CONTEC

Spirometer / SP90

Contec Medical Systems Co., Ltd.

Address: No. 112 Qinhuang West Street, Economic & Technical Development Zone, Qinhuangdao, Hebei Province,PEOPLE'S REPUBLIC OF CHINA

Tel: +86-335-8015430 Fax: +86-335-8015588

Technical support：0335-8015451 400-652-6552

E-mail：cms@contecmed.com.cn

Website： http://www.contecmed.com.cn

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Instructions to User

Dear users, thank you very much for purchasing the Spirometer.

Please read the User Manual carefully before using this device. The User Manual which describes the operating procedures should be followed strictly. Failure to follow the User Manual may cause measuring abnormality, equipment damage or human injury. The manufacturer is NOT responsible for the safety, reliability, performance issues and any monitoring abnormality, human injury and equipment damage due to users' negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.

Date of manufacture: see the label.

Owing to the forthcoming renovation, the specific products you received may not be totally consistent with the description of this User Manual. We would sincerely regret for that.

This product is a medical device, which can be used repeatedly.

This Manual contains instructions for use and technical description.

The patient is an intended operator.

Warning:

- Please obey physician's instruction during test process.
- Don't use the device when the environment temperature is low.
- Please refer to the correlative literature about the clinical restrictions and contraindications.
- This device is not intended for treatment.
- Do not refit the device.

The company supplies the qualified product to the user in accordance with enterprise standard.

The company is responsible for installation, debug and technical training of the device in accordance with the requirements in contract.

The company performs device repair in warranty period (a year) and maintenance after warranty period.

The company responds timely to the user's request.

The company reserves the right of final interpretation to this manual.

Product and registration information

Spirometer /SP90

Registrant name/Name of production enterprise/After sales service unit：Contec Medical Systems Co., Ltd.

Registered address/Domicile of production enterprise/production address：No. 112 Qinhuang West Street, Economic & Technical Development Zone,
Qinhuangdao, Hebei Province,PEOPLE’S REPUBLIC OF CHINA

Registrant/Manufacturing enterprise contact information：

Tel: +86-335-8015430 Fax: +86-335-8015588

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Chapter 1 Safety

1.1 Instructions for safe operations

- ✧ Check the main unit and all accessories periodically to make sure that there is no visible damage that may affect safety or performance. It is recommended that the device should be inspected weekly at least. When there is obvious damage, stop using it.
- ✧ Necessary maintenance can ONLY be performed by qualified service engineers designated by the manufacturer. Users are not permitted to maintain it by themselves. If necessary, our company can provide technical support, component list, drawing, calibration rule, or other materials that can help qualified technical personnel to repair the device.
- ✧ The device is powered by a lithium battery, when replacing or maintaining the battery, it must be carried out by qualified technical personnel designated by the manufacturer. When it was disposed casually by a person without adequate training, hazards such as battery leakage, fire or explosion may occur.
- ✧ The product can not be used together with devices not specified in User Manual. Only the devices appointed or recommended by the manufacturer can be used with it.
- ✧ This device has been calibrated before leaving factory.

1.2 Warning

- Explosive hazard - DO NOT use the device in environment with inflammables such as anesthetic.
- Please check the device and accessories in accordance with the list to avoid that the device can not work normally.
- Don't use the device in environment with strong electromagnetic interference, direct breeze source, cold source and hot source.
- The disposal of scrap device, its accessories and packing (including mouthpiece, plastic bags, foams and paper boxes) should follow the local laws and regulations, as improper disposal may pollute the environment.
- Please choose the accessories appointed or recommended by the manufacturer to avoid damage to the device.
- Don't use the device with the airflow collector of other similar products. When replacing it, please use the one specified by our company. Please calibrate it before use.

1.3 Caution

- Keep the device away from dust, vibration, corrosive or inflammable substances, high or low temperature and humidity.
- If the device gets wet or coagulates, please stop operating.
- Please use the device within the required altitude, temperature and humidity range. When the device is moved from the highest or lowest storage temperature environment to a room temperature environment, it must be prevented from working for half an hour.
- High temperature or high pressure steam disinfection to the device is not permitted. Refer to relative chapter (7.1) in User Manual for cleaning and disinfection.
- Do not immerse the device into liquid. When it needs clean, please wipe its surface with medical alcohol. Do not spray any liquid on the device directly.
- When cleaning the device with water, the temperature should be lower than 60℃.
- When the data can't be displayed continuously or other cases happened during test, restart the device.
- The device has ten-year service life.
- When the measurement result goes beyond the range, there will be a prompt for exceeding limit.
- The device may not be suitable for all people, if you can't get a satisfactory result, please stop using it.
- The device should be calibrated prior to first use each day. Please calibrate it in time when an obvious data deviation was found; if repeated calibration fails, please contact your local customer service center.
- Please use the device properly to measure each lung function following the User Manual, to get the optimal results.
- During use, in order to ensure the measurement accuracy, please do not cough or spit to the device to avoid its blocking due to foreign matter
- Patients with respiratory communicable disease or infectious diseases should not take lung function test during acute phase; low immunity population is not appropriate to do lung function tests either. If necessary, disease control and protection should be done strictly.
- Please consult your doctor before using this device.
- When other devices need to connect with this product for use, only the ones met relevant standards (such as IEC 60601-1) can be connected.
- Users should pay attention to preventing tightening caused by excessively long data cables.
- Pressing buttons may cause the operator to experience silicone allergies.
- Try to avoid cotton lint and dust from affecting this instrument as much as possible.
- Otherwise, degradation of the performance of this equipment could result."
- The device needs to be kept out of the reach of children or pets, to prevent animal hair or dirt entering affecting use.
- The part of the application expected to be contacted by the patient is mouth piece.

1.4 Contraindications

No.

Chapter 2 Overview

The Spirometer is a common device measured lung capacity and expiratory flowrate, it is an important examination content in chest-lung disease and respiratory health, an indispensable test project in modern Pulmonary inspection. At the same time, it has great significance in respiratory diseases diagnosis, differential diagnosis, therapeutic evaluation and selection of surgical indications. Thus, with the rapid development of clinical respiratory physiology, clinical applications of lung capacity inspection are also gaining popularity.

The Spirometer is a hand-held device for testing pulmonary function, it adopts differential pressure acquisition principle to measure parameters related to FVC, SVC, MVV and MV, it can display respiratory waveform: flow-volume loop and volume-time curve, connect with the master device to realize the real-time display of the waveform, which is applicable for diagnosis and therapeutic evaluation of lung diseases (such as asthma, COPD, pulmonary fibrosis and cough, etc.), preoperative safety evaluation and routine physical examination, etc. It can be used in many scenarios, such as respiratory medicine, thoracic, anesthesiology, surgery, prevention and control institutions of occupational disease, physical examination institutions, etc. It can provide the test results of pulmonary function for the users and the basis for the medical staff to make diagnosis.

2.1 Features

1) Collect the data by a differential pressure sensor, more accurate in results and more sensitive in response.
2) Small in volume, light in weight.
3) Convenient to disassemble, easy to clean, disinfect and replace components.
4) TFT HD LCD display, clear in results.
5) Information indicator: be used to indicate the working state of the device.
6) Voice prompt function (optional).
7) Transmission mode: Bluetooth, USB data cable
8) The user's information can be edited, stored and uploaded.
9) Use with PC software, realizes real-time test, real-time display of waveform and data.

2.2 Applied range

The device can be used in many scenarios, such as respiratory medicine, thoracic, anesthesiology, surgery, prevention and control institutions of occupational disease, physical examination institutions, etc. It is required that the user operates the device according to User Manual.

2.3 Environment requirements

Storage environment

a. Temperature: - 20 ℃ ~ + 45 ℃ b. Relative humidity: ≤ 95 % c. Atmospheric pressure: 500 hPa ~ 1060 hPa

Operating environment.

a. Temperature: + 10 ℃ ~ + 40 ℃ b. Relative humidity: ≤ 80 % c. Atmospheric pressure: 700 hPa ~ 1060 hPa

Chapter 3 Principle

The Spirometer adopts differential pressure sensing method for signal acquisition. When the test airflow passes through the flowrate collector, the collector converts the airflow signal into a differential pressure signal, which is proportional to the airflow data; the high-precision differential pressure sensor obtains the differential pressure signal and transmits it to the processor, the processor analyzes and obtains the flow rate and volume, then via processing, generates the data required by each test parameters and curve drawing.

Chapter 4 Technical Specification

4.1 Main function

1) Measure and display the test items related to FVC, SVC, MVV and MV.
2) Display the respiratory waveform measured, use it with the master device to realize real-time test.
3) With management functions of user information and case data.
4) Built-in multiple predicted values, display the ratio of the measured value and the predicted value.
5) BTPS correction functions, measure environment parameters automatically.
6) Support bronchial test.
7) Voice prompt function (optional).
8) With calibration and verification functions, ensure the test accuracy.
9) Data transmission: Bluetooth, USB data cable.
10) One-button test function.
11) Rechargeable lithium battery, battery power indication.

4.2 Main parameters

Volume range. 0 ~ 10 L (FVC value) (BTPS)

Flow range. 0 L/s ~ 16 L/s (BTPS)

Volume accuracy. ±3 % or 0.05 L (whichever is greater)

Flow accuracy. ±5 % or 0.17 L/s (whichever is greater)

Type of protection against electric shock: internally powered equipment.

Degree of protection against electric shock. type BF applied part

Degree of protection against ingress of liquid: IP22.

Electro Magnetic Compatibility: Group Ⅰ class B.

Resistance to flow: < 0.35 KPa / (L/s)

Battery：3.7V，2200mAh Li-On rechargeable，the placement cycle shall not be less than 300 times.

Equipment operation time：Estimated 24 hours.

Chapter 5 Installation

5.1 Brief introduction

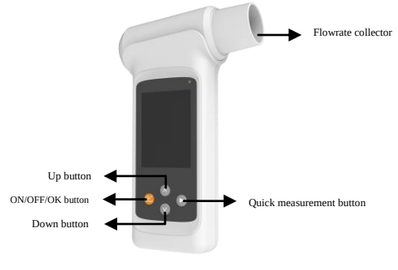

Figure 5-1

5.2 Disassembly and assembly

1) Disassembly

The outline drawing of the device is shown as Figure 5-1. The flowrate collector is the signal acquisition part, which needs to be disassembled and cleaned after test. The disassembly steps are shown in the Figure below:

Figure 5-2: Push the inner sleeve out according to the direction indicated by the arrow

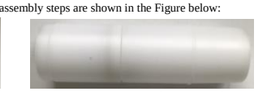

Figure 5-3: Inner sleeve removed

Figure 5-4: Outer sleeve of the main unit

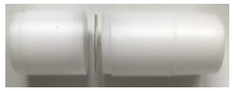

Figure 5-5: Unscrew the inner sleeve and disinfect the two parts of the inner sleeve and the screen

2) Installation

After cleaning and airing, install it in the reverse order of disassembly.

Note: push the inner sleeve to the position where the limit bulge and the outer sleeve contact closely, and no gap among them.

5.3 Accessories

a. A User Manual b. A nose clip c. Mouthpiece (disposable) d. A USB data cable

e. PC software

Chapter 6 Operation

6.1 Use method

6.1.1 ON/OFF

1) After installing the device properly, long press “ON/OFF/OK” button to turn on the device.
2) Under “ON” state, long press “ON/OFF/OK” button to turn off the device.

6.1.2 Operation process

After power-on, it enters the main interface as shown in Figure 6-1.

Figure 6-1

6.1.2.1 Users

Enter the main interface, if there is no user, please create a user firstly. In the main interface, press “Up” or “Down” button to select “Users” as shown in Figure 6-2, press “ON/OFF/OK” button to enter the user management interface, as shown in Figure 6-3. Select “New user” to enter its editing interface as shown in Figure 6-4, select a item, press “ON/OFF/OK” button, then the parameters to be set and angle brackets will appear on the right side of the selected item, as shown in Figure 6-5. Under this state, the item can be edited, press “Up” or “Down” button to edit the user information, press “ON/OFF/OK” button to finish editing, after editing each information well, select “Save” and press “ON/OFF/OK” button to finish creating the user as shown in Figure 6-6.

After creating a user, various tests of lung function can be performed. After selecting the corresponding user, return to the main interface, then select the corresponding test item to start the test.

For an existing user, select "Users" in the main interface to enter the interface shown in Figure 6-6, press “Up” or “Down” button to select the corresponding user, and press “ON/OFF/OK” button to enter the personal information interface. After confirming that there is no error, use “Up” or “Down” button to select "Sel", then press “ON/OFF/OK” button, the user will be selected, return to the main interface, you can select the corresponding test item to test.

Figure 6-2

Figure 6-3

Figure 6-4

Figure 6-5

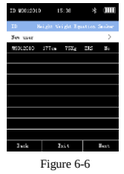

Figure 6-6

6.1.2.2 FVC (forced vital capacity)

Under the main interface as shown in Figure 6-1, select “FVC” to enter FVC test interface as Figure 6-7.

Figure 6-7

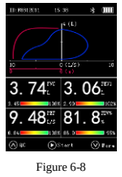

Figure 6-8

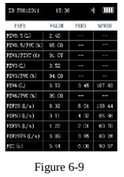

Figure 6-9

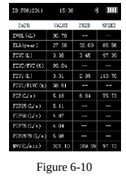

Figure 6-10

Under this interface, seal the lips around the mouthpiece closely, after trying to inhale as much as possible to total lung capacity, exhale as soon as possible to the residual volume, as shown in Figure 6-8. Press “Down” button under this interface to check other parameters as Figure 6-9 and Figure 6-10. Under the interface of Figure 6-8, press “Up” button to check the assessment of test results.

Test procedure

1) Seal the lips around the mouthpiece closely, breathe calmly for 3-5 times;
2) Take a deep breath to the maximum at the end of a calm expiration;
3) Forced exhale all air out as fast as possible in the shortest time;
4) Forced inhale to the maximum;
5) Repeat above steps for several times, and select the best value to display.

Note: the maximum effective flow rate: ≤ 16 L/s.

Quality control

Repeatability criteria:

- At least 3 acceptable curves;
- Deviation of the two maximum values of FVC: ± 5 % or ± 0.150 L, whichever is greater, if FVC < 1 L, the deviation < 0.1 L;
- Deviation of the two maximum values of FEV1: ± 5 % or ± 0.150 L, whichever is greater;
- Deviation of the two maximum values of PEF: ± 5% or ± 0.150 L/s, whichever is greater.

Other criteria:

Extrapolation volume (EVOL): the explosive force is strong when no hesitation at the beginning of expiration. It should be less than 5 % of the FVC or 0.150L, whichever is greater. Otherwise, if the subject hesitated at the the beginning of of expiration, the explosive force is not enough.

Expiration time for children under 10 years old is greater than or equal to 3 seconds.

Expiration time for subjects over 10 years old is greater than or equal to 6 seconds.

Note: The above criteria are part of the reference standards for quality control. The test results cannot be negated solely because the graphs or values are not repeatable. They must be analyzed in combination with the actual situation of the subject. According to the partial quality control standards given in the software combined with the overall judgment of the curve shape, the acceptable curve is selected. Other unacceptable graphs can be ignored or deleted, and not involved in the calculation of the software.

6.1.2.3 VC (vital capacity)

Under the main interface as shown in Figure 6-1, select “SVC” to enter SVC test interface as Figure 6-11.

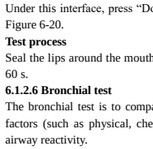

Figure 6-11

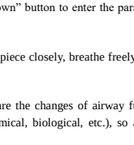

Figure 6-12

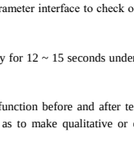

Figure 6-13

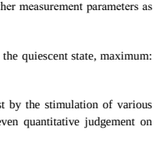

Figure 6-14

Lung capacity of slow breathing. Under a relaxed condition, the subject does not need to breathe quickly, but fully breathe in and breath out to take the vital capacity test, as shown in Figure 6-12. Under this interface, press “Down” button to check other parameters as Figure 6-13 and Figure 6-14.

Test procedure

1) Seal the lips around the mouthpiece closely, keep breathing calmly (at least four steady breaths), a sound prompt appears after four smooth breaths;
2) Breath in deeply (or breath out deeply) to the maximum at the end of a calm expiration;
3) Exhale (or inhale) at a moderate speed until full exhalation (or inhalation) ;
4) Then breath calmly.

6.1.2.4 MVV (maximal voluntary ventilation)

Under the main interface as shown in Figure 6-1, select “MVV” to enter MVV test interface as Figure 6-15.

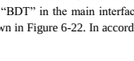

Figure 6-15

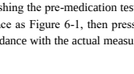

Figure 6-16

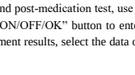

Figure 6-17

The ventilation of repeated maximal autonomous respiration during a unit of time in a manner that as fast as possible and as deep as possible, as shown in Figure 6-16. Under this interface, press “Down” button to enter the parameter interface to check other measurement parameters as Figure 6-17.

Test procedure

Seal the lips around the mouthpiece closely, breathe quickly for 12 ~ 15 seconds with the maximum inspiration and maximum expiration.

6.1.2.5 MV (minute ventilation volume)

Under the main interface as shown in Figure 6-1, select “MV” to enter MV test interface as Figure 6-18.

Figure 6-18

Figure 6-19

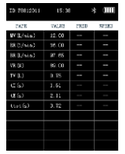

Figure 6-20

Under the quiescent state, ventilation volume obtained by spontaneous breathing, the test result is shown as Figure 6-19. Under this interface, press “Down” button to enter the parameter interface to check other measurement parameters as Figure 6-20.

Test process

Seal the lips around the mouthpiece closely, breathe freely for 12 ~ 15 seconds under the quiescent state, maximum: 60 s.

6.1.2.6 Bronchial test

The bronchial test is to compare the changes of airway function before and after test by the stimulation of various factors (such as physical, chemical, biological, etc.), so as to make qualitative or even quantitative judgement on airway reactivity.

Therefore, the bronchial test needs to compare the test data before and after external stimulation.

In the test interface of FVC, MVV, etc., there are options for whether to take medication, as indicated by the box in Figure 6-21. Press “Up” or “Down” button to switch whether to take medication. The bronchial test needs to compare the data of the pre-medication test and the post-medication test, so it is necessary to test in two states: PRE, POST.

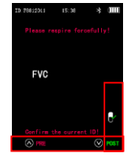

Figure 6-21

Figure 6-22

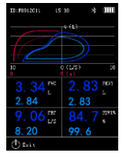

Figure 6-23

According to the doctor’s advice, after finishing the pre-medication test and post-medication test, use “Up” or “Down” button to select “BDT” in the main interface as Figure 6-1, then press “ON/OFF/OK” button to enter its comparison interface as shown in Figure 6-22. In accordance with the actual measurement results, select the data of pre-medication

and post-medication to enter the data comparison interface as shown in Figure 6-23, which displays the comparison for data and waveform of pre-medication and post-medication.

6.1.2.7 Setting

Under the interface of Figure 6-1, select “Settings” to enter the setting interface as Figure 6-24.

Figure 6-24

a. Storage: in Figure 6-24, the first item represents the current remaining storage space;
b. Date and time: in Figure 6-24, use “Down” button to select “Date and time”, then press “ON/OFF/OK” button to enter the time setting interface, when the cursor is on the "Year", press “ON/OFF/OK” button, and angle brackets appear on the right parameter, which indicates that it can be edited. Adjust the parameter value by “Up” or “Down” button, then press “ON/OFF/OK” button to finish setting. Press “Up” or “Down” button to adjust the month, day, hour and minute in turn as shown in Figure 6-25, select “Exit” after setting to finish the time setting, and return to the setting interface as Figure 6-24.

Figure 6-25

c. Calibration: in Figure 6-24, use “Up” or “Down” button to select “Calibration”, then press “ON/OFF/OK” to enter the calibration setting interface as shown in Figure 6-26.

Under the calibration setting interface as shown in Figure 6-26, press “ON/OFF/OK” button to select "Cali Volume/L", press “Up” or “Down” button to adjust the volume of the Pulmonary Syringe, after selecting, press “ON/OFF/OK” button to enter the calibration interface as shown in Figure 6-27, it displays "Push & Pull". Under this interface, connect the Pulmonary Syringe and the device properly, then operate it following the operation prompts. During the process of pushing and pulling the Pulmonary Syringe, the number of calibration will be displayed in turn as shown in Figure 6-28. After completing the calibration following the prompts, the device will automatically exit the calibration operation and return to the interface as Figure 6-26.

Under the calibration setting interface as shown in Figure 6-26, select "Adjust" option to enter the interface as Figure 6-29. Under this interface, you can set the parameters. First press “ON/OFF/OK” button to select a parameter, then use “Up” or “Down” button to adjust the coefficient. After adjusting, press “ON/OFF/OK” button to confirm. Note: please do not set this parameter randomly without technical guidance, to avoid affecting its accuracy. After adjusting, select “Exit” and press “ON/OFF/OK” button to return to the interface as Figure 6-26.

Under the calibration setting interface as shown in Figure 6-26, use “Up” or “Down” button to select "BTPS" option, then press “ON/OFF/OK” button to select “Open” or “Close”, after selecting, press “ON/OFF/OK” to confirm, as shown in Figure 6-30. Then select “Exit” and press “ON/OFF/OK” button to return to the interface as Figure 6-26.

Under calibration setting interface, select “Exit” to return to the interface as Figure 6-24.

Figure 6-26

Figure 6-27

Figure 6-28

Figure 6-29

Figure 6-30

d. Language: in Figure 6-24, use “Up” or “Down” button to select “Language”, then press “ON/OFF/OK” to enter the language setting interface as shown in Figure 6-31, press “Up” or “Down” button to select the required language, then press “ON/OFF/OK” to confirm and return to the interface as Figure 6-24.
e. About: in Figure 6-24, use “Up” or “Down” button to select “About”, then press “ON/OFF/OK” to enter the device information interface as shown in Figure 6-32, press “ON/OFF/OK” to return to the interface as Figure 6-24.
f. Factory reset: in Figure 6-24, use “Up” or “Down” button to select “Factory reset”, then press “ON/OFF/OK” to enter its setting interface as shown in Figure 6-33, select “No” to return to the interface as Figure 6-24, “Yes” to restore to factory settings, please choose it carefully.

Figure 6-31

Figure 6-32

Figure 6-33

g. Return: press “ON/OFF/OK” to return to the main interface as Figure 6-1.

6.1.2.8 History

Under the main interface of Figure 6-1, select “History” to enter the historical data setting interface, as shown in Figure 6-34.

Figure 6-34

a. Review Function: select “Review Function” to enter the interface as shown in Figure 6-35, select the user to be reviewed, press “ON/OFF/OK” to enter the selection interface of the test item as shown in Figure 6-36. Among four test items, the one with ">" option on the right represents that it had the tested data, press “ON/OFF/OK” button to check the lists tested as Figure 6-37, press “ON/OFF/OK” button again to check the specific test data.
b. Trend Curve: select “Trend Curve” to enter the interface as shown in Figure 6-35, select the user to be reviewed, press “ON/OFF/OK” to enter the trend curve interface as Figure 6-38, press “Up” or “Down” button to check the trend curve of other parameters.
c. Delete Data: select “Delete Data” to enter the interface as shown in Figure 6-35, select the user to be deleted, press “ON/OFF/OK” to enter the deletion interface as Figure 6-39, select “Exit” to return to the interface as shown in Figure 6-35, press “ON/OFF/OK” to delete all storage records about this user, after deleting, return to the interface as shown in Figure 6-35.
d. Exit: select “Exit”, press “ON/OFF/OK” button to return to the main interface as Figure 6-1.

Figure 6-35

Figure 6-36

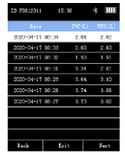

Figure 6-37

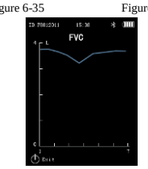

Figure 6-38

Figure 6-39

6.1.3 Automatic shutdown

The device will automatically shut down when there is no operation within 2 minutes.

6.1.4 Charging

When charging, the device will enter the charging interface automatically, display the charging state, under this interface, the button operation is invalid, the device can not be used.

Two charging modes:

a. Connect one end of the data cable with the computer, the other end to the device, then the device will be charged.
b. Insert one end of the power adapter to the power socket, the other end to the device by the data cable, then the device will be charged.

Please do not use the device during charging.

It indicates that the device is charging when the indicator on upper left is orange, and it is blue after fully charged.

Do not place the device to the place where it is difficult to disconnect it from the mains when charging. After fully charged, unplug the power adapter to disconnect it from the mains.

When charging, if the power adapter selected is not provided by our company, it should meet the following requirements: output voltage: DC 5 V, current: ≥ 1 A, and meet local laws and regulations requirements.

6.1.5 Data transmission

The device can communicate with the master device (PC or other devices that can be connected) by the USB data cable or Bluetooth.

a. Connect the device with the master device by the data cable, the device will turn on, then open the PC software to operate for data transmission.
b. With Bluetooth transmission function. When the device is turned on, the Bluetooth is always “ON”, and there is a Bluetooth icon, which indicates that it can be searched and connected. After the connection is established, it can cooperate with the main device to complete the communication. It displays the data transmission icon after connecting successfully.

6.2 Software introduction

Operating system: Windows XP or other operating systems that support the software

Display: 1024 * 768 or higher

Chapter 7 Maintenance, Transport and Storage

7.1 Cleaning and disinfection

In order to ensure users’ safety and test accuracy, the device must be cleaned in time; use the medical alcohol to wipe the enclosure of the device, then nature dry or clean it with a clean and soft cloth. After using, disassemble the flowrate collector for cleaning, Disassemble according to the disassembly method, unscrew the inner sleeve and disinfect the two parts of the inner sleeve and the screen, immerse the two parts of the inner sleeve and the screen removed into the disinfectant for soaking for 30 minutes. Note, keep them completely submerged. Then take it out, rinse it with distilled water, after drying, re-install it for use. This disinfection method will not cause pollution to the environment, it is recommended to clean after each use or clean them according to the cleaning procedure of the institution (note: the disinfectant is 75% medical alcohol or chlorine-containing disinfectant or glutaraldehyde at 2% concentration. Concentration of chlorine-containing disinfectant:500mg/L recommended, double for infectious patients after use, not recommended to exceed 2000mg/L).

When cleaning, it is recommended to wear disposable gloves or disinfect hands in time to protect nursing staff.

Please do not clean and maintain it during use.

7.2 Maintenance

a. Please clean and disinfect the device before using according to the User Manual (7.1).
b. The device should be calibrated prior to first use each day. Please calibrate it in time (or calibrate according to the calibration procedure of use institution) when an obvious data deviation was found; if repeated calibration fails, please contact your local customer service center.
c. The device is powered by a lithium battery, in order to prolong its service life, please charge it as soon as possible when the low battery symbol “ ” appears. It should be charged once per six months when it was not used for a long time, which can prolong its service life. The battery can not be replaced by the operator and it can only be replaced with a tool. If replacement is necessary, please contact the local designated service center or our company.

7.3 Transport and storage

a. The packed device can be transported by ordinary conveyance or according to transport contract. The device can not be transported mixed with toxic, harmful, corrosive material.
b. The packed device should be stored in room with no corrosive gases and good ventilation. Temperature: -20 ℃ ~ + 45 ℃; Relative Humidity: ≤95 %.

Chapter 8 Troubleshooting

Problems	Possible Reason	Solution
After waiting for a long time, the device can't finish measurement, and the data can't be displayed.	Not measure according to the required methods, the device does not measure.	Remeasure according to User Manual.
	The device can not measure due to malfunction.	Press “Quick measurement button” to measure again or restart it.
False test data.	Storage error due to misoperation.	Please operate it properly in accordance with User Manual.
	The malfunction of the device.	Contact the local service center.
The device can not be turned on.	Low battery or the power is used up.	Please charge the battery.
	The device is damaged.	Contact the local service center.
The display disappears suddenly.	The device will shut down automatically when there is no operation within 2 minutes.	Normal.
	Low battery.	Please charge the battery.
The use time is too short after fully charged.	The battery was not fully charged.	Please charge the battery.
	The battery is damaged.	Contact the local service center.
The battery can not be fully charged after charging for 10 hours.	The battery is damaged.	Contact the local service center.
	The data cable is damaged.	Contact the local service center.

Chapter 9 Symbols Interpretation

Symbol	Meaning	Symbol	Meaning
	Type BF applied part		Keep dry
	Attention! Please refer to the accompanying documents	SN	Serial number
	Atmospheric pressure limitation		Manufacturer
	Temperature limitation	IP22	Enclosure protection degree
	Humidity limitation		Do not re-use
	Fragile		This way up
	Data of manufacture		WEEE (2002/96/EC)
LOT	Batch code	REF	Catalogue number

Chapter 10 Parameter introduction

10.1 FVC

Parameter	Description	Unit
FVC	Forced vital capacity (total expiratory volume)	L
FEV0.5	Forced expiratory volume in 0.5 second	L
FEV0.5/FVC	Ratio of FEV0.5 to FVC	%
FEV1	Forced expiratory volume in one second	L
FEV1/FVC	Ratio of FEV1 to FVC	%
FEV1/FIVC	Ratio of FEV1 to FIVC	%
FEV3	Forced expiratory volume in three seconds	L
FEV3/FVC	Ratio of FEV3 to FVC	%
FEV6	Forced expiratory volume in six seconds	L
FEV6/FVC	Ratio of FEV6 to FVC	%
PEF	Peak expiratory flow	L/s
FEF25	Forced expiratory flow at 25 % of FVC	L/s
FEF50	Forced expiratory flow at 50 % of FVC	L/s
FEF75	Forced expiratory flow at 75% of FVC	L/s
FEF2575	Average expiratory flow between 25 % and 75 % of the FVC	L/s
FET	Forced expiratory time to reach 100 % of FVC	s
EVOL	Extrapolation volume	ml
ELA	Estimated lung age	Year
FIVC	Forced inspiratory vital capacity	L
FIVC/FVC	Ratio of FIVC to FVC	L/s
FIV1	Forced inspiratory volume in one second	L
FIV1/FIVC	Ratio of FIV1 to FIVC	%
PIF	Peak inspiratory flow	L/s
FIF25	Forced inspiratory flow at 25 % of FVC	L/s
FIF50	Forced inspiratory flow at 50 % of FVC	L/s
FIF75	Forced inspiratory flow at 75 % of FVC	L/s
FIF2575	Average inspiratory flow between 25 % and 75 % of the FVC	L/s
MVV(cal)	Maximal voluntary ventilation (by calculation)	L/min
FEV1/VC	Ratio of FEV1 to VC	%
FEV1/FEV6	Ratio of FEV1 to FEV6	%
FIV1/FVC	Ratio of FIV1 to FVC	%
FEV3/VC	Ratio of FEV3 to VC	%
FIV0.5	Forced inspiratory volume in 0.5 second	L
FIV0.5/FIVC	Ratio of FIV0.5 to FIVC	%
FIV3	Forced inspiratory volume in three seconds	L
FIV3/FIVC	Ratio of FIV3 to FIVC	%
FIV6	Forced inspiratory volume in six seconds	L
FIV6/FIVC	Ratio of FIV6 to FIVC	%
FEV0.55	Forced expiratory volume in 0.55 second	L
FEV0.6	Forced expiratory volume in 0.6 second	L
FEV0.65	Forced expiratory volume in 0.65 second	L
FEV0.7	Forced expiratory volume in 0.7 second	L
FEV0.75	Forced expiratory volume in 0.75 second	L
FEV0.8	Forced expiratory volume in 0.8 second	L
FEV0.85	Forced expiratory volume in 0.85 second	L
FEV0.9	Forced expiratory volume in 0.9 second	L
FEV0.95	Forced expiratory volume in 0.95 second	L
FEV2	Forced expiratory volume in two seconds	L
FEV4	Forced expiratory volume in four seconds	L
FEV5	Forced expiratory volume in five seconds	L
FVC+FEV1	Sum of FVC and FEV1	L
FVC best	FVC best value	L
FEV1 best	FEV1 best value	L
FEV0.55/FVC	Ratio of FEV0.55 to FVC	%
FEV0.6/FVC	Ratio of FEV0.6 to FVC	%
FEV0.65/FVC	Ratio of FEV0.65 to FVC	%
FEV0.7/FVC	Ratio of FEV0.7 to FVC	%
FEV0.75/FVC	Ratio of FEV0.75 to FVC	%
FEV0.8/FVC	Ratio of FEV0.8 to FVC	%
FEV0.85/FVC	Ratio of FEV0.85 to FVC	%
FEV0.9/FVC	Ratio of FEV0.9 to FVC	%
FEV0.95/FVC	Ratio of FEV0.95 to FVC	%
FEV0.5/FEV6	Ratio of FEV0.5 to FEV6	%
FEV0.55/FEV6	Ratio of FEV0.55 to FEV6	%
FEV0.6/FEV6	Ratio of FEV0.6 to FEV6	%
FEV0.65/FEV6	Ratio of FEV0.65 to FEV6	%
FEV0.7/FEV6	Ratio of FEV0.7 to FEV6	%
FEV0.75/FEV6	Ratio of FEV0.75 to FEV6	%
FEV0.8/FEV6	Ratio of FEV0.8 to FEV6	%
FEV0.85/FEV6	Ratio of FEV0.85 to FEV6	%
FEV0.9/FEV6	Ratio of FEV0.9 to FEV6	%
FEV0.95/FEV6	Ratio of FEV0.95 to FEV6	%
FEV3/FEV6	Ratio of FEV3 to FEV6	%
FEV1/VC pred	Ratio of FEV1 to VC_{pred}	%
MEF	Mean expiratory flow	L/s
PEF Time	Time to reach PEF	ms
PEFR	Peak expiratory flow rate	%
PEF best	PEF best value	L
MET2575	Time from 25 % to 75 % of FVC	s
FEF0.2~1.2	Average expiratory flow from 0.2 L to 1.2 L	L/s
FEF10	Forced expiratory flow at 10 % of FVC	L/s
FEF85	Forced expiratory flow at 85 % of FVC	L/s
FEF90	Forced expiratory flow at 90 % of FVC	L/s
FEF7585	Average expiratory flow between 75 % and 85 % of FVC	L/s
FEF25/FEF10	Ratio of FEF25 to FEF10	%
FEF50/FEF25	Ratio of FEF50 to FEF25	%
FEF50/FEF75	Ratio of FEF50 to FEF75	%
FVC/Ht	Ratio of FVC to height	L/m
FEV1/Ht	Ratio of FEV1 best to height	L/m
PEF/Ht	Ratio of PEF best to height	L/s/m
FEF10/Ht	Ratio of FEF10 best to height	L/s/m
FEF25/Ht	Ratio of FEF25 best to height	L/s/m
FEF50/Ht	Ratio of FEF50 best to height	L/s/m
MIF	Mean inspiratory flow	L/s
FIF2550	Average inspiratory flow between 25 % and 50 % of the FVC	L/s
FIF50/FEF50	Ratio of FIF50 to FEF50	%
EVOL/FVC	Ratio of EVOL to FVC	%
OI	Occlusion index	/
ATI	Airway collapse index	%
CVI	Check valve index	/
MTC7550	Slope between 75 % and 50 % on the FV curve	
MTC5025	Slope between 50 % and 25 % on the FV curve	

Note:The starting time of time-related parameters in this part is time zero.Time zero is found by drawing a line with a slope equal to peak flow through the point of peak flow on the volume–time curve and setting Time zero to the point where this line intersects the time axis.

10.2 VC

Parameter	Description	Unit
VC MAX	Vital capacity	L
IC	Inspiratory volume	L
ERV	Expiratory reserve volume	L
IRV	Inspiratory reserve volume	L
EVC	Expiratory vital capacity	L
IVC	Inspiratory vital capacity	L
TV	Tidal volume	L
VE	Minute ventilation	L/min
RR(vc)	Respiratory rate	times/min
tI	Tidal inspiratory time	s
tE	Tidal expiratory time	s
ttot	Total respiratory time	s
tI/tE	Ratio of tI to tE	%
TV/tI	Ratio of TV to tI	L/s
tI/ttot	Ratio of tI to ttot	%
tE/ttot	Ratio of tE to ttot	%
TLC	Total lung capacity (enter RV manually)	L
FRC	Function residual capacity (enter RV manually)	L
RV/TLC	Ratio of RV to TLC	%
VC/Ht	Ratio of VC to height	L/m
60%VC	60 % of VC	L

10.3 MVV

Parameter	Description	Unit
MVV	Maximal voluntary ventilation	L/min
RR(MVV)	Respiratory rate of MVV	times/min
TV(MVV)	Tidal volume of MVV	L
BSA	Body surface area	
MVV/BSA	Ratio of MVV to BSA	%
MVVT	Measurement time for MVV	s
AVI	Ratio of MVV to VC	/
MVV43	MVV calculation value (43 times)	L/min
MVV/(FEV1*40)	Ratio of MVV to FEV1*40	%
tI(MVV)	Inspiratory time of MVV	s
tE(MVV)	Expiratory time of MVV	s
ttot(MVV)	Total respiratory time of MVV	s

10.4 MV

Parameter	Description	Unit
MV	Minute ventilation	L/min
RR(MV)	Respiratory rate of MV	times/min
BR	Breath reserve	L/min

VR	Breath reserve ratio	%
TV(MV)	Tidal volume of MV	L
tI(MV)	Inspiratory time of MV	s
tE(MV)	Expiratory time of MV	s
ttot(MV)	Total respiratory time of MV	s

10.5 Initial recommended class and common reasons

a. Normal lung volume test

b. Restrictive abnormalities

Lung cavity becomes smaller - after be surgically removed, interstitial fibrosis, tumor, silicosis, etc.

Thorax activities restricted - pleural effusion, thickening, adhesion, thoracic deformity, etc.

Thoracic compression - ascites, pregnancy, obesity, etc.;

Respiratory muscle weakness - diaphragm fatigue, muscle weakness, muscle atrophy, malnutrition.

c. Obstructive abnormalities

Chronic obstructive pulmonary disease, such as asthma, emphysema, etc.;

Upper respiratory tract tumor, foreign body, inflammation, tracheal or bronchial tumor, stenosis, etc.

d. Class of pulmonary dysfunction

Minor moderate medium serious serious critical

Appendix I

1. Instructions for use

The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments

Warning: Don't 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.

Warning: Use of this equipment 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.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

2. Instructions for use

all necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life.

Guidance and manufacturer's declaration -electromagnetic emissions and Immunity.

FCC Caution:

Part 15.21

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

Part 15.19

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.

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.

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

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

—Reorient or relocate the receiving antenna.

—Increase the separation between the equipment and receiver.

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

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

Table 1

Guidance and manufacturer's declaration – electromagnetic emission	
Emission test	**Compliance**
RF emissions CISPR 11	Group 1
RF emission CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Comply

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity		
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**
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
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV for power supply lines Not applicable 100 kHz repetition frequency
Surge IEC 61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5 kV, ±1 kV differential mode Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines	0 % UT; 0,5 cycle. At 0 °, 45 °, 90 °, 135 °, 180 °, 225 °, 270 °and 315 ° 0 % UT; 1 cycle and 70 % UT; 25/30	0 % UT; 0,5 cycle. At 0 °, 45 °, 90 °, 135 °, 180 °, 225 °, 270 °and 315 ° 0 % UT; 1 cycle and 70 % UT; 25/30
IEC 61000-4-11	cycles; Single phase: at 0 °. 0 % UT; 250/300 cycle	cycles; Single phase: at 0 °. 0 % UT; 250/300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
NOTE U_T is the a.c. mians voltage prior to application of the test level.		

Table 3

Guidance and manufacturer's declaration – electromagnetic immunity						
	Test Frequency (MHz)	Band (MHz)	Service	Modulation	IEC 60601-1-2 Test Level (V/m)	Compliance level (V/m)
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	385	380 –390	TETRA 400	Pulse modulation 18 Hz	27	27
	450	430 –470	GMRS 460, FRS 460	FM ±5kHz deviation 1 kHz sine	28	28
	710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	9	9
	810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28	28
	1720 1845 1970	1700 –1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28	28
	2450	2400 –2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28	28
	5240 5500 5785	5100 –5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9	9

Table 4

Guidance and manufacturer's declaration - electromagnetic Immunity				
Radiated RF IEC61000-4-39 (Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields)	Test Frequency	Modulation	IEC 60601-1-2 Test Level (A/m)	Compliance level (A/m)
	30 kHz	CW	8	8
	134,2 kHz	Pulse modulation 2.1 kHz	65	65
	13,56 kHz	Pulse modulation 50 kHz	7,5	7,5

Attention: With the exception of energy exchange and cables sold by manufacturers of lung function devices as spare parts for internal components, the use of accessories and cables other than those specified will result in increased product emission or reduced anti-interference.

The following cable types must be used to ensure compliance with interference radiation and immunity standards.

Table:Cable overview

Number	Model	Cable length (m)	Mask or no	Remark
1	Power adapter cable	1.50	YES	/