

YM-3R* Series Portable Mesh Nebulizer User's Manual



Models: YM-3R9, YM-3R6, YM-3R901,
YM-3R902, YM-3R903, YM-3R601,
YM-3R602,

Doc No: IMDK/RD-CE-YM3RX-01-18

Version No.: V1.2

Issue Date: 2020.06.24

Software version number: V1.0

Modify date: 2021.05.12

Contents

Foreword.....	1
Chaper 1 Safty Guides and Symbols	2
Chaper 2 Product Introduction.....	7
Chaper 3 Installation of Nebulizer.....	13
Chaper 4 Fill the medication	17
Chaper 5 Operating the Nebulizer.....	18
Chaper 6 Replace the medicine cup.....	19
Chaper 7 Power Supply.....	20
Chaper 8 Cleaning and Disinfection.....	22
Chaper 9 Product Specifications.....	23
Chaper 10 Product characteristics.....	27
Chaper 11 Solving Problems.....	29
Chaper12 EMC Declaration	31
Annex I Warranty Card.....	34
Manufacturer Information.....	35

Foreword

0.1 Copyright

©Shenzhen IMDK Medical Technology Co.,Ltd . All rights reserved.

0.2 Note

Copyright, no part of this manual may be photocopied, copied or translated into another language without the prior written consent of IMDK.

0.3 Manufacturer's responsibility

IMDK is responsible for the safety, reliability and performance of the instrument only if:

Assembly operations, expansion, firstly modification, and repair are performed by personnel approved by IMDK, and the electrical installation of the relevant site complies with relevant standards. The instrument is used in accordance with the instruction manual. At the request of the user, IMDK provides technical documentation or schematics to the company's accredited service engineers to maintain and repair the machine.

0.4 Warranty

This instrument cannot be repaired by the user. All repairs should be performed by a company-approved technician. The warranty for this unit is for all instrument failures caused by failure of the material device or production process. All defective parts can be repaired and replaced free of charge during the warranty period. Man-made damage is not covered by the warranty.

Chapter 1 Safety Guides and Symbols

1.1 General Safety

This instrument is an internal power supply device, and the degree of protection against electric shock is bf type. Carefully inspect the nebulizer (hereafter referred to as the instrument) and accessories to ensure that the host and accessories have no visible impairments that affect patient safety and instrument performance. It is recommended to check before each use.

Please pay attention to warnings, CAUTIONS and CAUTIONS to avoid possible injuries.

note:

a. Please read this instruction carefully before use and operate according to it.

b. Please keep this instruction manual in a safe place for future reference.

c. This product is for personal use. Do not use the same nebulizer by many people.

In order to allow you to use this product safely and correctly, please read the instructions carefully before use.

1.2 Warning

⚠ Warning: Follow the doctor's instructions, the type, dosage and method of use of the drug;

⚠ Warning: Do not put the liquid specified by the doctor into the vial;

⚠ Warning: This product is for personal use. Do not use the same instrument by many people;

⚠ Warning: If you purchase the nebulizer for the first time or do not use the instrument for a long time, be sure to clean the relevant parts of the instrument before use;

⚠ Warning: After each use, the medicine cup, the medicine cup cover, mask, and the mouthpiece must be cleaned with pure water. Then, immediately dry the cleaned parts ;

⚠ Warning: The first use of the mask connecting tube and the suction mask must be washed with pure water and dried before use. These parts are single-use parts, please do not use them after washing;

⚠ Warning: The repair of this product is repaired by Shenzhen IMDK Medical Technology Co.,Ltd. or an authorized qualified engineer. If the user needs any service/maintenance information, please contact the company by contact number;

⚠ Warning: This instrument is equipped with USB cable. If the power adapter is connected, the power adapter must meet the requirements of IEC60601-1 IEC60601-1-11;

⚠ Warning: When using, do not connect devices other than those specified in the manual.

⚠ Warning: Parts and materials that can be removed without using accessories other than those specified in the instruction manual.

⚠ Warning: Do not modify this device.

⚠ Warning: Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

⚠ 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 Nebulizer(YM-3R9,YM3R6,YM-3R901,YM-3R902,YM-3R903,YM-3-6 -R601,YM-3R602), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

If any: a list of all cables and maximum lengths of cables (if applicable),transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY).ACCESSORIES may be specified either generically (e.g. shielded cable, load impedance) or specifically (e.g.by MANUFACTURER and EQUIPMENT OR TYPE REFERENCE).

If any: the performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES (the defined term "ESSENTIAL PERFORMANCE" need not be used). In order to avoid possible injury, please use it within the validity period of the instrument. The service life of this instrument is 3 years, and the production date can be found on the instrument label.Always follow the instructions when operating the instrument.

⚠ CAUTION: Do not strike the instrument severely to prevent damage or damage to the instrument and affect normal use.

⚠ CAUTION: Do not touch the spray bottle of the vial with a cotton swab or other items as this may result in the possibility of being unusable.

⚠ CAUTION: Every time you use the instrument, you need to clear the instrument, otherwise the possibility that the nebulizer will not work may be caused.

⚠ CAUTION: If you find that the drug has been used up and the nebulizer cannot be turned off automatically, immediately press the switch to shut down to avoid rupture of the spray net.

⚠ CAUTION: Water is not suitable for cleaning the instrument and distilled water is required.

⚠ CAUTION: Do not immerse the instrument and the appropriate power source in water.

⚠ CAUTION: Do not drop the micro-network ultrasonic nebulizer.

⚠ CAUTION: When liquid is contained in the cup, do not tilt it to prevent liquid from leaking out.

⚠ CAUTION: Do not leave the device in an area accessible to infants, children, or mentally ill patients after use.

⚠ CAUTION: Children or mentally ill patients should be used under the supervision of an adult.


















⚠ CAUTION: When the disposable battery is not in use for more than 1 week, remove the battery.

⚠ CAUTION: This instrument is disposed of in accordance with local regulations upon return to the manufacturer for recycling after an effective life.

⚠ CAUTION: Dispose of used batteries, mouthpiece, masks, and mask connection tube, etc. according to local environmental requirements.Waste machines and accessories also need to be disposed of in accordance with local laws and regulations.

⚠ CAUTION: After the nebulizer is used, be careful not to expose it to direct sunlight or pay attention to dust, etc., so as to avoid accelerated aging and dust accumulation, which will eventually affect the spray volume and speed.

1.3 Symbol

symbol	Explanation
	BF type Application Part
	Reference manual
	Caution
	Separate Collection
	Avoid rain
	Switch
IP22	Waterproofing Grade
	CE Mark
	Serial Number
	Date of manufacture
	Manufacturer
	See the Instruction
	European Union Representative
	Environment-friendly Use period
	Do not reuse
	Non Sterile
	Medical devices do not contain "DEHP"
	Warning

Chapter 2 Product Introduction

1. Components

1.1 The nebulizer mainly composed of main unit, and accessories (Portable Mesh Nebulizer kit (model: YM-3R*Series), micro USB cable).

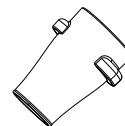
Portable Mesh Nebulizer kits (model: YM-3R*Series) are including medicine cup, child mask, adult mask, mouthpiece and Mask connection tube



Child mask



Adult mask



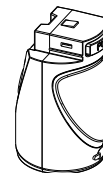
Mouthpiece



Mask connection tube



Medicine cup



Main unit

1.2 accessories

The accessories of the device see the following table

Name	Model/specification	Q'TY
Micro USB cable	USB-DC3.5-1.5M	1
Portable Mesh Nebulizer kit	F224R*E001	1

The following parts was packaged in the Portable Mesh Nebulizer kit (model: F224R*E001)

Part name	material	Part No.	Q'TY
medicine cup	PC 110	Y299R*A001	1
child mask	PVC	Y298R*A901	1
adult mask	PVC	Y297R*A901	1
mouthpiece	Silica gel HT-8150	Y272R*G10	1
Mask connection tube	PC 110	Y268R*A901	1

2. Comparison of Series models:

2.1 Series of YM-3R9 and YM-3R6 the differences are: Part of the plastic case color, PCBA layout, and Power Indicator position.

Series of YM-3R9*



YM-3R9(blue)

YM-3R901(gray)

YM-3R902(green)

YM-3R903(brown)



YM-3R6(silver)



YM-3R601(gold)



YM-3R602(white)

2.2 The electronic components on the main board are the same, but the positions of the components are different

3. Intended use / user

Intended use:

The portable mesh nebulizer is intended to convert the drug fluid into an aerosol for inhalation by adult or pediatric patients

Target user group:

Adults, adolescents and children aged 4 to 11 years.

The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments and so on.

4. Product contraindications:

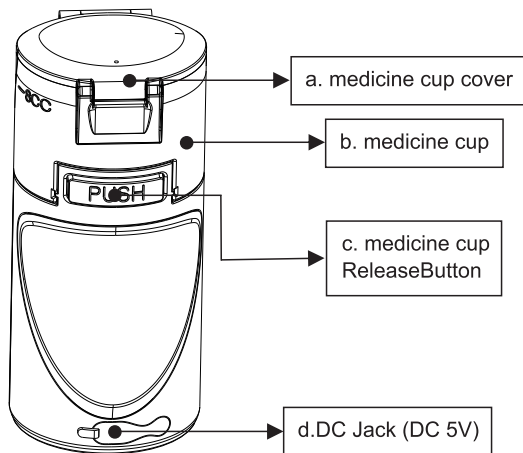
Should not be used in patients with asthma This product is not suitable for oily drugs;

The equipment does not apply to drugs supplied in suspension or high viscosity form;

This product not suitable for use in anaesthetic breathing system or lung ventilator;

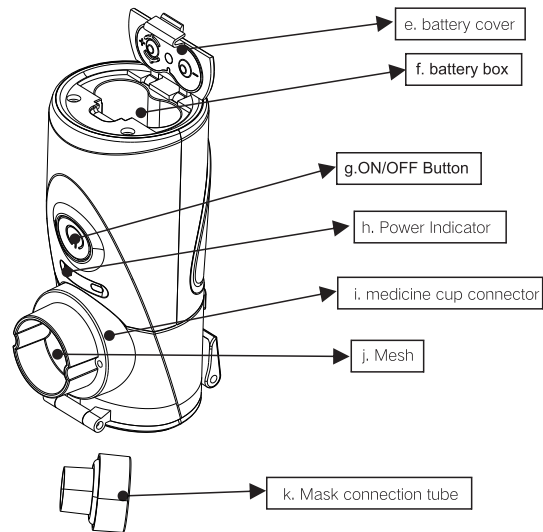
In such cases, information should be sought from the Drug supplier.

5.Part Names and Functions



Back view of YM-3R* Series

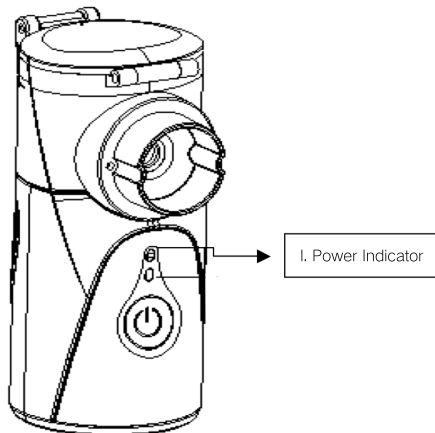
- a. medicine cup cover
- b. medicine cup
- c. Press Release Button to remove the medication cup
- d. DC Jack: plug in the applicable DC plug (DC 5V)



Front view of YM-3R*Series

- e. After the battery is installed, close the battery cover
- f. Press + - here to install the battery.(The battery is not included in the package)
- g. ON/OFF Button: Press ON/ OFF Button to turn on the power.
- h. Power Indicator(YM-3R9*Series):
 Green light on: Ongoing Operation
 Red light on/ flash: Low power/ Malfunction
 No light : Malfunction
- i. medicine cup connector:
 Connect the Mouthpiece directly
- j. Mesh : Atomization mesh
- k. Mask connection tube(application part)

- I. Power Indicator(YM-3R6*Series):
 Green light on: Ongoing Operation
 Red light on/ flash: Low power/ Malfunction
 No light : Malfunction



Front view of YM-3R6*Series

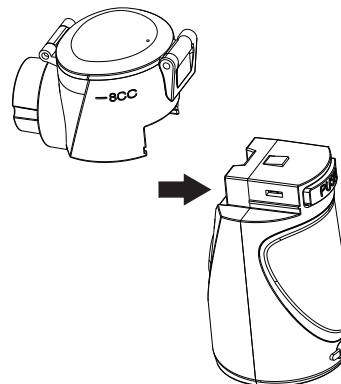
- m. The Portable Mesh Nebulizer Kits (model: YM-3R*Series) is individual disposable products and cannot be re-used. And the Portable Mesh Nebulizer Kits (model: YM-3R*Series) just for single person to use and to prevent the cross infection. Please purchase from Shenzhen IMDK Medical Technology Co.,Ltd.
- n. The specification of the battery is 2 Alkaline AA batteries,The user buys it from a qualified manufacturer there.
- o. power adapter: Specification is input100-240VAC 50Hz/60Hz Output:5VDC,the user buys it from a qualified manufacturer there.

Chapter 3 Installation of Nebulizer

1. Cleaning before use:Relevant parts of the Nebulizer must be cleaned and dried before use.

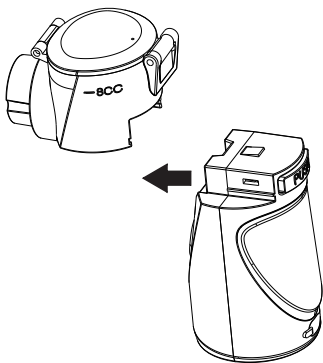
2. Set up the medication cup

Align the three ribs on the back of the medicine cup with three trenches of the main unit to insert the medicine cup into the main unit. Please make sure it is OK until you hear [ka] sound.



Medicine cup Install Note:

- It is necessary to ensure that the medicine cup is assembled in place, otherwise it will cause unreachable and cannot be sprayed.
- Keep the main unit and the medicine cup clean, otherwise it may cause the possibility of spraying.



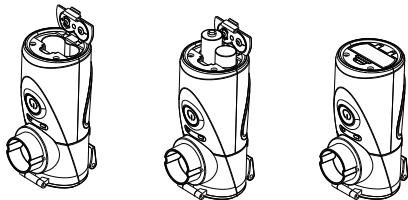
Medicine cup Remove Note:

- Press the [push button] and push the cup to avoid damage to the Nebulizer.
- Do not insert your finger or other items into the spray net during the disassembly process to avoid rupture of the spray net.

3. Install the battery or Connect with adapter

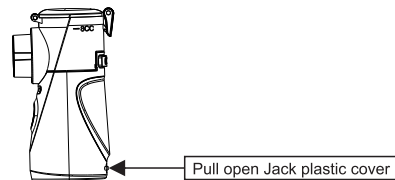
△ CAUTION: Do not Install both at the same time!

3.1 Battery installation: Open the battery cover and put the 2 alkaline batteries into the battery compartment according to the + - mark, as shown below.



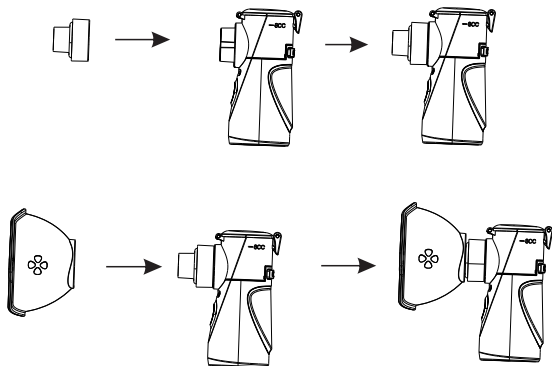
3.2 Or Connect with adapter

- Open the DC Jack
 - Plug the cable into the power adapter jack on the main unit.
 - Plug the adapter into a standard electrical outlet.
- *The power adapter is an optional accessory and it is not included in the package.

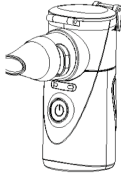


4. Attachments installation:

4.1 Install the mask, as shown below:



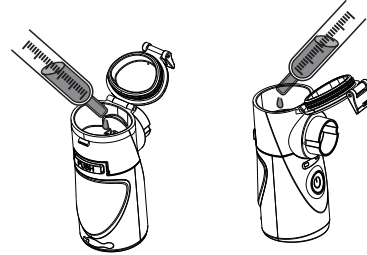
4.2.Or Install the mouthpiece, as shown below:
installed directly in the medicine cup connector



Chapter 4 Fill the medication

1. Fill the medication

Fill the medication as shown in Figure:



- Open the medicine cup cover;
- Fill the medicine cup with prescribed medication;
- The applicable liquid of this nebulizer is Ventolin and pulmicort;
- The maximum capacity of medicine cup is 8 ml;
- Close the medicine cup cover properly.

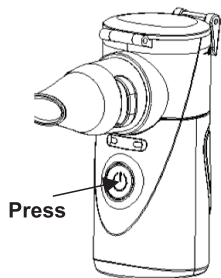
⚠ WARNINGS

- Tilt the device slightly, while the solution is almost exhausted to make sure that the residual solution contact the mesh and is sprayed completely;
- If high-viscosity solution is used, nebulization may be reduced;
- If excessive solution is accumulated on the mesh, nebulization may stop. In this case, turn off the power and absorb the solution by gauze or lint-free towel.

Chapter 5 Operating the Nebulizer

1. Inhalation

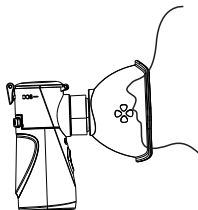
- Press ON/OFF button to turn on the device (light Indicator turns on in green);
- Place the mouthpiece between your teeth, with your lips firmly sealed around the mouthpiece;



note:

- If the battery is low, light indicator turns on in red. Please replace the battery or charge in time.
- If the drug is not loaded, the power indicator will flash for 1 second - 3 seconds after power on, and will automatically shut down.
- When the device is taken from the highest/low storage environment and the temperature is 20 ° C, it can be used immediately without waiting.

- If you use a mask, place the mask over your mouth and nose;
- Breathe in and out slowly through your mouth until aero-sol formation stop;

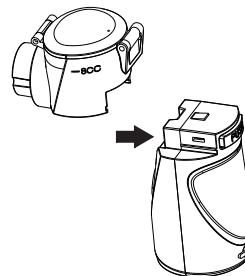


2. End of Inhalation

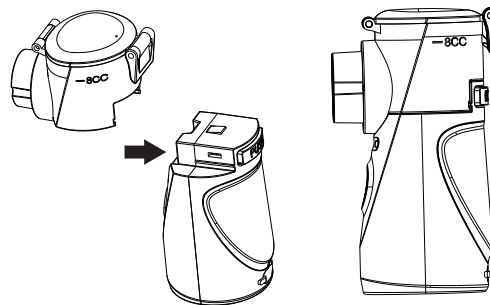
Press ON/OFF button to turn it off. Remove the batteries from the main unit.

Chapter 6 Replace the medicine cup

1. Remove the medicine cup from the nebulizer: press the push button on the main unit and push the medicine cup toward the front of the main unit.



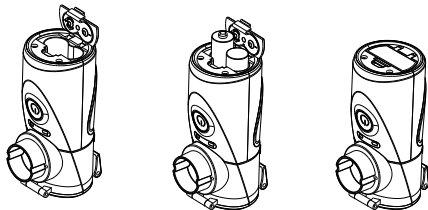
2. Put the new medicine cup back on the nebulizer.



Chapter 7 Power Supply

This nebulizer uses batteries and an external power supply.

1. Insert the batteries (load 2 AA alkaline batteries).

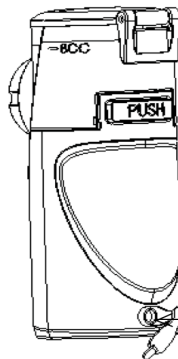


- Turn the unit upside down.
- Push back and pull up the battery cover to open it.
- Insert two AA alkaline batteries according to the battery polarity indicated inside the battery compartment.
- Put down and close the battery cover to lock it.
 - ⚠ CAUTION: Batteries are not included in the package;
 - ⚠ CAUTION: Battery life and battery replacement Battery life is usually depending on the capacity and condition of the batteries;
 - ⚠ CAUTION: When the power indicator turns into Red (means low power), please replace both batteries with new ones.

2. How to operate with adapter

2.1 Please see page 20 introduction to chapter 3 section 3.2

2.2. Overcurrent and overvoltage protection: The nebulizer detects the overcurrent or short circuit of the protection working circuit through a set of circuits and software.



Note: The company does not provide a power adapter

- Please purchase a power adapter with a normal manufacturer output voltage of DC 5V 1A. and comply with IEC 60601-1, provided at least two MOPP between AC input and DC output as well.
- Unplug the power adapter after use. Wire plug, do not connect for a long time power supply.

Chapter 8 Cleaning and Disinfection

The Accessories (Portable Mesh Nebulizer Kits: model: YM-3R*Series) is disposable products and cannot be re-used. The accessories must be cleaned and disinfected before use. Please turn off the power before cleaning and disinfection, Detailed cleaning and disinfection methods with step by step are as follows:

1.The first step-Cleaning the medicine cup

- 1.1 open the medicine cup installed on the main unit;
- 1.2 Pour a small amount of (Less than or equal to 8ML) hot distilled water into the medicine cup and close the medicine cover, but suggest that the water temperature is 30-60°C;
- 1.3 press the power button for 3-5 seconds, turn on the device and nebulize the distilled water for 1-2 minutes;
- 1.4 Rinse the medicine cup and medical cap and mesh holes with distilled water. Gently wipe off excess water with a soft clean cloth
- 1.5 Immerse the medicine cup in 75% medical alcohol disinfecting at least 3 minutes .
- 1.6 Finally, take out the medicine cup, gently wipe off excess alcohol with a soft clean cloth, and let it dry for use.

2.The second step-Cleaning and disinfecting masks,mouthpiece,mask Connection tube

- 2.1 rinse the accessories with pure water for 2-3 minutes (Water temperature $\leq 50^{\circ}\text{C}$)
- 2.2 Dry moisture with medical gauze
- 2.3 Wipe the accessories with 75% medical alcohol at least 3 minutes to disinfect.

⚠ CAUTION: If the device is not cleaned and disinfected correctly as indicated, microorganisms may remain in the unit and cause risk of infection.

3 Cleaning the main unit(Mainframe maintenance and cleaning after atomization)

- After use the main unit, you should clean the main unit.
- 3.1 Clean the surface of main unit with a soft clean cloth and Gently wipe the main unit with 75% medical alcohol;
 - 3.2 Clean the electrodes with a soft clean cloth, in order to make the device work normally.

⚠ CAUTION:

- 1) Do not wipe the main unit with other volatile liquid, such as Benzene or Thinner.
- 2) Do not rinse or immerse the main unit any liquid

Chapter 9 Product Specifications

Product Name	Portable Mesh Nebulizer
Models	YM-3R9, YM-3R6, YM-3R901, YM-3R902, YM-3R903, YM-3R601, YM-3R602
Dimensions	Approx. 45(L)mmx45(W)mmx100(H)mm
Weight (g)	Approx. 100g (without battery)
Power Supply	Battery (Two AA alkaline batteries) (not included) Power supply: voltage 3v, current: 1A; Power Adapter (not included): voltage 5v, current: 1A
Power Consumption	Approx. 2.0w
Oscillating Frequency	Approx. 110KHz \pm 10%
Nebulization Rate	$\geq 0.2\text{ml/min}$
Medicine Temperature	$\leq 60^{\circ}\text{C}$

Working Noise	≤50dB(A)(Around 1 meter)
Particle Size	The proportion of fog particles with a diameter of <5μm in diameter is greater than 50%.
Mass Median Aerodynamic Diameter (MMAD)	<5μm
Medicine Cup Capacity	8 ml max
Guarantee Time	Main Unit 1 Year (Medicine cup is not included)
Expected lifespan	Main Unit 3 Years
	Portable Mesh Nebulizer Kits Shelf-Life is 1 year
Operating temperature and humidity	Temperature: 5 °C-40 °C Relative Humidity: ≤ 93%RH(no condensation) Air pressure: 800hPa-1060hPa
Storage and delivery condition	Temperature: -20° C-50 °C Relative Humidity: ≤ 93%RH(no condensation) Air pressure: 800hPa-1060hPa

The manufacturer reserves the right to make changes in the design of the device.

⚠ WARNINGS

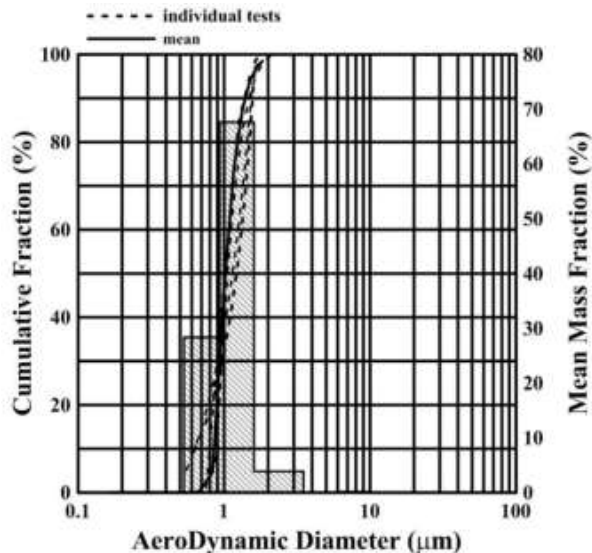
The optional power adaptor shall be fulfilled in compliance with the requirements of IEC60601-1:2005. Contact to the nearest dealer for further information.

2. Test with Pulmicort , and under normal temperature of 24±2 °C,Relative humidity: 45-75%,Pressure: from 86 kpa to 106 kpa, - for detailed information(Picture1):

●Test drugs:

1. For particle sizing- Solution of Budesonide (Pulmicort) 0.025%(M/V).

2. For the aerosol output rate and the aerosol output- Solution of Budesonide (Pulmicort) 0.05% (MV).

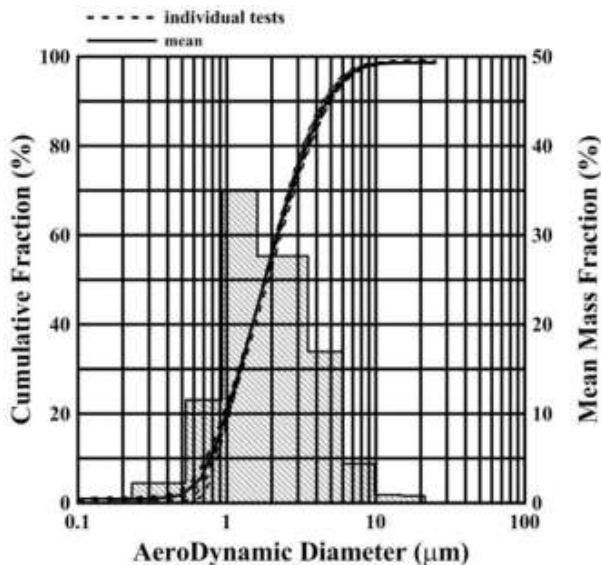


3. Test with Ventolin, and under normal temperature of 24 ± 2 °C, Relative humidity: 45-75%, Pressure: from 86 kpa to 106 kpa, -for detailed information(Picture2):

●Test drugs:

1. For particle sizing- Solution of Salbutamol (Ventolin) 0.2%(M/V).

2. For the aerosol output rate and the aerosol output- Solution of Salbutamol (Ventolin) 0.2% (M/V).



Chapter 10 Product Characteristics

Classified by type of electric shock	Internal power supply
Classified by the degree of protection against electric shock	Bf type
power supply	Battery (Two AA alkaline batteries)(not included) Power supply: voltage 3v, current:1A; Power Adapter (notincluded) :voltage 5v, current: 1A
Press IEC60529 dustproof and waterproof protection	IP22
Classification of safety levels when used in the presence of flammable anesthetic gases mixed with flammable anesthetic gases or nitrous oxide mixed with air	Non-ap/apg device
Classified by operating mode	continuously working
Classification according to manufacturer's recommended disinfection and sterilization methods	No special sterilization method

Chapter 11 Solving Problems

If you encounter any abnormality when using the nebulizer, please refer to the following table for solution.

Abnormal phenomenon	Possible cause	Solution
Reduced spray capacity	The medicine cup has not been put in place	According to this manual, re-install the medicine cup in place and restart it.
	There is dirt on the spray net on the medicine cup Blocked.	Clean the medicine cup according to this manual. It will not be used after cleaning. Please replace it with a new one.
	There is residual medicine on the upper electrode of the cup Object or water	Remove residual drug and water according to this manual, and then restart.
	The contact electrode on the nebulizer and the cup is dirty.	Clean the electrode according to this manual and turn it on again.
After the power is turned on, the power indicator lights up for 1 second and then turns off immediately.	The medicine cup has not been put in place	According to this manual, re-install the medicine cup in place and restart it.
	The medicine cup has not been loaded with drugs	According to this manual, put the medicine into the cup.
	The contact electrode on the nebulizer and the cup is dirty.	Clean the electrode according to this manual and turn it on again.

Abnormal phenomenon	Possible cause	Solution
The power indicator is not lit and the nebulizer is not sprayed	The positive and negative directions of the battery are reversed	Press the battery to mark the positive and negative poles and reload the battery in the correct direction.
	Very low battery	Follow the instructions in this manual to replace the battery.
	The power adapter and nebulizer are not properly connected	Reconnect correctly according to this manual, and then reboot.
	The spray net on the medicine cup has serious dirt and blockage	Clean the cup according to this manual. After cleaning, it will not be used. Replace the new cup.
	The contact electrode on the nebulizer and the cup is dirty.	Clean the electrode according to this manual and turn it on again.
The nebulizer automatically shuts down during use	The medicine cup is not assembled in place	Reinstall the medicine cup according to this manual and restart it.
	The power adapter and nebulizer are not properly connected	Reconnect correctly according to this manual, and then reboot.
	Medicine cup failure	Fill in the new medicine cup according to this manual.

	Drug is exhausted	Reload the drug into the medicine cup.
Medicine cup drug spill	The cup is broken or the seal is aging	Replace the new medicine cup and install it according to this manual.

Abnormal phenomenon	Possible cause	Solution
The drug is exhausted, but the nebulizer cannot automatically shut down	Some drugs may produce some foam in the medicine cup	Press the [ON/OFF] button to turn it off and clear the foam inside the cup.
	There is residual drug or water on the upper electrode of the cup	Press the [ON/OFF] button to turn it off and remove residual drug or water.
	The contact electrode on the nebulizer and the cup is dirty.	Clean the electrode according to this manual and turn it on again.
	Medicine cup failure	Fill in the new medicine cup according to this manual.

Chapter 12 EMC Declaration

1. The Portable Mesh Nebulizer (models YM-3R9, YM-3R901, YM-3R902, YM-3R903, YM-3R6, YM-3R601, YM-3R602) is suitable for home healthcare environment and hospitals except for near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.

2. CAUTION: 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 Portable Mesh Nebulizer (models:YM-3R*Series), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

3. IEC 60601-1-2:2014 ME EQUIPMENT and ME SYSTEMS identification, marking and documents for Class B product.

4. Technical description

4.1. All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life.

4.2. Guidance and manufacturer's declaration -electromagnetic emissions and Immunity.

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A

Voltage fluctuations/ flicker	Compliance
emissions IEC 61000-3-3	Compliance

Table 2

Guidance and manufacturer's declaration - electromagnetic Immunity		
Immunity Test	IEC 60601-1-2 Test level	Compliance level
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
Electrical fast transient/burst IEC 61000-4-4	Power supply lines: ±2 kV 100 kHz repetition frequency	Power supply lines: ±2 kV 100 kHz repetition frequency
Surge IEC 61000-4-5	line(s) to line(s):±1KV.	line(s) to line(s):±1KV.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle	0% 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF IEC61000-4-6	150KHz to 80MHz: 3Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	150KHz to 80MHz: 3Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz

Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
NOTE UT is the a.c. mains voltage prior to application of the test level.		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity							
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSED PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (Mhz)	Band (Mhz)	Service	Modulation	Modulation (W)	Distance(m)	IMMUNITY TEST LEVEL (V/m)
		385	380-390	TETRA 400	Pulse modulation 18 Hz	1,8	0.3
450		430-470	GMRS 460, FRS 460	FM ±5 kHz deviation 1 kHz sine	2	0.3	28
710		704-787	LTE Band 13,17	Pulse modulation 217 Hz	0,2	0.3	9
745							
780							
810		800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870							
930							
1720		1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT, LTE Band 1,3,4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1845							
1970							
2450		2400-2750	Bluetooth, WLAN, 802.11b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240		5100-5800	WLAN 802.11a/n	Pulse modulation 217 Hz	0,2	0.3	9
5500							
5785							

YM-3R* Series Portable Mesh Nebulizer Service Warranty Card

Product name	
Model	
User unit/person name	
TEL	
Date of purchase	
Contact address	
Dealer name And contact information	
Maintenance records	



Manufacturer Information

Shenzhen IMDK Medical Technology Co.,Ltd .

Registrant / Manufacturer Name:

Shenzhen IMDK Medical Technology Co.,Ltd .

Registrant/Production Enterprise Residence:

C Zone,10F,Building 16,Yuanshan Industrial B Area,
Gongming Street,Guangming District,Shenzhen China.

Production address:

C Zone,10F,Building 16,Yuanshan Industrial B Area,
Gongming Street,Guangming District,Shenzhen China.

Phone: 86-755-36637905

EC REP Authorized European Representative:

MedNet EC-REP GmbH

Borkstrasse 10,48163 Münster,Germany,

After sales service

Shenzhen IMDK Medical Technology Co.,Ltd .

C Zone,10F,Building 16,Yuanshan Industrial B Area,
GongmingStreet,Guangming District,Shenzhen China.

Tel: 86-755-36637905; E-mail:service@imdker.com

See chapter 9 of the specification for lifetime