GIMA

PROFESSIONAL MEDICAL PRODUCTS

SPIROMETRO TASCABILE SP-10
SP-10 POCKET SPIROMETER
SPIROMÈTRE DE POCHE SP-10
ESPIRÓMETRO DE BOLSILLO SP-10

Manuale d'uso
User manual
Manuel de l'utilisateur
Guía de uso

ATTENZIONE: *Gli operatori devono leggere e capire completamente questo manuale prima di utilizzare il prodotto.*

ATTENTION: *The operators must carefully read and completely understand the present manual before using the product*

AVIS: *Les opérateurs doivent lire et bien comprendre ce manuel avant d'utiliser le produit.*

ATENCIÓN: *Los operadores tienen que leer y entender completamente este manual antes de utilizar el producto*

GIMA 33536

CONTEC MEDICAL SYSTEMS CO., LTD
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Made in China

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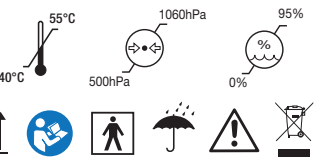

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Instructions to User

Dear users, thank you very much for purchasing the SPIROMETER.
Please read the User Manual carefully before using this product. The User Manual which describes the operating procedures should be followed strictly. Failure to follow the User Manual may cause measuring abnormality, equipment damage and human injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, human injury and equipment damage due to users' negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.
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.
This product is medical device, which can be used repeatedly.

WARNING:

- For accuracy,it is recommended that the SPIROMETER should not be tested on the same testee for more than 5 times.
- The testee should breathe out all air during testing, don't exchange air or cough.
- Don't use the device in environment with lower temperature.
- Automatic power off when there is no operation in one minute.
- Please refer to the correlative literature about the clinical restrictions and caution.
- This device is not intended for treatment.
- Our company reserves the final elucidative right.

Chapter 1 Safety

1.1 INSTRUCTIONS FOR SAFE OPERATIONS

- Check the main unit and all accessories periodically to make sure that there is no visible damage that may affect patient's safety and monitoring performance. It is recommended that the device should be inspected weekly at least. When there is obvious damage, stop using the device.
- All maintenance must be performed by qualified service engineers ONLY. Users are not permitted to maintain it by themselves.
- The SPIROMETER cannot be used together with devices not specified in User Manual. Only the accessory that is appointed or recommendatory by manufacture can be used with this device.
- This product has been calibrated before leaving factory.

1.2 WARNING

- Explosive hazard—DO NOT use the SPIROMETER in the environment with tinder 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.
- Portable or mobile RF equipment with strong electromagnetic interference may influence the accuracy of this device.
- Improper disposal of device and its accessories and packing (include mouthpiece, plastic bags, foams and paper boxes) may cause environment pollution, please follow the local laws and regulations.
- Please choose the accessories which are appointed or recommended by the manufacturer for avoiding device damage.
- Don't use the device with the turbine of the same kind product.
- DO NOT use the device when it is under charging state.
- The red and green indicators are all highlight in charging state, the red indicator goes out when the charge has finished.

1.3 ATTENTION

- Keep the SPIROMETER away from dust, vibration, corrosive substances, tinder, high temperature and moisture.
- If the SPIROMETER gets wet, please stop operation.
- When it is carried from cold environment to warm or humid environment, please do not use it immediately.
- DO NOT operate button 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 SPIROMETER immerged in liquid. When it needs cleaning, please wipe its surface with medical alcohol by soft material. Do not spray any liquid on the device directly.
- When cleaning the device with water, the temperature should be lower than 60℃.

- The display period of data is less than 5 seconds, which is changeable according to the end rate.
- When data can't be displayed at all times or other cases happened during testing, press "repeated measure" key to remeasure, or power off to restart.
- The device has normal life for three years since the first electrified use.
- When the data goes beyond the limits, the main screen shows "Error!".
- The device doesn't suit 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 forced SPIROMETER, according to the User Manual to use right to gain best result.

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 beats/min;
- The one with pneumothorax or giant pulmonary bulla and not plan for surgical treatment;
- The one with pregnancy;
- 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.

1.5 EMC DECLARATION:

- When this device is installed or putted into service, EMC should be paid more attention, as the portable and mobile RF communications equipment with higher EM interference can affect this device.
- The internal components and cables should not be changed, as this may decreased IMMUNITY of the device.
- The SPIROMETER should not be used adjacent to or stacked with other equipments.

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 indispensable testing project in modern Pulmonary inspection. At the same time, it has great significance in respiratory diseases, 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 SPIROMETER is small in volume, low in power consumption, convenient in operation and portable. With high-definition display screen, the device is concise and fashion. It is only necessary for patient to breath in fully and seal the lips around the mouthpiece and blast the air out in best times for measure, then the display screen will directly show the Forced Vital Capacity (FVC), Forced Expired Volume in one second (FEV1), Peak Expiratory Flow (PEF) with the high veracity and repetition.

2.1 FEATURES

1) Ultra-thin design, concise and fashion.
2) Small in volume, light in weight and convenient in carrying.
3) Low power consumption.
4) TFT display.
5) Reflect lung function by measuring FVC, FEV1, PEF etc.

2.2 MAJOR APPLICATIONS AND SCOPE

The SPIROMETER is a hand-held equipment for examining lung function. The product is fit for hospital, clinique, family for ordinary test. 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

Storage Environment:
Temperature: -40℃~+55℃
Relative humidity: ≤95%
Atmospheric pressure: 500hPa~1060hPa
Operating Environment:
Temperature: +10℃~+40℃
Relative Humidity: ≤80%
Atmospheric pressure: 700hPa~1060hPa

Chapter 3 Principle

Firstly, testee deep inspires, then seals the lips around the mouthpiece and blasts all air out as forcefully as possible, the exhalant gas transforms to rotary airflow by turbine, then makes the blade rotate. The reception part of the infrared pair diodes (one is for infrared emission, the other is reception) towards to the blade is used for receiving the infrared ray, when the blade rotates, the received ray strength of the reception diode will be different as the difference of the blade angle, so form the various signal of same proportion in reception diode, which forms acquisition signal by SCM after processing. At last, various parameters to be measured formed from the information which were processed by the microprocessor, and displayed from the screen.

Chapter 4 Technical Specifications

4.1 MAIN PERFORMANCE

- 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), 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.
- Calibration.
- Information prompts when volume or flow goes beyond the limits.
- Automatic power off when there is no operation in one minute.
- Rechargeable lithium battery and with charging tips.
- Battery power display.
- 4.2 Main Parameters
- Volume Range: 10L
- Flow range: 0 L/s~16 L/s
- Volume accuracy: ±3% or 0.05L (whichever is greater)
- Flow accuracy: ±5% or 0.2L/s (whichever is greater)
- Working current: 60mA
- Power supply: DC3.7V 820mAh rechargeable lithium battery
- Classification:
- EMC: Group I Class B.
- According to the MDD 93/42, the classification of this medical device: IIa.
- The type of protection against electroshock: Internally powered equipment.
- The degree of protection against electroshock: Type BF applied part .
- International Protection: IP22.

Chapter 5 Installation

5.1 VIEW OF THE FRONT PANEL

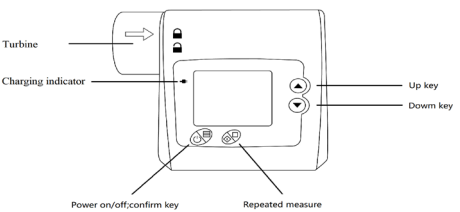


Figure 1 Front panel view

5.2 ASSEMBLY AND DISASSEMBLY

1) Turbine assembly: Hold the turbine, align the arrowhead of the turbine

with the triangular shape on the shell, gently insert it to the bottom, counterclockwise rotate to lock it

2) Turbine disassembly: clockwise rotate the turbine, gently pull it out
3) Mouthpiece assembly: insert the mouthpiece into the turbine port directly

5.3 ACCESSORIES

1) A User Manual
2) A USB data line
3) A mouthpiece
4) A power adapter
5) PC software
6) A nose clip (optional)

⚠ **Other type adapter should meet the following conditions: output voltage:DC 5V; output current≥500mA, the power adapter must meet the requirements of EN60601 related standards and have the CE mark.**

Chapter 6 Operating Guide

6.1 HOW TO USE

6.1.1 Power on/off

1. After assembly, long press “power on” key to turn on the device.
2. When device is powered on, long press “power off” key to turn it off.

6.1.2 MEASUREMENT

1. The device is in (Selective interface) after turn on as shown in Fig.2, press “up” or “down” key to select “No”, then press “confirm” key to enter (Testing) interface as shown in Fig.3. (Note: If select “Yes”, it will enter (Personal information) interface to edit personal information, after exit, 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 a minimal amount of time, wait for a few seconds, the device will enter (Main parameter) interface as shown in Fig.4.

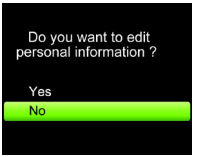


Figure 2 Selective interface

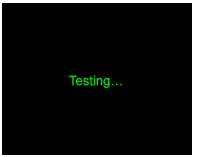


Figure 3 Testing

6.1.3 Main interface

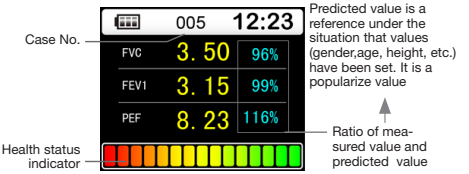


Figure 4 Main parameter interface

a. Main parameter interface: display the ratio of predicted value and measured value of three main parameters. Ratio reflects health status, correct settings of personal information is the key to obtain accuracy ratio. Besides, this interface can also display battery status, time, case number and health status indicator, as shown in Fig.4.

b. Health status indicator: indicate the ratio of measured value and the predicted value, display the testee health condition in image. I.e. Compare the measured value with the reference value in same situation. When the value is lower than 50%, only red indicator is displayed, which means testee should pay attention and go to hospital in time. When the value is in range from 50%-80%, red and yellow indicator are displayed, which means it should be noticed. When the value is higher than 80%, all red, yellow and green indicator are displayed, which means healthy. The determinate item of health status indicator is optional, it can be set in “Denote value”

under “Date management”.

c. Other parameter interface: display four parameters except the main parameter, as shown in Fig.5.

d. Under (Main parameter) interface, press “Up” or “Down” key will enter (Other parameter) (Flow rate-volume chart) (Volume-time chart) in turn, as shown in Fig.5, 6, 7. The four interfaces above are (Main interface).

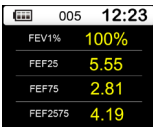


Figure 5 Other parameter interface

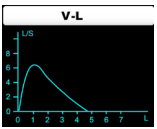


Figure 6 Flow rate-volume chart

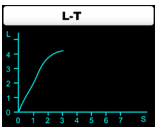


Figure 7 Volume-time chart

6.1.4 Menu

Under (Testing) or (Main interface), press confirm key to enter (Menu) interface as shown in Fig.8. Under the interface, functions such as modify personal information, data management, device setting, power off can be realized. Press “Up” or “Down” key to move the selection toolbar to the item that need to modified, then press “Confirm” key to enter the sub-menu. See the following steps for details:

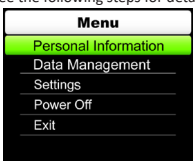


Figure 8 Menu interface

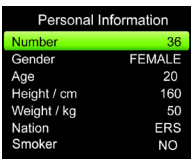


Figure 9 Personal information interface

a. Personal information

Under (Menu) interface, select “Personal information” to enter its interface as shown in Fig.9, in which user can edit patient information (Note: Under (Selective interface) as shown in Fig.2, if selected”Yes”, you can enter (Personal information)interface also.).

1. Case number

“Number” is the case number displayed at present. For example, if you are the 36th testee, the “Number” will be 36. Case number can increase automatically, no need to set manually.

2. Gender setting

Under (Personal information) interface, press “Up” or “Down” key to move the selection toolbar to “Gender”, then press “Confirm” key to select “female” or “male”.

3. Setting of age, height, weight

Under (Personal information), select “Age” to enter (Age edit) interface, as show in Fig.10. Press “Up” or “Down” key to change the value. At each pressing of “Up” or “Down” key, the value will plus or minus 1. When long press the“Up” or “Down” key, the value will increase or decrease continuously. Press “Confirm” key to back to (Personal information) interface.

The modification of “Height” and “Weight” is similar to the “Age”. In which, range of “Age” is 6~100 years old, range of “Height” is 80~240 cm, range of “Weight” is 15~250 kg.

Figure 10 Age edit interface

4. Nation setting

The modification of “Nation” is similar to the “Gender”. The standard of predicted value can be set under “Nation” interface, which including ERS, KNUDSON and USA. ERS is the European standard, KNUDSON is the Asian standard, USA is the American standard.

5. Setting of smoker and drug

The modification of “Smoker” and “Drug” is similar to the “Gender”, in which patient information of smoker and drug can be modified.

For the display of screen is limited, the device won’t display all items at the same time. When selection toolbar moved to “Smoker”, press “Down” key, the item of “Drug” and “Exit” will appear, as shown in Fig. 11, 12.

6.Exit

Under (Personal information) interface, select “Exit” to return to (Menu) interface.

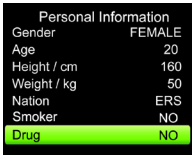


Figure 11

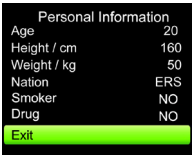


Figure 12

b. Data management

Under (Menu) interface, select “Data management” to enter (Data management) interface, as shown in Fig.13. Under the interface, functions such as review, view trend curve, delete data, denote value setting can be realized.

Figure 13 Data management interface

Figure 14 Case selection interface

(1) Review function

Under (Data management) interface, select “Review function” to enter (Case selection) interface as shown in Fig.14, press “Up” or “Down” key (long press is available) to change case number, then press “Confirm” key, the device will enter (Main interface) and display history data on it. Under (Main interface), press “Up” or “Down” key continuously can review data in adjacent case number, press “Confirm” key to return to (Menu) interface.

(2) Trend curve

Under (Data management) interface, select “Trend Curve” to enter (Trend curve selection) interface as shown in Fig.15. Select the determinant parameter, then press “Confirm” key to enter (Trend curve display) as shown in Fig.15. The curve is a summary of stored data for selected parameter. It displays the change trend in form of visual image, which is convenient for comparison. If the data is too much, press “Up” or “Down” key to browse all data trend curves orderly. Press “Confirm” key to return to (Data management) interface.

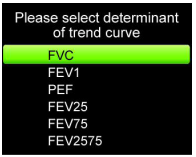


Figure 15 Trend curve selection interface

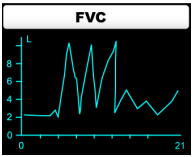


Figure 16 Trend curve display interface

(3) Delete data

Under (Data management) interface, select “Delete data” to enter (Delete data) interface as shown in Fig.17. If choose “Yes”, the screen displays “waiting...”, all data will be deleted, then return to (Data management) interface. If choose “No”, it will return to (Data management) interface directly.

Figure 17 Delete data interface

(4) Denote value

Under (Data management) interface, select “Denote value” to enter (Denote value setting) interface as shown in Fig.18. Select one parameter to

decide the denote value, after that, it will automatically return to (Data management) interface.

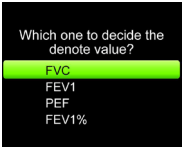


Figure 18 Denote value setting interface

(5) Exit

Under (Data management), select "Exit" to return to (Menu) interface.

c. Settings

Under (Menu) interface, select "Settings" to enter (Settings) interface as shown in Fig.19. Under this interface, settings of language, Bluetooth on/off, time and calibration, and view device information can be realized.

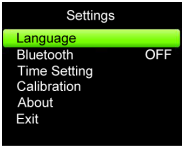


Figure 19 Setting interface

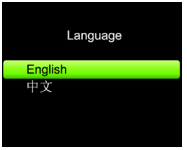


Figure 20 Language setting interface

(1) Language setting

Under (Settings) interface, select "Language" to enter (Language setting) interface as shown in Fig.20. Select "English", the device language will be English, select "中文", the device language will be Chinese, after selected, it will automatically return to (Settings) interface.

(2) Bluetooth

Move selection toolbar to "Bluetooth", press "Confirm" key to select "ON" or "OFF" that can turn on or off the Bluetooth module (If there is no Bluetooth module in the device, the operation is invalid).

(3) Time setting

Under (Settings) interface, select "Time" to enter (Time setting) interface as shown in Fig.21. Select "Minute" to enter (Minute setting) interface, as shown in Fig.22. Press "Up" or "Down" key to change the value (long pressing is available), then press "Confirm" key to return to (Time setting) interface.

The operation of "Hour", "Day", "Month", "Year" is similar to the "Minute". The "Week" will be calculated according to "Year", "Month" and "Day", which does not need to set manually. Then select "Exit" to return to (Settings) interface.

Figure 21 Time setting interface

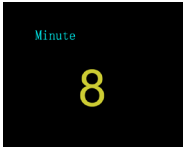


Figure 22 Minute setting interface

(4) Calibration

Under (Settings) interface, select "Calibration" to enter (Calibration setting) interface as shown in Fig.23. Select 2L or 3L based on the volume of syringe, then enter to (Calibrate) interface as shown in Fig.24.

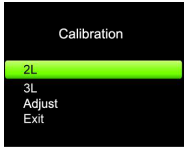


Figure 23 Calibration setting interface

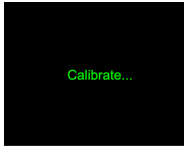
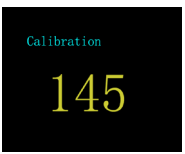


Figure 24 Calibrate interface

Under (Calibrate) interface, push the syringe once, the device will display "REPEAT", then push the syringe once again. After twice correct continuous operation, the calibrating will be succeed, and the device will display "OK!". Finally the interface will jump to the former interface before calibration (The former interface: If the device is calibrated after measure-

ment completed, it will return to (Settings) interface; if calibrated before measurement completed, it will return to (Testing) interface.).
If the device displays “Error ! Please repeat”, it indicates something wrong with the operation, please repeat the calibrating until succeeded. If the device displays “Select right volume”, please confirm whether the volume of syringe and calibration selection is accordant, then repeat the calibrating until succeeded. If you need to stop calibrating, just press the“Confirm” key to exit to the former interface before calibration.
Under (Calibration setting) interface, select “Adjust” to enter (Adjusting) interface, as shown in Fig.25. Press “Up” or “Down” key to change the value (long pressing is available), then press “Confirm” key to return to (Adjusting confirm) interface, as shown in Fig.26. Selecting “Yes” will save adjusted value, selecting “No” will cancel the setting, then the device will return to (Calibration setting) interface.

⚠ **Note: The value determines the accuracy of measurement, please do NOT change it randomly. After the turbine has been replaced, calibration shall be applied for inputting parameters of new turbine, which guarantees the accuracy of measurement after turbine replaced.**



F igure 25 Adjusting interface

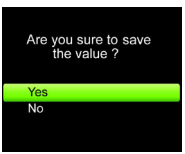


Figure 26 Adjusting confirm interface

Under (Calibration setting) interface, select “Exit” to return to (Settings) interface.

(5) About device

Under (Settings) interface, select “About” to enter (About) interface. User can view device name and software version. Press “Confirm” key to return to (Settings) interface.

(6) Exit

Under (Settings) interface, select “Exit” to return to (Menu) interface.

d. Power off

Under (Menu) interface, select “Power off”, the device will shut down.

Note: If there is no operation within 1 minute, the device will power off automatically.

e. Exit

Under (Menu) interface, select “Exit” to return to (Main interface). If the measurement is not completed before enter (Main interface), it will return to (Testing) interface.

6.1.5 Repeated measure

Measurement of the device is repeatable. Long press “Repeated measure” key to enter (Testing) interface. When the memory is full, it will display (Memory full) interface as shown in Fig.27. If you select “Yes”, it will enter (Delete data) interface; if you select “No”, it will enter (Menu) interface.

Figure 27

6.1.6 Charge

There are two kinds of charging methods:

1) Connect the device with computer by data line— then the device should be under charging state.
2) Connect the device with power supply by power adapter, then the device should be under charging state.

⚠ For device charging, connect it with the power where easy to be cut off, after charging completed, unplug the power adapter to cut off from power.

6.1.7 Upload Data

Install the PC software in the computer, then the following figure will appear after completing.

Figure 28

1) Connect the device with computer by data line,double press the icon to open the PC software procedure.
2) Press the corresponding key to achieve upload data, delete case, print information, background, select language, switch PDF format, set the testee information etc.
3) Press “Exit” to exit the software, unplug the data line from the computer to achieve uploading.

6.2 Attention

- Please check the device before using, and confirm that it can work normally.
- 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 and etc.
- Intense activity of the subject or extreme 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

Using medical alcohol to wipe the device for disinfecting, nature dry or clean it with clean soft cloth. It’s necessary to clean the turbine periodically for accuracy, keep the diaphaneity of the lucency part, and keep it away sundries (such as hair or lesser sediment). Immerse the turbine in disinfectant after use, clean it with clean water and dry standing vertically after soaked a few minutes (but don’t make the turbine rinsed with water directly), this type doesn’t 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 recharge the battery when the screen shows low-power (the battery power is ▭).
3) Recharge the battery soon after the over-discharge. The device should be recharged every six months when it is not regular used. It can extend the battery life following this guidance. If the battery is broken, DO NOT try to maintain it by yourself, please contact us or the local service center.
4) The device needs to be calibrated once a year (or according to the calibrating program of hospital). It also 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 material.
2) The packed device should be stored in room with no corrosive gases and good ventilation. Temperature: -40°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.
	The malfunction of the device.	Press "Repeated Measure" key to remeasure, or power off to restart.
The figure is wrong and unorderly.	The power turned off abnormally.	Delete the current case and remeasure.
	Operation is wrong.	Operate normally according to the user manual.
	The malfunction of the device.	Please contact the local service center.
The device can not be powered on.	Low battery or no power.	Please charge the battery.
	The malfunction of the device.	Please contact the local service center.

The display disappears suddenly.	The device is set to automatic power off when there is no operation in one minute.	Normal.
	The battery is drained away or almost drained away.	Please charge the battery.
The device can not be used for full time after charge.	The battery is not full charged.	Please recharge the battery.
	The battery is broken.	Please contact the local service center.
The battery can not be full charged even after 10 hours charging time.	The battery is broken.	Please contact the local service center.

Chapter 9 Key of Symbols

Symbol	Meanings
	Follow instructions for use
CE	Medical Device compliant with Directive 93/42/EEC
	Caution: read instructions (warnings) carefully
	WEEE disposal
	Type BF applied part
	Full-power
	Low-power
Error	Measured value goes beyond the limits
	Status indicator bar
	Atmospheric pressure limit

	Humidity limit
	Temperature limit
	Fragile, handle with care
	Keep in a cool, dry place
	This way up
	Date of manufacture
	Manufacturer
SN	Serial number.
	Charging indicator.
	Turn the turbine clockwise to unlock.
	Turn the turbine counterclockwise to lock.
IP22	Covering Protection rate
EC REP	Authorized representative in the European community
REF	Product code
LOT	Lot number
MD	Medical device

	Imported by

Chapter 10 Parameter Introduction

MEASURED PARAMETERS

Parameter	Description	Unit
FVC	Forced vital capacity	L
FEV1	Forced Expired Volume in one second	L
PEF	Peak expiratory flow	L/s
FEV1%	FEV1/FVC×100	%
FEF25	25% flow of the FVC	L/s
FEF2575	Average flow between 25% and 75% of the FVC	L/s
FEF75	75% flow of the FVC	L/s

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 UT is the a.c. mians voltage prior to application of the test level.		

Table 3

Guidance and manufacturer's declaration – electromagnetic immunity						
	Test Frequency (MHz)	Band (MHz)	Service	Modulation	IEC 60601-1-2 Test Level (V/m)	Compliance level (V/m)
Radiated RF IEC61000-4-3 (Test specifications for enclosure port immunity to RF wireless communications equipment)	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
Radiated RF IEC61000-4-3 (Test specifications for enclosure port immunity to RF wireless communications equipment)	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

Number	Model	Cable length (m)	Mask or no	Remark
1	Power adapter cable	1.50	YES	/

GIMA WARRANTY TERMS
The Gima 12-month standard B2B warranty applies

Disposal: *The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment*