Product user manual

Spirometer

Model: SP-01/SP-02/SP-03

SP-11/SP-12/SP-13

PLEASE READ ALL THE INFORMATION IN THE PACKAGE INSERT BEFORE USING THE Spirometer.

IF YOU DO NOT UNDERSTAND THE INSTRUCTIONS, CONSULT Beneware, CALL +86-512-66806855, OR WRITE TO service@beneware.net

Suzhou Beneware Medical Equipment Co., Ltd.

Document No.:BHHY-BZ-SM-0701 Version: V1 Release date: 2024.01.15

Foreword

Declaration

Thanks for choosing our product. Please read carefully the Operation Instruction before use and observe the safety requirements.

The Instruction is for your reference for the product operation and maintenance. Users should follow strictly the instruction. Where losses are caused by improper installation or operation, Suzhou Beneware Medical Equipment Co., Ltd. will assume no legal responsibilities.

Product Information

Product name: Spirometer

Product model: SP-01/SP-02/SP-03/ SP-11/SP-12/SP-13

Manufacturer Responsibility

Only under the following circumstances will Suzhou Beneware Medical Equipment Co., Ltd. be responsible for the safety, reliability and performance of the product: the installation, extension, re-adjustment, improvement and maintenance are performed by personnel approved by Suzhou Beneware Medical Equipment Co., Ltd. and the electrical installation environment of the room meets national standards and the device is operated as per the Instruction.

Required by users, Suzhou Beneware Medical Equipment Co., Ltd. may charge to provide circuit diagram and other information to enable proper and qualified technicians to maintain the device part that can be maintained by users.

FCC Statement

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.

Caution: Any changes or modifications to this device not explicitly approved by manufacturer could void your authority to operate this equipment.

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.

RF Exposure Information

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

Content

1. Product description

1.1 Product brief description

Product name: Spirometer

Model: SP-01/SP-02/SP-03/ SP-11/SP-12/SP-13

Embedded software release version: V1

Mobile software release version: V1

Computer software release version: V1

1.2 Intended use / indications for use

Beneware spirometer is intended to be used for measurement and data collection of lung function parameters. The system performs cooperation- dependent flow volume measurements. Mostly it will be used for COPD and Asthma patients. Measurements will be performed under the direction of a physician in the clinic, doctors' office, hospital or home use. It can be utilized for patients from 4 years of age and older as long as they can cooperate in the performance.

Beneware spirometer is powered by internal power supply (DC 3.7V) or external standard USB 2.0 and USB 3.0 interfaces. No energy is transferred to the patient.

The SP-1X series (Model: SP-11/SP-12/SP-13) spirometer is intended for home use and may also be used by clinicians for in-office monitoring.

The SP-0X series (Model: SP-01/SP-02/SP-03) spirometer is solely intended used by clinicians for in-office monitoring.

1.3 Requirements for patients

The device is designed for children greater than five years of age, adolescent and adult subjects.

1.4 Product introduction

1.4.1 Difference of models

A spirometer is an apparatus for measuring the volume of air inspired and expired by the lungs. A spirometer measures ventilation, the movement of air into and out of the lungs. A

spirometer is the main piece of equipment used for basic Pulmonary Function Tests (PFTs). Lung diseases such as asthma, bronchitis, and emphysema can be ruled out from the tests. In addition, a spirometer is often used for finding the cause of shortness of breath, assessing the effect of contaminants on lung function, the effect of medication, and evaluating progress for disease treatment.

The model specifications of Spirometer are as below:

Model / Performance	SP-01	SP-02	SP-03	SP-11	SP-12	SP-13
Sample frequency(Hz)	200K	100K	50K	200K	100K	50K
Function						
BTPS	Y	N	N	Y	N	N
Component						
LCD	N	N	N	Y	Y	Y

BTPS: body temperature and pressure, saturated

1.4.2 Main structure

The SP-0X series device is mainly composed of the main unit (Breathing signal acquisition circuit, microcontroller, buttons, and power module), disposable turbine with mouthpiece, flash disk and application software (computer software) .

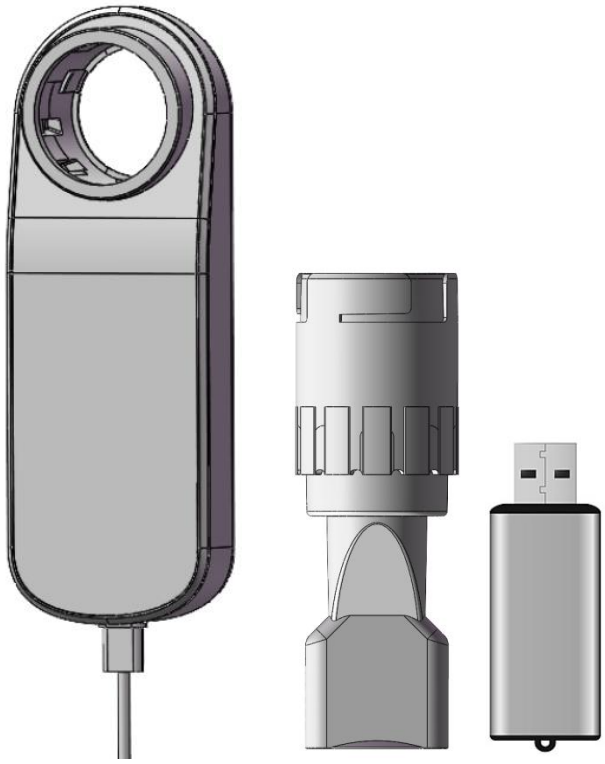


Figure 1 SP-0X seriesProduct structure composition

The SP-1X series device is mainly composed of the main unit (Breathing signal acquisition circuit, microcontroller, Bluetooth module, LCD display, buttons, and power module), disposable turbine with mouthpiece, USB cable, flash disk, application software (computer software, mobile software) and 2 LR03(AAA) batteries.

Figure 1 SP-1X series Product structure composition

The disposable turbine with mouthpiece is applied part.

1.5 Product performance

1.5.1 Measurement principle introduction

The device detects the signals generated by the turbine, measures the exhalation flow and then sends it the Mobile Medical Application / computer system. At the end of the expiration, the device calculates a range of respiratory parameters and sends them to the Mobile Medical Application / computer system.

1.5.2 Performance index

Expiration /inspiration flow (PEF)	Range：0-17L/s Accuracy：±0.17L/s or ±10% (whichever is greater) Repeatability：±5% Linearity：±0.17L/s or ±5% (whichever is greater) Frequency response: ± 0.25L/s or ± 12% (whichever is greater)
Volume (FEV1, FEV6 and FVC)	Range：0-10L Accuracy：±0.05L/s or ±3% (whichever is greater) Repeatability：<3%

	Linearity: < 3%
Airflow resistance	Flow measurement range < 0.35kPa / (L/s)

1.5.3 Parameter description

Table 1 Display measured value parameters in different modes

Mode	Measurement display parameters
Forced vital capacity	FVC、FEV1、FEV1/FVC、PEF、FEV0.5、FEV0.75、FEV2、FEV2/FVC、FEV3、FEV6、FEF25、FEF50、FEF75、FEF2575、FIV1、FIVC、PIF、FIF25、FIF50、FIF75、MET2575、 FET、EV、FEV0.75/FVC、FEV3/FVC、FEV0.75/ FEV6、FEV1/ FEV6、FEF50/FVC、FEF2575/FVC、MVV、Lung Age、Pre、%Pre、LLN、Z-score、SD
Slow vital capacity	EVC、IVC、TV、ERV、IRV、IC、FR、TI、TE、TV/TI、TI/Ttot
Maximum minute ventilation	MVV、TV、FR

1.5.4 Terms

No.	Symbol	Description	Unit
1.	FVC	Forced vital capacity	L
2.	FEV1	Absolute second capacity	L
3.	FEV1/FVC	Relative 1 second capacity of FVC in percent	%
4.	PEF	Peak expiratory flow	L/s
5.	FEV0.5	0.5 second capacity (forced expiratory volume in 0.5 seconds)	L
6.	FEV0.75	0.75 second capacity (forced expiratory volume in 0.75 seconds)	L
7.	FEV2	2 second capacity (forced expiratory volume in 2 seconds)	L
8.	FEV2/FVC	Relative 2 second capacity of FVC in per cent	%
9.	FEV3	3 second capacity (forced expiratory volume in 3 seconds)	L
10.	FEV6	6 second capacity (forced expiratory volume in 6 seconds)	L
11.	FEF25	Forced expiratory flow at 75% of FVC	L/s
12.	FEF50	Forced expiratory flow at 50% of FVC	L/s
13.	FEF75	Forced expiratory flow at 25% of FVC	L/s

No.	Symbol	Description	Unit
14 .	FEF2575	Average forced expiratory flow between 25% and 75% of FVC	L/s
15 .	FIV1	1 second capacity (forced inspiratory volume in 1 second)	L
16 .	FIVC	Forced inspiratory vital capacity	L
17 .	PIF	Peak inspiratory flow	L/s
18 .	FIF25	Forced expiratory flow at 75% of FIVC	L/s
19 .	FIF50	Forced expiratory flow at 50% of FIVC	L/s
20 .	FIF75	Forced expiratory flow at 25% of FIVC	L/s
21 .	MET2575	The time taken between 25% and 75% of the FVC	s
22 .	FET	Forced expiratory time	s
23 .	EV	Extrapolated Volume	L
24 .	FEV0.75/FVC	FEV0.75/FVC	%
25 .	FEV3/FVC	FEV3/FVC	%
26 .	FEV0.75/ FEV6	FEV0.75/FEV6	%
27 .	FEV1/ FEV6	FEV1/FEV6	%
28 .	FEF50/FVC	FEF50/FVC	%
29 .	FEF2575/FVC	FEF2575/FVC	%
30 .	MVV	Maximum voluntary ventilation	L/min
31 .	Lung Age	Lung Age	years
32 .	TV	Breath volume (Tidal Volume)	L
33 .	RR	Respiration rate	bpm
34 .	%Pre	Ratio of the actually measured value to the predicted value	%
35 .	LLN	Lower Limits of Normal	/
36 .	Z-score	Standard scores	/
37 .	SD	Standard deviation	/
38 .	EVC	Expiratory vital capacity	L
39 .	IVC	Inspiratory vital capacity	L
40 .	ERV	Expiratory reserve volume	L
41 .	IRV	Inspiratory reserve volume	L
42 .	IC	Inspiratory capacity	L
43 .	FR	Frequency of respiration	bpm

No.	Symbol	Description	Unit
44 .	TI	Average time of inspiration at rest	s
45 .	TE	Average time of expiration at rest	s
46 .	TV/TI	Ratio of tidal volume to time of inspiration	%
47 .	TI/Ttot	Ratio of time of inspiration in total time.	%

*=best values

1.5.5 Data transmission connection mode and description

Data transmission connection method	Illustrate
Bluetooth network (SP-1X only)	Connect the mobile terminal software via Bluetooth to realize the measurement data transmission
USB cable	Connect via USB cable to realize measurement data transmission

1.6 Contraindications

- Due to increases in myocardial demand or changes in blood pressure
  - Acute myocardial infarction within 1wk
  - Systematic hypotension or severe hypertension
  - Significant atrial/ventricular arrhythmia
  - Noncompensated heart failure
  - Uncontrolled pulmonary hypertension
  - Acute cor pulmonale
  - Clinically unstable pulmonary embolism
  - History of syncope related to forced expiration/cough
- Due to increases in intracranial/intraocular pressure
  - Cerebral aneurysm
  - Brain surgery within 4wk
  - Recent concussion with continuing symptoms
  - Eye surgery within 1wk
- Due to increases in sinus and middle ear pressures
  - Sinus surgery or middle ear surgery or infection within 1 wk
- Due to increases in intrathoracic and intraabdominal pressure
  - Presence of pneumothorax
  - Thoracic surgery within 4wk
  - Abdominal surgery within 4wk
  - Late-term pregnancy
- Infection control issues
  - Active or suspected transmissible respiratory or systemic infection, including tuberculosis
  - Physical conditions predisposing to transmission of infections, such as hemoptysis,

significant secretions, or oral lesions or oral bleeding.

Spirometer should be discontinued if the patient experiences pain during the maneuver. Relative contraindications do not preclude Spirometer but should be considered when ordering it. The decision to use the device is determined by the ordering healthcare professional on the basis of their evaluation of the risks and benefits for the particular patient.

1.7 Product list

Name	**Quantity**
Spirometer	×1
USB cable (SP-1X only)	×1
Disposable turbine with mouthpiece	×1
Flash disk	×1
LR03(AAA) battery (SP-1X only)	×2
User manual	×1
Quality certificate	×1
Warranty card	×1
Packing list	×1

1.8 Site requirements during use

1) There should be good ventilation equipment;
2) The venue should not be too narrow;
3) The indoor temperature and humidity should be relatively constant;
4) The indoor environment should be quiet;
5) If conditions permit, set up a waiting area;
6) Easy to rescue.

1.9 Other usage specifications

The device can only be operated by trained medical personnel.

1.10 Risks and benefits

Risks: 1) Before performing a pulmonary function test, the physician should understand and ask about the patient's disease history and determine whether the patient is suitable to use the device. At the same time, the physician shall observe the patient's reaction during the test, for example, when the patient feels pain during the procedure, the physician shall

consider stopping the pulmonary function test. These are the things that the pulmonary function physician or technician must pay attention to before testing.

2) Diagnosis based only on the results from Spirometer may not be accurate. The measurement results can only serve as a clinical reference which should be explained by professional medical personnel. A qualified physician must reassess all measurements. An interpretation by the medical device is significant only when considered together with other clinical findings.

Benefits: 1) Regular monitoring of pulmonary function parameters, especially beneficial for patients with asthma, COPD, etc.

2) The measurement results, together with other clinical finding can help doctor perform diagnosis, screening for pulmonary disease, decide treatment and assess the effectiveness of the current treatment.

2. Label symbol description

Graphics Symbols	Meaning
	**Prescription only.** CAUTION: FEDERAL U.S. LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.
	Refer to the instruction manual / booklet
	Keep away from rain
	Keep away from sunlight
	Fragile, handle with care
	Type BF applied part
	Low-frequency electromagnetic radiation
	“WEEE (Waste Electrical and Electronic Equipment)”. The waste products should be handled legally.

	Caution
	Serial number
	Manufacturer
	Date of manufacture
	Class II equipment
	Unique device identifier
IPX0	Not waterproof or dustproof

3. Precautions, warnings, and prompt instructions

- Please use within the temperature, humidity and atmospheric pressure range specified by the manufacturer, otherwise the equipment may not reach the claimed performance.
- Please operate strictly according to this user manual, or else there might be inaccurate measurements or device gets damaged.
- Please clean and disinfect the pressure taking structure according to the method specified in the product manual.
- Please connect the device to the designated device, otherwise the device will be unusable or the measurement data will be wrong.
- Please test according to the method specified in the product manual, and confirm that the current measurement mode and the blowing method are correctly matched, otherwise the measurement results will be inaccurate.
- Do not use this device in an environment that has anesthetics and other inflammables which may cause an explosion.
- Do not use this device in strong electromagnetic interference or direct wind source, and heat source environment.
- Do not spatter liquid onto this device which may cause damage.

- Do not place the equipment in a mechanically vibrating environment.
- Do not drop this device from a high place.
- Do not use sharp objects to press or scratch the equipment shell.
- Do not disassemble the device without permission. No part of the medical device may be replaced by the customer. Use only Beneware approved accessories and spare parts for this medical device.
- Keep accessories, packing material, cleaning and disinfection substances out of the reach of children.
- Do not place heavy objects on the device which may cause performance or mechanical damage.
- Do not use high temperature, high pressure or gas disinfection to disinfect the device.
- If the device continues to fail to display data or there are other abnormal conditions, press function button to remeasure, or power off the device and restart; please contact the after-sales customer service in time.
- After use, the device will produce some wastes such as disposable parts or vulnerable parts and when discarding the equipment itself. Disposing of these wastes arbitrarily will pollute the environment or cause cross-infection. It should be dealt with per laws, regulations and other relevant regulations.
- The measurement results can only serve as a clinical reference which should be explained by professional medical personnel. A qualified physician must reassess all measurements. An interpretation by the medical device is significant only when considered together with other clinical findings.
- Data collection and storage: When the user uses the software to measure the pulmonary function of the patient, the patient's name, gender, height, weight, date of birth, and race are collected as key information in the software, and the above information are only used to calculate the predicted value of the patient's pulmonary function. After the patient completes the pulmonary function test, the patient's own information and the indicators and chart reports generated by the pulmonary function test are stored in the local computer database/mobile tablet device for clinical analysis by the medical staff. This information are stored on the computer/mobile tablet device used by the user, or user shall determine the retention period of the information or delete it.

- User’s options for opting out of data collection and the ability of the device to control the collection of data: The information involved in this product are only the data related to the user's pulmonary function test: Users can choose to cancel the preservation of patient information or delete patient information according to their own needs, and the software has the automatic logout function to reduce the risk of unauthorized access in unattended workplaces. In addition, software vulnerabilities found are repaired and updated in a timely manner to ensure safe use of the product.
- When using the device, pay special attention to the user manual where this symbol ⚠ is marked.

4. Installation and use instructions

4.1 Check the equipment list

Check whether the product and its accessories are complete according to the product list in 1.7. If there is any missing or damaged, please contact the after-sales customer service center in time.

4.2 Equipment installation and preparation

Usually, you can use a spirometer to perform a lung function test and get the test results. In order to view and store detailed waveforms and test results, you can connect the device to a PC. To make the connection, attach the cable to the USB port of the PC. To control the proper connection between the device and the PC check that the led on the device is lit. The software can store the data and analysis results collected by the device on the PC, which is convenient for the doctor to review and print the report..

⚠ ***Caution:***

The user purchases a disposable turbine with mouthpiece.

Mouthpiece specifications: outer diameter 33.2mm. We recommend to use Beneware disposable turbine with mouthpiece.

4.3 Equipment use

4.3.1 Boot

Long press the Power button, after the device starts, the display shows the boot interface. After the above actions are completed, the boot operation is complete.

4.3.2 Start test

After entering the test mode interface, press the power button to start the test.

⚠ ***Caution:***

Physician shall instruct patients to not expect sputum or cough into the device during measurement, otherwise the performance of the device may be affected.

4.3.4 View test records

On the record interface, the data records already collected are displayed, and the lists are displayed by the descending order of the record time.

4.4 Pulmonary ventilation function measurement method

The device contains three measurement modes: forced vital capacity test, slow vital capacity test, and maximum minute ventilation test.

Use the corresponding breathing method to measure, see below for details.

⚠ ***Caution:***

1) In order to ensure the accuracy of measurement results, users are required to understand and master the blowing method of each measurement mode and instruct patients.

2) Physician shall instruct user to keep sitting and standing and keep his/her body stable during measurement.

3) Physician shall instruct user to not swing his/her head forcefully with body when blowing, which will affect the measurement results.

4.4.1 Forced vital capacity test

Physician shall instruct patient to conduct the following steps:

1) Practice forced breathing exercises according to the instructions of the technician or doctor, and master the essentials of FVC movements. Avoid fatigue of subjects and achieve satisfactory results.

2) Connect the mouthpiece to the mouth, wrap the mouthpiece tightly with your lips, and clamp the nose clip to ensure that the nose and mouth do not leak. If some subjects cannot guarantee that the corners of the mouth will not leak, a special mouthpiece with a tooth mask can be added.

3) Breathe calmly for 4-5 times. After the breathing is stable, take a deep breath, and then exhale forcefully, quickly and completely, all in one breath.

4) After the exhalation is complete, inhale strongly and quickly until it is complete, and then breathe calmly for 4-5 times to complete the test.

⚠ ***Caution:***

The same patient cannot be tested more than 8 times a day!

4.4.2 Slow vital capacity test

Physician shall instruct patient to conduct the following steps:

1）Connect the mouthpiece to the mouth, wrap the mouthpiece tightly with your lips, and clamp the nose clip to ensure that the mouth and nose do not leak. If some patients cannot guarantee that the corners of the mouth will not leak air, a special mouthpiece with a lip-tooth mask can be added.

2） Clamp the nose clip, connect the mouthpiece to the mouth, and breathe calmly for 4-5 times. After the breathing is stable, inhale as much as possible at the end of the expiration at a moderate speed (total lung volume), and then exhale to the end.

3) Repeat the above steps to check more than 3-5 times, and rest for more than 1 minute between the 2 times.

4.4.3 Maximum minute ventilation test

Physician shall instruct patient to conduct the following steps:

1）Connect the mouthpiece to the mouth, wrap the mouthpiece tightly with your lips, and clamp the nose clip to ensure that the mouth and nose do not leak. If some patients cannot guarantee that the corners of the mouth will not leak air, a special mouthpiece with a lip-tooth mask can be added.

2) Clamp the nose clip, connect the mouthpiece to the mouth, and breathe calmly for 4-5 times. After the exhalation is stable, continue to breathe for 12 or 15 seconds at the maximum breathing amplitude and maximum speed.

2) In the whole process of the inspection, the subjects can obtain the best cooperation according to the timely instructions and continuous counseling issued by the technician. Repeat the second and third inspections after 5-10 minutes of rest.

4.5 Shutdown

When the device is turned on, long press the power button, the instrument display screen displays the shutdown interface. After the above actions are completed, the device

shutdown is complete.

4.6 Use of batteries（SP-1X only）

1) 2 pieces of LR03(AAA) batteries are required for the main unit for about 15 days of service (based on 30 minutes each day).
2) When the main unit displays " ", it indicates a low battery. Please replace with new batteries.
3) When the product is not in use for a long time, please remove the batteries, otherwise a device malfunction may occur due to battery leakage.
4) Please don't use batteries other than externally specified.
5) Please pay attention to the positive ("+") and negative ("-") poles in mounting batteries.
6) Please never run the batteries under a temperature above 45℃, otherwise their performance and service life will be affected.
7) The discarded batteries should be disposed in accordance with your local urban regulations on environmental protection.

5. Instructions for using mobile software (see Annex 1 for details)

6. Instructions for using computer software (see Annex 2 for details)

7. Cleaning and disinfection methods

During the pulmonary function test, some parts of the equipment will be contaminated with bacteria. Therefore, the next subject may be at risk of bacterial infection.

Thorough disinfection of all contaminated parts can avoid potential risks of infection. Therefore, all parts should be disinfected regularly.

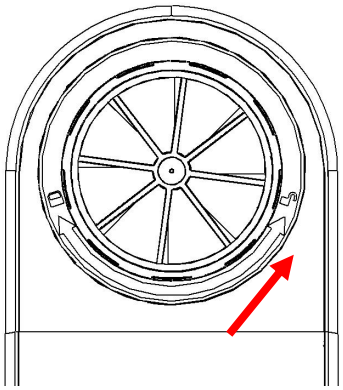
The spirometer main unit shall be cleaned and disinfected once every week.

⚠ ***Caution:***

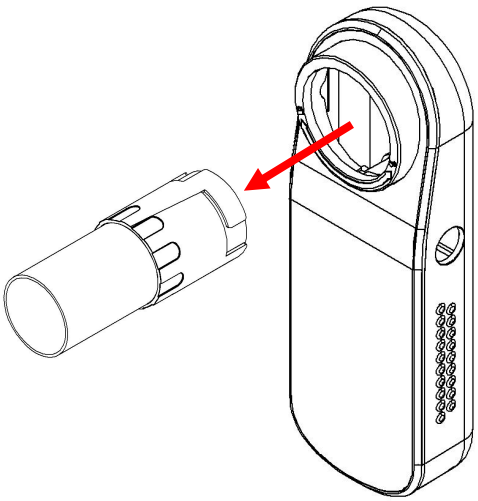
Thorough disinfection of all contaminated parts can avoid potential risks of infection. Thus, all parts shall be regularly disinfected, disposable products must be discarded.

7.1 Disassembly of Spirometer

Turn the flow sensor counterclockwise to loosen it from the body.



After releasing it, pull the flow sensor away from the body.



7.2 Cleaning and disinfection of the main unit shell

It is recommended to wipe the main unit surface of the Spirometer regularly to keep it clean.

① Cleaning: Use clean gauze dipped in 75% medicinal alcohol (gauze does not drip), to wipe the surface of the main unit.

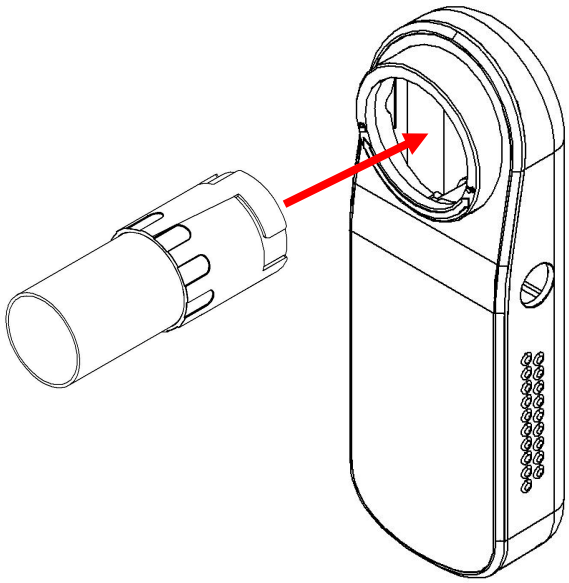
② Drying: Natural air drying or use clean dry gauze to wipe dry.

⚠ ***Caution:***

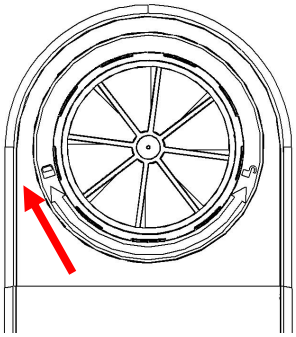
❖ **During cleaning and disinfecting of the equipment, it is forbidden to immerse the main unit in liquid!**

7.3 Reassembly of Spirometer

Insert the flow sensor into the body as shown in the figure below.



After inserting the flow sensor into the body, turn the flow sensor clockwise to lock it with the body.



⚠ ***Caution:***

Pay attention to press the quick release card lock tightly, to avoid air leakage!

8. Equipment maintenance

8.1 Maintenance

1) Regular inspections to ensure that the equipment has no obvious damage that affects safety or detection performance. It is recommended to inspect at least once a week. If there is obvious damage, stop using the equipment and contact after-sales customer service.

2) The maintenance of this equipment is limited to qualified personnel designated by the manufacturer. Users should not repair the equipment by themselves.

3) When the device prompts that the battery is low, use a power source that meets the USB specification to charge in time. If the battery is found to be used for too short a time, you should stop using the device and contact after-sales customer service.

4) Please use it in the specified working environment, keep the operating environment clean, free of corrosive or combustible substances, and free of excessively high or low temperature and humidity.

8.2 Work, storage and transportation requirements

8.2.1 Working environment

The device needs to work under the following environmental conditions:

Temperature: 5 ℃ ~ 40 ℃

Rel. humidity: 80%RH

Ambient pressure: 700hPa ~ 1060hPa

If it exceeds the above working environment, it will affect the measurement performance of the product.

8.2.2 Transport and storage environment

The device should be transported and stored under the following environmental conditions:

Temperature: -40 ℃ ~ +55 ℃

Rel. humidity: <93% RH

Ambient pressure: 560hPa ~ 1060hPa

Clean room without corrosive gas and well ventilated.

8.2.3 Transportation requirements

The following requirements must be met when transporting the device:

1) Avoid heavy objects squeezed;

2) Avoid direct sunlight;

3) Avoid getting wet from the rain;

4) Handle with care during the moving process.

9. Failure analysis and resolution

Failure phenomenon	Cause Analysis	Solution
Can not boot	Low battery	Please change the battery.
	Possible equipment damage	Please contact the after-sales customer service center.
Bluetooth network connection failed after power on	The Bluetooth function of the mobile phone is not turned on	Please turn on the Bluetooth function of the mobile phone.
	The distance between the device and the phone is too large	Please keep the distance between other Bluetooth and the device less than 5 meters.
	The Bluetooth communication module may be damaged	Please contact the after-sales customer service center.
The device uses the USB connection software successfully, but the communication is abnormal	Could not establish connection	The USB cable is damaged or the connection is loose.
	The connection has been established and the communication is abnormal	Disconnect the USB and reconnect or shut down and restart.
	Instrument damage	Please contact your local customer service center.
	Software program blocking	Close the software and reopen it.
No data can be detected for blowing	The instrument does not enter the detection state	Press the key again to measure or shut down and restart.
	Incorrect blowing posture	Please use the correct blowing method.

Data lost (software)	data lost	You can find the information under the backup in the software catalog or use the data recovery function of the system to find the lost data.
	Software crashes	During use, the logic of the application itself may be wrong, and the system may cause the software to crash. At this time, the software can be restarted to continue running.
Spirometry data at the end of the test are not acceptable	The turbine don't rotate correctly	Use a new turbine.
	The test is performed in a wrong way	Repeat the test following the indications on the screen.

10. Product quality information

10.1 Guarantee

1 . When starting to use the product of spirometer, users should fill in detail the Guarantee Card and timely send back to the company. Based on it, the company will establish the user profile and periodically learn the condition of the use, which facilitates the company to provide users with sustainable and targeted quality service.

2 . The spirometer and its accessories include no parts that can be repaired by users and users should not arbitrarily disassemble or repair the device; in principle, the company will not provide users with the circuit and working principle and other technical information. However, if it is required, users may contact the Technology Department of the company. Damaged parts may cause dangers and must be repaired or replaced in time. Please contact the technical service center of the company immediately. Users have access to free after service based on the terms and conditions specified in the Guarantee Card.

3 . The company may fulfill its obligation through door-to-door visit, instruction through phone and delivery to the company, and other methods.

4 . Even in the free guarantee period, the following service will be charged:

①Fault or damage caused by improper use of users;

②Fault or damage caused by transport and falling after purchase;

③Fault or damage caused by repair, transformation or disassemble in other places beyond the

company;

④Fault or damage caused by fire, earthquake or other force majeure after purchase;

⑤Fault or damage caused by not using the accessories designated by the company;

⑥Fault or damage caused by connecting other equipment;

⑦The guarantee seal is damaged;

⑧Users unilaterally revise or change the machine number or lead number.

The company will not be responsible for any fault of other connecting equipment caused directly or indirectly by any fault of the product.

5．If the guarantee label is damaged, the company may be exempted from the obligation of

6．12-month free maintenance service.

7．For charged maintenance service beyond the guarantee period, users are suggested to use the "Maintenance Contract System". Refer to the technical service center of the company for details.

8．Please select the accessories of the original factory for replacement.

10.2 Production date and expiry date

Product production date: see product label

Product expiration date: 5 years

11. Cybersecurity instructions

The device has the function of data transmission to mobile terminal software and computer terminal software.

11.1 Operating environment requirements

Software type	Hardware Configuration	Software Environment	Network conditions
Mobile	Memory: 2GB RAM or above;	Android 7.0 or above	Network

software	Storage hard disk space: 16GB or above		required
Computer software	Processor: Intel i3 2.4GHz or above; Memory: 4GB or above; Hard disk: 500GB or above;	Windows 8/10 or above	Network required

11.2 Security software

Users can choose conventional international mainstream antivirus software, such as Kaspersky, Symantec, McAfee, Norton, etc.

11.3 Data and equipment interface

Spirometer follows the BLE protocol to realize the communication between embedded devices and other Bluetooth devices.

Spirometer follows the USB protocol to realize the communication between the embedded device and the software.

11.4 User access control mechanism

User type	User rights	User authentication method	Password strength setting
General User	Access device measurement data	Individual user accounts, users cannot register independently by themselves, the administrator needs to assign them separately	Personal account: The account name matches the password. The password must have upper and lower case letters, numbers and special characters, and the length should not be less than 8 digits.
Administrator User	Access device data, perform software update and maintenance	Pass account password	The account name matches the password. The password must have upper and lower case letters, numbers and special characters, and the length should not be less than 8 digits.

11.5 Interoperability

Intended user: All interface operations shall be conducted by medical examination professionals, or trained doctors and nurses, or laboratory workers. The patient does not conduct any interface-related operations.

11.5.1 Interface

Interface type	Device to be connected	Device type and system version to be connected	Interface standard/ specification	Purpose of the interface	Transmission rate
USB	Computer	Windows 8/10 or above	USB2.0/3.0	Data transmission with computer software	12Mbps
Bluetooth（SP-1X only）	Android tablet	Android 7.0 or above	BLE5.0	Data transmission with mobile software	Baud rate 115200

Note 1: The Bluetooth of the device supports BLE5.0, which meets the FCC specifications.
Note 2: Users can check the connection status with the Spirometer main unit through the home page of the computer/mobile software.

Caution: Do not connect the device to any other medical devices or products through the above interfaces!

11.5.2 Data attributes to be exchanged

Data to be exchanged	Data attribute description
Device control instruction code and response	Request for preparing the blow, stop the blow, obtaining device number, calibrating device, obtaining calibration parameters
Instruction code and response for device measurement data	Data of measurement such as FVC, FEV1, PEF, and calibration measurement
Instruction code and response for test subject information	Predicted value of the test subject's pulmonary function indicators

11.5.3 Summary of the testing performed on the interfaces

Manufacture and model of devices installed with the software	Test interface	Test summary
Lenovo Laptop, Model: E431	USB	Connection test between Spirometer and computer software; The computer software controls the Spirometer to

		conduct pulmonary function test.
Mi 5S Plus	BLE	Connection test between Spirometer and mobile software; The mobile software controls the Spirometer to conduct pulmonary function test.

11.6 Cybersecurity maintenance and security incident response

11.6.1 Method for cybersecurity maintenance and device update

1) Email notification: If the customer has registered for the product or service, the manufacturer may send notices about fixes, patches and updates to the customer via email. These notifications usually contain detailed information such as the fixed issue, installation instructions, and release date.

2) Customer support: Customers can obtain information about fixes, patches and updates by contacting the manufacturer's customer support department. Customer support and maintenance personnel usually provide detailed information and help customers to complete the installation process.

3) Security Bulletin: Manufacturers may publish information about fixes, patches, and updates in their security bulletin. These announcements usually include fixes, installation instructions, and release dates.

4) Agent/after-sales engineer’s return visit: Agent/after-sales engineer will assist customers to complete the installation and update during the product after-sales service process.

11.6.2 Network use of the device

1) Computer software

The use of computer software does not require network connection. The test data is saved in local.

2) Mobile software

Only when logging in for the first time, user needs to go online to verify the account password. The test data is saved in local.

11.6.3 Cybersecurity detection and user notification

Users need to install anti-virus software on the PC/APP terminal, such as Kaspersky, McAfee, Norton. The antivirus software must be permanently running in the background of the system. When the antivirus software detects a cybersecurity threat (such as a Trojan

or worm virus), it will notify the user through the pop-up window.

11.6.4 Cybersecurity incident response

1) Disconnect from the network: If you suspect that the network has been attacked or infected, you can temporarily disconnect from the network to prevent the malware from further spreading or stealing data. This can be achieved by cutting off the network and turning off the WiFi.

2) Use security tools for detection and removal: Conduct comprehensive inspection using tools such as anti-virus software and security scanning tools to find and remove malware. Make sure to use the latest version of antivirus software and update viruses regularly.

3) Contact the manufacturer's agent/after-sales engineer for assistance: If you cannot solve the problem by yourself, you can contact the agent/after-sales engineer for help.

12. Electromagnetic compatibility instructions

12.1 Parameter description

Name	Working frequency	Modulation type	Maximum Tune-up power(dBm)
Bluetooth (SP-1X only)	2.4GHz ISM BAND	GFSK	4.00

Name	Cable length (m)	Whether to block	Remark
USB Cable	2.0	Yes	/

⚠ ***Warning***

Even if other equipment meets the emission requirements of the corresponding national standards, the equipment or system may still be interfered by other equipment.

12.2 EMC statement

The intended environment of use: In the clinic, doctors' office or hospital under the direction of physician, Don't be near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Essential performance: The device has no essential performance.

1） Model SP-01/SP-02/SP-03/SP-11/SP-12/SP-13 needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying document;

2 ） Portable and mobile RF communications equipment can affect model SP-01/SP-02/SP-03/SP-11/SP-12/SP-13.

⚠ **Warning:**

1） Use of accessories, transducers and cables other than those specified or provided by the manufacturer of Model SP-01/SP-02/SP-03/SP-11/SP-12/SP-13 could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

2） Use of Model SP-01/SP-02/SP-03/SP-11/SP-12/SP-13 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.

3） 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 Model SP-01/SP-02/SP-03/SP-11/SP-12/SP-13, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

4） Precautions regarding sources of EM energy that:

- emit levels of EM energy that exceed the immunity test levels of the referenced EMC standards used, or
- have other emission characteristics to which the medical device has not been tested for immunity.

5) Avoid using around RF emitters with wireless power transfer (WPT) and 5G cellular.

6) RFID equipment may interfere with the device and lead to performance degradation, caution should be paid when use the device around RFID equipment.

12.3 FCC declaration

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.

Note: This equipment has been tested and found to comply with the limits for a Class A digital device,pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

NOTE: “Harmful interference” is defined in 47 CFR §2.122 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

12.3.1 FCC RF Radiation Exposure Statement:

1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

2. This equipment complies with RF radiation exposure limits set forth for an uncontrolled environment.

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

12.3.2 FCC Caution:

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

12.4 Declaration of conformity

Table 1

<table>
<tr><th colspan="3">Guidance and manufacturer´s declaration – electromagnetic emission</th></tr>
<tr><td colspan="3">The Spirometer（SP-01/SP-02/SP-03/SP-11/SP-12/SP-13） is intended for use in the electromagnetic environment specified below. The customer or the user of Spirometer（SP-01/SP-02/SP-03/SP-11/SP-12/SP-13） should assure that it is used in such an environment.</td></tr>
<tr><td>Emissions test</td><td>Compliance</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>RF emissions

CISPR 11</td><td>Group 1</td><td>The Spirometer （SP-01/SP-02/SP-03/SP-11/SP-12/SP-13） uses RF energy only for its internal function. There for, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions

CISPR 11</td><td>Class B</td><td rowspan="3">The Spirometer（SP-01/SP-02/SP-03/SP-11/SP-12/SP-13） is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions

IEC 61000-3-2</td><td>Not applicable</td></tr>
<tr><td>Voltage fluctuations

flicker emissions

IEC 61000-3-3</td><td>Not applicable</td></tr>
</table>

NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Table 2

Guidance and manufacturer´s declaration – electromagnetic immunity			
The Spirometer（SP-01/SP-02/SP-03/SP-11/SP-12/SP-13） is intended for use in the electromagnetic environment specified below. The customer or the user of the Spirometer（SP-01/SP-02/SP-03/SP-11/SP-12/SP-13） 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 ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 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 ± 1 kV for input/output lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode	± 1 kV differential mode	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	0 % UT; 0,5 cycle g) 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	0 % UT; 0,5 cycle g) 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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Spirometer（SP-01/SP-02/SP-03/SP-11/SP-12/SP-13） requires continued operation during power mains interruptions, it is recommended that the Spirometer（SP-01/SP-02/SP-03/SP-11/SP-12/SP-13） be powered from an uninterruptible power supply or a battery.
Power frequency	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

(50/60 Hz) magnetic field IEC 61000-4-8			environment.
NOTE	U_T is the a. c. mains voltage prior to application of the test level.		

Table 3

Guidance and manufacturer´s declaration – electromagnetic immunity			
The Spirometer（SP-01/SP-02/SP-03/SP-11/SP-12/SP-13） is intended for use in the electromagnetic environment specified below. The customer or the user of the Spirometer（SP-01/SP-02/SP-03/SP-11/SP-12/SP-13） should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz	3 Vrms 150 kHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the Spirometer（SP-01/SP-02/SP-03/SP-11/SP-12/SP-13）, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 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 metres (m).[b]
Radiated RF IEC 61000-4-3	3 V/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 60601-1-2:2014)	3 V/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 60601-1-2:2014)	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.[b] 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 is affected by absorption and reflection from structures, objects and people.			
[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to			

6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

[b] 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 Spirometer （SP-01/SP-02/SP-03/SP-11/SP-12/SP-13） is used exceeds the applicable RF compliance level above, the Spirometer（SP-01/SP-02/SP-03/SP-11/SP-12/SP-13）should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Spirometer （SP-01/SP-02/SP-03/SP-11/SP-12/SP-13）.

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

Table 4

Recommended separation distances between portable and mobile RF communications equipment and the Spirometer (SP-01/SP-02/SP-03/SP-11/SP-12/SP-13)

The Spirometer （SP-01/SP-02/SP-03/SP-11/SP-12/SP-13） is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Spirometer（SP-01/SP-02/SP-03/SP-11/SP-12/SP-13）can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Spirometer （SP-01/SP-02/SP-03/SP-11/SP-12/SP-13） 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)		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.23\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.23
10	3.70	3.70	7.37
100	11.70	11.70	23.30

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 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. Contact information

Manufacturer: Suzhou Beneware Medical Equipment Co., Ltd.

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Tel.: +86-512-66806855

Email: service@beneware.net

Website: www.beneware.net