

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.

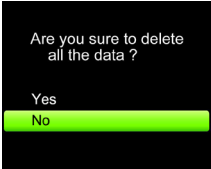


Figure 17 Delete data interface

(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.

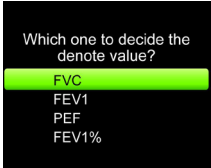


Figure 18 Denote value setting interface

(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.

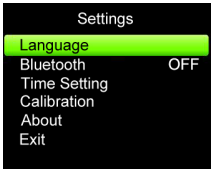


Figure 19 Setting interface



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.

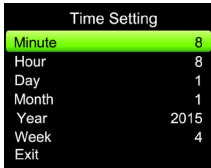


Figure 21 Time setting interface

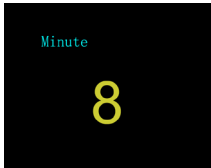


Figure 22 Minute setting interface

(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

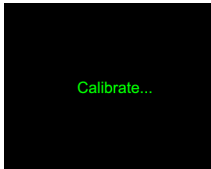


Figure 24 Calibrate interface

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 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.

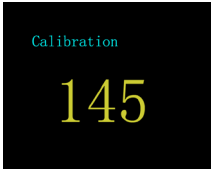


Figure 25 Adjusting interface

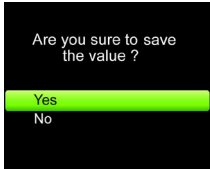


Figure 26 Adjusting confirm interface

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:

- Connect the device with computer by data line— then the device should be under charging state.
- 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

- Connect the device with computer by data line,double press the icon to open the PC software procedure.
- Press the corresponding key to achieve upload data, delete case, print information, background, select language, switch PDF format, set the testee information etc.
- 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 diaphanety 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

- Please clean and disinfect the device before using according to the User Manual (7.1).
- Please recharge the battery when the screen shows low-power (the battery power is .
- 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.
- 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.








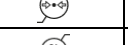













7.3 Transportation and Storage

- 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.
- The packed device should be stored in room with no corrosive gases and good ventilation. Temperature: -40℃~+55℃; 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 unorderedly.	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	Low battery or no power.	Please charge the battery.

on.	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.
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		
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 limitat		
	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		
	Authorized representative in the European community		
MD	Medical device		
REF	Product code		
LOT	Lot number		Importated 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/FVCx100	%
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

- 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.
Warnings: 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.
- 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.

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

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

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)
	385	380 –390	TETRA 400	Pulse modulation 18 Hz	27
	450	430 –470	GMRS 460, FRS 460	FM ±5kHz deviation 1 kHz sine	28
	710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	9
	810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	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
	2450	2400 –2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28
	5240 5500 5785	5100 –5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9

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

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

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



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 Gima 12-month standard B2B warranty applies