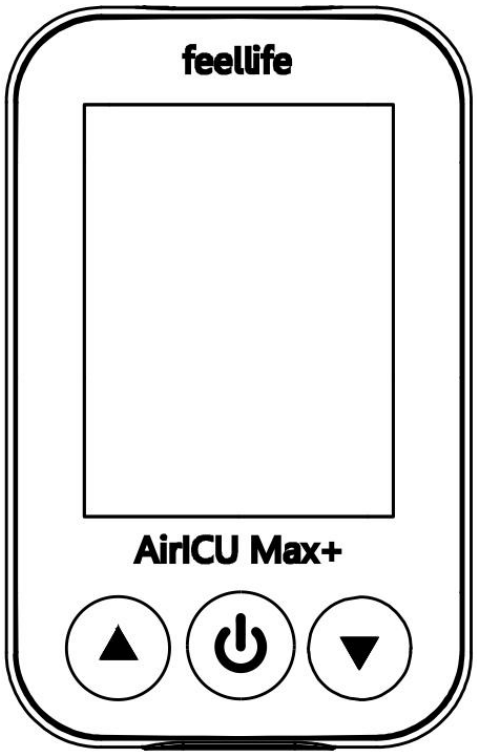
feellife

MD

User manual for Medical Mesh Nebulizer

Model: AirICU Max+



Doc: LFS-EN-UM-25F
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Rev.: A/0

Table of Contents

- Thank you very much for purchasing this Medical Mesh Nebulizer.
- Be sure to read this user manual carefully before using this device, so that you can use it safely and correctly.
- Please keep this instruction for use in a place where convenient for reading at any time.
- The illustrations in this instruction for use are schematic diagrams.
- This user manual is available in English.

1. Intended Use and Indications for Use

1.1 Intended use

The AirICU Max+ is a portable medical device for single patient use that is intended to aerosolize physician-prescribed solutions for inhalation to patients on and off ventilation or other positive pressure breathing assistance.

The Aerotank Kits is an accessory to The AirICU Max+. It facilitates intermittent and continuous nebulization and optional supply of supplemental Oxygen to pediatric (29 days or older) and adult patients in hospital use environments via a mouthpiece or aerosol mask. If supplemental oxygen is used, for pediatric patients under 18 years of age, a maximum flow rate of 2 LPM should be used.

Note: The mouthpiece should not be used for children under 5 years of age.

1.2 Indications for use

The AirICU Max+ is a portable medical device for single patient use that is intended to aerosolize physician-prescribed solutions for inhalation to patients on and off ventilation or other positive pressure breathing assistance.

The AirICU Max+ is suitable for use in pediatric (29 days or older) and adult patients.It is intended for hospital use only to nebulize physician-prescribed medications for inhalation which are approved for use with a general purpose nebulizer.

The Accessories are for single patient use only and the Main unit is for re-use.

2. Working Principle

The working principle of the atomizer is driven by the rapid oscillation of the circuit, the piezoelectric ceramic in resonance oscillation can slice, thus promote rapid oscillation microporous Aimesh, make solution through tiny mesh and Aimesh was rejected by the rapid, forming numerous tiny atomized particles and enters the patient's respiratory system through the nebulizer mask, the mouth bite, or the extended line between the applied parts to achieve the purpose of inhalation treatment. The respiratory system is an open system, after the liquid medicine is atomized into particles, the patient inhales the drug mist, the drug mist can be directly adsorbed and deposited in the patient's mouth,

throat, trachea, bronchus, alveoli and other places, through the mucosa and other tissues absorption to achieve the purpose of treatment.

3. Contraindications

None.

4. Important Safety Notes

1) For the type, dose, and regimen of the medication, be sure to follow the instructions of a doctor.

2) Operate the device only as the intended use which is mentioned in this instructions for use.

3) Do not use the device for any other purpose.

4) Inspect all parts before use, and do not use if any parts are missing, cracked or damaged. In case of missing parts,malfunction or damage, contact the after-sales service unit.

5) Read and study all instructions before using the AirICU Max+ System and accessories. Only trained medical personnel should operate the device.

Nursing staff and users should ensure to operate this device according to the correct operation requirements. Those who are not able to operate, please put it into use after attending the training or reading the manual in detail.

5. Package Contents and Overview

5.1 AirICU Max+ are composed of the Main Unit,Medication Cup, T-Piece, Aerotank Kits,Air Flow Sensor, Medical Power Supply,Type-C Cable, USB Cable,Support Frame Component,etc.

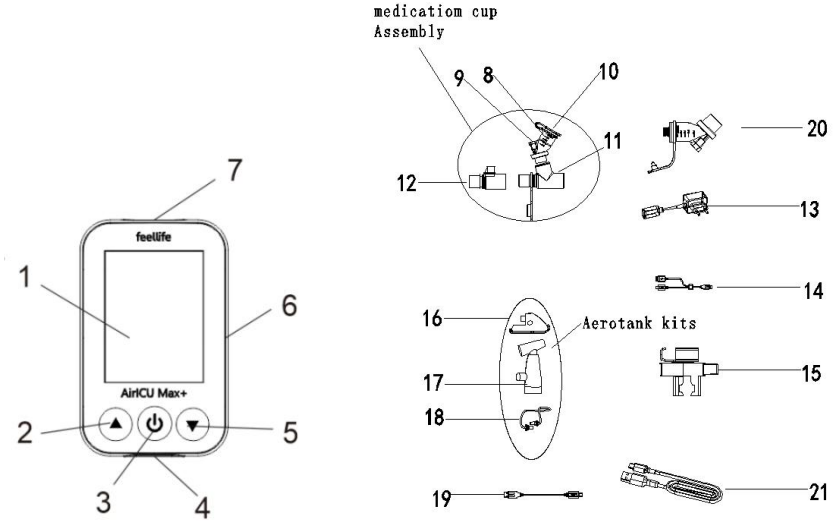
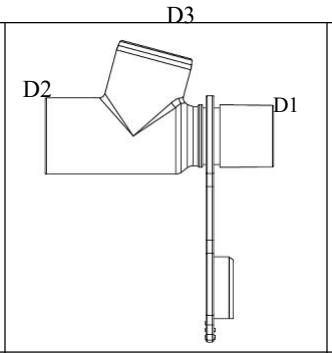
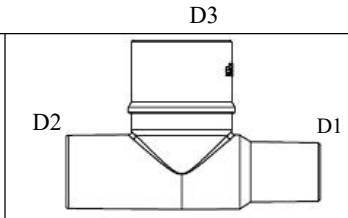
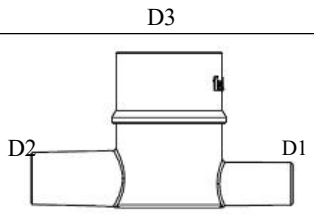


Figure 1. Product Contents

1	Display	12	Air flow sensor
2	Previous step	13	Medical Power Supply
3	Stand-by	14	USB cable (Y-type)
4	Charging interface	15	Support frame component
5	Next steps	16	Nebulizer mask(Adult and Child are for optional)
6	Main unit	17	Aerotank(With a mouthpiece)
7	USB Interface	18	Oxygen tube
8	Mediation cup (10 mL max)	19	USB cable (Linear type)
9	PIN connector	20	Mediation cup (10 mL max，Type of thread)
10	Medication cup cover	21	Type-C cable
11	Adult T-Piece (With the rubber plug)	/	/

Item			
Name	Adult T-Piece(With the rubber plug)	Child T-Piece	Infant T-Piece
Model	ICU TP1	ICU TP2	ICU TP3
D1	ϕ22mm （External diameter）	ϕ15mm （External diameter）	ϕ10mm （External diameter）
D2	ϕ22mm （Inner diameter）	ϕ15mm （Inner diameter）	ϕ12mm （External diameter）
D3	ϕ22.5mm （Inner diameter）	ϕ22.5mm （Inner diameter）	ϕ22.5mm （Inner diameter）

Name	Model	Specification
Aerotank Kits	ICU AT L6	Aerotank (110 mL max) Mouthpiece Oxygen tube Nebulizer Mask (Adult)
	ICU AT S6	Aerotank (110 mL max) Mouthpiece Oxygen tube

		Nebulizer Mask (Child)
Medication Cup	MAICU Pro3	10 mL (max)
Medication Cup	MAICU Pro4	10 mL (max)，Type of thread
Air Flow Sensor	ICU A1	ф27.5mm Length:67.3mm

Note:

There are 3 kinds of T-Piece and 2 kinds of Nebulizer Mask for you to choose.Please choose one which is suitable for the patient.

Medication Cup,T-Piece,Aerotank Kits,USB Cable,Air Flow Sensor are sold separately. Please contact your distributor for full parts list.

5.2 Functions of each component

Product components	Functions
Main Unit	Control the working state and mode of medical mesh nebulizer
Medication Cup（With the rubber plug）	Aerosolized particles are produced by vibration
Medication Cup（Type of threa， With the rubber plug）	Aerosolized particles are produced by vibration
Air Flow Sensor	The breath airflow regulates the fog discharge of medical mesh nebulizer
Aerotank	Storage aerosol
Oxygen tube	Oxygen Delivery
Mouthpiece	Inhale aerosol through the mouth
Adult T-Piece （With the rubber plug）	Connect the tube , humidifier or breathing sensor of the ventilator and the Medication Cup
Pediatric T-Piece	Connect the tube to the ventilator and the Medication Cup
Infant T-Piece	Connect the tube to the ventilator and the Medication Cup
USB Cable (Y-type)	Power Medication Cup and Air Flow Sensor
USB Cable (Linear type)	Power Medication Cup
Support Frame Component	Fixed host
Medical Power Supply	Charging Main Unit with the Type-C cable
Type-C cable	Charging Main Unit with the Medical Power Supply
Adult Nebulizer Mask	For adults to inhale aerosol through the mouth
Child Nebulizer Mask	For children to inhale aerosol through the mouth
1. Installation confirmation: 2. 1.Confirm that the link of each pipeline is firm and not loose. 3. 2.When the medication cup is connected with the humidifier and Aerotank, the center surface of the medication cup should be in the same plane as the center surface of the humidifier and Aerotank, and the medication cup side up. 3.When necessary, the rubber plug should cover the medication cup tightly.	

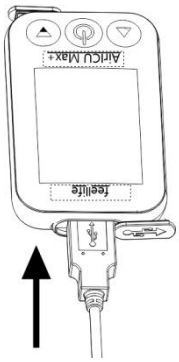
6. Product Technical Parameters

Product name	Medical Mesh Nebulizer
Model	AirICU Max+

Power source	Adapter: I/P: 100-240V~, 50/60Hz, 0.4A MAX O/P: 5.0V 2.5A Main unit: I/P: 5.0V 2.5A 3.7V/1000 mAh, 3.7Wh rechargeable Li-ion battery
Power consumption	3.7 Wh
Nebulization rate	Low: 0.15-0.60 ml/min Middle: 0.25-0.80 ml/min High: 0.35-0.90 ml/min
MMAD	＜5 μm
Medication cup capacity	10 mL (max)
Vibration Frequency	130 kHz±10%
Weight	71 g
Dimension(mm)	Length ： 86 mm Width ： 54mm Height ： 18 mm
Working environment	Temperature: +5℃ ~ +40℃ Relative Humidity: 15%~80% R.H.Non-condensing Atmospheric Pressure: 86 kPa ~ 106 kPa
Storage/delivery environment	Temperature: -20℃ ~ +55℃ Relative Humidity: 10% ~ 93% R.H.Non-condensing Atmospheric Pressure: 70kPa ~ 106kPa
Time auto-off	Power on, the working time is set to 45 minutes or 90 minutes, after the work of the set time automatically stop.
Applied part classified	The classified of applied part is BF.
The material of the applied part	Mask:PVC Mouthpiece:PP
Expect service life	Main Unit:5 years Medication Cup,T-Piece(including adult,child and infant),Air Flow Sensor: ·28 days (in intermittent use,4 treatments per day) ·7 days(continuous use) Aerotank Kits: ·20 treatments (in intermittent use,which is based upon a typical usage profile of four 3ml doses per day over 5 days, with an average treatment time of 9 minutes.) ·3 hours (in continuous use)
Shelf life	Main Unit:5 years Mediation Cup:2 years T-Piece(including adult,child and infant):2 years Aerotank Kits:2 years Air Flow Sensor:2 years

7. Installation and User Instructions

7.1 Connection of nebulizer with adapter and USB cable



USB cable connection interface

Adapter connection interface

Figure 2. Connection of nebulizer with Adapter and USB Cable

Note:The Main unit will have a audible alarm,when the USB cable not connect tightly with the Main unit.

7.2 Nebulization liquid Injection

7.2.1 Medication Cup（MAICU Pro3）

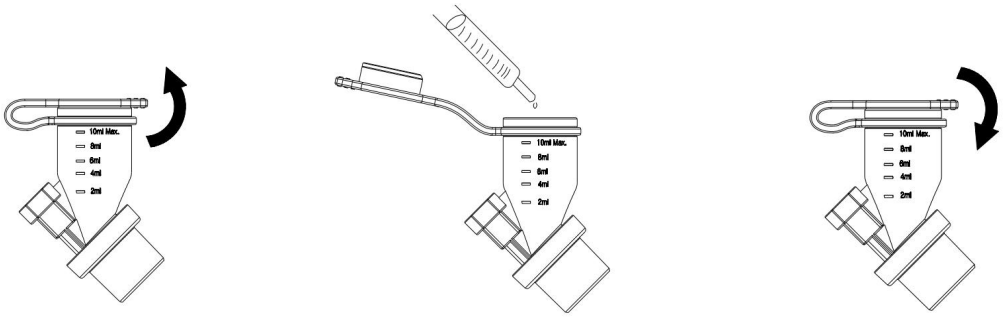


Figure 3. Add medicine liquid

Step 1:Open the medication cover and add medicine (at least 2ml, less than 10ml).

Step 2:Cover the lip of the medication cup.

7.2.2 Medication Cup（MAICU Pro4）

Continuous infusion of liquid medication for aerosolization

Syringe component（not supplied by feellife）

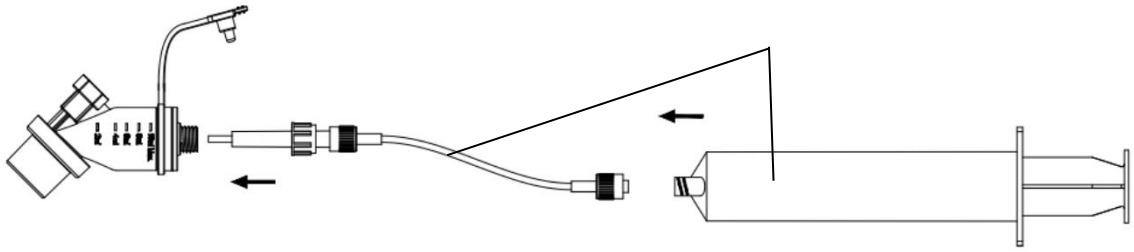


Figure 4. Add medicine liquid

Step 1:Open the medication cover .

Step 2:Connect the Medication Cup and Syringe component according to Figure 4.

Warning:

1) Follow the doctor's advice to inject medication,do not exceed the maximum capacity of the medication cup.

2) After injecting the medication, please be careful not to overflow.

3) Do not touch the electrical contact point or center area of the disc.

4) When injecting, inhalation solution cannot touch the USB port. We recommend that you use a syringe without a needle to add medication.

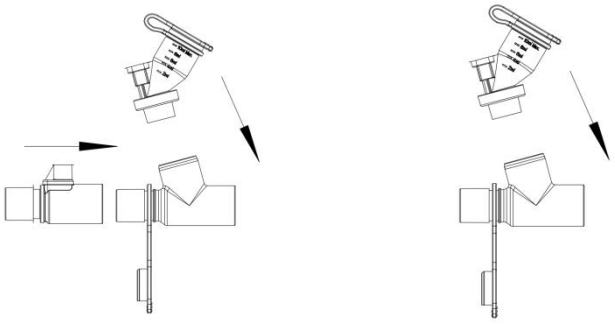
5) Please always keep the medicine cup upright so that the liquid can fully touches the Aimesh.

6) Use of the AirICU Max+ during the administration of volatile anesthetics may result in adverse effects on the constituent plastics. Do not use with volatile anesthetics unless known to be compatible. FEELLIFE have determined that, using anesthetic ventilators, the following volatile anesthetic agents are compatible under the stated conditions below:

Anesthetic Agent	Proprietary Name	Maximum Percentage of Anesthetic	Maximum Duration of Exposure
Isoflurane	FORANE®	3.5 %	12 hours
Sevoflurane	SEVOFLURANE®	8 %	12 hours
Desflurane	SUPRANE®	10 %	12 hours

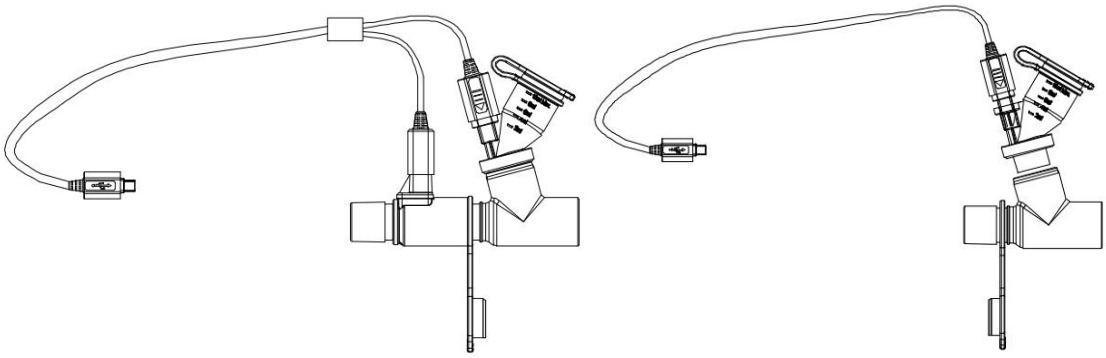
7.3 Three usage ways of AirICU Max+（The two kinds of medication cup are connected in the same way）

7.3.1 AirICU Max+ use with ventilator



① Connection of Air Flow Sensor ② Air Flow Sensor is not connected

Figure 5. Connection of T-Piece, Medication Cup



① Connection of Air Flow Sensor ② Air Flow Sensor is not connected

Figure 6. Connection of USB Cable (two ways)

1) Keep the T-Piece on the horizontal line and insert the Medication Cup to T-Piece.

2) Connect the USB cable to the Medication Cup and Air Flow Sensor.Whether connection of Air Flow Sensor,the device can work normally.Y type USB cable can be used in two modes, connecting and not connecting Air Flow Sensor. Linear Type USB Cable is only applicable to the mode where Air Flow Sensor is not connected.

3) For 22 mm adult breathing circuits connect the nebulizer with Adult T-Piece into the inspiratory limb of the breathing circuit before the patient Y (Figure 7).

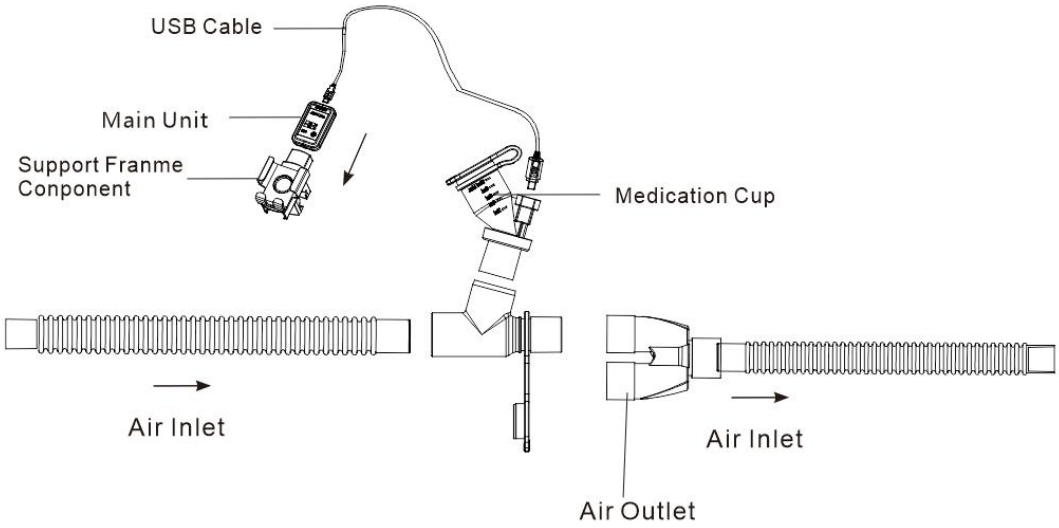


Figure 7. Connecting the T-Piece to an adult breathing circuit

4) Air Flow Sensor can be connected just as the following graphic.

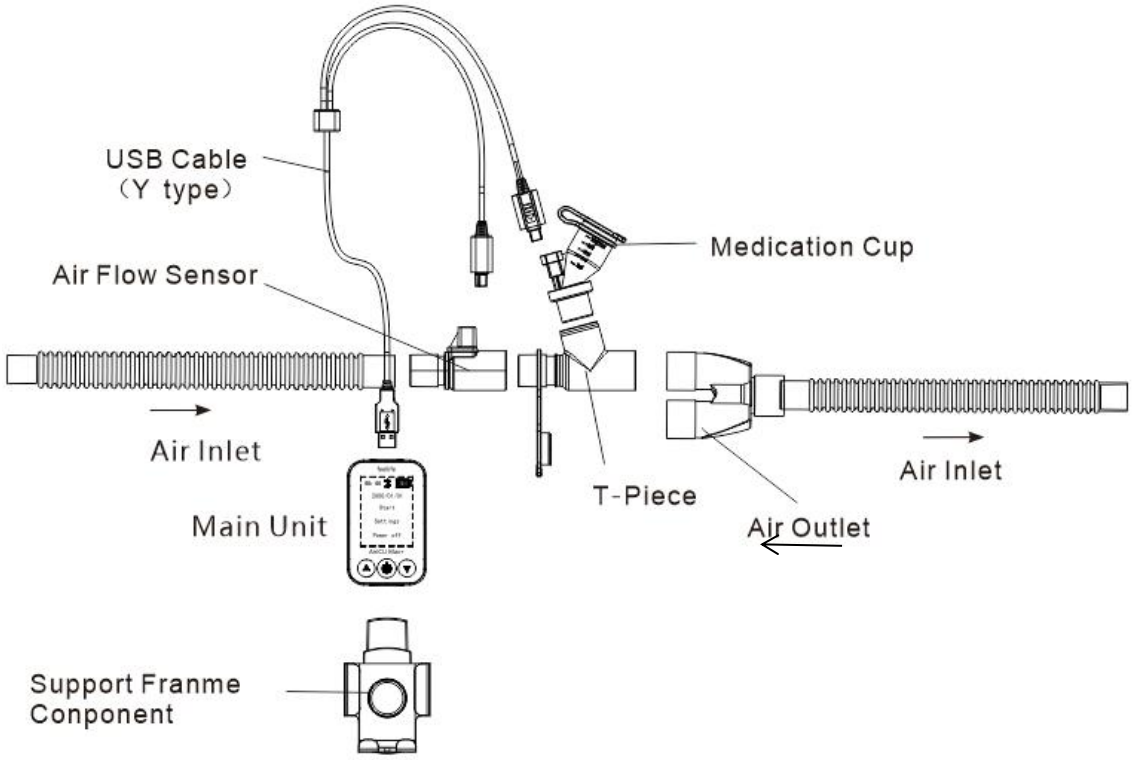


Figure 8. Connecting the T-Piece to an adult breathing circuit (including Air Flow Sensor)

5) The Air Flow Sensor just can be used in 22 mm adult breathing circuits,do not support 15 mm and 10 mm pediatric breathing circuits.

6) For 15 mm pediatric breathing circuits connect the nebulizer with the Child T-Piece into the inspiratory limb of the breathing circuit before the patient Y, as shown for the Adult T-Piece in Figure 9.

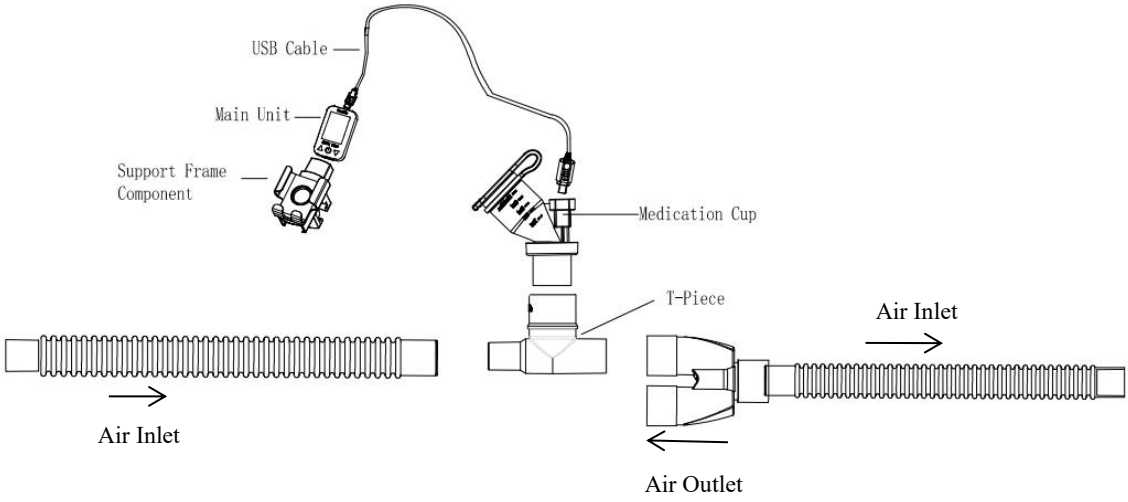


Figure 9. Connecting the T-Piece to a pediatric breathing circuit

7) The T-Piece can connect to 10 mm pediatric breathing circuits with the 10 mm Infant T-Piece. This can be positioned approximately 30cm (12 in.) back from the patient Y,as shown in Figure 10.

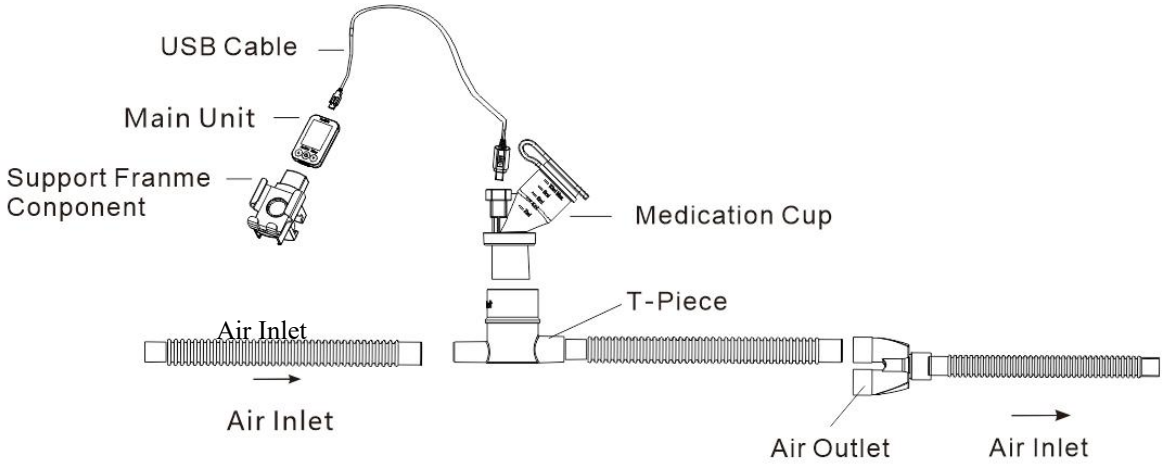
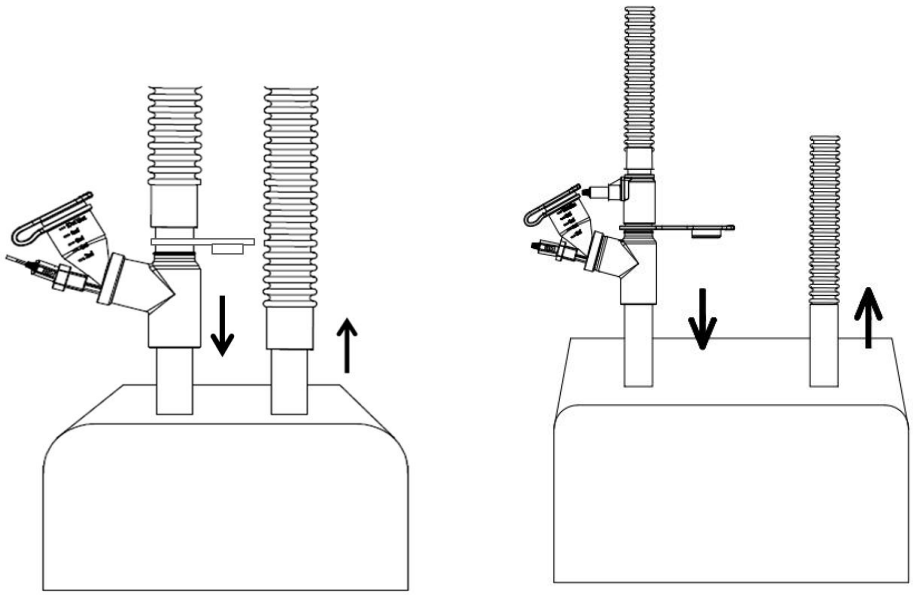


Figure 10. Connecting to a Infant breathing circuit

8) The T-Piece can be placed between the ventilator and the dry side of the humidifier. The Rubber Plug of the Adult T-piece can be take off when it is used in this situation. Figure 10 illustrates a set up for the T-Piece at the dry side of the humidifier. The T-Piece can be used with a nasal interface in this configuration.



① Air Flow Sensor is not connected ② Connection of Air Flow Sensor

Figure 11. T-Piece on dry side of humidifier

Warning:

1) Please connect breathing hose with the Medication Cup Assembly.For more detailed information please refer to the user manual of the ventilator.

2) Where a standard equipment mount is available,use the Support Frame Component to support the main unit.

3) The Medication Cup Assembly is translucent to allow visual monitoring of medication levels and aerosolization.

4) The operator should switch to the corresponding mode according to the patient condition.The operator cannot be the patient.

5) Ensure that the total combined volume of the nebulizer and T-sheet is appropriate for the tidal volume delivered and does not increase dead space and adversely affect the patient's ventilation parameters.

6) Do not use a filter or heat-moisture exchanger (HME) between the nebulizer and patient airway.

7) Condensate can collect and block ventilator circuit.Always position ventilator circuits so that fluid condensate drains away.

8) To avoid exhaled medication affecting the ventilator, follow ventilator manufacturer's recommendations for use of a bacterial filter in the expiratory limb of a breathing circuit. Always connect a bacteria filter to the expiratory inlet of the ventilator.Otherwise the function of the expiratory channel may be degraded.

9) Keep the device as vertical as possible during the operation.This orientation prevents

condensate from blocking the disc and ensures proper nebulization.Visually inspect the nebulizer prior to placing in the ventilator circuit to assure that no impurities are blocking the pipe during nebulization.

10) The ventilator is not supplied by FEELLIFE. The image of the ventilator has been included for demonstration purposes. It is the responsibility of the clinician to determine if a ventilator is required and the type of ventilator selected for use (Viral/Bacterial) in conjunction with the AirICU Max+.

7.3.2 AirICU Max+ use with T-Piece

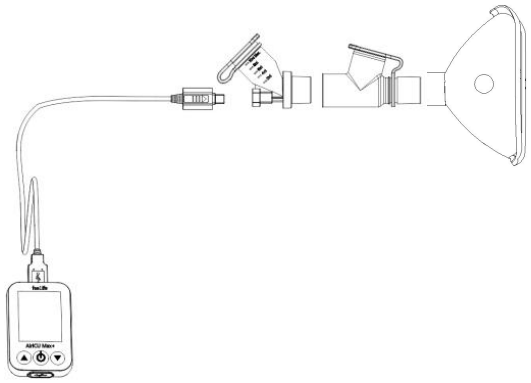


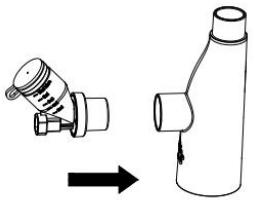
Figure 12.Installation of Medication Cup,Mask, USB Cable and Main Unit

1) Install the nebulizer components correctly according to Figure 12.
2) Cover the lid of the T-Piece.
3) Install the mask on the other side of T-Piece.(The Mask is not supplied by FEELLIFE.)
4) For atomization.The operator can be the patient.

This type of use is only suitable for adults.

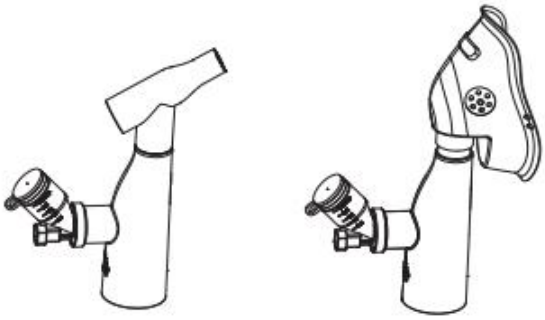
7.3.3 AirICU Max+ use with Aerotank Kits

The installation and user instructions of Aerotank Kits refer to the following.
Step 1 Connect with the medication cup

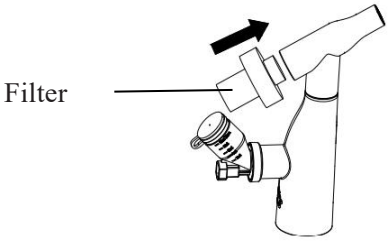


Step 2 Connect with the Oxygen tube (if applicable)

Step 3 Use with the mouthpiece or the mask

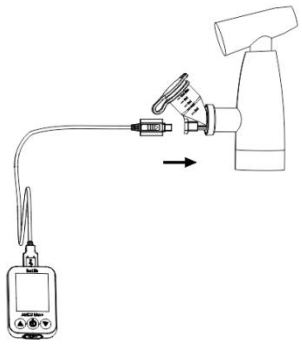


Step 4 Insert according to arrow

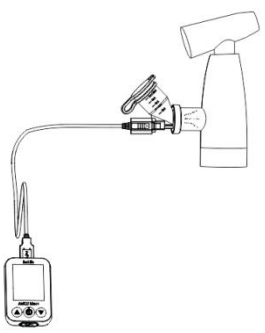


Note: The filter is not supplied by FEELLIFE.

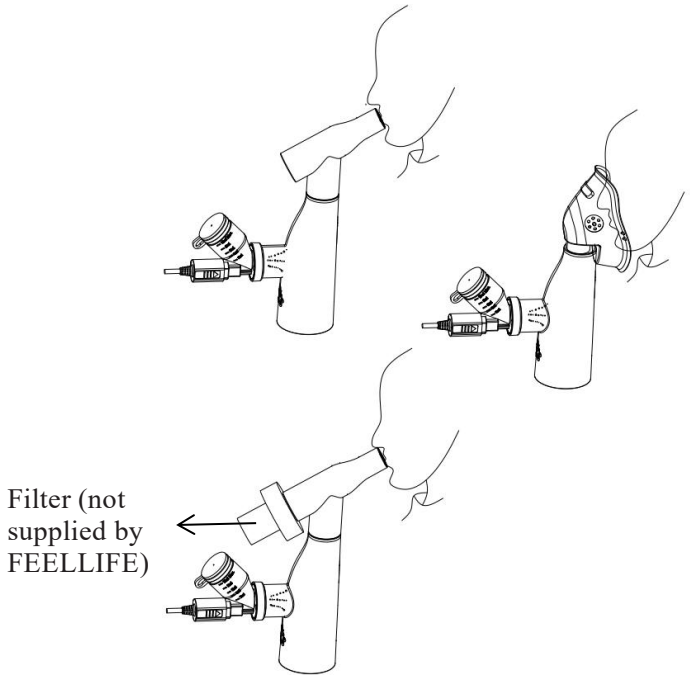
Step 5 Connect with USB cable



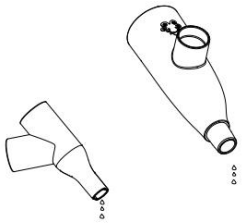
Step 6 Power on



Step 7 Inhalation



Step 8 Pour off the residual medication



• Aerotank Kits are accessories specific to the AirICU Max+.

1) It facilitates intermittent and continuous nebulization and optional supply of supplemental oxygen to pediatric (29 days or older) and adult patients in hospital use environments via mouthpiece or mask. If supplemental oxygen is used, for pediatric patients under 18 years of age, a maximum flow rate of 2 LPM should be used.

Note: The mouthpiece should not be used for children under 5 years of age.

2) Aerotank Kits are for spontaneous and conscious breathing patients only.

3) The Aerotank Kits are non-sterile.

4) The filter is not supplied by FEELLIFE.The image of the filter has been included for demonstration purposes.It is the responsibility of the clinician to determine if a filter is required and the type of filter selected for use (Viral/Bacterial) in conjunction with the Aerotank.

5) When selecting a filter for the attachment of the mouthpiece,we recommend using a filter with a minimum efficiency rating of 99.9% (Bacterial) or 99.8% (Viral).

6) If using the mouthpiece in conjunction with a filter, refer to the filter manufacturer’s

Instructions for Use for information including filter disposal.

7) For disposal of the Aerotank Kits,please refer to hospital or institutional protocol.

8) Aerotank Kits are designed to a single patient use.

9) Optimal aerosol delivery is achieved with valved mouthpiece or valved face mask (as supplied) with low/no oxygen flow.

10) The Aerotank Kits is a single patient use device with a validated defined life of:

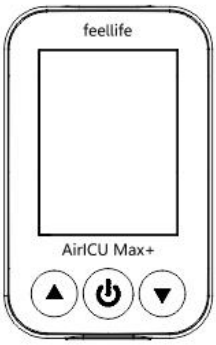
•In intermittent use for a maximum of 20 treatments,which is based upon a typical usage profile of four 3ml doses per day over 5 days, with an average treatment time of 9 minutes.or

•In continuous use, for a maximum of 3 hours.

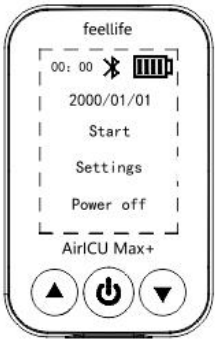
11) Remove excess rainout from the Aerotank periodically (hourly with continuous nebulization). To ensure optimum performance of the Aerotank, remove any residue by rinsing through with sterile water, shake off excess and allow to air dry.

7.3.4 Interface information

1) Main unit

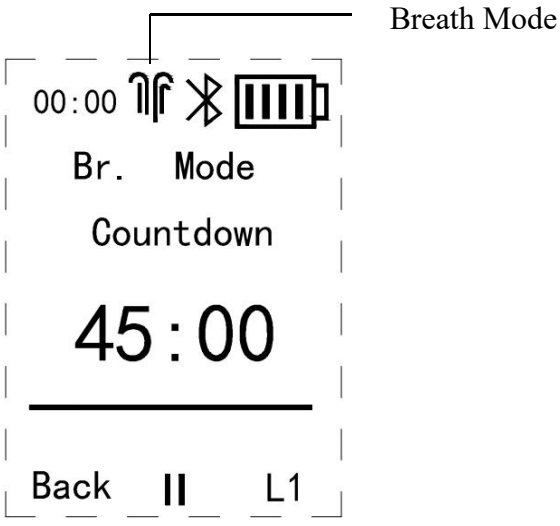


①Shutdown interface

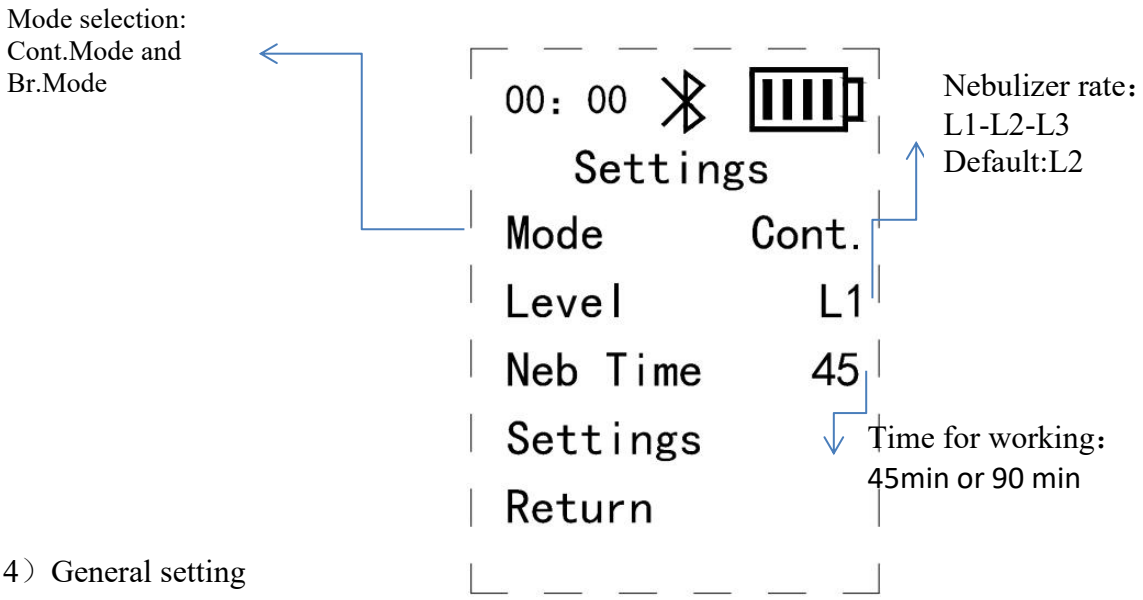


②Startup interface

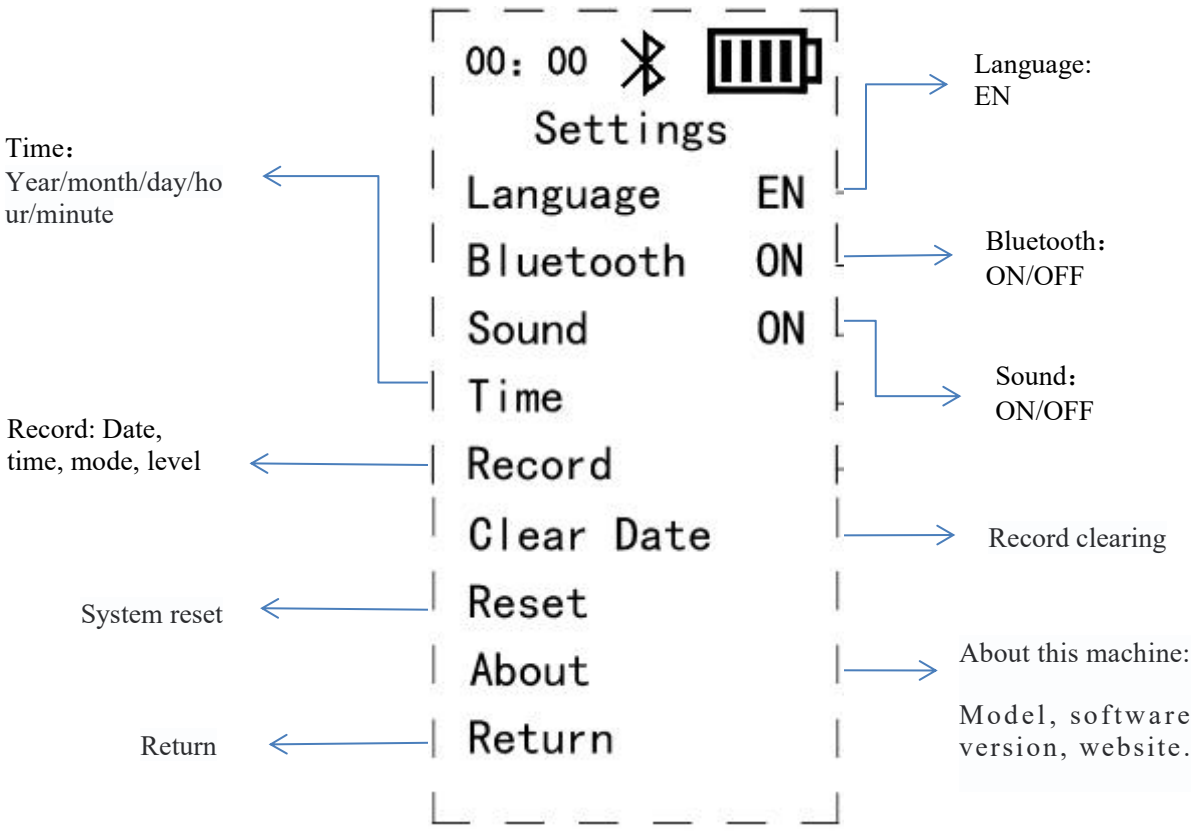
2）Start nebulizing



3）The main interface



4）General setting



7.4 Nebulization

1) The default working mode on startup

- 90 min Continuous nebulization mode.
- level：L2

⚠Note:

The device will automatically remember the last setting mode/gear/time, if you want to restore the factory settings, please click System Reset in the system settings.

2) Level

There are three gears in total. This is the nebulization rate adjustment function. L1 is the minimum rate and L3 is the maximum rate.Adjust the value based on the patient situation.

3) Operation mode

AirICU Max+ has two nebulization modes:

- 45 min or 90 min Continuous nebulization mode（Cont. Mode）.
- 45 min or 90 min Breath nebulization mode（Br. Mode）.

The default mode is 90 min Continuous nebulization mode.

4) Continuous nebulization mode

Long press the power switch(> 2 seconds) to turn on the main unit.It defaults to continuous nebulization mode.The continuous nebulization mode is used to transmit the aerosol to patient continuously.To switch modes, switch in the System Mode selection.

5) Breath nebulization mode

Breath nebulization mode should be used with Air Flow Sensor.

Using Breath nebulization mode is required to observe the following ventilation parameters:

Tidal volume:200-1000 ml

Inspiration/Exspiration:1:2（I:E）

Respiratory frequency:10-30/minutes

⚠Note:

1) Turn on the Main unit firstly,and then turn on the ventilator.If not,the Main unit cannot get into Breath nebulization mode.

2) In Breath nebulization mode, when there is no inhalation into the Air flow sensor, the main unit will shut down after 60 seconds.

3) The Main Unit will turn to continuous nebulization mode when the Main Unit do not get the signal from the Air Flow Sensor through the Y-type cable.

4) In Breath nebulization mode,when the Air flow sensor is not connect tightly,you should click “Start”.You can hear "drip" buzzer alarm continuously and the main unit will prompt “Connectiong Exception”.You can do this to interrupt the alarm and keep the Breath nebulization mode:①Connect the Air flow sensor again.②Press any button (＜1s).

Note:To switch to Breath nebulization mode, operate in the system-mode selection before making sure the Air flow sensor is properly connected.

5）In standby mode, the screen will go off after 60 seconds, and the device will be shut down after 5 minutes.

⚠Caution:

1) Working time: Depending on the patient's condition, we do not recommend the use time, please follow the advice of doctor.

2) To ensure uninterrupted operation of AirICU Max+,ensure power adapter is connected tightly.

3) Always perform a leak test of the breathing circuit after inserting or removing this device.Follow the Instruction of Use of ventilator to perform a leak test.

4) Use the Support Frame Component to fix the Main Unit to an IV pole or bed rail.

5) To stop the nebulizer at any time, press the "Stand-by" button.

6) Medication can be added to the Medication Cup during nebulization. This does not interrupt nebulization or ventilation.

7）If the Main Unit presses the "Start" option when the Medicine cup is not connected, the Main Unit will prompt "Connection Exception" on the display screen and beep the alarm. If it is necessary to close the honey, please connect the Medicine cup or long press to shut it off.

7.5 Instructions for use of app

7.5.1 Installation methods for different phone systems:

a. IOS system:

Connect the mobile phone to the Internet, scan QR code below, and download APP. Go back to the phone desktop to open the “iBreathe”.

b. Android system:

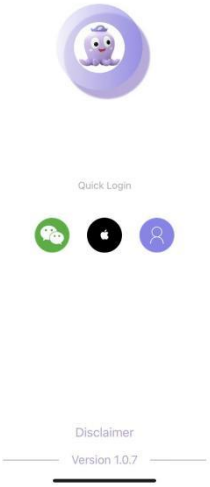
Connect the phone to the Internet, open the browser to scan the QR code below, and click "Click to install." Follow the prompts to install until it is finished. Go back to the phone desktop to open the “iBreathe”.

7.5.2 Open the application interface, click the device button.There are three log in methods:

a. Wechat

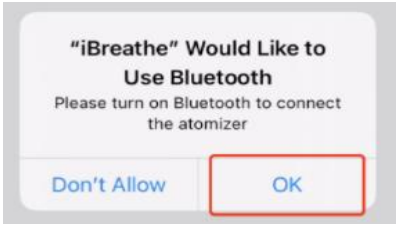
b. Apple ID

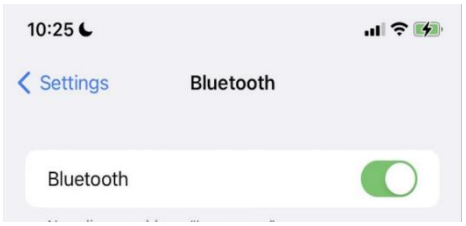
c. Tourist identify



7.5.3 Connect the AirICU Max+

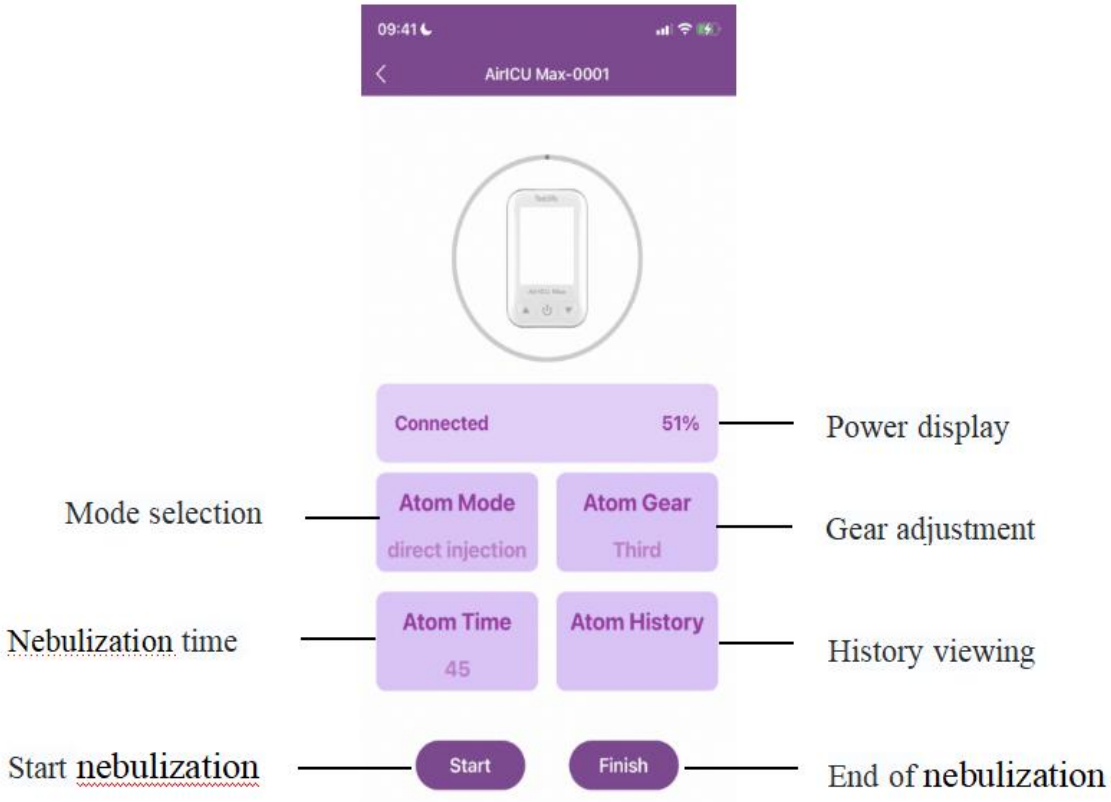
1) Turn on the Bluetooth and log in.





2) Turn on the AirICU Max+.

3) Search for the device , select the device, enter the main interface.



7.6 Automatic shutdown program

1) AirICU Max+ will have a short sound signal and automatically turn off when it reaches the maximum operating time.The maximum operating time is：

- 45 min or 90 min Continuous nebulization mode
- 45 min or 90 min Breath nebulization mode

7.7 Course of treatment

Medicine cup assembly are used by a single patient. The course of treatment please

follow the advice of the doctor.

7.8 Finish nebulization

1) When finishing nebulization, long press power switch to power off(＞2 seconds). It will send a short signal and turn off. Pour out the residual liquid,do not reuse. (As shown below)

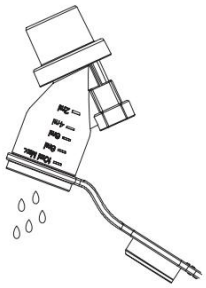


Figure 13. Pour out the residual liquid medication

⚠Caution:

1) When installing the Medication Cup Assembly, make sure the medicine liquid do not leakage from the medication cup and make sure the whole Medication Cup Assembly is well installed.

2) Keep the device on the horizontal orientation as possible during the operation.This orientation prevents condensate from blocking the disc and ensures proper nebulization.

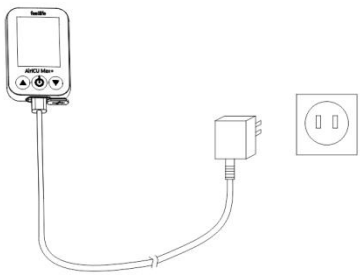
3) Holding your breath for a short while, can enhance the effectiveness of nebulization therapy. keep calm and relax, do not inhale too fast during the treatment process.

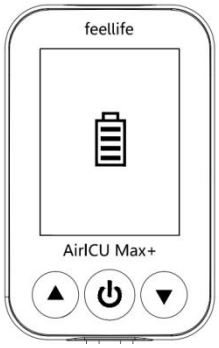
4) The Aimesh will be congealed by medication liquid which will infect nebulization rate. We suggest stopping nebulization and use clean medical gauze to clean the residue.

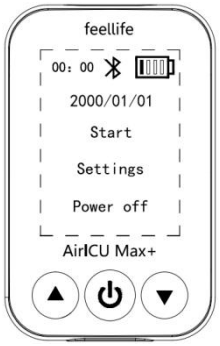
5) Any question in process of nebulizing, please contact manufacturer or authorized representative.

7.9 Charging

1) AirICU Max+ can be powered by built-in battery or power adapter which is AC 100 -240V~,50/60Hz,0.4A Max.While charging,this device can work normally.







①Charging image ②Turn off when charging ③Turn on when charging

Figure 13. Charging

2) Charging time

It takes about 2 hours to charge 80% battery capacity and takes about 3 hours to charge 100% battery capacity.

⚠ Caution:

1) Only the last grid is left and shown as red. It is remind you to charge as soon as possible.

2) When the battery is powered off and charged, the battery icon continuously flashes from low to high, and displays green after it is full;

3) When the battery is powered on and charged, the battery icon continuously flashes from low to high, and displays a full white cell after it is full.

4) Lithium battery is built-in, please do not disassemble.

5) If this device is placed in long-term storage,it is recommended that the battery be charged every months.

6) At least charge 30 minutes for the first use.

⚠ **Warning:**

1)At the end of expect service life, please dispose this device and accessories according to the local environmental regulation, do not dispose together with the domestic refuse to avoid environment pollution.

2）Do not disassemble or repair this device without permission, and do not disassemble or replace the battery without permission.If you need to replace the battery, please consult the manufacturer.

7.10 Functional Test

1) Perform a functional test of the AirICU Max+ prior to first use or at any time to verify proper operation. This test is to be carried out prior to inserting the T-Piece into a circuit.

2) Visually inspect each part of the system for cracks or damage and replace if any defects are visible.

3) Pour 1-6ml of normal saline (0.9%) into the Medication Cup.

4) Install the device according to section 7.3.1.

5) Press the power switch and confirm that the display is on and confirm that aerosols are visible in the corresponding working mode.

6) Disconnect the AC/DC adapter from the Main Unit and verify that nebulization

continues and that the charging status turns off.

7) Power off the Main Unit. Reconnect the AC/DC adapter to the Main Unit. Press and hold the button for at least 2 seconds. Verify that aerosol is visible.

8) Turn the Main Unit off .

7.11 Software version
WHQICU Max+ V1.0

8. Cleaning and Disinfection

Before and after use, be sure to clean and disinfect the Main Unit,the Support Frame Component,and the accessories.The Medication Cup Assembly and Air Flow Sensor are designed for single person.After each use,please clean and disinfect as the following ways.

8.1 Cleaning

1) Wipe the enclusure of the Main Unit with the clean medical gauze which suck up the water.

2) The accessories,including T-Piece,Medication Cup,Aerotank Kits,washed by warm (less than 40℃) and clean water.Then rinse with clean water and dry with clean medical gauze.

Warning:

1) The equipment waterproof classification is IP22.To prevent the ingress of water,this device cannot be washed by flowing water. If any liquid enters into the Main unit, it is necessary for the manufacturer to retest the operation state.

2) Please disconnect the power before cleaning the Main Unit.

3) The Air Flow Sensor does not need to be cleaned.

8.2 Disinfection

1) Wipe the enclosure of the Main Unit with the clean medical gauze which suck up the 70% ethyl alcohol disinfection.Then dry with clean medical gauze which suck up the water.

2) The accessories,including T-Piece,Medication Cup,Aerotank Kits.Soak them in 70% ethyl alcohol disinfection for 10minites.Then rinse with clean water and dry with clean medical gauze.

Warning:

1) Please don't use the disinfectant of Benzalkonium bromide or house bleach.

2) Never use Sodium hypochlorite, Hypochlorous acid or quaternary ammonium

compound to disinfect.

3) The disinfectant residues should be cleaned thoroughly.

4) Do not immerse the Air Flow Sensor into the liquids,it may be damaged.

5) The Air Flow Sensor does not require disinfection.

9. Storage Conditions

1) The storage and transportation conditions of the products are detailed in the Product Technical Parameters section.

2) Keep the device out of the reach of unsupervised infants and children. The small parts of this device may be swallowed by the infants and children.

3) Prevent pets and pests from damaging this device.

4) Dry the parts immediately after cleaning and disinfection. Store the device in the environment that meets the requirements, be careful to avoid collisions.

5) Direct sunlight, lint, dust may cause vibrating mesh rusted and oxidized and decrease nebulization rate.

10. Trouble Shooting

Item	Trouble	Possible cause/solution
1	Do not work when turn on	- Check if there is enough power. - Check if there is enough medication. - Check if the button is function well. - Clear the clogged medication in the vibrating mesh and restart the power.
2	Low nebulization rate	- Check if the medication cup been filled with right medication, which should be water-solubility, non-corrosive medication. - Check if the medication cup been filled with right volume. - Tilt Main Unit, so that the medication can contact with the vibrating mesh. - Re-assemble the medication cup correctly and restart the device. - Clean the medication cup and vibrating mesh. If it still cannot be used after cleaning, please check whether the vibrating mesh is broken or not. - Clear the clogged medication in the vibrating mesh and restart the power.
3	After power on, it power off immediately.	- Re-assemble the medication cup correctly and restart the power. - Tilt Main Unit, so that the medication can contact with the vibrating mesh. - Clear the clogged medication in the vibrating mesh and restart the power.

4	The mesh is clogged with medication.	- Take off the medicine cup, wash with warm water, air dry.
5	The medication cup assembly leakages.	- Re-assemble the medication cup correctly. - Contact the manufacturer or the distributor for a new one.
6	Residual medicine liquid in the medication cup.	- It is a normal phenomenon.Clean the medication cup after using.
7	Can not charge.	- Make sure the charging cable,the adapter are connected well. - Contact the manufacturer or the distributor for a new battery.
8	The display is not working	- Check if there is enough power. - Contact the manufacturer or the distributor for a new battery. - Keep the device away from other instruments with radiation

11. Note & Warning

11.1 Note and suggestion

• This device is a medical device,please read the user manual before using it.
• Please use required accessories, warranty service is not provided for damage caused by accessory beyond our list.
• Use a non-conforming adapter may cause equipment damage.
• Please refer to the user manual when there is problem, or contact the after-sales service unit for maintenance.
• Please clean and disinfect the Medication Cup Assembly when use it for the first time. You can refer to the clean and disinfect chapter.
• This device is for medication nebulization, not for humidification.
• Please assure all the accessories assembled rightly before using.
• Please use the accessory individually to avoid cross infection.
• Please keep it vertical when nebulizing.
• Don’t use the unit under inflammable gas environment or near the heating device or open flame.
• Don’t use the unit near high frequency products or electronic products.
• Do not use a microwave oven, oven, blow dryer or other house applications to dry nebulizer and accessories.
• Technical description is included in this user manual.
• The accessible materials used in the nebulizer are safe for common normal people. For very few operators with extreme skin sensitivity, if any skin discomfort occurs during the use of the nebulizer, please immediately stop using and seek medical advice.
• The nebulizer can only be used by operators who can understand this user manual.

• When the product is taken out from -20 ℃, it should be put in room temperature for 2 hours before use.
• When the product is taken out from 55℃, it should be put in room temperature for 2 hours before use.
• The USB interface is only used for power supply and cannot be connected to other devices.
• When the patient is an intended operator, all the accessories of the nebulizer cannot be serviced or maintained while it is in use.
• The contents that patients can maintain the devices are cleaning and disinfection. You can refer to the clean and disinfect chapter.
• Performance information provided by the this user manual in accordance with ISO EN 27427 may not apply to drugs supplied in high viscosity form. In such cases, information should be sought from the drug supplier.
• The life of the Medication cup has been validated for intermittent use for a maximum of 28 days based upon a typical usage profile of 4 treatments per day.For continuous use, the life of the Medication cup have been qualified for use for a maximum of 7 days.

11.2 ⚠ Warning

• Read and study all instructions before using the AirICU Max+.Only trained medical personnel should operate the device.
• One device suggest for single patient use and can be reusable by a single patient.Medicine cup assembly is designed for single patient and single use to avoid cross infection.Please follow the doctor ’s advice if you want to use more than once.
• When using with the ventilator,the users must be trained by medical professionals in order to safely operate this device.
• Please stop using it if you feel uncomfortable and please turn to doctor.
• Volatile oil are not allowed, may cause damage to disc.
• Water-soluble medication and saline dilution medication are allowed, but may cause Bronchospasm.
• Please do not use medicines containing esters, oils or suspended particles, including herbal extracts. It is recommended to use the standard atomizing liquid agent type according to the doctor's instructions.
• Only drugs that are prescribed by doctors for nebulization can be used.
• Do not service and maintain when the nebulizer is in use.
• Don’t modify the equipment without authorization of the manufacturer.Otherwise,it may cause damage to the main unit or damage to the user or patients.
• Do not use this equipment in the shower room. The equipment cannot be immersed in water and other liquids.Otherwise there will be danger of short circuit.
• Do not use mobile (cellular) telephones and other devices(such as MRI, diathermy, electrocautery, RFID and electromagnetic security systems) which generate strong electrical or electromagnetic fields, near the medical device.
• The manufacturer or manufacturer’s representative can assistant lay operator or lay responsible organization to set up,use or maintain this device when needed.Have any unexpected operation or events,please contact the manufacturer or manufacturer’s representative.
• Waste disposal: discard the main engine and accessories according to local laws and regulations.
• The USB cable should be kept away from children or out of the reach of children to avoid strangulation.
• All the accessories cannot be serviced or maintained while it is in use.

• Turn to doctor for help or contact the manufacturer if any changes in the performance of this device.
• Be careful the small parts of this device be swallowed by the infants or children.
• To avoid the risk of fire, do not use to aerosolize alcohol-based medications, which can ignite in oxygen-enriched air and under high pressure.
• Only use physician-prescribed solutions that are approved for use with a general purpose nebulizer. Consult drug manufacturer's instructions regarding suitability for nebulization.
• The accessories are not made with natural rubber latex.
• To avoid the risk of fire, do not use to aerosolize alcohol-based medications, which can ignite in oxygen-enriched air and under high pressure.
• Do not autoclave any component or accessory of the AirICU Max+.
• Do not use in the presence of flammable substances or flammableanesthetic mixtures combined with air, oxygen or nitrous oxid
• Use only with AirICU Max+ components, connectors and any accessories,which are specified by FEELLIFE in this instruction manual.
• Federal (US) Law restricts this device to sale by or on the order of a physician.
• Do not immerse or autoclave the Main Unit, USB Cable or adapter.
• Do not place the Main Unit in an incubator during use.

12. Electromagnetic Compatibility

EMC Declaration

• This device meet the requirement of electromagnetic compatibility in IEC 60601-1-2.
• The user needs to install and use according to electromagnetism compatibility information which is attached with it.
• Portable and mobile RF communication device and some household appliances, such as mobile, interphone, microwave oven, dry blower, may influence nasal rinse performance, so nasal rinse should be kept away from them during using.
• Guidance and manufacturer's declaration stated in the appendix.

EMC Information

With the increased number of electronic devices such as PC's and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation.

Medical devices should also not interfere with other devices.

In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the IEC 60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices.

Medical devices manufactured by FEELLIFE HEALTH INC. conform to this IEC 60601-1-2 standard for both immunity and emissions.

Warning:

1) Only use the AirICU Max+ with components specified in the Instructions for Use. Use with components other than those specified in the Instructions for Use may result in increased emissions or decreased immunity.

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

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

Guidance and Manufacturer's declaration – electromagnetic emissions		
This device is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	This device use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	This device is suitable for used in domestic establishment and in establishment directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's declaration – electromagnetic immunity			
This device is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that they are used in such an environment.			
Immunity test	IEC 60601 test level	Compliance	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least

			30 %.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for Input/output lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5kV,±1kV line to line ±0.5kV,±1kV line to ground	±0.5kV,±1kV line to line	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 IEC 61000-4-11.	<5 % U_T(>95 % dip in U_T.) for 0.5 cycle <5 % U_T(>95 % dip in U_T.) for 1 cycle 70 % U_T (30% dip in U_T) for 25/30 cycles <5 % U_T(>95 % dip in U_T.) for 5/6 sec.	<5 % U_T(>95 % dip in U_T.) for 0.5 cycle <5 % U_T(>95 % dip in U_T.) for 1 cycle 70 % U_T (30% dip in U_T) for 25/30 cycles <5 % U_T(>95 % dip in U_T.) for 5/6 sec.	Mains power quality should be that of a typical commercial or hospital environment. If the user of this device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or 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 U_T is the a.c. Mains voltage prior to application of the test level.			

Guidance & declaration – Electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that they are used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment –guidance
Radiated RF IEC 61000-4-3	6Vrms in ISM and amateur radio bands 10V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment(Refer to table 9 of IEC 60601-1-2)	6Vrms in ISM and amateur radio bands 10V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment(Refer to table 9 of IEC 60601-1-2)	Portable and mobile RF communications equipment should be used no closer to any part of this device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 3.5\sqrt{p}$ $d = 1.2\sqrt{p}$ 80 MHz to 800 MHz $d = 1.2\sqrt{p}$ 800 MHz to 2.7 GHz 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 meters (m). Field strengths from fixed RF

			transmitters, as determined by an electromagnetic site survey,*2) should be less than the compliance level in each frequency range.*3) Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

*2) 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating this device.

*3) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the device

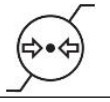
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
0.01	0.12	0.12	0.23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz. the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

13. Signs and Symbols

General symbol	Description / title	General symbol	Description / title

	Date of manufacture		General warning sign
	Manufacturer information		Refer to instructions for use
	Non-sterile		Keep dry
	Caution		This way up
	Fragile,handle with care		Temperature limit
	Type BF applied part		Humidity limitation
	Keep away from sunlight		Atmospheric pressure limitation
IP22	Degree of protection against the ingress of water.		When this device life expires,the end users should discard this device according to the requirements from the local environment protection authority.
	Batch code		LF electromagnetic radiation
	Medical device		Stand-by

14. After-sales Service

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

1. The period of Main Unit free for maintain service is 1 year. Medication cup and Air Flow Sensor are 6 months.Other components are not covered by warranty. On the Any repair service out of the scope of warranty will be charged accordingly.

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

Warranty conditions:

To obtain the warranty service, please present this warranty card and fill out the related content. The company provides 12 months (Main Unit) or 6 months (Medication cup and Air Flow Sensor),warranty from the date of purchase.

The warranty shall not apply:

a) Failure or damage caused by improper use.

b) Failure or damage caused by the dismantle movement of a non-our-company authorized maintainer.

c) Failure or damage caused by accidental falling, pressing, dropping, immersion etc.

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

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

15. Configuration List

Item	Model	Quantity	If Included	
			Yes	No
Main Unit	AirICU Max+	1	☑	☐
Medication Cup（With the rubber plug）	MAICU Pro3	1	☑	☐
Adult T-Piece（With the rubber plug）	ICU TP1	1	☑	☐
Medication Cup（With the rubber plug，Type of thread）	MAICU Pro4	1	optional	
Pediatric T-Piece	ICUTP2	1	optional	
Infant T-Piece	ICU TP3	1	optional	
Aerotank Kits	ICU AT L6	1	optional	
	ICU AT S6	1	optional	
Air Flow Sensor	ICU A1	1	optional	
USB Cable (Y-type)	SR-C0136-002	1	optional	
USB Cable (Linear type)	SR23-C0136-001	1	☑	☐
Medical Power Supply	SINGOF-15E-050250	1	☑	☐
Type-C cable	FS003	1	☑	☐
Support Frame Component	LFS-ICUMAX.01	1	☑	☐
Warranty Card	/	1	☑	☐
User Manual	/	1	☑	☐
User Guidance	/	1	☑	☐

Note:Medication Cup,T-Piece,Aerotank Kits,USB Cable,Air Flow Sensor are sold separately.Please contact your distributor for full parts list.

16. Disclaimer Clause

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

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

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

17. Manufacturer information

FEELLIFE HEALTH INC.

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E-mail:info@feellife.com

Website: http://www.feellife.com

FCC Warning

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 equipment.

Note: This equipment 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 equipment 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 equipment 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 radio/TV technician for help.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.