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MD

User Manual for
SPIROMETER

Model：Air Smart T1

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◆ Thank you for purchasing this product of FEELLIFE HEALTH INC.

◆ To ensure the correct use of this product, please read this instruction for use carefully before using.

◆ Please keep this instruction for use in a place where convenient for reading at any time.

◆ The illustrations in this instruction for use are schematic diagrams.

◆This user manual is available in English.

Safety Warning

◆ The use of this device for children and special groups like disabled,elderly must be carried out under the correct guidance and supervision.

◆ The user can only be used for the specified purpose, not for other purposes.

◆ Please be sure to clean and disinfect the accessories every time you use or store this device.

◆ If the parts are found damaged or fall into the water accidentally, please do not continue to use.

1. Intended Use

The spirometer is a hand-held equipment for examining lung function. The device is fit for hospital, clinic, family for ordinary test(FVC, FEV1, FEV1/FVC, PEF, etc.). The spirometer is intended to be used by a physician or by a patient under the instruction of a physician or paramedic.

2. Working Principle

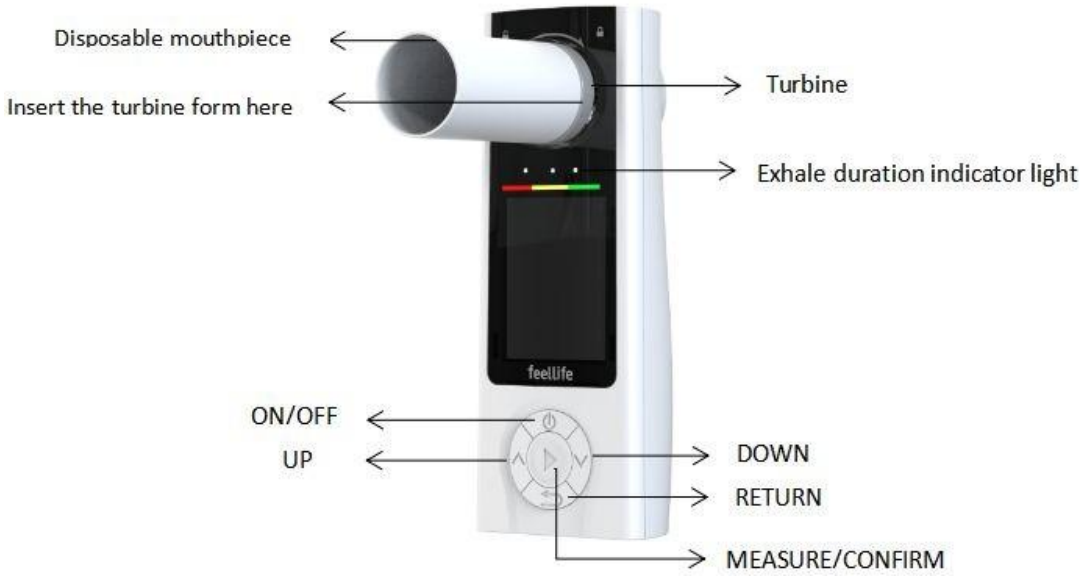
Inhale deeply, seal your lips around your mouthpiece, and blow the air out as hard as you can. The exhaled air passes through the turbine into a rotating air stream, which rotates the blades.The infrared transmitting tube and receiving tube inside the device are aligned with the blade. When the blade rotates, the receiving tube judges and transforms the received optical signal to form various signals related to blade rotation. After circuit processing, the single chip microcomputer forms identifiable signals and processes them, which will be converted into each measurement parameter and displayed on the screen.

3. Product Contents and Overview

3.1 Structural composition

It is mainly composed of the Main Unit, Turbine,Disposable Mouthpiece and USB Cable.

3.2 Product composition



4. Technical Specification

Product name	Spirometer
Model	Air Smart T1
Internal power supply	DC 3.7 V, 2000mAh, rechargeable lithium battery
External power supply	With DC 5 V, 1 A adapter
Display mode	LCD display
Flow range	±16 (l/s) (deviation: ± 10% or ± 0.3 (l/s), whichever is greater)
Volume range	0.5 (l) ～ 8 (l) (deviation:±2.5%or±0.05l,whichever is greater)
MVV	0(l/min)～250(l/min) (deviation:±10% or 15(l/min),whichever is greater)
Operation mode	Continuous operation
Operating time	10mins

Transportation and storage environment	Temperature：-20℃~+55℃ Relative humidity：10%~93% R.H. (Non-condensing) Relative atmospheric pressure:70kPa~106kPa
Operating environment	Temperature：+5℃~+40℃ Relative humidity：15%~80% R.H. (Non-condensing) Relative atmospheric pressure:86kPa~106kPa
Dimension(mm)	158(L)×60(W)×36.3(H) (Main Unit)
Weight(g)	178.8
Applied part classified	The classified of applied part is BF.
Battery service life	Battery service life can exceed 300 cycles.

Note:

1) Applied part：Mouthpiece or Disposable Mouthpiece
2) Connection device:ISO system
3) Bluetooth transmission has communication protocol requirements:4.0
4) Service life
The main unit:5 years
Turbine:1 year
5) Shelf life
Disposable mouthpiece:3years
Turbine:3years

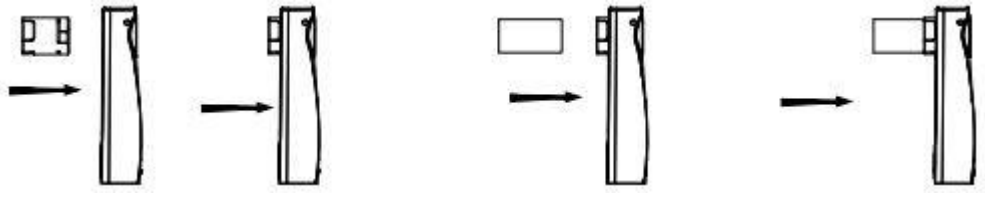
5. Installation Guideline

5.1 Turbine assembly: align the the turbine to the turbine hole on the shell, gently insert it to the bottom, clockwise rotate to lock it.During installation, you can hear a clear snap sound.

5.2 Turbine disassemble: counterclockwise rotate the turbine, gently pull it out.

5.3 Disposable mouthpiece assembly: insert one end of the mouthpiece into the turbine port directly.

Note: The turbine should be installed into the correct position,see the arrow on the device.
The turbine contains a mesh.Be careful to keep it.The use is to stop saliva.



Installation diagram of Spirometer

⚠ Caution:

1) The disposable mouthpiece is a paper material, it is designed for single user and single-use.It is not allowed for multi-users.

2) Any disposable mouthpieces included with the spirometer are only to be used as a reference guide to purchase the correct size mouthpiece required. These mouthpieces are clean but not sterile. To purchase appropriate mouthpieces, generally either paper or plastic.We suggest that you contact your local distributor.

Warning:

1) Use a bio-compatible mouthpiece to avoid any problems to the patient.Unsuitable materials could cause the device to malfunction, consequently providing incorrect test results.

2) The user is responsible for obtaining the proper mouthpieces for the device. The required mouthpiece is a standard type with an outside diameter of 30 mm, is of common use and in general easily procured.

5.4 Power supply preparation

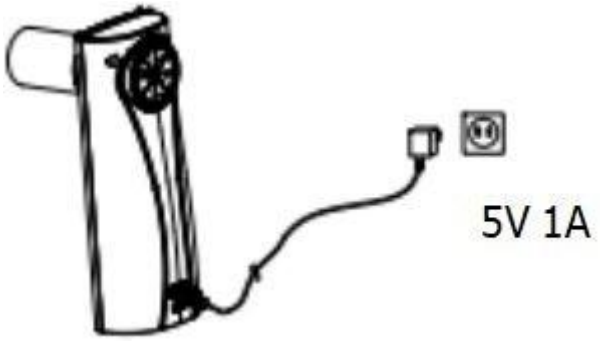
1) This device uses 3.7 V rechargeable lithium battery.It is not equipped with a power adapter. Please use an adapter which meets the requirements of IEC 60601-1.

2)The output voltage of the power adapter is DC 5 V, 1 A.

3) Use the USB cable to charge the lithium battery. While charging,the device can not work.

4) Battery charging

When this device is in low-battery state,please use an adapter to charge the lithium battery. During the charging process, the battery symbol on the display will flash and "Charging" will display on the screen.



Charging diagram of Spirometer

⚠ Caution:

1)The lithium battery has been built-in. Please do not disassemble it without permission.

2) This device cannot be used during charging.

3) Please charge for at least 30 minutes at the first use.

4)The battery symbol will flashes at the low-battery state. Please charge in time,otherwise this device will shuts down automatically.

5) The fully charged lithium battery can work continuously for about 72 h.

6) When it is not used for more than one month, it shall be charged at least once a month during the storage period.

7) Do not modify this equipment without authorization of the manufacturer.

8)At end of expect service life, please dispose this device according the local environmental regulation.

9)Do not disassemble or repair this device without permission, and do not disassemble or replace the battery without permission.If you need to replace the battery, please consult the manufacturer.

6. Operating Instructions

6.1 ON/OFF key

After assembly, long press (about 3 seconds) the ON/OFF key “⏻” to turn on/off the device.

6.2 Measurement

⚠ Caution:

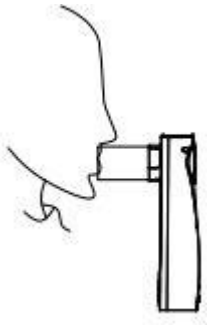
• In order to perform proper spirometry testing,please install this device refer to the "Installation guideline" section.

• Hold this device with both hands or grasp it like a mobile phone. The user should face with the display screen.

• Place the upper part of the mouthpiece in the mouth,and make sure that no air leaks from the mouth.

• It is recommended to stand up while testing. During expiration,it is recommended to bend forward the upper part of the body so as to release all the air out with the aid of the abdominal muscles.

• Accurate spirometry testing requires that the patient expire all the air in the lungs.



Measurement diagram

• Activities that should be avoid before Lung Function Testing

Smoking and/or vaping and/or water pipe use within 1 h before testing (to avoid acute bronchoconstriction due to smoke inhalation)
Consuming intoxicants within 8 h before testing (to avoid problems in coordination,comprehension,and physical ability)
Performing vigorous exercise within 1 h before testing (to avoid potential exercise-induced bronchoconstriction)
Wearing clothing that substantially restricts full chest and abdominal expansion (to avoidexternal restrictions on lung function)

1) After turning on the device, it will locate in selective interface shown as Figure 1, press UP or DOWN key to select.You can press CONFIRM key to select "No" and enter testing interface, shown as Figure 2 (Note: if select "Yes", it will enter Personal information interface to edit information.After exiting, it will return to testing interface.)

2) In Testing interface, breath in fully, seal the lips around the mouthpiece and blast all air out as forcefully as possible in the shortest time.Then wait for a few seconds, the device will enter main parameter interface as shown in Figure 3.

Figure 1 Selective interface

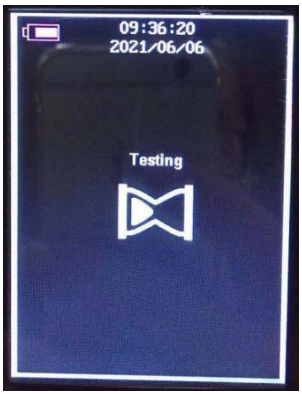


Figure 2 Testing interface

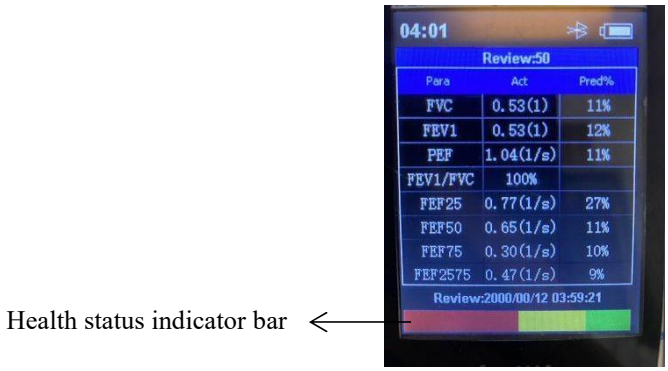


Figure 3 Main parameter interface

3) Main parameter interface: display 8 parameter values and the ratio of each parameter to its corresponding predicted value. The ratio reflects health status, correct settings of personal information is the key to obtain accurate ratio. Besides, this interface also displays power icon, current time, case number and health status indicator, as shown in Figure 3.

4) Health status indicator bar: indicates the measured state, displays the user health condition by the ratio of measured value to the predicted value vividly.The comparison of measured value with the reference value in same situation.It is red when the value is lower than 50%, which means that the user should pay attention to and go to hospital in time.It is yellow when the value is in range of 50%~80%, it means that the user should pay attention.It is green when the value is higher than 80%, which is normal.

Exhale duration indicator light:when the “Health status indicator bar” showing in the screen,the corresponding indicator light will on.

5) "Flow rate-volume chart" and "Volume-time chart" shown as Figure 4 will appear after pressing UP or DOWN key in Main parameter interface.

6) Under Figure 3 or Figure 4 interface,press RETURN key to enter the measurement interface for next test.Shown as Figure 2.

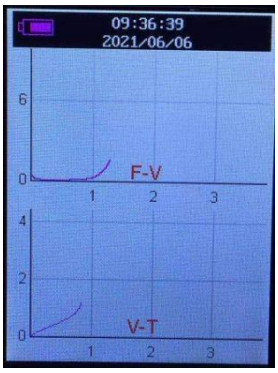


Figure 4 Flow rate-volume chart and Volume-time chart

6.3 Menu

In Testing interface,press CONFIRM key to enter Menu interface shown as Figure 5, "Personal Information", "Data Management", "Settings" and "Power Off" can be selected, press UP or DOWN key to select corresponding item, then press CONFIRM key to enter its sub-menu, methods are as followings:

Figure 5 Menu interface

- Personal information

Under Menu interface, select "Personal information" to enter its sub-menu as shown in Figure 6, in which user can edit user information (Note: Under Selective interface as shown in Figure 1, selecting "Yes" will enter Personal information interface too.).

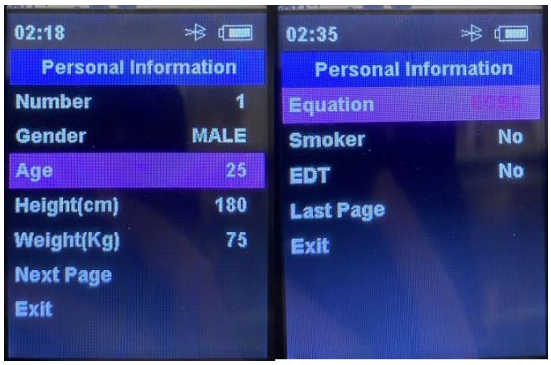


Figure 6 Personal information interface

1) Number

"Number"is the current case number. For example, if you are the 23th user, the "Number"will be 23. Case number can increase automatically, no need to set manually.

2) Setting

Select "Gender" and press CONFIRM key.Press UP or DOWN key to select "MALE" or "FEMALE", then press CONFIRM key to confirm.

The modification method of"Age" ,"Height","Weight","Equation","Smoker"and "BDT"is similar to the"Gender".

Note:

Adjustable range of "Age" is 6~101.Adjustable range of "Height" is 80~241 cm.

Adjustable range of "Weight" is 15~250 Kg.

The equation of predicted value can be set in "Equation" item, including "ECSC",

"KNUDSON" and "USA".

3) Exit

In Personal information interface, select "Exit" or press RETURN key to return to Menu interface.

- Data management

Select "Data management" in Menu interface to enter its sub-menu shown as Figure 7.

Figure 7 Data management interface

1) Review Function

Select "Review Function" in Data Management interface as shown in Figure 8.Press UP or DOWN key to review historical records.Press RETURN key to enter Data management interface.

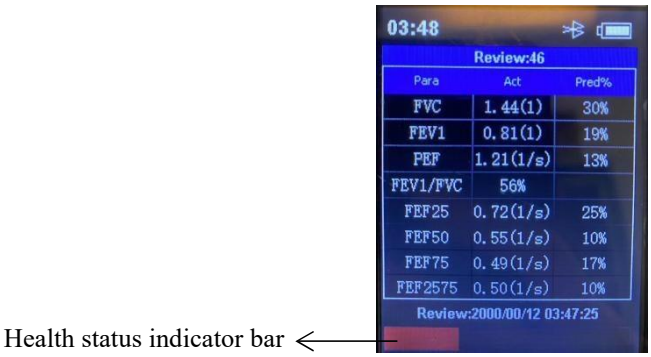


Figure 8 Review function interface

2) Trend Curve

Select "Trend Curve" in Data Management interface as shown in Figure 9.After selecting the parameter, press CONFIRM key to enter Trend curve display interface, as shown in Figure 10.The figure is a summary of all stored data aiming at the selected parameter.It displays the trend change vividly, which is convenient for user to compare. If there are too much data, press UP or DOWN key in the curve to browse all data trend in turn.Press CONFIRM key to return to Data Management interface.

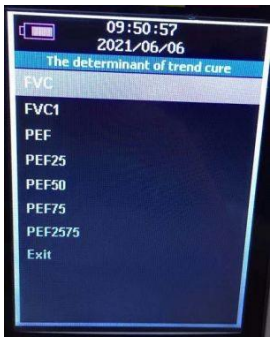


Figure 9 Trend curve selection interface

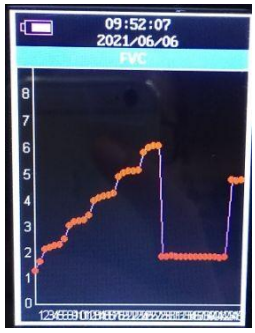


Figure 10 Trend curve display interface

3) Delete Data

Select "Delete Data" in Data Management interface as shown in Figure 11.Select "Yes" to delete all data and the screen will display "Waiting...". Few moments later,it will return to Data Management interface. Select "No" ,it will return to Data Management interface.

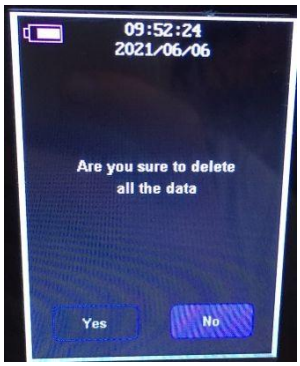


Figure 11 Delete selection interface

4) Denote Value

Select "Denote Value" in Data Management interface as shown in Figure 12, after selecting the parameter, it will automatically return to Data Management interface.The Health status indicator will show in accordance with the parameter you set.(as shown to Figure 3)

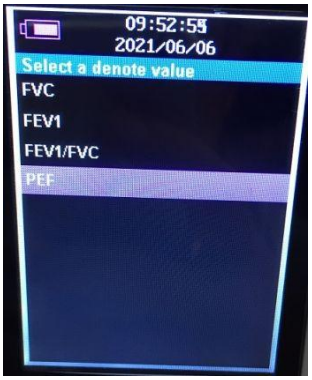


Figure 12 Denote value setting interface

5) Exit

In Data Management interface, select "Exit" or press RETURN to return to Menu interface.

- Settings

Select "Settings" in Menu interface to enter the setting interface as shown in Figure 13. Under this interface, you can set language, Bluetooth, time,etc.

Figure 13 Settings interface

1) Language

Select "Language" in Settings interface, then press UP or DOWN key to select "English" or "Chinese" (If this device does not have built-in language selection function, the operation is invalid).

2) Bluetooth

Select "Language" in Settings interface, then press UP or DOWN key to select "ON"/"OFF".Collect your phone and this device via Bluetooth.You can review the data by this way.

How to use the Bluetooth?

Step 1:Install the APP according to scan the QR code.

Step 2:Open the Bluetooth on your phone.Open the APP and the interface are shown as below.

Step 3:Click “Device”, and it will connect automatically.

Step 4:Click “Lung”,you can view your test result.

Step 5:Click “Experience” and the interface are shown as below.You can know more about our product by entering “Medical” and “Productions” module.

3) Time setting

Select "Time" to enter its setting interface, select "Year" to display current year as shown in Figure 14, press UP or DOWN key to change the value and press CONFIRM key to save.

The operation steps of "Month", "Day", "Hour", "Minute" and "Second" is the same with the "Year".

Figure 14 Time setting interface

4) About

You can select "About" in Settings interface to enter its sub-menu and check the device name and software version, then press CONFIRM or RETURN key you can return to Settings interface.

5) Exit

In Settings interface, select "Exit" or press RETURN to return to Menu interface.

- Power off

Select "Power Off" in Menu interface to turn off the device.

Note: If there is no operation within 2 minutes, the device will power off automatically.

- Exit

In Menu interface, select "Exit" or press RETURN to return to Testing interface.

6.4 Charging

The device will automatically enter the charging interface when it is charging. Under this interface,this device cannot be used.

The indicator light on the top left of the device is displayed in orange when the device is charging,and it turns to green after the device is fully charged.

Two methods for charging:

1)Charge the device by connecting to the power adapter which meets the requirements of IEC 60601-1.

When the device is charging, please place the device where easy to cut off from the mains supply. After the device is fully charged, unplug the power adapter to disconnect the device from mains supply.

6.5 Data transmission

1) The device has Bluetooth transmission function. After turning on the device, the Bluetooth is set to the ON state, the Bluetooth icon is displayed on screen. At this time, the device can be searched and connected with other devices. When the connection is built successfully, the device displays data transmission icon.

⚠ Caution:

1) This device will automatic power off when there is no operation after two minutes.

2) It is power supplied by rechargeable lithium battery.The battery is built-in.If have any problem with the battery,please contact the manufacturer or the distributor.

3) It is recommended that this device should be used in room.

4) Excessive ambient light may affect measurement accuracy. It includes fluorescent lamp, dual ruby light, infrared heater, direct sunlight, etc.

5) Intense activity of the subject or electrosurgical interference may also affect the accuracy.

6) Please clean and disinfect this device after using according to "Cleaning and Disinfection" section.

6.6 Measured parameters

Parameter	Description	Unit
FVC	Forced vital capacity (total expiratory volume)	l
FEV1	Forced Expiratory Volume in one second	l
PEF	Peak expiratory flow	l/s
FEV1/FVC	Forced expiratory rate in one second, FEV1/FVC×100	%
FEF25	Forced expired flow at 25% of FVC	l/s
FEF50	Forced expired flow at 50% of FVC	l/s

FEF75	Forced expired flow at 75% of FVC	l/s
FEF2575	Forced expiratory flow between 25% and 75% of	l/s

	FVC	

7. Cleaning and Disinfection

7.1 Cleaning

After each use, it is necessary to clean the turbine.The specific cleaning method is recommended as follows:

• Remove the reusable turbine from the main unit by rotating it counter-clockwise and apply slight pressure with a finger from the bottom of the turbine to lift it out of its housing. Immerse the turbine in a cold liquid solution and shake it so as to remove any impurities. Leave the turbine immersed for the time specified in the instruction of the solution. Shake off the excess water from the turbine and let it dry, position the turbine vertically on a dry surface.

Note: If no detergent solution is available, clean the turbine in clean water.

7.2 Disinfection

Disinfect the enclosure of the main unit once a day or every time changes the patient.The specific disinfection method is recommended as follows:

• Please shut down the machine when cleaning and do not connect the power supply. Soak sterile medical gauze with 70% medicinal alcohol and wipe the shell of the main unit. After cleaning, let it air dry. Do not put the device into water or other fluids.

⚠ Caution:

1) The main unit cannot be cleaned or soaked in clean water,so as to prevent water from entering it.

2) Use sterile gauze to wipe the main unit and turbine.Keep them dry.

3) The residual disinfectant on the main unit shall be wiped with medical gauze to ensure the next safe use.

4) Periodically check the inside of the turbine to ensure that there are no impurities, such as hairs.Otherwise it may block the turbine and as a consequence influence measurement accuracy.

5) To avoid irreparable damage to the reusable turbine please do not use any alcoholic or oily detergent solutions, and do not immerge the turbine in hot water or hot liquids. Do not place the turbine under a direct water jet or other liquid. If no detergent solution is available, clean the turbine in clean water. Do not use compressed air to clean the turbine.

6) After cleaning,keep this device in an environment that is dry and clean to avoid pollution.

7) The disposable mouthpiece is not require to clean and disinfection,as it is supplied clean in a sealed plastic bag.Suggest to dispose it after use.It is designed for single user and single use.

8) The turbine is forbidden to be washed under running water or be placed under direct air pressure.It is forbidden to be washed by hot fluids.

8. Storage and Maintenance

8.1 Storage conditions

1) Storage environment: please see “Transportation and storage environment” section for details.

2) Avoid direct sunlight, good ventilation, no corrosive gas, far away from heating device or open fire.

3) After use, this device shall be cleaned and disinfected in time. After it is completely dried,it shall be stored in the packing box and avoiding impact.

8.2 Maintenance

1) Please use this device under normal conditions.

2) Do not use this device near the heating device or open fire. It is forbidden to use microwave oven, oven, blower to dry this device.

3) Do not expose this device to corrosive liquids and gases.

4) Do not twist the USB cable.

5)If you have any trouble during using process, please seek solutions according to “Trouble Shooting” section. If this device still cannot work normally, please contact the manufacturer or the distributor.

6) Please charge this device when it is in low-battery state.

7) If the device is not used for a long time, it should be charged every 6 months, which could greatly extend the battery service life. Users are forbidden to replace the battery by themselves.If necessary, please contact the manufacturer or the distributor.

8)This measurement principle ensures accuracy and reproducibility, without requiring regular calibration.

9. Contraindications & Precautions and suggestive contents

9.1 Relative Contraindications for Spirometry

Due to increases in myocardial demand or changes in blood pressure
Acute myocardial infarction within 1 wk
Systemic hypotension or severe hypertension
Significant atrial/ventricular arrhythmia
Noncompensated heart failure
Uncontrolled pulmonary hypertension

Acute cor pulmonale
Clinically unstable pulmonary embolism
History of syncope related to forced expiration/cough
Due to increases in intracranial/intraocular pressure
Cerebral aneurysm
Brain surgery within 4 wk
Recent concussion with continuing symptoms
Eye surgery within 1 wk
Due to increases in sinus and middle ear pressures
Sinus surgery or middle ear surgery or infection within 1 wk
Due to increases in intrathoracic and intraabdominal pressure
Presence of pneumothorax
Thoracic surgery within 4 wk
Abdominal surgery within 4 wk
Late-term pregnancy
lnfection control issues
Active or suspected transmissible respiratory or systemic infection, including tuberculosis
Physical conditions predisposing to transmission of infections,such as hemoptysis,significant secretions, or oral lesions or oral bleeding

Note: Spirometry should be discontinued if the patient experiences pain during the maneuver. Patients with potential contraindications that would prevent testing in the primary care setting may be tested in a pulmonary function laboratory where operators are more experienced and there may be access to emergency care if needed. Furthermore, because spirometry requires the active participation of the patient, inability to understand directions or unwillingness to follow the directions of the operator will usually lead to submaximal test results.

9.2 Precautions and suggestive contents

1) If it is not used for a long time,it is necessary to disinfect and clean this device thoroughly,so as to avoid bacterial reproduction.

2) It is recommended that the mouthpiece is for single-use.

3) Please place it out of the reach of children, so as to avoid swallowing small parts by mistake or damaging this device.

4) Do not use this device during charging.

5) This device shall be cleaned, disinfected and dried before installation.

6) Avoid placing in the environment that is high temperature, humidity and direct sunlight.

7) Please do not use volatile oil or other organic solvents for cleaning,so as to avoid damaging this device.

8) Do not drop or impact this device strongly,so as to avoid damaging it.

9) It is forbidden to dry this device in microwave oven.

10) Do not dismantle, repair or refit this device to avoid electric shock and electric leakage.

11) This device shall be treated as medical waste at the end of service life.Please follow the local laws and regulations to disposal this device.Illegal disposal may cause environmental pollution.

10. Trouble Shooting

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 "Operational Guideline" section.
	Device malfunction	Please contact the manufacturer or distributor.
Data error	Operate the device falsely.	Operate the device according to the User Manual.
	Device malfunction	Please contact the manufacturer or distributor.
The device can not be powered on.	Low-battery state	Charge according to the "Battery charging" section.
	Device malfunction	Please contact the manufacturer or distributor.
The display disappears suddenly.	The device is set to automatic power off when there is no operation in 2 minutes.	Normal
	Low-battery state	Charge according to the "Battery charging" section.
The use time is too short after charging.	The device is not fully charged.	Charge according to the "Battery charging" section.
	The battery is damaged.	Please contact the manufacturer or distributor.

The device can not be fully charged after charging more than 10 hours.	The battery is damaged.	Please contact the manufacturer or distributor.

11. Note & Warning

11.1 Note and suggestion

• Spirometer is a medical device,please read the user manual before using it.
• Please use required accessories, warranty service is not provided for damage caused by accessory beyond our list.
• Use a non-conforming adapter may cause equipment damage.
• Please refer to the user manual when there is a problem, and contact the after-sales service for maintenance.
• Please clean and disinfect the accessories when use it for the first time. You can refer to "Cleaning and Disinfection" section.
• Please keep the accessories dry when store them.
• Please assure all the accessories assembled rightly before using.
• Don’t use this device under inflammable gas environment or near the heating device or open flame.
• Don’t use this device near high frequency products or electronic products.
• Do not use a microwave oven, oven, blow dryer or other house applications to dry the main unit and accessories.
• Technical description is included in this user manual.
• This device can only be used by operators who can understand this user manual. Children use this device should under adult supervision.
• When this device is taken out from -20℃, it should be put in room temperature for 2 hours before using.
• When this device is taken out from +55℃, it should be put in room temperature for 2 hours before using.

• The USB interface is only used for charging and cannot be connected to other devices.
• The patient is the intended operator and all functions of this device can be used by patients.
• The maintenance the user can perform are cleaning and disinfection. You can refer to "Cleaning and Disinfection" section.
• Turn to doctor for help or contact the manufacturer if any changes in the performance of this device.
• The highest rated operating altitude:1300m

11.2 Warning

• Please stop using it if you feel uncomfortable and please turn to doctor for help.
• Do not replace electronic components without manufacturer's authorization.
• All the accessories cannot be serviced or maintained while it is in use.
• Do not modify this equipment and replace electronic components without authorization of the manufacturer.Otherwise,it may cause damage to the main unit or damage to the user or patients.
• Do not use mobile (cellular) telephones and other devices(such as MRI, diathermy, electrocautery, RFID and electromagnetic security systems) which generate strong electrical or electromagnetic fields, near the medical device.
• Waste disposal: discard the main engine and accessories according to local laws and regulations.
• The USB cable should be kept away from children or out of the reach of children to avoid strangulation.
• The disposable mouthpiece in this device should be considered as disposable product.It is designed for single-use.
• Do not allow dust or impurities to enter the turbine sensor which may alter the correct functioning and possibly cause damage. The presence of any impurities (such as hair, sputum, threads etc.) in the turbine sensor may seriously influence measurement accuracy.
• The disposable mouthpiece must be replaced after a single user complete testing.
• The device can not be used in an oxygen rich environment.
• The machine cannot be serviced or maintained while it is in use.
• The degraded turbine and electrodes, or loosened electrodes can degrade performance or cause other problems.Please contact manufacturer for the problems.
• The accessible materials used in the spirometer are safe for common normal people. For very few operators with extreme skin sensitivity, if any skin discomfort occurs during the use of the spirometer, please immediately stop using and seek medical advice.

• Replacement of lithium batteries or fuel cells when incorrect replacement would result in an unacceptable RISK.
• The device needs to be kept out of the reach of children or pets, to prevent animal hair or dirt entering the turbine to affect its use.

12. After-sales Service

1) After this device is packed, under the condition of following the storage and use regulations, if the main unit fails to work normally within one year since the purchase of the machine, the manufacturer will repair and replace this device for the user free

of charge.All consumable parts,including reusable turbine,disposable mouthpiece are excluded from the terms of this guarantee.
2) Users can contact after-sales service if they have any questions during use.
3) If necessary, the circuit diagram and necessary data for repair can be provided to assist service personnel. If there is any problem in the maintenance of electrical circuit, you can contact the manufacturer.

13. Symbol description & Safety regulations & Electromagnetic compatibility

13.1 Symbol description

General symbol	Description / title	General symbol	Description / title
	Date of manufacture		General warning sign
	Manufacturer information		Refer to instructions for use
	Consult instructions for use		Keep dry
	Caution		This way up
	“ON” / “OFF”(push-push)		Temperature limit
	Type BF applied part		Humidity limitation
	Keep away from sunlight		Atmospheric pressure limitation
IP22	Degree of protection against the ingress of water.		When this device life expires,the end users should discard this device according to the requirements from the local environment protection authority.
	Do not re-use		Batch code

MD	Medical device		Charging indicator

13.2 Safety requirements

1) Classification by type of anti shock: internal power supply.

Classification according to the degree of anti electric shock: type BF application part.

Degree of protection provided by enclosure: IP22

2) According to the disturbance characteristics of Industrial Science and medical (ISM) radio frequency equipment, it is classified into 1 group and B group.

3) Classification according to the protection degree of liquid inlet: not applicable.

4) Classification according to the safety degree when using the flammable anesthetic gas mixed with air or oxygen or nitrous oxide: the equipment cannot be used when there is the flammable anesthetic gas mixed with air and oxygen or nitrous oxide.

5) Classified by operation mode: continuous operation.

6) Rated voltage: internal power supply voltage:DC 3.7V

7) Whether there is application part for protection of defibrillation discharge effect: no application part for defibrillation prevention.

8) Whether there is signal output or signal input part: there is signal input or signal output part.

9) Permanent installation equipment or non permanent installation equipment: non permanent installation equipment, portable ordinary equipment.

13.3 Electromagnetic compatibility

⚠ Caution:

1)This device meets the electromagnetic compatibility requirements of IEC 60601-1-2.
2)The user shall install and use according to the "EMC information" section.
3)Portable and mobile RF communication equipment may affect the performance of this device, and avoid strong electromagnetic interference when using, such as near mobile phones, microwave ovens, etc.
4)This device should not be used stacked with other devices. If it must,you should observe and verify that it can operate normally.

13.4 EMC information

Guidance and Manufacturer’s declaration – electromagnetic emissions
This device is intended for use in the electromagnetic environment specified below. The customer

or the user of this device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	This device use 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 emissions CISPR11	Class B	This device is suitable for used in domestic establishment and in establishment directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's declaration – electromagnetic immunity			
This device is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that they are used in such an environment.			
Immunity test	IEC 60601 test level	Compliance	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 1kV 1 00 kHz repetition frequency	± 1kV 1 00 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surges Line-to-ground IEC 61000-4-5	± 2kV	± 2kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations IEC 61000-4-11	<5 % U_T(>95 % dip in U_T.) for 0.5 cycle <5 % U_T(>95 % dip in	<5 % U_T(>95 % dip in U_T.) for 0.5 cycle <5 % U_T(>95 % dip in	Mains power quality should be that of a typical commercial or hospital environment. If the user of this device requires continued operation during power mains interruptions, it is

	U_T.) for 1 cycle 70 % U_T (30% dip in U_T) for 25/30 cycles <5 % U_T(>95 % dip in U_T.) for 5/6 sec.	U_T.) for 1 cycle 70 % U_T (30% dip in U_T) for 25/30 cycles <5 % U_T(>95 % dip in U_T.) for 5/6 sec.	recommended that the device be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz)magnetic field IEC 61000-4-8	0.3 A/m	0.3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. Mains voltage prior to application of the test level.			

Guidance & declaration – Electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that they are used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment –guidance
Radiated RF IEC 61000-4-3	6Vrms in ISM and amateur radio bands 10V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment(Refer to table 9 of IEC 60601-1-2:2014)	6Vrms in ISM and amateur radio bands 10V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment(Refer to the next table IEC 60601-1-2:2014)	Portable and mobile RF communicationsequipment should be used no closer to any part of this device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 3.5\sqrt{p}$ $d = 1.2\sqrt{p}$ 80 MHz to 800 MHz $d = 1.2\sqrt{p}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the

			recommended separation distance in meters(m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,*2) should be less than the compliance level in each frequency range.*3) Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, 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.

*2) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating this device.

*3) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and thedevice

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device 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		
	150 kHz to 80 MHz d = 1.2	150 kHz to 80 MHz d = 1.2	800 MHz to 2.5 GHz d = 2.3
0.01	0.12	0.12	0.23

0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
0.01	0.12	0.12	0.23

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.

14. Configuration List

Item	Quantity	If Included	
		Yes	No
Main unit	1	☑	☐
Turbine	1	☑	☐
Disposable mouthpiece	3	☑	☐
USB cable	1	☑	☐
Instructions for use	1	☑	☐
Velvet bag	1	☑	☐

15. Disclaimer Clause

Please read the user manual before using this device. We will not take any responsibility in case of damage caused by improper use of this device.

Please use or purchase original parts or accessories. The manufacturer does not take responsibility for the buyer or third parties for any damage or loss intentionally or unintentionally caused by improper use.

On the request for warranty service, please present your warranty card filled with purchase date and seal (with the store and address). Any repair service out of the scope of warranty will be charged accordingly.

16. Manufacturer and Rep. information

FEELLIFE HEALTH INC.

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E-mail:info@feellife.com

Website: http://www.feellife.com

FCC Warning

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-Reorient or relocate the receiving antenna.

-Increase the separation between the equipment and receiver.

-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-Consult the dealer or an experienced radio/TV technician for help.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.