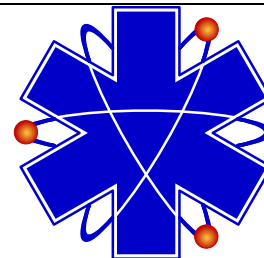




Company EKKOM



**Laboratory of biomedical electronics
Kharkiv**

DIGITAL SPIROMETER DSP-14\1



Made in Ukraine

1. DESCRIPTION OF THE SPIROMETER DSP-14/1

Spirometer is an electronic device designed to study of external respiration function (ERF) of patient. Spirometer can be applied in medical institutions at all levels, as well as on the patient's home for studies of pulmonary ventilation function.

1.1 Technical data

1.1.1 As the sensor in a Spirometer is used reusable turbine for prolonged use or disposable turbine for single patient use company MIR (Medical International Research), Rome, Italy.

1.1.2 As the batteries are used in a spirometer two galvanic cells AAA type with voltage 1.4-1.6 V.

1.1.3 Technical data of the Spirometer are given in table. 1.

Table 1

| № | Technical data | Value |
|---|--|--------|
| 1 | The range of flow rate measurement, l/s | 0-14 |
| 2 | Measurement error of the flow rate, not more than% | 5 |
| 3 | The measuring range of air volume, l | 0-9,99 |
| 4 | Measurement error of the volume, not more than% | 5 |

1.2 Composition of the spirometer

1.2.1 Spirometer DSP - 14/1 supplied in completeness specified in Table 2.

Table 2

| № | Product name, component , documentation | Quantity |
|---|---|----------|
| 1 | Spirometer DSP - 14/1 | 1 |
| 2 | Battery (AAA type) | 2 |
| 3 | Disposable turbine | 2 |
| 4 | The plastic clip for a nose | 1 |
| 5 | Disposable mouthpiece | 3 |

1.3 The design of of the spirometer and controls

Structurally Spirometer designed in a rectangular plastic case with dimensions 185x60x27 mm. The right side of of the spirometer is situated a bushing for installation of the removable turbine. Exterior view of the spirometer illustrated in Figure 1:

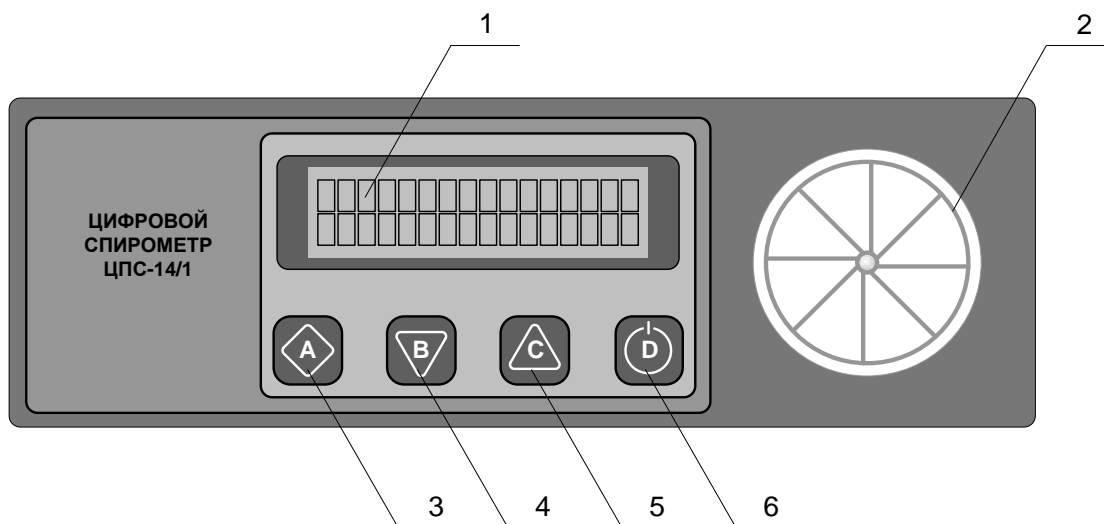






Figure 1 – View of the digital portable spirometer DSP - 14/1

- 1 – LCD indicator for showing current information about the process of testing;
- 2 – removable turbine;
- 3 – button , the default function "Exit";
- 4 – button , the default function "Down the menu";
- 5 – button , the default function "Up of the menu";
- 6 – button , the function of the default "Enter" (also by pressing and two-second hold – ON / OFF the Spirometer).

Batteries are located in the compartment, the lid is located on the bottom side of the spirometer.

2. DIAGNOSTICS OF THE EXTERNAL RESPIRATION FUNCTION (ERF)

2.1 The spirometer provides a definition of the following indicators of ERF:

- *FVC* – forced vital capacity - volume the full forced expiratory (*l*);
- *FEV1* – forced expiratory volume (*l*) in the first second;
- *FEV1 / FVC* – the index of Gensler (%);
- *PEF* – the peak value of the volumetric expiratory flow rate (*l/s*);
- *FEF25* – the instantaneous value of volumetric rate (*l/s*) during exhalation of 25 % *FVC*;
- *FEF50* – the instantaneous value of volumetric rate (*l/s*) during exhalation of 50 % *FVC*;
- *FEF75* – the instantaneous value of volumetric rate (*l/s*) during exhalation of 75 % *FVC*;
- *MEF25-75* – value of average volumetric rate (*l/s*) during exhalation from 25 to 75 % of *FVC*.

ERF parameters can be determined by analyzing the curves $Q(t)$ and $V(t)$ (Figure 2).

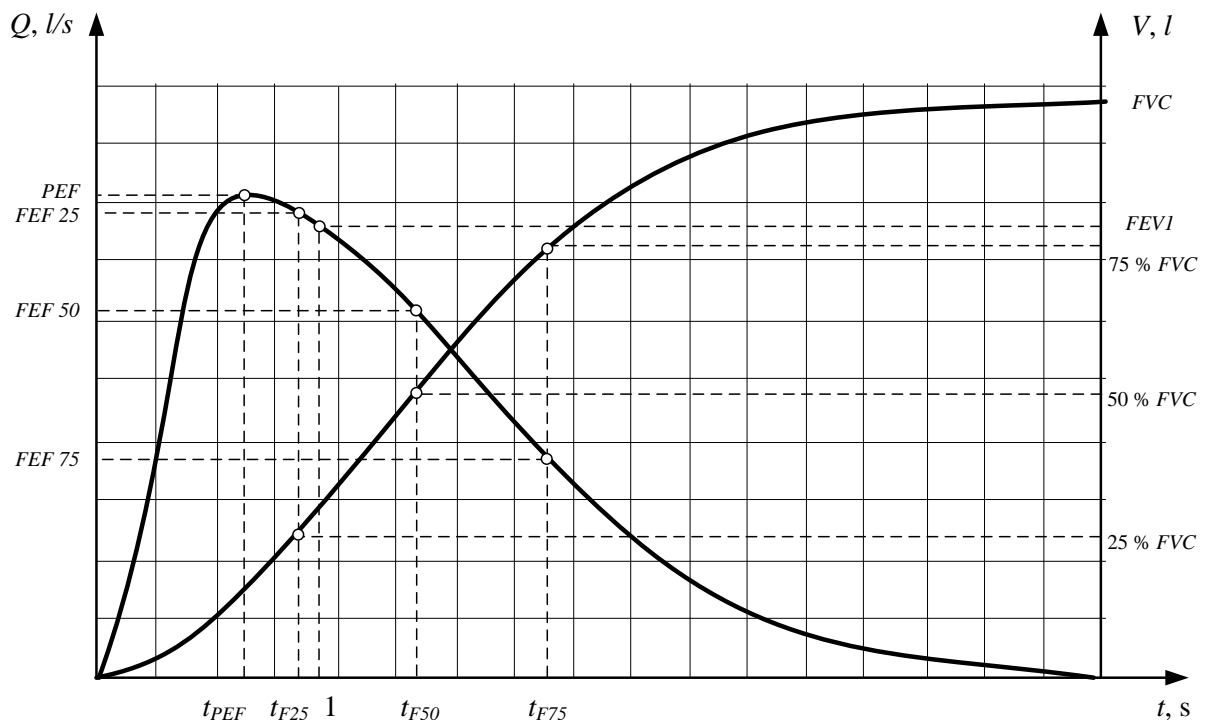


Figure 2 – The definition of basic indicators of ERF parameters

2.2 The spirometer provides AUTOMATIC comparison of the measured indicators shall, in accordance with statistical data (*Clement R.F*) in percentage ratio.

2.3 The spirometer provides storage for 20 test results in memory.

3. STUDY OF EXTERNAL RESPIRATION FUNCTION BY SPIROMETER

3.1 Preparing the Spirometer to work

3.1.1 Before working with the Spirometer must check the completeness of the Spirometer and verify the absence of mechanical damages of the case.

3.1.2 Before using spirometer should be not less than 24 hours in a dedicated operating indoors.

3.1.3 Before use, you must connect batteries to Spirometer according to the markings inside the compartment. If it necessary, replace the batteries.

3.1.4 Set a disposable turbine in bushing of the spirometer. What follows is install a disposable mouthpiece to turbine sensor. (Figure 3). Necessary to ensure leakproofness joining of the mouthpiece.

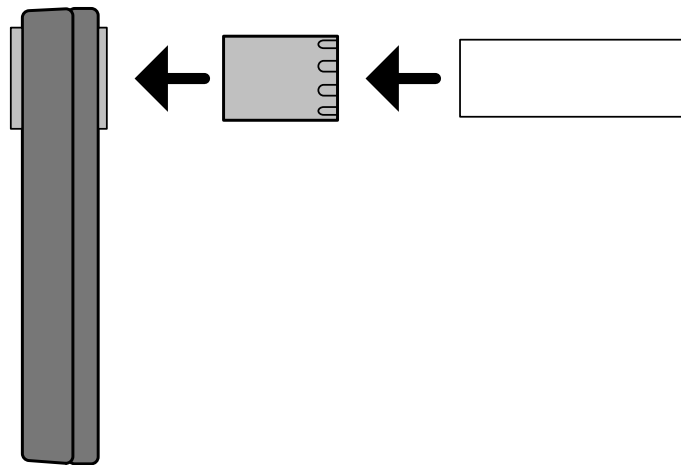


Figure 3 – Connection of measuring turbine and mouthpiece

3.1.5 Testing procedure carried out in accordance with the following technique.

3.1.6 Upon completion the research the turbine and the mouthpiece must be disposed of, and a nose clip – sterilized.

3.2 Technique of study conducting

3.2.1 Study ERF usually performed in a sitting position. During the execution of respiratory maneuvers patient should sit upright, not leaning back in his chair. Moving torso forward can lead to compression of the trachea. Young patient can be performed the test while standing.

3.2.2 Study of pulmonary ventilation should be performed in a relaxed and comfortable setting. The patient should rest for at least 10 min before the test.

3.2.3 Always necessary use a nasal clip.

3.2.4 Before the start of research necessary to fix the registration data of the patient, age, sex, height.

3.2.5 The patient should be tightly embrace the mouthpiece with his lips so that your teeth and tongue not impede the free flow of air (Figure 4).

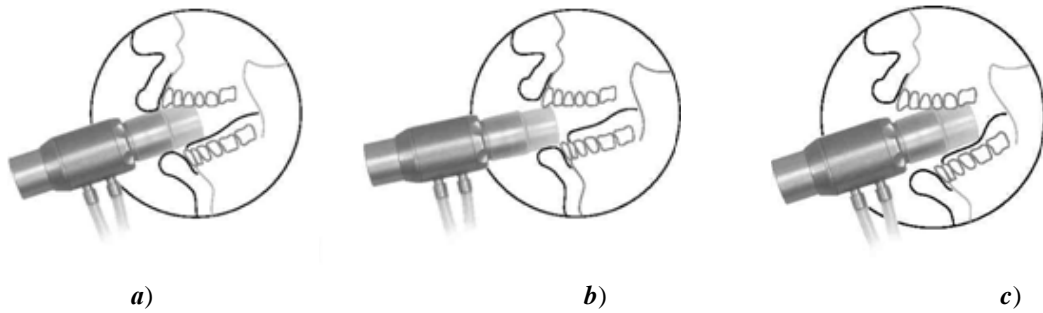


Figure. 4 – Correct and incorrect position of mouthpiece:

a - correct position of mouthpiece: it tightly gripped with lips, tongue and teeth do not prevent air movement; **b** - mouthpiece not deeply introduced into the mouth, teeth and tongue partly overlap its lumen; **c** - mouthpiece put too deep presses on the root of the tongue, the probable development of coughing or vomiting.

3.2.6 Between the tests necessary to take breaks at least 1-2 minutes.

3.2.7 Foreign objects and the patient's hand should not prevent the passage of air through the sensor in the process of the study.

3.3 Operating procedure with spirometer.

3.3.1 Turn ON/OFF the device.

- Press and hold for at least 2 seconds button **(D)**;
- After switching on the display shows the message

| | | | | | | | | | | | | | | | | | | | |
|--|--|----------|----------|----------|----------|----------|----------|----------|----------|--|--|--|--|--|--|--|--|--|--|
| | | E | K | K | O | M | | | | | | | | | | | | | |
| | | D | S | P | - | 1 | 4 | / | 1 | | | | | | | | | | |

- After 2 seconds the device is ready for operation;
- The display shows the mode selection page

| | | | | | | | | | | | | | | | | | | | |
|--|----------|----------|----------|----------|----------|----------|----------|--|--|----------|----------|----------|----------|----------|--|--|--|--|--|
| | T | E | S | T | - | 0 | 1 | | | | | | | | | | | | |
| | S | T | O | R | A | G | E | | | S | T | A | R | T | | | | | |

3.3.2 Performing the spirometric test:

- By pressing the **(B)** **(C)** select the number of the test to record;
- Press button **(D)** and perform study in accordance with paragraph 3.2. Exhale perform after the message appears

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|--|---|---|---|---|---|---|-----|--|--|
| F | O | R | C | E | D | | E | X | H | A | L | E | ... | | |
| | | | | | | | | | | | | | | | |

- After exhalation message will appear with the test results

| | | | | | | | | | | | | | | | |
|--|---|---|---|--|--|---|---|---|---|--|---|---|---|--|--|
| | F | V | C | | | 4 | , | 5 | 6 | | | | | | |
| | R | E | P | | | | | | | | C | F | M | | |

- To repeat the research necessary to press button
- If the test result is corresponds to the doctor expectations must save it (press button).

3.3.3 Processing of stored test:

- After storing the test message will appear

| | | | | | | | | | | | | | | | |
|--|---|---|---|---|--|---|---|---|---|--|--|--|--|--|--|
| | D | A | T | A | | | | | | | | | | | |
| | F | V | C | | | 4 | , | 5 | 6 | | | | | | |

- To listing the parameters necessary to use buttons
- On the screen will be displayed the following parameters

| | | | | | | | | | | | | | | | |
|--|---|---|---|--|--|---|---|---|---|--|--|--|--|--|--|
| | F | V | C | | | 4 | , | 5 | 6 | | | | | | |
| | P | E | F | | | 0 | 9 | , | 5 | | | | | | |

| | | | | | | | | | | | | | | | |
|--|---|---|---|---|--|---|---|---|---|--|--|--|--|--|--|
| | P | E | F | | | 0 | 9 | , | 5 | | | | | | |
| | F | E | V | 1 | | 3 | , | 9 | 8 | | | | | | |

| | | | | | | | | | | | | | | | |
|--|---|---|---|---|--|---|---|---|---|--|--|--|--|--|--|
| | F | E | V | 1 | | 3 | , | 9 | 8 | | | | | | |
| | F | E | F | ¼ | | 0 | 7 | , | 4 | | | | | | |

* - FEF ¼ corresponds FEF25

| | | | | | | | | | | | | | | | |
|--|---|---|---|---|--|---|---|---|---|--|--|--|--|--|--|
| | F | E | F | ¼ | | 0 | 7 | , | 4 | | | | | | |
| | F | E | F | ½ | | 0 | 6 | , | 3 | | | | | | |

* - FEF ½ corresponds FEF50

| | | | | | | | | | | | | | | | |
|--|---|---|---|---|--|---|---|---|---|--|--|--|--|--|--|
| | F | E | F | ½ | | 0 | 6 | , | 3 | | | | | | |
| | F | E | F | ¾ | | 0 | 5 | , | 1 | | | | | | |

* - FEF ¾ corresponds FEF75

| | | | | | | | | | | | | | | | |
|--|---|---|---|---|--|---|---|---|---|--|--|--|--|--|--|
| | F | E | F | ¾ | | 0 | 5 | , | 1 | | | | | | |
| | M | E | F | ¾ | | 0 | 7 | , | 3 | | | | | | |

* - MEF ¾ corresponds MEF25-75

| | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|--|--|
| | M | E | F | ¾ | | 0 | 7 | , | 3 | | | | | | |
| | F | E | V | 1 | / | F | V | C | | 0 | , | 8 | 4 | | |

- For displaying deviations from the norm button must be pressed on the page

| | | | | | | | | | | | | | | | |
|--|---|---|---|---|--|---|---|---|---|--|--|--|--|--|--|
| | D | A | T | A | | | | | | | | | | | |
| | F | V | C | | | 4 | , | 5 | 6 | | | | | | |

- Record data of the patient on a page

| | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|--|--|---|---|---|---|--|--|--|--|
| | H | - | 1 | 5 | 0 | | | S | - | M | | | | | |
| | A | - | 3 | 2 | | | | | C | F | M | | | | |

* H – height, cm; A – age, year; S – sex, male (M) / female (F)


- Data recording is performed by the button . The display shows the deviation from the norm




| | | | | | | | | | | | | | | | |
|--|---|---|---|--|--|---|---|---|---|--|---|---|---|--|--|
| | F | V | C | | | 4 | , | 5 | 6 | | 9 | 8 | % | | |
| | P | E | F | | | 0 | 9 | , | 5 | | 8 | 4 | % | | |

3.3.4 Viewing of recorded test in the archive:



- Press buttons for choosing interesting test on the page

| | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|--|--|---|---|---|---|---|--|
| | T | E | S | T | - | 0 | 1 | | | | | | | | |
| | S | T | O | R | A | G | E | | | S | T | A | R | T | |

- Press button . The display shows the stored parameters





| | | | | | | | | | | | | | |
|---|---|---|---|---|--|---|---|---|---|--|--|---|---|
|  | D | A | T | A | | | | | | | |  | |
|  | F | V | C | | | 4 | , | 5 | 6 | | | | A |

* in archive mode blinks symbol A in the right corner




- For listing the parameters necessary to use buttons  ;

3.3.5 Erasing the archive:

- Go to the page

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|--|---|---|---|---|---|---|
|  | T | E | S | T | - | 0 | 1 | | | | |  | | |
|  | S | T | O | R | A | G | E | |  | S | T | A | R | T |

- Press and hold simultaneously buttons   before the appearance of the page

| | | | | | | | | | | | | | | |
|---|---|---|---|---|--|---|---|---|---|---|---|---|---|--|
| C | L | E | A | R | | S | T | O | R | A | G | E | ? |  |
|  | N | O | | | | | | | |  | Y | E | S | |

- Press the button  to erase the storage test or  to cancel the action

4. OPERATIONAL RESTRICTIONS AND PECULIARITIES

4.1 The Spirometer DSP-14/1 complies with GOST 20790 (Devices, apparatus and medical equipment. General specifications) and DSTU 3798 (Medical electrical products. Part 1: General requirements for safety).

4.2 With the Spirometer should work medical professionals, who passed special training and studying "Description of the Spirometer DSP-14/1".

4.3 According to the degree of protection of patients and of medical staff from electric shock spirometer relates to medical devices of Class III type B.

4.4 The Spirometer should work in following condition:

- temperature – from + 20 ° C to + 30 °C;
- relative humidity – 80% (at 25 ° C);
- atmospheric pressure – from 570 to 760 mm Hg.