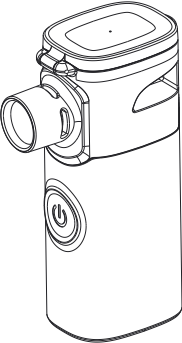


INSTRUCTION MANUAL

MESH NEBULIZER VP-M11



- Thank you very much for purchasing Vapo Nebulizer.
- Be sure to read this Instruction Manual before using the unit for you to use it safely and correctly.
- Please keep the manual appropriately for future reference.
- This instruction Manual is applicable for the Mesh Nebulizer.
- Additional features of the device are highlighted throughout the Manual.

2.4 Protect the Nature Environment

Please help to protect natural environment by respecting national and/or local recycling regulations when disposing of the battery and the product at the end of their useful live.

3 Principle of Mesh Nebulizer

3.1 Device Description

The Mesh Nebulizer (Model: VP-M11) uses the self-excited oscillation circuit technique, in which the ceramic sheets contained in nebulizing head together with the metal mesh are driven successively to oscillate at a high frequency to make the liquid flowing through the micromesh of the metal mesh being ejected and nebulized to form inhalant aerosol. It can be applied to both water soluble drugs and oil soluble drugs. The patient can use this aerosol for his/her respiratory therapy easier and more convenient. The device may be used with child and adult patients in the home, hospital, and sub-acute care settings, they are not intended for life support nor do they provide any patient monitoring capabilities. The device is single patient multiple use.

3.2 Advantages

- This product can make the medication solutions being nebulized to form nanoparticles approximately 5µm MMAD which may be used for the treatment of respiratory diseases such as asthma, allergies, etc.
- Mesh Nebulizer has portable hand-held appearance so customers can use it in the home, hospital, and sub-acute care settings conveniently.
- Two power sources, USB cable and batteries.
- Easy to use: One touch turns on.

3.3 Nebulization Principle

The Mesh Nebulizer (Models:VP-M11) uses the self-excited oscillation circuit technique, in which the ceramic sheets contained in nebulizing head together with the metal mesh are driven successively to oscillate at a high frequency to make the liquid flowing through the micromesh of the metal mesh being ejected and nebulized to form inhalant aerosol.

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1 Getting to Know Your Nebulizer

1.1 Intended Use

The Mesh Nebulizer (Model: VP-M11) are intended to aerosolize physician-prescribed solutions for inhalation that are approved for nebulization. The equipment operator may be a medical staff, or it may be operated by the patient himself. The device may be used with child and adult patients in the home, hospital, and sub-acute care settings, they are not intended for life support nor do they provide any patient monitoring capabilities.

1.2 Intended users

- Legally certified medical experts, such as doctor, nurse and therapist.
- Caregiver or patient under the guidance of qualified medical experts.
- The user should also be capable of understanding general operation of this device and the content of instruction manual.

1.3 Specification

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

Product Name	Mesh Nebulizer
Model	VP-M11
Applied Part	Mask, Mouthpiece(Type BF)
Power source	DC 3 V (two AA alkaline batteries), Or USB Cable (5V 1A)
Dimensions	35 (L) x 65 (W) x 107(H) mm
Weight (not including battery)	Approximately 78g
Battery Life	90 minutes with 2 AA alkaline batteries
Working Environment	Temperature: 10 to 40 °C Humidity: 30 to 85% RH Atmospheric Pressure: 700 hPa~1060 hPa
Storage Environment	Temperature: -20 to 50 °C Humidity: 30 to 85% RH Atmospheric Pressure: 700 hPa~1060 hPa
Classification of installation and use	Portable
Device type (component/sub-assembly/equipment/system)	Equipment
Mode of operation	Continuous
Power consumption	Approximately 2W
Sound Level	≤50 dB
Capacity of Medicine Cup	≤8 mL
Nebulization Rate	≥0.20 mL / min
Ultrasonic Frequency	Approximately 114 kHz
Particle Size	MMAD: approximately 5 µm Inhalable percentage ≤ 5 µm: ≥50%
Automatic power off	Power off automatically in 20 min When there is no liquid in the medicine cup, nebulization will stop, and the machine will power off automatically within 5 seconds.
Dustproof and waterproof	IP22
Service Life	Main unit: 2 years

- The device shall be disconnected from the power source after use.
- The mouthpiece and inhalation mask contact user directly, please keep it clean!
- If you have any problems with this device, such as setting up, maintaining or using, please contact with service personnel to Vapo Healthcare Co., LTD., Don't open or repair the device by yourself.
- Please report to Vapo Healthcare Co., LTD., if any unexpected operation or events occur.

4.2 Precautions for storage

- DO NOT store the device in locations exposed to high temperatures (over 40°C), low temperatures (below -10°C), high relative humidity (over 85%) or excessive amounts of dust. Never place any heavy objects on the storage case.
- Store the device and component in a clean, safe location.
- Keep the unit out of reach of small children.

4.3 Precautions for battery

- Do not use the battery with equipment other than your Mesh Nebulizer, or attempt to modify it for other use.
- Do not store the battery in direct sunlight, high temperature and high humidity.
- Avoid placing the battery on metal or wet surfaces or inside a metal box. This may short-circuit the battery's positive and negative contact causing the battery to heat up or explode.

4.4 Precautions for Maintenance

- If you are not going to use the unit for a long period of time (3 months or more), remove the batteries. If you leave the unit without using while keeping the batteries in it, the batteries may leak and cause trouble to the unit.
- DO NOT drop the device or subject it to other shocks or vibration.
- Never dry the parts in the microwave oven.
- Do not poke the Metal Mesh with a cotton swab or a pin. The Metal Mesh will be damaged and cannot be used.
- Do not carry or leave the nebulizer with medication in the medicine cup.

Note:

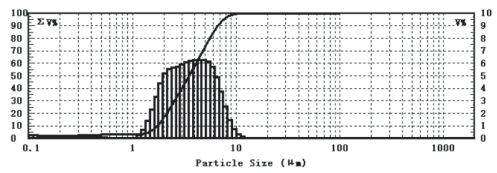
- This unit is a medical instrument. Be sure to follow the instructions of a doctor and use the unit correctly. For the type, dose, and regimen of medication, be sure to follow the instructions of a doctor.
- Nebulization rate is lowered at low temperature.
- Specifications and appearance may be changed without prior notice for improvement.

1.4 Software Release

Rev: V1

1.5 Plot of cumulative size distribution

The Plot of cumulative size distribution below is the results in the table of Mass fraction of the drug collected on each stage of the Marple Impactor. You can get detailed information from Vapo Healthcare Co., LTD.



1.6 Contraindications and Adverse reaction

- Patients allergic to aerosolized drug.
- The device should be used with caution or be used under the guidance of doctors by patients those who may show difficulty in breathing, apnea or continuous asthma during process of atomization.

1.7 Patient Populations

This product is only designed for patients (adult and children) who are able to breathe by themselves and are conscious. And need to be administered respiratory diseases through the respiratory tract.

4.5 Precautions for Cleaning

- Clean the casing of the main unit by using a soft cloth moistened with water or mild detergent. Do not use abrasive cleaners.

5 Name of Each Part

Figure 1 – Each part of main unit and medicine cup

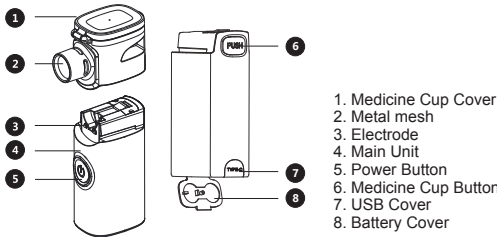
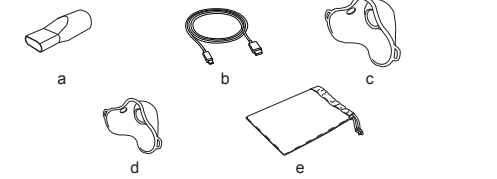


Figure 2 – Accessories



a.Mouthpiece
b.USB Cable (1M, without shielding)
c.Inhalation Mask (Adult)
d.Inhalation Mask (Child)
e.Storage Bag (Optional)

2 Warnings and Cautions

The device should be used with caution or be used under the guidance of doctors under the following circumstance.

2.1 Warnings

- (1)This product can be applied to both water soluble drugs and oil soluble drugs, and for the dose, and regimen of the medication, be sure to follow the instructions of a doctor. These products are not applied to Pentamidine drugs.
- Your symptom(s) may worsen.
- (2)The effect that 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.
- (3)When you use the unit for the first time after purchasing it or after not using it for a long period of time, be sure to clean and disinfect Medicine Cup.
- Miscellaneous bacteria may propagate and you may get infected.
- (4)Clean and disinfect Medicine Cup after each use. Be sure to dry the cleaned and disinfected parts promptly, and store them in a clean place.
- Miscellaneous bacteria may propagate and you may get infected.
- (5)This unit is designed for personal use. It is not appropriate for more than one users.
- (6)Keep the device upright during use.
- (7)Place the equipment where it is hard for children,infants,pets or pests to reach. To avoid strangulation caused by the USB cable.
- They may swallow small pieces. The Main Unit may be damaged or may cause injury to children or infants. In case a child swallows small pieces, immediately consult with a doctor.
- (8)Do not wash the Main Unit and USB Cable with water or hot water. Do not immerse them in water.
- The unit may experience electricity leakage or you may suffer electric shock.
- The unit will cause trouble and may not be able to be used.

6 Indications of the Light

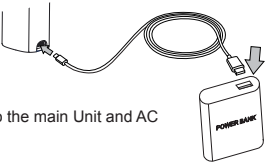
- i.When the light of below Power Button the color changes from green to orange and flash slowly (about 4 seconds interval). batteries will be worn out soon. Replace both batteries with new ones.
- ii.When during nebulization, the color is green and flash slowly (about 4 seconds interval).
- iii.Turn on the unit by press the Power Button. Then hold on the Power Button and don't release for more than 5 seconds, the light will be lighted green all the time indicating Self-cleaning mode entered.

7 Operation Procedure

7.1 Prepare the Power Source

The Unit uses batteries or USB Cable as the power source.

- 1.Power Source - USB Cable and Charging



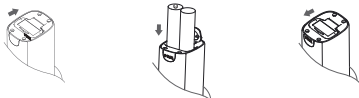
Step: Connect the USB cable to the main Unit and AC adapter as shown in the Figure.

Note: ⚠

- AC adapter is not supplied. Please use commercially available AC adapter which meets electrical grade and passes IEC 60601-1 and CE LVD certification.
- Be noted that this USB Cable is a Type-C and the designed output voltage is 5V.

- (9)Recommendations: Limit use to 25 minutes at a time is recommended, and allow a 40-minutes interval before using the Unit again. If used continuously for a long time, the maximum temperature of the main unit is 45.3°.
 - (10)Acute pulmonary edema might occur or water intoxication might occur.
 - (11)Always dispose of any remaining medication in the medicine cup after each use. Use fresh medication each time you use the device.
 - (12)Do not leave the device or its parts where it will be exposed to extreme temperature or changes in humidity, such as leaving the device in a vehicle during warm or hot months, or where it will be exposed to direct sunlight.
 - (13)This product is not suitable for wireless interference environment.
 - (14)This product should not be used in flammable gas, oxygen-rich environment and anesthetic gas.
 - (15)The maximum capacity of the medicine cup is 8 ml, and should not be overfilled.
 - (16)Electrical grade AC adapter is required to be used with USB Cable.
 - (17)Remove the battery if you do not use it for a long time.
 - (18)The nebulizer is not suitable for use in anaesthetic breathing systems or lung ventilator breathing systems.
 - (19)Do not maintain device while in use.
 - (20)The parts in contact with the human body contains PP/PVC and other materials, which may cause allergic reactions. People who are allergic to these materials should use with caution.
 - (21)If you take this product out of an environment beyond the operating temperature/humidity range, please let it stand in the working environment for no less than 1 hour before starting to use it.
- This device not be used with high-frequency surgical equipment.

- 2.Power Source – Batteries for the main unit



- Step 1: Open the Battery Cover.
- Step 2: Insert batteries correctly by aligning the polarities (+ and -) with the battery indication mark.
- Step 3: Close the Battery Cover.

Note: ⚠

- Two AA alkaline batteries are used for the Unit.
- Be noted that rechargeable batteries cannot be used in the Unit!

7.2 Battery life and battery replacement

When using alkaline batteries, the unit can be used for approximately 3 days (if it is used for 30 minutes a day). When the indicator light flashes quickly (less than 1 second), batteries will be worn out soon. Replace both batteries with new ones.

Note: ⚠

- Immediately replace the worn batteries with new ones.
- If you are not going to use the unit for a long period of time (3 months or more), remove the batteries.
- If you leave the unit without using while keeping the batteries in it, the batteries may leak and cause trouble to the unit.
- Do not use the batteries other than the ones specified for the unit. Do not use worn and new batteries together or different types of batteries together.
- Do not insert batteries with the polarities (+ and -) in the wrong direction.

7.3 Fill the Medication

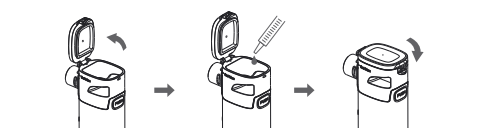
You can fill the medication in the assembled Unit directly or fill the medication in the medication cup separately.

2.2 Cautions

- (1)Do not inhale by using water in the Medicine Cup.
- Your symptom(s) may worsen.
- (2)Do not drop medication on the Main Unit. If you drop medication, immediately wipe it off.
- If you use the unit while it is wet, it may cause trouble or you may suffer electric shock.
- (3)Do not poke Metal Mesh with a cotton swab or a pin.
- The unit may be broken and cannot be used.
- (4)Do not drop or apply strong shock to the Main Unit or Medicine Cup.
- They may be broken and cannot be used or you may suffer electric shock.
- (5)Do not use the USB Cable other than the one supplied by Vapo. Do not use a broken USB Cable.
- The unit may be broken and cannot be used.
- (6)Do not use the accessories when you are allergic to the materials of the accessories and ask doctors. Do not use accessories other than the one supplied by Vapo.
- They may not work with the unit.
- (7)Do not use non-electrical grade AC adapter with USB Cable.
- The device may have risks caused by other AC adapter and may harm user's safety.
- (8)Do not disassemble, repair, or modify the unit.
- The unit may be broken and cannot be used.
- (9)The nebulizer is not suitable for use in anaesthetic breathing systems or lung ventilator breathing systems.
- (10)Take note of contraindications of the medicine in the accompanying package leaflet.
- (11)Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

2.3 In the use of instrument following phenomenon may occur

The nebulization characteristics of this unit differ by the properties of medication. Especially with the use of a medication having high surface activity or viscosity such as medication solubilizing agent or expectorant, the nebulization rate may be reduced. The nebulization rate may also be reduced when the temperature of medication is low.



- Step 1: Open the Medicine Cup as the shown in the picture above.
- Step 2: Fill the medication as the shown in the picture above.
- Step 3: Close the Medicine Cup tightly, otherwise the medication may splash out during usages as the shown in the picture above.

Note: ⚠

- The maximum capacity of Medication Bottle is 8 ml.
- You can fill the medication in the Main Unit directly or take out the Medicine Cup from the Main Unit and fill the medication in the Medicine Cup, then close the Medicine Cup closely and assemble the Medicine Cup to the Main Unit.

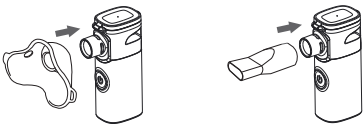
7.4 Install the Medicine Cup

When you fill the medication in the Medication Cup separately, please take out the Medicine Cup from the Main Unit and fill the medication in the Medicine Cup, then close the Medicine Cup closely and assemble the Medicine Cup to the Main Unit.



- Step 1: Press the Medicine Cup Button and keep holding on, then take out the Medicine Cup.
- Step 2: Assemble the Medicine Cup to the Main Unit. The Medicine Cup is fixed to the Main Unit only after a clear 'click' is noticed.

7.5 Install the Inhalation Mask or theMouthpiece



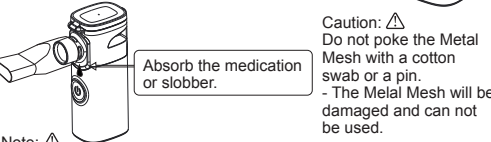
Step: Install the Inhalation Mask or the Mouthpiece, as shown in the picture above.

Note: ⚠ Inhalation Mask is recommended when the Unit is used by child less than 5 years old. It is not easy for the child to use the Mouthpiece correctly. The Mouthpiece or other small parts may be swallowed.

7.6. How to Inhale

Step 1: Push the switch on the battery box to the on position, and the green indicator will be displayed. Hold the Main Unit with your hand and turn on the Unit by press the Power Button. The indicator will flash slowly (about 4 seconds interval) during nebulization.

The backlight of the Power Button will be green during nebulization.



Note: ⚠

- Keep the device tilted at no more than 15° during use.
- If medication or slobber collects too much on the internal surface of the head of Medicine Cup, turn off the power and absorb the medication or slobber with new gauze. (If a medication has high surface activity, it may exude from Metal Mesh)

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- If the medication has high surface activity or viscosity such as medication solubilizing agent or expectorant, the nebulization rate may be reduced.
- Metallic sound may be generated, but it is not a trouble.

Step 2: When you finish inhalation, push the Power Button to turn off the power. The Unit will stop working if the medication in the Medicine Cup is used up.

Note: ⚠ When the USB Cable is used, unplug the USB Cable from the AC adapter.

8 Cleaning and Disinfection of the Device Before and After Use

Step 1: Remove Inhalation Mask, Mouthpiece and Medical nebulizer Cup from the Main Unit.
Step 2: Open the Medical nebulizer Cup and discard the medication

8.1. Cleaning of the mesh nebulizer cup

Pre-Cleaning
Do a manual pre-cleaning, until the devices are visually clean. Submerge the instruments in a cleaning solution. Clean the surfaces with a soft bristle brush.
Cleaning
Following conditions of manual cleaning can be performed for the products: 0.5%-1% neodisher MediClean forte, 10-30 minutes immersion time at 30 °C.
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.



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E. The product is brushed under the detergent solution with a soft, nylon bristled brush for 30 seconds until all visible residues are removed. Pay special attention to the product gaps. 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 10-30 minutes.

F. Remove the device from the cleaning basin. Rinse the device under running water for 30 seconds at room temperature.



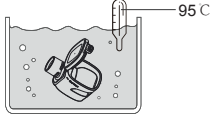
G. Put the cleaned and rinsed device into a suitable clean basin with fresh de-ionized water. Thoroughly rinse and flush the lumen of the device with the water for 5 minutes.
H. Dry the device through lint free towe.

ATTENTION:
If other cleaners are used, select immersion times, concentrations and temperatures of the solutions as instructed by the manufacturer of the cleaner.

8.2. Disinfection of mesh nebulizer cup

Boiling disinfection should be performed for 2 min.

A.Immerse the nebulizer cup in boiling water and boil for 2 minutes.



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B.After completion of the disinfection time, remove the devices from the boiling water carefully.

The disinfection process at 95 °C for 2 minutes has been validated to provide sufficient disinfection effect.

NOTE: ⚠
This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against interference in a residential installation. This equipment generates and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause interference to radio or television reception, which can be determined by turning the equipment off and on, please try to correct the interference through one or more of the following actions:
• Re-orient or relocate the receiving antenna.
• Increase the distance between the equipment and receiver.
• Connect the equipment into an outlet on a circuit different from that to which the receiver is needed - consult the dealer or an experienced radio/TV technician for advice and assistance.

CAUTION: To help to avoid the risk of electric shock, do not expose this appliance to rain or moisture.

Protect the environment!
This electronic equipment contains reusable material and must not be disposed of with domestic waste. Please take it to a collecting point for electric and electronic equipment (ask your local authorities for details).

13 Limited Warranty

IMPORTANT!
The Mesh Nebulizer is a personal care product. Please DO NOT return this product to the retailer you bought it from. If you have questions or need help, please call the Helpline on 0512-57990057 or email to market@vapohealth.com.

The main unit is guaranteed for two years.

If this main unit fails to function properly when used as directed under normal conditions within the two-year period, Vapo Healthcare Co., LTD. will either repair or replace the product, at our discretion, free of charge. Please contact the Vapo Healthcare Co., LTD. Helpline on 0512-57990057 or email to market@vapohealth.com.
The product must be accompanied by a proof of purchase, either a bill of sale or other proof that the device is within the warranty period. Vapo Healthcare Co., LTD. will bear the cost of repairing or replacing the product and shipping it back to you.

This warranty does not apply to a product which has been damaged as a result of improper maintenance, an accident, improper voltage supply or any other form of misuse. The warranty is also void if the owner repairs or modifies the product in any way. Vapo Healthcare Co., LTD. is not liable for any incidental or consequential damages with regard to this product. The warranty also excludes any liability other than what is stated above. No other warranty is given.

Legal rights vary from country to country. some countries do not allow the exclusion or limitation of incidental or consequential damages, so the above limitations may not apply to you. We are not in any way responsible for any outcome resulting from the use of this product.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference; and (2) this device must accept any interference received, including interference that may cause undesired operation. Warning: Changes or modifications to this equipment not expressly approved by the party responsible for compliance could void your authority to operate the equipment.

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8.3. Clean and Disinfection of main unit

After use, take the main unit for manual cleaning disinfection. Soak a dry soft cloth with 75% ethanol or other disinfects which are approved for its efficacy by FDA and/or Health Canada approval, VAH/DGHM-listing, CE marking, etc. and wipe all the surfaces of the device, until the surfaces of the device are visually clean. Repeat this step with a new soft cloth soaked in above-mentioned disinfectant. Further repetition may be performed, if necessary. Leave the surfaces to dry on its own.

Please follow the manufacturer's instructions of disinfectants.

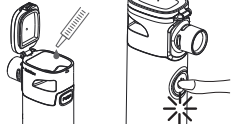
Note: ⚠ Please clean and disinfect each use! Never dry the parts in the microwave oven.

8.4. Storage:

Storage of processed products in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use.

8.5.Self-cleaning Mode

Storage of processed products in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use.



Step 1: Put clean water in the Medicine Cup.
Step 2: Turn on the Unit by press the Power Button.
Step 3: Then hold on the Power Button and don't release for more than 5 seconds, the backlight of Power Button will be lighted all the time indicating Self-cleaning mode entered.

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Note: ⚠

- Self-cleaning is recommended to be used after each use.
- After the water in the Medicine Cup is used up, the Unit will stop working.
- Wipe off the water with new gauze and dry the Unit thoroughly.

9 Replace the Medicine Cup



Medicine Cup is a consumable part

You can usually use a Medicine Cup for approximately 6 months (if it is used for 30 minutes a day). You can usually use mask, mouthpiece for approximately 6 months. However, the unit may not nebulize even before using it 6 months depending on how you use it. The unit also may not nebulize or nebulize extremely weak. In those cases, replace the Medicine Cup with a new one.
For the inquiry on where to purchase the Medicine Cup or the broken or lost accessory, contact the store where you purchased the unit or the nearest Vapo dealer.

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10 Troubleshooting problems

Trouble	Possible cause	How to correct
The nebulization rate is extremely low.	The indicator light flashed quickly (the interval is less than 1 second), and the batteries are low/worn out.	Replace the batteries with new ones.
	The Metal Mesh is stained.	Clean the Medicine Cup to remove the stain. - If the trouble cannot be corrected by the above-mentioned procedure, replace the Medicine Cup with a new one.
The unit does not nebulize.	The polarities (+ and -) of batteries are in the wrong direction.	Insert batteries in the correct alignment.
	The batteries are low.	Replace batteries with new ones.
	The USB Cable is not correctly connected.	Remove the USB Cable from theMain Unit and connect it correctly.
	The Medicine Cup is not installed correctly to the Main Unit.	Install the Medicine Cup correctly.
The backlight of Power Button works correctly but the unit does not nebulize.	The Metal Mesh is extremely stained	Replace the Medicine Cup with a new one.
	The Metal Mesh is broken.	Replace the Medicine Cup with a new one.
	Medication or water is collected on the Electrodes of the Main Unit.	Remove the medication or water.
	The Electrode of the Main Unit is stained.	Wipe off the stain.

Note: ⚠
If the unit does not nebulize normally after taking the above-mentioned procedure, contact the store where you purchased the unit or the nearest Vapo dealer.

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11 Symbol Form

Symbol	Explanation
⚠	Symbol for caution. This is a safety symbol that is used to highlight that there are specific warnings or precautions associated with the devices that are not otherwise found on the label. The symbol can also be used to mean "attention, see Instructions for Use."
IP22	Protection against ingress of dust and water, it means the device could protected against dust with $\phi \geq 12.5\text{mm}$ and vertical falling water drop 15°.
Manufacturer logo	Manufacturer Indicates the date when the medical device was manufactured.
IEC 60601-1 Type BF Applied Part	This symbol indicates that the device includes IEC 60601-1 Type BF Applied Part.
Recycling symbol	The symbol indicates that the device should be sent to the special agencies according to local regulations for separate collection after its useful life.
Read manual symbol	Symbol for "THE OPERATION GUIDE MUST BE READ". Indicates the need for the user to consult the instructions for use.
Importer logo	Importer
Class II	Class II
MD	Indicates the given product is a medical device.
SN	This symbol shall be accompanied by the manufacturer's serial number.
LOT	Symbol for lot number; Indicates the manufacturer's batch code so that the batch or lot can be identified.
EU REP	Indicates the Authorized representative in the European Community.
CE Mark	Symbol for CE Mark. This symbol certifies that a product has met European Union consumer safety, health, or environmental requirements.
UDI	Unique Device Identification
Handle With Care	Handle With Care

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A3 Guidance & Declaration - electromagnetic immunity concerning Conducted RF & Radiated RF

Guidance & Declaration – Electromagnetic immunity			
The Mesh Nebulizer is intended for use in the electromagnetic environment specified below. The customer or the user of Mesh Nebulizer should assure that they are used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands & amateur radio bands	Not applicable	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 Mesh Nebulizer, including cables specified by the manufacturer. Otherwise, degradation of this equipment could result.
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014+A1:2020)	10V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014+A1:2020)	

This instruction Manual is applicable for the Mesh Nebulizer. Additional features of the device are highlighted throughout the Manual. Please DO NOT return it to the store, but contact us initially for advice and assistance:
Customer Service Department:
Vapo Healthcare Co., Ltd.
Southern unit of third floor, building B, No.99, Yuda West Rd, High tech district, Kunshan, Suzhou, 215301 Jiangsu, P.R. China
Share info GmbH
Am Schulzentrum 12, 41564 Kaarst, Germany
Importeur
SCALA Electronic GmbH
Potsdamer Straße 85, 14513 Teltow, Germany
Made in China
Version:V1.1
Revision Date:2025-04-26

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14 Guidance and Manufacturer's Declaration

1)This equipment needs to be installed and put into service in accordance with the information provided in the ACCOMPANYING DOCUMENTS;

2)IMMUNITY TEST LEVELS for basic safety and essential performance of ME equipment and ME systems should be chosen based on a high probability of maintaining basic safety and essential performance, and shall be according to the professional Healthcare facility environment, home Healthcare environment, and special environment, based on the locations of intended use.

3)HOME HEALTHCARE ENVIRONMENT is dwelling place in which a patient lives or other places where patients are present, excluding professional Healthcare facility environments where operators with medical training are continually available when patients are present. Such as schools, outdoors, domiciles, vehicles hotels and pensions.

4)Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

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

EXAMPLE: As indicated in Table 6 of IEC 60601-1-2:2014 for ME EQUIPMENT, a typical cell phone with a maximum output power of 2 W yields d = 3.3 m at an IMMUNITY LEVEL of 3 V/m.

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A1 Electromagnetic Emissions-For all EQ UIPMENT and SYSTEMS

Guidance and manufacture's declaration-electromagnetic emission		
The "Mesh Nebulizer" is intended for use in the electromagnetic environment specified below. The customer or the user of the "Mesh Nebulizer" should assure that it is used in these electromagnetic environments.		
Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The Mesh Nebulizer uses RF energy only for its internal function. Therefore, its RF emissions are very low and is not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	The Mesh Nebulizer is 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.
Voltage function/flicker emissions IEC 61000-3-3	Not applicable	

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A2 Guidance & Declaration-electromagnetic immunity

Guidance & Declaration – Electromagnetic immunity			
The Mesh Nebulizer is intended for use in the electromagnetic environment specified below. The customer or the user of Mesh Nebulizer should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±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	±2 kV for power supply lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV, ±2 kV line to ground	Not applicable	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 _r (>95% dip in U _r) for 0.5 cycle <5% U _r (>95% dip in U _r) for 1 cycle 70% U _r (30% dip in U _r) for 25/30 cycles <5% U _r (>95 % dip in U _r) for 5/6 sec	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Electronic Stethoscope requires continued operation during power mains interruptions, it is recommended that the Electronic Stethoscope 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	
Proximity magnetic fields IEC 61000-4-39	CW 8A/m for 30KHz Pulse modulation 2.1KHz, 65A/m for 134.2KHz Pulse modulation 50KHz,7.5A/m for 13.56MHz	CW 8A/m for 30KHz Pulse modulation 2.1KHz, 65A/m for 134.2KHz Pulse modulation 50KHz,7.5A/m for 13.56MHz	Power frequency magnetic fields/ Proximity magnetic fields should be at levels characteristic of a typical location in a commercial or hospital environment.
NOTE : U _r is the a.c. mains voltage prior to application of the test level.			

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