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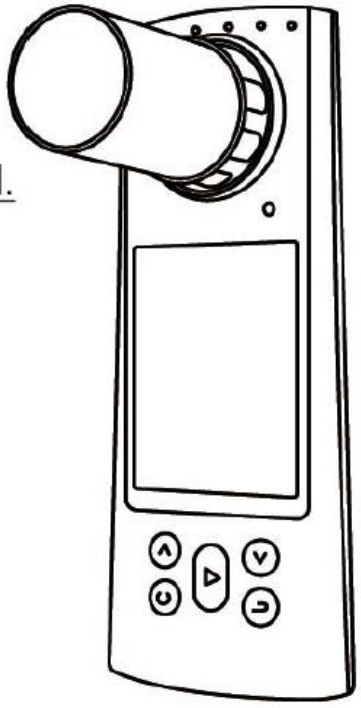
SPIROMETER



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Instructions to User

Dear users, thank you very much for purchasing the SPIROMETER.

Please read the User Manual carefully before using this product. The operating procedures specified in this User Manual should be followed strictly. This manual describes in detail the operation steps which must be noted, the procedures which may result in abnormality, and possible damage to the product or users. Failed to follow the User Manual may cause measuring abnormality, device damage or personal injury. The manufacturer is NOT responsible for the safety, reliability and performance issues of such results due to user's negligence of this manual for using, maintenance or storage. The free services and repairs does not cover such faults either.

Owing to the forthcoming renovation, the specific products you received may not be totally in accordance with the description of this User Manual. We would sincerely regret for that.

Date of manufacture: see the label.

This product is a medical device, which can be used repeatedly.

Warning:

- To ensure measurement accuracy, it is recommended that the device should not be tested continuously on the same testee for more than 8 times.
- The testee should breathe out all air during testing, don't exchange air or cough.
- Don't use the device in environment with low temperature.
- Automatic power off when there is no operation in 2 minute.
- This device is not intended for treatment.

The company supplies qualified products to users in accordance with enterprise standard.

The company provides services of installation, debugging and technical training according to the contract.

The company performs device repair in warranty period (a year) and maintenance after warranty period.

The company is responsible to respond to users' requirements in time.

The company reserves the final explanation right to this user manual.

Chapter 1 Safety

1.1 Instructions for safe operations

- ✧ Check the device periodically to make sure that there is no visible damage that may affect its safety or performance. It is recommended to inspect the device weekly at least. When there is obvious damage, stop using it.
- ✧ Necessary maintenance must be performed by qualified service engineers ONLY. Users are not permitted to maintain it by themselves. Our company may, upon request, provide technical support and materials such as components list, legend, calibration details or other materials that necessary for the maintenance by qualified technical staff.
- ✧ The device can not be used together with other equipment not specified in User Manual. Only the accessories appointed or recommended by manufacture can be used.
- ✧ This device has been calibrated before leaving factory.

1.2 Warning

- Please don't measure this device with functional tester for the device's related information.
- Explosive hazard—DO NOT use the device in environment with inflammables such as anesthetic.
- Please check the packing before use to make sure the device and accessories are totally in accordance with the packing list, or else the device may have the possibility of working abnormally.
- Don't use the device in environment with strong electromagnetic interference, direct breeze source, cold source and hot source.
- The disposal of scrap device, its accessories and packing (including mouthpiece, plastic bags, foams and paper boxes, etc.) should follow the local laws and regulations, as improper disposal may pollute the environment.
- Please choose the accessories appointed or recommended by the manufacturer to avoid damage to the device.
- Don't use the device with the turbine of other similar products. After replacing the turbine, it is recommended to calibrate the turbine before use.
- When patients use the device,the device is not allowed to be maintained.
- Refit of the device is not allowed.

1.3 Caution

- Keep the device away from dust, vibration, corrosive or inflammable substances, high or low temperature and humidity.
- If the device gets wet or coagulates, please stop operating.
- When it is carried from cold environment to warm or humid environment, please do not use it immediately.
- DO NOT operate keys on front panel with sharp things.
- High temperature or high pressure steam disinfection to the device is not permitted. Refer to User Manual in the relative chapter (7.1) for cleaning and disinfection.
- Do not have the device immersed into liquid. When wiping the device with medical alcohol, avoid spray any liquid on the device directly.
- When cleaning the device with water, the temperature should be lower than 60℃.
- Measured data will be displayed within 5 seconds after finishing the measurement, the delay time depends on the ending speed.
- If measured data can't be displayed or other abnormal happened during testing, please restart the device.
- The device has service life for three years.
- The device may suitable for all users, if you can't get good measurement data, please stop using it.
- The device needs to be calibrated once per year or less.
- The device is intended to test forced vital capacity, use it according to the User Manual to get best results.
- This user manual contains information about operation instructions and technical specifications.
- The device can not be operated until half an hour later when it is moved from the highest or lowest storage temperature environment to room temperature environment.
- The device needs to be kept out of the reach of children or pets, to prevent animal hair or dirt entering the turbine to affect its use.
- The equipment connected with this device via interfaces should compliance with IEC 60950 or IEC 60601-1.
- Please use medical power adapter when charging the device.
- Applied part：mouthpiece.
- The patient is an intended operator, the patient can measure data and charge battery under normal circumstances and maintain the device and its accessories according to the user manual.
- Mode of operation: continuous operation.
- The temperature of eyquipment application part and contactable part shall not exceed 41℃.
- Non-transit-operable.
- The mouthpiece is disposable, do not open its package if not use.

1.4 Contraindication

1.4.1 Absolute contraindication

- The one with MI or shock in recent 3 months;
- The one with serious cardiac function unstable or angina pectoris in recent 4 weeks;
- The one with massive hemoptysis in recent 4 weeks;
- The one who needs medication in epileptic seizure;
- The one with uncontrolled hypertensive disease (SYS>200mmHg, DIA>100mmHg);
- The one with aortic aneurysm;
- The one with serious hyperthyroidism.

1.4.2 Relative contraindication

- Heart rate >120 bpm;
- The one with pneumothorax or giant pulmonary bulla and not plan for surgical treatment;
- Pregnant woman;
- The one with tympanic membrane perforation (need to block the ear canal of affected side before taking measurement);
- The one with RTI recently (less than 4 weeks);
- The one with hypoimmunity;
- Patients of respiratory communicable disease or infectious disease shall not take lung function examination in the Acute stage. The one with low immunity is not appropriate to take the examination also. If it is necessary, disease control and protection shall be strictly followed.

Chapter 2 Overview

Forced Vital Capacity is the maximum expiration after taking a full breath, it's an important examination content in chest-lung disease and respiratory health, and it is an indispensable testing project in modern Pulmonary inspection. At the same time, it has great significance in respiratory diseases diagnosis, differential diagnosis, treatment evaluation and selection of surgical indications. Thus, with the rapid development of clinical respiratory physiology, clinical applications of lung capacity inspection are also gaining popularity.

The device is small in volume, low in power consumption, convenient in operation and portable. With high-definition display screen, the device is concise and fashion. To take a measurement, it is required to breathe in fully, and seal the lips around the mouthpiece and then breathe out all air as fast as possible, the screen will directly display the measured parameters, such as Forced Vital Capacity(FVC), Forced Expired Volume in one second(FEV1), Peak Expiratory Flow(PEF). This device has a high accuracy and repeatability.

2.1 Features

1) 2.8" screen, clear in displaying, low in power consumption.
2) Simple to operate, easy to understand.
3) Small in volume, convenient in carrying and testing at anytime.
4) Large capacity rechargeable lithium battery, environmental protection.
5) Specific test for FVC, orientation analysis.

2.2 Application scope

The SPIROMETER is a hand-held equipment for examining lung function. The device is fit for hospital, clinic, family for ordinary test(FVC, FEV1, FEV1/FVC, PEF, etc.). It's only required that the user operates it according to user manual, no need for specialized training, so the operation of the device would be as simple and easy as possible.

2.3 Environment requirements

Transport and storage environment:

Temperature: -30 ℃~+55 ℃

Relative humidity: ≤95 %

Atmospheric pressure: 500 hPa~1060 hPa

Operating Environment:

Temperature: +10 ℃~+40 ℃

Relative Humidity: ≤80 %

Atmospheric pressure: 700 hPa~1060 hPa

Chapter 3 Principle

Take a deep inspiration, seal the lips around the mouthpiece and blast all air out as forcefully as possible, the exhalant gas transforms to rotary airflow by turbine, then makes the blade rotate. The infrared emission tube and reception tube inside the device aim at the blade, when the blade rotates, the reception tube judges and transforms the light signal received, form the various signal related to blade rotation, via processing by amplification circuit, form the recognizable signal by SCM, via SCM processing, it will transform to each measurement parameter which will be displayed by the screen.

Chapter 4 Technical Specifications

4.1 Main functions

- Forced Vital Capacity (FVC), Forced Expired Volume in one second (FEV1), the ratio of FEV1 and FVC (FEV1%), Peak expiratory flow (PEF), 25% flow of the FVC (FEF25), 50% flow of the FVC (FEF50), 75% flow of the FVC (FEF75) and average flow between 25% and 75% of the FVC (FEF2575) can be measured. Besides, the testee condition can be shown by the ratio of the measured value and the predicted value.
- Flow rate-volume chart, volume-time chart display.
- Data memory, delete, upload and review.
- Trend chart display.
- Indicating exhalation duration in real-time
- Personal information(height, age, gender, etc.) can be set.
- Health status indication.
- Data transmission by Bluetooth and USB.
- Low voltage indication.
- Rechargeable lithium battery for power supply, with charging indication.
- Calibration function.
- Real-time clock can be set and displayed.
- Automatic power off function.

4.2 Main Parameters

Volume Range: 0~10 L

Flow rate range: 0 L/s~16 L/s

Volume accuracy: ±3 % or 0.05 L(whichever is greater)

Flow rate accuracy: ±5 % or 0.2 L/s(whichever is greater)

EMC: Group I Class B.

Working mode: continuous working

According to the MDD 93/42, the classification of this medical device: Ⅱa.

Type of protection against electric shock: internally powered equipment

Degree of protection against electric shock: type BF applied part 

Degree of protection provided by enclosure: IP22

Battery: 3.7V, 2200mAh, rechargeable lithium battery,discharge cycle not less than 300 times.

Chapter 5 Installation

5.1 View of the front panel

Figure 1-1 Front panel view

5.2 Assembly and disassembly

1)Turbine assembly: align the the turbine to the turbine hole on the shell, gently insert it to the bottom, clockwise rotate to lock it.

2)Turbine disassembly: counterclockwise rotate the turbine, gently pull it out.

3)Mouthpiece assembly: insert one end of the mouthpiece into the turbine port directly.

Note: The turbine should be installed into the correct position from the front side of the device, see the mark on the device.

5.3 Accessories

1)A User Manual

2)A USB cable

3)A mouthpiece (disposable)

4)A power adapter (optional)

5)PC software

6)A nose clip (optional)

Note: If other power adapters are used, the following requirements should be met: output voltage is DC 5 V, current is no less than 1A, and the power adapter should comply with IEC 60950 or IEC 60601-1.

Chapter 6 Operating Guide

6.1 Operating method

6.1.1 Power on/off

(1) After assembly, long press ON/OFF key to turn on the device.

(2) **Under "ON" state, long press ON/OFF key to turn it off.**

6.1.2 Measurement

(1) After turning on the device, it will locate in Selective interface shown as Figure 2, press UP or DOWN key to select "No", press CONFIRM key to enter Testing interface, shown as Figure 3 (Note: if select "Yes", it will enter Personal information interface to edit information, after exiting, it will return to Testing interface.).

(2) In Testing interface, breath in fully, seal the lips around the mouthpiece and blast all air out as forcefully as possible in the shortest time, the orange indicator on top right corner will flicker at a certain frequency. Then wait for a few seconds, the device will enter Main parameter interface as shown in Figure 4.

Figure 2 Selective interface

Figure 3 Testing interface

6.1.3 Main interface

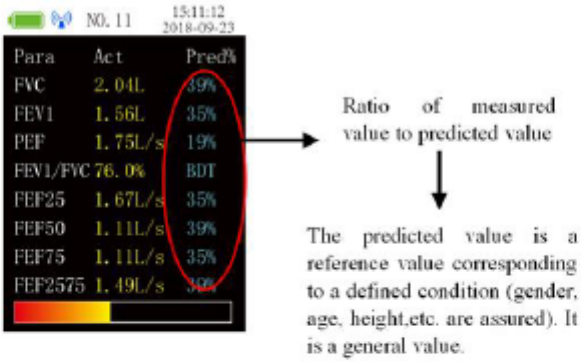

Figure 4 Main parameter interface

a. Main parameter interface: display 8 parameter values and the ratio of each parameter to its corresponding predicted value. **The ratio reflects health status, correct settings of personal information is the key to obtain accurate ratio.** Besides, this interface also displays power icon, current time, case number and health status indicator, as shown in Figure 4.

b. Health status indicator: indicates the measured state, displays the testee health condition by the ratio of measured value to the predicted value vividly, i.e. The comparison of measured value with the reference value in same situation, it is red when the value is lower than 50%, which means that the testee should draw attention and go to hospital in time; yellow in range of 50%~80%, it means that the testee should draw attention; it is green when the value is higher than 80%, which is normal. The determinate item of health status indicator is optional, it can be set in "Denote value" under "Data management".

c. "Flow rate-volume chart" and "Volume-time chart" shown as Figure 5 will appear after pressing UP or DOWN key in Main parameter interface, Figure 4 and Figure 5 are the Main interface.

d. Under Main parameter interface, after pressing UP or DOWN key simultaneously, the information "Are you sure to delete this data?" will appear, select "Yes", then press CONFIRM key to delete this data and enter the measurement interface. Select "No", press CONFIRM key to cancel deleting this data and enter the measurement interface for next test.

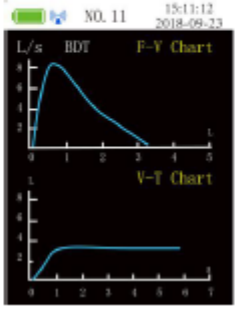

Figure 5 Flow rate-volume chart and Volume-time chart

6.1.4 Menu

In Testing interface or Main interface, press CONFIRM key to enter Menu interface shown as Figure 6, "Personal Information", "Data Management", "Settings" and "Power Off" can be selected, press UP or DOWN key to select corresponding item, then press CONFIRM key to enter its sub-menu, methods are as followings:

Figure 6 Menu interface

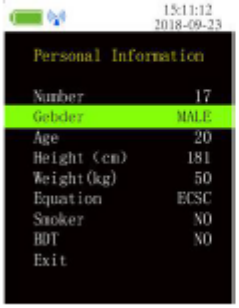

Figure 7 Personal information interface

a. Personal information

Under Menu interface, select "Personal information" to enter its sub-menu as shown in Figure 7, in which user can edit patient information (**Note:** Under Selective interface as shown in Figure 2, selecting "Yes" will enter Personal information interface too.).

(1) Case number

"Number" is the current case number. For example, if you are the 23th testee, the "Number" will be 23. Case number can increase automatically, no need to set manually.

(2) Gender setting

Use UP or DOWN key to select "Gender", press CONFIRM key and UP or DOWN key to select "MALE" or "FEMALE", then press CONFIRM key to return to the Personal information interface.

(3) Settings of age, height, weight

Select "Age" to adjust the age as shown in Figure 8. Press UP or DOWN key to change the value, the value will increase or decrease 1 after pressing UP or DOWN key once, then press CONFIRM key to return to Personal information interface.

The modification of "Height" and "Weight" is similar to the "Age". Adjustable range:

"Age": 6~100

"Height": 80~240 cm

"Weight": 15~250 Kg

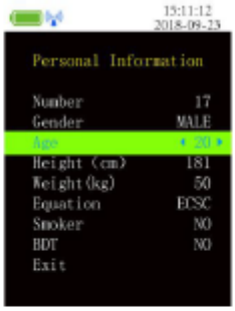

Figure 8 Age adjustment interface

(4) Equation setting

The modification step of "Equation" is the same to the "Gender". The equation of predicted value can be set in "Equation" item, including "ECSC", "KNUDSON" and "USA".

(5) Setting of smoker and BDT

The modification steps of "Smoker" and "BDT" are the same to the "Gender", in which smoker and BDT information can be edited.

(6) Exit

In Personal information interface, select "Exit" or press RETURN to return to Menu interface.

b.Data management

Select "Data management" in Menu interface to enter its sub-menu shown as Figure 9, then "Review Function", "Trend Curve", "Delete Data" and "Denote Value" can be selected.

Figure 9 Data management interface

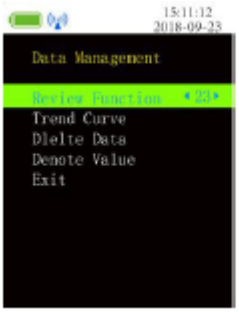

Figure 10 Case selection interface

(1) Review function

Select "Review Function" in Data Management interface to select the case number as shown in Figure 10, press UP or DOWN key to change the value, press CONFIRM key to enter Main interface to display the historical data, continuously press UP or DOWN key in Main interface to review the data in adjacent case number, press CONFIRM key to return to Menu interface.

(2) Trend curve

Select "Trend Curve" in to enter Trend curve selection interface. as shown in Figure 11, after selecting the parameter, press CONFIRM key to enter Trend curve display interface, as shown in Figure 12, the figure is a summary of all stored data aiming at the selected parameter, it displays the trend change vividly, which is convenient for tester to compare. If there are too much data, press UP or DOWN key in the curve to browse all data trend in turn, press

CONFIRM key to return to Data Management interface.

Figure 11 Trend curve selection interface

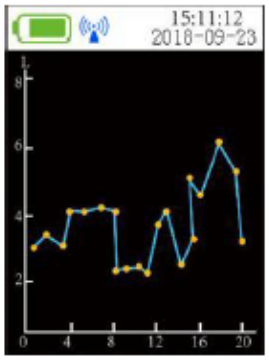

Figure 12 Trend curve display interface

(3) Delete data

Select "Delete Data" in Data Management interface to enter its sub-menu as shown in Figure 13, select "Yes" to delete all data, the screen will display "Waiting...", then it will return to Data Management interface. Select "No" to return to Data Management interface directly.

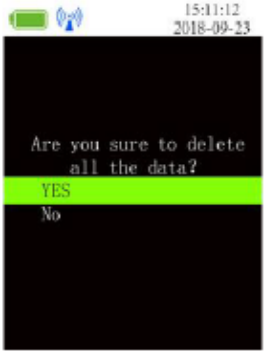

Figure 13 Delete selection interface

(4) Denote value

Select "Denote Value" in Data Management interface to enter its sub-menu as shown in Figure 14, after selecting the parameter, it will automatically return to Data Management interface.

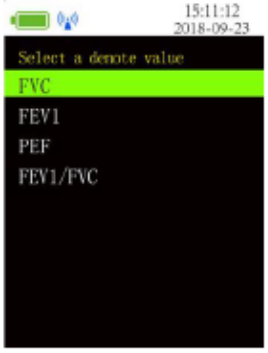

Figure 14 Denote value setting interface

(5)Exit

In Data Management interface, select "Exit" or press RETURN to return to Menu interface.

c.Settings

Select "Settings" in Menu interface to enter the setting interface as shown in Figure 15. Under this interface, settings of language, Bluetooth on/off, time and calibration, and view device information can be realized.

Figure 15 Settings interface

(1) Language

Select "Language" in Settings interface, then press UP or DOWN key to select "English" or "中文" (if the device does not have built-in language selection function, the operation is invalid).

(2) Bluetooth

After moving to "Bluetooth", press CONFIRM key to select "ON"/"OFF" to turn on/off the Bluetooth module (optional function, if there is no Bluetooth module in the device, the operation is invalid).

(3) Time setting

Select "Time" to enter its setting interface, select "Year" to display current year as shown in Figure 16, press UP or DOWN key to change the value, after selecting, press CONFIRM key to save.

The operation steps of "Month", "Day", "Hour", "Minute" and "Second" are the same to the "Year".

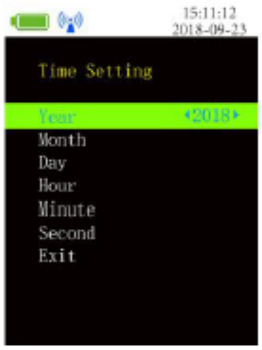

Figure 16 Time setting interface

(4) Calibration

Select "Calibration" in Settings interface to enter its sub-menu as shown in Figure 17, 2L and 3L are optional, after selecting, it will enter the calibration interface as shown in Figure 18.

Figure 17 Calibration selection interface

Figure 18 Calibration interface

Under Calibration interface, push the syringe once, the device will display "Please repeat", then push the syringe once again. After continuous three correct operations, the calibration is succeed, and the device will display "OK!". Finally the interface will jump to the former interface before calibration (The former interface: if calibrating after measuring, it will return to Settings interface; if calibrating before measuring, it will return to Testing interface.).

If the device displays "Error!", it indicates something wrong with the operation or the syringe selects improper volume, please confirm that the calibration volume is correct, then repeat calibrating until succeeding. If you need to stop calibrating, just press the CONFIRM key to exit to the interface before calibrating.

Select "Adjust" in Calibration interface to display the current calibration value as shown in Figure 19. Press UP or DOWN key to change the value, press CONFIRM key to save.

Note:

- **The value determines the accuracy of measurement, please do NOT change it randomly. After replacing the turbine, calibration shall be applied for inputting parameters of new turbine, which guarantees the accuracy of measurement after replacing.**
- **When replacing the turbine, please use the one recommended by our company.**
- **Improper calibration may affect the measurement accuracy, please be careful.**

Figure 19 Calibration adjustment interface

In Calibration selection interface, select "Exit" or press RETURN to return to Settings interface.

(5) About

Select "About" in Settings interface to enter its sub-menu to check the device name and software version, then press CONFIRM or RETURN key to return to Settings interface.

(6) Exit

In Settings interface, select "Exit" or press RETURN to return to Menu interface.

d.Power off

Select "Power Off" in Menu interface to turn off the device.

Note: If there is no operation within 2 minutes, the device will power off automatically.

e.Exit

In Menu interface, select "Exit" or press RETURN to return to Main interface, if the measurement is not completed before entering Main interface, it will return to Testing interface.

6.1.5 Repeated measure

The device has the function of repeated measurement, long press CONFIRM key for 2 seconds to enter Testing interface, when the memory is full, the information "The memory is full! Do you want to delete all the data" will display on the screen, shown as Figure 20, select "Yes" to enter data delete interface, select "No" to enter Menu interface.

Figure 20 Memory full interface

6.1.6 Charging

The device will automatically enter the charging interface when it is charging. Under this interface, all keys are unfunctional, and the device can't be used.

Two methods for charging:

1. Charge the device by connecting to a computer via USB cable.
2. Charge the device by connecting to the power adapter.

- **Do NOT use the device when charging.**
- **The indicator light on the top left of the device is displayed in orange when the device is charging, and it turns to green after the device is fully charged.**
- **When the device is charging, please place the device where easy to cut off from the mains supply. After the device is fully charged, unplug the power adapter to disconnect the device from mains supply.**

6.1.7 Data transmission

1) Install PC software into a computer, after that, connect the device with the computer by the equipped USB cable, open the software and turn on the device, then data transmission is available.

2) The device has Bluetooth transmission function. After powering on the device, the Bluetooth is in ON state, the Bluetooth icon is displayed on screen. At this time, the device can be searched and connected with other devices. When the connection is built successfully, the device displays data transmission icon, and this icon flickers during data transmitting.

6.2 Attention

- Please check the device before using to confirm that it can work normally.
- Automatic power off when there is no operation in two minutes.
- It is power supplied by rechargeable lithium battery.
- It is recommended that the device should be measured in room.
- Excessive ambient light may affect measurement accuracy. It includes fluorescent lamp, dual ruby light, infrared heater, direct sunlight, etc.
- Intense activity of the subject or electrosurgical interference may also affect the accuracy.
- Please clean and disinfect the device after using according to the User Manual (7.1).
- Please use the USB cable recommended by our company if it is necessary to replace the USB cable.

Chapter 7 Maintenance, Transportation and Storage

7.1 Cleaning and disinfection

Use medical alcohol to wipe the device enclosure, nature dry or clean it with a clean and soft cloth. It's necessary to clean the turbine periodically for accuracy, keep the diaphaneity of the lucency part, and keep it away from sundries(such as hair or lesser sediment). Immerse the turbine in disinfectant after use, after a few minutes, clean it with clean water and air dry (but don't make the turbine rinsed with water directly), this disinfection method will not bring pollution to environment. (Note: The disinfectant is 75% alcohol).

7.2 Maintenance

1)Please clean and disinfect the device before using according to the User Manual(7.1).

2)Please charge the device when the screen displays low voltage(the battery power is ).

3)Charge the battery in time after it is fully discharged. If the device is not used for a long time, it should be charged every 6 months, which could greatly extend the battery service life. Users are forbidden to replace the battery by themselves, if necessary, place contact the local service center or our company.

4)The device needs to be calibrated once a year(or according to the calibrating program of hospital). It can be performed at the state-appointed agent or just contact us for calibration.

7.3 Transportation and storage

1)The packed device can be transported by ordinary conveyance or according to transport contract. The device can not be transported mixed with toxic, harmful, corrosive materials.

2)The packed device should be stored in room with no corrosive gas and good ventilation. Temperature: -30°C~+55°C; Relative Humidity: ≤95%.

Chapter 8 Troubleshooting

Trouble	Possible Reason	Solution
The device can't finish measurement for a long time, and the data can't be displayed.	The start speed is too low, the device does not measure.	Remeasure according to the User Manual.
	Device malfunction.	Remeasure or restart the device.
Data error	Operate the device falsely.	Operate the device according to the User Manual.
	Device malfunction.	Please contact the local service center.
The device can not be powered on.	Low voltage or no voltage.	Please charge the device.
	Device damaged.	Please contact the local service center.
The display disappears suddenly.	The device is set to automatic power off when there is no operation in 2 minutes.	Normal
	Low voltage	Please charge the device.
The use time is too short after charging.	The device is not fully charged.	Please charge the device.
	Device battery damaged.	Please contact the local service center.
The device can not be fully charged after charging more than 10 hours.	Device battery damaged.	Please contact the local service center.

Chapter 9 Symbols

Symbol	Meaning	Symbol	Meaning
	Full battery		Keep dry
	Low battery		Non-ionizing radiation
	Health status indicator bar		Serial number
	Anticlockwise rotate to unlock the turbine		Date of manufacture.
	Clockwise rotate to lock the turbine		Manufacturer

	Do not re-use		Type BF applied part
	Do not insert		For indoor use only
	Atmospheric pressure limitation		Class II equipment
	Temperature limitation		WEEE (2002/96/EC).
	Humidity limitation		Refer to instruction manual/booklet
	Fragile, handle with care		Standby
	This way up		European Representative
IP22	The first number 2: Protected against solid foreign objects of 12.5 mm Φ and greater. The second number 2: Protection against vertically falling water drops when ENCLOSURE		This item is compliant with Medical Device Directive 93/42/EEC of June 14, 1993, a directive of the European Economic Community.

Chapter 10 Parameters

Measured parameters:

Parameter	Description	Unit
FVC	Forced vital capacity (total expiratory volume)	L
FEV1	Forced Expiratory Volume in one second	L
PEF	Peak expiratory flow	L/s
FEV1/FVC	Forced expiratory rate in one second, FEV1/FVC×100	%
FEF25	Forced expired flow at 25% of FVC	L/s
FEF50	Forced expired flow at 50% of FVC	L/s
FEF2575	Forced expiratory flow between 25% and 75% of FVC	L/s
FEF75	Forced expired flow at 75% of FVC	L/s

Appendix Ⅰ

Guidance and manufacturer's declaration – electromagnetic emissions-
for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic emission		
The SP80B is intended for use in the electromagnetic environment specified below. The customer of the user of the SP80B should assure that it is used in such and environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The SP80B uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The SP80B is suitable for use in all establishments, including domestic and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

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

Guidance and manufacturer's declaration – electromagnetic immunity			
The SP80B is intended for use in the electromagnetic environment specified below. The customer or the user of SP80B should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Mains power quality should be that of a typical commercial or hospital environment.
NOTE			

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

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The SP80B is intended for use in the electromagnetic environment specified below. The customer or the user of SP80B should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>10 V/m
80 MHz to 2.5 GHz</td><td>10 V/m</td><td>Portable and mobile RF communications equipment should be used no closer to any part of the SP80B, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz
$d=\left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 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).
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:  </td></tr>
<tr><td colspan="4">NOTE 1At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
</table>

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SP80B is used exceeds the applicable RF compliance level above, the SP80B should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SP80B.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT or SYSTEM

Recommended separation distances between portable and mobile RF communications equipment and the SP80B		
The SP80B is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SP80B can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SP80B 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)**	
	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.036	0.069
0.1	0.111	0.222
1	0.351	0.699
10	1.107	2.214
100	3.501	6.999
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 1At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		