

FaceLake®

# Instruction Manual

FL800 Intelligent Mesh Nebulizer



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### Intelligent Mesh Nebulizer User manual

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#### Indications for Use:

The FL800 Intelligent Mesh Nebulizer is designed to aerosolized liquid medications for inhalation by patient, the device may be used with pediatric (>4 years of age) and adult patients in the home, hospital and sub-acute care settings. It is not intended for use with Pentamidine.

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**Before you start**

Thank you for purchasing FL800 Intelligent Mesh Nebulizer (Hereinafter referred to the nebulizer or the device). Before using FL800 Intelligent Mesh Nebulizer for the first time, you need to read this Instruction Manual completely and pay particular attention to sections on device use procedures, device operation, and after-use procedures.

**SAVE THESE INSTRUCTIONS:**

We recommend you re-familiarize yourself with this Instruction Manual before each use of FL800 Intelligent Mesh Nebulizer. FL800 Intelligent Mesh Nebulizer is an electrical device. As such, it should be used with special attention to safety.

**READ ALL CONTRAINDICATIONS, WARNINGS AND SAFETY PRECAUTIONS BEFORE USE, AND STRICTLY FOLLOW THEM WHEN USING FL800 INTELLIGENT MESH NEBULIZER!**

**NOTE !**

**Before initial use please charge the nebulizer for minimum ONE hour so that the device can be activated. The device is not provided sterile, and it is reusable.**

**1. What is FL800 Intelligent Mesh Nebulizer?**

The nebulizer consists of two parts: physical device and mobile application program (App). The FL800 Intelligent Mesh Nebulizer is designed to aerosolized liquid medications for inhalation by patient, the device may be used with pediatric (>4 years of age) and adult patients in the home, hospital and sub-acute care settings. It is not intended for use with Pentamidine.

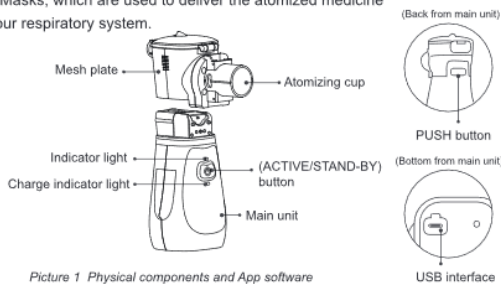
For App, it consists of interactive games and information display which could enhance entertainment and users' adherence to the nebulizer during treatment. It could be connected to the physical device by Bluetooth. If you wish not to use the App, the physical device will still provide an effective treatment with our extra benefits included. The atomizing function of the device is independent of the App.

**Package Contents**

- ◆ Upon opening FL800 Intelligent Mesh Nebulizer package, you will find the following parts:
- ◆ Main Unit, Atomizing Cup and Accessories (Mouthpieces and Masks)
- ◆ Instruction Manual
- ◆ Storage Bag and a USB charging cable.

**2. FL800 Intelligent Mesh Nebulizer description**

FL800 Intelligent Mesh Nebulizer consists of the Main Unit, Atomizing Cup, Accessories and mobile application program. The Atomizing Cup is used to be filled with the prescribed liquid medications. The Main Unit is used to supply electricity, and the Accessories consist of Mouthpiece and Masks, which are used to deliver the atomized medicine to your respiratory system.



Picture 1 Physical components and App software



**3. Getting to Know your Device**

Main Unit	Provide electricity
Atomizing Cup	Filled with the prescribed liquid medication
Mesh plate	Create low velocity aerosol
PUSH button	Disassemble the atomizing cup
(ACTIVE/STAND-BY) button	Active/Stand-by the nebulizer
Indicator light	Green light on when the nebulizer works regularly Flash blue light when the battery is running out Flash green light for 3s when there's no medicine liquid in the atomizing cup
Charge indicator light	Orange light on when charging regularly Green light on while finishing charging
USB interface	Connect the adaptor
App software	Interactive games and information display

Table 1 Components and functions

#### 4.FL800 Intelligent Mesh Nebulizer Indication for Use

The FL800 Intelligent Mesh Nebulizer is designed to aerosolized liquid medications for inhalation by patient, the device may be used with pediatric (> 4 years of age) and adult patients in the home, hospital and sub-acute care settings. It is not intended for use with Pentamidine.

The connection tube diameter of masks and mouthpieces shall be 20.0±0.1mm. The masks can be connected to the nebulizer tightly.

#### 5.Deciding to Use Device

The FL800 Intelligent Mesh Nebulizer is designed to aerosolized liquid medications for inhalation by patient, the device may be used with pediatric (> 4 years of age) and adult patients in the home, hospital and sub-acute care settings. It is not intended for use with Pentamidine. and it complies with the requirement of IEC 60601-1-11, which is an international standard for household medical device.

Ask yourself the following questions:

(1) Do you/your children have any respiratory problems and be appropriated to use the device?

(2) Have you consulted your doctor?

(3) Is device safe for you or your children to use?

Next, carefully review the Important Safety Information, Contraindications, Warnings, Precautions and Benefits sections found below, in order to decide if the device is safe for you or your children.

If you have determined that this device is safe for you or your children and answered "Yes" to all the questions above, then this device may be right for you! If you decide the risks outweigh the benefits, or that you cannot comply with any of the Contraindications, Warnings or Precautions, you should return your device within the first 30 days of purchase.

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**Warning:** To prevent cross infection, the device is used only by single patient.

**Warning:** Do not dry the device or its accessories with the microwave oven, oven drying, hair dryer, etc.

**Warning:** Do not make the nebulizer and its accessories contact corrosive liquids or gases.

**Warning:** Do not disassemble, repair or change the device in case of leakage or other failures .

**Warning:** The direct plug is considered as the disconnecter of the device. Please do not place the direct plug in a difficultly operation position.

**Warning:** Please be careful about strangulation due to cables and hoses, particularly due to excessive length. Keep this device out of the reach of children.



**WARNING – TO REDUCE THE RISK OF ELECTRIC SHOCK THAT MAY CAUSE SERIOUS INJURY OR DEATH:**

**Do NOT** use or store the device in humid locations, such as a bathroom, use the device within the operating temperature and humidity.

**Do NOT** operate the device or contact the Adapter socket or power switch with wet hands.

**Do NOT** immerse the Main Unit in water or other liquid.



**Never Open FL800 Intelligent Mesh Nebulizer !**

**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.

**Do Not** Install the Main Unit around the power lines.

**Do Not** Operate the device near the heating device or open fire.

**Do Not** Use the device before cleaning and disinfecting.

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### Important Safety Information



**Important Safety Information - Read Before Use!**

- 1) The device is only for single patient use!
- 2) The device cannot be used while charging!



**CONTRAINDICATIONS (Who should never use)**

- 1) The device cannot be applied to anaesthetic breathing systems.
- 2) children must be under adults' supervision while atomizing .
- 3) Pentamidine is not applicable to the device.
- 4) The APP software is not applicable to patients who can't distinguish "inhaling" or "exhaling" by him/herself, or in an emergency situation like Asthma exacerbation.
- 5) The nebulizer shall not be used in any MR environment.

If you are unsure the Device is right for you, contact your doctor please.

Consult your doctor firstly.

Discontinue to use if you encounter any discomfort. You may be allergic to accessories or another condition. Consult your doctor please.



**WARNING – No modification of this device is allowed**

**Warning:** For type or dose of medicine please follow the instructions of your physician and/or licensed healthcare practitioner.

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**Do Not** Use mouthpiece and masks if its package is broken.

**Do Not** Use the device if your hands are wet.

When using the nebulizer, the distance between the device with other wireless equipment should be at least 80cm.

Use the device only for its intended use and as described in its manual.



**PRECAUTIONS-Take the following precautions to avoid minor or moderate injury and damage to your device:**

**Do Not** Use this device if your skin is sensitive to mouthpiece and masks. The mouthpiece and masks meet requirements of CE .

**Do Not** Allow service or maintenance the equipment while used in patient. The patient is an intended operator and can perform the maintenance of the equipment.

If any operator requests more information such as circuit diagrams, parts list and product descriptions, for repairs carried out by qualified technical personnel, please contact manufacturer.

If any emergency happened, move the device off you first, then shut it off and contact the local dealer.

Do not use the nebulizer with any RF emitters, such as RFID, diathermy and security system. It may cause interference to the nebulizer, and the nebulizer's normal functions may be affected or the device may not operate properly.

**Do Not Use if any of the following conditions applies to you:**

- You have an active skin condition in the treatment area including sores, psoriasis, eczema, sunburns, herpes simples, open wounds or a rash.
- You have any other conditions, which in your doctor's opinion would make it unsafe for you to be treated.

**If you are not sure the device is safe for you or not, please consult your doctor.**

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## Safety Features of the Nebulizer

### 1. Additional considerations of using FL800 Intelligent Mesh Nebulizer

This device is approved for human use only.

### 2. Protect your FL800 Intelligent Mesh Nebulizer

- ◆ Please keep Main Unit and Atomizing Cup clean(see chapter 6) to avoid device malfunctions.
- ◆ Keep medicine liquid and mesh completely contacting.
- ◆ Do not rinse or immerse the Main Unit in any liquid.

## How To Use the Nebulizer

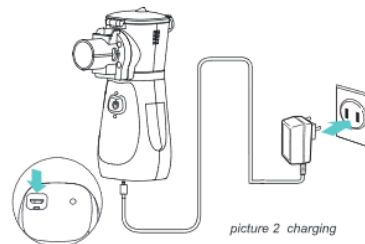
The device is a personal medical equipment. In order to prevent cross infection, the nebulizer is for personal use only. Please clean and disinfect the nebulizer before first and after use. Keep the nebulizer dry after finish using it. See Chapter 6 for more details.

### NOTE !

**Before initial use please charge the nebulizer for minimum ONE hour so that the device can be activated.**

### 1. Power Supply

- ◆ This nebulizer is powered with lithium batteries. The battery can be charged with Adapter (input: 5Vd.c. Min. 1.5A.)
- ◆ Adapter using
  - (1) Connect the nebulizer to Adapter;
  - (2) Connect Adapter to power.



picture 2 charging



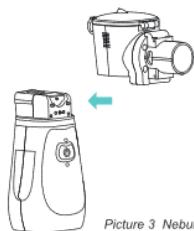
### PRECAUTION:

1. To ensure safe using, the Adapter should meet the electrical safety standard IEC 60601-1.
2. Adapter technical parameter as below :  
Input: 100-240V a.c. 47-63Hz 0.4-0.2A Output: 5Vd.c. 2.4A Max.  
Maximum length of USB cable: 132 cm
3. The battery charging needs about 4h.
4. DO NOT USE THE NEBULIZER WHILE CHARGING. THE NEBULIZER CAN NOT OPERATE WHILE CHARGING. WE DO NOT TAKE RESPONSIBILITIES OF USING CHARGER OR ADAPTER INAPPROPRIATELY.

### 2. Assembly Nebulizer

#### Installation

- (1) Please clean and disinfect nebulizer before first using and after each using, then dry it, see chapter 6 for details.
- (2) Use One hand to hold the Main Unit, the another hand to hold the Atomizing Cup. Push the cup along the slot ,until you hear a "Click" sound. (Picture 3 )



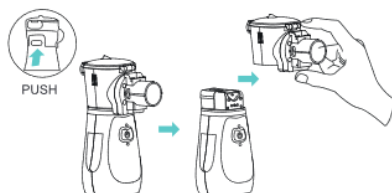
Picture 3 Nebulizer Assembly

### NOTE !

If the Atomizing Cup isn't assembled correctly, the device may not be able to operate normally.

#### Disassembling

To remove the atomizing cup from the main device,press the button at the rear of the main device and push the atomizing cup forward.



### NOTE !

- a. When removing the atomizing cup from the main unit, please check and confirm that the button is pressed, only then push the atomizing cup forward to avoid any damage to the device.
- b. Do not insert any object into the nozzle causing contact with mesh filter, this will damage its lifetime and efficiency.

### 3. Add medicine liquid

- (1) Hold the Main Unit and open Atomizing Cup buckle;
- (2) Add the prescribed medicine into the atomizing cup. Please note: Maximum medicine capacity is 8ml.
- (3) Tighten the Medication Cup cover by closing buckle on rear to prevent leakage.



Picture 4 Add Liquid Medicine

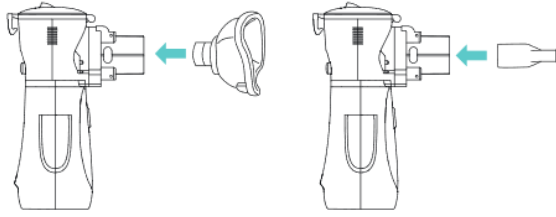
### NOTE !

- (1) After putting medicine liquid in, prevent nebulizer shaking or inverted which may cause the leakage of medicine liquid.
- (2) Remove the USB cable from the electrical outlet before using the device.

### 4. Usage of Nebulizer

Nebulizer Accessories are categorized as mouthpiece, adult mask and child mask. Please choose appropriate accessories according to your needs.

- (1) Attach mouthpiece or facemask as see in Picture 5.
- (2) Enable Bluetooth on your cell phone, and launch the App.



Picture 5 Mask Assembly and Mouthpiece Assembly

- (3) Push ACTIVE/STAND-BY button, the indicator light (Green Light) will light up and the device starts to work. Put the mouthpiece flat end into the mouth, lips slightly closed or take mask slightly close to face, better to cover nose cavity and mouth together.



Picture 6 start to atomize

- (4) Select the button "start"(picture 7) , the App will link to the available Nebulizer device automatically and enter the game interface(picture8). It will show you some directions, and follow them, and you will be able to play the game.After atomizing time is expired, you can check the game scores as picture 9.Press the" back" button on your cell phone or turn off the power button on the nebulizer device ,the game will be terminated and go to picture 9 which could display your scores.

- (5) Keep calm, relax and sit well holding the nebulizer smoothly, take deep and slow breaths and have more effective ,amusing treatment.

- (6) Users can adjust the nebulization rate via Power button or through the APP. Power button:Press and hold the button for 3 seconds during nebulization to adjust the rate until the green and blue indicators flash alternately.Release the button,the nebulization rate is adjusted successfully. APP:Simply click the "Setting" button as see in "picture 7" when you enter the App to choose your desired nebulization rate.

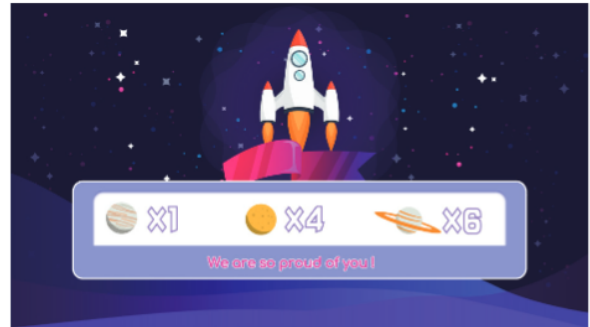
#### NOTE !

Foams are likely to be produced and accumulate near the mesh during operation,which will lead to a decrease of aerosol output and the nebulizer will shut down automatically.In this kind of situation please shake the device slightly or stand the device for a while until the foams disappear and then restart the nebulizer manually.

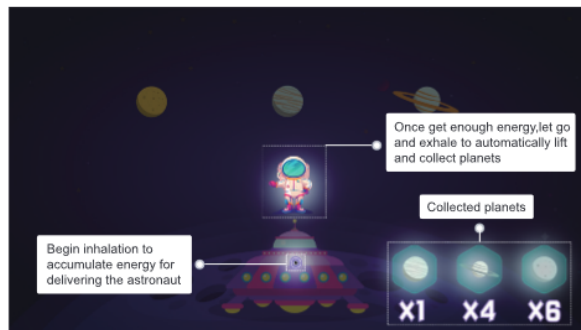
You can download and install App on your mobile phone tablet from the App store or Google play search keyword "iNeb" . If you would like to try the App, you MUST use the mouthpiece to enjoy games.



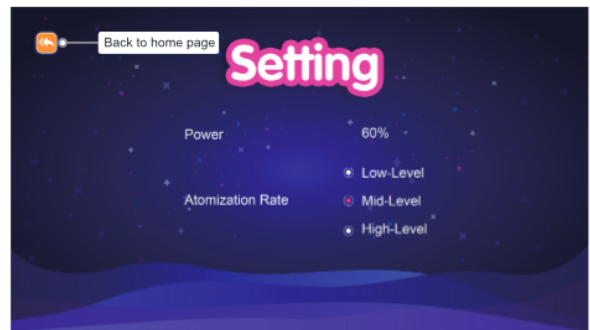
Picture 7



Picture 9



Picture 8



Picture 10

**CAUTION !**

Children must be under adults' supervision while atomizing and playing games.


**NOTE !**

- (1) If this nebulizer is being used to treat a life threatening condition, a backup device is necessary.
- (2) The nebulizer may be unable to be used due to power failure or mechanical malfunction. In order to avoid emergencies such as accidents or acute asthma attacks, it is recommended to have a backup device.

**NOTE !**

- (1) Pls use mouthpiece correctly by tightening, and make sure liquid medication does not go directly to the mouth.
- (2) Slightly tilt the Main Unit toward yourself to immerse the Vibrating Mesh in the medicine while the medication is nearly exhausted.
- (3) When the low battery light (Blue) continues to flash slowly, it means the power is running out, please charge Device as soon as possible.
- (4) The dosage of medication must follow physician's prescribed treatment.
- (5) If you are not interested in the App, please ignore 2), 4) and 6) in Section "4. Usage of Nebulizer". The atomizing function of device is independent of the App software.
- (6) Users cannot start the nebulizer through app, if you want to start it, you should push the ACTIVE/STAND-BY button.

(7) Do not press the two single-way switches (inhalation switch and exhalation switch) on Atomizing cup, which may cause failure of playing games.



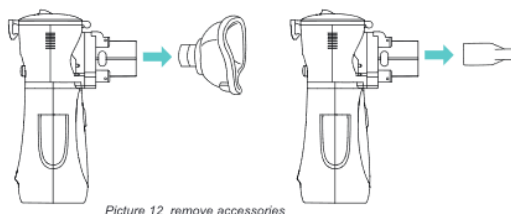
Picture 11

**5. Turn Off The Power**

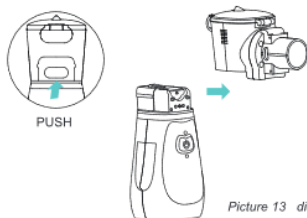
Press the ACTIVE/STAND-BY button to turn off the power, the Power Indicator (Green Light) will go out.

**6. After Using**

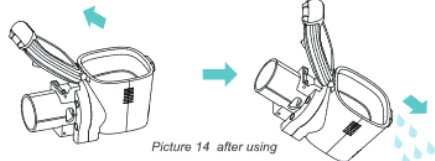
- (1) Remove the mouthpiece or mask



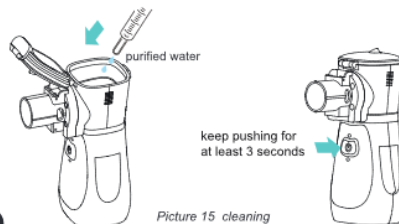
- (2) Hold the Main Unit by one hand, and Press the PUSH button behind the Main Unit. Hold the Atomizing Cup by the other hand, remove the Atomizing Cup along the slot.



- (3) Open the lid, pour all the residual liquid Atomizing Cup, and promptly clean and disinfect the device, allow the parts to air dry and store the device in a clean environment. See Chapters 6 for more information.



- 1.1 As shown in Figure 13, remove the atomizing cup from the nebulizer.
- 1.2 As shown in Figure 14, open the lid of the atomizing cup and pour out the residual liquid.
- 1.3 Add enough purified water (3-6ml) into the atomizing cup, then close the lid tightly. Shake the atomizing cup gently to dissolve the residual liquid in the water and pour out the liquid from the cup.
- 1.4 Re-add enough purified water (3-6ml) into the cup again. Keep pressing the power button for 3 seconds, the green and blue indicator lights will flash alternately. At this time, release the button and the nebulizer will enter cleaning mode. It will work for default time and turn off automatically.
- 1.5 After cleaning, dry the water, then put it in a dry and ventilated place.



**NOTE !**

- (1) Immediately clean the atomizing cup with distilled water after each inhalation.
- (2) Visually inspect the entire atomizing cup for visible dirt. If visible dirt is present, repeat all cleaning steps until device is visually clean.
- (3) It is recommended to pour out any residual liquid after each use to prevent any mesh obstruction.
- (4) In order to prevent thermal deformation, boiling water is not recommended.
- (5) DO NOT wipe the atomizing cup with cotton paper or other cloth. This will prevent any residual particles from blocking the mesh enclosure.
- (6) DO NOT touch mesh with fingers, swabs, or any objects to avoid damage.
- (7) DO NOT inhale the medicine in self-cleaning mode.

**Maintenance of the Nebulizer**

- ◆ After each use, discard all residual medication and remove the atomizing cup from the Main unit to clean and disinfect. Air dry the parts immediately after washing.
- ◆ Be sure to turn off the device.
- ◆ Do not store when Main Unit and Atomizing Cup have any remaining liquid or moisture.

**1. Cleaning**

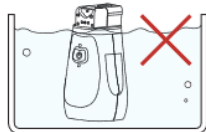
Atomizing cup

**Main unit**

- 2.1 Gently wipe the electrode of main unit and electrode of atomizing cup with a damp gauze and dry it with a new gauze.
- 2.2 Gently wipe the stain on the main unit with a damp gauze and dry it with a new gauze.

**NOTE !**

- (1) DO NOT wipe the device with volatile liquid (e.g. benzene, gasoline, diluent).
- (2) DO NOT touch the electrodes outside the device and the atomizing cup with cotton swab or other things, which would cause the fall out of electrodes.
- (3) DO NOT immerse the main device in any liquid to avoid the damage



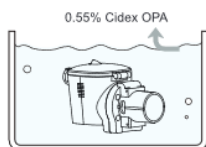
Picture 16 cleaning

**2. Disinfecting**

**Atomizing cup**

- 2.1 After cleaning,immerse the atomizing cup by using the following high-level disinfection:
- 2.2 Clean the atomizing cup and nozzle again in accordance with step 1.3 to 1.5 to avoid disinfectant residue.

Disinfection Agent: Cidex OPA  
 Concentration: 0.55%  
 Contact Type: Soak  
 Time: 5 min  
 Temperature: 20 °C



**2. Storage Instructions:**

- (1) Keep the device out of the reach of unsupervised children.
- (2) Clean and disinfect the device after using. Assemble and store the device in the storage bag or in a clean environment.
- (3) If the device has been storage at low or high temperature, the device needs more than half an hour to adjust, until it is ready for intended use.
- (4) Validity:When atomizing 0.9% sodium chloride solution for 2 times a day, and 15 minutes for each time, 3 years for main unit, 3 months for Atomizing cup. For the battery, the device can be used for approximately 8 days after charging if operating for 30 minutes a day. Lithium battery has 300 charge-discharge cycle. Masks and mouthpiece are single use only, please do not use repeatedly.

**5. Maintenance**

**1.Working Conditions**

- (1) Environment Temperature: 5 °C ~ 40 °C;
- (2) Relative Humidity: 15% ~ 90% R.H No condensation;
- (3) Air Pressure: 70.0 ~ 106.0 kPa;
- (4) Power: DC 3.7V lithium battery.

**2. Maintenance Instructions**

- (1) Operate the device in normal work condition;
- (2) Don't let the Nebulizer and its Accessories contact corrosive liquids or gases.
- (3) Refer to Chapter 7 for solution or contact the company or purchase dealer when the device cannot work.
- (4) Please clean and disinfect the nebulizer as above in this Chapter.
- (5) Please charge the device if you haven't used it for more than six months.

**6. To protect the environment**

The battery is not replaceable by yourself. Do not discard the device including its Accessories (mouthpiece and masks) optionally. You must contact the local authorities to determine the proper method of disposal because they may have potentially bio hazard.

**NOTE !**

- (1) To prevent disinfecting agent to touch skin,please wear rubber gloves.
- (2) Cidex OPA may be irritating to the respiratory tract and eyes, please use Cidex OPA media in a well-ventilated area.
- (3) Use medical gauze and medical cotton swabs to clean and disinfect.
- (4) Do not wipe the mesh with tissue paper or other cloth, otherwise the mesh will not nebulize normally.
- (5) Do not wipe or touch the mesh with your hand or any other sharp object.
- (6) Do not use other household bleach to clean the device in addition to the above solution.

**NOTE !**

It is recommended to change a new atomizing cup after about 3 months using (2 times a day,15min per time) for better treatment effects.

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

Discard the mouthpiece and mask after using to ensure the safety of your usage. The masks and mouthpiece FaceLake provides are disposable.If you plan to use mask and mouthpiece provided by other manufacturers,please follow the instructions for cleaning and disinfection provided by them. (The inner diameters of mask and mouthpiece are 20mm)

**4.Storage and transport**

**1. Storage and transport Conditions:**

- (1) Temperature: -25 °C ~ 70 °C;
- (2) Relative Humidity: ≤90% R.H.
- (3) Air Pressure: 70.0 ~ 106.0 kPa;
- (4) Other requirements: No direct sunlight, Ventilation, No corrosive gas, No heating device, or Open fire.

**Troubleshooting**

If you ever run into problems while using the device, please find solutions in the following table 2.

PROBLEM	CAUTION	SOLUTION
Cannot turn on	1.The battery is very low 2.The equipment is damaged 3.There are stains on metal contact points of nebulizer in contact with the Atomizing Cup	1.Pls recharge in time 2.Pls contact the authorized service center or manufacturer. 3.Clean the metal contact points of nebulizer and try again.
No mist	1.The device and atomizing cup are not correctly assembled. 2.The drug produces too much bubble. 3.The mesh plate is clogging. 4.The equipment is damaged.	1.Correct the device by pressing back button,releasing,and introduce the atomizing cup once again untile hear a "click". 2.Shake the device slightly or stand the device for a while until the foams disappear and then restart the nebulizer manually. 3.Clean the device by introducing water to atomizing cup,push "NO" button for 3 seconds,and leave device for self-wash. 4.Pls connect the authorized service center or manufacturer.
The device is on but weak	1.Battery has low electricity. 2.The mesh plate is clogging. 3.The medicine is not fit for this nebulizer. 4.The mesh plate in the atomizing cup is damaged. 5.The metal contacting point between atomizing cup and main unit is not clean.	1.Pls recharge in time 2.Clean the device by introducing water to atomizing cup,push "NO" button for 3 seconds,and leave device for self-wash. 3.The liquid medicine is unfit for this equipment,pls consult a doctor. 4.Pls contact the authorized service center or manufacturer 5.Clean the contact points and start

Table 2 Troubleshooting

PROBLEM	CAUTION	SOLUTION
Indicate light is blue	The battery is low.	Pls recharge in time
Which kind of medicine is suitable for atomization	Consult your doctor	Only use under guidance of doctor's prescription.
Mouthpiece ponding	Condensed into water droplets which is obstructing the mist.	Remove the mouthpiece and pour out all liquid.
Should everyone use their own Accessories	It must avoid cross infection	Everyone must use their Accessories by themselves.
Liquid medicine in the Atomizing Cup is leaking	Atomizing Cup is broken or plastic aging	Replace of new Atomizing Cup before filling the medicine
Noise become louder when the liquid is running out	The mesh plate vibrates without load while the liquid is running out.	Normal phenomenon
Can not turn on/off the device	1. The lithium battery is not enough electricity 2. The device gets stuck	1. Pls recharge in time. 2. Poke the button(power off) beside the USB interface with something poignant.
The device can not turn off by itself when the drug is exhausted	1. Some bubble produced by drug is left in the cup. 2. Atomizing cup failure. 3. There is drug/water left or stains on the electrode.	1. Press the ACTIVE/STAND-BY button and clear the bubble. 2. Pls contact the authorized service center or manufacturer 3. Press the ACTIVE/STAND-BY button and clear the electrode.

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

### Customer Service

If your FL800 intelligent mesh nebulizer is broken/damaged and need to repair or any other user assistance, please contact intelligent mesh nebulizer Customer Service:

Contact information:  
 LORTE TECHNOLOGIES INC.  
 1616 Barclay Blvd.  
 Buffalo Grove, IL 60089 USA  
 FaceLake.com  
 Tel:847-234-0754  
 Email: cs@facelake.com

### Quality Assurance

One year warranty for main unit.No warranty for accessories.

The following details are not included in warranty claims:

- ◆ Damages caused by users dropping, soaking the device.
- ◆ Damages caused by not following the correct operating instructions.
- ◆ Damaged by users accident.
- ◆ Due to disassembling and assembling devices without our company's authority.
- ◆ Products Serial No. is teared or can't be recognized
- ◆ No Original Invoice available.

### NOTE !

Take warranty card "Users Page" to contact local dealer 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.

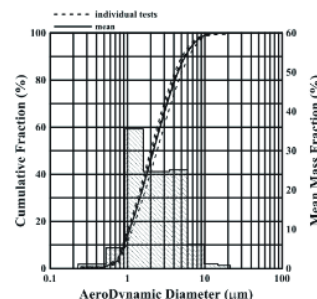
### Product Specifications

Name	Intelligent Mesh Nebulizer
Model	FL800
Dimensions	Approx. 50mm(L)×79mm(W)×111mm(H)
Weight	Approx. 106g
Switching power supply	Input: 100-240Va.c. 47-63Hz 0.4-0.2A Output: 5Vd.c. 2.4A Max.
Power Source	Input: 5Vd.c. 1.5A Min. ZN-103450 Lithium battery: 3.7Vd.c. 1800mAh
Safety Grade	BF, Internally powered equipment
Power Consumption	Approx.6W
Vibration Frequency	Approx.110KHz
Nebulization Rate	0.2ml/min minimum,adjust via App
Medicine Temperature	≤60°C
Working Voice	≤50dB
Particle Size	2.2µm±25%
Medicine Capacity	8ml maximum,0.5ml minimum
Battery Life	the battery can be used for approximately 8 days after charging if operating the device for 30 minutes a day and the battery cycle life is 300 cycles.
rotected against the ingress of water and particulate matter	IP22

Table3 Product Specifications

Guarantee Time	Main Unit 1 Year( Atomizing Cup is not included)
Operating Temperature	Environmental temp:5 °C~40°C, Relative humidity : 15~90% RH, not in Coagulation situation Air Pressure: (70.0~106.0)kPa
Storage and transport Temperature	Environmental temperature: -25°C~70°C Relative Humidity: ≤90%R.H. Air Pressure: (70.0~106.0)kPa
Accessory	Mouthpiece, adult Mask, child Mask, Instruction Manual

Aerosol particle equivalent volume (Picture 11)



Picture 17 Aerosol Particle Equivalent Volume

### NOTE !

- (1) It was tested by Pulmicort under the condition of temperature 24±2°C, humidity 45-75%R.H, Pressure: from 86 kpa to 106 kpa.
- (2) MMAD (µm): 2.2µm ±25%  
 Respirable fraction (% , 0.5-5 µm) : ≥ 80%  
 Aerosol output rate (ml/min) : 0.24 ± 0.02 ml/min



## Electromagnetic Compatibility

- Do not use the device in the direct vicinity of short-wave or microwave equipment.
- Do not connect this equipment to other equipment, consult your physician for users wearing the heart pacemaker.

### 1. Electromagnetic Compatibility

The FL800 Intelligent Mesh Nebulizer has been tested and found to comply with the limits for medical devices in IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. If other devices cause harmful interference to this device, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate this device.
- Increase the separation between the interference equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer for help.

**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 [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Guidance and manufacturer's declaration – electromagnetic emission – for all EQUIPMENT AND SYSTEMS

Guidance and manufacturer's declaration – electromagnetic emission		
The FL800 Intelligent Mesh Nebulizer is intended for use in the electromagnetic environment specified below. The customer or the user of the FL800 Intelligent Mesh Nebulizer should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR11	Group 1	The Intelligent 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 CISPR11	Class B	The Intelligent 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	N/A	
Voltage fluctuations flicker emissions IEC 61000-3-3	N/A	

Table 4 Guidance and manufacturer's declaration-electromagnetic emissions

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

Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT AND SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity			
The FL800 Intelligent Mesh Nebulizer is intended for use in the electromagnetic environment specified below. The customer or the user of the FL800 Intelligent Mesh Nebulizer should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 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 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	0% UT; 0.5 cycle At 0°/45°/90°/135°/180°/225°/270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0° 0% UT; 250/300 cycle	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Intelligent Mesh Nebulizer requires continued operation during power mains interruptions, it is recommended that the Intelligent Mesh Nebulizer be powered from an uninterruptible power supply or a battery.

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a. c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity –for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity			
The FL800 Intelligent Mesh Nebulizer is intended for use in the electromagnetic environment specified below. The customer or the user of the FL800 Intelligent Mesh Nebulizer should assure that it is used in such an environment.			
Immunity test	EN 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3V rms 150kHz to 80MHz 6V in ISM bands between 0.15MHz and 80 MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the Intelligent Mesh Nebulizer ,including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter  Recommended separation distance  $d=[3.5\sqrt{P}]\sqrt{f}$

Immunity test	EN 60601 test level	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	10V/m 80MHz to 2.7GHz	10V/m 80MHz to 2.7GHz	$d=[3.5/E1]\sqrt{P}$  $d=[7\sqrt{P}]\sqrt{f}$  where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.  Interference may occur in the vicinity of equipment marked with the following symbol:  NOTE1:At 80 MHz and 800 MHz, the higher frequency range applies. NOTE2:These guidelines may not apply in all situations. Electromagnetic 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 Intelligent Mesh Nebulizer is used exceeds the applicable RF compliance level above, The Intelligent Mesh Nebulizer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Intelligent Mesh Nebulizer. b.Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM -for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the FL800 Intelligent Mesh Nebulizer			
The FL800 Intelligent Mesh Nebulizer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the FL800 Intelligent Mesh Nebulizer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the FL800Intelligent Mesh Nebulizer as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output of transmitter(W)	Separation distance according to frequency of transmitter(m)		
	150kHz to 80MHz $d=[3.5\sqrt{P}]\sqrt{f}$	80MHz to 800MHz $d=[3.5/E1]\sqrt{P}$	80MHz to 2.7GHz $d=[7\sqrt{P}]\sqrt{f}$
0.01	/	0.035	0.07
0.1	/	0.11	0.22
1	/	0.35	0.7
10	/	1.11	2.21
100	/	3.5	7
For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (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 watts (W) according to the transmitter manufacture			

NOTE1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
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Bluetooth Technology Summary

Bluetooth Version	BLE 4.1
RF Frequency	2400 – 2483MHz
Power Output	0dBm
Modulation	GFSK
Expected Use Range	<5m
Need Quality of Service	Nebulizer Service
Security Measures	AES128
Minimum separation distance	80cm

## 2. Notes on FCC certification

This device has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This device generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this device does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-Reorient or relocate the receiving antenna.

-Increase the separation between the equipment and receiver.

-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-Consult the dealer or an experienced for help.










This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the device.

## Marks and Symbols

### 1. Marks and Symbols

	CE mark		Serial number
	Separate collection		Manufacturer
	See the Instruction	IP22	Waterproofing Grade
	BF type application part		MR Unsafe
	Notice		Non-ionizing radiation