

User Manual

Audiolyser[®] ADL-20



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1.Introduction

1.1. List of equipment supplied

The following equipment should be present in the packaging:

- AUDIOLYSER® ADL-20 device with headset and USB lead (in the cover)
- CD Rom containing user manual and Audiowin®20 software
- Information sheet
- Calibration certificate
- Transport cover

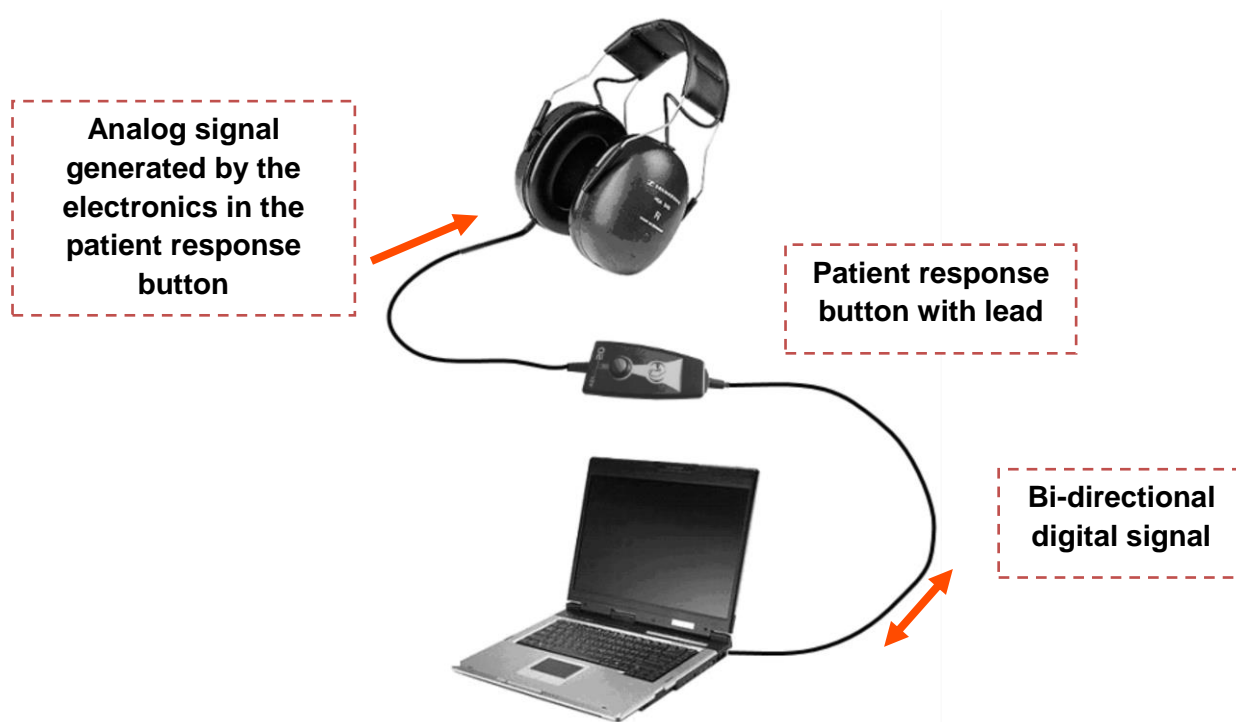
Note: The AUDIOLYSER® ADL-20 should be returned to the After Sales Service (for calibration or other services) in its original packaging and padding. Guarantee repairs will not be accepted without the original packaging box.

1.2. Audiometer presentation

The AUDIOLYSER® ADL-20 is a computerized digital audiometer. The electronics are integrated into the patient response button, rendering the device lightweight and easy to transport.

The AUDIOLYSER® ADL-20 can be set up with different headsets depending on user needs (refer §1.3).

One of the innovations of the AUDIOLYSER® ADL-20 is the Multilingual Vocal Assistant (MVA) which gives the patient the necessary instructions for the test and signals, if necessary, incorrect patient handling.



The DSP (Digital Signal Processor) located in the patient response button ensures communication with both the computer and the sound generation.

The AUDIOLYSER® ADL-20 is driven by the Audiowin® 20 software, a simple and intuitive interface. Audiowin® 20 stores information in a data base, which can also be printed, recorded and exported to other software.

Storage of audiometric curves and results enables consultation of files at a later date as well as statistics processing of results.

With all its features, the AUDIOLYSER® ADL-20 is a reliable, high-performance and progressive tool.

1.3. Technical features

AUDIOLYSER® ADL-20 features:	
Modes of use	Manual or automatic
Sound transmission	Continuous, inversed or pulsed mode
Harmonic distortion	± 2.5%
Frequency accuracy	± 2%
Headset soundproofing	10 - 40 dB (depending on model)
Length of lead	3 metres
Storage temperature	0 - 50°C
Temperature for use	15 - 35°C
Humidity	75% maximum
Altitude of operation	< 2000 metres
Voltage	5VDC (via USB port)
Supply current	210mA maximum
Reference standards	EN 60601-1, EN 60601-1-2, EN 60645-1, ISO 8253-1, ISO 389-1, ISO 389-5, ISO 389-8, ISO 7029
Type of audiometer	4
Medical class	Ila
Applied part	BF Type
Dimensions in packaging	255 x 210 x 100 mm
Total weight of device	500 - 850g approximately (depending on model)

Specific features of each headset:					
Type	BEYER DYNAMIC DT 48	TELEPHONICS TDH 39	SENNHEISER HDA 200	SENNHEISER HDA 300	HOLMCO PD-81
Calibration standard	ISO 389-1	ISO 389-1	ISO 389-5 ISO 389-8	ISO 389-5 ISO 389-8	Manufacturer
Headset weight	600g	430g	445g	490g	725g

Intensity limit for each headset:											
Frequencies (Hz)	125	250	500	750	1000	1500	2000	3000	4000	6000	8000
TELEPHONICS TDH 39 (dB)	70	90	100	110	110	110	110	110	100	90	80
SENNHEISER HDA 200 (dB)	70	90	100	100	100	100	100	100	90	90	80
SENNHEISER HDA 300	70	90	100	110	110	110	110	110	110	110	100
BEYER DYNAMIC DT 48 (dB)	70	90	100	110	110	110	110	110	110	90	80
HOLMCO PD-81 (dB)	70	80	90	100	100	100	100	100	100	90	80

1.4. Multilingual vocal assistant (MVA)

The AUDIOLYSER® ADL-20 has integrated a multilingual vocal assistant (MVA) system. By default, only the language of your country is available, but other languages may also be purchased (**French, English, Arab, German, Chinese Mandarin, Dutch**).

1.5. Symbols

Serial number labels display the following information:



0459

CE Marking Directive 93/42/EEC + N° of notified body



BF type applied part



Device should not be discarded with general household waste. Return it to the manufacturer for disposal



SN

Consult the accompanying documents

Serial number



Manufacturer identification

2.Safety

2.1. General

Caution:

- Do not use the AUDIOLYSER® ADL-20 in a non-medical environment.
- Do not expose a person to levels above 100 dB without having read the safety instructions (or without authorization).
- Do not dismantle or interfere with the internal components.
- Do not plug in or use the AUDIOLYSER® ADL-20 in an explosive environment or in the presence of anaesthetic gases.
- Do not drop the headset or the device.
- Do not splash or wet the headphones, even slightly (be careful of sprays and aerosol disinfectants).
- Clean only the headset pads (refer §5.2).
- Do not pull on the headset leads.
- Do not make sudden movements while wearing the headset.
- Do not let the PC and AUDIOLYSER® ADL-20 leads dangle on the ground and become entwined. This may cause it to fall, or degrade electrical connections.
- The operator should know whether the patient has an ear impairment and if a particular frequency or intensity could damage them. If this is the case, the operator should not perform the audiometry, or should be assisted by an authorized person who would be responsible for the test.
- The operator should ask the patient to remove glasses, hair accessories and/or hearing devices prior to an audiometry.
- Always use the AUDIOLYSER® ADL-20 connected to a computer according to IEC 60950-1

2.1. Users

The AUDIOLYSER® ADL-20 should only be used by health professionals (doctor, hearing aid specialist, ENT specialist ...). For health professionals, the device should not prove difficult to use.

The operator should be sufficiently trained in the use of computers and the associated operating system.

Curves and results should be interpreted by doctors having completed recognized training in the use of audiometers and the interpretation of audiograms. The operator should be aware of hygiene rules and bacterial contamination.

If in doubt, the health professional should refer to this user manual and/or contact the FIM MEDICAL company or their distributor.

2.1. Medical contraindications

- Do not perform an audiometry on patients with auditory prostheses.
- Do not perform an audiometry without prior otoscopic examination.

2.2. Environment for use

A noisy environment can disturb audiometry tests and results. In this case, we recommend an audiometric booth.

3. Installation

3.1. Prerequisite

3.1.1. Software recommendations

Prerequisites application software Audiowin20[®] are:

- Windows XP, Windows Vista, Windows 7, Windows 8

3.1.2. Equipment recommendations

Prerequisites application equipment Audiowin20[®] are:

- PC with a 1 GHz processor at least
- 512 Mo of RAM
- 500 Mo free space on the hard disk
- A graphic card (or graphic chipset) accepting a resolution of at least 1024x748
- A keyboard
- A mouse
- A USB port
- A screen with a resolution accepting a minimum resolution of 1024x748

3.2. Software use conditions

The Audiowin[®] software is licenced under the conditions defined below. If, before installation, or 48 hours after receiving the software, these conditions are refused, please return it to the distributor to receive a refund.

Software use implies total agreement with the following conditions:

The software supplied under licence remains the property of FIM MEDICAL who grants the right to use this product as long as the present conditions are respected.

This licence is granted for installation and use at one workstation only (desk top computer, lap top or terminal).

All new installations require the purchase of a new licence or uninstallation from the initial workstation.

The licence for use is nominative and should not be passed on or sold without the written agreement of FIM MEDICAL.

Copy or reproduction of FIM MEDICAL software supplied under licence is prohibited. Reproduction, even partial, of original screens or computer processes constitutes a violation of this agreement. The user accepts to take the necessary measures to avoid pirate copies or use by non-authorized third parties.

The FIM MEDICAL company cannot be held responsible in any way for malfunctions related to the installation of one of their programmes on a computer. Neither can the FIM MEDICAL company be held responsible for any consequences related to the installation of one of their programmes, such as partial or total loss of data.

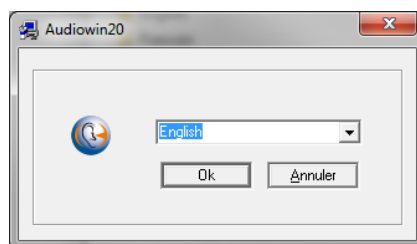
The user should be trained in the basic rules of handling computers. All precautions should be taken to guard against the risks of pirating programmes, divulging confidential data, attack by whatever type of computer virus or incorrect handling.

Special care should be taken to back up data recorded on the computer as often as possible, on a reliable media; we recommend performing this every day.

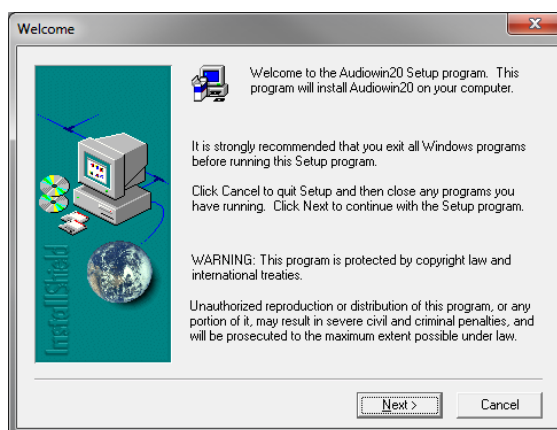
3.3. Installation procedure

The operator must possess all the administration rights on the workstation to be installed. Installation should be made in a clear space on a stable desk or table. The patient should not be able to see the screen, or the operator actions.

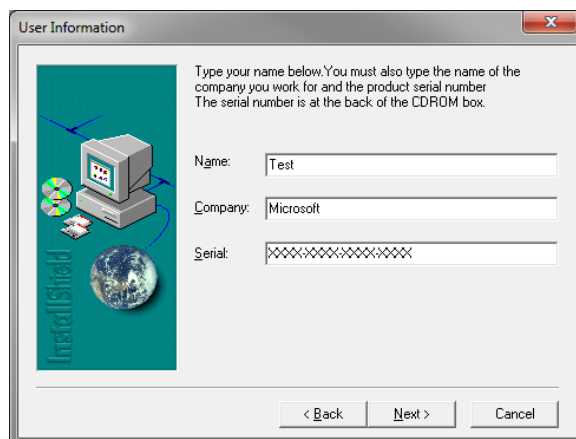
1. Switch on the computer.
2. Insert the Audiowin®20 software installation CD Rom into the CD reader.
3. Proceed to the software installation phase.
4. If your computer is set up for auto run, the installation procedure will run automatically.
5. If not, open Windows Explorer and search for "setup.exe" file in the root of the CD Rom, and run it.
6. Once the installation programme is run, follow the instructions.
7. Choose your installation language then click OK:



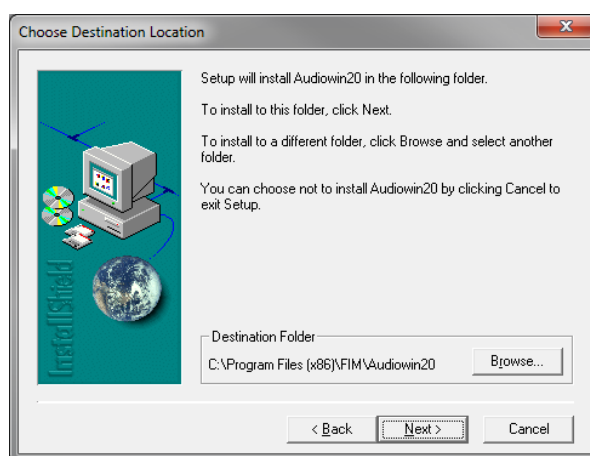
8. Click Next:



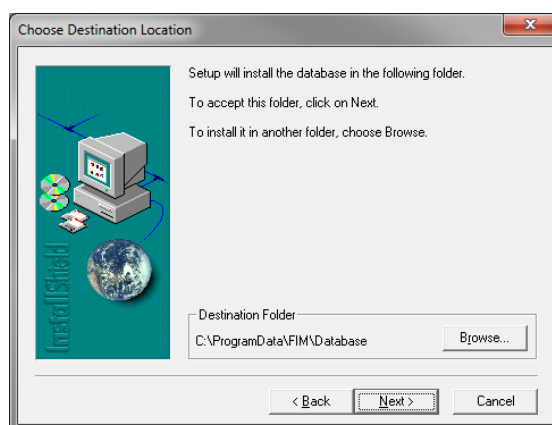
9. Enter the user code located on the back of the CD sleeve, then click Next:



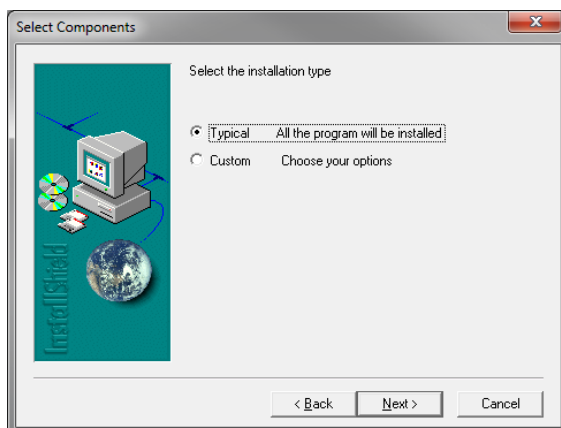
10. Choose the Audiowin® 20 software installation path (*optional*), then click Next:



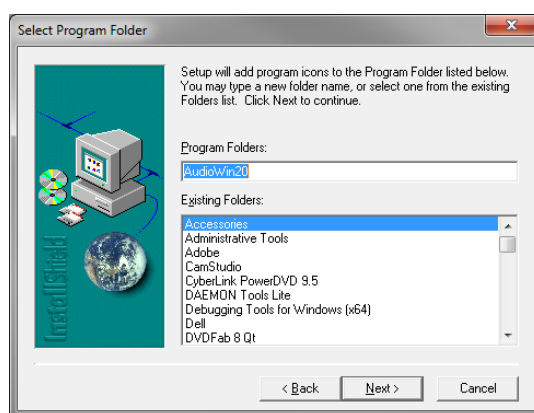
11. Choose the data base installation path (*optional*), then click Next :



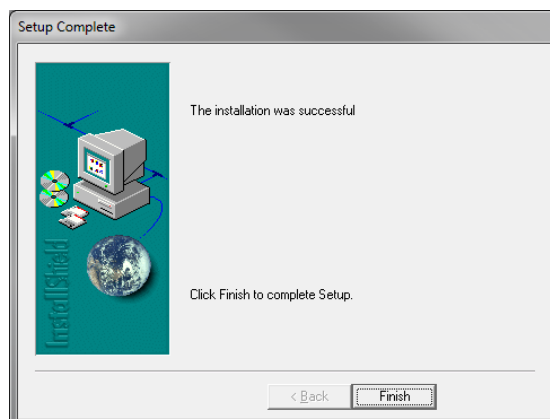
12. Click Next:



1. Click Next:



2. Click Finish :



Locate a **USB** connector on the computer and plug in the ADL-20.

The USB lead can pass through the wall of a booth. Request information from your booth manufacturer or distributor.

3.4. Stop the device

To stop the device:

1. Close the Audiowin® 20 programme window.
2. If the device is not to be used for an extended time, unplug the USB lead from the headset and store it in its packaging.

4. Use

4.1. Preliminary patient explanation

4.1.1. Headset position

Seat the patient comfortably and help them position the headset over the ears correctly. The pads should be centred over the ear holes, with the headband resting on top of the head, without forcing it.



4.1.2. MVA (multilingual vocal assistant)

Using software commands the MVA (multilingual vocal assistant) sends vocal instructions to the patient via the headset. These instructions come in several languages (optional), thus making audiometry screening accessible to a wide range of the public.

The MVA explains the test procedure as well as using the patient response button. It will also intervene if there is a usage error, during the familiarization phase.

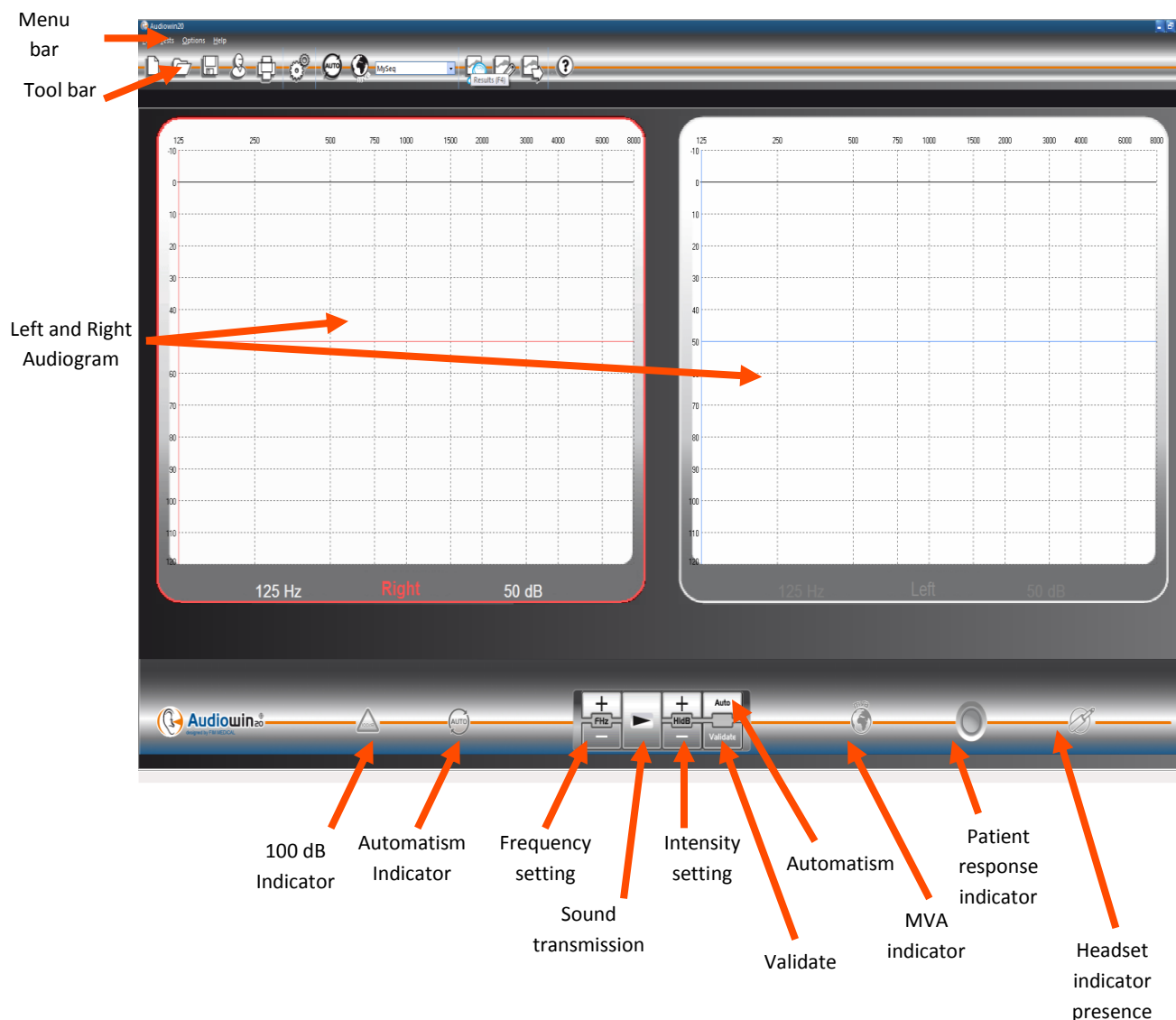
4.1.3. Most frequent errors

1. Continuous press on the response button.
2. Repeated and untimely presses on the response button.
3. Pressing too lightly.

If the patient is unable to get used to the response button, the perception of sound can be confirmed by raising an arm. In this case, the operator validates the threshold by clicking “Validate”, or pressing “Enter”.

4.2. Software use

4.2.1. Presentation



4.2.2. Checking function

When the Audiowin[®] 20 interface is run, the presence indicator turns from grey to blue. If this does not happen, check that:

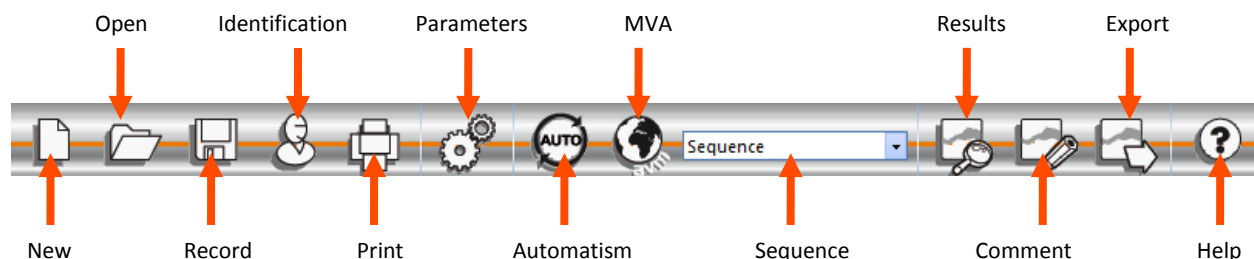
1. The USB lead is correctly inserted.
2. The software has not been run twice.
3. Installation of drivers was correctly done.

As soon as the presence indicator colours, click on the graph of the left or right ear at the intersection of an audible frequency and intensity.

Transmit the sound by pressing on the keyboard **space** bar; the chosen sound should be perceived.

4.2.3. Tool bar

To access main functions.



4.2.4. Menu bar

4.2.4.1. File

Function	Description
New	Create a new file
Open	Open a patient file and/or test
Record	Record the current file and test
Export	Export the test performed to the computer
Compare	Compare several curves from the same patient recorded in the data base
Follow up	Follow a patient on an index or frequency over time
Identification	Input or consultation of patient identification
Print	Print the test in progress
Selective print	Print a selection of the test according to certain criteria
Print preview	Display entire pages
Print set up	Choose and set up the printer
Exit	Exit the programme

4.2.4.2. Tests

Function	Description
Automatism	Start/stop automatism
Pause	Automatism pause, or rerun
MVA repeat	Repeat last MVA message to the patient
MVA	List of available languages
Comment	Post a comment related to the test
Results	Display audiometry result and the calculated indexes
+90d Authorization	Tick this menu to go over 90 dB value

4.2.4.3. Options

Function	Description
Parametres	Parameter the software

4.2.4.4. Help

Function	Description
About	Version and copyright information
System information	Environment and device information

4.3. Patient identification

4.3.1. Identification

Patient identification is required to record test results in the data base, but also to calculate and display the predicted response limits according to the age and gender of the patient.

Click "**Identification**" button before or after the audiometry.

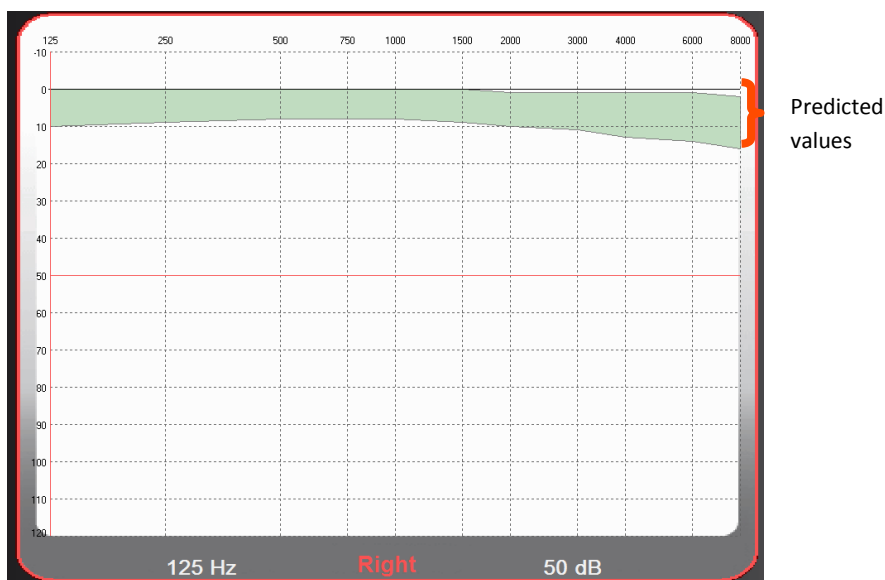
Fill in the required fields (fields with a red asterisk are compulsory). Go from one field to another by clicking on the box, or by pressing the "**Tab**" button.

Use the small 3-points button (...) located on the right of the last name to check if the patient has already been recorded, using only the first letters of the last name.

Date of birth can be input with or without spaces. The year can be 2 or 4 numbers, e.g.: 21/04/1981 or 21/04/81.

4.3.2. Display of predicted values

After identification, the graph appears as such:



Calculation of predicted values is based on the ISO 7029 standard.

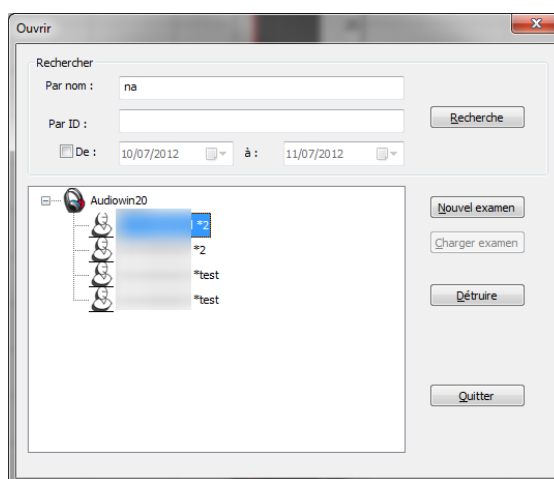
The colour can be changed in the "**Parametres**" window, "**General**" tab.

4.4. Open a patient file/test

4.4.1. Open a file

To locate the data of a recorded patient, proceed as follows:

Click "Open". The following screen appears:



Enter the first letters of the patient's surname in the **"By name"** box, then click **"Search"**. The list of names starting with these letters appears. Then click **"New exam"**. A patient search can also be carried out by identification number or date of recording.

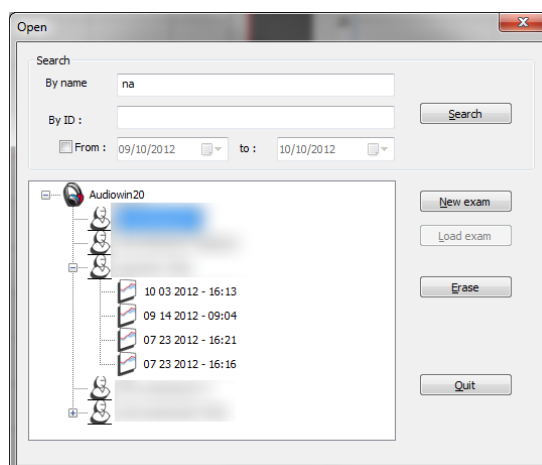
4.4.2. Open a test

To visualize or print an old test, the operator can call up a file.

Proceed as seen before. A small + sign is displayed next to the patient name, indicating that tests were done. Click on this + sign.

A list of dates and times are shown.

Double click on one of these dates or click **"Load exam"** to display the audiogram performed on this date.



4.5. Parameter the software

4.5.1. Screening

Recommended settings to perform a screening test:

"General" tab.

- | | |
|------------------------|--------|
| 1. Amplitude variation | 5 dB |
| 2. Sound transmission | Pulsed |

"Automatism" tab.

- | | |
|-------------------------|--|
| 1. Frequency | 1000 Hz, 2000 Hz, 4000 Hz, 6000 Hz, 8000 Hz, 500 Hz, 250 Hz. |
| 2. Lowest hearing level | 0 dB |
| 3. Presentation level | 50 dB |

"Automatism" tab.

- | | |
|-------------------------------|--|
| 1. Number of tests | 3 successive tests achieved |
| 2. Tolerance of doubtful test | 10 dB |
| 3. Duration per level | Choose a range between 15 - 30 tenths of a second. |

All these settings are programmed only once, but can be changed at any time.

4.5.2. Window parameters

To define software parameters:



Click on the parameters icon in the tool bar or select **Option** in the menu bar, then **Parameters**.

4.5.2.1. General tab

Function of transmission button on main interface. Sound is automatically transmitted when the mouse cursor is pointed over the button.

Modify the data base path. **Caution: Do not modify this parameter without knowledge of the consequences.**

Display, printing and colour of predicted value.

Action of high and low keyboard arrows.

Modify Audiowin®20 language.

Type of sound transmitted: pulsed or continuous.

Audiowin®20 can print the audiogram in colour (if printer is a colour printer) and choose the logo on the printing sheet.

Date format.

Inhibition of patient response button. The patient signals sound perception by raising one hand. The operator validates the measurement with the Enter key or the Validate button.

Amplitude variation

☒ 1 dB ☐ 5 dB ☐ 10 dB

Variation of sound amplitude.

Right and left arrows

☐ Sequence ☒ All frequencies

Parametering of right and left arrows function on an audiogram. Each frequency is swept in order, or only the selected sequence.

Display categorization

☐ None ☐ Merluzzi 1979 ☒ Degrees of hearing loss

Changing the display areas categorization of audiograms.

4.5.2.2. Automatism tab

Use this tab to:

- know the criteria used in the sequence by default
- create and manage sequences for automatic mode (refer § 4.8 automatic mode)

Parameters

General Automatism Calculations Export User

Trial

Trials number : 8

Doubtful test tolerance (dB) : 5

Sequence

Rapid MP 42

New Rename Erase

1: 1000	7: NO
2: 2000	8: NO
3: 4000	9: NO
4: 500	10: NO
5: NO	11: NO
6: NO	12: NO

Enter the order the frequencies will appear.
"NO" indicates that the frequency will not be tested.

Emitting time by level (1/10s)

☐ Fixed 30

☒ Random Min: 15 Max: 20

First ear : ☐ Right ☒ Left

☒ Alert at the end of test

Low level : 0 dB

Hearing level : 50 dB

1st hearing level : 50 dB

MVA Level : 255 ☒ MVA Options

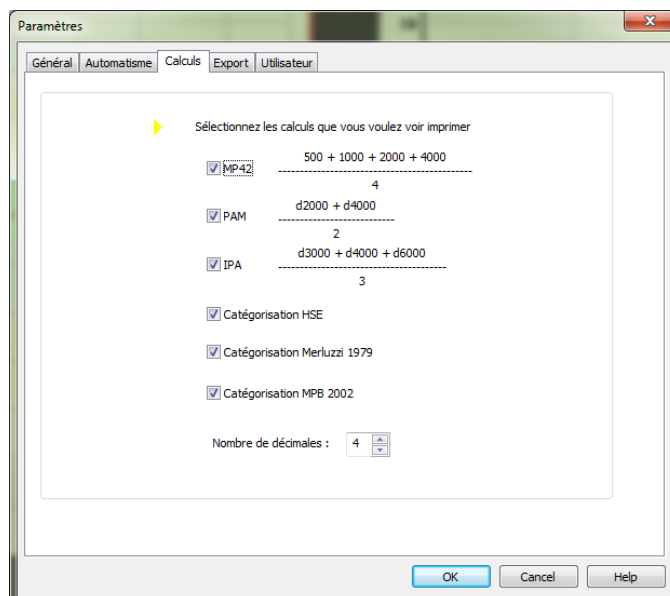
Play MVA

☐ First test ☒ Every tests

OK Cancel Help

4.5.2.1. Onglet Calculs

Calculations MP42 (Legal Index Table No. 42 Occupational Diseases of the general scheme), MAP (Mean Hearing Loss) and IPA (indicator of Precocious Alerts) or HSE¹ categorization, Merluzzi 1979² categorization or MPB 2002³ categorization are submitted by Audiowin® 20.

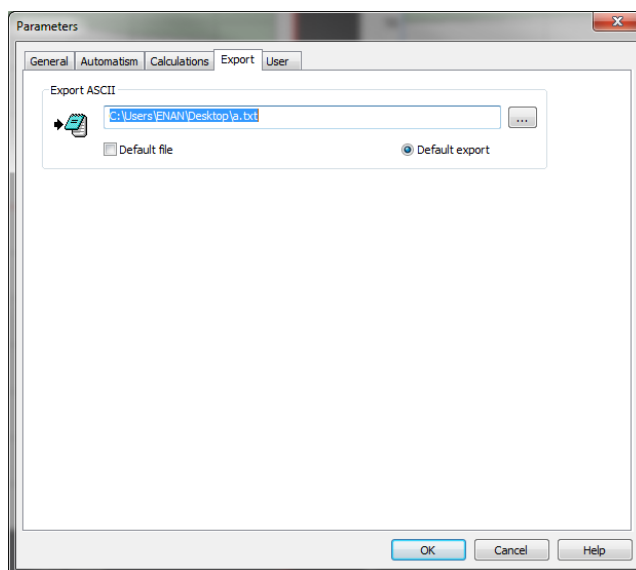


¹ For more information refer to "The Control of Noise at Work Regulations 2005":
<http://www.legislation.gov.uk/ukxi/2005/1643/contents/made>

² For more information, please consult the "Prevenzione dei danni uditivi rumore da di lavoro in ambient - linee guided proposte dalla società italiana di medicina del lavoro e igiene industrial"

4.5.2.2. Export tab

Use this tab to parameter the destination of the exported file when pressing on the F12 key. Choose the name of the file as well as the format by default.



4.5.2.3. User tab

Use this window to input your details and display them at the top of the reports page.

The screenshot shows the 'Parameters' dialog box with the 'User' tab selected. The form contains several input fields: 'Last name first name', 'Specialty' (with the value 'specialite'), 'Address', 'Town code country', 'Phone' (with the value '06'), 'Fax' (with the value '0152455845'), and a 'Print' checkbox which is checked. At the bottom of the dialog, there are 'OK', 'Cancel', and 'Help' buttons.

4.6. Display areas categorization

Audiowin20[®] allows the display area categorization to help the operator to get a quick overview of the trend of the results of the current review. Two types of zones are proposed:

Merluzzi 1979 :



Degrees of hearing loss:



Degrees of hearing loss	Hearing threshold	Hearing ability
None	0 to 20 dB	Considered normal hearing.
Light	21 to 40 dB	Difficult perception of light speaking and conversations, especially in noisy environments. Good perception in a quiet environment.
Moderate	41 to 55 dB	Difficult perception of speaking, especially when background noise. Tend to increase the volume of the television or radio.
Moderate to severe	56 to 70 dB	Speech perception greatly reduced. Participation in group discussions very difficult.
Severe	71 to 90 dB	Inability to hear speech to normal and also trouble with loud noises. The amplification is required.
Deep	91 dB and +	Environmental sounds and speech are almost imperceptible.

Audiometric classification of hearing impairment based on the recommendations of the International Bureau Audiophonology.

http://www.biap.org/index.php?option=com_content&view=article&id=5%3Arecommandation-biap-021-bis&catid=65%3Act-2-classification-des-surdites&Itemid=19&lang=fr

4.7. Manual mode

4.7.1. Operation

Audiowin®20 is designed to perform audiometries in automatic and manual mode.

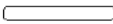









For manual mode, use the keyboard and/or the mouse to:

- Select frequency
- Select intensity
- Transmit sound
- Validate patient response (if the patient response button is not used)

These points are explained in the following chapter.



3-button mouse

Operation	Keyboard	Mouse left click	Mouse scrolling wheel
Sound transmission			Press on scrolling wheel
Select intensity	 		Use scrolling wheel to modify intensities
Select frequency	 		Use Ctrl + scrolling wheel to modify frequencies
Validate patient response			

Setting of frequencies and intensities can also be accessed with the mouse, using the right or left audiogram graphs, and clicking on the intersection of a frequency and intensity.

Note: To avoid handling errors, sudden changes in amplitude can be automatically controlled by the software, so as not to damage the patient's ear.

4.7.2. Keyboard keys



Page UP

Intensity to value of lowest hearing level.

Page Down

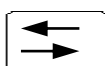
Intensity to a pre-determined high value in the "sequence" tab (presentation level).

So as to avoid repeated presses on the intensity settings arrows, use the "**page up**" and "**page down**" keys to pass from one extreme to the other on the intensities scale.



END

Stop automatic procedure.



Tab

Go from one ear to the other.



Enter

Operator validates patient response.



Space

Transmission of sound in manual mode.



Del/Erase

Delete a validation on an audiogram.



F12

Export the audiogram in progress to a file.



F4

Display audiogram results.

4.8. Automatic mode

4.8.1. Parameters

To use the audiometer in automatic mode, firstly ensure the programme is set up according to your usual working method.

Possible settings choices:

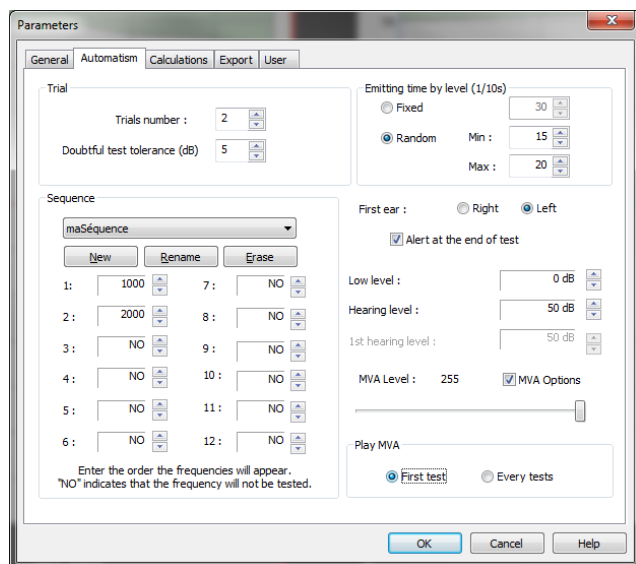
1. Frequencies tested.
2. Order of frequencies tested.
3. Amplitude variation (steps of 1.5 or 10 dB).
4. Signal type (continuous or pulsed).
5. First ear tested.
6. Number of test(s) per frequency.
7. Response level differences considered doubtful by Audiowin®20.
8. MVA language and volume.

These settings will apply throughout the test, the length of which is inversely proportional to the quality of the final audiogram.

To access the parametering window, in the "Options" menu, choose "Parameters".

Use the tabs located at the top of this window to access different settings.

Click on the "Automatism" tab.



4.8.2. Creation of sequences

Audiowin®20 also offers the possibility of creating personalized sequences: click "New", then name this sequence. Click "OK".

Select the frequencies to be tested and the different criteria of the test. In this example, the test will start at 1000 Hz frequency then 2000HZ, 4000Hz and 500 Hz. The other frequencies are positioned to NO.

The new sequence will automatically be recorded in the scrolling menu of the existing sequences.



4.8.3. Run automatic test

Place the headset on the patient's head and click "**Auto**".

The MVA gives the operating instructions to the patient. The test then starts with the familiarization phase at 50 db. During this phase, the software detects abnormalities linked to incorrect presses of the patient response button and the MVA informs the patient via vocal messages such as "**Release the button**".

The patient should press on the blue part of the patient response button if the sound is perceived. If not, the sound increases in intensity to 90 dB, then displays "**No response**".

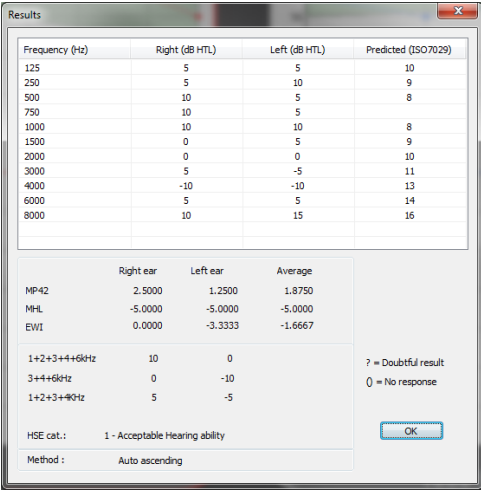
If the patient hears, Audiowin®20 runs the familiarization threshold search at 1000 Hertz, starting at 0 dB.

The programme then carries out the test of all frequencies on the two ears. If there is a doubtful response, a question mark is placed next to the patient response and will return to this test at the end of the sequence. If a doubt persists, a frequency may be retested in manual mode.

Tests in progress can be interrupted temporarily by pressing on the "Pause".

4.9. Display of results

Audiowin®20 displays a table of results summarizing the test in progress. It indicates certain other calculations.



Frequency (Hz)	Right (dB HTL)	Left (dB HTL)	Predicted (ISO7029)
125	5	5	10
250	5	10	9
500	10	5	8
750	10	5	
1000	10	10	8
1500	0	5	9
2000	0	0	10
3000	5	-5	11
4000	-10	-10	13
6000	5	5	14
8000	10	15	16

	Right ear	Left ear	Average
MP42	2.5000	1.2500	1.8750
MHL	-5.0000	-5.0000	-5.0000
EWI	0.0000	-3.3333	-1.6667

	Right ear	Left ear	
1+2+3+4+6kHz	10	0	? = Doubtful result
3+4+6kHz	0	-10	() = No response
1+2+3+9kHz	5	-5	

HSE cat.: 1 - Acceptable Hearing ability
Method : Auto ascending

OK

Summary contains:

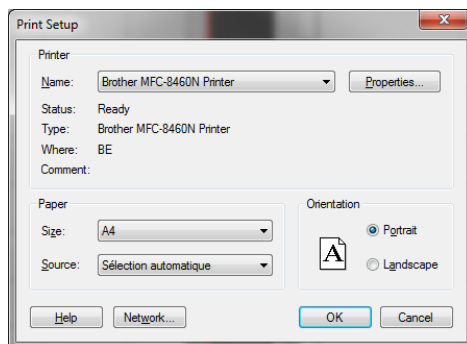
- Patient results
- MP42 (occupational diseases)
- PAM (Average Hearing Loss)
- IPA (Early Warning Indicator)
- HSE (Health and Safety Executive) categorization
- Merluzzi 1979 categorization
- MPB 2002 categorization
- Method of test performance

4.10. Print results

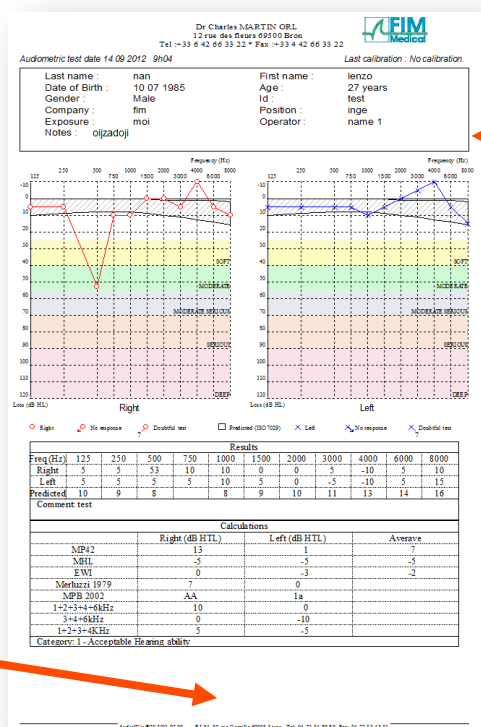
4.10.1. Simple printing

When the audiometric test is completed, and after recording the results, press "**Print**". Printing is immediate.

Printing can also be done from the "File" menu. In this case the following window, depending on printer type, appears:



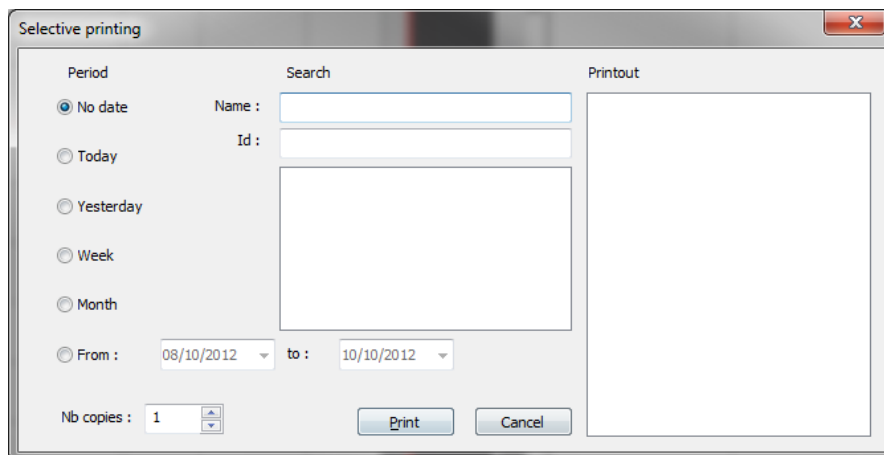
The document will be printed as such:



4.10.2. Selective printing

Printing one, or several documents, of tests performed on different dates can be programmed.

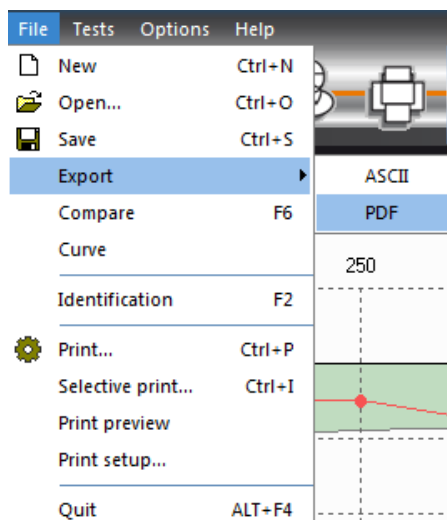
Click on the "File" menu then "Selective printing". The following window appears:



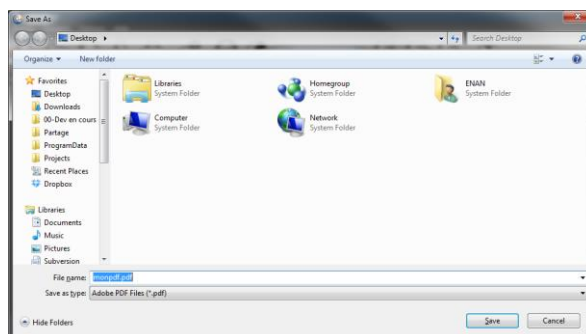
If printing several documents, ensure the paper supply is sufficient.

4.10.3. PDF printing

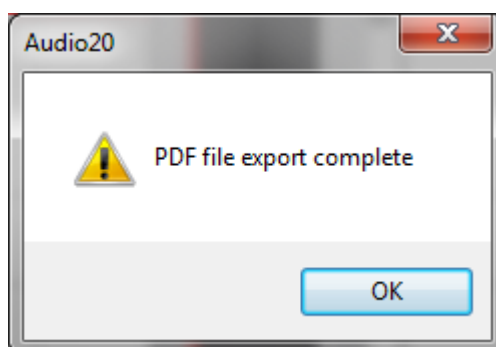
When the test is complete, click on **File** → **Export** → **PDF**.



Choose the location of the PDF file and the file name, then click on **“Record”**.



If PDF creation is successful, the following message appears:



5. Maintenance

5.1. Cleaning

The device should be cleaned after each use with a damp cloth and a bactericide solution. FIM MEDICAL recommends the use of Bactynyl® odourless cloths.

We recommend asking the patient to disinfect their hands before handling the device.

After each patient, clean the parts of the device in contact with the patient:

- Headset pads (take care not to wet the headphones)
- Head band
- Patient response button

The use of spray is not recommended; a misdirected jet may definitively damage the headphones.

5.2. Maintenance

To conform with the ISO 8253-1:2010 standard, audiometric equipment should be regularly checked and calibrated. Recommended:

- **Daily:** clean, check general state of equipment, check the device functions over the entire frequency range, check patient response button.
Checks should be made in the same environment as patient tests.
- **Annual service** performed by the manufacturer.

Only FIM MEDICAL is qualified to perform annual servicing of audiometers.

A calibration certificate is delivered.

The expiry date of the FIM MEDICAL calibration is indicated by the software. Before this expiry date, please return the device to FIM MEDICAL for calibration.

Caution: Have the device recalibrated before the expiry date. After expiry date, a drift may falsify results.

5.3. Guarantee

Within the framework of the contractual guarantee of one year, only repairs are covered. The guarantee is only applicable if normal and usual conditions of use are respected. During annual servicing, a certain number of preventive operations are performed; breakdowns following annual service are not covered by the guarantee.

6.FAQ

6.1. No sound is perceived

- Check the headset is connected.
- Check the indicator cone of headset presence on the software interface is coloured blue.

6.2. Error message appears at recording

6.2.1. *"Identification incomplete"*

- Check all the compulsory identification fields are filled in.

6.2.2. *"Operation must use updateable query"*

- This message is due to a problem of writing access rights on that computer. The administrator must give all tree structure rights, where the data base is found, to the operator.

6.3. Patient identification file found but not the tests

- Click "+" on the left of the patient's name in the "Open" dialogue box.

7. Declaration of Conformity

EC DECLARATION OF CONFORMITY

<u>Name</u>	<u>Version</u>	<u>Device Description</u>
Audiolyser®	ADL-20	Computerized audiometer

The device conforms to the following standards:

EN 60601-1:2006/AC: 2010: Medical electrical equipment – Part 1: General requirements for basic safety.

EN 60601-1-2:2007/AC: 2010: Medical electrical equipment - Part 1-2: General requirements for basic safety - Collateral standard: Electromagnetic compatibility - Requirements and tests.

IEC 60601-1-6:2007/AC: 2010: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.

EN ISO 10993-1:2009/AC: 2010: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

NF EN ISO 14971:2009: Medical devices - Application of risk management to medical devices.

NF EN 62304:2006 : Medical device software -- Software life cycle processes.

NF EN 1041 + A1: 2013: Information supplied by the manufacturer of medical devices.

IEC 60645-1: 2012 : Electroacoustics - Audiometric equipment - Part 1: Equipment for pure-tone audiometry.

ISO 8253-1: 2010 Acoustics - Audiometric test methods - Part 1: audiometry with pure air conduction and bone conduction sound.

ISO 389-1: 2000 Acoustics - Reference zero for the calibration of audiometric equipment - Part 1: Levels Reference equivalent threshold sound pressure earphones at supra-aural pure sounds.

ISO 389-8: 2004 Acoustics - Reference zero for the calibration of audiometric equipment - Part 1: Levels Reference equivalent threshold sound pressure for pure tones and circumaural headphones.

NF EN ISO 7029: 2000 Acoustics-statistical distribution of hearing thresholds as a function of age.

I the undersigned, Marie-Ange DEREI, President of the FIM MEDICAL. company, located at 30 rue Camille 69003 LYON-FRANCE, assure and declare that the medical device listed above belongs to class IIa (rule 10) and satisfies the provisions of annex VI (attestation CE n° 27671 rev.2 issued by LNE/G-MED) and annex VII (Audiolyser® ADL20 technical file evaluation) of the 93/42/EEC directive, amended by the 2007/47/EC directive.

Villeurbanne, 10/06/2014,

Marie-Ange DEREI

Présidente



CE
0459



*Thank you for reading this manual.
If you require further information please don't
hesitate to contact us.*



FIM MEDICAL

51 rue Antoine Primat 69100 Villeurbanne - FRANCE

Tel: (+33)04 72 34 89 89 - Fax: (+33)04 72 33 43 51

contact@fim-medical.com / www.fim-medical.com