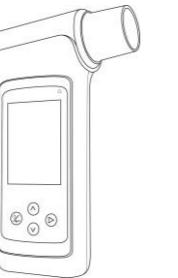


CONTEC Spirometer / SP90

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CMS2.782.563ESS/1.0 1.4.01.12.158 2021.10



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.

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.

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 it is carried from cold or dry environment to warm or humid environment, please do not use it immediately.
- ❖ 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°C.
- ❖ 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.

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 °C ~ +45 °C
- b. Relative humidity: ≤ 95 %
- c. Atmospheric pressure: 500 hPa ~ 1060 hPa

Operating environment

- a. Temperature: +10 °C ~ +40 °C
- 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.

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.

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

Chapter 5 Installation

5.1 Brief introduction

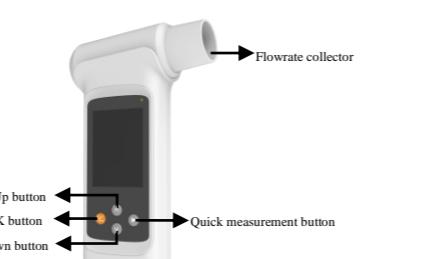


Figure 5-1

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

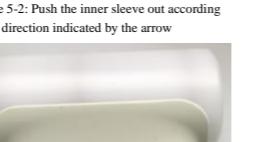


Figure 5-4: Outer sleeve of the main unit

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. A power adapter (optional)
- f. 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

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

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.

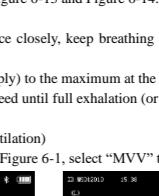


Figure 6-13

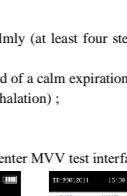


Figure 6-14

Test procedure

- 1) Seal the lips around the mouthpiece closely, keep breathing calmly (at least 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.

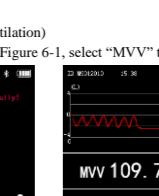


Figure 6-15

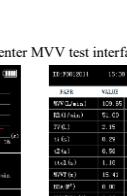


Figure 6-16

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.

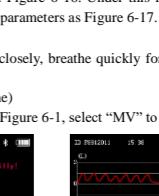


Figure 6-17

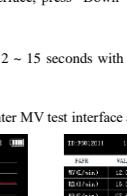


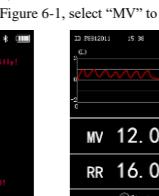
Figure 6-18

Test procedure

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

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.



6.1.2.7 Setting

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

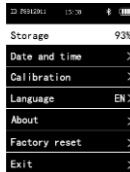


Figure 6-24

- Storage: in Figure 6-24, the first item represents the current remaining storage space;
- 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

- 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", 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

- 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.
- 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.
- 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.

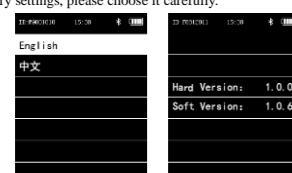


Figure 6-31



Figure 6-32

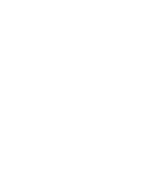


Figure 6-33

- 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.

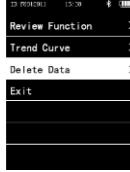


Figure 6-34

- 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.
- 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.
- 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.
- Exit: select "Exit", press "ON/OFF/OK" button to return to the main interface as Figure 6-1.

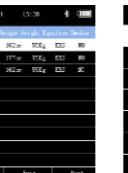


Figure 6-35



Figure 6-36



Figure 6-37

Figure 6-38

Figure 6-39

The display disappears suddenly.	The device will shut down automatically when there is no operation within 2 minutes.	Normal.
The use time is too short after fully charged.	Please charge the battery.	
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.	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		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)
	Batch code		Catalogue number

参数介绍

10.1 FVC 参数

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
FIP25	Forced inspiratory flow at 25% of FVC	L/s
FIP50	Forced inspiratory flow at 50% of FVC	L/s
FIP75	Forced inspiratory flow at 75% of FVC	L/s
FIP2575	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	%

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	Minut 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	%
TLC	Total lung capacity (enter RV manually)	L
FRC	Function residual capacity (enter RV manually)	L
RV/TLC	Ratio of RV to TLC	