Wearable Mesh Nebulizer

User Manual

Version: V1.0

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Contents

1. Safe

1.1 Security information

⚠ warning

- Use the atomizer according to the method specified in the instructions.
- This machine does not have the frequency scanning function.
- Do not use contusion, burn, inflammation, rash, trauma or allergy.
- It is not allowed to modify the equipment. In the case of faulty equipment, who can simply eliminate the problems can be solved by themselves. Do not remove the device, please contact and authorize the service center for repair.
- Prevent children, infants, mental illness patients when storage or use.(Small parts may be swallowed, in case of swallowing parts, should go to the hospital.）
- Holding the device at vertical 90 degrees during use.
- Do not use equipment near high-frequency electromagnetic transmitters. Excessive electromagnetic interference in the surrounding environment may affect the performance of the nebulizer.
- Do not use instruments near flammable air or a mixture of oxygen or anesthesia.
- Do not use the instruments during bathing.
- When cleaning, do not wash the entire device under tap water to prevent water into the device.
- Do not store the device in a wet and dust environment to avoid affecting the life or even damaging the product.
- The type, dosage, length and frequency of use should be used correctly as instructed by the doctor.
- If you have diabetes or other conditions, consult the appropriate doctor before using the device.
- If you feel any discomfort during the use of the device, please stop using it and consult the appropriate doctor immediately.
- The nebulizer can be used by many people, but the accessories (masks) in contact with the human body are only used by the same person to prevent cross-infection. If multiple people use one host and multiple accessories, each person's use accessories should be kept separately from the host.
- Do not keep the atomizer when the cup contains liquid or water.
- This product is not applicable in the respiratory anesthesia system and ventilator system and does not drive any gas.
- Do not make this product fall off or be hit.
- When the liquid is contained in the medicine cup, do not tilt to avoid liquid leakage.
- Tap water, pure water, mineral water is not suitable for use, if the use of atomization effect will not be

good, there may also be damage to the atomization film. The solution or saline formulated by the doctor should be used.

- Do not use cotton swabs or other items to contact the atomization tablets on the cup, otherwise it may prevent the cup.
- The attachment (adult mask and child mask) is made of PVC material, and its plasticizer component is DOP, suggesting clinical medical staff to use alternative products for high-risk groups.
- Be sure to connect a suitable power adapter (input: AC 100-240V, 50 / 60Hz; output: DC 5V), supply the device under ambient conditions of temperature of 15～35℃ and relative humidity of 40～70%, and prevent access from infants and mental illness.
- The equipment meets the requirements of isolation from the power supply when used or closed. The adapter acts as a disconnected device, please maintain a convenient position for operation.
- Check regularly to ensure that there is no obvious damage affecting the safety and test performance. It is recommended to check at least once a week. If there is obvious damage, stop using the instrument and contact the manufacturer for treatment.
- If performance is inconsistent with the description or changes, stop use immediately and contact the manufacturer.
- The use of accessories, removable parts and materials other than the instructions may cause the equipment to work properly or achieve the intended use.

1.2 Symbol introduction

symbols	Definitions	symbols	Definitions
	Stand-by		Serial number
	Caution		Batch code
	Humidity limitation		Fragile, handle with care
	Temperature limit		Keep dry
	Use-by date		Manufacturer
	Consult instructions for use		Date of manufacture
	Model number		This way up
IP22	Case protection grade		Refer to instruction manual

	separate collection for electrical and electronic equipment		

2. Product introduction

2.1 Measuring principle

The respiratory system is an open system. After the liquid is atomized into particles, the patient inhaled these drugs, the mist can directly adsorb in the patient's mouth, throat, trachea, bronchus, pulmonary alveoli etc, the purpose of treatment is achieved through the absorption of its mucous membrane.

2.2 Intended use

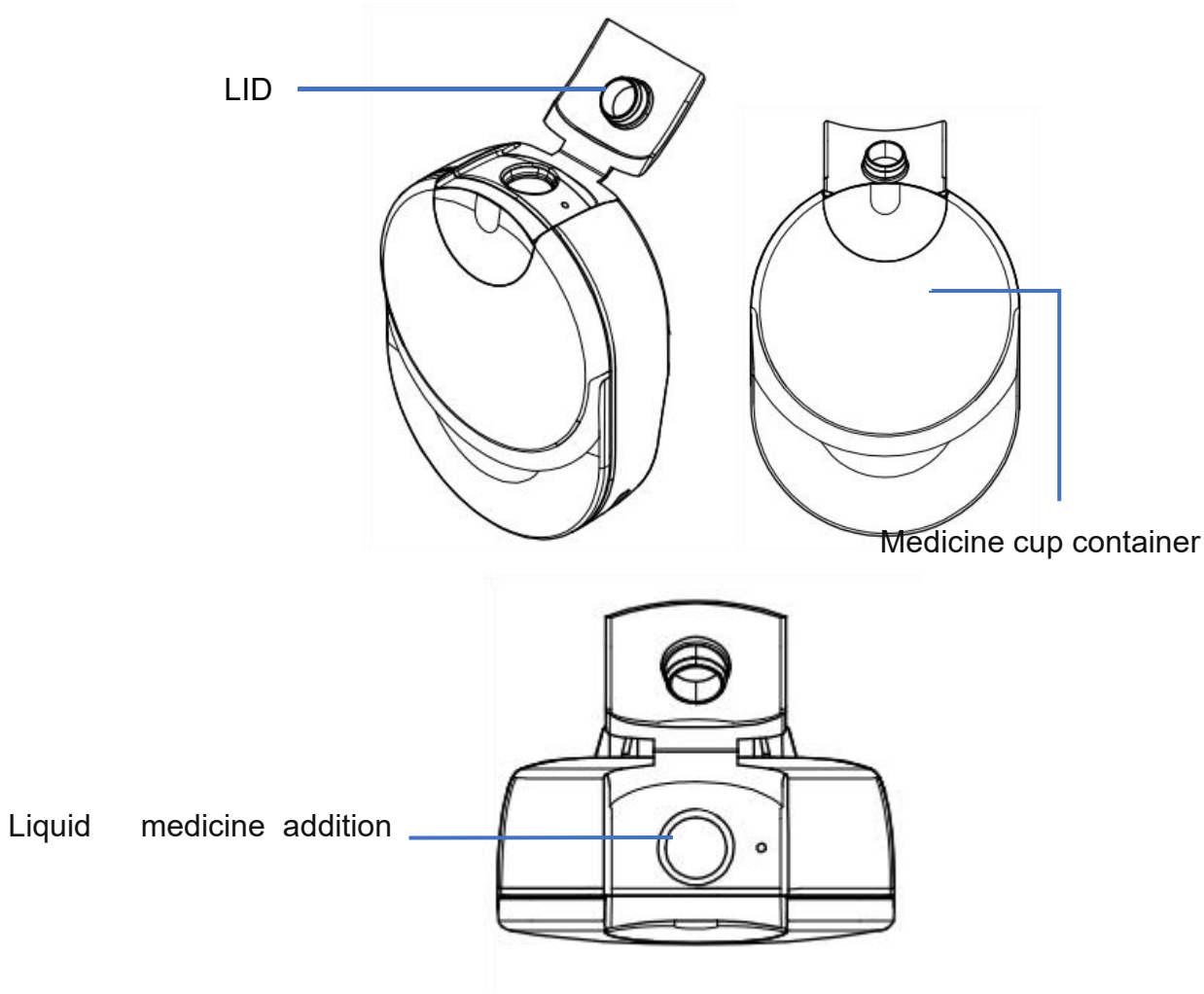
Suitable for atomization of liquid drug for patient inhalation treatment. Adults or children for home use, outdoor portable.

2.3 Contraindication

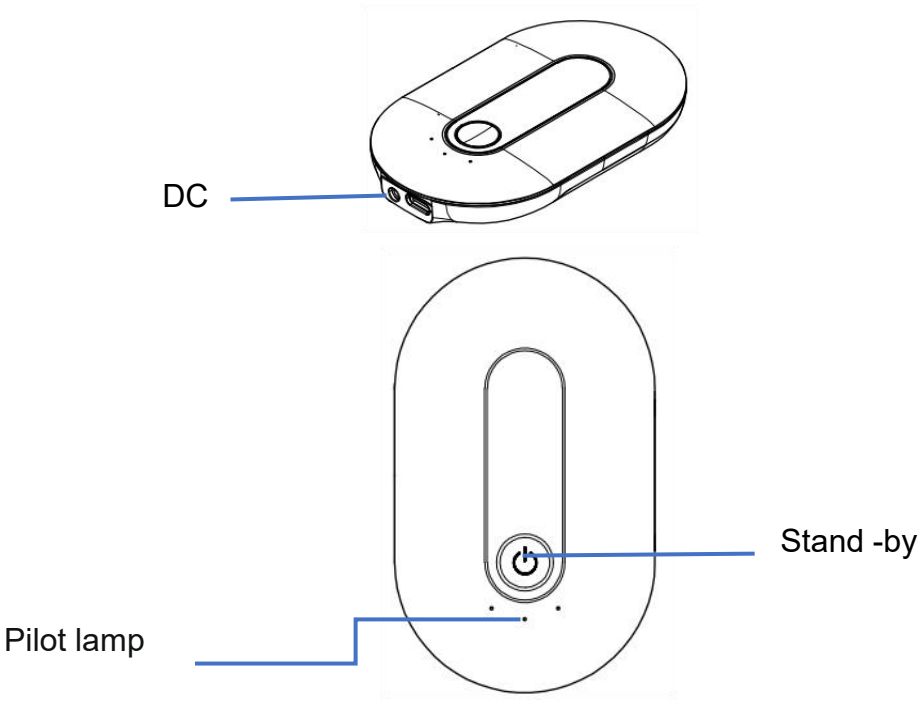
None

2.4 Product structure

The main body of the Wearable Mesh atomizer is divided into medicine cup part and handheld control part. The medicine cup part includes atomizing medicine cup, DC mouth, liquid adding outlet and fog outlet; the handheld part includes the DC mouth (connecting medicine cup) and switch button; the handheld part of the medicine cup and the handheld part are connected through a data line to realize the power supply and control of the serving cup of the handheld part. The main body of the atomizer is fixed to the mask, which is Wearable Mesh.



Medicine cup part-Figure ①



Handheld control part-Figure ②

3. Installation and Settings

3.1 Installation instructions

Before installing and debugging the product, the user should first check whether the appearance of the product is good, and the variety and quantity of the accessories. Whether it is consistent with the attachment list after the manual. If there is any defect, please contact the manufacturer in time.

One end of the connecting line is inserted into the DC port of the medicine cup part, and the other end is inserted into the DC port of the handheld controller part, without distinguishing between the input end and the output end.

Note: Do not insert or pull the cable with wet hand.

3.2 Instructions for use

3.2.1 Install mask

When using the mask for the first time, please clean it with pure water before drying it.

Use except except products and other products.

3.2.2 Add solution to the atomization cup

Open the lid of the atomized medicine cup, add the liquid to the medicine cup, close the lid, and confirm the seal.

The minimum volume of liquid medicine added should be 0.5ml, and the maximum should not exceed 12ml.

Caution:

- Be sure to follow the doctor's instructions to select the solution type, dose, and method of use.
- After adding the liquid, please tighten the lid of the atomized medicine cup to prevent the liquid leakage.
- using high concentration, high viscosity, suspension, and volatile solution.Be sure to follow the doctor's instructions.
- Do not shake the liquid or other liquid in the atomization cup. Insert one end of the connecting line into the bottom of the cup of the aerosolizing drug, and connect the other end to confirm that the connection is reliable.
- Do not insert fingers or other foreign objects from the fog outlet position and touch the fog pieces to avoid damage to the fog pieces.
- Press [⏻] to start the atomizer.

3.2.3 Fog quantity adjustment function:

① The atomization rate of this model of atomizer has both high and low modes. After the atomizer starts atomization, press [⏻] again and hold it for about 2 seconds (All lights flash together), then the atomization rate of the atomizer will switch between the high and low modes. Start-up is in the default low-speed mode.

② Please turn off the machine when the liquid medicine is exhausted.

③ When the liquid is about to run out, the user is advised to tilt the atomization medicine cup slightly towards himself, so that the remaining liquid can contact the fog tablet for atomization.

④ After the [⏻] key press, the atomizer will go through a short start period (within 1 second), and then start atomizing.

⑤ When using a mask, do not cover the mask air holes with hands or other objects.

⑥ During atomization inhalation, there are air holes on the cover of the cup, and do not shake the cup to avoid affecting the normal fog.

⑦ If the user feels unwell during the atomization process, please turn off the machine immediately and consult your doctor immediately.

⑧ In the process of atomization of some drug liquid, there will be a lot of foam concentrated near the fog tablet in the atomization drug cup, which is easy to cause air shock and damage of the fog tablet. Press [⏻] to close the atomizer, shake the cup module slightly, and then restart.

⑨ Turn off the power after the atomization completes.

⑩ During use, if you need to stop the use, press the [⏻] [start / stop] key to turn off the power. The nebugzer indicator (blue) goes out.

4. Battery

4.1 Electricity instructions

Description table of indicator light status:

Indicator lamp status	Indicate meaning
Three lights are always bright	Work normally, full charge
Two lights are always bright	Normal work, more than two-thirds of the electricity
Only 1 light will flash fast	The power is low (undervoltage), can continue to atomization, please replace the battery in time
Indicator light flashes in turn	Enter the cleaning mode

4.1.1 Battery maintenance:

- Working with a dry battery (battery model parameters:4×1.5V　AAA）
- When the battery supply is low, please replace the battery in time.
- If the battery is not used for a long time (more than 3 months), please remove the battery for storage. In addition, The machine is not used for a long time after being loaded with batteries, which may cause failure due to the battery leakage.

4.2 Battery recycling

The battery should be discarded in accordance with the relevant environmental protection regulations of the urban area and town where you live.

5. Maintenance and maintenance

In order to ensure the correct use of this product, please read this manual carefully and strictly according to the requirements of the manual. If in doubt, please contact the supplier or the manufacturer.

Warning

- Do not let the host, the atomizer cup fall or hit impacted.
- Do not stamp the mist sheet with a needle or other sharp object.
- Do not place the host and other components in extreme heat, low temperature or direct sunlight.
- This product is not applicable in the respiratory anesthesia system and respiratory system and does not drive any gas.
- When stored or used, do not place the atomizer where it is accessible to infants or people with mental illness. Small children or people with mental illness can only be used under the supervision of adults.
- Do not remove the host machine and try to repair it yourself.
- Do not keep the atomizer when the atomization drug cup contains liquid or water.

- This product should be purchased and used under the guidance of a doctor.

5.1 Maintenance

5.1.1 Clean up the residual liquid

1) Remove the mask from the spray cup.
2) Open the lid of the atomization cup and remove the remaining solution.
3) Fill a little (2 to 5 ml) of purified water into the atomizer cup and buckle the lid tightly. Gently shake the atomizer cup to dissolve the residual liquid in pure water.
4) Open the lid of the atomization cup and remove the solution from the cup.
   - Before cleaning the residual fluid, turn off the power supply and unplug cable
   - If the residual liquid is difficult to remove, warm water can be used to clean for several times.
   - Be sure to clean up the residual medicine liquid after each use, otherwise it will cause the blockage of the atomization medicine cup and affect the atomization effect.

5.1.2 Product cleaning

■ **Host cleaning:**

Use a wet gauze to gently wipe the surface of the medicine cup and handheld part of the atomizer, and then wipe the moisture off the surface with a dry gauze.

■ **Internal cleaning of the atomizer cup:**

1) **External cleaning of the atomizing medicine cup:**Fill a little (2 -5 ml) of purified water into the atomizer cup and buckle the lid tightly. Gently shake the atomizer drug cup.
2) Press and hold the [⏻] key until the indicator light flashes alternately and the atomizer enters the cleaning mode until the pure water is sprayed.
3) The nebulizer is often used or due to the different viscosity of the drugs used, the fog tablets will be blocked. At this point, the cleaning method is in the cup injection about 2ml acetic acid water (water: white vinegar =3:1), let sit for three minutes, and then hold the [⏻] key until the indicator light flashing alternately, atomizer into the cleaning mode and acetic acid water, to clean out the fog, and then inject a small amount of (2 ~ 5 ml) pure water, again into the cleaning mode, until the pure water spray.
4) Except for purified water, acetic acid water (water: white vinegar =3:1) is the only cleaning solution recommended. Do not use any other detergent or tap water cleaning cups or other parts.
5) The cleaning mode is only used for cleaning of fog tablets after atomization, and not for normal liquid atomization.

■

- Unplug the cable from the port before cleaning the parts.

- Do not wipe the atomizer with a volatile liquid (e.g., benzene, gasoline or thinner). Wipe the atomizer with pure water only.
- The connection port on the main engine and the atomizer cup, pay attention to no water when cleaning, and knock against it with hard objects, so as not to cause bad contact.
- It is strictly prohibited to wash or soak the atomization medicine cup and handheld part directly with water.
- Do not use cotton paper, cloth and other slag dropping items to wipe the atomization medicine cup, to prevent the residual paper scraps or cloth catkins from entering the fog mouth, the medicine cup to add blocked fog pieces, resulting the machine cannot work properly.
- Never use cotton swabs or other items to touch the fog pieces.

■ **Replacement of atomizing medicine cup and atomizing face mask**

- Abulized drug cup and atomized mask are vulnerable and vulnerable parts. In order to ensure safety and health requirements, functional capacity and safe treatment, it is recommended to replace them after 20 times.
- For the replacement of atomization drug cup and atomization mask, see the dosing and installation method of atomization drug cup and atomization mask.

5.2 Common faults and solutions

fault phenomenon	analysis of causes	The exclusion method
No fog or too small fog	The connection line is not inserted	Replug the cable,Restart after confirming the connection
	Connector failure	Replace the new cable
	The liquid is about to run out or not contact with the mist for more than 10 seconds	Tilting the front of the atomization cup toward the user, Make the liquid contact with the mist tablet
	The fog was blocked	Clean the atomized cup according to the instructions. If the fault is not removed after cleaning, please replace the new atomized cup
The indicator light is not on, and the nebulizer is not	Low battery power	Restart after replacing the battery

working		
The indicator light is on,But the atomizer does not work	Connector failure	Replace the new cable
	Severe blockage on the fog sheet	Clean the atomized cup according to the instructions. If the fault is not removed after cleaning, please replace the new atomized cup
Drug liquid leakage	The mug was damaged	Replace the new atomizer cup
	The aerosolizing medicine cup is not placed vertically	Put the atomization medicine cup vertically

6. Manufacturer’ s Declaration of the EUT

Statement:

1) The Wearable Mesh Nebulizer or user should use the product in the electromagnetic environment specified in the following table, otherwise it may cause abnormal operation of the product.
2) Wearable Mesh Nebulizer is a table-top equipment，it suitable for medical unit and home use.
3) Warning：Portable RF communications equipment (including peripherals such as antenna cables and external antennas)should be used no closer than 30cm(12 inches)to any part of theoximeter ,including cables specified by the manufacturer.Otherwise, degradation of the performance of this Wearable Mesh Nebulizer could result.
4) Warning: Use of this Wearable Mesh Nebulizer adjacent to or stacked with other equipment should be avoided because it could result in improper observed to verify that they are operating normally.
5) 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 impropre operation.

Guidance and manufacturer´s declaration – electromagnetic emission – for all EQUIPMENT AND SYSTEMS

Guidance and manufacturer´s declaration – electromagnetic emission	
The Wearable Mesh Nebulizer is intended for use in the electromagnetic environment specified below. The customer or the user of Wearable Mesh Nebulizer should assure that it is used in such an environment.	
Emissions test	Compliance

Radiated emissions CISPR 11	Group 1 Class B
Conducted emission CISPR 11	N/A
Harmonic emissions IEC 61000-3-2	N/A
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A

Guidance and manufacturer's declaration – electromagnetic immunity –

for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity		
The Wearable Mesh Nebulizer is intended for use in the electromagnetic environment specified below. The customer or the user of the Wearable Mesh Nebulizer should assure that it is used in such an environment.		
Immunity test	**EN 60601** **test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15kV air
Radiated RF EM fields IEC61000-4-3	10 V/m [f)] 80 MHz – 2,7 GHz [b)] 80 % AM at 1 kHz [c)]	1 0 V/m [f)] 80 MHz – 2,7 GHz [b)] 80 % AM at 1 kHz [c)]

Proximity fields from RF wireless communications equipment IEC61000-4-3	Table 3	Table 3
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	N/A
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	N/A
Conducted RF IEC 61000-4-6	150 kHz to 80 MHz 6 V in ISM and amateur radio bands between 0, 15 MHz and 80 MHz 80 % AM at 1 kHz	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0° 0 % U_T; 250/300 cycle	N/A

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30A/m
Proximity magnetic fields IEC61000-4-39	Table 4	Table 4
NOTE ： U_T is the a. c. mains voltage prior to application of the test level.		

Table 3 - Test specifications for enclosure port immunity to RF wireless communications equipment

Test frequency (MHz)	Band[a)] (MHz)	Service[a)]	Modulation [b)]	**IMMUNITY TEST LEVEL**

385	380 -390	TETRA 400	Pulse modulation [b)]	27
450	430 - 470	GMRS 460, FRS 460	FM[c)] ± 5 kHz deviation	28
710	704 - 787	LTE Band 13, 17	Pulse modulation [b)] 217 Hz	9
745				
780				
810	800 - 960	GSM 800/900. TETRA 800, iDEN 820,	Pulse modulation [b)] 18 Hz	28
870				
930				
1 720	1 700-1 990	GSM 1800; CDMA 1900; GSM 1900; DECT;	Pulse modulation [b)] 217 Hz	28
1 845				
1 970				
2 450	2 400-2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450	Pulse modulation [b)] 217 Hz	28
5 240	5 100-5 800	WLAN 802.11 a/n	Pulse modulation [b)] 217 Hz	9
5 500				
5 785				
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 61 000-4-3				

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, the carrier may be pulse modulated using a 50 % duty cycle square wave signal at 1 8 Hz. While it does not represent

Table 4 – Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields

Test frequency	Modulation	I MMUNITY TEST LEVEL (A/m)
30 kHz[a)]	CW	8
1 34,2 kHz	Pulse modulation[b)] 2,1 kHz	65[c)]
1 3,56 MHz	Pulse modulation[b)] 50 kHz	7,5[c)]
a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT b) The carrier shall be modulated using a 50 % duty cycle square wave signal. c) r.m.s., before modulation is applied.		

7. Appendix

7.1 Components

NO.	Name	Quantity	Unit
1	Host（Medicine cup par+Handheld control part）	1	Set
2	Nebulizer mask(adult + child)	1	Set
3	Hang ear rope	1	Pcs
4	User Manual	1	Pcs
5	Connecting line	1	Pcs
6	Power cord	1	Pcs
7	Storage bag	1	Pcs

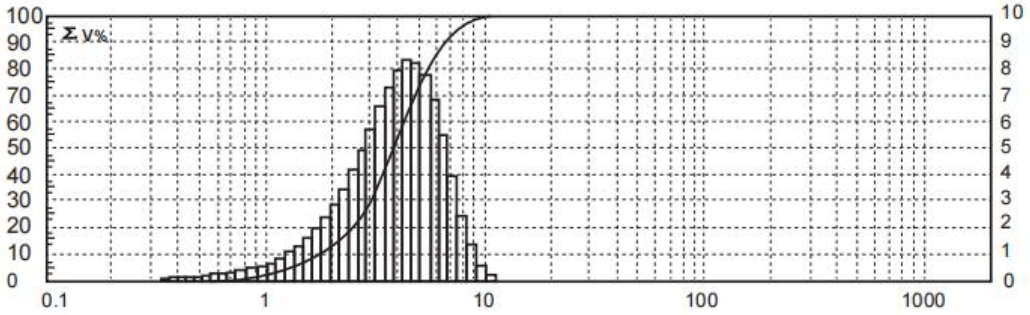
7.2 Product technical parameters and specifications

Power	4×1.5V AAA
Consumed power	About 2W
Abulizing medicine cup, external dimensions （L*W*H）	About 61mm x 45mm x 30mm
Handheld controller with external dimensions（L*W*H）	About 100mm x 60mm x 11mm
Medicine cup part weight	About 19g
Handheld control part weight	About 33g(Without battery)
Volume scale of the atomizer medicine cup	4ml, 8ml, 12ml, the error shall be 0.5 mL
Classification of electric shock protection	Type B application part
The amount of residual liquid in the pill cup	≤0.5 ml
Protective classification of harmful liquid inflow and particulate matter	IP22
The specified application section of the	Atomizing mask
Classification by operation mode	Aontinuously-running duty
The ultrasonic oscillation frequency of the nebulizer	110 kHz, the deviation shall be ± 10%
Noise during the host machine in operation	≤40dB
Water temperature in the atomizer medicine cup	≤50℃
Temperature rise of the solution in the cup of the atomizer	≤15℃
The maximum atomization rate of the nebulizer	≥0.2mL /min
Median particle size of the fog particle	4μm，±25%
Equivalent volume particle size distribution of fog particles produced by the atomizer	The proportion of the Φ 5 μ m particles was> 60%
Continuous working hours	Not less than 1h
Llife length	Five years
Operational condition	Ambient temperature range: 15℃ ~35℃

	Relative humidity range: 40% ～ 70% Atmospheric pressure range: 86 kPa ~ 106 kPa
Transportation and storage environment	Ambient temperature range: -40℃ ~ + 55℃ Relative humidity range: 15% ～ 93% Atmospheric pressure range: 70 kPa ~ 106 kPa. No corrosive gas, well ventilated, avoid direct sunlight in the room. The transportation process should prevent the rain and sun exposure.

7.3 Distribution profile of the equivalent volume particle size

The device has suction accessories (atomized mask), matching all accessories to the longest path during testing. When the ambient temperature is 15~35℃ and the relative humidity is 40%~70%, normal saline is used to measure the equivalent volume particle size distribution and the median particle size by laser scattering. The distribution curve of the equivalent volume of the fog particle is shown in the following figure, in which the median particle size of the fog particle is 4.0 μm.



8. After sale

8.1 Statement

1.The company is responsible for the return, replacement and repair of non-human factor quality problems occurring within one week from the date of sale of this product;and the Company will provide free maintenance; if the user can visit the after-sales service department, office or distributor of the company according to the invoice and warranty card, and the Company shall provide the parts for maintenance and charge reasonable fees. If the user cannot provide the invoice, the factory date of the product shall be extended for one month.

2.The following conditions are not covered by the warranty:

① Easy consumables: atomized medicine cup, atomized mask;

② Fault caused by unauthorized disassembly, repair and modification of the product;

③ Malfunction caused by accidentally falling in the process of use and handling;

④ Damage caused by improper use;

⑤ The user causes water, drugs and other liquids to enter the host and can not work normally;

⑥ Fault caused by not operating in the correct method according to the instructions;

⑦ Damage caused by unforeseen natural disasters (such as flood, earthquake, fire, etc.).

8.2 Description of the replaceable parts

- The atomizer medicine cup is a consumable. If the atomization quantity becomes small or the atomization is uneven after using it for a long time, please replace the medicine cup in time. To purchase the cup or atomization accessories, please contact the manufacturer or distributor.
- Only the original manufactured parts and accessories can be used, and if the accessories and components are not listed in the operation manual, the warranty will be invalid.
- After each use of the equipment, please clean and disinfect the medicine cup and the atomized mask according to the instructions.
- Atomizing mask (adult + children) is a non-sterile product and should not be used in a sterile environment.
- Do not use the atomizing mask(adult + children) if the package is damaged.
- Atomizing mask (adult + children) is valid for three years, see the attachment seal at the production date; do not use after the expiration date.
- Atomizing mask (adults + children) are consumable and should be treated as medical waste at the end of service life.