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 minutes. ◆ 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 materials such as circuit diagram, components list, legend, calibration details or other materials that necessary for the maintenance for users 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

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.

13 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. I) 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 •C. Measured data will be displayed within 5 seconds after finishing the measurement, which 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.

If the measured value exceeds the measurement range, the main interface prompts "OR!" .The device may suitable for all users, if you cant 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.

Applied part: mouthpiece

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. Ifit is necessarv. disease control and rotection shall be strictlv 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

Compact and fashion appearance design
Small in volume, light in weight and easy to carry
Low power consumption
TFT display screen
Parameters measurement, such as FVC, FEVI, PEF

2.2 Application scope

The SPIROMETER is a hand-held equipment for examining lung function. The device is fit for use in hospital, clinic, family for ordinary test. It's only required that the user operates the device according to user manual, no need for specialized training, so the operation Of the device would be as simple and easy as possible.

23 Environment requirements

Transport and storage environment:
Temperature: -30 •C ••55 °c
Relative humidity: 95 %
Atmospheric pressure: 500 hPa—1060 hPa Operating Environment:
Temperature: +10 C--+40 •C
Relative Humidity: 40 %
Atmospheric pressure: 700 hPa—1060 hPa

Chapter 3 Principle

Take a deep inspiration, seals the lips around the mouthpiece and blasts all air out as forcefully as possible, the exhaled gas transforms to rotary airflow after passing by turbine, then makes the blade rotate. The infrared transmitting tube and receiving tube in the device are aligned with the blade section, when the blade rotates, the light intensity received by the receiving tube will be different according to the angle of the blade, thus a changing signal will be proponionately generated in the receiving tube, after processed by amplifying circuit, it becomes the single that can be identified by the MCU. After processed and analyzed by MCU, measurement parameter are calculated. then displayed on the screen. Chapter 4 Technical Specifications

4.1 Main functions

Forced Vital Capacity (FVC), Forced Expired Volume in one second (FEVI), the ratio Of FEVI and FVC (FEVI%), Peak expiratory flow (PEE), flow ofthe PVC (FEF25), flow of the FVC (FEI50). flow of the PVC (FEF75) and average flow between and of the PVC (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.

◆ Calibration function.

Information prompts when volume or flow rate goes beyond the limits.

Automatic power off when there is no operation in two minutes.

◆ Two AAA batteries for power supply.

◆ Battery power display.

4.2 Main Parameters

Volume Range: 0—10 L
Flow rate range: O L/s—16 L/S

Volume accuracy: % or L(whichever is greater)
Flow rate accuracy: +5 % or 0.2 Vs(whichever is greater)
Maximum impedance of flow at the rate of 14 Vs: 6 Pa/L/s EMC: Group 1 Class B.
According to the MDI) 93/42, the classification of this medical device: Il a.
Type of protection against electric shock: internally powered equipment
Degree ofprotection against electric shock: type BF applied pan
Enclosure protection classification: IP22

Chapter 5 Installation

5.1 View Of the front panel

Figure I Front panel view

5.2 Assembly and disassembly

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

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

3) Mouthpiece assembly: insert (bigger diameter) ofthemouthpiece into the tulbinepoft directly. Note: The turbine should be installed into the correct position from the right side Of the device, see the mark on the device.

5.3 Accessories

1) A User Manual
2) A mouthpiece (disposable accessory)
3) A nose clip (optional)

Chapter 6 Operating Guide

6.1 Operating method

6.1.1 Power on/off

(l) After assembly, long press ON/OFF key to turn on the device.
(2) Under 'ION" state, long press ON/OFF key to turn it Off.

Chapter 5 Installation

6.1.2 Measurement

(l) After turning on the device, it will locate in Selective interface shown as Figure 2, press LEFT or RIGHT 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.

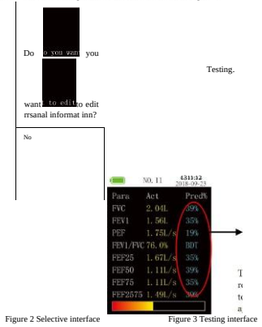


Figure 2 Selective interface Figure 3 Testing interface

6.13 Main interface

Ratio of measured value to predicted value

The predicted value is a reference value corresponding to a defined condition (gender, age, height,etc_ are assured). It is a general value.

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 ofhealth 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

LEFT or RIGHT key in Main parameter interface, Figure 4 and Figure 5 are the Main interface.

d. Under Main parameter interface, after pressing LEFT or RIGHT 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.

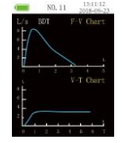


Figure 5 Flow rate-volume chart and Volume-time chart

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 LEFT or RIGHT 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 LEFT or RIGHT key to select "Gender", press CONFIRM key and LEFT or RIGHT key to select "MALE" or "FEMALE".

(3) Settings Of age, height, weight

Select "Age" to adjust the age as shown in Figure 8. Press LEFT or RIGHT key to change the value, the value will increase or decrease I after pressing LEFT or RIGHT 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

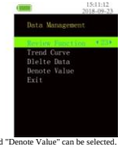
The modification steps Of "Smoke€' and "BDT" are the same to the "Gender", in which smoker and BDT information can be edited.

(6) Exit

Select "Exit" in Personal information interface 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 I O, press LEFT or RIGHT key to change the value, press CONFIRM key to enter Main interface to display the historical data, continuously press LEFT or RIGHT 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 1 1, 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

LEFT or RIGHT key in the curve to browse all data trend in turn, press CONFIRM key to return to Data Management interface.

Figure I I Trend curve selection interface

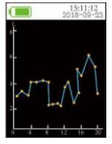


Figure 12 Trend curve display interface

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 (S)Exit

Select "Exit" in Data Management interface 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.

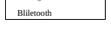


Figure 15 Settings interface

(1) Language

Select "Language" in Settings interface, then press LEFT or RIGHT key to select "English" or " J." (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 LEFT or RIGHT 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.

(3) Delete data

Select "Delete Data" in Data Management interface to enter its sub-menu as shown in

Figure 17 C

Cal ibrat ion—2L
1/3

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 LEFT or RIGHT 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.

Figure 19 Calibration adjustment interface

Select "Exit" in Calibration interface 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 key to return to Settings interface. (6) Exit

Select "Exit" in Settings interface 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

Guidance and manufacturer's declaration — electroma etic immuni

The SP70B is intended for use in the electromagnetic environment specified below. The customer or of SP70B should assure that it is used in such an environment.

Immunit y test	IEC 60601 test level	Complia nee level	Electromagnetic environment - guic
Radiated IEC 61	IOV/m 80 MHz to 2.5 GHz	IOV/m	Portable and mobile RF communications equ should be used no closer to any palt Of the including cables, than the recommended sep distance calculated from the equation applic 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 ratin transmitter in watts (W) according to the tra manufacturer and d is the recommended sep distance in metres (m). Field strengths from fi transmitters, as determined by an electrom site survey,ª should be less than the complian in each frequency range.ᵇ Interference may occur in the vicinity Of eq marked with the following symbol: (f))

NOTE I At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affe absolption and reflection from structures, Objects and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telepho land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be pr theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmi electromagnetic site survey should be considered.

If the measured field strength in the location in which the SP70B is used exceeds the applic compliance level above, the SP70B should be observed to verify normal operation. If ab performance is observed, additional measures may be necessary, such as reorienting or relocati

Trouble	Possible Reason	Solution
The device cant finish measurement for a long time, and the data cant be dis la ed.	The start speed is too low, the device does not measure.	Remeasure according to the User Manual.
	Device malfunction.	Remeasure or restart the device.
The displayed figure is wrong and unorderly.	Abnormal power interruption causes stora e error.	Delete the data and remeasure.
	Operate the device falsely.	Operate the device according to th User Manual.
The device can not	Device malfunction. Low battery or no power.	Please contact the local service cer Please replace batteries.
be powered on. The display disappears suddenly.	Device damaged. The device is set to automatic power Off when there is no operation in 2 minutes.	Please contact the local service ce Normal

Select "Exit" in Menu interface 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

6.2 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 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).

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 replace batteries when the screen displays low voltage(the battery power is

3)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.

73 Transportation and storage

1)The packed device can be transported by ordinary conveyance or according to transport contract.

The device can not be transpolted mixed with toxic, harmful, corrosive materials.

2)The packed device should be stored in room with no corrosive gas and good ventilation.

Temperature: -30℃~55 ℃; Relative Humidity: 95%.

Chapter 9 Symbols

Symbol	Meaning	Symbol	Meaning
	Refer to instruction manual/booklet.		Non-ionizing radiation
	Type BF applied part	SN	Serial number
	Full battery		Date of manufacture.
	Low battery		Manufacturer
	Health status indicator bar		WEEE (2002/96/EC).
	Atmospheric pressure limitation	EC REP	European Representative
	Temperature limitation		Do not insert
	Humidity limitation		Clockwise rotate to lock the turbine
	Fragile, handle with care		Anticlockwise rotate to unlock the turbine
	This way up		Do not re-use
	Keep dry		Standby
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 tilted up to 15°on either side of the vertical.	CE 0123	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:

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

n — electromagnetic emissions for all EQUIPMENT and SYSTEMS

Chapter 8 Troubleshooting

FEF /S	Forced expired flow at /5% of FVC	L/S

Appendix Ⅰ

Low battery Please replace batteries.

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

NOTE

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

Recommended separation distances between portable and mobile RF communications equipment and the SP70B		
The SP70B is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SP70B can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SP70B as recommended below, according to the maximum output power of the communications equipment.		
Rated maximum output power of transmitter	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
10	0.351 1.107	0.699 2.214 6.999
IOO	3.501	
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.		

a n u f a c t u r e r ' s d e c l a r a t i o

EQUIPMENT or SYSTEM

G u i d a n c e a n d m