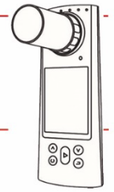
GIMA

PROFESSIONAL MEDICAL PRODUCTS

SP80B HANDHELD SPIROMETER

Use and maintenance book



ATTENTION: *Operators must read and understand this manual completely before using the product.*

GIMA 33551

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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.

The intended operator may be the patient.

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 Technical Specifications

1.1 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 shutdown when there is no operation within 2 minutes.

1.2 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 0.17 L/s(whichever is greater)

Highest resistance to flow at 16 L/s: ≤ 0.15KPa*s/L

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,number of discharge cycles: ≥ 300 times.

Operation time: about 24 hours

Note: BTPS is body conditions: normal body temperature (37 ℃), ambient pressure, saturated with water vapor.

1.3 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

Altitude: 0 ~ 1400 m

1.4 View of the front panel

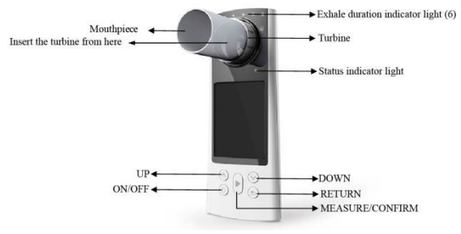

Figure 1-1 Front panel view

1.5 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.

1.5.1 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.

Applied scope: it is applicable for use in hospital, clinic, and home for testing the parameters related to forced vital capacity.

1.6 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.

Chapter 2 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 3 Contraindication, Attention, Warning

3.1 Contraindication

3.1.1 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.

3.1.2 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.

3.2 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.

3.3 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.
- When charging, do not position the device so that it is difficult to operate the disconnection device.
- The user should pay attention to preventing strangulation due to longer data cable.
- The disposal of waste device, its accessories and packing (such as mouthpiece, plastic bags, foams and paper boxes) 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.
- The battery of this device can only be used on this device. Any maintenance or replacement of this battery must be conducted by the service personnel trained and authorized by our company.
- Do not maintain this device during use.
- No modification of this device is allowed.

3.4 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.
- 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 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.
- The device cannot be used until half an hour after it is transferred from an environment of the highest or lowest storage temperature to an environment of room temperature.
- The device should be kept out of the reach of children or pets.
- Avoid insect, animal hair or dirt entering into the turbine, as this will affect the use of the device.
- Avoid cotton wool and dust as far as possible. If these conditions occur, please refer to section 5.1 for cleaning and disinfection.
- This user manual contains information about operation instructions and technical specifications.
- The equipment connected with this device via interfaces should compliance with IEC 60950 or IEC 60601-1.

Chapter 4 Installation

4.1 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.

4.2 Operating method

4.2.1 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.

4.2.2 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.

Note: when the measured value exceeds the measurement range, the prompt message "OR!" will display on the main interface.

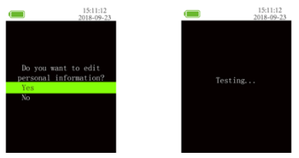

Figure 2 Selective interface

Figure 3 Testing interface

4.2.3 Main interface

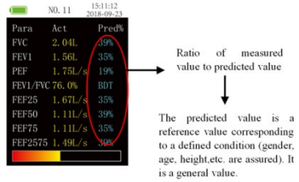

Figure 4 Main parameter interface

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.

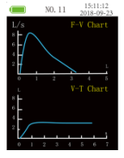

Figure 5 Flow rate-volume chart and Volume-time chart

4.2.4 Menu

In Testing interface or Main interface, press CONFIRM key to enter Menu interface shown as Figure 6, use UP or DOWN button to select an option, then press CONFIRM key to enter the corresponding interface (including personal information, data management and settings interface), shut down or exit.

The operation methods are as follows:

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

"NO."at the top of the interface is the current number of cases. For example, if you are the 23rd subject, it will be displayed as "NO. 23". The case number can be automatically accumulated without manual setting.

(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

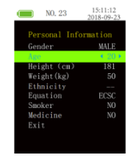

Figure 8 Age adjustment interface

(4) Equation setting

The operation steps of "Equation" is the same as "Gender". The predicted value standard can be selected here, including ECSC, KNUDSON, USA, SBPT and GLI.

(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.

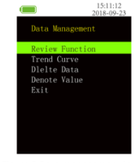

Figure 9 Data management interface

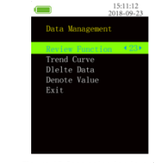

Figure 10 Case selection interface

(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

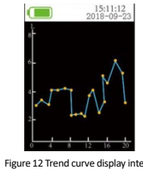

Figure 12 Trend curve display interface

(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

Note: when GLI or SBPT is selected, there is no PEF option in 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, where the language, time, and calibration can be set, and device information can be viewed.

Figure 15 Settings interface

(1) Language

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

(2) 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

(3) 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:

Number	Model	Cable length（m）	Mask or no	Remark
1	Power adapter cable	1.0	YES	/

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.

(4) 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.

(5) 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 two minutes, the device will shut down 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.

4.2.5 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

4.2.6 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 during charging.

During charging, the message "Charging..." displays on the interface, the battery icon is a lighting symbol, and the indicator light is orange. It is green after fully charged.

When charging, do not position the device so that it is difficult to operate the disconnection device. After charging, remove the power adapter and disconnect the device from the mains supply.

4.2.7 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 power on, the Bluetooth is always ON, which can be searched and connected. After the connection is established, the device can communicate.

4.3 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 5 Maintenance, Transportation and Storage

5.1 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).

5.2 Maintenance

1)Please clean and disinfect the device before using according to the User Manual(5.1).

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.

5.3 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℃~+55℃; Relative Humidity: ≤95%.

Chapter 5 Date of manufacture, service life and accessory list

6.1 Date of manufacture: see the label.

6.2 Service life: ten years from the date of manufacture.

6.3 List of accessories

Accessories	Quantity	Replacement cycle	Size	Replacement method	Remark
User Manual	1 pc	No need to replace.	——	——	——
USB cable	1 pc	Ten years or when it is damaged	——	——	Contact the supplier
Mouthpiece	2 pcs	Single-use	30 mm (outer diameter)	Refer to section 4.1.	Contact the supplier
Power adapter (optional)	1 pc	Ten years or when it is	——	——	Contact the supplier
		damaged			
PC software	——	No need to replace.	——	——	——
Nose clip (optional)	1 pc	Single-use	——	——	Contact the supplier
Disposable filter for respiratory (optional)	1 pc	Single-use	30 mm (outer diameter)	——	Contact the supplier

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 7 Symbols

7.1 Symbols

Symbol	Meaning	Symbol	Meaning
	Full battery	IP22	Covering Protection rate
	Low battery		Non-ionizing radiation
	Health status indicator bar	SN	Serial number
	Anticlockwise rotate to unlock the turbine		Manufacturer
	Clockwise rotate to lock the turbine		Type BF applied part
	Do not re-use		For indoor use only
	Do not insert		Class II applied
	Atmospheric pressure limit		WEEE disposal
	Temperature limit		Follow instructions for use
	Humidity limit	LOT	Lot number
	Fragile, handle with care		Date of manufacture
	This way up		Use-by date
	Keep in a cool, dry place	MD	Medical device
CE 0123	Medical Device compliant with Directive 93/42/EEC	EC REP	Authorized representative in the European community
REF	Product code		Imported By

7.2 Measured parameters

Parameter	Description	Unit
FVC	Forced vital capacity (total expiratory volume)	L
FEV1	Forced Expiratory Volume in one second	L
FEV6	Forced Expiratory Volume in six seconds	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

Remark:

time zero: at the PEF (peak expiratory flow) point on the volume-time chart, draw a tangent line with the same slope as the PEF, and the intersection point between the tangent line and the time axis is the time zero.

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.
	Aging of the sensor.	Please contact the local service center.
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.
	Aging or damage of the battery electrodes.	Please contact the local service center.
	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.

Appendix Ⅰ

1. Instructions for use

The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments

Warning: Don't 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.

Warning: Use of this equipment 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.

Warning: 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 equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

2. Instructions for use

all necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life.

Guidance and manufacturer's declaration -electromagnetic emissions and Immunity.

Table 1

Guidance and manufacturer's declaration – electromagnetic emission	
Emission test	**Compliance**
RF emissions CISPR 11	Group 1
RF emission CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Comply

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity		
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**
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
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV for power supply lines Not applicable 100 kHz repetition frequency
Surge IEC 61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5 kV, ±1 kV differential mode Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle. 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. 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
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
NOTE U_T is the a.c. mians voltage prior to application of the test level.		

Table 3

Guidance and manufacturer's declaration – electromagnetic immunity						
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	IEC 60601-1-2 Test Level (V/m)	Compliance level (V/m)
	385	380 –390	TETRA 400	Pulse modulation 18 Hz	27	27
	450	430 –470	GMRS 460, FRS 460	FM ±5kHz deviation 1 kHz sine	28	28
	710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	9	9
	810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28	28
	1720 1845 1970	1700 –1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28	28
	2450	2400 –2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28	28
	5240 5500 5785	5100 –5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9	9

Table 4

Guidance and manufacturer's declaration - electromagnetic Immunity				
Radiated RF IEC61000-4-39 (Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields)	Test Frequency	Modulation	IEC 60601-1-2 Test Level (A/m)	Compliance level (A/m)
	30 kHz	CW	8	8
	134,2 kHz	Pulse modulation 2.1 kHz	65	65
	13,56 kHz	Pulse modulation 50 kHz	7,5	7,5

Attention: With the exception of energy exchange and cables sold by manufacturers of lung function devices as spare parts for internal components, the use of accessories and cables other than those specified will result in increased product emission or reduced anti-interference.

The following cable types must be used to ensure compliance with interference radiation and immunity standards.

Table:Cable overview

Smaltimento: *Il prodotto non deve essere smaltito assieme agli altri rifiuti domestici. Gli utenti devo- no provvedere allo smaltimento delle apparecchiature da rottamare portandole al luogo di raccolta indicato per il riciclaggio delle apparecchiature elettriche ed elettroniche*

CONDIZIONI DI GARANZIA GIMA

Si applica la garanzia B2B standard Gima di 12 mesi