



> *POCKET*

Mesh Nebulizer

Quiet and Comfortable

INSTRUCTION MANUAL



Read this instruction manual
carefully before use.



MODEL

GM-380

Table of Contents

1. Intended Use	1
2. Contraindications	1
3. Important Safety Notes	2
4. Working Principle	2
5. Contents and Overview.....	3
6. Technical Parameters	4
7. Installation and User Instructions	7
8. Cleaning and Disinfection	9
9. Storage and Maintenance	9
10. Troubleshooting.....	10
11. Note & Warning.....	11
12. EMC Declarations	15
13. Signs and Symbols.....	20
14. After-sales Service.....	21
15. Configuration List	22
16. Disclaimer Clause	22

1. Intended Use

1.1. Intended purpose

Getwell Mesh Nebulizer GM-380 converts liquid medication into a fine mist for easy inhalation, allowing efficient delivery of medication in consistent particle size. This device provides treatment for patients with obstructive airway diseases such as: asthma, chronic obstructive pulmonary disease (COPD) and other pulmonary diseases. This device is not intended for life support nor they provide any patient monitoring capabilities.

1.2. Intended user

Intended for use by trained personnel. Users should read this instruction manual and understand the general operation before using this device.

1.3. Intended patient population

It is suitable for adults and children (≥ 3 years older) who require atomization therapy through mask or mouthpiece.

1.4. Intended environment

Intended for use in a medical facility, hospital clinics, homecare setting, indoor or outdoor environment.

1.5. Intended medical condition

Obstructive airway diseases (OADs), such as asthma, chronic obstructive pulmonary disease (COPD), and other pulmonary disorders.

1.6. Intended clinical benefits

The advantages associated with the use of portable mesh nebulizer is that it does not require patient coordination between inhalation and breathing, thus making it relatively easier for pediatric, geriatric, and ventilated patients.

2. Contraindications

- (1) Patient is allergic to aerosolized drugs
- (2) Pentamidine powder
- (3) Anesthetics agent

3. Important Safety Notes

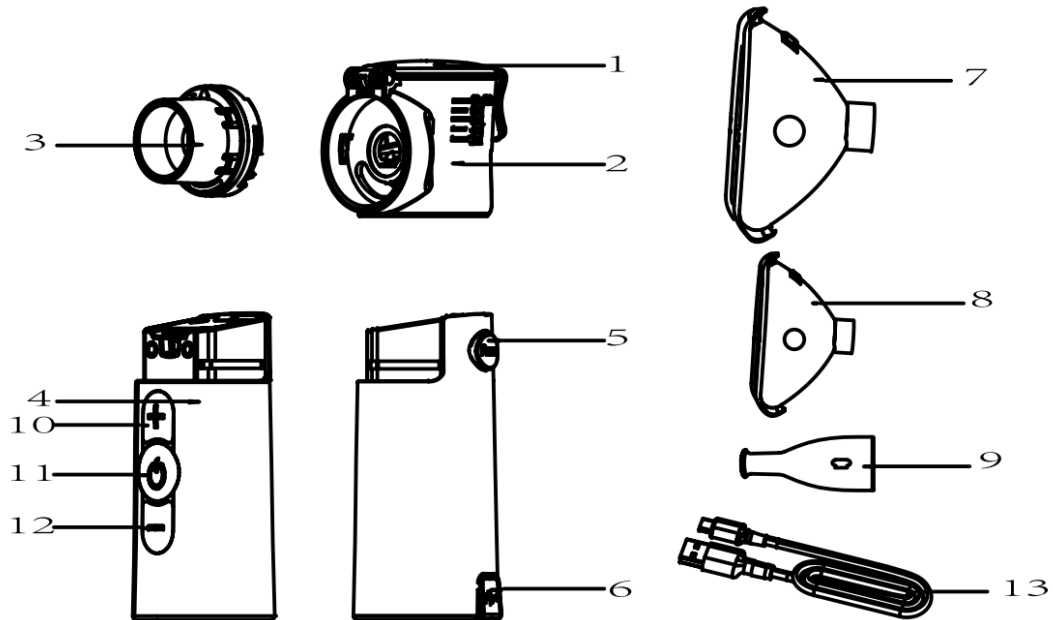
- | Before use, ensure that there is no visible damage to the device or accessories. In case of any doubt, do not use the device and contact your retailer or the local distributor.
- | Do not use health products or medication containing essential oils for nebulization.
- | Follow your doctor's instructions regarding the type of medication, the dosage, the frequency and the duration of inhalation. Only use liquid medications prescribed and recommended by your doctor or pharmacist.
- | The use of this product for children and persons with special needs must be carried out under correct guidance and supervision.
- | This unit is only used for nebulization. Do not use this device for any other purposes.
- | Clean and disinfect the medication cup and accessories before using or if the device is not used for quite a while
- | Please stop using the device if the components are damaged or if accidentally dropped in the water
- | It is crucial to keep the device away from the eyes during use. Nebulized medication, when directed at the eyes, can cause irritation, dryness, or potentially worsen existing conditions like glaucoma or cataracts.
- | Keep packaging material away from children (risk of suffocation).
- | Do not use any additional parts that are not recommended by the manufacturer.
- | If any serious incident that has occurred upon using this device, please report to your local distributor,

4. Working Principle

The working principle of the atomizer is driven by the rapid oscillation of the circuit, the piezoelectric ceramic creates harmonic oscillation, thus promote microporous mesh rapid oscillation, so tiny mesh on the mesh and solution was rejected by the rapid, forming numerous tiny atomized particles, the inhalation mask or mouthpiece to patients with respiratory system, to achieve the goal of inhalation therapy. The respiratory system is an open system, after the drug liquid is atomized into particles, the patient inhales the drug mist, the drug mist can be directly adsorbed and deposited in the patient's trachea, bronchus, alveoli and other places, through the mucosal tissue absorption to achieve the purpose of treatment.

5. Package Contents and Overview

This device is composed of the Main Unit, Medication Cup, Nebulization Module and accessories, etc.



1	Medication cover	8	Mask(child)
2	Medication Cup	9	Mouthpiece
3	Nebulization Module	10	Increase nebulization rate
4	Main Unit	11	Stand-by
5	"Press" Button	12	Decrease nebulization rate
6	Charging Interface	13	Type-C Cable
7	Mask(adult)		

Figure 1 Product Contents

6. Product Technical Parameters

Product name	Portable Mesh Nebulizer
Model	GM-380
Power source	DC3.7V rechargeable Li-ion batteries/DC 5V,1A adapter which meets IEC 60601-1 and 2MOPP.
Power consumption	<4.0 W
Nebulization rate	0.15mL/min - 0.90mL/min
MMAD	< 5 μ m
Medication cup capacity	10mL
Vibration frequency	130kHz,Deviation \pm 10%
Weight	90g(with battery)
Dimension(mm)	64mm(L) \times 39mm(W) \times 108mm(H)
Working environment	Temperature: +5 $^{\circ}$ C ~ +40 $^{\circ}$ C Relative Humidity: 15%~80% R.H.Non-condensing Atmospheric Pressure: 86kPa ~ 106kPa
Storage/delivery environment	Temperature: -20 $^{\circ}$ C ~ +55 $^{\circ}$ C Relative Humidity: 10% ~ 93% R.H.Non-condensing Atmospheric Pressure: 70kPa ~ 106kPa
Auto-off period	Power on, operate 10mins, then auto-off
Mode of operation	Continuous operation
Classification of installation and use, Applied part classified	Hand-held The classified of applied part is BF.
The maximum A-weighted sound pressure level	\leq 50 dB (A-weighted)

Note:

- 1) According to the type of anti-shock classification: Internally powered (ME) equipment.
- 2) Enclosures classified according to the degree of protection against ingress of water and particulate matter as per IEC 60529:IP22
- 3) Sterilize method: EO sterilization (only for mask).
- 4) The equipment is not intended for use in an oxygen rich environment and in presence of flammable anesthetic mixtures with air, oxygen or nitrous oxide.
- 5) Higher than 70% of the Initial Capacities of the Cells, Carries out >2000 cycles
Charge: 1.0C to 2.8V, Discharge: 1.0 C to 1.6 V, Temperature: $25 \pm 3^\circ\text{C}$.

★ Performance disclosure

The particle size and the aerosol output, aerosol output rate is measured according to the provisions of the EN ISO 27427:2023, Annex C (using breathing simulator) and D (using the multistage cascade impactor) separately.

The nebulization rate is measured with saline 0.9% solution at a temperature of $24 \pm 2^\circ\text{C}$ and a humidity of 45-75%. It may vary with medication and ambient conditions.

The test solution is albuterol 0.1 % (M/V) concentration in 0.9 % sodium chloride solution. Test conditions of the temperature is $24 \pm 2^\circ\text{C}$ and the humidity is 45-75%. And the plot of cumulative size distribution of the results as follows.

Aerodynamic Particle Size Distribution

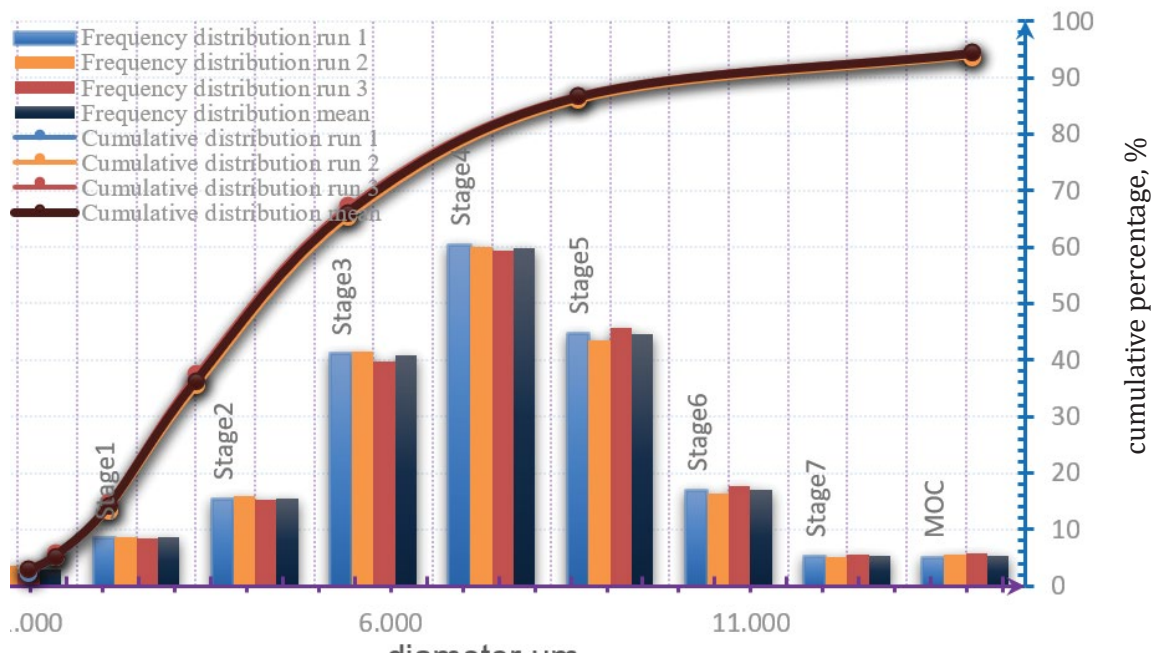


Figure 1 Technical Parameters

Note:

- 1) The particle size distribution and aerosol output may vary by combination of product, medication and ambient conditions such as temperature, humidity and atmospheric pressure.
- 2) Using a solution, suspension, or emulsion different from that recommended by the manufacturer, in particular, a suspension and/or high-viscosity solution, can alter the particle size distribution curve, the mass median aerodynamic diameter (MMAD), aerosol output, and/or aerosol output rate, which can then be different from those disclosed by the manufacturer. See drug supplier's data sheet for further details.
- 3) The effect that the following disclosures for nebulizer performance are based upon testing that utilizes adult ventilatory patterns and are likely to be different from those stated for paediatric or infant populations.
- 4) Essential performance: particle size and the aerosol output, aerosol output rate.
- 5) The proportion of mist particles with a diameter of 1 µm to 5 µm generated by the nebulizer is >50%.

7. Installation and User Instructions

7.1. Power Supply

This device has a Type-C cable for charging. It does not come with a power adapter. Please use an AC adapter (output: DC 5.0V 1.0A) approved by IEC 60601-1 for charging. It supports charging while working (as shown in Figure 2 below).

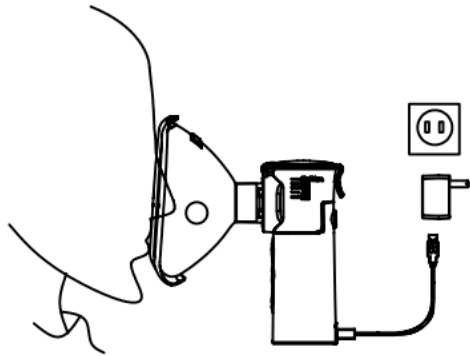


Figure 2

It shall be disconnected from the power source after use.

When you need to start the equipment room, please power it through a Type-C cable, and then it will be able to enter the standby state (as shown in Figure 3 below).

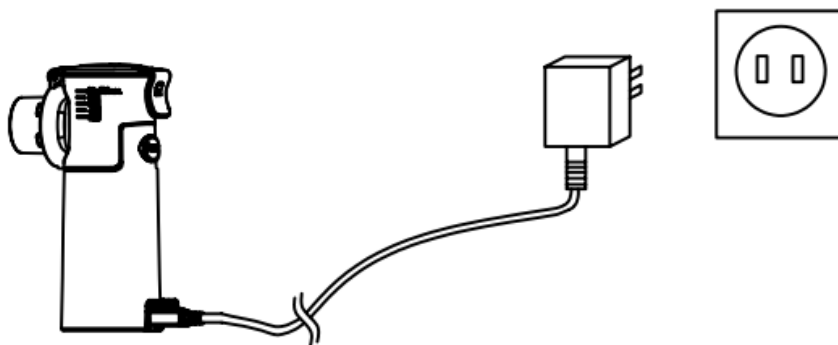


Figure 3 Power Supply Connection

 **Warning:**

- 1) At the end of expect service life, please dispose this device and accessories according to the local environmental regulation, do not dispose together with the domestic refuse to avoid environment pollution.
- 2) Please use the power adapter (DC 5.0V, 1A) which meets IEC 60601-1 to power this device.
- 3) Do not modify this equipment without authorization of the manufacturer.
- 4) Do not disassemble or repair this device without permission, and do not disassemble or replace the battery without permission.If you need to replace the battery, please consult the manufacturer.

 **Caution:**

- 1) When the battery capacity is insufficient,please powered by Type-C cable.
- 2) Keep charging the device at least once per month during the storage period exceed one month.
- 3) The device can work when charging.
- 4) The main unit is powered by secondary lithium batteries which comply with IEC 62133-2.

7.2. Use Instructions Step

Step 1: Add liquid to the medication cup

Open the medication cover and add medicine (at least 2mL, less than 8mL).

Note:

- 1) Cleaning and disinfecting the appearance that user could touched, the shell of the Main Unit,medication cup when use.
- 2) Follow the doctor's advice to inject medication.
- 3) After injecting the medication, please be careful to overflow.

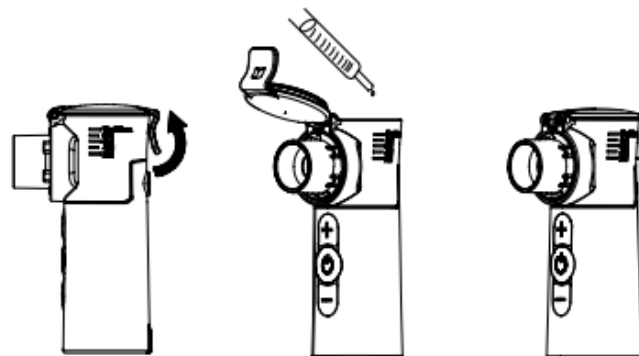
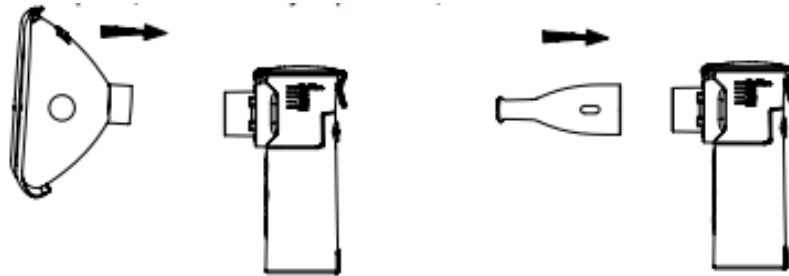


Figure 4 Filling Procedure

Step 2: Nebulization

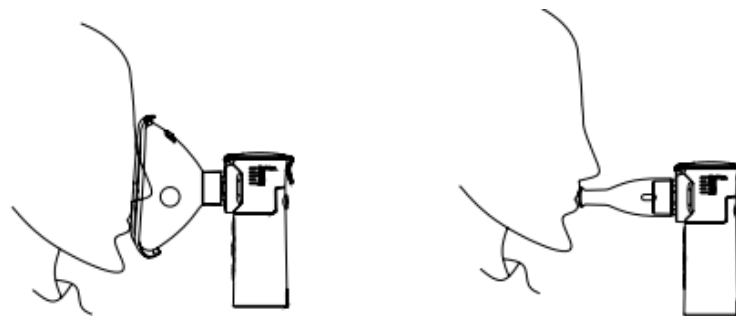
1) Connect mask or mouthpiece, click Stand-by to power on, start nebulization.

Operation mode



2) It starts with a middle nebulizer rate, and it can be adjusted by pressing "+" & "-" as needed.

3) Hold the nebulizer to keep medication contact with the vibrating mesh, using the following two ways of inhalation according to individual needs.



a. Connect mask

b. Connect mouthpiece

Figure 5 Two Ways of Inhalation

4) When finishing nebulization, press Stand-by to power off. Pour out the residual liquid from the medication cup.

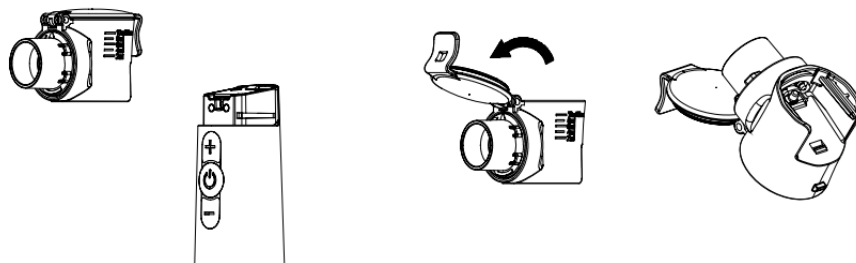


Figure 6 Pouring Out the Residual Liquid Medication

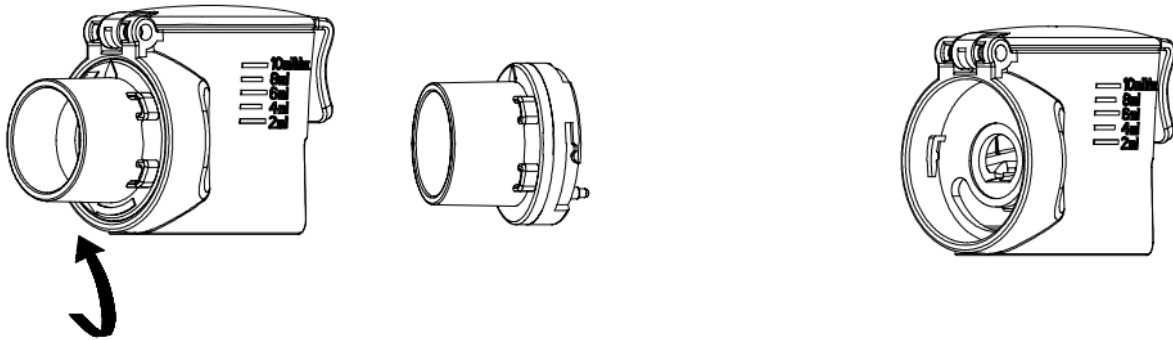


Figure 7 Take out the Nebulization module

7) Use clear water to clean the medication cup, then disinfect.

⚠ Caution:

- 1) When installing the medication cup, do not tilt, make sure the whole medication cup is well pressed.
- 2) Keep the device as vertical as possible during the operation, no shaking during nebulization.
- 3) Holding your breath for a short while, can enhance the effectiveness of nebulization therapy. Sit down and keep calm and relax, do not inhale too fast during the treatment process.
- 4) Replace the mask, mouthpiece if the inhalation method is changed. Please clean the medication cup after using. (see "Cleaning and disinfecting" chapter)
- 5) Mesh disc will be congealed by medication liquid which will infect nebulization rate. We suggest stopping nebulization and remove mouthpiece or mask, use clean medical gauze to clean the residue.
- 6) Any question in process of nebulizing, please contact manufacturer or authorized EU representative.
- 7) The default working mode on startup is middle rate.

7.3. Indicator light

Green light keeps on	Work by internal batteries or adapter
Green light flashes 10 times	10 minutes set time
Orange light flashes 10 times	No liquid, shut-down
Blue light flashes 5 times	Low-power, shut-down
Blue light keeps flashing	Charging
Blue light keeps on	Full Charged

8. Cleaning and Disinfection

1. Disassemble the parts by removing the mouthpiece or mask, the medication cup, and the mesh cap from the main unit.
 2. Rinse all removed parts thoroughly with a clean water (except for the nebulizer unit).
 3. Allow all parts to air dry completely in a clean, dry place or dry with a clean medical gauze or cloth.
 4. Clean the exterior of the nebulizer unit with a damp cloth, never immerse the compressor or the tubing in the water.
 5. Do not wipe the mesh caps, just let it air dry.
 6. Store all parts of the nebulizer and the main unit in a clean and dry place.
- Keep out of reach of children.

9. Storage and Maintenance

- 1) The storage and transportation conditions of the products are detailed in the Product Technical Parameters section.
- 2) Keep the device out of the reach of unsupervised infants and children. As the small parts of this device may be swallowed by them.
- 3) Keep the device away from pets and do not allow to be exposed to rodents and pests.
- 4) Dry the parts immediately after cleaning and disinfection. Store the device and the accessories in an environment that meets the requirements, be careful to avoid collisions.
- 5) Direct sunlight, lint, dust may cause rusting and oxidation to the vibrating mesh which could decrease the nebulization rate.
- 6) Make sure to unplug the power plug before storage.
- 7) Wipe out any residual liquid.
- 8) Wipe to dry the main unit with a soft cloth.
- 9) Unplug the power plug if not in use.
- 10) It should be stored in a place with no corrosive gas and good ventilation, please avoid severe shock during transportation.
- 11) Do not use benzene, diluents and flammable chemicals to clean the product.

10. Troubleshooting

Item	Problem	Possible cause/solution
1	Pressing on the power button but not working	<ul style="list-style-type: none"> • Check if there is enough power. • Check if there is enough medication. • Check if the button is functioning well. • Clear any clogged medication in the vibrating mesh and restart the power.
2	Low nebulization rate	<ul style="list-style-type: none"> • Check if the medication cup been filled with right medication, water-soluble and non-corrosive. • Check if the medication cup been filled with right volume. • Tilt the device, so that the medication can contact with the vibrating mesh. • Place the medication cup correctly and restart the device. • Clean the medication cup and the vibrating mesh . If it still cannot be used after cleaning, please check whether the vibrating mesh is broken or not • Clear the clogged medication in the vibrating mesh and restart the power.
3	After power on, it turned off immediately.	<ul style="list-style-type: none"> • Re-assemble the medication cup correctly and restart the power. • Tilt main Unit, so that the medication can contact with the vibrating mesh. • Clear the clogged medication in the vibrating mesh and restart power.
4	The mesh is clogged with medication.	<ul style="list-style-type: none"> • Take off the medicine cup. wash with warm water and air dry.
5	Leaks on the medication cup assembly.	<ul style="list-style-type: none"> • Re-assemble the medication cup correctly. • Contact your local distributor.
6	Residual liquid medication in the medication cup.	<ul style="list-style-type: none"> • It is a normal phenomenon. Clean the medication cup after every using.
7	Can not charge.	<ul style="list-style-type: none"> • Make sure the Type-C cable,the adapter are connected well. • Contact your local manufacturer.

11. Note & Warning

11.1 Note and suggestion

1.This is a medical device please read the user manual before using it.
2.Please use required accessories, warranty service is not provided any damage caused by accessories beyond the manufacturer's recommendation.
3.Use a non-conforming adapter may cause a device damage.
4.Please refer to the user manual for any problem, or contact the after-sales service unit for maintenance.
5.Please clean and disinfect the medication cup for first time use. You can refer to the clean and disinfect chapter.
6.This device is for medication nebulization, not for humidification, please avoid using distilled water, it may cause lower nebulization rate.
7.Please keep the medication cup empty and dry before storage.
8.Please assure all the accessories are assembled correctly before using.
9.Please use the accessory individually to avoid cross-infection.
10.Keep the device in a vertical position during usage.
11. Don't use the unit under inflammable gas environment or near a heating device or open flame.
12.Don't use the device near any high-frequency products or electronic devices.
13. Do not use a microwave oven, or any type of oven, blow dryer or other house applications to dry the nebulizer and the accessories.
14.Technical description is included in this user manual.
15.This device should only be used by a user who understands the operation of this manual. Children should used under adult supervision.
16.Refer to the storage condition of this device.

17. If the device is taken out from +55°C, it should be put in a room temperature for 2 hours before use.
18. The charging interface is only used for power supply and cannot be connected to other devices.
19. Pediatric patients should be guided by an individual, knowledgeable with the device operation.
20. This device and all its accessories cannot be serviced/maintained while in use.
21. Refer to the cleaning and disinfection section for any concern on this matter.
22. Performance information provided in this user manual in accordance with EN ISO 27427:2023 may not be applied with liquid medication supplied in high viscosity form. In such cases, information should be sought from the drug supplier.
23. The highest rated operating altitude: 1300m
24. The nebulizer device and the accessories (mask and mouthpiece) meet the requirements of ISO 18562-2, ISO 18562-3, ISO 18562-4
25. Any serious incident occurred in relation to the usage of this device should be reported to the local distributor.
26. The materials used in the components could not be compatible with some solutions/suspensions/emulsions that have not been evaluated. The liquid medication that have been evaluated are as follows: ambroxol hydrochloride solution for inhalation and salbutamol sulfate solution for inhalation
27. Check the power-on status after assembling the parts.
28. Please use or purchase original parts or accessories and recommended consumables

11.2.  Warning

<p>1.Please stop using this device if you feel all of a sudden dizzy and uncomfortable during the process of nebulization.</p>
<p>2.Volatile oil suspensions are not allowed, may cause damage to mesh</p>
<p>3.Water-soluble medication and saline dilution medications are allowed, for they may cause Bronchospasm.</p>
<p>4.Please do not use medications containing esters, oils or suspended particles, including herbal extracts. It is recommended to use the standard atomizing liquid agent type according to the doctor's instructions.</p>
<p>5.Do not service and maintain when the nebulizer is in use.</p>
<p>6.Don't modify the equipment without authorization of the manufacturer. Otherwise, it may cause damage to the main unit or harm to the user.</p>
<p>7.Replacement of lithium batteries or fuel cells may pose significant health and safety risk.</p>
<p>8. Suggested to be used individually by one patient only.</p>
<p>9.Do not use mobile (cellular) telephones and other devices(such as MRI, diathermy, electrocautery, RFID and electromagnetic security systems) which generate strong electrical or electromagnetic fields, near the device.</p>
<p>10.Contact your local manufacturer if you have any concern with the set up and the device's functionality.</p>
<p>11.Waste disposal: discard the main unit and the accessories according to local laws and regulations.</p>
<p>12.The Type-C cable should be kept away from children or out of the reach of children to avoid strangulation.</p>
<p>13.Contact your local distributor if changes were observed to this device.</p>

14. Small parts of this device could be swallowed by infants or children.
15. This device is not intended to supply heat to the patient
16. The nebulizing system is not suitable for use with the anesthetic breathing system or a ventilator breathing system
17. Use only the solutions recommended by the manufacturer.
18. The accessible materials used in the nebulizer are safe for common normal people. For very few operators with extreme skin sensitivity, if any skin discomfort occurs during the use of the nebulizer, please immediately stop using and seek medical advice.
19. Do not use the mask or the mouthpiece on multiple patients. (Single Patient Use Only).

12. EMC Declarations

1. This device meets the requirement of electromagnetic compatibility in IEC 60601-1-2.
2. The user needs to use this device according to electromagnetic compatibility
3. Portable and mobile RF communication device and some household appliances, such as mobile, interphone, microwave oven, blow dryer, may influence the performance of this device, keep the device away from these electronic devices during use.
4. Guidance and manufacturer's declarations are stated in this appendix.

1. The increased number of electronic devices such as PC's and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. 2. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation. 3. Medical devices should also not interfere with other devices. 4. In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the IEC 60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices.

Note:

The EMISSION characteristics of this equipment make it suitable for use in a residential environment (for which CISPR 11 class B is normally required).

 **Warning:**

1.The use of accessories and cables other than those specified by Getwell with the exception of cables sold by Getwell as replacement parts for internal components, may result in increased emission or decreased immunity of the device.

2.The medical devices should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, the medical device should be observed to verify normal operation in the configuration in which it will be used.

3.PORTABLE RF communications equipment(including peripherals as such as antenna cables and external antennas) should be used not closer than 30cm(12 inches)to any part of [ME EQUIPMENT or ME SYSTEM], including cables specified by the MANUFACTURER. Otherwise, it may result into degradation of the performance of thi device.

4.Do not use mobile (cellular) telephones and other devices, which generate strong electrical or electromagnetic fields, near this medical device. This may result ir incorrect operation of the unit and may create a potentially unsafe situation Recommendation is to keep a minimum distance of 7 m. Verify correct operation of the device in case the distance is shorter.

Details of cable:

Name	Type	Length(m)	Cable Shielded
Type-C Cable	Type-C	1.0	UnShielded

Guidance and Manufacturer's declaration – electromagnetic emission		
The devices are intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that they are used in such an environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The device use 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 device are suitable for use in all establishments,including domestic establishments and those directly connected to the public's low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emission IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emission IEC 61000-3-3	Complies	

Guidance & Declaration – electromagnetic immunity

The devices are intended for use in an electromagnetic environment specified below. The customer or the user of the devices should assure that it is used in such an environment.

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for Input/output lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1kV, ±2kV line to ground	±0.5 kV, ±1 kV line to line	Mains power quality should be that of a typical commercial or hospital environment.



















<p>Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11.</p>	<p><5 % <i>UT</i> (>95% dip in <i>UT</i>) for 0.5 cycle <5 % <i>UT</i> (>95% dip in <i>UT</i>) for 1 cycle 70% <i>UT</i> (30% dip in <i>UT</i>) for 25/30 cycles <5% <i>UT</i> (>95 % dip in <i>UT</i>) for 5 sec</p>	<p><5 % <i>UT</i> (>95% dip in <i>UT</i>) for 0.5 cycle <5 % <i>UT</i> (>95% dip in <i>UT</i>) for 1 cycle 70% <i>UT</i> (30% dip in <i>UT</i>) for 25/30 cycles <5% <i>UT</i> (>95 % dip in <i>UT</i>) for 5 sec</p>	<p>Mains power quality should be that of a typical commercial or hospital environment. If the user of the device require continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.</p>
<p>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</p>	<p>30 A/m</p>	<p>30 A/m</p>	<p>Power frequency magnetic fields/Proximity magnetic fields</p>
<p>Proximity magnetic fields</p>	<p>CW 8A/m for 30kHz Pulse modulation 2.1kHz,65A/m for 134.2kHz Pluse modulation 50kHz,7.5A/m for 13.56MHz</p>	<p>CW 8A/m for 30kHz Pulse modulation 2.1kHz,65A/m for 134.2kHz Pulse modulation 50khz,7.5A/m for 13.56MHz</p>	<p>should be at levels characterized of a typical location in a typical commercial or hospital environment.</p>
<p>NOTE <i>UT</i> is the a.c. mains voltage prior to application of the test level.</p>			

Guidance & Declaration – electromagnetic immunity

The device are intended for use in an electromagnetic environment specified below.
The customer or the user of the device should assure that they are used in such an environment.

<p>Conducted RF IEC 61000-4-6</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>6 Vrms in ISM and amateur radio bands</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>6 Vrms in ISM and amateur radio bands</p>	<p>Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used not closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.</p> <p>If higher IMMUNITY TEST LEVELS than those specified in Table 9 are used, the minimum separation distance may be lowered.</p>
<p>Radiated RF IEC 61000-4-3</p>	<p>3 & 10 V/m 80 MHz to 2.7 GHz</p> <p>385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014+A1:2020)</p>	<p>3 & 10 V/m 80 MHz to 2.7 GHz</p> <p>385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014+A1:2020)</p>	<p>Minimum separation distance for higher IMMUNITY TEST LEVELS shall be calculated using the following equation:</p> $E = [6/d] \times \sqrt{P}$ <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>

13. Signs and Symbols

General symbol	Description / title	General symbol	Description / title
	Date of manufacture		General warning sign
	Manufacturer information		Refer to instructions for use
	Authorised representative in the european community		Keep dry
	Caution		This way up
	Temperature limit		Batch code
	Type BF applied part		Humidity limitation
	Keep away from sunlight		Atmospheric pressure limitation
RoHS	This device complies with the requirements of the RoHS Directive 2011/65/EU and the RoHS Standards IEC 62321-1:2013.		When this device life expires,the end users should discard this device according to the requirements from the local environment protection authority.
	Medical device	IP22	Degree of protection against the ingress of water.
	Stand-by	CE_{xxxx}	Notified body
	EO sterile		

14. After-sales Service

Changes or modifications not expressly approved by the responsible party could void the user's warranty right to the equipment.

1.The period of Main Unit free for service maintenance is 1 year. Medication cup is 6 months. Other components are not covered by warranty. Any repairs out from the scope of the service warranty will be charged accordingly.

2.Please contact our after-sales service department to obtain warranty service.

Warranty conditions:

To obtain the warranty service, please present this warranty card and fill out the related content.

The warranty shall not apply:

- a. Failure or damage caused by improper use.
- b. Failure or damage caused by the dismantling or removal of parts done by an unauthorized personnel.
- c. Failure or damage caused by accidental falling, pressing, dropping, immersion etc.

If needed, we will provide circuit diagrams and component part lists to assist to user in parts repair.

The Company reserves the right of final interpretation of the warranty card, which may be subject to change without prior Notice.

15. Configuration List

Item	Model	Quantity	If Included	
			Yes	No
Main unit(including medication cup)	GM-380	1	☐	☐
Medication cup	MAiri	1	Optional	
Nebulization Module	MDAiriP	1	Optional	
Mask(adult)	L1	1	☐	☐
Mask(child)	S1	1	☐	☐
Mouthpiece	M1	1	☐	☐
Instruction for use	N/A	1	☐	☐
Silicone protective cover	N/A	1	☐	☐
Velvet bag	N/A	1	☐	☐
Mesh warning hangtag	N/A	1	☐	☐
Warranty card	N/A	1	☐	☐
User guidance	N/A	1	☐	☐
Type-C cable	UTC-021	1	☐	☐

16. Disclaimer Clause

Please read the user manual before using this device. We will not take any responsibility in case of damage caused by improper use of this device.

Please use or purchase original parts or accessories. The manufacturer does not take responsibility for the buyer or third parties for any damage or loss intentionally or unintentionally caused by improper use.

On the request for warranty service, please present your warranty card filled with purchase date and seal (with the store name and the address) Any repair service out of the scope of warranty will be charged accordingly.

✧ Getwell®



Inmed Corporation

5 Calle Industria, Bagumbayan,
Quezon City 1110, Philippines
Tel: 02.8571.1888
www.inmed.com.ph



4 806031 502225