

wellion® MESH-NEBULIZER

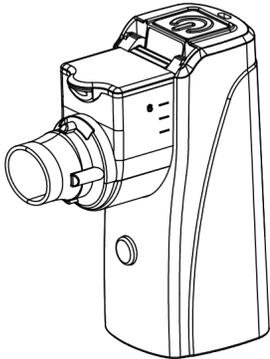
Introduction

Thank you for choosing the Wellion MESH-NEBULIZER. The Wellion MESH-NEBULIZER is a handheld device, designed to aerosolize medication for respiratory therapy purpose, which can be applied both at home or when travelling. This device can operate on an internal lithium titanate rechargeable battery. Due to this battery and the compact size, you are able to continue your treatment while you go on traveling. As this device is a medical device, please read the instruction manual before use. Be sure to follow the instructions of a health care professional and use the device correctly.

Product Features

- The aerosolization is achieved by microporous (Mesh) and oscillator technique.
- USB cable charging, easy to re-charge the battery.
- Compact design
- Palm size device - easy to carry
- Easy to operate
- Easy to clean & maintain

Intended Use: This device is designed to nebulize liquids into an aerosol for respiratory therapy purpose.
Intended User: Healthcare professionals, such as doctors, nurses, therapists or patients under the guidance of healthcare professionals. The user should also be capable of understanding general operation of this device and the content of the instruction manual.
Intended patients: This device design is suitable for all ages of patients, except patients who are unconscious, not breathing spontaneously or having pulmonary edema.
Recommended Operation Environment: This device is intended for use in a medical facility, such as a hospital, clinic and doctor's offices as well as in a private setting and water-protected open-air environment.
 Temperature range: 10 °C to 40 °C | Humidity: 30 to 85 % RH
Durability period: The durability period is as follows: The product is usually used to nebulize 0.9% Saline 2 times a day, 10 minutes each time at room temperature (23°C). Durability period may vary depending on environment and solution.
 Main unit: 36 months
 Medication cup: 12 months
Precautions for use: Warnings and cautions described in the manual must be observed.



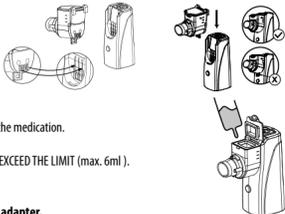
Pictures are for reference only.

Manual

Clean all parts of your portable mesh nebulizer before use, after each use and after a long-time storage.

1. Set up the medication cup

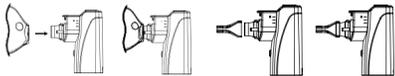
- Align the three contacts on the back of the medication cup with the three trenches of the main unit to insert the medication cup into the main unit.



2. Fill the medication

- Make sure that the indicator light is off before adding the medication.
- Open the medication cup cap.
- Fill the medication cup with medication DO NOT EXCEED THE LIMIT (max. 6ml).
- Close the medication cup cap properly.

3. Install the mask or the mouthpiece on the mask adapter.



The device is now ready for use. Refer to the next section how to inhale.

Caution: For type, dose and regime of medication, follow the instructions of your doctor or pharmacist.

1. Slightly tilt the mesh nebulizer as illustrated in the figure:

In this position, the vibrating element is immersed in the medication and nebulization will start after power on. In this position, the vibrating element has been immersed in the medication, the unit can be used under any angle. NOTE: In some positions (e.g. upright), nebulization may stop after a short while. In that case, briefly tilt the unit again in order to re-immers the vibrating element in the medication.

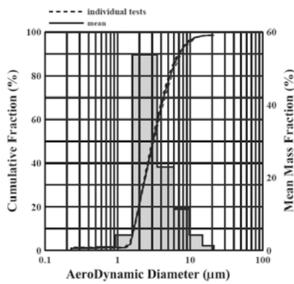


2. Place the mouthpiece in your mouth or place the mask over mouth and nose.

Technical Data

According to the Standard EN 13544-1:2007+A1:2009 „Respiratory therapy equipment - Part 1: Nebulizing systems and their components“, Annex CC.3 using the multistage cascade impactor method to measure the particle size.

Particle Size: MMAD 2.25±0.35µm (MMAD = Mass Median Aerodynamic Diameter)
 Medication Cup Capacity: 6 ml max
 Noise: Less than 50dB (1 meter distance)



In order to comply with the requirements for EMC with the aim to prevent unsafe product situations, the EN60601-1-2 standard has been applied. The nebulizer MESH-S600A meets the IEC 60601-1-2:2014, EN 60601-1-2:2015 standard for both immunity and emission. Nevertheless, do not use the nebulizer close to strong electrical or electromagnetic fields. This may result in incorrect operation and create a potential unsafe situation. Guidance and manufacturer's declaration-of mesh nebulizer

Safety Precautions

READ ALL WARNINGS AND INSTRUCTIONS BEFORE YOU USE THIS DEVICE.

As with any medical device, this product may become unusable due to an electrical outage, battery depletion, or mechanical failure. We recommend that you have a backup device available to you. When you use electrical products, always follow basic safety precautions. As with any electrical device take particular care around children.

WARNINGS

- Only use this device for medications prescribed by your doctor.
- The Wellion MESH-NEBULIZER is designed for respiratory therapy only. Any other usage of this device is improper and potentially dangerous. The manufacturer cannot be held liable for any damage caused by improper or incorrect use.
- Do not share your mesh nebulizer with others. It is intended to be used by a single user. If more than one person uses it, there is a risk of spreading infectious illness.
- Clean all parts of your nebulizer before use, after each use and after extended storage.
- Adult supervision is required when this device is used by children and individuals who require special assistance.
- Never operate this device if any of the parts are not working properly or have been damaged.
- Be sure the device has been properly cleaned before use to avoid possible contamination.
- Do not plug in or unplug the adapter from the electrical outlet with wet hands.
- Do not contaminate the main unit or the USB port with medication. If either area got into contact with medication, immediately wipe it off with gauze. If you use the device while it is still wet, it may cause damage or injury.
- Do not leave the device in a car where it could be exposed to significant heat or cold. The battery shall not be replaced, do not attempt to replace the battery by yourself because you may damage it. (could result in overheating or injury). NEVER incinerate the battery. NEVER immerse the battery in water, which would destroy the battery.
- The battery deteriorates over time if it is not used or charged. Do not store the device for a long period of time without charging it periodically. In case the device is not used or charged for a long period of time, the battery will be destroyed.
- Never use the device while it is charging.
- If you are not using the device for a long period of time, disconnect the USB charger.
- The device contains sensitive components, including a stainless-steel disk with carefully measured 3 ~ 5 micro holes. Do not drop, crush, puncture, bend, heat, incinerate or apply strong shock to the device or its parts.
- Do not wash the medication cup and mesh under running water or any other liquid.

CAUTIONS

- Do not attempt to clean the mesh with any foreign objects, as they may damage it. In case you dropped liquids on the main unit or the adapter, wipe it off immediately.
- Dropping the device could lead to malfunctions.
- Avoid exposure to direct sunlight or excessive heat or cold as this could damage the batteries.

2. After use the medication cup for 9 times:

Clean the medication cup with the approx. 60% acetic acid (descaling agent) after you used it for 9 times.

- Pour out the residual medication in the medication cup.
- Fill some distilled water into the medication cup.
- Pour out the distilled water in the medication cup.
- Fill the 3ml of the approx. 60% acetic acid (descaler) into the medication cup.
- Turn on the device to nebulizer the 60% acetic acid for 5 to 10 minutes to clean the mesh.
- Disconnect the adapter and remove the medication cup from the main unit.
- Wash and rinse the medication cup with distilled water.
- Shake off excessive water and allow parts to fully air dry on a clean place.
- Use gauze or a clean towel to wipe off the main unit if necessary.
- Make sure that the medication cup and other cleaned parts are completely dry before you store them or use them next time.

- Keep the battery compartment dry all the time.
- Do NOT poke the mesh with your finger, cotton swab or any objects.
- Do NOT clean parts in a dishwasher.
- Do NOT use microwave to dry any parts.
- Do not wash the medication cup and mesh under running water or any other liquid.

Daily disinfection

It is important to disinfect the medication cup on a daily basis.

- Disinfection by boiled water**
 - Rinse the medication cup with distilled water.
 - Bring a saucepan of DISTILLED water to a boil.
 - NOTE: Do NOT boil the medication cup directly**
 - Carefully immerse the medication cup in the boiled water for a maximum 15 minutes.
 - Carefully remove the medication cup from the boiled water and shake off excess water.
 - Allow parts cooling down and fully air dry on a clean, dry towel, out of the reach of children.
 - Make sure that all cleaned parts are completely dry before you store them or use them next time.
- Disinfection by alcohol**
 - Rinse the medication cup with distilled water.
 - Immerse the medication cup in 75% ethyl alcohol for 1 minute.
 - Rinse the medication cup with distilled water again, shake off excess water and allow parts to fully air dry on a clean, dry towel.
 - Make sure that all cleaned parts are completely dry before you store them or use them next time.

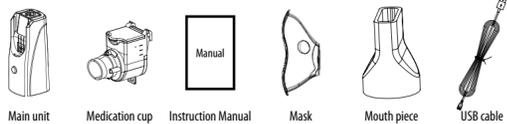
Alcohol is highly flammable. Do not use alcohol in close vicinity of open fire or smoke.

- Do not attempt to open, repair or modify this device.
- Do not drop any liquids on the main unit or on the adapter. If you drop liquids on them, wipe them off immediately.
- Follow local laws and recycling plans regarding disposal or recycling of components, batteries and packaging.
- If the USB wall charger and USB port do not join with reasonable ease, they probably do not match. Make sure that you are using the USB wall charger provided and that you have positioned it correctly.

Package Contents

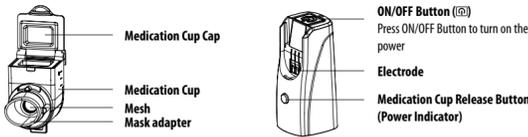
Check before use

The following items are included in the package:



Please check all parts for visible damage. Replace any damaged parts before you use this device. In case of missing parts, malfunction or damage, please contact the store where you purchased the product from or the nearest dealer.

System Overview



Blue light: during operation
Orange light blinking: low power, please charge the battery
Orange light: when charging the battery
Charge light: blue light when battery is fully charged

The following items are able to be disinfected by boiled water or alcohol: Medication cup

Parts below are NOT able to be disinfected by boiled water or alcohol: USB cable, Main unit

Do NOT rinse or immerse the main unit in any liquid.

Carrying and Storing

Put on the mouthpiece cover, store the device and the medication cup in a dry and clean environment.

- Do NOT leave or carry the device containing residual liquid in the medication cup.
- Do NOT leave the device under direct sunlight, in high humidity, extreme heat or cold environment.
- Keep this device away from fire, high electromagnetic fields and out of the reach of children.

Troubleshooting

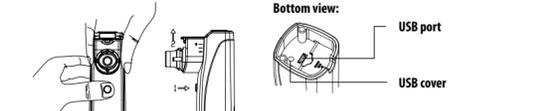
If any trouble occurs while you are using the device please check the following list first:

Problem	Possible Cause	Action
	Batteries are low (orange light).	Please charge the battery.
	The stains on the electrode cause a fault connection.	Use rubbing alcohol to clean the electrodes.
Low atomization	The mesh holes have been clogged or stained.	Refer to description of cleaning and disinfection procedure to clean the medication cup.
	The mesh is broken.	Replace the medication cup
After turning on the power: the power indicator is not on and no mist comes out.	Batteries are too low	Please charge the battery
	Faulty connection between adapter and main unit	Check and reconnect the USB charger to the main unit.
After turning on the power, the power indicator is on but no atomization takes place.	The medication cup is not installed properly.	Refer to Set up the medication cup procedure to re-install the medication cup.
	The mesh holes have been clogged or stained.	Refer to Cleaning and Disinfection procedure to clean the medication cup.
	The mesh is broken.	Replace the medication cup.
Power indicator turns into orange light.	Low battery power	Please charge the battery.

Guidance and manufacturer's declaration-electromagnetic emissions			
The mesh nebulizer is intended for use in the electromagnetic environment specified below. The customer or the user of the mesh nebulizer should assure that it is used in such an environment.			
Emission test	Compliance	Electromagnetic environment-guidance	
RF emissions CISPR 11	Group 1	The mesh nebulizer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF emissions CISPR 11	Class B	The mesh nebulizer is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.	
Harmonic emissions IEC 61000-3-2	Class A		
Voltage fluctuations/flicker Emissions IEC 61000-3-3	Compliance		
Guidance and manufacturer's declaration-electromagnetic immunity			
The mesh nebulizer is developed for use in the electromagnetic environment specified below. The customer or the user of the mesh nebulizer should guarantee 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	± 6 kV contact ± 8 kV air	± 6 kV 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	± 2kV for power supply lines ± 1kV for input/output lines	± 2kV for power supply lines not applicable	Main 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	± 1kV differential mode Not applicable	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11.	<5% UT(>95% dip in UT) for 0.5 cycle 40% UT(60% dip in UT) for 5 cycles 70% UT(30% dip in UT) for 25 cycles <5% UT(>95% dip in UT) for 5 s	<5% UT(>95% dip in UT) for 0.5 cycle 40% UT(60% dip in UT) for 5 cycles 70% UT(30% dip in UT) for 25 cycles <5% UT(>95% dip in UT) for 5 s	Main power quality should be that of a typical commercial or hospital environment. If the user of the mesh nebulizer requires continued operation during power mains interruptions, it is recommended that the mesh nebulizer be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	The mesh nebulizer power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration-electromagnetic immunity			
The mesh nebulizer is developed for use in the electromagnetic environment specified below.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3 Vms 150 KHz to 80 MHz	3 Vms	Portable and mobile RF communications equipment should be used no closer to any part of the mesh nebulizer including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d = 1.2 √P d = 1.2 √P 80MHz to 800 MHz d = 2.3 √P 800MHz to 2.5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Where P is the maximum output power rating of the transmitter in Watt (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ¹ , should be less than the compliance level in each frequency range ¹ . Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1: At 80 MHz and 800 MHz, 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.			
a. 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 mesh nebulizer is used exceeds the applicable RF compliance level above, the mesh nebulizer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the mesh nebulizer.			
b. Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distance between portable and mobile RF communications equipment and the mesh nebulizer.			
Rated maximum output power of transmitter	Separation distance according to frequency of transmitter m		
W	150 kHz to 80 MHz d = 1.2 √P	d = 1.2 √P	d = 1.2 √P
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 Watt (W) according to the transmitter manufacturer. NOTE 1: at 80 MHz and 800MHz, 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.			



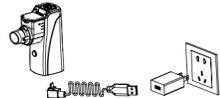
Press Release Button to remove the medication cup.

How to operate with battery

About the battery: The device has an internal lithium titanate rechargeable battery that you cannot replace, also NEVER use the device when it is charging. The device is charged through a USB port, just as many cell phones and portable electronic media devices are charged. You can only charge the battery by connecting to a wall outlet using the USB wall charger provided. NOTE: The USB charger is an optional accessory, only use an external charger that fulfills the requirements of IEC 60601-1:2012, output 5.0v 1~2A.

Charging the battery with a wall outlet:

- Open the USB cover to reveal the USB port.
- Gently insert the USB cable's cord into the USB port.
- Gently insert the USB cable's cord into the USB wall charger port.
- Insert the USB wall charger into a wall outlet.



Battery condition indicator:

When the device is not connected to a power source the ON-OFF indicator light has three different colors/conditions:
 No light: OFF
 Blue light: during operation
 Orange light blinking: battery is low

If the device is connected to a power source, the ON-OFF indicator light has two possible states:
 Orange light blinking: battery is charging
 Blue light blinking: battery is fully charged

NOTE: Rechargeable batteries do not have unlimited life, the battery life and number of charge cycles vary according to use.

- If the device does not nebulize normally after taking the above-mentioned procedures, please contact the store where you purchased the device or the nearest dealer.
- Never operate this device if any of the parts are not working properly or have been damaged.

Specifications

Model:	MESH-S600A
Product:	Mesh Nebulizer
Method of operation:	Active Vibrating Mesh Technology
Power supply:	Lithium titanate battery (DC 4.8V rechargeable)
Power consumption:	Approx. 2.0W
Auto off:	After 10 min.
Light indications:	Blue light: During operation
	Orange light blinking: battery is low
	Orange light blinking: battery is charging
	Blue light blinking: battery is fully charged
Vibrating frequency:	Approx. 107 kHz +/- 10%
Nebulization rate:	0.33±0.04 ml/min
Respirable Fraction 0.5-5µm:	88.08±1.91%
MMAD:	2.25±0.35µm
Capacity of medication cup:	Max 6ml
Noise level:	<40dBA (1 meter distance)
Battery charging voltage and current:	5.0V 2A max.
Battery charging time:	Approx. 90 minutes
Battery non-stop usage time:	Approx. 100 minutes
Lithium titanate battery life cycle:	Life cycle: 0.5C approx.7000 times, 1C approx. 4000 times
Dimension:	Approx. L77 X W40 X H92mm
Weight:	Approx.107g
Operating temperature and humidity:	10 ~40°C, 30 ~ 85 % RH, 800~1060hPa
Storage and transport condition:	-20~ 60°C, 20 ~ 75 % RH, 800~1060hPa
Safety level:	Type B Class II

Classification and Explanation of Symbols

	Warning / Caution / Note	IP22	Protected against foreign objects equal to or greater than 12.5mm in diameter and against drops of water falling at up to 15° from vertical
	Class II equipment per IEC 60601-1		Disposal of Electrical & Electronic Equipment (WEEE): Do not treat this product as household waste.
	Type B equipment per IEC 60601-1		This device complies with the requirements of the Medical Devices Directive 93/42/EEC.
	Consult instructions for use		Authorized Representative in the European Community
	Batch code		Operating temperature limits: 10°C to 40°C
	Medical device		Storage and transport temperature limits: -20°C to 60°C
	Keep dry		Operating humidity limits: 30 to 85% R.H
	Manufacturer		Storage and transport humidity limits: 20 to 75% R.H
	Date of manufacture		

WEEE (Directive on Wasted Electrical and Electronic Equipment)

This marking shown on the product indicates that it should not be disposed of with other household waste at the end of its working life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate this from other types of waste and recycle it responsibly to promote the sustainable reuse of material resources. Household users should contact either the retailer where they purchased this product, or their local government office, for details of where and how they can take this equipment for safe recycling.

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