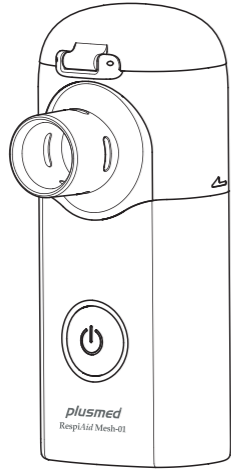


RespiAid Mesh-01

RespiAid Mesh-01

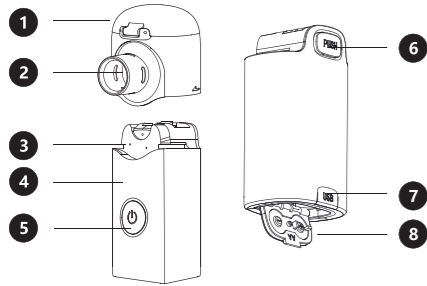
- TR Mesh Nebülizör Cihazı
- EN Mesh Nebulizer
- FR Nébuliseur à Tamis
- ES Nebulizador de Malla
- IT Nebulizzatore a Rete
- PT Nebulizador de Malha
- RU Сетчатый Небулайзер
- AR البخاخات الشبكية



Thank you very much for purchasing Plusmed Nebulizer.

Be sure to read this instruction Manual before using the unit for you to use it safely and correctly.

Name of the Parts



- 1 Medicine Cup Cover
- 6 Medicine Cup Button
- 2 Metal mesh
- 7 USB Cover
- 3 Electrode
- 8 Battery Cover
- 4 Main Unit
- 5 Power Button

Contents

- 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.
- 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.

■ Before Using the Unit

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■ Correct Use of the Unit

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How to Prepare the Power Source

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

How to use the USB Cable

Be noted that this USB Cable is a Micro USB and the designed output voltage is 5V

Connect the USB cable to the main Unit and power bank as shown in Figure



- Power bank is not included in the complete set of the product.

How to Insert Batteries

Be noted that rechargeable batteries can not be used in the Unit!

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



- 3 Close the Battery Cover.



Notes on Safety Be sure to read the notes on safety before using the unit

- The warning and the caution shown here are listed for you to use this product safely and correctly as well as to prevent the risk and the damage to you and others from happening.

⚠ Warning

For the type, dose and regimen of the medication, be sure to follow the instructions of a doctor.

- Your symptom(s) may worsen.
 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, Inhalation Mask and Mouthpiece. (Refer to Pages 8 to10)

- Miscellaneous bacteria may propagate and you may get infected.
 Clean and disinfect Medicine Cup, Inhalation Mask, and Mouthpiece after each use. (Refer to Pages 8 to10)

- 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.
 This unit is designed for personal use. It is not appropriate for more than one user.
 Keep the unit out of reach of children or infants.

- 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.
- 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.

⚠ Caution

Do not inhale by using water in the Medicine Cup.

- Your symptom(s) may worsen.
 Do not drop medication on the Main Unit. If you drop medication, immediately wipe it off with gauze.

- If you use the unit while it is wet, it may cause trouble or you may suffer electric shock.
- Do not poke Metal Mesh with a cotton swab or a pin.
- The unit may be broken and cannot be used.

- 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.
- Do not use the USB Cable other than the one supplied by Plusmed.
- Do not use a broken USB Cable.
- Do not disassemble, repair, or modify the unit.
- The unit may be broken and cannot be used.

How to Prepare the Power Source

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 backlight of the Power Button is red,batteries will be worn out soon.
 Replace both batteries with new ones.

General advice

- Do not insert batteries with the polarities (+ and -) in the wrong direction.
- 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.

How to Fill the Medication

- Open the Medicine Cup and fill the medication.

- 1 Open the Medicine Cup 2 Fill in the medication



Fill the medication as shown in the Figure.
 The maximum capacity of Medicine Cup is 8 ml.

- 3 Close the Medicine Cup cover tightly



Otherwise the medication may splash out during usages.

Product Introduction

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."
	Protection against ingress of water, it means the device could protected against vertical falling water drop 15°.
	Manufacturer
	This symbol indicates that the device includes IEC 60601-1 Type BF Applied Part.
	The symbol indicates that the device should be sent to the special agencies according to local regulations for separate collection after its useful life.
	Symbol for "THE OPERATION GUIDE MUST BE READ"; Indicates the need for the user to consult the instructions for use.
	Indicates the date when the medical device was manufactured.
	This symbol shall be accompanied by the manufacturer's serial number.
	Symbol for lot number; Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Indicates the Authorized representative in the European Community.
	Symbol for CE Mark. This symbol certifies that a product has met European Union consumer safety, health, or environmental requirements.

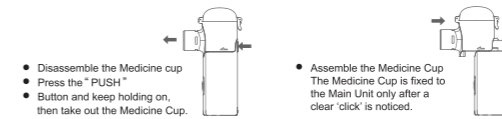
- This product is intended for the treatment of respiratory diseases such as asthma, allergies, etc.

- **Working principle:** thanks to the self-excited oscillation circuit,the ceramic sheets contained in nebulizing head together with the metal mesh are driven successively to oscillate at a high frequency,which makes the liquid flowing through the micromesh of the metal mesh and being ejected and nebulized to form an inhalant aerosol.

How to Fill the Medication

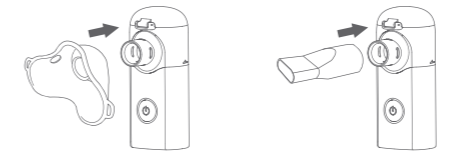
You can fill the medication in the assembled Unit directly or fill the medication in the Medication Cup separately.

When you fill the medication in the Medicine 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 tightly and assemble the Medicine Cup to the Main Unit.



- Disassemble the Medicine cup
 Press the " PUSH " Button and keep holding on, then take out the Medicine Cup.
- Assemble the Medicine Cup
 The Medicine Cup is fixed to the Main Unit only after a clear 'click' is noticed.

4 Install the Inhalation Mask or the Mouthpiece



How to install the Inhalation Mask

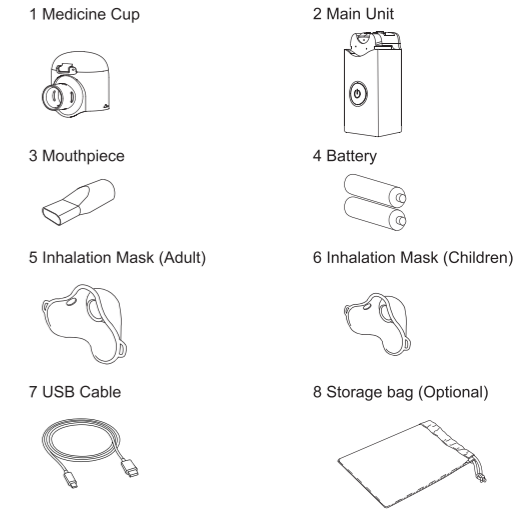
How to install the Mouthpiece

- 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.

Product Contents Please check the product

- The following items are contained in the box. If any item is missing, please contact the store where you purchased the product or the nearest Plusmed dealer.

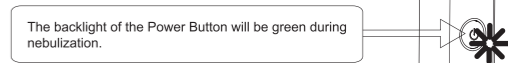


To start inhalation, you must assemble the unit.

- Please read Page 6, Page 7, Page 8 and understand the points for assembling before starting to use the unit.

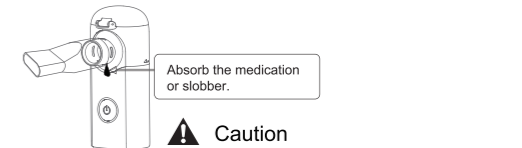
How to Inhale

- A** Hold the Main Unit with your hand and start inhalation



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

- 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.



⚠ Caution

- Do not poke the Metal Mesh with a cotton swab or a pin.
- The Metal Mesh will be damaged and can not be used

- 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.

- B** When you finish inhalation, push the Power Button to turn off the power

- When the USB Cable is used, unplug the USB Cable from the power bank. (Refer to Page 7)

How to Clean the Unit after Inhalation

A Be sure to clean and store the unit after inhalation.

A Remove the parts from the Main Unit

- Remove Inhalation Mask or Mouthpiece, and Medicine Cup from the Main Unit.



B Discard the remaining medication

- Open the Medicine Cup and discard the medication.



C Wash the parts sufficiently in water

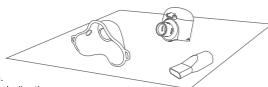
- Wash Inhalation Mask or Mouthpiece, Medicine Cup in water.



- Carefully rinse the Metal Mesh when using a medication having high surface activity or viscosity such as medication solubilizing agent or expectorant because the medication is often left on the Mesh.
- Do not to touch the metal mesh directly, otherwise, the metal mesh may be damaged and can not be used.

D Wash the parts sufficiently in water

- Immediately after washing the parts, wipe off water with new gauze and dry them thoroughly.



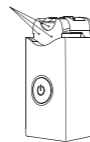
General advice
Never try to wipe off water with tissues or cloth.
Dust or lint left on the Metal Mesh may affect nebulization.

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How to Clean the Unit after Inhalation

E Wipe off the stain on the Main Unit

Keep the Electrodes clean and dry



F After assembling the unit, store it in a clean place

How to Disinfect

- The mouthpiece and inhalation mask contact user directly, please keep it clean!

Use 75% medical alcohol to scrub the mouthpiece and mask for more than 3 minutes, then dry the mouthpiece and mask and storage them in the clean area.



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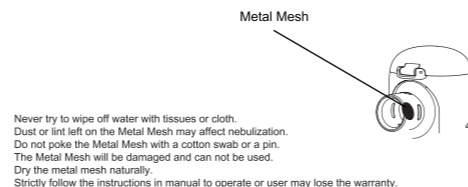
How to replace the Medicine Cup

- You can usually use a Medicine Cup for approximately 1 year (if it is used for 30 minutes a day).
- However, the unit may not nebulize even before using it for a year 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.



Medicine Cup is a consumable part

Cautions



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Troubleshooting

- If any trouble occurs while you are using the unit, please check the following first.

Trouble	Possible cause	How to correct
The nebulization rate is extremely low	The batteries are low/worn out.	Replace the batteries with new ones.(Refer to page 6)
	The Metal Mesh is stained.	Clean the Medicine Cup to remove the stain. (Refer to Page 11) If the trouble cannot be corrected by the above-mentioned procedure, replace the Medicine Cup with a new one.(Refer to Page 8)
The unit does not nebulize	The polarities (+ and -) of batteries are in the wrong direction.	Insert batteries in the correct alignment. (Refer to Page 6)
	The batteries are low.	Replace batteries with new ones.(Refer to Page 6)
	The USB Cable is not correctly connected.	Remove the USB Cable from the Main Unit and connect it correctly.(Refer to Page 6)
	The Medicine Cup is not installed correctly to the Main Unit.	Install the Medicine Cup correctly.(Refer to Page 8)
	The Metal Mesh is extremely stained.	Replace the Medicine Cup with a new one. (Refer to Page 12)
The backlight of Power Button works correctly but the unit does not nebulize	The Metal Mesh is broken.	Replace the Medicine Cup with a new one. (Refer to Page 12)
	Medication or water is collected on the Electrodes of the Main Unit.	Remove the medication or water.(Refer to Page 11)
	The Electrode of the Main Unit is stained.	Wipe off the stain. (Refer to Page 11)

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

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Specifications

Product Name	Plusmed Mesh Nebulizer
Model	RespiAid Mesh-01
Power Source	2 x1.5V AA alkaline batteries Micro USB (5V)
Power consumption	Approximately 2W
Nebulization Rate	≥ 0.20 ml / min
Particle Size	MMAD approximately 5 μm
Capacity of Medicine Cup	≤ 8 ml
Dimensions	46 (W)mm x 110 (H)mm x 60 (D)mm
Weight	Approximately 80 g (not including batteries)
Working Environment	Temperature: 10 to 40°C Humidity: 30 to 85% RH Atmospheric Pressure:86 kPa~106 kPa
Transport and Storage Environment	Temperature: -20 to 50°C Humidity: 30 to 85% RH Atmospheric Pressure:86 kPa~106 kPa
Pollution	Degree 2
Voltage Category	CATEGORY II
Altitude	≤ 2000 m

Specifications and appearance may be changed without prior notice for improvement.

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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.

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.

A1 Electromagnetic Emissions-For all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration-electromagnetic emission		
The " RespiAid Mesh-01" is intended for use in the electromagnetic environment specified below; The customer or the user of the " RespiAid Mesh-01" should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The " RespiAid Mesh-01" 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 " RespiAid Mesh-01" is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

A2 Electromagnetic Immunity -For Home Healthcare Environment EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
The " RespiAid Mesh-01" is intended for use in the electromagnetic environment specified below. The customer or the user of " RespiAid Mesh-01" 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 floor are covered with synthetic material, the relative humidity should be at least 30%.

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Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -guidance
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to ground	±1 kV line to line ±2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the " RespiAid Mesh-01" requires continued operation during power mains interruptions, it is recommended that the " RespiAid Mesh-01" be powered from an uninterruptible power supply or a battery.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation:
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	$E = \frac{6}{d} \sqrt{P}$ <p>Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.</p>

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Plusmed_IB_RespiAidMesh-01_VerA_00
Revision Date: 29/07/2022



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