

Model PN100

Micro-MESH NEBULIZER

■ Intended Use:

Legally certified medical experts, such as doctor, nurse and therapist, or healthcare personnel or patient under the guidance of qualified medical experts .

The user should also be capable of understanding general operation of PN100 and the content of instruction manual

■ Intended User:

Adult and pediatric patients suffer from asthma, Chronic Obstructive Pulmonary Disease (COPD) such as emphysema and chronic bronchitis, or other respiratory diseases that are characterized by obstruction to air flow

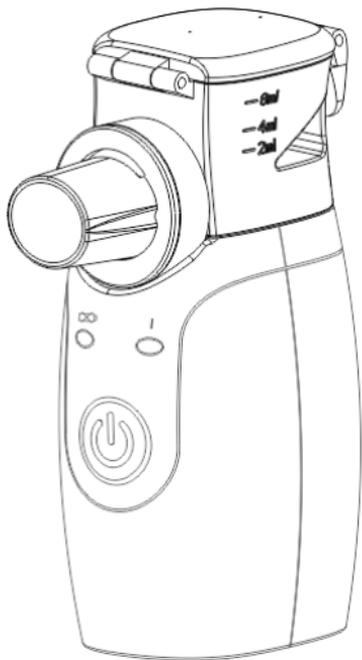
■ Environment

This product is intended for use in a medical facility, such as Hospital, clinic and doctor's office, in a room of general household, and in open-air environment with a roof.

■ Durable period

Durable periods are as follows, provided the product is used to nebulize saline 3 times a day for 10 minutes each time at room temperature (23°C).Durable period may vary depending on usage environment.

■CAUTION: Federal law restricts this device to sale by or on the order of a physician.



- Thank you for purchasing this product. To ensure safe and correct use of this product, please read the instruction manual carefully before using.
- Please keep the instruction manual at a proper place for future reference.
- This is a single patient device. Do not allow multiple patients to use the same device.
- These parts of mouth piece and masks can be reused after disinfecting treatment (please refer how to disinfect in page 16)

Contents

- A nebulizer is a type of medical apparatus. Please follow a doctor's instructions on choosing the correct type, dose, and regimen of medication.
- The nebulization characteristics of the unit differ by the properties of medication. The nebulization rate may vary with using different medicine.

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IMPORTANT CAUTION:

As with any mechanical device, this product may become unusable due to an electrical outage, battery depletion, or mechanical failure. We recommend that you have spare batteries and a backup device available to you.

Safety Precautions

To ensure safe and correct use of this product, please read the instruction manual carefully before using.

Warning!

- ◆ Please follow a doctor's instructions on choosing the correct type, dose, and regimen of medicine.
- ◆ Do not place any liquid in the medication chamber that is not prescribed by a physician.
- ◆ This is a single patient device. Do not allow multiple patients to use the same device.
- ◆ If you are using the nebulizer for the first time after purchasing it or you have not used it for a long time, please clean the nebulizer parts. (Please see page 13-14)
- ◆ After each use, please clean the medication chamber, and mouthpiece with distilled water. Dry the cleaned parts immediately and store in a clean place. (Please see page 13-14)
- ◆ The inhalation mask must be cleaned with distilled water and dried prior to first use.
- ◆ These parts of mouth piece and masks can be reused after disinfecting treatment (please refer how to disinfection page 16)
- ◆ Do not plug or unplug the AC adapter with wet hands.

Caution

- ◆ If device does not shut off automatically when medication is depleted and gives off a high frequency sound, press the "START/STOP" button to turn the power off immediately to avoid the mesh breaking. Please go to page 18 for troubleshooting.
- ◆ Please clean the nebulizer parts carefully after each use. Otherwise it may not function.
- ◆ Water is not applicable for use. If you fill water in the medication chamber, the nebulizer cannot be turned on. The distilled water can be used for cleaning the medication chamber under "clean process".
- ◆ Please do not allow Q-tips or any foreign objects to come in contact with the mesh of the medication chamber. Otherwise the unit may not function.
- ◆ Do not drop the nebulizer. Avoid severely impacting the nebulizer. Otherwise it may not function.
- ◆ Do not use the AC adapter other than the one specifically designed for this product
- ◆ Do not mix different types of batteries.
- ◆ Do not store or carry a nebulizer with liquid medication or water remaining in it.
- ◆ Do not immerse the nebulizer main unit and AC adapter in water.
- ◆ Keep the device out of the reach of infants and children. Children should use only under adult's supervision.

Product Features

1. Pocket-sized and easy to carry.
2. Low power consumption and low residual medication volume.
3. The nebulizer can function properly for a short time after being rotated to any angle. When the nebulizer is rotated such that the medication does not contact the mesh, it can nebulize properly for about 15 seconds. (Time varies depending on specific medication types.)

Components

The package contains the following components. If you find any components missing, please immediately contact the retailer from which you purchased the product.

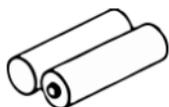
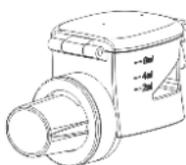
1. Main unit



2. Main unit cover



3. Medication chamber 4. Alkaline batteries



AA 1.5Vx2(Optional)

5. Mouthpiece



6. Carrying pouch



7. USB cable
(optional)

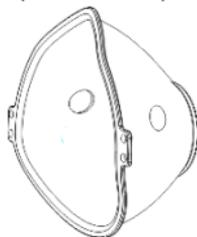


(USB cable is
Optional)

8. Inhalation mask

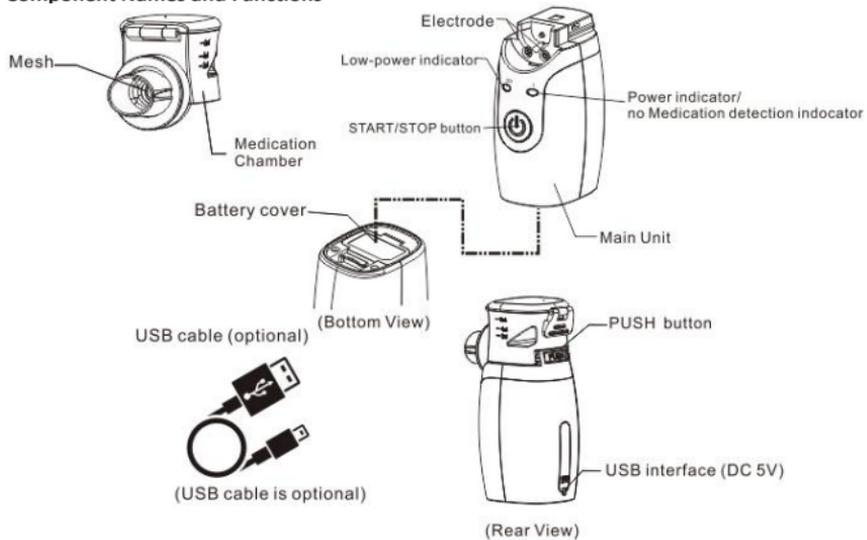


(Small multi-use)



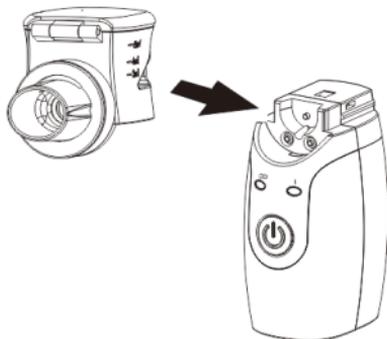
(Large multi-use)

Component Names and Functions



How to assemble the nebulizer

1. Attach the medication chamber to the main unit:



Attach the medication chamber while it gives off a sound "Click".

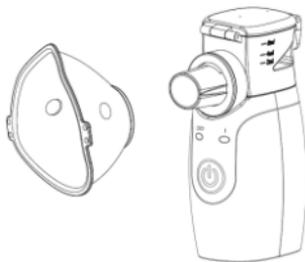
2. Attach the mouthpiece:

Please securely attach the Mouthpiece to main unit.



3. Attach the Inhalation mask:

- Inhalation mask for children is S size.
- Inhalation mask for adults is L size.



- Attach the Mask.

● Please ensure that the medication chamber is attached correctly; otherwise, it may result in a bad connection and the nebulizer may not function properly.

● Please keep the electrodes of main unit and medication chamber clean; otherwise, the nebulizer may not function properly.

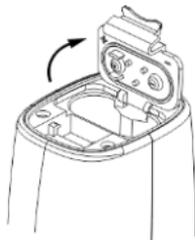
How to connect to the power Supply

This product can use either batteries or an AC adapter (optional) as its power supply.

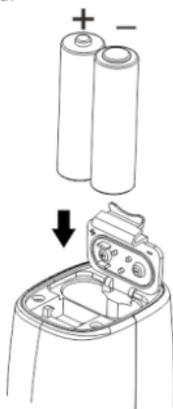
■ How to install batteries

Please open the battery cover and insert 2 "AA" alkaline batteries.

1. Open the battery cover.



2. Insert the batteries so that the polarities are oriented correctly, as indicated.

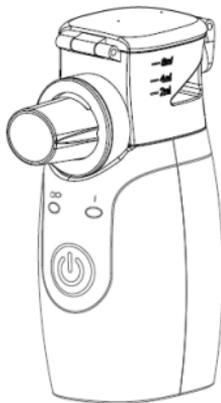


3. Close the battery cover.



Battery life and replacement

- Up to 3.0 hour if used continuously. (Use 2 "AA" (LR6) alkaline batteries) 6 days if used 3 times daily, 10minutesper time
- If the low-power indicator with orange color was lit to flash 2Hz, it means battery is almost run out. But Nebulizer still can be used around 30 minutes continuously.
- If the low-power indicator with orange color was lit constantly (orange color), it means that extremely low power caused the nebulizer not to work. Please immediately replace with new alkaline batteries.

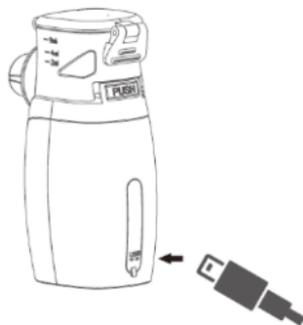


Attention

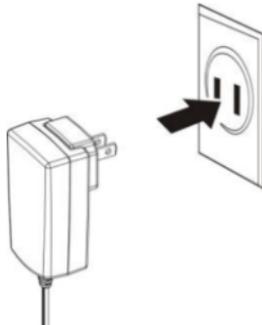
- Do not mix different types of batteries.
- Battery life may be different depending on type of the batteries used.

■ How to use the AC adapter (with USB connector)

1. Plug the USB connector into the main unit's power supply inlet.



2. Plug the AC adapter into an electric outlet.



General Recommendations

- Please purchase the AC adapter specifically designed for this product. Do not purchase and use AC adapters of other brands.
- Please unplug the AC adapter after using. Do not leave it connected to the power supply for a long time.

How to fill the medication

Please remove the main unit cover, mask adapter, and mouthpiece and inhalation mask first.

1. Remove the medication chamber from the main unit:

Press the PUSH button on the rear side of the main unit and push the medication chamber toward the front side of the main unit.

Attention

- To avoid damaging the nebulizer, please ensure the PUSH button is pressed down before pushing the medication chamber forward.
- To avoid rupturing the mesh, please do not poke it with your finger or other objects.

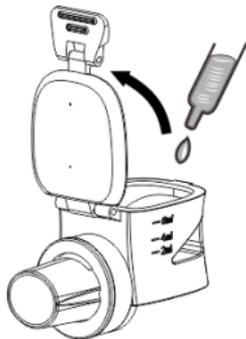


2. Fill the medication:

- Fill the medication as shown in the figure. (Recommended fill volume: Approx. 8 ml maximum / 0.5 ml minimum)
- Please close the cover of the medication chamber.

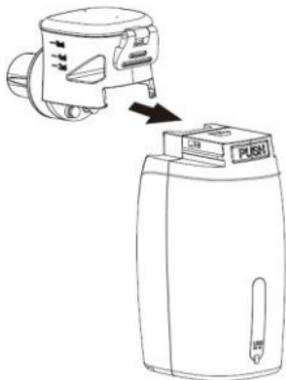
Attention

- To prevent the medication leaking from the chamber, ensure the cover is closed securely.
- The filling process should be done while the chamber is detached from the main unit.



3. Re-attach the medication chamber to the main unit:

Attach the medication chamber while it gives off a sound "Click".



Attention

- Make sure the medication chamber is attached correctly or the bad connection may result in malfunction.
- To ensure the nebulizer will function properly, keep the electrodes of the main unit and the medication chamber clean.

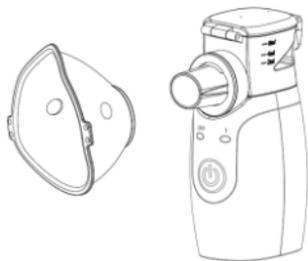
4. Attach the mouthpiece:

Please securely attach the Mouthpiece to main unit.



5. Attach the Inhalation mask:

- Inhalation mask for children is S size.
- Inhalation mask for adults is L size.



How to operate the nebulizer

You can also fill a 0.9 % Sodium Chloride (Table salt) solution in the medication chamber and then press "START/STOP" button for a function test after reassembly and before use. If the nebulizer can not spray out, please go to page 18 for troubleshooting.

1. Turn on the power:

Press the "START/STOP" button, and the power indicator (green) will light constantly. And medication chamber will be lit with blue color constantly .

Attention

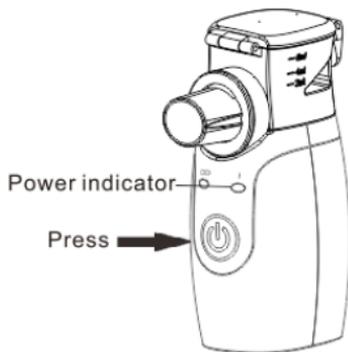
If there is no medication inside the medication chamber , and the power is turned on,

The nebulizer's power indicator (green) will be turned on around 0.5 second, then the power indicator will be changed to orange color immediately . after around 8 seconds ,then turned-off medication chamber light and shut-off power automatically

In the operation while medication was depleted : the power indicator will be changed to orange color immediately and turned-off medication chamber light ,then shut off automatically

the longest nebulization time : 30 minutes .

Pure water is not applicable for use. If you fill pure water in the medication chamber, the nebulizer can not be functioned well.



2. Inhalation :

Hold the nebulizer in your hand stably and start inhalation.



Attention!

Do not cover the vent when you inhale. Otherwise, that will decrease the nebulization rate.

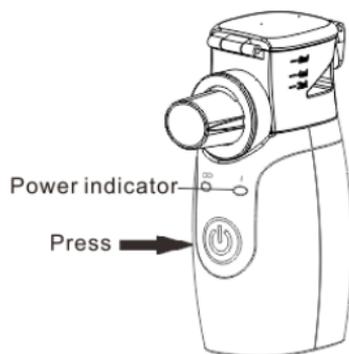


Attention

- If the device detects no medication in medication chamber, it will shut off automatically.
- If the device does not shut off automatically when medication depleted, press the “START/STOP” button to turn the power off immediately to avoid the mesh breaking. Please go to page 18 for troubleshooting.
- During the treatment, you may adjust the nebulizer to any angle. However, make sure the medication stays in contact with the mesh; otherwise, the nebulizer will shut off automatically after approximately 15seconds.
- When the medication is about to be depleted, it is recommended that you tilt the nebulizer (the buttons side) slightly toward you. This allows the remaining medication to contact the mesh to nebulization.
- Do not shake the nebulizer strongly in the usage. Otherwise, the nebulizer may shut off automatically.
- Provide close supervision when the nebulizer is used by children.

3. Turn off the power :

- The nebulizer shuts off automatically after the medication is depleted.
- If you wish to halt the treatment, press the "START/STOP" button to turn the power off. The power indicator light will go out.
- If the AC adapter is being used, please unplug from the wall outlet after turning off the power.
- The unit will turn off the power automatically when the medication is depleted.



How to clean after using

After each use, make sure to clean the nebulizer instantly with the mineral water before storing or carrying. **Attention**

1. Clean the remaining medication :

- Open the cover of the medication chamber and discard the remaining medication.
- Pour a small amount of mineral water into the medication chamber and close the cover.
- Press and hold 3 seconds “START/STOP” button ,the power indicator LED (orange) will be flashed and medication chamber will be lit on

blue color , then go to “cleaning process” to nebulize the water for 2 minutes to remove the residual medication in the medication chamber until the mineral water depleted.

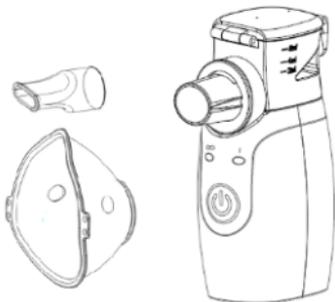
- If the device give off the high frequency sound and the mineral water is depleted, please release the “START/STOP” button to turn the power off. Otherwise, the mesh of the medication chamber may be broken.
- Please clean the remaining medication after each use. Otherwise, the mesh of the medication chamber may become blocked.

2. Dismantle the nebulizer:

Remove the medication chamber, and inhalation mask or mouthpiece from the nebulizer.

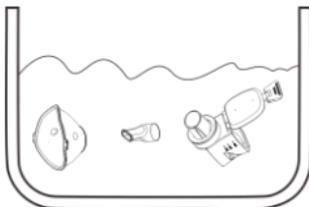
Attention

- The inhalation mask in first use must be cleaned with distilled water and dried. These parts can be reused after disinfecting treatment (please refer how to Disinfect in page 16)



3. Clean the parts with sufficient amounts of distilled water:

Clean the medication chamber, mouthpiece, inhalation mask with distilled water.

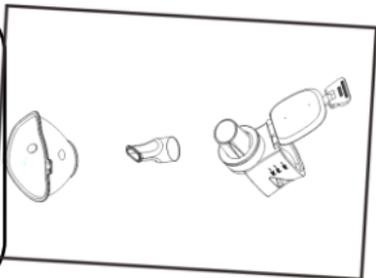


4. Dry the cleaned parts thoroughly:

After the parts are cleaned, dry with new gauze and air dry thoroughly.

Attention

- Please do not dry with cotton or cloths of other materials; otherwise, dust or cloth fiber may be left on the mesh, causing the nebulizer to malfunction.
- Please do not allow Q-tips or foreign objects in contact with the mesh of the medication chamber.



5. Wipe off the main unit with new gauze:

- Dab a piece of gauze with water and lightly wipe off the stains from the main unit. Then, use new gauze to dry.
- Please clean the electrodes on the main unit and medication chamber. This ensures a normal electrical conduction and hence a normal nebulization.

Attention

- Please clean the electrodes on the main unit and medication chamber. This ensures a normal electrical conduction and hence a normal nebulization.



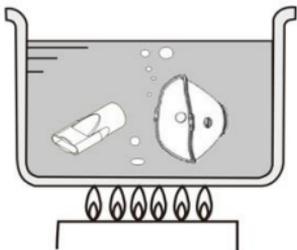
6. Attach the medication chamber and put on the main unit cover. Store all parts in a clean place.

7. Disinfecting

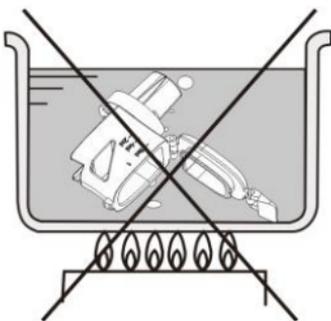
Attention

- In the case of infectious illnesses, the device must be disinfected every day or all attachments must be sterilized. You can also use alcohol or other common alcohol-based disinfectant sprays. Make sure that no disinfectant residues are left behind on the attachments to ensure safe inhalation when next used.

- Disinfect mouthpiece, and mask by boiling at 100°C for 3 minutes



- Please be careful , Don't boil the medication chamber , or damage may occur.



- Dry completely.

How to replace the medication chamber

The medication chamber is a maintenance part and does not carry any warranty. Under normal conditions, the lifetime of the medication chamber is approximately 6 months (three times usage per day or 45 minutes per day). However, the nebulization performance may start deteriorating in less than 6 months depending on the way you use it or the use of certain types of medication. If the nebulizer can not nebulize or the nebulization rate decreases significantly after clean, you must replace the medication chamber with a new one. (If you want to purchase a medication chamber, please contact the retailer from which you purchased the product or any nearby retailers.)

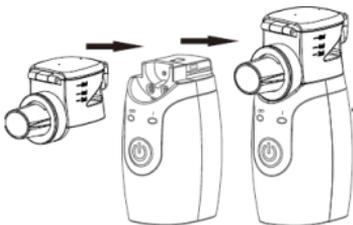
1. Remove the medication chamber from the nebulizer:

Press the PUSH button on the rear side of the main unit, and push the medication chamber toward the front side of the main unit.



2. Re-attach the medication chamber to the nebulizer

Attach the medication chamber correctly as shown in the figure.



Attention

- To avoid damaging the nebulizer, please ensure the PUSH button is pressed down before pushing the medication chamber forward.
- To avoid rupturing the mesh, please do not poke it with your finger or other foreign object.

Attention

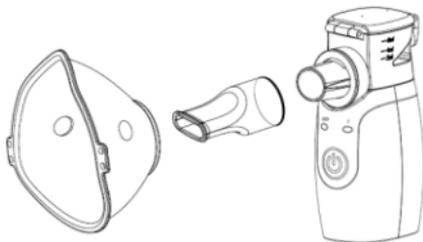
- Please ensure that the medication chamber is attached correctly; otherwise, it may result in a bad connection and cause the nebulizer to not function properly.
- Please keep the electrodes of the main unit and medication chamber clean; otherwise, the nebulizer may not function properly.
- Please clean the medication chamber before using.

How to carry the nebulizer

Please follow the steps below to dismantle the components first. Then, store them in the carrying pouch for carrying.

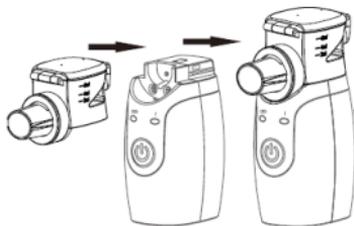
1. Dismantle the nebulizer:

Please remove the mouthpiece and inhalation mask as shown in the figure.



2. Put on the main unit cover:

Please put on the main unit cover as shown in the figure. This will protect the nebulizer from possible damage during carrying.



3. USB cable: optional

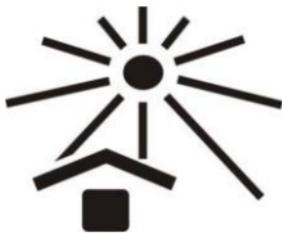
For easy carrying, please bind the USB cable and its electric wire together with a ribbon band as shown in the figure.



4. Place the main unit and associated parts into the carrying pouch for carrying.

Attention

- Please do not carry a nebulizer that still contains medication or water. The medication may leak out and damage or stain the nebulizer.
- Do not store the nebulizer in an area with high temperature or humidity, or in direct sunlight.



Troubleshooting

Please refer to the table below to troubleshoot any problems you may encounter when using the nebulizer.

Problems	Possible Causes	Solutions
Extremely low nebulization.	Medication chamber is not completely attached.	Re-attach the medication chamber correctly and restart the power. (See page 6)
	No contact between medication and mesh for more than 15 seconds.	Adjust the nebulizer's angle so the medication can come in contact.
	Mesh of medication chamber is clogged.	Clean the medication chamber. If it still cannot be used after cleaning, please replace with a new medication chamber.
	Electrodes on medication chamber are clogged with medication or water.	Clear the electrodes of clogged medication or water and restart the power. (See page 14)
	Electrodes on nebulizer and medication chamber are stained.	Remove the stains and restart the power. (See page 14)
After turning power on, power indicator lights for one second and then immediately goes out.	Medication chamber is not completely attached.	Re-attach the medication chamber correctly and restart the power. (See page 6)
	No medication in medication chamber.	Put in the medication in the medication chamber. (See page 9~10)
	No contact between medication and mesh.	Adjust the nebulizer's angle so the medication can come in contact. (See page 11)
	Electrodes on nebulizer and medication chamber are stained.	Remove the stains and restart the power. (See page 14)
Power indicator is not lit and nebulizer is not nebulizing.	Batteries installed backwards.	Re-install the batteries in the correct orientation and restart the power. (See page 7~8)

	Low battery power.	Replace with new batteries and restart the power. (See page 7~8)
	Incorrect connection of AC adapter to nebulizer.	Re-connect in the correct manner and restart the power. (See page 8)
Power indicator is lit and nebulizer is not nebulizing.	Low-power indicator is lit constantly, insufficient battery power, or battery has run out.	Replace with new batteries and restart the power. (See page 7~8)
	Rupture of mesh of medication chamber.	Replace with a new medication chamber and then put in the medication. (See page 16)
	Electrodes on medication chamber are	Clear the electrodes of clogged medication

	clogged with medication or water.	or water and restart the power. (See page 14)
	Electrodes on nebulizer and medication chamber are stained.	Remove the stains and restart the power. (See page 14)
	Mesh of medication chamber is severely clogged.	If it still cannot be used after cleaning, please replace with a new medication chamber. (See page 13~16)
Nebulizer shuts off in usage.	Medication chamber is loosened and not completely attached.	Re-attach the medication chamber correctly and restart the power. (See page 6)
	Connection of USB cable to nebulizer is loosened.	Re-connect in the correct manner and restart the power. (See page 8)
	Medication has run out.	Put in the medication in the medication chamber. (See page 9~10)
	No contact between medication and mesh for more than 15 seconds.	Adjust the nebulizer's angle so the medication can come in contact. (See page 11)

Nebulizer does not shut off automatically while medication depleted.	Nebulizer is being shaken in the use.	Hold the nebulizer in the hand stably. (See page 11)
	Medication chamber is broken.	Replace with a new medication chamber and then put in the medication. (See page 16)
	Some type of medications for nebulization maybe cause to produce a lot of foam in the medication chamber.	Clean the foam and restart the power. (See page 12)
	Electrodes on medication chamber are clogged with medication or water.	Clear the electrodes of clogged medication or water and restart the power. (See page 14)
	Electrodes on nebulizer and medication chamber are stained.	Remove the stains and restart the power. (See page 14)
	Medication chamber is broken.	Purchase and replace with a new medication chamber. (See page 16)
Overflow of medication from medication chamber.	Rupture of medication chamber or ageing of silicone ring.	Replace with a new medication chamber and then put in the medication. (See page 16)

If your nebulizer still does not function properly after taking the solution mentioned above, please contact the retailer from which you purchased the product.

Specifications

Product Name	Micro Mesh Nebulizer
Model	PN100A
Method of Operation	Ultrasonic
Dimensions	Approx.72 mm(L) × 40 mm(W) × 113 mm(H)
Weight	Approx. 98 g (Exclude batteries)
Power Supply	3V DC ("AA" 1.5V alkaline battery x 2) USB cable (Input: 100-240VAC, 50/60Hz, 0.2A Output: 5V DC, 1A)
Power Consumption	Approx. 1.2W
Vibrating Frequency	Approx. 113kHz
Nebulization Rate	>0.25 ml/min minimum
Particle Size	MMAD <5 um
Recommended fill volume	Approx. 8 ml maximum Approx. 0.1 ml minimum
Battery Life	Battery Life Up to 3.0 hour if used continuously 10 days if used daily for 20 minutes. (2 times/day). (Use 2 "AA" (LR6) alkaline batteries)
Durable period	Durable periods are as follows, provided the product is used to nebulize saline 3 times a day for 15 minutes each time at room temperature (23°C). Durable period may vary depending on usage environment. Main unit: 3 years Medication Chamber : 6 months
Allows operation in all directions	upside down or tilted for up to 15 seconds
Detection if no medication or medication depleted	LED orange indicator turn-on 8 sec, then power off
Auto-power in working	30 minutes
Warranty	2 years. (Excluded medication chamber& accessories)
Operating Conditions	10~40 °C (50~104 °F) , 15~93%R.H.
Storage Conditions	-20~70 °C (-4~158 °F) , ≦93%R.H.
Accessories	Main unit cover, mouthpiece, alkaline batteries, carrying pouch, instruction manual. inhalation mask(S), inhalation mask(L), USB cable (optional)

The nebulizer gives off the high frequency sound and shuts off automatically if the medication is not in contact with the mesh of the medication chamber for more than 15 seconds (time varies for different types of medication) or the medication is depleted. This is to help prevent damage to the Mesh

Technical data:

Note: **Test result of cascade impact measurements for particle size.**

- Performance may vary with different drugs such as suspensions or high viscosity. See drugs supplier's data sheet for further details.
- MMAD = Mass Median Aerodynamic Diameter.

Mass Median Aerodynamic Diameter.	MMAD 3.6 μ m (Mass Median Aerodynamic Diameter)
The Bottle Capacity	MAX.8ml
Noise	<50db(Range of 1m)

Particle size distribution compliant with EN 13544-1

Reference

Rubow, K. L., Marple, V. A., Olin, J., and Mccawley, M. A., 1987, "A Personal Cascade Impactor: Design, Evaluation and Calibration", *Am. Ind. Hyg. Assoc. J.* (48): 532-538.

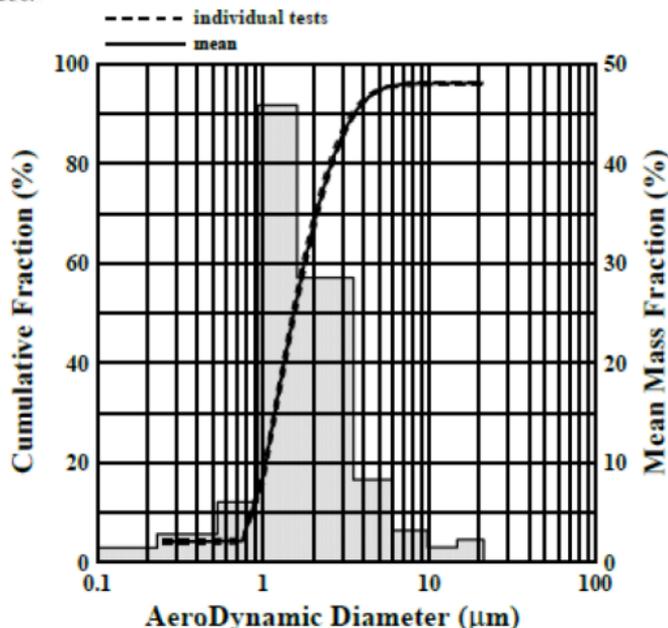
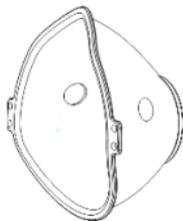


Figure 4 Plot of cumulative size distribution of results in table 3.

Accessories / Optional parts

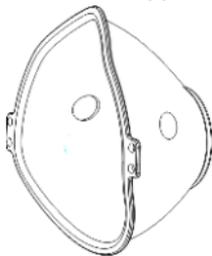
Accessories / Optional parts are shown below. If you wish to purchase any of them, please contact the retailer from which you purchased the nebulizer.

Inhalation mask (S)



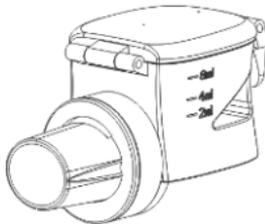
(For Children)

Inhalation mask (L)



(For Adult)

Medication chamber



Mouthpiece



Main unit cover



Carrying pouch



USB cable (optional)



Note:

The device complies with the FDA, CE, and TGA Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators.



Important / Caution / Note!
Read the instruction manuals.

**Classification:**

- Internally powered equipment
- BF type applied part
- IP22
- Not suitable for use in presence of flammable anesthetic mixture with oxygen or nitrous oxide.
- Continuous operation.



To avoid nebulizer's abnormal operation caused by electromagnetic interference between electrical and electronic equipment, do not use the device near a cell phone or microwave oven.



Discard the used product to the recycling collection point according to local regulations.



Wellkang Tech Consulting Suite B ,29 Harley Street, LONDON
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Reading Instruction Book before use



AC/DC Adapter



Manufacturer: Shenzhen Combei Technology Co., Ltd.,
11-5BNo.105, Huanguan South Road, Dahe Community, Guanlan,
Longhua New District, Shenzhen, 518110 Guangdong, China
manufacturer contact : Mr. Kevin Fong
email : kevin.fong@163.com TEL:+86-755-29588956 29408890
29408891 EXT:818,809

IMPORTANT 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 harmful interference in a residential installation. This equipment can generate, use and 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 harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Appendix A: EMC information

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Guidance and Manufacturer's declaration – electromagnetic emissions			
The device is 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.			
Emissions test	Compliance	Electromagnetic environment – guidance	
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF emissions CISPR 11	Class B	The device 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.	
Harmonic emissions IEC 61000-3-2	Class A		
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies		
Guidance and Manufacturer's declaration – electromagnetic immunity			
The device is 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 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	6kV contact 8 kV air	6kV contact 8 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	2kVfor power supply lines 1kVfor input/output lines	2kVfor power supply lines 1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.

Surge IEC 61000-4-5	1kV line(s) to line(s) 2kV line(s) to earth	1 kV line(s) to line(s) 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
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 40 % U_T (60 % dip in U_T) for 5 cycles	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible

	<p>70 % U_T (30 % dip in U_T) for 25 cycles</p> <p><5 % U_T (>95 % dip in U_T) for 5 sec</p>	<p>70 % U_T</p> <p>(30 % dip in U_T) for 25 cycles</p> <p><5 % U_T (>95 % dip in U_T) for 5 sec</p>	<p>power supply or a battery.</p>
<p>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</p>	<p>3 A/m</p>	<p>3 A/m</p>	<p>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</p>
<p>NOTE UT is the AC mains voltage prior to application of the test level.</p>			

Guidance and manufacturer's declaration – electromagnetic immunity – for device that is not LIFE-SUPPORTING.

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is 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 test level	Compliance level	Electromagnetic environment – guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2,5 GHz</p>	<p>3 Vrms</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> <p>$d = 1,2$ $d = 1,2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2,3 \sqrt{P}$ 800 MHz to 2,5 GHz</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div style="text-align: center;">  </div>
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> <p>Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.</p> <p>b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Recommended separation distances between portable and mobile RF communications equipment and the device – for device that is not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the device
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by

maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter		
	m		
	150 kHz to 80 MHz $d = 1,2$	80 MHz to 800 MHz $d = 1,2$	800 MHz to 2,5 GHz $d = 2,3$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

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

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

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

For any query Contact:- dr@drtrustusa.com