System Lungtest

LUNGTEST

RHINOMANOMETER RHINOTEST 500

OPERATOR'S MANUAL

Manufacturer:
MES Sp. z o.o.
ul. Krakowska 87
32-050 Skawina
phone/fax: +48 (12) 263 77 67
phone: +48 (12) 269 02 09
mes@mes.com.pl
www.mes.com.pl

CE 1011

EN ISO 13485:2016

Content

1. Introduction.

1.1. Lungtest system description.

Lungtest System was developed by MES team of engineers with many year experience in designing and manufacturing of pulmonological diagnostic units. Lungtest 1000, Rhinotest 1000 and Lungtest 500 included in the Lungtest System have been welcome as the most interesting modern spirometric and rhinomanometric units.

The basic novelty in this system is a measuring headpiece which eliminates all imperfections one meets in other diagnostic systems. The structure of the headpiece is registered as the exclusive development by MES. In our opinion , parameters and usable characteristics of the headpiece are a breakthrough in spirometric testing ,now more precise and safer for patients than ever.

Here are the basic advantages of the headpiece we are offering:
Operational qualities:
1) a new pneumotachometric headpiece is used for a test in each patient,
2) whole headpieces may be washed and sterilised , heating is not required,
3) headpieces do not need to be calibrated by a user, because they have been injection moulded as one element, and their parameters are perfectly replicable ,
4) headpieces are easily replaceable, it needs only connection of two air cables,
5) saliva does not affect the test results,
6) tests results cannot be altered because of patient's saliva as headpieces do not have any sieves or other air- flow resistant elements,
7) dead space of our headpieces is twice smaller than in heads used so far,
8) when a patient is breathing regularly , headpiece resistance is four times smaller than in headpieces used so far. Practically, a test is held in comfortable environment because **a patient is breathing in natural conditions,** without any additional air flow resistance. We would like to underline that Lungtest 1000 and Rhinotest 1000 operate in Windows 3.1 environment and transmit data to statistic programs
Up-to-date range of tests:
Lungtest 1000: spirometry, flow – volume, MVV , RRS, DRT, respiratory cycle covering: test of breath model, P 0.1 measurement in conditions of breathing atmospheric air , hypercapnia, hypoxia, hyperoxia, (tests developed in co-operation with Institute of Tuberculosis, Warsaw), bodypletysmography .
Rhinotest 1000: posterior nasal respiratory resistance (standard, Broms)
Anterior nasal respiratory resistance (standard, Broms)
rhinospirometry in forced flow conditions
nasal maximal minute ventilation.
Lungtest 500: spirometry, flow-volume, MVV, RRS, DRT.
Rhinotest 500: posterior nasal respiratory resistance test (standard, Broms)
anterior nasal respiratory resistance test (standard, Broms)
rhinospirometry in forced flow conditions
nasal maximal minute ventilation.

Rhinomanometr Rhinotest 500 is designed only for testing nasal resistance and flows. Tests of air passages through mouths may lead to faulty results.

1.2. Rhinotest 500 Structure.

Rhinomanometer Rhinotest 500 is a portable unit designed for respiratory system functio tests. Rhinotest 500 Standard consists of three basic elements:

- measurement unit with a specialised computer,
- MEFKA SQ thermal printer or computer printer
- software.

1.2.1. Measuring unit with a specialised computer.

The measuring unit is designed to process flow and pressure parameters in air inhaled and exhaled by a patient into electric signals. These signals are processed by a specialised computer, LCD displayed as curves and parameter values , and printed by an attached printer.

Equipment:

- pneumatach headpieces	4 pcs
- rhinomanometer large mask	1 pcs
- rhinomanometer small mask	1 pcs
- rhinomanometer large hard olive	2 pcs
- rhinomanometer small hard olive	2 pcs
- rhinomanometer small soft oval olive	2 pcs
- rhinomanometer large soft oval olive	2 pcs
- rhinomanometer small soft cylindrical-shaped olive	2 pcs
- rhinomanometer large soft cylindrical-shaped olive	2 pcs
- nasal tip	4 pcs
- silicone hose	1 m
- complete air cable (with terminal)	1 pc
- electric cable	1 pc
- interface cable	1 pc
- floppy disk with a program of extended database	1 pc
- operator's manual	1 pc

1.2.1.1. Working conditions.

Ambient temperature	10 - 45 ^{o}C
Relative humidity	10 - 100 %
Storage	-10 - +45 ^{o}C

1.2.1.2. Technical Parameters.

Flow sensor: silica type

Pressure mesaruring differential sensor: silica type

Spirometric flow measurement range:	+/- 18 l/s
Flow measurement accuracy	< 2 %.
Flow measurement resolution:	
measured	+/- 5 ml/s
usable	+/- 10 ml/s.
Pressure measurement range	*+/- 1,25 kPa.*
Pressure measurement accuracy	*1 %.*
Measuring headpiece resistance	0,075 cmH_2O/l/s flow 1l/s

Analogue flow signal output (ATP conditions)::

Analogue voltage range:	*+-5 V responds to (-+20l/s)*
Power supply	230 V 50 Hz.
Power intake	6 VA
Size	145x250x250 mm.
Weight (without a printer)	1,4 kg.
Protection class	B2.

1.2.1.3. Description of Casing.

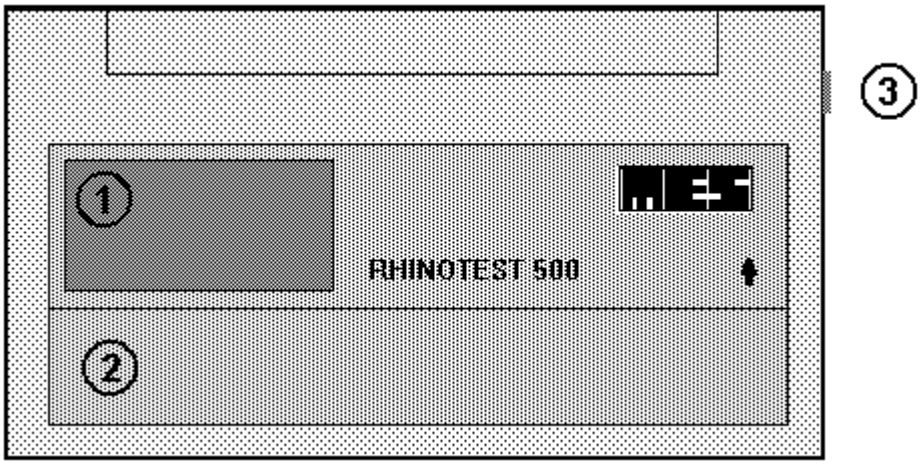


Fig.1. Front panel.

1. LCD
2. Keyboard
3. Power switch

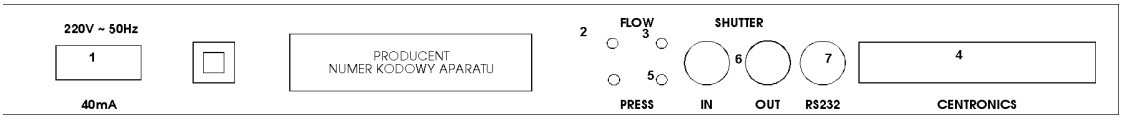


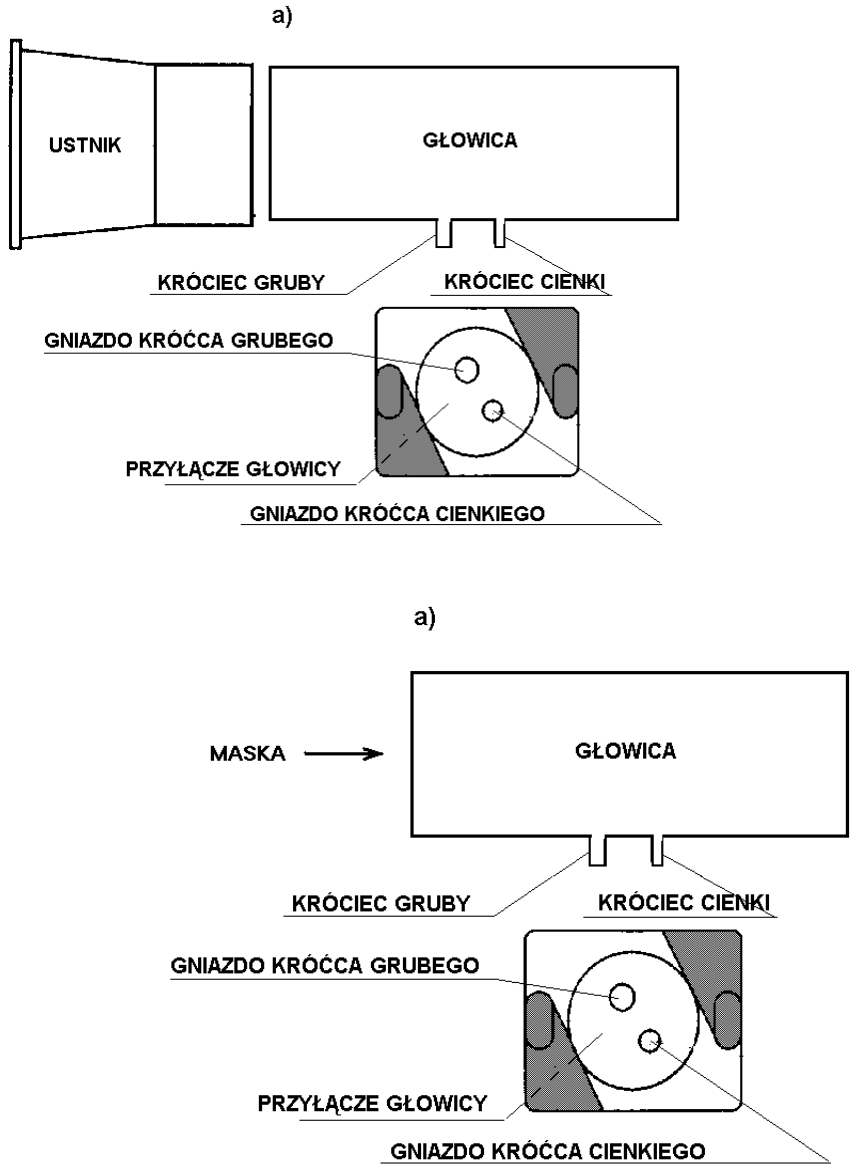
Fig.2. Back panel.

1. Power cable socket
2. RRS- pressure measurement stub
3. Pressure flow measurement stub
4..Centronics
5. Pressure flow measurement cable stub
6. Power socket of RRS closure
7. RS232.

1.2.1.4. Pneumotach Headpiece

Pneumotach headpiece is injection moulded. Parameters of all headpieces are precisely replicable. Only air cables connected with a measurement module are connected to the headpiece. Headpieces may be washed with any washing agents and gas sterilized. **A clean headpiece with a mask should be put on before a test in each new patient, and taken off after the test**. Control calibration of a newly placed headpiece is not

needed. Headpieces will have the same parameters until they are mechanically damaged.
Fig. 3 shows a headpiece with a holder and a mask.



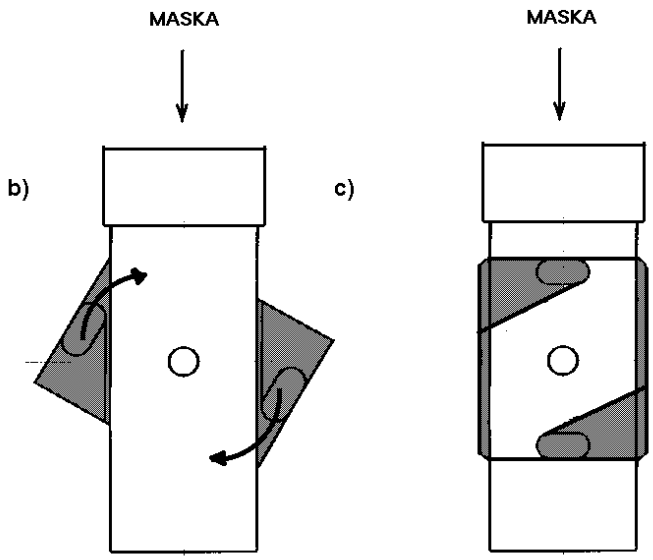
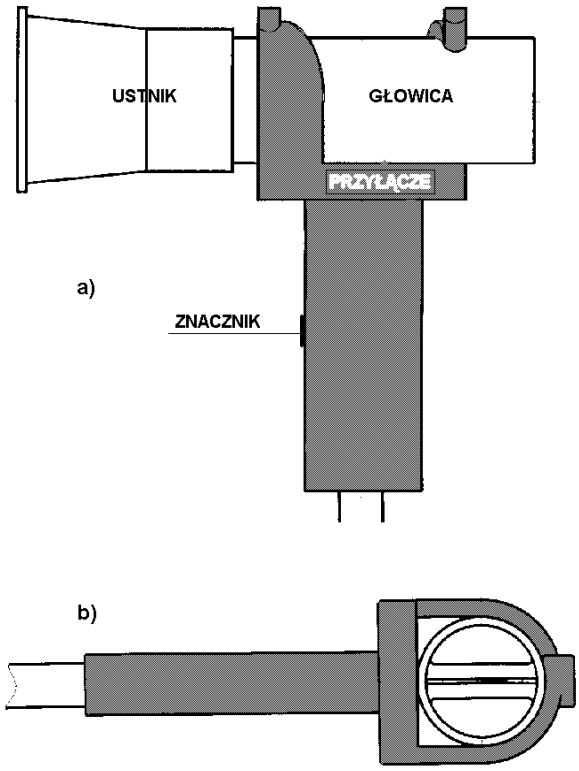


Fig.3 Pneaumotach Headpiece.

Before a headpiece is put into the holder , position the holder as shown in fig. 3b; in such a way that headpiece stub sockets in the upper part of the headpiece (fig.3a) be visible as shown in the figure. Then place the headpiece into the holder , slightly pushing stubs into the sockets. You will not make a mistake because stubs are of different diameters. If you have problems with pushing the stubs into the holder, turn the headpiece by 180^0 and push in again. Delicately push the headpiece home. When pushed in, turn upper part of the holder in direction shown in fig. 3b until holder clasps are snapped in position shown in fig. 3c.



1.3. Tests.

1.3.1. Rhinomanometer Calibration

A rhinamometer is calibrated by the manufacturer. Sensor and pneumotach headpieces are calibrated to the full extent of the measured flows with a precision flow calibration set Mde by Statham and do not require calibration by a user.

1.4. Measured Parameters

RHINOTEST 500 allows to indicate the following parameters:

nasal respiratory resistance:

Rn_{RSIn} [kPa/l/s]	Brom's standard anterior inspiration right nasal resistance
Rn_{RBIn} [kPa/l/s]	Brom's anterior inspiration right nasal resistance
Rn_{RSEx} [kPa/l/s]	Brom's standard anterior expiration right nasal resistance
Rn_{RBEx} [kPa/l/s]	Brom's anterior expiration right nasal resistance
Rn_{LSIn} [kPa/l/s]	Brom's standard anterior inspiration left nasal resistance
Rn_{LBIn} [kPa/l/s]	Brom's anterior inspiration left nasal resistance
Rn_{LSEx} kPa/l/s]	standard anterior expiration left nasal resistance
Rn_{LBEx} [kPa/l/s]	Brom's anterior expiration left nasal resistance
Rn_{RS} [kPa/l/s]	standard anterior right nasal resistance
Rn_{LS} [kPa/l/s]	standard anterior left nasal resistance
Rn_{AS} [kPa/l/s]	standard anterior full nasal resistance
Rn_{AB} [kPa/l/s]	Brom's standard anterior full nasal resistance

Rnp_{SIn} kPa/l/s]	standard posterior inspiration nasal resistance
Rnp_{BIn} kPa/l/s]	Brom's posterior inspiration nasal resistance
Rnp_{SEx} [kPa/l/s]	standard posterior expiration nasal resistance
Rnp_{BEx} [kPa/l/s]	Brom's posterior expiration nasal resistance
SD	standard deviation

Rhinospirometry under forced flow conditions:

NPEF [l/s]	nasal peak expiratory flow
NFEV 1 [l]	nasal forced expiratory volume in 1 second
$NFVC_{Ex}$ [l]	nasal forced expiratory vital capacity
NFVCIn [l]	nasal forced inspiratory vital capacity
NVC_{Ex} [l]	nasal expiratory vital capacity
NVC_{In} [l]	nasal inspiratory vital capacity
NMEF 75 [l/s]	nasal maximal expiratory flow at 75% NFVC
NMEF 50 [l/s]	nasal maximal expiratory flow at 50% NFVC
NMEF 25 [l/s]	nasal maximal expiratory flow at 25% NFVC
NPIF [l/s]	nasal peak inspiratory flow at 50% FVC

1.5. Measuring technique.

1.5.1. Rhinomanometry.

Measurements of relationships occurring between pressure and flow values in the nasal cavity may be conducted with the RHINOTEST 500 device when the active anterior or posterior rhinomanometry method is applied.

The anterior rhinomanometry technique is a very useful procedure for measurement as it depends upon the patient's co-operation only to a small degree. In this method, we simultaneously take measurements of pressure from one nasal opening and flow from the other nasal opening. The measurement is conducted with mouth closed and nasal breathing at rest conditions. The RN nasal resistance measurement for the left nasal opening consists in measuring this opening's flow and pressure from the right nasal opening. The RN nasal resistance measurement for the right nasal opening consists in measuring this opening's flow and pressure from the left nasal opening. The pressure/flow curves for the nasal cavity are obtained with a mask closely applied to the face. A pneumotachography tube is connected to the mask exhaust opening in which flow value is measured. Pressure measurement results are obtained inserting a closely fitted olive into the nasal opening, whose exhaust is connected with a small-diameter silicon pipe to the pressure probe.

Theoretically, resistance for the whole flow at both nasal openings is a function of resistance for each nasal opening separately.

$$1/NAR\ (full) = 1/NAR\ (left) + 1/NAR\ (right)$$

NAR – nasal airway resistance

However, the total NAR value as measured with the rhinomanometry technique is different from the sum of resistance values for both openings. This difference may be due to the different resistance components of the nasal cavity, to the deformation of the nasal opening resulting from improper olive setting or to the lack of pressurised measurement system

The posterior rhinomanometry technique consists in simultaneous measuring pressure in oral cavity and flow from both nasal openings. The measurement is conducted with mouth closed and nasal breathing under rest conditions. A mask closely applied to the face is used at the measurement. A pneumotachography tube is connected to the mask exhaust opening in which changes in flow value in nasal cavity are measured. Pressure measurement results are obtained from a small-diameter flexible pipe placed in the patient's oral cavity. Proper placement of the pipe in the oral cavity may be a little difficult. Improper placement of the pipe may result in artefacts on the curve of pressure changes due to the movements of the patient's tongue. Despite the fact that length and diameter of the pipe placed in the mouth are not critical, we suggest a 9 mm diameter pipe as the best solution for patients with poor control of tongue movements. In order to avoid artefacts, a short training is to be conducted with a patient and count only "smooth" pressure/flow curves into the calculations.

1.5.2. Nasal Flow/Volume Test

A patient is breathing through the nose with mouths closed through a mask and a pneumotachographic headpiece. After several regular breathes, a patient makes the fastest possible forced breath-out followed by maximally fast forced breath-out. Fast forced breaths out and in are repeated several times

1.5.3. Nasal Spirometry.

A patient is breathing through a mask and a pneumotachographic headpiece. After , at least, 10 regular breathes, a patient makes a slow deep breath – out followed by a slow deep breath-in. Then a patient breathes freely through measurement system.

1.5.4. Maximal nasal minute ventilation (MVV).

A patient is breathing through the nose through a mask and a pneumotachographic headpiece. The test is divided into two stages: resting stage and MVV stage. In the first stage, a patient is breathing freely, and at the strictly defined moment in the second stage, a patient is breathing as fast and deep a possible. The test ends when the second stage has been completed.

1.6. Principles of rhinomanometric parameters calculation

Calculation of parameters is done according to two methods in RHINOTEST 500 sets: the standard method and the Brom's method.

Standard method. The standard method determines the pressure value at which we calculate nasal resistance. The RHINOTEST 500 software system allows for changing the value of this pressure in the range from ± 25 to ± 250 Pa. 150 Pa is taken as the standard value.

Brom's method. The method devised by Broms takes the 0.2 l/s circle radius which intersects the pressure/flow curve thus determining the point which is used for nasal

resistance value calculations. The circle radius in the Brom's method is fixed.

2. Rhinotest 500 Software Operation.

2.1. General Information.

Rhinotest 500 software facilitates testing and provides easy access to test results. The manufacturer recommends to read the system operational manual supplied with the rhinomanometer

Rhinotest 500. Rhinotest 500 module performs the following functions:

- entering patient's data,
- selecting test parameters,
- testing,
- printing test results and curves,
- saving test results into the database.

The software designers focused on proving users with a software providing the highest comfort at testing. Rhinamometer software is easy to operate and allows:

- archivisation of results,
- viewing the results,
- printing test results,
- comparing results,
- transmitting data to PCs.

2.1.1. Initial Notes.

Rhinotst 500 is easily and fast operated with software based on a system of command lists (menus) displayed on the LCD screen. Menus are selected with four arrow keys. The selected menu is displayed in a negative moda (light letters and symbols, dark background). Pressing ENTER activates a selected command, except screens where particular functions are described directly with letters. Pressing a key with a letter described by a function program immediately activates such function.

2.1.2. Program auxiliary functions.

If you need a prompt how to go to further stages of the program, press F1 to see a prompt telling which keys to use to go to further functions. If a prompt window displays **I**, it means that more information about the test being presented on the screen is available. Such information includes time of the test and a comment on the test, if any. In order to go out of the information window and pass to the next part of the program, press any key.

2.2. Main Menu.

After company logo have been displayed and ambient conditions data have been entered, press ENTER to display Rhinotest 500 main menu. The main menu is shown below:

DANE PACJENTA	CECHOWANIE
BADANIE	BAZA
OPCJE	SERWIS

Fig.4. Main Menu

2.2.1. Description of Main Menu Functions

2.2.1.1. Patient data

When PATIENT DATA function is selected, fields to be filled in patient's data will be displayed. The unit stores the following information about a patient:

- first name
- surname
- date of birth
- weight
- height
- gender
- smoker/ non-smoker
- test number
- PESEL – personal identity number
- physician's name

Patient's data MUST be entered because the unit compares the values obtained from a test in patient with reference values and then print patient's data next to the test results.

2.2.1.2. Ambient Conditions

AMBIENT CONDITIONS function is used to change and control of pressure, temperature, and humidity values entered upon switching the unit on.

Entering wrong values of ambient parameters will result in errors in test results.

2.2.2. Test

Selecting TEST function results in displaying the next menu presented below:

POSTERIOR	ANTERIOR
NASAL FV	NASAL MVV
POWRÓT	

Fig.5.TEST Menu

Particular functions of this menu are described below.

2.2.2.1. POSTERIOR

Selection of this function activates the test mode. The unit will display a set of coordinates ready to display curves being generated during the test.

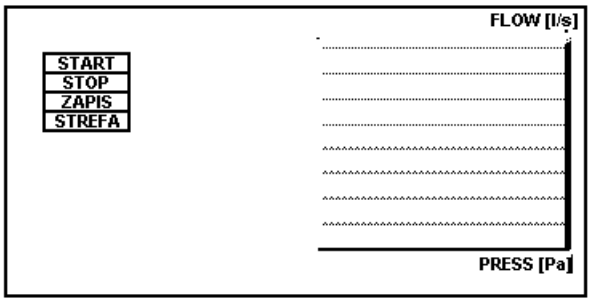


Fig.6. Screen displaying the course of a posterior test.

For a short time TEST will be displayed in the left top corner informing about an autotest of the unit. The a menu shown in fig. 6 above will appear. START enables displaying courses of pressure and flow. Selecting START function will reset the unit and enable visualisation of pressure and flow courses. RECORD function starts recording of test results. The unit stores last 10 manoeuvres. STOP function stops the test and automatically passes to analysis of results. ZONE function enables changing of a standard zone from 50 to 175 Pa.

2.2.2.2. ANTERIOR

Selection of this function activates the test mode. The unit will display a set of coordinates ready to display curves being generated during the test.

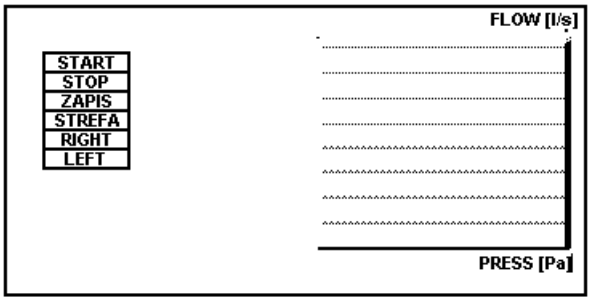


Fig.7. Screen displaying the course of an anterior test.

Anterior test program is operated same as the posterior one, except functions LEFT and RIGHT. These functions serves to provide the program with information which nasal duct is being examined. Information about a selected function is displayed in the left top corner of the screen.

2.2.2.3. Elaboration of POSTERIOR and ANTERIOR results

When the test is finished with STOP function, the program will display the screen shown below.

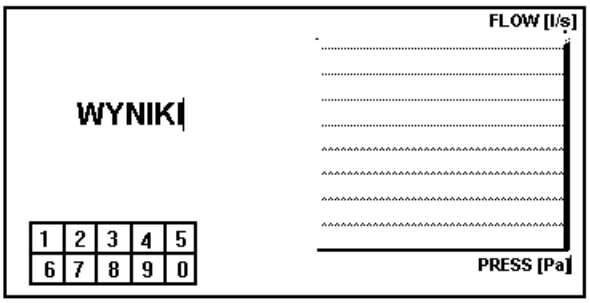


Fig.8. Anterior and Posterior results screen.

A user may view and select curves resulted from the test on the screen presented above. Moving a highlighted field along rectangles placed under coordinates, a user may watch particular result curves. These curves may be eliminated from average parameter calculations by pressing ENTER ("-" will be displayed next to a number of the curve). The curve needed for calculation of the average is restored by repressing ENTER ("+" will be displayed next to he curve). Numerical values of parameters calculate for each curve are displayed next to a plot of curves. When a test is completed, the unit normally display position "1" – average, where all the curves are attached, which may be viewed after pressing key . The unit "remembers" up to 10 last curves. The average of the selected curves and a curve being displayed are saved into the database.

2.2.2.4. NASAL FV

Selection of this function activates the test mode. The unit will display a set of coordinates ready to display curves being generated during the test.

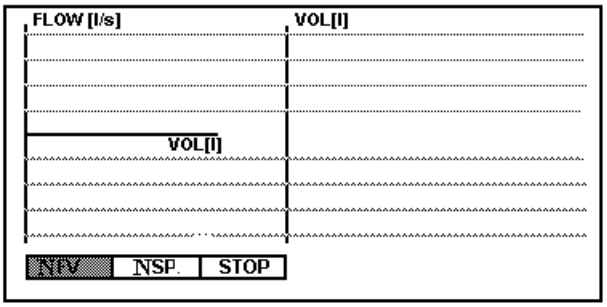


Fig.9. Screen representing spirometry and flow/volume test

NFV function starts flow/volume test, NSP starts spirometry. STOP function stops the test and allows displaying the result. Results are displayed as shown below:

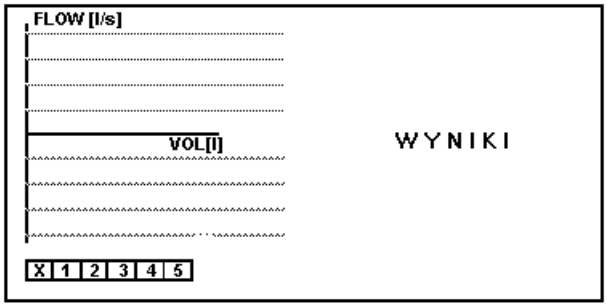


Fig.10. Elaboration of nasal flow/volume test results.

Flow/volume test results are normally calculated with envelope method. A user may select curves to be included in the envelope with the screen presented above. Moving a highlighted field along rectangles placed under coordinates, a user may watch particular result curves. .

These curves may be eliminated from the by pressing ENTER ("-" will be displayed next to a number of the curve). The curve needed for calculation of the envelope is restored by repressing ENTER ("+" will be displayed next to he curve). Numerical values of parameters calculate for each curve are displayed next to a plot of curves. When a test is completed, the unit normally displays position "X" – envelope, where all the curves are attached, numbers of curves are displayed on the screen . The unit "remembers" up to 5 last curves. The envelope of the selected curves is saved into the database. The below figure shows how to display results after envelope curves have been selected.

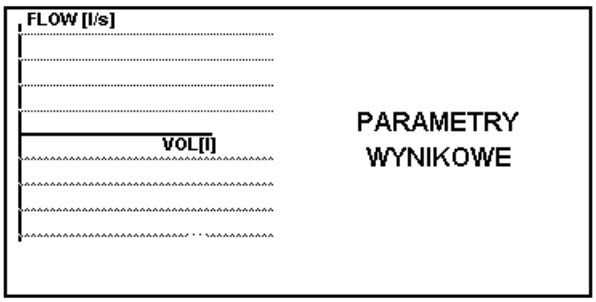


Fig.11. Results of nasal flow/volume test

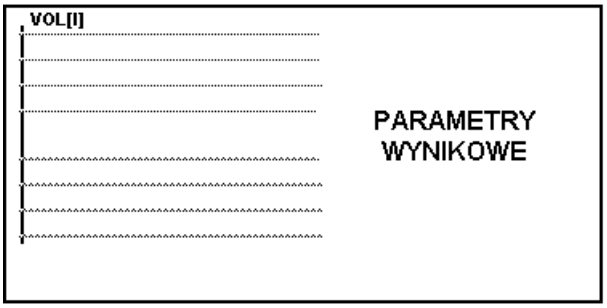


Fig.12. Results of nasal spirometry.

Spirometry parameters are automatically calculated by the unit upon completion of the test. The above figure shows how they are represented onscreen.

PARAMETR	AKT.	NAL.	%

Fig.13. Table of results.

The results displayed in the table allow comparison of values from the test (AKT) with reference values (NAL) expressed in %.

2.2.2.5. MVV nasal maximal voluntary ventilation

This function starts MVV test. The unit will display a screen where 12 or 15 second test phase may be selected. Standard setting is 12 s. When the phase length is set, the following coordinates will be displayed:

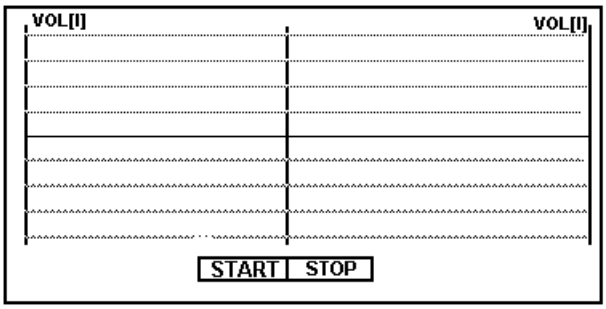


Fig.14. Nasal MVV test.

The test begins automatically with START and stops automatically or after manual introduction of STOP function before the time of test completion.

2.3. End of the Test

2.3.1. Saving results into database and printing test results.

After ending the test with STOP and pressing ENTER, the unit will display the following menu:

SAVE TEST INTO DATABASE
PRINT TEST
ACCEPT

Selection of one function or two functions simultaneously and ACCEPT allows printing of test results and/or saving the results into the database. If none of the functions is selected, the results will be irretrievably lost.

2.3.2. Repetition of the Test

It may be necessary to repeat a test in three cases:

1) a unit will display a message about error in the test and will demand repetition of the test

2) a course of the test needed for interpretation of the test has not been recorded

3) a user has decided that the obtained results are incorrect.

In case 1) press ENTER. The unit will return to the test menu. Select the required test from the menu and tun it from the beginning.

In case 2) the unit will return to the test menu after a test has been fended with STOP function. A test in question should be repeated now.

In case 3) do not save the test with SAVE TEST INTO DATABASE but select AACEEPT. The unit will return to the test menu. Now, repeat the test.

3. Running Tests.

This chapter includes practical guidelines how to use Rhinotest 500 efficiently and correctly.

3.1. Preparing the unit to work

In order to have the unit ready to work:
- connect air cable to stubs at the back panel,
- connect the pneumatech headpiece to the air cable and mask,
- connect the mask pressure cable
- connect the power cable to the power socket of the unit,
- connect the power cable to 220 v 50 Hz socket,
- switch the unit on with the power supply switch on the right of the casing.

Note. The manufacturer recommends to switch the unit on and wait at least 30 minutes before you start tests in order to stabilise working conditions.

To switch the unit off , do the same as for switching on, but in reverse order. If you do not move the unit to a different location, it is enough to switch off the power supply switch.

3.2. General guidelines on software operation

3.2.1. Keyboard

Communication with the unit is only via keyboard. The software is designed in such a way that it is impossible to disturb operation of the program by pressing a wrong key. Operation of the keyboard is very easy because the unit work is controlled only with **←, , →, ↓, Esc, ENTER, and F1 keys**. Other keys are used only for typing a text (first name, surname, header, description of a test). **←, , →, ↓** keys are used "to move" inside menus displayed by the program, to the left, to the right, up and down the screen. **Esc** is used to leave an option of the program and go to main menu. **ENTER** is to confirm an option or accept the introduced data, i.e. patient's data. Pressing **ENTER** maeks the program perform a command selected from the menu or save the introduced data. **F1** is to display prompts showing a table with active keys available for controlling the unit in the given moment. The message is displayed in the middle of the screen in a rectangular frame. A message is cancelled by pressing any key.

3.2.2. Menu System

The unit menu system displays a list of possible commands, and always one of the commands is displayed in light letters against the dark background. Such command will be answered by the unit after ENTER has been pressed. A highlighted field may be changed with ←, , →, ↓ keys. It is also possible to select commands in another way. Commands are written on the screen in the form of W-WYKONAJ (DO). In this case pressing W key will result in carrying out the selected command.

3.3. Beginning of Tests.

After the unit has been switched on, the manufacturer's trademark is display. Press ENTER to go to AMBIENT PARAMETERS. Enter current parameters: pressure, temperature and relative humidity. It is not possible to perform a test if ambient parameters have not been entered. WRONG AMBIENT PARAMETERS WILL RESULT IN TEST ERRORS.

After the data have been introduced press ENTER to go to the rhinanometer main menu.

3.3.1. Introduction of Patient's Data.

Select PATIENT'S DATA from the main menu. A screen with fields to be filled will be displayed. A place where each next font will be entered is indicated with a cursor in the firm of _ displayed onscreen. We position a cursor with ←, , →, ↓ keys. To replace an already typed sign with a new sign, place the cursor under the existing sign and press a new sign. The new sign will be introduced and the cursor will shift to the next position. SPACE key is used to leave an empty field, a space.
Notes.
To go to a new line use ↓.
Date of birth is entered as follows: day (two figures), month (two figures), year (four figures), for instance, 05-06-1967. "-" signs are displayed automatically.
Weight, height, identifier must be entered in a numerical form.
In case of error in data, the unit will not allow passing to the next line.
Fill in all fields and finish entering the data with ENTER key. (identifier and physician's name are optional).

Before the test is started, patient's data MUST be entered because the unit calculate reference parameter values on the basis of these data.

Patient's data may be also retrieved from the database by selecting a previous test of the patient and leaving the database screen with W key.

3.3.2. Delete patient's Data

To delete patient's data from PATIENT'S DATA" press F2 to delete all records from the fields. Empty fields will facilitate entering new patient's data.

3.4. Performing Tests

In order to perform a test, select TEST function from the menu. Available tests will be displayed.

3.4.1. Posterior Test

The posterior rhinomanometry method consists in simultaneous measuring pressure in oral cavity and flow from both nasal openings. The measurement is conducted with mouth closed and nasal breathing under rest conditions. A mask closely applied to the face is used at the measurement. A pneumotachography tube is connected to the mask exhaust opening in which changes in flow value in nasal cavity are measured. Pressure measurement results are obtained from a small-diameter flexible pipe placed in the patient's oral cavity. Proper placement of the pipe in the oral cavity may be a little difficult. Improper placement of the pipe may result in artefacts on the curve of pressure changes due to the movements of the patient's tongue. Despite the fact that length and diameter of the pipe placed in the mouth are not critical, we suggest a 9 mm diameter pipe as the best solution for patients with poor control of tongue movements. In order to avoid artefacts, a short training is to be conducted with a patient and count only "smooth" pressure/flow curves into the calculations.

In order to perform a posterior test, do the following:
- enter patient's data and check whether they are correct,
- select **POSTERIOR** from **TEST** menu ,
- a screen „test performed after....” will appear. Introduce a short comment (up to 15 signs). The comment will be saved and it will appear in the printout or onscreen during viewing the database (after pressing I key);
To give up a comment press **ENTER**.
- select **START** function from **POSTERIOR** menu,
- When **Zero** sign disappears insert olives into patient's nose, put pressure cable and the pneumatach headpiece,
- tell the patient to breath regularly,
- select **REGISTRATION** function,
- observe the curves being displayed,
- when correct curves have been registered stop registration with **STOP** function.

NOTE. The unit remembers 10 last curves.

3.4.2. Anterior Test

In the anterior rhinomanometry , we simultaneously take measurements of pressure from one nasal opening and flow from the other nasal opening. The measurement is conducted with mouth closed and nasal breathing at rest conditions. The RN nasal resistance measurement for the left nasal opening consists in measuring this opening's flow and pressure from the right nasal opening. The RN nasal resistance measurement for the right nasal opening consists in measuring this opening's flow and pressure from the left nasal opening. The pressure/flow curves for the nasal cavity are obtained with a mask closely applied to the face. A pneumotachography tube is connected to the mask exhaust opening in which flow value is measured. Pressure measurement results are obtained inserting a closely fitted olive into the nasal opening, whose exhaust is connected with a small-diameter silicon pipe to the pressure probe.

To run an anterior test the following should be done:
- introduce patient's data or check already introduced data for correctness,
- select ANTERIOR function from TEST menu,
- a screen „test performed after....” will appear. Introduce a short comment (up to 15 signs). The comment will be saved and it will appear in the printout or onscreen during viewing the database (after pressing I key);
To give up a comment press **ENTER**.
- select **START** function from **ANETRIOR** menu,
- when **Zero** sign disappears insert olives into patient's nose, put pressure cable and the pneumatach headpiece,
- tell the patient to breath regularly,
- select **REGISTRATION** function,
- when correct curves have been registered press Lft/Right key to change a nasal opening,
- take the olive off one nasal opening and put it into the other,
- observe the curves being displayed,
- when correct curves have been registered stop registration with **STOP** function.

3.4.3. Nasal Spirometry and Flow/Volume Test

In order to run nasal spirometry and flow/volume test, select NFV function. Coordinates needed for spirometry and flow/volume test will be displayed on the screen. Select NFV test and press ENTER. For a moment a ZERO message will be displayed (when ZERO is being displayed, a pneumotach headpiece should be motionless, preferably lying on a table). When ZEO disappears , the test starts. A patient is breathing through a mask and a pneumotachographic headpiece. After several regular breathes, tell a patient to make the fastest possible forced breaths-out followed by maximally fast forced breaths-in. Fast forced breaths out and in are repeated several times

All changes in the measured values are controlled in real time, and flow/volume and flow/time curves are displayed. Time of test running is unlimited. When the flow/volume test has been completed you may, without interrupting patient's breathing, shift to spirometry with NSP function. After you have selected NSP, press ENTER and start the test. Tell the patient to make 10 regular breathes, and then a slow deep breath – out followed by a slow deep breath-in. Then after several free breathes , stop the test. Registration of the test can be stopped any time with STOP key. .

In case a flow/volume curve „has escaped" during the test, you may go back to the beginning of the system of coordinates with F2 key.

3.4.4. MVV TEST.

In order to run MVV test select NASAL MVVV function from the menu. Two alternative phase lengths will be displayed. Accept the selected length pressing ENTER. Coordinates for the test will display. A patient is breathing through the nose through a mask and a pneumotach headpiece. The patient is breathing regularly. Start registration with START function and observe the V(t) curve . At the moment the line goes beyond the end of resting phase, tell the patient to breath as fast and deep as possible. When the line goes beyond the end of MVV phase, the test is automatically stopped.

3.5. Test Analysis and Recording in Database

test analysis consists in viewing results of the completed test in order to eliminate results of faulty tests and calculate relevant parameters or compare the results. Rhinotest 500 allows initial analysis of anterior, posterior, and flow/volume tests.

Each test may be recorded in the database together with result curves.

Description of test analysing is included in the previous chapter.

3.5.1. Saving Results into Database

The results are recorded in the database by pressing ENTER when the screen with spirometry results in SPIR-FV-1, and SPIR-FV-2 are displayed, and after MVV test has been stopped. The unit displays menu:

SAVE TEST RESULTS INTO THE DATABASE
PRINT TEST
ACCEPT

Select a required option from the menu and press ENTER. Next to the required item you will see a darken rectangle marking a command to the program. Select ACCEPT and press ENTER to have the selected options saved.

4. Database

4.1. General Description

The database is designed for **archivising, viewing, comparing, and printing** the results of the tests run with Rhinotest 500. It allows selective viewing of the results, free selection of the data to be viewed from the archivised test results. Test results following the analysis carried out by Rhinotest 500 program are saved into the database. The database is sufficient for archivising last 100 results.

4.1.1. Database Functions

Names of all patients whose tests have been archivised are displayed as a list of patients.To select a patient from the list, indicate the name and press ENTER. Now a field with the selected patient's name will change colour – it will be displayed as a negative. Data of such a patient may be processed by selecting a relevant function from the list situated below the table.

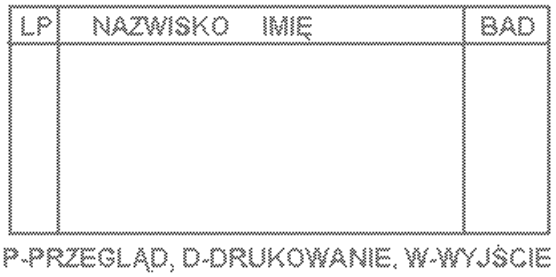


Fig15. Database functions

The table displays a number of the test (LP), surname and first name of the patient, type of the test (BAD) :
ANT - anterior
POST - posterior
NSP - spirometry
NFV – flow/volume
NMVV – maximal minute ventilation.
Viewing the result base you may get information on time of the test pressing I key. Information is displayed in a frame in the middle of the screen and cancel it with any key.
The table displays 10 items answering particular tests. To go to the next page of the test press Alt and keys at the same time, to go back to the previous page press Alt and ↓ keys at the same time.

4.2. Test Viewing

To view the curves and test results, select a test from the displayed list of tests and press P. Select a test with , ↓ and press ENTER. The selected test will be marked with a dark rectangle in the first line of the table.
After the test has been displayed, you can change a form of display (from curves to tables) with , ↓ keys. Press I to display additional information: a comment entered before the test, date and time of the test.

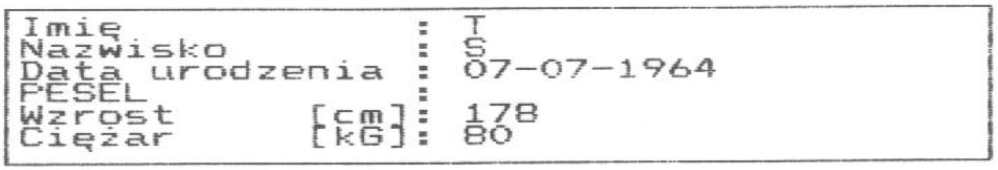
NOTE F1 function is more extensive, when pressed at any stage of operation, it will display the next step to choose- , I key displays „ an abreviated operational instruction".
If you want to go back to the test list, press ENTER at the time of viewing spirometry and MVV curves. Before the program goes back to the test list the foolowing menu is displayed:
PRINT
BACK
If you select PRINT, the test will e printed before the program returns to the test list.

4.3. Test Printing

To print a test, select a test from the list and press D key. A test for printing is selected in the same way as described in point 4.2 above.

4.4. Comparison of Tests

To compare tests select two tests of the same type in the same patient (the unit compares patient's data). After VIEW function as been selected, the unit will compare tests results and the result of comparison will be displayed (flow/volume test will be displayed with curves, other tests will be compared only in a numerical form). To print the compared tests go back to the test list from PRINT position or select 2 tests from the list and press D key).
Viewing of the test being compared is the same as viewing a single test.
It is not possible to compare two tests of different types or two tests in different patients.



Imię	:	T
Nazwisko	:	S
Data urodzenia	:	07-07-1964
PESEL	:	
Wzrost [cm]	:	178
Ciężar [kG]	:	80

1: ( ) 09:58,05-11-2004
2: ( ) 09:58,05-11-2004

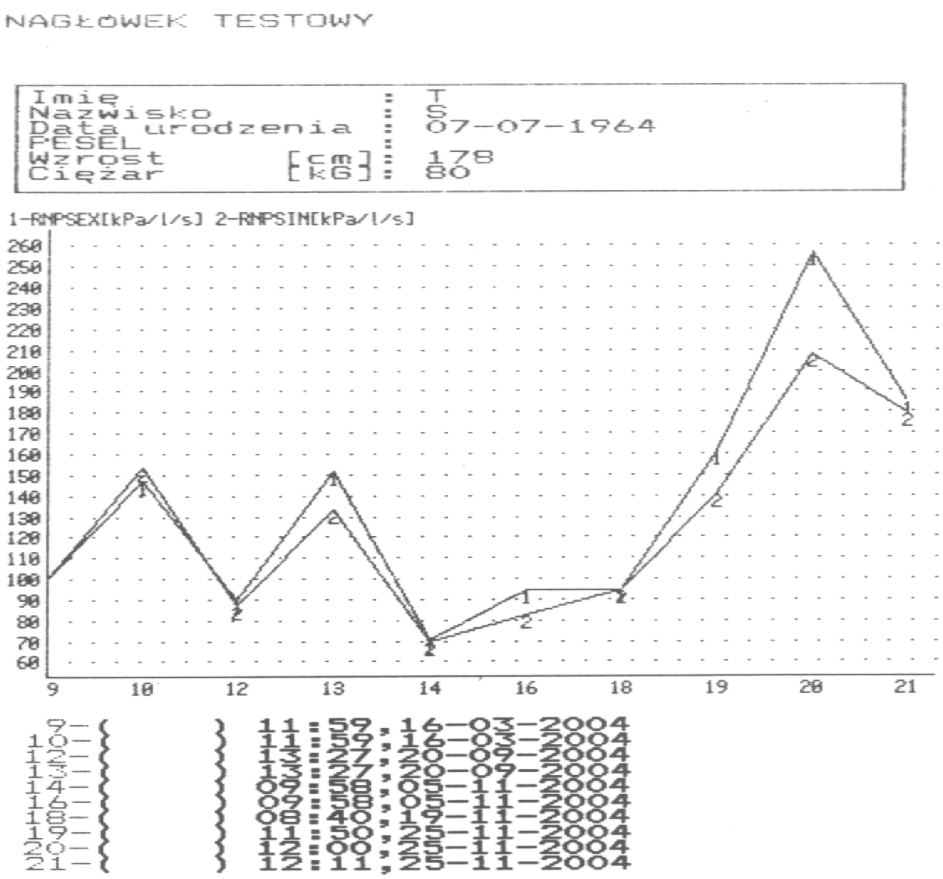
Anterior	Bad2	Bad1	2/1%
RNRSEX	0.28	0.29	96.50
RNRSIN	0.32	0.27	118.50
RNRBEX	0.21	0.19	110.50
RNRBIN	0.31	0.22	140.90
RNLSEX	0.30	0.24	125.00
RNLSIN	0.37	0.27	137.00
RNLBEX	0.28	0.23	121.70
RNLBIN	0.37	0.24	154.10
RNRS	0.30	0.28	107.10
RNLS	0.34	0.26	130.70
RNAS	0.16	0.13	123.00
RNAB	0.15	0.11	136.30
Standard	100	100	

Ocena badania:

4.5. TREND function

This function enables comparison up to four parameters from tests in one patient, presented in graphic form in order to define trends of the selected parameters.

Select tests (up to 30 tests) of the same type and in the same patient with ENTER, and press ‘T’ key. A list of parameters available for selection will be displayed. Press ENTER to select parameters. To give up a selected parameter press ENTER again. 4 parameters may be selected simultaneously. After the parameters have been selected press F3 (ac. To the prompt at the top of the screen : ‘F3 – graph’). A graph visualizing a trend for selected parameters will be displayed. Vertical scale is expressed in percent. Parameters of the first test (with the lowest serial number) het the value of 100%, and parameters of subsequent tests are expressed in a percent proportion to parameters of the first test. A horizontal scale includes numbers of tests corresponding to numbers in the database. Now, „D, P, and W’ keys are active. ‘D’ key is to print the displayed graph, ‘P’ key is to go back to the place of parameter selection and view the trend of other parameters from the same tests. ‘W’ key is to exit from TREND function. ‘Too big graph’ means that one of the parameters is bigger than the first parameter by more than 400% and the whole graph cannot be displayed on the screen. In such a case repeat selection of parameters. If the value of one of the selected parameters is lacking, a straight line will be drawn at 0% level.



4.6. DATABASE LOSS

The database may be destroyed in two cases:
- when the unit has not been plugged in for more than three weeks,
- in case of voltage failure during saving the data into the database.

In such a case, the unit will display a message about destruction of the database when it is plugged in again. It is possible to regain a part of the test results by transmitting the data to the computer or printing the data which has not been damaged. After the message about the destruction of the database, delete the content of the database before you start entering new data.

5. Additional functions

5.1. Options

When you have selected options from the main menu, the following menu will be displayed:
CALIBRATION
DATA TRANSMISSION
TIMER
CONFIGURATION
HEADER

BACK

5.1.1. Calibration

The measuring module is calibrated to the full extend with a precision flow generator, including correction of nonlinearity of the whole measuring set. Repeatability of pneumotach headpieces means that calibrating with 1 l pump is not necessary. However, a user may do it with a calibrated pump of 1l volume.
Volumetric calibration check requires smooth pump movements, a plunger cannot strike the casing as it will distort volume measurements. The manufacturer guarantees precision of flow calibration and that means that also volumetric calibration precision is guaranteed, because volume is the result of flow integration in time. To check calibration, select CALIBRATION option from the menu. When coordinates are displayed press START, allow at least four pump strokes and press STOP key. When calibration is completed, system correction coefficients are displayed. In case of discrepancies in volumetric calibration exceeding 5 % , repeat calibration with another pneumotach headpiece.

5.1.2. Data transmission

Selection of DATA TRANSMISSION will display the next menu:
TRANSMIT DATA
DELETE TESTS
ACCEPT
Commands DATA TRANSMISSION and ACCEPT sends test results in txt format to PC.

Before transmission of test results connect Rhinotest 500 with RS232 to any COM of the PC. Activate computer RT500 program supplied with the rhinomanometer. The program will auomatically find a COM where rhinamometer cable was connected and display WAITING message. Now select ACCEPT function from the rhinomanometer menu. “Data transmission...” message will be displayed and will be visible till the end of the transmission. The transmitted data will be saved in RT500 program under the name entered by a user.
Commands DELETE TESTS and ACCEPT delete irretrievably all the results from the database.

5.1.3. Timer

Timer function will display date and time. Date and time may be changed by entering relevant numbers from the keyboard. Time is entered in the form of (hour) (minute) (second), and date in the form of (day)-(month)-(year). To accept the date and time press ENTER six times. Each pressing of ENTER shifts the cursor by a group of two numbers.

5.1.4. Configuration

CONFIGURATION enables selection of transmitting data to the printer:
RS232 40 signs – thermal printer
CENTRONICS 80 signs – other printers with parallel transmission.

Configuration is set by the manufacturer upon selling the unit and should be modified only when you have changed a type of the printer connected to the rhinomanometer.

5.1.5. Header

HEADER function enables entering a header in a printout generated by the unit. A user can enter 3 lines of text, 38 signs in each. Position a cursor inside the displayed frame with ←, , →, ↓ keys. To end entering the text and go back to the menu, press ENTER. The text is "remembered" after the unit is switched off.

5.2. Service.

SERVICE function is for use by the manufacturer's sevice providers. I cae you pressed it, go back to the menu pressing ESC.

6. Maintenance of Rhinotest 500 rhinomanometer.

6.1. Operational guidelines

Pneumotach headpieces must be clean, dry, and free of foreign bodies. After each test, clean a headpiece carefully, remove all foreign bodies and dirt with a soft brush.

Note. When you finish washing and sterilising always check whether air ducts of the headpiece do not contain any liquid. Air ducts of the headpiece used for testing must be dry !!!

Pneumatech headpieces may be sterilized with gas or liquids available on the market.

Every day you must check:

- whether air ducts are patent
- condition of pneumotach headpieces
- condition of power supply cable

6.2. Maintenance

Casing should be washed with a damp sponge or soft cloth. You may use soap or mild cleaning agents not containing organic solvents.

Note. Do not flood the unit with liquid.

6.3. Disinfection and sterilisation.

After a test, place a pneumotach head and mask in a container with albumin removing liquid used for washing surgical instruments for time recommended by a manufacturer of disinfection liquids. Then rinse headpiece and mask with destilled water and dry with stream of warm air with temperature not exceeding 70^0C or rinse with ethyl alcohol and leave until alcohol evaporates.

Recommended desinfection agent: „Aldhesan" or „CIDEX" glutar aldehyde .

Disinfction and sterilisation must be performed in line with guidelines referring to disinfection and sterilisation means.

NOTE!

1/ Headpieces supplied with rhinomanometer may be also sterilised with gas and steam in temperature not exceeding 138 ºC.

2/ Masks may also be sterilised with gas in temperature not exceeding 70 ^{O}C, but air from sealing pads must be evacuated because pressure changes in the sterilizer damage pad covering.

NOTE!

Sterilised accessories should be separated from accessories infected during the test. Sterile accessories should be stored in distinctly marked packings or containers eliminating danger of using not sterile accessories for tests.

6.4. Accessories

- pneumatach headpieces
- rhinomanometer large mask
- rhinomanometer small mask
- rhinomanometer large hard olive
- rhinomanometer small hard olive
- rhinomanometer small soft oval olive
- rhinomanometer large soft oval olive
- rhinomanometer small soft cylindrical-shaped olive
- rhinomanometer large soft cylindrical-shaped olive
- nasal tip
- silicone hose
- complete air cable (with terminal)
- headpiece terminal

NOTE!

The unit is provided with the built-in battery producing power supporting memory systems of the database, manufacturer's calibration coefficients, and real time timer. Damage of the battery will lead to the loss of the database, calibration coefficients , stop the timer or give wrong time.

Permissible time of storage of the unit without power supply is 3 months.

It is recommended to connect the unit to power supply at least once a week for 4 hours.

REFERENCE:

1/Die Funktionsdiagnostik der behinderten Naseatmung W/Bachman
2/Clement, P.A.R.(1984) Committee report on Standardization of Rhinomanometry
3/K.Vogt, M.Schumacher Standard Computerized Rhinomanometry 2002
Standardization Committee on Objective Assessment of Nasal Airway