battery cover to lock it.



2. Set up medicine cup.

- Align the three ruts on the back of the medicine cup with three trenches of the main unit to insert the medicine cup into the main unit



Set up medicine cup

Fill the liquid

Important:

- a. Do not insert a battery with the positive (+) and negative (-) poles reversed;
- b. Do not use old and new batteries together or mixing batteries with different brands.

3. Fill the liquid.

Make sure that indicator light is off before adding the liquid.

- Open the cap of medicine cup.
- Fill the medicine cup with liquid, do not exceed the maximum limit (6ml).
- Close the cap properly.

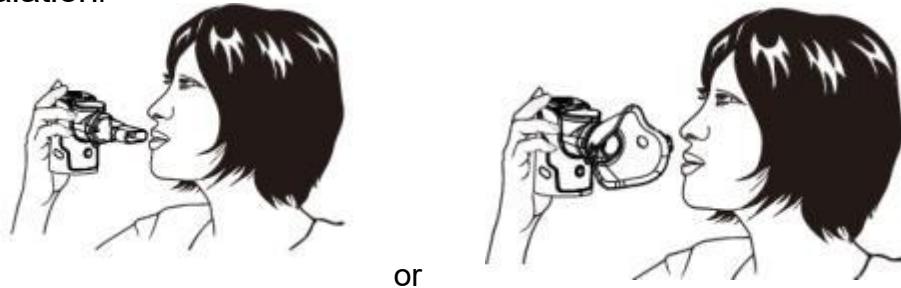
4. Inhalation

- Put mouthpiece into your mouth, with your lips firmly sealed around the mouthpiece or put mask close to your face.
- Press the top switch button to turn on the device (light indicator turn on in green).
- Breathe in and out slowly through your mouth until aerosol particulates stop.

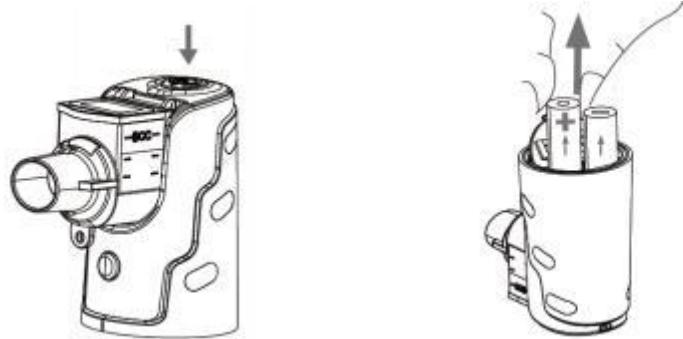
5. End of inhalation

- Press the top switch button to turn it off.
- Remove the batteries from the main unit.

Inhalation:



End of inhalation:

**Important:**

- a. Tilt the device slightly towards to the nozzle, while the solution is almost exhausted to make sure that the residual solutions contact the mesh and is nebulized completely.
- b. If the use of high-viscosity solution, nebulization may be reduced.

- c. If excessive solutions are accumulated on the mesh, nebulization may stop. In this case, turn off the device and absorb the solutions by gauze or lint-free towel.

Battery life and change

1. Battery life is usually depending on the capacity and condition of the batteries. In general, this device can operate about 4 days with two new AA alkaline batteries based on usage of 20 minutes a day.
2. When the power indicator turns into red (means low power), please replace the batteries at once.
3. Discarded batteries must not be disposed by following local laws and recycling plans regarding disposal or recycling of components, batteries and packaging.

4.2 How to operate with Adapter

Important:

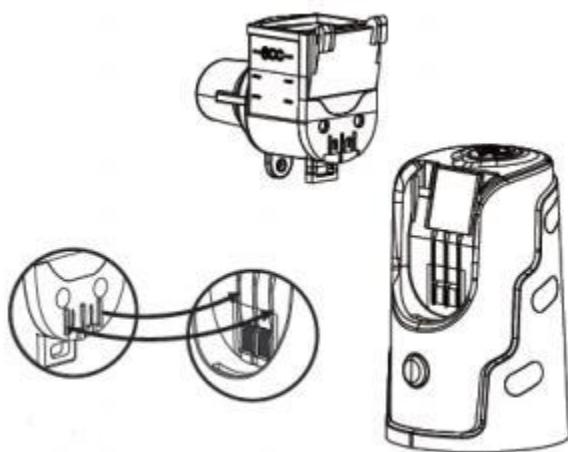
- A. The power adapter is optional accessories.
- B. Please use a.c 100-240V,50Hz adapter, and the connection jack should match a plug with outer diameter of 3.5mm, interior diameter of 1.35mm, 9.5mm in length and positive polarity.
- C. Adapter cannot charge battery, please remove the batteries before using the adapter.
- D. As with all electrical devices, it is recommended that keep the device unplugged when not in use.

1. Set up medicine cup

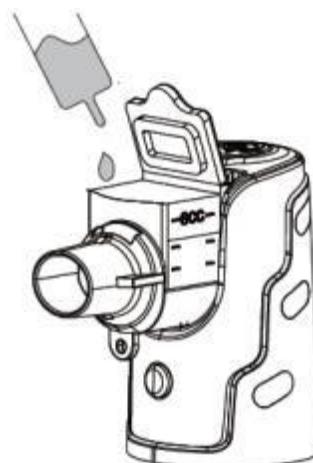
- Align the three rubs on the back of the medicine cup with three trenches of the main unit to insert the medicine cup into the main unit.

2. Fill the saline

- Open the cap of medicine cup.
- Fill the medicine cup with saline, do not exceed the maximum limit (6ml).
- Close the cap properly.



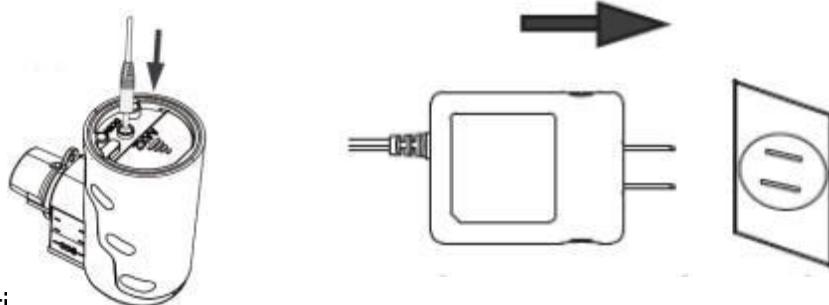
Set up medicine cup



Fill the saline

3. Connect with adapter

- Plug the cable into the power adapter jack on the main unit.
- Plug the adapter into a standard electrical outlet.



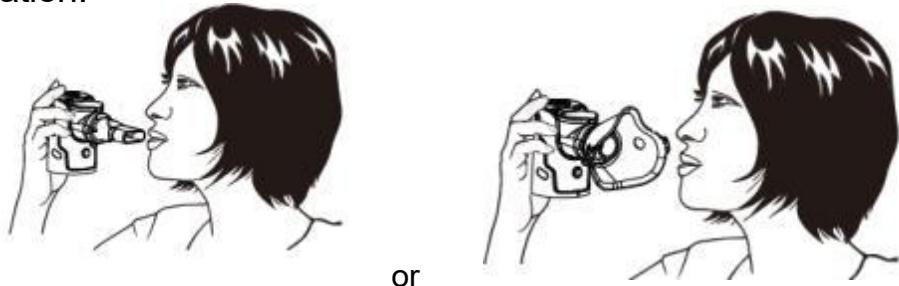
4. Inhalation:

- Put the mouthpiece in your mouth, with your lips firmly sealed around the mouthpiece.
- Press the top switch button to turn on the device (light Indicator turns on in green).
- Breathe in and out slowly through your mouth until aerosol particulates stop.

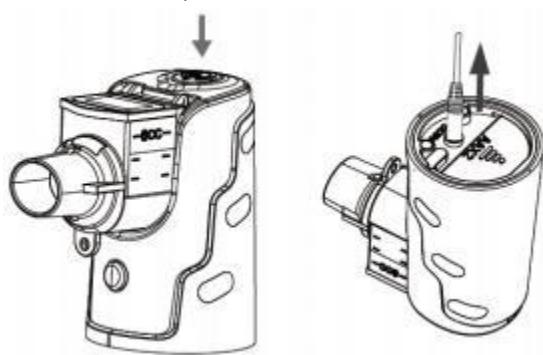
5. End of inhalation

- Press the top switch button to turn it off.
- Remove the adapter from main unit and electrical outlet.

Inhalation:



End of inhalation:



5. CLEANING

Important: If the device is not cleaned and disinfected correctly and frequently as indicated, microorganisms may remain in the unit and cause risk of infection.

All the accessories are for single patient multi-use, and need to clean.
After every use:

Clean the medicine cup with tap water after each inhalation.

1. Pour out the residual solutions in the medicine cup.
2. Pour some tap water into the medicine cup.
3. Turn on the device to nebulize the tap water for 1 to 2 minutes to clean the mesh.
4. Remove batteries or disconnect the adapter from the main unit.
5. Remove the medicine cup from the main unit.
6. Wash and rinse the medicine cup with tap water.
7. Shake off excess water and allow parts to be fully air dried on a clean, dry towel.
8. Use gauze or a clean towel to wipe off stains on the main unit if necessary.
9. Make sure that all cleaned parts are completely dry before you store them or use them next time.

Important:

- a. Keep the battery compartment stay in dry all the time.
- b. Do not use your fingers, cotton swab, or any object to poke the mesh.
- c. Do not use dishwasher to clean parts.
- d. Do not use microwave to dry any accessories.

Cleaning:

Please follow the following steps to disinfect your nebulizer. Make sure the medicine cup is cleaned after each use.

Cleaned by pure water:

After each inhalation treatment, please wash medicine cups with pure water.

- 1.Put the medicine in the rest of the solution.
- 2.Pour some water in the medication cup.
- 3.Boot burst with pure water for 1 to 2 minutes to clean the mesh.
- 4.Remove the batteries or unplug the adapter.
- 5.Remove cup from main unit.
- 6.Wash the medicine cup with pure water.
- 7.Rolled out excess water, ventilation of air dry or use dry towel to dry it.
- 8.IF necessary, use gauze or a clean towel dry dirt on machine .
- 9.Please make sure you store or use them at the next time, all the parts are completely dry erase.

Disinfection by alcohol:

1. After clean the medicine cup, immerse it into 75% ethyl alcohol for 5-10 minutes, make sure the accessories are immersed into the liquid level completely.
2. Then make an air dry for these accessories on a dry & clean cloth.
3. Make sure that all cleaned parts are completely dry before you store them or use them next time.

Important: Alcohol is highly flammable. Do not use alcohol in the vicinity of a fire or smoking.

6. Transportation and storage

Put on the mouthpiece cover, store the device and medicine cup in a dry and clean environment.

1. Do NOT leave or carry the device containing residual liquid in the medicine cup.
2. Remove the batteries if device is not in use for long periods. Failure to do so could result in damage due to battery leakage.
3. Do NOT leave the device under direct sunlight, in high humidity, extreme heat or cold environment.
4. Keep this device away from fire, high electromagnetic fields and out of the reach of children.

7. Troubleshooting

If any trouble occurs while you are using the device, please check the following list first.

Problem	Possible Cause	Action
Low atomization	Low battery power	Replace the batteries or use the adapter
	The stains on the electrode cause a fault connection	Use rubbing alcohol to clean electrodes
	The mesh holes have been clogged	Refer to Cleaning and Disinfection procedure to clean the medicine cup
	The mesh is broken	Replace the medicine cup
After turn on the power, power indicator is not on and no mist comes out.	The batteries are inserted in the wrong direction	Follow (+) and (-) mark on the battery cover to re-insert the batteries in correct direction
	Batteries are dead	Replace the batteries or use the adapter
	Fault connection between adapter and main unit	Check and reconnect the adapter to main unit
After turn on the power, the power indicator is on but no atomization.	The medicine cup is not installed properly	Refer to Set up the medicine cup procedure to re-install the medicine cup
	The mesh holes have been clogged	Refer to Cleaning and Disinfection procedure to clean the medicine cup
	The mesh is broken	Replace the medicine cup
Power indicator turns into orange light constantly	Low battery power	Replace the batteries or use the adapter
Power indicator turns into orange light and flashing.	Fault connection of electrode and main unit	Use rubbing alcohol to clean electrodes and re-stall the medicine cup
	The mesh is broken	Replace the medicine cup

Note:If necessary, follow the contact information provided in this manual, We will provide circuit diagrams, component part lists.descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair

8. EMC information

The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and the device can be affected by portable and mobile RF communications equipment.

EMC Warning:

- 1) The portable (ultrasonic) nebulizer is intended to be used in the hospital and family setting except for near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.
- 2) Do not use a mobile phone or other devices that emit electromagnetic fields near the unit. This may result in incorrect operation of the unit.
- 3) Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation.
- 4) Caution: 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 device and the other equipment should be observed to verify that they are operating normally.
- 5) Use of accessories other than those specified or provided by the manufacturer of this the nebulizer could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- 6) Do not expose the device to RFID systems.

Essential performance of the mesh nebulizer:

Model Number	JLN-MB001
Full battery indication	Green light
Low battery indication	Red light
Average Nebulization Rate	≥0.25mL/min

Guidance and manufacturer's declaration – electromagnetic emissions

The JLN-MB001 Mesh Nebulizer is intended for use in the electromagnetic environment specified below. The customer or the user of the JLN-MB001 Mesh Nebulizer should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The JLN-MB001 Mesh Nebulizer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The JLN-MB001 Mesh Nebulizer suitable for use in all establishments, including domestic
Harmonic emissions IEC 61000-3-2	Compliance	establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Compliance	

Guidance and manufacturer's declaration – electromagnetic immunity

The JLN-MB001 Mesh Nebulizer is intended for use in the electromagnetic environment specified below. The customer or the user of the JLN-MB001 Mesh Nebulizer should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8kV direct & indirect contact ±15kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. If ESD interfere with the operation of equipment, counter measurements such as wrist strap, grounding shall be considered.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for Power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<0 % UT for 0.5 cycles (0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°); 0% for 1 cycle; 70 % UT for 25/30 cycles (0); <0 % UT for 5 s (250/300 cycles)	<0 % UT for 0.5 cycles (0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°); 0% for 1 cycle; 70 % UT for 25/30 cycles (0); <0 % UT for 5 s (250/300 cycles)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the JLN-MB001 requires continued operation during power mains interruptions, it is recommended that the JLN-MB001 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m 50Hz/60Hz	30A/m 50Hz/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity

The JLN-MB001 Mesh Nebulizer is intended for use in the electromagnetic environment specified below. The customer or the user of the JLN-MB001 Mesh Nebulizer should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance

Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80 MHz, 6 Vrms in ISM bands 150 kHz to 80MHz, 80% AM at 1kHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the JLN-MB001, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	10V/m 80MHz to 2.7 GHz	10V/m 80MHz to 2.7 GHz	$d = 1.2 \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3 \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM

Recommended separation distances between Portable and mobile RF communications equipment and the JLN-MB001 MES			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	$d = 1.2 \sqrt{P}$	$d = 1.2 \sqrt{P}$	$d = 2.3 \sqrt{P}$
0.1	0.12	0.12	0.23
	0.38	0.38	0.73

1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

- a) For some services, only the uplink frequencies are included.
- b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
- c) 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.

9. SPECIFICATIONS

Power	Adapter: input :100-240Va.c., 50/60HZ,0.2A. Output 5V/1.0A Main unit 5.0Vd.c.,1.0A or internal batteries1.5Vd.c. x 2 AA)
Power Consumption	5W
Fusing resistor	4.7 Ω/1W
Ultrasonic vibration frequency	110Kz±10%
Medicine Capacity	≤6ml
Particle Size	1 to 5 um, >50%
MMAD	<5μm
Sound Level	≤45dB
Average Nebulization Rate	≥0.25ml/min
Continuous working time	4h
Operating Temperature Range	50°F to 104°F (10°C to 40°C)
Operating Humidity Range	30%RH to 75% RH
Operating Air pressure	70kPa to 106 kPa
Storage Temperature Range	-20°C-55°C
Storage Humidity Range	10%-93%RH
Storage Air pressure	50kPa to 106 kPa
Dimension (Lx W x H)	77*74*48mm
Weight	80g
Transportation conditions	-20°C-55°C, 10%-93%RH,50kPa to 106 kPa
Standard Accessories	Medicine cup; Mask; Mouthpiece;
Service life	3 years
Notice: The time required for the device to be ready for its intended use from the lowest storage temperature is 2 hours, when the ambient temperature is 20°C.	
The time required for the device to be ready for its intended use from the maximum storage temperature is 2 hours, when the ambient temperature is 20°C.	

10. Particulate distribution data

Test drug: Albuterol 0.1% (M/V) concentration in 0.9% sodium chloride solution.

Item	Big mask	Mouthpiece
Percentage of particulate distribution	>5 μm	12.90%
	2 μm to 5 μm	71.80%
	<2 μm	15.30%
MMAD	3.35μm	3.41μm
GSD	1.34	1.38
Respirable fraction	88.70%	86.30%
Residual volume	<0.60ml	<0.60ml

Protection against electric shock



- Type BF applied parts

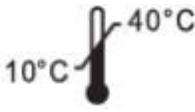
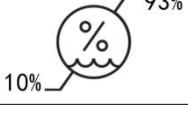


- Class II

Protection against harmful ingress of water: -IP22

Degree of safety in the presence of flammable anesthetics or oxygen

-No AP/APG (Not suitable for use in the presence of flammable anesthetic gas or oxygen)

Symbol	Explanation
	Manufacturer
	Authorised representative in the European Community
	Lot Number
	Serial Number
	Date of Manufacture
	Caution
	WARNING
	Batteries or electronic instruments must be disposed of in accordance with the locally applicable regulations, not with domestic waste.
	Refer to instruction manual/ booklet
	Power button
	DC
	AC
	Operating Temperature Range
	Storage Temperature Range
	Operating Humidity Range
	Storage Humidity Range

SN	serial number
	Keep dry
	Environmental protection cycle mark
	Recycling symbol
	Intertek Medical Notified Body AB



Shenzhen Homed Medical Device Co., Ltd.



Address:

Room 1601-1614, A Building, Jinxiu III, No. 85 Hudi Pai Songxuan

Community, Guanhu Street, Longhua District, Shenzhen, 518109, P.R.

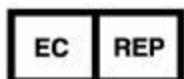
China (FIN FO05721)

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