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User Manual for Portable Mesh Nebulizer

Model: Air Pro VIII,Air Pro VIII-B,Air Pro VIII-Y,Air Pro VIII-PK, Air Pro VIII-VT

Model	Appearance
Air Pro VIII	
Air Pro VIII-B	
Air Pro VIII-Y	
Air Pro VIII-PK	
Air Pro VIII-VT	

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- Thank you very much for purchasing this Portable Mesh Nebulizer.
- Be sure to read this user manual carefully before using this device, so that you can use it safely and correctly.
- Please keep this instruction for use in a place where convenient for reading at anytime.
- The illustrations in this instruction for use are schematic diagrams.
- This user manual is available in English.

1.Intended Use

1.1.Intended purpose

The mesh nebulizer intended to convert certain inhalable drugs into an aerosol form for inhalation by a patient for the treatment of obstructive airway diseases (OADs), such as asthma, chronic obstructive pulmonary disease (COPD), and other pulmonary and even non-pulmonary disorders.
They are not intended for life support nor do they provide any patient monitoring capabilities.

1.2.Intended user

The mesh nebulizer is intended for use by trained professionals and lay persons.
- The user should also be capable of understanding general operation of this device and the content of this instruction manual.

1.3.Intended patient population

It is suitable for adults and children (≥3 years old) who require atomization therapy through mask or mouthpiece.

1.4.Intended environment

This product is intended for use in a medical facility, such as hospital, clinic and doctor's office, and in a room of general household.

1.5.Intended medical condition

Obstructive airway diseases (OADs), such as asthma, chronic obstructive pulmonary disease (COPD), and other pulmonary and even non-pulmonary disorders.

1.6.Intended clinical benefits

The advantages associated with the use of portable mesh nebulizer is that it does not require patient coordination between inhalation and actuation, thus making it relatively easier for pediatric, geriatric, and ventilated patients.

2.Contraindications

（1）Patient is allergic to aerosolized drugs.
（2）Pentamidine powder.
（3）Anesthetics agent.

3.Important Safety Notes

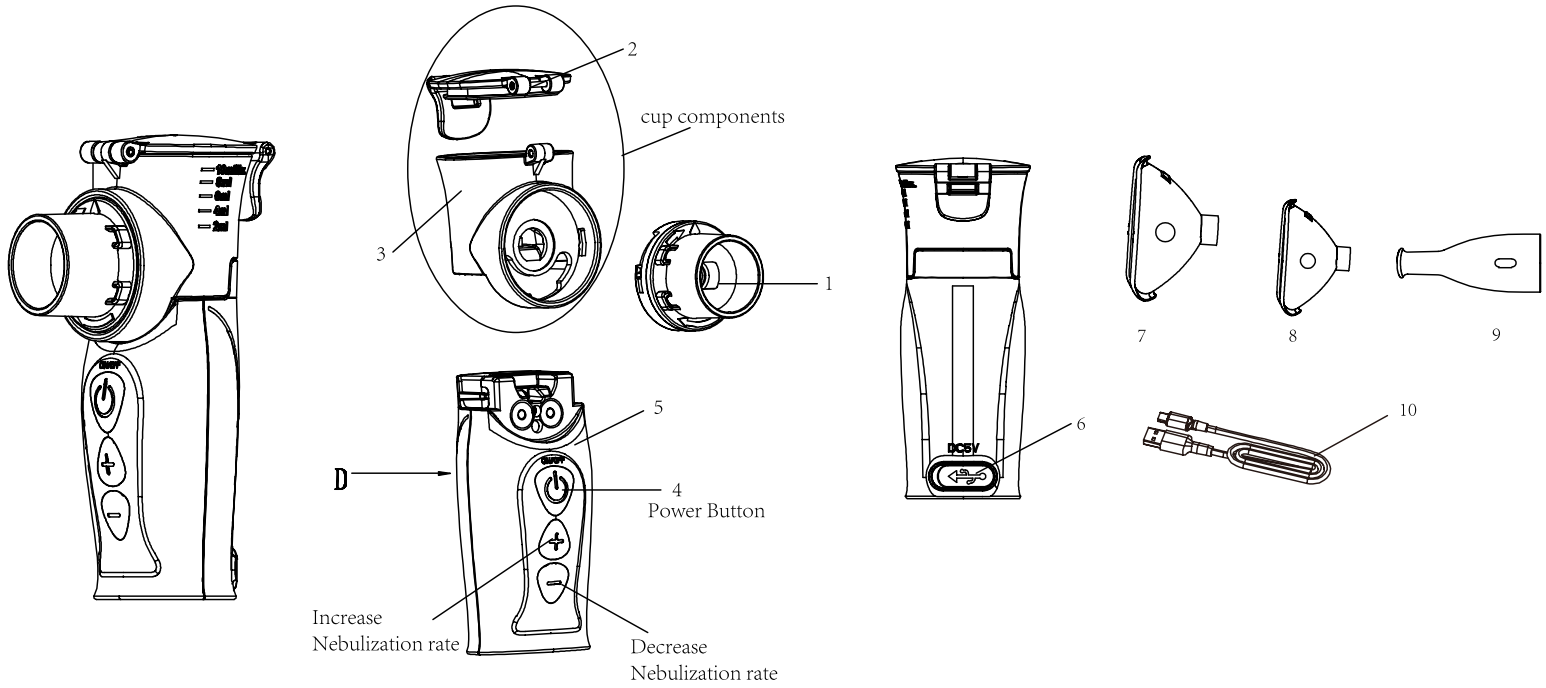
• Before use, ensure that there is no visible damage to the device or accessories. In case of any doubt,do not use the device and contact your retailer or the specified Customer Service address.
• Do not use health products or medicines containing essential oils for nebulization.
• You should always follow the instructions of your doctor regarding the type of medication to use.the dosage, and the frequency and duration of inhalation. Only use medication prescribed or recommended by your doctor or pharmacist.
• The use of this product for children and persons with special needs must be carried out under correct guidance and supervision.
• This unit is only used for specified purposes, only for nebulization. Do not use the device for any other purpose.
• Clean and disinfect the medication cup and accessories before using or not using the unit for quite awhile.
• Please stop using the device if the components are damaged or fall into the water accidentally.
• Keep the device away from your eyes when it is in use, as the nebulised medication could be harmful.
• Keep packaging material away from children (risk of suffocation).
• Do not use any additional parts that are not recommended by the manufacturer.
• If any serious incident that has occurred in relation to the device, please reported to the manufacturer and the competent authority of your member state immediately.

4.Working Principle

The working principle of the atomizer is driven by the rapid oscillation of the circuit, the piezoelectric ceramic in able to harmonic oscillation, thus promote microporous mesh rapid oscillation, so tiny mesh on the mesh and solution was rejected by the rapid, forming numerous tiny atomized particles, the inhalation mask or mouthpiece to patients with respiratory system, to achieve the goal of inhalation therapy. The respiratory system is an open system, after the drug liquid is atomized into particles, the patient inhales the drug mist, the drug mist can be directly adsorbed and deposited in the patient's trachea, bronchus, alveoli and other places, through the mucosal tissue absorption to achieve the purpose of treatment.

5.Package Contents and Overview

This device is composed of the Main Unit,Medication Cup, Nebulization Module and accessories,etc.



1	Nebulization Module	6	Charging Interface
2	Medication Cover	7	Mask(adult)
3	Medication Cup	8	Mask(child)
4	Stand-by	9	Mouthpiece
5	Main Unit	10	Type-C Cable

Figure 1 Product Contents

6.Product Technical Parameters

Product name	Portable Mesh Nebulizer
Model	Air Pro VIII, Air Pro VIII-B, Air Pro VIII-Y, Air Pro VIII-PK, Air Pro VIII-VT
Power source	DC 3.7V,rechargeable Li-ion battery or DC 5V,1A adapter which meets IEC 60601-1 and 2MOPP.
Power consumption	<4.0 W
Nebulization rate	Low:0.15mL/min-0.60mL/min Middle:0.25mL/min-0.80mL/min High:0.35mL/min-0.90mL/min
MMAD	＜5μm
Residual volume	≤0.3mL
The maximum temperature above ambient reached in the medication cup	＜30℃
Medication cup capacity	10mL (Max)
Vibration frequency	130kHz,Deviation ±10%
Weight	90.5g(with battery)
Dimension(mm)	60mm(L)×41mm(W)×104mm(H)
Working environment	Temperature: +5℃～+40℃ Relative Humidity: 15%~80% R.H.Non-condensing Atmospheric Pressure: 86kPa～106kPa

Storage/delivery environment	Temperature: -20℃～+55℃ Relative Humidity: 10%～93% R.H.Non-condensing Atmospheric Pressure: 70kPa～106kPa
Time auto-off	Power on, operate 10mins, then auto-off
Mode of operation	Continuous operation
Classification of installation and use	Hand-held
Applied part classified	The classified of applied part is BF.
The maximum A-weighted sound pressure level	≤50 dB (A-weighted)
Service life	Main unit:5 years
Shelf life	Medication cup:2 years Mask(adult):2 years Mask(child):2 years Mouthpiece:2 years
Material	Enclosure: PC+ABS Medication cup: PC Nebulization module: PCTG Button: TPE
Applied parts	Button

Note:

1) According to the type of anti-shock classification:Internally powered me equipment.

2) Enclosures classified according to degree of protection against ingress of water and particulate matter as per IEC 60529:IP22

3) Sterilize method:EO sterilization(only for mask).

4) The equipment is not intended for use in the oxygen rich environment and presence of flammable

anesthetic mixtures with air, oxygen or nitrous oxide.
5) Higher than 70% of the Initial Capacities of the Cells , Carry out ＞300cycle Charge: 0.5C to 4.2V Discharge: 0.5C to 3.0 V Temperature:25±3℃.

★Performance disclosures

The particle size and the aerosol output,aerosol output rateis measured according to the provisions of the EN ISO 27427:2023,Annex C(using breathing simulator) and D(using the multistage cascade impactor) separately.

The nebulization rate is measured with saline 0.9% solution at a temperature of 24 ± 2 ℃ and a humidity of 45-75%.It can be vary with medication and ambient conditions.

The test solution is albuterol 0.1 % (M/V) concentration in 0.9 % sodium chloride solution.Test conditions of a temperature is 24 ± 2 ℃ and a humidity is 45-75%.And the plot of cumulative size distribution of the results is as follows.

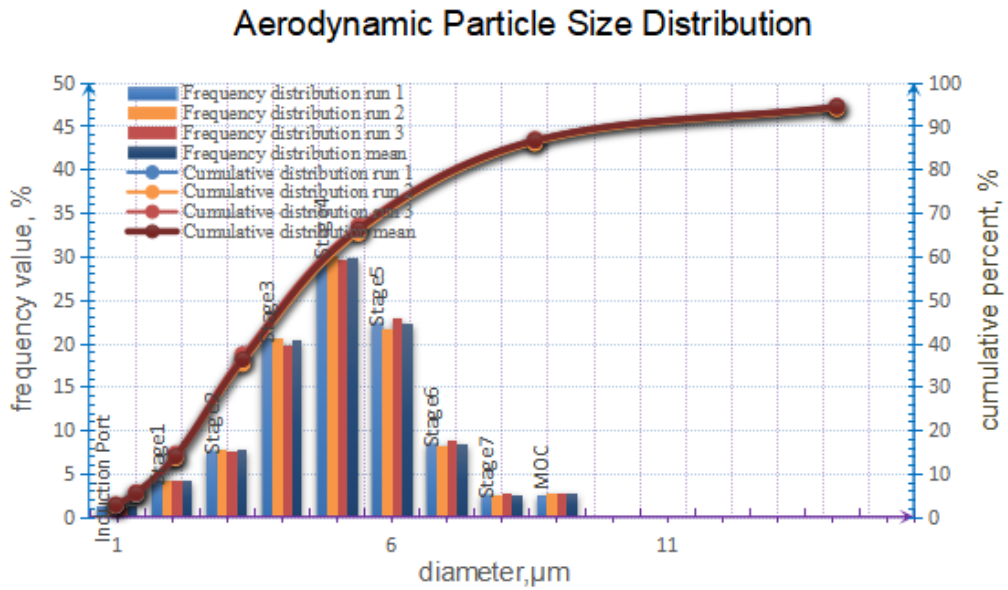


Figure 1 Technical Parameters

Note:

1) The particle size distribution and aerosol out put may vary by combination of product, medication and ambient conditions such as temperature,humidity and atmospheric pressure.

2) 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.See drug supplier's data sheet for further details.

3) The effect that the following disclosures for nebulizer performance are based upon testing that utilizes adult ventilatory patterns and are likely to be different from those stated for paediatric or infant populations.

4) Essential performance: particle size and the aerosol output, aerosol output rate.

5) The proportion of mist particles with a diameter of 1 μm to 5 μm generated by the nebulizer is >50%.

7.Installation and User Instructions

7.1. Power Supply

This device has a Type-C cable for charging. It does not come with a power adapter. Please use an AC adapter (output: DC 5.0V 1.0A) approved by IEC 60601-1 for charging.It supports charging while working (as shown in Figure 2 below).

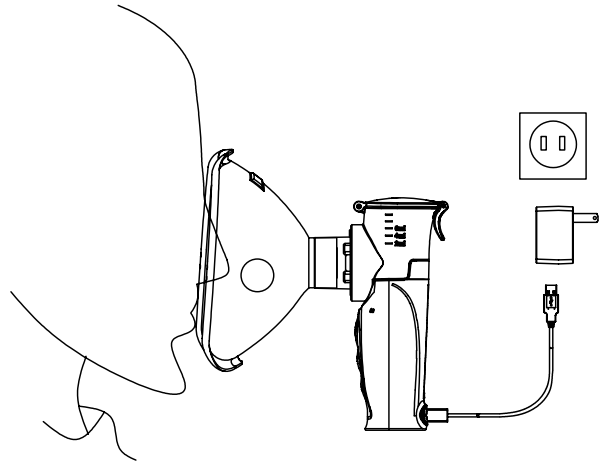


Figure 2

It shall be disconnected from the power source after use.

When you need to start the equipment room, please power it through a Type-C cable, and then it will be able to enter the stand-by state (as shown in Figure 3 below).

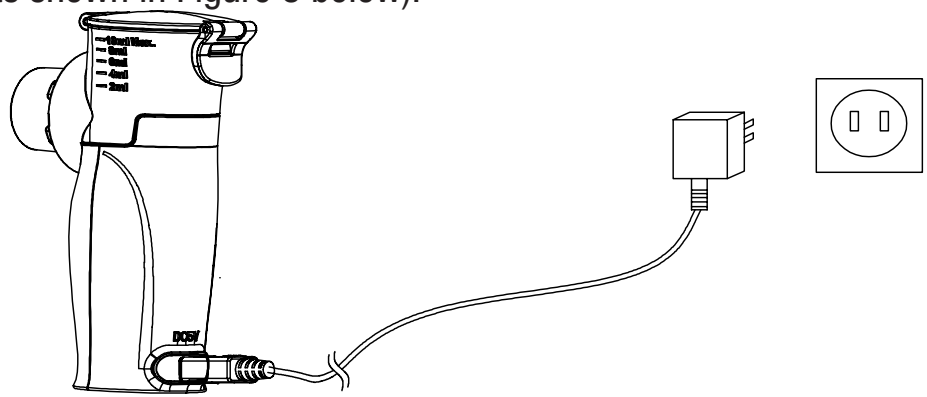


Figure 3 Power Supply Connection

⚠Warning:

1) At the end of expect service life, please dispose this device and accessories according to the local environmental regulation, do not dispose together with the domestic refuse to avoid environment pollution.
2) Please use the power adapter (DC 5.0V, 1A) which meets IEC 60601-1 to power this device.
3) Do not modify this equipment without authorization of the manufacturer.
4) Do not disassemble or repair this device without permission, and do not disassemble or replace the battery without permission.If you need to replace the battery, please consult the manufacturer.

⚠Caution:

1) When the battery capacity is insufficient,please powered by Type-C cable.
2) Keep charging the device at least once per month during the storage period exceed one month.
3) The device can work when charging.
4) The main unit is powered by secondary lithium batteries which comply with IEC 62133-2.

7.2.Use Instructions Step

Step 1: Add liquid to the medication cup

Open the medication cover and add medicine (at least 2mL, less than 10mL).

Note:

1) Cleaning and disinfecting the appearance that user could touched, the shell of the Main Unit,medication cup when use.
2) Follow the doctor's advice to inject medication.
3) After injecting the medication, please be careful to overflow.

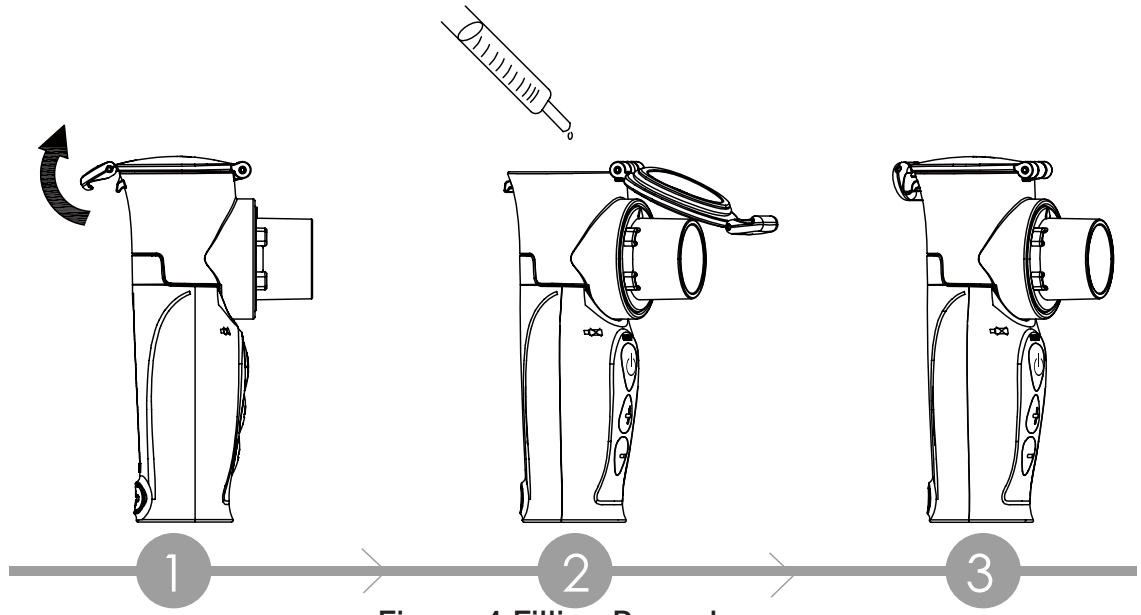
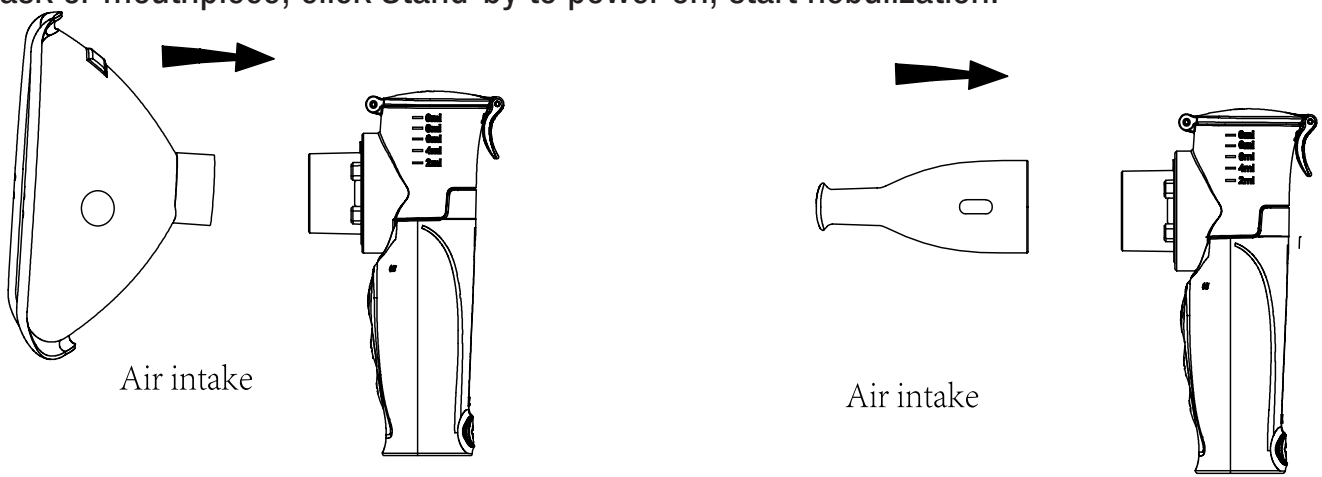


Figure 4 Filling Procedure

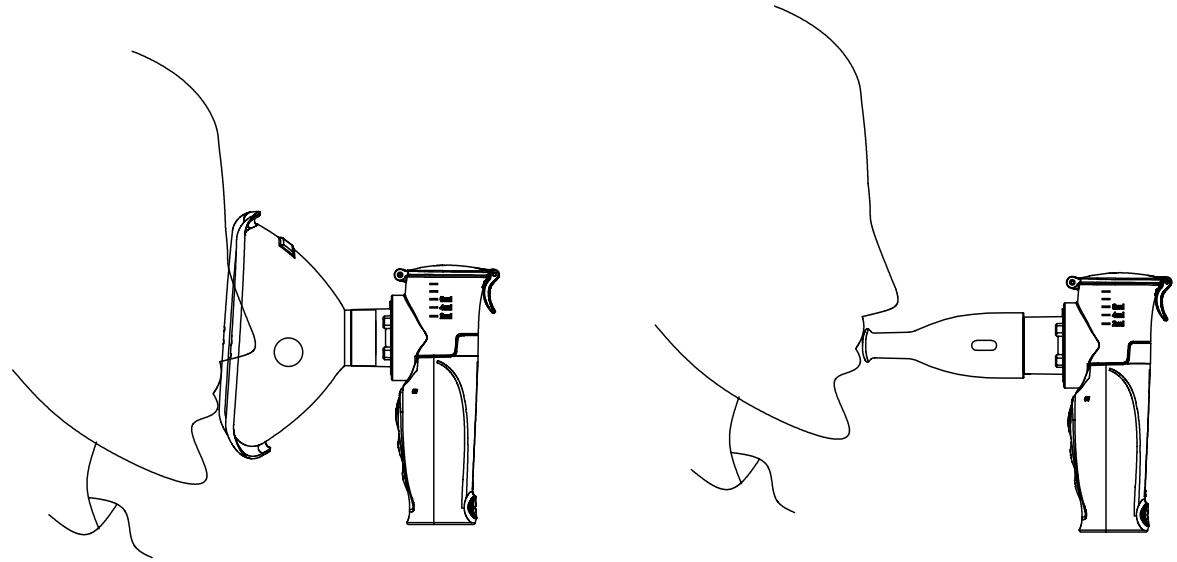
Step 2: Nebulization

1) Connect mask or mouthpiece, click Stand-by to power on, start nebulization.



2) It start with a middle nebulizer rate,and it can be adjusted by pressing “+” & “-” as needed.

3) Hold the nebulizer to keep medication contact with the vibrating mesh, using the following two ways of inhalation according to individual needs.



a.Connect mask b.Connect mouthpiece

Figure 5 Two Ways of Inhalation

4) When finishing nebulization, press Stand-by to power off. Pour out the residual liquid from the medication cup.

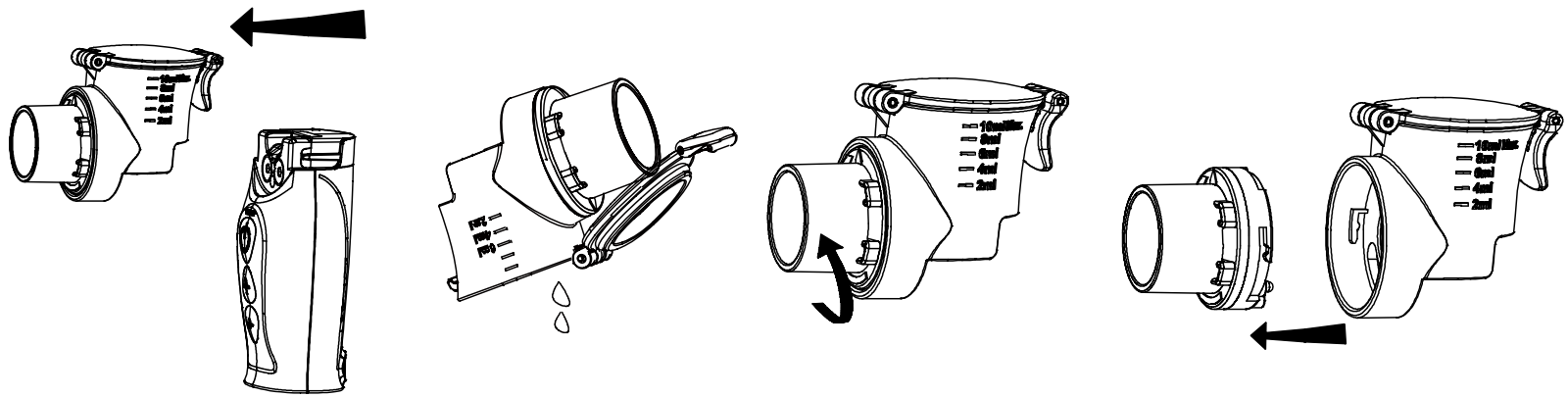


Figure 6 Pouring Out the Residual Liquid Medication

5) Use clear water to clean the medication cup and mesh, then disinfect.

⚠Caution:

1) When installing the medication cup, do not tilt, make sure the whole medication cup is well pressed.
2) Keep the device as vertical as possible during the operation, no shaking during nebulization.
3) Holding your breath for a short while, can enhance the effectiveness of nebulization therapy. Sit down and keep calm and relax, do not inhale too fast during the treatment process.
4) Replace the mask,mouthpiece if the inhalation method is changed. Please clean the mesh after using. (see "Cleaning and disinfecting" chapter)
5) Nebulizer module and mesh disc will be congealed by medication liquid which will infect nebulization rate. We suggest stopping nebulization and remove mouthpiece or mask, use clean medical gauze to clean the residue.
6) Any question in process of nebulizing, please contact manufacturer or authorized EU representative.
7) The nebulization module should not be unscrewed directly. If you need to take out the nebulization module, you should take out the medication cup from the main unit first, and then unscrew the module counterclockwise.

7.3.Indicator light

Green light keeps on	Work by internal battery or adapter
Blue light keeps on	Fully charged
Blue light keeps flashing	Charging
Blue light flashes 5 times	Low-power,shut-down
Green light flashes 10 times	10 min setting time
Orange light flashes 10 times	No liquid,shut-down

7.4.Software version

WHQPro VIII V1.1

8.Cleaning and Disinfection

Device	Medication cup, Nebulization Module, Mask and Mouthpiece
Advice	Reprocessing procedures have only limited implications to this product. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. From the processing side there is no maximum number of allowable reprocessing.The device should no longer be reused in case of signs of material degradation, e.g. cracks on the product, brittle, other change in the material, etc.
Reprocessing Instructions	
Preparation at the Point of Use	Remove gross soiling of the device with cold water (<40°C) immediately after use, if applicable. Don't use a fixating detergent or hot water (>40°C) as this can cause the fixation of residuals which may influence the result of the reprocessing process.
Transportation	Safely store the device in a humid surrounding and transport it to the reprocessing area to avoid any damage and contamination to the environment.
Preparation for Decontamination	The devices must be reprocessed in a disassembled state, as far as possible.
Pre-Cleaning	Do a manual pre-cleaning, until the devices are visually clean. Submerge the devices in a cleaning solution. Clean the surfaces with a soft lint-free cloth.

Cleaning	Regarding cleaning/disinfection, rinsing and drying, it is to distinguish between manual and automated reprocessing methods. Preference is to be given to automated reprocessing methods, especially due to the better reproducibility and standardization, and in personnel protection. Automated Cleaning: Use a washer-disinfector meeting the requirements of the ISO 15883 series. The instruments are placed on the cleaning rack of the WD. The instruments in the washer-disinfector are arranged in such a way that there is no rinsing shadow and the water drains off quickly. Start the program: • 4 min pre-washing with cold water (<40°C); • emptying • 5 min washing with a mild alkaline cleaner at 55°C • emptying • 3 min rinsing with warm water (40°C); • emptying • 5 min intermediate rinsing with warm water (40°C) • Emptying The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte. Note fresh de-ionized water should be used for the automated cleaning process. Water quality refer to EN 285. Manual Cleaning: Following conditions of manual cleaning can be performed for the product: 0.5%-1% neodisher MediClean forte, 10-30 minutes immersion time at 30 °C. If other cleaners are used, select immersion times, concentrations and temperatures of the solutions as instructed by the manufacturer of the cleaner. a.Wear disposable protective gloves. b.Put the device in a suitable cleaning basin.

	c.Create a detergent solution as instructed by the manufacturer of the detergent. d.Completely immerse the device in the detergent solution. Make sure that there are no air bubbles on the products while immersed. e.Dip a clean soft lint-free cloth in the detergent solution, and gently wipe all surfaces and lumen of the device until the device is visually clean. Pay special attention to the product gaps. When the cloth becomes obviously contaminated, discard it, and distribute a new cloth as needed. Then flush the lumen of the device with the detergent solution by using a syringe. Repeat the step for 5 times. The cleaning process takes about 10 minutes. f.Remove the device from the cleaning basin. Rinse the device under running water for 30 seconds at room temperature. g.Put the cleaned and rinsed device into a suitable clean basin with fresh de-ionized water. Thoroughly rinse and flush the lumen of the device with the water for 5 minutes. h.Dry the device through lint free towel.
Disinfection	Automated Disinfection Program (Glutaraldehyde Disinfectant): Start the program: • 5 min disinfecting with Belimed Protect™ Glutaraldehyde Disinfectant at 55°C • 1 min neutralising with water at ambient temperature • emptying • 1 min neutralising with water at ambient temperature • emptying • 8min drying at 50°C Manual Disinfection: Following parameters are used: Disinfectant: MetriCide™ OPA Plus; Concentration: Ready-to-use solution, undiluted; Temperature: ambient temperature; Soaking time: ≥5 min. a.Immerse the accessories in the disinfectant solution.

	b.Wipe the surface of the device with a sterile soft lint-free cloth to remove any air bubbles on the surface. c.After completion of holding time, remove the device from the disinfection solution. d.Rinsing the devices after manual disinfection with sterile water. e.Wipe and dry the device surface with a sterile lint-free cloth until the surface is free of water stains. The disinfection conditions described above are only recommended parameters, please refer to instructions for use of the disinfectant agent for actual use parameters and precautions.
Drying	Drying the device through drying cycle of washer/disinfector. If needed, (additional) manual drying can be performed through lint free towel. Insufflate cavities of products by using sterile compressed air. For manual reprocessing, drying takes place following the rinsing step after manual disinfection. Wipe and dry the device surface with a sterile lint-free cloth until the surface is free of water stains. Insufflate cavities of products by using sterile compressed air.
Functional Testing, Maintenance	Visual inspection for cleanliness of the products. All devices should be checked again for dryness. After cleaning and disinfection, a thorough inspection and maintenance ensures that the products are fit for use. -Check that the product has no dents, cracks, deformations, scratches, etc.; -Check all markings on the product for clear visibility. Discard and replace any components as necessary. Do not use the device with following defects: material deformation, cracks on the product, brittle or other change in the material, etc. Test and maintain the device acc. to manufacturer’s instruction.

Functional test	1.Visually inspect each part of the system for cracks or damage and replace if any defects are visible. 2.Pour 1-10 mL of normal saline (0.9%) into the nebulizer. 3. Functional test: --Press the Stand-by button, ensure the indicator is lit, and verify that aerosol is visible. --Press the Stand-by button again to turn the system off and confirm the indicator is off. Discard any remaining liquid before patient use.
Storage	Storage of processed devices in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use.
Additional Instructions: None	
It is the duty of the user to ensure that the reprocessing processes including resources, materials and personnel are capable to reach the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly.	

⚠Warning:

1) Please don't use the disinfectant of Benzalkonium bromide or house bleach.

2) Be careful not to damage the vibrating mesh when disinfecting and cleaning.Do not use medical gauze to wipe the residues in the vibrating mesh,you can let it air dry.

3) Never use Sodium hypochlorite, Hypochlorous acid or quaternary ammonium compound to disinfect.

Note:

1) The equipment waterproof classification is IP22.To prevent the ingress of water,this device cannot be washed by flowing water.

2) The disinfectant residues should be cleaned thoroughly to assure safe use next time.

3) Before cleaning and disinfection shall be carried out with the power source disconnected.

4) After cleaning and disinfection shall be reassembled according to 7.2.

9.Storage and Maintenance

1) The storage and transportation conditions of the products are detailed in the Product Technical Parameters section.
2) Keep the device out of the reach of unsupervised infants and children. The small parts of this device may be swallowed by the infants and children.
3) Prevent pets and pests from damaging this device.
4) Dry the parts immediately after cleaning and disinfection. Store the device and the components in the environment that meets the requirements, be careful to avoid collisions.
5) Direct sunlight, lint, dust may cause vibrating mesh rusted and oxidized and decrease nebulization rate.
6) Make sure that unplug the power plug before storing.
7) Screw off the cap and power out the residual liquid from the medication cup.Do not reuse.
8) Please wipe the shell of the Main Unit by a soft cloth.
9) When do not use the device for a long time, please unplug the power plug.
10) It should be stored in a place with no corrosive gas and good ventilation, please avoid severe shock during transportation.
11) Do not use benzene, diluents and flammable chemicals to clean the product.
12) The mask is provided by EO sterilization.It do not need to sterilize for the next time use but need to clean and disinfect according to Chapter 8.

10.Trouble Shooting

Item	Trouble	Possible cause/solution
1	Do not work when turn on.	•Check if there is enough power. •Check if there is enough medication. •Check if the button is function well. •Clear the clogged medication in the vibrating mesh and restart the power.
2	Low nebulization rate	•Check if the medication cup been filled with right medication, which should be water-solubility, non- corrosive medication. •Check if the medication cup been filled with right volume. •Tilt Main Unit, so that the medication can contact with the vibrating mesh. •Re-assemble the medication cup correctly and restart the device. •Clean the medication cup and vibrating mesh. If it still cannot be used after cleaning, please check whether the vibrating mesh is broken or not. •Clear the clogged medication in the vibrating mesh and restart the power.
3	After power on, it power off immediately.	•Re-assemble the medication cup correctly and restart the power. •Tilt Main Unit, so that the medication can contact with the vibrating mesh. •Clear the clogged medication in the vibrating mesh and restart the power.
4	The mesh is clogged with medication.	•Take off the medicine cup. wash with warm water and air dry.

5	The medication cup assembly leakages.	•Re-assemble the medication cup correctly. •Contact the manufacturer or the distributor for a new one.
6	Residual medicine liquid in the medication cup.	• It is a normal phenomenon.Clean the medication cup after using.
7	Can not charge.	•Make sure the Type-C cable,the adapter are connected well. •Contact the manufacturer or the distributor for a new one.

11. Note & Warning

11.1. Note and suggestion

1. This device is a medical device,please read the user manual before using it.
2. Please use required accessories, warranty service is not provided for damage caused by accessory beyond our list.
3. Use a non-conforming adapter may cause equipment damage.
4. Please refer to the user manual when there is problem, or contact the after-sales service unit for maintenance.
5. Please clean and disinfect the medication cup when use it for the first time. You can refer to the clean and disinfect chapter.
6. This device is for medication nebulization, not for humidification, please avoid use distilled water, it may cause lower nebulization rate.
7. Please keep the medication cup empty when store it.
8. Please assure all the accessories assembled rightly before using.
9. Please use the accessory individually to avoid cross infection.
10. Please keep it vertical when nebulizing.
11. Don’t use the unit under inflammable gas environment or near the heating device or open flame.
12. Don’t use the unit near high frequency products or electronic products.
13. Do not use a microwave oven, oven, blow dryer or other house applications to dry nebulizer and accessories.
14. Technical description is included in this user manual.
15. The nebulizer can only be used by operators who can understand this user manual. Children should used under adult supervision.
16. When the product is taken out from -20 ℃, it should be put in room temperature for 2 ours before use.
17. When the product is taken out from +55℃, it should be put in room temperature for 2 hours before use.

18. The charging interface is only used for power supply and cannot be connected to other devices.
19. The patient is the intended operator and all functions of the devices can be used by patients.
20. When the patient is an intended operator, all the accessories of the nebulizer cannot be serviced or maintained while it is in use.
21. The contents that patients can maintain the devices are cleaning and disinfection. You can refer to the clean and disinfect chapter.
22. Performance information provided by the this user manual in accordance with EN ISO 27427:2023 may not apply to drugs supplied in high viscosity form. In such cases, information should be sought from the drug supplier.
23. The highest rated operating altitude:1300m
24. The nebulizer device and the accessories (mask and mouthpiece) are meet the requirements of ISO 18562-2, ISO 18562-3,ISO 18562-4
25. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the local competent authority.
26. The materials used in the components could not be compatible with solutions/suspensions/emulsions that have not been evaluated. The medicines that have been evaluated:Ambroxol hydrochloride solution for inhalation and Salbutamol sulfate solution for inhalation.
27. Check the power-on status after reassembled.
28. Please use or purchase original parts or accessories.

11.2. ⚠Warning

1. Please stop using it if you feel uncomfortable and please turn to doctor.
2.Volatile oil are not allowed, may cause damage to mesh.
3.Water-soluble medication and saline dilution medication are allowed, but may cause Bronchospasm.
4.Please do not use medicines containing esters, oils or suspended particles, including herbal extracts. It is recommended to use the standard atomizing liquid agent type according to the doctor's instructions.
5.Do not service and maintain when the nebulizer is in use.
6.Don’t modify the equipment without authorization of the manufacturer.Otherwise,it may cause damage to the Main Unit or damage to the user or patients.
7.Replacement of lithium batteries or fuel cells when incorrect replacement would result in an unacceptable risk.
8.One device suggest for single patient use and can be reusable by a single patient.
9.Do not use mobile (cellular) telephones and other devices(such as MRI, diathermy, electrocautery, RFID and electromagnetic security systems) which generate strong electrical or electromagnetic fields, near the medical device.
10.The manufacturer or manufacturer’s representative can assistant lay operator or lay responsible organization to set up,use or maintain this device when needed.Have any unexpected operation or events,please contact the manufacturer or manufacturer’s representative.
11.Waste disposal: discard the main engine and accessories according to local laws and regulations.
12.The Type-C cable should be kept away from children or out of the reach of children to avoid strangulation.

13.Turn to doctor for help or contact the manufacturer if any changes in the performance of this device.
14.Be careful the small parts of this device be swallowed by the infants or children.
15.Applied parts not intended to supply heat to a patient.
16.The nebulizing system is not suitable for use in a anaesthetic breathing system or a ventilator breathing system.
17.The types of liquid (e.g. solution and suspension) the device is designed to nebulize.
18.The accessible materials used in the nebulizer are safe for common normal people. For very few operators with extreme skin sensitivity, if any skin discomfort occurs during the use of the nebulizer, please immediately stop using and seek medical advice.
19.Do not use the mask on multiple patients.(Single Patient Use Only). Re-use should according to the advice from doctor.
20.Applied parts do not intend to supply heat to a patient. The surface temperature applied parts exceeds 41℃ when test in both normal condition and single fault condition.(Outside plastic enclosure near battery:45.7°C. Button:45.5°C.) Contact time of applied parts when working:1 min ≤ t < 10 min

12. EMC Declarations

1. This device meet the requirement of electromagnetic compatibility in IEC 60601-1-2.
2.The user needs to install and use according to electromagnetism compatibility information which is attached with it.
3. Portable and mobile RF communication device and some household appliances, such as mobile, interphone, microwave oven, dry blower, may influence Portable Mesh Nebulizer performance, so Portable Mesh Nebulizer should be kept away from them during using.
4. Guidance and manufacturer's declaration stated in the appendix.

1.With the increased number of electronic devices such as PC's and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices.
2. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation.
3.Medical devices should also not interfere with other devices.
4. In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the IEC 60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices.
5. Medical devices manufactured by FEELLIFE HEALTH INC. conform to this IEC 60601-1-2 standard for both immunity and emissions.
Nevertheless, special precautions need to be observed:
Note:
The EMISSIONS characteristics of this equipment make it suitable for use in a residential environment (for which CISPR 11 class B is normally required).

⚠Warning:

1.The use of accessories and cables other than those specified by FEELLIFE, with the exception of cables sold by FEELLIFE as replacement parts for internal components, may result in increased emission or decreased immunity of the device.

2. The medical devices should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, the medical device should be observed to verify normal operation in the configuration in which it will be used.

3. PORTABLE RF communications equipment(including peripherals as such as antenna cables and external antennas) should be used no closer than 30cm (12 inches)to any part of [ME EQUIPMENT or ME SYSTEM], including cables specified by the MANUFACTURER. Otherwise, degradation of the performance this equipment could result.

4. Do not use mobile (cellular) telephones and other devices, which generate strong electrical or electromagnetic fields, near the medical device. This may result in incorrect operation of the unit and create a potentially unsafe situation. Recommendation is to keep a minimum distance of 7 m. Verify correct operation of the device in case the distance is shorter.

Details of cable:

Name	Type	Length(m)	Cable Shielded
Type-C Cable	Type-C	1.0	UnShielded

Guidance and Manufacturer's declaration – electromagnetic emissions		
The device are intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that they are used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The device use 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 CISPR11	Class B	The device are suitable for use in all establishments,including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

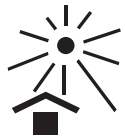
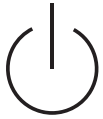
Guidance &Declaration – electromagnetic immunity			
The device are intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for Input/output lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1kV ,±2kV line to ground	±0.5 kV, ±1 kV line to line	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.	<5 % U_T (>95% dip in U_T.) for 0.5 cycle <5 % U_T (>95% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 25/30 cycles <5% U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95% dip in U_T.) for 0.5 cycle <5 % U_T (>95% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 25/30 cycles <5% U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device require continued operation during power mains interruptions, it is recommended that the devices be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields/ Proximity magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity magnetic fields	CW 8A/m for 30kHz Pluse modulation 2.1kHz,65A/m for 134.2kHz Pluse modulation 50kHz,7.5A/m for 13.56MHz	CW 8A/m for 30kHz Pluse modulation 2.1kHz,65A/m for 134.2kHz Pluse modulation 50khz,7.5A/m for 13.56MHz	
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance & Declaration – electromagnetic immunity			
The device are intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that they are used in such an environment.			
Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. If higher IMMUNITY TEST LEVELS than those specified in Table 9 are used, the minimum separation distance may be lowered. Minimum separation distance for higher IMMUNITY TEST LEVELS shall be calculated using the following equation: $E = [6/d] \times \sqrt{P}$ Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.
Radiated RF IEC 61000-4-3	3 &10 V/m 80 MHz to 2.7 GHz 385MHz- 5785MHz Test specification s for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014+A1:2020)	3 &10 V/m 80 MHz to 2.7 GHz 385MHz- 5785MHz Test specification s for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014+A1:2020)	

13. Signs and Symbols

General symbol	Description / title	General symbol	Description / title
	Manufacturer information		General warning sign
	Date of manufacture		Refer to instructions for use
EU REP	Authorised representative in the european community		Keep dry
	Caution		This way up
	Temperature limit	LOT	Batch code

	Type BF applied part		Humidity limitation
	Keep away from sunlight		Atmospheric pressure limitation
RoHS	This device complies with the requirements of the RoHS Directive 2011/65/EU and the RoHS Standards IEC 62321-1:2013.		When this device life expires,the end users should discard this device according to the requirements from the local environment protection authority.
	Medical device	**IP22**	Degree of protection against the ingress of water.
	Stand-by		EO sterile
CE 0197	Notified body		

14. After-sales Service

Changes or modifications not expressly approved by the responsible party could void the user's warranty right to the equipment.

1.The period of Main Unit free for maintain service is 1 year. Medication cup is 6 months.Other components are not covered by warranty. On the Any repair service out of the scope of warranty will be charged accordingly.

2.Please contact our after-sales service department to obtain warranty service.

Warranty conditions:

To obtain the warranty service, please present this warranty card and fill out the related content.

The warranty shall not apply:

a.Failure or damage caused by improper use.

b.Failure or damage caused by the dismantle movement of a non-our- company authorized maintainer.

c.Failure or damage caused by accidental falling, pressing, dropping, immersion etc.

If needed, we will provide circuit diagrams and component part lists to assist to user in parts repair.

The Company reserves the right of final interpretation of the warranty card, which may be subject to change without prior Note.

15.Configuration List

Item	Model	Quantity	If Included	
			Yes	No
Main unit(including medication cup)	Air Pro VIII or Air Pro VIII-B or Air Pro VIII-Y or Air Pro VIII-PK or Air Pro VIII-VT	1	☑	☐
Medication cup	MAPro8	1	Optional	
Nebulization Module	MDproXP	1	Optional	
Mask(adult)	L1	1	☑	☐
Mask(child)	S1	1	☑	☐
Mouthpiece	M1	1	☑	☐
Instruction for use	N/A	1	☑	☐
Silicone protective cover	N/A	1	☑	☐
Velvet bag	N/A	1	☑	☐
Mesh warning hangtag	N/A	1	☑	☐
Warranty card	N/A	1	☑	☐
User guidance	N/A	1	☑	☐
Type-C cable	UTC-021	1	☑	☐

16. Disclaimer Clause

Please read the user manual before using this device. We will not take any responsibility in case of damage caused by improper use of this device.

Please use or purchase original parts or accessories. The manufacturer does not take responsibility for the buyer or third parties for any damage or loss intentionally or unintentionally caused by improper use.

On the request for warranty service, please present your warranty card filled with purchase date and seal (with the store and address). Any repair service out of the scope of warranty will be charged accordingly.

17.Manufacturer and Rep. information

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