

# Instruction Manual



## Mesh Nebulizer (Model No. YS31)



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# Introduction

Thank you for purchasing YS31 mesh nebulizer (Hereinafter referred to the device), please read the manual carefully to make sure that you can operate it correctly and safely. Please store the manual well after reading it for later reading and referencing.

## 【Quality Assurance】

Main unit 12 months for free warranty, medicine bottle(including mesh plate) 3 months for free warranty. During warranty period, we depend on the damage to decide if maintenance is required or damaged part is to be changed.

Accessories are consumables, and thus do not belong to warranty range. If you need to change, we recommend our company's accessories.

The details given below not including in warranty range:

- The damage caused by human fall, touch, soaking, wet
- The damage caused by not in accordance with the correct operating instructions.
- Damaged by accident.
- Without our company's authority, users who disassemble and assemble by selves.
- Products Serial No. is teared or can't be recognized well, and no warranty card and No Original Invoice available.



**NOTE:** Take Warranty Card to contact local distributor or our company if your nebulizer needs to be repaired. Meanwhile please keep packing box in safe place so that it can be used when you send it to our company.

# Chapter 1 Product Introduction

## 1.Product Overview

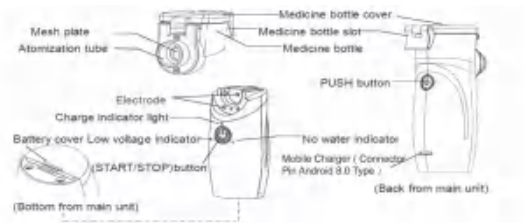
The device is designed for respiratory diseases treatment and respiratory tract infection prevention. The device is pushed by certain circuit frequency vibration to make piezoelectric ceramic vibrate harmony that caused high speed vibration of metal mesh. And the medicine liquid will be quickly popped through micro mesh hole of metal mesh plate to be countless micro atomizing particles. This will further transfer by inhalation treatment using masks or mouthpieces to patients' respiratory system.

## 2.Components

Main unit, Medicine bottle (including atomization tube and mesh plate),Accessories (mouthpiece, adult mask, child mask). Details see Picture 1:



Picture 1 Components



Picture 2 Detailed Components

### 3.Available Range

The nebulizer is designed for respiratory diseases treatment and respiratory tract infection prevention. It is widely used in curing diseases of respiratory system, such as cold, fever, bronchitis, asthma, pneumonia, pneumonic mycosis and pulmonary heart disease. It can also be used to cure occupational disease; give throat care to the artists, cure ENT (ear, nose, throat) diseases like chronic allergic rhinitis, acute laryngitis, acute pharyngitis, acute tonsillitis, etc.

The nebulizer shall be used with face mask, and the face mask's connection tube diameter shall be  $20.0 \pm 0.1 \text{ mm}$ , therefore the face mask can be connected to the nebulizer tightly.

### 4.Applicable people scope

The nebulizer is available to adults, aged people, infants and children must under adults supervision.

The nebulizer can be used at household environment, and it complies with requirement of IEC 60601-1-11.

#### Contraindications:

- 1) The device can not be applied to anesthesia breathing system and respiratory system.
- 2) Infants and children must under adults supervision.
- 3) Pentamidine is not applicable to the device.

### 5.Working Principle

The device is pushed by certain circuit frequency vibration to make piezoelectric ceramic vibrate harmony that caused high speed vibration of metal mesh. And the medicine liquid will be quickly popped through micro mesh hole of metal mesh plate to be countless micro atomizing particles. This will further transfer by inhalation treatment using masks or mouthpieces to patients' respiratory system.

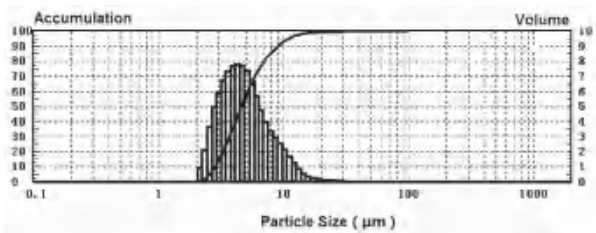
### 6.Main Performance Index

Please see Table 1, it was tested by 0.9% physiological saline under the condition of temperature  $25 \pm 3^\circ \text{C}$ , humidity  $60\% \pm 5\% \text{ R.H.}$

Fog particle equivalent volume (Picture 3)

**Table1 Main Performance Index**

Nebulizer ultrasonic working frequency	$120 \text{ KHz} \pm 10\%$
Nebulizer spraying rate	$\geq 0.2 \text{ ml/min}$
Medicine liquid temperature	$\leq 41^\circ \text{C}$
Working noise	$\leq 50 \text{ dB}$
Fog particle media diameter	$\text{MMAD } 5 \mu\text{m} \pm 25\%$



**Picture 3 Fog Particle Equivalent Volume**

**NOTE :** The horizontal line is particle diameter, the data are the logarithm distribution; Left vertical line is cumulative percentage of volume, corresponding to the curve upward trend; Right vertical line is a range of volume percentage, corresponding to Graph histogram or rolling.

## Chapter 2 Operation

To prevent cross infection, the nebulizer is used only by one person

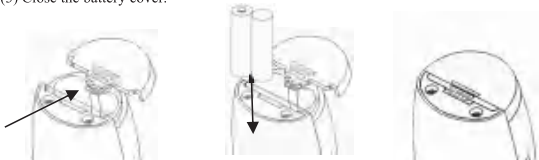
Please clean and disinfect nebulizer when you first using it or before and after using, then dry it, see Chapter 3.

### 1, Connect the power supply

This nebulizer can both with batteries and mobile charger with Android 8.0 flat pin (purchase additionally)

#### 1, Install batteries (Picture 4)

- (1) Open the battery cover;
- (2) Insert the batteries according to the illustration of polarity (2 Alkaline AA Batteries) ;
- (3) Close the battery cover.



1. Open the battery cover
2. Insert the batteries
3. Close the battery cover

**Picture 4 Installation of Batteries**



#### **NOTE:**

- 1) Please install batteries as per battery chamber polarity symbol.
- 2) Please do not use mix batteries of different styles or manufacturers or factories
- 3) Please remove the batteries if not using nebulizer.

### 2、Adapter using

- (1) Connect Android 8.0 output to Mobile Charger with similar type of flat pin( Picture 2);
- (2) Connect Mobile Charger to power.



#### **NOTE:**

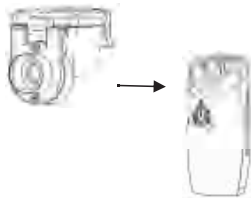
- 1) Users should purchase Mobile Charger additionally, please note that the output port of Mobile Charger should match with the AC power required;
- 2) To ensure safe using, please use Mobile Chargers that meet the electrical safety standard GB 9706.1-2007 or IEC 60601-1;
- 3) Mobile Charger technical parameter should satisfy as below :
- 4) Input voltage: AC 100~240V,50/60 Hz;

5) Output voltage: DC 3~5V,1~2A

## 2, Nebulizer Assembly

1, Please clean and disinfect nebulizer before using, then dry it, see chapter 3 in details)

2, Use One hand to hold the main unit, the other to hold the medicine bottle. push follow the slot until you hear a “Click” sound.(Picture 5 )



**Picture 5 Nebulizer Assembly**

### NOTE:

If not assemble medicine bottle in right place, that may caused electrode couldn't turn and nebulizer can't work.

Please keep main unit and medicine bottle clean (see chapter 3), or may cause nebulizer can't work.

## 3, Add medicine liquid (Picture 6)

1, One hand to hold the main unit, the other to open medicine bottle buckle;

2, Put medical liquid in the medicine bottle and then;

3, Tighten the medicine bottle cover.



1.Open cover, add medicine liquid



2.Close the cover, tighten the bottle

**Picture 6**

### **Add Liquid Medicine**



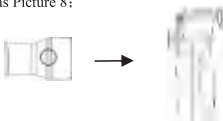
**NOTE:**

- 1) Suggestion: max medicine liquid 8ml, min 0.5ml
- 2) After putting medicine liquid in, prevent nebulizer shaking or inverted which may cause the leakage of medicine liquid.
- 3) Keep medicine liquid and mesh completely contacting to prevent mesh plate air shock.

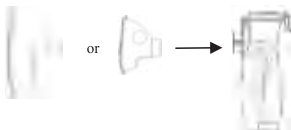
**4. Usage of Nebulizer**

Nebulizer accessories are grouped as mouthpiece, adult mask and child mask. If need to be treated by the throat, please use the mouthpiece; meanwhile if need to be treated by nasal cavity / or throat, please choose a mask.

1. Connect mouthpiece and sending pipe of main unit as Picture 7, or connect mask and sending pipe of main unit as Picture 8;



**Picture 7 Mouthpiece Assembly**




**Picture 8 Mask Assembly**

2. Push START/STOP button, the power indicator light (Blue Light) will light up and turn on;
  3. Keep calm, relax and sit well, with the hand holding the nebulizer smoothly, take deep and slow breathing, to have more effective treatment:
    - (1) When use mouthpiece, make the mouthpiece flat end into the mouth, lips slightly closed, so that the medicine liquid targeted to the affected area.
    - (2) When use mask, make mask slightly close to face, better for covering nose cavity and mouth:
      1. Treat by nose cavity, deep inhaling from nose cavity, exhaling from mouth.
      2. Treat by throat, inhaling from mouth, exhaling from nose cavity.
- ③ During treatment, can both use 1 and 2.

**NOTE:**

- 1) Put 0.9% physiological saline into medicine bottle, after assembly and before using, push START/STOP to test if it can't work well (Chapter 6)
- 2) Please follow Picture 7 and Picture 8, by accessories' connectors to assemble mouthpiece or mask.
- 3) Please use correctly using mouthpiece, don't spray the liquid to your tongue.
- 4) Don't swallow liquid and make sure liquid does not go direct to the affected area.

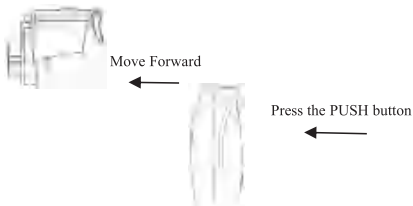
- 5) Improper gesture and not smooth breathing may cause respiratory passage blockage.
  - 6) If no medicine liquid is left in medicine bottle, after turning on the nebulizer the indicator (Yellow Light) will shine for one second and then turn off by self. While the medicine liquid is exhausted, the nebulizer will turn off by oneself.
  - 7) Slightly tilt the Main Unit toward yourself to immerse the Vibrating Mesh in the Medicine.
-  **NOTE:** If the vibrator is not immersed in the Medicine, the device will not nebulize within 10 seconds.
- 8) When the Medicine is not much, tilt the device toward yourself by START/STOP side) , make the Medicine gathered in mesh plate, in order to make full use of the residual Medicine.
  - 9) The device should avoid empty shock, in case of mesh plate broken.
  - 10) When Low Voltage Indicator (Red Light) continue to slow flash, the power will run out, please change new Alkaline Batteries as soon as possible.
  - 11) Do not strongly wave or vibrate the device in use, otherwise the device automatically shut down.
  - 12) Pure water is not suitable for normal working mode, otherwise the device will not turn on

### **5, Turn Off The Power**

1. Press the START/STOP button to turn off the power, the Power Indicator (Blue Light) will go out.
2. When the Mobile Charger is used, remove the power plug from the electrical outlet after using the device.

### **6, After Using**

1. Remove the mouthpiece or mask
2. Hold the Main Unit by one hand, and Press the [PUSH] button behind the Main Unit shown in Picture 9; Hold the Medicine bottle by the other hand, remove the Medicine bottle along the slot ;



**Picture 9**

3. Open the lid, pour all the residual liquid medicine bottle, and promptly clean the device, allow the parts to air dry and store the device in a clean environment. See Chapters 3 and 4.

## Chapter 3 Cleaning and Disinfecting

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

### Medicine bottle **This process is required before and after every use.**

1. Open the medicine bottle, and discard any residual medicine;
2. Pour a small amount of hot distilled water into the Medicine Bottle and close the Cap;



**NOTE:** Suggest that the water temperature is 30-60°C

3. Press the START/STOP button for 5 seconds, Power Indicator(Blue) and Low Water Indicator (Yellow Light) and Low Voltage Indicator (Red Light) constantly light, Turn on the device in cleaning pattern to nebulize the distilled water for 1 to 2 minutes to remove residual Medicine from the mesh holes.
4. Rinse the medicine bottle and Medical Cap with distilled water. Gently wipe off excess water with a soft clean cloth or allow the parts to air dry in a clean environment.
5. Immerse the medicine bottle in 75% medical alcohol disinfecting at least 3 minutes, then remove the medicine bottle in a clean environment to dry and store.



**NOTE:**

- 1) Use medical gauze and medical cotton swabs to clean and disinfect
- 2) Do not wipe in tissue paper or other cloth, otherwise the mesh will not nebulize normally.
- 3) Do not wipe with the sharp object or touch the mesh.
- 4) Disinfect the Mesh after the last treatment of each day in the following solution: 2ml Vinegar (1 part white vinegar and 3 parts distilled water), OR 2ml hot water (No more than 80 degrees C). Turn on the device to nebulize in the disinfecting solution until running out. Turn off the power, then soak the medicine bottle in vinegar or hot water for 3 minutes, then remove and rinse with pure water.
- 5) Do not use other household bleach to clean the device in addition to the above solution.

### 2. Cleaning the Main Unit

1. Gently wipe the Main Unit with 75% medical alcohol and wipe off excess water with a

soft clean cloth;

2. Clean the electrodes connecting the Main Unit and medicine bottle , 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 in any liquid.

**3. Cleaning and Disinfecting of Mouthpiece and Masks**

1. Remove the mouthpiece or masks;
2. Rinse the mouthpiece and Mask with pure water for 2 ~ 3 minutes(Water Temperature  $\leq 50^{\circ}\text{C}$  ) ;
3. Dry moisture with medical gauze.
4. Wipe the mask and mouthpiece with 75% of medical alcohol at least 3 minutes to disinfect, and store to air dry.



**NOTE:**

- 1) Clean and disinfect all the parts.
  - 2) Replace the aging/ broken mask or mouthpiece every one month or using over 90 times.
- In order to ensure the safety of your usage, please purchase the parts from the regular manufacturer.

## Chapter 4 Storage and Maintenance

### 1. Storage Conditions:

- (1) Temperature:  $-20\text{ }^{\circ}\text{C} \sim 55\text{ }^{\circ}\text{C}$ ;
- (2) Relative Humidity:  $\leq 80\%$  R.H.
- (3) Air Pressure :  $70.0 \sim 106.0\text{ kPa}$ ;
- (4) Other requirements: No direct sunlight, Ventilation, No corrosive gas, No heating device, or Open fire.

### 2. Storage Instructions:

- (1) The product's validity is advised as 3 years.
- (2) Clean and disinfect the device after each using .Assemble the device. Store the device in the Storage Case or in a clean environment.

**Validity:** The device is advised used in 3 years and in 4000 times; For the battery, the device can be used for approximately 8 days if operating for 30 minutes a day, after this, another battery or charging of battery shall be provided.

### 2.Maintenance of the Device

#### 1.Working Conditions

- (1) Environment Temperature:  $10\text{ }^{\circ}\text{C} \sim 40\text{ }^{\circ}\text{C}$ ;
- (2) Relative Humidity:  $\leq 80\%$  R.H., No condensation
- (3) Air Pressure:  $86.0 \sim 106.0\text{ kPa}$ ;
- (4) Power: DC  $3\text{V} \pm 10\%$  (2 Alkaline AA Batteries) or Mobile Charger (Buy additionally, Technical Parameter Requirements see Chapter 2)

#### 2. Maintenance Instructions

- (1) Operate the device in normal work condition;
- (2) Do not operate the device near the heating device or open fire. Do not dry the device and its accessories with the microwave oven, oven drying, hair dryer, etc.
- (3) Don't make the nebulizer and its accessories contact corrosive liquids or gases.
- (4) Do not install the Main Unit around the power lines.
- (5) Refer to Chapter 6 for solution or contact the company or purchase dealer when the device can not work.



**WARNING:** Prohibit to disassemble, repair or change the device.

# Chapter 5 Safety Information and Care

## 1. Safety Information

1. Do not use or store the device in humid locations, such as a bathroom. Use the device within the operating temperature and humidity.
2. Read all the information in the instruction book and any other literature included in the box before using the unit.
3. Accessories mentioned in the instruction manual are just for the device .
4. Do not subject the device or any of the components to strong shocks, such as dropping on the floor.
5. Do not shock the device in using.
6. Do not disassemble or attempt to repair the device or components.
7. Remove all batteries when the device does not work.
8. When the Mobile Charger is used, remove the power plug from the electrical outlet and clean the device.
9. Do not operate the device or contact the Mobile Charger socket or power switch with wet hands.
10. Do not immerse the main unit in water or other liquid, avoid splashing water or other liquid to the main unit or AC adapter; Turn off the power, and immediately dry with a clean cloth.
11. To prevent damage to the device, do not carry or leave the Medicine Bottle filled with Medicine or distilled water.
12. Do not operate the device with rechargeable batteries, Dispose of the device, components, and optional accessories according to applicable local regulations. Unlawful disposal may cause environmental pollution.
13. This device is approved for human use only.

## 2. Care for the Device

1. The nebulizer is a prescription medical device. For type or dose of Medicine follow the instructions of your physician and/or licenced healthcare practitioner
2. Do not use the Medicine with ester, fat or suspended particles, including herbal medicine, suggest use the standard nebulizing Medicine in accordance with the physician's advice.
3. The device nebulizes for 10 ~ 20 minutes each time, the amount of Medicine for 2 ~ 4 ml, but still can be used as the physician suggested.
4. The device is a personal medical equipment, Do not mix its usage with others.
5. Do not touch the mesh with your hand or any other object.
6. Keep the device out of the reach of unsupervised infants and children.
7. Suggest that the device be kept away from other electrical products with above 2W power consumption at least 3.3 meters, to avoid the electromagnetic interference; Consult your physician for users wearing the heart pacemaker.



**WARNING:** Pentamidine is not applicable to the device!

The device can not be applied to anesthesia breathing system and respiratory system!








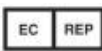





## Chapter 6 Trouble Shooting

There are something problem in using the device, please find solutions in the following table.

PROBLEM	CAUSE	SLOUTION
The device is on but nebulize weakly	The Medicine Bottle is not properly installed	Make sure the Medicine Bottle is properly installed
	The Medicine has not come in contact with the nebulizing parts above 10 seconds	Adjust the nebulizer angle and connect with the Medicine
	the mesh cap of Medicine bottle is not clean	Clean the Medicine bottle ,if still not work properly, change a new one
	the electrodes of the Medicine bottle is not clean with liquid or Medicine	Clean the electrodes and start
	the electrodes of the Medicine is not clean	Clean the electrodes and start
The power indicator Flashes 1 second and turn off	The Medicine Bottle is not properly installed.	Make sure the Medicine Bottle is properly installed
	Without Medicine in bottle	Fill the Medicine Bottle with the proper amount of prescribed Medicine
	Medicine is not connected with the mesh cap	Adjust the nebulizer angle and connect with the Medicine
	the electrodes of the Medicine is not clean	Clean the electrodes and start
The power indicator does not light, and the device not nebulize	The batteries have not been inserted properly	Replace the batteries correctly
	The battery is very low	Replace the new battery and turn the device on
	Mobile Charger and the device are not properly connected	Properly connect and turn the device on
	Low voltage indicator constantly illuminate, battery power is very low	Replace the new battery, and turn the device on
	The mesh of of the medicine bottle is broken	Replace of new medicine bottle before filling Medicine
	The electrodes of medicine bottle have Medicine or water	Clean Medicines or water, turn the device on
	the electrodes of the medicine bottle is not clean	Clean the electrodes, turn the device on
	The mesh of Medicine bottle is blocked with dirt	Clean medicine bottle, if still can't use, replace the new Medicine bottle
The device automatically shut down in use	The Medicine Bottle is not properly installed	Make sure the Medicine Bottle is properly installed and turn the device on
	Medicines has been run out	Fill the Medicine Bottle with the proper amount of prescribed Medicine
	Medicines did not contact with the mesh above 10 seconds	Adjust the angle of the device Medicine to connect with Medicine
	strong wave or vibrate the device in use	Hold the device securely
	medicine bottle cannot be used	Replace of new medicine bottle before filling Medicine
Medicine is running out but the device cannot automatically power off	Certain Medicines may produce some foam in the Medicine bottle	Press the START/STOP button to turn the device off, and clean the foam
	The electrodes of medicine bottle have Medicine or water	Press the START/STOP button to turn it off, and clean the remaining Medicines or water
	the medicine bottle or electrodes is not clean	Press the START/STOP button to turn it off, and clean the electrodes
	The Medicine bottle has something wrong	Purchase and replace a new medicine bottle
The Medicine of medicine bottle is leaking	medicine bottle is broken or plastic aging	Replace of new medicine bottle before filling Medicine

\* If you have tried the above solutions, and the device still cannot normally nebulize, suggest to contact your dealer.

## Chapter 7 Marks and Symbols

	CE Mark		Serial Number
	Separate Collection		Date Of Manufacture
	See The Instruction		Manufacturer
	BF Type Application Part		European Union Representative
	Notice		Power Indicator
	Low Liquid Indicator		Low Voltage Indicator
<b>IP22</b>	Waterproofing Grade		Environment-friendly Use Period



## Chapter 8 Product Specifications

Name	Mesh Nebulizer
Model	YS31
Dimensions	Approx. 45mm(L)×61mm(W)×121mm(H)
Power Source	DC 3V±10% (2 “AA” Alkaline Battery) OR AC adapter (Input: 100~240V, 50/60 Hz, Output: 3V~5V DC, 1~2A)
Safety Grade	BF
Power Consumption	1.5W
Vibration Frequency	120KHz ±10%
Nebulization Rate	≥ 0.2ml/min
Medicine Temperature	≤41℃
Working Voice	≤50dB
Particle Size	MMAD 5μm ±25%
Medicine Capacity	Max. 8ml, Min.0.5ml
Guarantee Time	Main Unit 1 Year ( medicine bottle not included); Medicine Bottle 3 Months
Operating Temperature	Environmental temp:10℃~40℃, Relative humidity :≤80% RH, not in Coagulation situation Air Pressure: (86.0~106.0)kPa
Storage Temperature	Environmental temperature: -20℃~55℃ Relative Humidity:≤80%R.H. Air Pressure: 70.0~106.0 kPa
Accessory	Mouthpiece, Adult Mask, Child Mask, Instruction Manual, Certification, Warranty Card, Carry Pouch

## Chapter 9. Guidance and manufacturer's declaration-electromagnetic emissions

Item	Applied standard	Result
<b>Emission Measurement</b>		
Radiated emission	IEC 60601-1-2:2014 CISPR11:2009+A1:2010	PASS
Conducted disturbance	IEC 60601-1-2:2014 CISPR11:2009+A1:2010	Not applicable
Harmonic current emission (harmonic)	IEC 60601-1-2:2014 IEC 61000-3-2:2005+A1:2008+A2:2009	Not applicable
Voltage fluctuations & Flicker (Flicker)	IEC 60601-1-2:2014 IEC 61000-3-3:2013	Not applicable
<b>Immunity Measurement</b>		
Electrostatic discharge	IEC 60601-1-2:2014 IEC 61000-4-2:2008	PASS
RF field strength susceptibility	IEC 60601-1-2:2014 IEC 61000-4-3:2006+A1:2007+A2:2010	PASS
Electrical fast transients/burst test	IEC 60601-1-2:2014 IEC 61000-4-4:2012	Not applicable
Surges test	IEC 60601-1-2:2014 IEC 61000-4-5:2005	Not applicable
Conducted susceptibility test	IEC 60601-1-2:2014 IEC 61000-4-6:2013	Not applicable
Power-frequency magnetic field susceptibility test	IEC 60601-1-2:2014 IEC 61000-4-8:2009	PASS
Voltage dips and interruptions test	IEC 60601-1-2:2014 IEC 61000-4-11:2004	Not applicable

## Chapter 10 Contact information

### **Manufactured for Caremax Australia by:**

Le Reve Healthcare Pty Ltd AKA Caremax

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## NOTE

