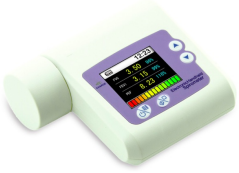


GIMA SP-10 Bluetooth Spirometer Instruction Manual

GIMA SP-10 Bluetooth Spirometer Instruction Manual

Contents

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 teste for more than 5 times.
- The teste 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

- **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.
  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

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.

  Contraindication

  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.

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 hypo immunity.

  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.

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 equipment's.

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.

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.
6. Take the function of wireless transmission.

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.
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, teste 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 microprocess sor, and displayed from the screen.

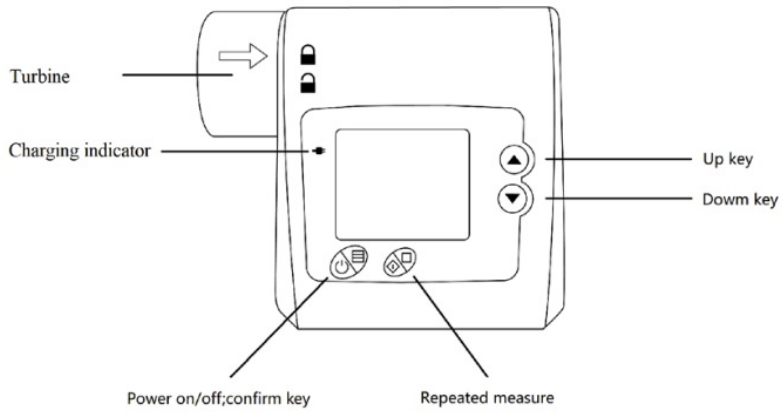
Chapter 4 Technical Specifications

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 teste 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.
  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 equipmen  t.
  The degree of protection against electroshock: Type BF applied part .
  International Protection: IP22.

Chapter 5 Installation

View of the Front Panel



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

Accessories

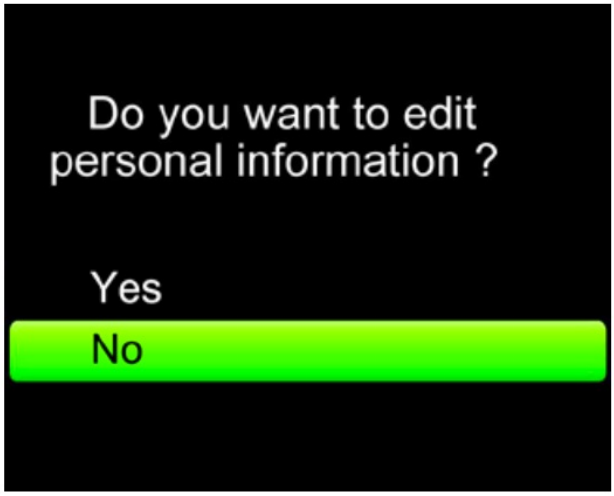
1. A User Manual
2. A USB data line
3. A mouthpiece
4. A power adapter
5. PC software
6. A nose clip (optional)

⚠ 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.

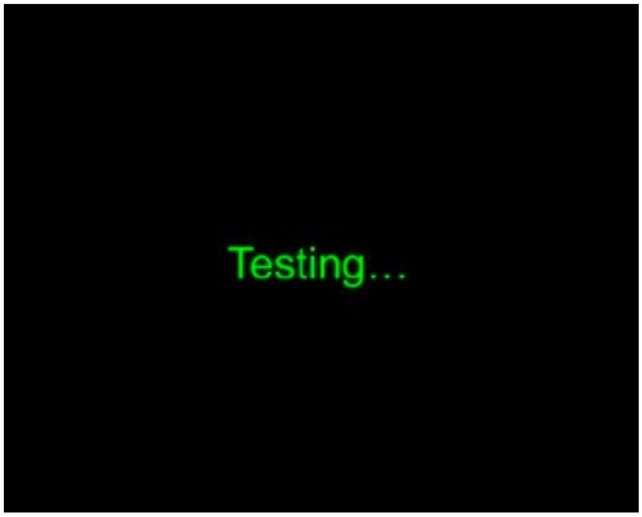
Chapter 6 Operating Guide

How to use
Power on/off
After assembly, long press “power on” key to turn on the device.
When device is powered on, long press “power off” key to turn it off.
Measurement
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.)
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.

Selective interface

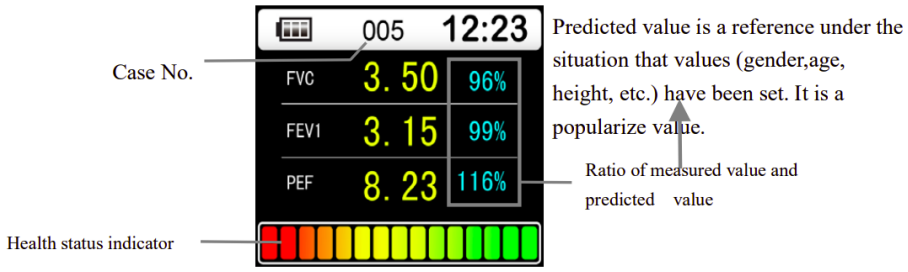


Testing



Main interface

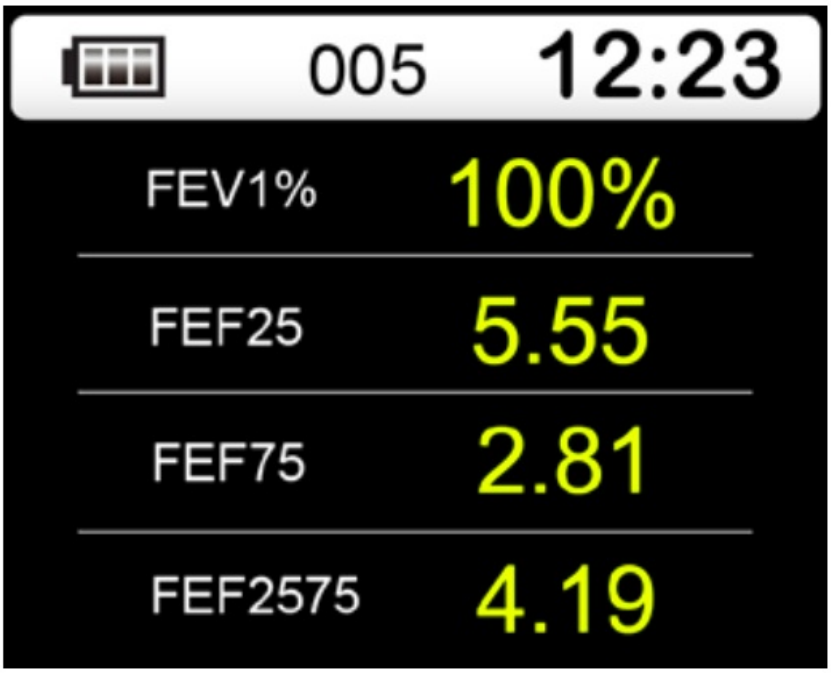
Main parameter interface



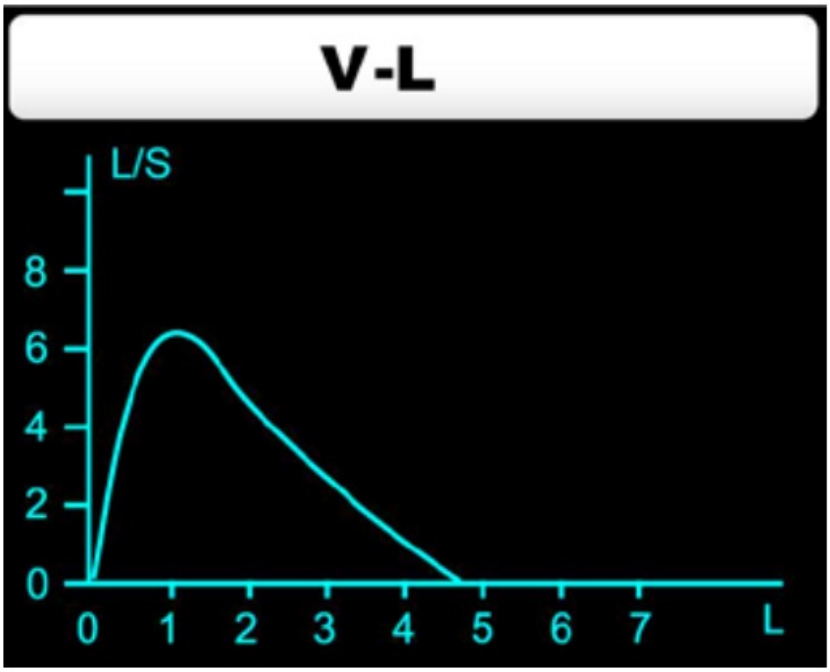
a. Main parameter interface: display the ratio of predicted value and measured value of three main parameters. Ratio reflects health status, correct settings of personal information is the key to obtain accuracy ratio. Besides, this
interface can also display battery status, time, case number and health status indicator, as shown in Fig.4.
health status indicator: indicate the ratio of measured value and the predicted value, display the teste 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 teste 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”.
clothier parameter interface: display four parameters except the main parameter, as shown in Fig.5.

dunker 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 .

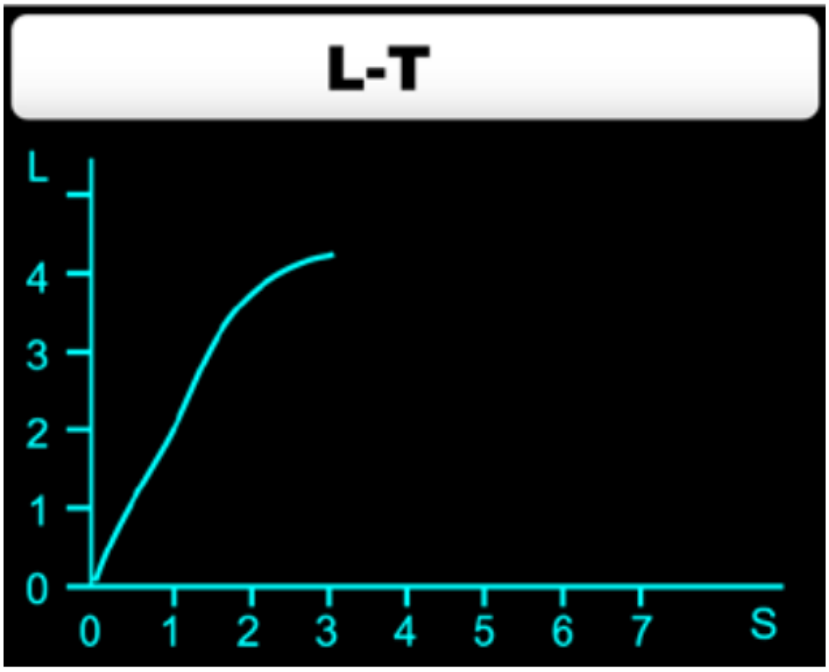
Other parameter interface



Flow rate-volume chart



Volume-time chart

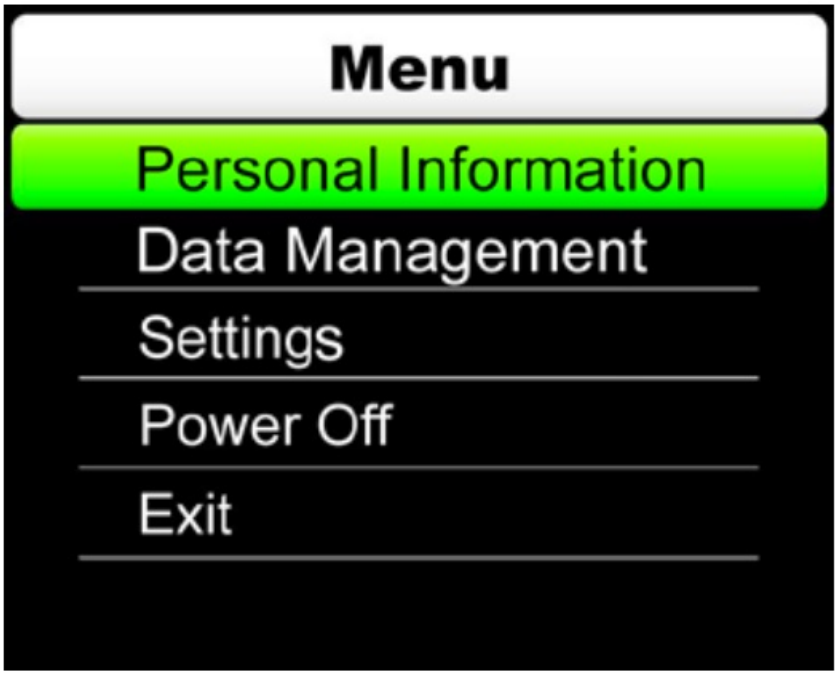


Menu

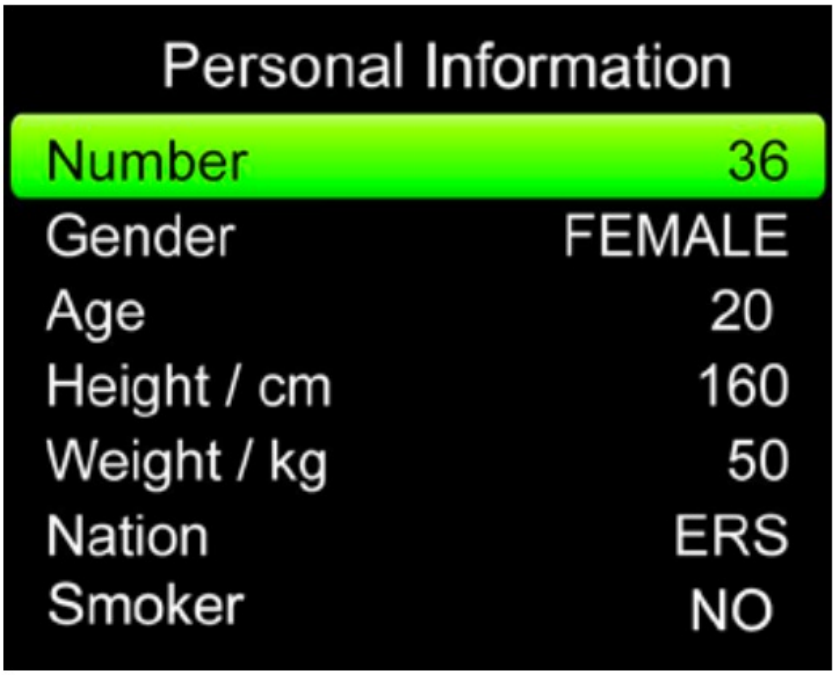
Under Testing or Main interface , press confirm key to enter Menu interface as shown in Fig.8. Under the interface, functions such as modify personal information, data management, device setting, power off can be realized.

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:

Menu interface



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 teste, 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

   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.

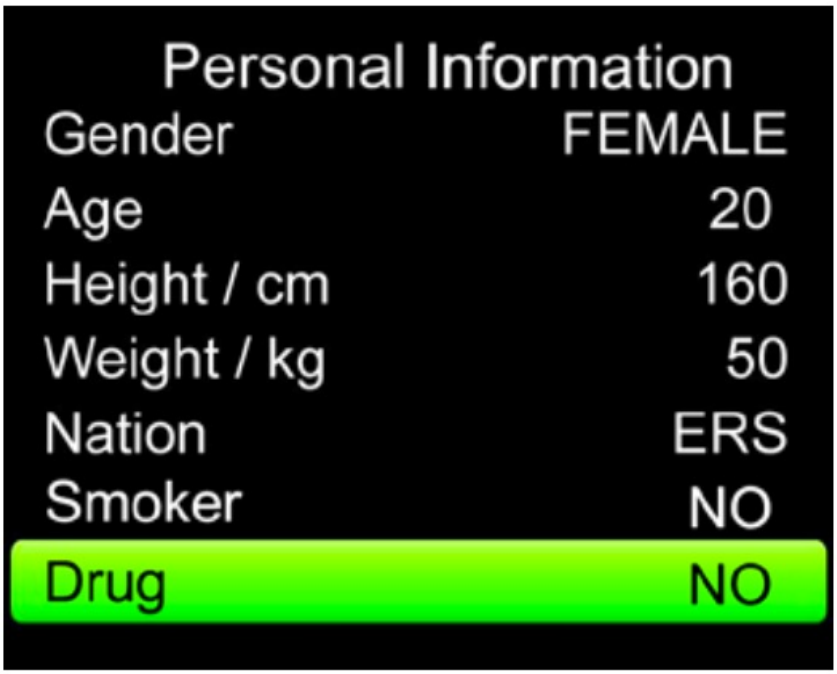
5. **Setting of smoker and drug**

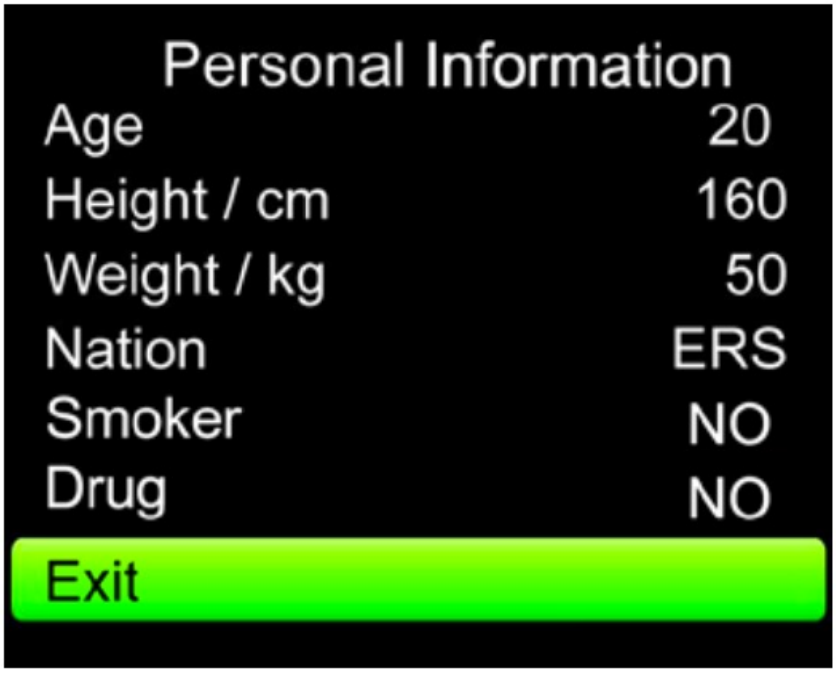
   The modification of “Smoker” and “Drug” is similar to the “Gender”, in which patient information of smoker and drug can be modified.

   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.





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.

Data management interface

Case selection interface

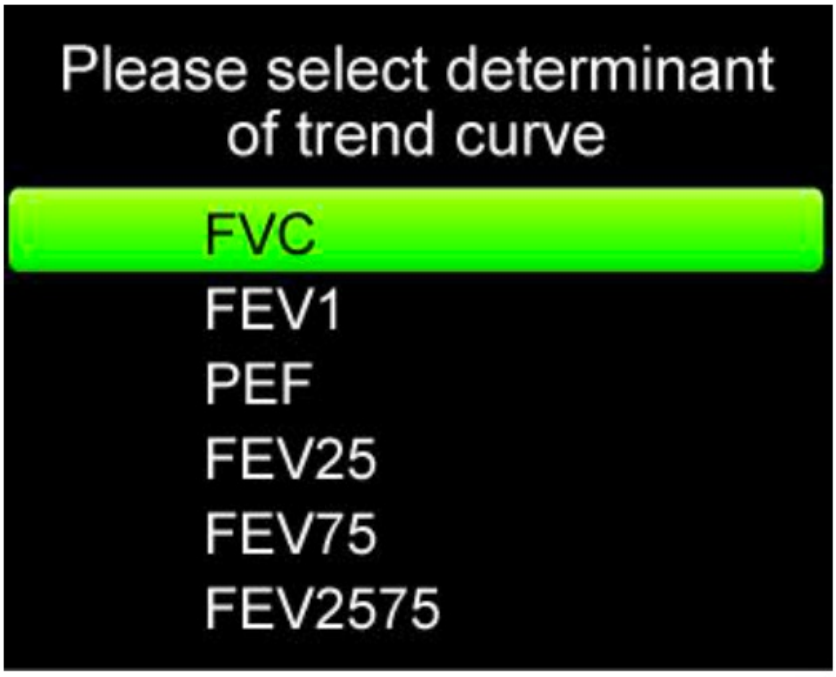
1. **Review function**

   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.

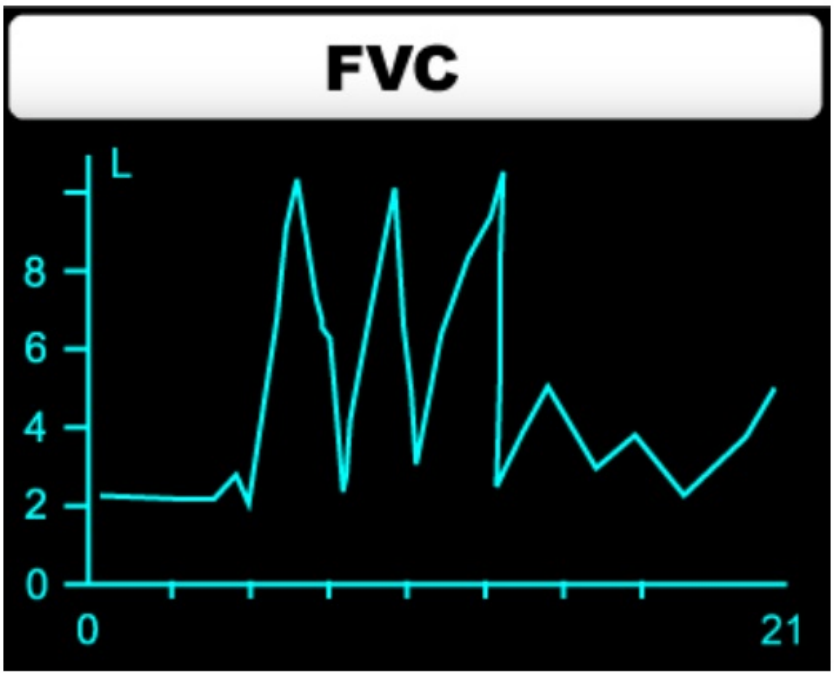
2. **Trend curve**

   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.

   Trend curve selection interface



   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 mana gemen t interface.

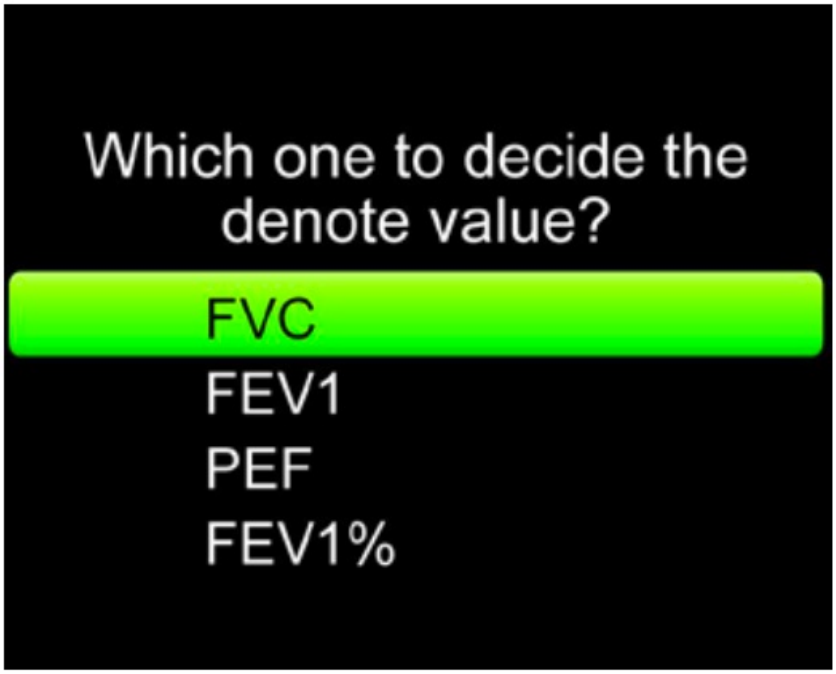
   If choose “No”, it will return to Data management interface directly.

   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.

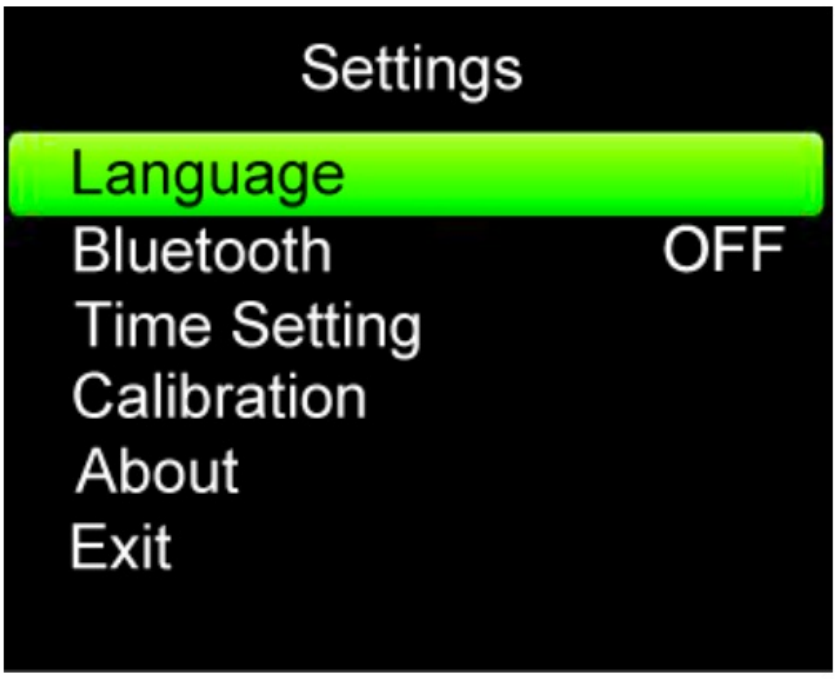
   Denote value setting interface



5. **Exit**

Under Data management , select “Exit” to return to Menu interface. cossetting’s 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.

Setting interface



Language setting interface

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 “ ”, the device language will be Chinese, after selected, it will automatically return to Settings interface.

2. **Bluetooth**

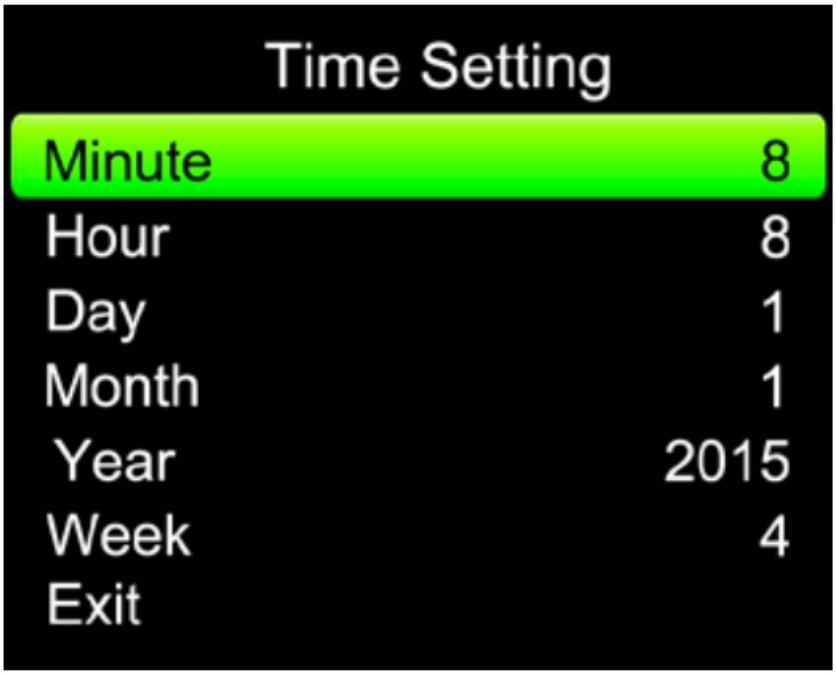
   Move selection toolbar to “Bluetooth”, press “Confirm” key to select “ON” or “OFF” that can turn on or off the Bluetooth module (If there is no Bluetooth module in the device, the operation is invalid).

3. **Time setting**

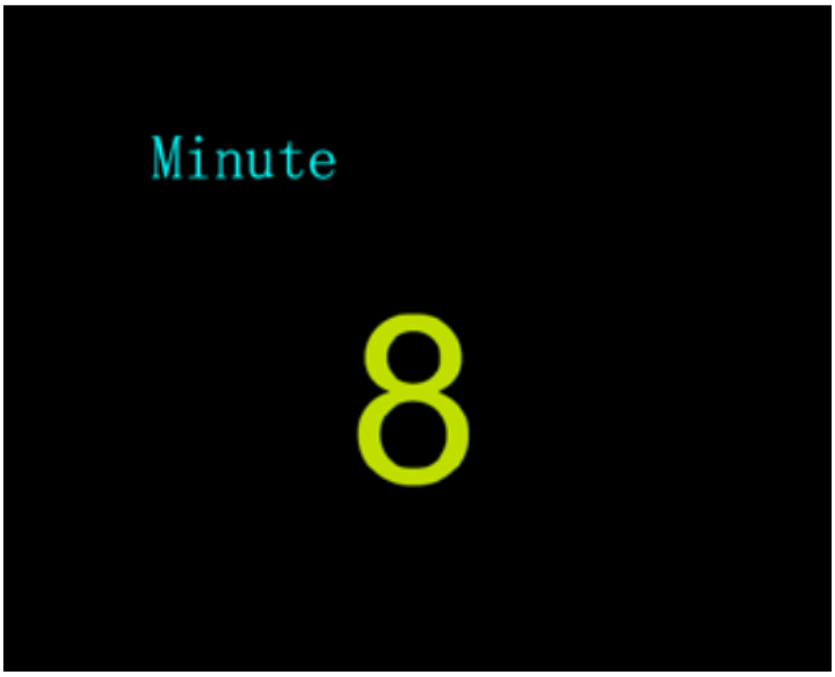
   Under Settings interface, select “Time” to enter Time setting interface as shown in Fig.21. Select “Minute” to enter Minute setting interface, as shown in Fig.22. Press “Up” or “Down” key to change the value (long pressing is available), then press “Confirm” key to return to Time setting interface.

   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.

   Time setting interface



Minute setting interface

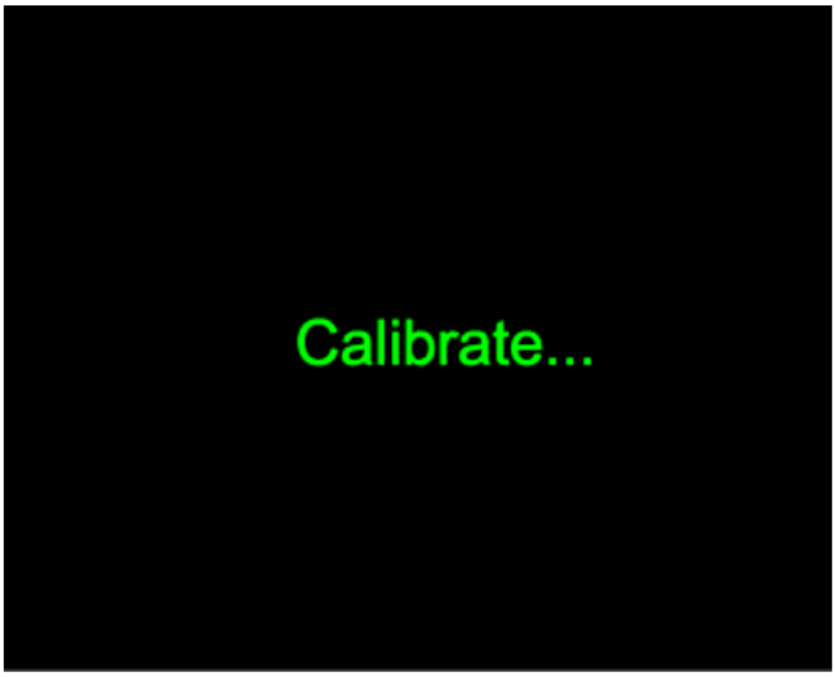


4. **Calibration**

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.

Calibration setting interface

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 measurement 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.

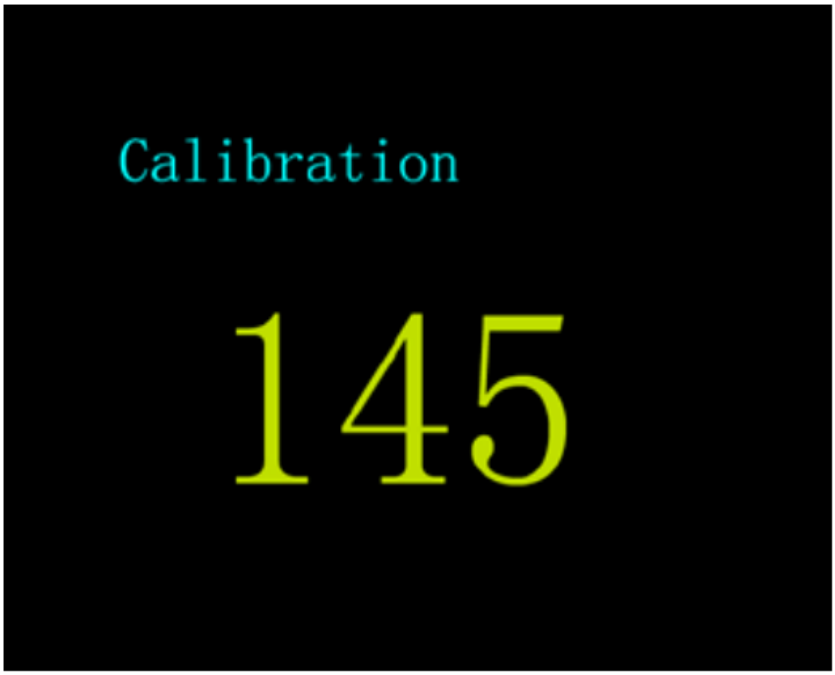
Under Calibration setting interface, select “Adjust” to enter Adjusting interface, as shown in Fig.25. Press “Up” or “Down” key to change the value (long pressing is available), then press “Confirm” key to return to Adjusting

confirm interface, as shown in Fig.26. Selecting “Yes” will save adjusted value, selecting “No” will cancel the setting,

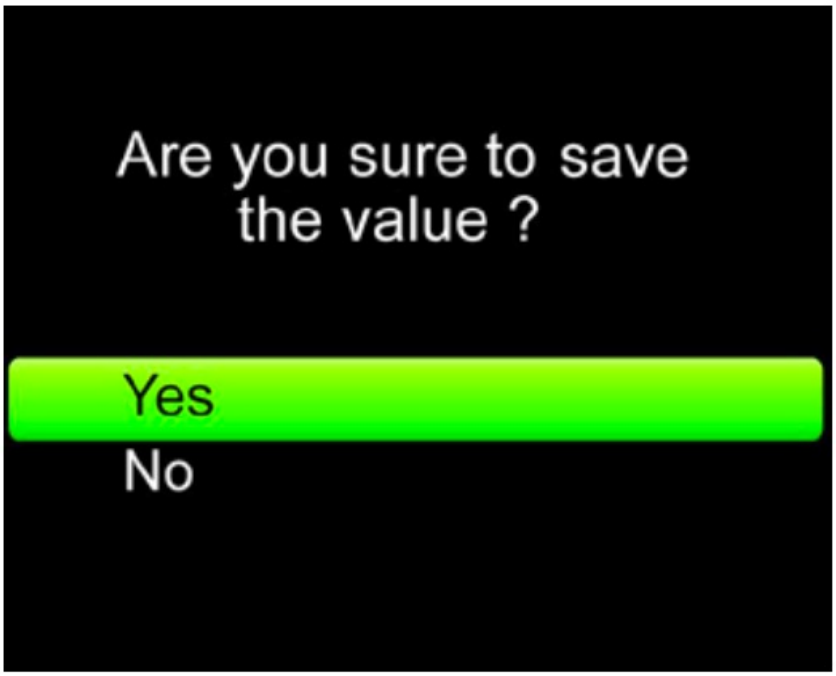
then the device will return to Calibration setting interface.

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.

Adjusting interface



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.

depower 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.

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.

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.

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.

Upload Data

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

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 teste information etc.
3. Press “Exit” to exit the software, unplug the data line from the computer to achieve uploading.

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

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 latency 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)

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.

Transportation and Storage

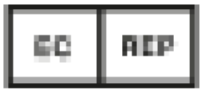
1. The packed device can be transported by ordinary conveyance or according to transport contract. The device can not be transported mixed with toxic, harmful, corrosive material.
2. The packed device should be stored in room with no corrosive gases and good ventilation. Temperature: -40°C~+55°C; Relative Humidity: ≤95%.

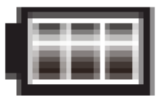
Chapter 8 Troubleshooting

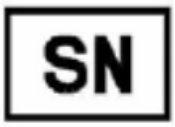
Trouble	Possible Reason	Solution
The device can't finish measurement for a long time, and the data can't be displayed.	The start speed is too low, the device does not measure.	Remeasure according to the user manual.
	The malfunction of the device.	Press "Repeated Measure" key to remeasure, or power off 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 hour charging time.	The battery is broken.	Please contact the local service center.
The device has built-in wireless module, but can't achieve wireless transmission.	The wireless module is broken, or the transmission route has problem.	Please contact the local service center.

Chapter 9 Key of Symbols

Symbol	Meanings
	Follow instructions for use
	Medical Device compliant with Directive 93/42/EEC
	Authorized representative in the European community

IP22	Covering Protection rate
	**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.
	Serial number.
	Charging indicator.
	Turn the turbine clockwise to unlock.
	Turn the turbine counterclockwise to lock.

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

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

Guidance and manufacturer’s declaration – electromagnetic emission		
The SP10W is intended for use in the electromagnetic environment specified below. The customer of the user of the SP10W should assure that it is used in such and environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The SP10W uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The SP10W is suitable for use in all establishments, including domestic and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

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

Guidance and manufacturer’s declaration – electromagnetic immunity			
The SP10W is intended for use in the electromagnetic environment specified below. The customer or the user of SP10W should assure that it is used in such an environment.			
Immunity test	IEC 60601 testlevel	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD)IEC 61000-4-2	±6 kV contact±8 kV air	±6 kV contact±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relativehumidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Mains power quality should be that of a typical commercial or hospital environment.
NOTE			

Guidance and manufacturer’s declaration – electromagnetic immunity – for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer’s declaration – electromagnetic immunity			
The SP10W is intended for use in the electromagnetic environment specified below. The customer or the user o f SP10W should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Complain cu level	Electromagnetic environment – guidance
Radiated RF IE C61000-4-3	3 V/m80 MHz to 2.5 G Hz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the SP10W, i ncluding cables, than the recommended separation d istance calculated from the equation applicable to th e frequency of the transmitter. Recommended separ ation distance*d* = é3.5ù *P* 80 MHz to 800 MHz *E* du e 1 ad = é 7 ù *Pea E* ú 800 MHz to 2.5 Ghazi 1 where P is the maximum output power ratin g of the transmitter in watts (W) according to the tran smitter manufacturer and d is the recommended sep aration distance in meters (m).Field strengths from fi xed RF transmitters, as determined by an electromag netic site survey, a should be less than the complianc e level in each frequency range’s Interference may o ccur in the vicinity of equipment marked with the follo wing symbol: 
NOTE 1At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land m obile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically wit h accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site sur vey should be considered. If the measured field strength in the location in which the SP10W is used exceeds th e applicable RF compliance level above, the SP10W should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SP10W.			

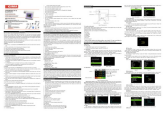
Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the SP10W		
The SP10W is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SP10W can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SP10W as recommended below, according to the maximum output power of the communications equipment.		
Rated maximum output power of transmitter(W)	Separation distance according to frequency of transmitter (m)	
	80 MHz to 800 MHz = é3.5ù *Pea E* due 1 û	da 800 MHz a 2,5 Gazed = é 7 ù *Pea E* due 1 û
0.01	0.12	0.23
0.1	0.37	0.7
1	1.17	2.33
10	3.69	7.38
100	11.67	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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.		

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.*

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

Documents / Resources

	GIMA SP-10 Bluetooth Spirometer [pdf] Instruction Manual SP-10 Bluetooth Spirometer, Spirometer, SP-10, SP-10 Spirometer, Bluetooth Spirometer

References

- User Manual