



SPIROMETER SMP 21/01 RD

User Manual

2022

2. APPLICATION INFORMATION

2.1. Spirometer is a stand-alone pulmonary function testing device intended to use by trained professionals in the different medical institutions.

2.2. Spirometer can provide test results interpretation (if the user enables this feature). These interpretations are for the exclusive use of licensed physicians. The interpretation and the numerical and graphical results should be examined with respect to the patient's overall clinical condition. Final analysis should always be determined by a physician.

2.3. Spirometer can be used at temperature ranges 10 - 35°C, relative humidity 80% at 25°C and lower (non-condensing), atmospheric pressure 84 - 106.7kPa (630 - 800mmHg).

3. GENERAL TECHNICAL CHARACTERISTICS

3.1. Air flow speed measurement range:

- **Inspiration:** from 0 to 1,5 l/sec, with accuracy $\pm 0,05$ l/sec; from 1,5 to 10,0 l/sec, with accuracy ± 3 %;
- **Expiration:** from 0 to 1,5 l/sec, with accuracy $\pm 0,05$ l/sec; from 1,5 to 16,0 l/sec, with accuracy ± 3 %.

3.2. Inhaled and exhaled **air volume measurement** range is from **0 to 10 liters** with **accuracy ± 3 %** or 0,05 l (whatever is bigger).

3.3. Spirometer displays on the screen and prints out on the internal thermal printer or an external printer (optional), the following parameters of lung ventilation:

No	Parameter (unit)	Description
Parameters measured in Vital Capacity (VC) test		
1	VC (l)	Vital Capacity
2	IRV (l)	Inspiratory reserve volume - is the amount of air that can be inspired after a tidal inspiration
3	ERV (l)	Expiratory Reserve Volume (ERV) is the amount of air that can be expired after a tidal expiration
4	IC (l)	Inspiratory Capacity



№	Parameter (unit)	Description
Parameters measured in Forced Vital Capacity (FVC) test		
5	FVC (l)	Forced Expiratory Vital Capacity is maximum volume that can be forcefully expired after maximum inspiration
6	FET (sec)	Forced Expiratory Time
7	PEF (l/sec)	Peak Expiratory Flow is the maximal flow achieved during the maximally forced expiration
8	TPEF (sec)	Time to Peak Expiratory Flow from start of expiration
9	FEV0.5 (l)	Forced Expiratory Volume during the first 0.5 second
10	FEV0.75 (l)	Forced Expiratory Volume during the first 0.75 second
11	FEV1 (l)	Forced Expiratory Volume during the first second
12	FEV3 (l)	Forced Expiratory Volume during the first 3 second
13	FEV6 (l)	Forced Expiratory Volume during the first 6 second
14	FEV _{tpef} (l)	Forced Expiratory Volume before peak expiratory flow reached
15	FEF25 (l/sec)	Forced Expiratory Flow at 25% FVC
16	FEF50 (l/sec)	Forced Expiratory Flow at 50% FVC
17	FEF75 (l/sec)	Forced Expiratory Flow at 75% FVC
18	FEF25-75 (l/sec)	Mean Forced Expiratory Flow at 25-75% FVC
19	FEF0.2-1.2 (l/sec)	Mean Forced Expiratory Flow from 0.2 to 1.2 liters
20	FEF75-85 (l/sec)	Mean Forced Expiratory Flow at 75-85% FVC
21	FMFT25-75 (sec)	Forced Mid-expiratory Flow Time: time between the 25% and 75% points of the FVC
22	A _{ex}	Area under Expiratory flow-volume curve
23	V _{ext} (l)	Extrapolated forced expiratory volume: expiratory volume exhaled before point of force expiration beginning. The back extrapolation method used to determinate this point.
24	FEV1 / FVC (%)	The FEV1 expressed as a percentage of the FVC
25	FEV _{tpef} / FVC (%)	The FEV1 expressed as a percentage of the FVC
Parameters measured in VC + FVC tests		
If VC and FVC tests performed sequentially in one test session, spirometer calculates all parameters for VC and FVC tests listed above, and additionally calculates one parameter:		
26	FEV1 / VC (%)	Tiffeneau index



No	Parameter (unit)	Description
Parameters measured in "Flow - volume loop" test		
In "Flow - volume loop" test spirometer calculates all the parameters by VC, FVC and VC + FVC tests, listed above (except IC, ERV and IRV) and additionally calculates the following parameters:		
27	FIVC (l)	Forced Inspiratory Volume
28	FIV1 (l)	Forced Inspiratory Volume during the first second
29	PIF (l/sec)	Peak Inspiratory Flow is the maximal flow achieved during the maximally forced inspiration
30	FIF25 (l/sec)	Forced Inspiratory Flow at 25% FIVC
31	FIF50 (l/sec)	Forced Inspiratory Flow at 50% FIVC
32	FIF75 (l/sec)	Forced Inspiratory Flow at 75% FIVC
Parameters measured in Minute Tidal Volume (MTV) test		
33	VE(l/min)	Volume Expired in 1 minute = TV × BF
34	BF (1/min)	Breath Frequency (1 minute averaged)
35	TV (l)	Tidal Volume: averaged volume inhaled and exhaled at one breath cycle during MTV test
36	te (sec)	Averaged expiratory time during MTV test
37	ti (sec)	Averaged inspiratory time during MTV test
38	VEd (l)	VE deviation of the predicted value
39	VEi	VE index
Parameters measured in Maximal Voluntary Ventilation (MVV) test		
40	TVmvv (l)	Tidal Volume: averaged volume inhaled and exhaled at one breath cycle during MVV test
41	BFmvv (1/min)	Breath frequency during MVV test
42	MVV (l/min)	Maximal Voluntary Ventilation = TVmvv × BFmvv

3.4. Spirometer provides following breathing graphs: "flow-volume" for FVC and FLOW-VOLUME LOOP tests, "volume-time" for VC, FVC, MVV and MTV tests.

3.5. Spirometer has POST-DRUG TEST mode, which is intended for analyze the effect of drugs on the patient forced expiratory parameters and provides the possibility to compare this test results with the base test performed before taking the drugs.



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Firmware version: CPU:01.10 APU:01.03 or later

Rev. 3.4.

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3.6. Spirometer provides correction of the measured and calculated volume and flow parameters to standard gas conditions (BTPS).

3.7. Spirometer allows choosing the standard of predicted values: Clement / Shiryayeva, Knudson, ECCS-93, ITS (Crapo, Hsu etc.)

3.8. Spirometer can provide test results interpretation and allows choosing the interpretation standard: Russia, ATS or disable interpretation.

3.9. The performance characteristics of spirometer meet the requirements of BS EN ISO 23747:2009 and BS EN ISO 26782:2009 standards.

3.10. Spirometer flow sensor based on Fleisch tube. Flow sensor resistance is not more than 150 Pa/l/sec in the **flow rate** range from **0 to 16 l/sec.**

3.11. Spirometer has a possibility of calibration with **3 liters syringe.**

3.12. The display of the spirometer has the following parameters:

Type:	TFT color display with LED backlight
Screen size:	116 x 88mm, diagonal size 5.6 inches (142mm)
Resolution:	640×480 dots
Brightness control:	5 gradations

3.13. Spirometer can print test results on the internal thermal printer, as well as on the external laser printer supporting PCL5 (or higher) via USB interface (optional).

3.14. Internal thermal printer has the following parameters:

Printing method:	high resolution thermal print
Printer resolution:	8 dots/mm
Thermal paper width:	110mm
Type of thermal paper:	roll paper: width 110mm, length ≤ 30m, inside diameter 12mm, winding: temperature-sensitive layer outside. Z-fold paper: width 110mm, page length 100mm, 200 pages in pack.
Printing width:	104mm
Printing speed:	50 mm/sec
Printout formats:	Graphs printing for each test may be enabled or disabled in the settings menu.
Printed data:	Tests results, predicted values, preliminary conclusion, date and time, patient's data, name of hospital (institution), doctor's name
Acoustic noise level during printing:	no more than 58dB



3.15. Spirometer has a combined alphanumeric keyboard to enter patient data. Also for the patient data entry a standard external keyboard can be connected to the spirometer via USB interface (optional).

3.16. Spirometer has built-in non-volatile **memory** to store up to **10000 patient records** (depending on the amount of tests in patient's records).

3.17. Spirometer has a sound signal of the maneuver start and the sound confirming keyboard pressing. The sound level is adjustable from 0 to 10.

3.18. Spirometer has **USB interface** (optional) for connection to a computer.

3.19. Power supply: AC, DC and **built-in batteries**.

AC main voltage	from 100 up to 240V
Mains frequency	50 or 60Hz
DC mains voltage	from 12 up to 16V (on-board power system of ambulance car)
Power consumption	AC mains operation: when printing: ≤ 30 VA without printing: ≤ 15 VA DC mains operation: when printing: ≤ 30 VA without printing: ≤ 9 VA
Internal battery	Li-Ion, 7.4V, 2Ah
Operating from battery time	about 4 hours with new, full charged battery
Battery charging time	6-7 hours, if battery was fully discharged

Spirometer can operate during battery charging.

Spirometer can operate from AC mains power upon battery lack (or its fault).

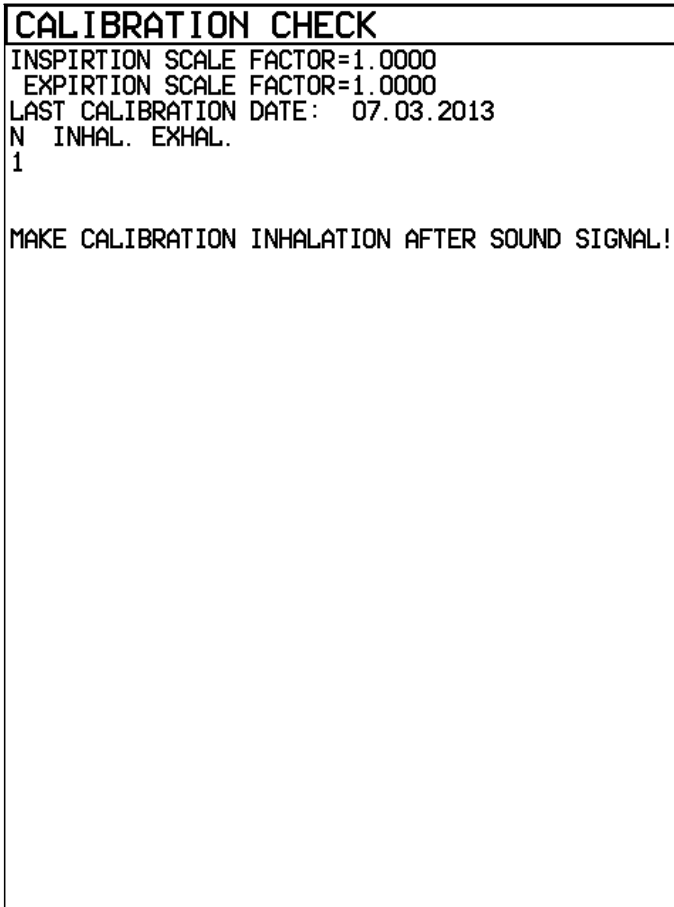
3.20. Spirometer meets safety standard IEC 60601-1 requirements, class II, internally powered product, type BF.

3.21. Warm-up time is not more than 1 minute after switching on.

3.22. Weight of the spirometer with an internal battery, no more than 1.5 kg (without a syringe).

3.23. Dimensions of the spirometer main unit 250 × 174 × 63 mm.





Make inspiration by pulling out the syringe handle to the end. The inspiration should be performed smoothly without jerks within 1-2 seconds time. Calibration result will appear on display and the message "MAKE A CALIBRATED INHALATION AFTER A SOUND SIGNAL!" will change into "MAKE A CALIBRATED EXHALATION AFTER A SOUND SIGNAL!"

Make expiration by pulling in the syringe handle to the end. The expiration should also be performed smoothly without jerks within 1-2 seconds time. Calibration result will appear on display and spirometer will offer to make a calibrated inspiration again.

Note: Don't pay attention to values of calibrated inspiration and expiration, which are shown by spirometer. These values used only to calculate the scale factors.

Calibration procedure consists of 3 consecutive inspirations and expirations. As a result of calibration spirometer defines the scale factors for expiration and inspiration procedures. If results of 3 attempts differ for more than 0.1 liter, the following message will appear on display:

TOO BIG ERROR! CALIBRATION ABORTED!
PRESS A KNOB FOR RETRY . . .

In this case press the control knob and repeat the calibration. After a successful calibration (the message CALIBRATION CHECK PASSED SUCCESSFULLY!) press the control knob to finish the calibration and to go to the main menu.

5.3.7. Connection to computer

Spirometer is capable to operating with a computer. When you select in main menu item CONNECTION TO PC the message PC MODE RUNNING . . . appears on the spirometer screen. To work with the spirometer in this mode you should use a PC computer with special software (optional).

To exit this mode, press EXIT button and spirometer will return to the main menu.



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