BreathHome

Product user manual

Pulmonary Function Tester

Model: A9

PLEASE READ ALL THE INFORMATION IN THE PACKAGE INSERT BEFORE USING THE PULMONARY FUNCTION TESTER.

IF YOU DO NOT UNDERSTAND THE INSTRUCTIONS, CONSULT HOMESUN, CALL 400-030-1510 (Working Time: from Monday to Friday, Beijing time 9:00-18:00), OR WRITE TO service@huxijia.cn.

Guangzhou Homesun Medical Technology Co., Ltd

Version: Release date:

Foreword

This product manual contains important content that must be understood for the safe and correct use of this product, and is a part of this product. Therefore, during the entire service life of this product, the instruction manual must be placed at the operating location of the equipment at any time for reference.

This product must be operated by personnel who have received relevant training and have relevant knowledge and experience. All personnel must read this manual carefully before using this product. This instruction manual should be forwarded to the subsequent owners or users of this product.

This product is safe and reliable to use, except for the dangers caused by special factors, such as: caused by non-professional operations or used for other purposes. Therefore, please observe the following rules when using them to avoid accidents.

This product must be instructed or authorized to operate.

Equipment maintenance must be performed by Guangzhou Homesun Medical Technology Co., Ltd technicians or skilled users and authorized operations.

If you have any operational problems that are not mentioned, please contact Guangzhou Homesun Medical Technology Co., Ltd in time.

Content

1. Product description

1.1 Product brief description

Product name: Pulmonary Function Tester

Model: A9

Embedded software release version: V1

Mobile software release version: V1

Computer software release version: V1

1.2 Intended use / indications for use

Pulmonary Function Tester is intended to be used for measurement and data collection of lung function parameters. The system performs cooperation-dependent flow volume measurements. Mostly it will be used for COPD and Asthma patients. Measurements will be performed under the direction of a physician in the clinic, doctors' office or hospital. It can be utilized for patients from 4 years of age and older as long as they can cooperate in the performance.

Pulmonary Function Tester is powered by internal power supply (DC 3.7V) or external standard USB 2.0 and above interfaces. No energy is transferred to the patient.

1.3 Requirements for patients

The device is designed for adults and children over 4 years of age with good understanding and cooperation ability.

1.4 Product main structure

The device is mainly composed of the main unit (display screen, sensor and communication module), USB cable, and application software (computer software, mobile software).

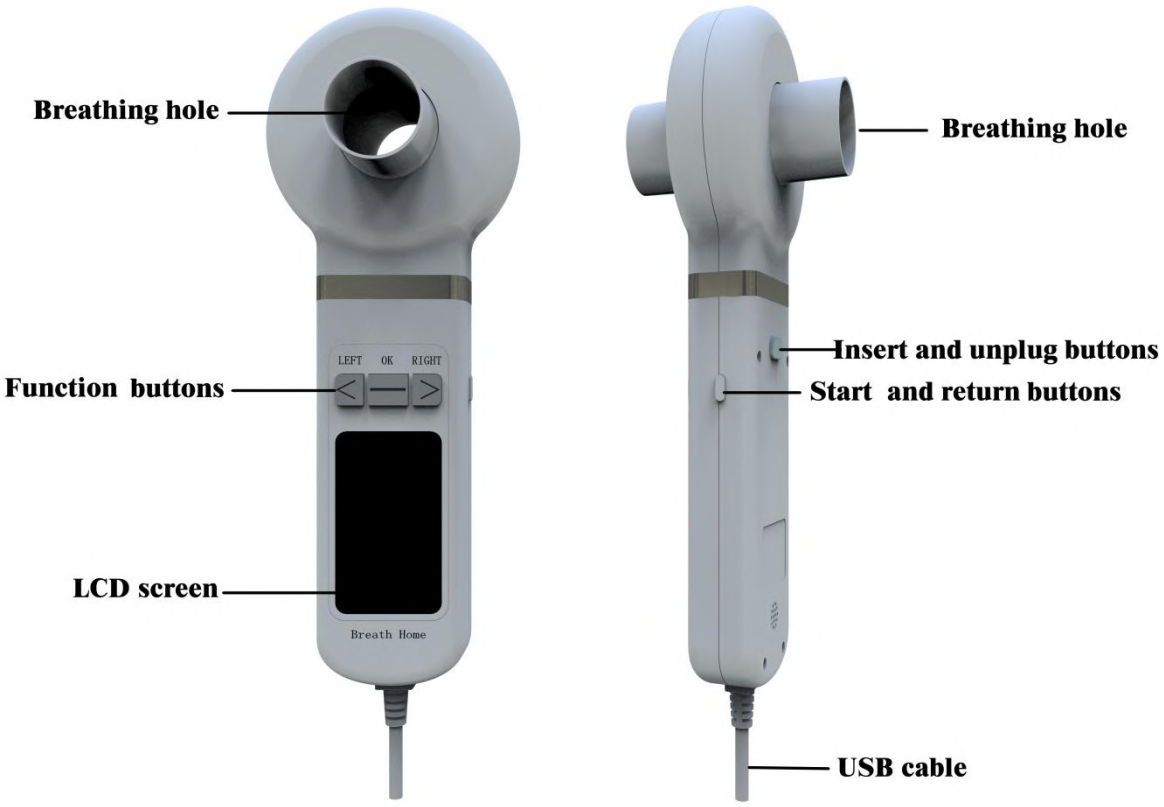


Figure 1 Product structure composition

1.5 Product performance

1.5.1 Measuring the amount of principle introduction

The device uses a flow sensor to measure the gas flow and volume of the patient's exhaled or inhaled gas. According to the volume-time curve and the flow-volume curve, the pulmonary ventilation indicators of human respiratory physiology are analyzed, such as slow vital capacity, maximum minute ventilation and forced vital capacity and other parameters.

The flow sensor is realized by the pressure difference method, and the flow rate $R=\Delta P/\Delta Q$ is determined by the dependence of the pressure P change of the air flow in the flow pipe with certain resistance and the flow rate. The differential pressure flow sensor consists of two parts: the flow pressure transducer with known resistance or resistance curve: realizes a conversion between gas flow and pressure difference. According to the difference of the gas flow through the transducer, the sensitive parts at both ends of the transducer are corresponding to the pressure difference, that is, the pressure difference signal changes

accordingly. Differential pressure sensor: converts the differential pressure signal proportional to the flow rate into a certain electrical signal, and displays it in digital or curve graphics after processing.

1.5.2 Performance index

Measurement parameters	Range	Maximum indication error
Expiration /inspiration flow	(0-16) L/s	±5% or ±0.17L/s , whichever is greater
Airflow resistance	/	Flow measurement range < 0.15 kPa / (L/s)
Volume	(0-10) L	±3% or ±0.05L , whichever is greater

1.5.3 Parameter description

Table 1 Display measured value parameters in different modes

Model	Measurement display parameters
Forced vital capacity	FVC、$FEV_{0.5}$、FEV_1、FEV_3、FEV_6、V backextrapol. ex、FIVC(FVC IN)、FIV_1、PEF、$FEF_{25\%}$、$FEF_{50\%}$、$FEF_{75\%}$、$FEF_{25\%-75\%}$（MMEF）、PIF、$FIF_{50\%}$、$FET_{100\%}$ 、FEV_1/FVC、FEV_3/FVC、FEV_1/VC max、V backextrapol.ex% FVC、$FEF_{50\%}$/FIF$_{50\%}$、FEV_1/FIV_1
Slow vital capacity	VC max、VC in、VC ex、IC、IRV、VT、ERV、MV、BF
Maximum minute ventilation	VT MVV、MVV、TIME MVV、BF MVV

1.5.4 Terms

Number	Abbreviation	Full Name
1-1	FVC	forced vital capacity
1-2	$FEV_{0.5}$	forced expiratory volume in half a second
1-3	FEV_1	forced expiratory volume in one second
1-4	FEV_3	forced expiratory volume in three seconds
1-5	FEV_6	forced expiratory volume in six seconds
1-6	V backextrapol.ex	back extrapolated volume
1-7	FIVC(FVC IN)	forced inspiratory vital capacity

1-8	FIV_1	forced inspiratory volume in one second
1-9	PEF	peak expiratory flow
1-10	$FEF_{25\%}$	forced expired flow at 25% of FVC
1-11	$FEF_{50\%}$	forced expired flow at 50% of FVC
1-12	$FEF_{75\%}$	forced expired flow at 75% of FVC
1-13	$FEF_{25\%-75\%}$（MMEF）	forced expiratory flow from 25 % -75 % of FVC
1-14	PIF	peak inspiratory flow
1-15	$FIF_{50\%}$	forced inspiratory flow at 50% of FIVC
1-16	$FET_{100\%}$	forced expiratory time to reach 100% of FVC
1-17	FEV_1/FVC	forced expiratory volume in one second to FVC ratio
1-18	FEV_3/FVC	forced expiratory volume in three seconds to FVC ratio
1-19	FEV_1/VC max	forced expiratory volume in one second to VC max ratio
1-20	V backextrapol.ex%FVC	back extrapolated volume to forced vital capacity ratio
1-21	$FEF_{50\%}/FIF_{50\%}$	forced expiratory flow at 50% of FVC to forced inspiratory flow at 50% of FIVC ratio flow at 50% of FIVC ratio
1-22	FEV_1/FIV_1	forced expired volume in one second to forced inspiratory volume in one second ratio
2-1	VC max	maximum vital capacity
2-2	VC in	inspiratory vital capacity
2-3	VC ex	expiratory vital capacity
2-4	IC	inspiratory capacity
2-5	IRV	inspiratory reserve volume
2-6	VT	tidal volume
2-7	ERV	expiratory reserve volume
2-8	MV	minute ventilation
2-9	BF	breath frequency
3-1	VT MVV	volume of maximal voluntary ventilation
3-2	MVV	maximal voluntary ventilation
3-3	TIME MVV	time of maximal voluntary ventilation
3-4	BF MVV	breath frequency of maximal voluntary ventilation

1.5.5 Data transmission connection mode and description

Data transmission connection method	Illustrate
Bluetooth network	Connect the mobile terminal software via Bluetooth to realize the measurement data transmission
USB cable	Connect via USB cable to realize measurement data transmission

1.6 Contraindications

1.6.1 Absolute contraindications

1) Suffered from myocardial infarction, stroke, and shock in the past 3 months;
2) Severe cardiac insufficiency, severe arrhythmia, and unstable angina in the past 4 weeks;
3) Large hemoptysis in the past 4 weeks;
4) Seizures need treatment;
5) Uncontrolled hypertension (systolic blood pressure > 200mmHg, diastolic blood pressure > 100mmHg);
6) Aortic aneurysm;
7) Severe hyperthyroidism.

1.6.2 Relative contraindications

1) Resting heart rate >120 beats /min;
2) Pneumothorax, giant bullae, and those who are not prepared for surgical treatment;
3) Pregnant women;
4) Tympanic membrane perforation (need to be measured after the affected ear canal is blocked);
5) Respiratory tract infection in the past 4 weeks;
6) People with low immunity and susceptible to infection;
7) Infectious diseases of the respiratory tract (such as tuberculosis, influenza, etc.);
8) Children with critical illnesses and children with blood oxygen saturation lower than 92% require oxygen therapy.

The contraindications for the operation and use of the equipment include but are not limited to the above symptoms.

1.7 Product list

Name	**Quantity**
Pulmonary Function Tester	×1
USB cable	×1
User manual	×1
Quality certificate	×1

Warranty card	×1

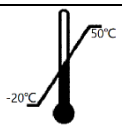
1.8 Site requirements during use

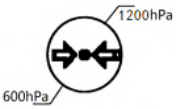
1) There should be good ventilation equipment;
2) The venue should not be too narrow;
3) The indoor temperature and humidity should be relatively constant;
4) The indoor environment should be quiet;
5) If conditions permit, set up a waiting area;
6) Easy to rescue.

1.9 Other usage specifications

The device can only be operated by trained medical personnel.

2. Label symbol description

Graphics Symbols	Meaning
	**Prescription only.** CAUTION: FEDERAL U.S. LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.
	Refer to the instruction manual / booklet
	Keep away from rain
	Keep away from sunlight
	Fragile, handle with care
	Temperature limit

	Humidity limitation
	Atmospheric pressure limitation
	Stacking limit by 5
	Type BF applied part
	Low-frequency electromagnetic radiation
	“WEEE (Waste Electrical and Electronic Equipment)”. The waste products should be handled legally.
	Caution
	Serial number
	Manufacturer
	Class II equipment
	Recyclable
	Unique device identifier

3. Precautions, warnings, and prompt instructions

- Please use within the temperature, humidity and atmospheric pressure range specified by the manufacturer, otherwise the equipment may not reach the claimed performance.
- Please operate strictly according to this user manual, or else there might be inaccurate measurements or device gets damaged.

- Please clean and disinfect the pressure taking structure according to the method specified in the product manual.
- Please connect the device to the designated device, otherwise the device will be unusable or the measurement data will be wrong.
- Please test according to the method specified in the product manual, and confirm that the current measurement mode and the blowing method are correctly matched, otherwise the measurement results will be inaccurate.
- Do not use this device in an environment that has anesthetics and other inflammables which may cause an explosion.
- Do not use this device in strong electromagnetic interference or direct wind source, and heat source environment.
- Do not spatter liquid onto this device which may cause damage.
- Do not place the equipment in a mechanically vibrating environment.
- Do not drop this device from a high place.
- Do not use sharp objects to press or scratch the equipment shell.
- Do not disassemble the device without permission. No part of the medical device may be replaced by the customer. Use only Homesun approved accessories and spare parts for this medical device.
- Keep accessories, packing material, cleaning and disinfection substances out of the reach of children.
- Do not place heavy objects on the device which may cause performance or mechanical damage.
- Do not use high temperature, high pressure or gas disinfection to disinfect the device.
- If the device continues to fail to display data or there are other abnormal conditions, press function button to remeasure, or power off the device and restart; please contact the after-sales customer service in time.
- After use, the device will produce some wastes such as disposable parts or vulnerable parts and when discarding the equipment itself. Disposing of these wastes arbitrarily will pollute the environment or cause cross-infection. It should be dealt with per laws, regulations and other relevant regulations.
- The measurement results can only serve as a clinical reference which should be

explained by professional medical personnel. A qualified physician must reassess all measurements. An interpretation by the medical device is significant only when considered together with other clinical findings.

- When using the device, pay special attention to the user manual where this symbol ⚠ is marked.

4. Installation and use instructions

4.1 Check the equipment list

Check whether the product and its accessories are complete according to the product list in 1.7. If there is any missing or damaged, please contact the after-sales customer service center in time.

4.2 Equipment installation and preparation

Put the round end of the detachable mouthpiece into the filter of the disposable pulmonary function tester, then connect it to the breathing hole of the pulmonary function tester, and apply a little pressure to make the filter and the breathing hole of the device tightly connected.

⚠ ***Caution:***

The user purchases a detachable mouthpiece and a disposable pulmonary function meter filter, which must be a legally marketed product registered by the FDA.

Mouthpiece specifications: inner diameter 30mm, outer diameter 32-34mm, height 50mm-120mm.

Specification of disposable pulmonary function meter filter: inner diameter 1=30mm

4.3 Equipment use

4.3.1 Boot

Long press the "ON / OFF" button, after the device starts, the display shows the boot interface, and the device emits a boot prompt sound. After the above actions are completed, the boot operation is complete.

⚠ ***Caution:***

Before using the equipment every day, a standard calibration and verification are required. In addition, a 3- flow calibration and verification is performed once a week. For specific methods, please refer to the calibration method in the corresponding software instructions.

4.3.2 Test mode selection

Press the left or right button on the device to select the test mode, and press the middle button to enter the corresponding test mode.

4.3.3 Start test

After entering the test mode interface, press the middle button and the device will give a voice prompt to start the test.

⚠***Caution:***

Do not expect sputum or cough into the device during measurement, otherwise the performance of the device may be affected.

4.3.4 View test records

In the test mode interface, select to view the last result, press the left button to view the historical data in sequence, and press the right button to view the test curve.

4.4 Pulmonary ventilation function measurement method

The device contains three measurement modes: forced vital capacity test, slow vital capacity test, and maximum minute ventilation test.

After selecting the measurement mode, short press the function key, the display shows the blowing interface, and after hearing the prompt sound from the device, hold the mouthpiece to ensure that there will be no air leakage when blowing. Use the corresponding breathing method to measure, see below for details.

⚠***Caution:***

1) In order to ensure the accuracy of measurement results, users are required to understand and master the blowing method of each measurement mode.

2) Please keep sitting and standing and keep your body stable during measurement.

3) Do not swing your head forcefully with your body when blowing, which will affect the measurement results.

4.4.1 Forced vital capacity test

1) Practice forced breathing exercises according to the instructions of the technician or

doctor, and master the essentials of FVC movements. Avoid fatigue of subjects and achieve satisfactory results.

2) Connect the mouthpiece to the mouth, wrap the mouthpiece tightly with your lips, and clamp the nose clip to ensure that the nose and mouth do not leak. If some subjects cannot guarantee that the corners of the mouth will not leak, a special mouthpiece with a tooth mask can be added.

3) Breathe calmly for 4-5 times. After the breathing is stable, take a deep breath, and then exhale forcefully, quickly and completely, all in one breath.

4) After the exhalation is complete, inhale strongly and quickly until it is complete, and then breathe calmly for 4-5 times to complete the test.

⚠ ***Caution:***

The same patient cannot be tested more than 8 times a day!

4.4.2 Slow vital capacity test

1）Connect the mouthpiece to the mouth, wrap the mouthpiece tightly with your lips, and clamp the nose clip to ensure that the mouth and nose do not leak. If some patients cannot guarantee that the corners of the mouth will not leak air, a special mouthpiece with a lip-tooth mask can be added.

2） Clamp the nose clip, connect the mouthpiece to the mouth, and breathe calmly for 4-5 times. After the breathing is stable, inhale as much as possible at the end of the expiration at a moderate speed (total lung volume), and then exhale to the end.

3) Repeat the above steps to check more than 3-5 times, and rest for more than 1 minute between the 2 times.

4.4.3 Maximum minute ventilation test

1) The mouthpiece is connected to the device, and breathe calmly for 4 to 5 times. After the exhalation is stable, continue to breathe for 12 or 15 seconds at the maximum breathing amplitude and maximum speed.

2) In the whole process of the inspection, the subjects can obtain the best cooperation according to the timely instructions and continuous counseling issued by the technician. Repeat the second and third inspections after 5-10 minutes of rest.

4.5 Shutdown

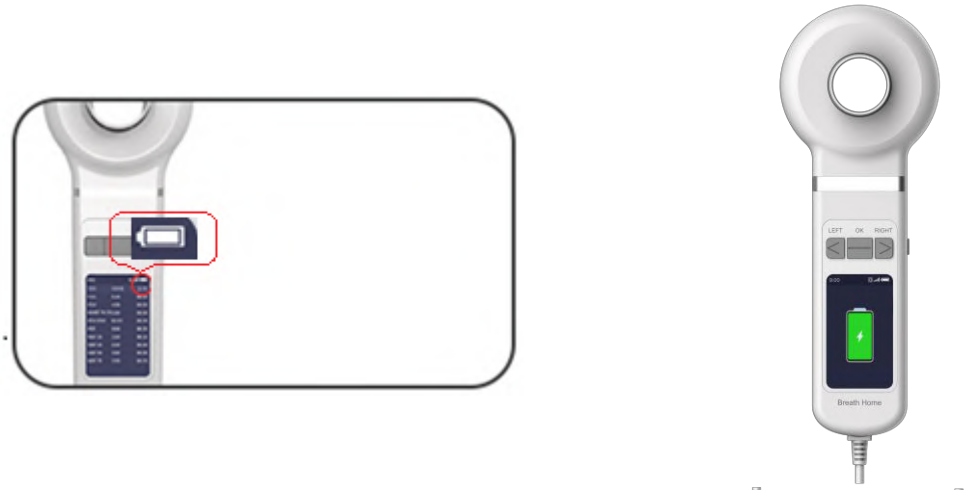
When the device is turned on, long press the shutdown button, the instrument display screen displays the shutdown interface, and the device emits a "shutdown in progress" prompt sound. After the above actions are completed, the device shutdown is complete.

4.6 Charging

Plug one end of the data cable into the USB port of the computer to charge the device.

When charging, a dynamic battery charging indicator icon will appear on the display.

When charging is complete, the battery charging indicator icon becomes stati



Charging indicator in power-on state Charging indicator in power- off state

Figure 2 Battery indicator diagram

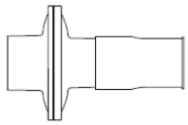
5. Instructions for using mobile software (see Annex 1 for details)

6. Instructions for using computer software (see Annex 2 for details)

7. Cleaning and disinfection methods

During the pulmonary function test, some parts of the equipment will be contaminated with bacteria. Therefore, the next subject may be at risk of bacterial infection.

Thorough disinfection of all contaminated parts can avoid potential risks of infection. Therefore, all parts should be disinfected regularly. See the table below.

	Disposable pulmonary function meter filter Discarded immediately after use in each patient

Special reminder: Disposable products must be discarded.

The following parts must be cleaned and disinfected once a day, see the following table：

	The screen is cleaned and disinfected once a day		The air head of the flow sensor is cleaned and disinfected once a day

⚠ ***Caution:***

Thorough disinfection of all contaminated parts can avoid potential risks of infection. Therefore, all parts should be disinfected regularly, and disposable products must be discarded!

7.1 Removal steps of flow sensor head

1) Press the button of the rear shell and pull out the flow sensor head forcefully at the same time;

2) Hold the sensor head flat, and carefully separate the front shell of the head and the back shell of the head in the up and down direction;

3) Remove the silicone parts from the cavity;

4) Open the quick release card lock to both sides;

5) Separate the parts of the cavity up and down to prevent the screen and the sealing ring from falling.

7.2 Cleaning and disinfection of the parts of the flow sensor head

1) Cleaning and disinfection of the parts of the flow sensor head under normal temperature and pressure:

① Pre-rinse with running distilled water immediately after use to remove residual saliva, dirt and other stains.

② Soak all the cleaned sensor head parts in 2% glutaraldehyde disinfectant solution for

about 15 minutes, and add 0.3% sodium bicarbonate to enhance its sterilization and disinfection effect.

③ After disinfection, rinse all parts with a large amount of distilled water and place them in a clean place to dry thoroughly.

It is recommended that all patients be cleaned and disinfected after the test on the same day, so that they can be dried naturally and used next time.

2) Cleaning and disinfection of the main body:

① Use clean gauze dipped in the appropriate amount of 75% medical alcohol (the gauze does not drip), and wipe the outside of the fuselage;

② Wair for natural air drying or use clean dry gauze to wipe dry.

3) Assemble and restore the disassembled parts according to their original positions.

⚠ ***Caution:***

❖ **cleaning and disinfecting the equipment, it is forbidden to immerse the main body in liquid!**

❖ **Do not use cloth, paper, or hard objects to clean the screen, if necessary, use the special brush provided by the company for cleaning!**

❖ **Do not use strong oxidizing disinfectant to clean the O -ring!**

⚠ ***Warning:***

Failure to follow the steps of the cleaning and disinfection methods mentioned above may result in cross-infection.

⚠ ***Caution***

After cleaning and disinfecting and before starting to use the equipment, complete the capacity calibration and 3 flow verification of the equipment in accordance with the description of the calibration in the accessory mobile software and the computer software.

8. Equipment maintenance

8.1 Maintenance

1) Regular inspections to ensure that the equipment has no obvious damage that affects safety or detection performance. It is recommended to inspect at least once a week. If there is obvious damage, stop using the equipment and contact after-sales customer

service.

2) The maintenance of this equipment is limited to qualified personnel designated by the manufacturer. Users should not repair the equipment by themselves.

3) When the device prompts that the battery is low, use a power source that meets the USB specification to charge in time. If the battery is found to be used for too short a time, you should stop using the device and contact after-sales customer service.

4) Please use it in the specified working environment, keep the operating environment clean, free of corrosive or combustible substances, and free of excessively high or low temperature and humidity.

8.2 Work, storage and transportation requirements

8.2.1 Working environment

The device needs to work under the following environmental conditions:

Temperature: +10 ℃ ~ +34 ℃

Rel. humidity: 15%RH ~ 95%RH

Ambient pressure: 700hPa ~ 1060hPa

If it exceeds the above working environment, it will affect the measurement performance of the product.

8.2.2 Transport and storage environment

The device should be transported and stored under the following environmental conditions:

Temperature: -20 ℃ ~ +50 ℃

Rel. humidity: 15 % RH ~ 95% RH

Ambient pressure: 600hPa ~ 1200hPa

Clean room without corrosive gas and well ventilated.

8.2.3 Transportation requirements

The following requirements must be met when transporting the device:

1) Avoid heavy objects squeezed;

2) Avoid direct sunlight;

3) Avoid getting wet from the rain;

4) Handle with care during the moving process.

9. Failure analysis and resolution

Failure phenomenon	Cause Analysis	Solution
Can not boot	Low battery	Please connect the charger to
	Possible equipment damage	Please contact the after-sales customer service center.
Bluetooth network connection failed after power on	The Bluetooth function of the mobile phone is not turned on	Please turn on the Bluetooth function of the mobile phone.
	The distance between the device and the phone is too large	Please keep the distance between other Bluetooth and the device less than 5 meters.
	The Bluetooth communication module may be damaged	Please contact the after-sales customer service center.
The device uses the USB connection software successfully, but the communication is abnormal	Could not establish connection	The USB cable is damaged or the connection is loose.
	The connection has been established and the communication is abnormal	Disconnect the USB and reconnect or shut down and restart.
	Instrument damage	Please contact your local customer service center.
	Software program blocking	Close the software and reopen it.
No data can be detected for blowing	The instrument does not enter the detection state	Press the key again to measure or shut down and restart.
	Incorrect blowing posture	Please use the correct blowing method.
The flight time after charging is too short	Battery is damaged	Please contact the after-sales customer service center.
Data lost (software)	data lost	You can find the information under the backup in the software catalog or use the data recovery function of the system to find the lost data.
	Software crashes	During use, the logic of the application itself may be wrong, and the system may cause the software to crash. At this time, the software can be restarted to

10. Product quality information

10.1 Warranty service

From the date of purchase, the product enjoys a free warranty within one year with the purchase invoice, but does not include the following failures caused by the user's personal reasons.

Such as unauthorized disassembly and assembly, malfunctions caused by product modification, malfunctions caused by accidental drops during handling, malfunctions caused by lack of reasonable maintenance, malfunctions caused by force majeure factors such as natural disasters.

The manufacturer does not assume any responsibility for problems caused by incorrect operation or use with other equipment or accessories.

10.2 Post-maintenance

If you need to apply for warranty and repair services, please contact after-sales customer service, fill in the warranty card, and take this product to a professional service point for repair.

If the product is repaired by the user or by a non-designated repair center, the warranty statement is invalid. If the equipment needs maintenance, the above requirements also apply.

In order to process your repair application more quickly, please provide the following product information:

1) Product number.

2) Detailed description of the fault.

⚠ ***warning:***

For safety reasons, maintenance center personnel have the right to reject products that have been contaminated. Products should be packaged in non-polluting packaging.

⚠ ***Caution:***

Please choose appropriate and strong packaging when sending it for repair (original packaging is best).

The manufacturer has the right to return the contaminated product to the shipper

10.3 Production date and expiry date

Product production date: see product label

Product expiration date: three years

11. Cybersecurity instructions

The device has the function of data transmission to mobile terminal software and computer terminal software.

11.1 Operating environment requirements

Software type	Hardware Configuration	Software Environment	Network conditions
Mobile software	Memory: 2GB RAM or above; Storage hard disk space: 16GB or above	Android 7.0 or above	no request
Computer software	Processor: Intel Core i3-2120 3.0GHz or above; Memory: 4GB or above; Hard disk: 100GB or above;	Windows 7/8/10 or above	no request

11.2 Security software

Users can choose conventional international mainstream antivirus software, such as Kaspersky, Symantec, McAfee, Norton, etc.

11.3 Data and equipment interface

Pulmonary Function Tester follows the BLE protocol to realize the communication between embedded devices and other Bluetooth devices.

Pulmonary Function Tester follows the USB protocol to realize the communication between the embedded device and the software.

11.4 User access control mechanism

User type	User rights	User authentication method	Password strength setting
General user	Access device measurement	Individual user accounts, users cannot register	Personal account: The account name matches the password. The

	data	independently by themselves, the company needs to assign them separately	password must have English capitalization and numbers, and the length should not be less than 6 digits.
Equipment maintenance personnel	Access device data, perform software update and maintenance	Pass account password	The account name matches the password. The password must have English capitalization and numbers, and the length should not be less than 6 digits.

12. Electromagnetic compatibility instructions

12.1 Parameter description

Name	Working frequency	Modulation type	Maximum Tune-up power(dBm)
Bluetooth	2.4GHZISM BAND	GFSK	-3.00

Name	Cable length (m)	Whether to block	Remark
USB Cable	2.0	Yes	/

⚠ ***Warning***

Even if other equipment meets the emission requirements of the corresponding national standards, the equipment or system may still be interfered by other equipment.

12.2 EMC statement

1） Model A9 needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying document;

2） Portable and mobile RF communications equipment can affect model A9.

⚠ **Warning:**

1） Don’t be 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.

2） Use of accessories, transducers and cables other than those specified or provided by

the manufacturer of Model A9 could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

3） Use of Model A9 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.

12.3 FCC declaration

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

⑴ This device may not cause harmful interference, and

⑵ This device must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for a Class A digital device,pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

12.3.1 FCC RF Radiation Exposure Statement:

1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

2. This equipment complies with RF radiation exposure limits set forth for an uncontrolled environment.

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

12.3.2 FCC Caution:

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

12.4 Declaration of conformity

Table 1

Guidance and manufacturer's declaration – electromagnetic emission		
The Pulmonary Function Tester（A9）is intended for use in the electromagnetic environment specified below. The customer or the user of Pulmonary Function Tester（A9）should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Pulmonary Function Tester（A9）uses RF energy only for its internal function. There for, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Pulmonary Function Tester（A9） is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations flicker emissions IEC 61000-3-3	Not applicable	

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity			
The Pulmonary Function Tester（A9） is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulmonary Function Tester（A9） should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment -guidance**
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	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least

			30 %.
Electrostatic transient / burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ±2 kV common mode	± 1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle g) 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 g) At 0°, 45°, 9 0°, 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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Pulmonary Function Tester（A9）requires continued operation during power mains interruptions, it is recommended that the Pulmonary Function Tester（A9）be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 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.			

Table 3

Guidance and manufactureŕs declaration – electromagnetic immunity			
The Pulmonary Function Tester（A9）is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulmonary Function Tester（A9）should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF	3 Vrms	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Pulmonary Function Tester（A9）, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

IEC 61000-4-6 Radiated RF IEC 61000-4-3	150 kHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 3 V/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)	150 kHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 3 V/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)	**Recommended separation distance** $d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [\frac{12}{V_2}]\sqrt{P}$ $d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 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 metres (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] 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 is affected by absorption and reflection from structures, objects and people.

[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

[b] 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 Pulmonary Function Tester（A9）is used exceeds the applicable RF compliance level above, the Pulmonary Function Tester（A9）should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Pulmonary Function Tester（A9）.

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

Table 4

Recommended separation distances between portable and mobile RF communications equipment and the Pulmonary Function Tester（A9）				
The Pulmonary Function Tester（A9）is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Pulmonary Function Tester（A9）can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Pulmonary Function Tester（A9）as recommended below, according to the maximum output power of the communications equipment				
Rated maximum output of transmitter W	**Separation distance according to frequency of transmitter m**			
	150 kHz to 80 MHz outside ISM and amateur radio bands $d = [\frac{3.5}{V_1}]\sqrt{P}$	150 kHz to 80 MHz in ISM and amateur radio bands $d = [\frac{12}{V_2}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.7 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.20	0.035	0.07
0.1	0.38	0.63	0.11	0.22
1	1.2	2.00	0.35	0.70
10	3.8	6.32	1.10	2.21
100	12	20.00	35	70
For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (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. Contact information

Manufacturer: Guangzhou Homesun Medical Technology Co., Ltd

Address: Floor 7th, TianxiangBusiness Building, No.28, Li Fu Road, Haizhu District, Guangzhou, GD .China

Tel.: 400-030-1510

Email: service@huxijia.cn

URL: https://www.huxijia.cn/index_english.html

Annex 1

Product user manual

Pulmonary function tester mobile software

Model: A9

Guangzhou Homesun Medical Technology Co., Ltd

Illustrate

Thank you for purchasing Homesun products.

Before using the product, please read the contents of this manual carefully so that you can use it correctly.

Keep this instruction manual properly after reading so that it can be consulted whenever you need it.

Product name: Pulmonary function tester mobile terminal software user manual

Software release version: V1

Manufacturer name: Guangzhou Homesun Medical Technology Co., Ltd

Manufacturer residence / Production Address: Floor 7th, TianxiangBusiness Building, No.28, Li Fu Road, Haizhu District, Guangzhou, GD. China

Date of production: See packaging label for details.

Intellectual property

The intellectual property rights of this instruction manual and its corresponding products belong to Guangzhou Homesun Medical Technology Co., Ltd (hereinafter referred to as " Homesun Company").

The copyright of Guangzhou Homesun Medical Technology Co., Ltd is owned. Without the prior written permission of Homesun, no one may use, disclose or allow others to obtain all or part of the information in this manual by any means. No one is allowed to take photos, copy, copy or translate all or part of the contents of this manual into other languages.

Homesun has the final right to interpret this manual.

Homesun reserves the right to modify the contents of the manual without prior Caution.

Homesun reserves the right to change the technology without prior Caution.

Homesun reserves the right to modify product specifications without prior Caution.

Statement

In the case of meeting all the following requirements, Homesun believes that it should be

responsible for the safety, reliability and performance of the product.which is:

The assembly operation, expansion, re-adjustment, improvement and maintenance are all carried out by professionals approved by Homesun;

The product operation is carried out in accordance with this instruction manual.

Warranty and repair service

The warranty period of the purchased product is subject to the sales contract.

The warranty period starts from the " installation date " filled in the "Equipment Warranty Card" attached to the product . The "Equipment Warranty Card" is the only proof for calculating the warranty period. To protect your rights, please fill out the warranty card in the device after the installation is complete, and warranty cards - Duplex (" Homesun company retained " linked) to the installer or mailed back to the company Homesun customer service department.

Please note that the software will not be covered by the warranty in any of the following situations:

1 ） Customer fails to fill in and return the warranty card within 30 days after the installation and acceptance is completed ;

2 ） The equipment serial number provided by the customer is incorrect.

During the warranty period, products can enjoy free after-sales service; but please note that even during the warranty period, for the following reasons made into a case of product needs to be repaired, the company will implement the fee Homesun service, you need to pay for repairs and accessories fee:

- Man-made damage;
- Improper use;
- Irresistible natural disasters;
- Repaired by personnel not authorized by Homesun;
- Other failures not caused by the product itself.

After the warranty period expires, Homesun can continue to provide chargeable maintenance services.

If you do not pay or delay payment for the paid repair service, Homesun Company will suspend the repair service until you pay.

After-sales service unit

Unit name: Guangzhou Homesun Medical Technology Co., Ltd

Address: Floor 7th, TianxiangBusiness Building, No.28, Li Fu Road, Haizhu District, Guangzhou,GD .China

Service Tel: 400-030-1510

DANGER

- The Software is only available to inspection professionals, doctors or laboratory personnel trained by Homesun or Homesun 's agents
- If each hospital or institution responsible for using this software fails to implement a satisfactory repair/maintenance plan, it may cause abnormal software failure and may endanger human health.
- Make sure to use the software under the conditions of use specified in the instruction manual. If the usage conditions are exceeded, the pulmonary function tester may not operate normally, the measurement results will be unreliable, and it may damage the software and cause personal injury.

CAUTION

The readers of this manual are the following professionals in the laboratory:

- Personnel who carry out the daily operation of the system;
- Personnel who carry out system maintenance and troubleshooting;
- Personnel who learn system operation.
- This manual is only for V1 version software operation.

Content

Chapter 1 Manual overview

1.1 Overview

This chapter describes how to use the software instruction manual, which is randomly included, and provides a detailed description of the purpose, function, and operation of the software. Before you use the software, read, and understand it carefully to ensure that the software is used correctly, performs at its best, and ensures the safety of the operator.

In the daily use of this software, please strictly follow the instructions in the manual.

1.2 Scope of application of the manual

This manual is suitable for medical examination professionals or trained doctors, nurses or laboratory workers to read. Used for:

1) Understand the software;

2) Set system parameters;

3) Perform daily operations;

4) Perform system maintenance and troubleshooting.

1.3 Guide to the manual

When you need ...	Reference ...
Understand the operating environment and performance parameters of the software	Chapter 2 Software introduction
Understand the measurement principle and process of software applications	Chapter 3 Working principle and scope of application
Understand the main structure of the software and its functions	Chapter 4 Main product structure

Understand the software installation method, installation steps and the correctness of the software Use tutorial	Chapter 5 Software installation and uninstallation
Input data, calculation and other settings, sample result report generation	Chapter 6 Software interface and operation
Understand the maintenance and precautions of the software	Chapter 7 Maintenance and precautions
Understand the handling methods and steps of software failures	Chapter 8 Failure analysis and treatment
Understand software electromagnetic compatibility	Chapter 9 Electromagnetic compatibility description

1.4 Symbol explanation

Symbols and their meanings that may appear in this manual:

Symbol	Significance
	Remind the operator to follow the instructions under the symbol, otherwise it may cause personal injury.
	Prompt the operator to follow the instructions under the symbol, otherwise it may cause the product to malfunction Failure, damage or affect the test results.
	Prompt the operator to follow the instructions under the symbol, emphasizing the important information in the procedure or what requires the operator's special attention.

1.5 Prerequisite information

Users of this software need to have an understanding of computer and pulmonary function examination professional business, and be familiar with the professionalism of the corresponding business.

Users of this software are required to have normal hearing and keyboard operation ability, and be able to correctly recognize simplified Chinese or English.

1.6 System related characteristics

1.6.1 Causes a system failure or termination condition:

There may be a software failure:

When there is an error input caused by the user's carelessness or the software itself has an error, the software can recover by itself without an infinite loop.

1.6.2 The key functions of the system

The key functions of this software include patient management, slow vital capacity test, forced vital capacity test, maximal voluntary ventilation test, bronchial diastolic test, historical data review, and print report functions.

This instruction manual focuses on the description of a single program, making it as simple and easy to understand as possible. With the help of the manual, users, especially medical staff, should be able to use all programs of this software. In the case that the user does not know other programs, each program can be used by the user through a certain explanation.

Chapter 2 Software description

2.1 Operating environment

1) Hardware standard configuration requirements:

Memory: 2GB RAM or above;

Storage hard disk space: 16GB or above;

2) Software standard configuration requirements

Operating system: Android 7.0 or above;

Precautions, warnings, and prompt content.

The software is a clinical examination software used for screening. When making clinical judgments based on analysis results, doctors are required to consider clinical examination results or other test results at the same time.

2.2 Technical parameters

2.2.1 Operating environment

1) Hardware configuration

Memory: 2GB RAM or above;

Storage hard disk space: 16GB or above;

Display resolution: 1280×800 or higher;

2) Software environment

Operating system: Android 7.0 or above;

2.2.2 Processing object

The software should be able to calculate and analyze pulmonary function test data curve data.

2.2.3 Maximum concurrent number

The maximum number of concurrent users of this software is 1.

2.2.4 Data interface

Use the USB/Bluetooth interface to transmit to the mobile terminal platform where the software is located.

2.2.5 Specific hardware

A9

2.2.6 Clinical function

1) Forced vital capacity

The forced vital capacity test program includes: flow-volume curve display, volume-time curve display, end-tidal flow guidance, and forced vital capacity display parameters.Preview reports, generate reports, and print reports based on report style templates.

2) Slow vital capacity

The slow vital capacity test program, including: volume-time curve display, slow vital capacity display parameters. Preview reports, generate reports, and print reports based on report style templates.

3) Maximal voluntary ventilation

Maximal voluntary ventilation test program, including: volume-time curve display, maximal voluntary ventilation display parameters. Preview reports, generate reports, and print reports based on report style templates.

4) Bronchial diastolic test test

Perform pulmonary function tests before and after diastolic medication, generate diastolic test reports and print reports.

5) Calibration

Scaling comprising: capacity scaling, 3 flow verification, temperature and humidity, the atmospheric pressure data acquired automatic / manual input, temperature, and humidity adjustment of the degree of influence on the measurement results.

6) Patient management

Patients create, edit, query, delete, view patient file details, and view patient history test records.

7) Data management

Report query and data search.

8) System settings

■ Basic settings include information settings for hospitals, departments, operators, and doctors;

■ Account settings include account sign-out;

■ Report settings include report title prefix setting, default display options setting, and report template display index editing;

■ The drug setting is used to record the category, drug name, specification, and unit information of the drug used in the diastolic test.

■ The software upgrade module is to check the version. If the testing software is upgraded, contact your local agent.

2.2.7 Restrictions on use

Only English letters and numbers can be entered for the login user name and password.

2.2.8 User access control

The user needs to log in to the account and password to use this product, and all functions of this product should be used after logging in.

2.2.9 Copyright protection

Use encrypted installation for protection.

2.2.10 User Interface

Users can operate through buttons, menus, dialog boxes, and drop-down menus.

2.2.11 Message

The message mechanism of the software includes prompt, error report, and selection confirmation.

2.2.12 Maintainability

■ Software should be able to automatically generate error messages for the monitoring

log recording program;

- Software should have maintenance contact information in the "About" information.

2.2.13 Quality requirements

Shall comply with Chapter 5 (except 5.3.9 ~ 5.3.13) of ISO / IEC 25051: 2014 Software engineering - Systems and Software Quality Requirements and Evaluation (SQuaRE) – Requirements for quality of Ready to Use Software Products (RUSP) and instructions for testing.

Chapter 3 Working principle and scope of application

3.1 Working principle

This software is suitable for data detection based on the pulmonary function tester produced by our company. The software supports 4 different types of pulmonary function tests: FVC, SVC , MVV and bronchial diastolic test.

The software works as follows: 1. through the USB / Bluetooth acquired detection of human pulmonary function tests, and increasing the number of data curve data; 2. Read and calculate curve data. According to the technical principle of the product, each measurement mode has its own unique breathing mode for detection, and the software can automatically calculate various pulmonary function parameters in different modes.

3.2 Scope of application

The software is used in conjunction with the pulmonary function tester to print test data and reports in FVC, SVC, MVV and bronchial diastolic test modes.

Chapter 4 Major component structure

The product consists of login, homepage, forced vital capacity, slow vital capacity, maximum minute ventilation, bronchial diastolic test, calibration, patient management, data management, and system setting modules.

Chapter 5 Software installation and uninstallation

5.1 Overview

This application software is dedicated software, and there are full-time after-sales personnel to guide the installation. Please notify Homesun or the local agent after receiving the pulmonary function tester product.

5.2 Installation requirements

Before installation and use, be sure to read the instruction manual carefully, and the operator must be familiar with the use and operation methods to ensure that the software can work normally.

5.3 Installation method

1) Software acquisition

   Please contact Homesun company or local agent immediately.

2) Get an account password

   Please contact Homesun immediately.

3) Install the software

   a) Obtain the mobile software of the pulmonary function tester through technical support, click install, as follows:

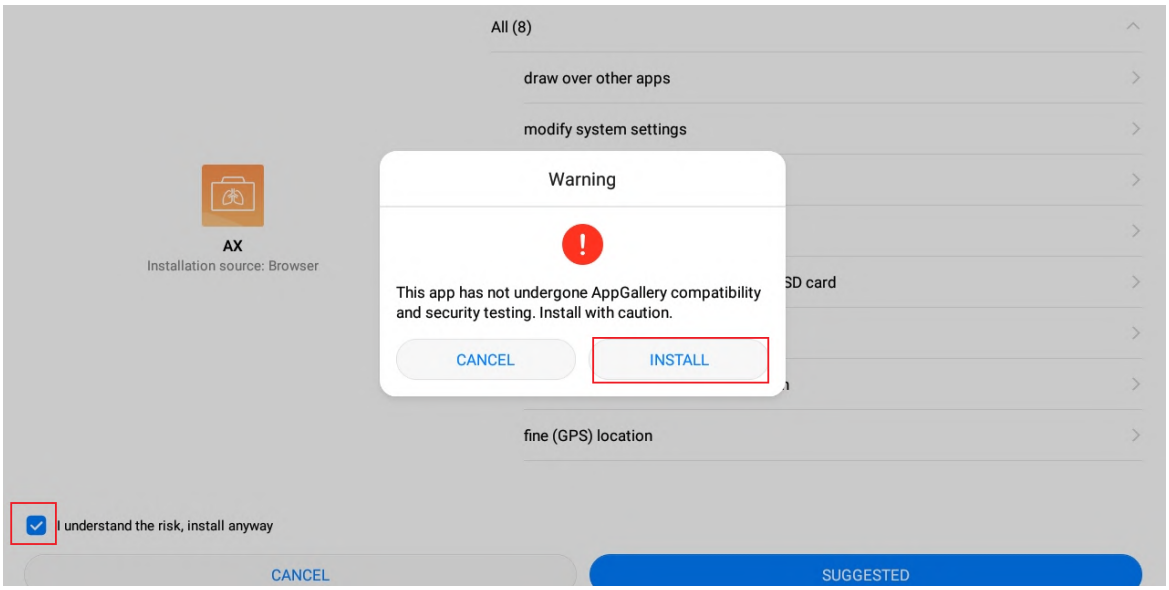


Figure 1 Installation interface

b) Wait for the software to automatically complete the installation, and generate a software startup shortcut icon on the desktop.

Figure 2 Desktop icon interface

c) Click the software startup icon to use it.

5.4 Software uninstallation procedures

1) Open the settings of the Android system, select the application, and select the AX program.

2) The uninstall dialog box pops up, select uninstall to complete the deletion.

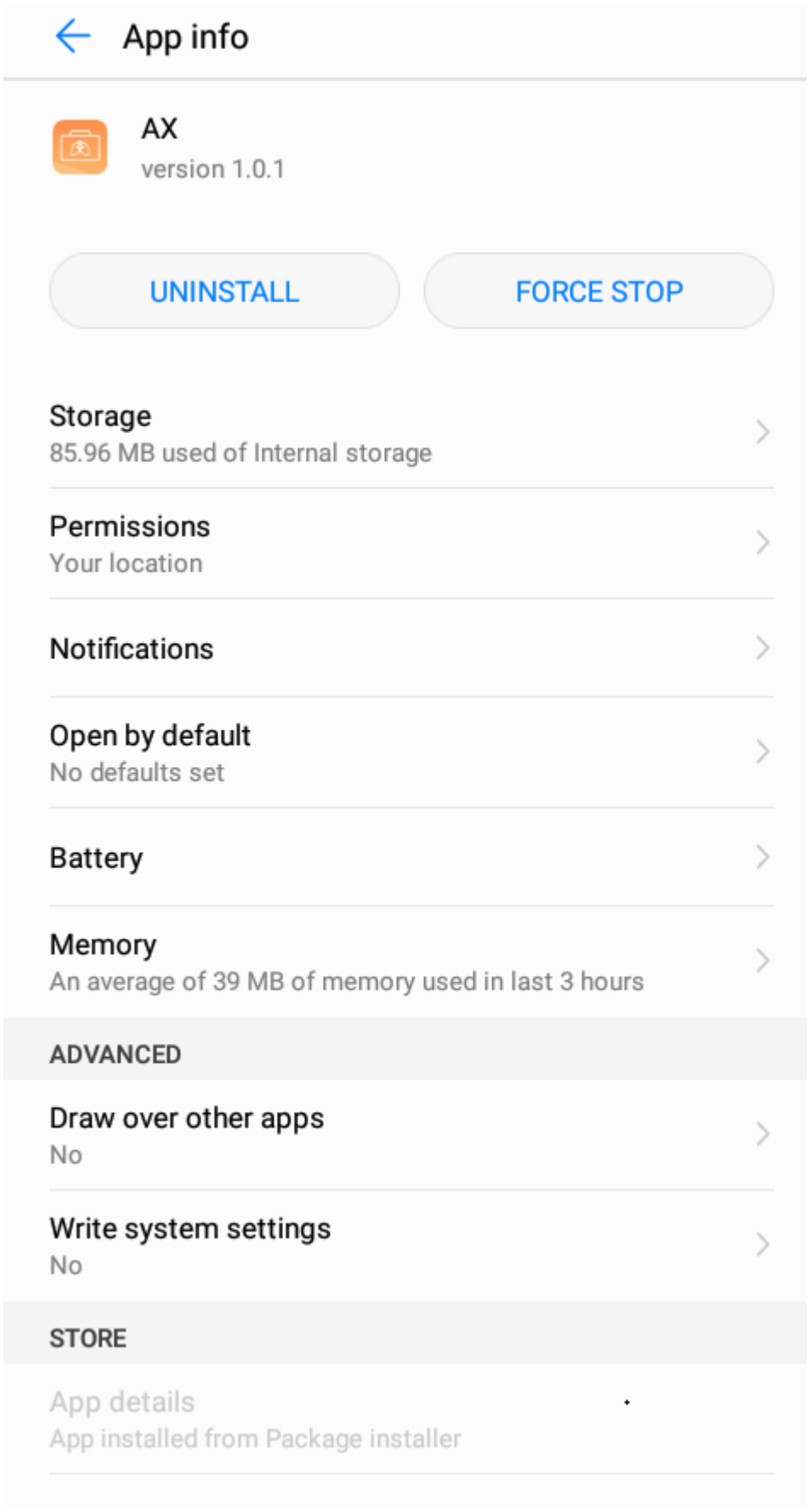


Figure 3 Uninstall interface

5.5 Parts list

Number	Accessory name	Quantity	Remark
1	User manual	1	Standard accessories

Chapter 6 Software interface and operation

6.1 User login

As shown in the figure below, after the software is started, the user login dialog box is automatically displayed. After entering the user name and password, click [Login], and you can enter the main interface after logging in successfully. The initial user account of the software can be obtained from Homesun after-sales personnel.

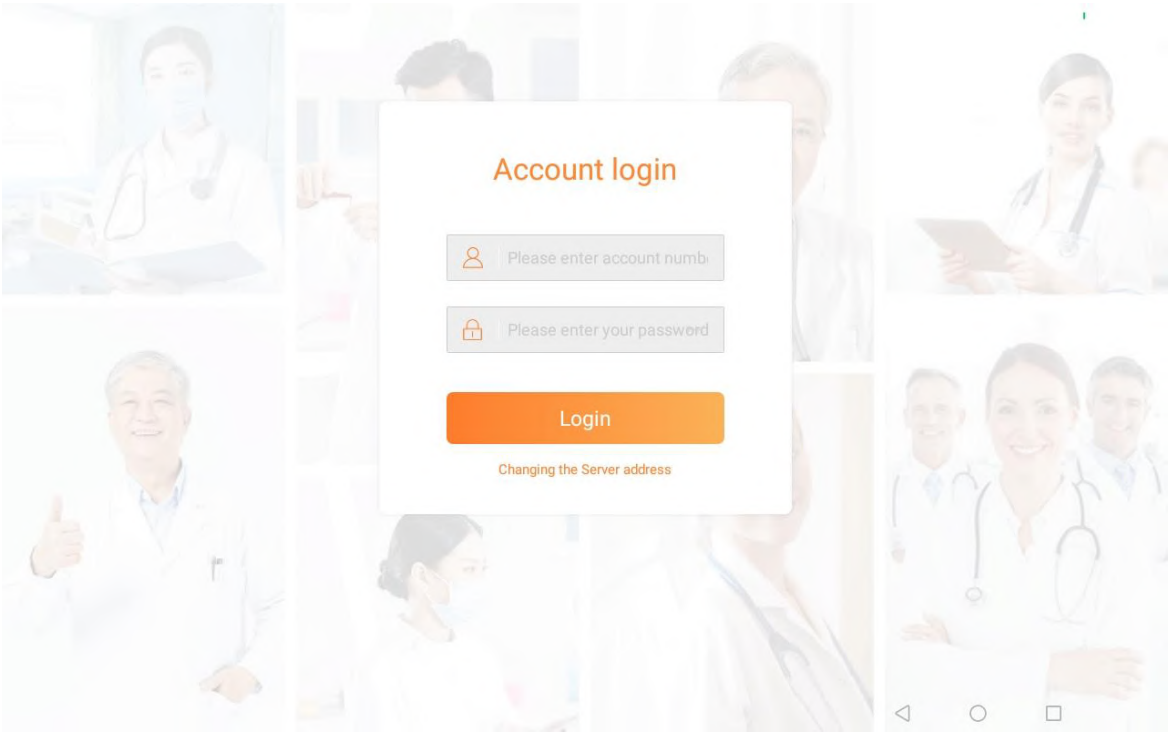


Figure 4 Login dialog box

Forgot password description: Since this test system does not support the online password retrieval function, if you need to retrieve the password, please contact Homesun Customer Service.

6.2 Home

The navigation homepage the user logs into. And through the USB/Bluetooth to connect with the device.

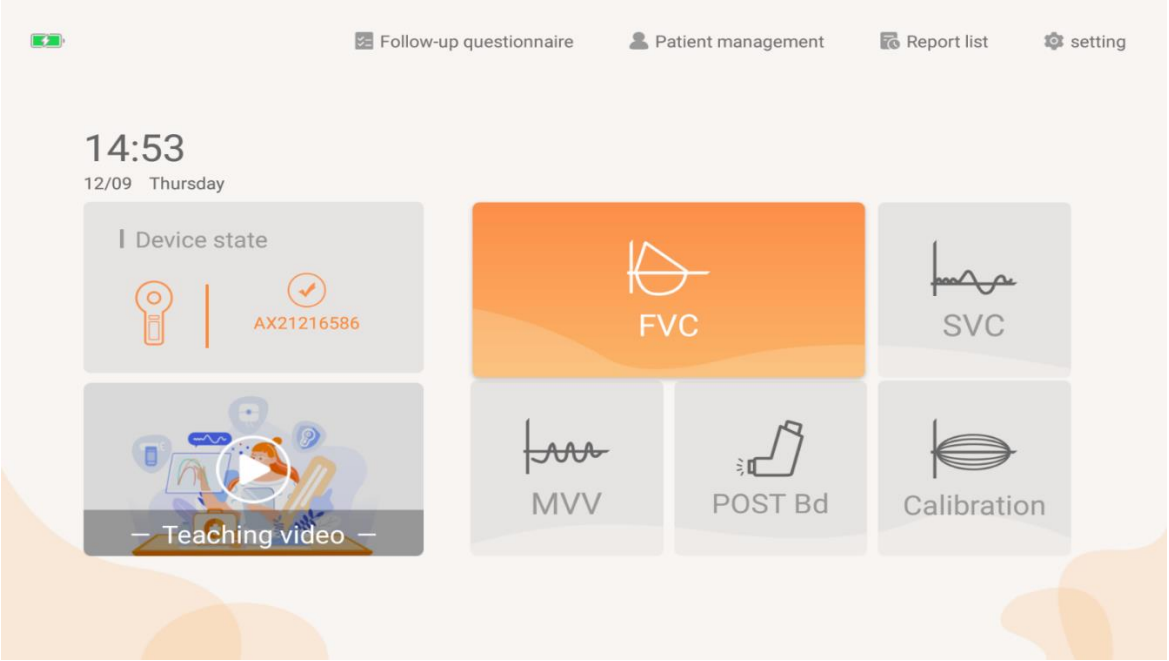


Figure 5 main interface

1) FVC mode. Click the FVC button to perform FVC detection.

2) SVC mode. Click the SVC button to perform SVC detection.

3) MVV mode. Click the MVV button to perform MVV detection.

4) Bronchial Diastolic Test. Click the POST Bd button to perform a pulmonary function test before and after diastolic medication.

5) Calibration. Click the "Calibration" button to calibrate the device.

6) Patient management. Click "Patient management" to see a list of historical patients.

7) Report. Click "Report list" to view a list of reports generated in history.

8) Settings. Click "Settings" to make system related settings.

6.3 Calibration

6.3.1 Calibration tool

3L calibration pump.

⚠ Caution:

The 3L calibration pump is purchased by the user, and its requirements are 3L±0.5% .

6.3.2 Standard calibration

1) The 3L calibration pump and pulmonary function testing instrument are connected, select in the software "3L", click the upper right corner of the "standard" button, click "Start" button, enter the standard monitor calibration measurement page.

2) After entering the environment information in the upper right corner, click "New Test" to start the measurement, use the 3L calibration pump to smoothly move the calibration pump handle, do not pause during a single push or pull, and ensure that each push and pull is in place. "The number of exhalation and inhalation push-pull times is reached, the system can automatically prompt to stop the operation", then the push-pull calibration pump will stop after returning to its original position.

3) If the relative 3L error exceeds ±10%, please repeat this step and re-calibrate.

   Special reminder, if the calibration fails, the calibration needs to be repeated until the calibration is passed.

   After the daily calibration is completed, if you start to re-calibrate, it will prompt " The calibration has been determined today, whether to re-calibration?"

4) Click the "Return" button in the upper left corner to exit the calibration.

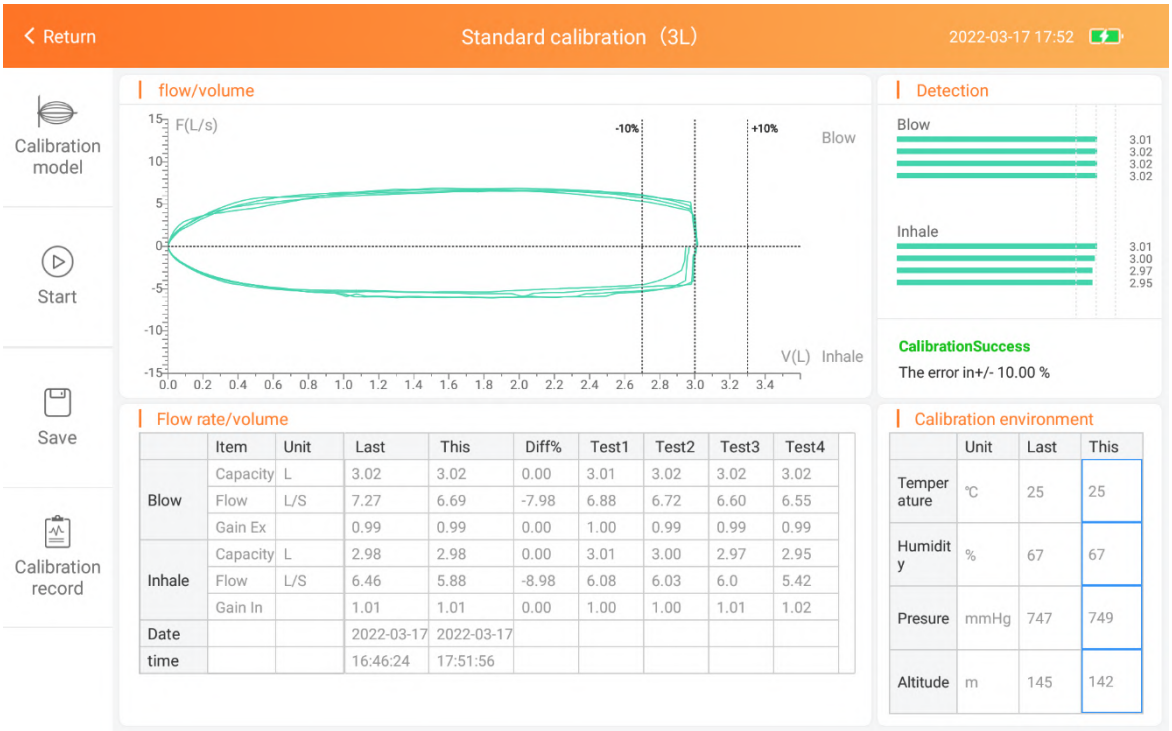


Figure 6 Calibration test interface

6.3.3 3 Flow verification

1) The 3L calibration pump with the device connected, select the software "3L", click on the top right "3flow" button, click "Start" button, enter the 3 flow calibration verification page;

2) After entering the environmental information in the upper right corner, click "New Test" to start the measurement, use the 3L calibration pump to push and pull, and check the monitoring progress bar on the page at the same time;

3) Push and pull the calibration pump at three different speeds, so that the flow rate capacity curve crosses the gray effective area of the three flow rates of low, medium and high, and ensures that the exhalation and inspiration are successfully crossed through each flow rate area at least 3 times, and the order can be unlimited;

   During this period, the number of completions of the corresponding area will be recorded from 0 to 3 on the right side of the successfully traversed area. When all the upper and lower 6 areas show at least 3 three-flow calibrations passed, the three- flow calibration verification is completed.

   It is recommended to complete one speed verification before performing another speed push-pull verification;

4) Click "Stop" to save the measured data;

5) If the 3 flow verification fails, please re-calibrate according to the "equipment calibration" step, and perform 3 flow verification again until it passes;

6) Click the "return" button in the upper left corner to exit the calibration.

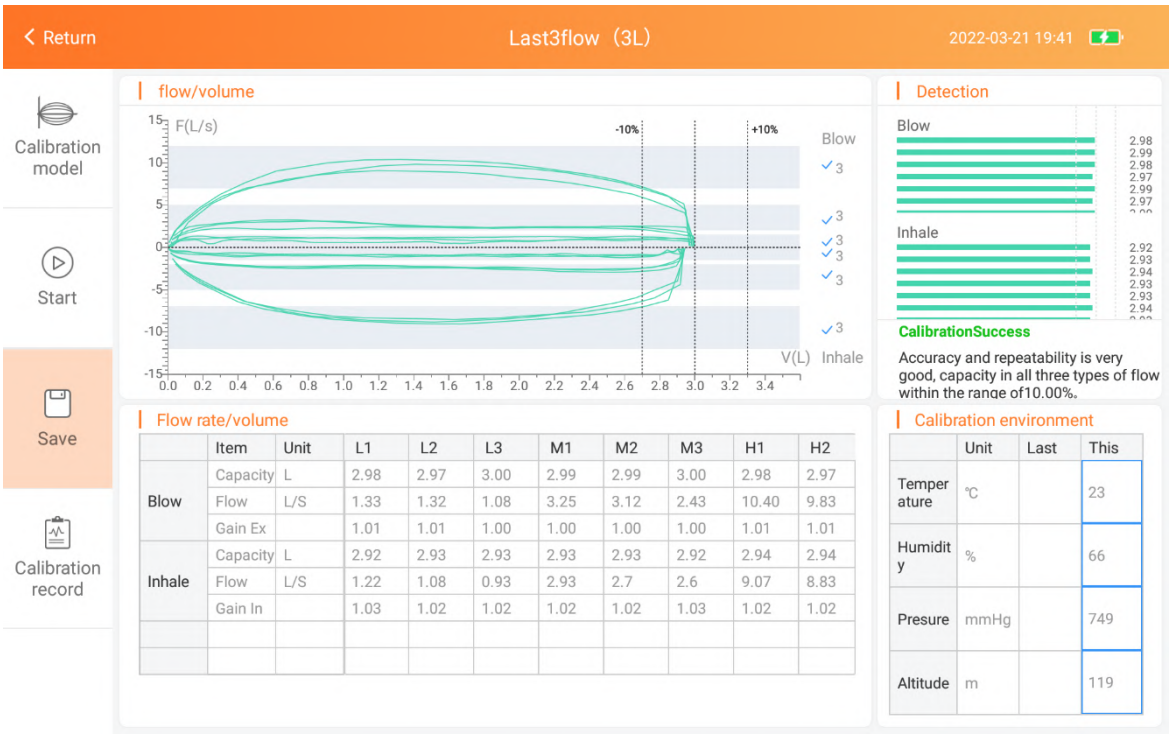


Figure 7 3 flow verification interface

6.4 Forced vital capacity test procedure

6.4.1 Forced vital capacity test

Select the forced vital capacity test (FVC) to prepare to start the test.

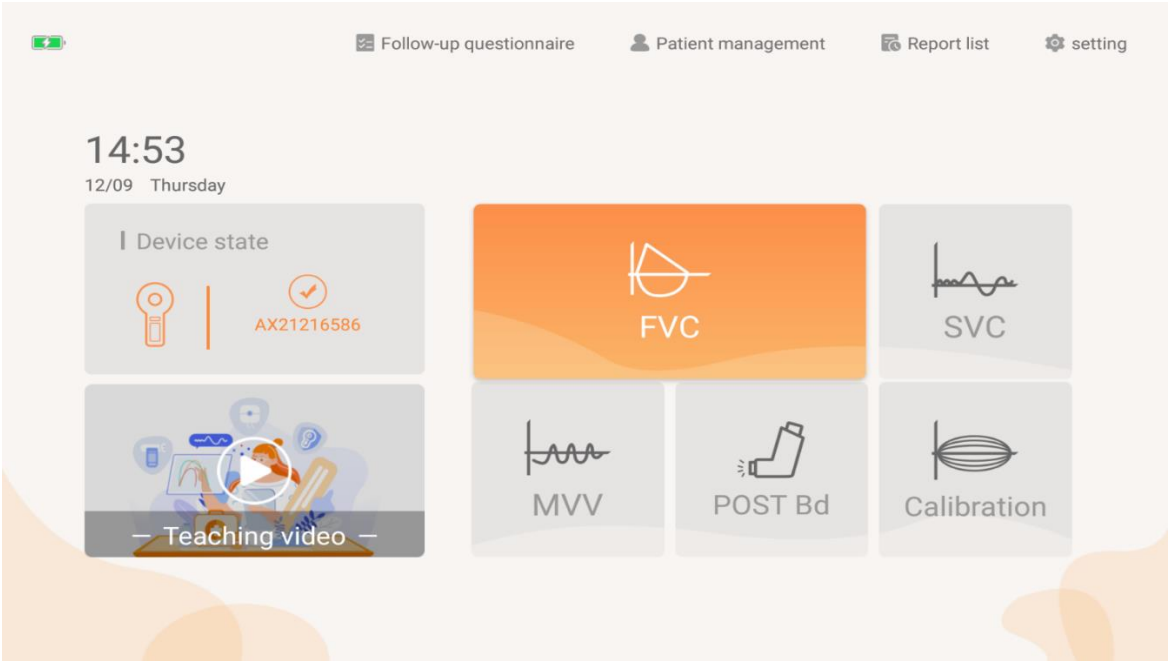


Figure 8 Measurement mode selection interface

6.4.1.1 Description of function homepage

1) Test items - FVC, FEV1, FEV1% FVC, PEF, FEF25, FEF50, FEF75, MMEF and so on were used as the measured indexes of FVC.

2) Measured curve graph-flow rate - volume F(L/s)-V(L) graph and volume - time V(L)-T(s) graph show each measured data of the patient in different colors , and show Waveform or arc, the operator can selectively view or compare the actual measurement records to determine the flow rate-The black waveform on the volume F(L/s)-V(L) graph is used as the predicted value of the tested patient, and the predicted value is compared with the actual measurement record.

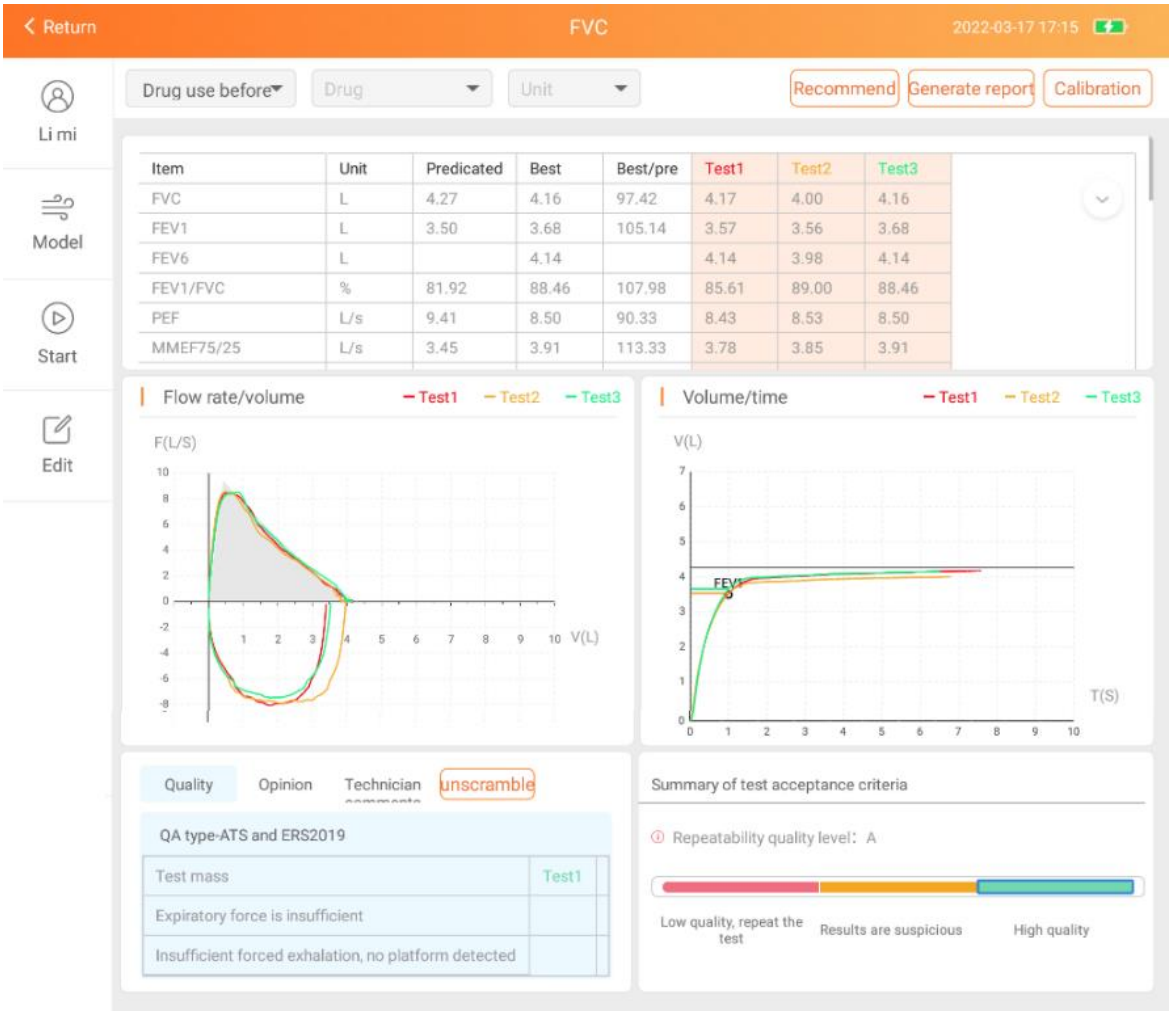


Figure 9 FVC measurement results interface

6.4.1.2 Description of operating real-time measurement homepage

Figure 10 FVC measurement real-time interface

1) Real-time dynamic display of flow rate - volume curve during breathing .

2) Real-time dynamic display of tidal volume and respiratory rate during steady breathing, guiding the user to measure the steady control progress value within the green range.

3) Real-time dynamic lung breathing status, which intuitively reflects the arrow down when the user inhales and the arrow goes up when the user exhales, guiding the patient to breathe abruptly.

4) Real-time dynamic display of the stability of vital capacity, when the tidal stable breathing state is reached, the baseline turns to red, and the user can proceed to the next step of inhaling deeply and then exhaling immediately with explosive force.

6.4.1.3 Operation steps

1) Practice forced breathing according to the instructions of the technician or doctor, and master the essentials of FVC. Avoid fatigue subjects achieved full intended results.

2) Connect the mouthpiece to the mouth, wrap the mouthpiece tightly with your lips, and clamp the nose clip to ensure that the mouth and nose do not leak. If some subjects

cannot guarantee that the corners of the mouth will not leak, a special mouthpiece with lip and tooth cover can be added.

⚠ Caution:

The user purchases a detachable mouthpiece and a disposable pulmonary function meter filter, which must be a legally marketed product registered by the FDA.

Mouthpiece specifications: inner diameter 30mm, outer diameter 32-34mm, height 50mm-120mm.

Specification of disposable pulmonary function meter filter: inner diameter 1=30mm.

3) Breathe calmly for 4-5 times. After the breathing is stable, take a deep breath, and then exhale forcefully, quickly, and completely, in one breath.

4) Exhalation is complete, inhale strongly and quickly until it is complete, and then breathe 4-5 times calmly to complete the test.

⚠ ***Caution: The same patient should not be tested more than 8 times a day!***

5) Each time the patient completes a set of measured values, the monitoring page will indicate whether the measured results are acceptable. Such as ticking is acceptable, you can click "end" to end this test and save the data. Such as the cross is an unacceptable result and the reason is prompted, you can click "New Test" to start a test.

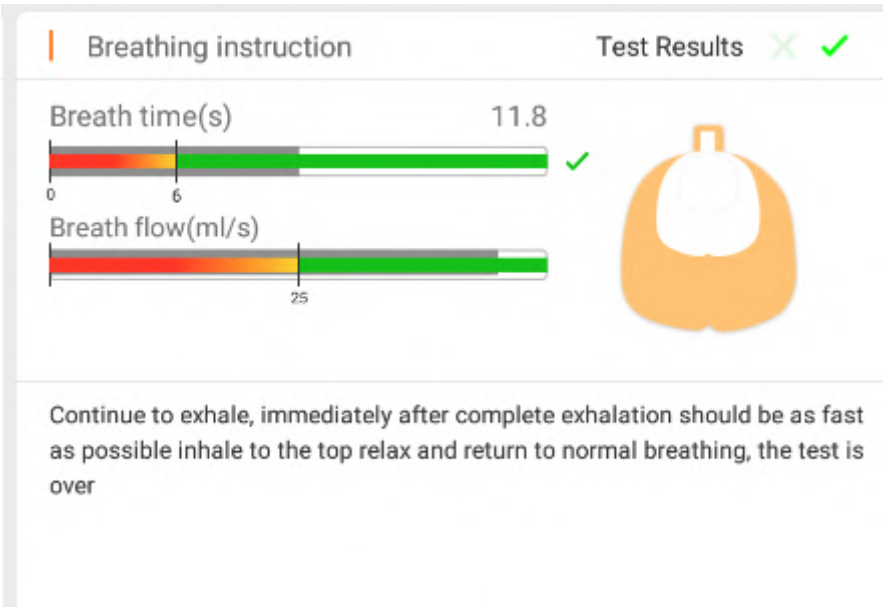


Figure 11 FVC single measurement quality control prompt interface

6) When completion of the blow 3 times after the actual measurement, the system automatically obtains the repeatable quality level according to the quality control standard, if there is a low-quality measurement record that is unacceptable for a single operation, you can click to select the actual measurement record to delete it.

7) Click "Generate Report" to generate the report and enter the report preview page.

8) After the forced vital capacity test (FVC) measurement is over, please choose whether to proceed with other mode tests according to the actual situation.

6.4.1.4 Report preview

Click the "Preview" button to automatically jump to the "FVC report" interface, as follows:

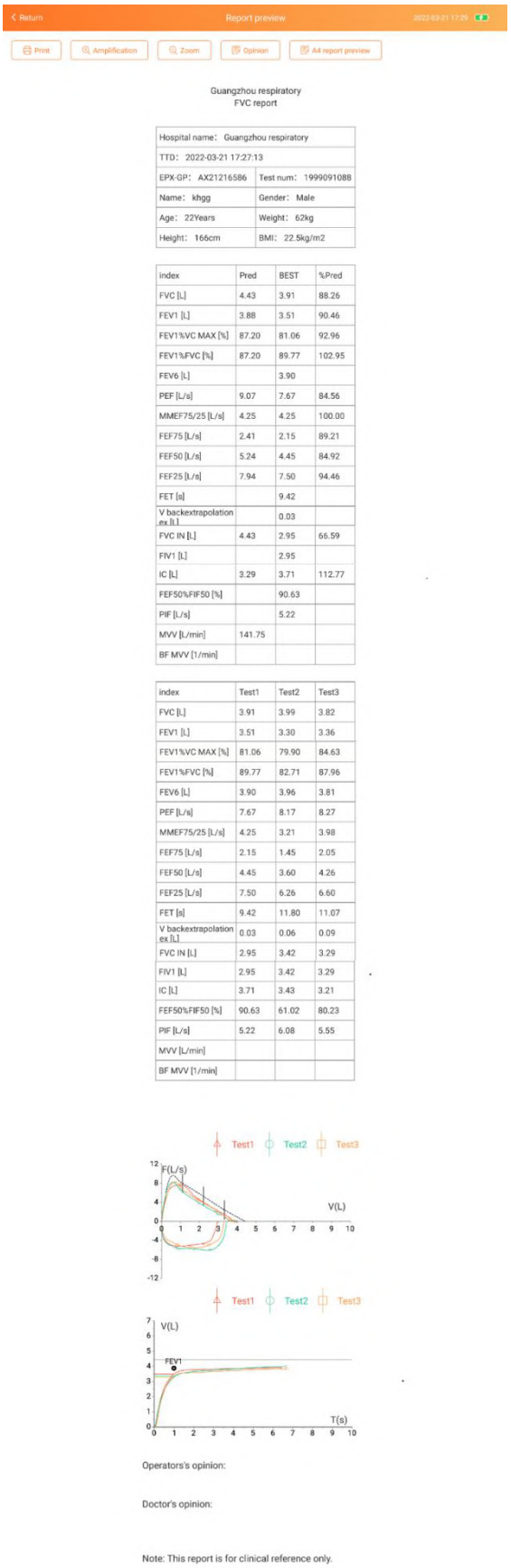


Figure12 FVC report interface

6.5 Maximum minute ventilation test procedure

Select the maximum minute ventilation test (MVV) to prepare to start the test.

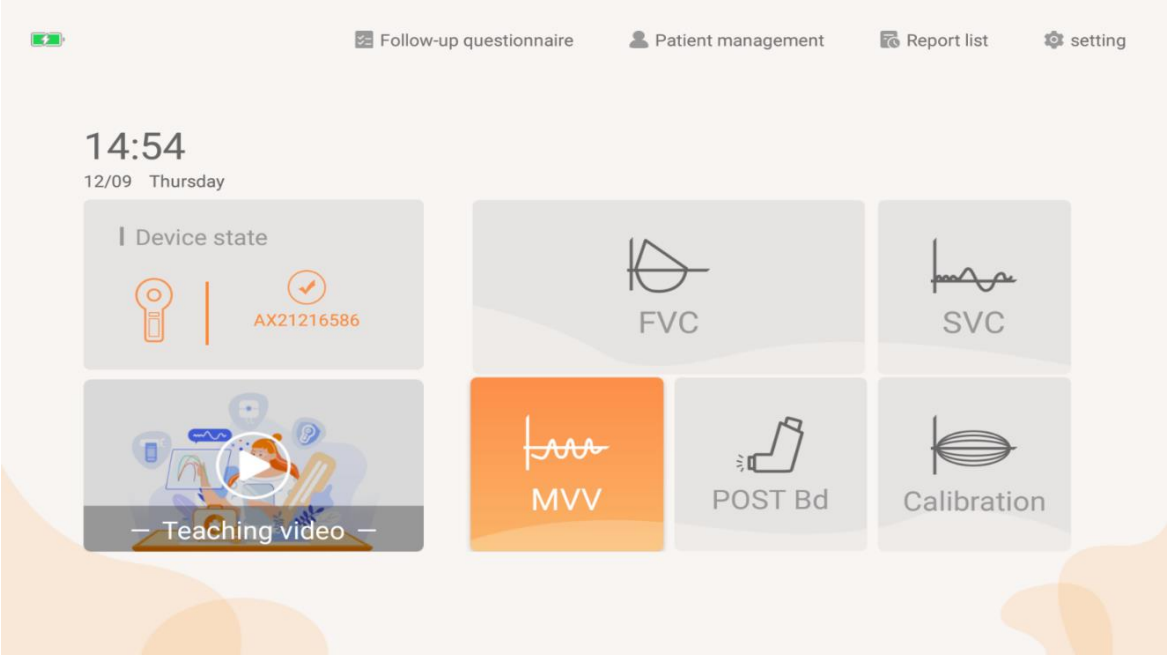


Figure 13 Measurement mode selection interface

Select or create the patient to be tested, manually select the "MVV" mode, and automatically load the patient's actual measurement record (if the patient has not been tested, it will be blank);

Test items-MVV, VT MVV, BF MVV, TIME MVV indicators;

Actual measurement chart - are volume - Time V (L) -T (s) graph, based on the measurement guidance text, quiet breathing 4 after time, the original point of the horizontal line appears moisture baseline respiration can be carried out the next step. After the actual measurement, the MVV curve can be obtained, the left side is the inspiratory accumulation value of the test patient, and the right side is the test inspiratory and blowing status display of the test patient; The operator can choose to display or suppress the measured value curve.

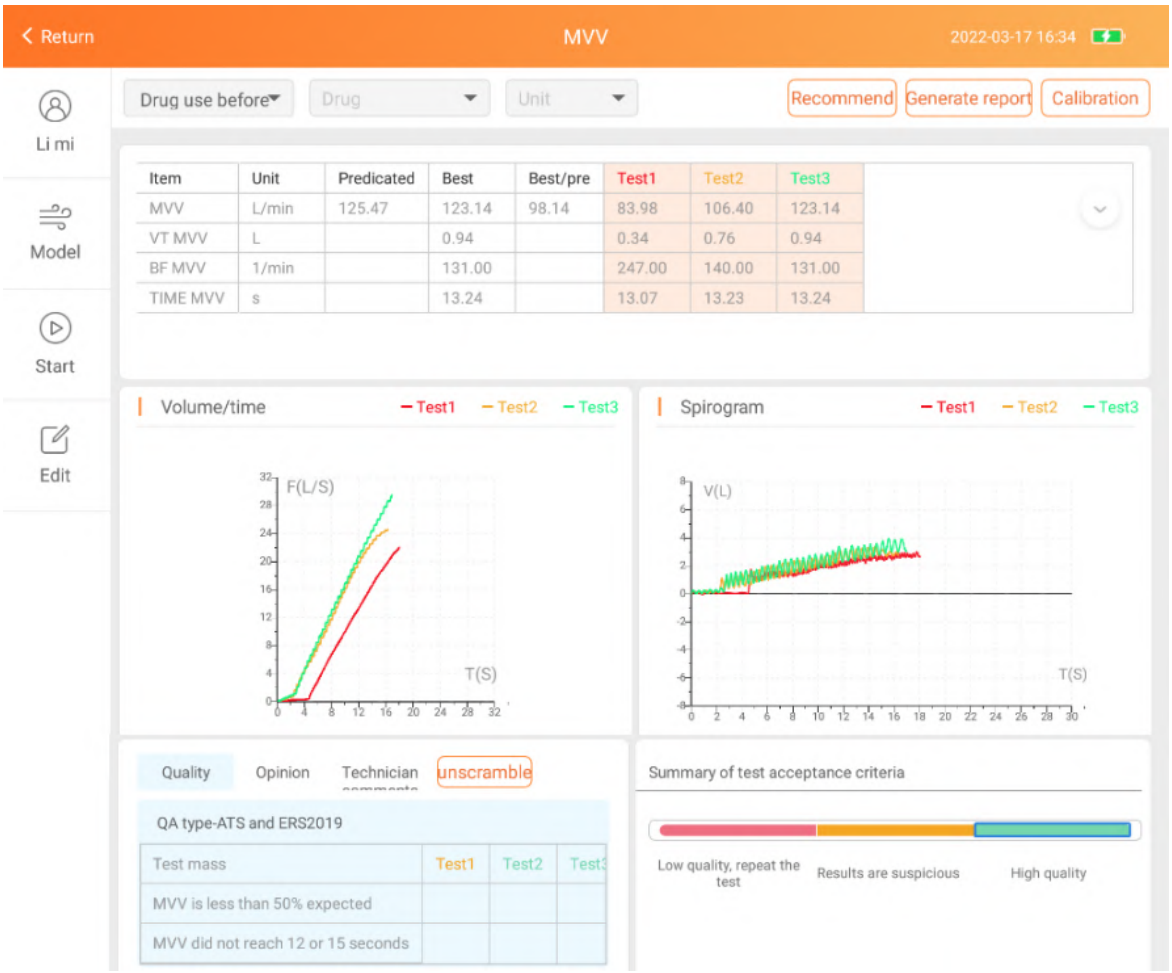


Figure 14 MVV measurement results interface

6.5.1 Operation steps

1) Subject takes a standing or sitting position, clamps the nose clip, and connects the mouthpiece to the device, and breathes calmly for 4 to 5 times. After the exhalation is stable, continue to breathe for 12 or 15 seconds at the maximum breathing amplitude and maximum speed.

   ⚠ Caution:

   The user purchases a nose clip, which must be a legally marketed product registered by the FDA.

2) The whole inspection process, the subjects can obtain the best cooperation according to the timely instructions and continuous guidance issued by the technician. Repeat the second and third tests after rest of 5 to 10 minutes.

3) Each time the patient completes a set of measured values, the monitoring page will prompt whether the measured results are acceptable. Such as ticking is acceptable, you can click "end" to end this test and save the data. Such as the cross is an unacceptable result and the reason is prompted, you can click "New Test" to start a test.

4) Report preview and printing: When the MVV test is completed, the actual measurement record quality control meets the requirements, click the "Preview Report " button to enter the report preview function page. After selecting the report template, the MVV index will be displayed in the report index area and the volume - time chart of the MVV test will be displayed in the graph area ;

5) Maximal voluntary ventilation (MVV) program is finished, Please choose whether to continue the test in other modes according to the actual situation.

6) After the maximal voluntary ventilation test (MVV) measurement is over, please choose whether to proceed with other mode tests according to the actual situation.

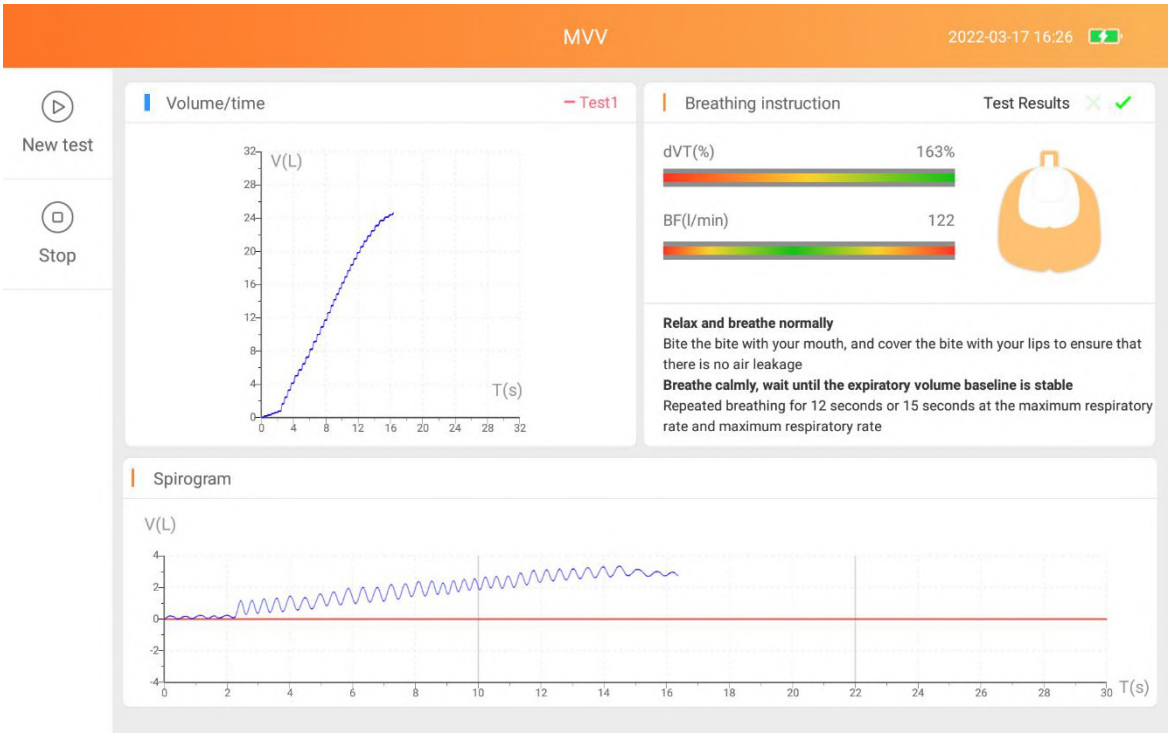


Figure 15 MVV single measurement interface

6.5.2 Report preview

Click the "Preview" button to automatically jump to the "MVV report" interface, as follows:

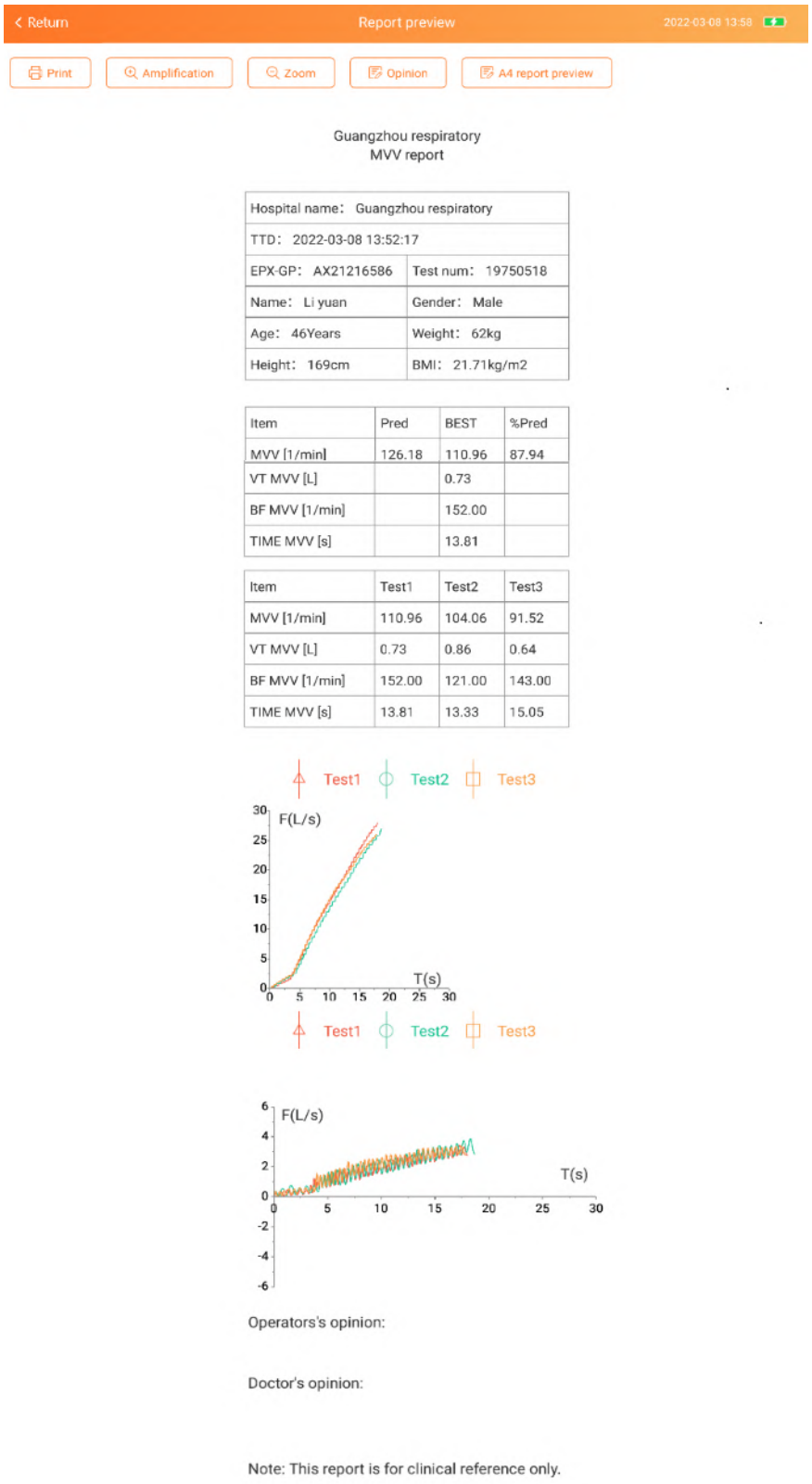


Figure16 MVV report interface

6.6 Slow vital capacity test procedure

Choose slow vital capacity test (SVC) to start the test.

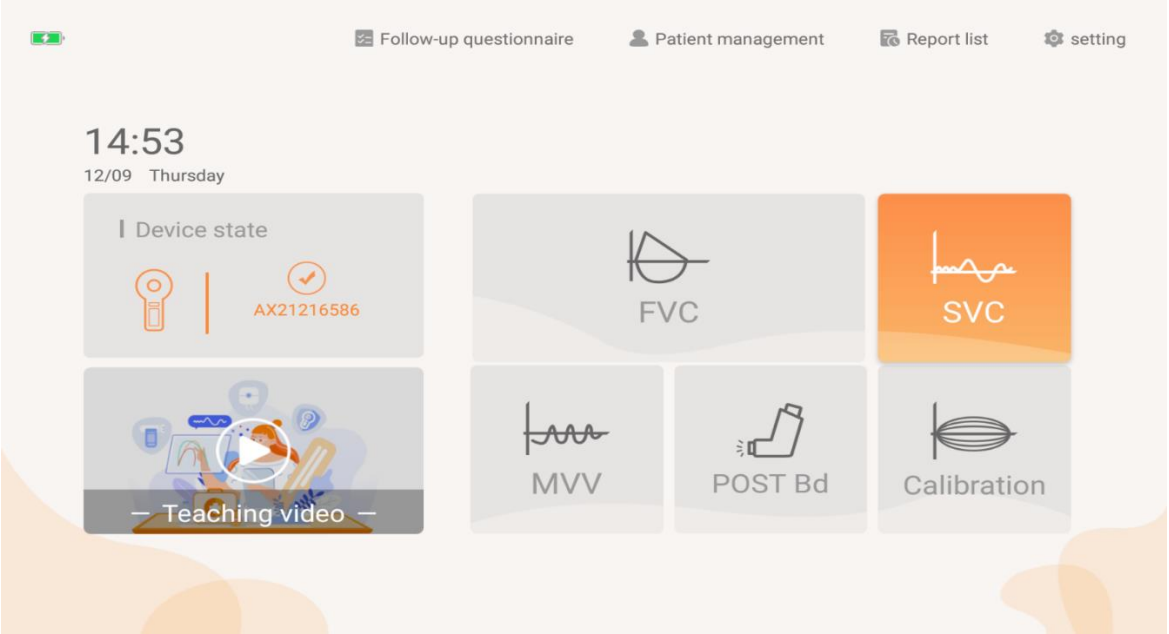


Figure 17 Measurement mode selection interface

6.6.1 Function description

Select or create the patient to be tested, manually select the "SVC" (before medication) mode, and automatically load the patient's actual measurement record (if the patient has not been tested, it will be blank) , and the static pulmonary function test is currently completed ;

Test items-VC, VT, IRV and other items are used as the measured indicators of the SVC test mode of the tested patient;

Measured value graph-the volume-time V(L)-T(s) graph on the left will splice the measured waveforms together, and the volume-time V(L)-T(s) graph on the right will show the measured vital capacity and VT of each group tide histogram; you can choose to display or cancel the actual measurement graph.

Select the " SVC (before medication)" mode, click "Start" to start the test, and click "End" to end the test.

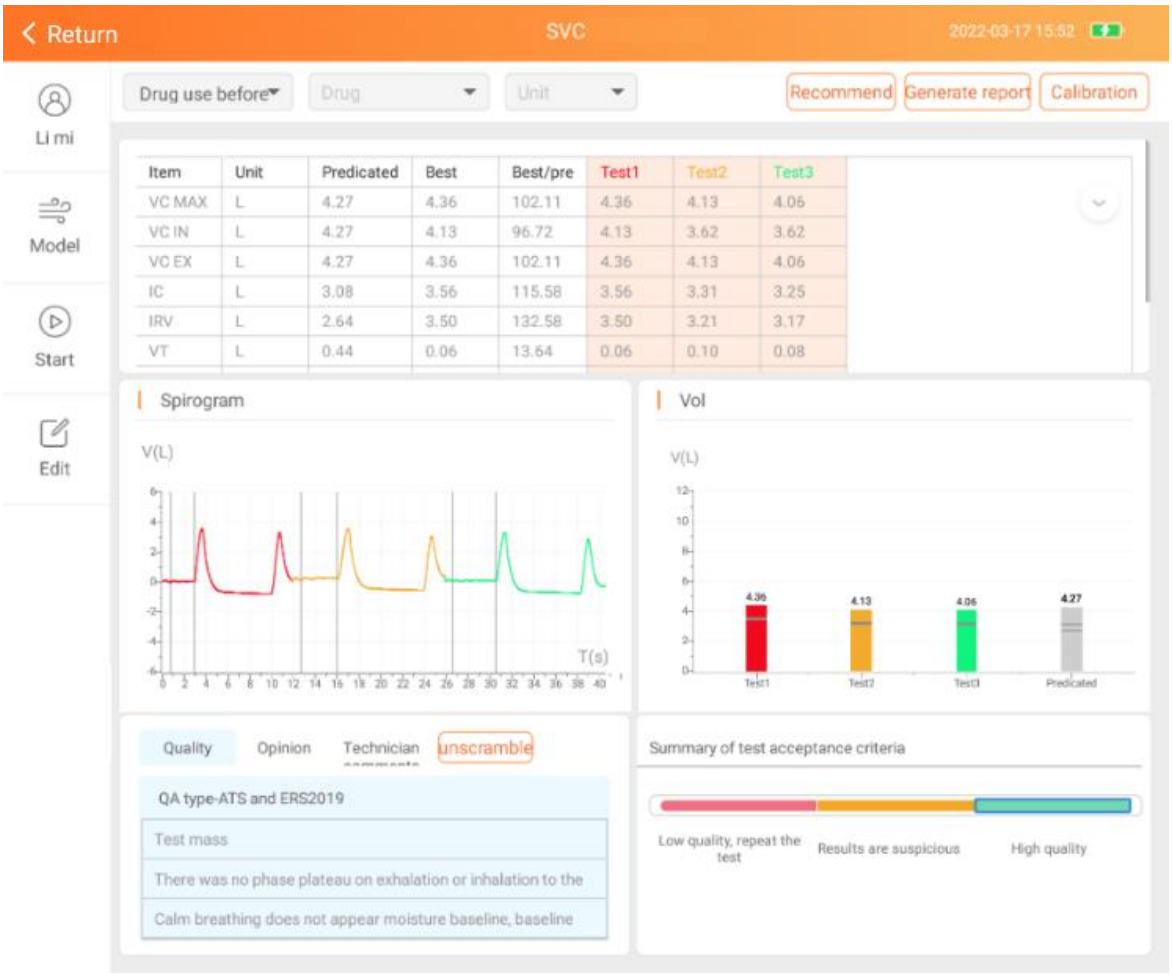


Figure 18 SVC measurement result interface

6.6.2 Operation steps

1) Connect the mouthpiece to the mouth, wrap the mouthpiece tightly with your lips, and clamp the nose clip to ensure that the mouth and nose do not leak. If some patients cannot guarantee that the corners of the mouth will not leak air, a special mouthpiece with lip and tooth cover can be added.

   ⚠ Caution:

   The user purchases a detachable mouthpiece and a disposable pulmonary function meter filter, which must be a legally marketed product registered by the FDA.

   Mouthpiece specifications: inner diameter 30mm, outer diameter 32-34mm, height 50mm-120mm.

   Specification of disposable pulmonary function meter filter: inner diameter 1=30mm.

2) Clamp the nose clip, connect the mouthpiece, and breathe calmly for 4-5 times. After

the breathing is stable, inhale as much as possible at the end of the expiration at a moderate speed (total lung volume), and then exhale to the end completely.

⚠ Caution:

The user purchases a nose clip, which must be a legally marketed product registered by the FDA.

3) Repeat the above steps to check more than 3-5 times, and rest for more than 1 minute between 2 times.

4) When completion of the blow 3 times after the actual measurement, the system automatically obtains the repeatable quality level according to the quality control standard, if there is a low-quality measurement record that is unacceptable for a single operation, you can click to select the actual measurement record to delete it.

5) At the end of the preview report, the operator can use a local printer that has been successfully connected and print the patient report at the default A4 paper size.

6) Slow vital capacity test program (SVC) measurement is over, please choose whether to continue other mode tests according to the actual situation.

Figure 19 SVC single measurement interface

6.6.3 Report preview

Click the "Preview" button to automatically jump to the "SVC report" interface, as follows:

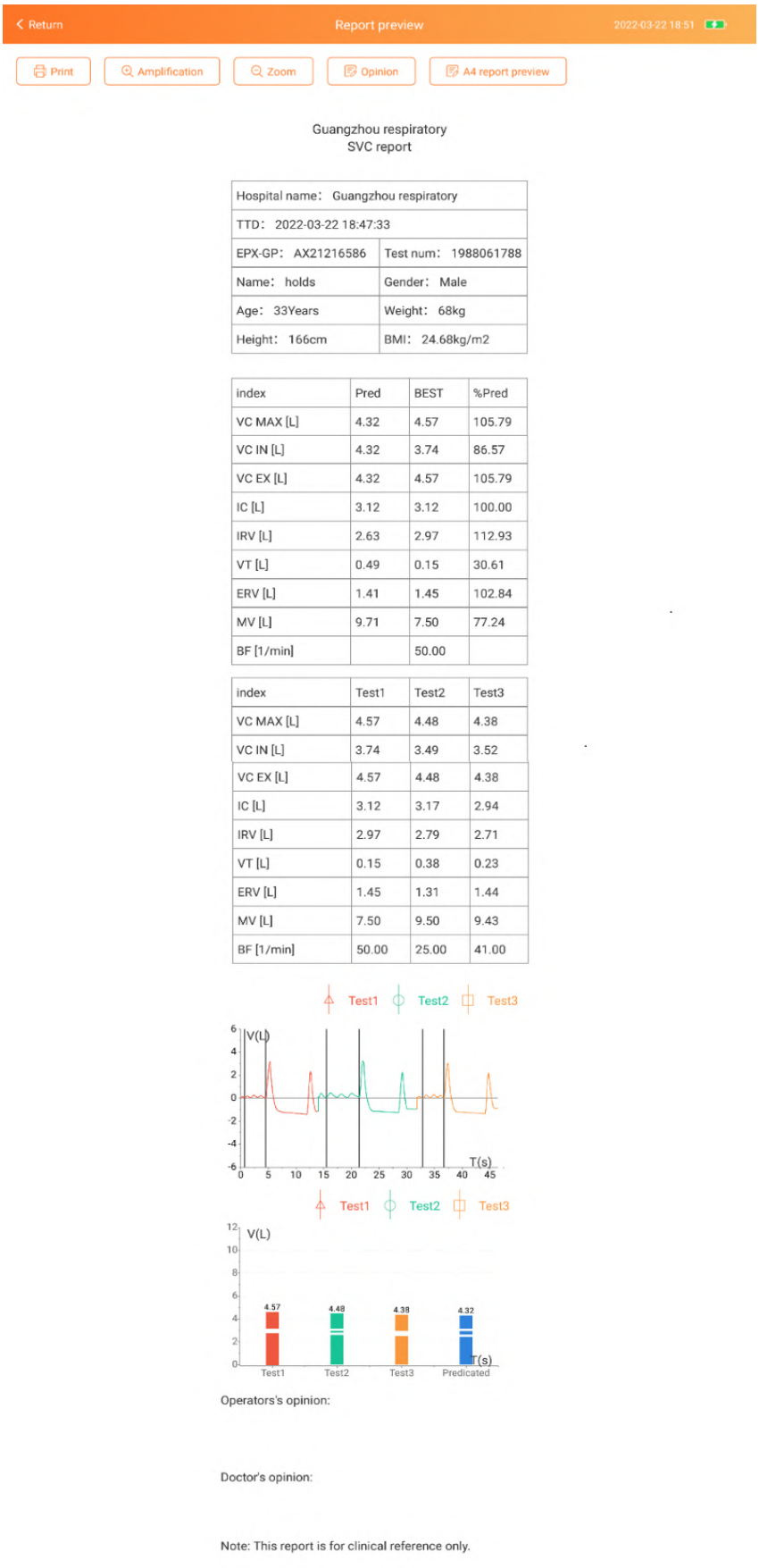


Figure20 SVC report interface

6.7 Bronchial diastolic test procedure

Select the POST Bd on the homepage and prepare to start the test. For the specific test, refer to the forced vital capacity test procedure. The diastolic test requires a forced vital capacity test before and after the medication. After completion, a bronchodilation report can be generated.

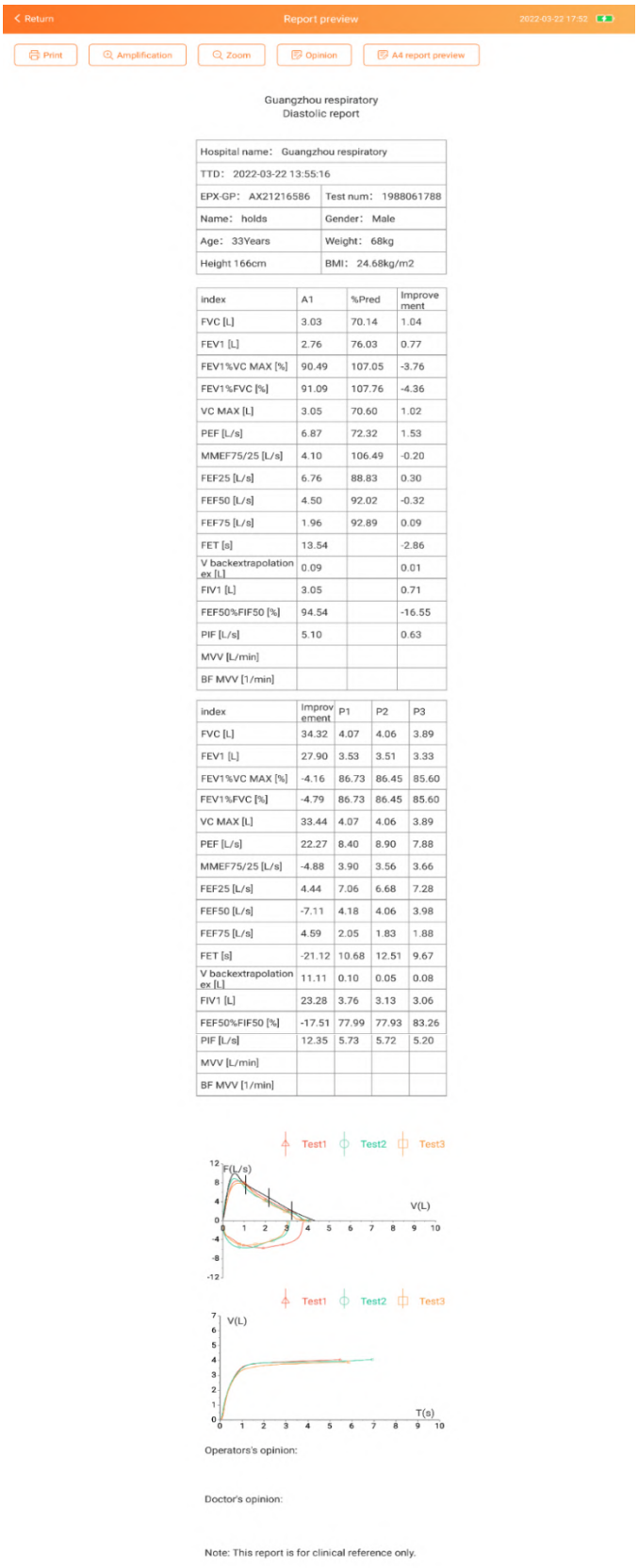


Figure21 POST Bd report interface

6.8 Data management

6.8.1 Patient management

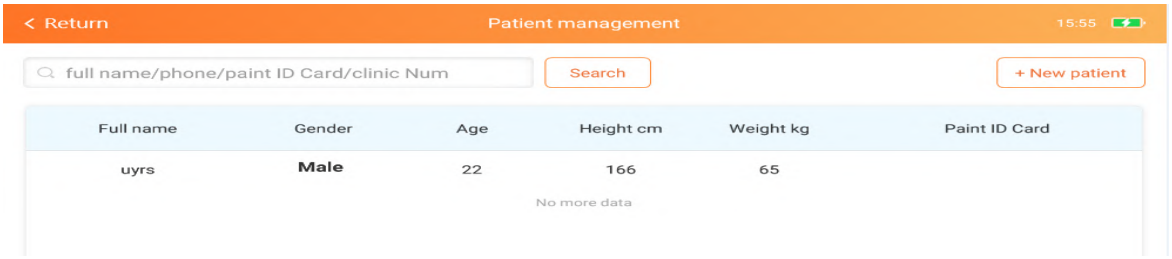


Figure 21 Patient management interface

Click the new patient button to add patients; Click the patient record in the patient list to enter the patient details page, where you can view the patient's detailed information and measurement record. At the same time, edit and delete the patient information.

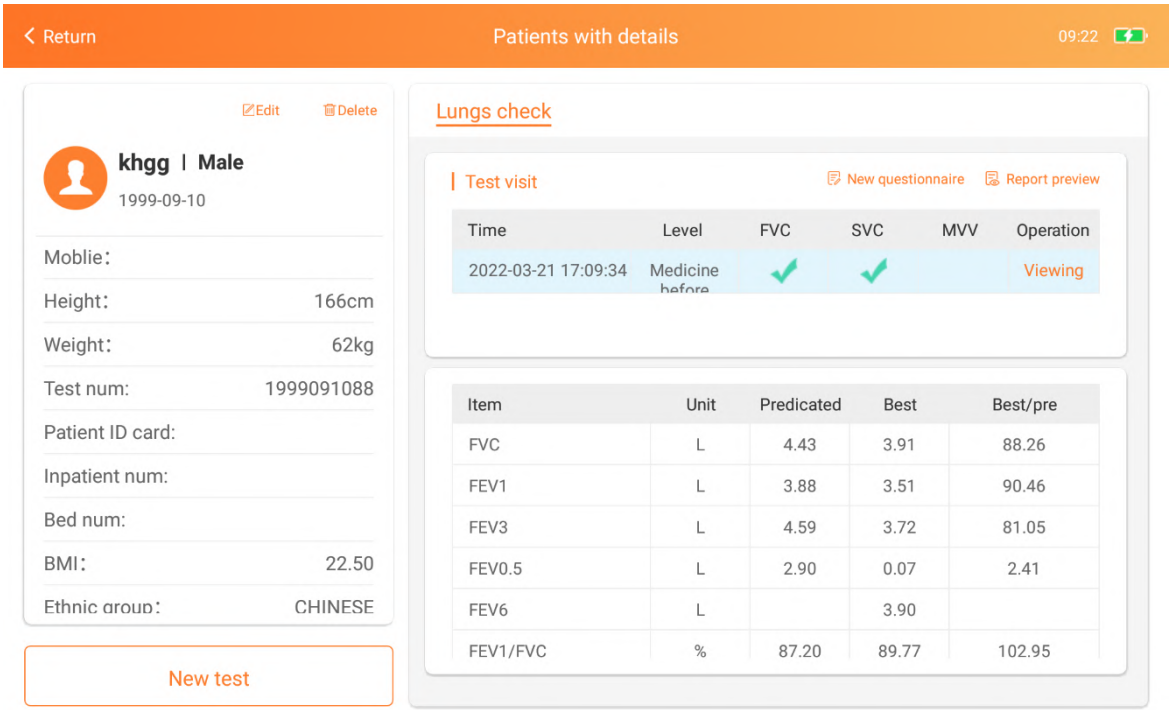


Figure 22 Patient information view interface

6.8.2 New patient

Click "+New Patient " and fill in the patient information according to the facts (items with * are required).

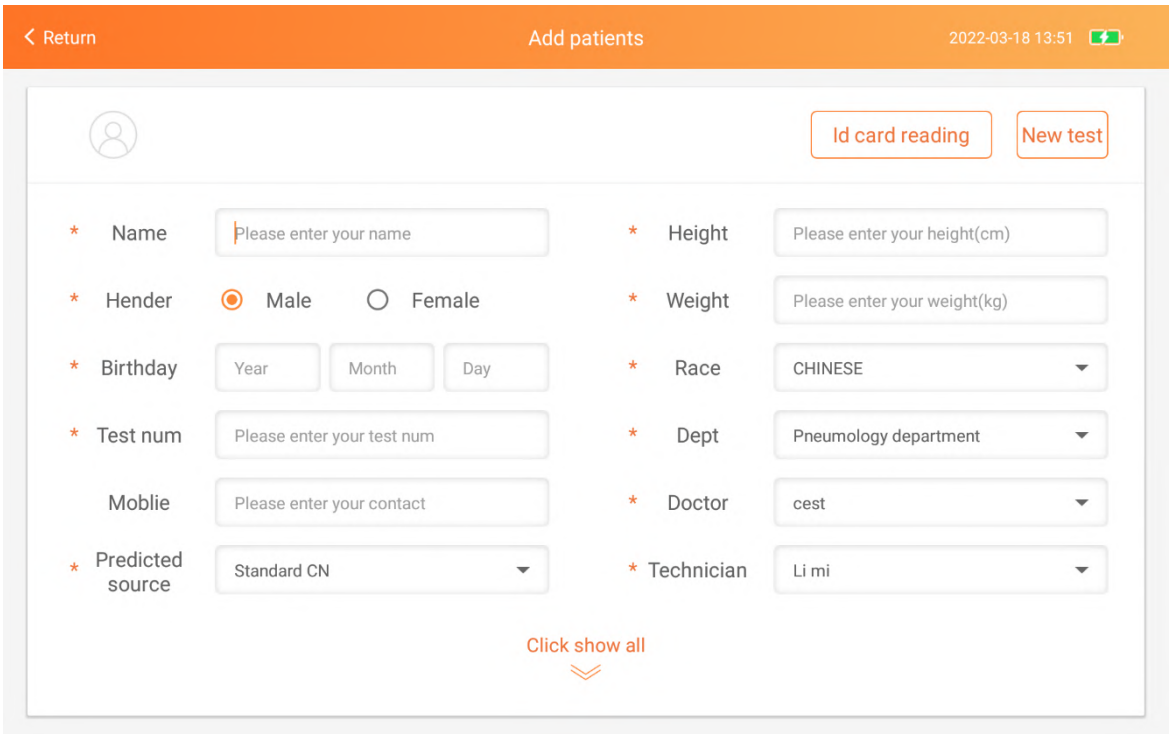


Figure 23 New patient interface①

Id card reading：Click the "ID card reader" button, place the ID card correctly, read the information successfully, automatically fill the information obtained by the card reader into the create patient popup, click the "Next" button to complete the patient creation

New test：After filling in the patient information, click "Next" button to enter the measurement page.

Click "click show all" to display patient details

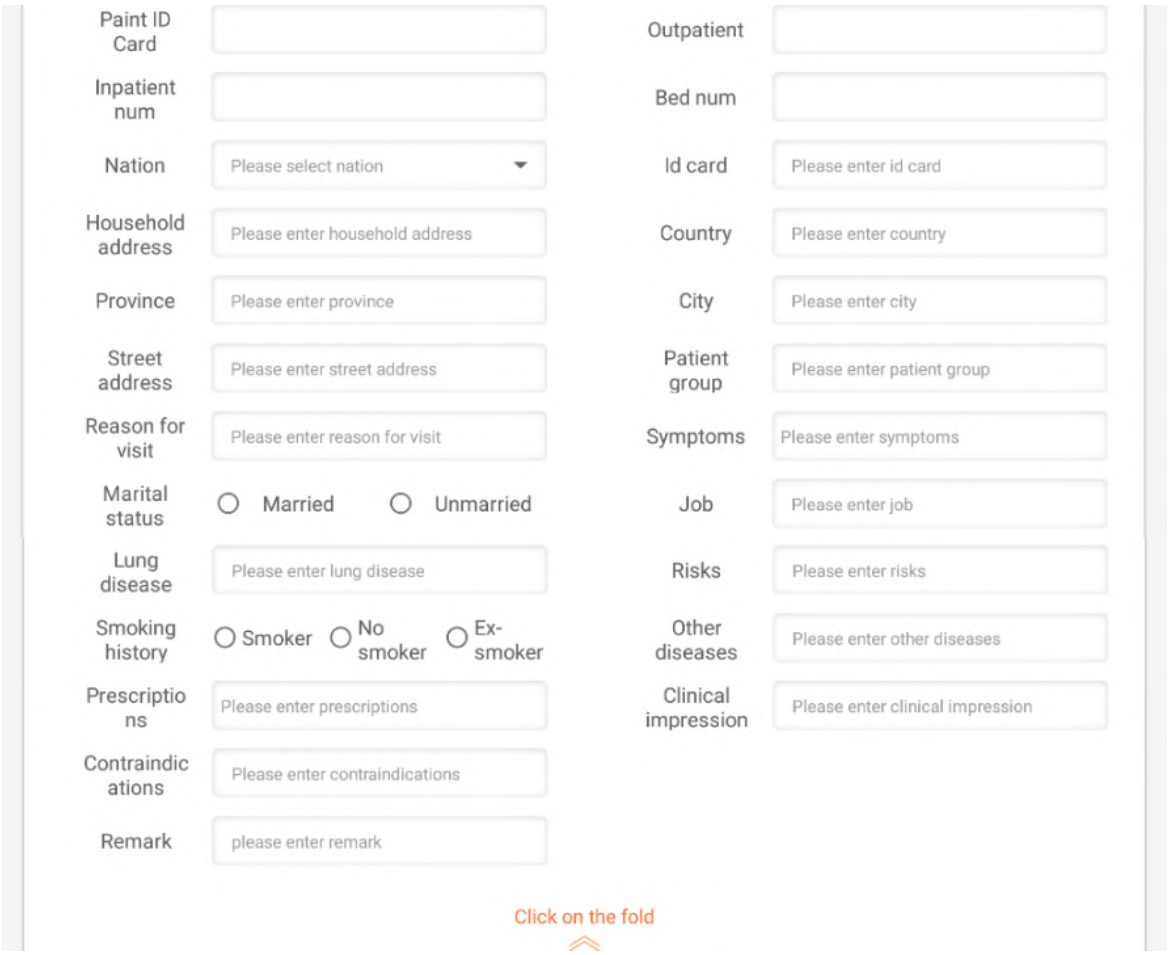


Figure 24 New Patient Interface②

After filling in the new patient information, click the "New test" button to return to the patient management page, and the new patient information appears on the patient management page.

6.8.3 Edit patients

Select any patient information in the patient list on the patient management page to enter the patient details page. Click the "Edit" button to enter the patient editing page.

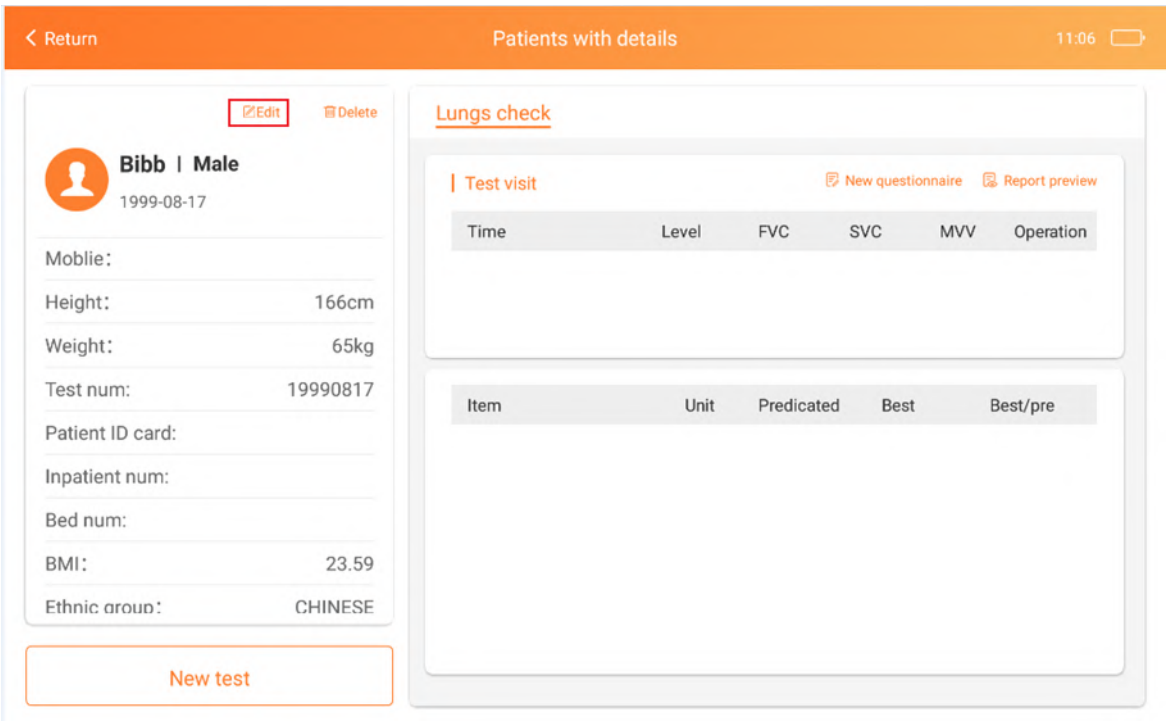


Figure 25 Patient information Interface

Enter the patient editing page：

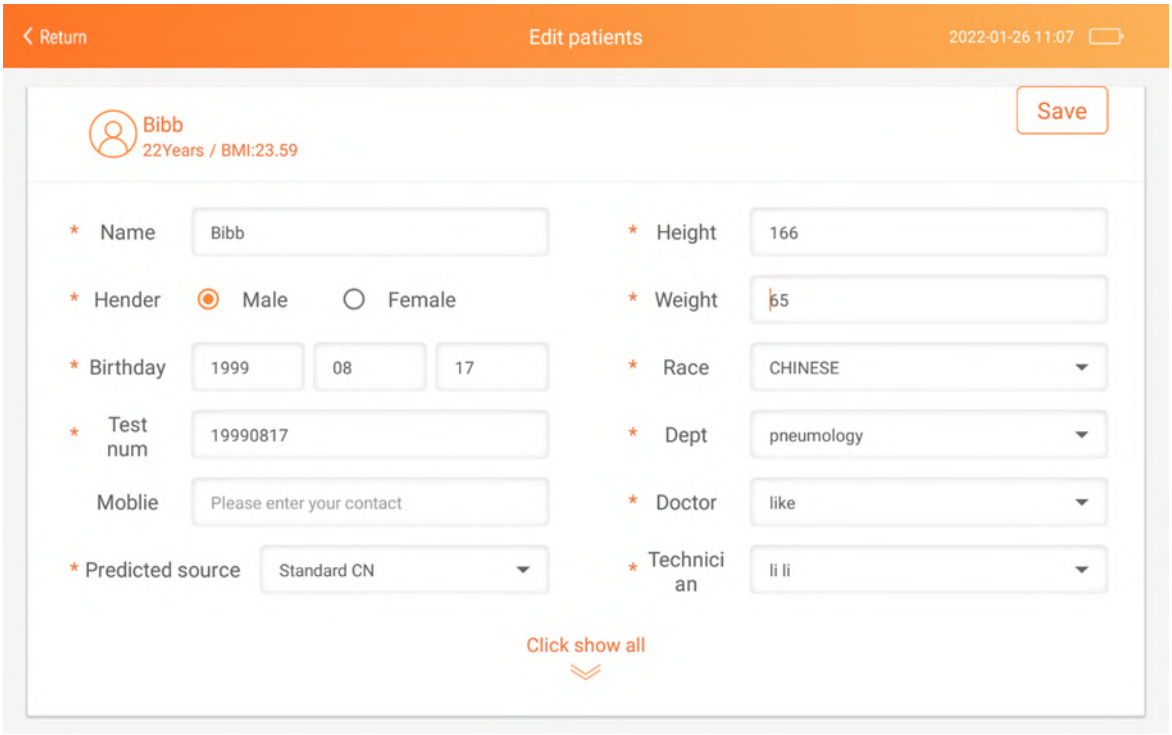


Figure 26 Patient edit Interface

Clicking Save will display the created test patient information.

6.8.3 Delete patient

Click "Delete", it will prompt whether to delete patient information.

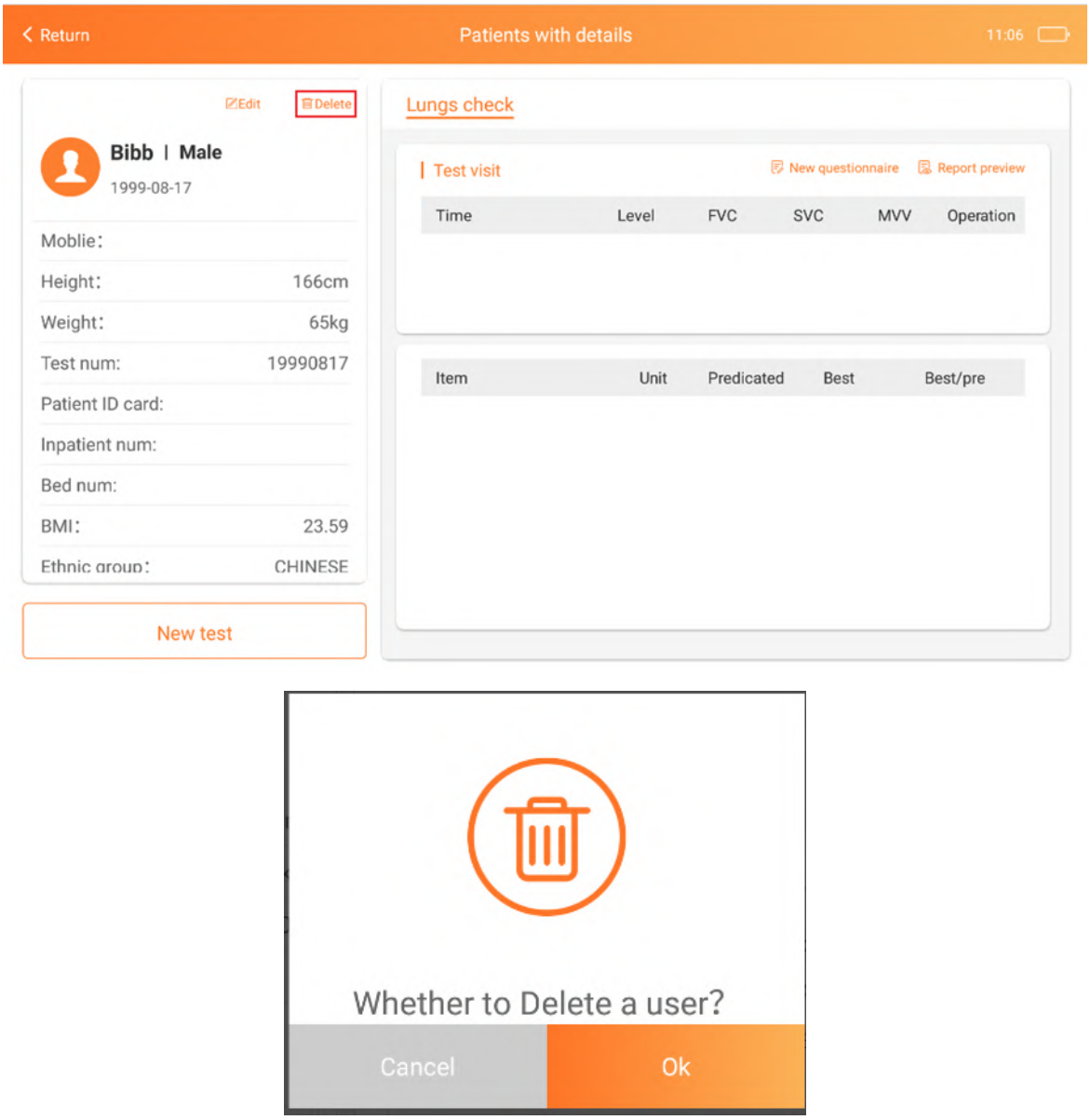


Figure 27 Deleting the patient prompt interface

6.9 Report management

On this page, you can view generated reports. Click upload report to synchronize the unuploaded reports to the computer software. The computer software can view and browse the report.

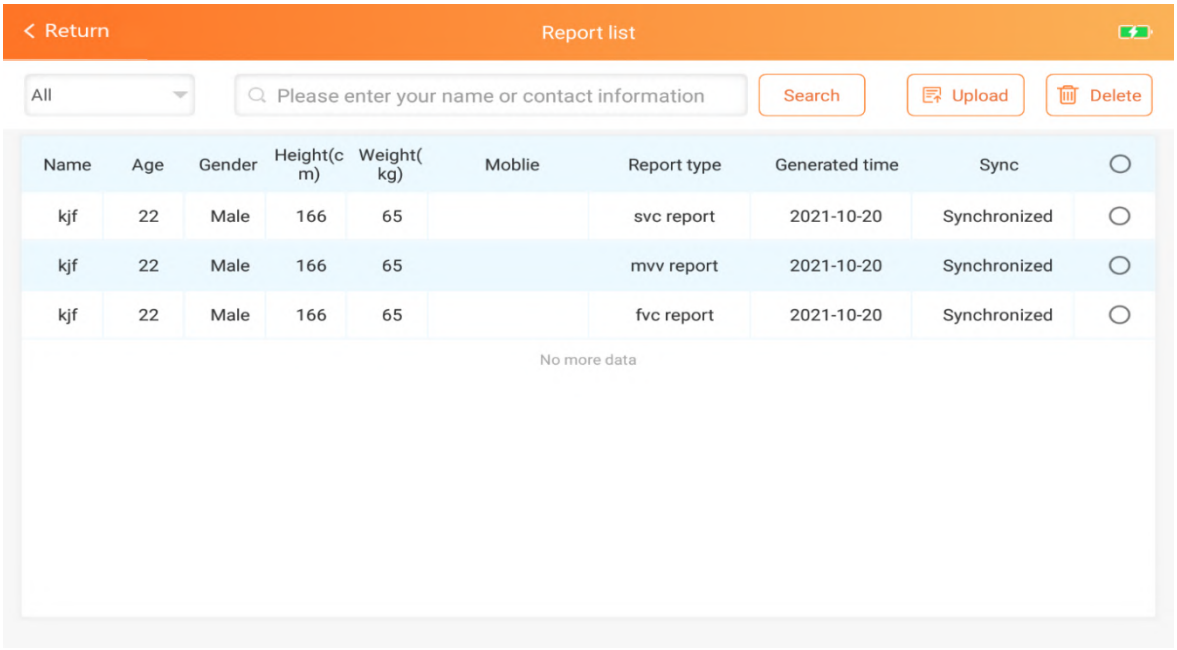


Figure 28 Report management interface

6.10 System settings

System settings are divided into system settings and pulmonary function settings.

1) System settings include account management, hospital Setting, server address, sound/brightness, and updates.

⑴Account manage

Click the "EN /EN" button to switch between Chinese and English.

Click the "Log out" button to log out of the current account.

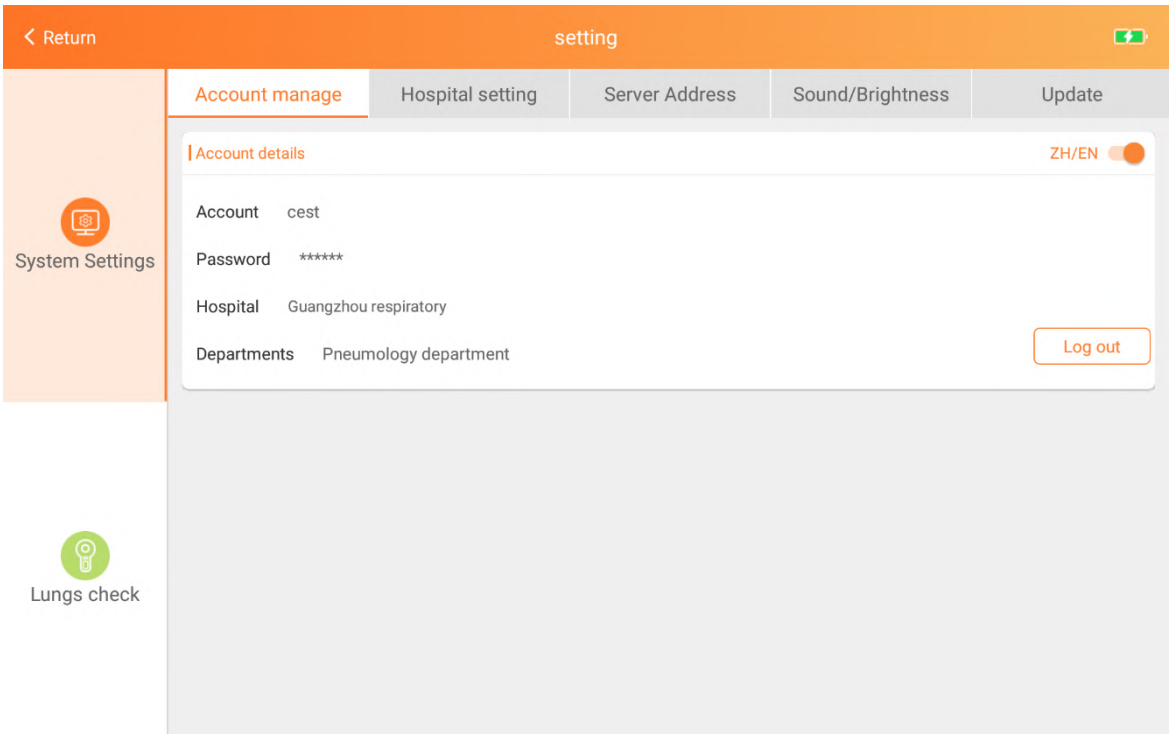


Figure 29 Account manage interface

②Hospital Setting

Edit: Edits hospital information

Add hospital: Add hospital information. Note: The new hospital information will replace the original hospital information.

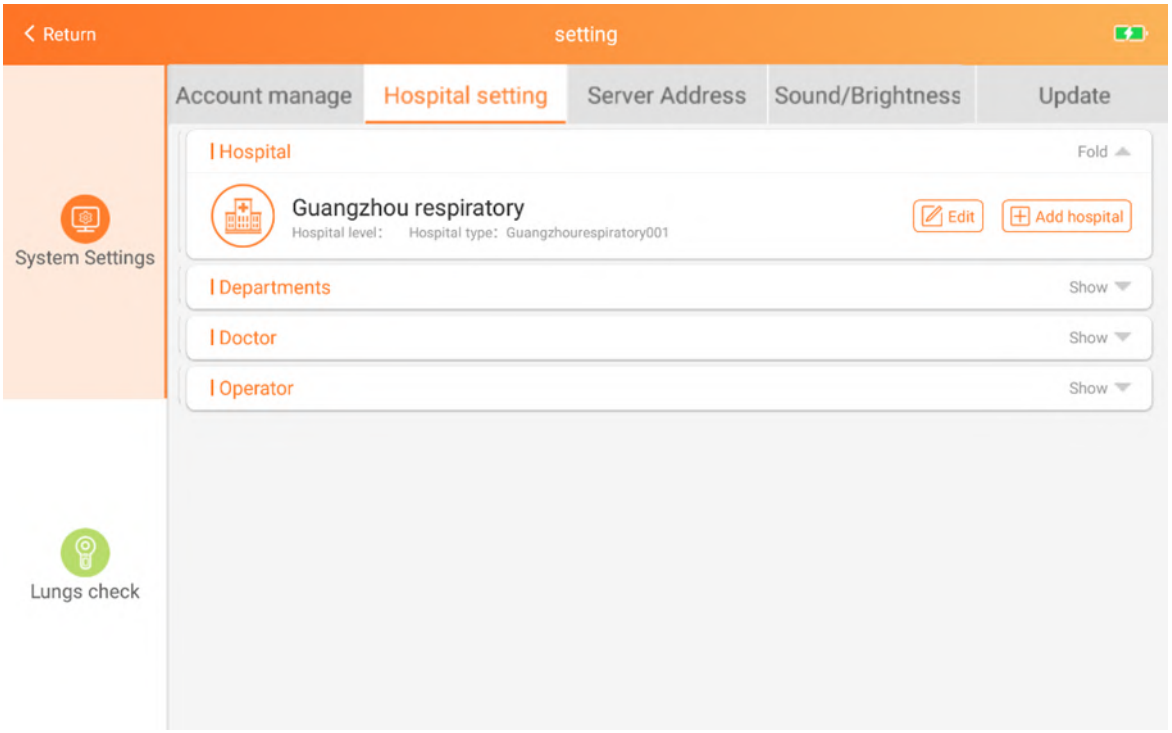


Figure 30 Hospital setting interface①

Select departments, doctors, operators and other options to display the information of departments, doctors, and operators of the current hospital, and add, modify, and delete them.

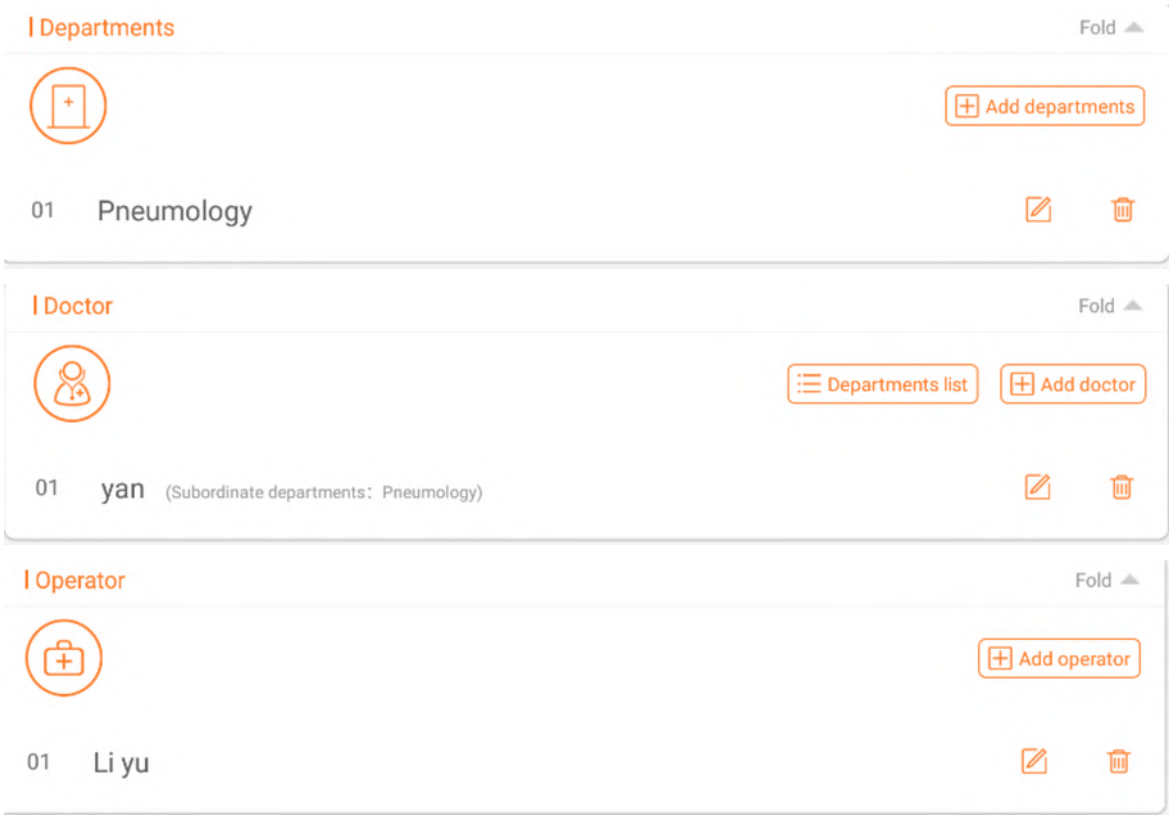


Figure 31 Hospital setting interface②

③Server address

It is used to manage server addresses. If you select the server address below the URL, the server address will be automatically added to the URL. Click “Save”. After saving the address, the login will be automatically logged out and you need to log in again.

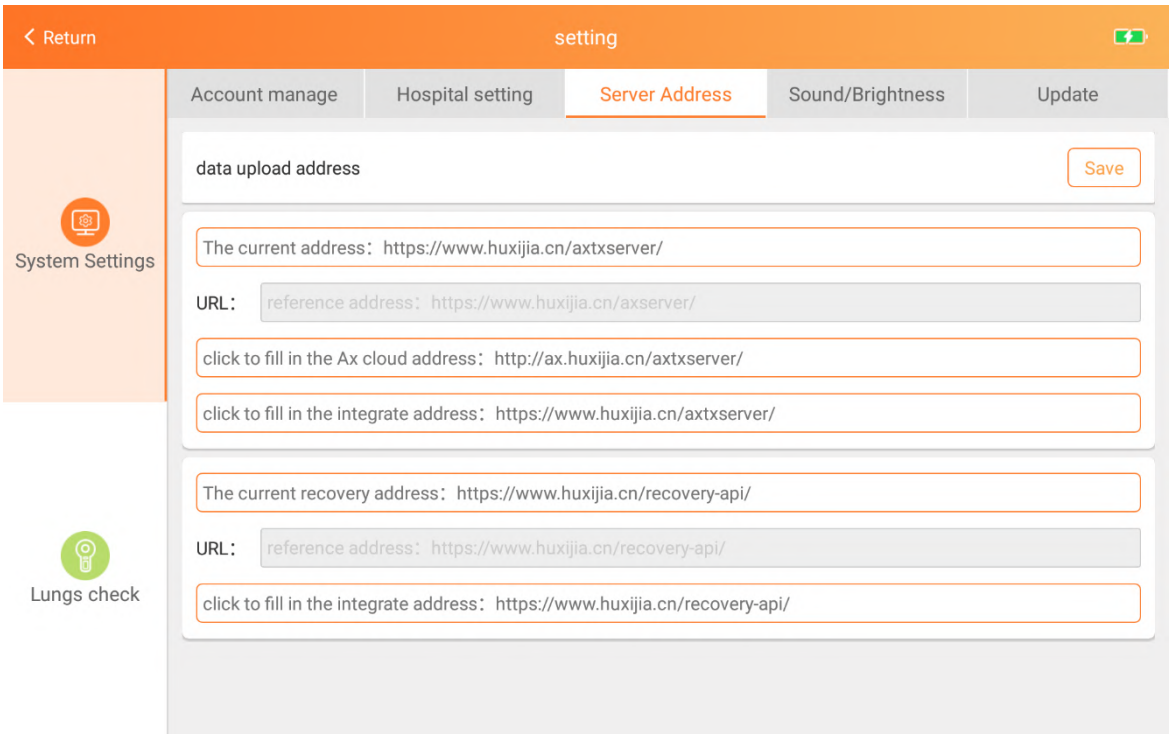


Figure 32 Server Address interface

④Sound/Brightness

Adjust sound/brightness

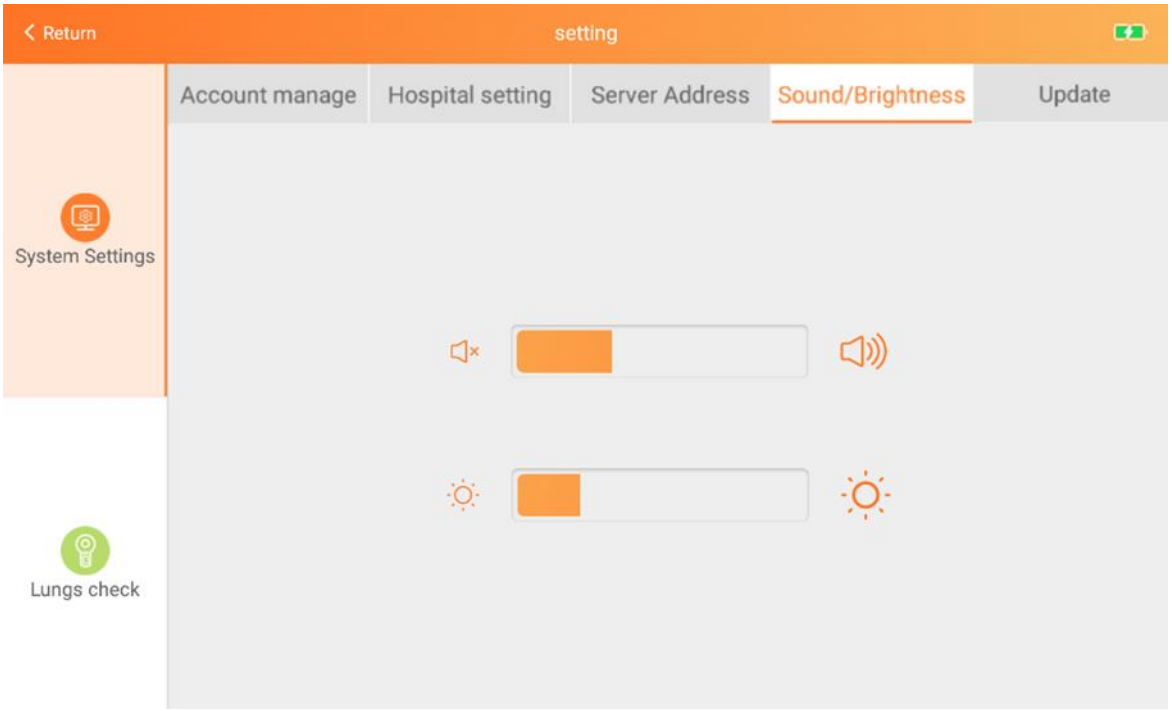


Figure 33 Sound/Brightness interface

⑤Update

The software upgrade module is to check the version. If the testing software is upgraded, contact your local agent.

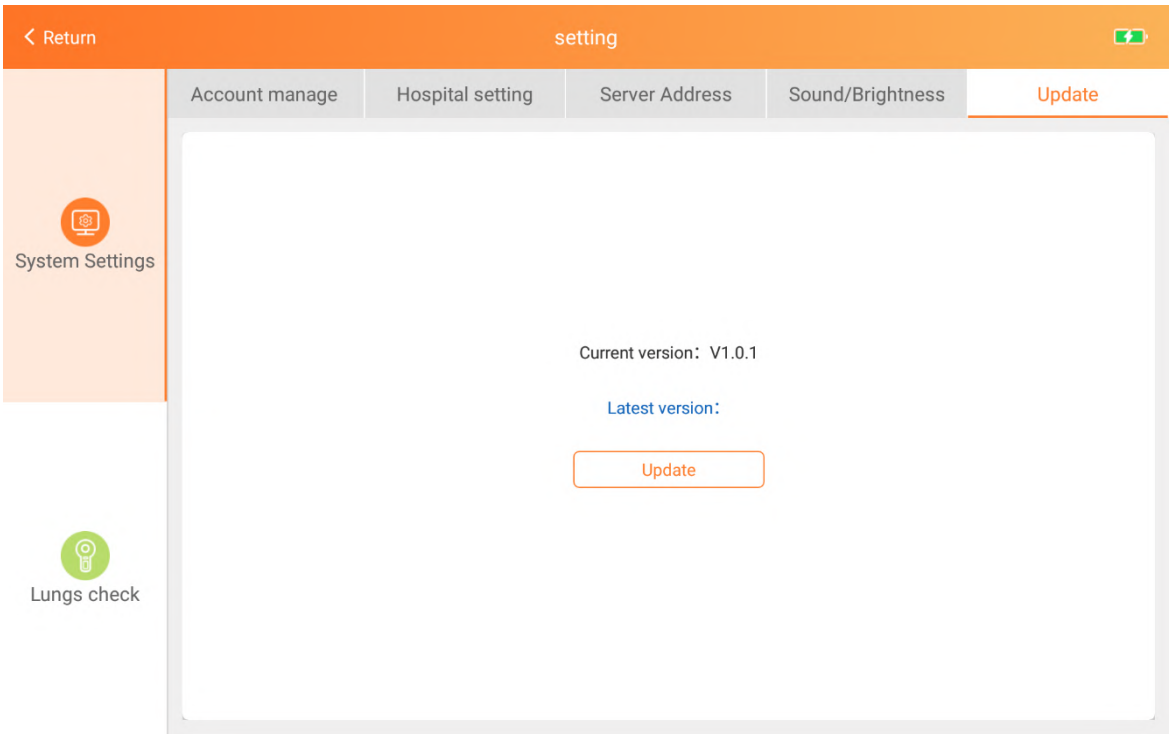


Figure 34 Update interface

2) The pulmonary function settings include report setting, medicine setting, parameter setting and question setting.

①Report setting

Predicted source: Select a mode from the drop-down list box to switch the expected value mode.

Report subtitle: Click the edit button at the bottom right of the subtitle bar to enter the edit box and edit the report subtitle.

Report mode: Click the edit button on the right to display and hide the report indicators in the mode.

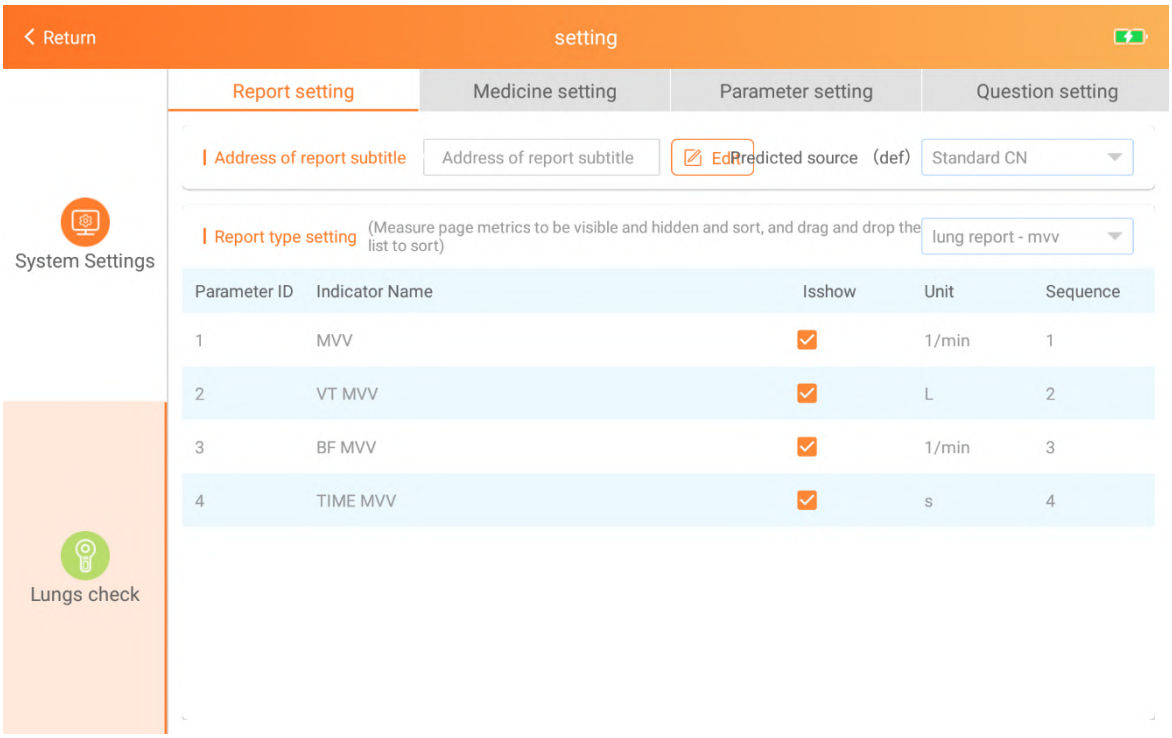


Figure 35 Report setting interface

②Medicine setting

Drug search: click the search button to search for drugs according to the drug category and drug name in the drop-down box

Add medicine: click "New" button to enter the popup window of add medicine for adding the medicine

Drug information editing: Click the edit button in the drug list to modify the drug information

Delete drug: Click the delete button in the drug list to delete the drug.

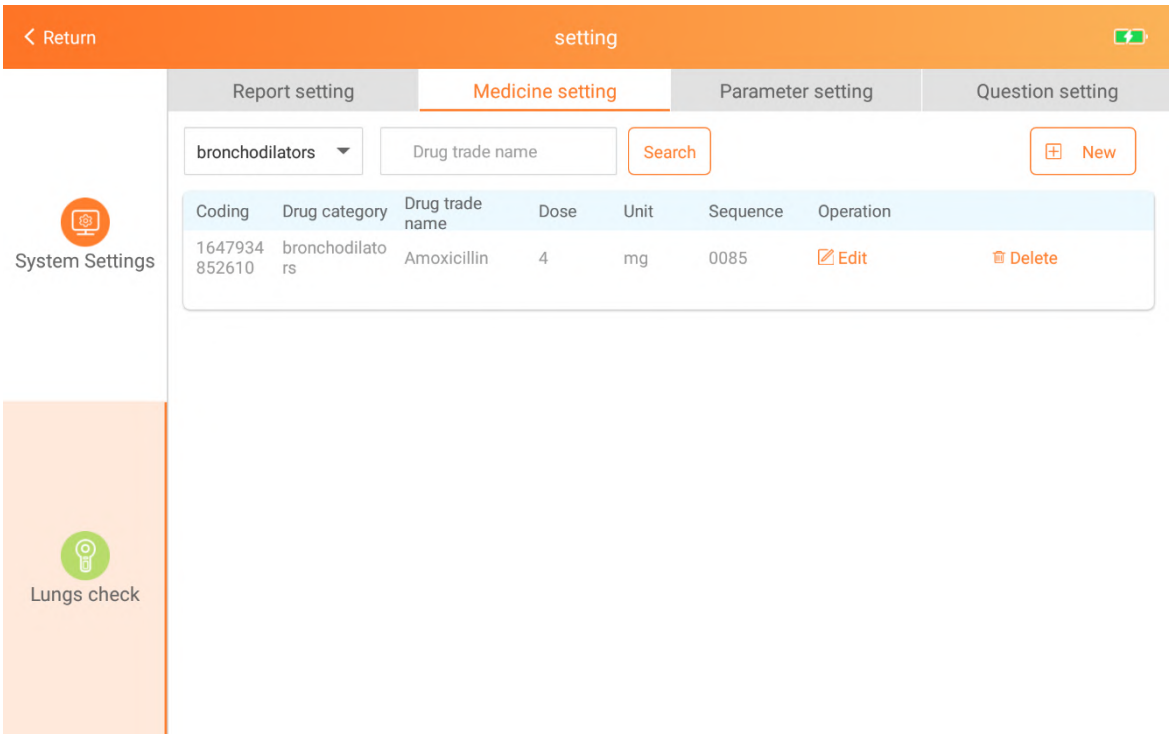


Figure 36 Medicine setting interface

③Parameter setting.

Report setting: Click the drop-down box to switch measurement mode, mode switch, and the parameter list below follows the switch.

Parameter list operation: display and hide parameters when changing measurement mode.

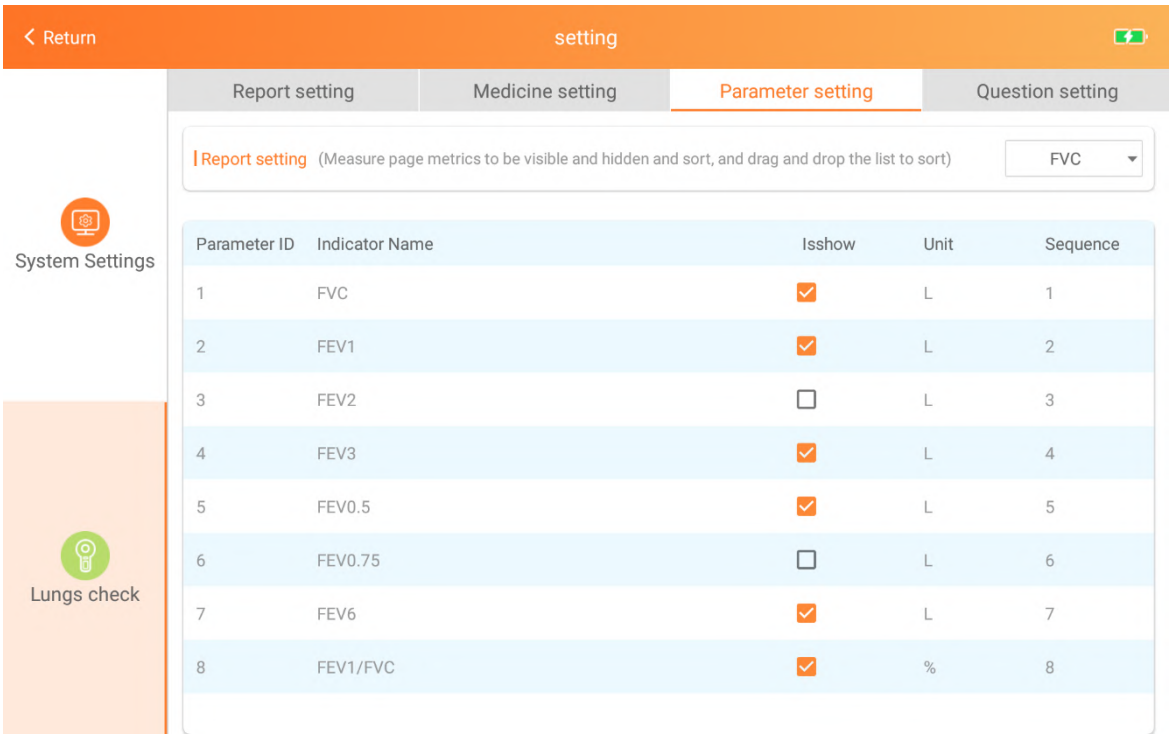


Figure37 Parameter setting interface

④Questionnaire setting

Select the type of the poll to control the type of the new poll displayed or hidden.

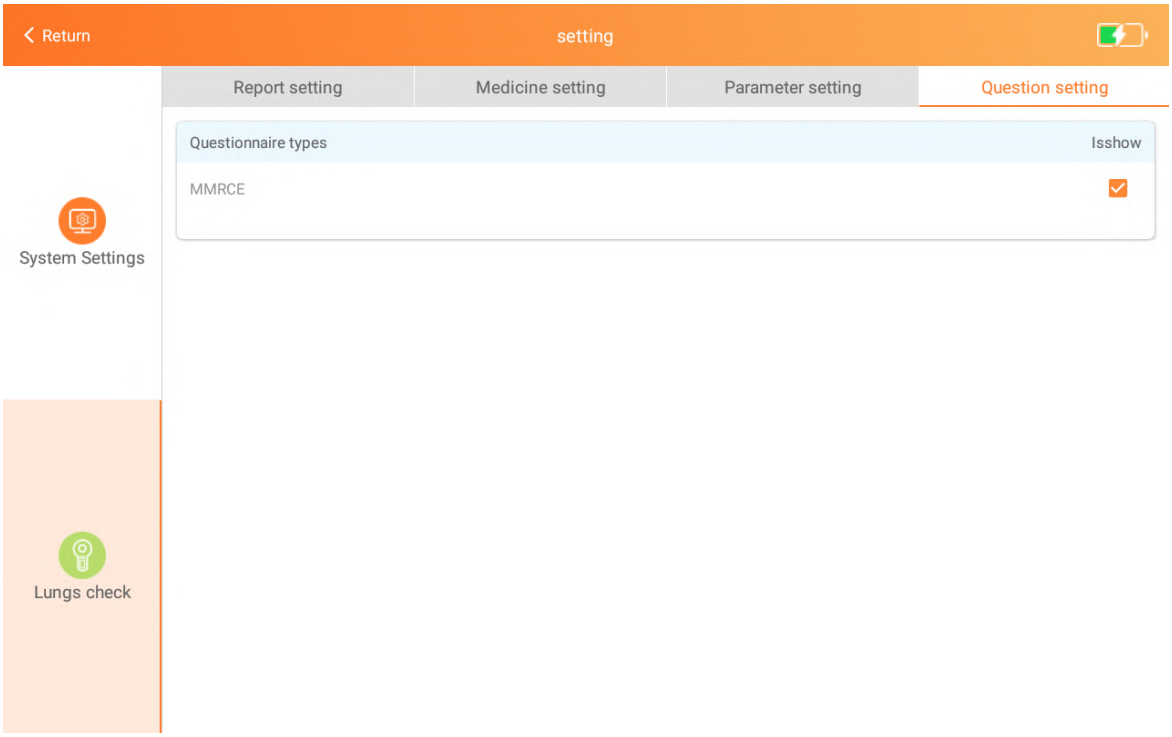


Figure38 Questionnaire setting interface

Chapter 7 Maintenance and precautions

7.1 Overview

In order to give full play to the performance of this software, ensure its reliability, and prolong its service life, please maintain, and maintain it strictly in accordance with the requirements of this chapter.

7.2 Routine maintenance method

Such as occurs when the software failed to start, run-time error, etc., should stop using, and contact Guangzhou Homesun Medical Technology Co., Ltd., or local agents.

7.3 Daily use precautions

■ Do not copy the software to other machines for installation and use without the written authorization of the manufacturer or its sales representative.

■ Before using the software, please read the " user manual" of this product carefully, and use it by trained and qualified personnel.

7.4 Quality control

It is only used by authorized personnel trained by Guangzhou Homesun Medical Technology Co., Ltd., or its agents, otherwise the test results may be adversely affected.

Chapter 8 Failure analysis and treatment

8.1 Overview

This chapter introduces the handling methods and steps of common software failures. If you still cannot eliminate the failure according to the work instructions in this chapter or need more and more detailed information, please contact Homesun 's after-sales service department.

CAUTION

This manual is not equivalent to the maintenance manual. It only provides the measures that the operator should take when the analyzer has a fault alarm.

8.2 Simple troubleshooting

After the following malfunctions occur in the software, the troubleshooting methods in the following table should be used to solve them. If you can not solve or cause other problems now like, please do not resolve itself, please contact with us.

Summary of daily software failure analysis and handling

Failure phenomenon	**Cause Analysis**	**Method of exclusion**
The software does not start normally	Operating environment hardware does not support	Replace the hardware environment
No response after software button is clicked	The software is abnormal or the program file is damaged	Contact after-sales service personnel for maintenance
Other failures	When other failures occur	Please contact the after-sales service

Chapter 9 Electromagnetic compatibility statement

9.1 Parameter description

Name	Working frequency	Modulation type	Maximum Tune-up power(dBm)
Bluetooth	2.4GHZISM BAND	GFSK	-3.00

Name	Cable length (m)	Whether to block	Remark
USB Cable	2.0	Yes	/

WARNING

Even if other equipment meets the emission requirements of the corresponding national standards, the equipment or system may still be interfered by other equipment.

9.2 EMC statement

1) Model A9 needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying document;

2) Portable and mobile RF communications equipment can affect model A9.

WARNING

1) Don’t be 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.

2) Use of accessories, transducers and cables other than those specified or provided by the manufacturer of Model A9 could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

3) Use of Model A9 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.

9.3 FCC declaration

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

⑴ This device may not cause harmful interference, and

⑵ This device must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for a Class A digital device,pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

9.3.1 FCC RF Radiation Exposure Statement:

1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

2. This equipment complies with RF radiation exposure limits set forth for an uncontrolled environment.

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

9.3.2 FCC Caution:

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

9.4 Declaration of conformity

Table 1

Guidance and manufactureŕs declaration – electromagnetic emission

The Pulmonary Function Tester（A9）is intended for use in the electromagnetic environment specified below. The customer or the user of Pulmonary Function Tester（A9）should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Pulmonary Function Tester（A9）uses RF energy only for its internal function. There for, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Pulmonary Function Tester（A9） is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations flicker emissions IEC 61000-3-3	Not applicable	

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity			
The Pulmonary Function Tester（A9） is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulmonary Function Tester（A9） should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment -guidance**
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	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge			Mains power quality should be

IEC 61000-4-5	± 1 kV differential mode ±2 kV common mode	± 1 kV differential mode ±2 kV common mode	that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle g) 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 g) 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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Pulmonary Function Tester（A9）requires continued operation during power mains interruptions, it is recommended that the Pulmonary Function Tester（A9）be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 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.			

Table 3

Guidance and manufactureŕs declaration – electromagnetic immunity			
The Pulmonary Function Tester（A9）is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulmonary Function Tester（A9）should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF	3 Vrms 150 kHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 3 V/m	3 Vrms 150 kHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Pulmonary Function Tester（A9）, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [\frac{12}{V_2}]\sqrt{P}$

IEC 61000-4-3	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)	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)	$d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 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 metres (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] 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 is affected by absorption and reflection from structures, objects and people.

[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

[b] 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 Pulmonary Function Tester（A9）is used exceeds the applicable RF compliance level above, the Pulmonary Function Tester（A9）should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Pulmonary Function Tester（A9）.

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

Table 4

Recommended separation distances between **portable and mobile RF communications equipment and the Pulmonary Function Tester（A9）**
The Pulmonary Function Tester（A9）is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Pulmonary Function Tester

(A9) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Pulmonary Function Tester (A9) as recommended below, according to the maximum output power of the communications equipment

Rated maximum output of transmitter W	**Separation distance according to frequency of transmitter m**			
	150 kHz to 80 MHz outside ISM and amateur radio bands $d = [\frac{3.5}{V_1}]\sqrt{P}$	150 kHz to 80 MHz in ISM and amateur radio bands $d = [\frac{12}{V_2}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.7 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.20	0.035	0.07
0.1	0.38	0.63	0.11	0.22
1	1.2	2.00	0.35	0.70
10	3.8	6.32	1.10	2.21
100	12	20.00	35	70

For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (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.

Annex 2

Product user manual

Pulmonary function tester computer software

Model: A9

Guangzhou Homesun Medical Technology Co., Ltd

Illustrate

Thank you for purchasing Homesun products.

Before using the product, please read the contents of this manual carefully so that you can use it correctly.

Please keep this instruction manual after reading it so that you can refer to it at any time when you need it.

Product name: Pulmonary Function Tester

Model: A9

Software release version: V1

Manufacturer name: Guangzhou Homesun Medical Technology Co., Ltd

Manufacturer residence / Production Address: Floor 7th, TianxiangBusiness Building, No.28, Li Fu Road, Haizhu District, Guangzhou, GD. China

Production date: See package label

Intellectual property

Statement

Under the condition that all the following requirements are met, Homesun Company believes that it should be responsible for the safety, reliability, and performance of the product, namely:

The assembly operation, expansion, re-adjustment, improvement, and maintenance are all carried out by professionals approved by Homesun;

The product operation is carried out in accordance with this instruction manual.

Warranty and repair service

The warranty period of the purchased product is subject to the sales contract.

The warranty period starts from the "Installation Date" filled in the "Equipment Warranty Card" attached to the product. The "Equipment Warranty Card" is the only proof for calculating the warranty period. In order to protect your rights and interests, please fill in the warranty card after the equipment is installed, and deliver the second copy of the warranty card ("Homesun Company ") to the installer or mail it back to Homesun 's customer service department.

Please note that the software will not be covered by the warranty in any of the following situations:

1) Customer fails to fill in and return the warranty card within 30 days after the installation and acceptance is completed;

2) The equipment serial number provided by the customer is incorrect.

During the warranty period, the product can enjoy free after-sales service; but please note that even if the product needs to be repaired due to the following reasons during the warranty period, Homesun will implement a fee-based repair service, and you will need to pay for the repair and accessories:

- Man-made damage;
- Improper use;
- Irresistible natural disasters;
- Repaired by personnel not authorized by Homesun;
- Other failures not caused by the product itself.

After the warranty period expires, Homesun can continue to provide chargeable maintenance services.

If you do not pay or delay paying the fee for the maintenance service fee, Homesun will temporarily suspend the maintenance service until you pay.

After-sales service unit

Unit name: Guangzhou Homesun Medical Technology Co., Ltd.

Address: Floor 7th, TianxiangBusiness Building, No.28, Li Fu Road, Haizhu District, Guangzhou, GD . China

Service Tel: 400-030-1510

DANGER

- This software is limited to inspection professionals, doctors or experimenters trained by Homesun or Homesun 's agents.
- If each hospital or institution responsible for using this software fails to implement a satisfactory repair/maintenance plan, it may cause abnormal software failure and may endanger human health.
- Ensure that the software is used under the conditions of use specified in the instruction manual. As beyond the conditions of use, the pulmonary function tester may not operate properly, the measured amount of results will be unreliable, and may damage software and cause injuries to people.

CAUTION

The readers of this manual are the following professionals in the laboratory:

- Personnel who carry out the daily operation of the system;
- Personnel who carry out system maintenance and troubleshooting;
- Personnel who learn system operation.
- This manual is only for V1 version software operation.

Content

Chapter 1 Manual overview

1.1 Overview

This chapter describes how to use the software manually, this instruction booklet comes with it and the purpose, function and operation of the software are described in detail. Before using the software, please read and understand the contents carefully, to ensure the correct use of the software, to play its best performance, and to ensure the safety of the operator.

In the daily use of this software, please strictly follow the instructions in the manual.

1.2 Scope of application of the manual

This manual is suitable for medical examination professionals or trained doctors, nurses, or laboratory workers to read. Used for:

1) Understand the software;
2) Set system parameters;
3) Perform daily operations;
4) Perform system maintenance and troubleshooting.

1.3 Guide to the manual

When you need **...**	Reference ...
Understand the operating environment and performance parameters of the software	Chapter 2 Software introduction
Understand the measurement principle and process of software applications	Chapter 3 Working principle and scope of application
Understand the main structure of the software and its functions	Chapter 4 Main product structure
Understand the software installation method, installation steps and the correctness of the	Chapter 5 Software installation and uninstallation

software	
Understand the import data, calculation and other settings, sample result report generation	Chapter 6 Software interface and operation
Understand the maintenance and precautions of the software	Chapter 8 Maintenance and precautions
Understand the handling methods and steps of software failures	Chapter 9 Failure analysis and treatment
Understand software electromagnetic compatibility information	Chapter 10 Electromagnetic compatibility description

1.4 Symbol explanation

Symbols and their meanings that may appear in this manual:

Symbol	Significance
	Prompt the operator to follow the instructions under the symbol, as this may result in personal injury.
	Prompt the operator to follow the instructions under the symbol, otherwise it may cause the product to malfunction failure, damage or affect the test results.
	Prompt the operator to follow the instructions under the symbol, emphasizing the important information in the procedure or what requires the operator's special attention.

1.5 Prerequisite information

Users of this software need to have an understanding of computer and pulmonary function examination professional business, and be familiar with the professionalism of the corresponding business.

Users of this software are required to have normal hearing and keyboard operation ability, and be able to correctly recognize simplified Chinese or English.

1.6 System related characteristics

1.6.1 System failure or termination conditions

May cause software failure:

1) There will be an error message when there is no network or the network signal is extremely poor.
2) When there is an error input caused by the user's carelessness or the software itself has an error, the software can recover by itself without an infinite loop.

1.6.2 The key functions of the system

The key functions of this software include patient management, forced vital capacity test, slow vital capacity test, maximum minute ventilation test, bronchial diastolic test, historical data review, and print report functions.

This instruction manual focuses on the description of a single program, making it as simple and easy to understand as possible. With the help of the manual, users, especially medical staff should be able to use all programs of this software. In the case that the user does not know other programs, each program can be used by the user through a certain explanation.

Chapter 2 Software introduction

2.1 Operating environment

1) Hardware standard configuration requirements

Processor: Intel Core i3-2120 3.0GHz or above

Memory: 4GB or above

Hard disk: 100GB or above

2) Software standard configuration requirements

Operating system: Windows 7/8/10 or above

Precautions, warnings, and prompt content

This software system is the supporting software part of the pulmonary function tester, and is used in conjunction with the hardware part of the pulmonary function tester to complete the forced vital capacity, slow vital capacity, and maximum minute ventilation tests.

2.2 Technical parameters

2.2.1 Operating environment

2.2.1.1 Hardware configuration

Processor: Intel Core i3-2120 3.0GHz or above

Memory: 4GB or above

Hard disk: 100GB or above

2.2.1.2 Software environment

Operating system: Windows 7/8/10 or above

2.2.2 Processing object

The software should be able to calculate pulmonary function test data.

2.2.3 Maximum concurrency

The maximum number of concurrent users of this software is 1.

2.2.4 Data interface

Use the USB/Bluetooth interface to transmit to the computer platform where the software is located.

2.2.5 Specific hardware

A9

2.2.6 Clinical function

1) Forced vital capacity

   The forced vital capacity test program includes: flow-volume curve display, volume-time curve display, and forced vital capacity display parameters. Preview reports, generate reports, and print reports based on report style templates.

2) Slow vital capacity

   The slow vital capacity test program, including: volume-time curve display, slow vital capacity display parameters. Preview reports, generate reports, and print reports based on report style templates.

3) Maximum minute ventilation

   Maximum minute ventilation test program, including: volume-time curve display, maximum minute ventilation display parameters. Preview reports, generate reports, and print reports based on report style templates.

4) Bronchial diastolic

   Perform Pulmonary function tests before and after diastolic medication, generate diastolic test reports and print reports.

5) Calibration

   Calibration includes: capacity calibration, 3 flow verification, automatic acquisition of atmospheric pressure data / manual input, and adjustment of the influence of temperature and humidity on the measurement results.

6) Patient management

   Patients create, edit, query, delete, view patient file details, and view patient history test records.

7) Data management

Report query and data search.

8) System settings

① Basic settings include information settings for hospitals, departments, operators, and doctors;

② Account settings include account cancellation;

③ Report settings include report title prefix setting, default display options setting, and report template display index editing;

④ The drug setting is used to record the category, drug name, specification, and unit information of the drug used in the diastolic test.

⑤ The software upgrade module is to check the version. If the testing software is upgraded, contact your local agent.

2.2.7 Restrictions on use

Only English letters and numbers can be entered for the login user name and password.

2.2.8 User access control

The user needs to log in to the account and password to use this product, and all functions of this product should be used after logging in.

2.2.9 Copyright protection

Use encrypted installation for protection.

2.2.10 User Interface

Users can operate through buttons, menus, dialog boxes, and drop-down menus.

2.2.11 Message

The message mechanism of the software includes prompt, error report, and selection confirmation.

2.2.12 Maintainability

1) software should be able to automatically generate error messages for the monitoring log recording program;

2) software should have maintenance contact information in the "About" information.

2.2.13 Quality requirements

Shall comply with Chapter 5 (except 5.3.9 ~ 5.3.13) Section 5.3.9 to Section 5.3.13 of ISO / IEC 25051: 2014 Software engineering - Systems and Software Quality Requirements and Evaluation (SQuaRE) – Requirements for quality of Ready to Use Software Products (RUSP) and instructions for testing.

Chapter 3 Working principle and scope of application

3.1 Working principle

This software system is the supporting software part of the pulmonary function tester, and is used in conjunction with the hardware part of the pulmonary function tester to complete the forced vital capacity, slow vital capacity, maximal voluntary ventilation and bronchial diastolic tests.

The software works as follows: 1. Through the USB / Bluetooth acquired detection of human pulmonary function tests, and increasing the number of data curve data; 2. Read and calculate curve data. According to the technical principle of the product, each measurement mode has its own unique breathing mode for detection, and the software can automatically calculate various pulmonary function parameters in different modes.

3.2 Scope of application

This software system is the supporting software part of the pulmonary function tester. It is used in conjunction with the hardware part of the pulmonary function tester to complete forced vital capacity, slow vital capacity, and maximum minute ventilation tests and report printing.

Chapter 4 Main structure

The product consists of login, homepage, forced vital capacity, slow vital capacity, maximal voluntary ventilation, bronchial diastolic test, calibration, patient management, data management, and system setting modules.

Chapter 5 Software installation and uninstallation

5.1 Overview

This application software is dedicated software, and there are full-time after-sales personnel to guide the installation. Please notify Homesun or the local agent after receiving the pulmonary function tester product.

5.2 Installation and uninstallation requirements

Before installation, be sure to read the instruction manual carefully, and the operator must be familiar with the use and operation methods to ensure that the software can work normally.

5.2.1 Installation method

5.2.1.1 Install the software

In order to better guide customers to use this product, the following describes a complete installation and opening process on the Windows 7 operating system

1) Obtain the computer software of the pulmonary function tester through technical support, as follows:

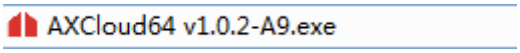


Figure 1 installation program

2) In the Windows 7 operating system, double-click the exe installation program and complete the software installation according to the prompts. After the installation is successful, the software will start the shortcut icon on the desktop, as follows:

Figure 2 Software startup shortcut icon

3) When the program is opened, the software has a power-on self-check function of the running environment. If the hardware environment of the running software is not supported, the software will prompt the related reasons (such as “connection failed,

please check the network"). If it supports, enter the login interface, and enter the account password, as follows:

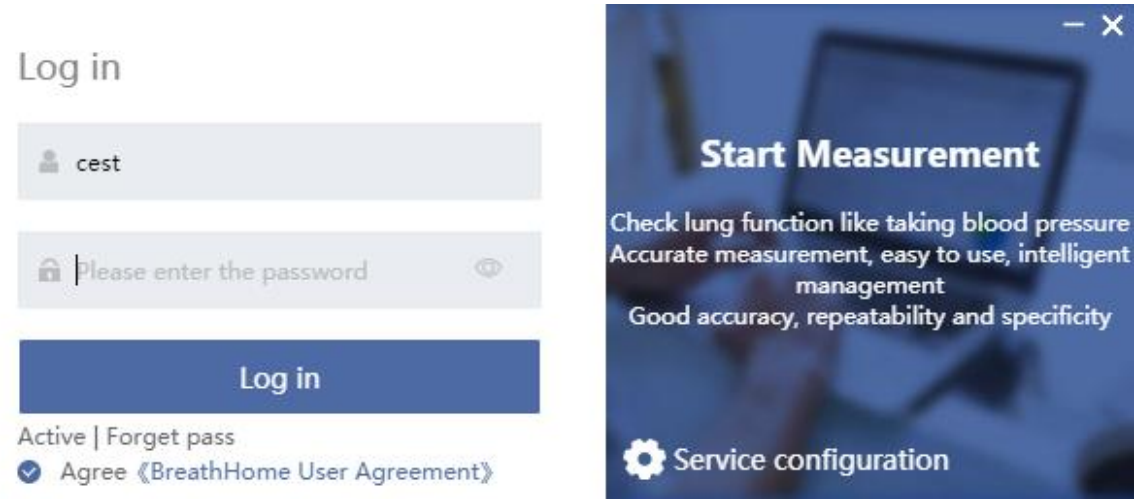


Figure 3 Software login interface

4) The interface after successful login is as follows：

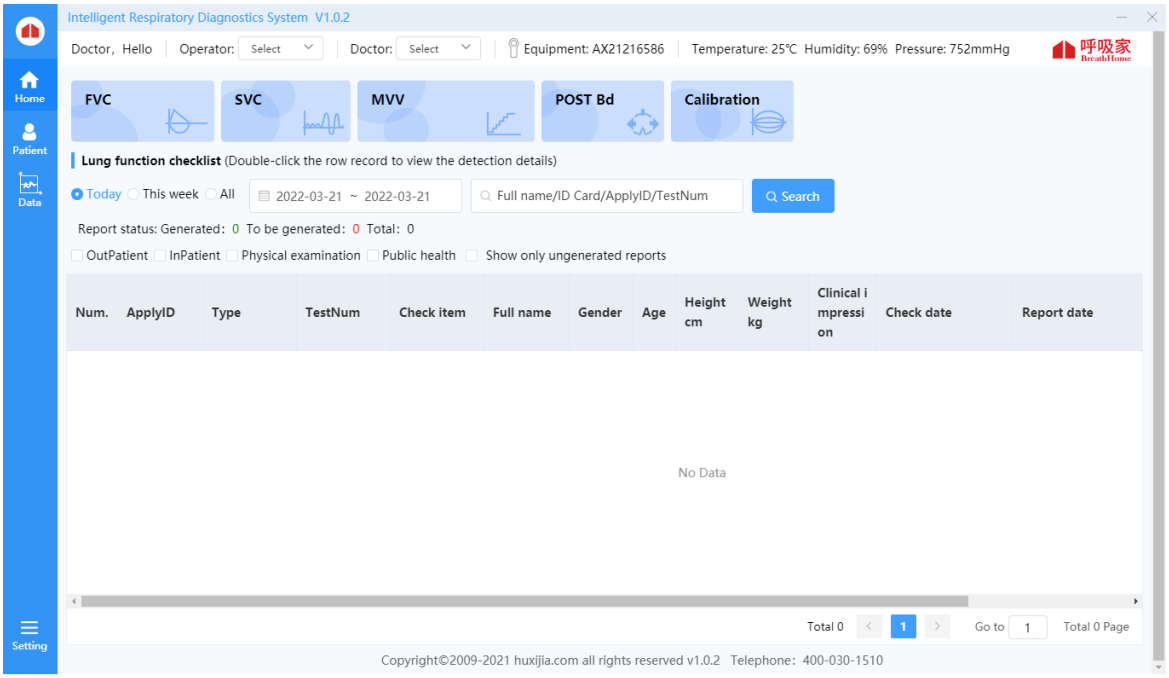


Figure 4 Software home page interface

5.2.2 Software uninstallation procedures

1) Open the directory where the software is located and double-click unins000.ex

Figure 5 Software uninstallation diagram①

2) The uninstall dialog box pops up, select the“Y” button to complete the deletion

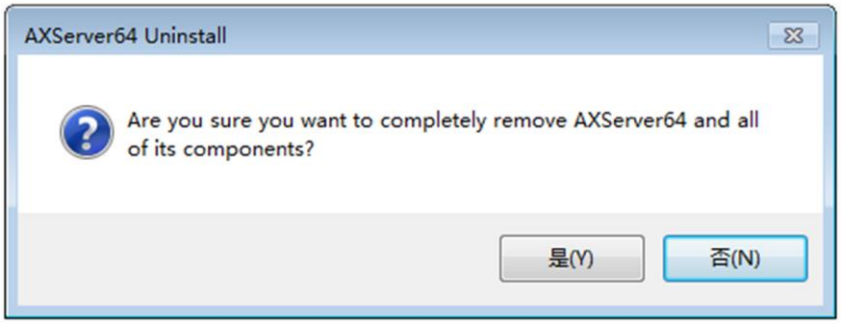


Figure6 Software uninstallation diagram②

Chapter 6 Software interface and operation

6.1 Login

The software has a self-checking function for the running environment. If the hardware environment of the running software is not supported, the software will prompt.

The client doctor account is not open for registration, and the company generates an account and password on demand.

Enter the correct account and password to log in to the software. If you forget the password, click the reset button. After the operation is confirmed, the doctor's account will be reset to the initial password.

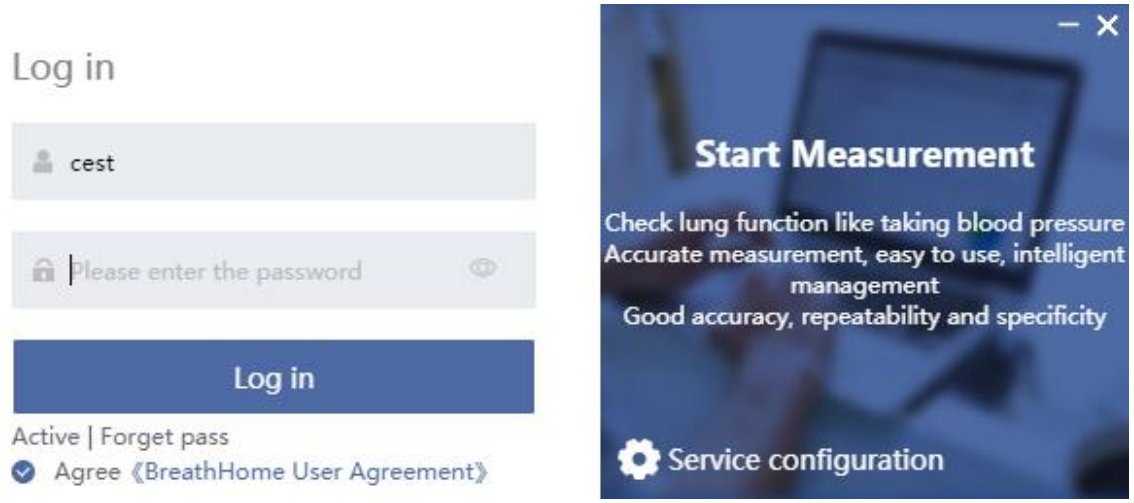


Figure 7 Software login interface

6.2 Software home page

The navigation homepage the user logs into.

- The navigation menu is on the left side of the home page.
- The status of the connected device is displayed at the top of the home page. After connecting to the environment collection device, collect environment information.
- The application button and the application measurement record are displayed in the middle of the home page.

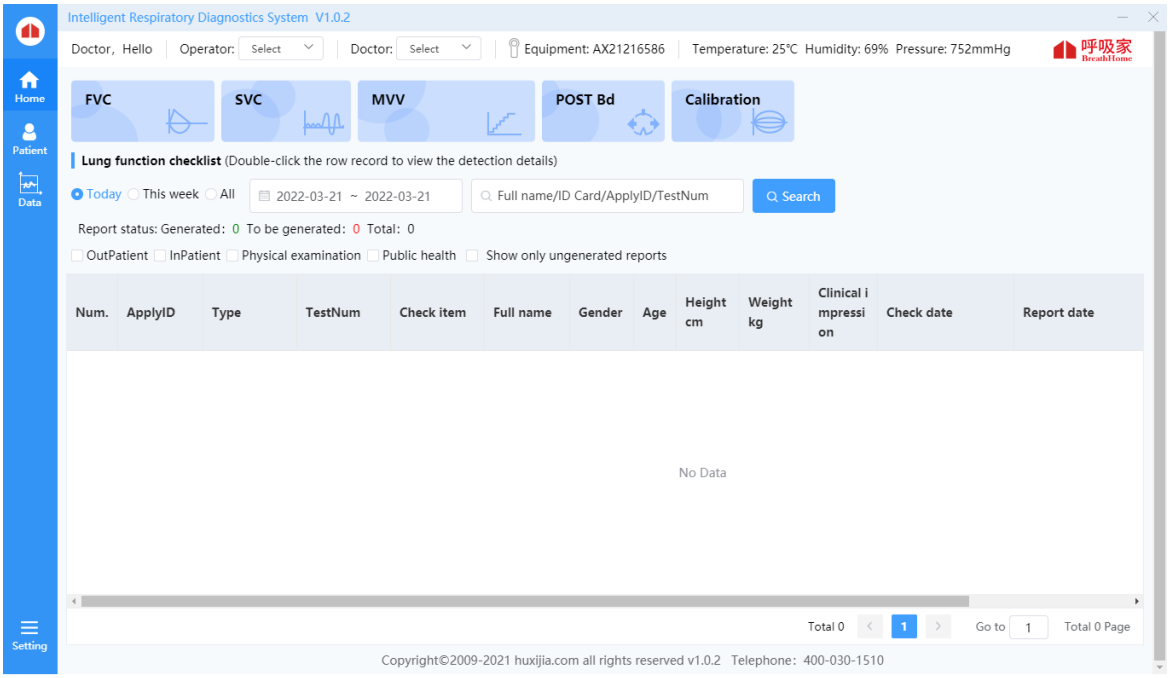


Figure8 Software home page

6.3 Calibration

6.3.1 Calibration tool

3L calibration pump.

⚠ Caution:

The 3L calibration pump is purchased by the user, and its requirements are 3L±0.5%.

6.3.2 Volume calibration

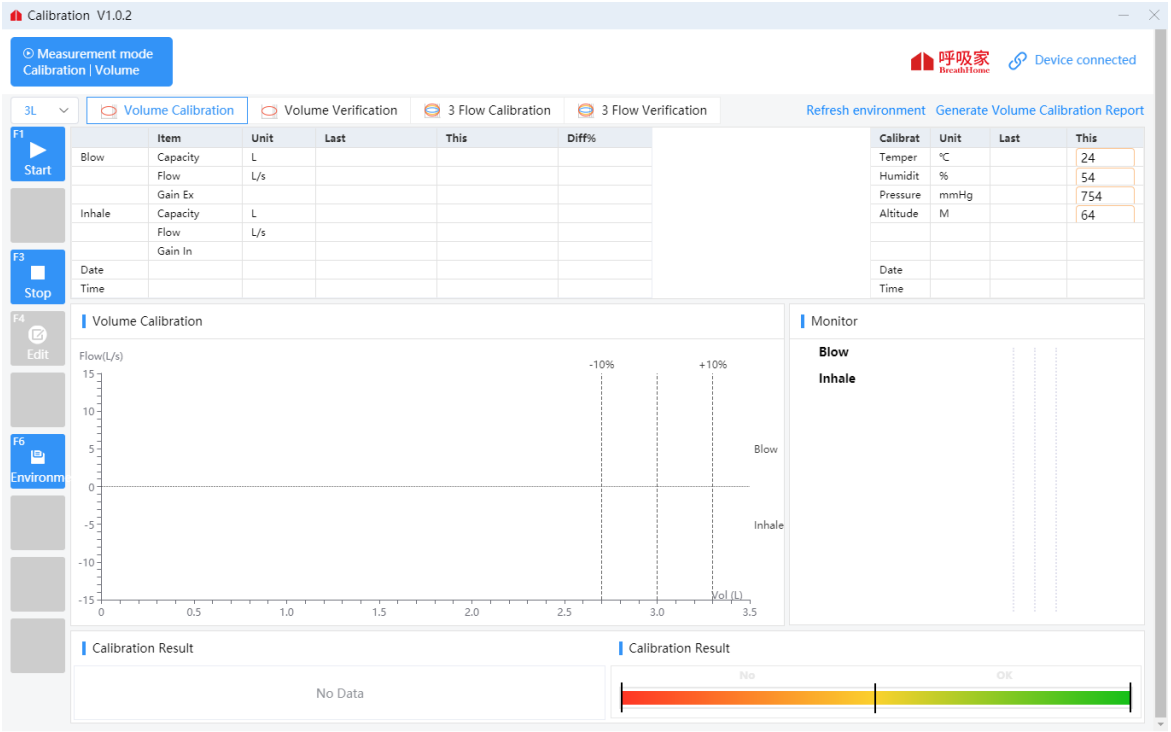


Figure 9 Calibration homepage Figure

1) Enter environmental information before calibration: temperature, humidity, pressure, altitude. Click < F6 > to save the updated environmental conditions.

2) Standard calibration measurement steps:

■ Select Calibration on the home page and enter the calibration interface. After selecting the calibration volume " 3L ", click the " Standard calibration " button in the upper right corner to enter the standard calibration page.

■ After entering the environmental information in the upper right corner, press the "F1 Start" button, use the 3L calibration pump to smoothly move the calibration pump handle, do not stop during a single push or pull, and ensure that each push and pull is in place. "Inspiratory and expiratory sliding times the number reached, the system can automatically prompt to stop operation", the push-pull tube stop after scaling back into place. Click the "F3 Stop" button to save the measured data.

■ Page jumps to the calibration test result page. If the capacity in the measurement curve is within the allowable range of ±10%, the standard calibration is passed; if the capacity exceeds the limit of ±10%, you need to perform the high, medium, low-speed standard calibration test again. Usually after multiple calibrations, the corresponding coefficients can be re-calibrated according to the calibration to reduce the accuracy error

of the calibration volume. In the case of calibration failure, it is necessary to check whether the following conditions exist: air leakage, pause in the middle, improper push and pull, flow sensor needs to be cleaned, equipment failure, calibration pump failure or other reasons.

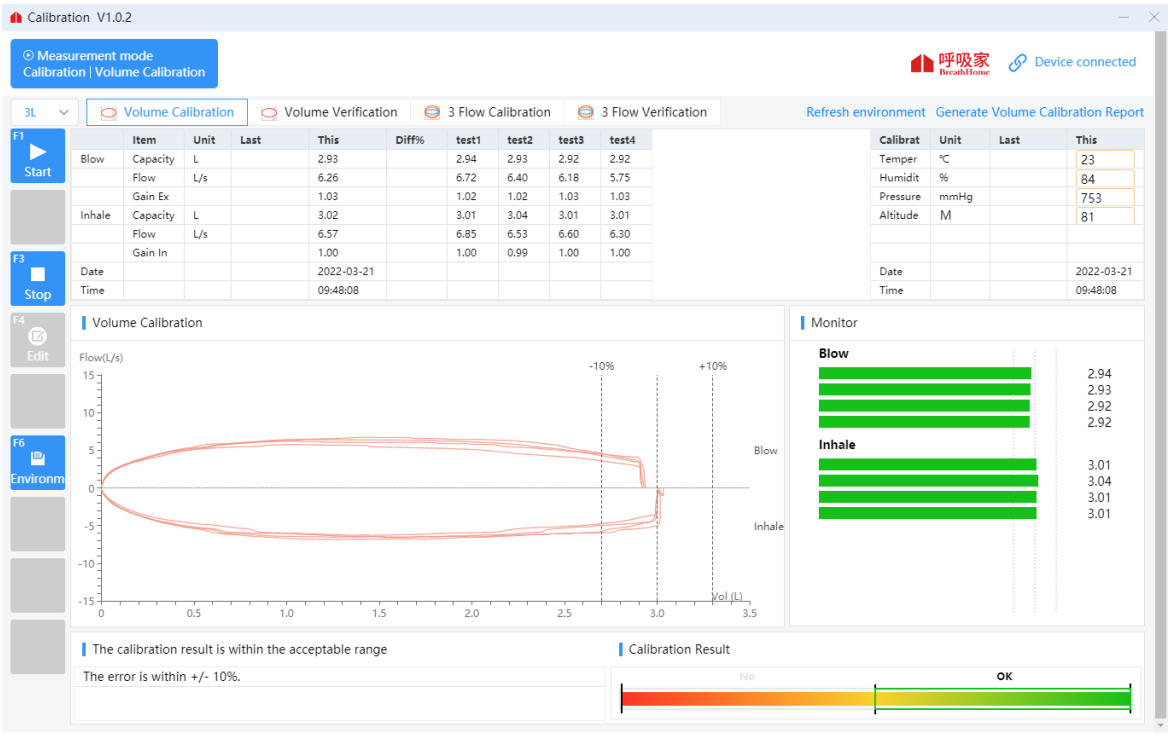


Figure10 Schematic diagram of calibration results

6.3.2 3 flow verification

In order to verify the linearity of the flow sensor, 3 flow verification can be performed after each standard calibration.

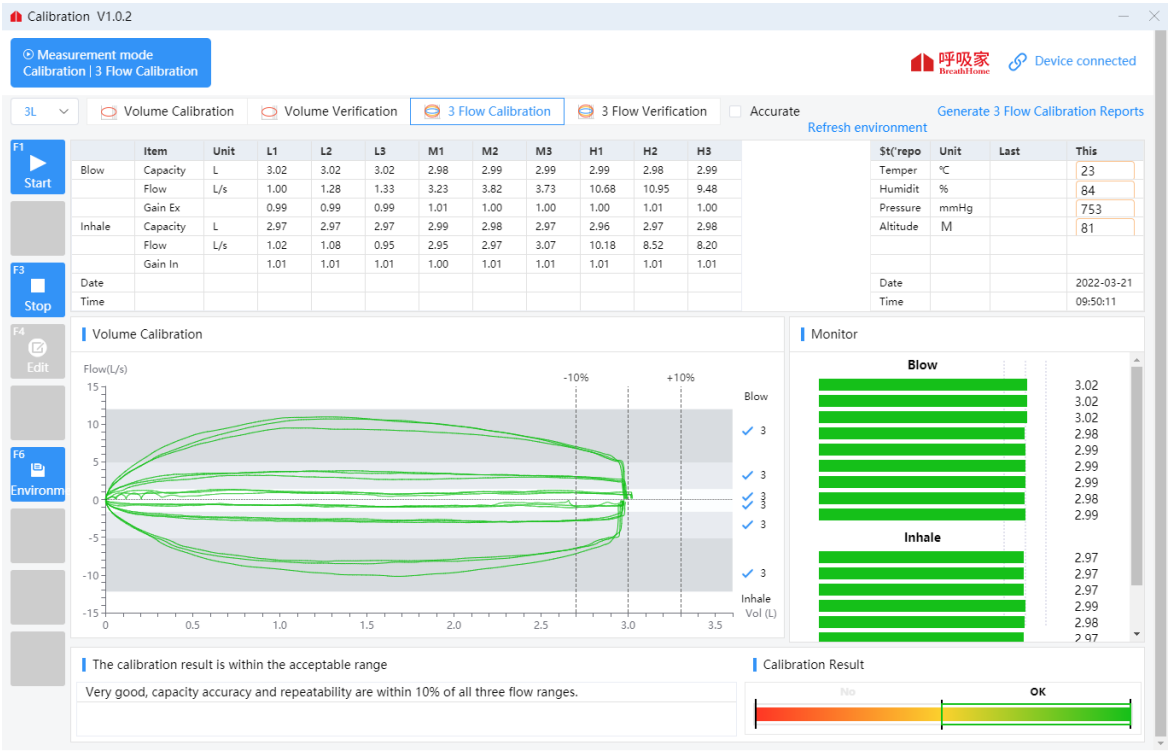


Figure 11 3 Flow Verification Diagram

Selecting the calibration volume " 3L ", click the "3 flow" button in the upper right corner, and click the "F1 Start" button to enter the three-flow calibration page.

Push and pull the calibration pump at three different speeds: high, medium, and low, so that the flow-volume curve respectively crosses the gray effective area ones of the high, medium, and low flow rates and ensure that each flow area is successfully traversed at least 3 times in the expiration and inhalation respectively, and the order can be unlimited. Suggested completion push and pull at another speed after exhalation reaches 3 times in one speed zone. Click "F3 Stop" to save the measured data.

The page jumps to the test result page: judge that the highest point of the push-pull curve of exhalation and inhalation is in the high, medium, and low shadow range, and the capacity range is within ±3.5%, then the three-flow calibration verification is passed, such as measuring 3 times If it still fails the three-flow calibration verification, it needs to be re-calibrated to replace the current calibration, and then perform the three-flow standard calibration verification test again.

Click the"F3 Stop " button in the upper left corner to exit the calibration.

6.4 Patient information input

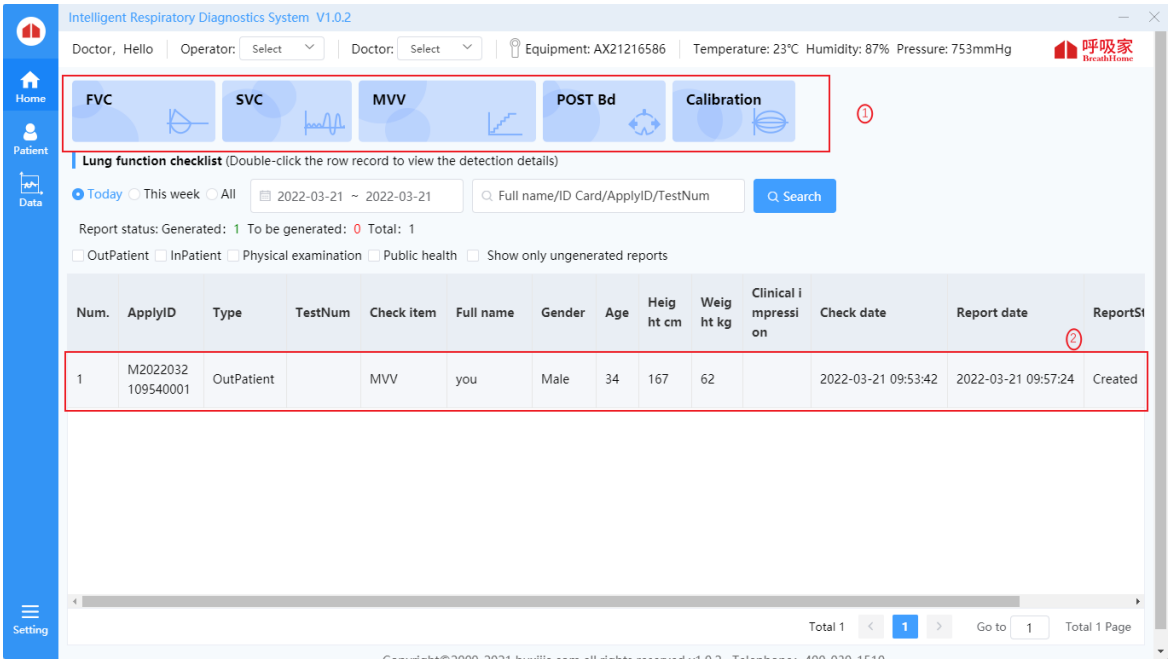


Figure 12 Enter the diagram of patient information input

①Click on the program button for entering new patient data. Or entering the select row patient's test program.

②If there are test records in the table, double-click the line record to enter the recorded measurement program.

After clicking FVC/SVC/MVV/POST Bd test lung function test button, the screen displays:

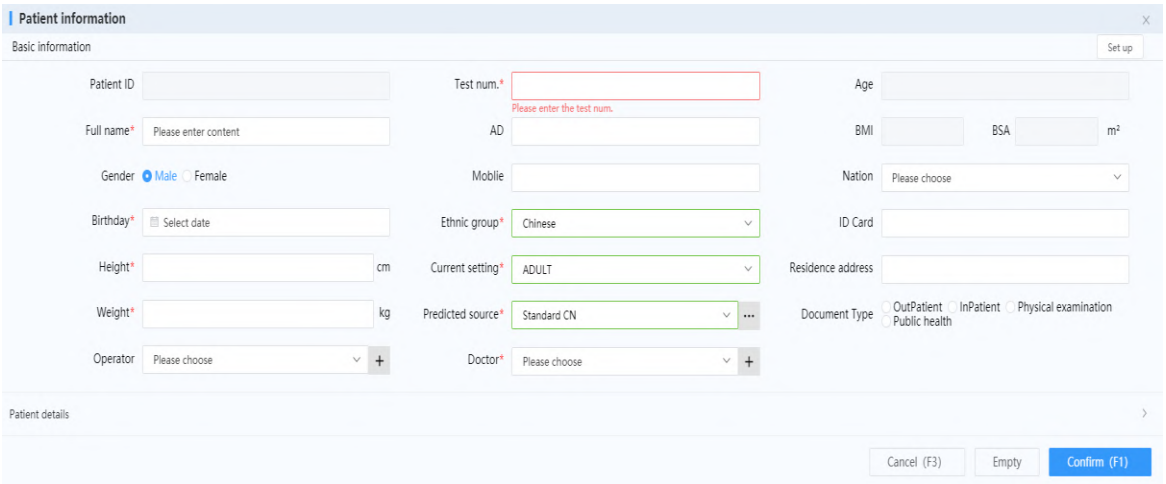


Figure13 Patient information interface

The Patient Chart is displayed. The cursor flashes in the first entry field "Test num".

Patient ID is generated by the system without input, The program is ready for entering data. Patient Charts marked with an “*” are mandatory fields. These data are the patient’s master data including biometric details used to calculate predicted values. All other entries are optional. You can configure whether to display or mandatory fields. Click Save data "Confirm(F1)" to save data.

⚠ Caution:

Personal data of the subject must be stored in a database prior to the first measurement.

6.5 Forced vital capacity test procedure

Select the Forced Vital Capacity Test (FVC) to prepare to start the test.

6.5.1 Description of function homepage

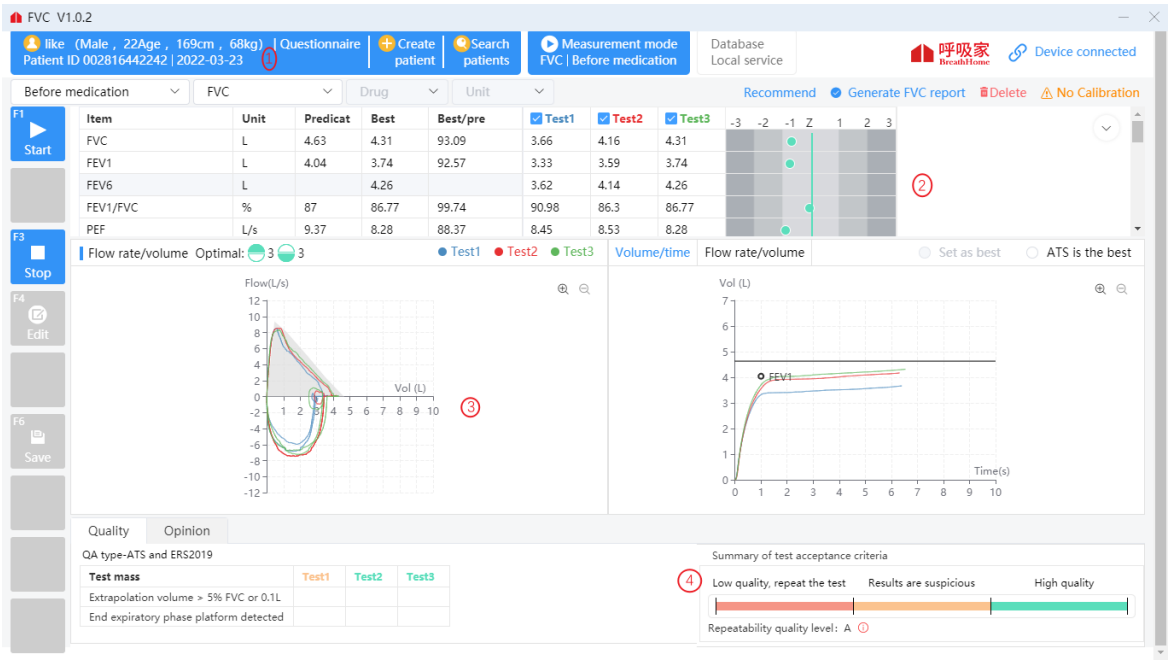


Figure 14 Forced vital capacity test interface

Test Project - has FVC, FEV1, FEV1/FVC, PEF, FEF25, FEF50 , FEF75 , MMEF and many other parameters as for the subject patient FVC measured indicators, test items display parameters can be set to display and hide.

Measured curve graph-flow-volume F(L/s)-V(L) graph and volume-time V(L)-T(s) graph show each measured data of the patient in different colors, and show a waveform or arc shape, the operator can selectively view or compare the actual measurement records, and use the black waveform on the flow-volume graph as the predicted value of the tested

patient, and compare the predicted value with the actual measurement record.

6.5.2 Real-time measurement page description

Figure 15 Real-time measurement page

1) Real-time dynamic display of flow-volume curve during breathing.

2) Real-time dynamic display of tidal volume and respiratory rate during steady breathing, guiding the user to measure the steady control progress value within the green range.

3) Real-time dynamic lung breathing status, which intuitively reflects the arrow down when the user inhales and the arrow goes up when the user exhales, guiding the patient to breathe abruptly.

4) Real-time dynamic display of ventilation stability, when the tidal stable breathing state is reached, the baseline turns to red, and the user can take the next step to take a deep breath, and then immediately exhale with explosive force.

6.5.3 Operation steps

1) Practice forced breathing according to the instructions of the technician or doctor, and master the essentials of FVC. Avoid fatigue subjects achieved full intended results.

2) Connect the mouthpiece to the mouth, wrap the mouthpiece tightly with your lips, and clamp the nose clip to ensure that the mouth and nose do not leak. If some subjects

cannot guarantee that the corners of the mouth will not leak, a special mouthpiece with a tooth mask can be added.

⚠ Caution:

The user purchases a detachable mouthpiece and a disposable pulmonary function meter filter, which must be a legally marketed product registered by the FDA.

Mouthpiece specifications: inner diameter 30mm, outer diameter 32-34mm, height 50mm-120mm.

Specification of disposable pulmonary function meter filter: inner diameter 1=30mm.

3) Breathe calmly for 4-5 times. After the breathing is stable, take a deep breath, and then exhale forcefully, quickly, and completely, in one breath.

4) After the exhalation is complete, inhale strongly and quickly until it is complete, and then breathe 4-5 times calmly to complete the test.

Caution: The same patient cannot be tested more than 8 times a day!

5) Each time the tested patient completes a set of measured values, the monitoring page will prompt whether the measured result is acceptable. Such as ticking is acceptable, you can click "end" to end this test and save the data. Such as the cross is an unacceptable result and the reason is prompted, you can click " F1 New Test" to start a test.

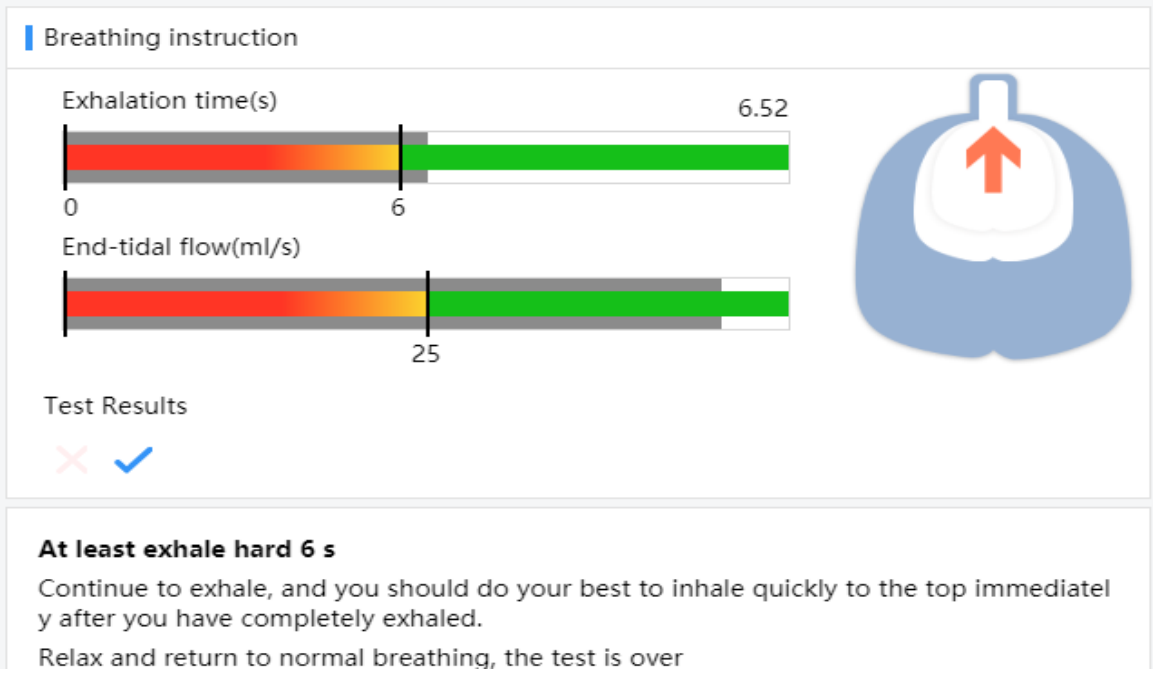


Figure 16 Test result monitoring page①

6) After 3 blows are completed, the system will automatically obtain the repeatability quality level according to the quality control standard. If there is a low-quality measurement record that is unacceptable for a single operation, you can click to select the measured record to delete it.

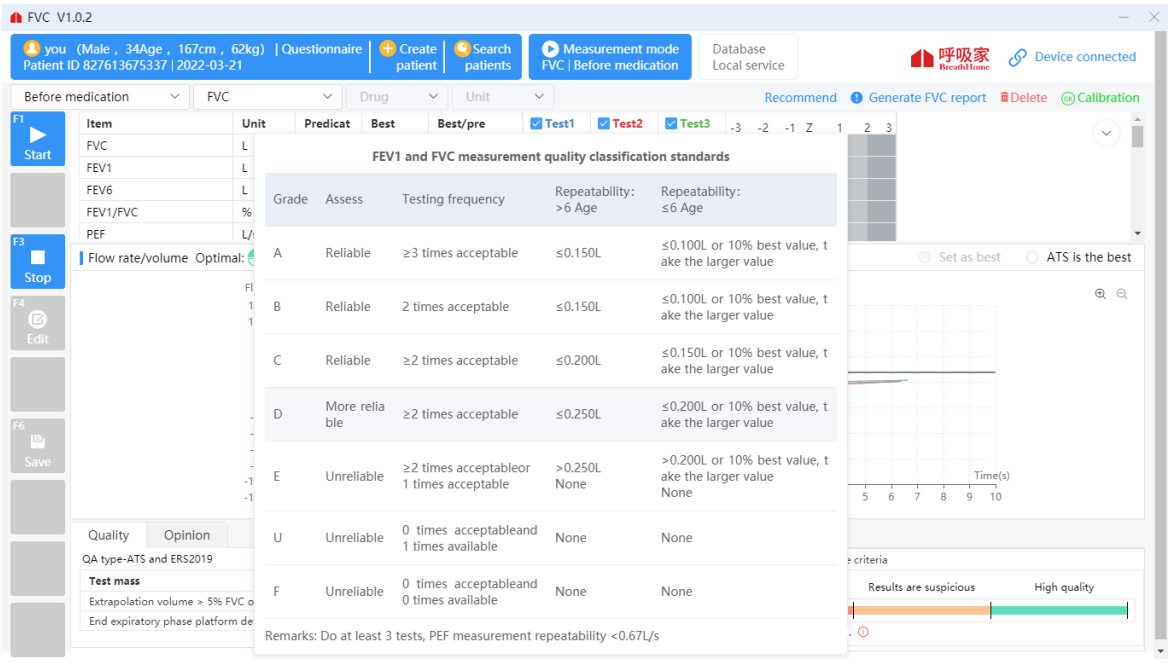


Figure 17 Test result monitoring page②

6.5.4 Preview report

Click the "Generate FVC report" button to enter the report preview and operation process page:

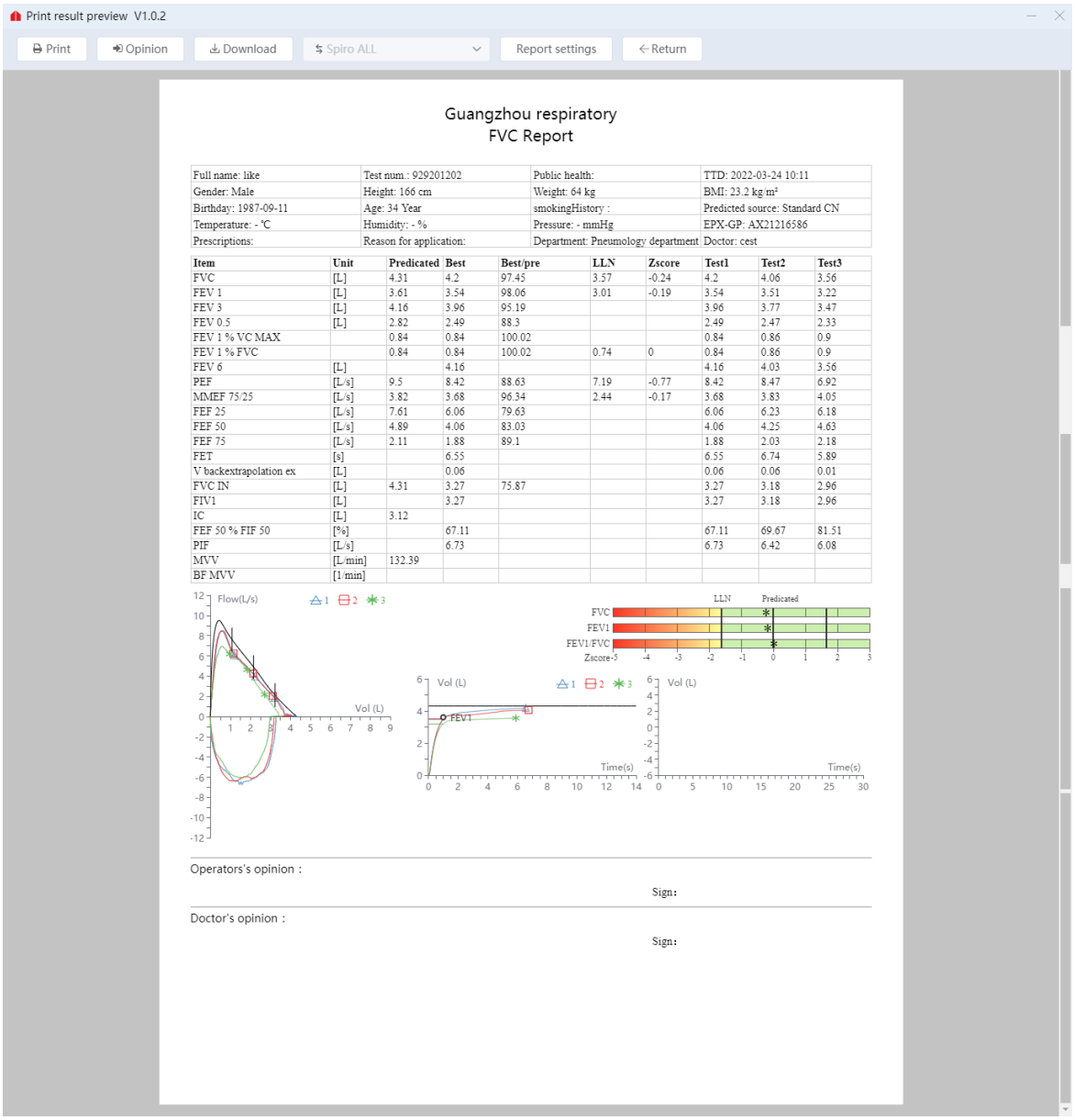


Figure 18 Generate report interface

- Opinion filling: pop up form, modify report result analysis content, operator's opinion, save report content.
- Download the report: Select the download path and download the report to the path in PDF format.
- Report Settings: The report title prefix and the indicators displayed in the report can be edited in the system Settings module. You can modify the report title prefix, default report template, and indicator parameters displayed in the report template.

■ Return: Exit the report preview page

Please choose whether to continue with other mode tests based on facts.

6.6 Maximum minute ventilation test procedure

Select the maximum minute ventilation test (MVV) and prepare to start the test.

6.6.1 Home page function description

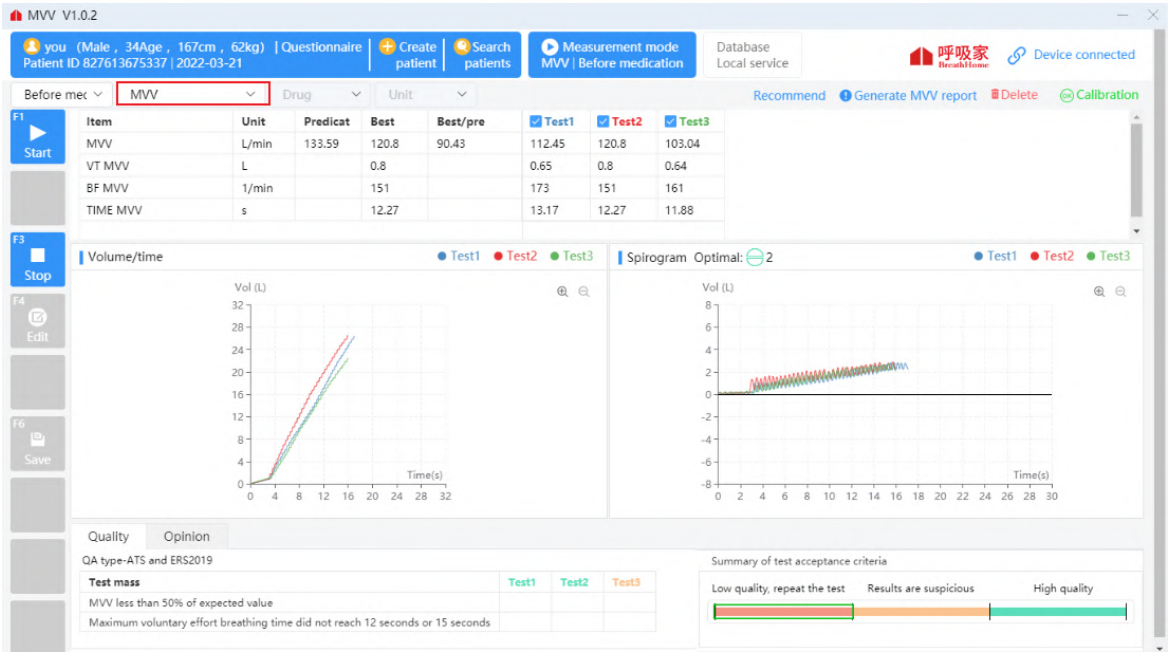


Figure 19 The main interface of maximum minute ventilation

1) To select or create the patient to be tested, manually select the maximum minute ventilation test mode, and automatically load the patient 's measured records (if the patient did not do the test as blank). Objective To complete the maximum minute ventilation test.

2) Test items-MVV, VT, BF, TIME indicators, test item display parameters can be displayed or hidden in the settings.

3) Measured curve graph-All are volumetric time V(L) -t (S) diagrams. According to the description of the measurement instructions, after calm breathing, the moisture baseline appears on the horizontal line of the origin, and the next breathing action can be carried out. The MVV curve can be obtained after measurement. The left side is the cumulative expiratory value of the tested patients, and the right side is the inspiratory and blowing state of the tested patients. The operator can select or deselect to display the measured curve.

6.6.2 Description of real-time measurement page

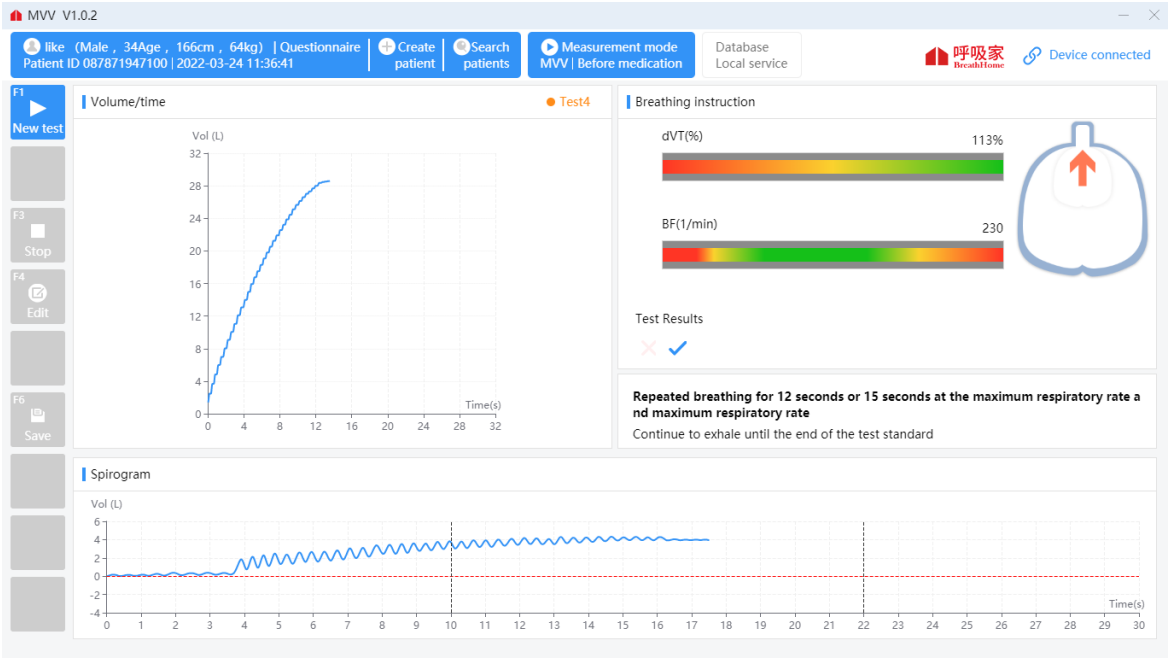


Figure 19 Maximum minute ventilation test interface

1) Real-time dynamic display of breathing volume-time curve.

2) Real-time dynamic display of tidal volume and respiratory rate during steady breathing, guiding the user to measure the steady control progress value in the green range.

3) Real-time dynamic pulmonary breathing state, intuitive reflection of the measurement user in the inspiratory arrow down, expiratory arrow up, guide the patient's respiratory nodule.

4) Real-time dynamic display vent stability, when the tidal breathing steady state baseline to red, the user can enter to the next step deep enough air, and then immediately with the maximum amplitude of the respiration, the maximum rate of sustained rebreathing.

6.6.3 Operation steps

1) Subjects stand or sit, nose clip, mouthpiece connected to the device, calm breathing 4 to 5 times, after breathing smoothly, with maximum breathing amplitude, maximum speed continuous breathing 12 seconds or 15 seconds.

⚠ Caution:

The user purchases a nose clip, detachable mouthpiece and disposable pulmonary

function meter filter, which must be a legally marketed product registered by the FDA.

2) The whole inspection process, the subjects can obtain the best cooperation according to the timely instructions and continuous guidance issued by the technician. Rest for 5-10 minutes and repeat the second and third tests.

3) Each time the tested patient completes a set of measured values, the monitoring page will prompt whether the measured results are acceptable. Such as ticking is acceptable, you can click "F3 Stop" to end this test and save the data. Such as the cross is an unacceptable result and the reason is prompted ,you can click " F1 start" to start a test.

4) The system will obtain an acceptable quality level after completing 3 blows. If there is a low-quality measurement record that is unacceptable for a single operation , you can click to select the measured record to delete it.

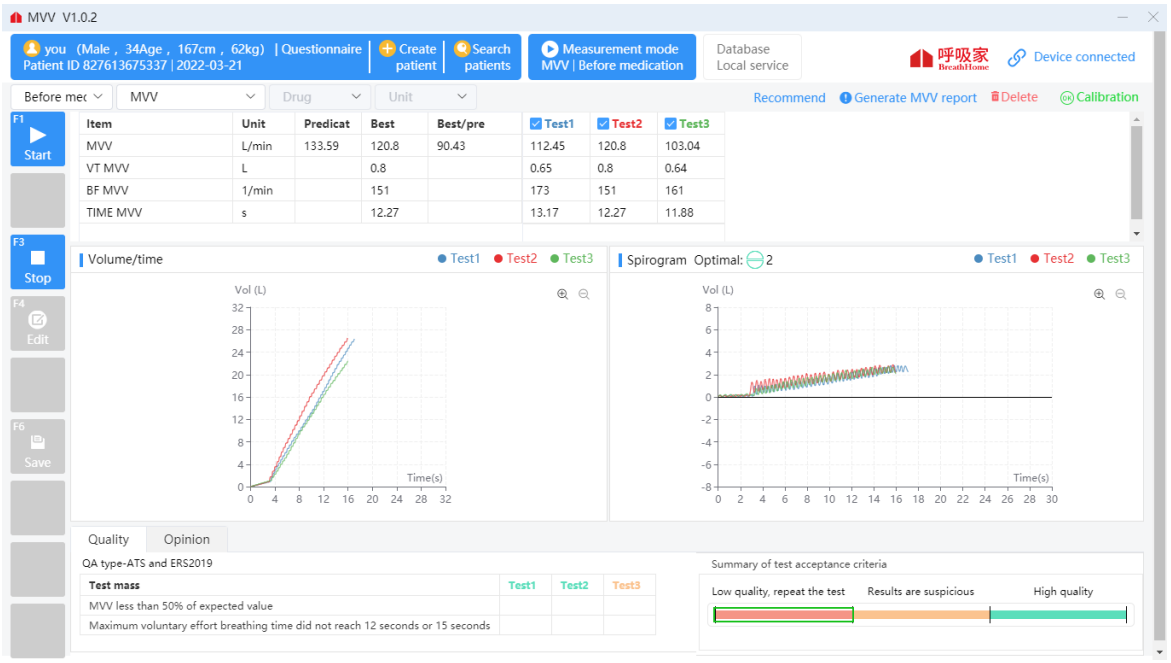


Figure 20 Maximum minute ventilation test interface

6.6.4 Report preview

Click the "Generate MVV report" button to enter the report preview and operation process page:

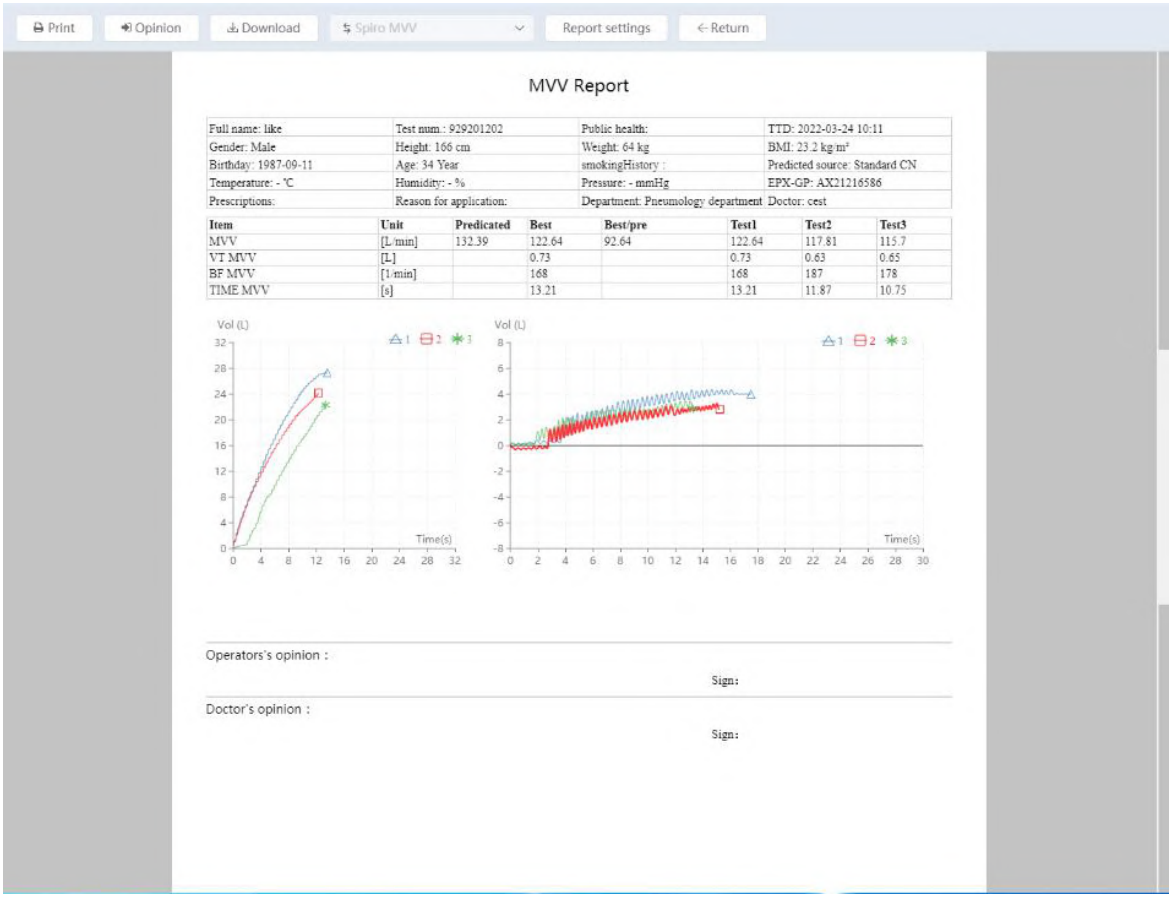


Figure 21 Maximum minute ventilation report

- Opinion filling: pop up form, modify report result analysis content, operator's opinion, save report content;
- Download the report: Select the download path and download the report to the path in PDF format.
- Report Settings: The report title prefix and the indicators displayed in the report can be edited in the system Settings module. You can modify the report title prefix, default report template, and indicator parameters displayed in the report template.
- Return: Exit the report preview page.

  Please choose whether to continue with other mode tests based on facts.

6.7 Slow vital capacity test procedure

Choose slow vital capacity test (SVC) to start the test.

6.7.1 Description of function homepage

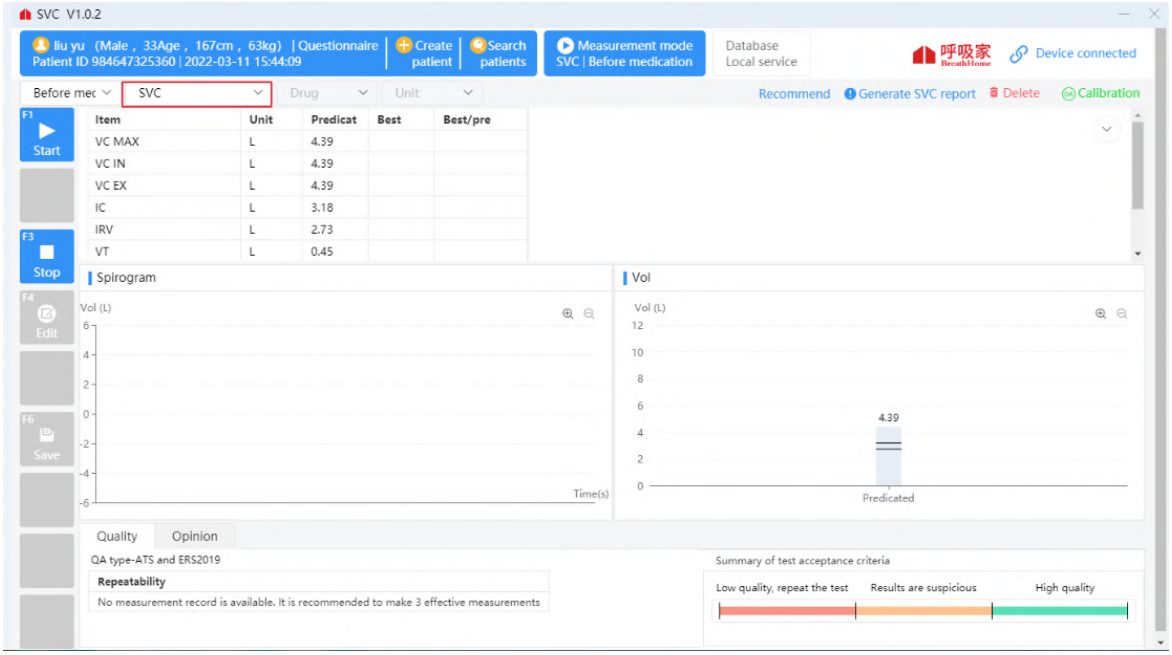


Figure 22 Main screen for slow lung capacity test

1) Select or create the patients to be tested, manually select the slow vital capacity test mode, and automatically load the measured records of the patients (if the patients do not test as blank). At present, the static pulmonary function test is completed.

2) Test items-VC, VT, BF and other items are used as the actual measurement indicators of the SVC test mode of the tested patient. The display parameters of the test items can be displayed or hidden in the settings.

3) Measured curve graph-In the volume-time V(L) -t (S) figure on the left, all measured waveforms are displayed together. In the volume-time V(L) -t (S) figure on the right, the measured vital capacity and VT tidal column of each group are shown. You can select or deselect to display the measured graph.

6.7.2 Real-time measurement homepage

Figure23 The main interface of the slow lung capacity test

1) Real-time dynamic display of the volume-time curve during breathing.

2) Real-time dynamic display stable respiratory tidal volume and respiratory frequency, measuring user guide stability control progress value range in the green inner periphery.

3) Real-time dynamic pulmonary breathing state, intuitive reflection of the measurement user in the inspiratory arrow down, expiratory arrow up, guide the patient's respiratory nodule.

4) Real-time dynamic display vent stability, when the tidal breathing steady state baseline to red, the user can enter to the next step deep enough air, and then immediately to completely exhale breath, then inhale completely to relax calm breathe.

6.7.3 Operation steps

1) Connect the mouthpiece to the mouth, wrap the mouthpiece tightly with your lips, and clamp the nose clip to ensure that the mouth and nose do not leak. As some patients can not guarantee card mouth does not leak, it can be added with tape special mouthpiece to cover the lips and teeth.

⚠ Caution:

The user purchases a nose clip, detachable mouthpiece and disposable pulmonary function meter filter, which must be a legally marketed product registered by the FDA.

2) Clamp the nose clip, connect the mouthpiece, and breathe calmly for 4-5 times. After the breathing is stable, inhale as much as possible at the end of the expiration at a moderate speed (total lung volume), and then exhale to the end.

3) Repeat the above steps to check more than 3-5 times, and rest for more than 1 minute between the 2 times.

4) Each time the tested patient completes a set of measured values, the monitoring page will prompt whether the measured result is acceptable. Such as ticking is acceptable, you can click "F3 Stop" to end this test and save the data. Such as the cross is an unacceptable result and the reason is prompted, you can click " F1 start" to start a test.

5) The system will automatically obtain an acceptable quality level after the completion of 3 blows. If there is a low- quality measurement record that is unacceptable for a single operation, you can click to select the measured record to delete it.

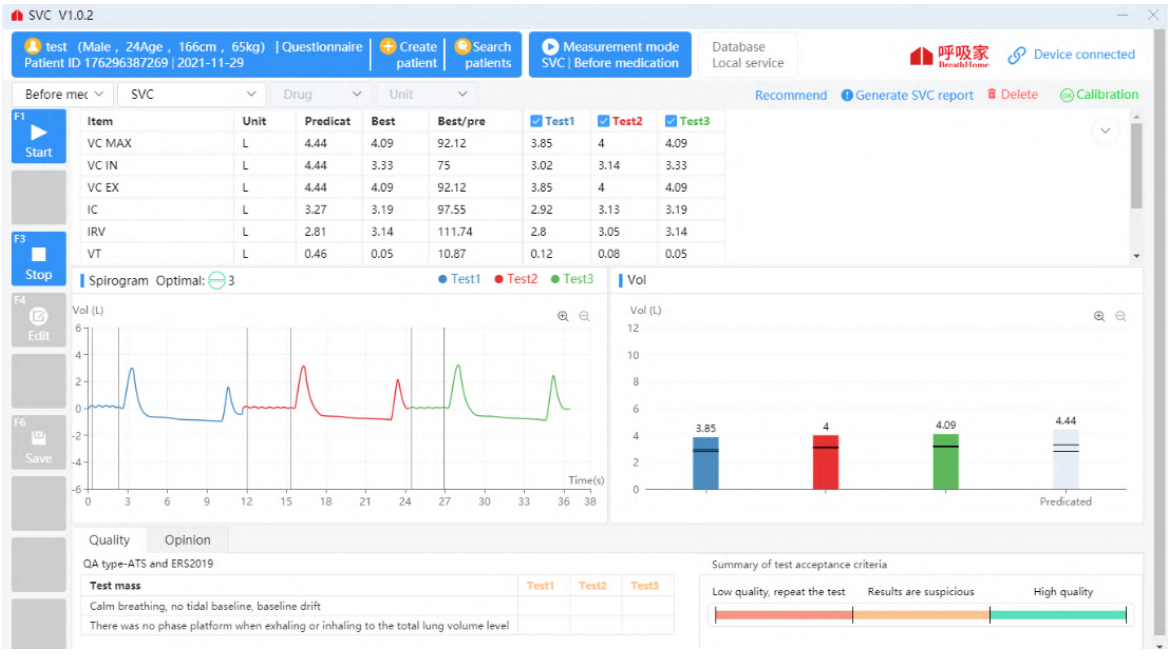


Figure 24 Slow vital capacity measurement interface

6.7.4 Report preview

Click the "Preview report" button to enter the report preview and operation process page:

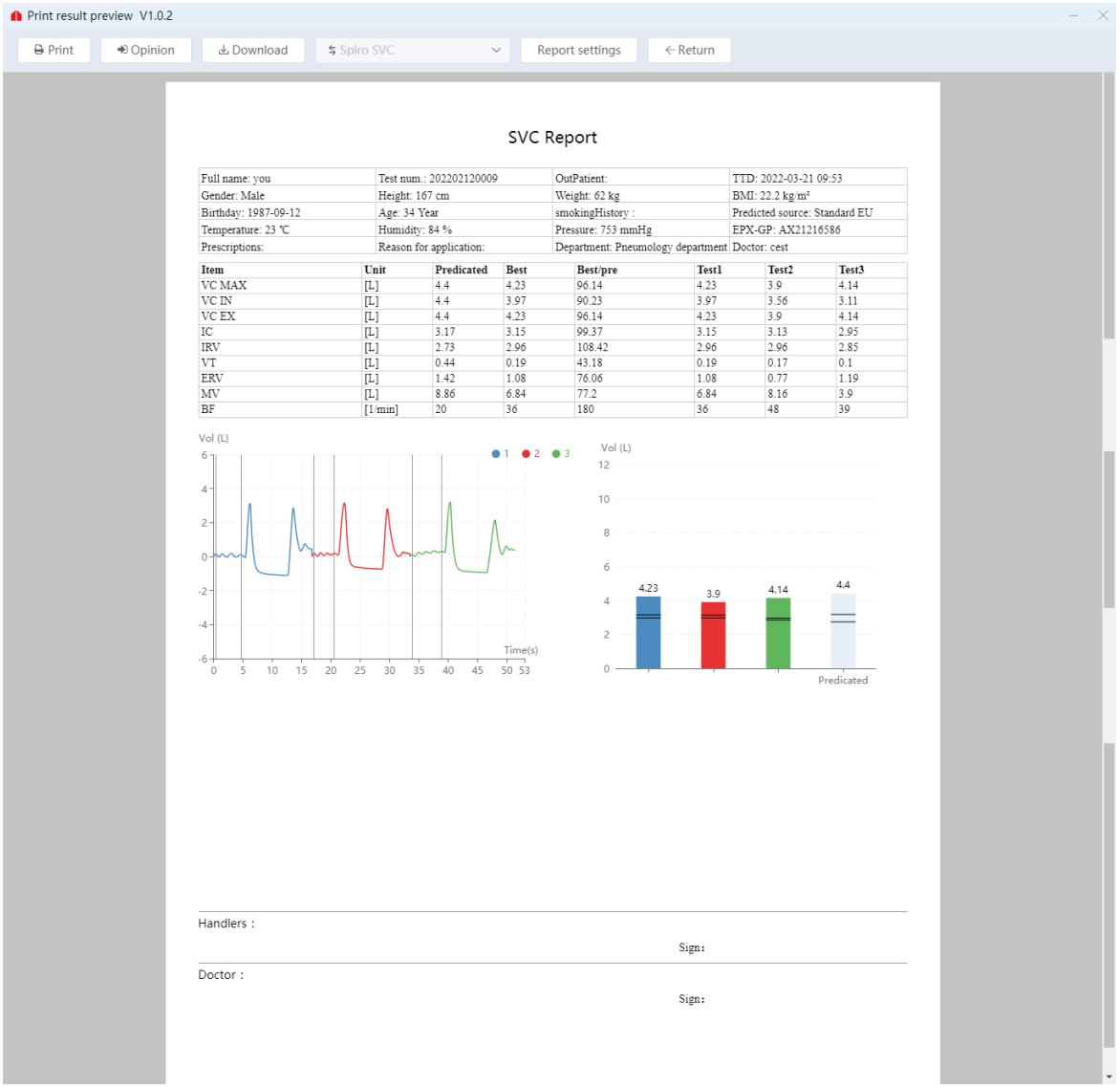


Figure 25 Slow vital capacity measurement interface

- Opinion filling: pop up form, modify report result analysis content, operator's opinion, save report content;
- Download the report: Select the download path and download the report to the path in PDF format.
- Report Settings: The report title prefix and the indicators displayed in the report can be edited in the system Settings module. You can modify the report title prefix, default report template, and indicator parameters displayed in the report template.
- Return: Exit the report preview page.

  Please choose whether to continue with other mode tests based on facts.

6.8 Bronchial diastolic test procedure

The pulmonary function test before and after medication was performed, and the measurement record before medication was used as the benchmark test. The doctor analyzed the patients who met the requirements of the diastolic test and gave them diastolic drugs offline. According to the effective time of the drug, the doctor re-entered the function of each measurement mode and selected the drug name and unit for testing. Enter the preview report page and select the diastolic test report template. The system displays the diastolic test report, generate report and print report by comparing the indicators of the post-medication test record with the benchmark test record.

Figure 26 The main interface of bronchial diastolic test

Bronchial diastolic test report preview page:

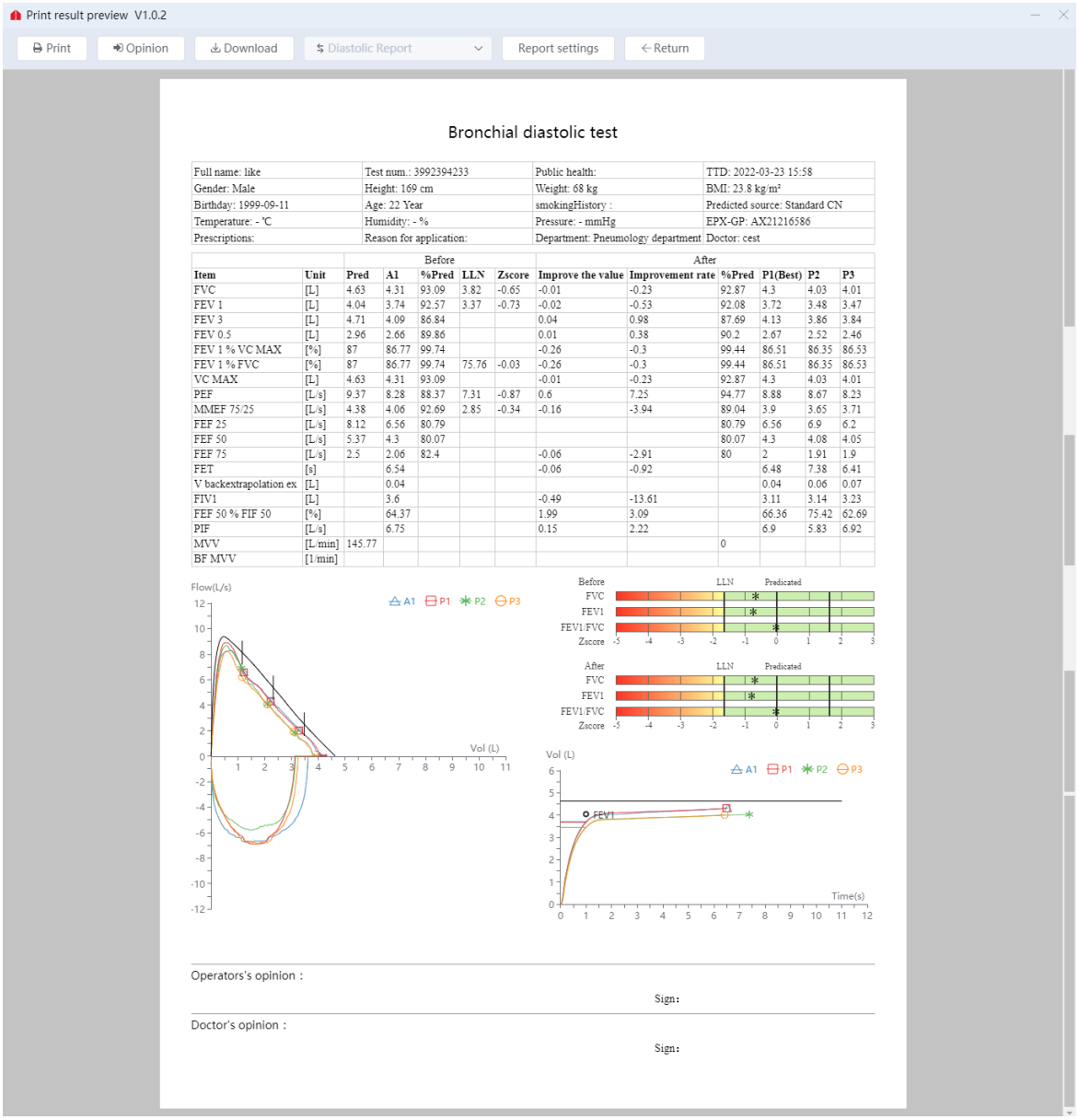


Figure 27 Diastolic test report page

- Opinion filling: pop up form, modify report result analysis content, operator's opinion, save report content.
- Download the report: Select the download path and download the report to the path in PDF format.
- Report Settings: The report title prefix and the indicators displayed in the report can be edited in the system Settings module. You can modify the report title prefix, default report template, and indicator parameters displayed in the report template.
- Training suggestions: Give suggestions on breathing training
- Return: Exit the report preview page

Please choose whether to continue with other mode tests based on facts .

6.9 Patient management

The patient management module includes searching patients, creating patients, editing patients, viewing patients' detailed information, and visiting history, importing patients' data, registering patients' questionnaires in batches before physical examination, etc.

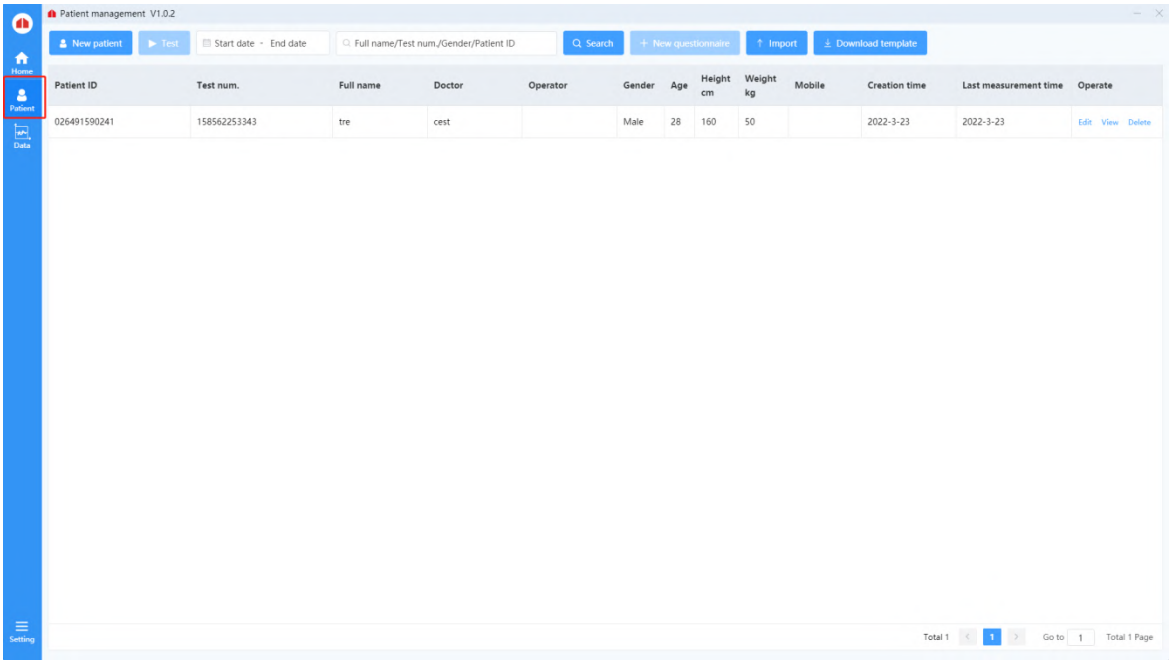


Figure 28 Patient management page

6.9.1 Create and edit Patients

■ If you need to create patient information, click 

to go to the create patient page. See 6. Subject information input data.

■ To edit patient information, click "Edit"in the row.

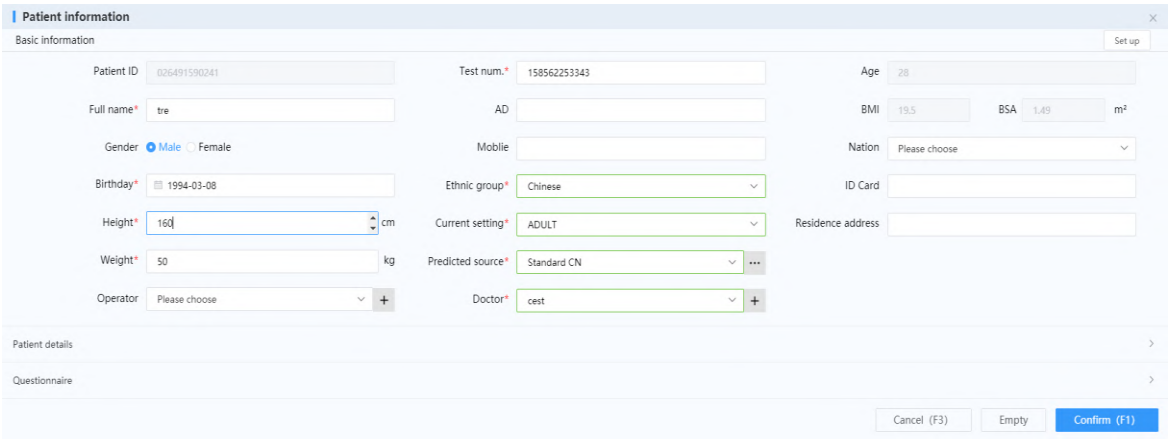


Figure 29 Patient edit page

6.9.2 Search patient

■ Query patients based on query conditions.

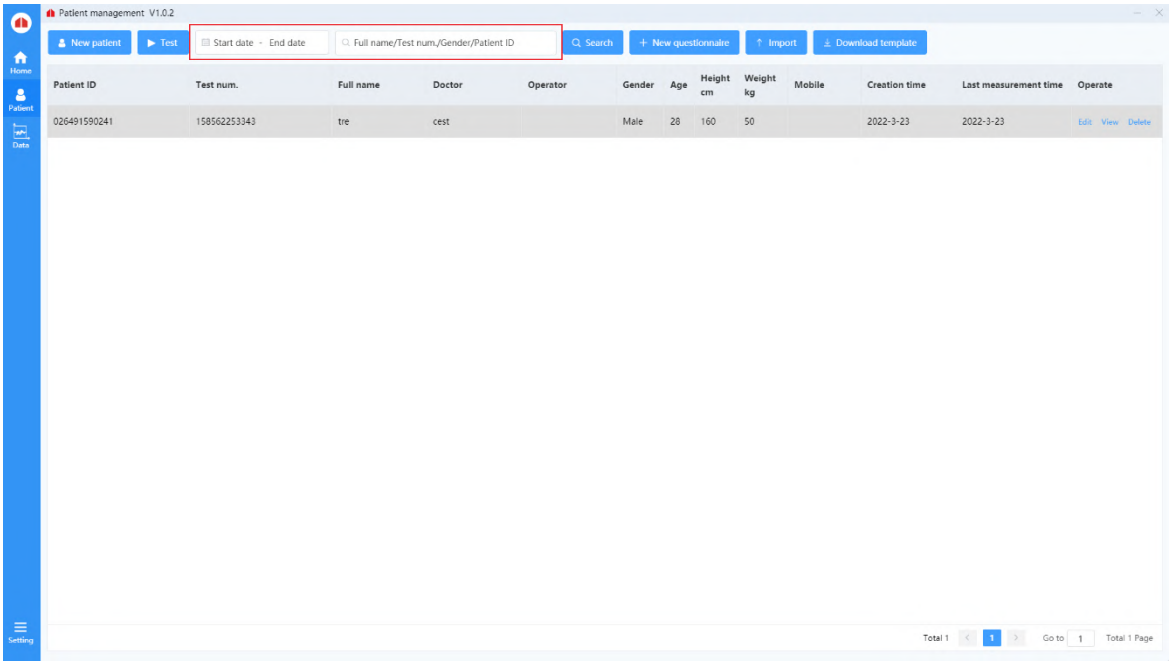


Figure 30 Finding patients schematic①

■ Similarly, you can also search for the patient's examination record on the homepage, and double-click the row to view it.

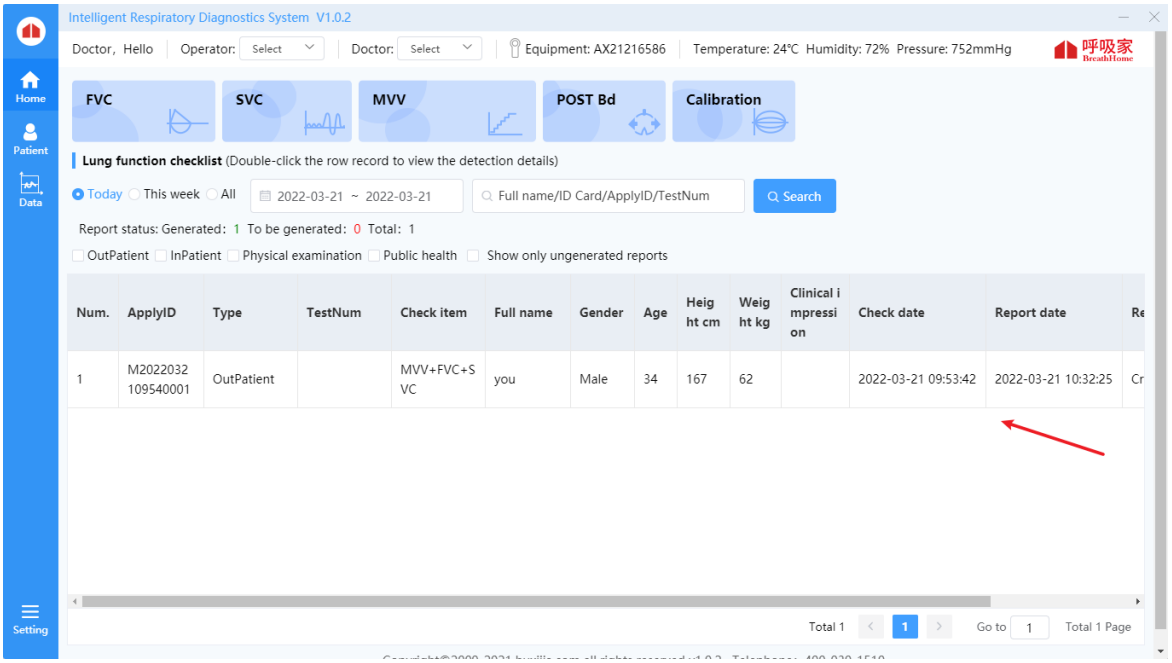


Figure 31 Finding patients schematic②

6.9.3 Viewing patient information

To view the patient information, click " View " in the row you want to view. Then the screen will display the patient's information page.

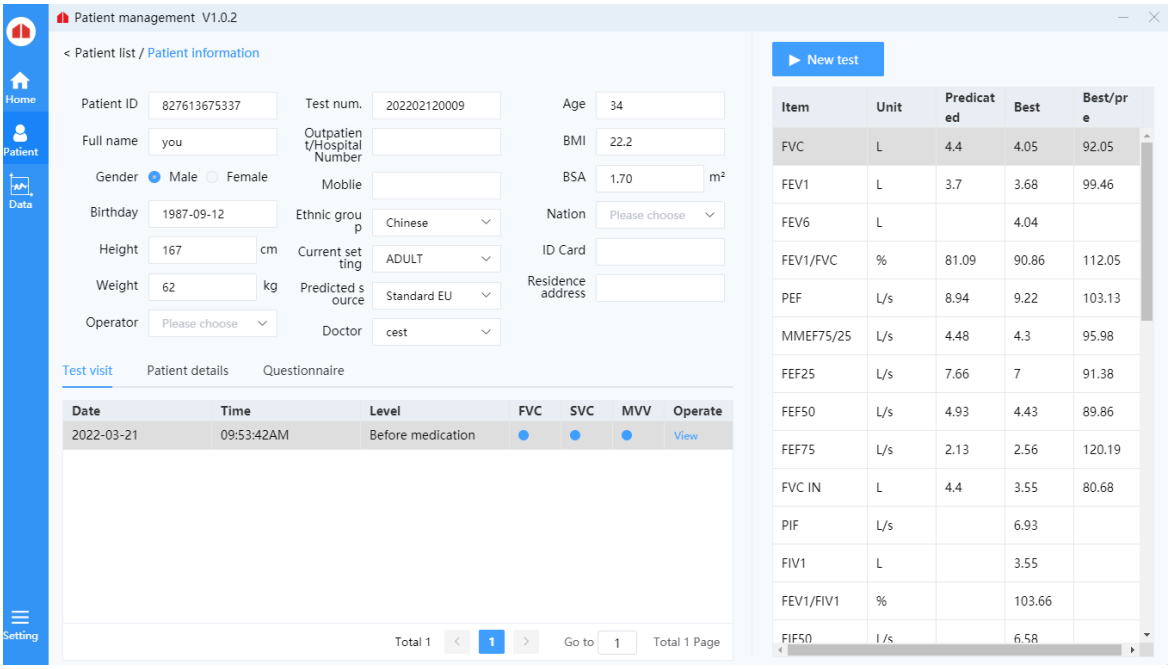


Figure 32 patient's information page interface

6.9.4 Import patient

In order to initialize the existing patient data into the pulmonary function tester in advance, please click the "download template" button to download the excel form, and add the basic information of the patient to be checked into the excel form; click the "import" button, select the Completed excel form, batch import patient information.

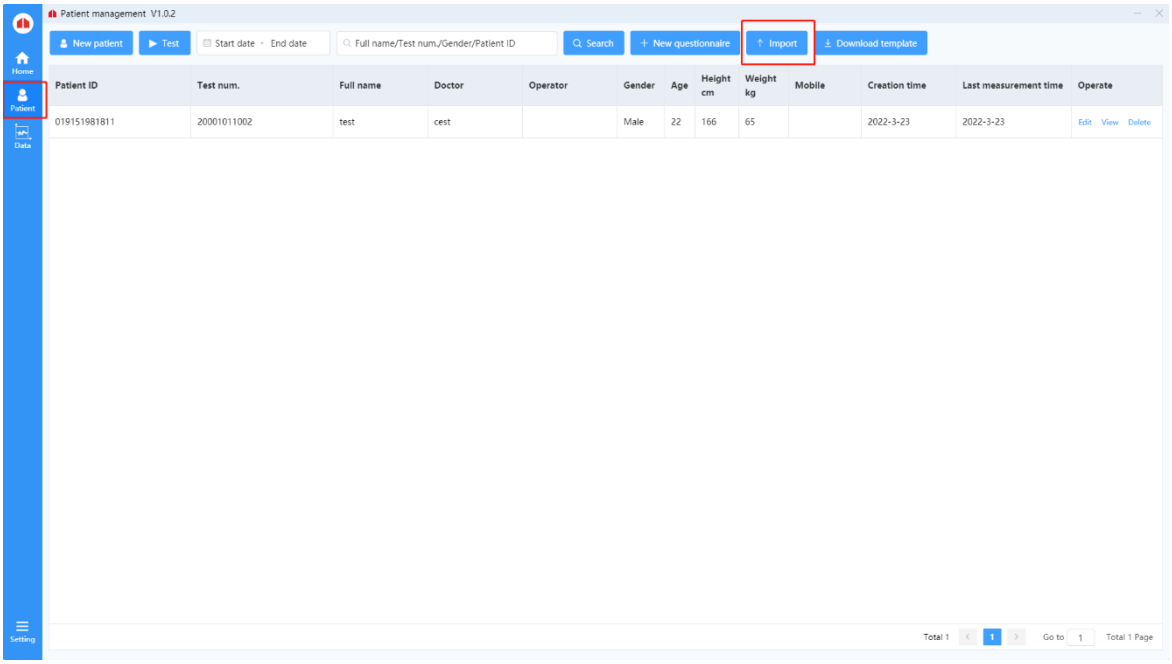


Figure33 Import patient schematic diagram

6.9.5 Delete patients

To delete patient information, click the Delete line. The system will prompt you whether to delete the patient information. For example, confirm deletion of patient test records, generated test reports, and patient basic information.

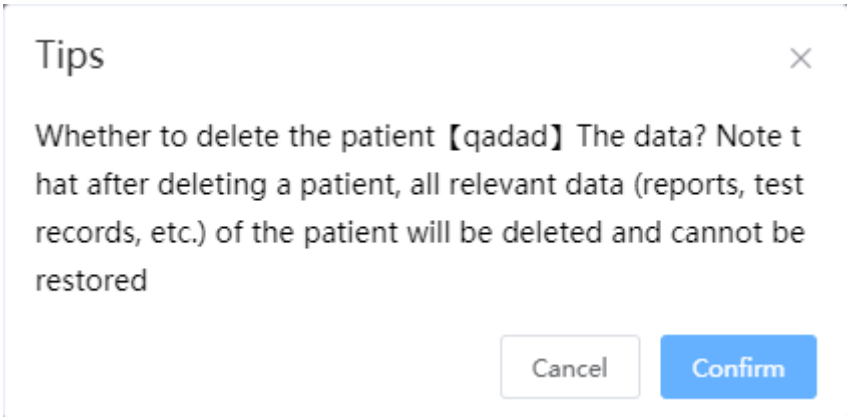


Figure34 Delete patient's tips interface

6.10 Data administration

Data management includes five modules: report list, data query, trend chart, calibration report list and follow-up questionnaire.

⑴Report list：Click the "Report List" button to view the generated report records of all

patients. Through the conditional search, click the operation in the list record information for auxiliary management.

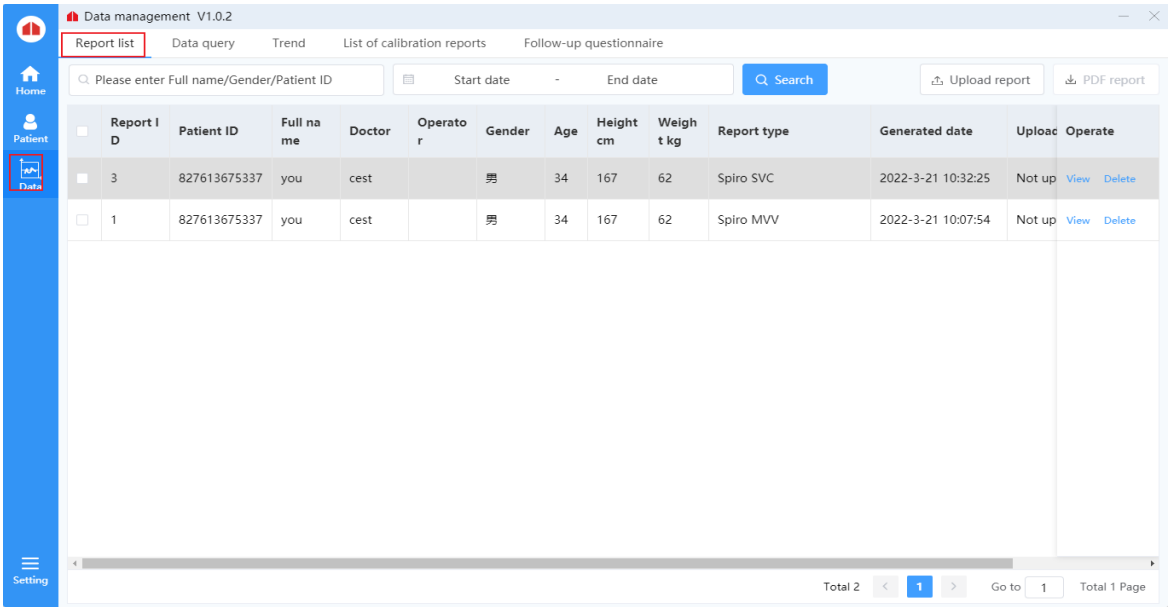


Figure35 Report list interface

⑵Data query：Click the "Data query" button, according to the filled search conditions for the data query after the corresponding operation.

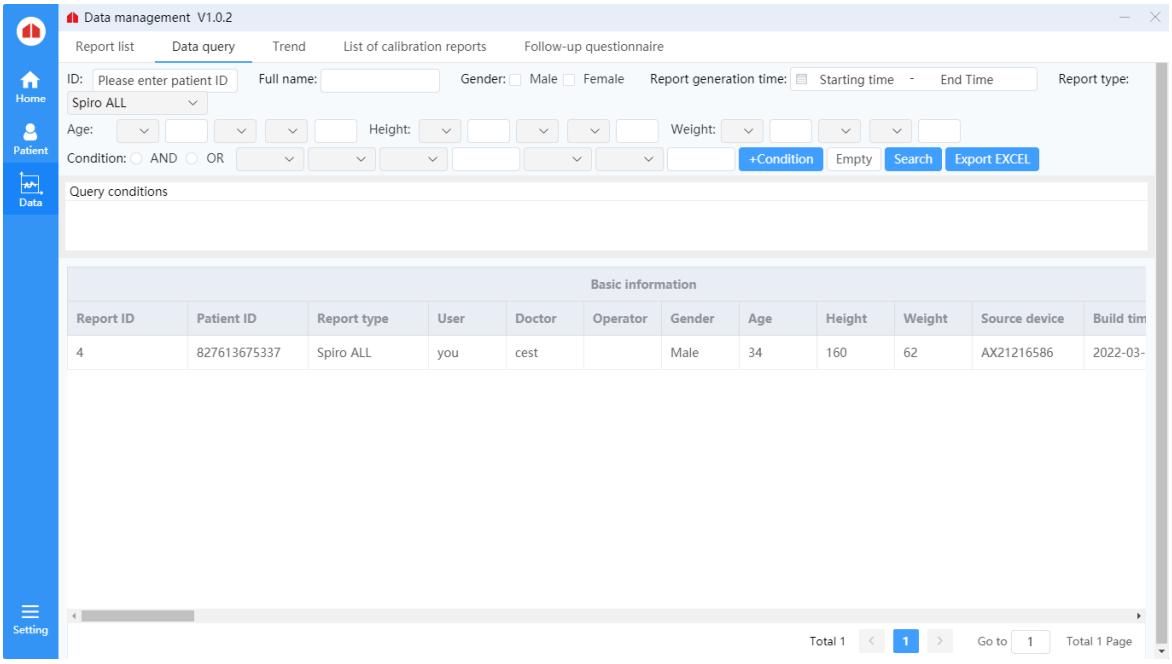


Figure36 Data query interface

⑶Trend：Click the "Trend" button to query the trend change of lung function test records

of patients according to the search criteria.

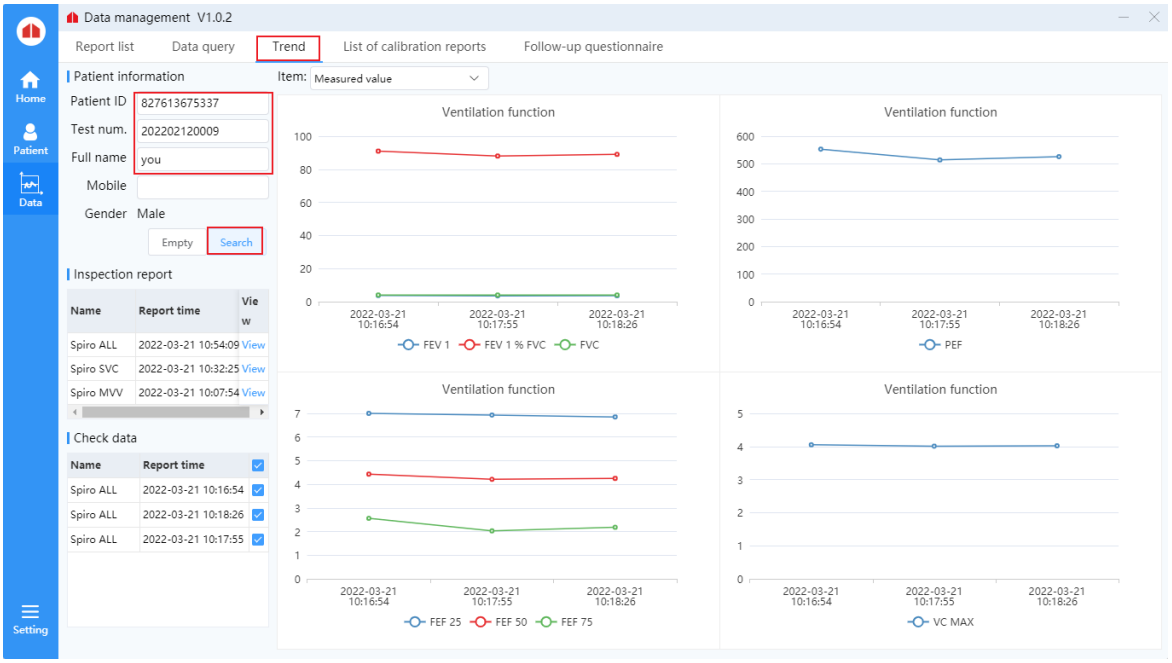


Figure37 Trend view interface

⑷List of calibration reports：Click the "List of Calibration Reports "button to view the calibration report generated.

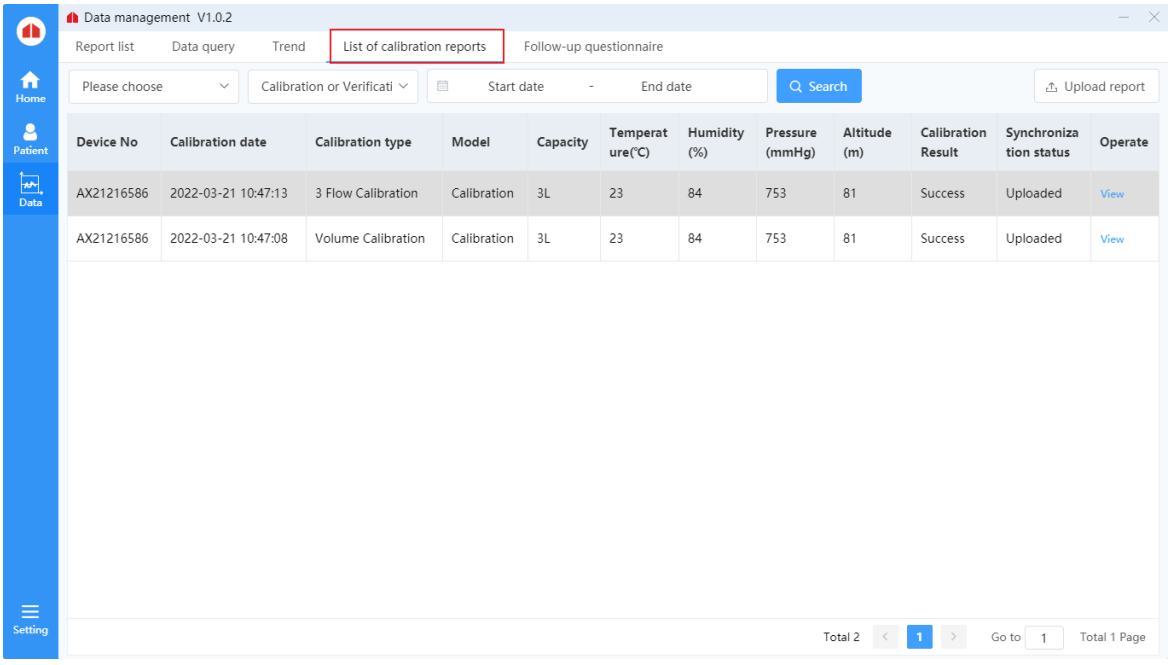


Figure38 List of calibration reports interface

⑸Follow-up questionnaire：Click the button "Follow-Up questionnaire" to check the follow-up questionnaire filled in by the patient and make suggestions to the patient through the suggestions.

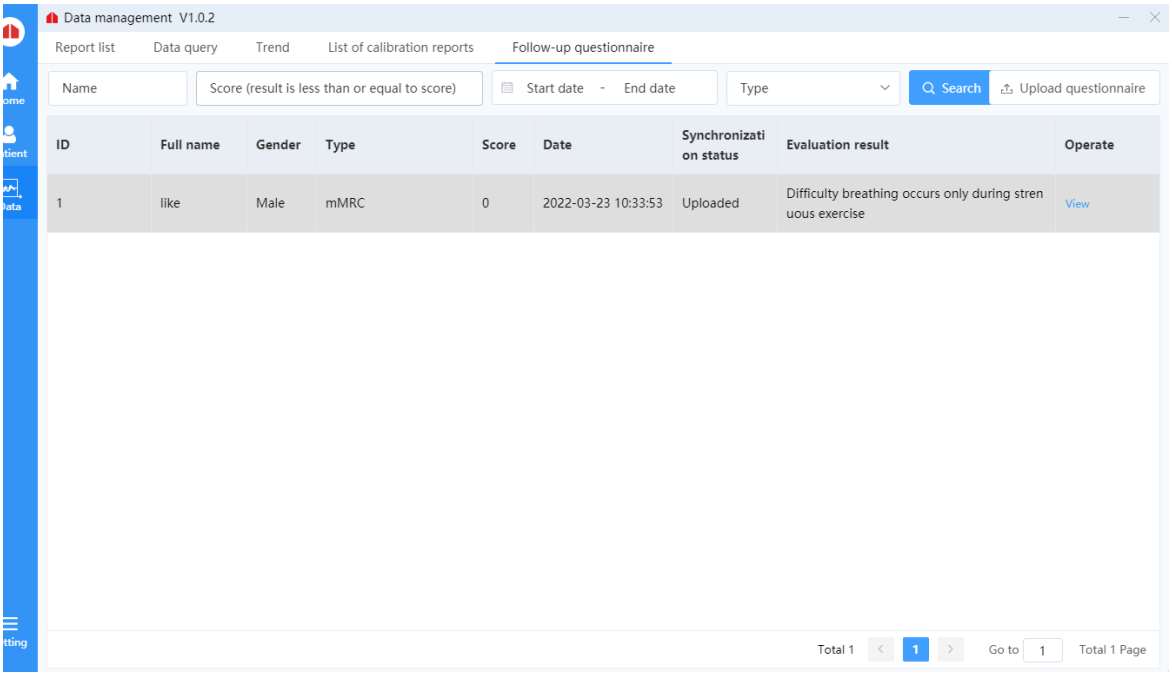


Figure39 Follow-up questionnaire interface

6.11 System settings

System Settings are divided into hospital configuration, account management, report setting, drug setting, parameter setting, expected value module, questionnaire survey, equipment management, data backup, help, software upgrade, HIS configuration and operation diary.

⑴Hospital configuration

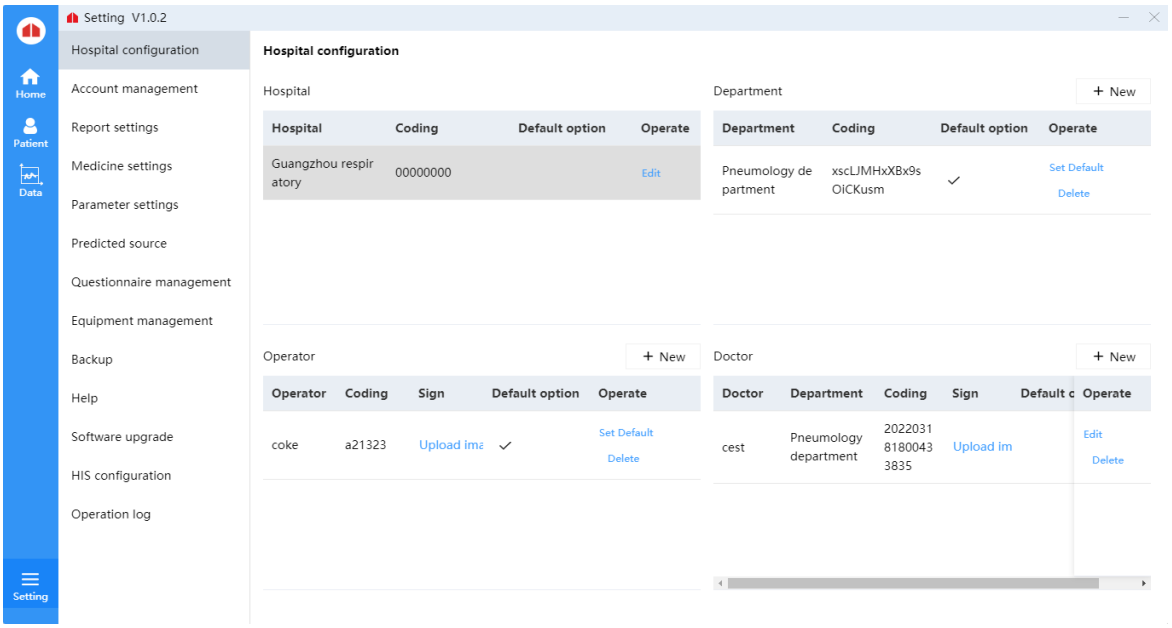


Figure40 Hospital configuration interface

Hospital: Click the Edit button in the hospital information table to edit the hospital name.

Department/Technician/Doctor : Click the "+New" button on the right of the department, operator and doctor to enter the "+New " popup. After adding, it will be updated in the table. Click the "set as default" button in the table to set the selected department/operator as the first selected object. Click the "edit" button in the table, you can edit the information of the selected object. After editing, the table will be updated. Click the "Delete" button in the table to delete the selected object information

⑵Accout management

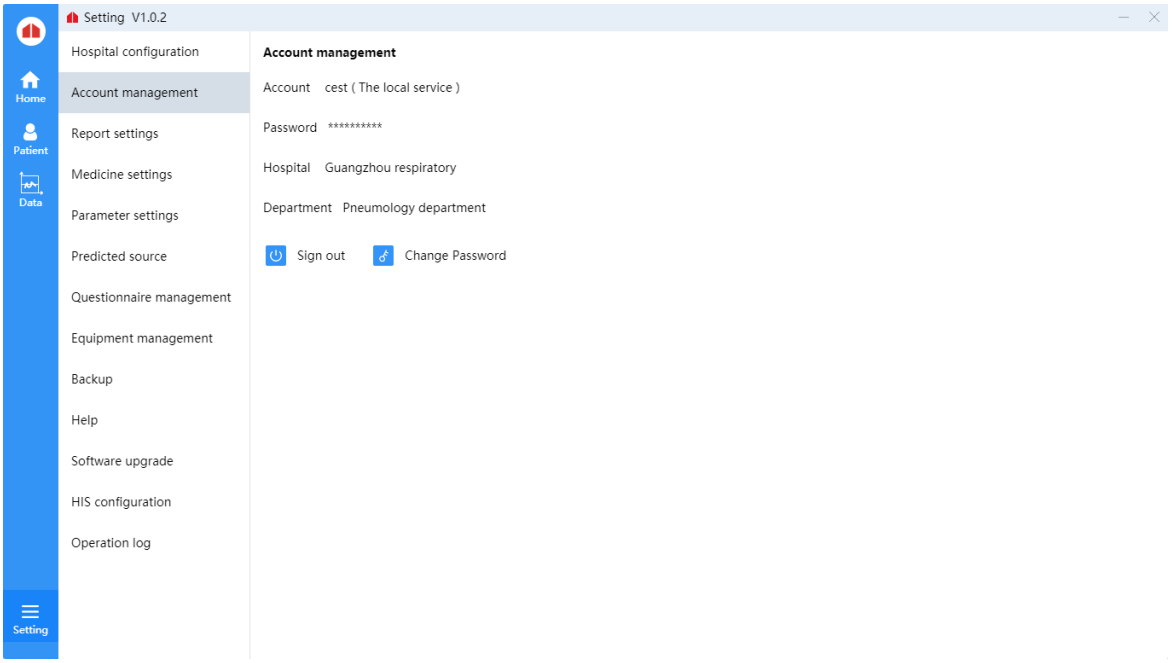


Figure41 Account management interface

Sign out: Click the" Sign out" button to log out of the current account .

Change password: Click The "Change password" button, enter the Change password pop-up window, fill in the old password, new password, confirm the password change, log out of the account, need to use the new password login.

⑶Report settings

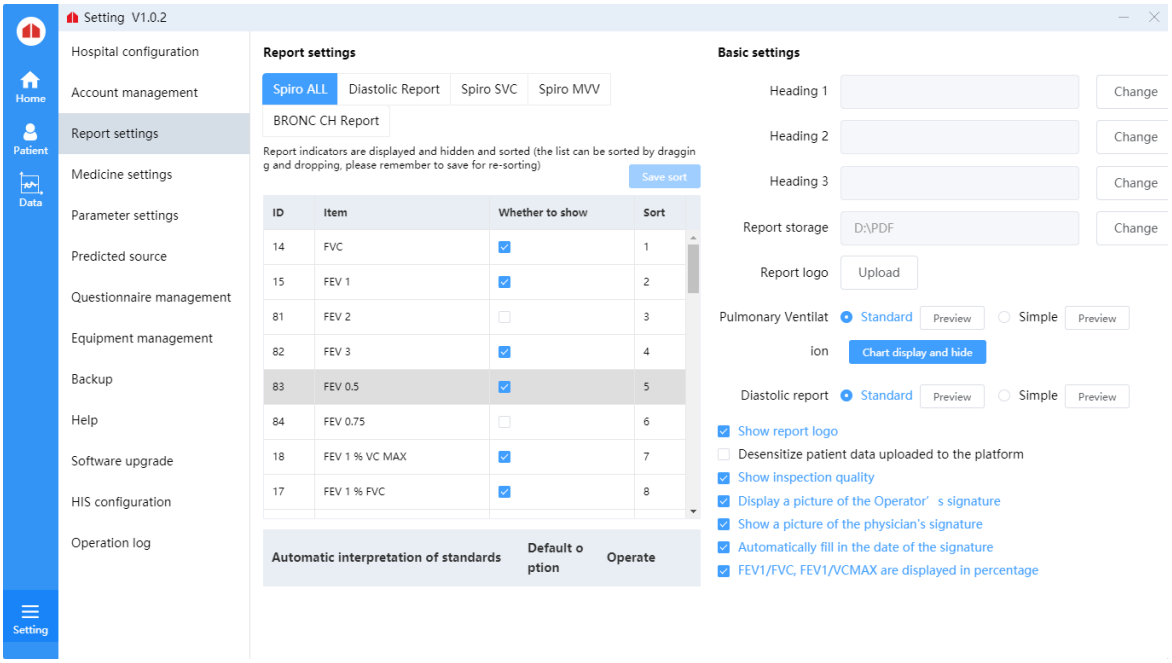


Figure42 Report settings interface

Report settings : Select the report type to switch the report template display. Drag to change the index parameter sorting. You can select "Whether to Show" to display or hide indicator parameters.

Basic settings : Click the "Change" button to edit the information you want to modify, and click "Save" to complete the information editing. Pulmonary Ventillat Selects the reporting mode according to actual needs; Select Settings for other base Settings depending on your needs.

(4)Medicine settings

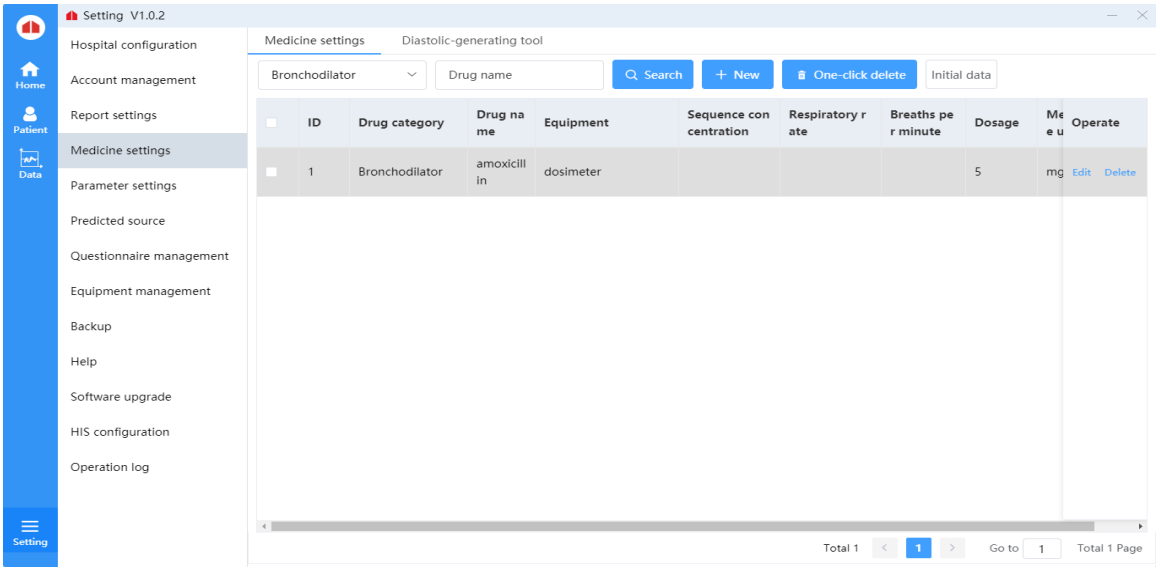


Figure43 Medicine settings interface

Medicine settings: Select the drug type, enter the drug name, and click the “search” button to search the drug.

New drug: Click the “+New” button to enter the new drug popup window and fill in the drug information. After confirming, the drug list will update the new drug.

Delete drugs: Select “Delete” button in the operation of drug list to delete drug information, or select single or multiple drug information and click “one-click Delete”.

Edit drug information: Click the “Edit” button in the drug list to Edit the drug information;

Initial Data: Click the "Initial Data "button to initialize the drug information and add the drug information stored in the database to the drug management.

⑸Parameter settings

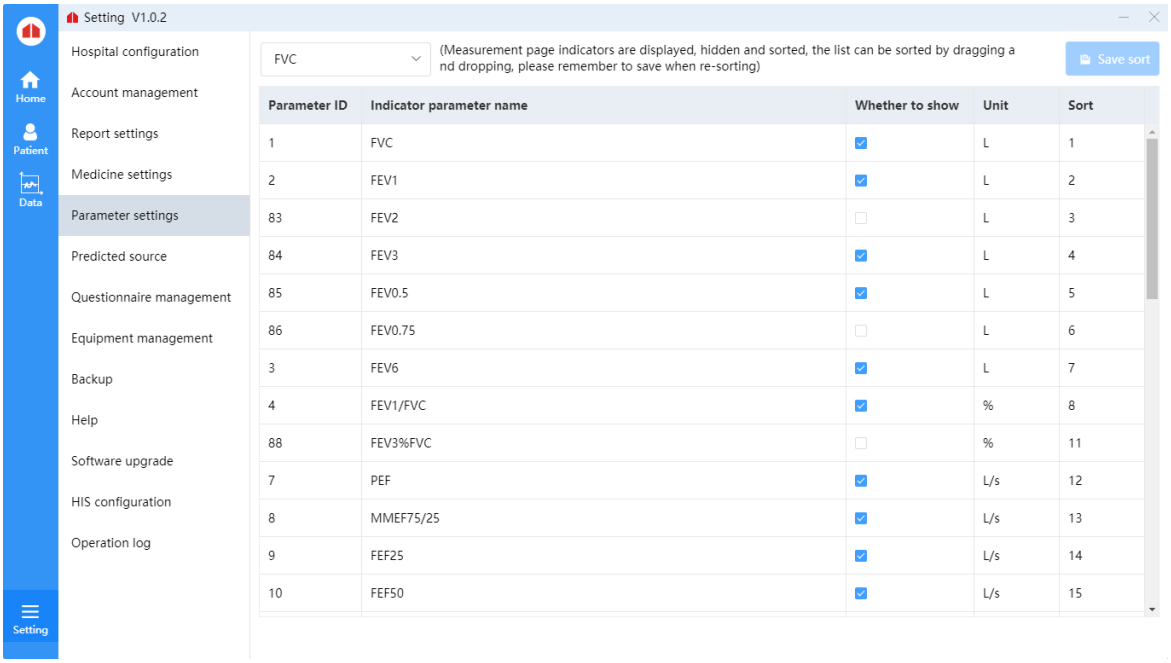


Figure44 Parameter settings interface

Select the drop-down box to switch between different measurement modes.

Explicit implicit and sorting of indicators on the measurement page: The index list can be sorted by dragging and dropping. After resorting, you need to click the save sorting button to save the sorting.

⑹Predicted source

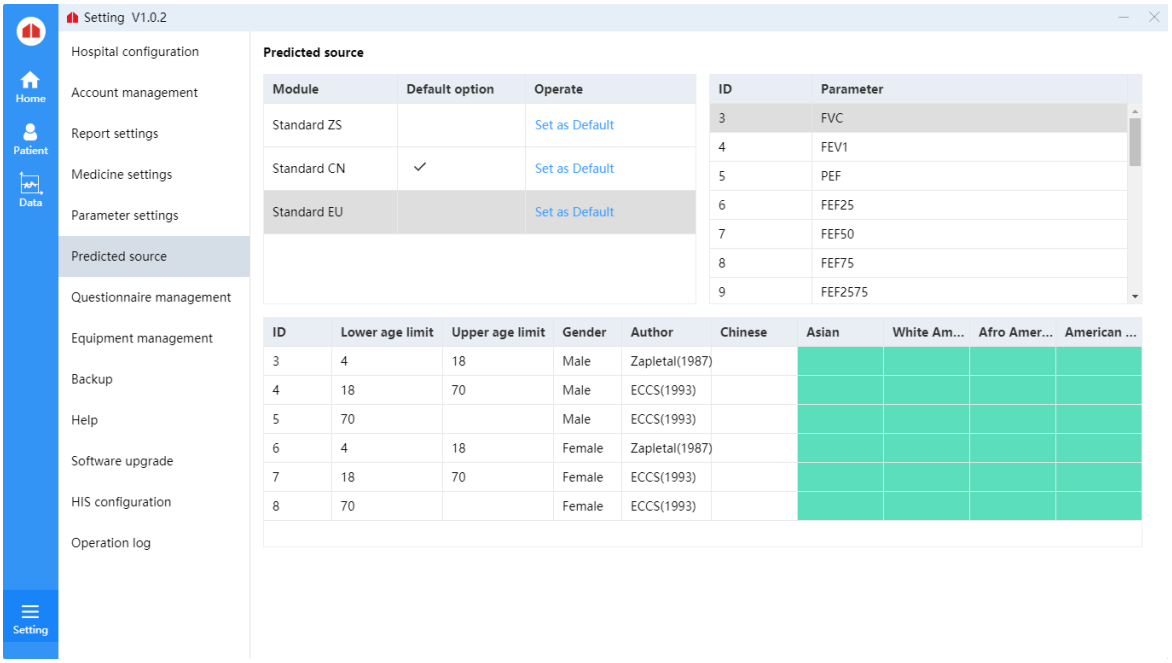


Figure45 Predicted source interface

Set the default expected value mode.

Parameter information in view mode is displayed in the list.

(7)Questionnaire setting

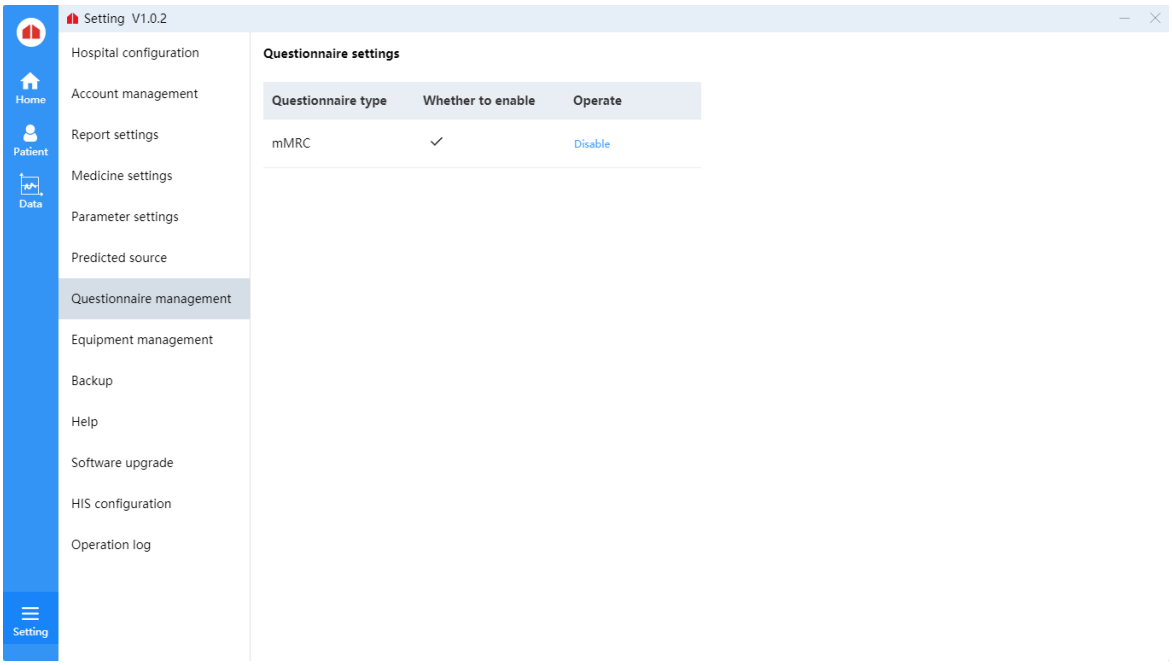


Figure46 Predicted source interface

In the list whether to Enable, click Disable or Enable to enable or disable the management of

the questionnaire type.

⑻Equipment management

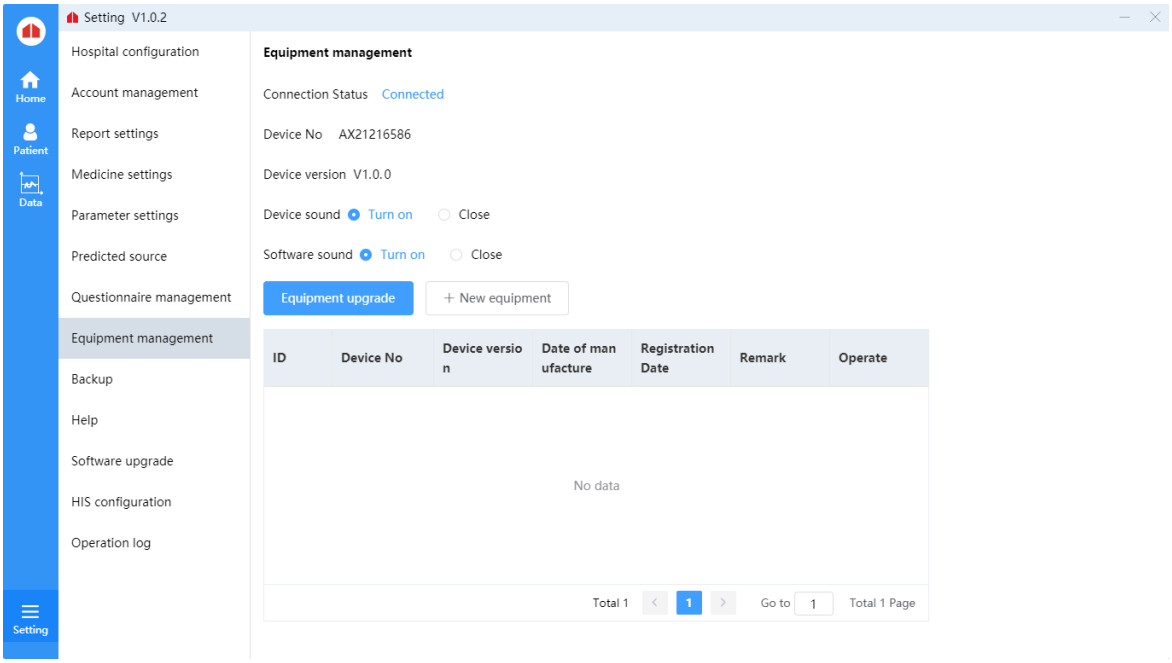


Figure47 Equipment management interface

Device management: You can manage devices only when devices are connected. You can view basic device information.

Turn on/off device sound and software sound.

Upgrade equipment: Click the upgrade button, input the correct upgrade code, and proceed under the guidance of the technical personnel. The equipment cannot be used until the upgrade is successful.

New device: Added a management device. The device information is displayed in the list below.

⑼Backup

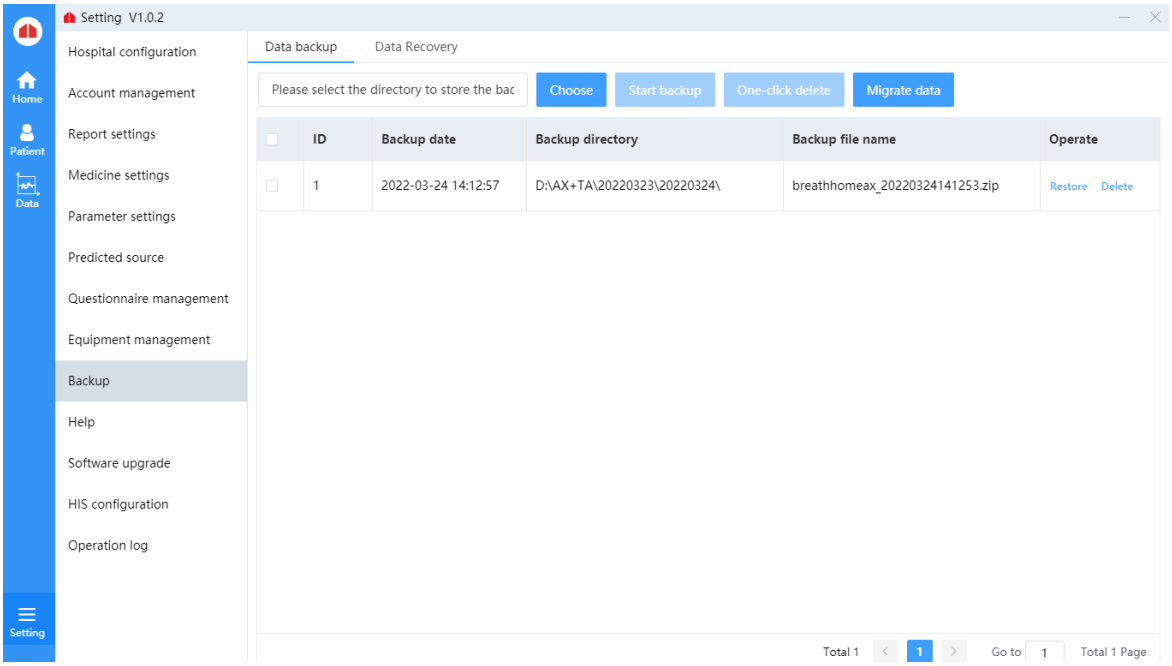


Figure48 Backup interface①

■ Data backup：

Choose: Click "Choose" button to select the storage path of backup files. The path appears in the text box, and the migrated data and data backup will be saved in the selected path.

Start backup：After selecting a storage path, click "Start Backup" to start backing up data.

One-click delete：Select the backup record you want to delete and click the "One-click Delete" button to delete the backup record.

Migrate：Migrate the data of the current account. After clicking, there will be a prompt whether you are sure to migrate the data. All the data of the current doctor account will be migrated to the target account, and the data of the current doctor account will be cleared and cannot be viewed.

■ Data Recovery

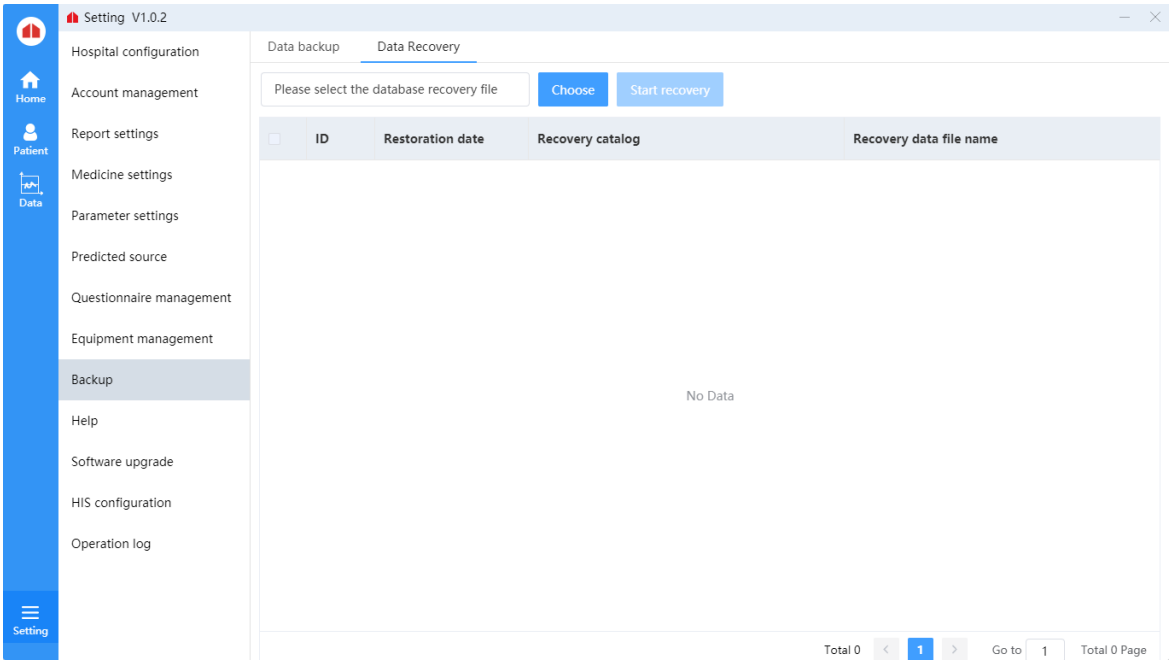


Figure49 Backup interface②

Choose: Click the "Choose" button to select the data backup path.

Start recovery: After selecting the peak path of data, click the Start recovery button to restore the previous backup data.

⑽Help

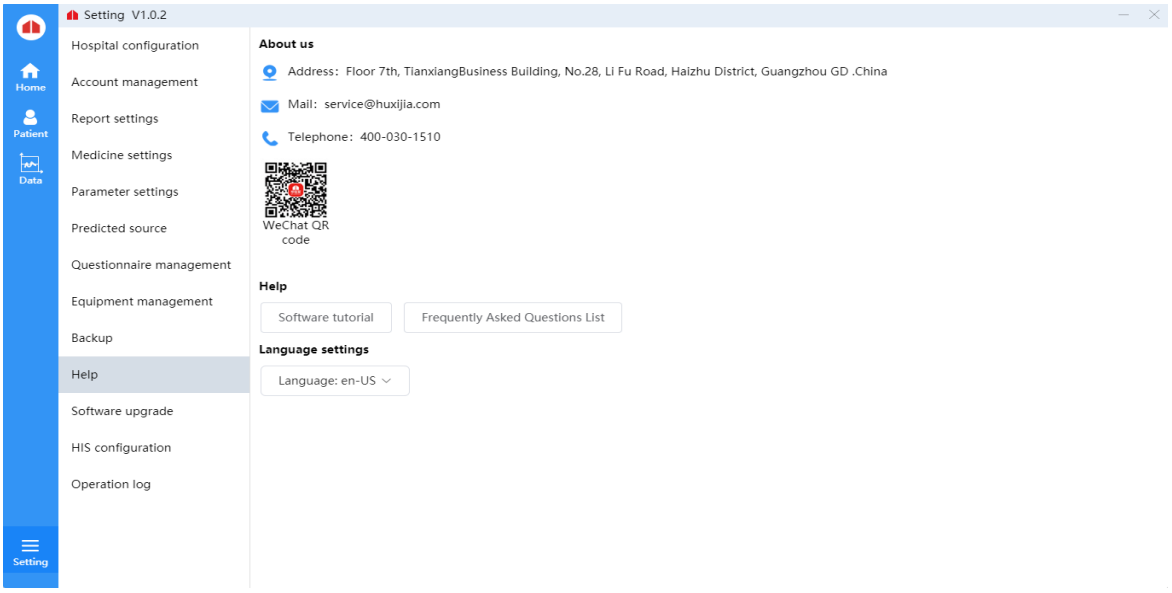


Figure50 Help interface

About us：The basic information and contact information of the company are displayed

Help：Click "Software use Tutorial", "Frequently Asked Questions List" buttons to enter the download path selection, after the selection is completed, the tutorial document will be downloaded to the selected path.

Language settings：Switch the language display according to the language in the select drop-down box.

⑾Software upgrade：

Figure51 Software upgrade interface

Software upgrade needs to contact technical personnel, so provide after-sales service telephone to users for easy contact

⑿HIS configuration

HIS address configuration can effectively serve for hospital management and operation

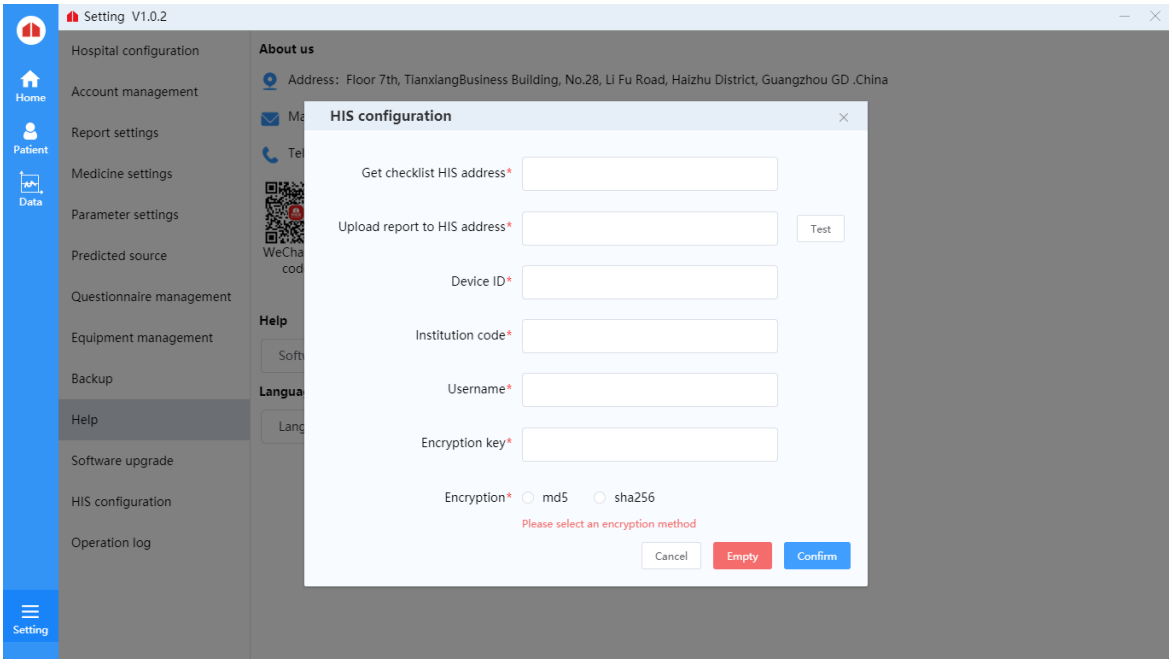


Figure52 HIS configuration interface

⑬Operation log

View operation logs for easy management and maintenance.

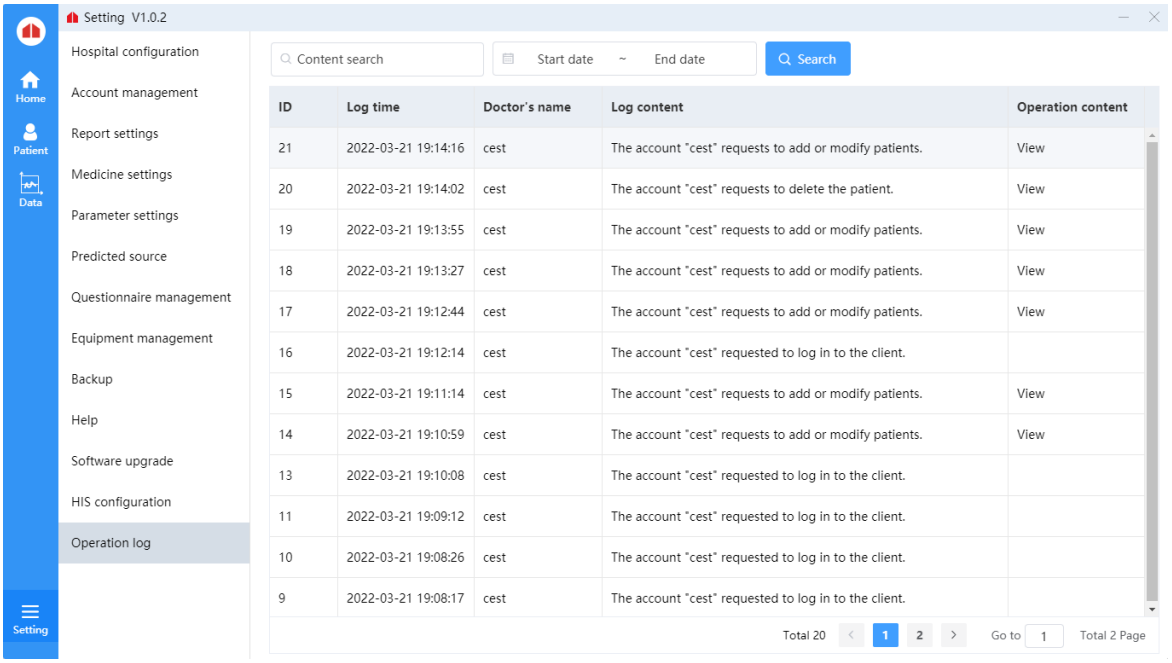


Figure53 Operation log interface

Chapter 7 Maintenance and precautions

7.1 Overview

In order to give full play to the performance of this software, ensure its reliability, and prolong its service life, please maintain, and maintain it strictly in accordance with the requirements of this chapter.

7.2 Daily maintenance methods

Such as occurs when the software failed to start, run-time error, etc., should stop using, and contact Guangzhou Homesun Medical Technology Co., Ltd., or local agents.

7.3 Daily use precautions

■ Do not copy the software to other machines for installation and use without the written authorization of the manufacturer or its sales representative.

■ Before using the software, please read the " user manual" of this product carefully, and use it by trained and qualified personnel.

7.4 Quality control

Personnel to operate only through the use of Guangzhou Homesun Medical Technology Co., Ltd. or its agents trained and authorized, or may adversely affect the test results can be.

Chapter 8 Failure analysis and treatment

8.1 Overview

This chapter introduces the handling methods and steps of common software failures. If you still cannot eliminate the failure according to the work instructions in this chapter or need more and more detailed information, please contact Homesun's after-sales service department.

CAUTION

This manual is not equivalent to the maintenance manual. It only provides the measures that the operator should take when the analyzer has a fault alarm.

8.2 Simple troubleshooting

After the following malfunctions occur in the software, the troubleshooting methods in the following table should be used to solve them. If you can not solve or cause other problems now like, please do not resolve itself, please contact with us.

Summary of daily software failure analysis and handling

Failure phenomenon	**Cause Analysis**	**Method of exclusion**
The software does not start normally	The pulmonary function tester is damaged	Reinstall the software
No response after software button is clicked	The software is abnormal or the program file is damaged	Contact after-sales service personnel for maintenance
Other failures	When other failures occur	Please contact the after-sales service

Chapter 9 Electromagnetic compatibility description

9.1 Parameter description

Name	Working frequency	Modulation type	Maximum Tune-up power(dBm)
Bluetooth	2.4GHZISM BAND	GFSK	-3.00

Name	Cable length (m)	Whether to block	Remark
USB Cable	2.0	Yes	/

Even if other equipment meets the emission requirements of the corresponding national standards, the equipment or system may still be interfered by other equipment.

9.2 EMC statement

1 ） Model A9 needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying document;

2 ） Portable and mobile RF communications equipment can affect model A9.

1 ） Don’t be 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.

2 ） Use of accessories, transducers and cables other than those specified or provided by the manufacturer of Model A9 could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

3 ） Use of Model A9 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.

9.3 Declaration of conformity

Table 1

Guidance and manufacturer's declaration – electromagnetic emission		
The Pulmonary Function Tester（A9）is intended for use in the electromagnetic environment specified below. The customer or the user of Pulmonary Function Tester（A9）should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Pulmonary Function Tester（A9）uses RF energy only for its internal function. There for, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Pulmonary Function Tester（A9） is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations flicker emissions IEC 61000-3-3	Not applicable	

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity			
The Pulmonary Function Tester（A9） is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulmonary Function Tester（A9） should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment -guidance**
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	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least

			30 %.
Electrostatic transient / burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ±2 kV common mode	± 1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle g) 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 g) 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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Pulmonary Function Tester（A9）requires continued operation during power mains interruptions, it is recommended that the Pulmonary Function Tester（A9）be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 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.			

Table 3

Guidance and manufactureŕs declaration – electromagnetic immunity			
The Pulmonary Function Tester（A9）is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulmonary Function Tester（A9）should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF	3 Vrms	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Pulmonary Function Tester（A9）, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

IEC 61000-4-6	150 kHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz	150 kHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz	**Recommended separation distance** $d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [\frac{12}{V_2}]\sqrt{P}$
Radiated RF	3 V/m	3 V/m	
IEC 61000-4-3	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)	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)	$d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 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 metres (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] 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 is affected by absorption and reflection from structures, objects and people.

[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

[b] 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 Pulmonary Function Tester（A9）is used exceeds the applicable RF compliance level above, the Pulmonary Function Tester（A9）should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Pulmonary Function Tester（A9）.

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

Table 4

Recommended separation distances between

portable and mobile RF communications equipment and the Pulmonary Function Tester（A9）

The Pulmonary Function Tester（A9）is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Pulmonary Function Tester（A9）can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Pulmonary Function Tester（A9）as recommended below, according to the maximum output power of the communications equipment

Rated maximum output of transmitter W	**Separation distance according to frequency of transmitter m**			
	150 kHz to 80 MHz outside ISM and amateur radio bands $d=[\frac{3.5}{V_1}]\sqrt{P}$	150 kHz to 80 MHz in ISM and amateur radio bands $d=[\frac{12}{V_2}]\sqrt{P}$	80 MHz to 800 MHz $d=[\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.7 GHz $d=[\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.20	0.035	0.07
0.1	0.38	0.63	0.11	0.22
1	1.2	2.00	0.35	0.70
10	3.8	6.32	1.10	2.21
100	12	20.00	35	70

For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (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.