

CE Technical File Spirometer	Document no.	LFS-EN-UM-24E
	Version	A/0

feellife



User Manual for SPIROMETER

Model: Air Smart TA-B,Air Smart TA-Y,Air Smart TA-GN,Air Smart TA-G,Air Smart TB,Air Smart TT-B,Air Smart TT-Y,Air Smart TT-GN,Air Smart TT-G

Air Smart TA-B	
Air Smart TA-Y	
Air Smart TA-GN	
Air Smart TA-G	
Air Smart TB	

CE Technical File Spirometer	Document no.	LFS-EN-UM-24E
	Version	A/0

Air Smart TT-B	
Air Smart TT-Y	
Air Smart TT-GN	
Air Smart TT-G	

Doc:LFS-EN-UM-24E
Issue date:Oct.,12,2023
Rev.:A/0

CE Technical File Spirometer	Document no.	LFS-EN-UM-24E
	Version	A/0

- ◆ 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.

CE Technical File Spirometer	Document no.	LFS-EN-UM-24E
	Version	A/0



Safety Warning

- ◆ The use of this device for special groups like children, elderly and disabled 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. Indications for use

The spirometer is a diagnostic tool to measure the maximal volume and flow of air that can be moved in and out of a patient's lungs. The system is intended for use with pediatric (5 to 21 years) and adult (22 years and older) patients in the home, hospitals, physician's offices, laboratories, occupational health environments.

2. Working Principle

Inhale deeply, seal your lips around the blow pipe, 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 APP.

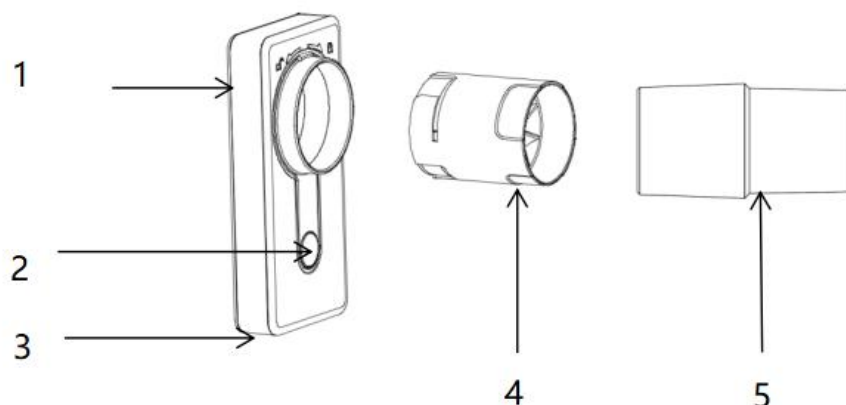
3. Product Contents and Overview

3.1 Structural composition

It consists of the Main unit, Blow pipe, Turbine and Type-C cable.

3.2 Product composition

CE Technical File Spirometer	Document no.	LFS-EN-UM-24E
	Version	A/0



No.	Name
1	Main unit
2	ON/OFF switch
3	Charging socket (Type-C)
4	Turbine
5	Blow pipe
6	Type-C cable

Note:The Turbine and Blow pipe are designed for single patient use.If you want to buy,please contact the distributor or manufacturer for full parts list.

4. Technical Specification

Product name	Spirometer
Model	Air Smart TA-B, Air Smart TA-Y, Air Smart TA-GN, Air Smart TA-G, Air Smart TB, Air Smart TT-B, Air Smart TT-Y, Air Smart TT-GN, Air Smart TT-G
Power source	DC 3.7V rechargeable Li-ion batteries/DC 5V,1A adapter
Power consumption	<4.0 W
Volume range	0.5 (l) ~ 8 (l) (deviation: $\pm 2.5\%$ or $\pm 0.05l$, whichever is greater)

CE Technical File Spirometer	Document no.	LFS-EN-UM-24E
	Version	A/0

Flow range	± 16 (l/s) (deviation: $\pm 10\%$ or ± 0.17 l/s, whichever is greater)
Diameter of the blow pipe	30mm
Weight	187g(with battery)
Dimension(mm)	Length 60mmxWidth 36mmxHeight 158mm
Working environment	Temperature: $+5^{\circ}\text{C} \sim +40^{\circ}\text{C}$ Relative Humidity: 15%~80% R.H.Non-condensing Atmospheric Pressure: 86kPa~106kPa
Storage/delivery environment	Temperature: $-20^{\circ}\text{C} \sim +55^{\circ}\text{C}$ Relative Humidity: 10%~93% R.H.Non-condensing Atmospheric Pressure: 70kPa~106kPa
Time auto-off	Operate 5mins, then auto-off when connecting Bluetooth
Applied classified part	The classified of applied part is BF.
Service life/Reuse life	Main unit:5 years Turbine:2 year Blow pipe:2 year
Shelf life	Main unit:5 years Turbine:5 years Blow pipe:5 year
Material of the applied part	Blow pipe:PP
Battery supply time	The battery group can supply power up to 60 minutes continually after full charging.

Note:

1) Applied part:Blow pipe

2)Connection device:IOS V1.1.6 and Android 1.1.0

3)More information about Bluetooth:

Bluetooth transmission has communication protocol requirements:4.0

Each frequency or frequency band of transmission:ISM 2.4G

The type and frequency characteristics of the modulation:GFSK

The effective radiated power:4dB

Note:The aim of connection for Bluetooth just for data transformation from device to APP.

4) Software version:

Air Smart TA-B, Air Smart TA-Y, Air Smart TA-GN, Air Smart TA-G:FGN-ASTA-V1.0

Air Smart TB:FGN-ASTB-V1.0

Air Smart TT-B, Air Smart TT-Y, Air Smart TT-GN, Air Smart

CE Technical File Spirometer	Document no.	LFS-EN-UM-24E
	Version	A/0

TT-G:FGN-ASTT-V1.0

5)The visual inspect:the visual inspection criteria related to device performance such as unacceptable deterioration,corrosion, discoloration, pitting, or cracked seals.If you find the circumstance as above,you should replace a new one by contacting the manufacturer or the distributor.

6)Duration of contacting the Blow pipe: ≤ 10 min

5. Installation and Usage Guideline

5.1.Assemble and disassemble

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

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

5.1.3 Blow pipe assembly: insert one end of the blow pipe into the turbine port directly.

Note: The turbine should be installed into the correct position,see the arrow on the device.

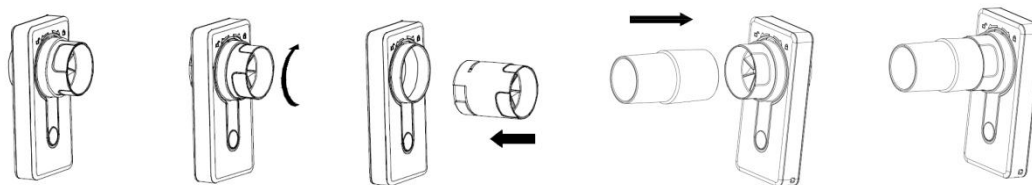


Figure 1

Caution

1)The Blow Pipe is designed for single user and re-use.It is not allowed for multi-users.

2)Any Blow Pipe included with the Airflow Tester are only to be used as a reference guide to purchase the correct size blow pipe required. These blow pipes are clean but not sterile. To purchase appropriate blow pipes, generally plastic.We suggest that you contact your local distributor.

3)The user is responsible for obtaining the proper blow pipes for the device. The required blow pipe is a standard type with an outside diameter of 30 mm, is of

CE Technical File Spirometer	Document no.	LFS-EN-UM-24E
	Version	A/0

common use and in general easily procured.

5.2 More information about App

5.2.1 Download of APP

IOS system: search for “iBreathe” from APP store, to download. Or connect the mobile phone to the Internet, scan QR code below, and download APP. Go back to the phone desktop to open the “iBreathe”.



Figure 1

5.2.2 Open the application interface, .Turn on the Bluetooth.

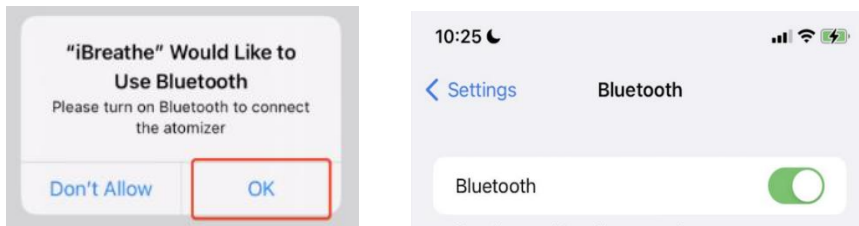
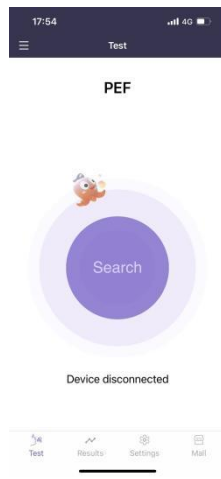


Figure 2

5.2.3 APP control

Open the application interface, Wait for device connection.



CE Technical File Spirometer	Document no.	LFS-EN-UM-24E
	Version	A/0

Figure3

Long press (about 3s) to turn on the main unit. Then the indicator light will be on and the

buzzer will ring. In the interface of APP, click the icon on the top left corner “”.

Choose “Air Smart TA/Air Smart TB/Air Smart TT” to connect the device. As following

picture shows.

The main unit will shut down automatically and the buzzer will ring when no operation after

5min.



Figure4

5.2.4 APP operation

a. Personal information setting

Set the personal information just as the following picture. Target theoretical value will change depend on age, height, and gender. It can be modified as shown below.

CE Technical File Spirometer	Document no.	LFS-EN-UM-24E
	Version	A/0

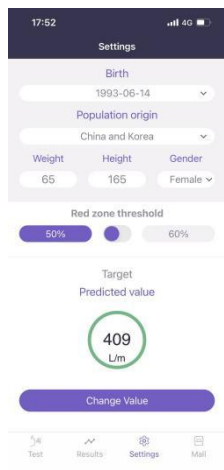


Figure5

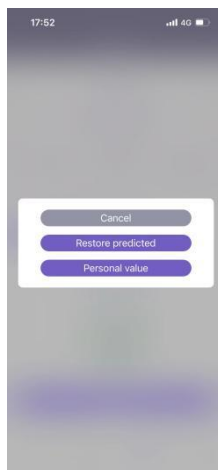


Figure6



Figure7

b. After connecting, the interface of APP will display “Device connected” and the models just as the following picture. Click the yellow button to start the test.

c. After deep inhalation (inhale as much as you can), hold the blow pipe immediately and exhale all the air with maximum strength. During the test, the target value and the test value of the two balls will change dynamically from low to high. The larger your exhaled air, the higher of the ball. After the test is completed, the PEF is displayed in the interface. (Right picture below)

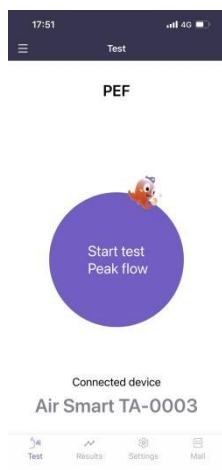


Figure8



Figure9

5.2.5 Results

Click "Results", and PEF, FEV1 and lung-age reference values are available. Click top right corner "☰" icon to browse test results.

When the test value is more than 85% of the target value, the result will appear

CE Technical File Spirometer	Document no.	LFS-EN-UM-24E
	Version	A/0

green. When the value is less than the set threshold, the color is red. When between the threshold and 85% of the target value, the color is yellow.




Figure10



Figure11

5.2.6 Share the test results

Click the icon “” to share the test results. Select the date you want to send, As following picture shows.

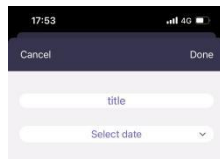


Figure12

5.2.7 Link to mobile phone health data

Connect the test results to the “Health” if necessary. Setting-Health-Data Access & Devices-iBreath, Click "Open All" as shown below.

CE Technical File Spirometer	Document no.	LFS-EN-UM-24E
	Version	A/0

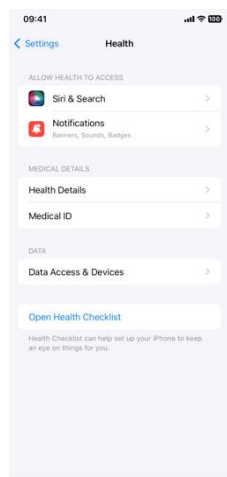


Figure13

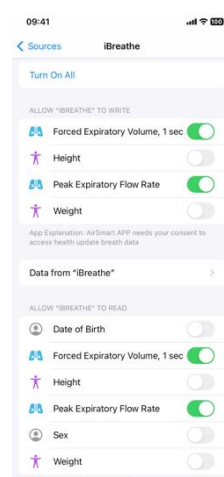


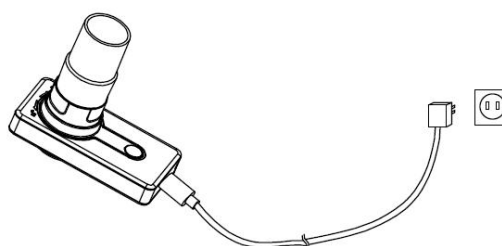
Figure14

Description of abbreviations in APP

Number	Acronym	Define
1	FEV1	The maximum volume of exhaled air after forced and rapid exhalation for 1 second; The most commonly used clinical indicator, have good repeatability and strong force dependence. Both restrictive and obstructive disorders can cause decline.
2	PEF	Peak expiratory flow, also known as maximum expiratory flow, refers to the instantaneous flow rate when the expiratory flow is the fastest during forced vital capacity measurement; It mainly reflects the strength of respiratory muscles and whether the airway is blocked.

5.3 Power supply

Use the Type-C cable for charging. The white light will flash when the device in low batteries or a charging state. Also, the APP will indicate you the device is in a low-power state.



CE Technical File Spirometer	Document no.	LFS-EN-UM-24E
	Version	A/0

Figure 14

Note:

- 1) Please use the power adapter (DV 5.0V, 1A) to power this device.
- 2) 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.
- 3) The device cannot work when charging.

 **Caution:**

- 1) When the battery capacity is insufficient, please power by charging cable.
- 2) Keep charging the device at least once per month during the storage period exceeding one month.

6. Cleaning and disinfection

6.1 Cleaning

After each use, it is necessary to clean the shell of the Main Unit, Turbine and Blow pipe. The Turbine and Blow pipe can be disassembled for cleaning and disinfection. The specific cleaning method is recommended as follows:

- 1) Please shut down the machine when cleaning and do not connect the power supply.
- 2) Please soak sterile medical gauze with clean water and wipe the shell of the Main Unit.
- 3) Soak Turbine and Blow pipe in clean and warm water for 3 minutes. After cleaning, dry with sterile gauze or air dry naturally. Be careful, do not immerse the main unit to the water.

6.2 Disinfection

After thorough clean, it is necessary to disinfect the shell of the Main Unit, Turbine and Blow pipe. The specific disinfection method is recommended as follows:

- 1) Please soak sterile medical gauze with 70% medical alcohol and wipe the shell of the Main Unit.
- 2) Soak Turbine and Blow pipe in 70% medical alcohol for 10 minutes. After disinfection, dry with sterile gauze or air dry naturally. Be careful, do not immerse the main unit to the alcohol.
- 3) Keep this device in an environment that is dry and clean to avoid pollution.

 **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, turbine and blow pipe. Keep them dry.
- 3) The residual disinfectant on the main unit, turbine and blow pipe shall be wiped with medical gauze to ensure the next safe use.

CE Technical File Spirometer	Document no.	LFS-EN-UM-24E
	Version	A/0

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 immerse 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 Blow pipe can be reusable by single patient.

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.

9) Please do not use volatile oil or other organic solvents for cleaning, so as to avoid damaging this device. Turbine and Blow pipe are designed for reuse and single patient use.

10) We suggest visual inspection at the end of the cleaning step. To determine if it is necessary to repeat the relevant previous cleaning steps. Safely dispose of the device, when it is unacceptable deterioration, corrosion, discoloration, pitting, or cracked, so that a visibly soiled device is not used again.

7. Storage and Maintenance

7.1 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 type-c 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.

CE Technical File Spirometer	Document no.	LFS-EN-UM-24E
	Version	A/0

7) If the device is not used for a long time, it should be charged every month, 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 calibration.

The device has been calibrated before it is put into market.

When is necessary to calibrate the device?

- ① The device fall on the floor and suffer a strong shock.
- ② The device fall into the water.
- ③ The device is stored or used in unexpected environment.
- ④ For the same tester, the latest test data is too far from the historical record and judged by doctors that it was the problem of the equipment' accuracy.

How to calibrate the device?

Calibration cylinder with 3 L standard solvent and volume error no more than $\pm 0.5\%$ shall be used for standard calibration. A new breathing set must be changed before calibration to prevent cross infection of the calibration cylinder (pollution caused by repeated use of the calibration cylinder). Connect the calibration cylinder with the breathing kit, turn on the equipment according to the operation procedure of the equipment, and pull the calibration cylinder back completely to the end. Then the calibration was carried out in accordance with the operation in 6.3.2, and then the calibration lead was pushed to the bottom completely, the FVC value of the device was read, and the operation was repeated for 3 times to obtain the FVC value of 3 times. According to the FVC value of 3 times, the average value of FVC was calculated and confirmed whether the average value was within the range of $3.0 \pm 2.5\%$ (2.92 L-3.07 L).

More details about calibration can be found in ATS 2019.

8. Contraindications

8.1 Relative Contraindications for Spirometry

1) Due to increases in myocardial demand or changes in blood pressure Acute myocardial infarction within 1wk.

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.

2) Due to increases in intracranial/intraocular pressure Cerebral aneurysm Brain surgery within 4wk.

Recent concussion with continuing symptoms Eye surgery within 1wk.

3) Due to increases in sinus and middle ear pressures.

Sinus surgery or middle ear surgery or infection within 1wk.

4) Due to increases in intrathoracic and intraabdominal pressure Presence of

CE Technical File Spirometer	Document no.	LFS-EN-UM-24E
	Version	A/0

pneumothorax.

Thoracic surgery within 4wk Abdominal surgery within 4wk Late-term pregnancy.

5) Infection 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.Note & Warning

9.1 Note

• 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°C, it should be put in room temperature for 2 hours before using.
• When this device is taken out from +55°C, it should be put in room temperature for 2 hours before using.

CE Technical File Spirometer	Document no.	LFS-EN-UM-24E
	Version	A/0

- 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.
- Do not use this device during charging.
- Do not drop or impact this device strongly, so as to avoid damaging it.
- Do not dismantle, repair or refit this device to avoid electric shock and electric leakage.

9.2 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 charging cable should be kept away from children or out of the reach of children to avoid strangulation.
- 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 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.

CE Technical File Spirometer	Document no.	LFS-EN-UM-24E
	Version	A/0

9. 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 "Installation and usage 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 "Power supply" 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 5 minutes.	Normal
	Low-battery state	Charge according to the "Power supply" section.
The use time is too short after charging.	The device is not fully charged.	Charge according to the "Power supply" section.
	The battery is damaged.	Please contact the manufacturer or distributor.

10. Note & Warning

10.1 Note and suggestion

1. Spirometer is a medical device, please read the user manual before using it.
2. Please use required accessories, warranty service is not provided for damage caused by accessory beyond our list.
3. Use a non-conforming adapter may cause equipment damage.
4. Please refer to the user manual when there is a problem, and contact the after-sales service for maintenance.
5. Please assure all the accessories assembled rightly before using.
6. Please do not use the accessories for several person, so as to avoid cross infection.

CE Technical File Spirometer	Document no.	LFS-EN-UM-24E
	Version	A/0

7. Don't use this device under inflammable gas environment or near the heating device or open flame.
8. Don't use this device near high frequency products or electronic products.
9. Do not use a microwave oven, oven, blow dryer or other house applications to dry the main unit and accessories.
10. Technical description is included in this user manual.
11. The accessible materials used in this device are safe for common normal people. For very few operators with extreme skin sensitivity, if any skin discomfort occurs during the use of this device, please immediately stop using and seek the help from doctor.
12. This device can only be used by operators who can understand this user manual. Children use this device should under adult supervision.
13. When this device is taken out from -20°C, it should be put in room temperature for 2 hours before using.
14. When this device is taken out from +55°C, it should be put in room temperature for 2 hours before using.
15. The Type-C interface is only used for charging and cannot be connected to other devices.
16. The patient is the intended operator and all functions of this device can be used by patients.
17. The maintenance the user can perform are cleaning and disinfection. You can refer to "Cleaning and Disinfection" section.
18. Turn to doctor for help or contact the manufacturer if any changes in the performance of this device.

10.2 Warning

1. Please stop using it if you feel uncomfortable and please turn to doctor for help.
2. 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.
3. One device (main unit) can be for multiful patients to use and can be reusable.
4. 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.
5. Waste disposal: discard the main engine and accessories according to local laws and regulations.
6. The Type-C cable should be kept away from children or out of the reach of children to avoid strangulation.
7. The Turbine and Blow pipe are designed for single patient use and can be reuse. The other patient use the device must replace the accessories after they complete testing.
8. The device can not be used in an oxygen rich environment.
9. The machine cannot be serviced or maintained while it is in use.
10. The degraded sensors and electrodes, or loosened electrodes can degrade performance or cause other problems. Please contact manufacturer for the problems.

CE Technical File Spirometer	Document no.	LFS-EN-UM-24E
	Version	A/0

11.The performance of the SPIROMETER can be affected by the PATIENT spitting or coughing into the SPIROMETER during expiration or by extremes of temperature, humidity and altitude if applicable.
12.If you feel dizzy when training with the Airflow Tester, slow your breathing or pause until you are fully recovered.
13.If you have a cold, sinusitis, or respiratory infection, we recommend that you do not use this device until symptoms develop.
14.Some users may experience mild ear discomfort when the cold is not cured, which is caused by the imbalance of pressure on both sides. If symptoms persist, consult a doctor.











11. After-sales Service

After this device is packed, under the condition of following the storage and use regulations, if the main unit (except for the Turbine and Blow pipe) 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.






Users can contact after-sales service if they have any questions during use.

If necessary, the circuit diagram and necessary data for repair can be provided. If there is any problem in the maintenance of electrical circuit, you can contact the manufacturer.

12. Symbol description & Safety regulations & Electromagnetic compatibility

General symbol	Description / title	General symbol	Description / title
	Date of manufacture		General warning sign
	Manufacturer information		Refer to instructions for use
	Consult IFU		Keep dry
	Caution		This way up
	Stand-by		Temperature limit

CE Technical File Spirometer	Document no.	LFS-EN-UM-24E
	Version	A/0

	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.
MD	Medical device	LOT	Batch code

12.1 Safety requirements

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

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

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

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.

Classified by operation mode: continuous operation.

Rated voltage: internal power supply voltage: DC 3.7V

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

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

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

12.2 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.

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.

This device should not be used stacked with other devices. If it must, you should observe and verify that it can operate normally.

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.