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USER MANUAL

Audiolyser®
ADL20®

FIM Medical

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Table of contents

1. Introduction

1.1. List of equipment supplied

The following equipment should be present in the packaging:

- Audiolyser® ADL20 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® ADL20 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® ADL20 is a computerized digital audiometer. The electronics are integrated into the patient response button, rendering the device lightweight and easy to transport.
The Audiolyser® ADL20 can be set up with different headsets depending on user needs (refer §1.3).
One of the innovations of the Audiolyser® ADL20 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® ADL20 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® ADL20 is a reliable, high-performance and progressive tool.

1.3. Technical features

Audiolyser® ADL20 features	
Modes of use	Manual or automatic
Sound transmission	Continuous, inversed or pulsed mode
Harmonic distortion	± 3%
Frequency accuracy	± 2,5%
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, IEC 60601-1-6, EN 62366-1, EN ISO 10993-1, EN ISO 10993-5, EN ISO 10993-10, NF EN ISO 14971, IEC 60645-1, ISO 8253-1, NF, ISO 389-1, ISO 389-8, ISO 7029, EN 62304, NF EN 20417, EN ISO 15223-1, NF EN ISO 13485
Type of audiometer	4
Medical class	IIa (rule 10)
GMDN Code Audiometer	41187
Applied part	BF Type
Dimensions in packaging	255 x 210 x 100 mm
Total weight of device	500 - 850g approximately (depending on model)
Altitude of operation	< 2000 metres

Year of 1st EC marking: 2010
NB: Under normal conditions of use, no heating time required for the equipment (§5.4 IEC 60645-1: 2012).

Specific features of each headset			
Type	Sennheiser HDA 300	Holmco PD-81	RadioEar DD65
Calibration standard	ISO 389-5 ISO 389-8	Manufacturer	Manufacturer
Headset weight	490 g	725 g	500g

The ADL20® can output a maximum decibel (dB) threshold of 100 dB. The table above can be used to cross-reference the intensities in dB and the related frequencies in Hz.

Intensity limit for each headset (dB)											
Frequencies (Hz)	125	250	500	750	1000	1500	2000	3000	4000	6000	8000
dB max	70	80	90	100	100	100	100	100	100	90	80

Biocompatible single use earpad covers	
Material	Unwoven PP (Polypropylene) 35g
Diameter	11 cm
Reference standards	EN 62366-1, EN ISO 10993-1, EN ISO 10993-5, EN ISO 10993-10, NF EN ISO 14971, IEC 60645-1, ISO 8253-1, NF EN 1041+A1, EN ISO 15223-1
Medical class	I (rule 1)
Earpad covers GMDN code	63091

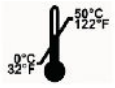
Year of 1st EC marking: 2018

1.4. Multilingual Vocal Assistant (MVA)

The Audiolyser® ADL20 possesses a multilingual vocal assistance (MVA) system. By default, only the language of the country in which the product was purchased is available, but other languages are available and may be specified at the time of purchase (French, English, Arabic, German, Mandarin Chinese, Dutch, Italian, Portuguese, etc.)

1.5. Symbols

Serial number labels display the following information:

CE 0459	CE Marking Directive 93/42/EEC or MDR 2017/745 + N° of notified body
	BF type applied part
	Device should not be discarded with general household waste. Return it to the manufacturer for disposal.
	Consult the accompanying documents
SN	Serial number
	Manufacturer identification
	Do not re-use. Single use.
LOT	Lot number
	Expiration date of use
	Storage temperature
(01)XXXXXXXXXXXXXX	**UDI** Identification Unique identification number of the product
(10)XXXXXX	UDI Identification Batch number
(11)XXXXXX	UDI Identification Date of manufacture

(17)XXXXXX	UDI Identification Expiry date
	Medical Device
	Date of manufacture
	Humidity limit

2. Safety

2.1. General

Attention :

- Do not use the Audiolyser® ADL20 in a non-medical environment.
- The product should be used on healthy skin
- During an examination the operator must ensure that the total sound emission time of 80dB or higher lasts no longer than 15 minutes and does not exceed the maximum threshold of 100 dB.
- Do not dismantle or interfere with the internal components.
- Do not plug in or use the Audiolyser® ADL20 in an explosive environment or in the presence of anaesthetic gases.
- Do not drop the headset or the device.
- Do not immerse, splash or wet the device, even only slightly (beware of aerosol sprays and disinfectants), when cleaning or during any other operation.
- Do not pull on the headset leads.
- Do not make sudden movements while wearing the headset.
- Do not let the PC and Audiolyser® ADL20 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® ADL20 connected to a computer according to IEC 60950-1
- In the conditions of use of the ambient test environment (see section 1.3), the Audiolyser® ADL20 does not need warm-up period.
- For hygiene and biocompatibility reasons, it is compulsory to use the FIM Medical brand of single-use earpad covers with audiometric headphones.
- These earpad covers have been developed specifically to meet ISO 10993 material biocompatibility requirements as well as guaranteeing perfect sound transmission whilst respecting IEC 60645-1.
- The operator may perform several examinations of indefinite duration without any risk to the patient provided that he or she complies with the intended use and hygiene conditions, i.e. changes the single-use headphone covers between each patient.

Caution: to meet ISO 10993 material biocompatibility requirements, it is compulsory to use the FIM Medical brand of hygienic single-use earpad covers with Holmco PD-81, Sennheiser HDA200, HDA300 and RadioEar DD65 audiometric headphones.

2.2. Description

The Audiolyser® ADL20 is an electromedical device composed of:

- The ADL20 device
- Audiowin®20 software (integrated into Audiolyser®)
- The single-use earpad covers

2.3. Intended use

The Audiolyser® ADL20 is a computerized audiometer intended solely for the exploration of hearing function. It is a tool for detecting possible defects in the patient's hearing.
The biocompatible single-use earpad covers are adapted to the ADL20® headphones for biocompatibility between the skin and the eyecups, and ensure protection against bacteriological risks between two patients.

2.4. Planned operators

The Audiolyser® ADL20 should be used exclusively by healthcare professionals such as medical secretaries, nurses, doctors, ENT or other specialist doctors who have received recognized and comprehensive training in the use of audiometers and the interpretation of audiometric results. Through their medical curriculum, healthcare professionals are made aware of the rules of hygiene and bacterial contamination.

Users must be trained and experienced in the elementary manipulations required to use a computer. They should take all the steps necessary to prevent software piracy, to safeguard confidential data, to prevent computer virus attacks and to avoid incorrect software and hardware manipulations.

They will take particular care to take regular back-ups on reliable media of the data recorded on the computer. It is recommended that this operation is carried out on a daily basis.

Users are reminded that the Audiowin®20 software is delivered under a licence contract which defines the conditions of use. This licence is granted for installation and use of the software on a single workstation. Any new installation will require the purchase of a supplementary licence.

In case of doubt, the healthcare professional should refer to the user manual and / or contact FIM Medical or its distributor.

2.5. Patient population

The patient population that can use this device is:
• People over 4 years old
• Anyone able to press the button to give their answer, or, if they are unable to do so, to give the answer to the operator
• All people not suffering from a contraindication related to their hearing condition

2.6. Medical indications and contraindications

Indication: The ADL20 Audiolyser® is used to explore the hearing function and screen potential hearing disorders in patients.

Contraindications / limitations:

- Do not perform audiometry on patients wearing hearing aids.
- Do not perform audiometry without examining the ear in advance using otoscopy.
- Use of the ADL20 Audiolyser® is reserved for individuals aged over 4 years.

2.7. Environment of use

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

2.8. Clinical benefits and risks associated with using this device

The audiometer must be able to analyze the patient's hearing function in order to assess the level of hearing. The device assesses the patient's hearing loss by comparing audiometric curves with those of a statistical distribution of hearing thresholds as a function of age and sex (predicted by ISO 7029). Audiometric tests are used to detect occupational hearing loss using audiometric calculations and interpretation aids. Periodic follow-up of patients makes it possible to assess the impact of the work environment on hearing.
The performance, technical characteristics, measurement precision and IEC 60645-1 compliance of the Audiolyser® ADL20 and its Audiowin®20 software confer a qualitative clinical benefit for the patient in the area of diagnosis. The audiometric measurement precision associated with interpretation aids enable measuring the state of a patient's hearing and its progression over the long term.
There is no limitation on the number of examinations per patient using the Audiolyser® ADL20.

2.9. Serious incidents or risk of incident

If any serious incident or risk of a serious incident is detected, the healthcare professionals should make an appropriate declaration to the competent authorities of the Member State. In all such cases, the manufacturer must be informed as quickly as possible so that a material vigilance declaration can be made and acted upon.

2.10. Adverse effects and potential side effects

No adverse effects or incidents relating to the clinical performance, clinical safety or usability have been reported since the ADL20 Audiolyser® has been available for sale. The complaints that have been reported have been linked exclusively to a device failure or logistical issues without any impact on clinical performance or safety.

Moreover, no serious adverse event or serious adverse effect regarding any type of screening audiometer (conventional or computerised) has been reported in the scientific literature or in the main databases of the health authorities.

As a result, FIM MEDICAL does not claim any adverse effect(s) and / or potential secondary effect(s) regarding the use of the ADL20 Audiolyser®.

3. Installation

3.1. Minimum configuration

- Operating system supported by the Audiolyser® ADL20: **Windows 7**, **Windows 8**, **Windows 10**, **Windows 11.**
- 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 condition

The **Audiowin®20 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. Prerequisites

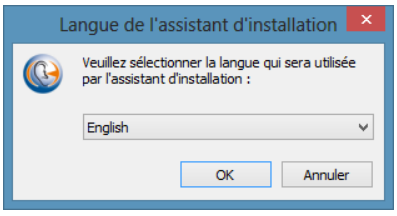
Components required to be installed with the software:

- Adobe Reader
- Silicon Labs drivers for CP210x (component which ensures the device's USB communication)

3.4. Installation procedure

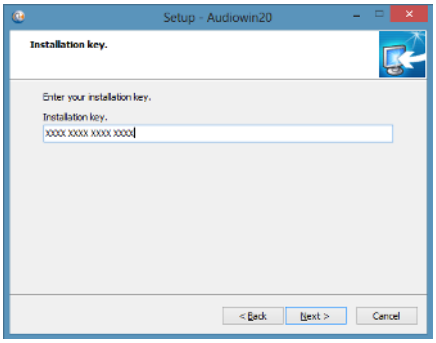
Note: To be able to install Audiowin®20 you need to be in administrator mode.
The operator must possess all the administration rights on the workstation to be installed. Installation should be made in a clear space on a stable desk or table. The patient should not be able to see the screen, or the operator 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:

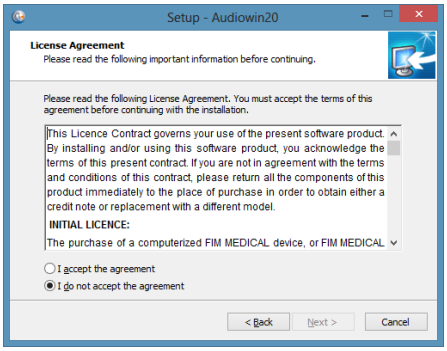


8. Click Next:

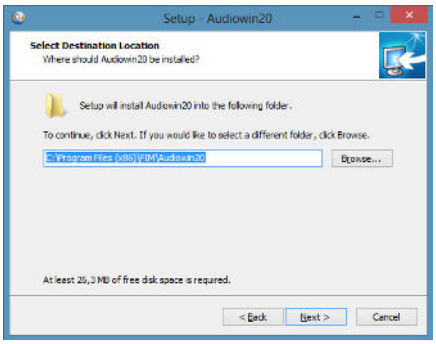
9. Enter the user code located on the back of the CD sleeve, then click Next:



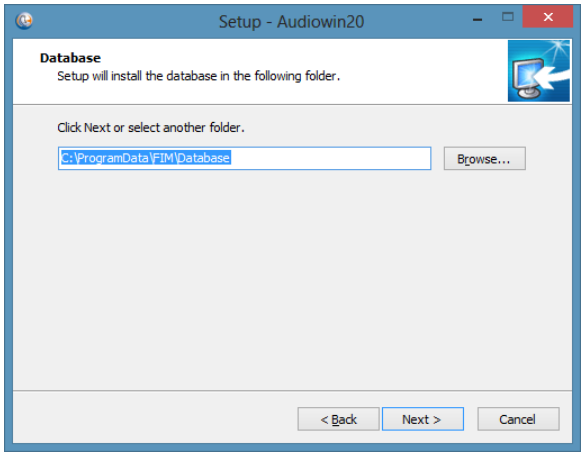
10. Accept the agreement and click « Next »:



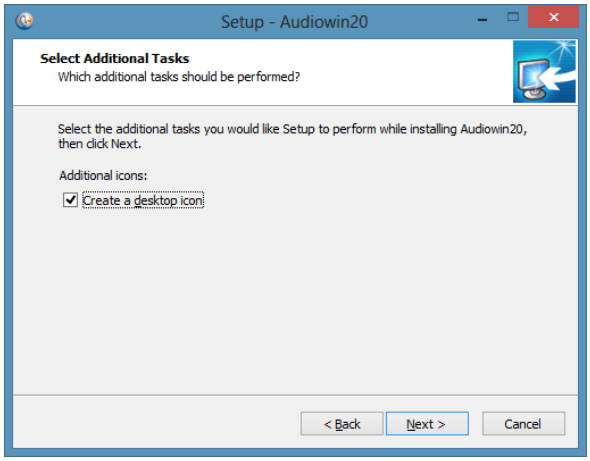
11. Choose the Audiowin® 20 software installation path (*optional*), then click Next:



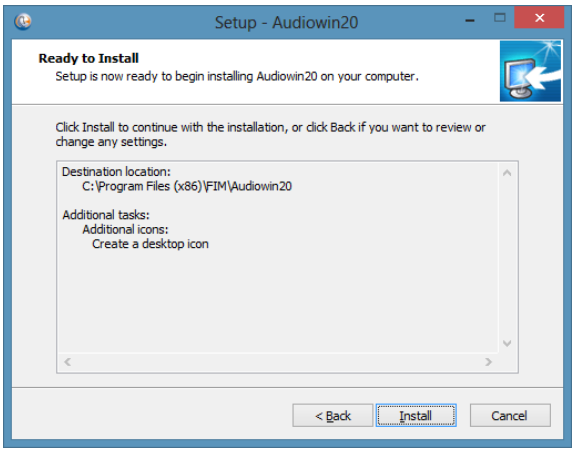
12. Choose the data base installation path (*optional*), then click Next :



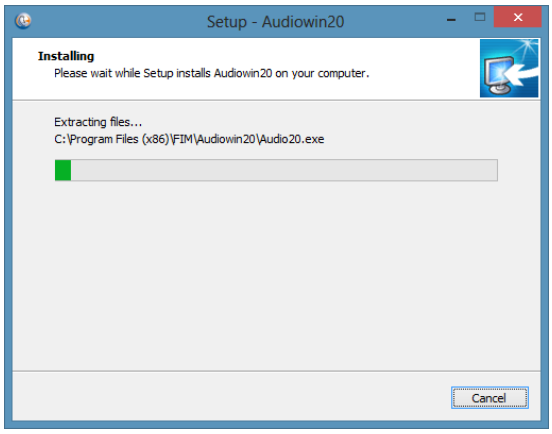
13. Click Next:



14. Click Install:



15. Wait while install :



16. Click Finish :

Locate a **USB** connector on the computer and plug in the ADL20.
The USB lead can pass through the wall of a booth. Request information from your booth manufacturer or distributor.

3.5. The database

3.5.1. The database for Audiowin®20

Audiowin®20 uses a specific database format:

- A local Microsoft Access database (*.mdb)

3.5.2. Retrieving a former database

If you are updating from Audiowin® to Audiowin®20, there is no need for any action to transfer the database as this is done automatically.

3.6. Connecting & disconnecting the device

After installation set up, you may connect the Audiolyser® ADL20 to the PC using the USB cable.
If the installation has been correctly carried out, the device should be recognised at the first connection (the connection is displayed in the right-hand bottom corner where the icon becomes blue):

If this is not the case, check that the device is properly plugged in, then de-install the Audiowin®20 and carry out a manual installation of the drivers. The set-up modules are in the 'Drivers' directory on the CD-ROM. Double click on CP210xVCPInstaller.exe and follow the instructions.
Then connect the Audiolyser® ADL20, which should be recognised automatically by the operating system.

To stop the audiometer, close the Audiowin®20 software window. If you are closing down the system for a lengthy period, disconnect the USB cable from the headphones which should then be stored in their packaging.

3.7. De-installation

If you have no further use for the Audiowin®20 software, you may de-install it from your computer. To de-install programs consult 'Programmes and Functions'.

1- Open 'Programmes and Functions'. In the Windows control panel, click on 'Programmes', then on 'Programmes and Functions''. Note: Access to the de-installation panel may differ depending on the Windows version.
2- Select Audiowin®20, then click on 'De-install'.
3- De-install the 'Silicon Labs. CP210x USB to UART Bridge' drivers.

Note: Before de-installing any driver, make sure no other software uses it.

4. Use

4.1. Using the hygienic single-use earpad covers

The FIM Medical company has specifically developed hygienic single-use earpad covers to be used with the Audiolyser® ADL20 audiometer.

Caution: These hygienic single-use earpad covers should be systematically used for each test, and changed after each patient. If disposable covers are re-used for subsequent patients, there is a risk of cross-contamination (bacterial or viral contamination) on contact with the ears.

Caution: **For hygiene and biocompatibility reasons, it is compulsory to use the FIM Medical brand of single-use earpad covers with these audiometric headphones.**
These earpad covers have been developed specifically to meet ISO 10993 material biocompatibility requirements, as well as guaranteeing perfect sound transmission whilst respecting IEC 60645-1.

Using the single-use earpad covers:
Place a single-use earpad cover over each of the audiometric headphone earpads (speaker side)
Adjust the earpad covers so that there are no material folds between the headphone and the patient

4.2. Preliminary explinations to the patient

4.2.1. Positionning of the headset

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. Hair and bulky earrings should be removed to prevent sound leakage.

Red earphone
On the right ear

Blue earphone
On the left ear

4.2.2. 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.

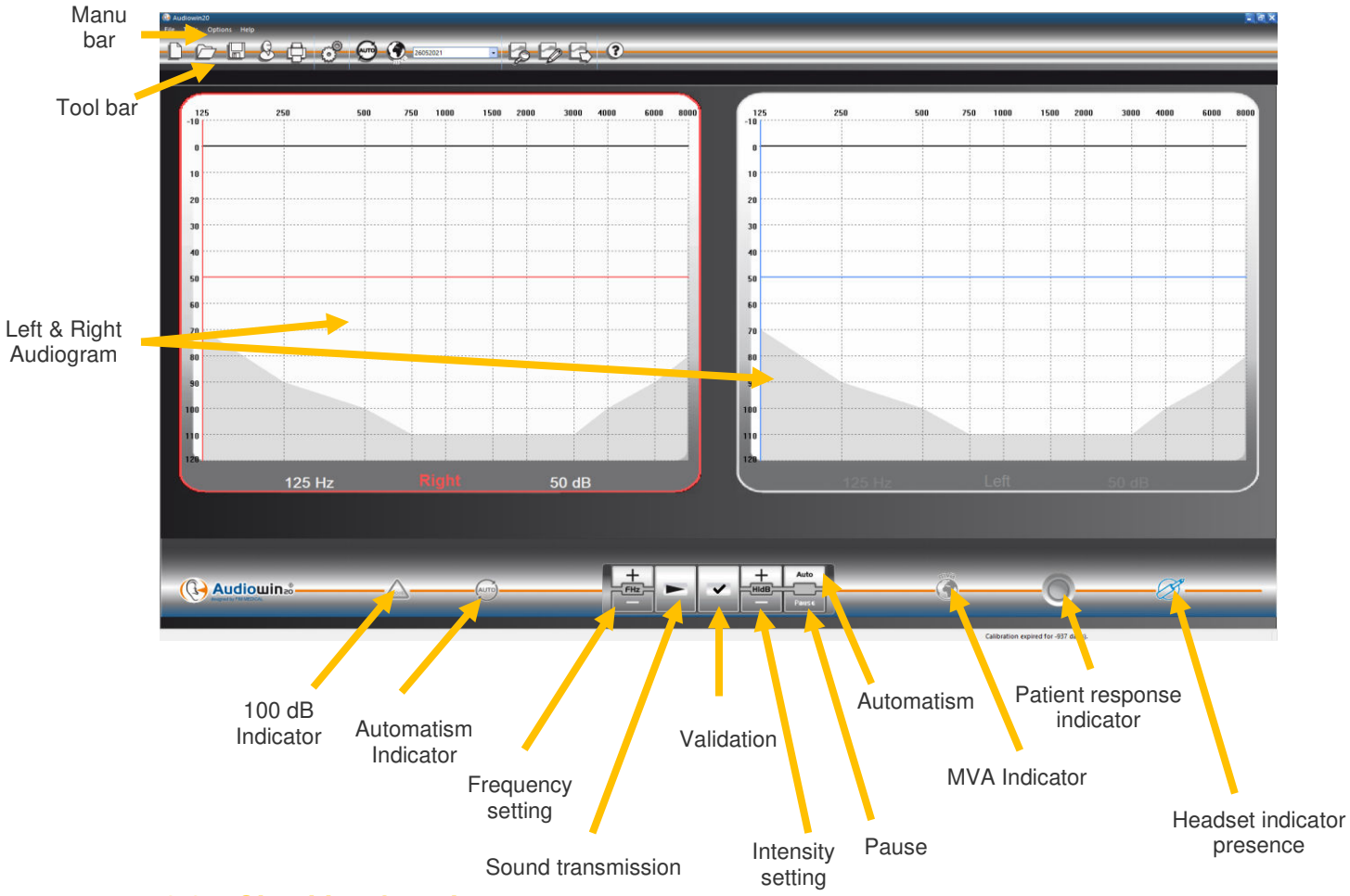
4.2.3. Most frequent errors

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”.

4.3. Software use

4.3.1. Presentation



4.3.2. Checking function

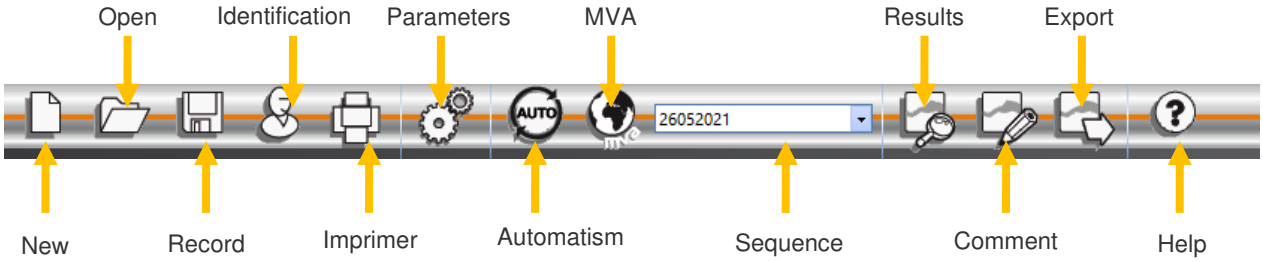
When the Audiowin®20 interface is run, the presence indicator turns from grey to blue. If this does not happen, check that:

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.

4.3.3. Tool bar

To access main functions:



4.3.4. Menu bar

4.3.4.1. File

Fonction	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

4.3.4.2. Tests

Fonction	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

4.3.4.3. Options

Fonction	Description
Parametres	Parameter the software
Parametres Import/Export	Allows to duplicate data from one workstation to another

4.3.4.4. Help

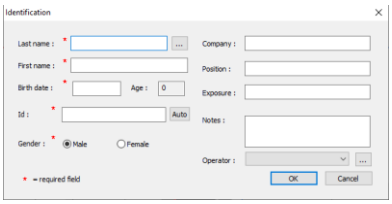
Fonction	Description
About	Version and copyright information
System information	Environment and device information
User manual	Access to the PDF version of the device's user manual
TeamViewer	Allows you to connect remotely with our teams if necessary

4.4. Patient identification

4.4.1. 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 (cf. ISO 7029).

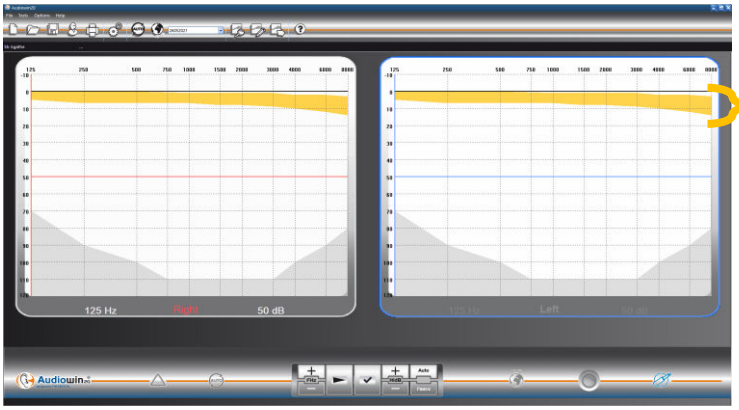
Click "**Identification**" button before or after the audiometry.



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.

4.4.2. Viewing predictions

After identification, the graph appears as such:



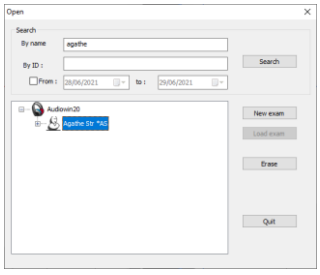
Predicted values

Calculation of predicted values is based on the ISO 7029 standard.
The colour can be changed in the "**Parametres**" window, "**General**" tab.

4.5. Open a patient/file test

4.5.1. Open a file

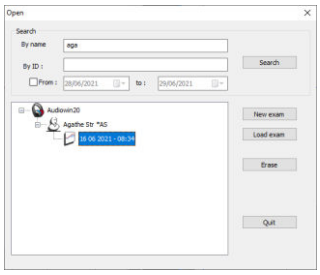
To locate the data of a recorded patient, proceed as follows:
Click “**Open**”. The following screen appears:



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.

4.5.2. Open an exam

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.



4.6. Parameter the software

4.6.1. 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.

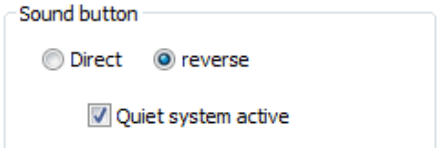
1.	Number of tests	3 successive tests achieved
2.	Tolerance of doubtful test	10 dB
3.	Duration per level	Choose a range between 15 - 30 tenths of a second.

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

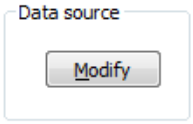
4.6.2. Window parameters

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

4.6.2.1. General tab

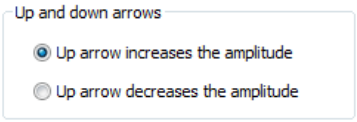


Function of transmission button on main interface. Sound is automatically transmitted when the mouse cursor is pointed over the button.



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

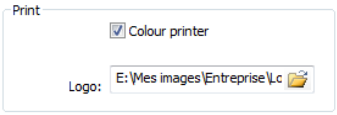
Display, printing and colour of predicted value.



Action of high and low keyboard arrows.

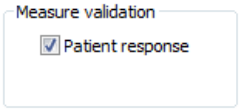
Modify Audiowin®20 language.

Type of sound transmitted: pulsed or continuous.

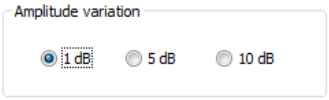


Audiowin®20 can print the audiogram in colour (if printer is a colour printer) and choose the logo on the printing sheet.

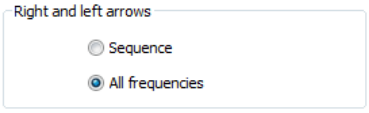
Date format.



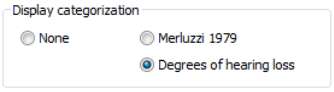
Inhibition of patient response button. The patient signals sound perception by raising one hand. The operator validates the measurement with the Enter key or the Validate button.



Variation of sound amplitude.



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

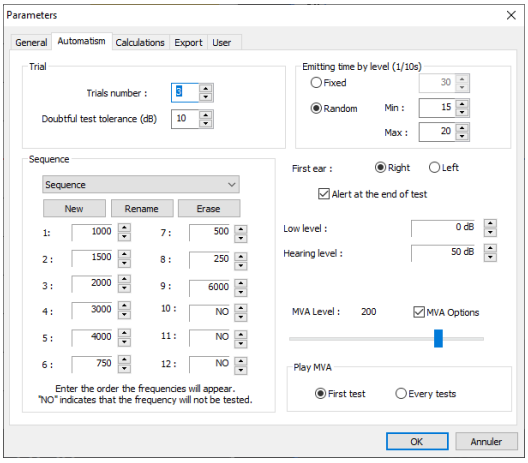


Changing the display areas categorization of audiograms.

4.6.2.2. Automatism tab

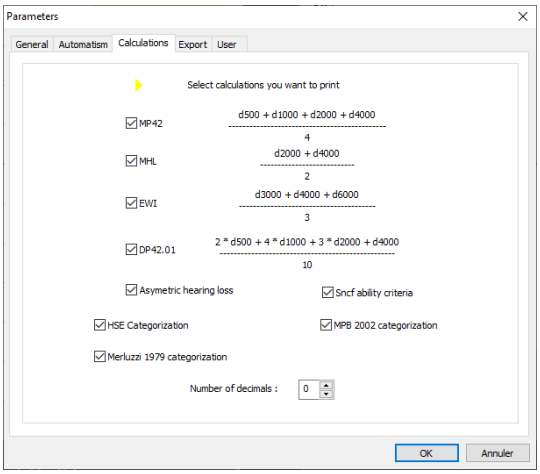
Use this tab to:

- Know the criteria used in the sequence by default
- Create and manage sequences for automatic mode (refer § 4.9 automatic mode)



4.6.2.3. Calculation tab

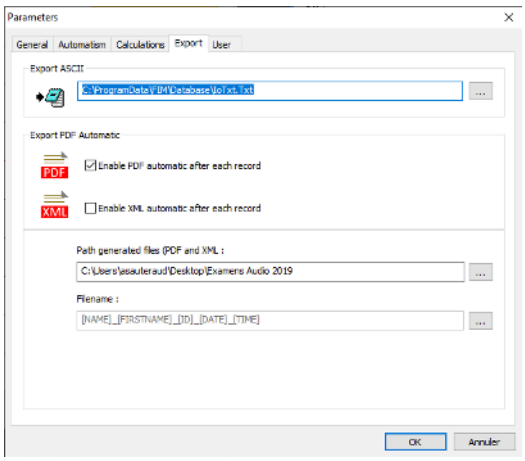
Calculations of MP42[3] (Legal index table n°42 of Occupational Diseases of the general scheme), of PAM[3] (Average Hearing Loss), of IPA[3] (Early Warning Indicator), and DP42.01 (Doenças profissionais 42.01), or asymmetric hearing loss, HSE[1+3] categorization, Merluzzi 1979[2+3] categorization, MPB 2002[3] categorization, SNCF[3] aptitude criterion are performed by Audiowin®20.



[1] For more information, you can consult "The Control of Noise at Work Regulations 2005"
[2] For more information, you can consult "La prevenzione dei danni uditivi da rumore in ambiente di lavoro - linee guida proposte dalla società italiana di medicina del lavoro e igiene industrial"
[3] For more information, you can consult the document "Calculations and indicators in audiometry".

4.6.2.4. 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.

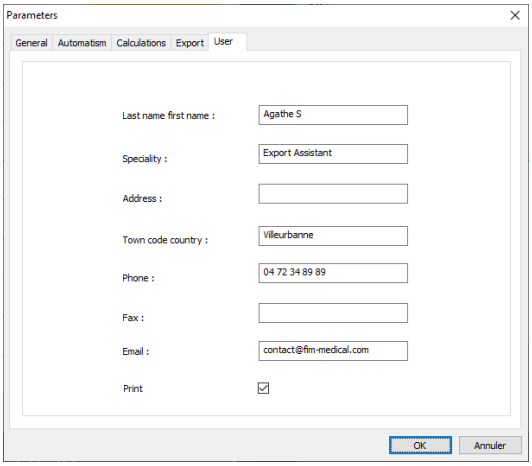


You can also parameter the export in a PDF file automatically after each recording.
Destination file can be chosen from the files generated, as well as the file name. File name can be customized and certain variables can be used. However, at least two variables cannot be modified: test time and date, so as to differentiate files.
[NAME] → Patient surname
[FIRSTNAME] → Patient first name
[ID] → Patient ID

Note: these variables can be automatically filled in by ticking the appropriate box.

4.6.2.5. User tab

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



4.7. 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.

Source : Audiometric classification of hearing impairment based on the recommendations of the International Bureau Audiophonology.
https://www.biap.org/en/component/content/article/65-recommendations/ct-2-classification/5-biap-recommendation-021-bis

4.8. Manual mode

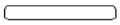
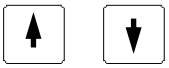
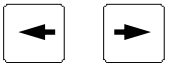
4.8.1. Operation

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)

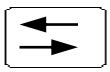
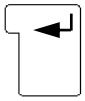
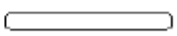
These points are explained in the following chapter.

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.

4.8.2. Keyboard keys

	Page UP Page Down	Intensity to value of lowest hearing level. 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	F4	Display audiogram results.

4.9. Automatic mode

4.9.1. Parameteres

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

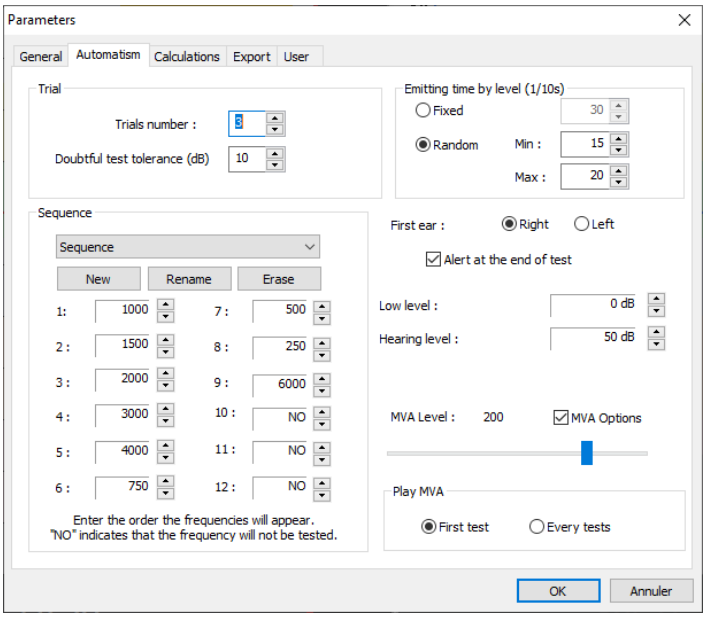
Possible settings choices:
1. Frequencies tested.
2. Order of frequencies tested.
3. Amplitude variation (steps of 1.5 or 10 dB).
4. Signal type (continuous or pulsed).
5. First ear tested.
6. Number of test(s) per frequency.
7. Response level differences considered doubtful by Audiowin®20.
8. MVA language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

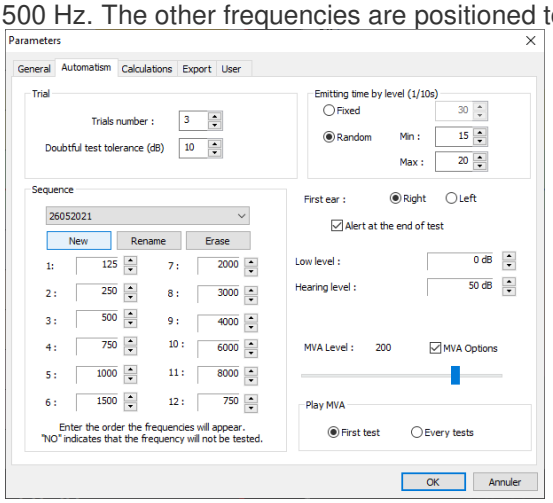
Use the tabs located at the top of this window to access different settings.

Click on the "Automatism" tab.



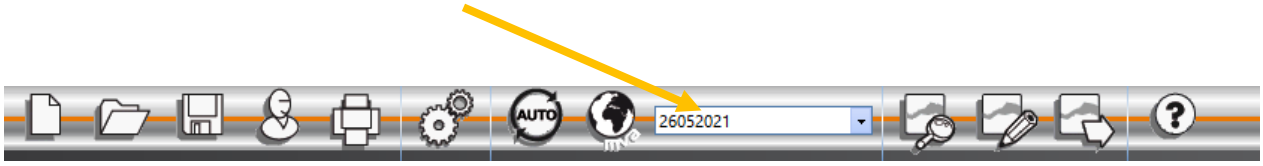
4.9.2. Creation of sequences

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.



4.9.3. 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**”.

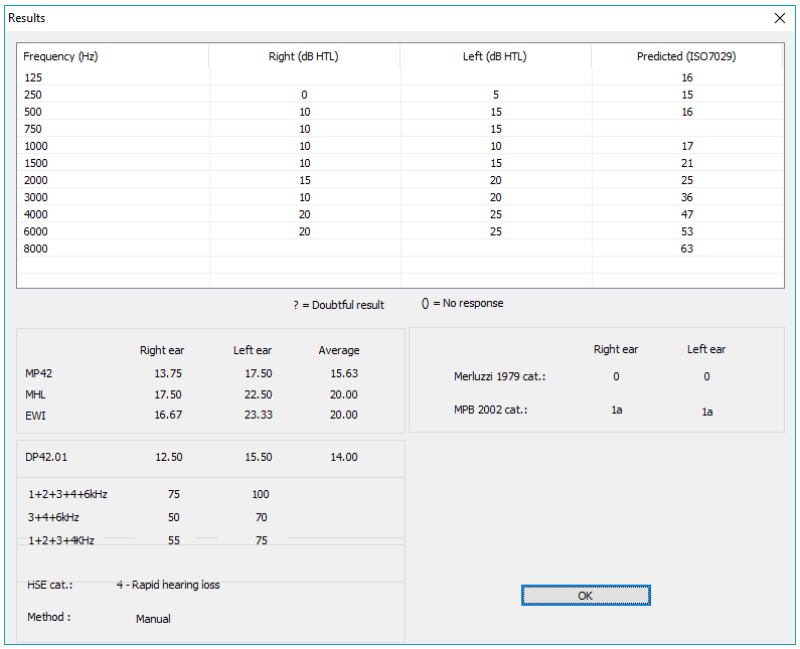
The patient should press on the blue part of the patient response button if the sound is perceived. If not, the sound increases in intensity to 90 dB, then displays "**No response**".

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**".

4.10. Display of results

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



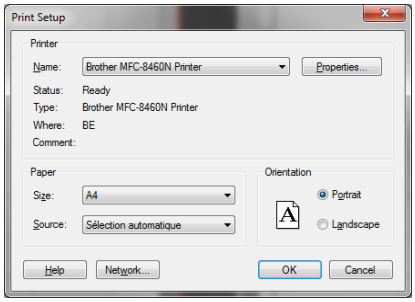
Summary contains:

- Patient results
- MP42 (occupational diseases)
- PAM (Average Hearing Loss)
- IPA (Early Warning Indicator)
- DP42.01 (Doenças profissionais 42.01)
- Asymmetric hearing loss
- HSE (Health and Safety Executive) categorization
- Merluzzi 1979 categorization
- MPB 2002 categorization
- SNCF suitability criterion
- Method of test performance

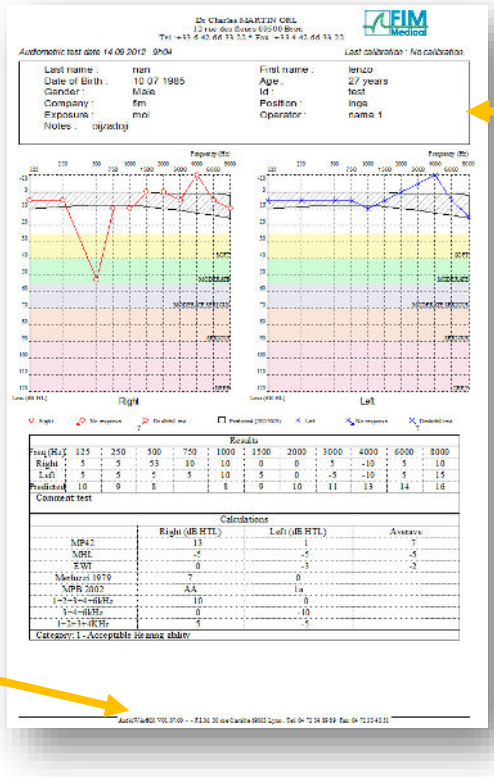
4.11. Print results

4.11.1. 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:

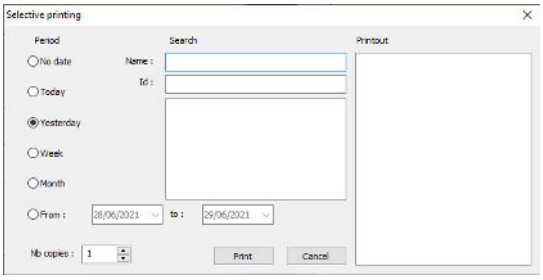


The document will be printed as such:



4.11.2. Selective printing

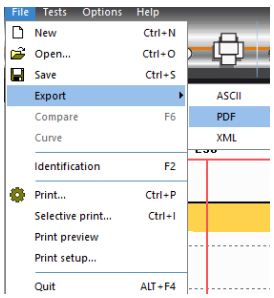
Printing one, or several documents, of tests performed on different dates can be programmed.
Click on the "**File**" menu then "**Selective printing**". The following window appears:



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

4.11.3. PDF printing

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



5. Maintenance

5.1. List of generic bactericidal fungicides validated by FIM Medical

Due to a very large number of brands and references of decontaminating wipes present on the market, the company FIM Medical has validated references for its products that do not alter the appearance or the resistance of the plastic materials of the shells of its devices.

The company FIM Medical validates, for the decontamination of its Audiolyser® ADL20®, the use of the wipes or rags soaked below:

- Isopropylic alcohol 70 %
- Bactinyl® disinfectant wipes
- Clorox® Healthcare Bleach
- Sani-Cloth® Bleach
- Sani-Cloth® Plus
- Sani-Cloth® HB
- Super Sani-Cloth®
- Sanicloth® AF3
- Formula 409®
- Virex® Plus
- Mikrozid® AF wipes
- Mikrozid® Universal wipes premium

5.2. Cleaning of the Audiolyser® ADL20®

The Audiolyser® ADL20 housing can be cleaned with a damp cloth and a generic fungicide bactericide. FIM Medical requires the use of the products mentioned in paragraph 5.1.

We recommend asking the patient to disinfect their hands before handling the device.
After each patient, clean the parts accessible to patients, namely:
• the earphone cushions (taking care not to get the earphones wet)
• the hoop
• the patient answer remote

The use of spray is not recommended because a badly directed jet can permanently damage the headphones.

5.3. Annual 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. Your Audiowin®20 software will warn you of the need to recalibrate your headphones 30 days before the cut-off date.
This maintenance can be requested by the customer or by FIM Medical if the preventive operations appear necessary for the correct functioning of the device.

Caution: When sending a device for service, it should be shipped in its original packaging.

5.4. Garantee

The Audiolyser® ADL20 is guaranteed for 2 years from the date of purchase. Within the framework of the contractual guarantee, only repairs are covered. The warranty will only apply if the normal and customary conditions of use of the device have been observed. During the annual maintenance, a certain number of preventive operations are carried out; the overhaul cannot constitute a guarantee of support for any breakdown that may occur after this overhaul.

5.5. Lifetime

The lifetime of the Audiolyser® ADL20 is determined at 9 years on the condition that the user carries out the required maintenance as outlined in the above maintenance section.

FIM Médical will not be held liable for the loss of performance of the device in the event of non-fulfilment of the required maintenance.

6. Available accesories

Biocompatible single-use earpad covers

FIM Medical has specifically developed single-use earpad covers for use with Audiolyser® ADL20 audiometers.

Warning: These single-use earpad covers must always be used for each examination and must be replaced between each patient. If the earpad covers are not changed and reused between two patients, a risk of cross-contamination (bacterial or viral contamination) is possible during contact with the ears.

Warning: For hygienic and biocompatibility reasons, it is essential to use FIM Medical brand single-use earpad covers with audiometric headsets. These windshields have been specifically developed to meet the material biocompatibility constraints of ISO 10993 as well as to guarantee perfect sound transmission while respecting IEC 60645-1.
If you want FIM Medical single-use earpad covers, contact FIM Medical or your distributor.

Audiolyser® headset holder

FIM Medical has developed an adjustable headset holder that you can attach to a desk, table, etc. This allows you to have your Audiolyser® ADL20 within easy reach and to preserve the life of its cables.

7. F.A.Q.

7.1. No sound is perceived

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

7.2. Error message appears at recording

7.2.1. « Identification incomplete »

Check all the compulsory identification fields are filled in.

7.2.2. « 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.

7.3. Patient identification file found but not the test

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

If, despite the indications given above, you are unable to resolve the problem, or if this is another difficulty that you are experiencing, do not hesitate to contact us, a technical team is at your disposal.

Thank you for reading this manual.
If you need more information, please, contact us.

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