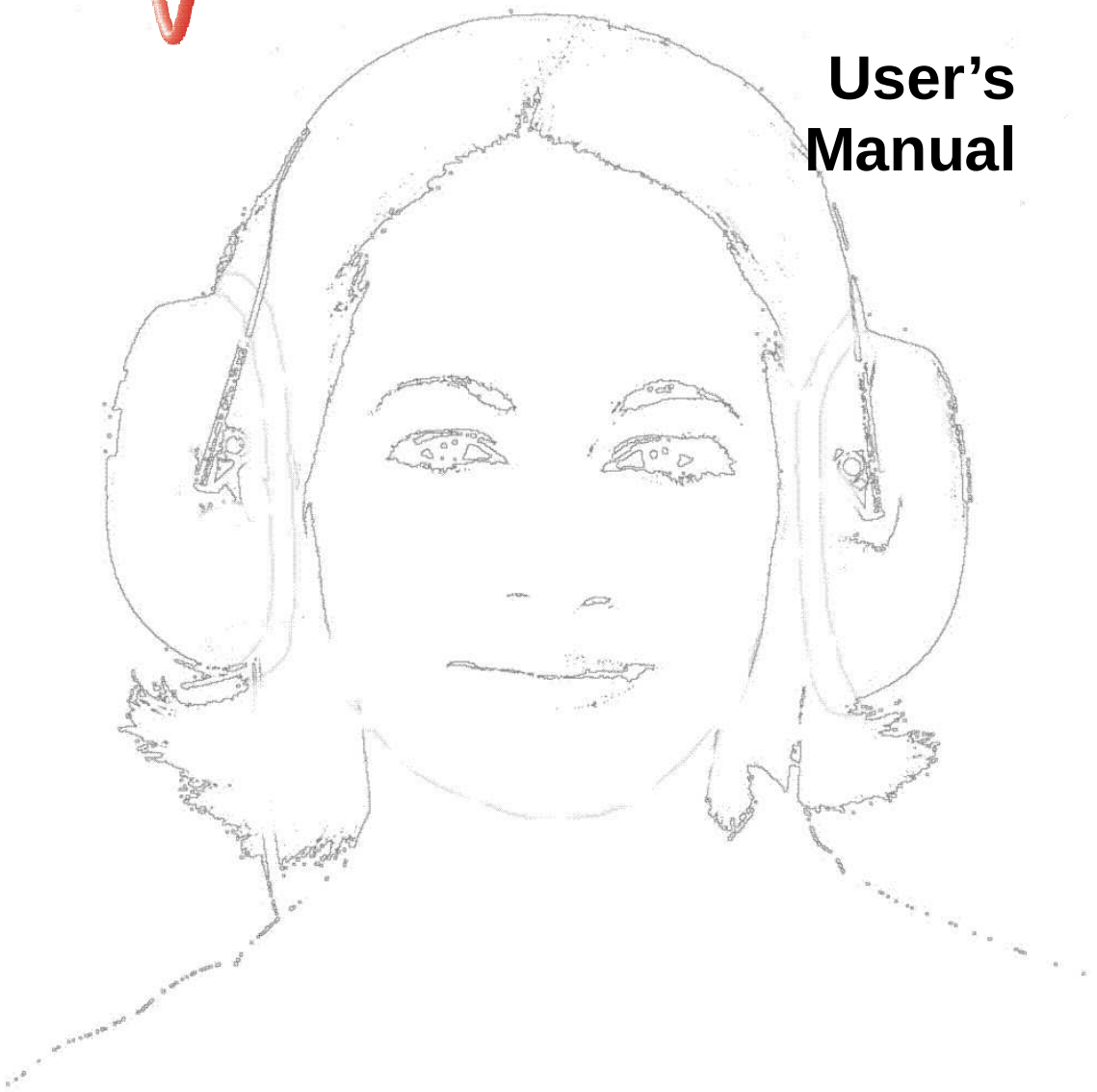
User's Manual



Supported devices

PDD-401 Audiometer

Piston Ltd.

1033 Budapest, Szőlőkert u. 4/b

CE 1979

Rev 1.02

December 21. 2011.

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Introduction

The PDD-401 is an IBM/PC based screening audiometer for air conductive testing the hearing system.

There are two versions of the program one is the modular version and the other one is with database management.

The modular version can be called from the host system. In this case the host system has its own database management.

The database version has an integrated database management system.

The PDD-401 makes easy to measure the hearing level. It is well suited for screening and following up changes in hearing level.

Thanks to the IBM/PC base it is easy to handle but at the same time offers a lot of features. During measurement the hearing level is shown in real time. Results can be printed out even in colours.

The PDD-401 screening audiometer provides the following modes and services:

- Continuous signal
- Impulse signal
- Continuous interrupted signal
- Manual mode
- Ascending algorithm
- Descending algorithm
- Automatic sequence

General information

Information on the main components of the audiometer:

Portable device

Connecting to a laptop PC full portability is provided even in battery mode. The audiometer takes power supply only from the USB port of the PC

Headset

Type: Telephonics TDH 39
Speakers built into a Peltor noise protecting case with 40 dB attenuation

Noise protecting case

Type: Peltor OPTIME II

Hand switch

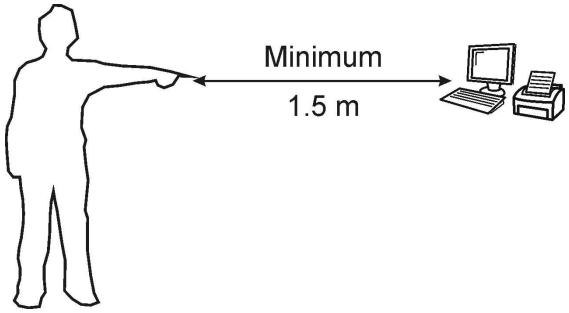
Robust hand switch for the patient’s feed back

Electric shock protection

The safety precautions in this chapter must be followed!

Only Piston Ltd., as manufacturer, or its authorized distributor's personnel, or the distributor's representatives may install the lung diagnostics device. The above mentioned companies only accept responsibility for systems installed by them.

Before installing the lung diagnostics devices the personnel must make sure the computer, the monitor and the printer installed as medical electronic devices comply with the standards, for the given country or the user declares concerning this with responsibility.



Information exchange with the computer goes through USB connection. For low leakage current relating to medical devices standards this connection is optically isolated inside the device.

Before shipping we check the device's leakage current. The operator has the opportunity to have the leakage current checked periodically, if he / she finds it necessary.

The system must be installed so the examined person is at least 1.5m away from those devices that are electrically connected to the computer equipment.

Parts of the system (computer, monitor and printer) can only be replaced in case of failure, modification or for any other reason, if the part to be installed has the same electric shock protection conditions as the original one.

The personnel installing the device will train the operator concerning operation electric shock protection. This training includes the contents of this section. The operator verifies the training in official written form.

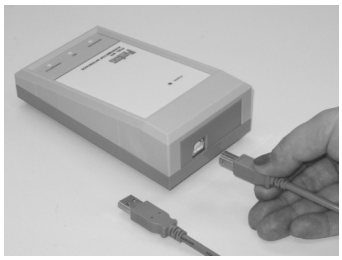
Minimum PC configuration

The operation of the audiometric system requires a personal computer with the following minimum configuration:

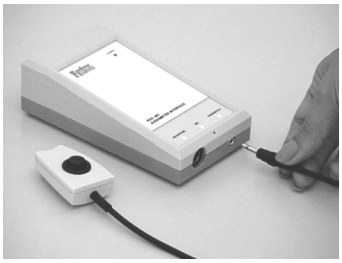
Description	Minimum	Recommended
Operating system	Windows XP	
Processor for PDD-301 family	600 MHz	Intel Celeron / Pentium 3 / Core 2 family AMD K6 / Athlon / Duron family
Processor for PDT-111 family	1 GHz	Intel Celeron/Pentium 4 / Core 2 family AMD K6/Athlon/Duron family
Screen resolution	1024×768	1280×1024
Printer	Windows compatible	Colour
Internet connection		For software updates

Installation of PDD-401 audiometer

The hearing test should be performed in an environment where the background noise level doesn't exceed the 18 dB sound pressure according to the 11th paragraph of the ISO 8253-1:1989 standard



Connect the Audiometer to a free USB port of the IBM/PC



Connect the patient feedback switch to the Audiometer

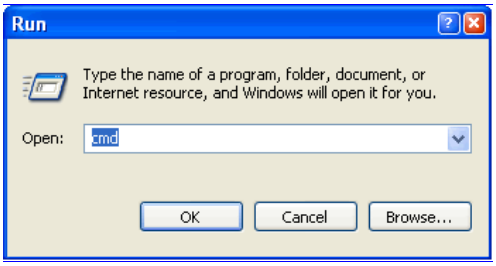
Connect the headphone set to the Audiometer

Software installation

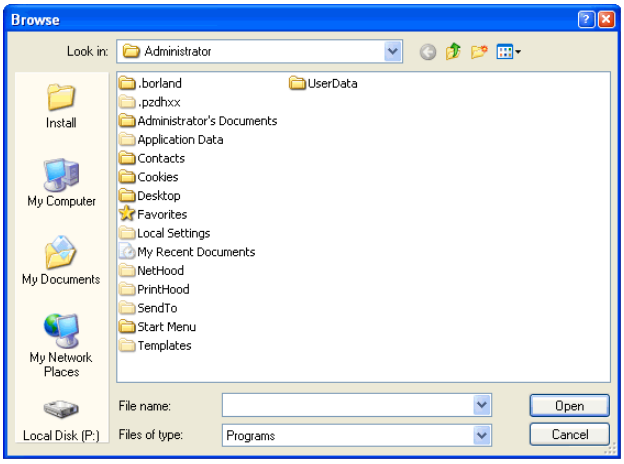
Perform the installation from the included CD.

The most up-to-date version is available from our website:

http://www.pistonmedical.com In the Downloads / Software section.



Click on the **Start** menu and select **Run**

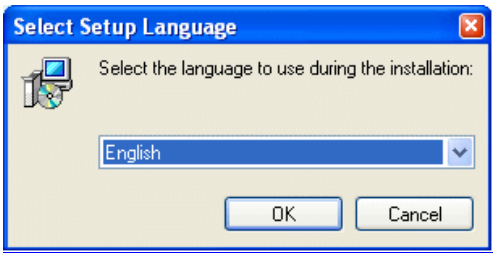


Click on the **Browse** button and select the install program.

When installing from the CD select the CD drive.

Find the pxp_setup.exe file in the Programs folder.

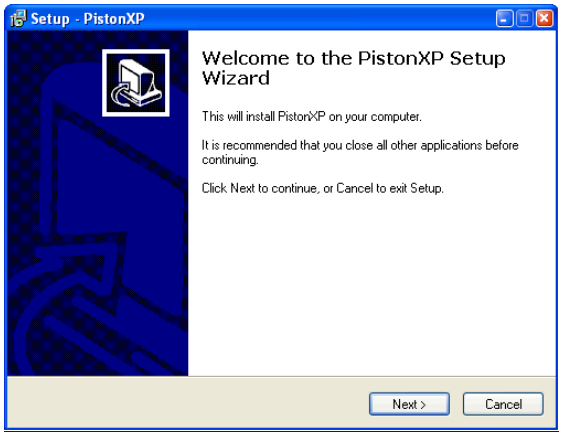
Click **OK**



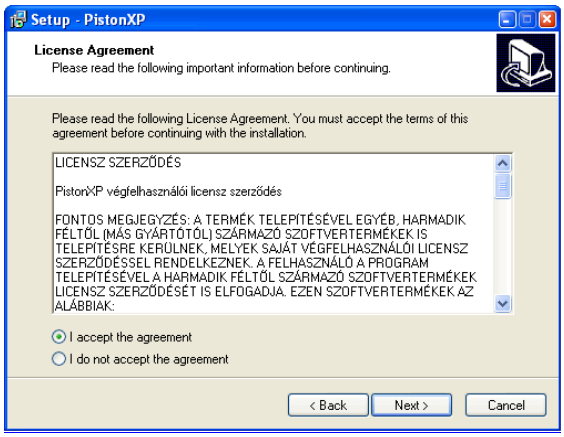
The install program starts

Select the preferred language for the setup and the installed software

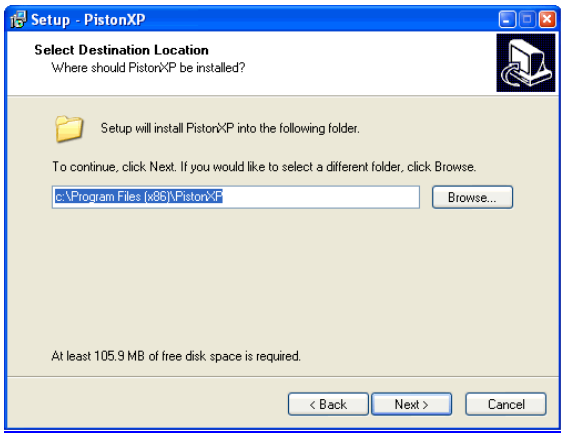
Click **OK**



A welcome screen appears, just click **Next**

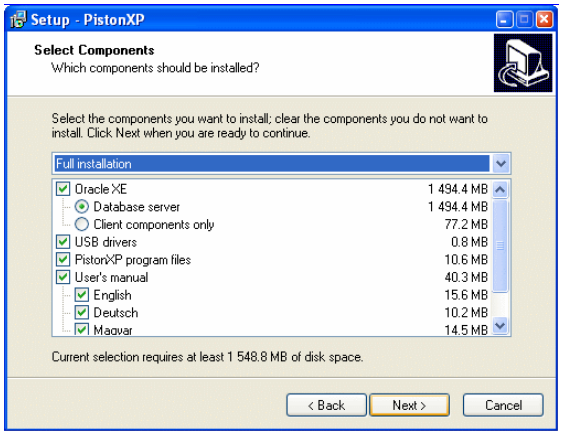


Carefully read the License Agreement, click **I accept the agreement** and click **Next**
If you do not accept the agreement, exit the installation

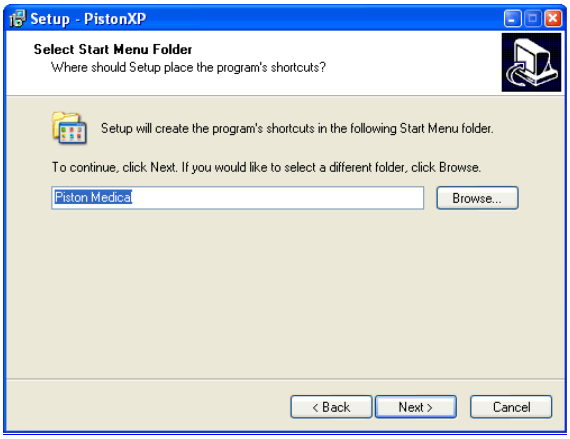


You can specify the install destination.

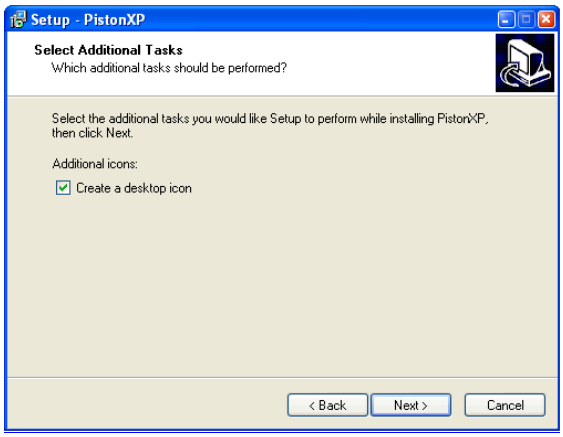
Click **Next**



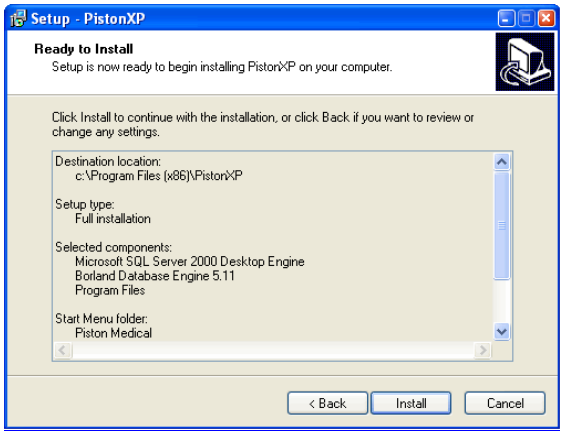
You can select which part of the program to install (experienced users)
Click **Next**



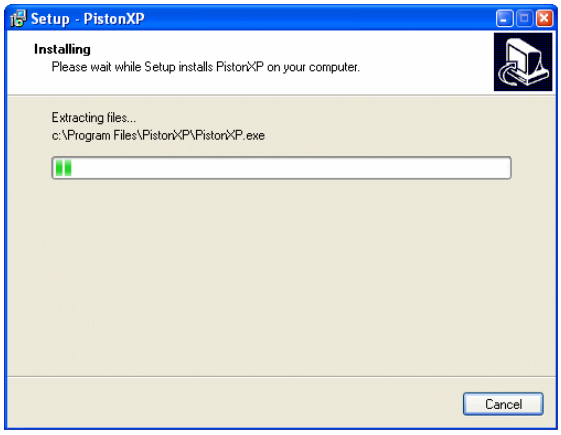
You can enter the name the program appears under in the Start menu (experienced users)
Click **Next**



You can select whether a PistonXP icon should be created on the desktop (experienced users)
Click **Next**



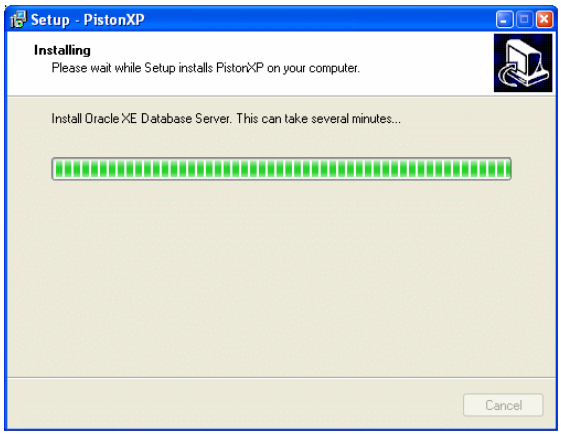
An install summary window appears, and if all settings are acceptable
Click **Install**



The install process begins

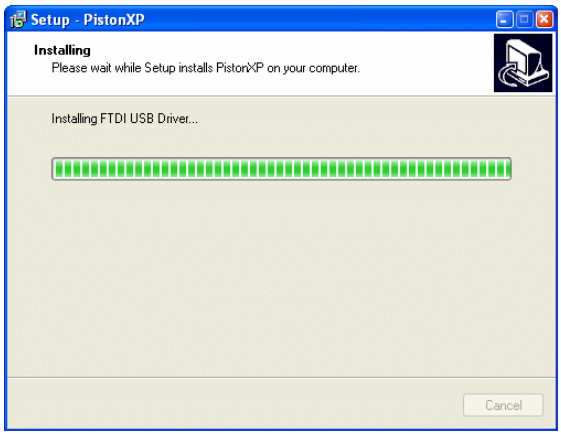
Please wait until it finishes installing the software

After installing the software, external components will be installed also



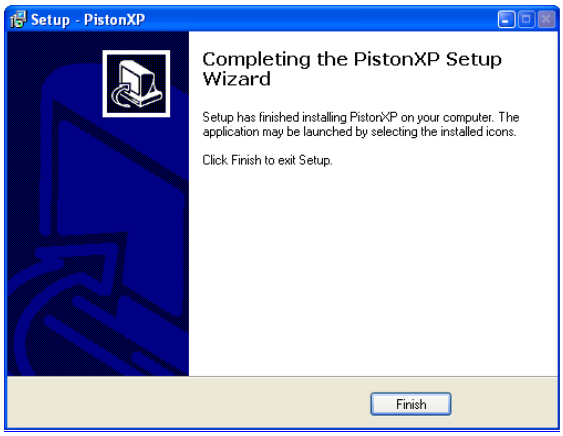
The installation of the Oracle XE Database Server / Client runs in background and the process can take several minutes

Please wait until it finishes installing the software



Finally USB Drivers are being installed

Please wait until it finishes installing the software



A window indicates the end of the installation

Click **Finish** to close the install wizard

This concludes installation
Start the program
The program automatically detects the connected devices

Device maintenance

The audiometer doesn't request any special maintenance.

Parts which are getting in direct contact with the patient like headset and the hand switch should be disinfected after every use.

For disinfection the mentioned parts a formaldehyde-free detergent should be used which is recommended for electronic devices.

Always follow instructions of the manufacturer.

Disinfecting comprehensive table

In the table below we comprehend which parts of the audiometer should be cleaned and disinfected and some sample materials are given for use. Of course always follow the regulations of the cleaning and disinfecting materials.

Name	Material	Cleaning and disinfecting material
Patient's feedback switch	Unbreakable Polystyrene	Incidur spray
Headset	Unbreakable Polystyrene PVC pillow	Incidur spray
Case	Unbreakable Polystyrene	Incidur spray

Possible problems

Audiometry		
Malfunction	**Diagnose**	**Fixing**
No signal in headsets	Connection problem	Check the connection of the headset
	Communication problem	Reconnect the device to the PC
The signal of the hand switch is not detected by the software	Connection problem	Check the connection of the hand switch
	Communication problem	Reconnect the device to the PC

Patient database

The software is able to store any number of the patients and any number of the test

Automatic safety backup

The software makes automatic safety backups according to the user definable intervals

Available tests

The air conductive hearing level of the patient can be determined by the audiometer

Test modes

The following test modes are available:

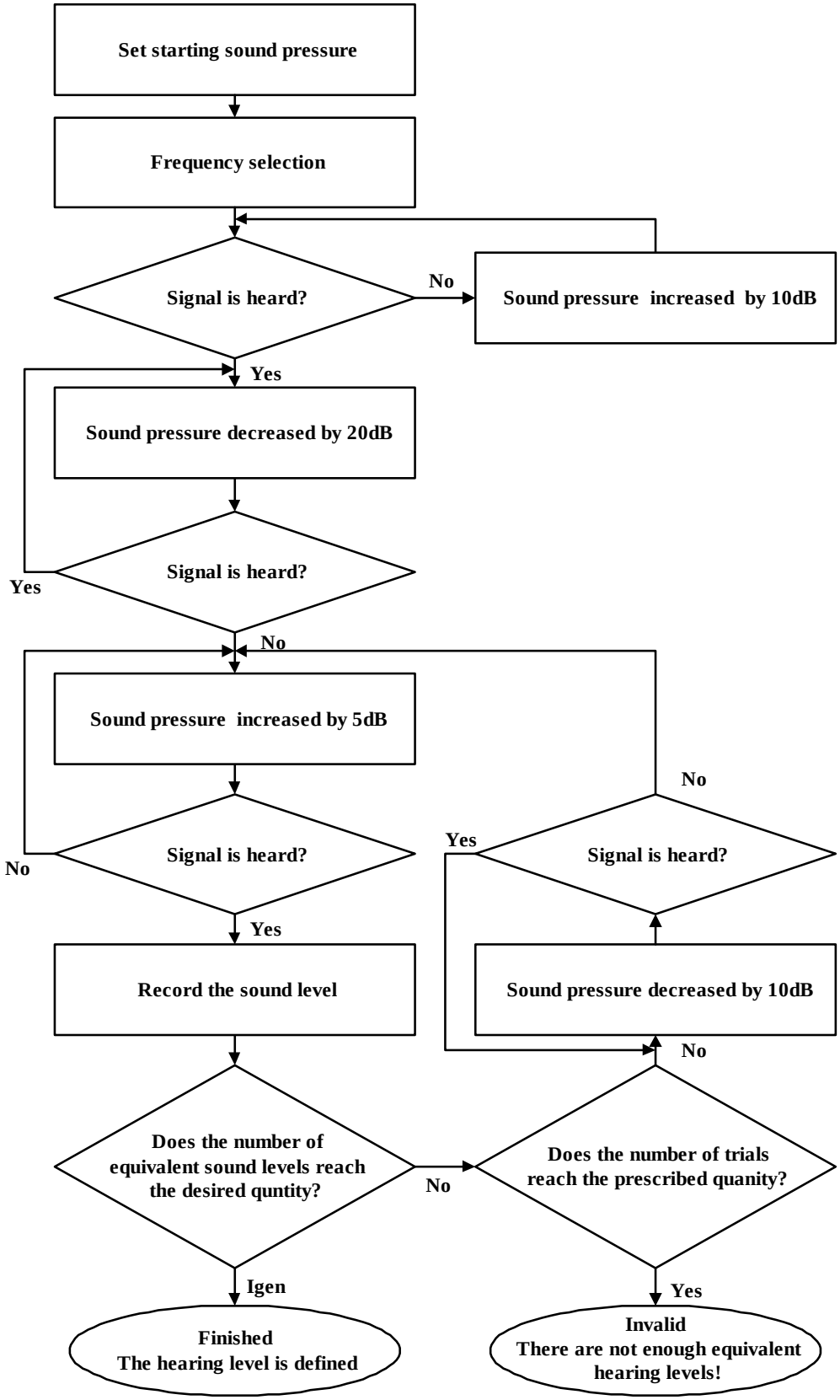
- Manual
- Semi automatic ascending iteration according to Hughson-Westlake protocol
- Semi automatic descending iteration
- Programmable automatic sequence

Manual mode

Frequency and the sound level is set by the user manually

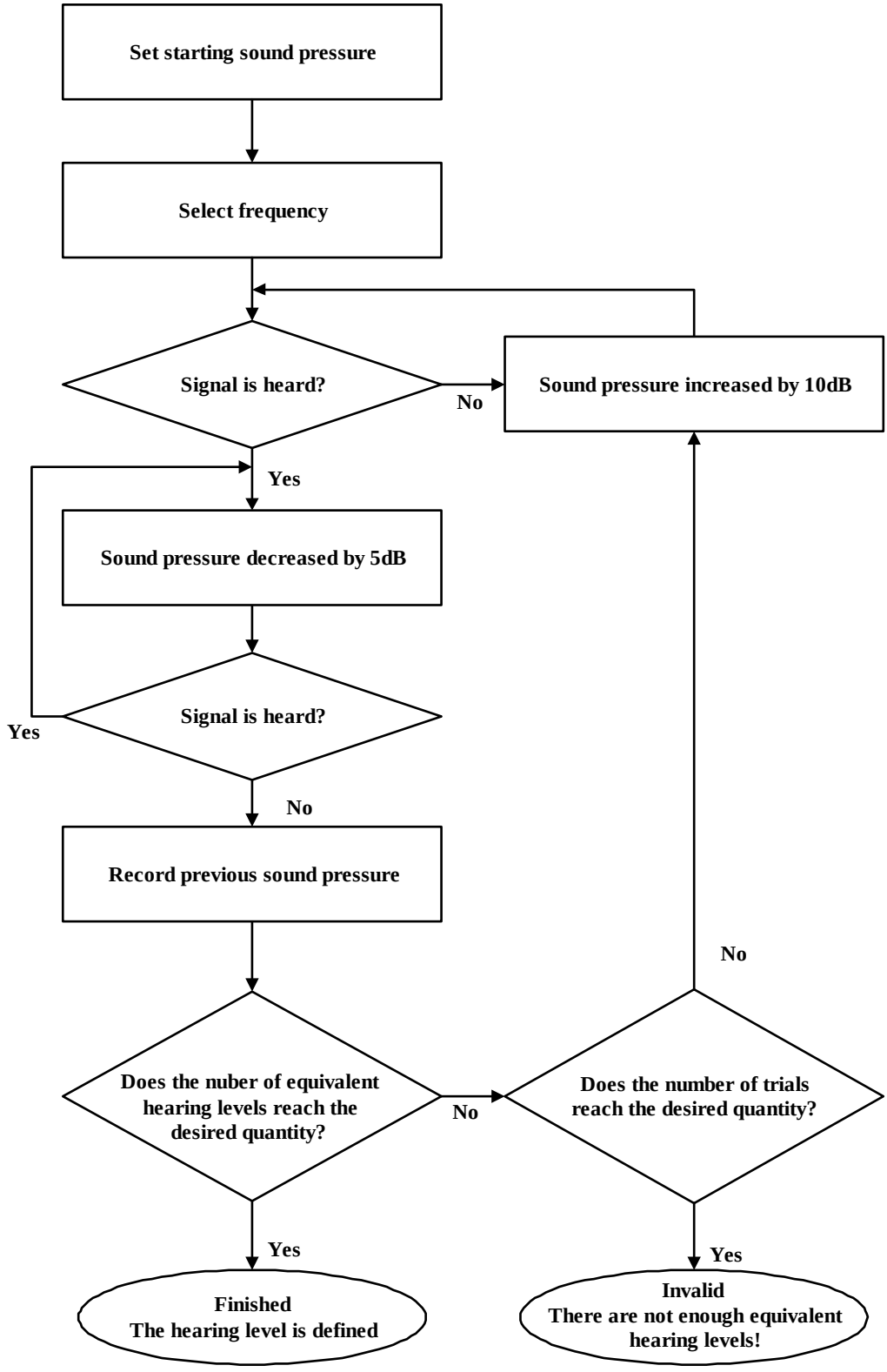
Ascending iteration

In the ascending iteration the sound level is raised from the unheard level to the level when the patient indicates that the sound is heard already.



Descending iteration

In the descending iteration the sound level is decreased from the well heard level to the level when the patient indicates that the sound is not heard yet.



Automatic sequence

The automatic test sequence can be compiled and stored by the operator and the hearing test will be performed according to the previously compiled sequence.

Icons

Main window


Open patient database


Open comment opinion editor


Open lung function test sub-menus


Health Level Seven (HL7) and GDT import and export functions


Open report editor, printing


Exit the program

Main window – Audiometry


Audiometry


User's Manual

Patient database


Clear patient quick search fields


Enter new patient


Modify patient data


Store entered / modified data


Cancel changes


Load all measurements from the selected meeting(s)


Load selected measurements


Health Level Seven (HL7) import and export functions

Settings


Set institute data


Doctor records


Devices' settings connected to the PC


Program operation related settings


Display graphs and other program parts


Maintenance, safety backup related settings


Reference value calculating algorithms


List of parameters to be displayed


Service panels


Enter new doctor

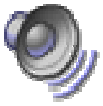

Modify doctor's data


Store entered / modified data


Cancel changes


Accept changes and close Options panel

Measurement windows – Audiometry

	Test of left ear
	Test of right ear
	Turn on microphone
	Muting
	Manual mode
	Ascending mode
	Descending mode
	Impulse signal
	Continuous interrupted signal
	Continuous signal
AUTO MODE	Start automatic sequence
	Configuration of automatic sequence
	Store results

Report editor

Print preview for audiometry

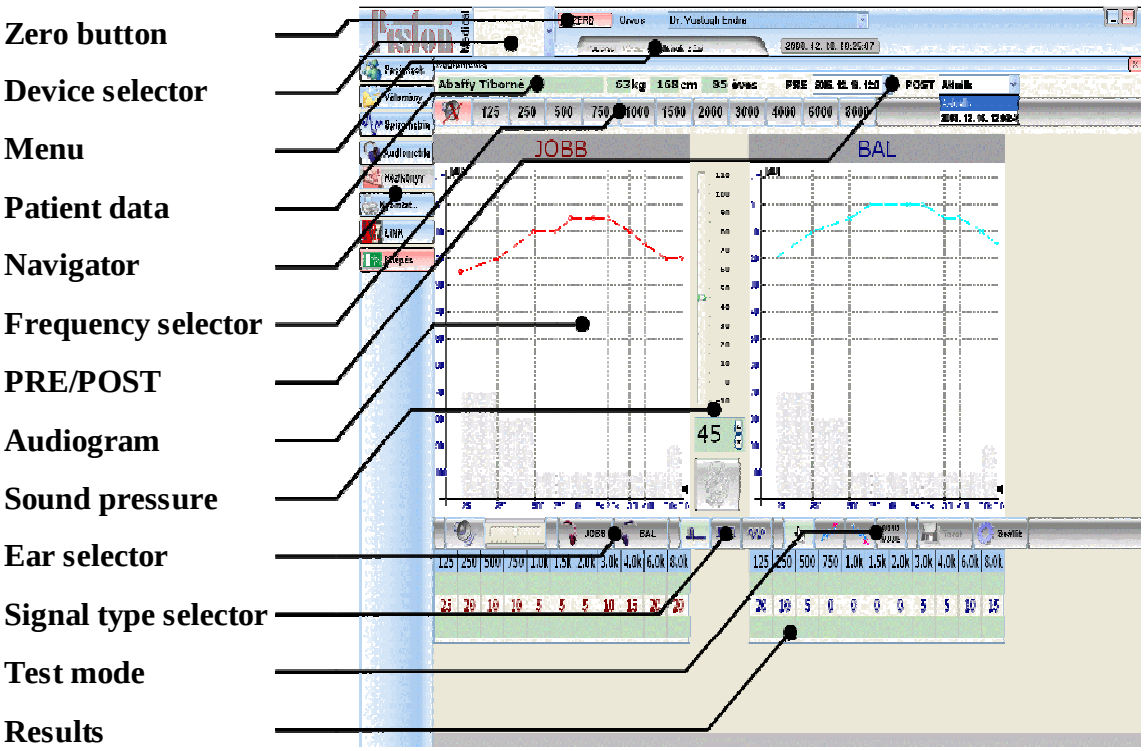
Print selected measurement results

Store a report as PDF document or image

Close Report editor

User interface

The mainframe software provides control of pulmonary function tests.



Device selector

The device selector indicates the connected devices. Select the device to be used from the drop down list.

Menu

The program's general main menu, which contains the grouped basic functions.

Patient data

Contains the most important measurement data for the patient selected from the database.

Navigator

Controls that group the basic phases of daily routine

Frequency selector

Selection of frequency of the generated signal

PRE/POST

PRE/POST comparison can be compiled of the actually measured tests and of the retrieved tests from database

Audiogram

Graphic presentation of the hearing level

Sound pressure

The sound pressure can be entered by numbers or by the vertically sliding control

Ear selector

The left or right ear can be selected for the tests

Signal type selector

For selection of the sound signal type

Test mode

For selection of the tests mode

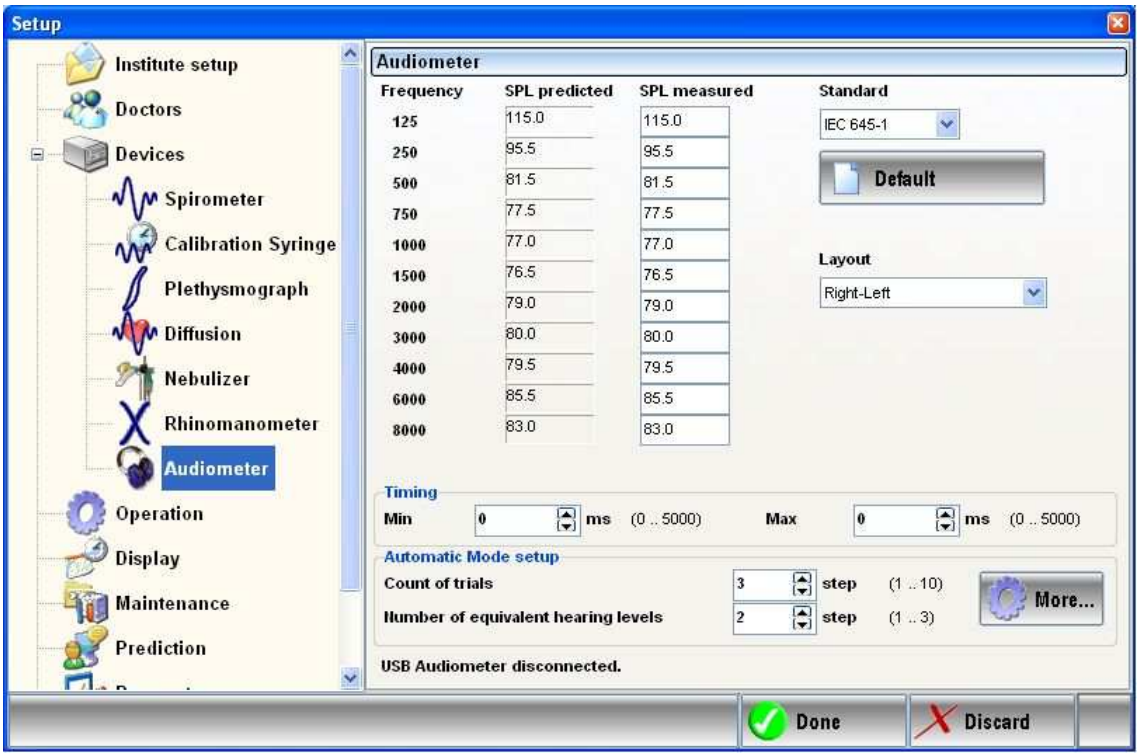
Results

The result table shows the values of the actual and previous tests and the difference of them

The **Ustawienie/Opcje** menu item allows customization of the system.

Settings that can be changed during measurement are also available in the **Ustawienie** tab of the measurement windows.

Program settings appear grouped on the left side.



Dane instytucji

You can enter the following information at the **Ustawienie/Opcje/Dane instytucji** menu item:

Institute name, Site address, Mailing address, Phone number, Fax number, Web page, E-mail address.

This data appears in the header of the printed report.

Lekarze

The doctor's data can be entered at the **Ustawienie/Opcje/Lekarze** menu item.

New doctor

Press the **[Nowy lekarz]** button to enter data for a new doctor.

Complete the fields.

Make sure that two doctors cannot have the same identifier.

Press the **[Zapisać]** button to store the entered data.

Modify data

Select the doctor from the **[Nazwisko lekarza]** drop down list whose data you would like to modify.

Click the **[Modyfikuj]** button.

Change the desired fields.

When done, press the **[Zapisać]** button.

You will see feedback about the success of the data storage.

If you do not wish to store the entered data, press the **[Odrzuć]** button.

About deleting …

To preserve consistency and for future searches, it is not possible to delete from the database.
All diagnosis has traces in the database.

Language selection

You can select the program's language in the **Ustawienie/Opcje/Zadanie** menu item.

All supported languages are displayed in English and in the specific language as well.

Select the language you would like to use.

Patient identification format

You can enter the patient identification format in the **Ustawienie/Opcje/Zadanie** menu item.

Format descriptions may be found in the Appendix I. (page 54) section.

Graph settings

Graph displays may be set in the **Ustawienie/Opcje/Wyświetlacz** menu item.

Schemat graficzny

You can select the graph color settings:

- Ciemne tło, jasne wykresy
- Jasne tlo, ciemne wykresy
- Tak jak na wydruku (white background)

Raster

The grid may be enabled or disabled on the graph

Pokaż krzywe

It can be selected for several same type measurements:

- The diagrams appear in one coordinate system.
- All the diagrams appear in different coordinate systems.

Devices

Some of the parameters may seriously influence the accuracy of the measurements.

These parameters are only shown on the user's screens and these can't be modified.

These parameters can be modified in the PistonXP.ini file but only by a trained person.

Audiometer

Select the **Audiometer group** in the **Ustawienie/Opcje/Urządzenia** menu

Calibration

Values of the Calibration Sheet for the older series can be entered in this window. For more detailed information please refer to the Calibration chapter (page 43)

Ustawienie czasu

The waiting period prior to signal generation can be specified.

The waiting period is randomly set between the minimal and maximal values.

Automatyczna konfiguracja

Fix początkowego ciśnienia akustycznego

The initial sound pressure for the automatic iterations

If this option is set, this initial sound pressure will be valid instead of the value specified in the measuring window.

Wzrost ciśnienia akustycznego w stanie początkowym (rosnąco i malejąco)

The initial value of the increasing sound pressure for the coarse determination of hearing level during automatic iterations

Spadek ciśnienia akustycznego w stanie początkowym (rosnąco)

The initial value of the decreasing sound pressure for the coarse determination of hearing level during automatic iterations

Liczba prób

Number of repeated trials for Rosnąco and Malejąco iterations to determine the hearing level

Liczba równoważnych progów słuchu

During Rosnąco and Malejąco iterations the hearing level is determined repeatedly. The iteration declared to be successful when the number of equal hearing levels reaches the value specified here.

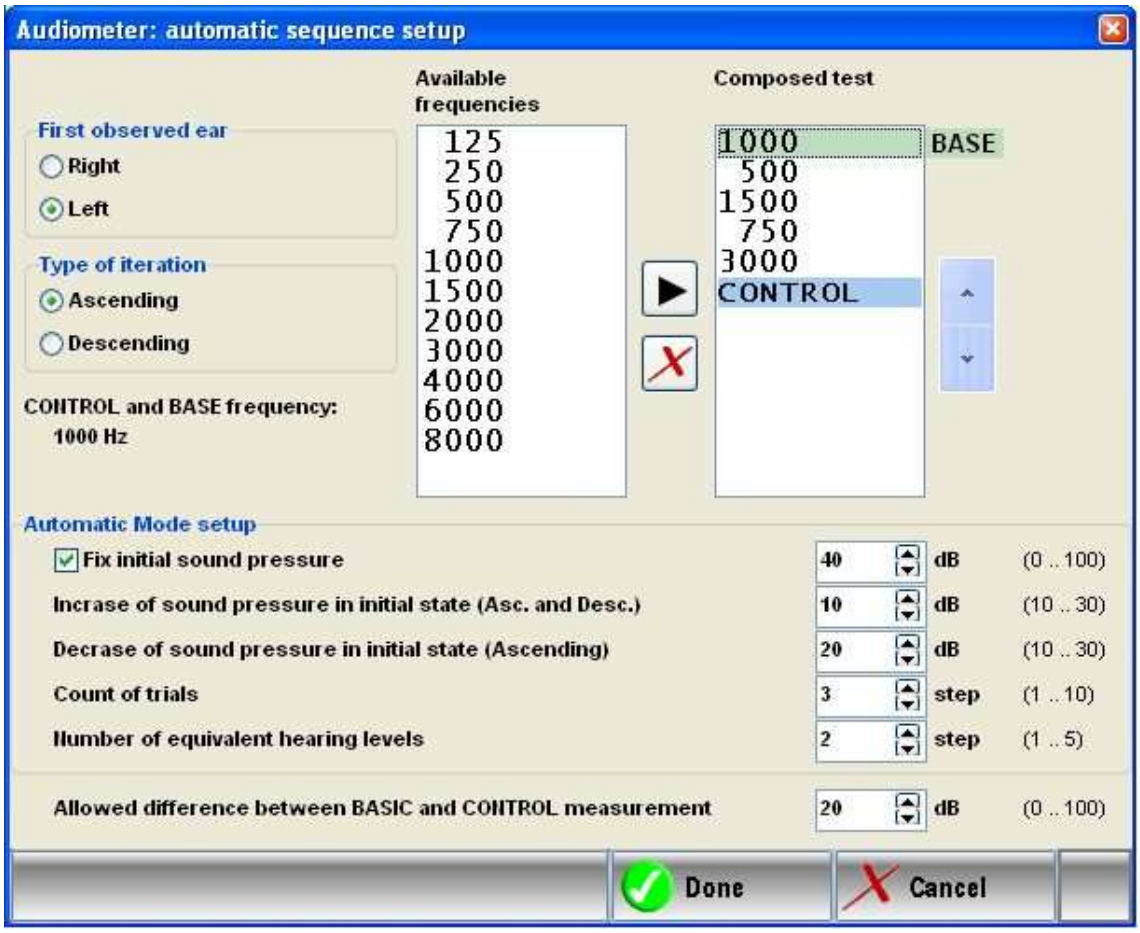
Automatyczna konfiguracja sekwencji

Select the **Audiometer group** in **Ustawienie/Opcje/Urządzenia** menu

Click ont he [**Inne...**] button

or

Click on the [**Konfiguruj...**] button at the Audiometer test window



Po raz pierwszy badane ucho

Here you can select which ear to be tested first

Rodzaj iteracji

Here you can select which type of iteration to be used Rosnąco or Malejąco

Setting of automatic sequence can be done here as well.

For more information refer to the Automatyczna konfiguracja chapter (page 28.).

Akceptowana różnica między pomiarem BAZA a KONTROL

A KONTROL test can be included into the automatic sequence.

The frequency of the KONTROL test equals to the frequency of the BAZA test.

After the KONTROL test the software compares the hearing level value of the very first BAZA test. The difference of these two tests can't exceed the specified value of this field.

Compilation of Automatic Test Sequence

Drag the desired frequency from the [Dostępne częstotliwości] list and drop into the [Test złożony] list. For insertion the [▶] button can be used as well.

The undesired frequencies can be dropped back to the [Dostępne częstotliwości] list or can be deleted with the [✗] button.

The compiled list of frequencies can be modified with mouse or the [⮝] and [⮟] buttons.

Connection of an audiometer device will be detected within 2 seconds.

User interface overview

Main window

Quick search
Helps find a patient.

Patient list
A list of patients meeting the search criteria.

Details
Displays the selected patient's most important parameters for the selected measurement.

Control panel
Basic database operations: enter new patient, modify patient data, store.

Visits
Dates of previous visits.

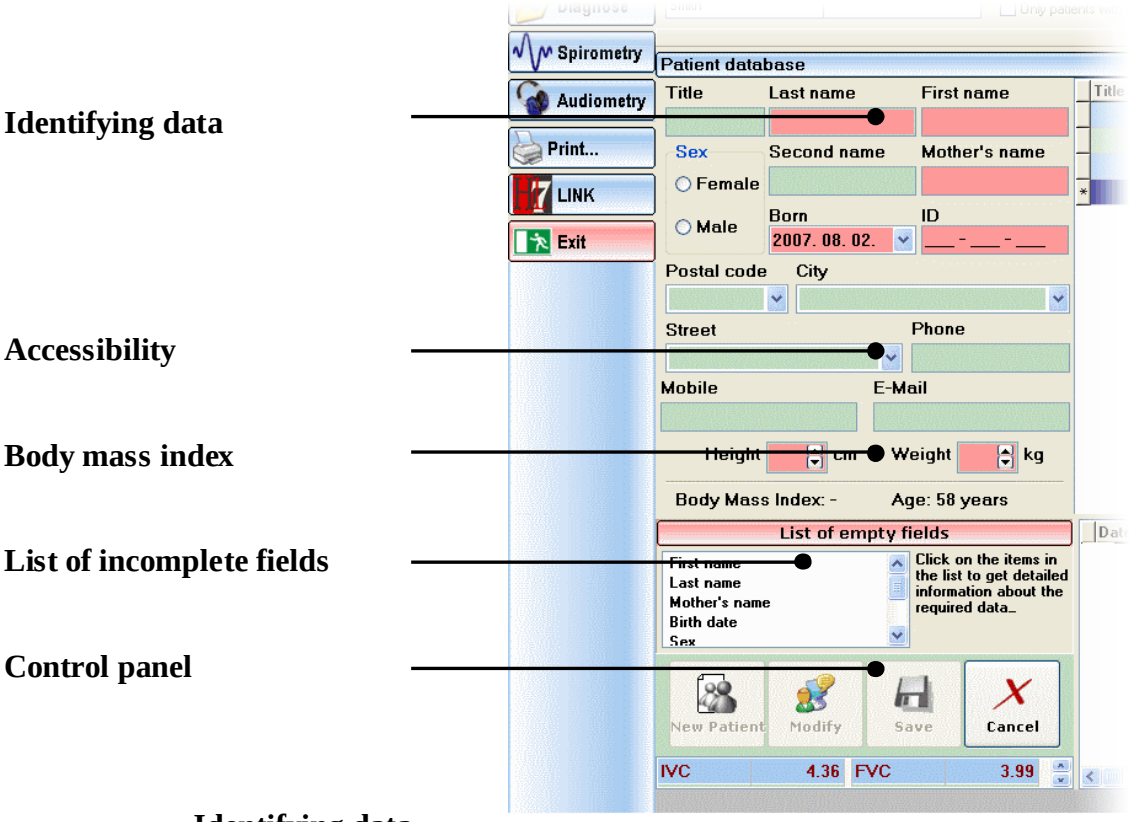
Measurements
A list of measurements for the selected date or measurement type.

Load
Control buttons to display the selected measurements.

Measurement selection
Measurements may be listed according to measurement type as well.

Data input form

Content of the Data input form can be set in the menu **Ustawienie** / **Opcje** / **Wyświetlacz** / **Zawartość arkusza pacjenta ***



Identifying data

Group of data essentially identifying the patient: Name, date of birth, social security number, sex, etc.

Accessibility

Patient's accessibility: Address, phone numbers, e-mail address.

Body mass index (calculated value)

The patient's current body weight index: square of the height of the patient in meter divided by body weight

List of incomplete fields

A list of fields that either have to be completed and are still empty, or that have been filled out incorrectly.

Control panel

Basic database operations: new patient, modification, store.

* Musisz zamknąć bazę danych pacjenta, aby zachować zmiany!

Patient's personal data

The program can store an arbitrary number of patients.

Pink fields indicate fields that have to be completed.

New patient

To enter a new patient, press the **[Nowy pacjent]** button. Complete the fields and make sure that two patients cannot have the same identifier.

To store the patient, press the **[Zapisać]** button.

You will receive feedback about the success of data storage.

If you do not wish to save the data, press the **[Anulować]** button.

Modify data

Select the patient to modify

Click on the **[Modyfikuj]** button

After modification press the **[Zapisać]** button

You will receive feedback about the success of data storage

If you do not wish to save the modified data, press the **[Anulować]** button

About deleting …

To preserve consistency and for future searches, it is not possible to delete from the database. All diagnosis has traces in the database.

Finding a patient in the database

The top section of the patient database window is the search block.

You can search based on several criteria. When those criteria change, the program automatically lists the patients meeting the updated criteria

Normal search

Search only based on the patient's family and surname.

Enter the patient's name or part of it.

Detailed search

Click the **[Szczegółowe wyszukiwanie]** button.

You can refine the search criteria in the window:

- patient‘s sex
- date of birth with interval
- address or part of it
- doctor
- identifier (social security number)

Viewing previous measurements

All previous measurements can be reloaded, so reports can be printed at anytime.

Viewing previous measurements

To reload previous measurements:

- Select the patient
- Select the visit by date
- If you only wish to view the results of certain measurement mode select the one from the list
- Select required measurements

If you wish to see all measurement results of a selected visit, click the **[Otwórz]** button
If only certain measurements are important; click them while holding the CTRL button down
After selection click on the **[Otwórz]** button!

If you wish to include further measurements to the report click the **[Baza danych** pacjentów**]** button to reopen the Patient database.

Select further measurements and click the **[Dodaj pomiar]** button to include them to the report.

WARNING:
You can only simultaneously load eight measurements of the same mode.
For this reason, the [Załaduj wszystko] button is not always available.

PRE / POST evaluation

To load the data for all previous visits, check the **[Wszystkie pomiary]** checkbox.

This displays a patient's all previous measurements sorted according to the following:

- Date
- Measurement mode
- Measurement results quality

Select the results of at least two identical measurement mode, for example two FVC measurements.

Load the data as mentioned earlier.

PRE / POST measurements are detailed in the PRE / POST section (Page 48).

Comment field for patients

Comments may be entered about the patients even for every visit. All comments are stored separately in the database and may be retrieved individually.

To enter a comment:

- Open the Patient database
- Selected the desired patient
- Click the **[Diagnoza]** button to open the text editor window
- Select the **[Pacjent]** operating mode from the list
- Enter the comment
- Press the **[Przechowaj]** button to store the comment

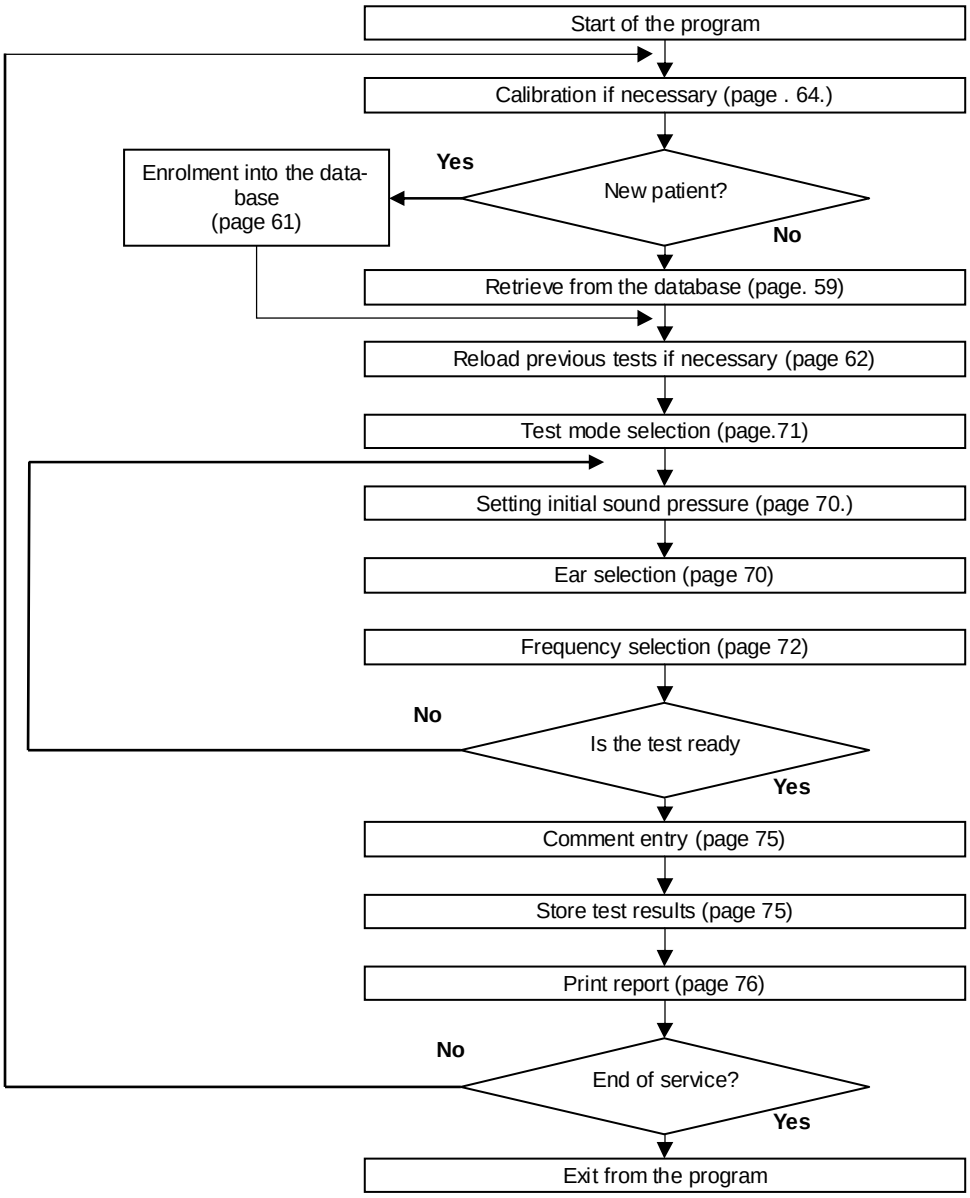
Previous diagnosis

All previous comments about the patient may be retrieved from the **[Historia]** list.

The currently entered text is not lost when viewing a previous diagnosis.

To display the currently entered text again, select the **[Pacjent]** option from the list of operating modes again.

General measurement process – daily routine



Patient selection

Before starting the measurement it is necessary to enter patient data using one of the following methods:

- Enter new patient
- Search for patient already in the database

Preparations

Device

Connection

Make sure that the device you wish to use is connected to the computer.

If not, connect the device as detailed in the Installation (6. page) section.

Selection

The **Audiometer** might be selected from the **Device selection** list.

If there are no other devices the Audiometer is selected automatically.

Parts in direct contact with the patient

It is advisable to disinfect both the headset and the hand switch after each patient (see chapter Maintenance, page 13)

Environment

The hearing test should be performed in an environment where the background noise level doesn't exceed the 18 dB sound pressure according to the 11th paragraph of the ISO 8253-1:1989 standard

Patient

Recommended body position

- Sitting on a chair
- Straight back
- Level head

Directions

The hearing level test requires co-operation from the patient so it is necessary to inform and prepare the patient for the test.

- Let know the patient about the goal and process of the test
- Pay attention the proper adjustment and setting of the headset
- Teach the patient how to use the hand switch. It is advisable to monitor the proper operation of the hand switch on the screen. Select any frequency and sound level and by pushing the hand switch observe the hand switch state icon.

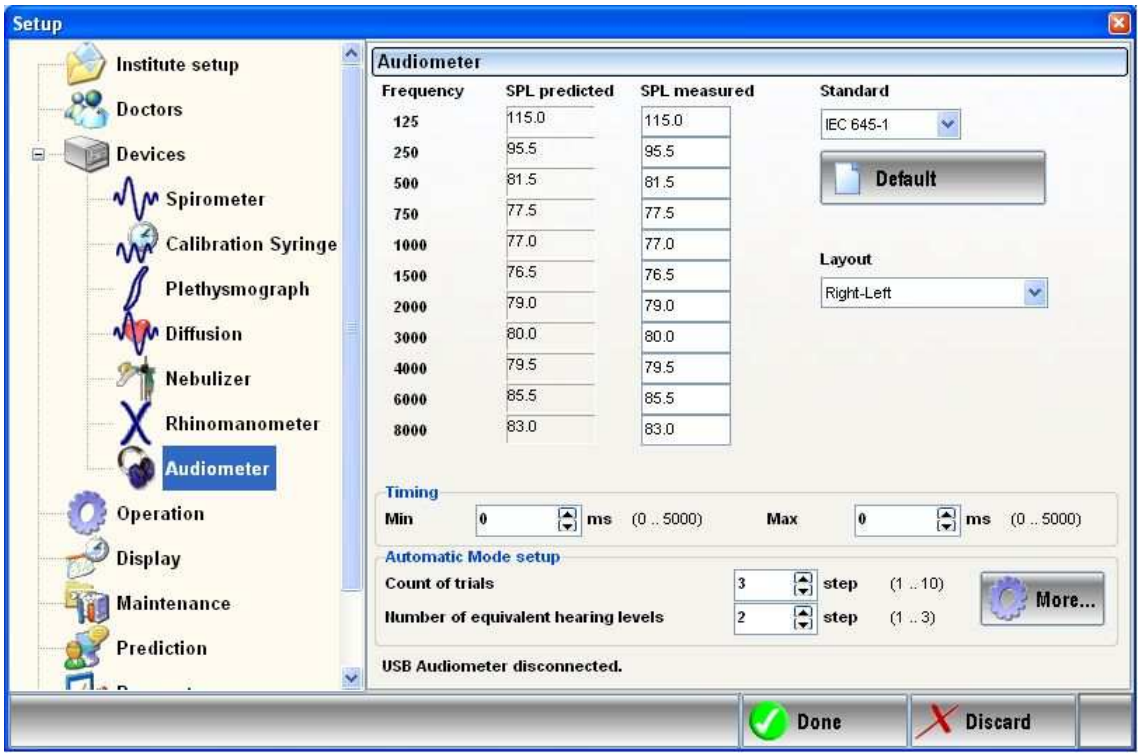
Measurements

Detailed description of the hearing test can be found in the Calibration procedure of the audiometer depends on the serial number of the device.

Devices from the newer series don't need manual calibration because correction Sound Pressure Levels are stored in the device.

Device with serial number of the interval 401-U-2004-001 to 401-U-2008-118 needs entering the Sound Pressure Levels for all frequencies manually. Calibration sheet is included to the set of the audiometer. Please refer to the following paragraph.

Select the **Audiometer group** in the **Ustawienie/Opcje/Urządzenia** menu



Select the desired SPL correction option from the [Standard] rolling down:

- IEC 645-1 Most accepted standard
- SABS 0154 Standard for South African Republic

To return the original settings push the [**Domyślnie**] button

Enter into the [**SPL mierzone**] column values from the Calibration sheet „Average Measured SPL".

Please pay special attention during entering the correction values because these values strongly influent the accuracy of the device.

We don't take any responsibility of the consequences of the faulty entered SPL correction values.

If there is no other regulation in the Quality Management System of the user it is advisable to validate the audiometer annually. Validation can be done only by a calibrated sound pressure meter.

The periodic validation and recalibration of the audiometer has to be done in the similar way as it was done during the very first installation.

To save modifications push the **[Wykonano]** button or to cancel modification push the **[Odrzuć]** button.

Measurement chapter (page 43)

Enter comment

A separate comment may be entered for all measurement modes.

All comments are stored separately in the database.

- Click on the **[Diagnoza]** icon to open Kreator diagnozy
- Select the measurement mode or the Patient mode from the list to which you would like to add a comment
- Enter the comment
- Press the **[Przechowaj]** button to store the comment in the database attached to the measurement

Previous comments

Previously created comments for the given measurement mode can be viewed anytime in the **[Historia]** list. The currently entered comment is not lost when viewing a previous or another measurement modes' comments. To display the comment select the measurement mode you would like to edit from the list.

Store

To store curves marked **Visible** and **Questionable**, press the **[Przechowaj]** button

Successful data storage returns a feedback

Printing

PRE / POST

The system can print two types of reports:

- Normal report: Three measurements' results simultaneously.
- PRE / POST report: Two measurements' results simultaneously and their difference in absolute and percentage format.

Customized reports

The printed report has the following parts:

- Header

- Parameter table
- Graphs
- Comment

The header is the only fixed part of the header, the other three may be turned on and off arbitrarily, only the desired parts make it into the report.

Highlight rows

To highlight odd rows at colour or grayscale printing select the **[Zaznacz nieparzyste wiersze]** checkbox

Simplified report

To print only the best measurements of all modes select the **[Tylko najlepszy pomiar]** checkbox

Printing

Before printing measurement results have to be stored so the printed reports can be followed up.

- Click the **[Drukuj…]** icon in the main menu
- Select the graphs, tables and manual diagnosis you would like to print
- Select the report language
- Select the report type: normal or PRE / POST
- Click on a button in the **[Podgląd wydruku]** section to view the print preview
- After making the necessary settings, click the **[Print]** button

During printing graph display is similar to on-screen display:

- Complete curve or only the representative curve section
- One or more graphs

Export report into graphical formats

This feature provides export of the printed report into the commonly used graphical formats. Exported reports can be stored and for example sent as an attachment to an e-mail.

Supported formats

- PDF, Adobe Acrobat document
- GIF picture
- JPEG picture
- BMP Windows Bitmap picture
- EMF and WMF vector graphics

Settings

The Export function is in the Report edition window

- Click on the **[Drukuj…]** button at the main menu

Contents and the format of the exported report are fully identical to the printed version. More information can be found in the chapter Printing on page 39.

Export procedure

Prior to printing and exporting results of measurements have to be stored in order to provide reliable traceability

- Click on the **[Drukuj…]** button at the main menu
- Select graphs, tables and text fields to be exported
- Select the language of the report
- Select the type of the report PRE / POST
- For previewing the report click on any button at the **[Podgląd wydruku]** section
- After setting click on the **[Przechowaj]** button

Exported graphs are fully identical to the graphs shown on the screen:

- Full curve or only the important part
- One or more graphs

Interface to information systems

Interface to frame systems

Our system provides communication according to the more commonly used protocols:

- Health Level Seven (HL7, USA)
- Geräte Daten Träger (GDT, Germany)

These protocols provide exchange of the patient data and measured results between the lung diagnostics equipment and the frame systems.

These protocols are predefined by the System administrator consequently can not be modified by the user.

Receiving the request for tests

Click on the [LINK…] button in the main menu and open the Import/Export window

According to your frame system type click one of the **[HL7]** or **[GDT]** buttons in the Import section in order to receive a Request for tests

If a Request for test is available the system automatically acquires it and lists all the requested tests

Exporting

Click on the [LINK…] button in the main menu and open the Import/Export window

According to your frame system type click one of the **[HL7]** or **[GDT]** buttons in the Export section. The system automatically exports the results of the tests.

Filling special forms

The system provides filling customer defined forms. Templates of the forms can be compiled in any ASCII format (HTML, XML, CSV etc.). Compilation of the form is the competence of the System administrator.

Filling a form

User may select a form from the preinstalled templates.

Click on the [**LINK...**] button in the main menu to open the Import/Export window

Click on the [**HTML**] button to open the Raport indywidualny window

Select the desired template from the a [**Szablony**] list

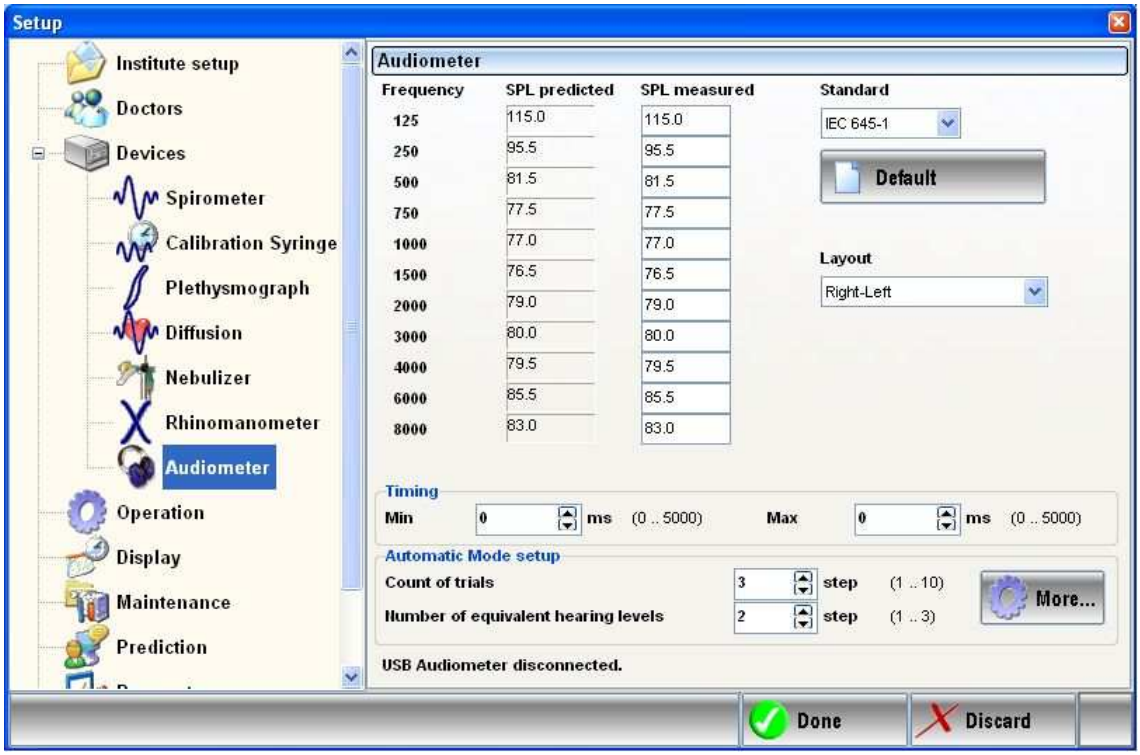
Click on the [Wybierz] button and the form is automatically filled out

Calibration procedure of the audiometer depends on the serial number of the device.

Devices from the newer series don't need manual calibration because correction Sound Pressure Levels are stored in the device.

Device with serial number of the interval 401-U-2004-001 to 401-U-2008-118 needs entering the Sound Pressure Levels for all frequencies manually. Calibration sheet is included to the set of the audiometer. Please refer to the following paragraph.

Select the **Audiometer group** in the **Ustawienie/Opcje/Urządzenia** menu



Select the desired SPL correction option from the [Standard] rolling down:

- IEC 645-1 Most accepted standard
- SABS 0154 Standard for South African Republic

To return the original settings push the [**Domyślnie**] button

Enter into the [**SPL mierzone**] column values from the Calibration sheet „Average Measured SPL".

Please pay special attention during entering the correction values because these values strongly influent the accuracy of the device.

We don't take any responsibility of the consequences of the faulty entered SPL correction values.

If there is no other regulation in the Quality Management System of the user it is advisable to validate the audiometer annually. Validation can be done only by a calibrated sound pressure meter.

The periodic validation and recalibration of the audiometer has to be done in the similar way as it was done during the very first installation.

To save modifications push the **[Wykonano]** button or to cancel modification push the **[Odrzuć]** button.

Goal of the measurement

The air conductive hearing level at different frequencies can be determined by the device.

Reference values

The system displays the Statistical Distribution of hearing thresholds as function of age according to the NF EN ISO 7029:2000 standard.

Meaning of the curves:

There is a percentage value at the right side of all curves which shows the ratio of the population which has better hearing ability.
For example 75% means that ¾ of the population have a better hearing ability.

Process of measurement

Measurement modes:

- Manual mode
- Ascending iteration
- Descending iteration
- Automatic sequence

Signal types

- Continuous
- Impulse
- Interrupted

When the selected signal is generated and the signal is audible for patient the patient has to push the hand switch.

If there is a proper feedback the actual sound level is stored for that frequency.

Signal types

Continuous

Signal is generated continuously.

This signal type is available only at Manual mode.

Impulse

The signal generated only once for adjustable time (typically 1-2 seconds)

This signal type is available for all measurement modes.

Interrupted

The continuous signal is interrupted and attenuated by 20 dB.

This signal type is available only at Manual mode.

Measurement modes

Manual mode

Sound pressure and frequency can be set freely

Select Manual mode

Select signal type

Set the desired sound pressure

Select ear

Set frequency

Tip:
If you click with the mouse at any point of the audiogram signal whit the selected frequency and sound pressure will be generated right away

Rosnąco mode

During Rosnąco mode a week inaudible signal generated and the sound pressure level is incremented till the moment the patient indicates that the signal is audible already.

Select Rosnąco mode

Set the initial sound pressure

Select ear

Set frequency

Malejąco mode

During Malejąco mode a strong surely audible signal generated and the sound level decreased till the moment the patient indicates that the signal is inaudible already

Select Malejąco mode

Set the initial sound pressure

Select ear

Set frequency

Automatic sequence

Automatic sequence provides full automatic hearing level determination for both ears.

For configuration of Automatic sequence please refer to the Automatyczna konfiguracja sekwencji chapter (page 29)

To start the measurement push the [**AUTO MODE**] button

Evaluations of the results

During Automatic sequence an icon is shown after each step

✓	Successful iteration
✗	Unsuccessful iteration
✓✓	Successful KONTROL test
⚠	Unsuccessful KONTROL test: difference between the BAZA and the KONTROL tests exceeds the allowed tolerance
✗✗	Unsuccessful KONTROL test: any of the BAZA and/or the KONTROL test was unsuccessful

The PRE / POST measurement

The system supports measurement comparison – previous measurements may be compared against measurements made later:

- Select the patient
- Select and load the PRE (or previous) measurements
- Measure the current, POST values with the patient
- Select the two measurement to be compared
- Print the PRE / POST report

Retrieve measurement

Perform the steps in the Baza danych pacjentów (page 2.) section:

- Open the database
- Select the patient
- Select one or more measurements
- Load the measurement results

Max. 8 measurements may be displayed simultaneously, so if you loaded 6 measurements, you can perform 2 more measurements.

Notice

The program also makes it possible to print the PRE / POST report from the actually performed measurements.

Report compilation

Procedure of the compilation of PRE / POST report:

- Select two measurements from the PRE / POST list
- Upon selection the result table will be refreshed automatically

Printing

Printing is identical to the regular report automatically a PRE / POST report will be printed out

Warranty

The device complies with the effective Technical Specifications.

The manufacturer guarantees the product according to the terms of the Installation/Delivery protocol.

The warranty does not cover post-delivery careless shipping, unprofessional storage, violent damaging, abnormal operation, unprofessional operation, inefficient protection against external effects, natural disasters, or not following the contents of the User Manual.

Check package condition after delivery.
If packaging is damaged, notify the carrier and Piston Ltd., or its representative.

Limited liability

Piston Ltd. and its carriers, according to the valid laws, do not accept any responsibility for any individual, unforeseeable, direct or indirect damages (including loss of business profit, interruption of business activity, loss of business data, or any other damages due to financial loss), resulting from the use or non-usefulness of the product.

Safety instructions

To avoid possible damages and accidents, please pay attention to the following safety instructions:

- Make sure the mains voltage is the same as that on the product label
- Make sure the connection cable is not damaged
- Take care of your device according to the maintenance section
- Only use the device according to the manual
- Do not use any accessories not recommended for the device
- Store the device in a dry place
- Keep the cable away from heat source, sharp objects, rough surfaces and check the cable's good condition
- Do not expose the device to direct sunlight or strong light (more than 1500 lux)
- Do not use the device in a highly dusty environment
- Do not use the device in a highly vibrating environment
- Take care to ensure the current environmental conditions

The device complies with the contents of the detailed standards in the **Hiba! A hivatkozási forrás nem található.** section (**Hiba! A könyvjelző nem létezik.** page).

Shipping conditions

Air temperature: ..... -30 °C ÷ +60 °C
Relative humidity: ..... 10% ÷ 100%
Atmospheric pressure: ..... 500 ÷ 1060 mbar

Storage conditions

Air temperature: ..... 0 °C ÷ +50 °C
Relative humidity: ..... 10% ÷ 85%
Atmospheric pressure: ..... 500 ÷ 1060 mbar

Operating conditions

Air temperature: ..... +10 °C ÷ +40 °C
Relative humidity: ..... 30% ÷ 75%
Atmospheric pressure: ..... 700 ÷ 1060 mbar

Informing values

Expected lifetime

Devices ..... 8 years

Electrical data

The connected computer's and printer's electrical data is found in the respective manufacturer provided specifications.

The following values apply only to the Piston Ltd. manufactured devices:

PDD-401 – Audiometer

PC connection ..... USB 1.1
Power ..... Does not require external power
Maximal supply current ..... 360 mA

Mechanical data

PDD-401 – Audiometer

Size: .....L 150 * W 82 * H 45 mm
Weight including headset:.....960 g
Headset:.....TDH 39
Noise attenuation of protecting case: .....40 dB
Expected lifetime of the device: .....5 years
Step of sound pressure:.....5 dB
Frequencies: 125Hz, 250Hz, 500Hz, 750Hz, 1kHz
..... 1,5kHz, 2kHz, 3kHz, 4kHz, 6kHz, 8kHz
Sound pressure level:.....-10dB HL - +110dBHL

Guaranteed values

PDD-401 – Audiometer

Total harmonic distortion:.....< 1%
Accuracy of frequency: .....±1%

List of accessories

Included accessories

The current Shipping contract contains the list of accessories included in the purchase price.

Optionally purchased accessories

The following information must be provided when ordering accessories and disposables:

- Description
- Type
- Part number
- Device type and serial number for which the accessories are used

CERTIFICATES OF QUALITY MANAGEMENT SYSTEM

Tanúsítvány HU11/6220

Tanúsítjuk, hogy a(z)

Piston Kft.

1033 Budapest, Szőlőkert u. 4/b.

irányítási rendszerét auditáltuk és az megfelel az alábbi szabvány követelményeinek

MSZ EN ISO 13485:2004

A tanúsítás az alábbi tevékenységekre érvényes:

Audiométerek, légzésdiagnosztikai berendezések és kapcsolódó szájcsutora valamint baktérium szűrők gyártása és forgalmazása.

A tanúsított területtel és az MSZ EN ISO 13485:2004 szabvány követelményeinek alkalmazhatóságával kapcsolatban további információ a szervezettel való konzultáció útján nyerhető.

A tanúsítvány 2011. december 21-től 2014. december 20-ig érvényes, sikeres felülvizsgálatok esetén.
Megújító audit esedékes legkésőbb 2014. december 13-ig.
Kiadás 1. Tanúsítva 2011. december 21-től.

Jóváhagyta:

Tohl András

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MIR TANÚSÍTÓ
(MSZ EN ISO 13485)
NAT-4-0085/2010

Oldalszám 1 / 1

HU11/6221 számú tanúsítvány fordítása

Tanúsítjuk, hogy a(z)

Piston Kft.

1033 Budapest, Szőlőkert u. 4/b.

irányítási rendszerét auditáltuk és az megfelel az alábbi szabvány követelményeinek:

ISO 9001:2008

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Kiadás 1. Tanúsítva 2011. december 21-től.

Jóváhagyta:

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Oldalszám 1 / 1

Cégünk ezt a dokumentumot a "Tanúsítási Szolgáltatás Általános Szerződési Feltételei" szerint állította ki. A szabályzat teljes szövege megtalálható a www.sgs.com/terms_and_conditions.htm webcímen, amely különös figyelmet szentel a felelősségi, kártalanítási és jogi kérdésekre. Ezen nyomtatott dokumentum hitelességét a http://www.sgs.com/clients/certified_clients.htm webcímen lehet ellenőrizni. Minden jogosulatlan módosítás, tartalmi vagy kinézettbeli változtatás hamisításnak minősül, tehát törvénybe ütköző és jogi eljárást vonhat maga után.

Format of the patient identification field

The format of the patient identification filed can be any free text or some predefined format according to a special mask.

If this mask is defined the ID field is compulsory to fill during adding a new patient. Otherwise the field can be left empty.

!	If a ! character appears in the mask, optional characters are represented in the text as leading blanks. If a ! character is not present, optional characters are represented in the text as trailing blanks.
>	If a > character appears in the mask, all characters that follow are in upper-case until the end of the mask or until a < character is encountered.
<	If a < character appears in the mask, all characters that follow are in lower-case until the end of the mask or until a > character is encountered.
<>	If these two characters appear together in a mask, no case checking is done and the data is formatted with the case the user uses to enter the data.
****	The character that follows a \ character is a literal character. Use this character to use any of the mask special characters as a literal in the data.
L	The L character requires an alphabetic character only in this position. For the US, this is A-Z, a-z.
l	The l character permits only an alphabetic character in this position, but doesn't require it.
A	The A character requires an alphanumeric character only in this position. For the US, this is A-Z, a-z, 0-9.
a	The a character permits an alphanumeric character in this position, but doesn't require it.
C	The C character requires an arbitrary character in this position.
c	The c character permits an arbitrary character in this position, but doesn't require it.
0	The 0 character requires a numeric character only in this position.
9	The 9 character permits a numeric character in this position, but doesn't require it.
#	The # character permits a numeric character or a plus or minus sign in this position, but doesn't require it.
:	The : character is used to separate hours, minutes, and seconds in times. If the character that separates hours, minutes, and seconds is different in the regional settings of the Control Panel utility on your computer system, that character is used instead.
/	The / character is used to separate months, days, and years in dates. If the character that separates months, days, and years is different in the regional settings of the Control Panel utility on your computer system, that character is used instead.