

# SPECIFICATION

**Product Name: Handheld Ultrasonic Pulmonary Function Spirometer**

**Module Item No.: Gasboard-7020**

**Version: V0.1**

**Date: November 01, 2018**

# Revision

No.	Version	Content	Reviser	Date
1	V0.1	First Edition	Mei Yang	2018-11-01

# Handheld Ultrasonic Pulmonary Function Spirometer Gasboard-7020



## Applications

- ✧ Pulmonary function test
- ✧ Certain types of lung disease diagnosed
- ✧ Measurement of progress in disease treatment
- ✧ Assessment for the effect of medication

## Description

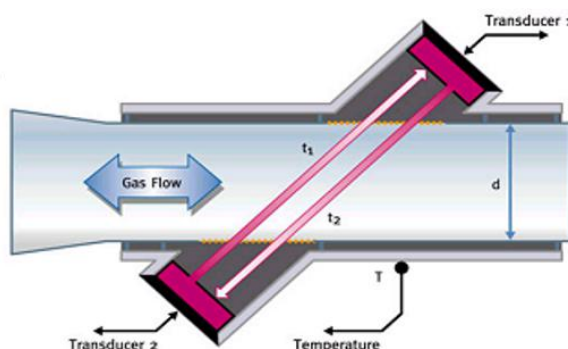
Handheld ultrasonic pulmonary function spirometer Gasboard-7020 adopts ultrasonic gas flow sensor to measure body's respiratory and inspiratory function. It can convert the patient breathing signal into electrical signal which is sent to corresponding signal processing circuit, to display real-time respiratory flow curve and then to calculate a variety of physiological and spirometric parameters. It can be used to monitor static vital capacity, forced vital capacity and maximum voluntary ventilation rate. And the matched software can automatically do BTPS correction and evaluate the pulmonary function.

## Features

- Ultrasonic technology
- No drift, no warm-up, no calibration, no maintenance
- Non-contact flow detection technology, ultrasound probe does not contact the patient to avoid cross infection
- High measurement accuracy, especially for very weak airflow
- Wide linear range, no nonlinear distortion
- There is no obstacle in the middle of the breathing tube, no breathing resistance
- Water-vapor-proof, real-time BTPS correction
- Not affected by humidity, air pressure and pollution
- Can detect gas concentration at the same time
- Greatly expanded scope of application: adult-child-newborn
- Accurate two-way detection
- Perfect supporting system

## Working Principle:

Through ultrasonic gas flow sensor, this product can measure body's respiratory function and inspiratory function, it converts the patient breathing signal into electrical signal, sends to the corresponding signal processing circuit, thus calculate a variety of physiological parameters. Then through the analysis, processing, LCD display and printing, the results can become the doctor's diagnosis reference.



## Performance Indicators

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### Specification

<b>Handheld Ultrasonic Pulmonary Function Spirometer Specification</b>	
<b>Transducer Type</b>	Gasboard-7020
<b>Principle of Operation</b>	Ultrasonic Technology
<b>VC Range</b>	0.5~8L
<b>Max VC Indication Accuracy</b>	±3% or ±0.050L, whichever is greater
<b>FVC Range</b>	0.5~8L
<b>Max FVC Indication Accuracy</b>	±3% or ±0.050L, whichever is greater
<b>MVV</b>	250L/min
<b>Max MVV Indication Accuracy</b>	±3% or ± 4.5L/min, whichever is greater
<b>Working Temperature</b>	5 °C ~ 40 °C;
<b>Relative Humidity</b>	≤80% RH (non-condensing)
<b>Atmospheric Pressure</b>	80kPa ~ 106kPa
<b>Power Supply</b>	DC4.75V ~ DC5.25V (powered by the USB interface);
<b>Transportation and Storage Temperature</b>	-40 °C ~ 70 °C
<b>Transportation and Storage Humidity</b>	≤ 80% RH (non-condensing)
<b>Data Output</b>	USB2.0
<b>Dimensions</b>	170 mm *95 mm *75mm

# Installation

## 1. System Installation

The equipment needs to be co-operating with the computer, and the computer system requirements:

- ✧ P4 2.0 or above;
- ✧ Windows XP operating system and .NET Framework 3.5 Software installation environment;
- ✧ 512MB memory;
- ✧ 1G free disk space;
- ✧ CD-ROM drive;
- ✧ 1024 × 768 display resolution, at least 256 colors.

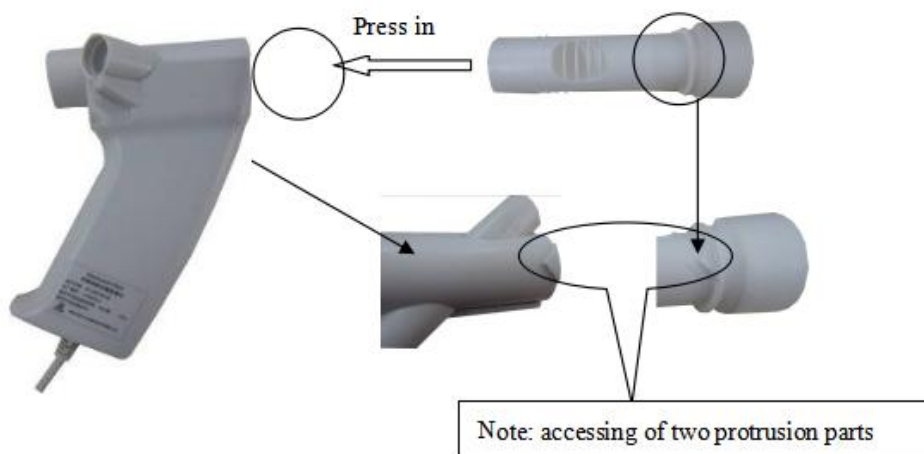
## 2. Installation



Structure of Handheld Spirometer

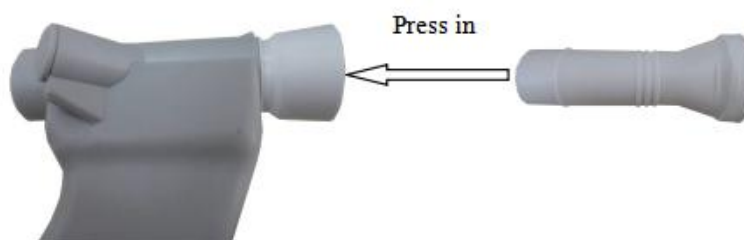
### 2.1 Installation of Hand-held Part

1. Snorkel installation step 1:



# Installation

## 2. Mouthpiece install step 2



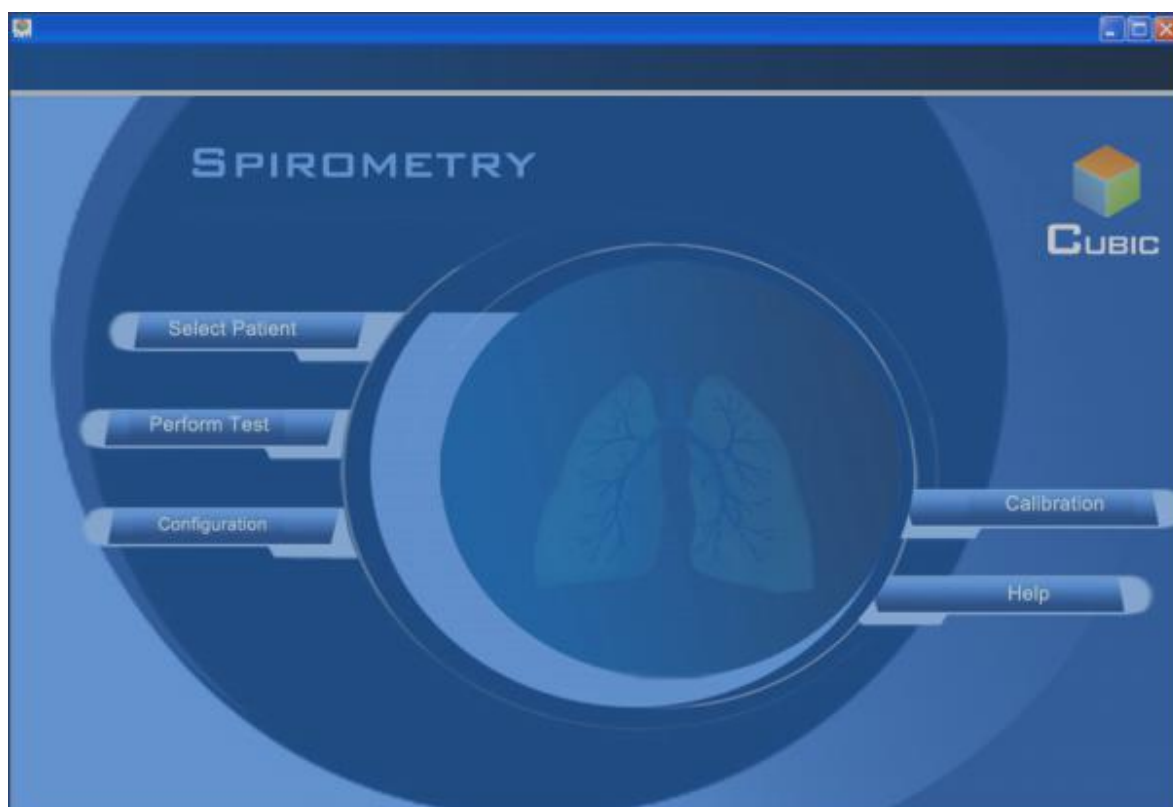
3. Installation of hand-held part is completed after the above two steps, and then connect the USB on the handheld part to the computer's USB port, to make it in test ready condition.

## 2.2 Software Installation

See the software installation instruction

## 2.3 Run the Software

Connect the USB on the handheld part to the computer, double click the software running file, enter the following main interface.



"Configuration" includes the environmental parameter, device information, test report and other procedures.

"Select Patient" includes all relevant information procedures about the patient.

"Perform Test" includes VC, FVC, MVV and other testing procedures.

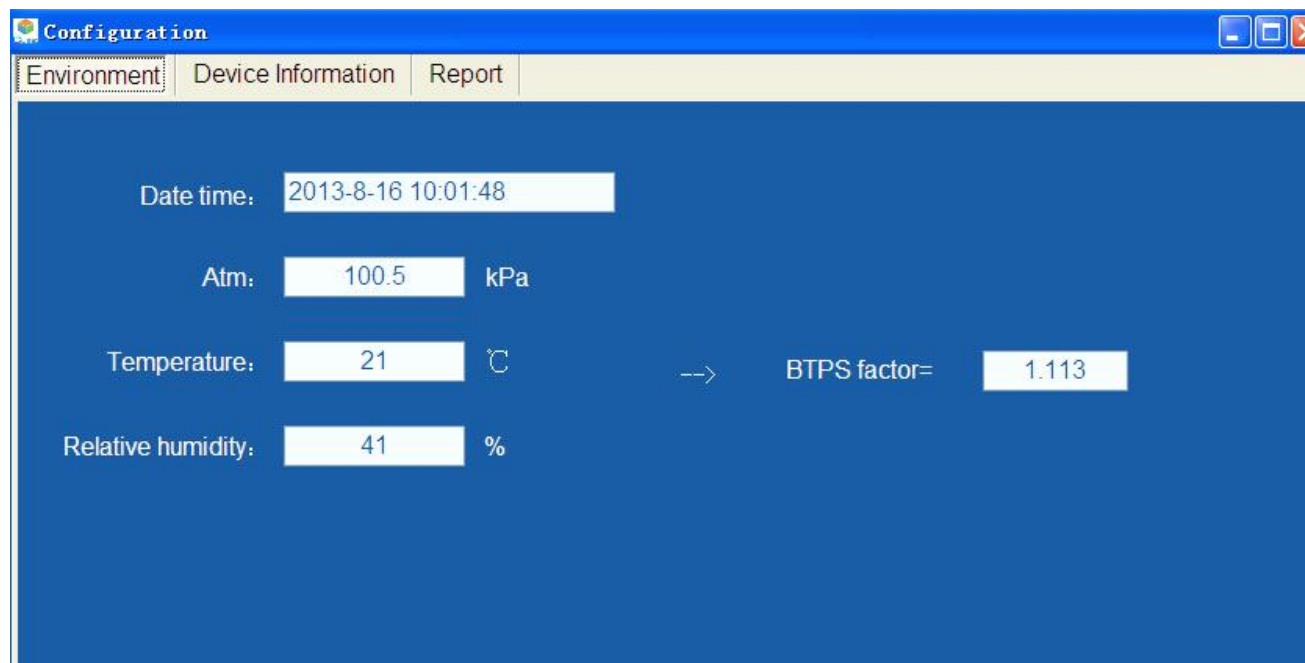
"Calibration" includes a variety of calibration procedures.

"Help" includes this USERS

# Operation Instruction

## 1 Configuration

**1.1 Environmental Parameters Principle:** Pulmonary Function measurement parameters is influenced by the environment, in order to make the measured results comparable, the data must be restored to the BTPS state (37°C, 100% relative humidity, standard atmospheric pressure), the environmental parameter automatically measurement module is to complete this function.



Operation: Just run the program, wait a moment, then you can see the time, pressure, temperature, relative humidity and other data, manually fill them into the appropriate form, then click "Save" to exit. If you click "Return" , it means not save the environment parameters.

**1.2 Device Information:** you can view the equipment information used; click "About", it displays the software version and manufacturer information.

## 2. Calibration

### 2.1 Overview

The program is for quality control of flow sensor, so as to ensure the accuracy of the flow rate and capacity test. Therefore, calibration is needed before patient testing every day, or after replacing the flow sensor.

Each calibration results are generally the same, and test without calibration is also available, but there might have some problem on the accuracy.

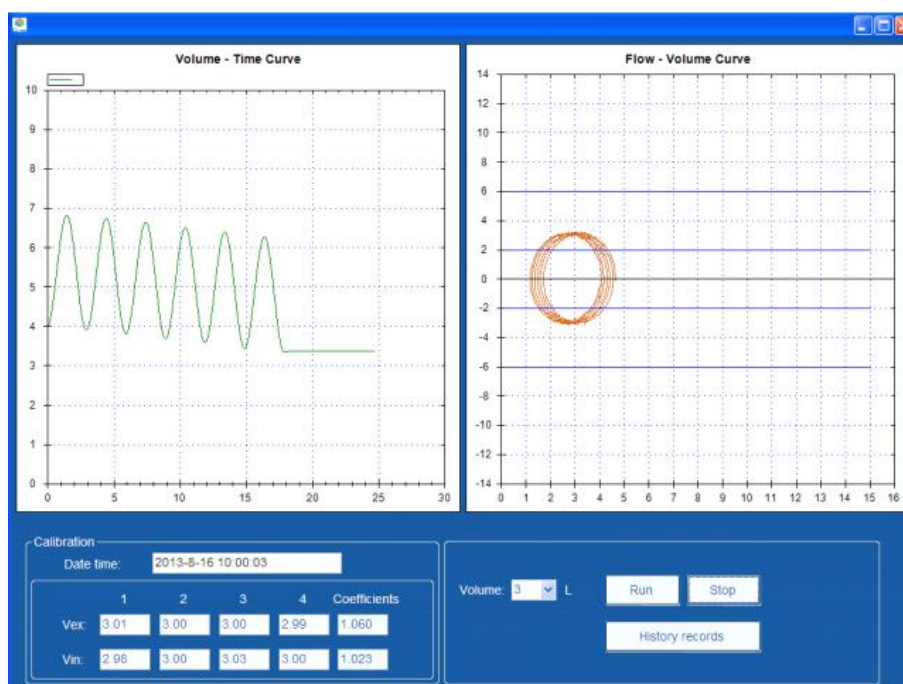
### 2.2 Principle

Through back and forth twitching of calibration cylinder with fixed volume to generate air flow, use flow sensor to measure the flow rate and integral gain volume. Calibration must under constant temperature and pressure conditions, so the "environmental parameters" correction is needed before volume calibration.

### 2.3 Operation

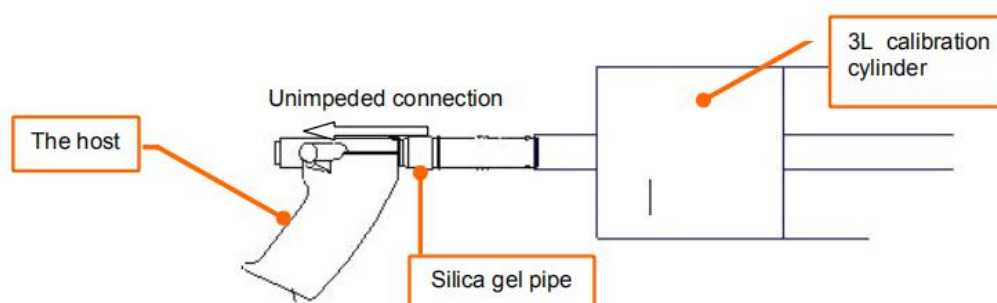
Click calibration button to enter the calibration procedures; the pop-up icon shows calibration interface as below:

## Operation Instruction



Calibration in this interface with the 3L spirometer calibration cylinder, steps are as follows:

1) Connect the spirometer calibration cylinder vent to the mouthpiece through silica pipe unimpededly, as shown below:



2) After connection, push the calibration tube to the smallest state of zero volume, ie push the piston to the bottom of calibration cylinder.

3) Click the "Run" button on the calibration interface, enter the calibration status. Push the handle 12 times at a constant rate, thus get capacity value, average value and calibration factor of four times push-and-pull in Vex, Vin.

4) After calibration, the capacity value of four times push-and-pull in vex, vin should be between 2.91 - 3.09, then the calibration is successful.

5) Click "History records" button, it'd display the preserved historical calibration records on the right margin.

**Note:** The software always use the latest saved calibration results when do pulmonary function test.

### 3 Select Patient

#### 3.1 Overview:

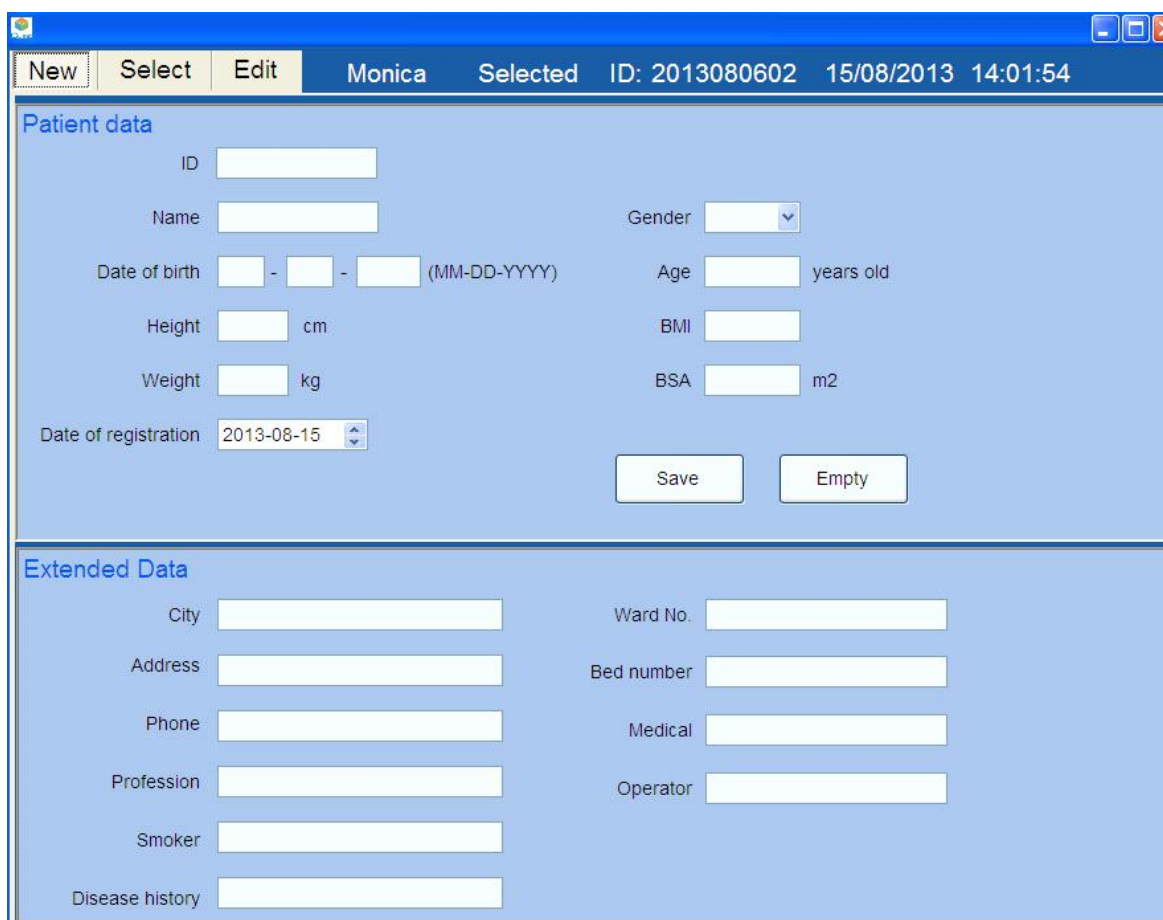
Select Patient including the registration of new patient information and output of the old patient information.

#### 3.2 Operation:

Click the "Select Patient" button, there are new user dialog as below:



## Operation Instruction



**Patient data**

ID

Name  Gender

Date of birth  -  -  (MM-DD-YYYY) Age  years old

Height  cm BMI

Weight  kg BSA  m2

Date of registration

**Extended Data**

City  Ward No.

Address  Bed number

Phone  Medical

Profession  Operator

Smoker

Disease history

Patient data information required, Extended data is optional. Enter the appropriate information for new patient register → Click "Save" → "New patient registration is successful!" → Click "OK" to make the patient become the current patient automatically . Click "Close the window" will return to the main interface.

**3.3 Select:** Search the registered patients by ID, name or date of registration, then in the search results list, double-click the selected patient as the current patient. From the top tips you can view the currently selected patient.








**3.4 Edit:** This interface displays all the information of currently testing patient. You can also modify all the patient information here, except the ID.

### 4 Perform Test

Click the button to enter Pulmonary Function Testing, and there have testing item buttons on the left side, as shown below. Select the items to be tested (VC testing, FVC testing, or MVV testing) , click "Run" to begin, "Stop" to complete the test, and calculate the tested parameters to be displayed in the list on the right.

Click "All tests" button, you can check the previous tested data. Select one and double-click can open the group data of the selected test .

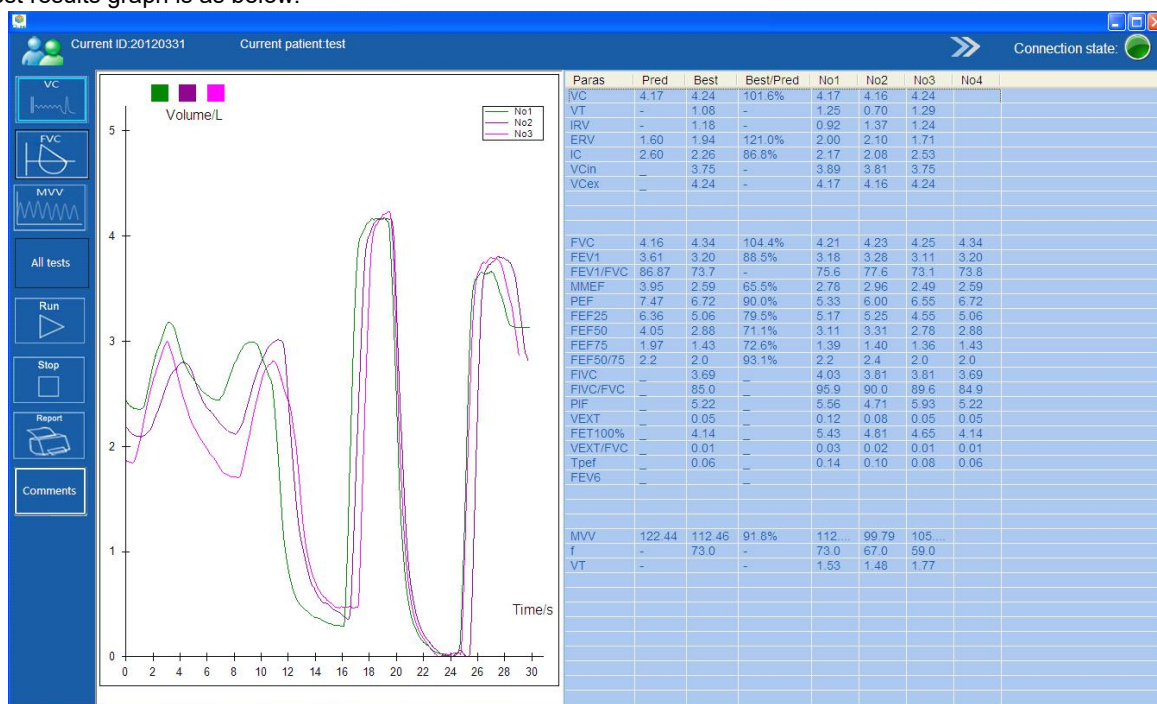
# Operation Instruction

	Vital Capacity Test
	Forced Vital Capacity Test
	Maximum Ventilatory Volume Test
	See all tests of current patient
	Start the test
	Stop the test
	Preview Report and Print



## 4.1.VC Testing Method:

Click "VC" button on the pulmonary function test interface, enter the VC test interface. Test method: sitting with mouthpiece, nose clips, and mouth breathing, after calm breathing five times, make the peak inspiration at the end-expiratory, then exhale slowly to the maximum capability.

**Note:** VC test needs to be repeated at least 3 times, at most 8 times, have a rest more than 1min between each time tests. It should take the largest two tests for repeated measurements, and the error between the best value and second-best value should be <0.15L. Test results graph is as below:



# Operation Instruction

In the curve interface, the different colors curves indicate the patient test results, you can click  and  to view

single curve, or  to view all curves.



Different colors in the left represent the 1-8 times testing, each test can be deleted or set to be optimum operation. Left -click on the mouse button is the delete and restore switching, and right-click is the optimum operation (which is also suitable for FVC testing, MVV testing).

## 4.2 FVC Testing Method:

Click "FVC" button on the pulmonary function test interface, enter the FVC test interface. Test method: sitting with mouthpiece, nose clips, and mouth breathing, inhale completely after 5s calm breathing, then exhale hard, fast, full, all in one. The whole process should without breaking breath until exhale completely, avoid coughing, double inspiration or double expiration. The expiration time should extend as far as possible, up to 6s is better, then fast forced inhale immediately after exhale completely.

**Note:** During FVC testing, extrapolation capacity FVC <5% FVC (or 0.15L, whichever is larger), at least check three times, but usually no more than eight times, test interval between two times is from 30s to several minutes, which is depending on the patient's condition, then take the larger value. Variation between FVC and FEV1 best value and second-best value is <5% or 0.2L.

Test results graph is as below.



## Operation Instruction

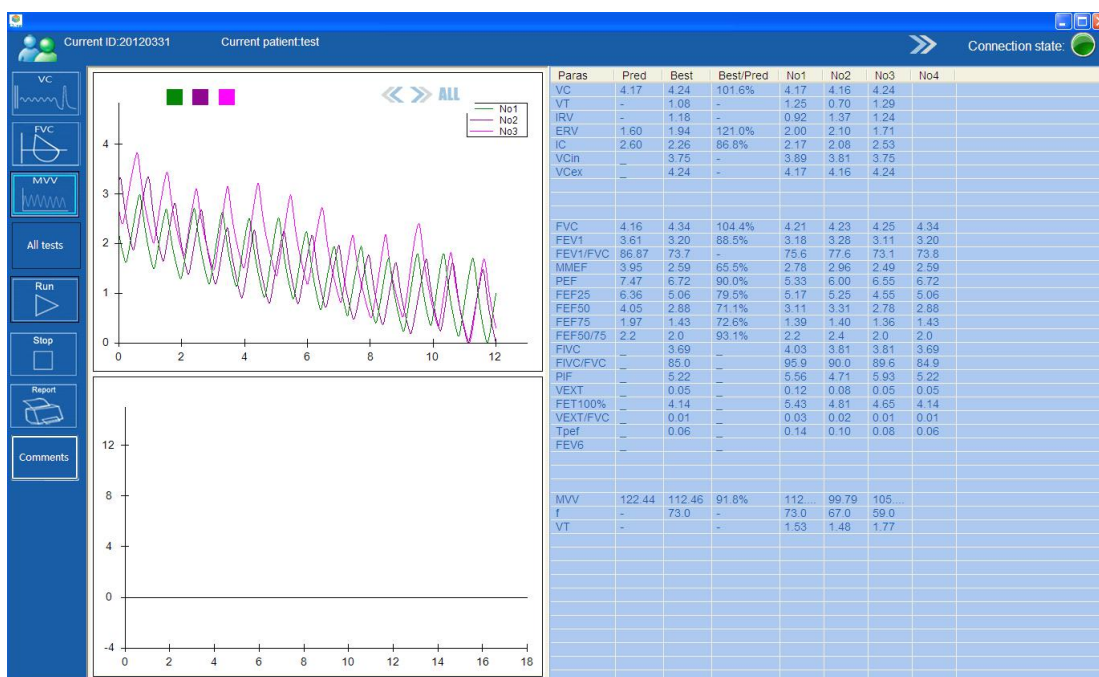
### 4.3 MVV Testing Method:

Click "MVV testing" button on the pulmonary function test interface, enter the MVV test interface.

Test method: sitting with mouthpiece, nose clips, sustained respiration for 12s with the maximum respiration amplitude and respiration rate.

**Note:** MVV testing should be at least two times, and rest for 5-10min between two tests, take the two maximum values as the best, with error <10%. 12s maximum ventilation testing is the severe respiratory movement, which is not suitable for patients with serious cardiopulmonary diseases and hypothesis.

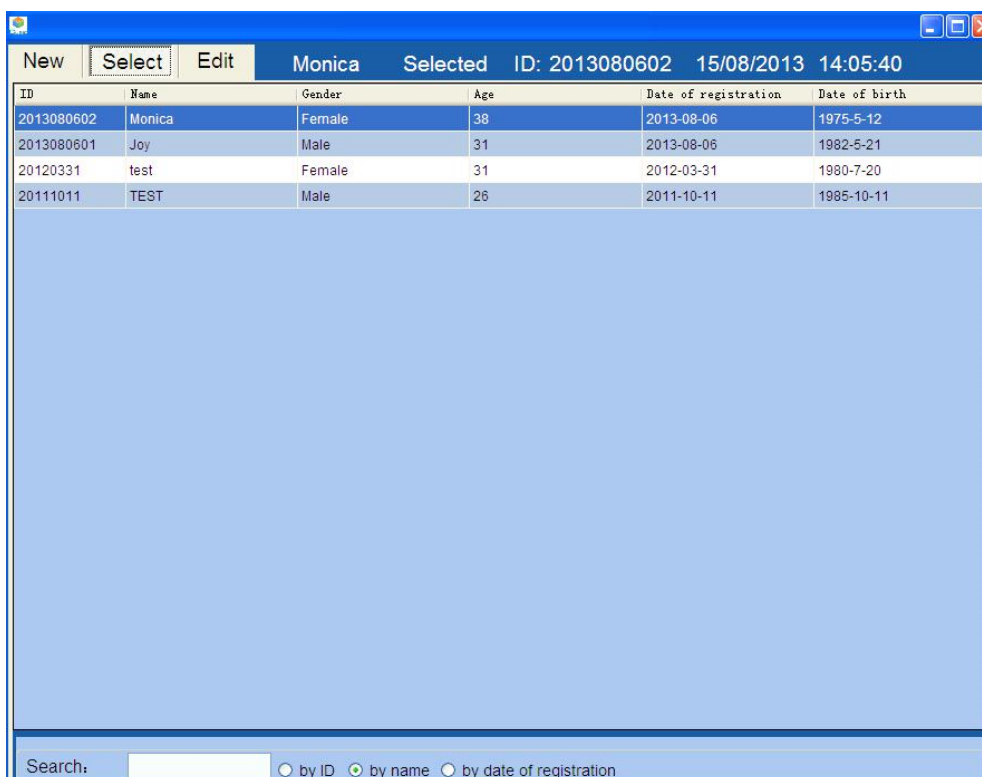
Test results graph is as below.



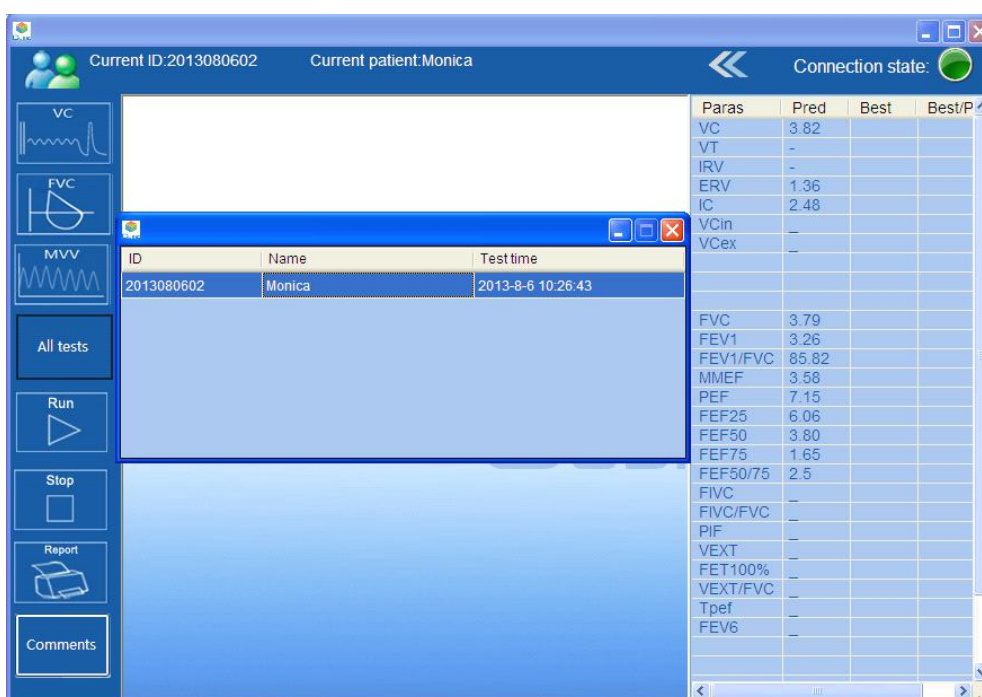
## Operation Instruction

### 5 Method of See History Test

In the main menu, click Select Patient button and push Select to open the Select tabpage, the screen will display all patients' ID, name, and test time.



Double-click the above information box to select one patient, then close this form to return to the main interface, click Perform Test to open the test form, then click All tests, the pop-up dialog box would display all previous tests of the user as shown below, double-click one test, it will show the test data on the right.




Click the above buttons of "VC testing" "FVC testing" "MVV testing", it'd display the patient's VC testing, FVC testing, and MVV testing records.

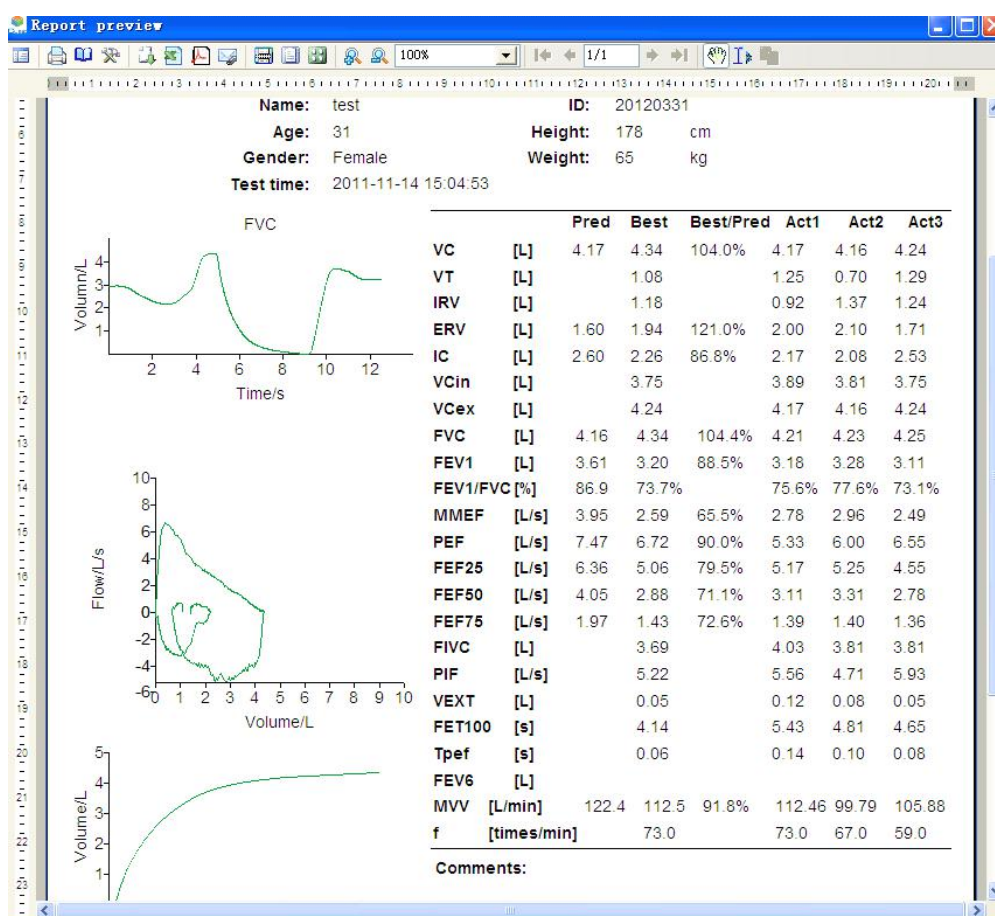
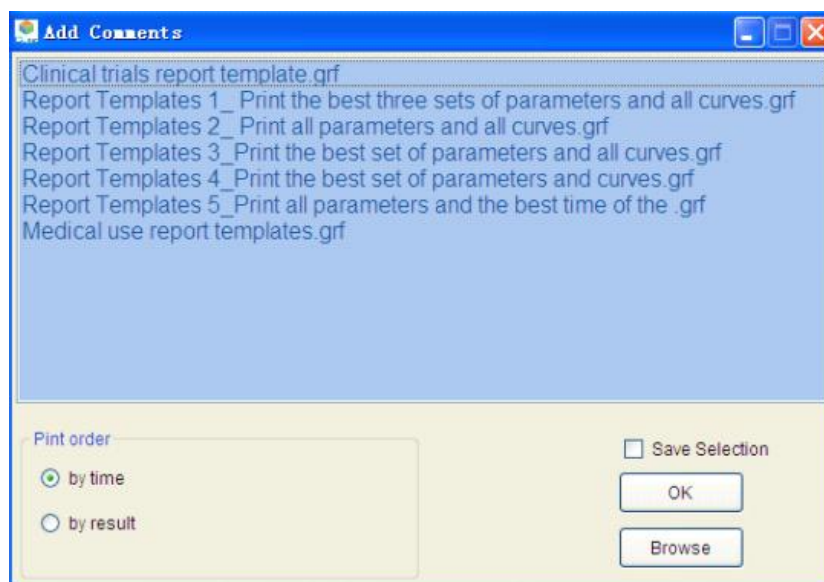
## Operation Instruction

### 6 Print

The user can print the current test results, print method as below:

Click on "Report", the print report selection dialog box will pop up, click ok after selecting a print report format, then you can preview

the report, click on the button  in the upper left to print.



## Operation Instruction

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### 7 Maintenance

(1). The maintenance must be carried out by the professionals.

(2). Regularly clean the surface with a damp cloth, then dry it; do not use the dissolvent Reagent.

(3). Warrantee time of consumables mouthpiece is two years, please keep it dry.

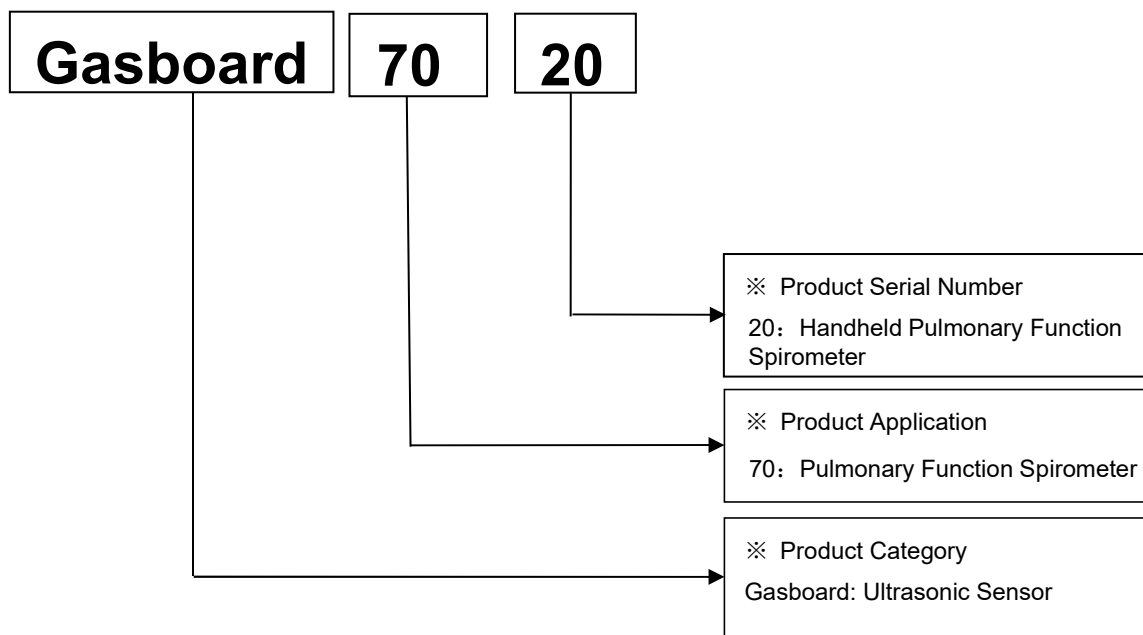
a. Consumables mouthpiece is for single usage, the replacement method see "Mouthpiece installation steps"; installation size of mouthpiece end is  $\Phi 27$ , and international standards is 0 ~ 14L / s flow range, the resistance should be less than 1.5cmH<sub>2</sub>O (L·s) , filtration efficiency of international standards required to achieve 95% or more.

b. Please read the mouthpiece labels, safety precautions and usage guidelines carefully before usage.

c. Snorkel and nose clip can be reused, but must be soaked for disinfection.

## Product Code Instruction

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## User Attention

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### 1 Operation Requirements:

It should work under non-corrosive gases and well-ventilated environment, avoid direct sunlight.

### 2 Transportation Requirements:

Wet, crash, extrusion and violence loading & unloading are prohibited. It is strictly prohibited to be put together with corrosive materials.

### 3 Storage Requirements :

The packaged product should be stored in dry, ventilated, non-corrosive environment.

## After-Sales Services and Consultancy

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