User Manual for Mesh Nebulizer

(H6)

Qingdao Future Medical Technology Co. Ltd.

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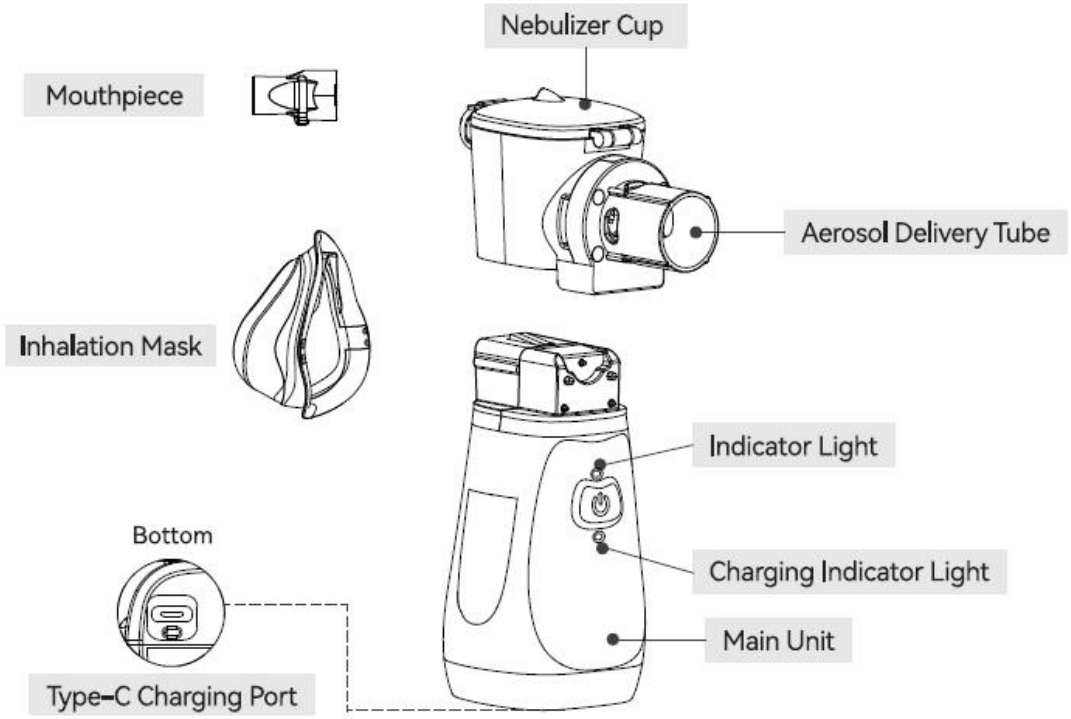
1. Product Information

1.1 Basic Product Information

Product Name	Mesh Nebulizer
Model	H6

1.2 Structure and Composition

The Mesh Nebulizer consists of a main unit, a nebulizer cup, and optional accessories. The main unit includes an adjustment and control system; the nebulizer cup comprises a medicine cup, a micro-mesh spray sheet, and an aerosol delivery tube. The main unit housing is made of ABS material, the nebulizer cup is made of PC material, the inhalation mask is made of PP+TPE+silicone material, and the mouthpiece is made of PP+silicone material. Optional accessories include inhalation masks (available in child and adult sizes), mouthpieces, and power cords. The product assembly structure diagram is as follows:



1.3 Indications for Use

1) Intended Use: The Mesh Nebulizer designed to aerosolized liquid medications for inhalation by patient.
2) Patient Population: Pediatric over 2 years and adult patients with upper and lower respiratory system diseases.
3) Intended User: Health care professionals, such as doctors, nurses and therapist; Patients with upper and lower respiratory system diseases, including pediatric patients over 2 years and their supervisors, such as their parents; Adult patients.
4) Indications: Upper and lower respiratory system diseases.
5) Contraindications: Do not use if allergic to the product materials or the medications used. Please refer to the accompanying medication instructions.
6) Clinical Benefits: Directly deliver the medication to the target organs of respiratory system

- Lower doses of the medication are required;
- Higher local bioavailability of the medication;
- Shorter treatment time and more effective treatment outcome;
- Reduced side effects compared to systemic administration.

1.4 Types of Nebulized Drugs

The nebulizer can atomize various low-concentration inhalation therapeutic medications, such as bronchodilators, corticosteroids, antibiotics, propellants, and antihistamines. Consultation with a physician is required before using the medication. The nebulizer should not be used with high-viscosity liquids.

1.5 Product Performance - Aerosol Characteristics according to ISO 27427

The aerosol characteristics presented in the user manual were determined in accordance with ISO 27427 using an NGI with salbutamol solution at Qingdao Future Medical Laboratory. If nebulization is performed under different laboratory conditions (such as different laboratory temperatures or using other solutions or suspensions), the aerosol characteristics may differ from the values shown.

The following table is based on standard tests conducted using the adult mouthpiece breathing mode. Therefore, these values may differ from the corresponding values calculated for pediatric and infant populations.

Adult Breathing Patterns with Mouthpiece	**Salbutamol (2mL:5mg)**
MMAD (μm)	3.72
GSD	1.67
Respirable Fraction (%, <5μm)	70.10
Respirable Fraction (%, <2μm)	11.67
Respirable Fraction (%, >2μm <5μm)	58.43
Aerosol Output (ml)	2.17
Aerosol Output Rate (ml/min)	0.15
Residual Volume (ml)	0.032
Percentage of Fill Volume Emitted per Minutes (%/min)	26.42

1.6 Product Specifications

Category	**Indicator**	**Parameter**
Power Parameters	Input Voltage	Power Adapter 100-240Vac, Special Power Supply (USB Power Supply) DC5.0V, Build-in Battery (Rechargeable Lithium Battery) DC3.7V
	Rated Input Power of the Equipment	Specific Power Supply (USB interface power supply): 2W Internal Power Supply (Rechargeable Lithium Battery): 2W
	Battery Capacity	1200mAh
	Continuous Operation Time	≥120min
	Output Voltage	AC RMS ≤50V
	Output Frequency	110kHz±10%
	Output Power	≤2W
Specifications	Residual Liquid Volume	≤0.2mL
	Atomization Rate	≥0.2mL/min
	Operating Noise	≤45dB (A weighted)
	Nebulizer cup Capacity	8mL±0.2mL
	Power Cord Dimensions	1000mm±15mm/φ3.5mm±0.15mm
	Controller Dimensions	75mm(L)×50mm(W)×111mm(H)±2mm
	Weight	95g±5g
Electrical Safety	Operation Mode	Continuous Operation
	Electrical Safety Class	Internal Power Device, Specified Power Device, Class II, BF

		Type
	Liquid Ingress Protection	IP22
Environmental Requirements	Operating Temperature Range	5℃～40℃
	Operating Humidity Range	30%～80% (RH) (No Condensation)
	Operating Atmospheric Pressure Range	70kPa～106kPa
	Storage/Transport Temperature Range	-25℃～60℃
	Storage/Transport Humidity Range	15%～90% (RH)
	Storage/Transport Atmospheric Pressure Range	70kPa～106kPa
Software Release Version	Yirdoc Mesh Nebulizer Software	V1.0

2.Cautions and Warnings

2.1 Cautions

1. Purchase and use this product under the guidance of a doctor. Follow the doctor's instructions regarding the type, dosage, and usage method of the medication.
2. The nebulizer is a medical device; use it strictly according to the operation steps in the manual or under a doctor's guidance.
3. The product should be repaired by the company's after-sales technicians or designated personnel. Do not disassemble the main unit or attempt to repair it yourself. Any consequences resulting from such actions will be the responsibility of the user.
4. Use only the parts or accessories provided by the company. Using non-provided parts or accessories may reduce the product's safety. In case of damage caused by the use of parts or accessories not listed in the user manual, the product will not be covered by the warranty, and the company will not assume any responsibility for any issues arising from this.
5. The nebulizer is intended for use with nebulized medications for aerosol drug delivery treatment.
6. Do not shake the nebulizer violently or carry it around with liquid in the nebulizer cup.
7. Please remove all packaging and ensure the completeness of all parts before use.
8. Please check the packaging before use. Do not use if damaged or expired.
9. The main unit can be used by multiple people, but the components in contact with the medication (nebulizer cup, mouthpiece, inhalation mask) are for single-person use only.
10. Do not inhale water to avoid exacerbation of symptoms. To prevent misuse, the product cannot nebulizer water during normal operation.
11. The product is not suitable for use in respiratory anesthesia systems or respiratory systems and does not drive any gases. Do not use the nebulizer near flammable gases or mixtures of oxygen and anesthetics.
12. Do not use the nebulizer during a shower or bath.
13. Dispose of waste generated during use and at the end of the product's life according to local regulations. Dispose of old batteries at designated locations.
14. Please keep it out of reach of children and pets to prevent accidental drops or ingestion.

2.2 Warnings

1. Purchase and use this product under the guidance of a doctor. Follow the doctor's instructions regarding the type, dosage, and usage method of the medication.
2. Consult a doctor if you have diabetes or other conditions before use.

3. If any discomfort occurs during use, stop immediately and consult your doctor.
4. Do not use volatile, high-viscosity, large-particle, or oily liquids to avoid damage to the nebulizer cup.
5. Use only water-soluble medications or medications diluted with saline.
6. Do not spill medication on the main unit to avoid electric shock or malfunction.
7. Dispose of remaining medication according to relevant national laws or doctor's advice after nebulization.
8. Children should use the nebulizer under adult supervision.
9. The product is intended for individuals with respiratory diseases. The nebulizer may become unusable due to factors such as battery depletion or mechanical failure. To avoid emergencies such as unexpected malfunctions or acute asthma attacks, it is recommended to have an additional nebulizer of the same model as a backup.
10. Do not plug or unplug the power adapter with wet hands.
11. Ensure that this device has acclimated to room temperature before nebulizing the medication. Nebulizing the medication after an extreme temperature change could lead to less nebulization. We recommend waiting for approximately 2 hours for the device to warm up or cool down when the device is used at an environment within the temperature specified as operating conditions after it is stored either at the maximum or at the minimum storage temperature. The product contains cables. Ensure they are properly placed during use or storage to avoid strangulation hazards from overly long cables.
12. Avoid exposing the product to lint or dusty environments, as this may reduce performance or cause damage
13. Do not store the product in direct sunlight for extended periods to prevent reducing the device's lifespan.
14. Avoid dropping or hitting the nebulizer to maintain nebulization performance.
15. Do not operate the device without medication or water in the nebulizer cup to prevent damage.
16. Do not insert fingers or foreign objects into the spray port or touch the mesh membrane to avoid damage.
17. Do not use needles or other objects to touch the mesh membrane.
18. Avoid deliberately touching the electrodes on the main unit and the nebulizer cup with cotton swabs or other objects to prevent detachment.
19. Dispose of the product in accordance with local regulations when its service life ends.
20. Do not use the device in environments with equipment that generates strong electromagnetic fields, such as MRI machines.
21. Before use, ensure that the inhalation mask or mouthpiece is securely attached to prevent it from falling off during nebulization.

3. Battery Information

Power Supply: DC3.7V lithium battery
Power Adapter: This product does not come with a power adapter. Please use an adapter from a reputable manufacturer (compliant with IEC60601-1 requirements, output: DC5V 1000mA).

Battery Safety Usage and Maintenance Instructions：
1) If the product will not be used for an extended period, fully charge the battery before storage and recharge it every six months.
2) Use the product under the conditions specified in this manual. Do not use it in environments with excessively high or low temperatures to avoid damaging the battery's lifespan.
3) Battery replacement should only be performed by our company’s technicians or authorized personnel. Refer to the battery specifications for identification details.

4. Installation and Usage

To ensure the proper use of this product, please carefully read this manual and strictly follow the usage requirements outlined herein. If you have any questions, please contact the supplier or manufacturer.

4.1 Unboxing and Inspection

4.1.1 Before installing and using the product, first check the product's appearance for any damage and verify that the accessories and quantities match the accessory list. If there are any discrepancies, please contact the supplier or manufacturer promptly.
4.1.2 Remove all packaging before use.

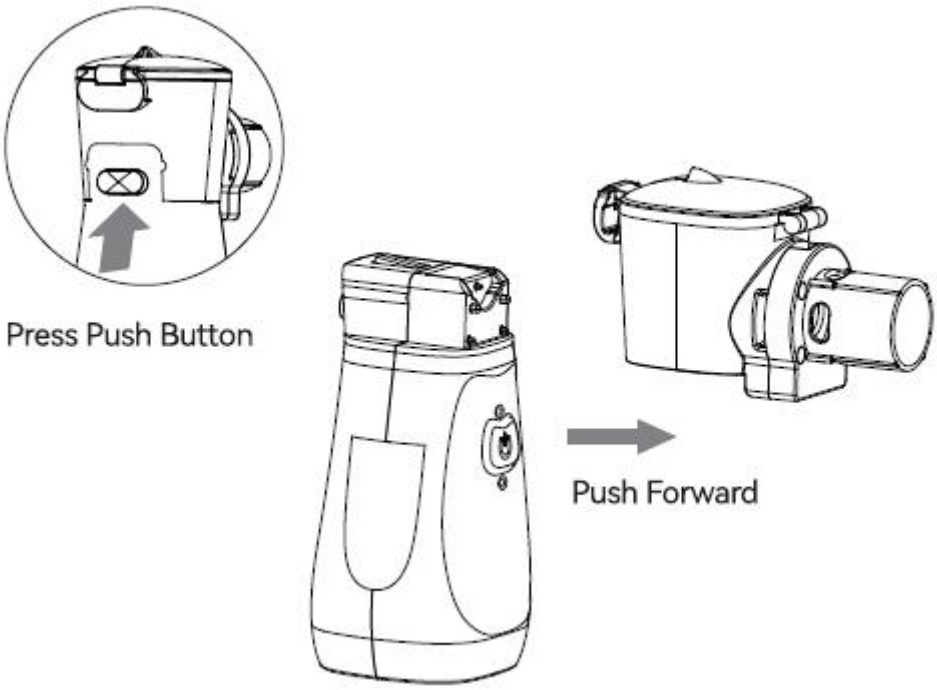
4.2 Battery Charging

Charge the battery fully before first use. When the nebulizer's battery is low, the blue operation indicator on the top will remain on continuously. At this point, the remaining usage time is less than 5 minutes, please charge the lithium battery. Connect the power adapter to the interface at the bottom rear of the main unit and the power outlet. While charging, the blue charging indicator at the bottom will remain on. When the battery reaches the working voltage, the device can operate normally. The charging indicator will turn green when fully charged. At this point, the remaining usage time is more than 120 minutes.

4.3 Installation and Removal of the nebulizer cup

4.3.1 Installation: Insert the nebulizer cup into the main unit in the direction shown in the illustration. A clicking sound will be heard when the cup is successfully installed.

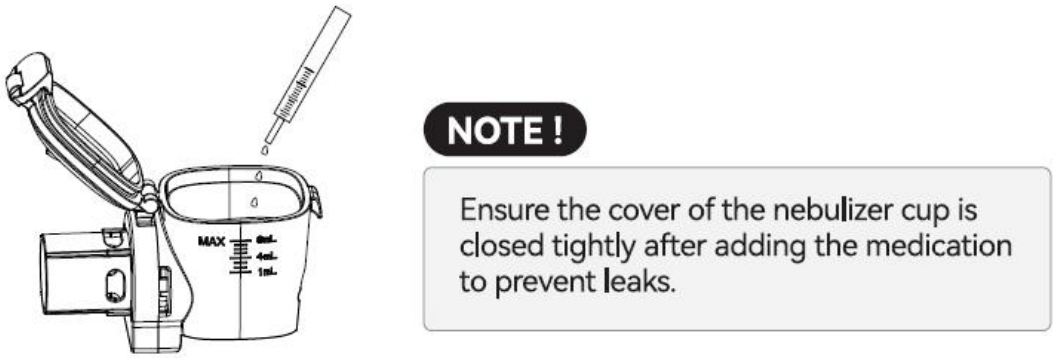
4.3.2 Removal: To remove the nebulizer cup assembly from the nebulizer, press the button on the back of the main unit and push the nebulizer cup forward to detach it.



Note: Ensure the button is fully pressed before pushing the nebulizer cup to avoid damaging the nebulizer.

4.4 Adding Medication

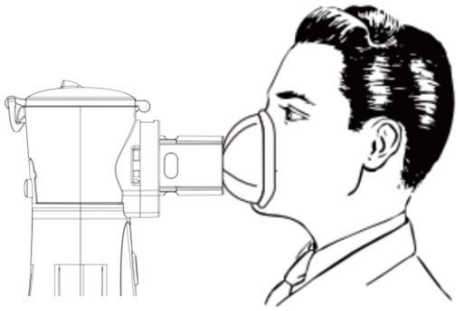
4.4.1 Adding Medication (as shown): Open the top cover of the nebulizer cup, add the medication, and close the cover tightly after adding the medication.
4.4.2 Each medication dose should be no less than 0.5mL, with a maximum capacity of 8mL for the nebulizer cup.
Note: Ensure the cover of the nebulizer cup is closed tightly after adding the medication to prevent leaks.



4.5 Install the Inhalation Mask or Mouthpiece, ensuring it is securely attached.

4.6 Nebulization Treatment

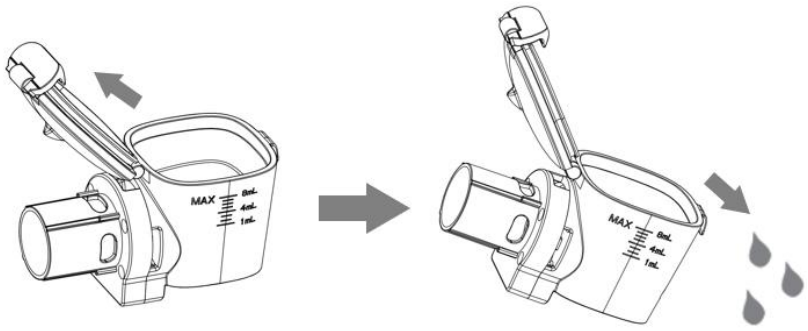
4.6.1 Press the power switch, and the green operation indicator will stay on. Release the power switch within 3 seconds to start the nebulizer.
4.6.2 Breathe slowly and deeply. Holding your breath briefly after inhaling the medication can improve the treatment's effectiveness. Stay calm and relaxed during the treatment, and do not inhale too quickly.
4.6.3 The nebulizer has an automatic shutdown feature that turns off the device after 15 minutes. If the treatment is not complete, restart the device to continue nebulization.
4.6.4 When inhaling with the nebulizer, keep the device as vertical as possible to ensure the nose and mouth are fully covered by the mask, as shown in the illustration.



4.6.5 Do not cover the vent hole on the top cover of the nebulizer cup during normal nebulization or cleaning modes to avoid improper or no nebulization.
4.6.6 When the medication is nearly depleted, tilt the nebulizer slightly towards you to fully utilize the medication.
4.6.7 If excessive foam or residual medication in the nebulizer cup reduces the nebulization rate, causing the device to fail to shut down automatically, manually shut down the device immediately to avoid damaging the nebulizer cup and the nebulizer.
4.6.8 After manual shutdown, gently shake the device to concentrate the foam or medication at the mesh membrane area. Restart the device after the foam reduces to achieve better nebulization.

4.7 Turning Off the Device

4.7.1 The nebulizer will automatically shut down when the medication is depleted.
4.7.2 To stop nebulization during use, press the power switch to turn off the device, and the indicator light will go out.
4.7.3 If there is any remaining medication, pour it out and do not reuse it.
4.7.4 After nebulization, promptly clean the nebulizer cup with bottled water.
4.7.5 Wash your face and rinse your mouth with water after nebulization.



Note: Clean any residual medication after each use to avoid clogging the mesh membrane area, which can affect nebulization performance.

4.8 Low Battery Alert

The nebulizer has a low battery alert feature. During nebulization or cleaning mode, when the battery is low, the indicator light will stay on blue continuously. If you need to continue nebulization or cleaning mode, charge the device promptly.

4.9 Automatic Shutdown Without Medication

The nebulizer has an automatic shutdown feature when there is no medication. If the nebulizer cup is empty or the medication is nearly depleted, the device will detect the absence of liquid, and the green light indicator will flash slowly (alternating on and off every second). If no liquid is detected after five flashes, the device will shut down.

5. Cleaning, Disinfection, and Maintenance

5.1 Cleaning, Disinfection

Component	Cleaning Method			Disinfection Method		
	Rinse, Self-cleaning and Wipe	Wipe	Soak and Wipe	Wipe	Soak	Boiling
Nebulizer Cup	◎	N/A	N/A	N/A	◎	◎
Main Unit	N/A	◎	N/A	◎	N/A	N/A
Inhalation Mask, Mouthpiece	N/A	N/A	◎	N/A	◎	◎
Agents	Bottled water			70-75% alcohol		Bottled water
Frequency	After each use			Weekly		
Notes	1. Clean and disinfect before first use, and when the device has not been used for a long time. 2. Please perform disinfection after cleaning the device. 3. Except when using the self-cleaning function of the nebulizer cup, ensure the device is disconnected from the power source during all other cleaning and disinfection steps. 4. When cleaning the nebulizer cup, avoid direct water flow on the micro-mesh spray area to prevent reducing its lifespan or causing damage. 5. Do not use sodium chloride solution or acidic/alkaline solutions, or high concentration (99% anhydrous alcohol) alcohol for soaking, as this may damage the nebulizer cup. 6. Do not use volatile liquids (such as benzene, gasoline, or thinners) to wipe the nebulizer. 7. Do not use lint-prone paper or other cloth to wipe the nebulizer cup to prevent residual paper scraps or cloth fibers from entering and clogging the mesh membrane, leading to malfunction. 8. Due to material properties and compatibility, this product is not suitable for high-pressure steam sterilization.					

5.2 Cleaning Methods

5.2.1 Cleaning the Nebulizer Cup

5.2.1.1 Nebulizer Cup Rinsing

① Open the nebulizer cup lid and add 4mL–8mL of bottled water, with the water temperature controlled between 5℃ - 40℃.

② Close the nebulizer cup lid and gently shake the cup for at least 2 minutes. Open the lid and pour out the remaining liquid.

③ Repeat this process 3 times, then shake off excess water and set aside for use.

5.2.1.2 Self-Cleaning the nebulizer cup

① Add 4mL ~ 8mL of bottled water into the nebulizer cup and securely close the lid.

② Press and hold the power button for 3 seconds. The operating status indicator will alternate between blue and green, indicating the nebulizer is in cleaning mode. The nebulizer will run in normal spray mode for 3 minutes before shutting down.

③ After the self-cleaning mode ends, pour out the remaining liquid from the nebulizer cup.

④ Add 4mL ~ 8mL of bottled water back into the nebulizer cup, rinse the cup, then shake off the excess water and set it aside.

5.2.1.3 Wiping the nebulizer cup

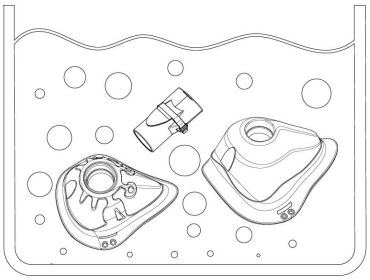
Use medical gauze moistened with bottled water to gently wipe the outer surface of nebulizer cup and aerosol delivery tube at least 5 minutes. Replace a new medical gauze if there is too much soil on the wipe. Use a new piece of medical gauze to dry it. After cleaning, place the nebulizer in a dry and clean place to prevent contamination.

5.2.2 Cleaning the Main Unit

Use a medical gauze moistened with bottled water to gently wipe the stains on the main unit in one direction for no less than 5 minutes. Replace a new medical gauze if there is too much soil on the wipe, until no dirty is visible. Then, use a new medical gauze to dry the unit. After cleaning, place the nebulizer in a dry, clean place to prevent contamination.

5.2.3 Cleaning the Inhalation Mask and Mouthpiece

Prepare a clean container filled with an adequate amount of bottled water (5-40°C), ensuring that the water level can fully submerge all parts (inhalation mask and mouthpiece). Soak for 10 minutes, then use a medical gauze dampened with bottled water to gently wipe the stains on the inhalation mask and mouthpiece in one direction for at least 5 minutes, until no contamination is visible with unaided vision. If the gauze becomes too soiled, replace it with a new one. Shake off the excess water and use a new piece of medical gauze to wipe it, and allow them to air dry naturally.



5.3 Disinfection Methods

5.3.1 Disinfection with 70-75% alcohol

①Use medical gauze dampened with an appropriate amount of disinfectant (70~75% alcohol) to wipe the surface of the main unit. Ensure a contact time of no less than 10 minutes.

②Soak the nebulizer cup, inhalation mask, and mouthpiece in the disinfectant solution (70~75% alcohol) for no less than 10 minutes. Shake off excess liquid and allow to air dry.

5.3.2 Boiling Water Disinfection

The nebulizer cup, inhalation mask, and mouthpiece can be disinfected by boiling.

① Boil bottled water that can submerge the nebulizer cup, inhalation mask, and mouthpiece.

② Place the nebulizer cup, inhalation mask, and mouthpiece into the boiling water, and continue boiling for 10 minutes. Afterward, remove the parts, shake off excess water, and allow them to air dry naturally.

5.4 Product Maintenance and Care

5.4.1 If the nebulizer will not be used for a long period, fully charge it and store it in a cool, dry place, away from dust and light.

5.4.2 Do not place the main unit and other components in extreme high or low temperatures, or in direct sunlight.

5.4.3The nebulizer does not have moisture or dust protection, so avoid placing it in humid or dusty environments.

5.4.4 Waste generated during the use of the nebulizer, as well as the device at the end of its lifespan, should be disposed of and recycled in accordance with local regulations.

6. Common Troubleshooting and Solutions

Issue	Possible Cause	Solution

Low aerosol output	Nebulizer cup not properly assembled	Reassemble the nebulizer cup and restart
	Medication is running out	Tilt the nebulizer to make the medication contact the spray mesh
	Blocked mesh membrane	Clean the nebulizer cup as instructed; if unresolved, replace the cup
	Electrode dirt on the main unit or nebulizer cup	Clean the electrodes and restart
The green operation status indicator flashes and then turns off after power on.	Nebulizer cup not properly assembled	Reassemble the nebulizer cup and restart
	No medication or medication is exhausted	Fill the medication
	Electrode dirt on the main unit or nebulizer cup	Clean the electrodes and restart
The status indicator light is off, and the nebulizer is not working.	Button stuck	Contact authorized service center or manufacturer
	Low battery	Recharge promptly
Blue light flashes and device shuts down with no aerosol	Low battery	Recharge promptly
Green light on but no aerosol	Dirty or blocked mesh membrane	Clean the nebulizer cup as instructed; if unresolved, replace the cup
	Faulty nebulizer cup	Replace with a new nebulizer cup
	Excessive medication bubbles	Turn off the device, gently shake it, then restart once bubbles are cleared
Cleaning mode produces no aerosol	Faulty or blocked nebulizer cup	Contact supplier
Aerosol is produced normally, but the blue indicator light remains on.	Low battery	Recharge promptly, then restart the device.
Device shuts down automatically during use	Nebulizer cup not properly assembled, detaching during use.	Reassemble the nebulizer cup and restart
	No medication or medication is exhausted	Refill the medication
	Excessive medication bubbles	Gently shake to clear bubbles then restart
	Shaking or vibrating the nebulizer vigorously during use.	Hold the nebulizer steadily during use
	Faulty nebulizer cup	Replace with a new nebulizer cup
The nebulizer is unable to shut down automatically	Electrode dirt on the main unit or nebulizer cup	Clean the electrodes and restart
Medication leakage	Damaged or aged sealing ring in nebulizer cup	Replace with a new nebulizer cup

7. Product Service Life and After-Sales Service

7.1 Product Service Life

Product shelf life: 3 years.
Nebulizer cup: Recommended to be used within 1 month after opening (with usage of 3 times a day, 30 minutes per session);
Mouthpiece and inhalation mask (child and adult): Recommended to be used within 1 year after opening (with usage of 3 times a day, 30 minutes per session).
Battery Service Life: 3 years (same as the main unit).

7.2 After-Sales Service

- Under normal use and storage conditions, the main unit (excluding the nebulizer cup) is warranted for free repairs within one year if quality issues arise. The nebulizer cups, mouthpieces, and inhalation masks are consumable parts and not covered by the warranty. In practice, the lifespan of the nebulization cup may vary depending on the medication used and the method of use. If the nebulizer does not produce aerosol or the aerosol output significantly decreases even after cleaning and troubleshooting, please replace the nebulizer cup.
- After the warranty period, if quality issues arise, users can present the warranty card to our after-sales service department, office, or authorized dealer. The company provides spare parts and offers repair services at a cost.
- The following conditions are not covered by the warranty:
  ① Consumable parts: nebulizer cup, inhalation mask, mouthpiece;
  ② Malfunctions caused by unauthorized disassembly, repair, or modification;
  ③ Malfunctions caused by dropping during use or transportation;
  ④ Malfunctions caused by liquid entering the main unit due to improper use;
  ⑤ Damages caused by unforeseen natural disasters (e.g., floods, fires, earthquakes).

Batch Number: On Package.
Manufacturing Date: On Package.
Accessory List: Inside the packaging: main unit, nebulizer cup, optional accessories (inhalation mask, mouthpiece, power cable), user manual.

8. Symbol Description

	Refer to Instructions Manual		Do Not Dispose of Randomly
IP22	Protection Level IP22		Power On/Off Button (Standby)
	Class II Equipment		Serial Number
	BF Type Equipment		Keep Dry
	Caution, See Accompanying Documents		Manufacturer
	This Way Up		Date of Manufacture
	Fragile, Handle with Care	LOT	Batch Number
UDI	Unique Device Identifier		Non-Ionizing
EU REP	Authorized Representative in the European Community	CE	CE Marking

	Temperature Limit		Humidity Limitation
	Medical Device		Single Patient Multiple Use
	Non-sterile		

9. Electromagnetic Sensitivity Statement

This device complies with the Electromagnetic Compatibility (EMC) requirements of IEC 60601-1-2:2014/AMD1:2020. This includes resistance to disturbances from radiofrequency electromagnetic fields and electrostatic discharge, as well as other usage requirements specified in this standard. Compliance with EMC standards does not guarantee complete immunity to interference; certain devices (such as mobile phones, radiofrequency base stations, etc.) used near medical equipment may disrupt the normal operation of these devices. For issues related to the use and placement of devices that may interfere with the operation of medical equipment, please follow relevant medical regulations.

Note: This device is classified as Class II, Type BF medical electronic equipment and complies with specified safety levels for electrical insulation and current leakage. The power adapter does not have a ground connection since the required protection level has been achieved through the use of double insulation.

10. Electromagnetic Compatibility Information

10.1 This section provides specific guidance on electromagnetic compatibility (EMC). The mesh nebulizer should be installed and used according to the EMC information in this chapter.
10.2 Mobile RF communication devices may affect the operation of the mesh nebulizer. It is recommended to keep the nebulizer away from mobile RF communication devices or ensure such devices are turned off during use.
10.3 Warning: Using components not supplied by the company may increase emissions or decrease the device's immunity to interference.
10.4 The mesh nebulizer should not be used in close proximity to or stacked with other devices. If such use is necessary, proper observation and validation are required to ensure normal operation in the intended configuration.
10.5 Essential performance: The atomization rate of the mesh nebulizer should not be less than 0.2 mL/min.
10.6 To ensure normal operation and maintain emissions control and immunity, use only the accessories provided by the company.

11. Notification of Incidents

For users/patients in the European Union and identical regulation systems (EU Medical Device Regulation (MDR) 2017/745), the following applies: If a major incident occurs during or through use of the product, notify the manufacturer and/or their representative of this as well as the respective national authority of the member state in which the you are located.

Appendix 1: Electromagnetic Compatibility Table

The mesh nebulizer is expected to be used in the specified electromagnetic environments. The purchaser or user should ensure that it is used in such electromagnetic environments:

Table 1 Guidelines and Manufacturer's Declarations – Electromagnetic Emissions

Transmitter Test	**Compliance**	**Electromagnetic Environment – Guidelines**
Radiated Emission IEC 60601-1-2: 2014+AMD1: 2020 CISPR 11:2015/AMD2:2019	1 Group	The nebulizer utilizes radiofrequency energy solely for its internal functionalities. As a result, its radiofrequency emissions are very low, and the likelihood of causing interference to nearby electronic devices is minimal.
Radiated Emission IEC 60601-1-2: 2014+AMD1: 2020 CISPR 11:2015/AMD2:2019	Class B	The nebulizer is suitable for use in all facilities, including household settings and those directly connected to the residential public low-voltage power grid.
Harmonic Current IEC 60601-1-2: 2014+AMD1: 2020 IEC 61000-3-2: 2018+AMD1: 2020	Class A	
Voltage Fluctuation and Flicker IEC 60601-1-2: 2014+AMD1: 2020 IEC 61000-3-3: 2013+A1: 2017+A2: 2021	Compliance	

Table 2 Guidelines and Manufacturer's Declarations – Electromagnetic Immunity

Immunity Test	Test Level	Compliance Level	Electromagnetic Environment – Guidelines
Electrostatic Discharge IEC 60601-1-2: 2014+AMD1: 2020 IEC 61000-4-2: 2008	±8 kV Contact Discharge ±15 kV Air Discharge	Air Discharge：±2/4/8/15 kV; Contact Discharge：±2/4/6/8 kV; Indirect Discharge：±2/4/6/8 kV;	The flooring should be made of wood, concrete, or tiles. If synthetic materials cover the floor, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst Test IEC 60601-1-2: 2014+AMD1: 2020 IEC 61000-4-4: 2012	±2 kV for Power Lines ±1 kV for Input/Output Lines	Power Lines：±2kV@5kHz、100kHz;	The power outlet should have the quality typical for use in commercial or hospital environments.
Surge Test IEC 60601-1-2: 2014+AMD1: 2020 IEC 61000-4-5:2014+AMD1:2017	±1 kV Line-to-Line ±2 kV Line-to-Ground	Line-to-Line：±0.5/1kV;	The power outlet should have the quality typical for use in commercial or hospital environments.
Voltage Dips and Interruptions Test IEC 60601-1-2: 2014+AMD1: 2020 IEC 61000-4-11: 2020	＜ 5%U_T, lasting for 0.5 cycles （On U_T，Temporary drop >95%） 40% U_T，lasting for 5 cycles （On U_T，Temporary drop 60%） 70% U_T，lasting for 25 cycles （On U_T，Temporary drop 30%） ＜ 5% U_T,lasting for 5 seconds （On U_T，Temporary drop >95%）	＜ 5%U_T, lasting for 0.5 cycles （On U_T，Temporary drop >95%） 40% U_T，lasting for 5 cycles （On U_T，Temporary drop 60%） 70% U_T，lasting for 25 cycles （On U_T，Temporary drop 30%） ＜ 5% U_T,lasting for 5 seconds （On U_T，Temporary drop >95%）	。The power outlet should have the quality typical for use in commercial or hospital environments. If users of the nebulizer require continuous operation during a power outage, it is recommended to use an uninterruptible power supply or battery power for the nebulizer.

Power Frequency Magnetic Field Susceptibility Test IEC 60601-1-2: 2014+AMD1: 2020 IEC 61000-4-8: 2009	3 A/m	3 A/m，50Hz/60Hz	The power frequency magnetic field should exhibit characteristics typical of the power frequency magnetic field levels found in typical commercial or hospital environments.

Table 3 Guidelines and Manufacturer's Declarations – Electromagnetic Immunity

Immunity Test	Test Level	Compliance Level	Electromagnetic Environment – Guidelines
Conducted Susceptibility Test IEC60601-1-2: 2014+AMD1: 2020 IEC61000-4-6: 2013+AC:2015 Radiated susceptibility Test IEC60601-1-2: 2014+AMD1: 2020 IEC 61000-4-3: 2020	3 V（Effective value） 150 kHz～80 MHz 3 V/m 80 MHz～2.5 GHz	[3] V [3] V/m	The use of portable and mobile radio frequency communication devices should not be brought closer to any part of the nebulizer (including cables) than the recommended isolation distance. This distance should be calculated using a formula corresponding to the transmitter frequency. Recommended isolation distance: d =1.2 d =1.2 80 MHz～800 MHz d =2.3 800 MHz～2.5GHz In the formula:； P——Maximum rated output power of the transmitter provided by the transmitter manufacturer, measured in watts (W).； d——Recommended isolation distance, measured in meters (m). The field strength of fixed radio frequency transmitters is determined by surveying the electromagnetic field (a), and it should be lower than the specified levels in each frequency range (b). Devices marked with the following symbols may cause interference 
Note 1: At the frequency points of 80 MHz and 800 MHz, the formula for the higher frequency range is applied. Note 2: These guidelines may not be applicable to all situations, as electromagnetic propagation is influenced by the absorption and reflection of buildings, objects, and the human body.			

a. Fixed transmitters, such as wireless (cellular/cordless) telephones and base stations, land mobile radios, AM and FM radio broadcasts, and television broadcasts, have theoretically unpredictable field strengths. To assess the electromagnetic environment of fixed radio frequency transmitters, an electromagnetic field survey should be considered. If the field strength measured in the location of the nebulizer exceeds the applicable radiofrequency compliance levels mentioned above, it is advisable to observe the nebulizer to verify its normal operation. If abnormal performance is observed, it may be necessary to take additional measures, such as reorienting or relocating the nebulizer.
b. Across the frequency range of 150 kHz to 80 MHz, the field strength should be below [3] V/m.

Table 4 Recommended Isolation Distances Between Portable and Mobile Radio Frequency Communication Devices and Mesh Nebulizer

The nebulizer is expected to be used in an electromagnetic environment where radiofrequency radiation is controlled. Based on the maximum output power of communication devices, purchasers or users can prevent electromagnetic interference by maintaining the recommended minimum distance between portable and mobile radio frequency communication devices (transmitters) and the nebulizer.

The maximum rated output power of the transmitter /W	The isolation distance corresponding to different frequencies of the transmitter / m		
	150 kHz～80 MHz d = 1.2	80 MHz～800MHz d = 1.2	800 MHz～2.5GHz d =2.3
0.01	0.12	0.12	0.23
0.1	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 transmitter maximum rated output powers not listed in the table, the recommended isolation distance (d) in meters (m) can be determined using the formula in the corresponding transmitter frequency column, where P is the maximum rated output power of the transmitter provided by the transmitter manufacturer, measured in watts (W).
Note 1: The formula for the higher frequency range is applied at the frequency points of 80 MHz and 800 MHz.
Note 2: These guidelines may not be applicable to all situations, as electromagnetic propagation is influenced by the absorption and reflection of buildings, objects, and the human body.

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