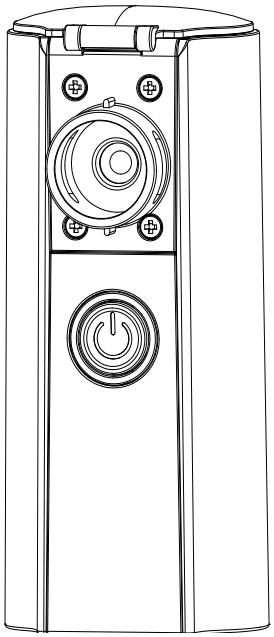
Nebulizer

(Model: LT–N400)



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Users’ Manual

Contents

Chapter 1 Safety Guide

Please read this manual carefully to ensure safe and correct use of this product.

1. Electrical safety

- Classified as Class lla active (non-implanted) medical device according to the Regulation (EU) 2017/745 on medical devices (MDR).
- Classified according to the type of protection against electric shock: Equipment with internal internal power supply.
- Classified according to the degree of protection against electric shock: BF type application part
- Classified according to electromagnetic compatibility: Group I class B. Shell protection grade: IP22

2. Safety information

⚠ Warning: Information that you should know in order to avoid injury to patients and medical staff.

⚠ Note: Important information that should be emphasized.

➢ Warning:

- For use by lay persons, the user should consult a healthcare professional before use.
- Please kindly follow the doctor’s advice about the drug, dosage and operation method.
- Any medicine out of doctor’s prescription are forbidden.
- Do not use the medicines in suspension or in high viscosity form.
- The device is for single patient only. Sharing is prohibited.
- Proper guidance and supervision are required for children and people with special needs during operation.
- This product mustn't be used in anesthesia and ventilator systems.
- The product cannot work with medical oxygen system.
- Do not store this device in places subject to direct sunlight, high temperature, dusty, lint or water.
- Do not carry or store the nebulizer that still has liquid.
- Do not put the device in water.
- Do not disassemble or modify this device.
- Do not reuse the device if damaged, the switch button failure, indicator light failure, beyond the service life, medication cup damaged or deformed.
- Do not use the device in MR environments.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member

State in which the user and/or patient is established.

- This device cannot be used with other equipment.

⚠ Note:

- The nebulizer can only be used for the specified purpose, i.e. nebulization.
- Only use the applicable liquids under the guidance of your physician.
- Always clean and disinfect the nebulizer parts in contact with the liquid before using this device.
- Remove the stains on the electrodes, or else it may reduce the nebulization effect.
- Do not clean the mesh of the medication cup with cotton swabs or brushes.
- Before using the nebulizer, you must visually check whether the medication cup is filled with medicine in order to prevent damage to the mesh.
- If the instrument isn't used for a long time, remove the batteries.
- Do not drop the nebulizer in order to prevent damage.
- Keep it out of reach of infants, children and people with mental illness when storing or using.

⚠ Limitation :

Do not use disinfection solution containing sodium hypochlorite.

• The Mesh may not be able to be used after getting covered with rust.

Do not inhale by using water in the medication bottle.

• Your symptom(s) may worsen.

Do not drop medication on the Main Unit or AC Adapter. If you drop medication, immediately
wipe it off with gauze.

• If you use the unit while it is wet, it may cause trouble or you may suffer electric shock.

Do not poke Mesh or Vibrator with a cotton swab or a pin.

• The unit may be broken and cannot be used.

Do not drop or apply strong shock to the Main Unit, AC adapter, Medication Bottle, or Mesh Cap.

• They may be broken and cannot be used or you may suffer electric shock.

Do not use the AC adapter other than the one supplied by Omron. Do not use a broken
AC adapter. (AC adapter is an optional part.)

• It may catch fire, you may suffer electric shock or the main unit may cause trouble.

Chapter 1 Safety Guide

⚠ Warning

Residual liquid medicine may do harm to environment, please dispose according to local law. Please make sure to clean the liquid cups and other parts to prevent the residual liquid in the atomizing cup from drying out, leading to infection prevention.

The nebulizer main unit or power adapter should not be washed with water or immersed water, or the liquid be spilled onto it, otherwise it may cause electric leakage, electric shock or malfunction. When spilling the liquid, Wipe it off with gauze immediately.

Waste disposal:

Do not dispose of electrical appliances as unsorted municipal waste, use separate collection facilities. Contact the local government for information regarding the collection systems available. Remove the battery and circuit board when discarding. Contact the local waste disposal department to dispose of the battery and circuit board according to the specified WEEE requirements. Dispose the shell materials as common garbage. If electrical appliances are disposed of in landfills or dumps, hazardous substances can leak into the groundwater and get into the food chain, damaging your health.

3. Explanation of symbols

S/N	Symbol	Explanation
1		BF type application part
2		Note, refer to the attached file
3		Refer to the manual
4		Serial number
5	IP22	Shell protection grade
6		Disposal of waste electrical and electronic equipment separately (Follow local government regulations and recycling instructions for batteries)
7		Non - ionizing radiation
8		Date of manufacture
9		Manufacturer
10		Use-by date
11		Comply with the Regulation (EU) 2017/745
12		Authorized representative in the European Union
13		Medical device
14		Unique device identifier
15		Single patient multiple use

4. environmental protection.

The device (disposable accessories) and battery contains heavy metal and plastic which may do harm to environment, please dispose according to local law.

Chapter 2 Product Overview

1. Working principle and mechanism of action

1.1 Working principle

The nebulizer with the nominal ultrasonic oscillation frequency of 110 kHz is driven by the rapid oscillation of the circuit, which makes the piezoelectric ceramic transducer oscillate resonantly, thus driving the rapid oscillation of the microporous metal mesh. It converts the electrical energy into mechanical energy and generates ultrasonic vibration, which makes the shock wave squeeze the liquid in the medicine cup. The liquid is popped up quickly through the tiny mesh on the metal mesh to form countless tiny nebulized particles, which are guided to the patient's respiratory system through the inhalation mask, so as to achieve the purpose of inhalation treatment.

1.2 Mechanism of action

The respiratory system is an open system, after the liquid is nebulized into particles and inhaled by the patient, the drug mist can directly adsorb on the patient's mouth, throat, trachea, bronchi and alveoli, and is absorbed by the mucous membrane to achieve the purpose of treatment.

2. Product composition

The nebulizer is mainly composed of a main unit and a Micro USB cable.

3. Intended patient population & intended user

The nebulizer is intended to be used for adult and pediatric patients over 2 years old.
The nebulizer is intended for use by trained professionals and lay persons.

4. Intended purpose

The Lintemed nebulizer is an ultrasonic vibrating mesh nebulizer system designed to aerosolize physician-prescribed solutions for inhalation to adult and pediatric patients over 2 years old.

5. Intended environment

It's suitable for medical institutions and home care use.
The nebulizer suitable for sabutamol, ipratropium, levalbuterol, epinephrine.

6. Contraindications

1) Patient is allergic to aerosolized drugs.
2) Patient with asthma.
3) Pentamidine powder and suspension.
4) Anesthetics agent.

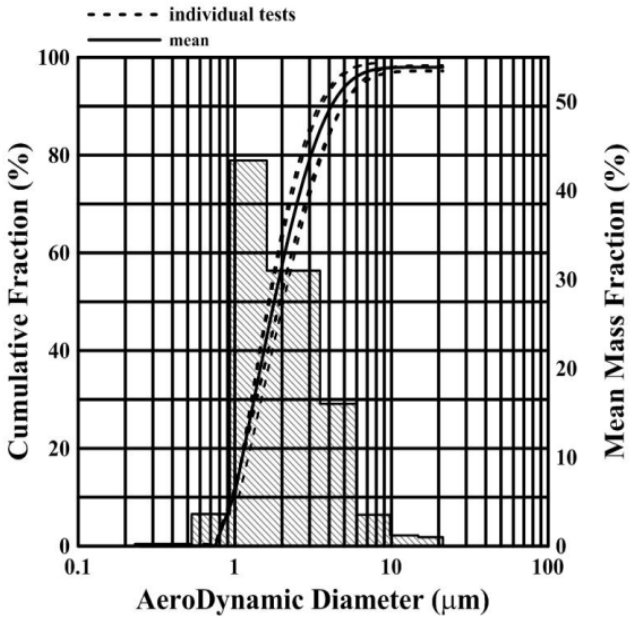
7. Medical indications

Acute and chronic respiratory disease including upper respiratory tract infection, acute bronchitis, acute pharyngitis, pneumonia, chronic bronchitis.

8. Product performance

Chapter 2 Product Overview

Power supply: Built-in 3.7V batteries or DC 5 V, 1 A (Class II adaptor with IEC60601-1 approval)
Power: < 3.0 W
Ultrasonic oscillation frequency: Nominal frequency of the nebulizer is 110 kHz, and the deviation of the ultrasonic oscillation frequency of the nebulizer from the nominal frequency is ≤±10 %
Maximum nebulization rate: ≥ 0.2 ml / min
Temperature inside the sink : ≤ 60℃
Operating noise: ≤ 50 dB (A weighting)
Low water level reminder or stop device: After the nebulization of liquid medicine is completed, the instrument will stop automatically.
Continuous working time (battery life): 10 minutes for each use, 3 times consecutive nebulization.
Median particle size of the mist particles: The median size of the nebulizer mist particles is 3 μm. and the error should not exceed ± 25%.
Equivalent volume particle size distribution : The diameter of the mist particles produced by the nebulizer is 1 μm ~ 5 μm, and the proportion of mist particles is greater than 50%.



Distribution of equivalent volume and particle size of fog particles

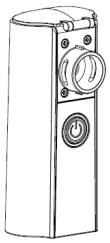
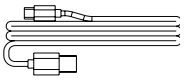
Test conditions: temperature is 23±2℃, humidity range: 56% ~59%；The composition of the test solution is 0.9% sodium chloride solution. (Test data may vary with test conditions and drug solution)
Maximum capacity of medication cup: 8 ml
Product size: 48 (L) X43 (W)X 107 (H) mm
Weight: About 87 g (excluding battery)

Operating environment:

Temperature: 5℃~35℃

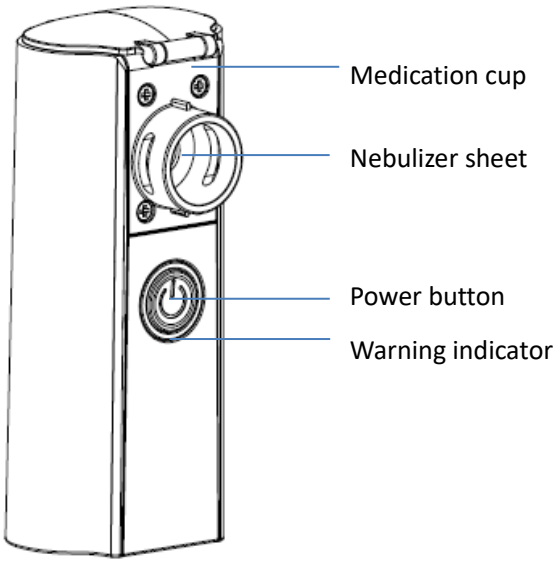
Relative humidity: ≤ 80 % , non-condensing
Atmospheric pressure: 86.0~106.0 kPa
Transportation / storage environment:
Temperature: -20℃ ~ 55℃
Relative humidity: ≤ 93 % , non-condensing state
Atmospheric pressure: 70.0~106.0 kPa

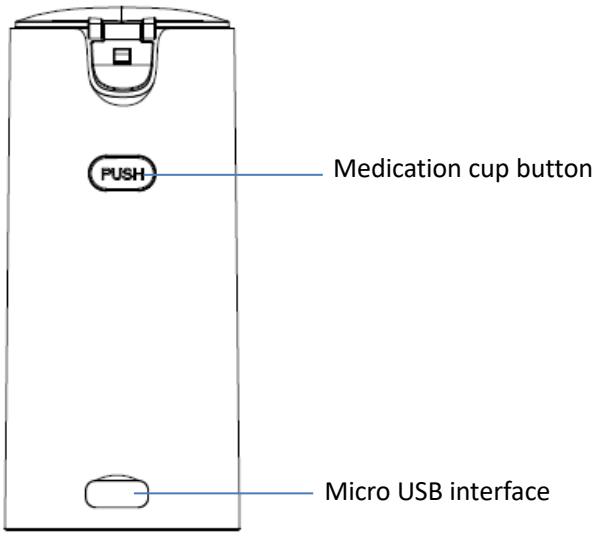
9. Configuration list

Description	diagram	QTY
Main unit		1 pc
Micro USB cable		1 pc

Note: The above parts are necessary for normal use of the product and comply with relevant standards.

Chapter 3 Product Appearance

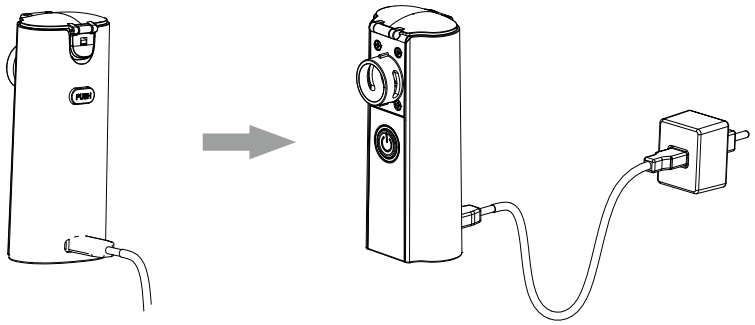




Chapter 4 Power Use

Using external power supply

1. connect one end of the USB cable to the Micro USB port of the main unit and the other end to the USB power adapter.
2. Plug the USB adapter into the power outlet.
3. When charging, the indicator light flashes blue, and when it is full, it is blue and always bright.
4. When fully charged, the lithium battery can work for 30 minutes.
5. The lithium battery is charged and discharged 300 times, and the battery capacity is less than 80%.



⚠ Note:

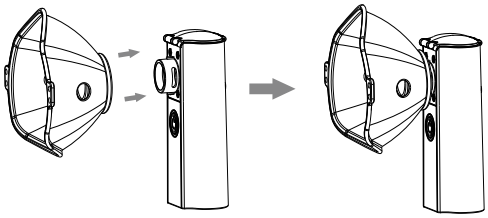
1. Be sure to use the power adapter provided by manufacturer that meets the requirements of the IEC60601-1 standard. (Adapter Manufacturer: Shenzhen Longic Power Supply Co., LTD, Type: LXCP12-005100AFG)
2. The nebulizer cannot work during charging.

Chapter 5 How to Use

⚠ Please refer to the user's manual for the use of the mask.

⚠ Each component needs to be cleaned and dried before installation.

Attach mask to the medication cup.



⚠ Note: Please select the correct mask.

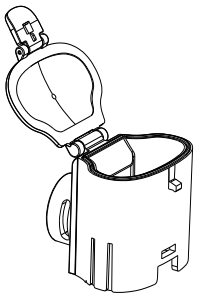
a) The large mask is suitable for adult, small mask is suitable for pediatrics.

b) The mask can be reused 20 times. If necessary, please contact our company or purchase it with regular channels such as drug stores and hospitals.

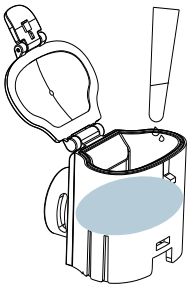
c) Please operate in reverse order to remove.

d) Compatible device: Huizhou Kaiyi Technology Co., Ltd. Manufacturer type: NC180801.

3. Pour the liquid into the cup, and fasten the lid to prevent the liquid from leaking out.



① Open the medication cup cover



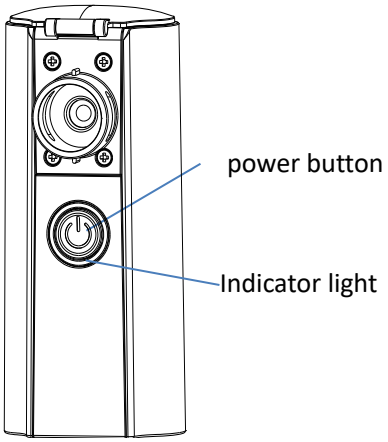
② Fill in the drug liquid

③ Cover and fasten the lid

⚠ Note:

- Please consult your physician for the dosage of the drug liquid. Maximum capacity 8ml, Minimum capacity 0.5 ml.
- Do not use suspended, highly viscous or high-concentration liquids, as this may cause the nebulization sheet clogged or damaged and not function properly.

4. Nebulization



1. Press the power button for short duration, the indicator light (green) will be on.

2. After cleaning, green constant light, nebulization start.

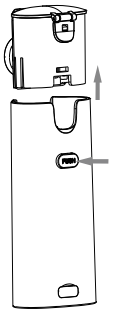
3. The nebulizer works 10 min for each use. If you Want to continue to use after power off automatically, please press on/off button for short duration again

4. When the nebulization is completed, press the on/off button for short duration to power off the device.

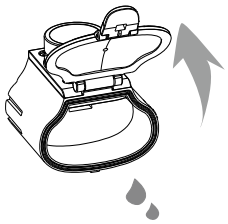
Chapter 6 Cleaning and Disinfection

Do not share your nebulizer accessories, otherwise there should be risk of spreading infection and illness among different user.
Please refer to the user's manual for cleaning the mask.

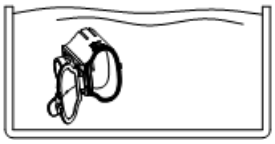
1. Cleaning the accessories
Upon first use and at the end of each application.



① Remove the medication cup from the main unit liquid.



②Pour out the remaining .



③ Clean the medication cup and mask with clean purified water which not exceeding 40 ℃.

④ Dry the medication cup in a ventilated place, and then put it on the main unit.

2. Cleaning the main unit
The main unit must be cleaned with a soft dry cloth and non-abrasive cleaners.
Let it air dry on a clean paper towel.

⚠ Note:

1. Clean all parts of the nebulizer after each treatment to reduce the risk of infection, illness, or injury from contamination. Clean or replace accessories after each treatment.
2. Only original nebulizer and accessories can guarantee a proper treatment.
3. Please refer to the mask's manual for cleaning the mask.

Chapter 7 Troubleshooting

If you have any problem or doubt when using the nebulizer, please troubleshoot according to the following list.		
No.	Failure	Possible cause/Solution
1	The device does not work when power on	1) Please check the power of the nebulizer. Recharge the battery if the indicator flashing blue. 2) Check the medicine cup if the liquid is sufficient.
2	Nebulization rate is very low	1) Check the liquid, it must be water-soluble, non-corrosive. 2) Check the liquid is lack. 3) Tilt the device and make liquid keep contacting with nebulization sheet. 4) The nebulization sheet may be clogged. please boil the medication cup with normal saline or white vinegar for 10 minutes, and then completely dry and cool it down. If it still can't be improved, please change the medication cup. If problem not solved, please change the medication cup. 5) The water level probe in the medication cup is dirty. Please clean the medication cup in time to keep the probe clean.
3	The warning indicator flashes in yellow	1) The drug liquid in the medication cup is lack. 2) The medication cup is not fixed properly. Please re-install the cup.
4	The nebulizer stops automatically during use	1) Please recharge the battery. 2) The medication cup is not in place. Please reinstall the medication cup. 3) Lack of liquid. Please refill it. 4) There is shaking during use so that the liquid and the nebulization sheet are not in full contact. Hold the nebulizer steadily.

Chapter 8 EMC

⚠ Note:

- The instrument conforms to the requirements of IEC 60601-1-2 standard for electromagnetic compatibility.
- The user shall install and use the EMC information provided in the random file.
- Portable and mobile RF communication equipment may affect the performance of the instrument, avoid strong electromagnetic interference when using, such as close to the mobile phone, microwave oven, etc.
- The guidance and manufacturer's declaration are detailed in the table below .

⚠ Warnings:

- The instrument should not be close to or stacked with other equipment. If it must to be close to or stacked, it should be observed and verified to be able to operate normally under its configuration.
- In addition to the cables sold by the instrument manufactures as spare parts for internal components, the use of other accessories and cables may result in increased emission or reduced Immunity.

Chapter 8 EMC

Guidance and Manufacturer Declaration - Electromagnetic Emissions		
The instrument is intended to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in such electromagnetic		
Emission test	Compliance	Electromagnetic environment - guidance
Radio frequency emission EN 55011	Group 1	The instrument uses RF energy only for its internal functions. Therefore, its RF emissions are low and there is little possibility of interference with nearby electronic equipment.
Radio frequency emission EN 55011	Class B	The instrument is suitable for use in all facilities, including domestic facilities and direct connection to residential low-voltage power grids
Harmonic emission IEC 61000-3-2	N/A	
Voltage fluctuation / flicker emission IEC 61000-3-3	N/A	

Guidance and Manufacturer Declaration – Electromagnetic Immunity			
The instrument is intended to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in such electromagnetic environment:			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge IEC 61000-4-2	± 8 kV contact discharge ± 2 kV , ± 4kV, ± 8kV, ± 15kV air discharge	± 8 kV contact discharge ± 2 kV , ± 4kV, ± 8kV, ± 15kV air discharge	The ground should be wood, concrete or ceramic. If the floor is covered with synthetic material, the relative humidity should be at least 30 %.

Electrical fast transient burst IEC 61000- 4- 4	±2 kV to power line, 100 KHz frequency	N/A	/
Surge IEC 61000- 4- 5	±1 kV line to line ±2 kV line to ground	N/A	/
Voltage dip IEC 61000-4-11	0 %UT; lasts 0.5 cycle 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 %UT; 1 cycle 70 %UT; 25/30 cycles	N/A	/
Voltage interruption IEC 61000- 4- 11	0 %UT; 250/300 cycles	N/A	/
Power frequency magnetic field IEC 61000- 4- 8	30 A/m	30 A/m, 50/60 Hz	/
Note: UT refers to the AC grid voltage before the test voltage is applied.			

hapter 8 EMC

Guidance and Manufacturer Declaration – Electromagnetic Immunity			
The instrument is intended to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in such electromagnetic			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Radio frequency conduction IEC 61000- 4- 6	3 V 150 kHz～80 MHz 6 V 150 kHz～80 MHZ 80% AM，1 kHz	3 V 6 V	Portable and mobile RF communications equipment should not be used closer to any part of the instrument than the recommended isolation distance, including cables. This distance is calculated by a formula corresponding to the transmitter frequency. Recommended isolation distance
Radio frequency radiation IEC 61000-4-3	3 V/m 80 MHz～2.7 GHz 80 % AM，1 kHz	3 V/M	d =1.2$\sqrt{P}$ d =1.2$\sqrt{P}$ 80MHz~800MHz d =2.3$\sqrt{P}$ 800MHz~2.7GHz In the formula: P— Maximum rated output power according to the transmitter manufacturer, in watts (W). d— The recommended isolation distance, in meters (m)b. The field strength of a fixed RF transmitter is determined by a survey c of the electromagnetic field, and each frequency range d should be lower than the compliance level. Interference may occur near devices marked with the following symbol. 

Note 1: At 80MHz and 800MHz frequencies, the formula for the higher frequency band is used. Note 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects and human bodies
A For fixed transmitters, such as base stations for wireless (cellular/cordless) telephones and terrestrial mobile radios, amateur radios, AM and FM radio broadcasts and television broadcasts, the field strengths are not predictable theoretically. In order to assess the electromagnetic environment of a fixed RF transmitter, the survey of the electromagnetic field should be considered. If the field strength of the location where the instrument is located is higher than the above-mentioned applicable RF compliance level, the instrument should be observed to verify that it is functioning properly. Additional measures may be necessary if abnormal performance is observed, such as reorienting the instrument. B The field strength should be less than 3V/m over the entire frequency range from 150kHz to 80MHz.

Recommended Isolation Distance Between Portable and Mobile RF Communications Equipment and Instruments			
The instrument is expected to be used in an electromagnetic environment where radio frequency disturbances are controlled. Depending on the maximum rated output power of the communication device, the purchaser or user can prevent electromagnetic interference by maintaining the minimum distance between the portable and mobile RF communication device (transmitter) and the instrument as recommended below.			
Rated maximum output power of the transmitter W	Isolation distance corresponding to different frequencies of the transmitter / m		
	150 kHz ~ 80 MHz $d = 1.2\sqrt{P}$	80 MHZ ~ 800 MHz $d = 1.2\sqrt{P}$	800 MHZ ~ 2.7 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
100	12	12	23

For the maximum rated output power of the transmitter not listed in the above table, the recommended isolation distance d (in meters (m)) can be determined by the formula in the corresponding transmitter frequency column, where P is the maximum rated output power provided by the transmitter manufacturer, in watts (W).

Note 1: At the 80MHz and 800MHz frequency points, the formula for the higher frequency band is used.

Note 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects and the human body.

Chapter 9 Warranty

1. If the product has a fault, please contact your local dealer or manufacturer.
2. This product from the date of sale: the main unit is free warranty for 1 year, medicine cup (including nebulizer sheet) warranty for 3 months.
3. We will charge for relevant fees as appropriate when the warranty period expires.
4. Consumables (masks) are not covered by the warranty.
5. The following conditions are not covered by the free warranty:
   Damage caused by drop, impact, soaking in water or getting wet.
   Damage caused by improper operation.
   Damaged caused by an accident.
   Failure caused by reconstructing or altering the altering the original structure.

Disclaimer: We are not responsible for any problem of the instrument if any parts are repaired by unqualified personnel.

Warranty Card

product		model	
Production date		purchasing date	
Invoice number			
Address			
contact		tel:	
service record	description		Repairer
Remarks	Please present this card for machine maintenance		

QC card

product _____

model _____

lots number _____

Date _____

Inspector _____

Zhuhai Linte Medical Instrument Co., Ltd.
4th Floor, Building 1, No.66, Yongda Road, Hongqi Town, Jinwan District, 519090 Zhuhai, Guangdong, PEOPLE'S REPUBLIC OF CHINA

EC REP Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany

Use period: Three years

Shelf life: Three years

Software version: V1.1

NO.: IFU-N400-01

Version: A/2

Created Date: 2018.10

Date of revision: 2022.11

CE 0123