

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 <u>HOMESUN</u>, CALL <u>400-030-1510</u> (Working Time: from Monday to Friday, Beijing time 9:00-18:00), OR WRITE TO <u>service@huxijia.cn.</u>

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 manual contains copyright information, and Guangzhou Homesun Medical Technology Co., Ltd reserves all rights. Without the prior written approval of Guangzhou Homesun Medical Technology Co., Ltd copying or translating this manual into any language is not allowed. Guangzhou Homesun Medical Technology Co., Ltd reserves the right to modify the information included in this document without Caution.

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.

1. Product description
1.1 Product brief description1
1.2 Intended use / indications for use1
1.3 Requirements for patients1
1.4 Product main structure1
1.5 Product performance
1.6 Contraindications
1.7 Product list
1.8 Site requirements during use
1.9 Other usage specifications
2. Label symbol description
3. Precautions, warnings, and prompt instructions7
4. Installation and use instructions
4.1 Check the equipment list9
4.2 Equipment installation and preparation9
4.3 Equipment use9
4.4 Pulmonary ventilation function measurement method10
4.5 Shutdown
4.6 Charging12
5. Instructions for using mobile software (see Annex 1 for details)12
6. Instructions for using computer software (see Annex 2 for details)12
7. Cleaning and disinfection methods12
7.1 Removal steps of flow sensor head13
7.2 Cleaning and disinfection of the parts of the flow sensor head
8. Equipment maintenance
8.1 Maintenance
8.2 Work, storage and transportation requirements15
9. Failure analysis and resolution16
10. Product quality information17
10.1 Warranty service17
10.2 Post-maintenance
10.3 Production date and expiry date18
11. Cybersecurity instructions
11.1 Operating environment requirements18

Content

11.2 Security software	18
11.3 Data and equipment interface	18
11.4 User access control mechanism	18
12. Electromagnetic compatibility instructions	19
12.1 Parameter description	19
12.2 EMC statement	19
12.3 FCC declaration	20
12.4 Declaration of conformity	21
14. Contact information	24

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	$\pm 5\%$ or $\pm 0.17 L/s$, whichever is greater
Airflow resistance	/	Flow measurement range < 0.15 kPa / (L/s)
Volume	(0-10)L	$\pm 3\%$ or $\pm 0.05L$, whichever is greater

1.5.3 Parameter description

Table 1	Display	measured	value	parameters	in	different	modes
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Model	Measurement display parameters		
	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%} ,		
Forced vital capacity	$FEF_{25\%\text{-}75\%}$ (MMEF) , PIF , $FIF_{50\%}$, $FET_{100\%}$, FEV_1/FVC ,		
	FEV_3/FVC , FEV_1/VC max, V backextrapol.ex% FVC,		
	$\text{FEF}_{50\%}/\text{FIF}_{50\%}$, $\text{FEV}_1/\text{FIV}_1$		
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
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;
- 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;
- 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.);
- 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	×
USB cable	×
User manual	×
Quality certificate	X

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
$R_{\!XOnly}$	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
Ĵ	Keep away from rain
×.	Keep away from sunlight
	Fragile, handle with care
-20°C	Temperature limit

95%RH	Humidity limitation
1200hPa	Atmospheric pressure limitation
	Stacking limit by 5
Ŕ	Type BF applied part
(((••)))	Low-frequency electromagnetic radiation
X.	"WEEE (Waste Electrical and Electronic Equipment)". The waste products should be handled legally.
Â	Caution
SN	Serial number
	Manufacturer
	Class II equipment
RA RA	Recyclable
UDI	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.

A 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.

A 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.

ACaution:

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

A 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.

A 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.

A 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 °C \sim +34 °C

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 °C ~ +50 °C

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	
	Low battery	Please connect the charger to	
Can not boot	Possible equipment damage	Please contact the after-sales customer service center.	
	The Bluetooth function of the mobile phone is not turned on	Please turn on the Bluetooth function of the mobile phone.	
Bluetooth network connection failed after power on	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.	
	Could not establish connection	The USB cable is damaged or the connection is loose.	
The device uses the USB connection software successfully, but the communication is abnormal	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	The instrument does not enter the detection state	Press the key again to measure or shut down and restart.	
for blowing	Incorrect blowing posture	Please use the correct blowin 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.

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

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	4	User	access	control	mechanism
------	---	------	--------	---------	-----------

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

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

Marning

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:

(1) This device may not cause harmful interference, and

(2) 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 manufacturers' declaration – electromagnetic emission					
The Pulmonary Function	n Tester (A9) is	intended for use in the electromagnetic environment specified			
below. The customer or an environment.	the user of Pulmo	onary Function Tester(A9)should assure that it is used in such			
Emissions test	Compliance	Electromagnetic environment - guidance			
RF emissions	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			
CISPR II		electronic equipment.			
RF emissions CISPR 11	Class A				
Harmonic emissions IEC 61000-3-2	Not applicable	The Pulmonary Function Tester (A9) is suitable for use in			
Voltage fluctuations flicker emissions IEC 61000-3-3	Not applicable	all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.			

Table 2

Guidance and manufacturers' declaration – electromagnetic immunity						
The Pulmonary Fun	ction Tester (A9) is inte	ended for use in the electr	omagnetic environment specified			
below. The custome such an environment	r or the user of the Pulmo t.	nary Function Tester(A9) should assure that it is used in			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -guidance			
Electrostatic discharge (ESD)	±8 kV contact ±2 kV, ±4 kV, ±8 kV,	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV,	Floors should be wood, concrete or ceramic tile. If floors are covered with			
IEC 61000-4-2	±15 kV air	±15 kV air	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; 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°	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		
	0 % UT; 250/300 cycle	0 % UT; 250/300 cycle	(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 manufacturers' declaration – electromagnetic immunity					
The Pulmonary F	unction Tester ((A9) i	is intended for use in t	the electromagnetic environment specified	
below. The custor	mer or the user of	of the P	ulmonary Function Te	ester (A9) should assure that it is used in	
such an environm	ent.				
Immunity test	ity test IEC 60601 test Compliance level Electromagnetic environment - guidance				
				PortableandmobileRFcommunicationsequipmentshouldbeusednoclosertoanypartof	
				Pulmonary Function Tester (A9),	
including cables, than the recommended separation distance calculated from the equation applicable to the frequency of					
Conducted RF	3 Vrms		3 Vrms	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)	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P} 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1}\right]\sqrt{P} 800 \text{ MHz to } 2.7 \text{ GHz}$ where <i>p</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> 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

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).

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

	Separation distance according to frequency of transmitter						
		m					
Rated maximum output of transmitter W	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 $d = \left[\frac{12}{V_2}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	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

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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.

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
1.2 Scope of application of the manual1
1.3 Guide to the manual
1.4 Symbol explanation2
1.5 Prerequisite information
1.6 System related characteristics2
Chapter 2 Software description
2.1 Operating environment4
2.2 Technical parameters4
Chapter 3 Working principle and scope of application
3.1 Working principle
3.2 Scope of application
Chapter 4 Major component structure
Chapter 5 Software installation and uninstallation10
5.1 Overview
5.2 Installation requirements10
5.3 Installation method10
5.4 Software uninstallation procedures11
5.5 Parts list
Chapter 6 Software interface and operation
6.1 User login
6.2 Home
6.3 Calibration15
6.4 Forced vital capacity test procedure
6.5 Maximum minute ventilation test procedure24
6.6 Slow vital capacity test procedure
6.7 Bronchial diastolic test procedure
6.8 Data management
6.9 Report management
6.10 System settings
Chapter 7 Maintenance and precautions
7.1 Overview

7.2 Routine maintenance method	
7.3 Daily use precautions	48
7.4 Quality control	48
Chapter 8 Failure analysis and treatment	49
8.1 Overview	49
8.2 Simple troubleshooting	49
Chapter 9 Electromagnetic compatibility statement	50
9.1 Parameter description	50
9.2 EMC statement	50
9.3 FCC declaration	51
9.4 Declaration of conformity	51

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	Chapter 2 Software introduction	
performance parameters of the software	Chapter 2 Software Introduction	
Understand the measurement principle and	Chapter 3 Working principle and scope of	
process of software applications	application	
Understand the main structure of the	Chapter 4 Main product structure	
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
DANGER	Remind the operator to follow the instructions under the symbol, otherwise it may cause personal injury.
WARNING	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 \sim 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:

All (8)	^
draw over other apps	
modify system settings	>
Warning	>
•	>
This app has not undergone AppGallery compatibility SD card	>
CANCEL INSTALL	
	>
fine (GPS) location	
	AI (8) draw over other apps modify system settings Warning () This app has not undergone AppGallery compatibility and security testing. Install with caution. CANCEL INSTALL fine (GPS) location

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.

App info	
AX version 1.0.1	
UNINSTALL FORCE STOP	
Storage 85.96 MB used of Internal storage	>
Permissions Your location	>
Notifications	>
Open by default No defaults set	>
Battery	>
Memory An average of 39 MB of memory used in last 3 hours	>
ADVANCED	
Draw over other apps No	>
Write system settings No	>
STORE	
App details • • • • • • • • • • • • • • • • • • •	

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.





- 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.

A Caution:

The 3L calibration pump is purchased by the user, and its requirements are $3L\pm0.5\%$.

6.3.2 Standard calibration

- 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 $\pm 10\%$, 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.

< Return					Stanc	lard ca	libratio	n (3L)						69
Calibration model	15 F(L/ 10 F(L/	volume /s)					-10%		+10	% Blow	Blow	ction		3.01 3.02 3.02 3.02 3.02
(Þ) Start	-100										Inhale			3.01 3.00 2.97 2.95
	-15 0.0 0	.2 0.4 0.4	5 0.8	1.0 1.2 1.4	1.6 1.8	2.0 2.2	2.4 2.6	2.8 3.0	3.2 3.4	V(L) Inhale	Calibrati The erro	onSucces r in+/- 10.	ss 00 %	ent
Save		Item	Unit	Last	This	Diff%	Test1	Test2	Test3	Test4		Unit	Last	This
		Capacity	L	3.02	3.02	0.00	3.01	3.02	3.02	3.02	-			
	Blow	Flow	L/S	7.27	6.69	-7.98	6.88	6.72	6.60	6.55	ature	°C	25	25
[*]		Gain Ex		0.99	0.99	0.00	1.00	0.99	0.99	0.99				
		Capacity	L	2.98	2.98	0.00	3.01	3.00	2.97	2.95	Humidit	%	67	67
Calibration	Inhale	Flow	L/S	6.46	5.88	-8.98	6.08	6.03	6.0	5.42	У			
record		Gain In		1.01	1.01	0.00	1.00	1.00	1.01	1.02	Broouro	mmlla	747	740
	Date			2022-03-17	2022-03-17	7					Presure	mmHg	/4/	749
	time			16:46:24	17:51:56									
											Altitude	m	145	142

Figure 6 Calibration test interface

6.3.3 3 Flow verification

- 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;
- 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.

< Return						La	st3flov	v (3L)							660
Calibration model	flow/v	volume (s)						-10%		+10%	Blow ~ 3 ~ 3 ~ 3 ~ 3 ~ 3 ~ 3 ~ 3 ~ 3	Blow Inhale Calibrati	onSucces	35	2.98 2.99 2.97 2.97 2.97 2.97 2.97 2.93 2.93 2.93 2.93 2.93 2.93
ē	-15-0.0 0	.2 0.4 0.4	6 0.8	1.0 1.2	1.4 1.6	1.8 2.0	2.2 2.4	4 2.6 2	.8 3.0	3.2 3.4	(L) Inhale	Accuracy good, ca within th	y and rep pacity in e range o	eatabilit all three f10.00%	y is very types of flow
Save	Flow rate/volume								Calibr	ation en	vironm	ent			
Guve		Item	Unit	L1	L2	L3	M1	M2	M3	H1	H2		Unit	Last	This
		Capacity	L	2.98	2.97	3.00	2.99	2.99	3.00	2.98	2.97	Temper	°C	23	23
~	Blow	Flow	L/S	1.33	1.32	1.08	3.25	3.12	2.43	10.40	9.83	ature	C		20
<u></u>		Gain Ex		1.01	1.01	1.00	1.00	1.00	1.00	1.01	1.01	1.1			
Calibration		Capacity	L	2.92	2.93	2.93	2.93	2.93	2.92	2.94	2.94	v	%		66
record	Inhale	Flow	L/S	1.22	1.08	0.93	2.93	2.7	2.6	9.07	8.83	,			
		Gain In		1.03	1.02	1.02	1.02	1.02	1.03	1.02	1.02	Presure	mmHg		749
												Altitude	m		119

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.

										5 🛤	
8	Drug use before▼	Drug	•	Unit	•		Recom	mend) Generati	e report	alibration	
Li mi										1	
	Item	Unit	Predicated	Best	Best/pre	Test1	Test2	Test3			
20	FVC	L	4.27	4.16	97.42	4.17	4.00	4.16		(v)	
Madal	FEV1	L	3.50	3.68	105.14	3.57	3.56	3.68			
Model	FEV6	L		4.14		4.14	3.98	4.14			
	FEV1/FVC	%	81.92	88.46	107.98	85.61	89.00	88.46			
(\triangleright)	PEF	L/s	9.41	8.50	90.33	8.43	8.53	8.50			
Start	MMEF75/25	L/s	3.45	3.91	113.33	3.78	3.85	3.91			
Edit	P(L/S)	3)4 5	6 7 8	9 10 V(L	v (7 6 5 4 3 2 1 1	FEV 0 1 2	2 3 4	5 6 7	8 9	T(S)	
	Quality Opinio	n Technic	ian unscramt	ble	3 Re	nary of test	t acceptance quality level	criteria			
	Commence and the second										
	Test mass			Test1					0	-	
	Test mass Expiratory force is ins	ufficient		Test1	Low	quality, repe	at the Recu	ts are susnicious	C. High gu	ality	

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 .
- 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.
- 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

- 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.

A 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.

\triangle 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.





- 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:

< Return			Report preview		2022-03-21 17:29
e Print	Q Amplification	Q Zoom	(Opinion	A4 report preview	

Guangzhou respiratory FVC report

Hospital name: Guangz	hou respiratory
TTD: 2022-03-21 17:27	:13
EPX-GP: AX21216586	Test num: 1999091088
Name: khgg	Gender: Male
Age: 22Years	Weight: 62kg
Height: 166cm	BMI: 22.5kg/m2

		1	1
index	Pred	BEST	%Pred
FVC [L]	4.43	3.91	88.26
FEV1 [L]	3.88	3.51	90.46
FEV1%VC MAX [%]	87.20	81.06	92.96
FEV1%FVC [%]	87.20	89.77	102.95
FEV6 [L]		3.90	
PEF [L/s]	9.07	7.67	84.56
MMEF75/25 [L/s]	4.25	4.25	100.00
FEF75 [L/s]	2.41	2.15	89.21
FEF50 [L/s]	5.24	4.45	84.92
FEF25 [L/s]	7.94	7.50	94.46
ET [s]		9.42	
/ backextrapolation		0.03	
VC IN [L]	4.43	2.95	66.59
IV1 [L]		2.95	
C [L]	3.29	3.71	112.77
EF50%FIF50 [%]		90.63	
PIF [L/s]		5.22	
/VV [L/min]	141.75		
BF MVV [1/min]			
ndex	Test1	Test2	Test3
VC [L]	3.91	3.99	3.82
EV1 [L]	3.51	3.30	3.36
EV1%VC MAX [%]	81.06	79.90	84.63
EV1%FVC [%]	89.77	82.71	87.96
EV6 [L]	3.90	3.96	3.81
PEF [L/s]	7.67	8.17	8.27
MMEF75/25 [L/s]	4.25	3.21	3.98
EF75 [L/s]	2.15	1.45	2.05
EF50 [L/s]	4.45	3.60	4.26
EF25 [L/s]	7.50	6.26	6.60
ET [s]	9.42	11.80	11.07
/ backextrapolation	0.03	0.06	0.09
	2.95	3.42	3.29
1/1 [1]	2.95	3.42	3.29
C [L]	3.71	3.43	3.21
FF50%FIF50 (%)	90.63	61.02	80.23
DE [1 /o]	5.22	6.08	5.55
W/W/IL (min)	v	0.00	0.00
		-	-
sr MVV [1/min]			



Note: This report is for clinical reference only.

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.

< Return					MV				2022-03-17 16:34		
8	Drug use be	efore▼	Drug	*	Unit	*		Recommend Generate report Calibration			
Linn	Item	Unit	Predicated	Best	Best/pre	Test1	Test2	Test3			
-00	MVV	L/min	125.47	123.14	98.14	83.98	106.40	123.14	~		
-	VT MVV	L		0.94		0.34	0.76	0.94			
Model	BF MVV	1/min		131.00		247.00	140.00	131.00			
	TIME MVV	S		13.24		13.07	13.23	13.24			
Edit	Quality QA type-AT Test mass MVV is less	ime 32 24 24 20 16- 12 8 4 0 0 pinion S and ERS: than 50% of	/S) 8 12 16 20 Technician 2019 expected	T(S) 24 28 3: unscrar	rest2 – Tet nble Test2 Test	sum Sum Low	a ↓ V(L) ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓	acceptance crit	- Test1 - Test2 - Test3		
	QA type-AT Test mass MVV is less MVV did no	than 50% of treach 12	expected or 15 seconds	Test1	Test2 Test	Low	r quality, repea test	at the Results a	re susp		

Figure 14 MVV measurement results interface

6.5.1 Operation steps

 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.

A 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:



Guangzhou respiratory MVV report

Hospital name: Guangz	hou respiratory
TTD: 2022-03-08 13:52	:17
EPX-GP: AX21216586	Test num: 19750518
Name: Li yuan	Gender: Male
Age: 46Years	Weight: 62kg
Height: 169cm	BMI: 21.71kg/m2

Item	Pred	BEST	%Pred
MVV [1/min]	126.18	110.96	87.94
VT MVV [L]		0.73	
BF MVV [1/min]		152.00	
TIME MVV [s]		13.81	
lite and	Test	Teet2	Teet2
item	Test	Testz	Testa
MVV [1/min]	110.96	104.06	91.52
VT MVV [L]	0.73	0.86	0.64
BF MVV [1/min]	152.00	121.00	143.00
TIME MVV [s]	13.81	13.33	15.05



Note: This report is for clinical reference only.

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

 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.

A 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.

A 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:

< Return	Report preview	2022-03-22 18:51 🗰
Print Q Amplification Q Zoom	Opinion A4 report preview	

Guangzhou respiratory SVC report

Hospital name: Guangz	hou respiratory
TTD: 2022-03-22 18:47	:33
EPX-GP: AX21216586	Test num: 1988061788
Name: holds	Gender: Male
Age: 33Years	Weight: 68kg
Height: 166cm	BMI: 24.68kg/m2

index	Pred	BEST	%Pred
VC MAX [L]	4.32	4.57	105.79
VC IN [L]	4.32	3.74	86.57
VC EX [L]	4.32	4.57	105.79
IC [L]	3.12	3.12	100.00
IRV [L]	2.63	2.97	112.93
VT [L]	0.49	0.15	30.61
ERV [L]	1.41	1.45	102.84
MV [L]	9.71	7.50	77.24
BF [1/min]		50.00	
index	Test1	Test2	Test3
VC MAX [L]	4.57	4.48	4.38
VC IN [L]	3.74	3.49	3.52
VC EX [L]	4.57	4.48	4.38
IC [L]	3.12	3.17	2.94
IRV [L]	2.97	2.79	2.71
VT [L]	0.15	0.38	0.23
ERV [L]	1.45	1.31	1.44
MV [L]	7.50	9.50	9.43
BF [1/min]	50.00	25.00	41.00



Doctor's opinion:

Note: This report is for clinical reference only.

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.

Return			Report preview		2022-03-22 17:52
C Print	Amplification	Q Zoom	Dinion	A4 report preview	

Guangzhou respiratory Diastolic report

Hospital name: Gu	angzh	ou	re	spirat	ory			
TTD: 2022-03-22 1	3:55:1	6						
EPX-GP: AX21216586			Test num: 1988061788					
Name: holds			Gender: Male					
Age: 33Years		W	eig	ht:	68kg			
Height 166cm		BI	11:	24.	68kg	/m	2	
index	A1			%Pre	ed	In	nprove	
FVC [L]	3.03			70.1	4	1	.04	
FEV1 [L]	2.76			76.0	3	0	77	
FEV1%VC MAX [%]	90.4	9		107.	05	-3	.76	
FEV1%FVC [%]	91.0	9	-	107.	76	-4	.36	
VC MAX [L]	3.05			70.6	0	1	.02	
PEF [L/s]	6.87			72.3	2	1	53	
MMEF75/25 [L/s]	4.10			106.	49	-0	.20	
FEF25 [L/s]	6.76			88.8	3	0	30	
FEF50 [L/s]	4.50			92.0	2	-0	.32	
FEF75 [L/s]	1.96			92.8	9	0	.09	
FET [s]	13.5	4					.86	
V backextrapolation	0.09					0	.01	
FIV1 [L]	3.05					0.71		
FEF50%FIF50 [%]	94.5	4					-16.55	
PIF [L/s]	5.10		(0	63		
MVV [L/min]								
BF MVV [1/min]						-		
	Imer	ov				-		
index	emer	nt	P	1	P2		P3	
FVC [L]	34.3	2	4.	07	4.06		3.89	
FEV1 [L]	27.9	0	3.	53	3.51		3.33	
FEV1%VC MAX [%]	-4.16	5	8	5.73	.73 86.45		85.60	
FEV1%FVC [%]	-4.79	2	88	.73 86.4		5	85.60	
VC MAX [L]	33.4	4	4.	07 4.06			3.89	
PEF [L/s]	22.2	22.27 8.40		40 8.90			7.88	
MMEF75/25 [L/s]	-4.88	•	3.	90	3.56		3.66	
FEF25 [L/s]	4.44		7.	06	6.68		7.28	
FEF50 [L/s]	-7.11		4.	18	4.06		3.98	
FEF75 [L/s]	4.59		2.	05	1.83		1.88	
FET [s]	-21.1	2	10	0.68	12.5	1	9.67	
V backextrapolation ex [L]	11.1	1	0.	10	0.05		0.08	
FIV1 [L]	23.2	в	3.	76	3.13		3.06	
FEF50%FIF50 [%]	-17.5	1	77	7.99	77.9	3	83.26	
PIF [L/s]	12.3	5	5.	73	5.72		5.20	
MVV [L/min]								
BF MVV [1/min]								



Figure21 POST Bd report interface

6.8 Data management

6.8.1 Patient management

					15:55 💌
♀ full name/phone/p	aint ID Card/clinic	Num	Search		+ New patient
Full name	Gender	Age	Height cm	Weight kg	Paint ID Card
uyrs	Male	22	166	65	
			No more data		

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.

		0					
	⊠Edit în Delete	Lungs check					
khgg Ma	le	Test visit		P	New questior	nnaire 🗔	Report preview
		Time	Level	FVC	SVC	MVV	Operation
Moblie:		2022-03-21 17:09:34	Medicine	1	1		Viewing
Height:	166cm		hetore				
Weight:	62kg						
Test num:	1999091088	Item	Unit	Predicated	Best		Best/pre
Patient ID card:		FVC	L	4.43	3.91		88.26
Inpatient num:		FEV1	L	3.88	3.51		90.46
Bed num:		FEV3	L	4.59	3.72		81.05
BMI:	22.50	FEV0.5	L	2.90	0.07		2.41
Ethnic aroup:	CHINESE	FEV6	L		3.90		
			0/	07.00	00 77		100.05

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).

eturn	Add p	atients	2022-03-18 13:51 💽
			Id card reading New test
* Name	Please enter your name	* Height	Please enter your height(cm)
* Hender	● Male ○ Female	* Weight	Please enter your weight(kg)
* Birthday	Year Month Day	* Race	CHINESE
* Test num	Please enter your test num	* Dept	Pneumology department 🔹
Moblie	Please enter your contact	* Doctor	cest 💌
* Predicted source	Standard CN 👻	* Technician	Li mi 👻
	Click s	show all	

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

Inpatient num		Bed num	
Nation	Please select nation	ld card	Please enter id card
Household address	Please enter household address	Country	Please enter country
Province	Please enter province	City	Please enter city
Street address	Please enter street address	Patient group	Please enter patient group
Reason for visit	Please enter reason for visit	Symptoms	Please enter symptoms
Marital status	O Married O Unmarried	Job	Please enter job
Lung disease	Please enter lung disease	Risks	Please enter risks
Smoking history	O Smoker O No Smoker O Ex-	Other diseases	Please enter other diseases
Prescriptio ns	Please enter prescriptions	Clinical impression	Please enter clinical impression
Contraindic ations	Please enter contraindications		
Remark	please enter remark		

Figure 24 New Patient Interface 2

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.
Return		Patients with	n details				11:00
	☑Edit	Lungs check					
Bibb Mal	e	Test visit		Ø	New questio	nnaire (Report preview
Moblie:		Time	Level	FVC	SVC	MVV	Operation
Height:	166cm						
Weight:	65kg						
Test num:	19990817	Item	Unit	Predicated	Best		Best/pre
Patient ID card:			Unit	Treateuro	Deet		beethie
Inpatient num:							
Bed num:							
	22.50						
BMI:	23.59						

Figure 25 Patient information Interface

Enter the patient editing page :

Urn Bibb 22Ye	Edi ars / BMI:23.59	t patients		2022-01-26 11:07
* Name	Bibb	* Height	166	
* Hender	• Male O Female	* Weight	65	
* Birthday	1999 08 17	* Race	CHINESE	•
* Test num	19990817	* Dept	pneumology	•
Moblie	Please enter your contact	* Doctor	like	•
* Predicted	Source Standard CN -	* Technici an	li li	•
	Clic	k show all		

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.

Return		Patients with	n details				11:06
Bibb Mal	⊠Edit ≅Delete	Lungs check					
1999-08-17		Test visit		5	New questic	nnaire (Report preview
Moblie:		Time	Level	FVC	SVC	MVV	Operation
Height:	166cm						
Weight:	65kg						
Test num:	19990817	Itom	Unit	Dradiastad	Post		Post/pro
Patient ID card:		item	Unit	Predicated	Dest		best/pre
Inpatient num:							
Bed num:							
BMI:	23.59						
Ethnic aroup:	CHINESE						
Nowt	oot						
New G	est						
			2				
			IJ				
	W	hether to Del	ete a use	er?			

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.

< Return					Repo	rt list			
All	-		Please	enter your	name or contac	t information	Search	🔄 Upload] Delete
Name	Age	Gender	Height(c m)	Weight(kg)	Moblie	Report type	Generated time	Sync	0
kjf	22	Male	166	65		svc report	2021-10-20	Synchronized	0
kjf	22	Male	166	65		mvv report	2021-10-20	Synchronized	0
kjf	22	Male	166	65		fvc report	2021-10-20	Synchronized	0
					No mo	re data			

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.

(1)Account manage

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

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

< Return	setting									
	Account manage	Hospital setting	Server Address	Sound/Brightness	Update					
System Settings	Account details Account cest Password ****** Hospital Guangzhou r Departments Pneum	ZH/EN								
Page 2015 Check										

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.

< Return	setting									
	Account manage	Hospital setting	Server Address	Sound/Brightness	Update					
System Settings	Hospital	I Hospital								
	Guanga Hospital lev	+ Add hospital								
	I Departments	Show 💌								
	Doctor	Show 🔻								
	I Operator	Show 🔫								
Provide the second seco										

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 interface 2

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.

< Return		setting									
	Account manage	Hospital setting	Server Address	Sound/Brightness	Update						
(III) System Settings	data upload address	Save									
	The current address: https://www.huxijia.cn/axtxserver/ URL: reference address: https://www.huxijia.cn/axserver/ click to fill in the Ax cloud address: http://ax.huxijia.cn/axtxserver/										
	click to fill in the integrate address: https://www.huxijia.cn/axtxserver/										
	The current recovery address: https://www.huxijia.cn/recovery-api/										
B Lungs check	URL: reference address: https://www.huxijia.cn/recovery-api/										

Figure 32 Server Address interface

④Sound/Brightness

Adjust sound/brightness

< Return			etting		FB
	Account manage	Hospital setting	Server Address	Sound/Brightness	Update
System Settings		⊲ ×		口»)	
Reference to the construction of the construct		÷Ģ:		÷ờ.	

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.

< Return					
(International System Settings	Account manage	Hospital setting	Server Address	Sound/Brightness	Update
(B) Lungs check			Current version: V1.0.1 Latest version: Update		

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.

< Return			setting			64
	Report s	etting	Medicine setting	Parameter setting	r setting Question se	
System Settings	Address of report subtitle		Address of report subtitle	EdPredicted source (def)	Standard	CN 👻
	Report type	setting (Measu list to s	ire page metrics to be visible and ort)	hidden and sort, and drag and drop the	lung repo	rt - mvv 🔍
	Parameter ID	Indicator Nam	ne	Isshow	Unit	Sequence
	1	MVV			1/min	1
	2	VT MVV			L	2
	3	BF MVV			1/min	3
	4	TIME MVV			S	4
8						
Lungs check						

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.

< Return		setting								
	Repo	ort setting	Med	icine setti	ng	Paramete	er setting	Question setting		
System Settings	bronchod	ilators 🔻	Drug trade na	ime	Sear	rch		🗄 New		
	Coding	Drug category	Drug trade name	Dose	Unit	Sequence	Operation			
	1647934 852610	bronchodilato rs	Amoxicillin	4	mg	0085	🖉 Edit	🗊 Delete		
Page 2015 Europe 2										

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.

< Return			setting			60
	Report se	etting	Medicine setting	Parameter setting	(Question setting
	Report setting	(Measure pag	e metrics to be visible and hidden a	and sort, and drag and drop the list	to sort)	FVC -
System Settings	Parameter ID	Indicator Nan	ne	Isshow	Unit	Sequence
	1	FVC			L	1
	2	FEV1			L	2
	3	FEV2			L	3
	4	FEV3			L	4
	5	FEV0.5			L	5
	6	FEV0.75			L	6
Lungs check	7	FEV6			L	7
	8	FEV1/FVC			%	8

Figure37 Parameter setting interface

④Questionnaire setting

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

< Return				5 0
	Report setting	Medicine setting	Parameter setting	Question setting
	Questionnaire types			Isshow
System Settings	MMRCE			
(Providence) Lungs check				

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.

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.

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

Summary of daily software failure analysis and handling

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:

(1) This device may not cause harmful interference, and

(2) 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 manufacturers' 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		
Harmonic emissions IEC 61000-3-2	Not applicable	The Pulmonary Function Tester (A9) is suitable for use in all establishments other than domestic and those directly	
Voltage fluctuations flicker emissions IEC 61000-3-3	Not applicable	connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.	

Table 2

Guid	ance and manufacturers	declaration – electron	agnetic immunity
The Pulmonary Fun	ction Tester (A9) is inte	ended for use in the electr	omagnetic environment specified
such an environmen	r or the user of the Pulmo	nary Function Tester(AS) should assure that it is used in
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

	\pm 1 kV differential	\pm 1 kV differential	that of a typical commercial or
IEC 61000-4-5	mode	mode	hospital environment.
	±2 kV common mode	±2 kV common mode	
Voltage dips, short	0 % UT; 0,5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and	0 % UT; 0,5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Pulmonary Function
interruptions and	315°	315°	Tester (A9) requires continued
on power supply input lines	0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	operation during power mains interruptions, it is recommended that the Pulmonary Function Tester
	0 % UT; 250/300 cycle	0 % UT; 250/300 cycle	(A9) be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial
IEC 61000-4-8			or hospital environment.
NOTE	U_T is the a. c. matrix	ains voltage prior to appli	cation of the test level.

Table 3

Gu	idance and manufact	urers' declaration -6	electromagnetic immunity
The Pulmonary F	unction Tester (A9) i	s intended for use in t	he electromagnetic environment specified
below. The custor	mer or the user of the P	ulmonary Function Te	ester (A9) should assure that it is used in
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			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
Conducted RF	3 Vrms	3 Vrms	
IEC 61000-4-6	150 kHz to 80 MHz	150 kHz to 80 MHz	Recommended separation distance
	6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz	6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz	$d = \left[\frac{3.3}{V_1}\right]\sqrt{P}$ $d = \left[\frac{12}{V_2}\right]\sqrt{P}$
Radiated RF	3 V/m	3 V/m	

IEC 61000-4-3	80 MHz to 2.7 GHz	80 MHz to 2.7 GHz	$d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz
	385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	$d = \left[\frac{7}{E_1}\right]\sqrt{P} 800 \text{ MHz to } 2.7 \text{ GHz}$ where <i>p</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> 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).

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

	Separatio	n distance according (to frequency of tran	nsmitter
		m		
Rated maximum output of transmitter	150 kHz to 80 MHz outside ISM and amateur radio bands $d = \begin{bmatrix} 3.5 \\ 1 \end{bmatrix} \sqrt{D}$	150 kHz to 80 MHz in ISM and amateur radio bands	80 MHz to 800 MHz $d = \left[\frac{3.5}{\sqrt{P}}\right]\sqrt{P}$	800 MHz to 2.7 GHz $d = [\frac{7}{2}]\sqrt{P}$
W	$a = \left[\frac{1}{V_1}\right] \sqrt{P}$	$d = \left[\frac{12}{V_2}\right] \sqrt{P}$	E_1	E_1
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

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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

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.

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
1.1 Overview	1
1.2 Scope of application of the manual	1
1.3 Guide to the manual	1
1.4 Symbol explanation	2
1.5 Prerequisite information	2
1.6 System related characteristics	2
Chapter 2 Software introduction	4
2.1 Operating environment	4
2.2 Technical parameters	4
Chapter 3 Working principle and scope of application	8
3.1 Working principle	8
3.2 Scope of application	8
Chapter 4 Main structure	9
Chapter 5 Software installation and uninstallation	0
5.1 Overview	0
5.2 Installation and uninstallation requirements	0
Chapter 6 Software interface and operation	3
Chapter 6 Software interface and operation	3
Chapter 6 Software interface and operation	3 3 3
Chapter 6 Software interface and operation. 1 6.1 Login 1 6.2 Software home page. 1 6.3 Calibration. 1	.3 .3 .3 .4
Chapter 6 Software interface and operation. 1 6.1 Login 1 6.2 Software home page. 1 6.3 Calibration. 1 6.4 Patient information input 1	.3 .3 .3 .4 .7
Chapter 6 Software interface and operation. 1 6.1 Login 1 6.2 Software home page. 1 6.3 Calibration. 1 6.4 Patient information input 1 6.5 Forced vital capacity test procedure 1	.3 .3 .4 7 9
Chapter 6 Software interface and operation. 1 6.1 Login 1 6.2 Software home page. 1 6.3 Calibration. 1 6.4 Patient information input 1 6.5 Forced vital capacity test procedure 1 6.6 Maximum minute ventilation test procedure 2	.3 .3 .4 .7 9
Chapter 6 Software interface and operation. 1 6.1 Login 1 6.2 Software home page. 1 6.3 Calibration. 1 6.4 Patient information input 1 6.5 Forced vital capacity test procedure 1 6.6 Maximum minute ventilation test procedure 2 6.7 Slow vital capacity test procedure 2	.3 .3 .4 .7 .9 .4 .7
Chapter 6 Software interface and operation16.1 Login16.2 Software home page16.3 Calibration16.4 Patient information input16.5 Forced vital capacity test procedure16.6 Maximum minute ventilation test procedure26.7 Slow vital capacity test procedure26.8 Bronchial diastolic test procedure3	.3 .3 .4 .7 .9 .4 .7 .7 .2
Chapter 6 Software interface and operation16.1 Login16.2 Software home page16.3 Calibration16.4 Patient information input16.5 Forced vital capacity test procedure16.6 Maximum minute ventilation test procedure26.7 Slow vital capacity test procedure26.8 Bronchial diastolic test procedure36.9 Patient management3	3 3 4 7 9 4 7 2 3
Chapter 6 Software interface and operation16.1 Login16.2 Software home page16.3 Calibration16.4 Patient information input16.5 Forced vital capacity test procedure16.6 Maximum minute ventilation test procedure26.7 Slow vital capacity test procedure26.8 Bronchial diastolic test procedure36.9 Patient management336.10 Data administration	.3 .3 .4 .7 .9 .4 .7 .9 .4 .7 .2 .3 .7
Chapter 6 Software interface and operation16.1 Login16.2 Software home page16.3 Calibration16.4 Patient information input16.5 Forced vital capacity test procedure16.6 Maximum minute ventilation test procedure26.7 Slow vital capacity test procedure26.8 Bronchial diastolic test procedure36.9 Patient management36.10 Data administration36.11 System settings4	.3 .3 .4 .7 .9 .4 .7 .2 .3 .7 .0
Chapter 6 Software interface and operation16.1 Login16.2 Software home page16.3 Calibration16.4 Patient information input16.5 Forced vital capacity test procedure16.6 Maximum minute ventilation test procedure26.7 Slow vital capacity test procedure26.8 Bronchial diastolic test procedure36.9 Patient management336.10 Data administration36.11 System settings4Chapter 7 Maintenance and precautions	.3 .3 .4 .7 .9 .4 .7 .9 .4 .7 .9 .4 .7 .9 .4 .7 .9 .4 .7 .9 .4 .7 .9 .4 .7 .9 .4 .7 .9 .4 .7
Chapter 6 Software interface and operation 1 6.1 Login 1 6.2 Software home page 1 6.3 Calibration 1 6.4 Patient information input 1 6.5 Forced vital capacity test procedure 1 6.6 Maximum minute ventilation test procedure 2 6.7 Slow vital capacity test procedure 2 6.8 Bronchial diastolic test procedure 3 6.9 Patient management 3 6.10 Data administration 3 6.11 System settings 4 Chapter 7 Maintenance and precautions 5 7.1 Overview 5	3 3 4 7 9 4 7 9 4 7 9 4 7 9 4 7 9 4 7 9 4 7 9 4 7 9 4 7 9 4 7 9 4 7 9 4 7 9 4 7 9 4 7 9 4 7 9 4 7 9 4 7 9 10 10 10 <
Chapter 6 Software interface and operation16.1 Login16.2 Software home page16.3 Calibration16.4 Patient information input16.5 Forced vital capacity test procedure16.6 Maximum minute ventilation test procedure26.7 Slow vital capacity test procedure26.8 Bronchial diastolic test procedure36.9 Patient management336.10 Data administration36.11 System settings4Chapter 7 Maintenance and precautions57.1 Overview57.2 Daily maintenance methods	.3 .3 .4 .7 .9 .4 .7 .9 .4 .7 .9 .4 .7

7.4 Quality control	50
Chapter 8 Failure analysis and treatment	51
8.1 Overview	51
8.2 Simple troubleshooting	51
Chapter 9 Electromagnetic compatibility description	52
9.1 Parameter description	52
9.2 EMC statement	52
9.3 Declaration of conformity	53

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.

CAUTION

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

software	
Understand the import data, calculation and other	Chapter 6 Software interface and
settings, sample result report generation	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	Chapter 10 Electromagnetic
compatibility information	compatibility description

1.4 Symbol explanation

Symbols and their meanings that may appear in this manual:

Symbol	Significance						
DANGER	Prompt the operator to follow the instructions under the symbol, as this may result in personal injury.						
WARNING	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

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 $5.3.9 \sim 5.3.13$) 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

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

AXCloud64 v1.0.2-A9.exe

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 :

	Intelliger	t Respiratory	Diagnostics Syste	em V1.0.2									
•	Doctor,	Hello Ope	erator: Select	 ✓ Docto 	r: Select 🗡	Equipm	ent: AX2121	16586	Tempera	ature: 25°C	Humidity: 69	% Pressure: 752mmHg	▲ 呼吸家 BreathHome
fome	FVC	₽	svc	Mi	vv	P	OST Bd	\$	Calibrat	ion			
itient	Lung	Lung function checklist (Double-click the row record to view the detection details)											
⊿∿ Data	O Today ◯ This week ◯ All 📄 2022-03-21 ~ 2022-03-21 ◯ . Full name/ID Card/ApplyID/TestNum Q Search												
	Report status: Generated: 0 To be generated: 0 Total: 0 OutPatient												
	Num.	ApplyID	Туре	TestNum	Check item	Full name	Gender	Age	Height cm	Weight kg	Clinical i mpressi on	Check date	Report date
	No Data												
	•												•
etting											lotal 0 <	Go to	1 Iotal 0 Page

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 diagram ①

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



Figure6 Software uninstallation diagram⁽²⁾

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.

	Intelliger	nt Respiratory	Diagnostics Syste	em V1.0.2											- ×
•	Doctor,	Hello Ope	erator: Select	 ✓ Doctor 	Select \checkmark	P Equipme	ent: AX2121	16586	Tempera	ature: 25°C	Humidity: 69	1% Pressure: 75	2mmHg	● 呼吸 Breath	家 Iome
Home	FVC	Þ	SVC	M	<i>I</i> V	PC	OST Bd		Calibrat	ion					
Patient	Lung f	unction check	klist (Double-clic	k the row record	to view the dete	ection details)									
<mark>≁≁,</mark> Data	O Today	O This week	: O All 🗐 202	2-03-21 ~ 202	2-03-21	Q Full name/ID	Card/Appl	yID/Test	:Num	Q Sear	ch				
	Report	status: Genera	ated: 0 To be ge	enerated: 0 Tota	al: 0										
	OutPa	atient 🗌 InPat	ient 🗌 Physical e	examination 🗌 P	ublic health	Show only ung	enerated re	eports							
	Num.	ApplyID	Туре	TestNum	Check item	Full name	Gender	Age	Height cm	Weight kg	Clinical i mpressi on	Check date		Report date	
									No Data						
	4														Þ
Setting											Total 0 <	1	Go to	1 Total 0 P	age
				C	opyright©2009	-2021 huxijia.co	m all rights	reserve	d v1.0.2 T	elephone: 4	400-030-151	0			

Figure8 Software home page

6.3 Calibration

6.3.1 Calibration tool

3L calibration pump.

A Caution:

The 3L calibration pump is purchased by the user, and its requirements are $3L\pm0.5\%$.

6.3.2 Volume calibration

Calibrat	tion V1.0.2												
⊙ Meas Calibrati	urement mo ion Volume	de								1	呼吸家 BreathHom	🖁 🔗 De	vice connected
3L ~		lume Calibration	🔘 Vo	lume Verification	3 Flow Calibration	🥥 3 Flov	v Verification		Refresh en	vironment	Generat	e Volume Ca	alibration Repo
		Item	Unit	Last	This	Diff%				Calibrat	Unit	Last	This
	Blow	Capacity	L							Temper	°C		24
tart		Flow	L/s							Humidit	96		54
		Gain Ex								Pressure	mmHg		754
	Inhale	Capacity	L							Altitude	M		64
		Flow	L/s										
		Gain In											
	Date									Date			
OD	Time									Time			
ß	Volume	Calibration							Monitor				
lit	Flow(L/s)					-10%	+1	096	Inhale				
2 onma	0							Blow					
_	-5 -10							Inhale					
	-15	0.5	1.0	1.5	2.0	2.5	3.0	<u>Vol (L)</u> 3.5					
	Calibrat	ion Result					alibration Re	sult					
				No Data				No				ОК	

Figure 9 Calibration homepage Figure

- 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 $\pm 10\%$, the standard calibration is passed; if the capacity exceeds the limit of $\pm 10\%$, 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.

ation Volu	mode ime Calibra	tion										計 Breat	股家 。 の D	evice connecte
~ 0	Volume Ca	alibratio	n 🖸 V	olume Verificati	on 😑	3 Flow C	Calibratio	n 🔾	3 Flow Verification	on	Refresh environn	ment Gen	erate Volume (Calibration Rep
	Item	Unit	Last	This	Diff%	test1	test2	test3	test4		Calib	brat Unit	Last	This
Blow	Capacity	L		2.93		2.94	2.93	2.92	2.92		Tem	per ℃		23
	Flow	L/s		6.26		6.72	6.40	6.18	5.75		Hum	nidit 96		84
	Gain Ex			1.03		1.02	1.02	1.03	1.03		Pres	sure mmł	Hg	753
Inhale	Capacity	L		3.02		3.01	3.04	3.01	3.01		Altit	ude M		81
	Flow	L/s		6.57		6.85	6.53	6.60	6.30					
	Gain In			1.00		1.00	0.99	1.00	1.00					
Date				2022-03-21							Date	,		2022-03-2
Time				09:48:08							Time			09:48:08
10-										Blow	Inhale			2.92
5						in tr								3.01 3.04 3.01 3.01

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.

asureme ation 3	ent mode Flow Calibration	n											I	卧呼吸 BreathHo	🖹 🔗 De	evice connecte
~	🔿 Volume Cali	bration	🔾 Vo	lume Verit	fication	🧿 3 F	low Calib	ration	🥥 3 Flo	w Verifica	tion	Accurate	Refresh environme	Genera	te 3 Flow Ca	libration Repo
	Item	Unit	L1	L2	L3	M1	M2	M3	H1	H2	H3		St('rep	o Unit	Last	This
Blow	Capacity	L	3.02	3.02	3.02	2.98	2.99	2.99	2.99	2.98	2.99		Tempe	°C		23
	Flow	L/s	1.00	1.28	1.33	3.23	3.82	3.73	10.68	10.95	9.48		Humid	t 96		84
	Gain Ex		0.99	0.99	0.99	1.01	1.00	1.00	1.00	1.01	1.00		Pressu	e mmHa		753
Inha	le Capacity	L	2.97	2.97	2.97	2.99	2.98	2.97	2.96	2.97	2.98		Altitud	M		81
	Flow	L/s	1.02	1.08	0.95	2.95	2.97	3.07	10.18	8.52	8.20					101
	Gain In		1.01	1.01	1.01	1.00	1.01	1.01	1.01	1.01	1.01					
Date	•												Date			2022-03-
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10												✓ 3				3.02 3.02 2.98
10 5 -5 -10										·		 ✓ 3 ✓ 3 ✓ 3 ✓ 3 ✓ 3 	Ir	hale		3.02 3.02 2.98 2.99 2.99 2.99 2.99 2.98 2.99 2.97 2.97 2.97
10 5 -5 -10 -15	e calibration re	5 sult is witi	1.0		1.5	· · · 2.0		2.5	3.	0	3.5	 3 3 3 3 1nhale Vol (L) 	Ir niion Result	hale		3.02 3.02 2.98 2.99 2.99 2.99 2.99 2.98 2.99 2.97 2.97 2.97 2.97 2.97 2.97 2.97

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 $\pm 3.5\%$, 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

Intelliger Doctor,	It Respiratory [Hello Ope	Diagnostics Systemator: Select	stem V1.0.2	octor: Select	✓ 9 E	quipment:	AX2121	6586	Tempera	iture: 23°C +	lumidity: 87% Pressure	: 753mmHg	一 呼吸家 BreathHome
FVC	Þ	SVC		MVV	Z	POST	Bd	÷	Calibrat	ion	0		
Lung f	function check	(list (Double-cl	lick the row re	ecord to view th	ne detection de	etails)							
Today	🗸 🔿 This week	○ All 🗎 2	022-03-21 ~	2022-03-21	Q. Full n	ame/ID Car	d/Appl	/ID/TestN	um	Q Sear	ch		
Report	status: Genera	ted: 1 To be	generated: 0	Total: 1							_		
OutPa	atient 📃 InPati	ient 🗌 Physica	l examinatior	Public heal	th 📃 Show o	nly ungene	rated re	ports					
Num.	ApplyID	Туре	TestNum	Check item	Full name	Gender	Age	Heig ht cm	Weig ht kg	Clinical i mpressi on	Check date	Report date	Repor
1	M2022032 109540001	OutPatient		MVV	you	Male	34	167	62		2022-03-21 09:53:42	2022-03-21 09:57:24	Create

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:

Patient information					
sic information					Set up
Patient ID		Test num.*		Age	
Full name*	Please enter content	AD	Please enter the test num.	BMI	BSA m ²
Gender	• Male	Moblie		Nation	Please choose V
Birthday*	Select date	Ethnic group*	Chinese v	ID Card	
Height*		cm Current setting*	ADULT ~	Residence address	
Weight*		kg Predicted source*	Standard CN \checkmark	Document Type	OutPatient InPatient Physical examination Public health
Operator	Please choose V	+ Doctor*	Please choose V +		
nt details					
					Cancel (F3) Empty Confirm (F1)

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.

\triangle 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.

FVC V1.0.2 Database 1 like Patient COS6 ▲ 呼吸家 S Device co ocal service Refore (dicatio FVC Test1 Item Unit Predicat Best Best/pre Test2 Test3 FVC 4.63 4.31 93.09 3.66 4.16 4.31 FEV1 4.04 3.74 92.57 3.33 3.59 3.74 2 FEV6 4.26 4.26 3.62 4.14 FEV1/FVC 87 99.74 90.98 86.3 86.77 86.77 88.37 8.45 8.53 8.28 PEF L/s 9.37 8.28 • Test1 Test2 • Test3 ATS is the best Flow rate/volume Optimal: — 3 Flow rate/volume Flow(L/s Vol (L) € Ð 12 Vol (L) 3 5 6 7 8 9 10 9 Ouality Opinion OA type-ATS and ERS2019 Test mass Results are suspic High quality Low quality, repeat the test Extrapolation volume > 5% FVC or 0.1L End expiratory phase platform detected atability quality level: A 🛈

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.
- 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.
- 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

- 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.

A 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.



Continue to exhale, and you should do your best to inhale quickly to the top immediatel y after you have completely exhaled.

Relax and return to normal breathing, the test is over

Figure 16 Test result monitoring page ①

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.

you (ent ID	(Male, 34Age, 16) 827613675337 20)	7cm , 62kg) 22-03-21) Quest	tionnaire 🕂	Create Contract Contrac	Measurement FVC Before medic	mode Databa cation Local s	ase ervice		● 呼吸家 BreathHome	S Device connect
ore me	edication \checkmark	FVC		 ✓ Drug 	✓ Unit	\sim		Recommend	Generation	ate FVC report	Delete 🛞 Calibrat
	ltem	Unit	t Pr	redicat Best	t Best/pre	Test1 Test2	✓ Test3 _3	-2 -1 Z 1	2 3		\bigcirc
t	FVC	L		FEV	'1 and FVC measureme	ent quality classificat	ion standards				
	FEV1	L									
	FEV6	L	Grade	Assess	Testing frequency	Repeatability:	Repeatability:				
	FEV1/FVC	%				>6 Age	≤6 Age				
	PEF	L/:					≤0.100L or 10%	best value, t			
	Flow rate/volume	Optimal: 🧲	A	Reliable	≥3 times acceptable	≤0.150L	ake the larger va	alue		Set as bes	t O ATS is the be
		FI									(
		1	В	Reliable	2 times acceptable	≤0.150L	≤0.100L or 10% ake the larger v	alue best value, t			Q. 1
		1									
			С	Reliable	≥2 times acceptable	≤0.200L	≤0.150L or 10%	best value, t			
							ake the larger va	alue			
				More relia	· 2 //	-0.2501	≤0.200L or 10%	best value, t			
		1	D	ble	22 times acceptable	S0.250L	ake the larger va	alue			
		-					>0.200L or 10%	hest value t			
		-1	E	Unreliable	≥2 times acceptableo	r >0.250L	ake the larger va	alue		Time	(s)
		-1			r times acceptable	None	None		5 6	7 8 9 1	D
	Quality	ion			0 times acceptablear	nd					
	OA have ATC and SPCC	010	U	Unreliable	1 times available	None	None				
	CA type-ATS and EKS2	1019							e criteria		
	Extrapolation volume	> 5% EVC o	F	Unreliable	0 times acceptablear 0 times available	na None	None		Results	are suspicious	High quality
	End augisstees also	nlatform da							-		

Figure 17 Test result monitoring page ②

6.5.4 Preview report

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

			Guan	gzhou resp FVC Repo	oiratory rt				
Full name: like Gender: Male		Test num.: 929 Height: 166 cm	201202	Public Weigh	health: t: 64 kg		TTD: 20 BMI: 23	22-03-24 10: 2 kg/m²	11
Birthday: 1987-09-11		Age: 34 Year		smoki	ngHistory :		Predicted	l source: Star	idard CN
Temperature: - °C		Humidity: - %		Pressu	re: - mmHg		EPX-GP	: AX2121658	36
Prescriptions:		Reason for app	lication:	Depart	ment: Pneumoi	logy departmer	nt Doctor: o	cest	
Item	Unit	Predicat	ed Best	Best/pre	LLN	Zscore	Testl	Test2	Test3
FVC FEV 1	[L]	4.31	4.2	97.45	3.57	-0.24	4.2	4.00	3.20
FEV 3	[L]	4 16	3.96	95.00	5.01	-0.19	3.96	3.77	3.47
FEV 0.5	[L]	2.82	2.49	88.3			2.49	2.47	2.33
FEV 1 % VC MAX		0.84	0.84	100.02			0.84	0.86	0.9
FEV 1 % FVC		0.84	0.84	100.02	0.74	0	0.84	0.86	0.9
FEV 6	[L]		4.16				4.16	4.03	3.56
PEF	[L/s]	9.5	8.42	88.63	7.19	-0.77	8.42	8.47	6.92
MMEF 75/25	[L/s]	3.82	3.68	96.34	2.44	-0.17	3.68	3.83	4.05
FEF 25	[L/s]	7.61	6.06	79.63			6.06	6.23	6.18
FEF 75	[L/S]	4.89	4.00	83.03			4.00	4.20	4.03
FET	[L/S]	2.11	6.55	09.1			6.55	6 74	5.80
V backextrapolation ex	[1]		0.06				0.06	0.06	0.01
FVC IN	[L]	4.31	3.27	75.87			3.27	3.18	2.96
FIV1	[L]		3.27				3.27	3.18	2.96
IC	[L]	3.12							
FEF 50 % FIF 50	[%]		67.11				67.11	69.67	81.51
PIF	[L/s]		6.73				6.73	6.42	6.08
MVV	[L/mir	i] 132.39							
	V 5 6 7	ol (L) 4 - 	Vol (L)	*	FEV1 FEV1/FVC Zscore-5 1 2 *	-4 -3 3 6 Vol (L 4 - 2 - - - - - - - - - - - - -	-2 -	* 1 0 15 20	Time(s)
-10- -12 Operators's opinion :						Sign:			
						·0			
Doctor's opinion :									
						Sign:			

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.

you tient II	(Male , 34Age , 167cn D 827613675337 2022-	1,62kg) C 03-21	Questionnaire	e 🔂 Creat patier	te <table-cell> Search nt patients</table-cell>	D Mea MVV B	surement r efore medi	node cation	Database Local service	meathHome	S Device connected
fore m	nec ~ MVV	× [Drug ~	Unit	~				Recommend	Generate MVV report	Delete 🛞 Calibratio
	Item	Unit	Predicat	Best	Best/pre	Test1	Z Test2	Test3	1		
rt	MVV	L/min	133.59	120.8	90.43	112.45	120.8	103.04			
	VT MVV	L		0.8		0.65	0.8	0.64			
	BF MVV	1/min		151		173	151	161			
	TIME MVV	s		12.27		13.17	12.27	11.88			
	Volume/time				• Test1 • Te	est2 • Test	3 Spir	ogram Op	otimal: \ominus 2	•	Test1 • Test2 • Test3
e		32 28 24 20 16 12 8 4 0 0 4	8 12 16	20 24 28	p(s) 32			8 4 2 -2 -4 -6 -8		0 12 14 16 18 20 22 24	Time(c) 1 26 28 30
ī	Quality Opinion QA type-ATS and ERS2019								Summary of test accepta	nce criteria	
	Test mass				т	est1 Test	Test3		Low quality, repeat the t	est Results are suspicious	High quality
	MVV less than 50% of ex	pected value							ter quanty, repear are a		

Figure 19 The main interface of maximum minute ventilation

- 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

 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.

A 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.

- 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.

V V1.0.	.2											-
ou (M ent ID 8	Male , 34A 27613675	ge,167cm 337 2022-03	, 62kg) C 3-21	Questionnaire	e 🗧 🛟 Creat patier	te Osearch nt patients	MVV	easurement r Before medi	node cation	Database Local service	● 呼吸家 BreathHome	S Device connected
re mec	~ MV	ſV	~ E	Drug 🗸	Unit	~				Recommend	Generate MVV report	Delete 🛞 Calibratio
ľ	ltem		Unit	Predicat	Best	Best/pre	Test1	🔽 Test2	Test3	1		
N	MVV		L/min	133.59	120.8	90.43	112.45	120.8	103.04			
N	VT MVV		L		0.8		0.65	0.8	0.64			
E	BF MVV		1/min		151		173	151	161			
Т	TIME MVV		s		12.27		13.17	12.27	11.88			
			Vol (L) 32 28 24 20 16 12 8 4 0 0	. 12 16	7 Tim	e(s)	Đ	Q	V 8 (4 			€ €
Q	Quality A type-ATS	Opinion and ERS2019								Summary of test acceptan	ce criteria	
	Test mass					т	st1 Te	t2 Test3		Low quality, repeat the tes	t Results are suspicious	High quality
	MVV less th	an 50% of expe	ected value									
	Maximum voluntary effort breathing time did not reach 12 seconds or 15 seco											

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.

liu yı ent II	u (Male , 33 D 984647325	Age, 167cm 360 2022-03	, 63kg) -11 15:44:(Questionna 09	ire 🔂 Cr pa	eate <table-cell> Search tient patients</table-cell>	SVC Bef	urement mode ore medication	Database Local service	● 呼吸家 BreathHome	S Device connected
fore m	nec V SVC	0	~	Drug ~	Unit	~			Recommend	Generate SVC report	Delete 🐼 Calibratio
	Item		Unit	Predicat	Best	Best/pre					~
rt	VC MAX		L	4.39							
	VC IN		L	4.39							
	VC EX		L	4.39							
	IC		L	3.18							
	IRV		L	2.73							
	VT		L	0.45							
р	Spirogram							Vol			
	Vol (L)						⊕ ⊝	Vol (L)			•
	67							12			
-	4-							10			
	2-							8			
	2							6			
	0-									4.39	
	2-							4			
-	.4 -							2			
							Time(s)	0		Readicated	
	-6-1									ricultated	
	Quality	Opinion									
	QA type-ATS	and ERS2019							Summary of test accepta	nce criteria	
	Repeatabili	ty							Low quality repeat the te	ect Results are suspicious	High quality
	No measure	ment record is	available. It i	is recommended	d to make 3 e	effective measureme	nts		Letting and the second se		

6.7.1 Description of function homepage

Figure 22 Main screen for slow lung capacity test

- 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.
- 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.
- 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

 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.

A 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.

test ient l	(Male, 24Age, 166 ID 176296387269 202	cm , 65kg) 1-11-29	Questionnaire	Creat	e Search at patients	SVC	Neasurer Before	ment mode medication	Database Local service		Marcath Home	S Device connect
fore r	mec 🗸 🛛 SVC	~	Drug V		~				Recomme	nd O	Generate SVC report	Delete 🛞 Calibra
	Item	Unit	Predicat	Best	Best/pre	Z Test	1 🔽 1	Test2 🔽 T	est3			0
	VC MAX	L	4.44	4.09	92.12	3.85	4	4.09				
	VC IN	L	4.44	3.33	75	3.02	3.14	4 3.33				
	VC EX	L	4.44	4.09	92.12	3.85	4	4.09				
	IC	L	3.27	3.19	97.55	2.92	3.13	3 3.19				
	IRV	L	2.81	3.14	111.74	2.8	3.05	5 3.14				
	VT	L	0.46	0.05	10.87	0.12	0.00	8 0.05				
р	Spirogram Optimal	: 🖯 3			• Test1 • Te	est2 • T	est3	Vol				
		Λ	Λ	Λ		٨	9	12 10 8				a i
-	-2						Time(s)	4 2 0	3.85	4	4.09	4.44
	Quality Opinic	9 12	15 18	21 24	27 30	33 30	38					Predicated
	QA type-ATS and ERS20	19							Summary of test acc	eptance	criteria	
	Test mass					Test1	Test2	Test3	Low guality, repeat t	he test	Results are suspicious	High quality
	Calm breathing, no tid	al baseline, basel	ine drift						1			3.43

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.

▲ FVC V1.0.2				- ×
2 you (Male , 34Age , 167cm , 62kg) Questionnaire Greate Search Patient ID 827613675337 2022-03-21 09:53:42 patient patients	Measurement mode FVC After medication	Database Local service	● 呼吸家 BreathHome Ø Device co	nnected
After medication \checkmark FVC \checkmark Amoxicillin \checkmark 4.0/mg	×	Recommend	9 Generate a diastolic report 🛚 🛱 Delete 🛛 🚱 Ca	libration

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.

Patient management V1.0.2												
🛔 New patient 🕨 Fest	Start date - End date	Q Full name/Te	st num./Gender/Patient ID	Q Search	+ N	ew ques	tionnaire	↑ Imp	ort 🛓 Do	wnload template		
Patient ID	Test num.	Full name	Doctor	Operator	Gender	Age	Height cm	Weight kg	Mobile	Creation time	Last measurement time	Operate
026491590241	158562253343	tre	cest		Male	28	160	50		2022-3-23	2022-3-23	Edit View I

Figure 28 Patient management page

6.9.1 Create and edit Patients

■ If you need to create patient information, click create patient page. See 6. Subject information input data.

New patient to go to the

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

formation									Set
Patient ID	026491590241		Test num.*	158562253343		Age	28		
Full name*	Full name* tre Gender O Male Female Birthday* 1994-03-08		AD			BMI		BSA 1.49	m²
Gender			Moblie			Nation	Please choose		~
Birthday*			Ethnic group*	Chinese	~	ID Card			
Height*	160	\$	cm Current setting*	ADULT	~	Residence address			
Weight*	50		kg Predicted source*	Standard CN	~				
Operator	Please choose	~	+ Doctor*	cest	~ +				
details									
nnaire									

Figure 29 Patient edit page

6.9.2 Search patient

Query patients based on query conditions.

	Patient manageme	ent V1.0.2													- ×
•	A New patient	► Test	Start date - End date	Q Full name/Test	num./Gender/Patient ID	Q Search	+ N	ew ques	tionnaire	↑ Imp	ort 🛓 Dow	nload template			
Home	Patient ID		Test num.	Full name	Doctor	Operator	Gender	Age	Height cm	Weight kg	Mobile	Creation time	Last measurement time	Operate	
Patient	026491590241		158562253343	tre	cest		Male	28	160	50		2022-3-23	2022-3-23	Edit View	Delete
Data															
Setting												Total 1	< 1 > Go to	1 Tota	al 1 Page

Figure 30 Finding patients schematic ①

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

	Intelliger	nt Respiratory (Diagnostics Syste	em V1.0.2										- ×
•	Doctor,	Hello Ope	erator: Select	 ✓ Doctor 	Select V	P Equipm	ent: AX2121	6586	Tempe	erature: 2	4°C Humidi	ty: 72% Pressure: 752mi	mHg	家
Home	FVC	Þ	SVC	M'	vv	P	OST Bd	\Rightarrow	Calibra	ation	•			
Patient	Lung	function check	list (Double-clic	k the row record	to view the dete	ection details)								
Data	O Today	y 🔿 This week	⊖ All 🗎 202	22-03-21 ~ 2023	2-03-21	् Full name/ID	Card/Appl	yID/Tes	tNum	٩	Search			
	Report	status: Genera	ted: 1 To be ge	enerated: 0 Tota	al: 1									
	OutPa	atient 📃 InPati	ent 🗌 Physical e	examination 🗌 P	ublic health	Show only ung	penerated re	eports						_
	Num.	ApplyID	Туре	TestNum	Check item	Full name	Gender	Age	Heig ht cm	Weig ht kg	Clinical i mpressi on	Check date	Report date	Re
	1	M2022032 109540001	OutPatient		MVV+FVC+S VC	you	Male	34	167	62		2022-03-21 09:53:42	2022-03-21 10:32:25	Cr
													*	
 Setting	4										Total 1	< 1 > G	o to 1 Total 1 Pag	ge
				-		2021			4.400	Televis		1510		

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.

	🊹 Patient mana	agement V1.0.2													-	×
	< Patient list /	Patient informatic	'n								New test					
Home	Patient ID	827613675337		Test num.	202202120009		Age	34			Item	Unit	Predicat ed	Best	Best/pr e	
Section Patient	Full name	you		Outpatien t/Hospital Number			BMI	22.2			FVC	L	4.4	4.05	92.05	^
	Gender	💿 Male 🔵 Fem	ale	Moblie			BSA	1.70		m²	FEV1	L	3.7	3.68	99.46	L
Data	Birthday	1987-09-12		Ethnic grou p	Chinese \vee	N	lation	Please cho	oose	~	FEV6	L		4.04		L
	Height	167	cm	Current set ting	ADULT \vee	ID	Card				FEV1/FVC	%	81.09	90.86	112.05	1
	Weight	62	kg	Predicted s ource	Standard EU 🛛 🗸	Resid	dence Idress				PEF	L/s	8.94	9.22	103.13	1
	Operator	Please choose	\sim	Doctor	cest \vee						MMEF75/25	L/s	4.48	4.3	95.98	
	Test visit	Patient details	Qu	estionnaire							FEF25	L/s	7.66	7	91.38	
	Date	Time			Level	FVC	SVC	MVV	Opera	ite	FEF50	L/s	4.93	4.43	89.86	
	2022-03-21	09:53	:42AN	A	Before medication	•	•	•	View		FEF75	L/s	2.13	2.56	120.19	
											FVC IN	L	4.4	3.55	80.68	
											PIF	L/s		6.93		
											FIV1	L		3.55		
_											FEV1/FIV1	%		103.66		
Setting					Total 1 🧹 🚺	\rightarrow	Go to	1 Te	otal 1 Pa	ge	FIF50	/s		6.58	ŀ	.

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.

	Patient manageme	ent V1.0.2									_				×
	New patient	► Test	Start date - End date	् Full name/Test nu	m./Gender/Patient ID	Q Search	+ Ne	w quest	tionnaire	↑ Imp	ort 🛓 Down	load template			
Home	Patient ID		Test num.	Full name	Doctor	Operator	Gender	Age	Height cm	Weight kg	Mobile	Creation time	Last measurement time	Operate	
Patient	019151981811		20001011002	test	cest		Male	22	166	65		2022-3-23	2022-3-23	Edit View Delete	•
Data															
=												Tetal 1	(1) Cata	1 Total 1 Page	10
Setting												Total 1	0010	, iotai i Pagi	~

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.

Tips		×
Whether to delete the patient (or hat after deleting a patient, all re records, etc.) of the patient will b restored	adad] The d levant data (r e deleted and	ata? Note t eports, test d cannot be
	Cancel	Confirm

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.

(1)Report 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.

	🏚 Da	ata managen	nent V1.0.2											- ×
•	Rep	ort list	Data query	Trend	List of calib	oration repor	ts Foll	ow-up	questionna	ire				
ft Home	Q	Please enter	Full name/Gender	/Patient ID		Star	t date	-	End da	te	Q Search	⊥ Upload re	port	▲ PDF report
Patient		Report I D	Patient ID	Full na me	Doctor	Operato r	Gender	Age	Height cm	Weigh t kg	Report type	Generated date	Upload	Operate
Data		3	827613675337	you	cest		男	34	167	62	Spiro SVC	2022-3-21 10:32:25	Not up	View Delete
		1	827613675337	you	cest		男	34	167	62	Spiro MVV	2022-3-21 10:07:54	Not up	View Delete
	•													Þ
Setting											Total 2	< 1 > Go	to 1	Total 1 Page

Figure35 Report list interface

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

	🂧 Data managemen	t V1.0.2										- ×
-	Report list Da	ata query Trend	List of calibrati	on reports	Follow-up	questionnaire	е					
fraction for the second	ID: Please enter pa Spiro ALL	tient ID Full nam	ie:	Gender	: Male	Female Re	eport generat	ion time: 📋	Starting time	e – Endi	ime R	eport type:
2 Patient	Age:		Height:	× (Weight:		⊂ _	Caseh Eu		
Data	Query conditions			×)		· · · · ·		+Condition	Empty	Search	DOREACEL	
						Basic inform	nation					
	Report ID	Patient ID	Report type	User	Doctor	Operator	Gender	Age	Height	Weight	Source device	Build tim
	4	827613675337	Spiro ALL	you	cest		Male	34	160	62	AX21216586	2022-03-
	•											
Setting								T	Total 1 <	1	Go to 1	Total 1 Page

Figure36 Data query interface

(3)Trend : Click the "Trend" button to query the trend change of lung function test records

of patients according to the search criteria.

	🏠 Data ma	nagement V1.0.2		- ×
•	Report list	t Data query	Trend List of calibration reports Follow-up questionnaire	
n	Patient inf	ormation	Item: Measured value	
Home	Patient ID	827613675337	Ventilation function	Ventilation function
Dationt	Test num.	202202120009	600	0
	Full name	you	80 500	0 0
Data	Mobile		60	
	Gender	Male	40	
		Empty Search	200	
	Inspection	i report	100	
	Name	Report time W	0 2022-03-21 10:16:54 10:17:55 10:18:26 0 0 0	2022-03-21 2022-03-21 2022-03-21 10:16:54 10:17:55 10:18:26
	Spiro ALL	2022-03-21 10:54:09 View	-O- FEV 1 -O- FEV 1 % FVC -O- FVC	-O- PEF
	Spiro SVC	2022-03-21 10:32:25 View	Vestilation function	Ventilation function
	Spiro MVV	2022-03-21 10:07:54 View	7 • • • • • • • • • • • • • • • • • • •	ventilation function
	Check dat	a	6	°
	Name	Report time 🔽	5	
	Spiro ALL	2022-03-21 10:16:54 🔽	4 3 3	
	Spiro ALL	2022-03-21 10:18:26 🔽	3 2 -	
	Spiro ALL	2022-03-21 10:17:55 🔽	1	
			0	2022_03_21 2022_03_21 2022_03_21
E				10:16:54 10:17:55 10:18:26 -O- VC MAX

Figure37 Trend view interface

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

	▲ Data management V1.0.2 — ×												
•	Report list	Data query Trend	List of calibration	reports	Follow-up qu	estionnaire							
ft Home	Please choose	e ~ Calibrat	tion or Verificati ~	Start c	late -	End da	ate	Q Search			⊥ Upload report		
e Patient	Device No	Calibration date	Calibration type	Model	Capacity	Temperat ure(°C)	Humidity (%)	Pressure (mmHg)	Altitude (m)	Calibration Result	Synchroniza tion status	Operate	
Data	AX21216586	2022-03-21 10:47:13	3 Flow Calibration	Calibration	3L	23	84	753	81	Success	Uploaded	View	
	AX21216586	2022-03-21 10:47:08	Volume Calibration	Calibration	3L	23	84	753	81	Success	Uploaded	View	
Setting													
Setting								T	otal 2 <	1 > 0	io to 1 Te	otal 1 Page	

Figure 38 List of calibration reports interface

(5) Follow-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.

🊹 Data manage	ement V1.0.2							_
Report list	Data query	Trend	List of calibration reports	s Fol	low-up questionnaire			
Name	Sco	re (result is les	s than or equal to score)		Start date - End date	Туре	✓ Q Search	oad questionnaire
ID	Full name	Gender	Туре	Score	Date	Synchronizati on status	Evaluation result	Operate
1	like	Male	mMRC	0	2022-03-23 10:33:53	Uploaded	Difficulty breathing occurs only during stren uous exercise	View

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.

(1)Hospital configuration

	Setting V1.0.2														>
•	Hospital configuration	Hospital config	uration												
∱ Home	Account management	Hospital						Department						+ New	
e Patient	Report settings	Hospital	Codi	ing	Default opti	on	Operate	Departme	nt	Coding		Default optic	on Ope	rate	
* *	Medicine settings	Guangzhou res atory	spir 0000	00000			Edit	Pneumolo	gy de	xscLJM	4xXBx9s	~	Set D	efault	
Data	Parameter settings							partment		Olekusi			Del	ete	
	Predicted source														
	Questionnaire management														
	Equipment management														
	Backup	Operator					+ New	Doctor						+ New	
	Help	Operator C	oding 9	Sign	Default option	Ope	ate	Doctor	Depai	rtment	Coding	Sign	Default c	Operate	
	Software upgrade	coke a	21323	Upload ima	~	Set D	efault	cest	Pneur	nology	2022031 8180043	Upload im		Edit	
	HIS configuration					Del	ete		uepai	unent	3835			Delete	
	Operation log														
■ Setting								4					-		F

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

(2)Accout management



Figure 41 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.

(3)Report settings

	Setting V1.0.2						- ×			
•	Hospital configuration	Report	settings			Basic settings				
fi Home	Account management	Spiro	ALL Diastolic Report	Spiro SVC Spiro MVV		Heading 1	Change			
Batiant	Report settings	BRON	C CH Report			Heading 2	Change			
tadent	Medicine settings	g and dro	opping, please remember to s	save for re-sorting)	Save sort	Heading 3	Change			
Data	Parameter settings	ID	Item	Whether to show	Sort	Report storage D-\PDF	Change			
	Predicted source	14	FVC		1		chunge			
	Ouestionnaire management	15 FEV 1			2	Report logo Upload				
		81	FEV 2		3	Pulmonary Ventilat O Standard Preview O Simple Pr	eview			
	Equipment management	82	FEV 3		4	ion Chart display and hide				
	Backup	83	FEV 0.5		5	Diastolic report O Standard Preview O Simple Pr	eview			
	Help	84	FEV 0.75		6	Show report logo				
	Software upgrade	18	FEV 1 % VC MAX		7	 Desensitize patient data uploaded to the platform 				
	HIS configuration	17	FEV 1 % FVC		8	 Snow inspection quality Display a picture of the Operator's signature 				
	Operation log	Auton	natic interpretation of s	Default o tandards Dtion	perate	 Show a picture of the physician's signature Automatically fill in the date of the signature FEV1/FVC, FEV1/VCMAX are displayed in percentage 				
E Setting										

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

	A Setting V1.0.2												- ×
•	Hospital configuration	Medi	cine setti	ngs Diastolic-ge	nerating to	ol							
file Home	Account management	Bror	nchodilat	or ~ Dru	ig name		Q Searct	h + New	a One-click d	elete	data		
2 Patient	Report settings		ID	Drug category	Drug na me	Equipment		Sequence con centration	Respiratory r ate	Breaths pe r minute	Dosage	Me e u	Operate
**.	Medicine settings				amoxicill								
Data	Parameter settings		1	Bronchodilator	in	dosimeter					5	mg	Edit Delete
	Predicted source												
	Questionnaire management												
	Equipment management												
	Backup												
	Help												
	Software upgrade												
	HIS configuration												
	Operation log												
=		4										-	•
Setting									Total 1	< 1 >	Go to	1	Total 1 Page

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.

(5)Parameter settings

	▲ Setting V1.0.2 — ×													
•	Hospital configuration	FVC	(Measurement page indicators are displayed, hidden and sorted, the list of dropping, please remember to save when re-sorting)	st can be sorted by dra	gging a	Save sort								
Home	Account management	Parameter ID	Indicator parameter name	Whether to show	Unit	Sort								
2 Patient	Report settings	1	FVC		L	1								
* *	Medicine settings	2	FEV1		L	2								
Data	Parameter settings	83	FEV2		L	3								
	Predicted source	84	FEV3		L	4								
	Questionnaire management	85	FEV0.5		L	5								
	Equipment management	86	FEV0.75		L	6								
	Backup	3	FEV6		L	7								
	Help	4	FEV1/FVC		%	8								
	Software upgrade	88	FEV3%FVC		%	11								
	HIS configuration	7	PEF		L/s	12								
		8	MMEF75/25		L/s	13								
	operation log	9	FEF25	~	L/s	14								
=		10	FEF50		L/s	15								
Setting														

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.

(6)Predicted source

	Setting V1.0.2															
•	Hospital configuration	Predicted	source													
fanne Horme	Account management	Module		Defau	It option	Operate		ID	Paramete	r						
2	Report settings	Standard	i ZS			Set as Defau	lt	3	FVC							
tient		Standard	ICN	~		Set as Default Set as Default		4	FEV1	FEV1						
~	Medicine settings	otandare						5	PEF FEF25							
ata	Parameter settings	Standard	i EU					6								
	Deedlated environ							7	FEF50	FEF50						
	Predicted source							8	FEF75							
	Questionnaire management							9	FEF2575							
	Equipment management	ID	Lower age lin		Upper age lin	nit Gender	Author	Chinese	Asian	White Am	Afro Amer	American .				
		3	4		18	Male	Zapletal(1987	")								
	Backup	4	18		70	Male	ECCS(1993)									
	Help	5	70			Male	ECCS(1993)									
	Software upgrade	6	4		18	Female	Zapletal(1987	")								
	Software upgrade	7	18		70	Female	ECCS(1993)									
	HIS configuration	8	70			Female	ECCS(1993)									
	Operation log															

Figure45 Predicted source interface

Set the default expected value mode.

Parameter information in view mode is displayed in the list.

Setting V1.0.2 Hospital configuration Questionnaire settings Home Patient Account management Questionnaire type Whether to enable Operate Report settings mMRC \checkmark Disable Medicine settings Parameter settings Predicted source Questionnaire management Equipment management Backup Help Software upgrade HIS configuration Operation log E Setting

(7)Questionnaire setting



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

the questionnaire type.

(8)Equipment management

	Setting V1.0.2												
	Hospital configuration	Equipment	t management										
fi Home	Account management	Connection	Status Connec	ted									
2 Patient	Report settings	Device No	AX21216586										
**.	Medicine settings	Device vers	ion V1.0.0										
Data	Parameter settings	Device sou	nd 🧿 Turn on	O Close									
	Predicted source	Software so	ftware sound Turn on Close Equipment upgrade + New equipment										
	Questionnaire management	Equipm											
	Equipment management	ID	Device No.	Device versio	Date of man	Registration	Pemark	Operate					
	Backup	ID	Dencento	n	ufacture	Date	Kennar K	operate					
	Help												
	Software upgrade												
	HIS configuration				No data								
	Operation log												
					Tatal		Co to 1	Tetel 1 Deee					
Setting					Iotai		GO TO	Total T Page					

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.

(9)Backup

	Setting V1.0.2							- ×
•	Hospital configuration	Data t	backup	Data Recovery				
↑ Home	Account management	Pleas	e select the	directory to store the bac	Choose Start backup	One-click de	lete Migrate data	
2 Patient	Report settings		ID	Backup date	Backup directory	Ba	ckup file name	Operate
	Medicine settings		1	2022-03-24 14:12:57	D:\AX+TA\20220323\20220324\	bre	athhomeax_20220324141253.zip	Restore Delete
Data	Parameter settings							
	Predicted source							
	Questionnaire management							
	Equipment management							
	Backup							
	Help							
	Software upgrade							
	HIS configuration							
	Operation log							
 Setting								
							Total 1 < 1 > Go to	D 1 Total 1 Page



■ 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

	Setting V1.0.2					- ×
W	Hospital configuration	Data backup	Data Recovery			
fraction for the second	Account management	Please select t	he database recovery file	Choose Start recovery		
2 Patient	Report settings	ID	Restoration date	Recovery catalog	Recovery data file name	
** ,	Medicine settings					
Data	Parameter settings					
	Predicted source					
	Questionnaire management					
	Equipment management					
	Backup			No Data		
	Help					
	Software upgrade					
	HIS configuration					
	Operation log					
Setting						
g					Total 0 < 1 > Go to 1	Total 0 Page

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.

(10)Help





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.

(11)Software upgrade :

Software upgrade	×
To ensure data sec	rity, please contact technical personnel for upg rade
с	ontact number: 400-030-1510
	Figure51 Software upgrade interface

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

(12)HIS configuration

HIS address configuration can effectively serve for hospital management and operation



Figure 52 HIS configuration interface 48

(13)Operation log

View operation logs for	easy management and maintenance.
-------------------------	----------------------------------

	Setting V1.0.2				- ×	
	Hospital configuration	Q Content search		Start date	~ End date Q Search	
ff Home	Account management	ID	Log time	Doctor's name	Log content	Operation content
2 Patient	Report settings	21	2022-03-21 19:14:16	cest	The account "cest" requests to add or modify patients.	View
	Medicine settings	20	2022-03-21 19:14:02	cest	The account "cest" requests to delete the patient.	View
Data	Parameter settings	19	2022-03-21 19:13:55	cest	The account "cest" requests to add or modify patients.	View
	Predicted source	18	2022-03-21 19:13:27	cest	The account "cest" requests to add or modify patients.	View
	Questionnaire management	17	2022-03-21 19:12:44	cest	The account "cest" requests to add or modify patients.	View
	Equipment management	16	2022-03-21 19:12:14	cest	The account "cest" requested to log in to the client.	
	Backup	15	2022-03-21 19:11:14	cest	The account "cest" requests to add or modify patients.	View
	Help	14	2022-03-21 19:10:59	cest	The account "cest" requests to add or modify patients.	View
	Software upgrade	13	2022-03-21 19:10:08	cest	The account "cest" requested to log in to the client.	
	HIS configuration	11	2022-03-21 19:09:12	cest	The account "cest" requested to log in to the client.	
	Operation log	10	2022-03-21 19:08:26	cest	The account "cest" requested to log in to the client.	
=		9	2022-03-21 19:08:17	cest	The account "cest" requested to log in to the client.	
Setting		Total 20 < 1 2 > Go to 1 Total 2 Page				to 1 Total 2 Page

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.

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.

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

Summary of daily software failure analysis and handling

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	/

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 Declaration of conformity

Table 1

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

Table 2

Guid	Guidance and manufacturers' declaration – electromagnetic immunity				
The Pulmonary Fun	ction Tester (A9) is inte	ended for use in the electr	omagnetic environment specified		
below. The custome such an environmen	below. The customer or the user of the Pulmonary Function Tester(A9) should assure that it is used in such an environment.				
Immunity test	amunity test IEC 60601 test level Compliance level Electromagnetic environm -guidance				
Electrostatic discharge (ESD)	$\pm 8 \text{ kV}$ contact	$\pm 8 \text{ kV}$ contact $\pm 2 \text{ kV} \pm 4 \text{ kV} \pm 8 \text{ kV}$	Floors should be wood, concrete or ceramic tile. If floors are covered with		
IEC 61000-4-2	± 15 kV air	± 15 kV air	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; 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°	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	
	0 % UT; 250/300 cycle	0 % UT; 250/300 cycle	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 manufacturers' 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
			Portable and mobile RF communications equipment should be used no closer to any part of the
	Pulmonary Function Tester (A9) including cables, than the recommender separation distance calculated from the equation applicable to the frequency		
Conducted RF	3 Vrms	3 Vrms	the transmitter.

IEC 61000-4-6	150 kHz to 80 MHz	150 kHz to 80 MHz	Recommended separation distance
	6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz	6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz	$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{12}{V_2}\right]\sqrt{P}$
Radiated RF	3 V/m	3 V/m	
IEC 61000-4-3	80 MHz to 2.7 GHz	80 MHz to 2.7 GHz	$d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz
	385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY	385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY	$d = \left[\frac{7}{E_1}\right]\sqrt{P} 800 \text{ MHz to } 2.7 \text{ GHz}$
	communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	where <i>p</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> 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:
			$\begin{pmatrix} ((\bullet)) \end{pmatrix}$

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).

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

	Separation distance according to frequency of transmitter			
		m		
Rated maximum output of transmitter W	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 $d = \left[\frac{12}{V_2}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	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.