# LUNGTEST *Mobile*

## User Manual


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Congratulations!

We congratulate you on your choice of the Lungtest *Mobile* spirometer. We hope that it will meet your expectations as a high-quality device characterised by the highest standard of workmanship and attention to details. The apparatus is the result of efforts of a team of people for whom the testing of respiratory system functions, in addition to its scientific aspects, is an excellent opportunity to develop designs of equipment that extends measurement possibilities. MES has manufactured and sold spirometers for more than 20 years. Now, we are proud to deliver our newest product: Lungtest *Mobile*.

Definitions of signs used:

Alerts the user against possible danger resulting from the characteristics of the product and its intended purpose.

Informs about important aspects and features of the product resulting from its characteristics and intended purpose.

# 1 General information

## *1.1* System specification

Lungtest Mobile is a small, portable diagnostic spirometer. The use of the spirometer is made comfortable by its large, colour, LCD touch display characterised by a high resolution and a wide viewing angle. The integrated fast thermal printer enables the user to immediately print the test results. The integrated precise measuring module and specialised computer guarantee the correct conduct of tests and a reliable result processing. The tests are performed with the use of patented removable pneumotachographic units that protect the patients against infection.

Lungtest Mobile is simple in use and easy in operation. Resting spirometry tests and the determination of the Flow-Volume curve are facilitated by the high accuracy of measurements and advanced software solutions. The algorithm applied in the spirometer for full control of test correctness and quality, conforming to the ATS/ERS 2005 standard, ensures an accurate interpretation of test results based on specialised diagnostic system.

Major advantages and features of the Lungtest Mobile spirometer:

- a removable pneumotachographic unit without antibacterial filter, fully protecting the patient against infection during tests
- automated control of test correctness conforming to the ATS/ERS 2005 standard, with additional comments
- automated classification of test performance quality according to an AF scale
- automated assessment of bronchial obstruction reversibility test, compliant with the recommendations of the ERS
- the option to switch on an automated diagnostic system
- the option to display resting spirometry and the volume curve
- the comparison of test results with predicted normal values
- the option to prepare a graphic and numeric comparison of results for a maximum of 30 recorded tests
- a colour, high resolution touch screen
- operated with fingers using a screen interface with large icons
- very fast and quiet thermal printer
- the option to connect an external printer
- immediate access to a database with test results for 1000 patients
- calculations of standard deviations and percentiles of normal values
- the option to export test results and curves to external software
- the option to control spirometer calibration using a syringe with a capacity of 3l
- ergonomic handle of the pneumotachographic unit
- low weight
- two USB ports

**Statement of technical parameters**

- Measured flow range: +/- 18 l/s
- Accuracy of flow measurement < 2 %.
- Resolution of flow measurement +/- 10 ml/s
- Resistance of the measuring unit 0.9 cmH2O/l/s at a flow of 12l/s
- Power supply 110-240V, 50-60Hz
- Power consumption 30VA
- Dimensions 223 x 261 x 54 [mm].
- Weight 1.2 kg
- Device class II A

## *1.2* Structure of the Lungtest Mobile spirometer

The Lungtest spirometer consists of 3 basic modules, cf. Fig 1 Modules of the Lungtest Mobile spirometer

1. The connection and pneumotachographic head module
2. The computer module
3. The thermal printer module

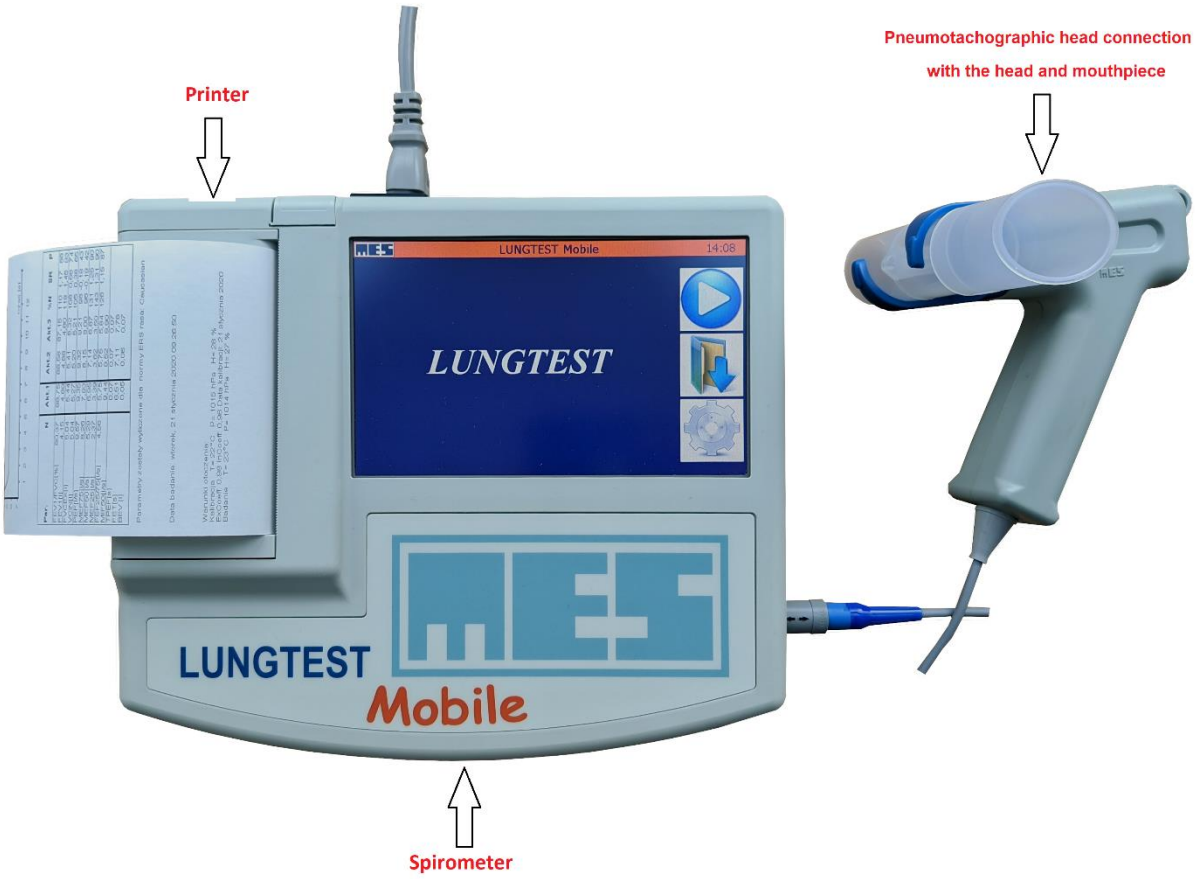



*Fig 1 Modules of the Lungtest Mobile spirometer*

### 1.2.1 The connection and pneumotachographic head module

The pneumotachographic head is a measuring unit of the spirometer. Its design guarantees accuracy and repeatability of parameters. The head is connected through a handle with the measuring module. The heads may be washed using generally available cleaning agents, and sterilised using gas. A clean head should be attached each time a new patient is to be tested and detached immediately after the test. No calibration check of the device is required upon the replace ment of the head.

The heads preserve their parameters until their physical damage. A temperature exceeding 121ºC may also cause deformations in the pneumotachographic head.

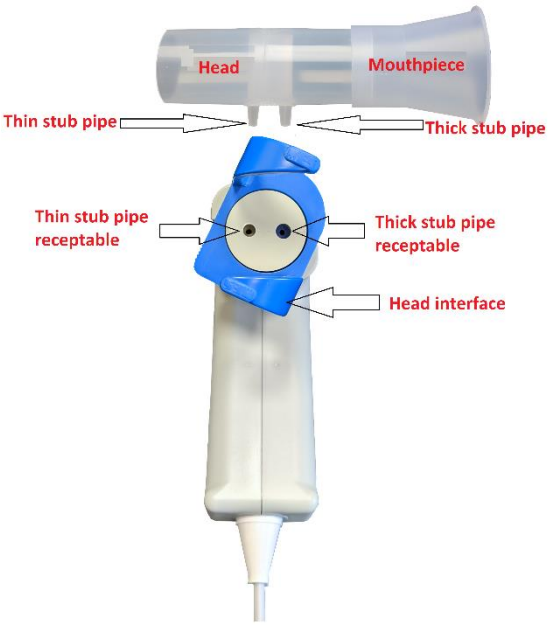



*Fig 2 The pneumotachographic head with the handle and mouthpiece.*

Before the head is mounted on the handle, the rotating part of the handle should be positioned as shown on Fig 2 so that the receptacles for the head stubs situated in the upper part of the head handle (Fig. 2) are visible as shown on the drawing. Then, the head should be attached to the handle by inserting and gently pressing the stubs into the receptacles. The risk of mistake (reversed installation of the head) is prevented by different external diameters of the stubs. If it is difficult to insert the stubs in the handle, rotate the head by 180º, so that the stubs are placed over the receptacles with appropriate diameters and repeat the operation. The head should be pressed until slight but distinct resistance is felt. Once the stubs of the head are inserted in the receptacles, the upper part of the head handle should be gently rotated in the direction shown on Fig 3a until the handle catches are locked in the position shown on Fig. 3 b.

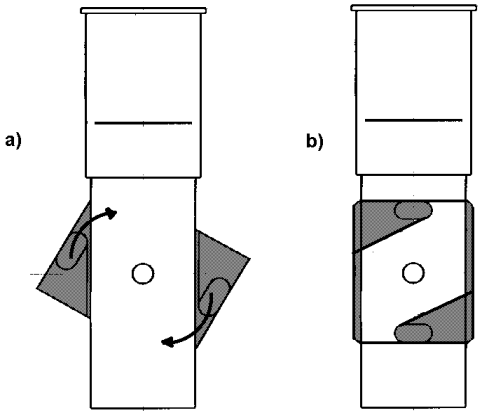



*Fig 3 Installing the pneumotachographic head*

Mount the mouthpiece on the head according to the drawing on the handle (Fig. 3a).

The terminal of the head is connected with the computer module using a flexible air conduit. The ends of the air conduit are mounted on metallic connecting pipes.

**The end marked with a black band must be mounted on the connecting pipe marked with a black band.**

## 1.2.2 The computer module

The task of the measuring module is to convert the values of flow and pressure of air exhaled by the patient into electric signals. The measured signals are converted into graphic curves and parameters shown on the colour LCD. Communication with the user is ensured by the touch panel displayed on the LCD.

The main components of the computer module are shown on Fig 4 Spirometer module components

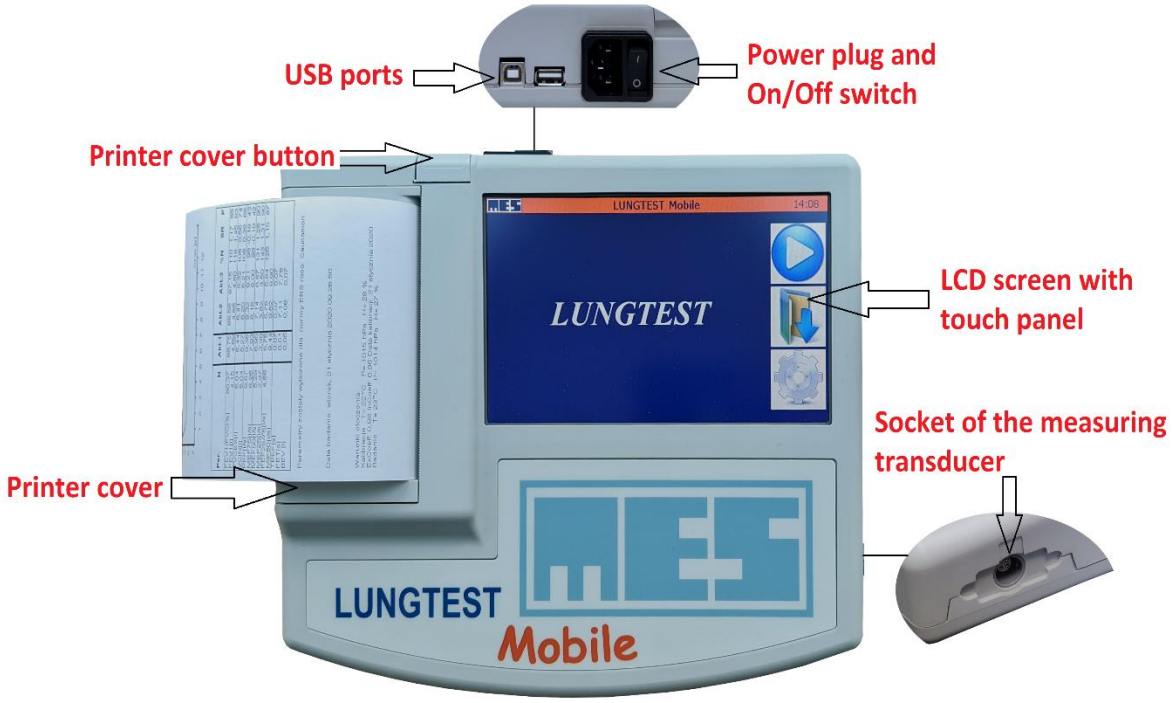



*Fig 4 Spirometer module components*

1. **Socket of the measuring transcuder**

The socket is equipped with a positioner that enables precise connection of the measuring transducer connector.

2. **Sockets and ports**

The sockets are installed on the rear panel of the apparatus: Fig 5 A view of the rear panel of the computer module

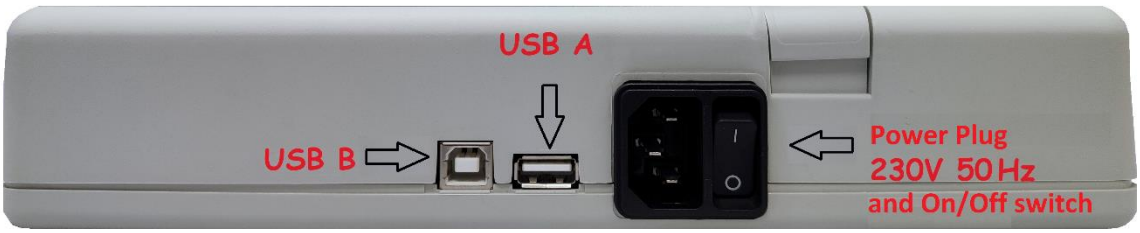



*Fig 5 A view of the rear panel of the computer module*

*"Power supply socket"* to connect to the mains 110-230 V, 50-60 Hz
*"USB B"* to connect a PC for data transmission and archiving
*"USB A"* to connect additional devices: a weather station, external printer

3. **LCD screen with a touch panel**

The colour LCD screen with resolution 800x600 pixels features a top touch panel. The touch panel is used for the purposes of communication between the device and the user. The displayed icons and buttons are pressed to communicate with the device.
The following rules must be adhered to when using the panel:

- Use the stylus delivered with the set or your finger.
- Do not exercise excessive pressure on the stylus; this may lead to accelerated wear or damage of the display unit.
- Do not use pointed objects (ballpoint pen, pencil) instead of the stylus. This may lead to scratches or damages on the display surface.
- Use a soft cloth to clean the display, and if necessary apply a special liquid designed to clean monitor screens. Do not use conventional window cleaning solutions and other preparations containing alcohol.
- Do not place any objects on the screen.

4. **Main screen of the Lungtest Mobile spirometer**


*Fig 6 The main screen of the Lungtest Mobile spirometer*

The features offered by the icons shown on the picture:

| | |
|---|---|
| "*Start Test*" | initiates the test process |
| *"Manage Tests*" | used to complete operations on completed tests recorded in the memory |
| *"Settings*" | selection of spirometer settings |

## 1.2.3 The thermal printer

The thermal printer is used to print test results on thermal paper with a standard width of 112 mm.

Rules for secure storage of results printed on thermal paper:

- store the printed paper in a dark place, prevent its exposure to sun rays
- avoid contact of paper with alcohol or other solvents
- do not store in PVC covers
- store in a temperature below 25 C

Correct paper loading in the thermal printer is shown on Fig 7 Printer flap and Fig 8 Paper loading

To load a new roll of paper, press the button on the casing to open the paper compartment, and then lift the flap:


*Fig 7 Printer flap*

Insert a roll of paper and unwind it as shown on the picture:


*Fig 8 Paper loading*

Gently close the flap until a click is heard.

### 1.2.4 External printer

The device can be used for printouts of an external printer connected via the USB port. To do this, select the external print option in the test settings (select "Printer: External") and connect the printer to the device. The device works with printers that support the PCL5, PCL6 standard. The spirometer has been tested with a wide variety of printing devices. In order to confirm whether a given printer model has been tested with a spirometer, please contact the MES service.

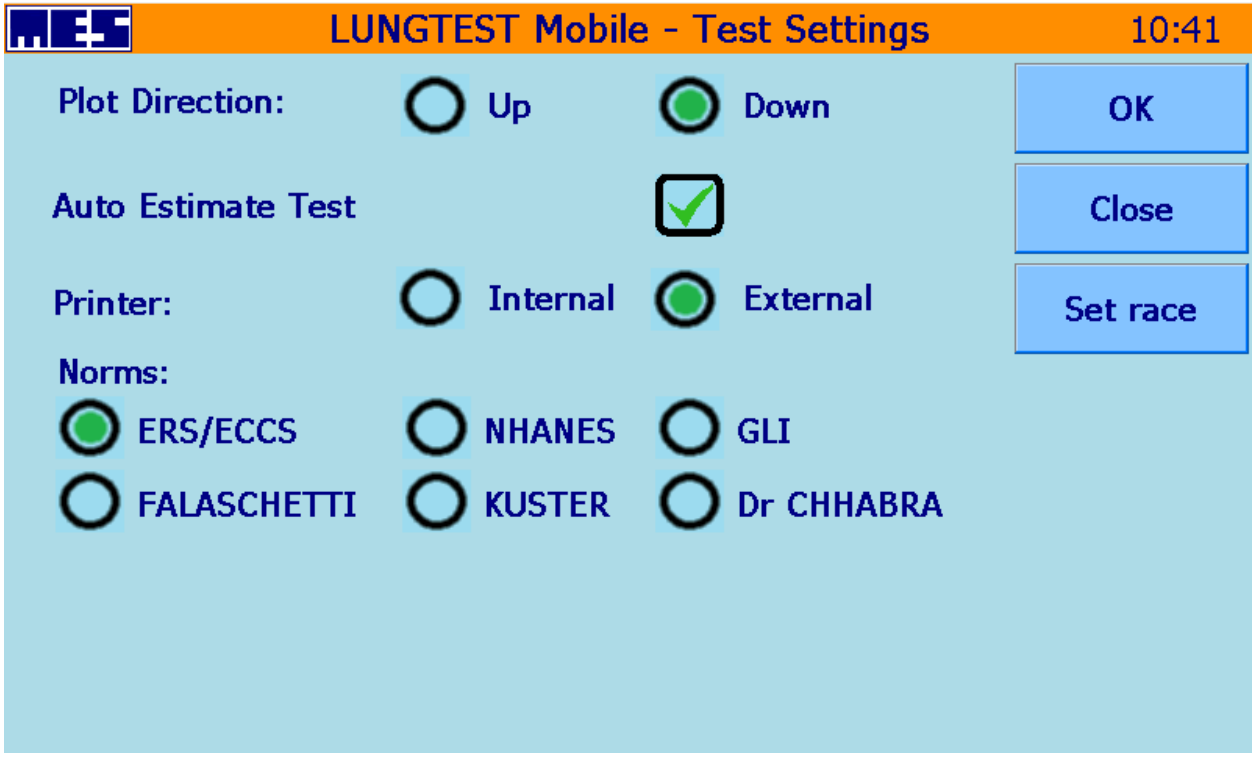



*Fig 9 "Settings" menu screen*

### 1.2.5 Power battery

Lungtest Mobile is available with a built-in internal battery. The spirometer battery allows the device to be used in places where access to power sources is limited. The battery panel has two lights and a power button Fig 10 Lungtest Mobile with battery

The external power lamp (next to the plug symbol) indicates that the device is connected to the 230V mains with a power cable.

External Power Modes:

1.The spirometer power supply - solid green light,
2.Connection to the 230V mains (with the spirometer turned off) - slowly blinking green light.

The battery light (next to the battery symbol) shows the current battery mode.

The battery modes are:

1.The spirometer power supply - solid green light,
2.Charging - solid red light,
3. Discharging - red light flashing.

The power button turns the device on and off. To turn on the device, press and hold the power button until one of the lights, depending on the power source, changes from fast blinking to

continuous green light. To turn off the device, perform the same maneuver until the light goes out or flashes slowly.


*Fig 10 Lungtest Mobile with battery*

## *1.3* Data safety

The user is obliged to create backups on CDs or on other data carriers (pen drive, HDD, network drive). If the computer to which the Lungtest Mobile spirometer is connected (while data archiving) works in a LAN, WLAN, etc. or is connected to the Internet, the user is obliged to secure such connection.

**The user of the spirometer is solely responsible for the safety of patient data.**

# 2 Preparing for tests

Both the apparatus and the patient to be examined must be prepared before a test is commenced.

## *2.1* Preparing the apparatus

- Connect the apparatus to the mains (230V 50 Hz). Switch on the apparatus using the switch installed in the rear panel.
- Wait for 10 minutes until the measuring conditions are stabilised.
- Ensure that there is sufficient quantity of paper in the printer to prepare printouts.
- Ensure that the air conduit is correctly connected to the stubs of the apparatus.
- Prepare sufficient number of pneumotachographic heads and mouthpieces, depending on the number of planned tests.
- Read the values of ambient conditions in the location of spirometry tests: the temperature, pressure, air humidity in order to correct the values of measured volumes

**According to the applicable standards, all values of measured volumes and their predicted normal values are given for BTPS conditions. As the tests are performed in ATP conditions, it is necessary to convert measured volumes from ATP conditions to BTPS conditions.**

## *2.2* Preparing the patient

The patient should be advised of the following requirements applicable to the scheduled tests:

1. Avoid physical strain before the tests and relax for 15 minutes before the tests are commenced.
2. Refrain from smoking.
3. Do not take drugs that may affect the results of the tests.
4. Do not eat heavy meals (for 2 hours preceding the tests).
5. Wear clothing that does not constrain your chest.

Ensure that the following details are known before the tests commence: the patient's age, height and weight. These details are required by the application installed in the spirometer and used to calculate predicted normal values.
The method used to perform the test should be exactly explained to the patient. It is important that the patient understands the tasks he or she will complete during the test.
During the test, the patient should receive short, unambiguous and comprehensible instructions, motivating the patient to contribute to achieving the best effects of the test.

During the test, the patient should:

1. Remain in an upright sitting position with slightly lifted chin (obese patients should stand).
2. Refrain from changing position during the test, leaning or bending backwards.
3. Tightly hold the mouthpiece with the lips, rest the teeth on the mouthpiece and keep the tongue under the mouthpiece
4. Have the nose closed with a clip

## *2.3* Patient's details

To enter the patient's details, touch the "*Start Test*" button on the main screen Fig 6 The main screen of the Lungtest Mobile spirometer

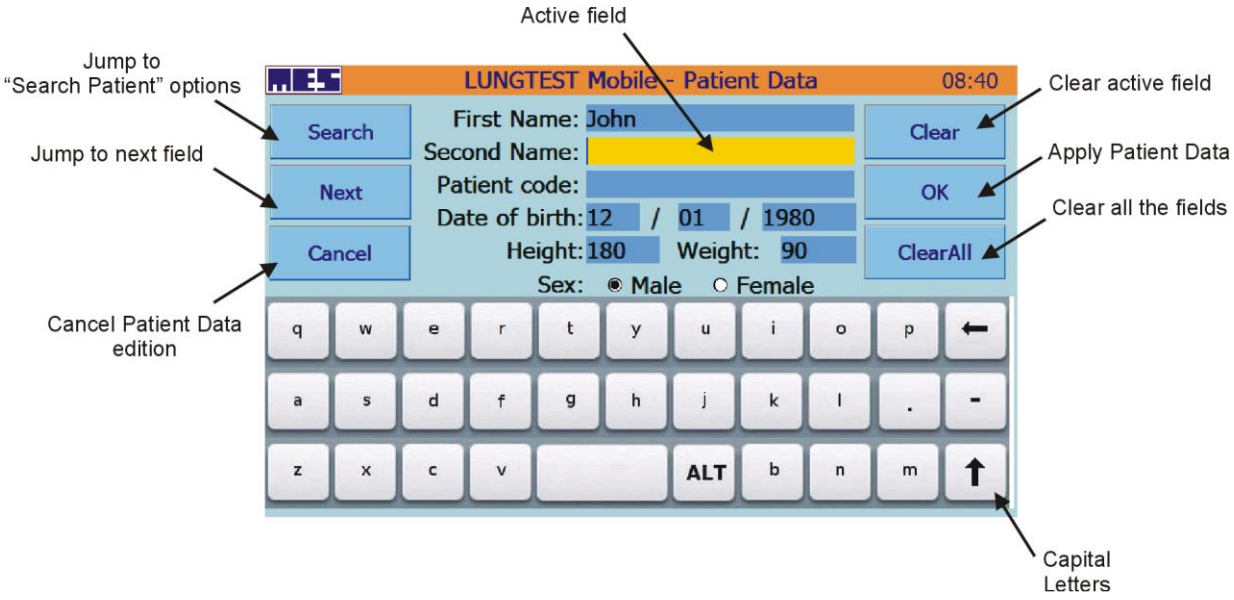



*Fig 11 The "Patient Data" screen on the Lungtest Mobile spirometer*

The "Patient Data" screen contains a set of fields used to enter information according to the labels displayed next to each field:

| | |
|---|---|
| "*First name*" and "*Second name*" | a string of letters and the – sign for double surnames |
| "*Date of birth*" | date of birth of the patient in the following format: day/month/year |
| *"Height"* | patient's height expressed in cm |
| *"Weight"* | patient's weight in kg |
| *"Patient code"* | this field is used to enter any string of digits, may be ignored |

An edition field must be touched to activate it. The active edition field is displayed with a yellow background.

Data is entered using displayed keyboards. An alphabetical keyboard is used to complete text fields, and a numeric keyboard is displayed for numeric fields.
Modifier keys of the alphabetical keyboard:

| | |
|---|---|
| "*ALT*" | used to enter Polish diacritics. When touched, a set of Polish letters appears on the screen |
| *"↑"* | used to change letter case. |

The features offered by the remaining buttons on the "Patient Data" screen:

| | |
|---|---|
| *"Clear"* | deletes (clears) all characters in the currently selected edition field |
| *"Search"* | used to search and select a patient from a list recorded in the database |
| *"Next"* | used to move to the next edition field |
| *"OK"* | used to confirm entered data and proceed to the next step |
| *"Cancel"* | used to interrupt the data entry process and return to the main screen of the spirometer |

The correct entry of data is required not only to identify patients – correct data is of crucial importance for diagnostics and the assessment of test results. Predicted normal values are calculated on the basis of patients' details.

If the values entered in individual fields are incorrect, Patient Data will not be accepted and the erroneous fields will be displayed with a red background.

## *2.4* Data before tests

The following test details may be entered before the test is commenced: comments and ambient conditions in the location where the test is performed.

The details are entered by touching appropriate buttons on the screen shown on Fig 12 that is displayed once the patient's details have been accepted.

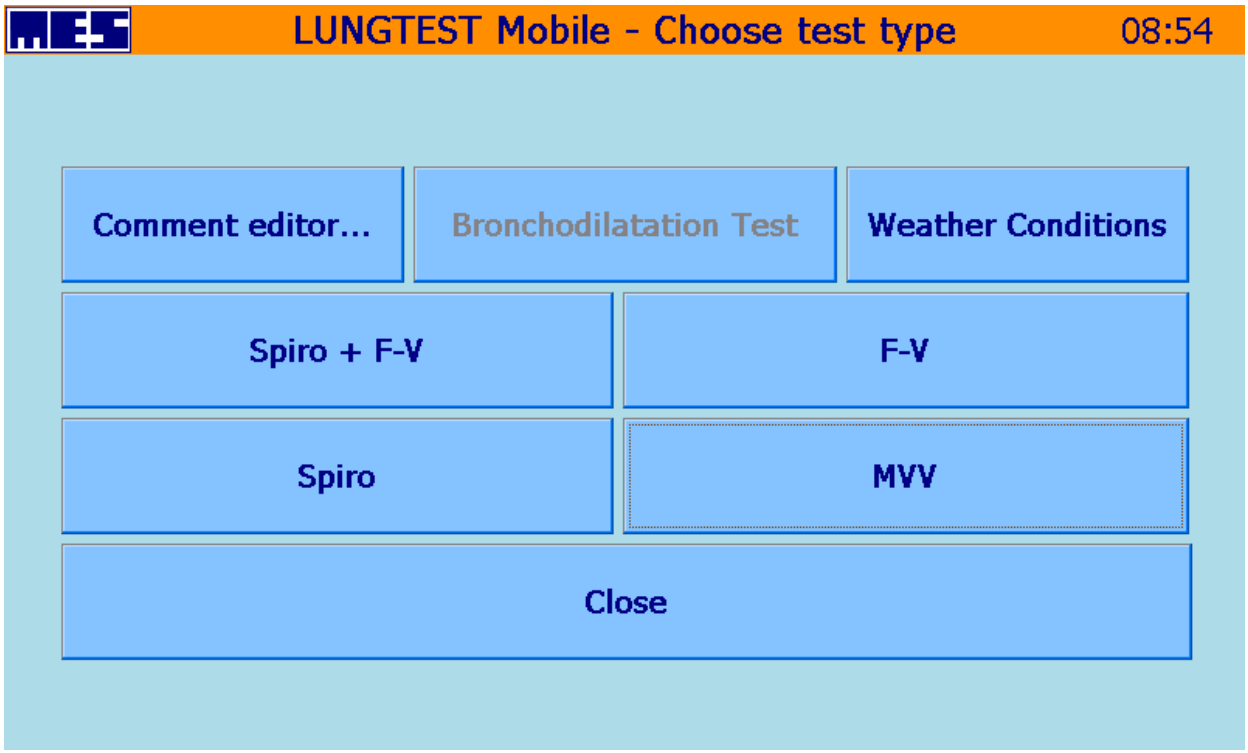



*Fig 12 The "Choose Test Type" screen*

### 2.4.1 Comment

The comment (a description of the test to be performed) can be entered before the test is commenced. The comment describes the conditions accompanying the test and will appear on the printout of the final report on the test, next to its results.

The comment may not be added when the test is completed

To enter a comment, touch the "Comment Editor" button on the screen shown on Fig 12 The "Choose Test Type" screen.

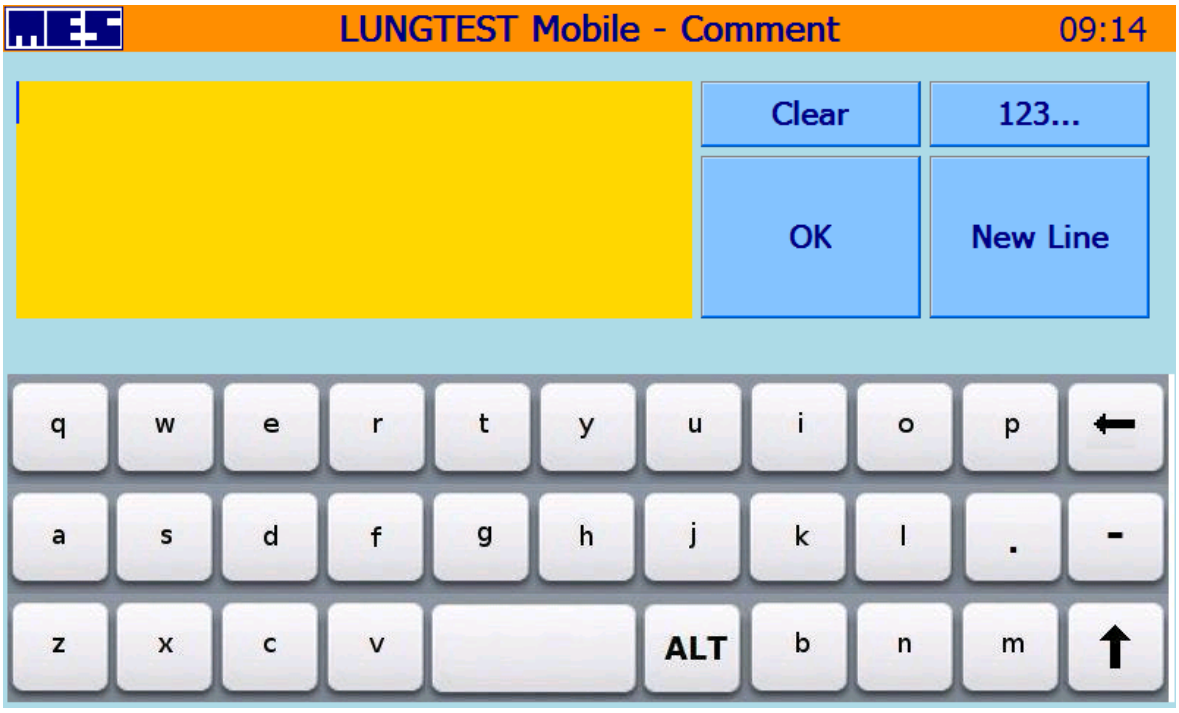



*Fig 13 The "Comment" screen*

The comment entered in the "Comment" screen may consist of 4 lines containing any string of letters and digits.
Characters are entered using the alphabetical or the numeric keyboard.
The features offered by the "Comment" screen buttons:

*"Clear"* deletes all entered characters
*"123..."* replaces the alphabetical keyboard with a numeric one
*"abc.."* replaces the numeric keyboard with an alphabetical one
*"New Line"* used to continue edition in a new line
*"OK"* used to confirm entered characters and proceed.

## 2.4.2 Weather conditions

Weather conditions are entered using the screen shown on Fig 14 The "Weather Conditions" screen. The user can select this screen from the screen shown on Fig 12.

To enter actual ambient conditions, correct the values given in individual fields displayed on the screen.
Touch a field to activate the edition function. The active edition field is displayed with a yellow background.
The features offered by the displayed buttons:

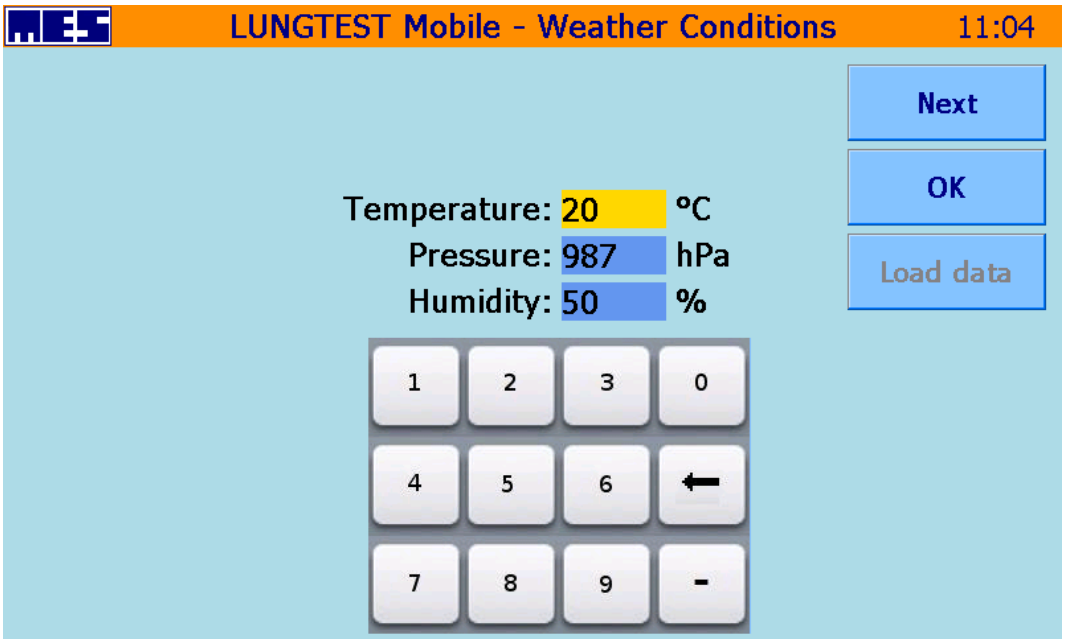



*Fig 14 The "Weather Conditions" screen*

"Next" proceed to the next edition field
"OK" confirm entered data and proceed to the next step
"Load data" load data from weather station

If incorrect data is entered in a field, the field is displayed with a red background.

Program will check if the provided data are valid and will mark incorrect data by highlighting fields that require correction with red colour. If there is weather station module connected with device by usb cable, measured data will load on entering the screen. If reload is required, use "Load Data" button. Chose "OK" to save values and continue.

**Correct data must be entered to convert ATP values to BTPS values and to ensure the required accuracy of measurements.**

*Fig 15 The module for automatic measurement of environmental conditions*

# 3 Performing the test

The Lungtest Mobile spirometer in its standard version is designed to perform two types of tests:

1. slow spirometry (Spiro)
2. forced Flow-Volume curve (F-V)

We recommend that both types of tests be performed during one session, one following another, in order to determine the accurate value of the Tiffeneau index, i.e. the obstruction index.

The method used to complete spirometry tests and the criteria for the reliability of their results have been developed by the European Respiratory Society (ERS) and are recommended by the Polish Society of Lung Diseases (PTChP).

The Lungtest Mobile spirometer controls the method and quality of conducted tests and advises the user, on an ongoing basis, of test compliance with the recommendations of the ERS.

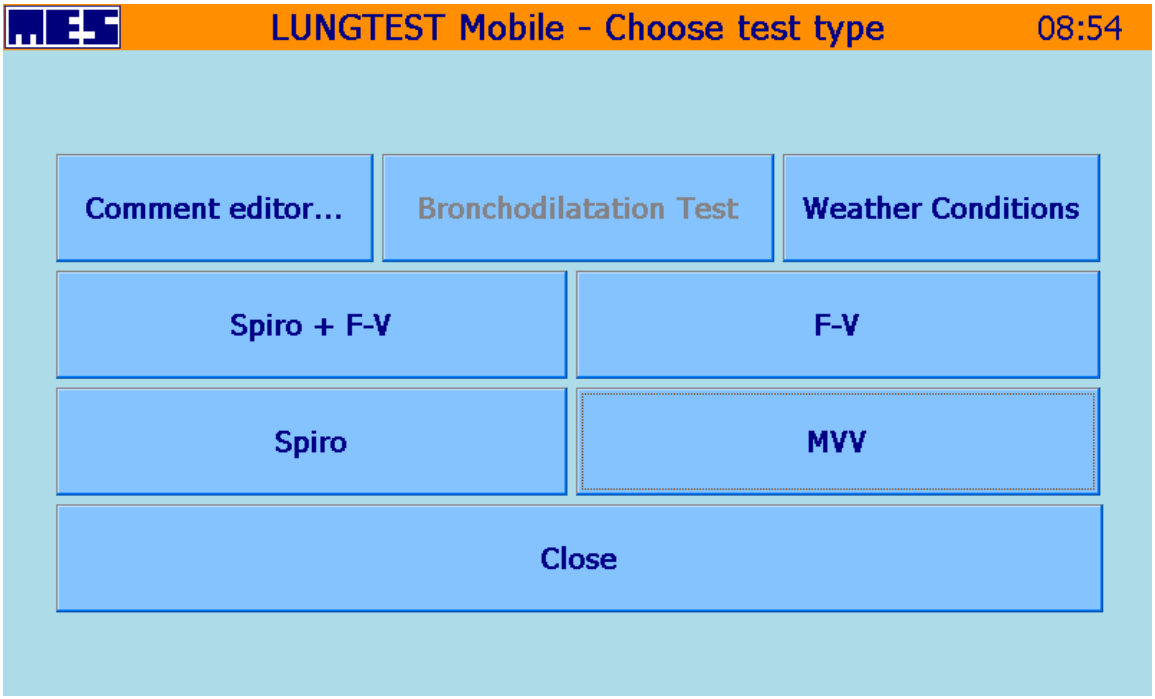



*Fig 16 The "Choose Test Type" screen*

The selection buttons are used to:

*"F-V"* perform a test of forced Flow-Volume curve
*"Spiro"* perform a resting spirometry test
*"Spiro + F-V"* perform a combined resting spirometry test and test of forced Flow-Volume curve
"Bronchodilation Test" perform a test of Bronchodilation test
"MVV" perform a maximal ventilation test

The patient breathes during the test through a measuring unit that consists of a mouthpiece and a measuring head. Small mouthpieces are designed for children aged up to 10; large mouthpieces are designed for other patients. The mouthpiece is put in mouth so that the patient's teeth rest on the mouthpiece and lips are sealed around it. The tongue is placed under the mouthpiece, and the patient's nose is closed with a clip Fig 17.

The test results are compared with predicted normal values.

*Fig 17 A correctly connected measuring unit with the mouthpiece and the head*

## *3.1* Predicted normal values

Predicted normal values are defined as a set of expected values of the measured quantities. They are obtained as a result of tests performed in a population and established correlations between specific values and characteristics of tested people, usually their height, weight, sex and race.

**There are no standards for patients aged 71 and more. In MES software, we have applied approximation of ERS standards for people aged up to 95.**

The following standards are applied in the spirometers:

1) **ERS -** a standard for adults aged 18 and more
2) **Zapletal** - a standard for children aged up to 18
3) **Falaschetti**
4) **Nhanes**
5) **Kuster**
6) **GLI**
7) Dr Chhabra

## *3.2* Spirometry

Resting spirometry is performed as the first test to determine the VC (vital capacity) and IC (inspiratory capacity) indices. The measurement of these parameters taken when the patient breathes quietly and steadily gives the most accurate results.

| **Name of parameter:** | **Unit:** | **Description:** |
|---|---|---|
| VC | l | vital capacity |
| IC | l | Inspiratory capacity |
| ERV | l | expiratory reserve volume |

| | | |
|---|---|---|
| TV | l | tidal volume |
| BF | 1/min | steady breathing frequency |

## 3.2.1 Procedure and requirements

There are two techniques used to perform spirometry tests. The following 3 phases may be distinguished in each technique:

### 3.2.1.1 Technique 1 (recommended): VC measurement during inhalation

To understand how to perform a resting spirometry test using the "inspiratory VC" method, cf. Fig 18 A resting spirometry test performed using the inspiratory VC method

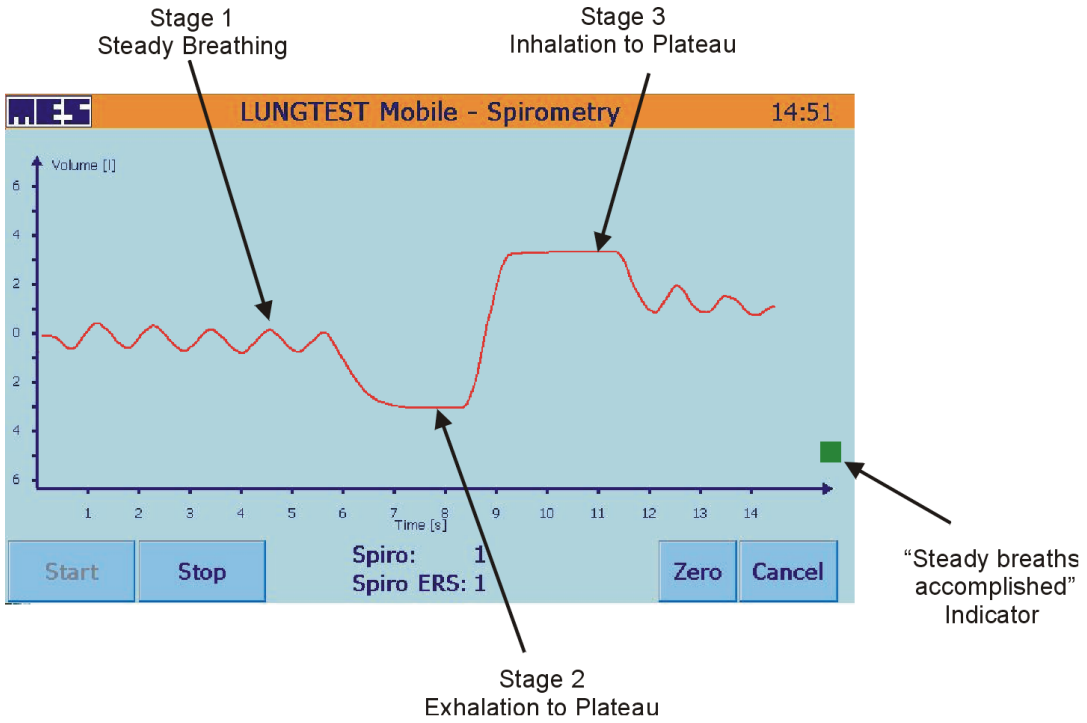



*Fig 18 A resting spirometry test performed using the inspiratory VC method*

Phase 1- steady breaths
The patient breathes normally through the spirometer head. Please wait until the patient's breaths become even and uniform.
Usually, 5 – 10 normal breaths are required.
Phase 2 – exhalation
The patient slowly exhales as deeply as possible until the air flow completely stops. Interrupted air flow is seen as a flat section of the volume-time curve. This section is known as the plateau and should last for at least 1 s.
Phase 3- inhalation
The patient inhales until the patient's lungs are completely filled with air. The achievement of maximum lung capacity should be clearly displayed as a plateau. Once the plateau is achieved, the patient resumes normal breathing.

According to the ERS criteria, a plateau is a section of the volume-time curve characterised by volume changes not exceeding 25 ml within 1 s.

### 3.2.1.2 Technique 2: VC measurement during exhalation

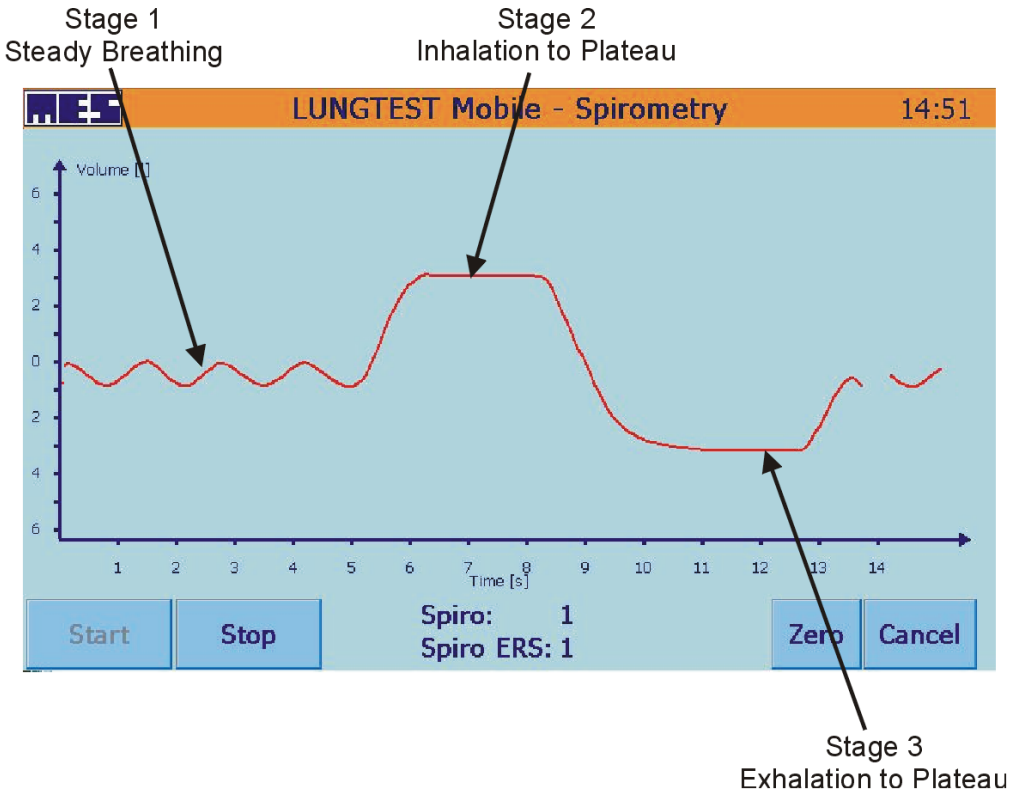



*Fig 19 A resting spirometry test performed using the expiratory VC method*

Phase 1- steady breaths
The patient breathes normally through the spirometer head. Please wait until the patient's breaths become even and uniform.
Usually, 5 – 10 normal breaths are required.
Phase 2 - inhalation
The patient slowly inhales as deeply as possible until the air flow stops. Interrupted air flow is seen as a flat section of the volume-time curve. This section is known as the plateau and should last for at least 1 s. (According to the ERS criteria, a plateau is a section of the volume-time curve characterised by volume changes not exceeding 25 ml within 1 s.)
Phase 3 - exhalation
The patient slowly exhales as deeply as possible. Complete exhalation should be clearly displayed as a plateau. Then, the patient resumes normal breathing.

Take at least 2 measurements that fulfil the repeatability condition – this means that the difference of measured VC values should not exceed 150 ml. If repeatability cannot be achieved in 2 measurements, the number of spirometric manoeuvres may be larger but should not exceed 4.

### 3.2.2 Performing a spirometry test

To start a spirometry test, select the Spiro+FV or the Spiro button from the “Choose Test Type” screen, as required. The screen shown on Fig 20 Test Screen – starting spirometrywill be displayed.

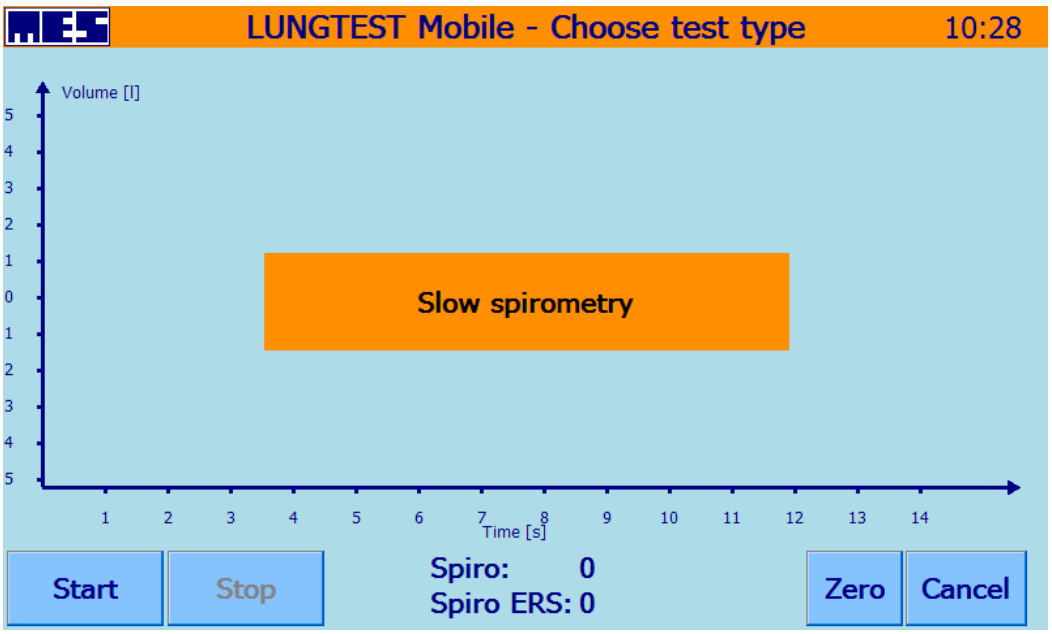



*Fig 20 Test Screen – starting spirometry*

To commence measurements, press the Start button. This will initiate the resetting (“zero”) procedure, and prepare the device for test recording.

**During resetting, the head with the handle should rest on a fixed surface under control of the spirometer operator. The patient may not hold it under any circumstances. Air may not flow through the head (pay attention to fans). Initial measurement conditions are determined during this resetting process. The correct completion of the process has a significant effect on the results and quality of the test.**

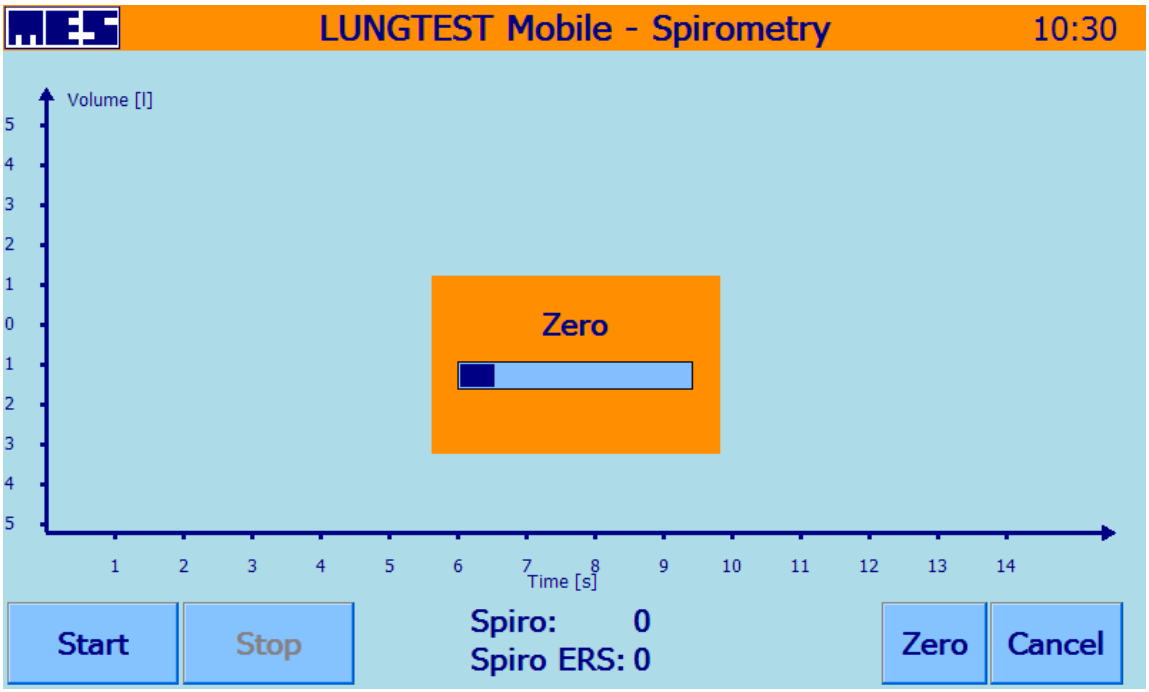



*Fig 21Resetting the measuring system*

A correct reset is indicated by a horizontal volume line without any declines or increases.

Once the resetting process is completed, the patient starts to breathe through the measuring unit and participates in the test according to the described procedure.
Note: The time at which the recording of steady breaths is completed will be indicated by a green square displayed in the right hand section of the screen.
From this time on, a spirometric manoeuvre may be performed, starting from exhalation or inhalation, according to the adopted technique. The time at which a plateau is achieved will be indicated by a message displayed in the right hand section of the screen.

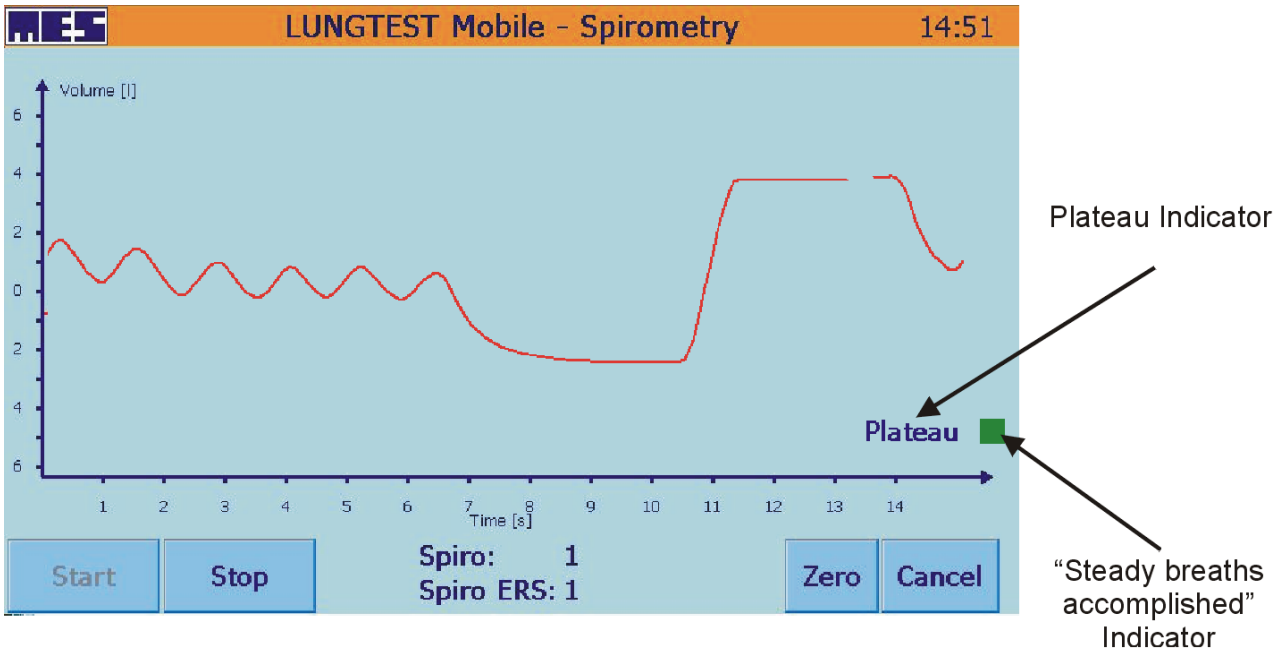



*Fig 22 A correct resting spirometry manoeuvre with displayed indicators of test correctness*

Counters providing information are displayed in the bottom section of the screen.
The "Spiro" counter provides the operator with information about the number of completed and technically correct spirometric manoeuvres.
The "Spiro ERS" counter provides the operator with information about the number of completed, correct and repeatable spirometric manoeuvres.
Once at least 3 trials – including 2 repeatable ones – are completed, the test is automatically ended.
The test may also be ended at any time using the following buttons:

"Stop" ends the test and displays the results or proceeds to an FV test if the Spiro + FV test type has been selected

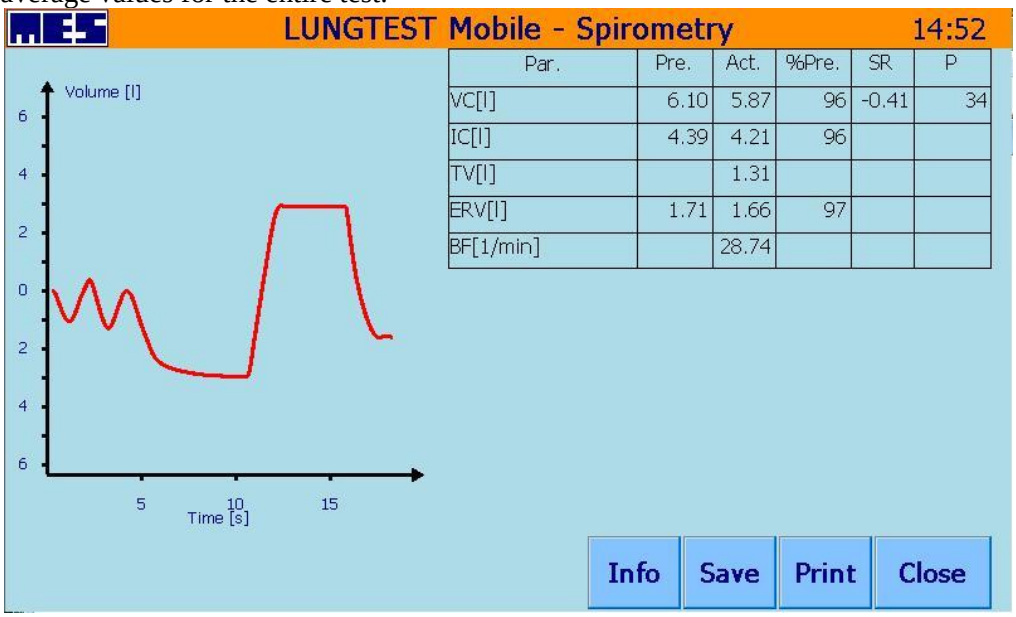
"Cancel" ends the test without displaying its results

"Zero" used to reset the unit during the test (the patient may not breathe through the mouthpiece at this moment).

### 3.2.3 Test result

The test result is the best of measurements taken. The selection criterion is the value of the *VC* parameter. The graphic representation of the result includes (i) a spirogram showing the measurement process and (ii) a table with test parameters.

The VC value in the table is the highest value achieved during repetitions while ERV and IC represent average values for the entire test.




| Par. | Pre. | Act. | %Pre. | SR | P |
|---|---|---|---|---|---|
| VC[l] | 6.10 | 5.87 | 96 | -0.41 | 34 |
| IC[l] | 4.39 | 4.21 | 96 | | |
| TV[l] | | 1.31 | | | |
| ERV[l] | 1.71 | 1.66 | 97 | | |
| BF[1/min] | | 28.74 | | | |

*Fig 23 Resting spirometry results*

The table consists of six columns:

| No. | Name | Description | Notes |
|---|---|---|---|
| 1 | Par. | Name of the parameter | |
| 2 | Pre. | Predicted normal value of the parameter | |
| 3 | Act. | Actual value of the parameter | The value obtained as the measurement result |
| 4 | %Pre. | The actual value compared to the normal value | A/N % – ratio of the actual value to the predicted normal value expressed as a percentage |
| 5 | SR | Number of standard deviations | $SR = \frac{Act - \Pr e}{\delta}$ where δ is the standard deviation of the predicted normal value |
| 6 | P | Percentile | An *n* rank percentile shows that *n*% of people in a population have values of the parameter not exceeding the *actual value* |

A printout of a spirometric test contains in addition parameters of 3 spirometric manoeuvres.

The buttons of the "Spirometry" screen offer the following features:

*"Info"* a preview of test quality assessment, completed taking into account the ERS criteria. This information also appears on the printout.

*"Save"* saves the performed test in the database of the Lungtest Mobile spirometer.

*"Print"* prints a report on the test

*"FV"* a preview of the results of the Flow-Volume test if it is performed in the same cycle with spirometry

## *3.3* Flow-Volume

The purpose of the Flow-Volume test is to measure maximum ventilation parameters of the patient's lungs. This is a forced test and the operator must ensure that the patient exercises maximum effort.

The test requires as rapid and long expiration as possible, following a deep inhalation.

Before the test is commenced, the patient should be advised of its physical, forced nature and should be motivated to achieve the best possible parameters.

The parameters measured during the Flow-Volume test:

| **Name of the parameter:** | **Unit:** | **Description:** |
|---|---|---|
| FEV 1 | **L** | **FORCED EXPIRATORY VOLUME IN 1 SECOND** |
| FVC EX | **L** | Forced expiratory vital capacity |
| VC IN | l | Forced inspiratory vital capacity |
| PEF | l/s | Peak expiratory flow |
| MEF 75 | l/s | Maximal expiratory flow, where 75% of *FVC EX* remains to be expired |
| MEF 50 | l/s | Maximal expiratory flow, where 50% of *FVC EX* remains to be expired |
| MEF 25 | l/s | Maximal expiratory flow, where 25% of *FVC EX* remains to be expired |
| FEF 25/75 | l/s | |
| TPEF | s | Time at *PEF* |
| FET | s | Forced expiration time |

Note: The printout contains in addition:

| | | |
|---|---|---|
| BEV | l | Back extrapolated volume |

### 3.3.1 Procedure and requirements

The test procedure consists of 4 phases Fig 24 Phases of forced Flow-Volume curve test

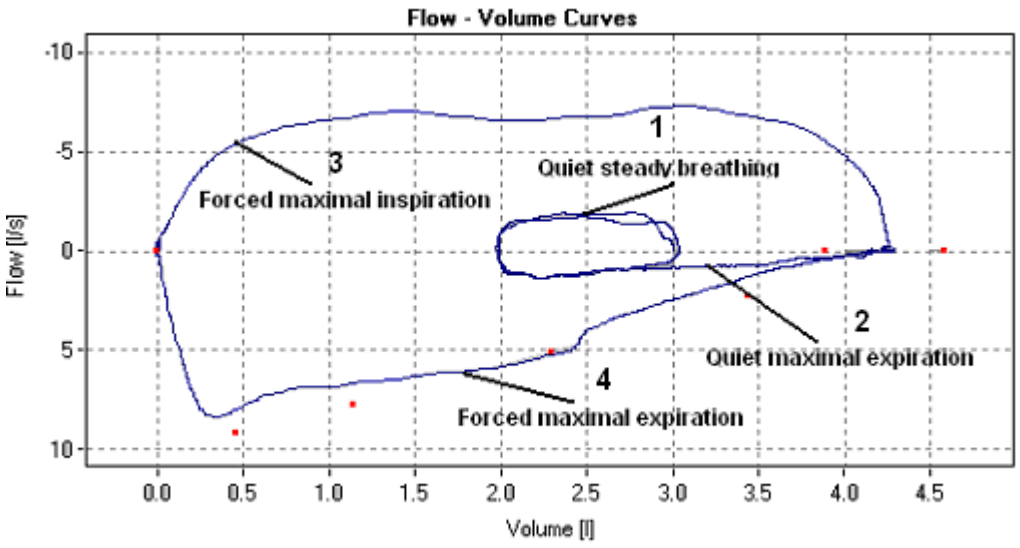



*Fig 24 Phases of forced Flow-Volume curve test*

Phase 1
The patient breathes quietly through the measuring unit. A few quiet, steady breathes should be taken.
Phase 2
The patient quietly exhales until air is removed from the lungs.
Phase 3
The patient rapidly inhales air as deeply as possible.
Phase 4
The patient, immediately upon a deep inhalation, rapidly exhales air with maximum effort as long as possible. The exhalation phase should be continued until air is completely expired from the lungs.

The established criteria for test correctness define the start and the end of the expiration phase.

1) The start of the forced expiration manoeuvre is satisfactory, i.e. the back extrapolated volume of forced exhalation BEV is lower than 5%FVC or 150ml.
2) Forced expiration is rapid enough, i.e. the time needed to achieve PEF should be as short as possible, not more than 300 ms.
3) The time of forced expiration is not shorter than 6 s in adults and not shorter than 3 s in children aged below 10.
4) The volume-time graph includes a distinct plateau, i.e. changes in volume are lower than 25ml for a second.

At least 3 measurements must be taken, of which 2 must fulfil the repeatability condition. The repeatability condition is applicable to the FEV1 and FVCEX parameters. The parameters should not differ by more than 150 ml (for volumes lower than 1 l, the repeatability requirement is not more than 100ml)

The test should not include more than 8 technically correct manoeuvres, and forced manoeuvres should be separated by several steady, quiet breaths.

### 3.3.2 Performing the test

To perform forced Flow-Volume curve test, select the required button on the “Choose Test Type” screen: “Spiro+FV” or “FV”.
If the “Spiro + FV” test type is selected, perform in the first place at least one resting spirometry manoeuvre, then the test of forced FV curve will be enabled.
The measurement is initiated using the “Start” button. Once the button is pressed, the apparatus is reset and test recording commences.

**During resetting, the head with the handle should rest on a fixed surface under control of the spirometer operator. The patient may not hold it under any circumstances. Air may not flow through the head (pay attention to fans). Initial measurement conditions are determined during this resetting process. The correct completion of the process has a significant effect on the results and quality of the test.**

If there are doubts as to whether the reset has been successful or not, use the “*Zero*” button to repeat the resetting process.

Once the resetting process is completed, the patient starts to breathe through the measuring unit (Fig 17 A correctly connected measuring unit with the mouthpiece and the head) and participates in the test according to the described procedure.

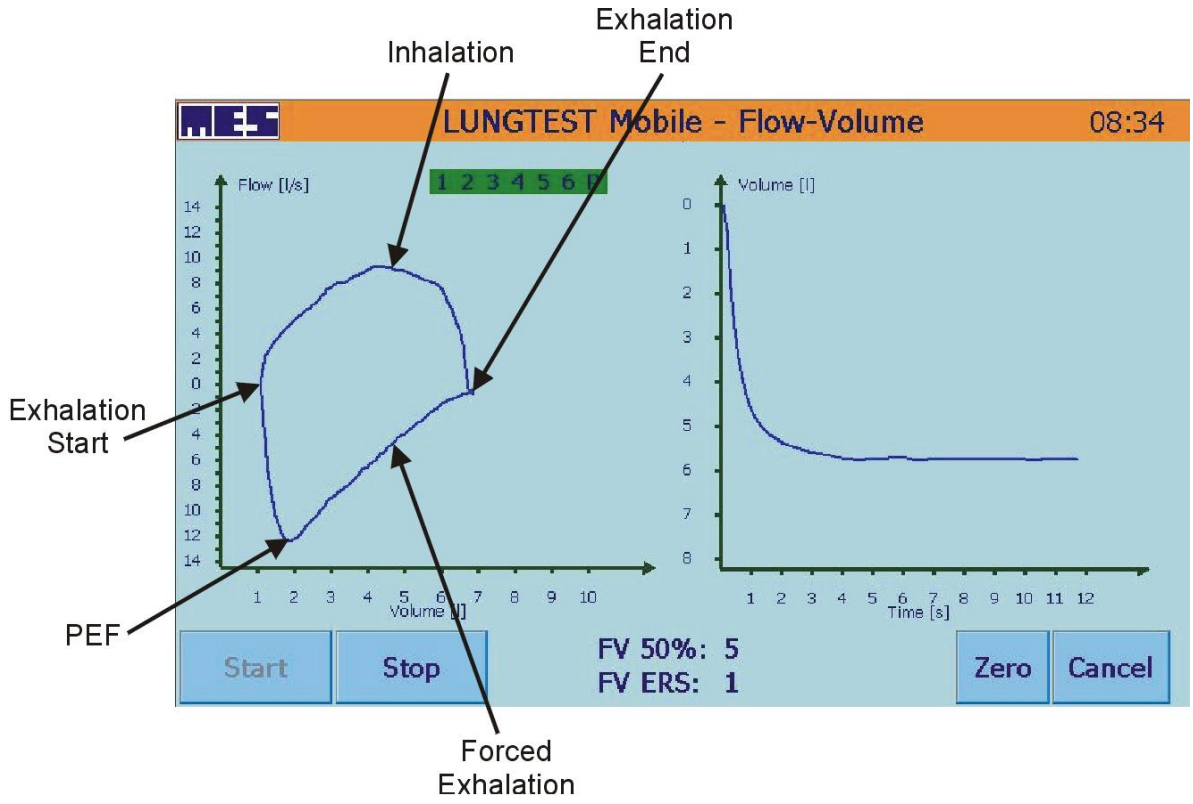



*Fig 25 The Flow-Volume test screen*

The operator should watch the curves emerging on the screen and adapt instructions given to the patient during the test to the current observed phase. The operator should continually assess the quality of performed test, correct errors and motivate the patient to exhale air as rapidly and as long as possible.
The following indications displayed on the spirometer screen is useful during the test Fig 26 Graphic time counter

1. A graphic time counter Fig 26 provides information about the length of forced exhalation and about the achieved plateau marked with the letter P

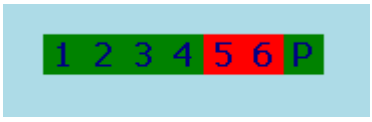
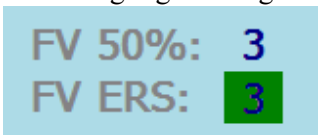



*Fig 26 Graphic time counter*

2. The counter of FV 50% forced curves shows the number of forced exhalations completed by the patient during the test.
3. The counter of FV ERS curves shows the number of curves that meet the ERS criteria.

Once the minimum required number of technically correct curves, meeting the repeatability criterion, is achieved, the number titled “FV ERS” will be highlighted to green, and the test will be possible to finish.



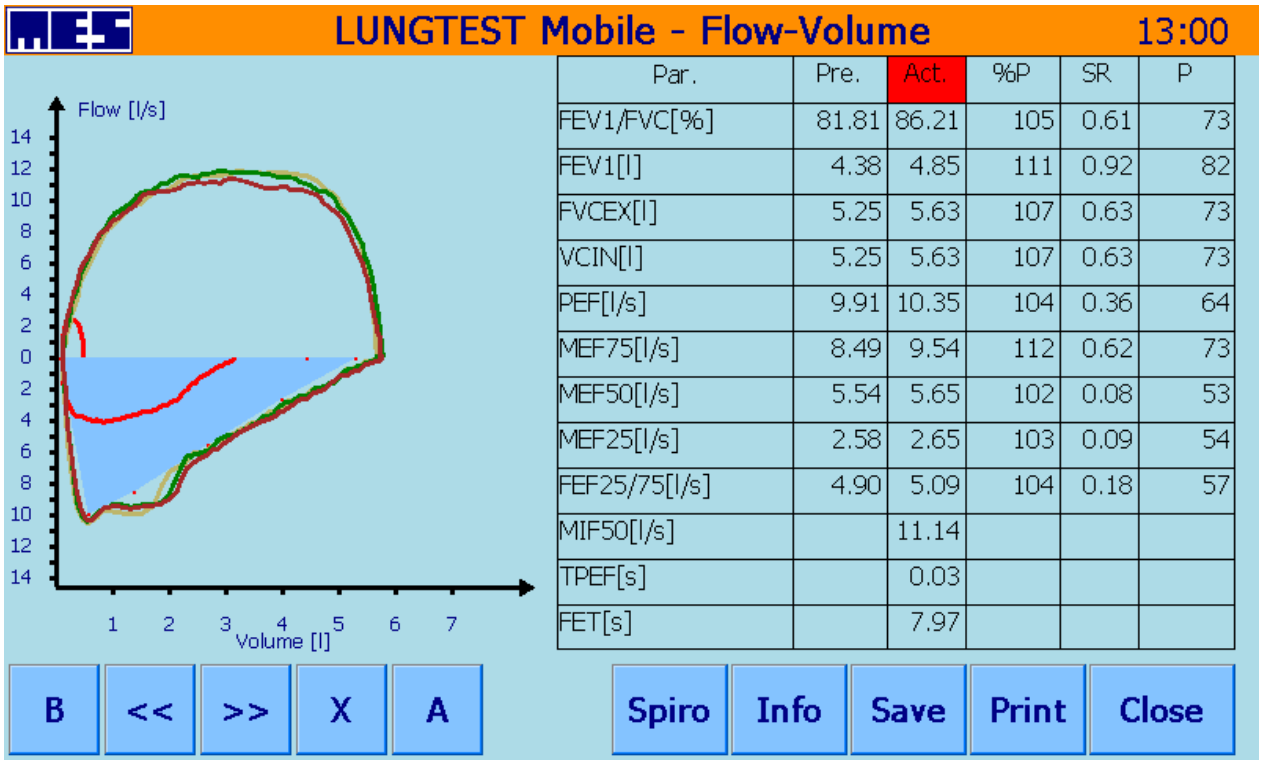

The features offered by the remaining buttons on the screen:
*“Stop”* used to finish the measurement at any time and to display its results
*“Cancel”* used to abandon the test without displaying its results.

### 3.3.3 Test results

The results of the test consist of up to 8 largest curves achieved by the patient and a table of measured values. The table consists of six columns:

| No. | Name | Description | Notes | |
|---|---|---|---|---|
| 1 | Par. | Name of the parameter | | |
| 2 | Pre. | Predicted normal value of the parameter | | |
| 3 | Act. | Actual value of the parameter | The value obtained as the measurement result | |
| 4 | %Pre. | The actual value compared to the normal value | A/N % – ratio of the actual value to the predicted normal value expressed as a percentage | |
| 5 | SR | Number of standard deviations | $SR = \frac{Act - Pre}{\delta}$ | where δ is the standard deviation of the predicted normal value |
| 6 | P | Percentile | An *n* rank percentile shows that *n*% of people in a population have values of the parameter not exceeding the *actual value* | |

Immediately upon test completion, the table shows the parameters of the best measured Flow-Volume curve; the colour visible in the *Act.* column is the colour of the best curve.




| Par. | Pre. | Act. | %P | SR | P |
|---|---|---|---|---|---|
| FEV1/FVC[%] | 81.81 | 86.21 | 105 | 0.61 | 73 |
| FEV1[l] | 4.38 | 4.85 | 111 | 0.92 | 82 |
| FVCEX[l] | 5.25 | 5.63 | 107 | 0.63 | 73 |
| VCIN[l] | 5.25 | 5.63 | 107 | 0.63 | 73 |
| PEF[l/s] | 9.91 | 10.35 | 104 | 0.36 | 64 |
| MEF75[l/s] | 8.49 | 9.54 | 112 | 0.62 | 73 |
| MEF50[l/s] | 5.54 | 5.65 | 102 | 0.08 | 53 |
| MEF25[l/s] | 2.58 | 2.65 | 103 | 0.09 | 54 |
| FEF25/75[l/s] | 4.90 | 5.09 | 104 | 0.18 | 57 |
| MIF50[l/s] | | 11.14 | | | |
| TPEF[s] | | 0.03 | | | |
| FET[s] | | 7.97 | | | |

*Fig 27 Results of forced Flow-Volume curve test – screen 1*

The tool bar *Curve selection* is used to complete operations of the curves.
Features of the "Curve selection" tool bar:

*"B"* displays the best curve

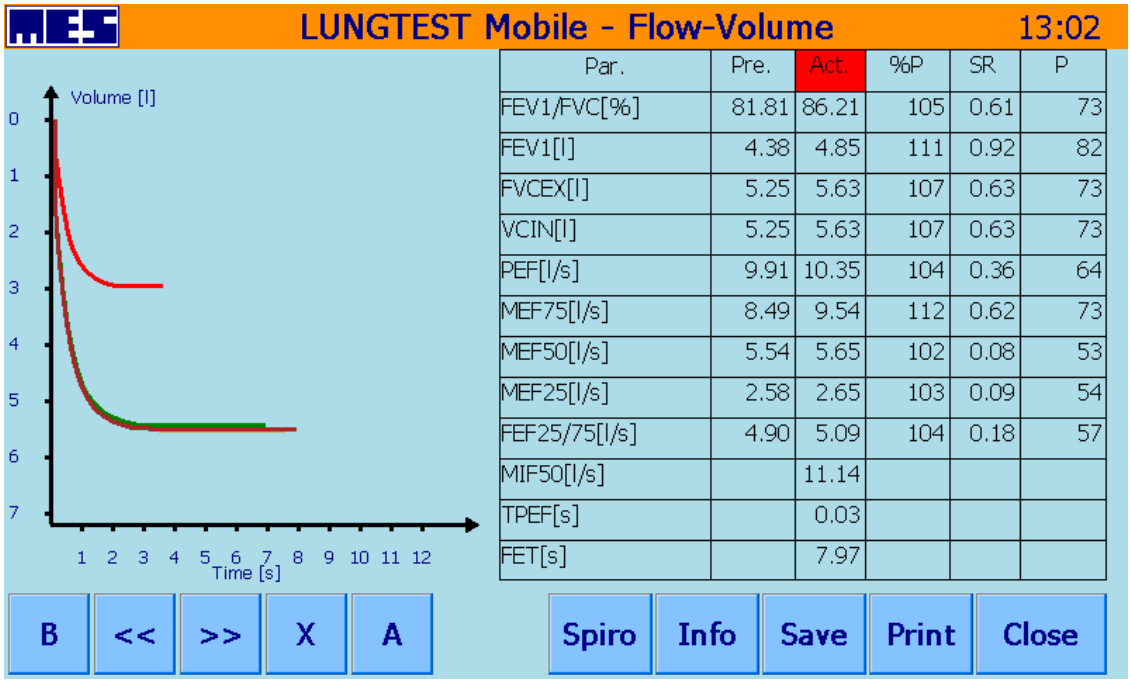
*"<<" and ">>"* are used to view individual curves with their corresponding parameters displayed in the table

*"X"* is used to exclude the curve currently displayed from the analysis or to include the curve if it was formerly excluded. Excluded (non-active) curves are displayed as thin lines.

Warning! Turning of curves might result in affect degree of repeatability in scale NLHEP!

*"A"* is used to display all recorded curves; the parameters of the best curve will be displayed in the table

The recorded Flow-Volume curves may also be viewed using the volume-time coordinates. To activate this view, press the graph field. Press the graph field again to restore the Flow-Volume coordinates.
Fig 28 The results of Flow-Volume curve test – screen 2




| Par. | Pre. | Act. | %P | SR | P |
|---|---|---|---|---|---|
| FEV1/FVC[%] | 81.81 | 86.21 | 105 | 0.61 | 73 |
| FEV1[l] | 4.38 | 4.85 | 111 | 0.92 | 82 |
| FVCEX[l] | 5.25 | 5.63 | 107 | 0.63 | 73 |
| VCIN[l] | 5.25 | 5.63 | 107 | 0.63 | 73 |
| PEF[l/s] | 9.91 | 10.35 | 104 | 0.36 | 64 |
| MEF75[l/s] | 8.49 | 9.54 | 112 | 0.62 | 73 |
| MEF50[l/s] | 5.54 | 5.65 | 102 | 0.08 | 53 |
| MEF25[l/s] | 2.58 | 2.65 | 103 | 0.09 | 54 |
| FEF25/75[l/s] | 4.90 | 5.09 | 104 | 0.18 | 57 |
| MIF50[l/s] | | 11.14 | | | |
| TPEF[s] | | 0.03 | | | |
| FET[s] | | 7.97 | | | |

*Fig 28 The results of Flow-Volume curve test – screen 2*

The remaining buttons of the Results of Flow-Volume test screen offer the following features:

*"Info"* a preview of test quality assessment, completed taking into account the ERS criteria. This information also appears on the printout.

If the Flow-Volume test has been completed according to the ATS or ERS criteria, information about the degree of repeatability of manoeuvres (curves) will be displayed according to the NHELP scale. The scale includes 5 degrees:

A – at least two correct, repeatable manoeuvres (the two largest values of FEV1 and FVC differ by not more than 100 ml)

B – at least two correct manoeuvres where the difference between the two largest values of FEV1 and FVC does not exceed 150 ml

C – at least two correct manoeuvres where the difference between the two largest values of FEV1 and FVC does not exceed 200 ml

D – one or more correct manoeuvres, but the difference between the two largest FEV1 and FVC parameters exceeds 200 ml (the result will not be interpreted)

F – no correct manoeuvres (the result will not be interpreted)

*"Save"* saves the performed test in the database of the Lungtest Mobile spirometer.
*"Spiro"* used to view the results of a spirometry test if it was performed previously
*"Print"* an immediate printout of the test results
*"Cancel"* used to abandon the "Test Result" screen and return to the "Choose Test Type" screen

## *3.4* Maximal voluntary ventilation

### 3.4.1 Procedure and requirements

Maximal voluntary ventilation is divided on two steps:
Phase 1: Tranquil breaths.
When patient does doing calm stable breath red square(on the right side of plot) will change color to green and “Go” button will be visible. Press “Go” to pass to next phase.
Phase 2: Maximal ventilation.
Patient tries to make deep, dynamic, fast breaths for the selected time period. Time to end of phase is displayed next to green square. The test will end automatically and results will be displayed on screen in form of plot with table.

### 3.4.2 Performing test

To make Maximal voluntary ventilation examination press “MVV” button in “Chose Test Type” screen. On Test screen press “Start” to begin. This will initiate the resetting (“zero”) procedure, and prepare the device for test recording.

**During resetting, the head with the handle should rest on a fixed surface under control of the spirometer operator. The patient may not hold it under any circumstances. Air may not flow through the head (pay attention to fans). Initial measurement conditions are determined during this resetting process. The correct completion of the process has a significant effect on the results and quality of the test.**

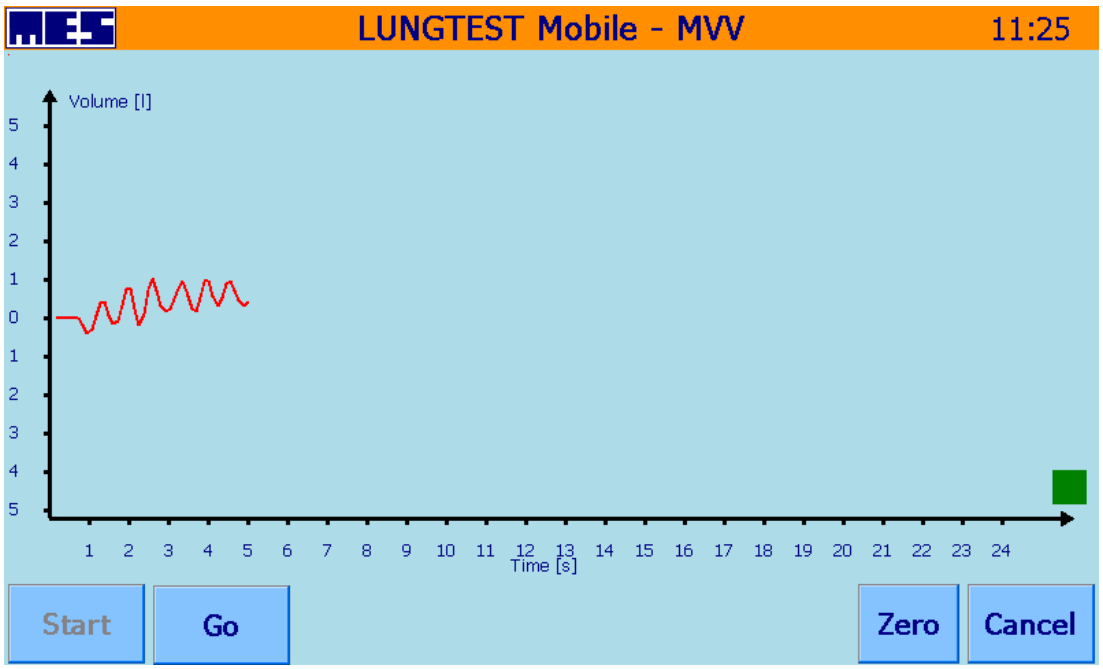



*Fig 29 Tranquil phase*

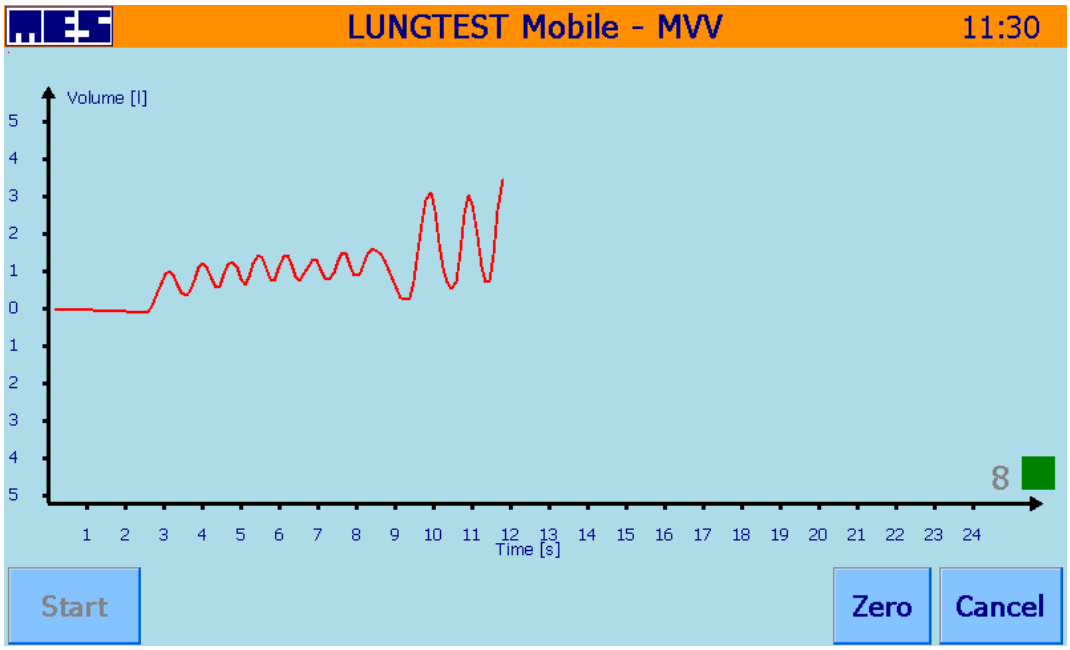



*Fig 30 Maximal ventilation phase*

### 3.4.3 Test results

As result we get a spirogram illustrating the measurement and a table with test parameters.

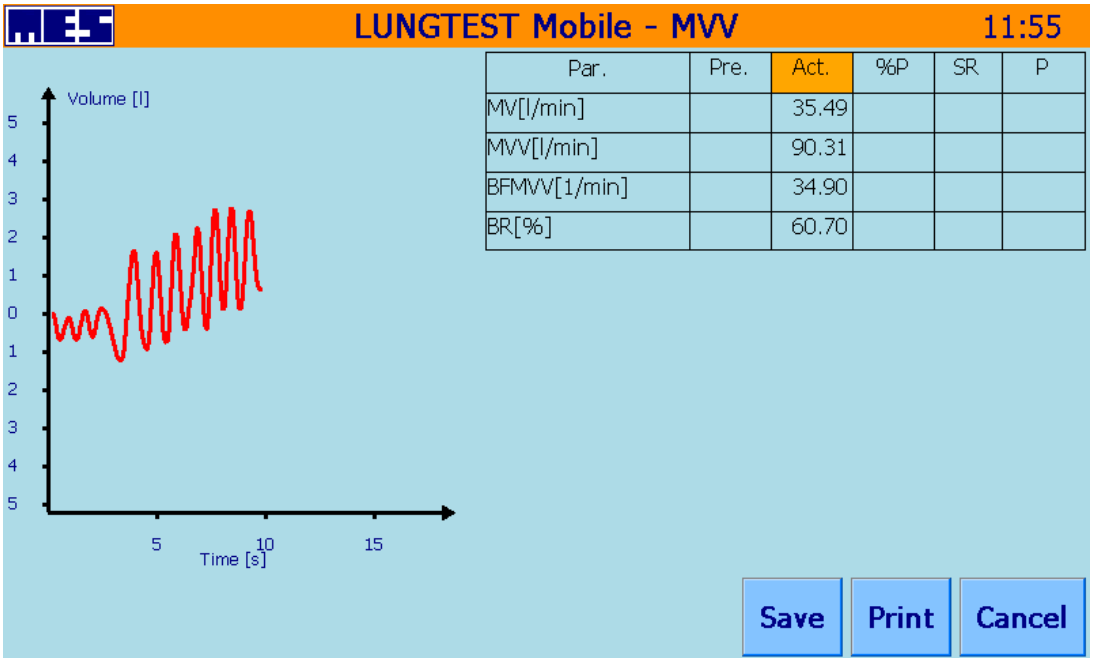



*Fig 31 Test results*

| **Parameter name:** | **Unit:** | **Description:** |
|---|---|---|
| MV | **L/MIN** | Minute ventilation |

| | | |
|---|---|---|
| MVV | **L/MIN** | Maximal voluntary ventilation |
| BF MVV | 1/min | Breath frequency during maximal ventilation |
| BR | % | Breath reserve |

### 3.4.4 Test settings

Test settings can be change from the Device option menu by pressing “MVV Settings” button. From the following screen chose desired maximal ventilation time and press “OK”

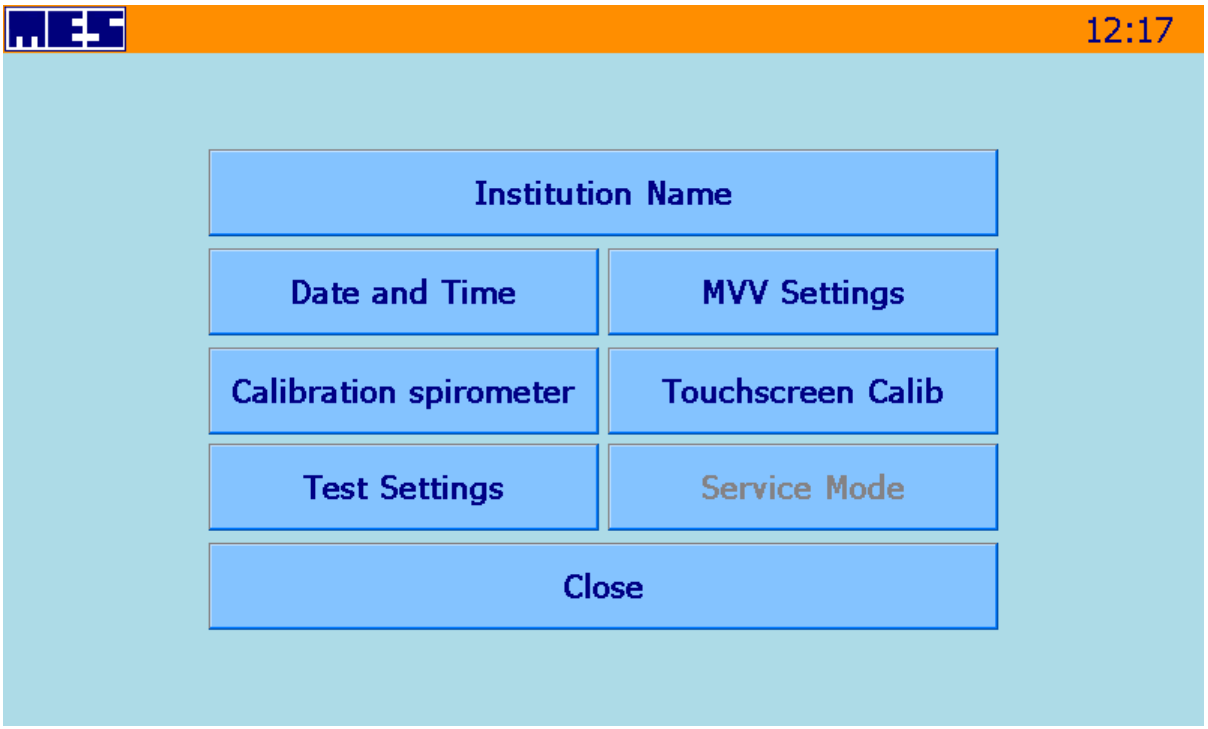



*Fig 32 Device options*

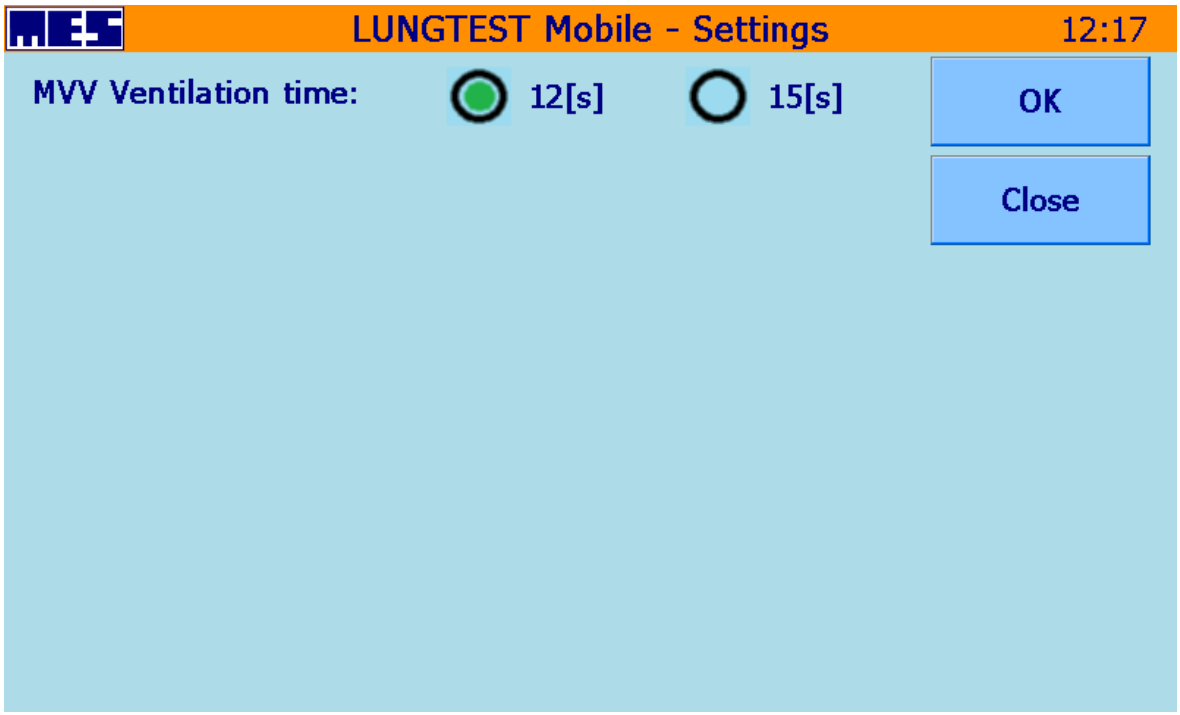



*Fig 33 MVV settings*

# 4 Patient Database

All recorded test results are stored in the patient database of the Lungtest Mobile spirometer. The database is displayed as a list of patients organised according to the times of entries in the database. A list of tests performed is assigned to each patient. The tests are identified using the dates and times of their completion.

Details of 1000 patients may be stored in the database, and the number of tests is unlimited. Once details of the 1000th patients are recorded, the database must be archived. The Lungtest Mobile Backup program is designed to make backup copies of the database.

Features of the database:

1. Fast search and selection of the patient in order to complete another test
2. Preview and printout of tests completed for the selected patient
3. A comparison of 2 tests completed for the same patient and the assessment of a bronchial obstruction reversibility test, if performed previously
4. A comparison of more tests displayed as a trend

To access the patient database, select the “Manage Tests” button on the main screen of the Lungtest Mobile spirometer: Fig 6 The main screen of the Lungtest Mobile spirometer

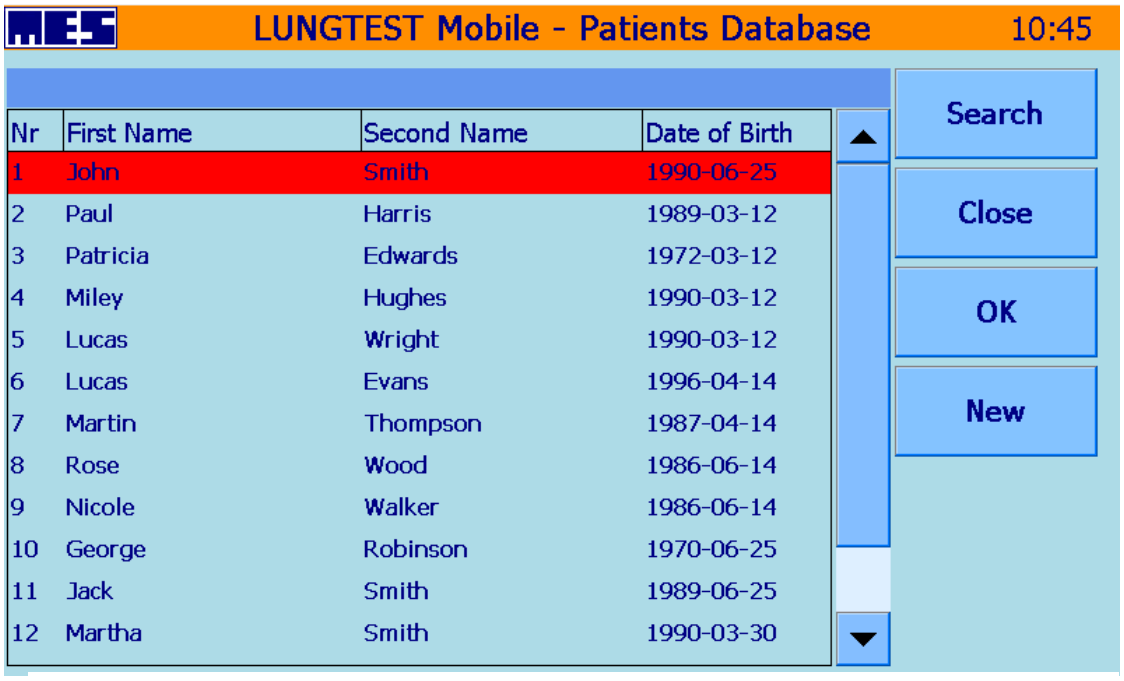



*Fig 34 The “Patients base” screen*

## *4.1* Finding a patient

The scroll bar may be used to search a patient. Drag the scroll thumb up or down to browse the list of patients. When the details of the searched patient appear on the screen, select the patient pressing the line with the patient's forename and surname. Cf. Fig 35 The patient search screen with an active edition field

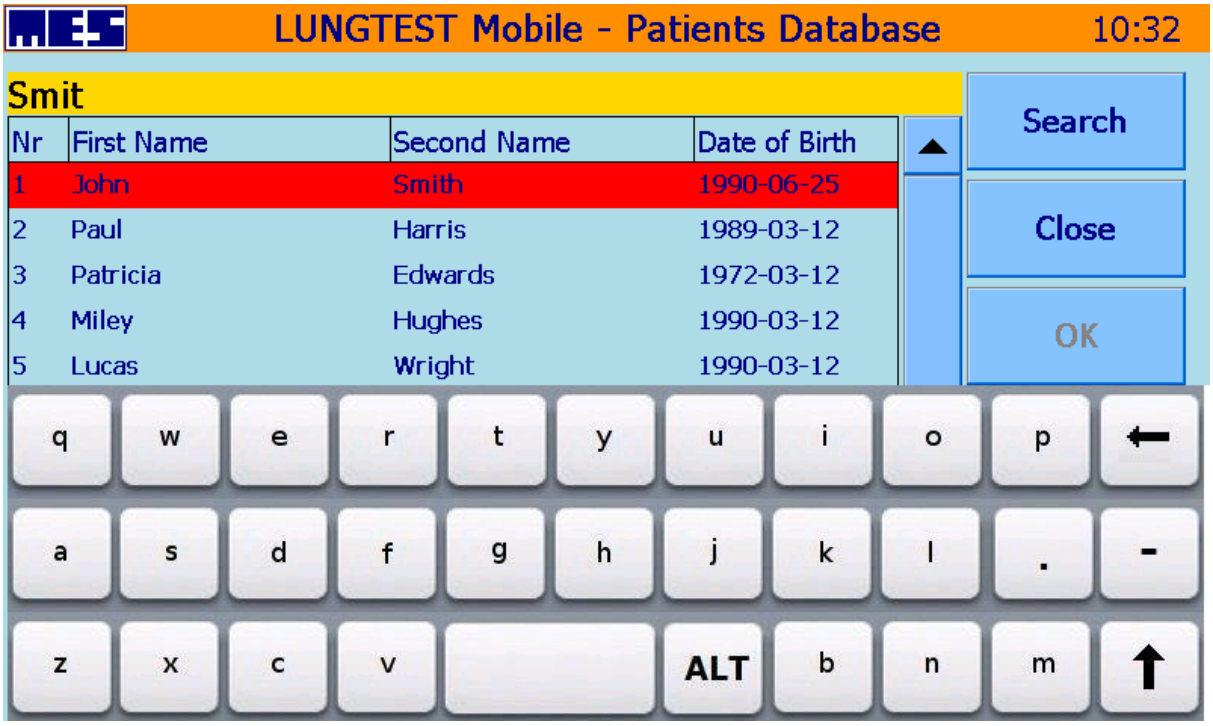



*Fig 35 The patient search screen with an active edition field*

Patients may also be found with the use of the automated function of name edition (full surname or its part may be entered). To this purpose:

- Press the edition field to activate it.
- Use the displayed keyboard to enter the searched patient's surname or its part.
- Press the "*Search*" button – a list will be displayed with patients whose names match the entered text.
- Now, you can select one of the patients – press the line with the patient's forename and surname.

Once the "New Test" button is pressed, the patient's data is instantaneously copied and a new test can be commenced.

Do not forget to update the patient's weight (and height if applicable).

## *4.2* Test preview and printout

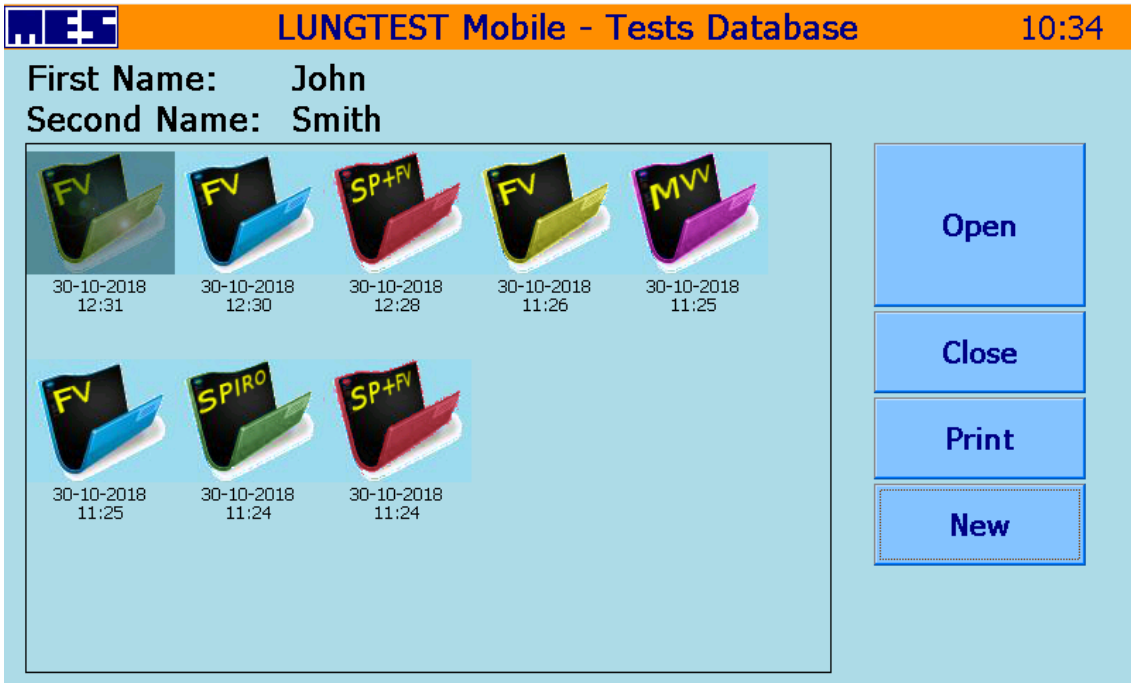



*Fig 36 The screen with a list of patient's tests and a selected test*

The test preview and printout are made possible once the list of tests for the selected patient is displayed. To display the list press the OK button on the "Patients base" screen (Fig 34 The "Patients base" screen), and then select the requested test.

The tests are identified by their types (SP – spirometry, FV – Flow-Volume, SP+FV a combined spirometry and Flow-Volume test) and by the dates and times of their completion.

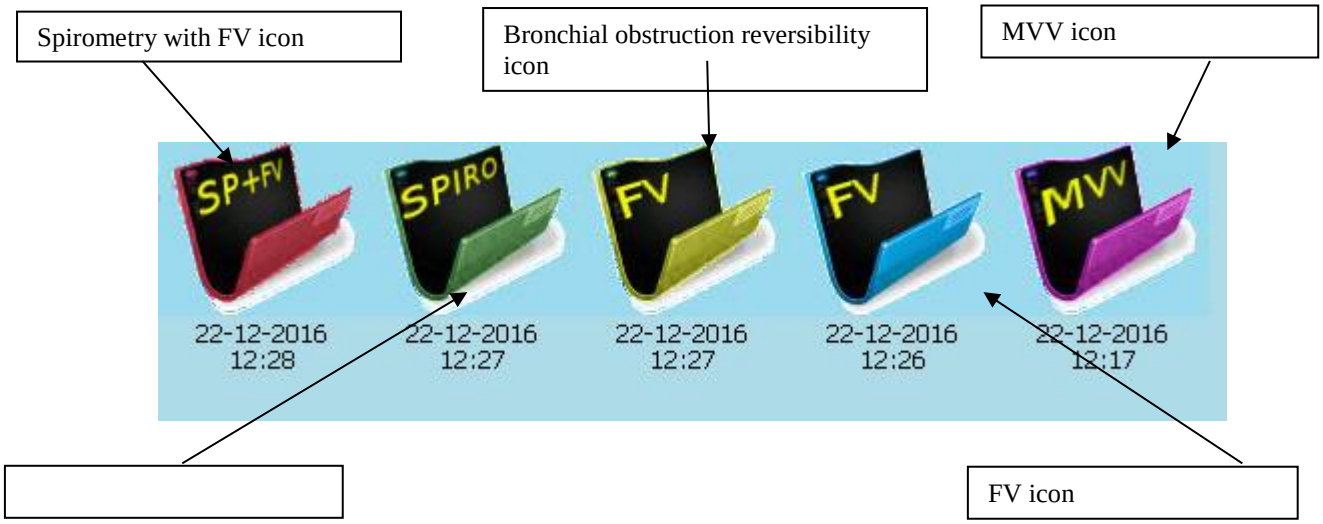



*Fig 37 The icons with test types*

The requested test is selected by clicking on the icon (the icon will be highlighted); the indicated test now has the status of a viewed test. Cf. Fig 36 The screen with a list of patient's tests and a selected test

To print the selected test, press the "Print" button; to view the test, press the "Open" button.
To abandon the marked test, press the test icon again. The highlighted background of the icon disappears, and none of the tests is marked.

The test is viewed using the same procedure as immediately after the test. The difference is that the "*Save*" button is replaced with the "*New*" button that enables the user to perform a new test for the viewed patient.

## *4.3* Compare tests

A comparison of tests consists in the calculation of changes in individual parameters included in a test type. The changes may also be displayed as a graph. The tests of the same type performed for the same patient may be compared.

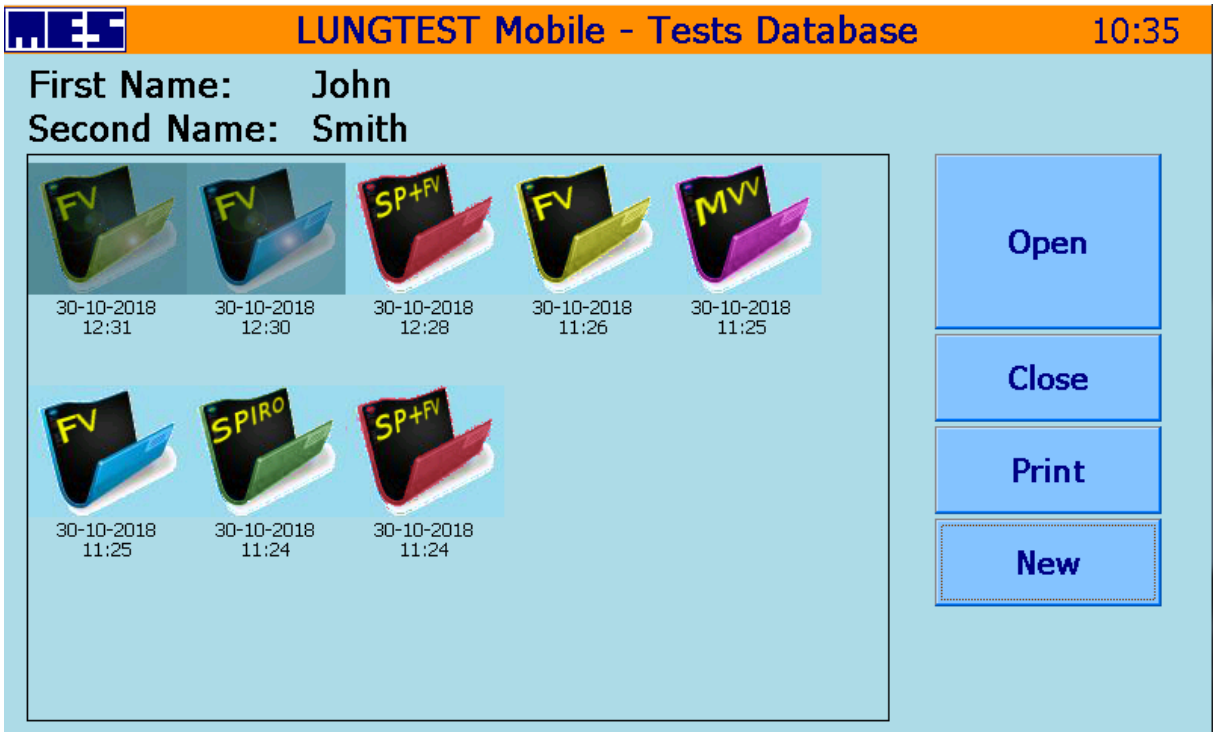
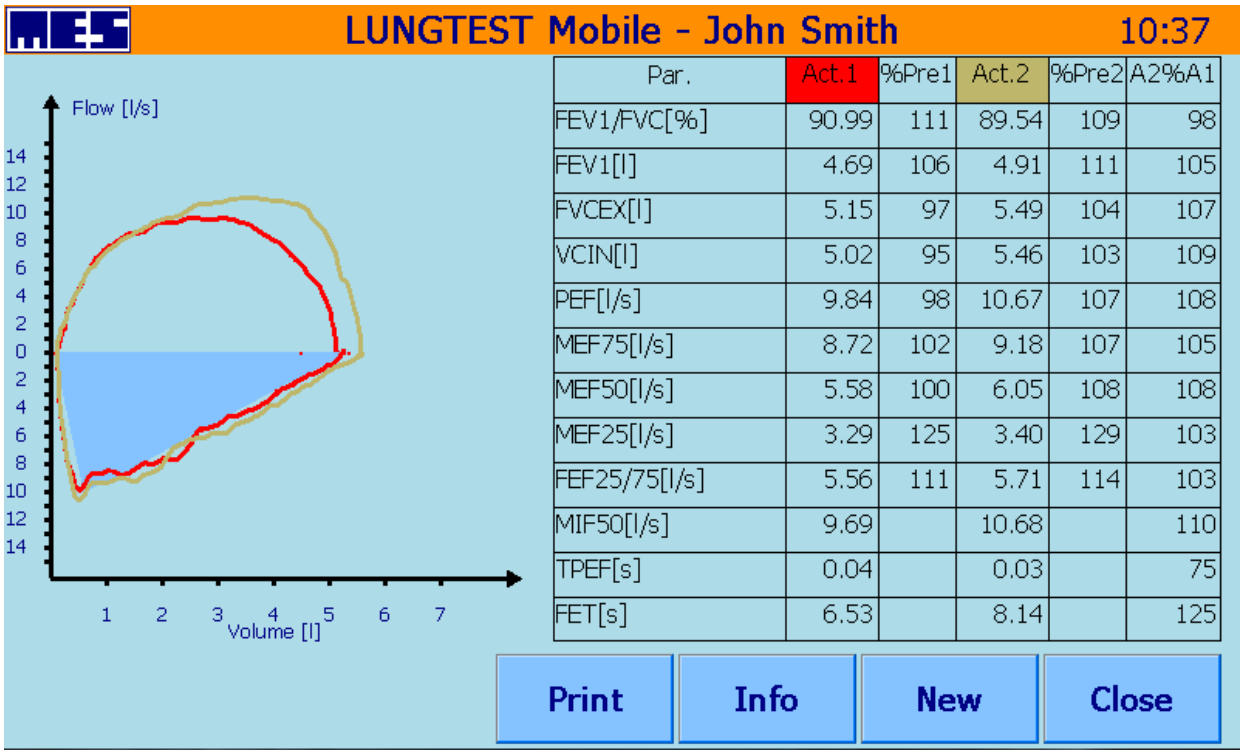



*Fig 38 A list of patient's tests with two selected tests*

To compare tests, mark two or more of them.
The tests must include the same parameters. This means that an SP spirometry and an FV test cannot be compared.

Once two tests are marked and selected using the "*Open*" button, the tests will be superimposed (on a graph) and a new column will appear in the table with parameters: A2%A1, defining the percentage change in the second test (performed on a later date) as compared to the first test (performed on an earlier date).

The picture contains two superimposed graphs generated during the selected tests.




| Par. | Act.1 | %Pre1 | Act.2 | %Pre2 | A2%A1 |
|---|---|---|---|---|---|
| FEV1/FVC[%] | 90.99 | 111 | 89.54 | 109 | 98 |
| FEV1[l] | 4.69 | 106 | 4.91 | 111 | 105 |
| FVCEX[l] | 5.15 | 97 | 5.49 | 104 | 107 |
| VCIN[l] | 5.02 | 95 | 5.46 | 103 | 109 |
| PEF[l/s] | 9.84 | 98 | 10.67 | 107 | 108 |
| MEF75[l/s] | 8.72 | 102 | 9.18 | 107 | 105 |
| MEF50[l/s] | 5.58 | 100 | 6.05 | 108 | 108 |
| MEF25[l/s] | 3.29 | 125 | 3.40 | 129 | 103 |
| FEF25/75[l/s] | 5.56 | 111 | 5.71 | 114 | 103 |
| MIF50[l/s] | 9.69 | | 10.68 | | 110 |
| TPEF[s] | 0.04 | | 0.03 | | 75 |
| FET[s] | 6.53 | | 8.14 | | 125 |

*Fig 39 A comparison of two Flow-Volume tests*

Press the field with the curves to switch between the Flow-Volume and volume-time coordinates – this feature is also available when viewing test results immediately upon its completion.

### 4.3.1 An assessment of bronchial obstruction reversibility test

A bronchial obstruction reversibility test (post-bronchodilator or bronchodilator response test) consists in the performance and comparison of two Flow-Volume tests. The following conditions must be fulfilled for the obstruction reversibility test to be assessed by the Lungtest Mobile spirometer:

- - the tests must be completed on the same day
- - test 2 performed after administration of a drug must be executed by the “Bronchodilation test” button (Fig. 2.10.) “Choose test type” screen.

To interpret the tests as a post-bronchodilator test, they must be compared (4.3 Compare Tests). Once the tests are compared, press the *“Info”* button. If the selected tests fulfil the conditions described above, an active “*Bronchodilator”* button will appear. Cf.

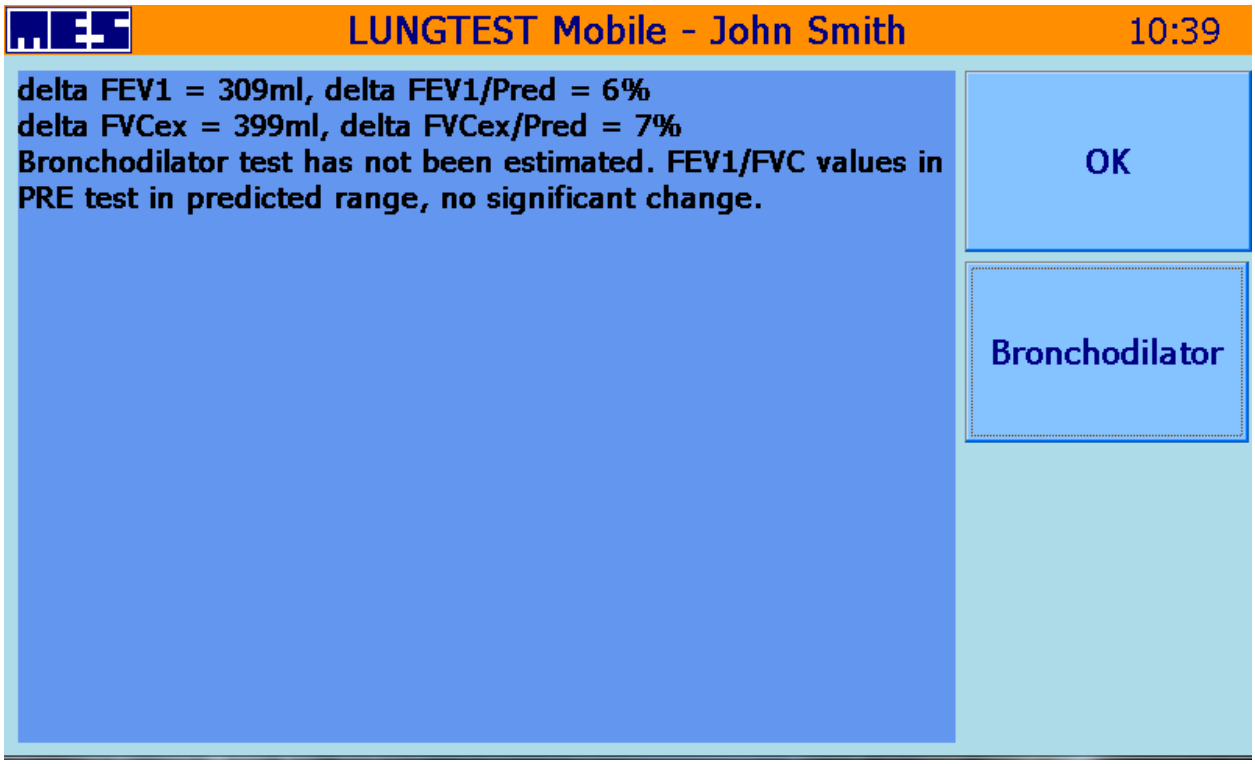



*Fig 41 Info screen with the possibility of evaluating the diastolic test*

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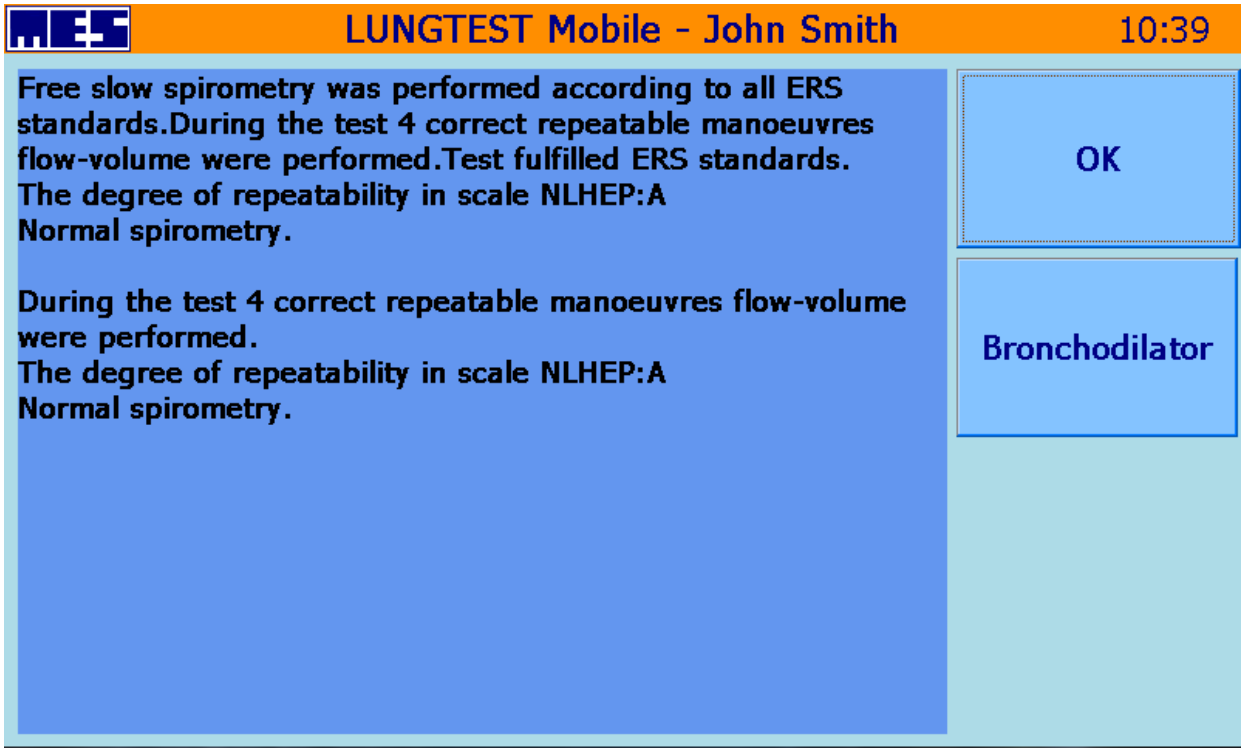


*Fig 40 The Info screen with available assessment of obstruction reversibility test*

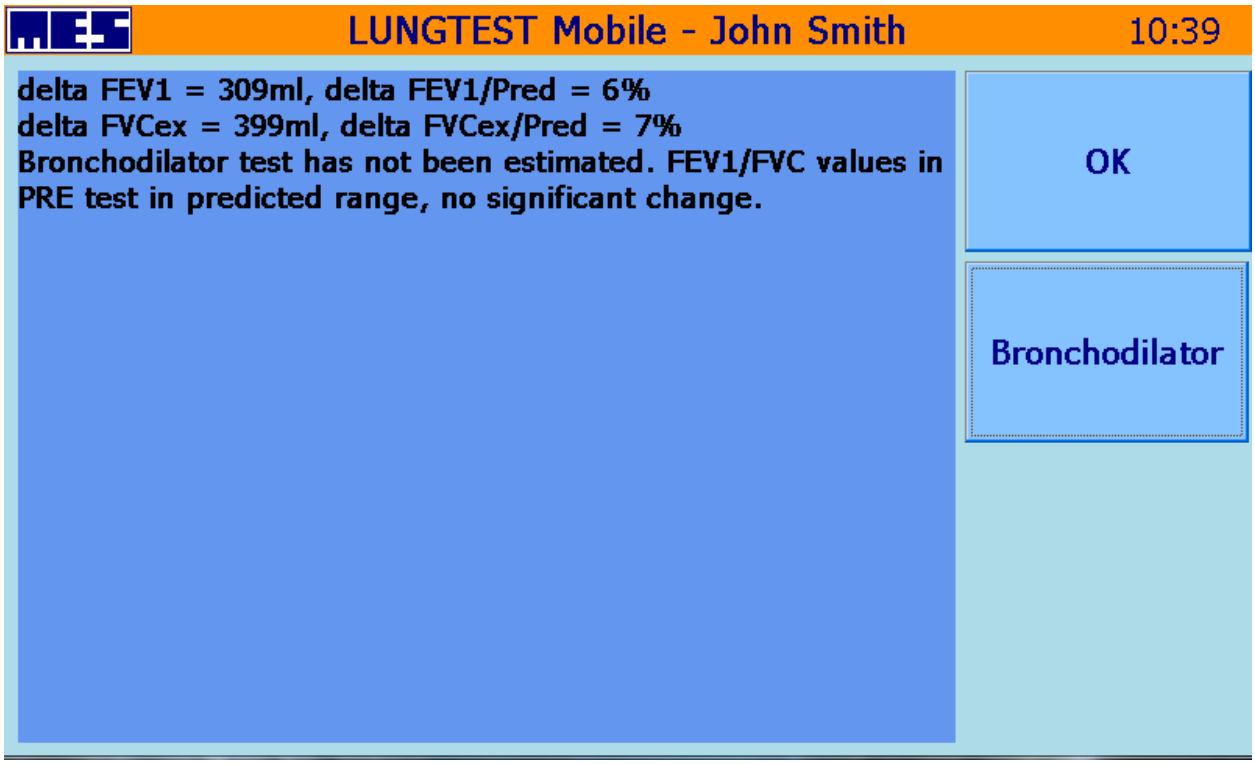


*Fig 41 Info screen with the possibility of evaluating the diastolic test*

Once the button is pressed, the computer-generated comment to the obstruction reversibility test is modified.

**The Bronchodilator function may only be used for actually performed bronchial obstruction reversibility tests.**

### 4.3.2 Comparison displayed as a trend

The comparison of a larger number of tests includes the calculation of changes in selected parameters, the presentation of these changes in a table and on a trend graph. The results of test comparisons may be saved and printed, similarly to test results.
The comparison is made using the following method:

- Mark more than 2 tests of the same type on the list of tests performed for the selected patient. Confirm the selection pressing the "*Open*" button.
- Select not more than 4 from the list of available parameters, pressing the colour field with parameter description, and press the *"Plot"* button. Cf. Fig 42 Select parameters for comparison
- A graph presenting the selected parameters will be displayed.
- The horizontal axis indicates the tests with the times of their completion. Parameter values, referred to the Y axis, show percentage changes of parameters as compared to the first test with the earliest completion time. Cf. Fig 43 Trends in selected parameters

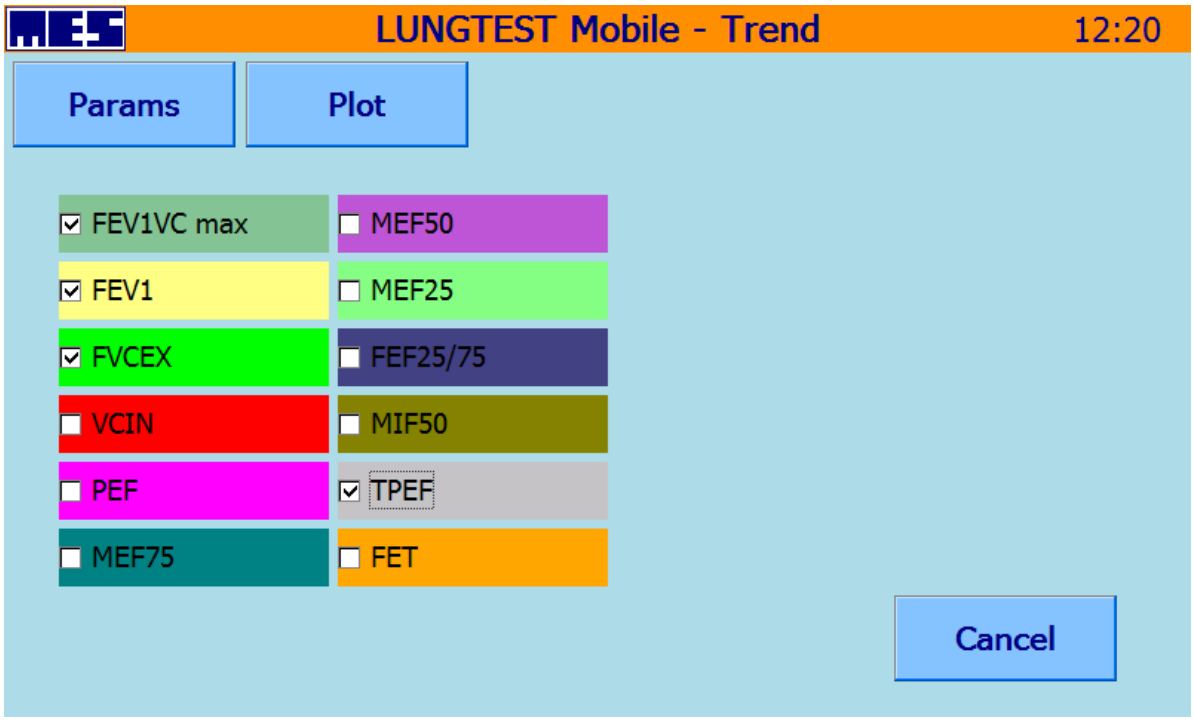


*Fig 42 Select parameters for comparison*

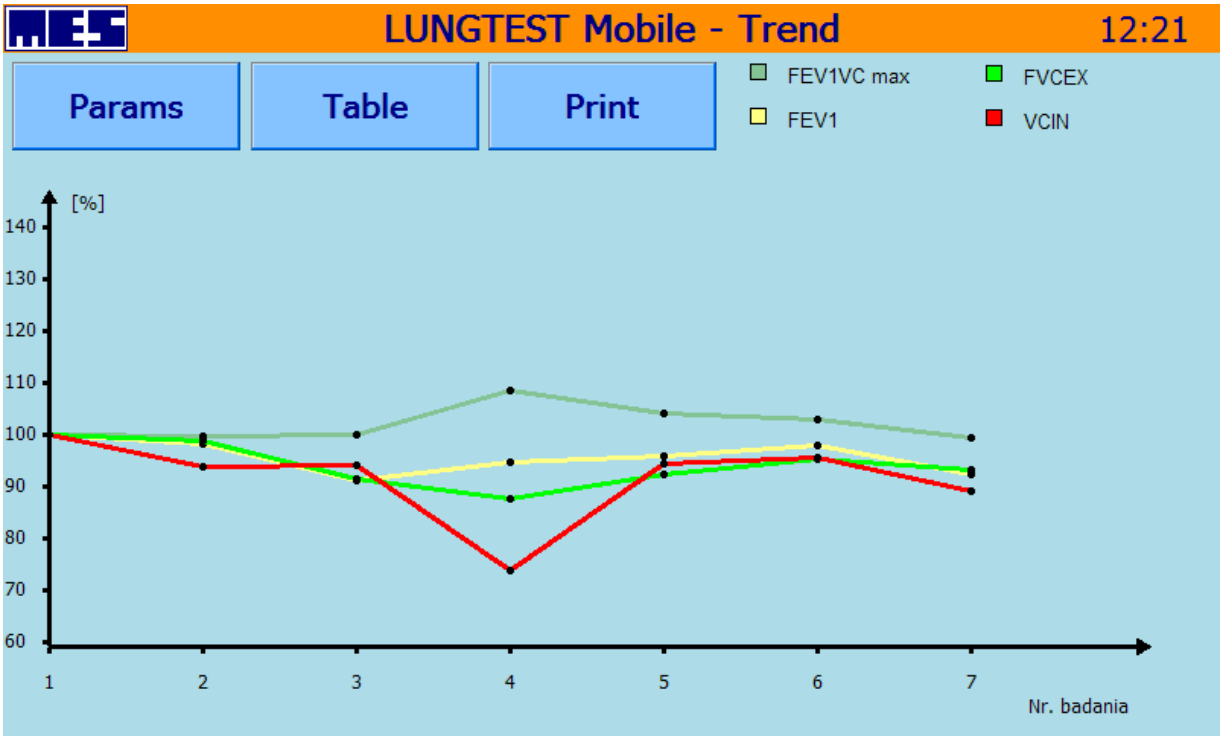


*Fig 43 Trends in selected parameters*

The "*Table*" button is used to view a table that presents changes in parameters Fig 44 A table presenting trends in selected parameters


| Nr/Dates | | FEV1VC max | | FEV1 | | FVCEX | | VCIN | |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 18-04-2012 07:49 | 85.24 | 100 | 4.25 | 100 | 4.98 | 100 | 4.82 | 100 |
| 2 | 18-04-2012 08:22 | 84.89 | 100 | 4.18 | 98 | 4.92 | 99 | 4.52 | 94 |
| 3 | 18-04-2012 09:42 | 85.13 | 100 | 3.88 | 91 | 4.56 | 92 | 4.53 | 94 |
| 4 | 18-04-2012 09:46 | 92.58 | 109 | 4.03 | 95 | 4.36 | 88 | 3.56 | 74 |
| 5 | 18-04-2012 10:17 | 88.79 | 104 | 4.08 | 96 | 4.60 | 92 | 4.55 | 94 |
| 6 | 18-04-2012 10:47 | 87.82 | 103 | 4.16 | 98 | 4.74 | 95 | 4.61 | 96 |
| 7 | 18-04-2012 11:05 | 84.73 | 99 | 3.93 | 92 | 4.64 | 93 | 4.30 | 89 |

*Fig 44 A table presenting trends in selected parameters*

*"Params"* press this button to return to the parameter selection screen
"*Print*" press this button to print the trend graph and the table with the parameters

If the number of selected parameters exceeds 2, parameter changes are presented on separate graphs.

# 5 Settings

The Settings functionality is available from the main screen of the spirometer, and activated with the use of the “Settings” button.
This functionality includes a series of commands designed to configure the operation of the spirometer.
The commands are used rarely, or even only once during the installation of the spirometer.
The commands are displayed on the “*Settings*” screen, cf.Fig 45 The "Settings" screen of the spirometer.

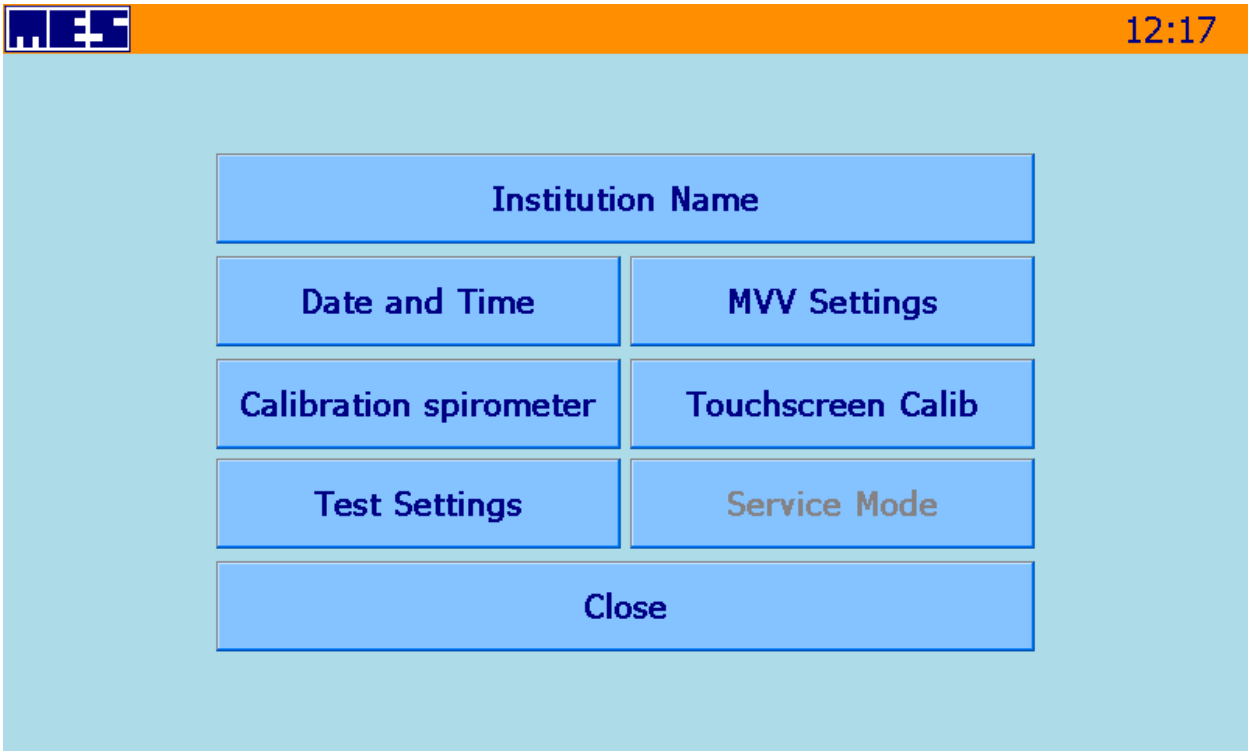


*Fig 45 The "Settings" screen of the spirometer*

## *5.1* Name of the institution

This screen is used to enter the name of the user. The name will appear in the heading of each printout.
The name is entered on the “Institution Name” screen in the field with a yellow background. 5 text lines may be entered.


*Fig 46 Enter institution details*

User details are entered with the use if two keyboards displayed: an alphabetic keyboard used to enter text and a numeric keyboard used to enter digits.
The buttons displayed on the screen offer the following features:

| | |
|---|---|
| *"123.."* | switch between the alphabetic and the numeric keyboards |
| *"OK"* | accept entered text and exit the "Institution Name" function |
| *"New Line"* | continue edition in a new line |
| *"Clear"* | delete all entered details |

## *5.2* Date and time

This function is used to adjust the date and time displayed by the spirometer.

**All tests recorded in the database of the spirometer are identified using the set date and time. The date set in the spirometer is used to calculate the age of the patient and affects the norms and diagnosis.**

Date and time are set on the screen shown on Fig 47 The "Date and Time" screen used to change the date and time on the spirometer

Adjust the entries in the relevant fields marked with labels, using the numeric keyboard.
Press subsequent editable fields to select them or use the following buttons:

| | |
|---|---|
| *"Next"* | press to select subsequent editable fields |
| "*OK*" | press to accept entered changes |
| *"Close"* | press to ignore entered changes |

If an erroneous value is entered, the error is indicated by a red background in the value field.


*Fig 47 The "Date and Time" screen used to change the date and time on the spirometer*

## *5.3* Calibration of the spirometer

The Lungtest Mobile spirometer does not require daily calibration. In exceptional cases, the "Calibration" function may be used to check measured values of volume, and correct them if necessary.

**The user, when calibrating the device, accepts responsibility for calibration results and must be prepared for measurement errors, if the calibration is not precise enough. The manufacturer does not recommend that calibrations of the spirometer be completed outside the service network of the manufacturer.**
**The manufacturer recommends that calibration of the spirometer be completed once a year by the manufacturer's service. Each calibration of the spirometer is confirmed by a calibration certificate.**

Calibration is done using a 3L calibration syringe. The syringe is connected to the spirometer through the pneumotachographic head using a rubber adapter.

Before the syringe is used, check the validity of the calibration certificate of the 3L syringe.

To initiate the calibration procedure:

- Press the "*Start"* button and wait until the reset process ends.
- Commence uniform, regular movements with the calibration syringe; avoid excessive knocking in the syringe walls.
- Once 10 regular, measured movements are completed, the spirometer will interrupt the procedure and display the calibration results.

The remaining buttons offer the following functions:
The "Stop" button: discontinue calibration

The “Save” button: used to record calibration results. The button is not available until the calibration process is completed
The “Close” button: closes the dialogue window

If the window is closed after calibration without pressing the “Save” button, the results of calibration will be lost.

The calibration results may be printed as a report on the thermal printer.

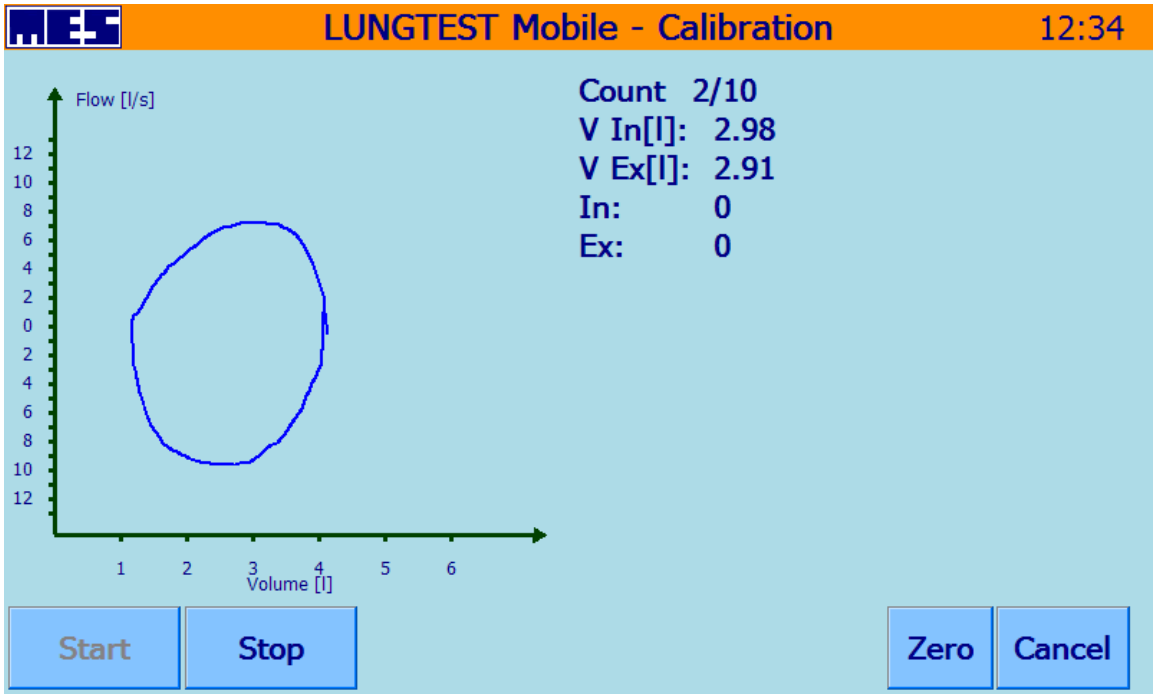


*Fig 48 The calibration screen of the Lungtest Mobile spirometer*

## *5.4* Test Settings

The “Test Settings” function lets the user to change some features listed below:

- Plot orientation:
  1. Exhalation section on the top
  2. Exhalation section on the bottom
- Automatic test interpretation:
  To change the presentation mode, mark the required option “Auto Estimate Test” on the screen shown on Fig 45 The "Settings" screen of the spirometer
- Printer:
  Possibility of choosing prefered printing device.
- Norms:
  Gives a possibility of choosing the predicted value system according to which the test will be interpreted
- Set Race:
  Possibility of setting the subject’s race

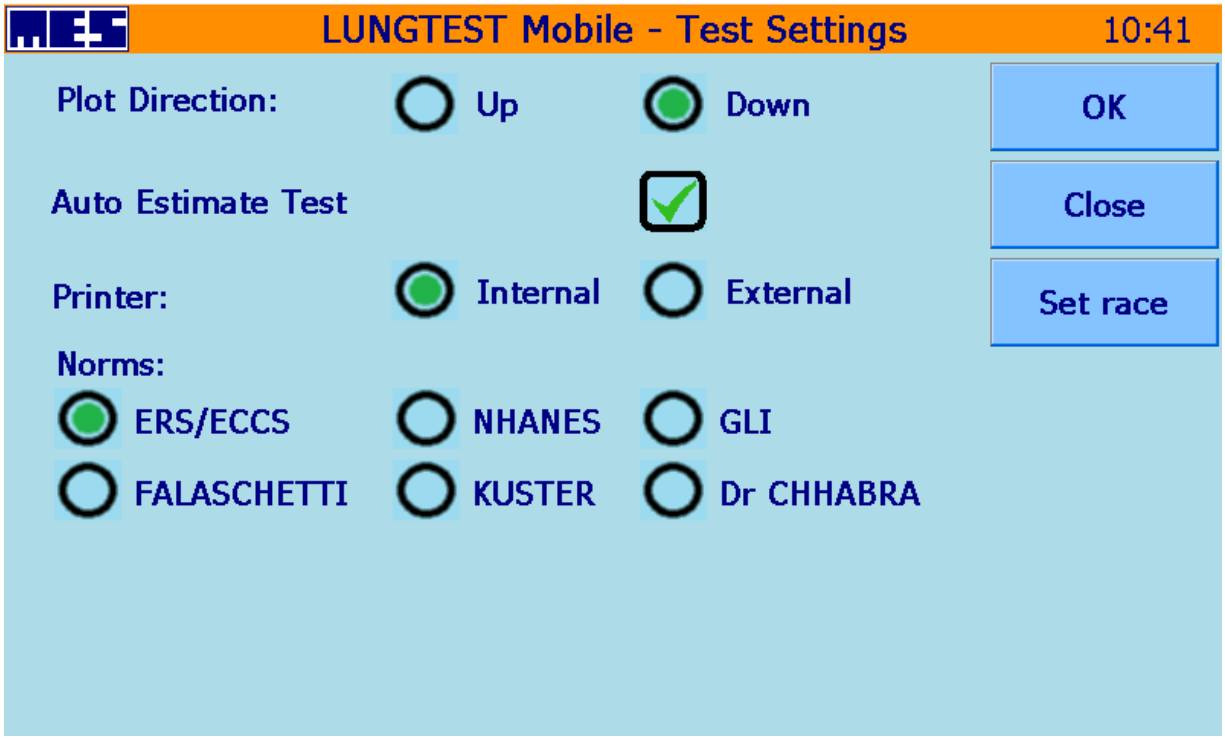


*Fig 49 The Test Settings screen*

## *5.5* Screen calibration

Screen calibration should be done when there is a distinct inconsistency between the point pressed and the activated button or key on the LCD screen or when pressed button fails to initiate a function.

Once the "Screen Calibration" option is selected, a screen with a target on a bright background is displayed.

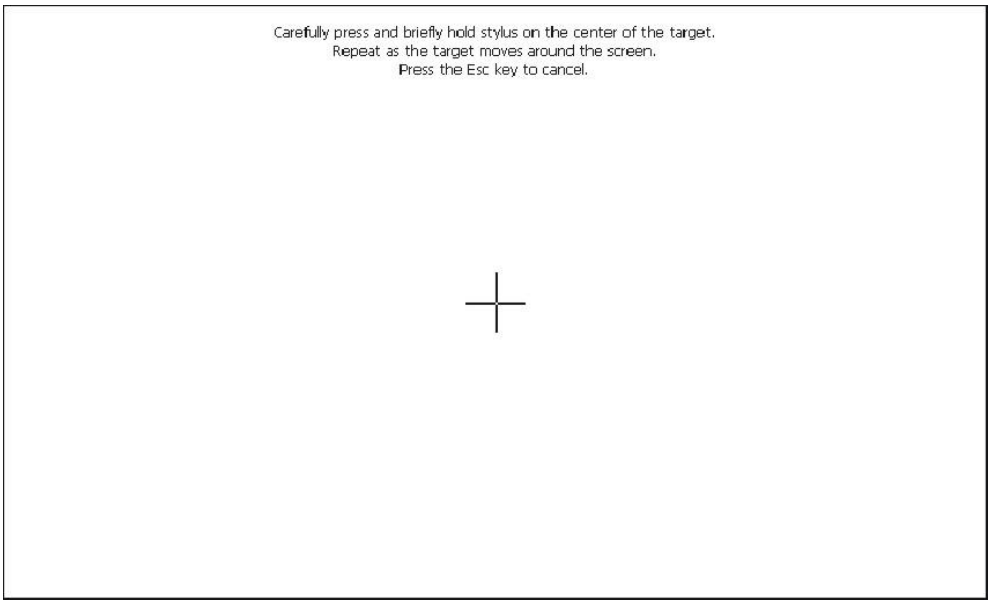


*Fig 50 LCD screen calibration window*

To calibrate the screen

1. Point the centre of the target with the stylus and hold it until the target moves to the left top section of the screen.
2. Point the centre of the target again and repeat the step for all corners.
3. Once the target disappears, the calibration process is completed. Press “Enter” in the text displayed in the top section of the screen to confirm calibration.
4. To cancel calibration results, press “Esc”,

# 6 Electromagnetic Compatibility. Manufacturer's instructions and declarations

The product meets the requirements of the EN 60601-1-2 electromagnetic compatibility directive.

Medical electronic equipment requires special precautions regarding EMC. The product requires installation and servicing in accordance with the EMC information provided below. Portable and mobile RF communications equipment (e.g. cell phones) can affect medical electronic equipment.

The product complies with CISPR 11, Class A, Group 1. RF emissions are very low and are not likely to cause any interference with nearby electronic equipment.

The motors used in the product design comply with CISPR 14-1

The product meets the following requirements:

**EN 55011** Interference voltages
150 kHz to 500 kHz (66 µV average / 79 µV peak) and 500 kHz to 30 MHz (60 µV level) average / 73 µV peak).
The limits for the average values were not exceeded. Peak values below average. Positive result.

**EN 55011** Radio frequency emissions
30 MHz to 230 MHz level 40dB (µV) quasi peak and 230 MHz to 1000 MHz level 47dB (µV) quasi peak.
The limits have not been exceeded. 90 cm test distance. Positive result.

**EN 61000-3-2** Harmonic emissions
Maximum RMS value. Harmonics 1-40.
for voltage of 230.59 Vms; THD = 0.03%; THV = 0.067V; POHV = 0.007V; PWHD = 0.03% for the current of 9,270 Ams; THD = 19.33%; THC = 1.759A; POHC = 0.051A; PWHD = 8.06% power factor 0.607; cosPhi = 0.618 Positive.

**EN 61000-3-3; EN 61000-4-15** Voltage fluctuations and flicker
Limits: Pst 1,000; Sliding 0.650; Tmax 0.500s; I have 6,000%
Result: Pst 0.006; Sliding 0.006; Tmax 0.000s; I dm 0.000%
Positive result.

**EN 61000-4-2** Immunity to electrostatic discharge ESD ± 8 kV contact / ± 15 kV air. Positive result.

**EN 61000-4-3** Radio frequency / electromagnetic fields 80 MHz - 2700 MHz (healthcare environment limit 3 V / m, H / V polarization) RF wirless communication 358 MHz - 5785 MHz Successful.

**EN 61000-4-4** Fast transient EFT / Burst ± 2 kV / 100 kHz. Positive result.

**EN 61000-4-5** Immunity Surge
0.5 kV; 1 kV / 2 kV. Positive result.

**EN 61000-4-6** Conducted RF 150 kHz to 80 MHz / 3V RMS and 6V RMS
**IEC 61000-4-8** Magnetic field immunity for 50-60 Hz power frequency. X-Y-Z polarization 30 A / m. Positive result.

**EN 81000-4-11** Resistance to voltage drops, drops and dips 230V / 50 Hz. Positive result.

**EMC information**
Meeting the requirements for electromagnetic compatibility depends on the following requirements:

- The product is intended for indoor use only, in hospitals, clinics and similar.
- The product must be connected to an earthed power supply network.
- Use the supplied power cord that is permanently connected to the electrical system.
- Keep a distance of not less than 30 cm from other electronic and radio devices.
- The operator cannot use cell phones during the procedure, and third parties should not be in the immediate vicinity of the product.
- The product is safe for other medical devices.
- Do not place other medical and non-medical electrical devices on top of the device.

The full EMC test report is available on request at the manufacturer's premises.

# 7 Error detection and recovery

## *7.1* The device does not turn on

- Check the mains voltage by an authorized person.
- If the device does not turn on, check the connection of the power cord to the spirometer. The cable provided with the device by the manufacturer should be used. If the cable shows any signs of damage, replace it immediately with a new one.

## *7.2* Incorrect connection of the measuring transducer with the lead

- Check that the transducer is properly connected to the spirometer. When connecting, you should hear a characteristic "click". If it did not, try to reconnect.
- Patient cable - in the case of spirometers using an air line with PVC tubing, remember that the tubing with the black band is connected to the stub with the black mark.

## *7.3* The touch screen is not working properly

- When touching the touchscreen is not diagnostic when operating the spirometer, restart the touchscreen calibration (explanation in section 5.5 Touchscreen calibration)

## *7.4* Incorrect calibration of the spirometer

- Calibration factors outside the acceptable range - check the calibration pump and the pneumotach head used to calibrate the spirometer.
- Calibration should be performed with a calibration pump that has a valid certificate.

## *7.5* Abnormal test result

- If the test result is incorrect (assuming the test was performed correctly), check:
  - Head connection (handle held by the patient) - check if the hook (head latch) is not damaged. Performing tests with a broken head catch is incorrect, because due to the leakage between the head connectors and sockets in the head holder, the measured pressure values are significantly reduced, and thus the measured flows are underestimated.
    If you try to suddenly close the head hook when the head is installed incorrectly, the head hook may break.
  - The pneumotach head - does not have any signs of mechanical damage, does not contain liquid inside the nozzles. In this case, replace the head with a new one.
  - Patient's mouthpiece - the mouthpiece should be connected in accordance with the connection diagram (sticker) located on the handle held by the patient. Performing the test with the mouthpiece on the wrong side causes the inhalation and exhalation to swap.
  - Incorrect zeroing before the test - during the zeroing, the head with the handle should rest still, under the supervision of the spirometer service. Under no circumstances should the patient hold her. No air stream should flow through the head (watch out for the fans). When the spirometer is reset, the initial measurement conditions are established. The correctness of its implementation has a large impact on the result and quality of the test.

If in doubt whether the spirometer has been properly reset, use the "reset" button.

- If the above suggested solutions do not solve the problem with the test result, contact the MES service.

## *7.6* The machine does not print or the printout is unreadable

- Connection problem:
  - When printing on an external printer, check the correct connection of the spirometer to the printer. If the USB cable shows signs of damage, replace it immediately with a new one.
  - Check the selection of the printer that is currently in use (selection in the settings between external and internal printer)
- An illegible printout may occur in the event of mechanical damage to the internal printer mechanism. In this case, contact the MES service.,

**If there is any problem not described above, please contact the MES service.**

## *7.7* Potential risks and errors of using the Lungtest Mobile spirometer

### 7.7.1 During normal use:

- One of the test leads is disconnected.
- Incorrectly connected transducer
- Reverse connection of the mouthpiece to the measuring head.
- No nose clip.
- No forced and rapid exhalation.
- Patient stopping exhalation prior to the inhale command.

### 7.7.2 Resulting from user error:

- Incorrect values of atmospheric conditions.
- Incorrect patient parameters and, consequently, incorrect selection of due values.
- Lack of control and communication with the patient.
- Re-use of the mouthpiece and head after another patient.
- Performing the test on the patient without 15 minutes of rest.
- Placing the patient's head at the wrong height.
- Failure to maintain the correct position during the test.
- Lack of training and ignorance of the operating instructions.
- The service does not supervise the examination - conversation with another person, telephone conversation, etc.
- The device has not been calibrated annually.

### 7.7.3 Resulting from the working environment:

- The room is smoky.
- The room is very cold.
- The room is noisy and makes it impossible to communicate properly.
- The flow through the measuring head may be disturbed by a running fan.

### 7.7.4 Patient related:

- The patient did not report smoking.
- Before the examination, the patient did not stop taking drugs that affect the test result.
- The patient ate less than 2 hours prior to the test.

- The patient's dress is too tight.

### 7.7.5 Related to readability:

- The screen is illuminated directly by sunlight or other strong light source.
- No user manual.

### 7.7.6 Related to hygiene:

- Lack of proper product cleanliness.
- No disinfection of accessories.
- The patient is sick (coughing, haemoptysis, dizziness, difficulty concentrating).

### 7.7.7 Result of dangerous situations and possible damage:

- Failure to follow the rules of disinfecting mouthpieces and heads. Possibility of transferring diseases to another patient.
- Power cord damaged. Electric shock possible.
- Flooding the inside of the device with liquids. Possible damage.

## *7.8* Misuse scenarios E

| Nr | Usage error function E | Effect |
|---|---|---|
| E-1 | Reverse connection of the mouthpiece to the head | Possibility to swap inspiration and exhalation |
| E-2 | One test tube is disconnected | Very low flow signal |
| E-3 | Incorrect weather conditions | Distortion of measured values |
| E-4 | Incorrect patient parameters | Incorrectly calculated due values affect the possibility of making a wrong diagnosis |
| E-5 | Reuse the mouthpiece and head after another patient | Possibility of patient infection. No effect on test result |
| E-6 | Performing the test on a patient without a nose clip in place | Underestimated values of the measured lung capacity lead to misdiagnosis |
| E-7 | Performing the examination with the head lowered | Understated values of the measured flows lead to a wrong diagnosis |
| E-8 | Conducting a stressed flow-volume curve study with no required pause between strenuous maneuvers | This leads to patient fatigue and a reduction in the measured flow rates and volumes |
| E-9 | Perform more than 8 studies of the intensity flow-volume curve | This leads to patient fatigue and a reduction in the measured flow rates and volumes |
| E-10 | Perform the test in tight clothing | Underestimated values of the measured lung capacity result in a misdiagnosis |
| E-11 | Performing the test without a properly shaped mouthpiece | Underestimated values of the measured lung capacity result in a misdiagnosis |
| E-12 | Performing the test on the patient without 15 minutes of rest | This leads to patient fatigue and a reduction in the measured values of flows and volumes, and thus leads to misdiagnosis. |
| E-13 | Failure to read the operating instructions | Giving incorrect instructions to the patient, leading to erroneous test results |

## *7.9* Abnormal Use Scenarios A

| Nr | Misuse function A | Effect |
|---|---|---|
| A-1 | No calibration within the specified period of time | The possibility of distorting the measured values of the flow rates and lung volumes leads to an incorrect diagnosis |
| A-2 | Incorrect disinfection of mouthpieces and heads | Infection of the patient's respiratory tract and / or damage to the measuring elements, thus obtaining erroneous results |
| A-3 | No head change after patient | Infection of the patient's respiratory tract |
| A-4 | Turning on the device flooded with water | Damage to the device and exposure of personnel and patients to electric shock |
| A-5 | Switching on the device with a clearly damaged power cord | Exposure of personnel to electric shock |
| A-6 | Performing an examination with a broken head holder latch | Underestimated values of the measured lung capacity result in a misdiagnosis |
| A-7 | Performing an examination with a mechanically damaged pneumotach headpiece | Underestimated values of the measured lung capacity result in a misdiagnosis |
| A-8 | Performing a test with a wet pneumotach headpiece | False values of the measured lung capacity result in a misdiagnosis |
| A-9 | Switching on the device immediately after storing it in very low, negative temperature, e.g. in the trunk of a car in winter | Damage to the device and exposure of personnel to electric shock |
| A-10 | Performing the test in a room with high drafts. | False values of the measured lung capacity result in a misdiagnosis |
| A-11 | Washing the device with plenty of water | Exposure of personnel to electric shock |

# 8 Cleaning, disinfection, Sterilization

## *8.1* MES DV40 Pneumotachograph Headpiece

*Fig 51 MES DV40 Pneumotachograph Headpiece*

### 8.1.1 Preparing for sterilization and disinfection

Cleaning, disinfection and sterilization of accessories connected during the test may only be performed after prior disconnection. All elements such as the mouthpiece, RRS shutter, air filter, etc. should be disconnected from the pneumotachograph headpiece.
After disassembly, the pneumotachograph headpiece should be placed in a container with washing liquid to remove protein residues, then rinse thoroughly in cold water. They should be thoroughly washed after each examination. All foreign bodies and visible dirt should be removed with a soft brush.

### 8.1.2 Sterilization

Before sterilization, the pneumotachograph headpieces must be clean and free of protein residues, dry and free of foreign bodies in the baffle orifices. Pneumotachograph headpieces can be sterilized by gas, plasma, steam and in an autoclave at a temperature of up to 121ºC for 15 min (for devices purchased after March 31, 2003 and older. Also for headpieces and mouthpieces replaced with new - transparent - ones made of polypropylene heat resistant) and high-quality disinfectants accessible on the market.
After gas sterilization with ethylene oxide at a temperature up to 54ºC, the headpieces should be allowed to degass for at least 12 hours after vacuum pumps phase.

### 8.1.3 Disinfection

Washed and protein-residue-free headpieces should be placed in a container with disinfectant liquid for the time specified in the disinfectant fluid manufacturer's instructions.
After removing from the disinfectant liquid, headpiece should be rinsed in distilled water and then dried. In the case of drying with a stream of warm air, do not allow its temperature to be exceeded above 121ºC (for headpieces made of high temperature resistant polypropylene).

**Proposed disinfecants: GIGASEPT AF Forte, Sekusept Pulver, Sekusept Aktiv, Aniosyme DD1, Aniosept Activ, Perform**

**The guaranteed number of correctly made sterilizations for pneumotachograph headpieces is 10,000.**

**CAUTION!!!**

**Do not allow the pneumotachograph headpieces to be crushed by other ones, especially heavy and metal objects when sterilizing at high temperature up to 121ºC (for 15 minutes).**

**It should always be checked that the air passages of the pneumotachograph headpiece do not contain any liquid left after washing and sterilization. The air channels of the test head must be thoroughly dried !!!**

## *8.2* Mouthpieces for adult and children

*Fig 52 Mouthpieces for adult*

*Fig 53 Mouthpieces for children*

### 8.2.1 Preparing for sterilization and disinfection

Cleaning, disinfection and sterilization of accessories connected during the test may only be performed after prior disconnection. All elements such as headpiece, RRS shutter, air filter, etc. should be disconnected from the mouthpiece.
After disassembly, the mouthpiece should be placed in a container with washing liquid to remove protein residues, then rinse thoroughly in cold water. They should be thoroughly washed after each examination.

### 8.2.2 Sterilization

Before sterilization, the mouthpieces must be clean and free of protein residues, dry and free of foreign bodies in the baffle orifices. Mouthpieces can be sterilized by gas, plasma, steam and in an autoclave at a temperature of **up to 121ºC for 15 min** (for devices purchased after March 31, 2003 and older. Also for headpieces and mouthpieces replaced with new - transparent - ones made of polypropylene heat resistant) and high-quality disinfectants accessible on the market.
After gas sterilization with ethylene oxide at a temperature up to 54ºC, the mouthpieces should be allowed to degass for at least 12 hours after vacuum pumps phase.

### 8.2.3 Disinfection

Washed and protein-residue-free mouthpieces should be placed in a container with disinfectant liquid for the time specified in the disinfectant fluid manufacturer's instructions.
After removing from the disinfectant liquid, mouthpiece should be rinsed in distilled water and then dried. In the case of drying with a stream of warm air, do not allow its temperature to be exceeded above 121ºC (for mouthpieces made of high temperature resistant polypropylene).

**Proposed disinfectants: GIGASEPT AF Forte, Sekusept Pulver, Sekusept Aktiv, Aniosyme DD1, Aniosept Activ, Perform**

**The guaranteed number of correctly made sterilizations for mouthpieces is 10,000.**

**CAUTION!!!**
**Do not allow the mouthpieces to be crushed by other ones, especially heavy and metal objects when sterilizing at high temperature up to 121ºC (for 15 minutes).**

## *8.3* Nasal Clip (plastic one)

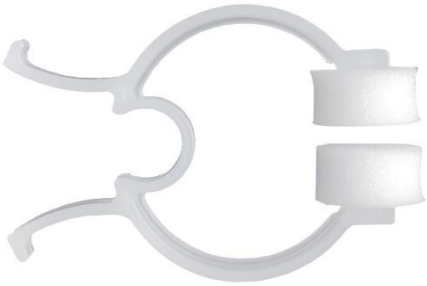

*Fig 54 Nasal Clip (plastic one)*

Disposable product

## *8.4* Nasal Clip (metal one) - reusable

*Fig 55 Nasal Clip (metal one) - reusable*

Reusable nasal clips can be sterilized by gas, ultrasound, radiation or high grade disinfectants accessible on the market.
The reusable nasal clip for high-grade disinfection should be placed in a container with washing liquid before disinfection to remove residual protein, and then thoroughly rinsed in cold water. Then it shold be placed in a container with disinfectant for the time specified in the disinfectant fluid manufacturer's instructions. After removing from the disinfectant liquid, the accessories should be rinsed in distilled water.

**Proposed disinfectants: GIGASEPT AF Forte, Sekusept Pulver, Sekusept Aktiv, Aniosyme DD1, Aniosept Activ, Perform**

**It is recommended to put disposable swabs on the nose under the clip clamps.**

## *8.5* Flow Transducer with a Cable


*Fig 56 Flow Transducer with a Cable*

We recommend periodically (e.g. every 6 months) sterilization of the transducer. (in cool condition, in ethylene oxide at temperatures up to 54ºC)
After gas sterilization with ethylene oxide at a temperature up to 54ºC, it should be allowed to degass for at least 12 hours after vacuum pumps phase.

## *8.6* Air Tube with Coupler


*Fig 57 Air Tube with Coupler*

We recommend periodically (e.g. every 6 months) sterilization of the air tube. (in cool condition, in ethylene oxide at temperatures up to 54ºC)

After gas sterilization with ethylene oxide at a temperature up to 54ºC, it should be allowed to degass for at least 12 hours after vacuum pumps phase.