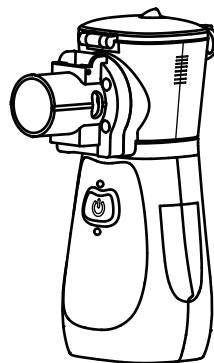




Instruction Manual

Mesh Nebulizer with Rechargeable Battery

NEB401



Rx Only

Manufactured for
Sunset Healthcare Solutions
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Chicago, IL 60601
www.sunsethcs.com

NEB401-IFU V1.00
2020-06-23

Indications for Use

The Mesh Nebulizer with Rechargeable Battery is designed to aerosolize liquid medications for inhalation by patient, the device may be used with pediatric (>4 years of age) and adult patients in the home, hospital and sub-acute care settings. It is not intended for use with Pentamidine.

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Chapter 1 Before you start

Thank you for purchasing the Mesh Nebulizer with Rechargeable Battery (Hereinafter referred to the nebulizer or the device). Before using the device for the first time, please read this Instruction Manual completely.

SAVE THESE INSTRUCTIONS

READ ALL CONTRAINDICATIONS, WARNINGS AND SAFETY PRECAUTIONS BEFORE USE, AND STRICTLY FOLLOW THEM WHEN USING THE NEB401 MESH NEBULIZER!

NOTE !

Before initial use please charge the nebulizer for minimum ONE hour so that the device can be activated.

1. What is the Mesh Nebulizer with Rechargeable Battery?

The Mesh Nebulizer with Rechargeable Battery is designed to aerosolize liquid medications for inhalation by patient. The device may be used with pediatric (>4 years of age) and adult patients in the home, hospital and sub-acute care settings. It is not intended for use with Pentamidine.

Package Contents

Upon opening Mesh Nebulizer package, you will find the following parts:

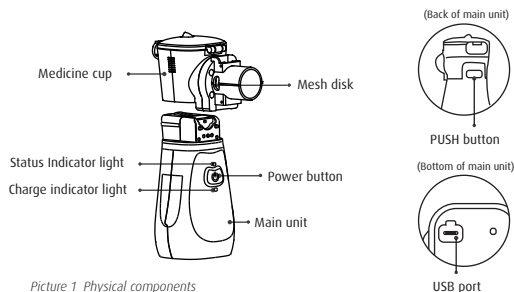
- ♦ Main Unit, Medicine Cup and Accessories (Mouthpiece and Masks)
- ♦ Instruction Manual
- ♦ Storage Bag and a USB charging cord.

2. Mesh Nebulizer Components

The Mesh Nebulizer with Rechargeable Battery consists of the Main Unit, Medicine Cup, and Accessories.

The Medicine Cup is used to hold prescribed liquid medications.

The Main Unit is used to supply power, and the Accessories consist of Mouthpiece and Masks, which are used to deliver the aerosolized medicine to your respiratory system.



Picture 1 Physical components

3. Getting to Know your Device

Main Unit	Provides power
Medicine Cup	Holds the prescribed liquid medication
Mesh Disk	Creates aerosol
PUSH Button	Detaches the medicine cup
Power Button	Turns the nebulizer on and off
Status Indicator Light	Green light indicates nebulizer is working regularly. Flashing blue light indicates battery is low. Flashing green light for 3 seconds indicates no medicine in the medicine cup.
Charge Indicator Light	Orange light on while charging. Green light on when charging is complete.
USB Port	Connects USB charging cord

Table 1 Components and functions

4. Indications for Use

The Mesh Nebulizer with Rechargeable Battery is designed to aerosolize liquid medications for inhalation by patient, the device may be used with pediatric (>4 years of age) and adult patients in the home, hospital and sub-acute care settings. It is not intended for use with Pentamidine.

Chapter 2 Important Safety Information



Important Safety Information - Read Before Use!

- 1) The device is only for single patient use!
- 2) The device cannot be used while charging!
- 3) Caution: Federal law restricts this device to sale by or on the order of a physician.



CONTRAINDICATIONS

- 1) The device cannot be applied to anaesthetic breathing systems.
- 2) Children must be under adult supervision while using.
- 3) Pentamidine is not applicable to the device.
- 4) The nebulizer shall not be used in any Magnetic Resonance environment.



WARNING – No modifications of this equipment are allowed

Warning: For type or dose of medicine please follow the instructions of your physician and/or licensed healthcare practitioner.

Warning: To prevent cross infection, the device is used only by single patient.

Warning: Do not dry the device or its accessories with an oven, microwave, hair dryer, etc.

Warning: Ensure that corrosive liquids or gases do not come in contact with the nebulizer and its accessories.

Warning: Do not disassemble, repair or change the device in case of leakage or other failures .

Warning: Please be careful about strangulation due to cables and hoses, particularly due to excessive length. Keep this device out of the reach of children.



WARNING – TO REDUCE THE RISK OF ELECTRIC SHOCK THAT MAY CAUSE SERIOUS INJURY OR DEATH:

Do NOT use or store the device in humid locations, such as a bathroom. Use the device within the operating temperature and humidity.

Do NOT operate the device or contact the adapter socket or power switch with wet hands.

Do NOT immerse the main unit in water or other liquid.



Never Open the Mesh Nebulizer !

Do NOT use the medicine with alcohol, oil, or suspended particles, including herbal medicine. Use only standard nebulizing medicine in accordance with your physician's advice.

Do NOT use the main unit around power lines.

Do NOT operate the device near a heating device or open fire.

Do NOT use the device before cleaning and disinfecting.

Do NOT use mouthpiece and masks if its package is broken.

Do NOT use the device if your hands are wet.

When using the nebulizer, the distance between the device with other wireless equipment should be at least 80cm.

Use the device only for its intended use and as described in its manual.



PRECAUTIONS-Take the following precautions to avoid minor or moderate injury and damage to your device:

Do NOT use this device if your skin is sensitive to mouthpiece and masks.

Do NOT repair the unit yourself.

If any emergency occurs, move the device away from your face, then shut it off and contact the local dealer.

Do not use the nebulizer with any Radio-frequency (RF) emitters, such as Radio-frequency identification (RFID), diathermy, or security systems. It may cause interference to the nebulizer, and the nebulizer's normal functions may be affected or the device may not operate properly.

Chapter 3 Safety Features of the Nebulizer

1. Additional considerations

This device is approved for human use only.

2. Protect your Mesh Nebulizer

- ◆ Please keep Main Unit and Medicine Cup clean (see Chapter 5) to avoid device malfunction.
- ◆ Keep medicine liquid and mesh in contact while using.
- ◆ Do not rinse or immerse the Main Unit in any liquid.

Chapter 4 How To Use the Nebulizer

The device is personal medical equipment. In order to prevent cross infection, the nebulizer should only be used by one person.

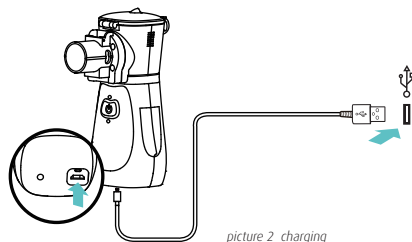
Please clean and disinfect the nebulizer before first and after use. Keep the nebulizer dry after finish using it. See Chapter 5 for more details.

NOTE !

Before initial use please charge the nebulizer for a minimum of ONE hour so that the device can be activated.

1. Power Supply

- ◆ This nebulizer is powered with a built-in lithium battery. The battery can be charged with the USB cord.
- ◆ To connect
 - (1) Connect small end of USB cord to the USB port on the bottom of the nebulizer.
 - (2) Connect large end of USB cord to a USB port such as a USB phone charger or USB port on a computer.

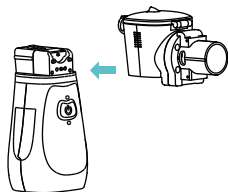


PRECAUTION:

1. Electrical Rating:
Input:100-240V AC 47-63Hz 0.4-0.2A
Output:5V DC 2.4A Max. Maximum length of USB cable: 52 inches (132cm)
2. The battery typically needs about 4 hours to charge.
3. **DO NOT USE THE NEBULIZER WHILE CHARGING. THE NEBULIZER CAN NOT OPERATE WHILE CHARGING. WE DO NOT TAKE RESPONSIBILITY FOR USING CHARGER OR ADAPTER INAPPROPRIATELY.**

2. Nebulizer Assembly

- (1) Please clean and disinfect nebulizer before first using and after each using, then dry it. See Chapter 5 for details.
- (2) Use one hand to hold the Main Unit, the other hand to hold the Medicine Cup. Push the cup along the slot ,until you hear a "Click" sound. (Picture 3)



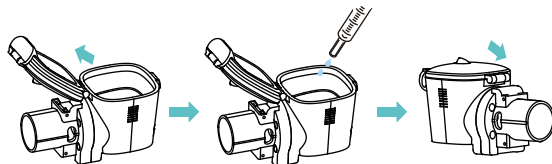
NOTE !

If the Medicine Cup isn't assembled in the right place, the device may not be able to operate normally.

Picture 3 Nebulizer Assembly

3. Add medication

- (1) Hold the Main Unit and open Medicine Cup clip;
- (2) Add medication into the Medicine Cup. Please note: Max volume is 8 ml.
- (3) Tighten the Medicine Cup cover.



Picture 4 Add Liquid Medicine

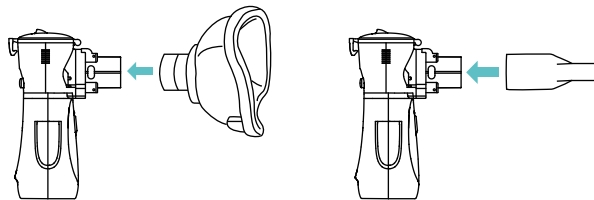
NOTE !

- (1) After putting medication in, avoid shaking your device, which may cause leakage of medication.
- (2) After charging, make sure you remove the power cable from the device before using.

4. Usage of Nebulizer

Nebulizer Accessories are categorized as mouthpiece, adult mask and child mask. Please choose appropriate accessories according to your needs.

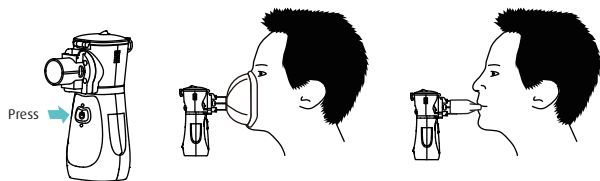
- (1) Attach mouthpiece or facemask as see in Picture 5.



Picture 5 Mask Assembly and Mouthpiece Assembly

- (3) Push the power button. The indicator light (Green Light) will light up and the device will start to work. Put the narrow end of the mouthpiece into the mouth, lips slightly closed.

Or, hold mask close to face, covering the nose and mouth.



Picture 6 start to aerosolize

(3) Sitting upright, calm, and relaxed, hold the nebulizer carefully. Take deep and slow breaths for a more effective, enjoyable treatment.

NOTE !

Foam is likely to be produced and accumulate near the mesh during operation, which may lead to a decrease of aerosol output and the nebulizer shutting down automatically. In this situation please shake the device slightly or stand the device for a while until the foam disappears and then restart the nebulizer manually.

CAUTION !

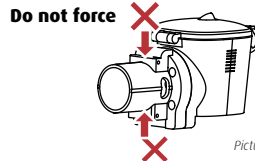
Children must be under adult supervision while nebulizing.

NOTE !

- (1) If this nebulizer is being used to treat a life threatening condition, a backup device is necessary.
- (2) The nebulizer may be unable to be used due to power failure or mechanical malfunction. In order to avoid emergencies such as accidents or acute asthma attacks, it is recommended to have a backup device.

NOTE !

- (1) Please use mouthpiece correctly by tightening, and make sure liquid medication does not go directly to the mouth.
- (2) Slightly tilt the Main Unit toward yourself to immerse the Vibrating Mesh in the medicine as the supply diminishes.
- (3) If the Low Battery Light (Blue) continues to flash slowly, it means the power is running out, please charge device as soon as possible.
- (4) The dosage of medication must follow physician's prescribed treatment.
- (5) Do not press the two single-way switches (inhalation switch and exhalation switch) on Medicine Cup, which may cause failure of the mesh technology.



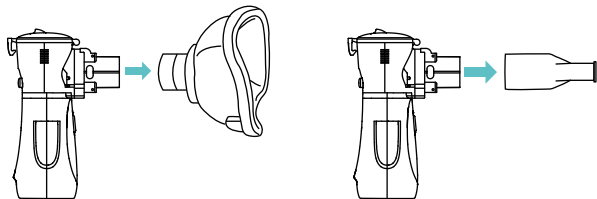
Picture 7

5. Turn Off Power

Press the Power button to turn off the power. The Power Indicator (Green Light) will go out.

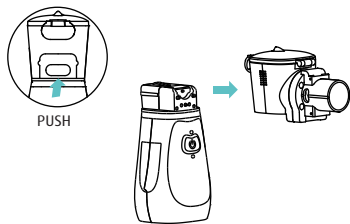
6. After Using

(1) Remove the mouthpiece or mask



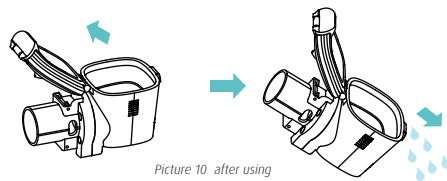
Picture 8 remove accessories

(2) To remove the Medicine Cup from the main device, press the button at the rear of the Device and push Medicine Cup forward.



Picture 9 disassemble the Medicine Cup

(3) Open the lid, pour out all the residual liquid, and promptly clean and disinfect the device, allow all the parts to air dry and store the device in a clean environment. See Chapter 5 for more information.



Picture 10 after using

Chapter 5 Maintenance of the Nebulizer

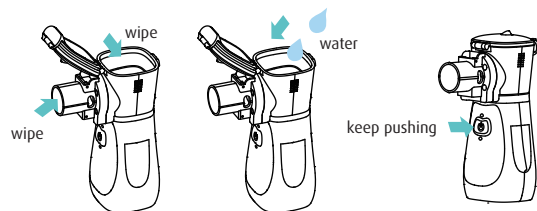
- ◆ Be sure to turn off the device.
- ◆ After each use, first discard all residual medicine, and remove the attachment from the Main Unit to clean and disinfect. Dry the parts immediately after washing.
- ◆ Do not store when Main Unit and Medicine Cup have any remaining liquid or moisture.

1. Cleaning

1. Medicine Cup

- 1.1 Take the Medicine Cup off the nebulizer, open the cover and pour out the residual liquid.
- 1.2 Add enough purified water (3-6ml) to the Medicine Cup and then close the cover tightly. Shake the cup gently to dissolve any residual medication with purified water.
- 1.3 Open the cover of Medicine Cup and pour out all the liquid.

- 1.4 Wipe the chambers of the Medicine Cup with a lint-free towel moistened with 70% ethyl alcohol at least 3 times and air dry; Then re-add purified water (3-6 ml).
- 1.5 Press and hold the Power button for 3 seconds WHILE THE DEVICE IS OFF, this will turn on the light and alternate between green and blue colors. Release the button allowing the device to enter into cleaning mode for 2 minutes. The purified water is "nebulized" to clear up any residual liquid on the mesh of the Medicine Cup.



Picture 11 cleaning

NOTE !

- (1) It is recommended to pour out any residual liquid after each use to prevent any mesh obstruction.
- (2) In order to prevent thermal deformation, boiling water is not allowed.
- (3) DO NOT wipe the Medicine Cup with cotton paper or other cloth. This may cause residual particles to block the mesh enclosure.
- (4) DO NOT touch mesh with fingers, swabs, or any objects to avoid damage.

2. Main Unit

- 2.1 After use, gently wipe the Main Unit and Electrodes (connecting the Main Unit and Medicine Cup) with a dry clean medical gauze to ensure an effective connectivity between them.
- 2.2 If there is still debris, clean the Main Unit and Electrodes with a medical gauze soaked with 70% ethyl alcohol, and wipe off the excess liquid to make the device work normally.

NOTE !

DO NOT wipe the device with volatile liquid (e.g. benzene, gasoline, diluent).
DO NOT touch the electrodes outside the device and the Medicine Cup with cotton swab or other things, which would damage the electrodes.
DO NOT immerse the main device in any liquid to avoid damage.



Picture 12

2. Disinfecting

1. Medicine Cup

After cleaning, Immerse the Medicine Cup by using the following high-level disinfection:

Disinfection Agent: Cidex OPA

Concentration: 0.55%

Contact Type: Soak

Time: 5 min

Temperature: 20 °C

Then rinse cup and dry with medical gauze.

NOTE !

- (1) To prevent disinfecting agent from touching skin, please wear rubber gloves.
- (2) Do not wipe the mesh with tissue paper or other cloth, otherwise the mesh will not nebulize normally.
- (3) Do not wipe or touch the mesh with your hands or any other sharp objects.
- (4) Do not use household bleach to clean the device.

3. Cleaning and Disinfecting of Mouthpiece and Masks

The masks and mouthpiece provided are disposable. If you plan to use masks and mouthpieces provided by other manufacturers, please follow the instructions for cleaning and disinfection provided by them.

4. Storage and transport

1. Storage and transport Conditions:

- (1) Temperature: -13°F — 158°F (-25°C — 70°C)
- (2) Relative Humidity: ≤90% R.H.
- (3) Air Pressure: 70.0 ~ 106.0 kPa;
- (4) Other requirements: No direct sunlight, Ventilation, No corrosive gas, No heating device, or Open fire.

2. Storage Instructions:

- (1) Keep the device out of the reach of unsupervised children.
- (2) Clean and disinfect the device after using. Assemble and store the device in the storage bag or in a clean environment.

(3) If the device has been stored at low or high temperature, the device needs more than half an hour to adjust, until it is ready for intended use.

Validity: When nebulizing 0.9% sodium chloride solution for 2 times a day, and 15 minutes for each time, 3 years for main unit, 3 months for Medicine Cup. For the battery, the device can be used for approximately 8 days after charging if operating for 30 minutes a day. Lithium battery has 300 charge-discharge cycle. Masks and mouthpiece are single use only, please do not use repeatedly.

5. Maintenance

1. Working Conditions

- (1) Environment Temperature: 41°F — 104°F (5°C — 40°C)
- (2) Relative Humidity: 15% ~ 90% R.H No condensation;
- (3) Air Pressure: 70.0 ~ 106.0 kPa;
- (4) Power: DC 3.7V lithium battery.

2. Maintenance Instructions

- (1) Operate the device in normal work condition;
- (2) Don't let the Nebulizer and its Accessories contact corrosive liquids or gases.
- (3) Refer to Chapter 7 for solution or contact the company or purchase dealer when the device cannot work.
- (4) Please clean and disinfect the nebulizer as stated in this Chapter.

6. To protect the environment

The battery is not replaceable. Do not discard the device, including its Accessories (mouthpiece and masks), in household trash. Follow local regulations to determine the proper method of disposal.

Chapter 6 Troubleshooting

PROBLEM	CAUSE	SOLUTION
Cannot turn on	<ol style="list-style-type: none"> 1. The battery is very low 2. The equipment is damaged 3. There are stains on metal contact points of nebulizer in contact with the Medicine Cup 	<ol style="list-style-type: none"> 1. Recharge the battery before use 2. Contact your place of purchase 3. Clean the metal contact points of nebulizer and try again
No mist	<ol style="list-style-type: none"> 1. The device and Medicine Cup are not correctly assembled. 2. The drug produces too much foam. 3. The mesh plate is clogging. 4. The equipment is damaged. 	<ol style="list-style-type: none"> 1. Correct the device by pressing back button, releasing, and introduce the Medicine Cup once again until you hear a "click". 2. Shake the device slightly or stand the device for a while until the foam disappears and then restart the nebulizer manually. 3. Clean the device by adding water to the Medicine Cup, press the power button for 3 seconds, then let the self-cleaning cycle run until complete. 4. Contact your place of purchase.
The device is on but weak	<ol style="list-style-type: none"> 1. Battery has low electricity. 2. The mesh plate is clogging. 3. The medicine is not fit for this nebulizer. 4. The mesh plate in the Medicine Cup is damaged. 5. The metal contacting point between Medicine Cup and main unit is not clean. 	<ol style="list-style-type: none"> 1. Recharge the battery before use 2. Clean the device by adding water to the Medicine Cup, press the power button for 3 seconds, then let the self-cleaning cycle run until complete. 3. The liquid medicine is unfit for this equipment, please consult a doctor. 4. Please contact the authorized service center or manufacturer 5. Clean the contact points before use

Table 2 Troubleshooting

PROBLEM	CAUSE	SOLUTION
Indicator light is blue	The battery is low.	Recharge battery before using.
Unsure which medicine is suitable for nebulization	Consult your doctor.	Only use under guidance of doctor's prescription.
Water buildup in mouthpiece obstructs mist	Condensation	Remove the mouthpiece and pour out all liquid.
Single patient use	It is necessary to avoid cross infection.	Everyone must use their Accessories only by themselves.
Liquid medicine in the Medicine Cup is leaking	Medicine Cup is broken or plastic is worn out.	Replace with new Medicine Cup.
Noise becomes louder towards end of nebulization cycle	The mesh plate vibrates without load while the liquid is running out.	Normal phenomenon.
Can not turn on/off the device	<ol style="list-style-type: none"> 1. The lithium battery has not been charged sufficiently. 2. The device gets stuck. 	<ol style="list-style-type: none"> 1. Recharge battery before using. 2. Press the reset button beside the USB interface on the bottom of the unit with a small pointed object.
The device can not turn off by itself when the drug is exhausted	<ol style="list-style-type: none"> 1. Some foam produced by drug is left in the cup. 2. Medicine Cup failure. 3. There is drug/water left or stains on the electrode. 	<ol style="list-style-type: none"> 1. Press the Power button and clear the bubble. 2. Please contact the authorized service center or manufacturer. 3. Press the Power button and clear the electrode.

* If you have already tried the above solutions and the device still cannot nebulize normally, we suggest you to contact your place of purchase.

Chapter 7 Customer Service

If mesh nebulizer is broken/damaged and needs repair or any other user assistance, please contact your place of purchase.

Warranty Information

One year for free warranty for Main Unit. Accessories as consumed products do not belong to warranty range.

The details as following are not included in warranty range:

- ◆ Damage caused by users dropping, touching or soaking the device.
- ◆ Damage caused by not following the correct operating instructions.
- ◆ Damaged by user's accident.
- ◆ Main unit has been disassembled.
- ◆ Product's Serial Number is torn or can't be recognized.
- ◆ No original invoice available.

NOTE !

Take warranty card "Users Page" to your place of purchase if the nebulizer needs to be repaired. Meanwhile please keep packing box in safe place so that it can be used for shipping in the event of repair or replacement.

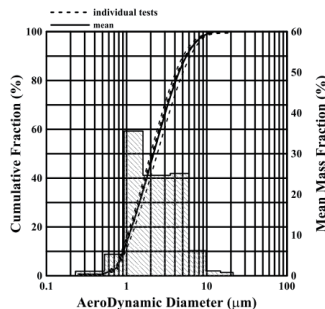
Chapter 8 Product Specifications

Name	Mesh Nebulizer with Rechargeable Battery
Model	NEB401
Dimensions	Approx. 50mm(L)×79mm(W)×111mm(H)
Weight	Approx. 106g
Switching power supply	Model: HPU15-102. Input: 100-240Va.c. 47-63Hz 0.4-0.2A Output: 5Vd.c. 2.4A Max.) It is considered as a part of equipment
Power Source	Input: 5Vd.c. 1.5A Min. ZN-103450 Lithium battery: 3.7Vd.c. 1800mAh
Safety Grade	BF, Internally powered equipment
Power Consumption	Approx. 6W
Vibration Frequency	Approx. 110KHz
Nebulization Rate	0.2ml/min minimum, adjust via App
Medicine Temperature	≤60°C
Working Voice	≤50dB
Particle Size	2.2μm±25%
Medicine Capacity	8ml maximum, 0.5ml minimum
Battery Life	the battery can be used for approximately 8 days after charging if operating the device for 30 minutes a day and the battery cycle life is 300 cycles.
Protected against the ingress of water and particulate matter	IP22

Table3 Product Specifications

Guarantee Time	Main Unit 1 Year (Medicine Cup is not included)
Operating Temperature	Environmental temp: 5°C~40°C, Relative humidity : 15~90% RH, not in Coagulation situation Air Pressure: (70.0~106.0)kPa
Storage and transport Temperature	Environmental temperature: -25°C~70°C Relative Humidity: ≤90%R.H. Air Pressure: (70.0~106.0)kPa
Accessory	Mouthpiece, adult Mask, child Mask, Adapter, Instruction Manual

Aerosol particle equivalent volume (Picture 13)



Picture 13 Aerosol Particle Equivalent Volume

NOTE !

(1) It was tested by Pulmicort under the condition of temperature $24 \pm 2^\circ\text{C}$, humidity 45-75%R.H, Pressure: from 86 kpa to 106 kpa.

(2) MMAD (μm): $2.2\mu\text{m} \pm 25\%$

Respirable fraction (% , 0.5-5 μm) : $\geq 80\%$

Aerosol output rate (ml/min) : 0.24 ± 0.02 ml/min

Chapter 9 Electromagnetic Compatibility

- ◆ Do not use the device in the direct vicinity of short-wave or microwave equipment.
- ◆ Do not connect this equipment to other equipment. Consult your physician for users wearing a heart pacemaker.

1. Electromagnetic Compatibility

The Mesh Nebulizer with Rechargeable Battery has been tested and found to comply with the limits for medical devices in IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

If other devices cause harmful interference to this device, the user is encouraged to try to correct the interference by one or more of the following measures:

- ◆ Reorient or relocate this device.
- ◆ Increase the separation between the interference equipment.
- ◆ Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- ◆ Consult the manufacturer for help.



Warning: 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.



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



Warning: 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 [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Table 4 Guidance and manufacturer's declaration-electromagnetic emissions

Item	Applied standard	Result
<i>Emission Measurement</i>		
Radiated emission	IEC 60601-1-2:2007 CISPR 11:2010	PASS
Conducted disturbance	IEC 60601-1-2:2007 CISPR 11:2010	Not applicable
Harmonic current emission (harmonic)	IEC 60601-1-2:2007 IEC 61000-3-2:2014	Not applicable
Voltage fluctuations & Flicker (Flicker)	IEC 60601-1-2:2007 IEC 61000-3-3:2013	Not applicable
<i>Immunity Measurement</i>		
Electrostatic discharge	IEC 60601-1-2:2007 IEC 61000-4-2:2008	PASS
RF field strength susceptibility	IEC 60601-1-2:2007 IEC 61000-4-3:2010	PASS
Electrical fast transients/burst test	IEC 60601-1-2:2007 IEC 61000-4-4:2012	Not applicable
Surges test	IEC 60601-1-2:2007 IEC 61000-4-5:2014	Not applicable
Conducted susceptibility test	IEC 60601-1-2:2007 IEC 61000-4-6:2013	Not applicable
Power-frequency magnetic field susceptibility test	IEC 60601-1-2:2007 IEC 61000-4-8:2009	PASS
Voltage dips and interruptions test	IEC 60601-1-2:2007 IEC 61000-4-11:2004	Not applicable

Guidance and manufacturer's declaration - electromagnetic emission - for all EQUIPMENT AND SYSTEMS

Guidance and manufacturer's declaration - electromagnetic emission		
<p>The Mesh Nebulizer with Rechargeable Battery is intended for use in the electromagnetic environment specified below.</p> <p>The customer or the user of the Mesh Nebulizer with Rechargeable Battery should assure that it is used in such an environment.</p>		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR11	Group 1	The Mesh Nebulizer with Rechargeable Battery 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 CISPR11	Class B	The Mesh Nebulizer with Rechargeable Battery 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	N/A	
Voltage fluctuations flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Mesh Nebulizer with Rechargeable Battery is intended for use in the electromagnetic environment specified below. The customer or the user of the Mesh Nebulizer with Rechargeable Battery should assure that it is used in such an environment.			
<i>Immunity test</i>	<i>IEC 60601 test level</i>	<i>Compliance level</i>	<i>Electromagnetic environment - guidance</i>
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 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 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode	N/A	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 EN 61000-4-11	0% UT; 0.5 cycle At 0°/45°/90°/135°/180°/225°/270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Mesh Nebulizer with Rechargeable Battery requires continued operation during power mains interruptions, it is recommended that the Mesh Nebulizer with Rechargeable Battery 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 should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a. c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Mesh Nebulizer with Rechargeable Battery is intended for use in the electromagnetic environment specified below. The customer or the user of the Mesh Nebulizer with Rechargeable Battery should assure that it is used in such an environment.			
<i>Immunity test</i>	<i>EN 60601 test level</i>	<i>Compliance level</i>	<i>Electromagnetic environment - guidance</i>
Conducted RF IEC 61000-4-6	3V rms 150kHz to 80MHz 6V in ISM bands between 0.15MHz and 80 MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the Mesh Nebulizer with Rechargeable Battery, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter Recommended separation distance \sqrt{P} $d = [3.5/V1]$

Immunity test	EN 60601 test level	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	10V/m 80MHz to 2.7GHz	10V/m 80MHz to 2.7GHz	$d = [3.5/E1] \sqrt{P}$ $d = [7/V1] \sqrt{P}$ <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 metres (m).b</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>
<p>NOTE1:At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE2:These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.</p> <p>a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cord-less) 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 Mesh Nebulizer with Rechargeable Battery is used exceeds the applicable RF compliance level above, The Mesh Nebulizer with Rechargeable Battery should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Mesh Nebulizer with Rechargeable Battery.</p> <p>b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.</p>			

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM -for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the Mesh Nebulizer with Rechargeable Battery			
The Mesh Nebulizer with Rechargeable Battery is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Mesh Nebulizer with Rechargeable Battery can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Mesh Nebulizer with Rechargeable Battery as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output of transmitter(W)	Separation distance according to frequency of transmitter(m)		
	150kHz to 80MHz $d = [3.5/V1] \sqrt{P}$	80MHz to 800MHz $d = [3.5/E1] \sqrt{P}$	80MHz to 2.7GHz $d = [7/V1] \sqrt{P}$
0.01	/	0.035	0.07
0.1	/	0.11	0.22
1	/	0.35	0.7
10	/	1.11	2.21
100	/	3.5	7
For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (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 manufacture			

NOTE1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

2. Notes on FCC certification

This device 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 device generates uses 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 device 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 for help.

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.

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

Chapter 10 Symbol Glossary

	Do not dispose in household trash		Serial number
	Read instructions		Date of manufacture
	BF type application part		Manufacturer
	Notice	IP22	Waterproofing Grade
	Non-ionizing radiation		MR Unsafe
	Item/model number		Single patient use
Rx only	Caution: Federal law restricts this device to sale by or on the order of a physician.		

Mesh Nebulizer with Rechargeable Battery
Service Warranty Card

Name		Product model	
Tel		Date of purchase	
Address		Sales shop name	
Zip code		Sales shop address	

Dealer info

WARNING – No modifications of this equipment are allowed

