Version 1.1

LUNGTEST Handy



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Congratulations!

Congratulations on selecting the Lungtest *Handy* spirometer. We hope it will meet your expectations as a high-class piece of equipment featuring the highest manufacturing quality and attention to detail. The device has been developed by a team of people who treat respiratory system functional measurements not only as a scientific field, but also as an opportunity to develop innovative equipment that extends measuring capabilities. The MES company has been manufacturing and selling spirometers for 15 years. Today we are introducing our latest product, the Lungtest *Handy*.

Definitions of symbols used throughout the text:



Warning against potential hazard resulting from the specific design features of the product and its intended use



Information about important features and capabilities of the product resulting from its specific design features and intended use



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1. Licence and warranty conditions

The licence allows you to install the Lungtest *Handy* device on one computer only. The spirometer is assigned to the computer on which it is installed by a unique digital code created during the first installation. Once installed, the spirometer will not work with any other computer. The spirometer is covered by a 12-month manufacturer's warranty which also includes hidden defects not visible on the day of purchase and potential software errors. The warranty does not cover mechanical failures and failures resulting from improper usage of the device.



WARNING!!!

In the case of problems concerning communication between the spirometer and the computer (USB connection error message), the USB plug should be removed from the computer slot and reconnected after 10 seconds.

2. Product technical specification

2.1 System description

The Lungtest system has been developed by the MES company's engineering team, who have many years of practical experience in the design and manufacture of pulmonary diagnostic equipment. The elements of the Lungtest system (Lungtest *Handy*, Lungtest 1000, Lungtest 1000S, Lungtest 1000SB, Rhinotest 1000, Lungtest 500, Rhinotest 500, Lungtest 250, Lungtest 250 Compact) have been welcomed with great interest as the most modern devices for spirometric and rhinomanometric measurements. The measuring head is the main novelty of our system. It eliminates all deficiencies of the diagnostic systems used so far for this purpose. Design of the measuring head is patent-protected as a proprietary MES design. We believe its parameters and functional advantages constitute a breakthrough in the field of spirometric measurements by making them more accurate and safer for patients.

The main functional advantages of our measuring head are as follows:

- 1) Each patient is examined using a sterile pneumotachographic measuring head,
- 2) Heads can be washed and sterilized as complete units, they do not require pre-heating,
- 3) Heads do not require user calibration since they are manufactured by injection moulding as complete units and therefore have repeatable parameters,
- 4) Head replacement is easy,
- 5) Heads do not have meshes or any other flow restrictors which may change parameters during measurement due to being contaminated by a patient's saliva,
- 6) The dead volume of the head is two times smaller than in other measuring heads,
- 7) The flow resistance of the head during regular respiration is four times smaller than in other heads. In the Lungtest system, **patients breathe practically in physiological conditions**, without any additional flow restrictors over their respiratory systems.

Technical specification

	L	
1)	Flow measurement range	+/- 18 l/s
2)	Flow measurement accuracy	< 2 %
3)	Flow measurement resolution	+/- 10 ml/s
4)	Measuring head resistance	0,9 cm H2O/l/s at a flow rate of 12 l/s
5)	Power supply	5V (from a PC USB port)
6)	Power consumption	<1W
7)	Dimensions	138 x 133 x 52 [mm]
8)	Weight (without computer and printer)	110 g
9)	Class of the device	II A

2.2 Pneumotachographic head

The pneumotachographic head is made by injection moulding. Parameters of all heads exactly repeatable. The head is attached to the measurement module by means of a holder. The head can be washed with commonly available washing agents; it can be also gas-sterilised. A clean head should always be connected before starting a new patient's examination and disconnected immediately after the measurement is made. A calibration check is not necessary after each replacement of the head. The heads maintain their parameters for as long as they are not damaged mechanically. The head may be deformed if subjected to temperatures above 138°C. Figure 2.1 shows the pneumotachographic head together with the mouthpiece and the holder.





Fig.2.1. Pneumotachographic head with a mouthpiece and a holder

Before the head is placed into the holder, the rotating part of the holder must be turned to the position shown in Fig. 2.2a, ensuring that the orientation of the stub pipe receptacles located in the upper part of the holder is like the one shown in the picture. Then the head is placed in the holder by gently pressing the stub pipes into the corresponding receptacles. Errorproofing against reversing the head is ensured by using stub pipes of different diameters. If the stub pipes cannot be inserted into their receptacles, rotate the head by 180 degrees, align the stub pipes with the corresponding receptacles and repeat the operation. The head should be pushed until a slight but detectable resistance is felt. After pressing the stub pipes into their receptacles, the upper part of the holder is rotated gently in the direction indicated in Fig. 2.2a until the locating pins of the holder are latched in the position shown in Fig. 2.2b.



Fig. 2.2. Installation of the pneumotachographic head

The mouthpiece is attached to the head following the picture on the holder (Fig. 2.1a). During the measurement, the pneumotachographic head should be held in the position shown in Fig. 2.2b.



2.3 Sterilisation

Pneumotachographic heads and mouthpieces can be sterilised by means of gas, steam, ultrasound, radiation, or sterilising fluids available on the market.



WARNING!!!

Washing, disinfection and sterilisation of measuring accessories attached for the time of measurement can be done only after disconnecting them from the device. The mouthpiece must be disconnected from the pneumotachographic head.

Procedure for the washing, disinfection and sterilisation of Lungtest pneumotachographic heads and mouthpieces in fluids

After measurement, the pneumotachographic head and the mouthpiece should be placed in a container with washing fluid in order to remove proteins and then carefully rinsed with cold water. Pieces freed from proteins should be placed in a container with disinfecting fluid for the period of time indicated by the disinfection fluid manufacturer's guidelines.

After removing the head and mouthpiece from the disinfecting fluid, they should be washed with distilled water and dried, or washed in ethyl alcohol and kept until the alcohol evaporates completely. When drying with hot air, the air temperature must not exceed 138°C. Recommended disinfecting agent: CIDEX Solution.



WARNING!!!

Pneumotachographic heads and mouthpieces can be gas- or steam-sterilised up to a temperature of 138°C.



3. Installing the software

3.1 Hardware requirements

- Operating system: RAM: Communication: Printer:
- Windows XP or Vista (32-bit)
- 256MB or more
- at least 2 free USB ports available
- ink-jet (colour) or laser printer

3.2 Installation





Connect the Lungtest Handy direct to the computer.



When the installation is finished, click "Finish". Run the Lungtest program from the Start menu. The first time the software is run, a message confirming successful activation of the spirometer should appear.

Next, run *setup.exe* from the attached CD. When the welcome screen appears, select "Next".

Spirometer c	alibration	Þ
Volume-	Calibration manoeuvres Count: 15 Unevenness: 1 %	Sa <u>v</u> e
	Calibration pump Capacity: 3.0 🛨 I	<u>C</u> lose <u>D</u> efault
	Calibration coefficients Ex 0.9782 In 0.9431	
EX	Even manoeuvres count	
Ente	er calibration parameters, then cli	ck Start

During the last step of the installation, the calibration data for the spirometer should be entered. During the first attempt to run the measurement, a calibration window appears. Select "Default" and click "OK" to confirm.



4. Basic information

4.1. How to operate the spirometer

Before running the software, confirm that the device is connected to the computer. After starting the software, the main screen of the program is displayed. First, enter the patient data. To do this, click the *New Patient* icon in the upper left corner of the screen. Precise rules for entering patient data are given later in the manual, however one should remember that the age and height of the patient must be entered properly to ensure correct interpretation of the results.

When the patient data have been entered correctly, his/her name is displayed in the upper bar of the program window. Now, one of three available test procedures can be selected on the screen. Buttons corresponding to these procedures are located on the right hand side of the screen, in the following sequence: Spirometry, Flow-Volume, and MMV. If the Flow-Volume option is selected, the program will automatically start from initial spirometry in order to determine the VC parameter value. This can be abandoned and one can move directly to spirometry, which is described later in this manual. In each case, an examination is initiated by clicking on the icon with a green circle *Start Test* in the upper portion of the screen. The program will always start by zeroing the spirometer.

A message informing the user how much time is needed to stabilise the spirometer temperature appears if the time elapsed since switching the spirometer on is not enough to stabilise the thermal conditions of the spirometer. This amount of time is required to ensure the proper operation of the equipment.

4.2 Description of the measurement routine and predicted normal values

How to perform the spirometric measurement correctly. Initial remarks:

- 1) Make sure that the spirometer is working properly.
- 2) Plan the dates and times of spirometric measurements in a way that the time of the subsequent measurement is similar for the same patient. Results of spirometric measurements for the same person show fluctuations over a 24 hour period.
- 3) The patient should be instructed to refrain from the following before the measurement:
 - a) significant physical effort (30 minutes),
 - b) smoking (1 hour),
 - c) heavy meals (2 hours),
 - d) drinking alcohol, strong tea, coffee, cocoa, cola-type soft drinks.
- 4) A spirometric measurement that is intended to be the reference measurement should be done a minimum of 8 hours after administering a beta-mimetic inhalant.
- 5) The patient should rest at least 15 minutes after arrival at the examination site.
- 6) The patient cannot wear clothes limiting free movement of his/her chest.
- 7) The height of the patient should be accurately measured and the patient's personal data should be entered without errors.
- 8) Accurate data regarding ambient conditions should be entered as well: temperature, humidity, ambient pressure (ATP conditions).

Why is it necessary to apply correction factors for the measured volumes with reference to the actual measurement conditions described by temperature, ambient pressure and air humidity?

According to the compulsory standards, all measured volumes and predicted normal values of volume should be given at BTPS conditions. Since the measurements are taken under ATP conditions, it is necessary to convert the measured volumes from ATP conditions to BTPS conditions.



GLOSSARY:

BTPS- Body Temperature Pressure Saturated (human body temperature, atmospheric pressure, humidity of air saturated with vapour)

ATP- Ambient Temperature Pressure (temperature, pressure and humidity in the room where the measurement is being performed)

Preparing the patient:

- 1) The patient should be seated straight with his/her chin slightly elevated. Obese patients should be standing.
- 2) During the measurement, the patient should neither change position nor lean forward.
- 3) Lips should be kept tight around the mouthpiece. The surface of the mouthpiece should support the teeth, and the lips should tightly enclose it.
- 4) The tongue should be slightly retracted.
- 5) If the patient has never undergone spirometric measurements before, it is advisable to let the patient breathe through the mouthpiece for several minutes before the actual measurement is conducted, in order to get used to gripping the mouthpiece in the required manner.
- 6) Clip on the nose clip.
- 7) Before starting the measurement, inform the patient how the measurement is conducted.
- 8) During the measurement, give clear and understandable instructions.
- 9) Adult patients should not see the monitor during the measurement. If the spirometer is fitted with a motivation function for children, examined children should observe the screen during the measurement.

According to the ERS standards, complete and correct spirometric examination includes:

- first
- Slow spirometry
 - and then
- Forced flow-volume curve

4.2.1 Spirometry

The patient breathes through the mouthpiece and pneumotachographic head. After six quiet, uniform breaths, the patient breathes out slowly, as deeply as possible, and then breathes in just as slowly, and as deeply as possible. When this manoeuvre is finished, the patient continues to breathe freely through the measuring system. The parameters determined during this measurement are described in the appendix.

Acceptance criteria for slow spirometry:

- 1) During the test, the patient should breathe steadily at a comfortable pace and should not demonstrate forceful breathing at any time, but he/she cannot breathe too slowly as this may lead to overestimation of the VC parameter.
- 2) Before the actual manoeuvre for the evaluation of VC, IC and ERV values, the patient should breathe quietly a minimum of five times.
- 3) Evaluation of the VC value can be done using two equivalent methods:
 maximal, quiet inspiration after maximal, quiet expiration,
 maximal, quiet expiration after maximal, quiet inspiration.
- 4) In a spirometric test, the instruction to perform a deep, quiet expiration must be given at the beginning of a quiet expiration. This pertains to patients of normal weight.





In the case of obese patients, the manoeuvre to determine the ERV value should be started with a quiet, maximal inspiration, and the instruction to perform a deep, quiet inspiration must be given at the beginning of a quiet inspiration.



- 5) At least three, and not more than four slow spirometry tests should be performed, which means that after the fourth test it is recommended that the test be halted, and the interval between manoeuvres to determine the VC value should not be shorter than 1 minute.
- 6) Quiet, maximal inspiration and expiration should be performed at relatively steady flow. For a healthy patient, the maximal inspiration and expiration levels are attained after 5-6 seconds.
- 7) Reaching a plateau at the end of maximal inspiration and expiration is the condition to obtain true and repeatable values of spirometric parameters VC, IC, ERV.
- 8) Spirometry is done correctly when the difference between the two highest values of VC is not greater than 150 ml.
- 9) The measurement report shows the maximum obtained VC value and the average ERV and IC values from the whole measurement.

4.2.2. Flow – volume measurement

The patient breathes through the mouthpiece and pneumotachographic head. After several quiet breaths, the patient breathes out in order to remove air from the lungs, and then performs as deep and as rapid an inspiration as possible, followed by the maximally quick and forceful expiration. This manoeuvre is

EN ISO 13485:2016 CE 1011



repeated several times. The Parameters determined during this measurement are described in the appendix.

Criteria for the proper cooperation and acceptability of a forced flow-volume curve test

- 1) The beginning of the forced expiration manoeuvre is satisfactory, i.e. the extrapolated start of forced exhalation occurs before reaching 5% of FVC or 150 ml.
- 2) The forced expiration is sufficiently dynamic, i.e. the shortest possible time is needed to reach PEF. If the spirometer displays the TPEF value, it should be shorter than 300 ms.
- 3) The time of forceful expiration is not shorter than 6(3) s. A healthy person exhales: 83% of V

839 949

83% of VC in 1 second 94% of VC in 2 seconds 97% of VC in 3 seconds

It can be assumed that FEV 3.0 = VC,



WARNING!!!

Following the ERS recommendations, the time of forceful expiration should not be shorter than 6 seconds for adults and children below 10 years of age!

or

4) The volume-time curve shows a clear plateau, i.e. the volume change within a second is lower than 25 ml,

or

- 5) The patient cannot or should not continue breathing out.
- 6) The flow-volume curve test can be terminated and considered as correct if the patient has done at least three technically correct measurements with the required repeatability as defined below:
 the difference between the two highest values of FVC and FEV1 is not greater than 150 ml, or
 - the difference between the two highest values of FVC and FEV1 is not greater than 100 ml when the FVC value is below 1 litre.
- 7) The flow-volume curve test can be terminated and considered as successful if the patient has done further technically correct measurements and obtained the following repeatability:
 - the difference between the two highest values of FVC and FEV1 is smaller than 150 ml, or

- the difference between the two highest values of FVC and FEV1 is not greater than 100 ml, when the value FVC is below 1 litre.

- 8) The flow-volume curve test should be terminated if the patient has already done eight measurements.
- 9) The flow-volume curve test should be terminated if the patient cannot or should not continue the tests.
- 10) It is desirable to obtain closed inspiration-expiration curves, but in the case of bronchial obturation, the value of vital capacity obtained at forceful expiration is smaller that the value of inspiratory capacity.
- 11) Between forced measurements, the patient should be instructed to breathe quietly for a minimum of 15 seconds.
- 12) The sequence of inspiration and expiration manoeuvres is important for the flow-volume measurement.





- a) the patient breathes quietly, uniformly and steadily,
- b) before a quiet expiration, the patient is instructed to perform a quiet, maximal expiration to the RV level (only the residual volume of air remains in the lungs),
- c) the patient performs a forceful, maximal inspiration (breathes in the volume of FVC IN),
- d) the patient performs a forceful, maximal expiration (breathes out the volume of FVC EX); when finished, only the residual volume of air remains in the lungs.

4.2.3 Maximal minute voluntary ventilation MVV.

The patient breathes through the mouthpiece and pneumotachographic head. The test is divided into two phases: the quiet phase and the MVV phase. In the first phase the patient breathes quietly and freely, while in the specified period of time in the second phase he/she breathes maximally quickly and deeply. After the second phase, the test is finished.





5. General test procedure

5.1 Patient data

Patient data are a collection of information necessary for patient identification and for the evaluation of predicted normal values of the test parameters. No test can be performed without these data. Patient data can be entered in four ways:

- 1) By entering new patient data.
- 2) By selecting the patient from the data base.
- 3) By indicating the file with former test results for the same patient *Patient from File* command (*File* menu).
- 4) By opening and then closing the file with former test results for the same patient.

After entering the patient data, all measurements will be performed for the selected patient until they are changed. In order to examine another patient, it is first necessary to enter that patient's data.

New patient data are entered in the *Patient Data* dialog box available after selecting the *New Patient* command (*File* menu). The window contains a set of fields that should be filled with the information indicated in the label of each field.

The Patient Code field can be omitted, data entry is not obligatory here.

Note: The second surname or the second name can be entered after '-' or after a space.

Patient Data		X
<u>L</u> ast name:	Smith	OK
<u>F</u> irst name:	John	Cancel
<u>P</u> atient Code:	73122976221	
<u>D</u> ate of birth:	21 💌 December 💌 💌 1973	
<u>H</u> eight:	186 → cm <u>W</u> eight: 82.0 → kg	
<u>S</u> ex:	C F <u>e</u> male 💿 M <u>a</u> le	
<u>H</u> eight: <u>S</u> ex:	186 ; cm <u>W</u> eight: 82.0 <u>;</u> kg ○ F <u>e</u> male	

Fig. 5.1. *Patient Data* dialog box

Modification

Modification of the patient data can be done in the <u>Patient</u> Data dialog box invoked by selecting the *Edit Patient Data* command (*File* menu). Data modification is possible only after entering the data, but it can be done before any measurement is started. Only *Height* and *Weight* can be modified.

Reviewing the data

Patient data (corresponding to the date of the measurement being viewed) can be reviewed in the *Patient Data* dialog box (Fig. 5.1) invoked by selecting the *Edit Patient Data* command (*File* menu). Data for the same patient for different measurements may differ as regards height or weight parameters only.



Verification

Before starting each new measurement, the Lungtest system automatically opens the window with the patient data and gives the possibility of modifying the height and weight of the patient. <u>One should</u> remember that if the patient data are extracted before examination by opening the file with previously performed measurements, the weight and height of the patient written in the file may not correspond to the current patient data and must be changed in order to perform a new measurement with the current data..

5.2 Predicted normal values

Predicted normal values are the predicted values of measurements. They are obtained by examining a specific population of people and finding the relationship between these measurements and the features of an individual, most frequently his/her height, weight, sex and race.

Note: Weight is not taken into account in the majority of used standards with the exception of the **IGiChP Warszawa** standard for the breath standard where the BMI [kg/m²] (Body Mass Index) value is calculated.

The BMI value is calculated for each patient and printed besides the height and weight: <u>Height/Weight/BMI</u>

Configuration of predicted normal values

Configuration of predicted normal values is done in the *Configure predicted values* dialog box invoked by selecting the appropriate command in the *Tools* menu.

Configure	predicted values	X
✓ ERS ✓ Zapleta ✓ Chernia ✓ Macfie ✓ Ulmer	I ck	OK Cancel
Koliern Knudso Morris ✓ Forche Piii->	n _	<u>R</u> eset
Cotes	~	None

Fig. 5.3. Configuration of predicted normal values

The *Configure predicted values* dialog box is identical to the *Configure parameters* dialog box; therefore all actions in this box are also identical.

Predicted normal values are calculated following the authors who are marked with a tick, in the same sequence as listed in the window. Example: we are calculating the MVV according to the configuration shown. ECCS – no result given. Zapletal – not taken into account. Cherniack – no result given. Macfie – results given – no further search. It is possible to reorder the above list by clicking the left mouse button on the selected item, moving it to the required position, and releasing the button.



Warning!!!

Selection of the authors of the standards should be done carefully and consciously. Predicted normal values of the individual parameters given by various authors may differ significantly. Therefore the parameters of one set, if they are based on different authors, may be contradictory.



The table contains a special column (\mathbf{Ref}) in which information about the standards used to calculate the predicted normal value of individual parameters is given. Letter codes are assigned to the methods in the legend shown below the table in the printout.



Warning!!!

There are no standards for patients aged 71 and older. The MES software uses an approximation of the ECCS standards up to the age of 95. Information about the approximation is placed in the comments accompanying the examination "*Predicted values for patients years old and older are calculated by aproximation*".



List of standards used by the software (applicable test type shown in the brackets)

- 1) **Billiet** (Diffusion SB);
- 2) Cherniack (MVV);
- 3) Cotes (Diffusion SB);
- 4) **ECCS** (Bodypletismography, Compliance, Diffusion SB, Flow–Volume, RRS, Spirometry, FRC);
- 5) Forche (Diffusion SB, MVV, Spirometry, FRC);
- 6) KellerHerzog (Diffusion SB, Spirometry, FRC);
- 7) Knudson (Diffusion SB, FRC, Flow–Volume, Spirometry);
- 8) **Macfie** (Flow–Volume);
- 9) Morris (Flow–Volume);
- 10) Ulmer (Diffusion SB, Spirometry, FRC);
- 11) **Zapletal** (Bodypletismography, Compliance, Diffusion SB, Flow–Volume, MVV, Spirometry, RRS, FRC);
- 12) ZPIGiCHPRabka (Flow–Volume, RRS);
- 13) IGiCHPWarszawa (Respiratory model);
- 14) Hankinson (Flow–Volume);
- 15) Polgar (Flow–Volume);
- 16) Crapo (Flow–Volume);
- 17) **HSE** (Flow–Volume);

5.3 Test descriptions

The following sections of this manual contain descriptions of tests that can be performed by means of the *Lungtest* software. Each of them contains sections common to all tests, and sections specific to the particular measurement. The common sections are as follows:

1) Test parameters

This section contains a list of all parameters determined during each test, their names, units, and short description.

2) Test options

This section contains descriptions of options which influence the way a measurement is conducted. These options are changed in the *Test Options* dialog box invoked by selecting the *Test Options* command (*Tools* menu). This window contains a series of tabs, each tab corresponding to one specific measurement and bearing the name of this measurement. Additionally, the window contains the *OK* and *Cancel* buttons, the first to accept, and the second to cancel the changes made.

3) **Test procedure**

This section describes test procedures.

4) Test results



This section shows sample test results. Each set of results includes a table of test parameters. Flow and volume axes are identified by IN and EX to show the direction of flow.

No.	Name	Description	Comments		
1	No	Parameter number			
2	Parameter	Parameter name			
3	Unit	Parameter unit			
4	Ref	Author of the standard	The legend is placed	in the printout below the table	
		used to calculate			
		predicted normal values			
		(<i>Pred</i> column)			
5	Pred	Predicted normal value	Section 5.11		
		of the parameter			
6	Act	Actual value of the	Value obtained in the measurement		
		parameter			
7	$\pm A/P \%$	Comparison of the	$\pm A/P$ % – percentage	deviation of the actual value from the	
	or	predicted value with	predicted normal valu	ie	
	A/P %	actual value	A/P % – percentage r	atio of the actual value to the predicted	
			normal value		
8	SR	Number of standard	$\mathbf{SP} = Act - Pred$	where δ is the standard deviation of	
		deviations	$\delta = \frac{\delta}{\delta}$	the predicted normal value	
9	Р	Percentile	<i>n-th</i> percentile indicates that for $n\%$ of the people contained		
			in the population, the value of the parameter does not exceed		
			the actual measured value		



Warning!!!

When conducting tests which may produce several sets of values, the table contains an additional column for each set. Each of these columns contains a comparison of the actual values of each set with the actual reference values indicated as reference levels by means of the *Next comparison* command (system menu of the table). The headers of these columns show $\pm A_i/A_j$ % or A_i/A_j %, where *i* is the index of the given set, and *j* is the index of the reference set. The header depends on the selected comparison method (relative or absolute).

5.4 Spirometry

Test parameters				
Parameter name:	Parameter name: Unit: Description:			
VC	L	Vital Capacity		
IC	L	Inspiratory Capacity		
ERV	L	Expiratory Reserve Volume		
IRV	L	Inspiratory Reserve Volume		
TV	L	Tidal Volume		
MV	l/min	Minute Ventilation		
BF	1/min	(Quiet) Breathing Frequency		
FEV 1	L	Forced Expiratory Volume in one second		
FEV 1 % VC	%	Percentage FEV 1 to VC ratio		

1) Select the *Spirometry* command (*Test* menu).

- 2) Check test options.
- 3) Start the measurement using the *Start Test* command (*Tools* menu).
- 4) Perform the test divided into the following phases:



- a) Quiet respiration. When the respiration becomes stable, the prompt bar displays the following message: *After inspiration, perform maximal expiration*
- **b)** Expiration to the *RV* level. The patient performs maximal expiration, after which the lungs contain only the residual air volume. When no volume changes are recorded on the spirogram (plateau reached), next phase can be started. In terms of breathing dynamics during the spirometric phase (items b through d), both inspirations and expirations should resemble sighs. Breathing can be neither slowed down nor forced.
- c) **Inspiration to the** *TLC* **level.** The patient performs maximal inspiration of the *VC* value. When, as in the previous phase, no volume changes are recorded on the spirogram (plateau reached), next phase can be started.
- **d**) **Expiring air from the lungs.** The patient lets the air out of the lungs approximately to the *ERV* level, and continues quiet breathing.
- e) Terminating the measurement. When the patient expires the volume of TV or $\frac{1}{4}$ of VC (whichever is smaller) from the *TLC* level, this terminates the measurements. If all the phases have been correctly performed, the *Lungtest* considers the test as correctly completed and adds increments to the correct measurements counter.
- **f) Repeating the measurement.** If the *number of measurements* option is greater than 1, the measurement is repeated (the application returns to phase a) until the required number of measurements is reached.
- **g**) *FEV 1* measurement. This measurement is conducted after all spirometric measurements are completed, but only when the option *Execute FEV1* field is checked. The measurement procedure is described in the section of Flow-Volume measurement.

If the **Start the manoeuvre with inspiration** option is checked, the patient (when breathing becomes stable) breathes in to the TLC level, then breathes out to the RV level and resumes quiet breathing.

If the *number of measurements* option is greater than 1 and if the *Execute FEV1* is checked, then it is possible, after completing one spirometric measurement, to abandon subsequent measurements and to move to the *FEV 1* measurement by selecting the *Next Phase* command (*Test* menu). If this command is not selected, the application automatically moves to the *FEV 1* measurement as soon as the number of spirometric measurement reaches the value equal to the *number of*

measurements option.

Test result

The measurement which is better than all the others is regarded as the test result. The VC value is taken as the criterion of selection. If the measurement of the *FEV 1* value has been conducted, then the best measurement is also selected from those available. The graphical representation of the results contains a spirogram of the measurement and a table with test parameters.

The table with values shows the maximum VC value obtained from all repetitions and the average ERV and IC values from the whole measurement.





Fig. 5.4. Results of spirometric test

Table with measured parameter values

This table (a portion of the test results) contains values for all the test parameters

🗖 Test parameters 🛛 🔀						
No.	Parameter	Unit (Pred >	Act	±A/P%	
1	VC	1	5.22	3.56	-32	
2	IC	1	3.67	2.02	-45	
3	ERV	1	1.55	1.54	-1	
4	IRV	1		1.52		
5	TV	1		0.50		
6	MV	1/min		19.32		
7	BF	1/min		38.65		
8	FEV 1	1	4.18			
9	FEV1%VC	%	81.63			

Fig. 5.5. Table with measured test parameters



(i) 5.5 Flow-volume measurement

Test parameters				
Parameter name:	Unit:	Description:		
FEV 0,5	L	Forced Expiratory Volume in half a second		
FEV 1	L	Forced Expiratory Volume in one second		
FEV 2	L	Forced Expiratory Volume in two seconds		
FEV 3	L	Forced Expiratory Volume in three seconds		
FEV 6	L	Forced Expiratory Volume in six seconds		
FEV 1 % FEV 3	%	FEV 1 to FEV 3 ratio shown as percentage		
FEV 1 % FEV 6	%	FEV 1 to FEV 6 ratio shown as percentage		
FVC EX	L	Forced Vital Capacity during expiration		
FIV 1	L	Forced Inspiratory Volume in one second		
FVC IN	L	Forced Vital Capacity during inspiration		
VC	L	Vital Capacity		
VC MAX	L	Vital Capacity as the maximum of VC and FVC EX		
TV	L	Tidal Volume (quiet breathing)		
VPEF	L	Volume at <i>PEF</i>		
VPIF	L	Volume at <i>PIF</i>		
FEV 1 % EVC EX	<u>2</u> %	Percentage ratio of <i>FEV</i> 1 to <i>FVC EX</i>		
FEV 1 % FVC IN	/0 0/0	Percentage ratio of FEV 1 to FVC IN		
FEV 1 % VC	<i>√</i> ₀	Percentage ratio of FEV 1 to VC		
DEE	70 1/s	Peak Expiratory Flow		
MEE 75	1/5	Maximal Expiratory Flow at 75% of the remaining EVC EV		
MEE 50	1/8	Maximal Expiratory Flow at 75% of the remaining FVC EX		
MEF 30	1/5	Maximal Expiratory Flow at 50% of the remaining FVC EX		
MEF 25	1/S	Maximal Expiratory Flow at 25% of the remaining FVC EX		
MEF JU % FVC	%0	Percentage ratio of MEF 50 to FVC EX		
EA MEE 75 % VC	0/	Demoentage notic of MEE 75 to VC		
MEF 73 % VC	% 	Percentage ratio of MEF 75 to VC		
MEF 50 % VC	%	Percentage ratio of MEF 30 to VC		
MEF 25 % VC	%	Percentage ratio of <i>MEF 25</i> to VC		
MEF @ FKC	1/S	Maximal Expiratory Flow at FRC		
FEF /5/85	1/S	Forced Expiratory Flow between /5 and 85% of FVC EX		
FEF 25/75	1/s	Forced Expiratory Flow between 25 and 75% of FVC EX		
PIF	l/s	Peak Inspiratory Flow		
MIF 50	Ĺ	Maximal Inspiratory Flow at 50% of the remaining FVC IN		
MTT	S	Medium Transit Time		
TPEF	S	Time at <i>PEF</i>		
TMEF 75	S	Time at <i>MEF</i> 75		
TMEF 50	S	Time at <i>MEF 50</i>		
TMEF 25	S	Time at <i>MEF 25</i>		
TPIF	S	Time at <i>PIF</i>		
FET	S	Forced Expiration Time		
FIT	S	Forced Inspiration Time		
TTOT	S	Total time of forced respiration $(FET + FIT)$		
TPEF % FET	%	Percentage ratio of TPEF to FET		
TPIF % FIT	%	Percentage ratio of TPIF to FIT		
FET % FIT	%	Percentage ratio of FET to FIT		
TC 25/50	1/s	Time constant between 25 and 75% FVC EX		
AEX	$1^{2}/s$	Area of expiratory portion of flow-volume curve		

Performing the test



- 1) Select the *Flow-Volume* command (*Test* menu).
- 2) Verify test options.
- 3) Initiate the test by using the *Start Test* command (*Tools* menu).
- 4) Perform the test divided into the following phases:
 - a) Quiet respiration. When the respiration becomes stable, the prompt bar displays the following message: *After inspiration, perform maximal expiration*, and the *Confirm the manoeuvre* command (*Test* menu) becomes available. This command, in fact, is made available when the patient breathes out, and is blocked when the patient breathes in. Making this command available should be understood as the following question: *Is the patient breathing out just before a forceful inspiration?* If this is the case, this command must be selected to confirm that the manoeuvre has started. This also triggers transition to the next phase.
 - **b)** Expiration to the *RV* level. The patient performs maximal expiration (not forceful at this time), after which the lungs contain only the residual air volume. When no volume changes are recorded on the spirogram, the next phase can be started.
 - c) Forceful inspiration to the *TLC* level. The patient performs forceful, maximal inspiration of the *FVC IN* value. When no volume changes are recorded on the spirogram, the next phase can be started.
 - **d**) **Forceful expiration to the** *RV* **level.** The patient performs forceful, maximal expiration of the *FVC EX* value, after which the lungs contain only the residual air volume.
 - e) Terminating the measurement. Forceful expiration is considered completed when:
 - The patient starts to breathe in,
 - The time of expiration exceeds 15 seconds,
 - The volume change within the last second does not exceed 25 ml.

If all the test phases have been completed correctly, the *Lungtest* considers the test as correctly carried out and adds increments to the correct measurements counter.

- **f**) **Repeating the measurement.** If the *Number of measurements* option is greater than 1, the measurement is repeated (the application returns to phase a) until the required number of measurements are reached.
- **g**) **Performing** *Spirometry*. Spirometry is performed before the flow-volume measurements, but only when the option of the *Spirometry* field has been ticked. Spirometry may be omitted by

using the key, even if it is activated in the test options. The test procedure is described in the section about spirometric measurements.



Warning!!!

If the *Request quiet breathing* option is not checked, the phase of quiet respiration "a)" is omitted, and each breath is analysed in terms of its dynamics. If the measurement is repeated, after a forceful expiration, the phase of forceful inspiration "c)" is started immediately. Such a sequence may lead to repeated forceful breaths, one after another. The application does not expect that all breaths to be forceful. They can be freely alternated with quiet breaths, but these quiet breaths are not analysed in terms of their uniformity.

Additionally, if the *Request quiet breathing* option is not checked, the flow-volume test will never be terminated automatically, even after reaching the required number of measurements. The test must be manually terminated with the *Discontinue the test* command (*Test* menu). Such behaviour is caused by the impossibility of determining whether the accepted measurements pertain to really forceful manoeuvres, or to manoeuvres similar to quiet breathing, especially if the *Use extrapolation on expiration* option is deactivated.

In the flow-volume test, only those measurements are accepted where the *FVC EX* value is not lower than 50% of the highest *FVC EX* value of all the measurements conducted. Such a procedure may lead to the counter of correct measurements remaining unchanged, or decreasing in numerical value after accepting the measurement that is just finished, if this measurement is the best of all the measurements taken so far.

A graphical timer is displayed during expiration on the flow-volume plot. The timer takes the form of a circle that is filled with red during the first three seconds, yellow - during the next three seconds and green – during the following six seconds.





Fig. 5.6. Graphical timer

Test results

The results of the test are shown in the form of a collection of all the accepted measurements and a table with corresponding parameters. The obtained curves can be manipulated by means of the *Curve selection* toolbar.

In cases when the Flow-Volume test has been carried out according to ATS criteria, the table contains a **Grade** parameter which defines the repeatability of the manoeuvre (the curve). The **Grade** parameter has 5 possible levels:

- A at least two correct, repeatable manoeuvres (two highest FEV1 and FVC values that differ by more than 100 ml),
- B- at least two correct manoeuvres, where the difference between the two highest FEV1 and FVC values is not greater than 150 ml,
- C at least two correct manoeuvres, where the difference between the two highest FEV1 and FVC values is not greater than 200 ml,
- D one or more correct manoeuvres, but where the difference between the two highest FEV1 and FVC values is greater than 200 ml (not interpreted),
- F no correct manoeuvres (not interpreted).



Fig. 5.7. Flow-Volume test result.

Motivating system

A motivating system has been developed aimed at small children who often have problems conducting the test correctly. It is designed to help them to achieve more adequate results. Nothing also stops older children and even adults from taking advantage of the system. The system is activated by selecting the *Motivational system* command (*Tools* menu), but only after prior selection of the *Flow-Volume* command (*Test* menu).

The motivating system consists of six candles (Fig. 5.8.), which should be blown out by the person being examined.



Fig. 5.8. Motivating system for the Flow-Volume test.

The simulation of each candle's flame shape and the instant when it is extinguished are based on the predicted normal values for the patient, according to the table shown below. The values in the table are just exemplary.

Candle no.	Parameter	Value	Attained at	Calculated as
1	PEF	10,0 l/s	0,501	0,10 FVC EX
2	MEF 75	7,5 l/s	1,251	0,25 FVC EX
3	MEF 50	5,0 l/s	2,501	0,50 FVC EX
4	MEF 25	2,5 l/s	3,751	0,75 FVC EX
5	FEV 1	4,01	2,0 l/s	Extrapolation
6	FVC EX	5,01	0,0 l/s	End of expiration

Each candle corresponds to certain volume and flow values. A candle will be extinguished when the actual volume is equal to or greater than the volume corresponding to that candle, and when the actual flow is equal to or greater than the flow corresponding to that candle, but only if the preceding candle has already been extinguished. This in practice means that the expiratory curve must surround the array of predicted normal values.

The motivating system can be rescaled to extinguish the candles at different flows and volumes. Rescaling consists in multiplying all candle parameters by a coefficient defined by the % of predicted values command (context menu of the motivating system window). The coefficient can be changed only before the test or when the test is paused, by means of the *Pause* command (*Test* menu). The current value of the coefficient is displayed on the motivation system window title bar.

Rescaling yields linear reduction or magnification of the predicted normal values array. Candles linked to the volumetric parameters FEV 1 and FVC EX will be extinguished when the ratio of values obtained in the test to the predicted normal values exceeds the value of the rescaling coefficient. In case of the flow descriptors PEF, MEF 75, MEF 50 and MEF 25, candles may be extinguished earlier than at the moment when the ratio mentioned earlier exceeds the value of the rescaling coefficient. To explain why this may happen, let us assume that the rescaling coefficient equals 80%, which means that all the predicted normal values are multiplied by 0.8. This gives:

Candle no.	Parameter	Value	Attained at
1	PEF	8.0 l/s	0.41
2	MEF 75	6.0 l/s	1.01
3	MEF 50	4.0 l/s	2.01
4	MEF 25	2.0 l/s	3.01



5	FEV 1	3.21	1.6 l/s
6	FVC EX	4.01	0.0 l/s

By analysing the MEF 25 parameter we can see that for the 80% of the predicted normal values, the MEF 25 value equals 2 l and is reached at the volume of 3 l, while for 100% – the MEF 25 equals 2.5 l at the volume of 3.75 l. For 80% – at the volume of 3.75 l, the required flow is 0.5 l/s (extrapolated). If the expiratory curve surrounds the rescaled array of predicted normal values from both sides, all the candles will be extinguished despite the fact that, in reality, the MEF 25 value can only be at the level of 20% of the predicted normal value (0.5 / 2.5).

5.6 Maximal voluntary ventilation

Test parameters

Parameter name:	Unit:	Description:
MV	1/min	Minute Ventilation
MVV	l/min	Maximal Voluntary Ventilation
BF MVV	1/min	Breathing Frequency at Maximal Ventilation
BR	%	Breathing Reserve

Performing the test:

- 1) Select the *MVV* command (*Test* menu).
- 2) Verify test options (Section 5.5).
- 3) Initiate the test by using the *Start test* command (*Tools* menu).
- 4) Perform the test divided into the following phases:
 - a) Quiet respiration. When the respiration becomes stable, the prompt bar displays the following message: *Begin maximal ventilation phase*, and *Confirm the manoeuvre* command (*Test* menu) becomes available. Selecting this command triggers transition to the next phase.
 - **b) Maximal ventilation.** The patient breathes as deeply and as rapidly as possible over the time interval set by the *Measurement time* option. Time remaining in the test is displayed on the prompt bar. When the time expires, the test is automatically terminated.

Test results

Test results are in the form of a spirogram of the measurement and a table with test parameters.





Fig. 5.9. Test results for Maximal Voluntary Ventilation.

5.7 Recording test results

Test results can be recorded in a file by means of the *Save* and *Save as* commands (*File* menu). Each test is recorded in a separate file. Each patient has his/her folder on the disk with the path defined as *C:\MESTest results\Surname Name Second Name, Date of Birth*. This folder contains subfolders named after test procedures to which the patient has been subjected. As a standard, test results are stored in these subfolders, and the default name of each file is composed of the date and time of the test. It is recommended that test results should be stored under default names, which facilitates file recognition when the test results are reviewed and compared. Test results can also be stored under any user-defined name in any other folder.

5.8 Reviewing test results

In the *Lungtest* application, test results formerly stored on the disk can be reviewed. A file with test results can be opened by means of the *Open* command (*File* menu).

While reviewing test results stored on the disk, it is noticeable that files being compared are marked with different icons. Normal tests are represented by green lung icons, and the tests being compared have blue icons.



Open 🤶 🏹
Look jn: 🗁 Flow - Volume 💽 🖛 🛍 📸 📰 -
1000 1000
File name:

Fig. 5.10. Dialog box with *File/Open* menu

A set of test results for a given patient

It is possible to load a set of test results belonging to the currently selected patient. The set will contain only those tests which have been stored under default names. After loading, the test results can be reviewed using the *Test Manager* toolbar.

The set of test results can be loaded by taking the following steps:

- 1) Enter the data of the selected patient (Section 5.1).
- 2) Select the *Load tests* command (*File* menu). This will create a list of tests belonging to the currently selected patient and the *Test type* list will be dropped down in the *Test Manager* toolbar.

Test Manager			×
	-	v	_
Breath Pattern	~		
Breath Pattern E E			
Compliance	=		
Diffusion SB	_		
DRT	_		
Flow - Volume			
MVV	~		

Fig. 5.11. Test Manager toolbar with Test Type list dropped down

3) On the *Test Type* list, select the item corresponding to the type of tests that are going to be reviewed. This will drop down the *Main test date* list. Master tests and sub-tests are described in Section 5.10.

Test Manager				X
Flow - Volume			-	
	2006-06-02	08:50:36		
	2009-01-30	09:14:41	Р	

Fig. 5.12. Test manager toolbar with Main test date list expanded.

4) From the *Main test date* list, select the item containing the date of the test you want to open. The selected test will then be loaded and displayed on the screen.



To open any other test of the selected type, indicate its date on the *Test Date* list. To change test type, select its name from the *Test type* list.

5) If a test opened in 4) has any sub-tests, after opening, the *Subordinate test date* list will be expanded.

Test Manager				X
Flow - Volume	2009-01-30	09:14:41 p 💌		•
		i	2009-01-30	09:16:01

Fig. 5.13. Test Manager toolbar with the Subordinate test date list expanded.

To view the sub-test results, select its date from the *Subordinate test date* list. To return to the master test, select its date again from the *Main test date* list.

5.9 Searching test results

The program can search for a patient whose test results are stored in the *MES / Test Results* folder. Searching is done by selecting the *Patient Search* command or by clicking on the button with the binoculars placed on the toolbar. A window will appear:

Patient	t search, (7 z 7)					×
Patier Last	nt list filter Name	Name	Е	lorn		
So	rt by Last Name	Sort	by Name	Sort	by Born Date	
Lp	Last name	,	First name		Born	
1.	Denys		Piotr		28-12-1974	
2.	Juzala		Ireneusz		25-03-1956	
3.	Komorowska-Kulińs	ska	Iwona		26-12-1974	
4.	Olechowska		Krystyna		11-01-1953	
5.	Stalmach		Urszula		29-01-1957	
6.	Test		Tes		03-01-1910	
7.	Węgrzyniak		Karolina		08-01-1956	
Ret	ouild list		Cancel		Set	

Fig. 5.14. Patient search.

A patient can be found by giving his/her name, surname and date of birth. By entering these criteria in the corresponding fields, a list of search results (patients) will be displayed and it change automatically in accordance with the criteria entered. When the patient is selected, the *Test Manager* window can be used.



5.10 Comparing test results

Test results can be compared by selecting the *Compare* command (*File* menu). The command calculates changes of individual parameter values belonging to a specific type of tests. It is also possible to plot these changes. Only tests of the same type, belonging to the same patient, can be compared. A master test can be compared with other master tests or with sub-tests corresponding to the master test. A sub-test can be compared with its master test and/or with other sub-tests of the same master test. Master tests and subtests are described in Section 5.10.

Test results comparisons can be saved and printed in the same way as test results.

Make a comparison by taking the following steps:

- 1) Open one of the tests to be compared. If we compare a master test with other master tests that master test should be opened. If we compare a master test with its sub-tests we should open one of the subtests.
- 2) Select the *Compare* command (*File* menu). A dialog box *Compare tests* will be opened. The *Test Date* list will show the highlighted date of the test opened in step 1) above.
- 3) Select the dates of the other tests on the opened list and click *OK*. This will display a test results comparison.
- 4) To add or remove test results from the comparison, open again the *Compare tests* dialog box by selecting the *Compare* command (*File* menu).

Selecting test results for comparison

Test results for comparison are selected in the *Compare tests* dialog box available after selecting the *Compare* command (*File* menu).

Compare Tests - Flow - Vo	lume 🛛 🔀
Date of a pre-tes 2008-11-05 10:18	st 3:18
Date of the test:	
2008-11-05 10:18:18 2008-11-05 10:19:00	OK
2000 11 00 10.10.00	Cancel
	<u>A</u> dd
	<u>R</u> emove
,	

Fig. 5.15. Compare tests dialog box (dedicated to Spirometry).

The window contains the following elements:

1) Title bar:

Contains the title (*Compare tests*) and the type of tests currently being compared.

2) Main test date field:

When a master test is compared with its sub-tests, this field contains the date of the master test. If a master test is compared with other master tests, this field is empty.

3) *Test date* list:

Contains dates of tests found automatically or added by means of the Add button.

4) *OK* button:



Confirms selection of tests for comparison, closes the dialog box, and executes the comparison.

5) *Cancel* button:

Cancels all changes in the dialog box and closes the dialog box.

6) Add button:

Adds tests to the *Test Date* list. Only tests of the same type, belonging to the same patient can be added. Additionally, if a master test is compared with other master tests, only master tests can be added. If a master test is compared with its sub-tests, only subtests of this master test can be added.

7) *Delete* button:

Deletes tests selected on the Test Date list.



Warning!!!

The set of parameters of a specific test which will be used for comparison is identical to those selected for storage in the database.

Results of comparison

The picture below shows an example of a test results comparison. The comparison yields a plot showing selected parameter changes and a table with the current parameter values of the compared tests. Additional columns containing comparison of individual actual values may be added as well.



Fig. 5.16. Example of a test results comparison

5.11 Printing test results

Test results are printed by means of the *Print* command (*File* menu). The printout can be configured using the *Print settings* and *Print configuration* commands. A printout preview (simulation of the printout on the screen) can be obtained by selecting the *View Print* command. These commands are also selected from the *File* menu.



Print	×
Institution Name	OK Cancel
Zoom Options Chart: 100 ÷ % Table: 11 ÷ Color Print Append Comment	MES Size: large
MES Special Raport Comparison to predict values Print © Best FV © Envelope FV	C MaxMin

Fig. 5.17. Print Configuration dialog box.

This window contains the following elements:

1) Institution Name field:

Two lines that can be edited. The name of healthcare institution conducting the tests should be entered here. This name will be shown in the printout header.

2) Zoom field:

a) Chart box:

Magnification factor for the printed plot can be entered here. This factor is entered as a percentage.

b) *Table* box:

Magnification factor for the table can be entered here. This factor is a multiplier.

3) *Options* field:

a) *Color Print* option:

If this option is checked, the printout will be in colour (only when the system is equipped with a colour printer).

b) Append Comment option:

If this option is checked, a comment regarding the test entered in the *Edytor komentarza* field (*Narzędzia* menu) will be added to the printout.

4) MES Special Report field:

a) Print option

If this option is checked, a non-standard report will be printed out (Section).

- b) FidelComparition to predicted values field
- Here you can select the reference column for the predicted normal values (Section 5.1).

5) *MES* field:

a) *Size* selection list:

This list allows you to size the MES bitmap shown in the page header.

6) *OK* button:

Accepts changes.

7) *Cancel* button:

Cancels changes.

30



6. Calibration of the spirometer

The spirometer is calibrated using the *Spirometer Calibration* dialog box (Fig. 6.1.) available by selecting the *Calibrate Spirometer* command (*Tools* menu). Calibration is done with a calibrating pump (with a capacity of a few litres) and consists of several manoeuvres. The process yields two calibration coefficients: EX – for expirations, and IN – for inspirations, defined as the ratio of the pump volume to the actual volume measured by the measuring system.

Spirometer c	alibration	X
Volume IN	Calibration manoeuvres C <u>o</u> unt: 15 ; Unevenness: 1 ; %	<u>Start</u> Sa <u>v</u> e
	Collection over	<u>C</u> lose
	Calibration pump Capacity: 3.0 📫	<u>D</u> efault
	Calibration coefficients	
	Ex 0.9782	
	In 0.9431	
	Even manoeuvres count	
EX		
Ente	r calibration parameters, then clic	:k Start

Fig. 6.1. Spirometr Calibration dialog box.



The window contains the following elements:

1) Calibration manoeuvers field:

a) Count box:

In this box one should enter the number of consecutive manoeuvres that will be undertaken with the calibration pump during calibration, maintaining the permissible nonuniformity set by the *Unevenness*.

b) Unevenness box:

In this box one should enter the maximum permissible deviation of each individual manoeuvre from the average, in order for the manoeuvre to be considered as correct.

2) Calibration pump field:

a) Capacity box:

In this box should be entered the volume of the pump used for calibration purposes.

3) Calibration coeficients field:

a) *EX* field:

Contains the calibration coefficient for expirations.

b) *IN* field:

Contains the calibration coefficient for inspirations.

4) Eden manoeuvres count field:



While calibrating the equipment, this field shows how many manoeuvres completed so far meet the uniformity criterion (Section 5) and have been considered as correct.

5) Prompt field:

This field displays instructions for the person performing the calibration about the execution of the procedure.

6) *Capacity* field:

This field displays the current volume in the form of a bar chart.

7) *Start* button:

Initiates calibration.

8) *Stop* button:

Terminates calibration.

9) Save button:

Saves calibration results. This button is only available when the calibration is finished.

10) Close button:

Closes the dialog box. If the box is closed without clicking on the *Save* button after the calibration has been finished, the calibration results are lost.

Preparations for calibration:

Check the flexible hoses connecting the pneumotachographic head. During the calibration of the spirometer, the head should be attached directly to the outlet of the calibrating pump.



Calibration procedure:

- 1) Open the *Spirometer calibration* dialog box by selecting the *Calibrate Spirometer* command (*Tools* menu).
- 2) Fill the *Calibration manoeuvres* and *Calibration pump* fields, and click the *Start* button.
- **3**) Quietly and uniformly make use of the calibrating pump. The calibration is finished automatically when the preset number of manoeuvres meets the uniformity criterion.
- 4) Click on the *Save* button to save the calibration results. The uniformity condition involves two parameters:
- 1) the number of consecutive breaths
- 2) permissible non-uniformity

N consecutive breaths are considered as uniform if the deviation of each inspiration from the average of all inspirations, and the deviation of each expiration from the average of all expirations, does not exceed the permissible non-uniformity Δ .

Example: We have N = 5 consecutive inspirations: 1.0; 0.8; 1.1; 1.2; 0.9 [1]. Average = 1.0.

- a) For $\Delta = 10 \%$ (0.1), the condition is not satisfied because the deviation of the second and fourth inspiration from the average equals 0.2 and exceeds 10 %.
- b) For $\Delta = 20 \%$ (0.2), the condition is satisfied because the deviations for all inspirations are below 20 %.



7. Volume calibration system

The volume calibration system is a tool in the LUNGTEST 1000 program which allows the measuring system to be verified visually and the calculation of the calibration coefficients *kEx* and *kIn*.

Preparation for calibration:

Check the flexible hoses connecting the pneumotachographic head. During the volume calibration routine, the head should be attached directly to the outlet of the calibrating pump.



Calibration procedure:

- 1) The volume calibration is initiated by the *Volume Calibration Sysytem* command from the *Tools* menu.
- 2) In the next step, the program asks for the volume of the calibrating pump being used (Fig. 7.1)

Pump calibrat	ion volume	×	
Choose pump o	alibration volume		
C 2 litres			
⊂ 5 litres	OK	Cancel	



- 3) Next, a test window is displayed, divided into three plot areas:
 - a. Flow as a function of volume
 - b. Spirogram
 - c. Flow-volume curves
- 4) Calibration is started by clicking the started button on the toolbar/
- 5) Then, an information window appears with instructions on how to run the calibration (Fig. 7.2).



Fig. 7.2. Dialog box with information supporting execution of the volume calibration procedure



6) The volume calibration procedure generates a report which can be printed out on a printer, and calibration coefficients which are stored in the system register.



Warning:

A calibration report is not stored anywhere and closing the program means losing it. Therefore, to store it, a hardcopy should be printed out.

LungTes	stHandy
(į)	I M P O R T A N T !!! Calibration procedure is not save to memory. Will be save only calibration coefficients: kEx and kIn. If You want to get calibration protocol, print it now (press "Print preview" and next "Print").
	ОК

Fig. 7.3. Dialog box with information concerning the progress of the volume calibration procedure

LUNGTEST Handy Calibration "Flow - Volume" 30 January 2009 9:53 Calib ration FV date: - Moneuvers -Number: 1 Inspirations: 293 Expirations: 302 3 -2 92 3 02 4 -2.93 3.01 5 -2 92 3 04 6 -3.94 3.01 8 -296 301 10 -2.95 3.00 2 -2 92 3 0 2 7 -2.94 3.01 9 -2.94 3.01 - Results -Correction Mm = 1.022 $ME_{\pi} = 0.995$ %Target 979 1003 Tarset -3.00 3.00 Mean -2.94 3.02 Inspirations: Expirations:

Fig. 7.4. Preview of the volume calibration report printout



(i)

Menu commands - translation and description

File menu:

New Patient	<i>New Patient</i> (\Rightarrow Section. 5.1)
Edit patient's data	<i>Edit Patient Data</i> (\Rightarrow Section 5.1)
Patient from file	Patient from File
Open	$Open (\Rightarrow$ Section 5.1)
Close	<i>Close</i> (Closes the active document)
Save	Save (\Rightarrow Section 5.1)
Save As	Save As (Saves test results under the indicated name)
Load Tests	Load Tests (\Rightarrow Section 5.1)
Compare	<i>Compare</i> (\Rightarrow Section 5.1)
Print	<i>Print</i> (\Rightarrow Section 5.10)
Printout Prview	<i>Printout Preview</i> (⇔ Section 5.10)
Printout Settings	<i>Printout Settings</i> (\Rightarrow Section 5.10)
Printout Configuration	<i>Printout Configuration</i> (\Rightarrow Section 5.10)
List of Recently Opened Files	List of Recently Opened Files
End Program	End Program

View menu:

Toolbars	<i>Toolbars</i> (Shows or hides the toolbar indicated in the submenu)
Status Line	Status Line (Shows or hides the status line)
Windows Background	Windows Background (Changes windows background colour to
	the one indicated in the submenu)
Table	<i>Table</i> (Shows or hides the table with test parameters) (\Rightarrow Section
	5.3).

Test menu:

MVV	Minute Voluntary Ventilation
Flow-Volume	Flow-Volume
Spirometry	Spirometry
Confirm Manoeuvre	Confirm Manoeuvre (Confirms initiation of the manoeuvre)
Pase	Pause (Pauses or re-initiates test execution)
Next Phase	Next Phase (Initiates subsequent test phase)
Terminate Test	Terminate Test (Terminates test execution. If the minimum
	number of measurements has been conducted, the test is
	terminated).



Tools menu:

Start Test	Start Test (Initiates test execution).
Perform Master Test	Perform Master Test (\Rightarrow Section 5.10)
Motivating System	<i>Motivating System</i> (\Rightarrow Section 5.5)
Test Options	<i>Test Options</i> (\Rightarrow Section 5.3)
Ambient Conditions	Ambient Conditions (Displays dialog box to enter ambient
	conditions)
Comments editor	Comments Editor (Displays a dialog box to enter test comments)
Zero Spiromter	Zero Spirometer (Zeroes the spirometer)
Calibrate Spirometer	Calibrate Spirometer (\Rightarrow Section 6)
Select Connection	Select Connection (Displays a dialog box to enter the virtual
	communication port)

Window menu:

Cascade	<i>Cascade</i> (Cascades windows inside the main application window)
Tile Horizontal	Tile Horizontal (Tiles windows horizontally so they do not
	overlap)
Tile Vertical	<i>Tile Vertical</i> (Tiles windows vertically so they do not overlap)
Distribute Icons	Distribute Icons (Distributes icons along the lower edge of the
	application window)

Help menu:

Abort the program	About the program (Displays information about the program:
	version no., copyright, etc.)