

HEARING SCREENING



USER

MANUAL

AUDIOLYSER® ADL CONNECT



CE
0459

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Table of Content

1. Introduction	3
2. Instructions for your safety	4
3. Electromagnetic compatibility	5
4. Clinical information	6
5. Technical description	8
6. Technical characteristics	10
7. Symbols	12
8. Installing the Audiolyser® ADL Connect	13
9. Preliminary explanations to the patient	16
10. Using the Audiolyser® ADL Connect	17
11. AudioWin® Software first connection	19
12. AudioWin® Software Home Page	20
13. Conducting an exam	34
14. Displaying results	36
15. Maintenance of the Audiolyser® ADL Connect	37
16. Troubleshooting and error messages	40

1. Introduction

The **Audiolyser® ADL Connect** is a **computerized digital audiometer for the exploration of hearing function**. The device present different sounds to the patient, and, depending on what the patient perceives, it allows to detect possible defects in patient hearing.

The **important symbols** used in these instructions are shown below:



WARNING: Indicates conditions or practices which, if not avoided can cause danger to the patient and/or user.



CAUTION: Indicates conditions or practices that could result in damage to the equipment.



NOTE: Indicates important information about the use of the device.

2. Instructions for your safety



WARNING: Do not modify this device without authorization of the manufacturer.

WARNING: Do not open the device or insert object in it.

WARNING: To reduce the risk of fire, electric shock or electrical interference, use only IEC 60950-1 or IEC 62368-1 compliant hardware.

WARNING: Do not use any cable or accessories other than those provided with the device, as this may compromise its performance and safety.



CAUTION: Do not store or use the device outside the environmental conditions specified in section 6.

CAUTION: Do not immersed or sprayed with liquid the device.

CAUTION: Do not use the device if it is showing visible signs of damage

3. Electromagnetic compatibility

The Audiolyser® ADL Connect meets the requirements of EN 60601-1-2 regarding the electromagnetic compatibility of medical devices.

Its electronic design ensures robust immunity to surrounding electromagnetic disturbances.

As a result, the presence of radio frequency equipment does not affect the reliability of audiometric screening tests.

4. Clinical information

Intended use

The Audiolyser® ADL Connect is a computerized digital audiometer intended solely for the exploration of hearing function. It is a device used to detect possible defects in patient hearing.

Indications for use

The Audiolyser® ADL Connect allows the exploration of the auditive function and the screening of potential patient auditive troubles.

Audiometry is recommended in the following cases:

- ✓ To screen and assess the severity of hearing loss (in children and adults), especially in those exposed to loud noises or who have received certain treatments.
- ✓ To differentiate conductive hearing loss (due to damage to the outer ear, such as earwax blockage or a problem with the eardrum or middle ear, such as an ear infection or damage to the ossicles) from sensorineural hearing loss (due to a dysfunction of the inner ear, such as damage to sensory cells or the auditory nerve).

Device users



CAUTION: The Audiolyser® ADL Connect must be used exclusively by trained healthcare professionals who are qualified to interpret the results and ensure compliance with hygiene and bacterial contamination rules. Test results must always be communicated with appropriate medical interpretation.

The Audiolyser® ADL Connect should not be used for medical prescription purposes and can under no circumstances give rise to a medication prescription or a pre- or post-surgical diagnosis.

Only a medical specialist can confirm and corroborate the results obtained with the Audiolyser® ADL Connect by other examinations in order to prescribe a correction or surgical intervention.

Patient population

The Audiolyser® ADL Connect is suitable for audiometric screening in patients over 4 years of age who are able to understand and follow test instructions.

Environmental conditions

To achieve correct audiometry, the test should be conducted in an environment free of outside noise. The use of an audiometric booth is recommended.

Contraindications

Do not perform audiometry on a patient wearing hearing aids.

Limitations of use

The patient cannot understand and follow test instructions,
The headphones cannot be fitted.

Clinical benefits and risks associated

The audiometer must be able to analyse 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 (according to 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 details and compliance with IEC 60645-1 of the Audiolyser® ADL Connect and its AudioWin® software ensure a qualitative clinical benefit in terms of diagnosis assistance for the patient.

The precision of the audiometric measurements associated with the interpretation aids make it possible to diagnose the patient's deafness levels as well as the evolution of his hearing over the long term.

The diagnostic assistance by detection of hearing loss allows a therapeutic orientation to improve access to care and guide rehabilitation that constitutes a positive impact on patient management and public health.

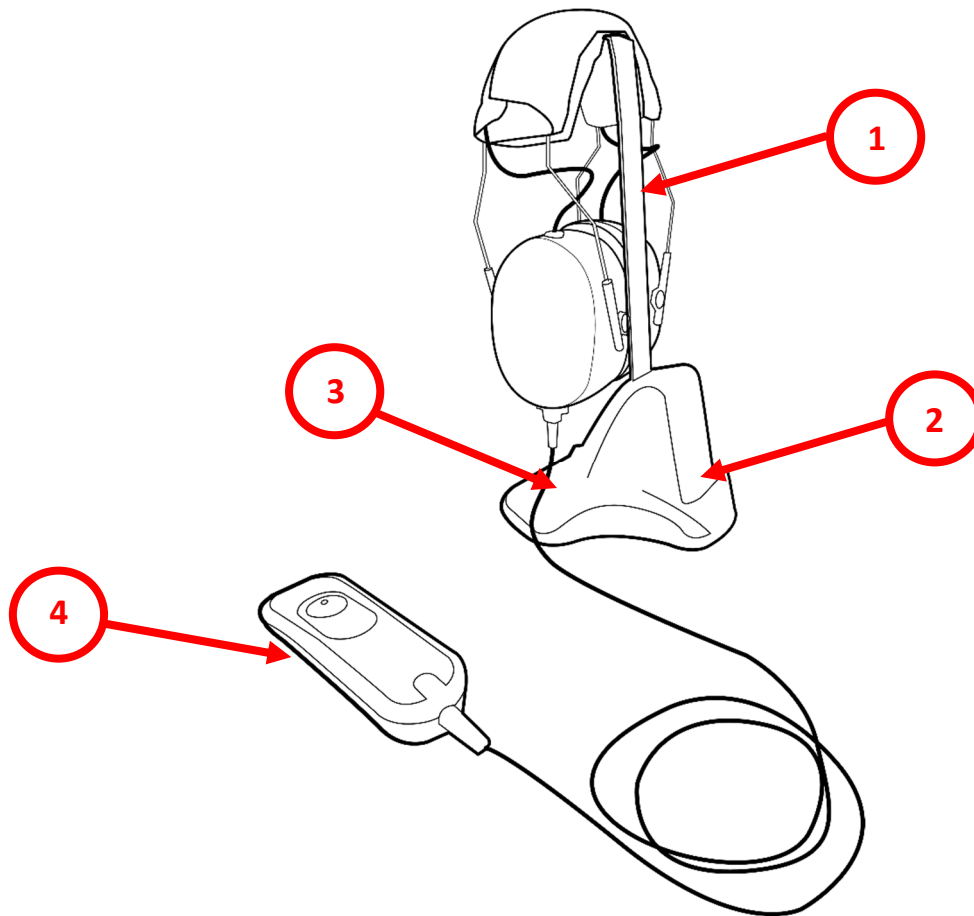
There is no limitation on the number of examinations per patient using the Audiolyser® ADL Connect.

Adverse effects and potential side effects

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

5. Technical description

Device presentation



1. Headphone holder
2. Docking station: location for recharging the response button
3. Docking station: series of LEDs to indicate the charging status of the response remote and the stability of the connection of the docking station with the response remote
4. Response remote
5. Single-Use earpad covers



Materials provided

Audiolyser® ADL Connect device:

- | | |
|---|-------------------------------------|
| - Docking station | - Certificate of conformity |
| - Headphone equipped with its response remote | - Information sheet |
| - Headphone holder | - Audiowin® software |
| - USB Type B to Type A cable | - 1 box of single-use earpad covers |
| - Carrying case | |

Optional: single-use earpad covers

Device overview

The Audiolyser® ADL Connect is a computerized digital audiometer.

The Audiolyser® ADL Connect can be set up with different headsets depending on user needs (see section 6. Technical characteristics).

The electronics are integrated into the response remote, rendering the device lightweight and portable. Inside the response button, in addition to the button and electronics, a battery is added to allow for wireless operation of headphones and patient response remote.

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

Audiolyser® ADL Connect is designed to assess an individual's quality of hearing by evaluating the sound levels and frequencies perceived by the patient.

Thus, the Audiolyser® ADL Connect should:

- Connect to a computer to communicate with its specific software.
- Assess an individual's hearing quality by generating sound levels and frequencies that are perceptible.
- Allow audiometric headphones to be positioned on the patient's head.
- Capture patient answers in a simple way

AudioWin software

The Audiolyser® ADL Connect is driven by the AudioWin® software, a simple and intuitive interface.

AudioWin® is able to control and access results from the audiometer.

AudioWin® stores information in a database, 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.

Single-Use earpad covers

The earpads covers are adapted to the Audiolyser® ADL Connect headphones for biocompatibility between the skin and the eyecups and ensure protection against bacterial risks between 2 patients.

The single-use earpad covers are packaged separately from the Audiolyser® ADL Connect.



6. Technical characteristics

Features of the Audiolyser ® ADL Connect

Modes of use	Manual mode Or automatic		
Sending sound	Continuous, inverted or pulsed mode		
Patient response time in automatic mode	Adjustable, Between 15 and 30 tenths of a second		
Distortion harmonic	± 2.5%		
Frequency accuracy	± 2%		
USB cable length	3 m		
Storage temperature	-10 to 60°C		
Temperature of use	15 to 35°C		
Humidity	30 to 90%RH		
Operating altitude	< 2000 m		
Tension	5 VDC (via USB port)		
Connectivity	USB cable and/or Bluetooth BLE 2402 - 2480 MHz		
Battery Type	Rechargeable Lithium Polymer	Autonomy	Approx. 8h
Battery capacity / voltage	3.7V / 1500mAh		
Battery charging time	Approx. 3h	Cyclic endurance	≥ 500
Current	Typical power consumption: 350mA		Maximum power consumption: 1,1A
Compliance regulatory	MDR 2017/745, ISO 10993		
Technical compliance	IEC 60645-1, ANSI S3.6, ISO 389-1, ISO 389-8		
Security Compliance	EN 60601-1, EN 60601-1-2, IEC 62133, UN 38.3		
Audiometer type	4 (Pure-Tone)		
Medical class	Class IIa (rule 10)		
Software class	Class A		
EMDN code	Z121401 - Audiometers		
GMDN code	41187 - Tone audiometer, automated		
Part applied	Response box	Type BF	
Dimensions / Weight	255 x 210 x 100 mm, 800g		
Device weight complete	Between 500 and 850 g approximately (depending on the model)		
Protection against electric shock	Internally powered ME equipment.		



NOTE: Under normal conditions of use, no time is required for the equipment to reach its functioning temperature (§5.4. IEC 60645-1 : 2017).

Headphones Technical Characteristics

Helmet model	Holmco PD-81	RadioEar DD65
Soundproofing	10 - 40 dB (depending on model)	10 - 40 dB (depending on model)
Calibration standard	Manufacturer	Manufacturer
Helmet weight	730 g	500g
Static Force	10 N ± 0.5 N	10 N ± 0.5 N
Transducer type	Dynamic Moving Coil	Dynamic Moving Coil

Intensity limits (dB)

Audiolyser® ADL Connect has a maximum threshold in decibels (dB) of 100dB. The table below allows you to make the correspondence between the intensities in dB and the associated frequencies in Hz.

Intensity limits (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





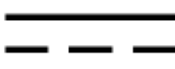












AudioWin® software

Software AudioWin®	Minimum configuration	Recommended configuration
Operating system	Windows 10	Windows 10 or 11
Processor	Pentium IV 2.8GHz	Intel Core i3 or higher
Architecture	64-bit	64-bit
Memory	2GB of RAM	4GB of RAM
Disk space	16GB	20GB
Graphics card	256MB	512MB
Resolution Monitor	1024x768	1920x1080

Specific characteristics of single-use earpad covers

Biocompatible single-use caps	
Matter	PP (Polypropylene) non-woven 35g
Diameter	11 cm
Compliance regulatory	ISO 10993-1
Technical compliance	IEC 60645-1 :2017
Medical class	Class I (rule I)
GMDN code	63091

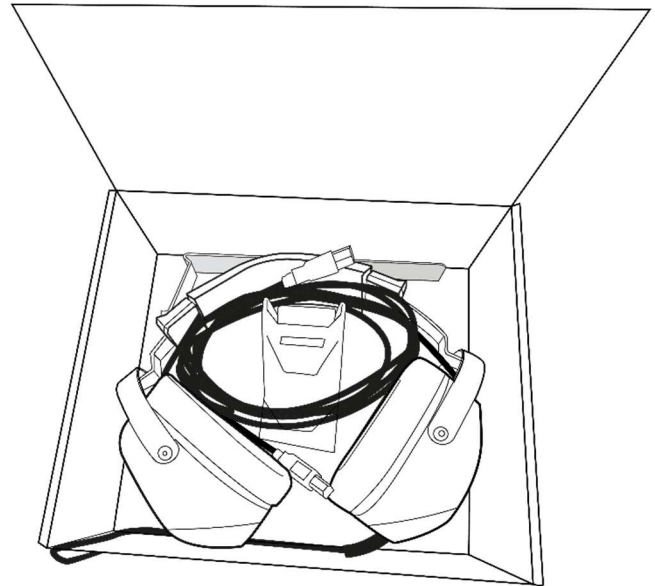
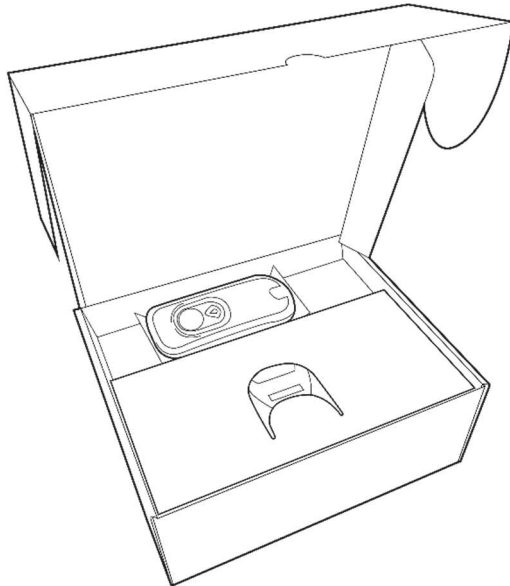
7. Symbols

 0459	CE marking according to Medical Device Regulation (UE) 2017/745	   	Bluetooth Frequency: Between 2402 MHz and 2480 MHz Mandatory reading of the user manual Device user manual Direct current
 	Type BF applied part Must not be disposed of with unsorted waste, but treated in accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive	  	   Serial number Do not reuse. Single use only. Date of manufacture
	Storage temperature between -10°C and 60°C		Deadline of use
 (01)XXXXXXXXXXXXXX (11)XXXXXX	Unique Device Identifier UDI Identification Unique product identification number UDI Identification Date of manufacture	 (10)XXXXXX (17)XXXXXX	Reference UDI Identification Batch number UDI Identification Expiration date

8. Installing the Audiolyser® ADL Connect

Unpacking the device

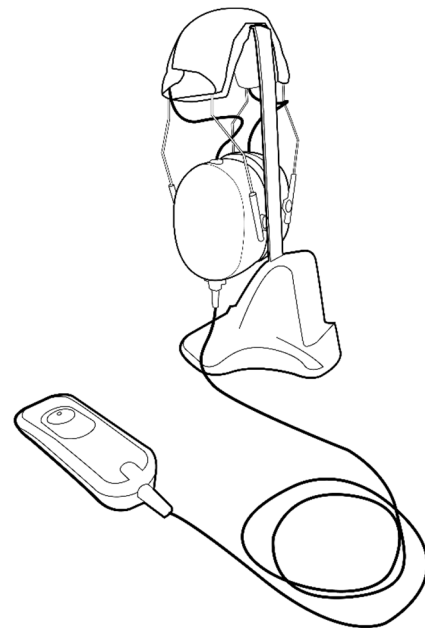
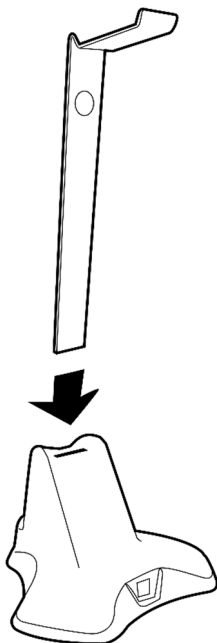
To access the Audiolyser® ADL Connect, open the box and carefully remove the cardboard protection on which the response remote is located.



NOTE: The box and cables should be retained for maintenance.

Assembling the docking station and headset holder

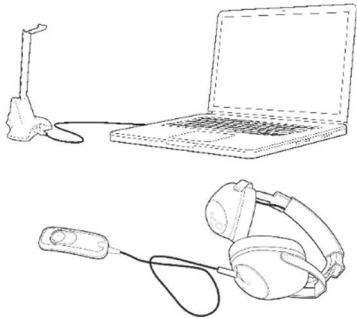
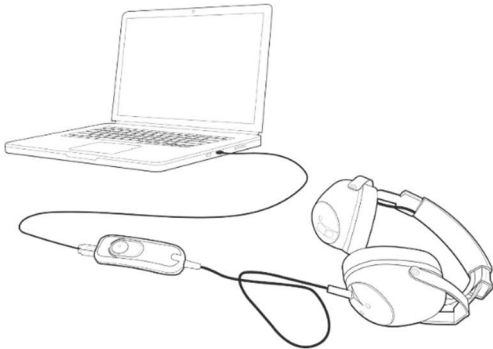
Insert the headset holder into the designated space on the back of the docking station. This will allow you to place your headset on it later.



Connecting the cables



CAUTION: Use only the accessories supplied with the Audiolyser® ADL Connect to ensure performance and safety.

<p><i>Bluetooth configuration:</i></p> <p>Connect the USB cable from the docking station, Type B connector to the docking station, Type A to the PC.</p>	<p><i>Wired patient button configuration:</i></p> <p>Connect the USB cable of the response button, Type B connector on the response remote, Type A on the PC.</p>
	

AudioWin® installer



NOTE: Administrator rights are required to install AudioWin® software.

NOTE: The installation file copy time may take longer than via internet download.

Link to download AudioWin® software is available on the information sheet provided with Audiolyser® ADL Connect.

Once the Audiolyser® ADL Connect is connected to the PC, it is also possible to access the AudioWin® software installation executable file or the PDF version of the user manual by pressing the response button for 30 seconds immediately after switching on the device. The Audiolyser® ADL Connect is then recognized as a mass storage device by Windows, which opens a folder in File Explorer.

Installation of single-use earpad covers



WARNING: For reasons of hygiene and biocompatibility, it is essential to use FIM Medical single-use hygienic earpad covers with Audiolyser® ADL Connect headsets.

WARNING: Single-use earpad covers must be used systematically for each examination and replaced between each patient.



NOTE: These earpad covers meet the material biocompatibility requirements of ISO 10993 and guarantee perfect sound transmission in compliance with IEC 60645-1:2017.

Single-use earpad covers are:

- ✓ Biocompatible,
- ✓ Compatible with for Audiolyser® ADL Connect,
- ✓ Ensure sound transmission in accordance with IEC 60645-1.



Installation of single-use earpad covers:

- ✓ Place the single-use earpad covers on each shell of the audiometric headphones (speaker side),
- ✓ Adjust the earpad covers to avoid excess thickness due to possible folds between the headphones and the patient.

9. Preliminary explanations to the patient

Helmet positioning

It is necessary to seat the patient comfortably and help them position the headphones on their ears. The cushions should be centered on the auricles of the ears, and the headband should rest on the crown of the head without forcing it. Hair and bulky earrings should be removed to prevent sound leakage.



The AVM (Multilingual Voice Assistant)

The AVM (Multilingual Voice Assistant) is a feature that, using software commands, issues voice instructions to the patient through the headphones.

Instructions are available in several languages, which allows audiometry to be performed on a wide audience.

Common mistakes



NOTE: Continuously pressing the button

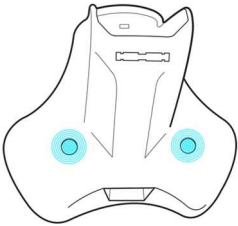
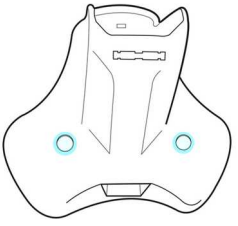
NOTE: Repeated and untimely pressing button

NOTE: Too light pressure on the button

If the patient is unable to adjust to the operation of the response button, they can confirm the perception of the sound by raising their hand. The operator then validates the threshold by clicking on the "Validate" button or pressing the "Enter" key.

10.Using the Audiolyser® ADL Connect

Checking the connection between the Docking station and the response remote

<p>As soon as the Docking Station is connected to your computer, a flashing blue light indicate that the device is trying to detect the response remote.</p>	
<p>Once the connection between the docking station and the patient remote is established and stable, you will see that this blue light will be steady.</p>	



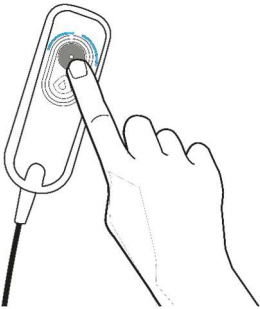
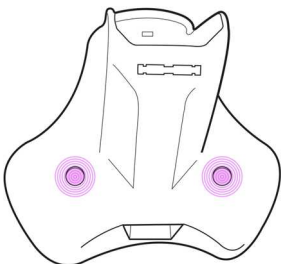
NOTE: If the Audiolyser® ADL Connect is not used for 2 hours, the device will automatically go into standby mode.

The operator will be informed because the docking station will switch off automatically (the LEDs will no longer be lit).

NOTE: To switch the device back on, press the button on the response remote once.

Indicator light during the examination

Using a response remote is essential for the smooth running of examinations. To help you perform your examinations in the best possible conditions, the response remote has indicator lights that will provide you with information regarding its use by the patient and its battery level:

	
<p>BLUE: Indicates that the patient is pressing the button.</p>	<p>As soon as the patient presses the button on the response remote, a PURPLE light will come on the docking station to inform the operator.</p>

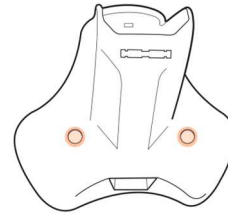
Charging the response button



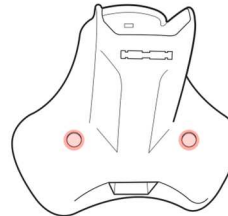
NOTE: Do not charge the response remote with any method other than that recommended by FIM Medical:

- Placing the response remote on the docking station
- Connecting the response remote via USB to the computer (see section 8 « Connecting the cables »).

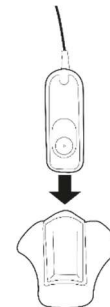
Steady **ORANGE**: Indicates that the response remote battery is low (less than 20% charge).



Steady **RED**: Indicates that the response remote battery is very low (less than 10% charge). The response remote needs to be charged immediately.

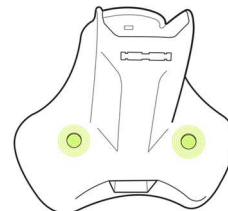


To recharge the response remote, you must slide it into the small dedicated compartment at the front of the docking station.



Once the response button is correctly placed on the docking station, you can monitor the battery charging progress using the lights on the docking station.

Flashing **GREEN**: response remote charging



Steady **GREEN**: response remote fully charged

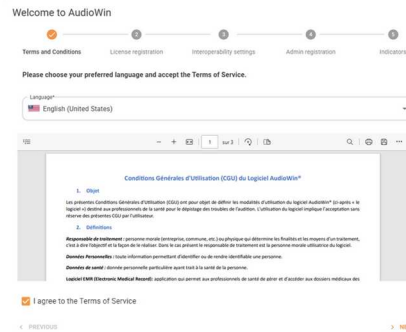


11.AudioWin® Software first connection

When using AudioWin® software for the first time, you will be prompted to perform the following steps:

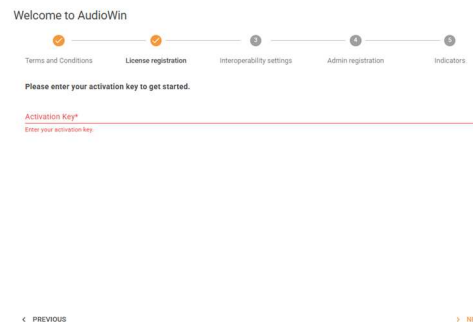
Select your language and accept the terms of use

When you open the software, select your preferred language. You will then be presented with the terms and conditions of use. Please read them carefully, then accept them to continue.



Enter Activation Key

Once you have accepted the terms of use, you will be asked to enter the Software Activation Key. This key can be found on the Information Sheet included in the box with your device.

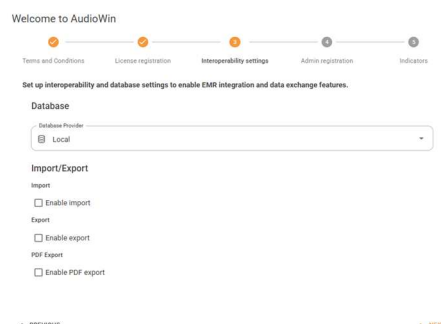


Interoperability settings

Once you've validated the Activation Key, you'll be taken to the interoperability settings, which ensure communication between AudioWin® and your business software (EMR).

Available options:

- Enable import: allows patient files and previous exams to be imported from your EMR.
- Enable export: exports patient data and results to your EMR.
- Enable PDF export: saves examination reports in PDF format.



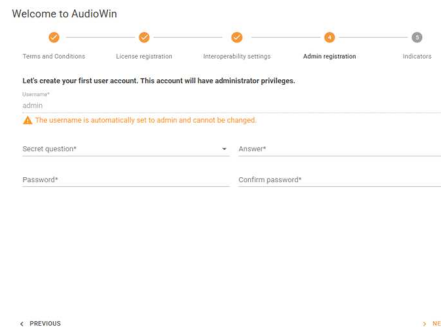
Creating the Administrator account



NOTE: A fixed username “admin” is automatically created when AudioWin® is first installed.

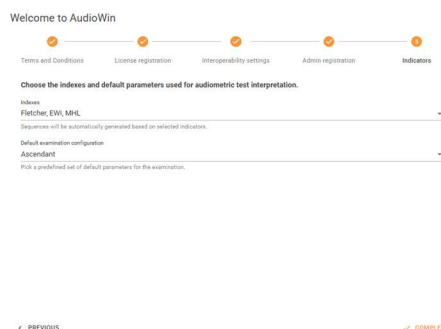
NOTE: Be sure not to forget the password, as it cannot be reset and access to the database cannot be restored if it is lost.

When you first connect to the software, you will need to create an administrator account by registering a user name and password. This password must comply with local security regulations, particularly with regard to minimum length and complexity (upper and lower case, numbers and special characters).



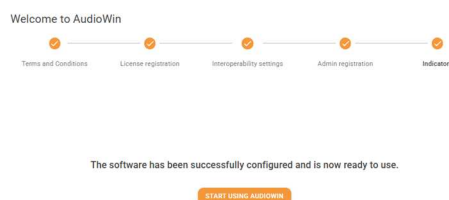
Selecting the default indicators and testing parameters

In this window you will choose the default parameters for your tests, as well as the indexes that will be used to calculate the scores and generate the interpretation of the audiometric results.

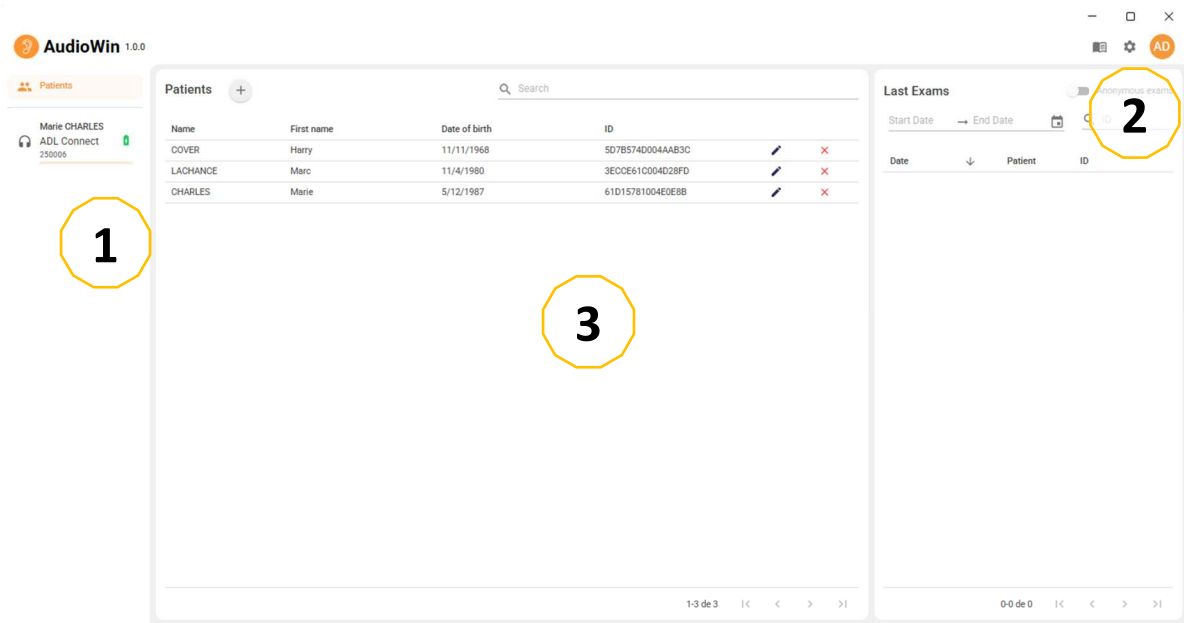


End of software pre-configuration

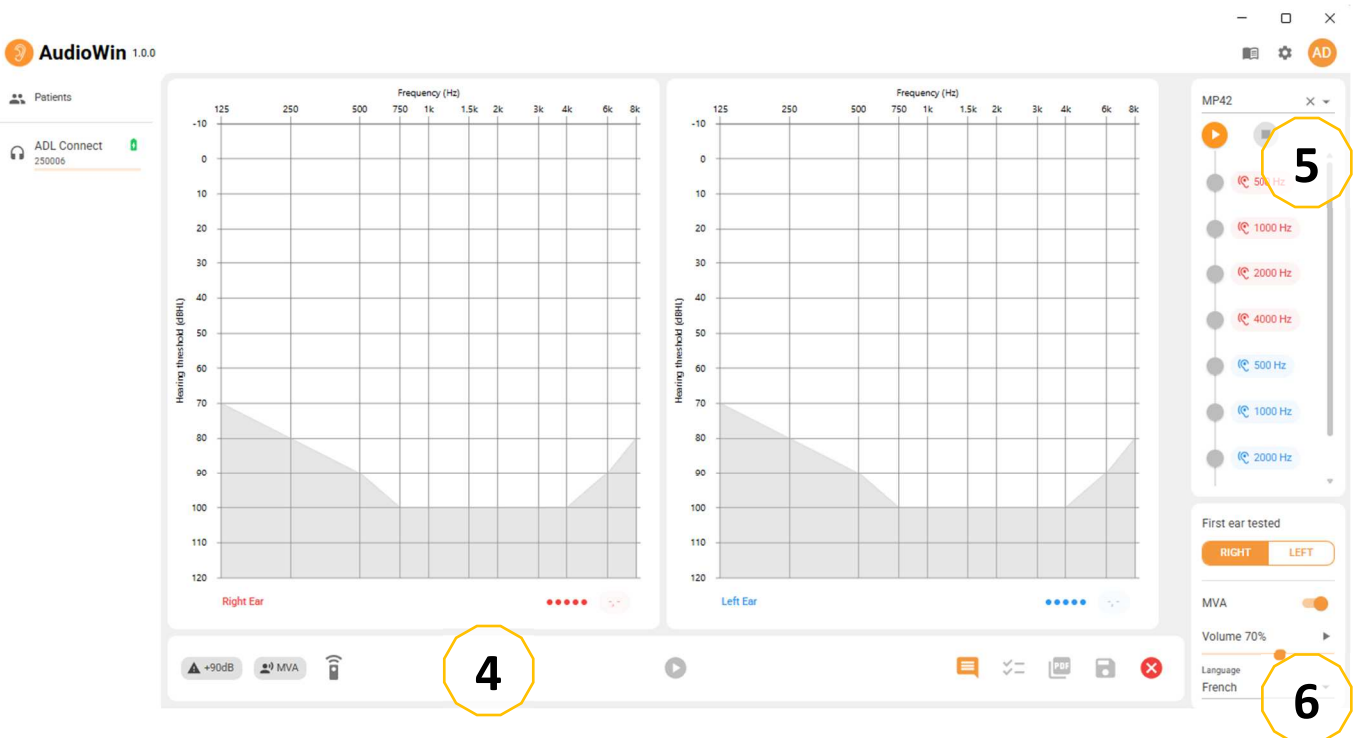
As soon as you have completed these pre-configuration steps, a window will appear to inform you that the software is ready for use.



User Interface Description



- 1 **Navigation menu:** Access to the list of patients and connected audiometers
- 2 **Settings:** User profile, software settings, user manual
- 3 **Working window:** Management of parameters, patient profiles, examination, report
















- 4 **Toolbar:** Access to indicators, comment section, indicator buttons, report generation and saving the current exam.
- 5 **Sequence settings menu:** Selection and launch of a test sequence.
- 6 **Test setup:** Access to test parameters to select the first ear to be tested (you can right-click to select just one ear), activate or deactivate the AVM, and choose the language and volume.

Description of the icons

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July 2025

	Create new profiles (Users, patients, etc.)
	Access settings
	View user manual
	Edit profiles (Users, patients, etc.)
	Start a test
	The patient does not press the response button
	The patient presses the response button
	Pause the sequence
	Delete the selected profiles (Users, patients, etc.)
	Audiolyser® connected headset
	Restart uncertain answers
	Remote control battery level
	User profile

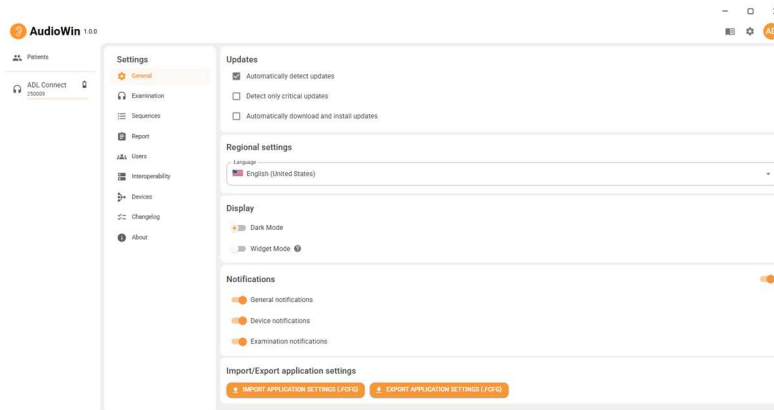
AudioWin® Software settings

General



NOTE: If you do not check the “Automatically download and install updates” box , when the software starts AudioWin® a window information will apbutton to inform you of availability of an update.

NOTE: If you wish to update, you will have to click on the “Update” button that will apbutton at the top right corner of your AudioWin® software



The General options are divided into 5 sections:

Updates:



NOTE: Patient button updates are not available when connected via Bluetooth.

Allows you to choose your preferences regarding the automatic updating of the AudioWin® software

Once connected, the connected remote control and docking station can be updated. When an update is detected, a pop-up window will appear in the bottom right-hand corner of your screen, asking if you want to update the equipment.

Regional setting:

Changes the display language

Display setting:

Allows you to choose between normal and dark mode, and to activate or deactivate widget mode (when activated, the software appears as a shortcut in the bottom right-hand corner of your screen, allowing you to follow the progress of the exam while using other applications).

Notifications:

Choose whether you want to receive notifications from the software, from the connected device or from exams in progress.

IMPORT/EXPORT application settings:

Automatic import: Allows the operator to import patient data into the AudioWin® software, view previous examinations carried out, perform new tests and export them to the business software subsequently.

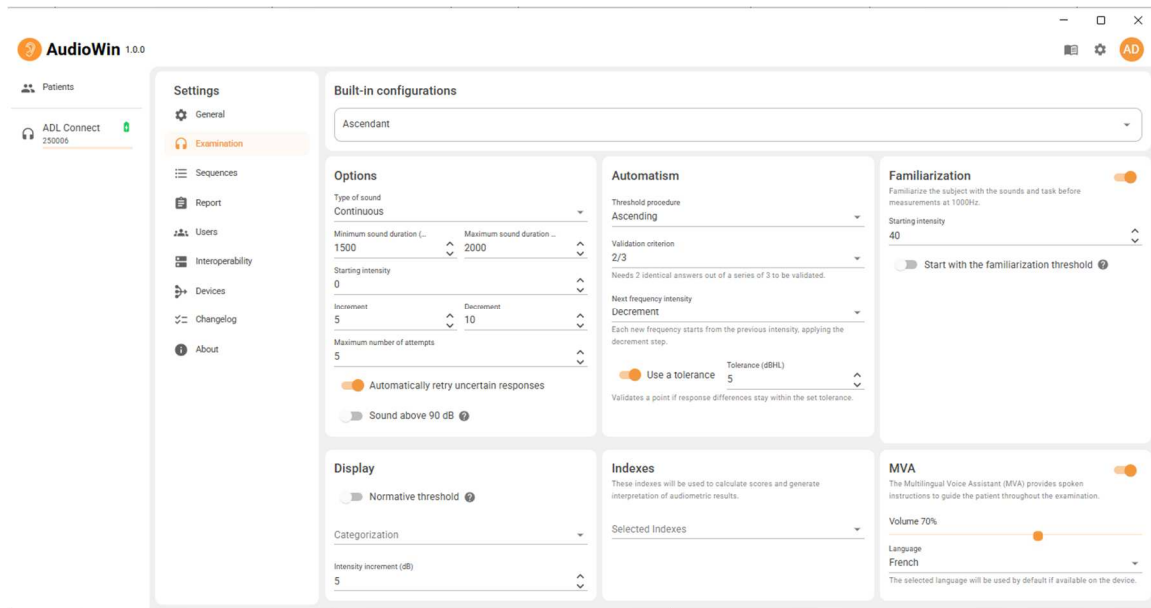
Automatic export: Exporting data from the AudioWin® software to the most widely used business software is possible, thus ensuring the interoperability of the Audiolyser® ADL Connect.

AudioWin® software uses the regional settings of the Windows operating system by default.

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Examination



Gives you access to in-depth examination configuration parameters.

Options section:

- **Sound Type:** Selection between continuous or pulsed sound.
- **Sound Duration:** Minimum and maximum
- **Starting Intensity:** The initial sound level played at the beginning of the main test (after any familiarization).
- **Intensity Variation:** (Increment/Decrement)
- **Maximum Number of Attempts:** The maximum number of tries allowed for a given condition if no response is detected.
- **Retry Uncertain Responses Automatically:** When enabled, frequencies where the response was uncertain will be re-tested automatically.
- **If a Sound Above 90 dB can be played**

Automatism section:

- **Threshold Procedure:**
 - **Up-Down:** Intensity increases until no response, then decreases once the sound is heard. The threshold is defined as the first response heard after the first response missed.
 - **Ascending:** Starts at a low intensity and gradually increases until the subject responds. This response determines the threshold.
 - **Validation criterion:** Number of responses required for validation
 - **Next Frequency Intensity:**
 - **Decrement:** The next frequency tested will start at a lower intensity than the previous one.
 - **Fixed Intensity:** Each frequency will begin at a pre-defined fixed sound level.
 - **Use Tolerance (dB HL):** Allows you to set the range in which the answers will be considered valid.

Familiarization section:

Allows you to set the starting intensity of the sound which will allow the subject to familiarize with the sounds and task before starting the real examination.

Display section:

- **Normative Thresholds:** Reference hearing thresholds based on age and gender will be displayed.
- **Categorization:** Allows for the classification of hearing loss according to standard scales.
- **Intensity Increment (dB):** Adjusts the vertical scale of the graph

Indices section:

Used for automatic analysis of hearing test results. Activated indices help generate scores or interpretations for different contexts.

The following indices are available:

- Asymmetric Hearing Loss
- Fletcher (weighted)
- Early Warning Indicator
- Mean Hearing Loss
- Fletcher
- SIGYCOP note
- The criterion SNCF aptitude
- Health and Safety Executive categorization
- Merluzzi Pira Bosio (MPB 2002 categorization)
- The Merluzzi 1979 categorization

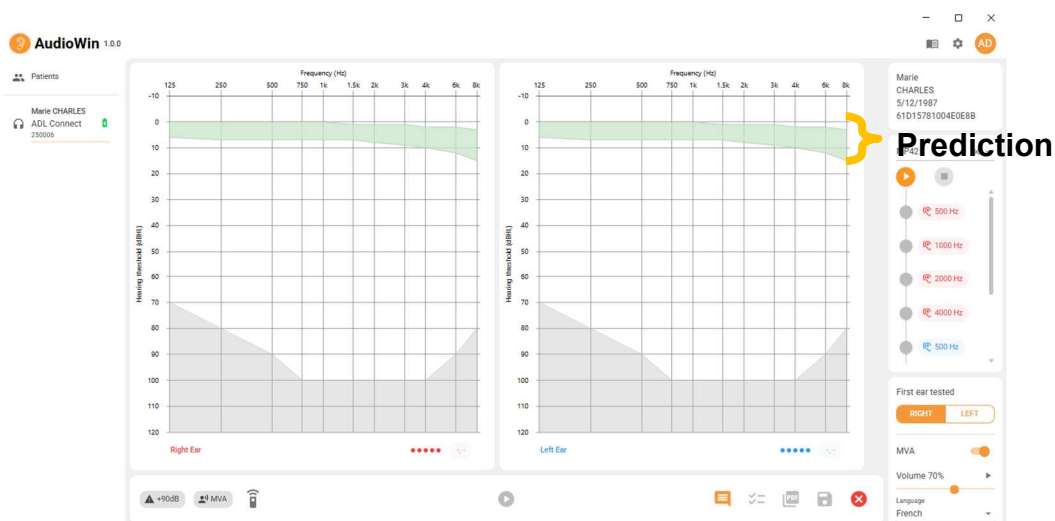
If you do not know which index is suitable for your usage, please call FIM Medical.

MVA – Multilingual Voice Assistant section:

Access to in-depth parameters of the MVA

Displaying predictions

After selecting *Normative threshold* (Display section of the Examination parameters), the graph will appear as follows:



The calculation of these predictions is based on the ISO 7029:2017 standard.

✓ Displaying categorization areas

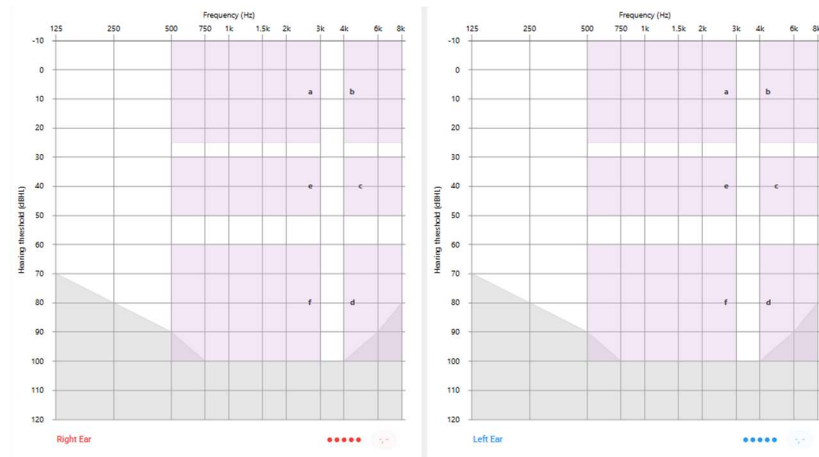
AudioWin® allows the display of categorization areas to help the operator get a quick overview of the trend of the current examination results.

Three types of zones are offered:

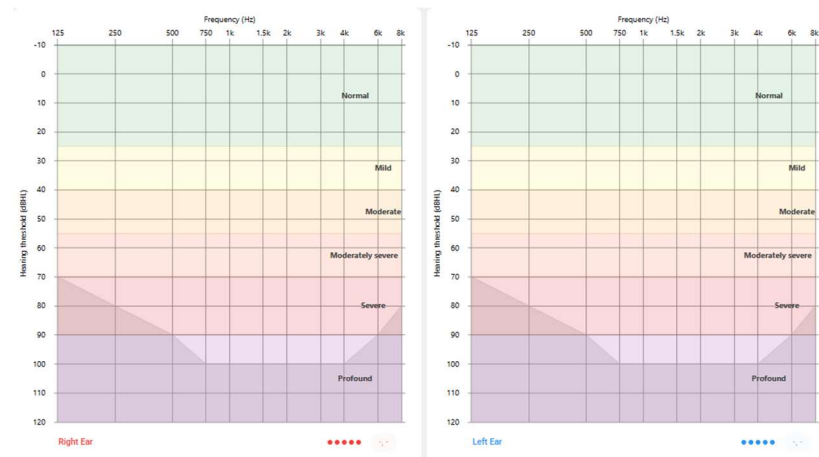
FF1166.MUT.102 V01.01.00

July 2025

✓ Merluzzi 1979:



✓ Degrees of loss hearing:



Degrees of hearing loss	Threshold hearing	Hearing ability
None	0 to 20 dB	Hearing considered as normal
Light	21 to 40 dB	Difficulty perceiving quiet speech and conversations, especially in a noisy environment. Good perception in a noisy environment. calm .
Average	41 to 55 dB	Difficulty hearing speech, especially in the presence of background noise. Tendency to turn up the volume on the television or radio.
Moderate to severe	56 to 70 dB	Speech perception is greatly reduced. Participation in group discussions becomes very difficult.
Severe	71 to 90 dB	Inability to hear speech at its normal level and also difficulty with loud noises. Amplification is essential.
Deep	91 dB and +	Surrounding sounds and speech are virtually imperceptible.

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

✓ SIGYCOP:

The **SIGYCOP** is a medical rating system used by military physicians to assess fitness **for service**.

It applies:

- To candidates for enlistment or volunteering in the armed forces
- To candidates for the reserve
- To active military personnel (career or contract)

Principle of SIGYCOP

- Each person is assessed according to **7 medical criteria**.
- These criteria are represented by the letters: **S, I, G, Y, C, O, P**.
- A **numerical coefficient** is assigned to each criterion.
- The lower the number, the higher the suitability (0 = suitability without restriction).
- Higher coefficients indicate a **limitation or inability**.

Letter	Function evaluated
S	Shoulder girdle and upper limbs
I	Pelvic girdle and lower limbs
G	General condition
Y	Vision (excluding color perception)
C	Color perception (chromatic sense)
O	Hearing and hearing aids (ears)
P	Mental balance and behavior

Rating of the acronym O

- The "O" rating depends on hearing but also on the severity of the impairment.
- The same hearing loss can have very different causes, benign or serious.
- It is therefore not enough to measure a drop in hearing to set the "O" level.

Two levels of expertise are possible:

1. Basic assessment:

- Performed routinely
- Includes pure airborne tonal audiometry (e.g. **Audiolyser® ADL Connect**)

2. Specialized assessment:

- Requires additional examinations in case of doubt or severe pathology
- Used for contentious cases or complex conditions

✓ Pure-tone audiometry by air.

Pure-tone audiometry is used to assess hearing acuity. It is reliable if performed correctly after a clinical examination.

Conditions of implementation

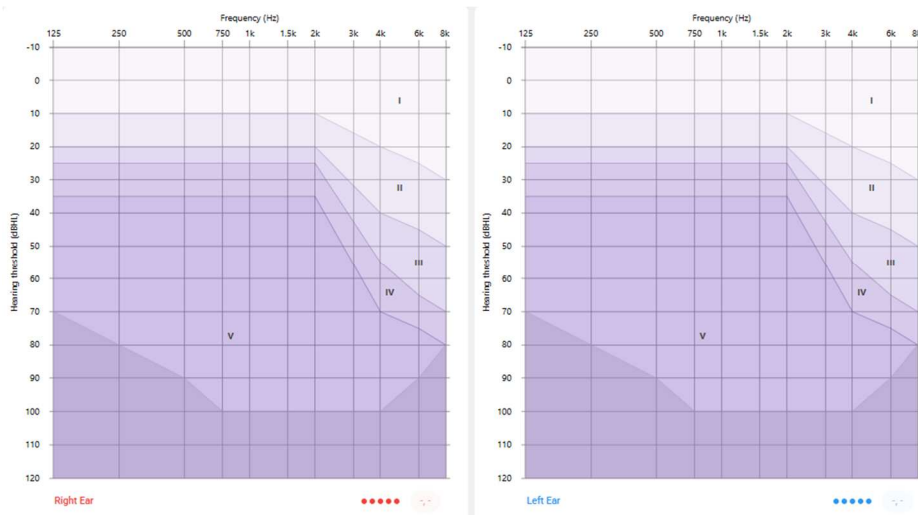
- Examination can be carried out in a unit medical department or expert center.
- The audiometer should be placed in a soundproof room or, ideally, a booth.
- The subject should be seated, without seeing the controls, and wearing headphones that fit snugly over both ears.

Method

- **Ascending threshold** method: The intensity is increased by **5 dB** until the subject hears the sound.
- Frequencies tested (SIGYCOP sequence): **1000 – 2000 – 4000 – 6000 – 8000 – 1000 – 500 – 250 Hz** (*1000 Hz is tested twice*)

Results

- Each ear receives a score in **Roman numerals (I to V)** according to the lowest threshold.
- An **isolated scotoma** is noted in the affected area.



O coefficient of the SIGYCOP profile reflects the overall hearing function. It is determined from the hearing class (I to V) of the right ear and the left ear, according to the table below:

Hearing acuity in each ear.	I	II	III	IV	V
I	1	2	3	4	5
II	2	2	4	5	5
III	3	4	5	5	5
IV	4	5	5	5	6
V	5	5	5	6	6

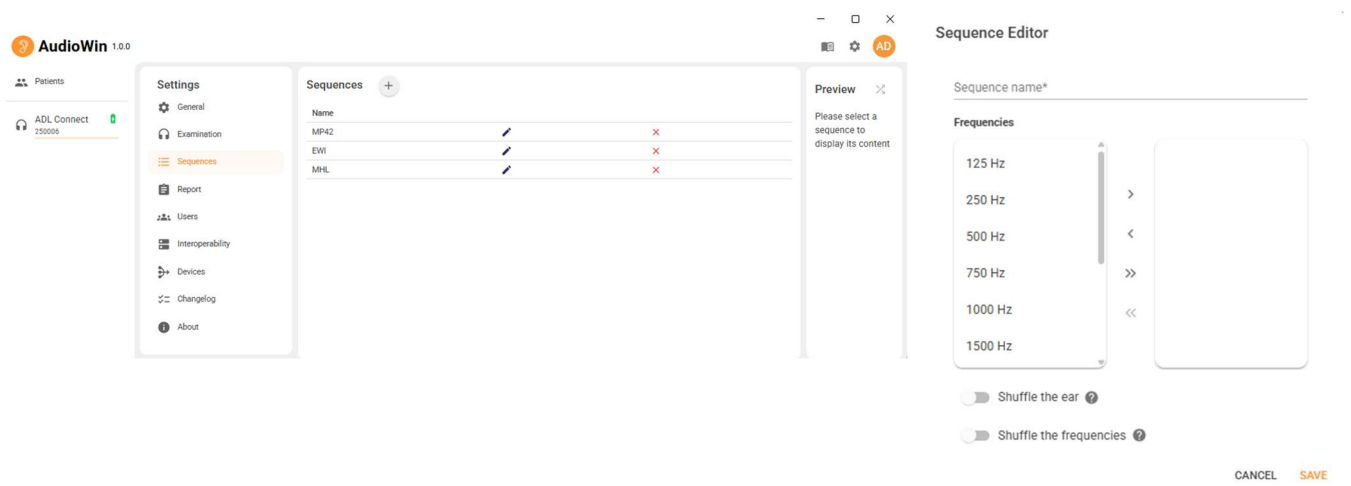
Special case :

If **O > 3** , **speech audiometry** can complete the assessment. (*Not integrated into the AudioWin® software*)

If the patient achieves **100% intelligibility at ≤ 50 dB**, a classification of **O = 3** can be retained.

Source: INSTRUCTION N° 2100/DEF/DCSSA/AST/AME of October ¹, 2003

Sequence



You can thus:

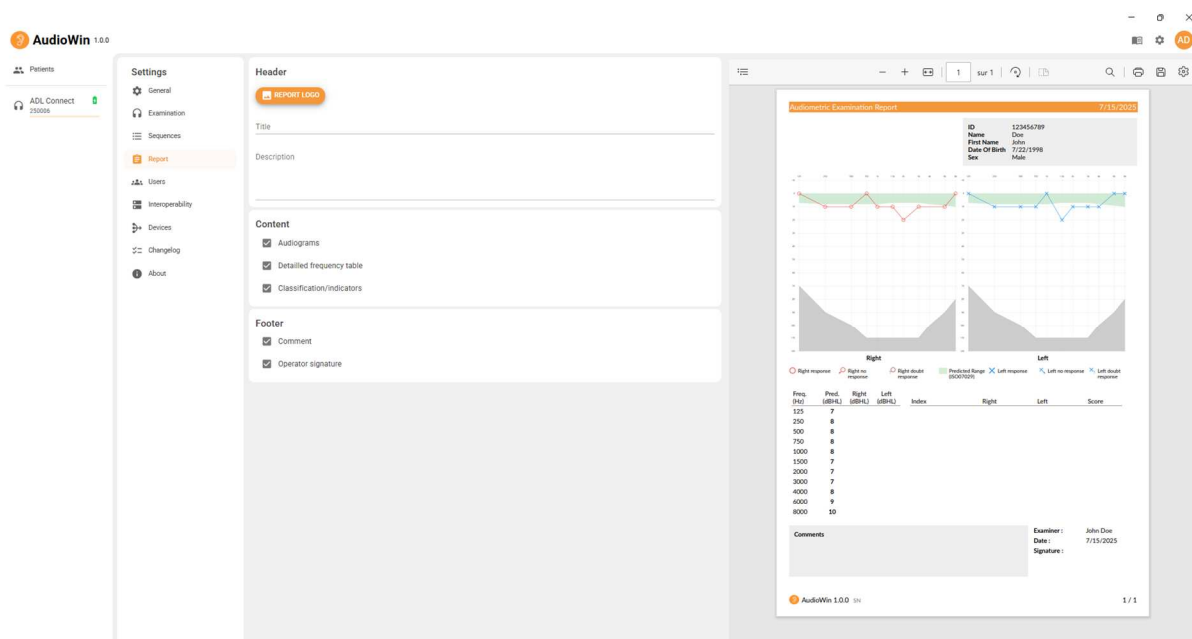
- Find all the sequences you have already recorded on the software.
- Name your new sequence.
- Edit existing sequences
- Delete sequences
- Select the frequencies you wish to test during the exam
- Choose whether you wish to alternate between left or right ear and/or frequencies
- After you have configured your sequence, click on Save

Report

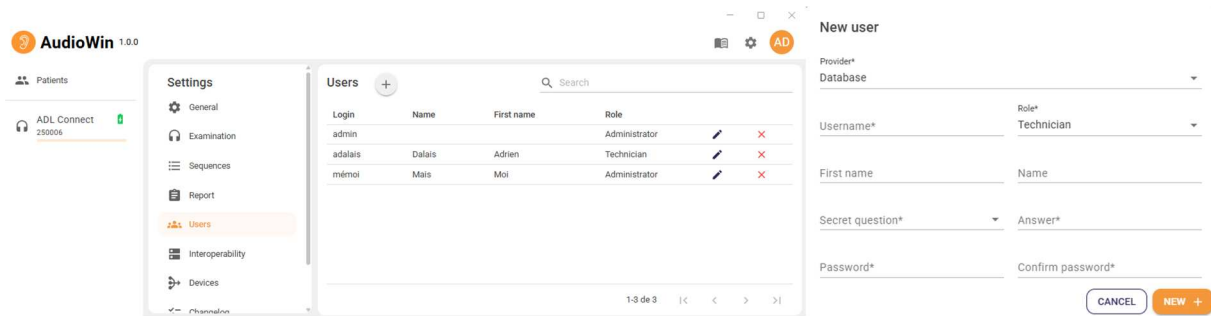


CAUTION: To ensure the protection of patient data, it is strongly recommended not to disable access control to the AudioWin® software by secure authentication.

This tab allows you to customize your reports, for example by including information such as your logo, contact details, among others.



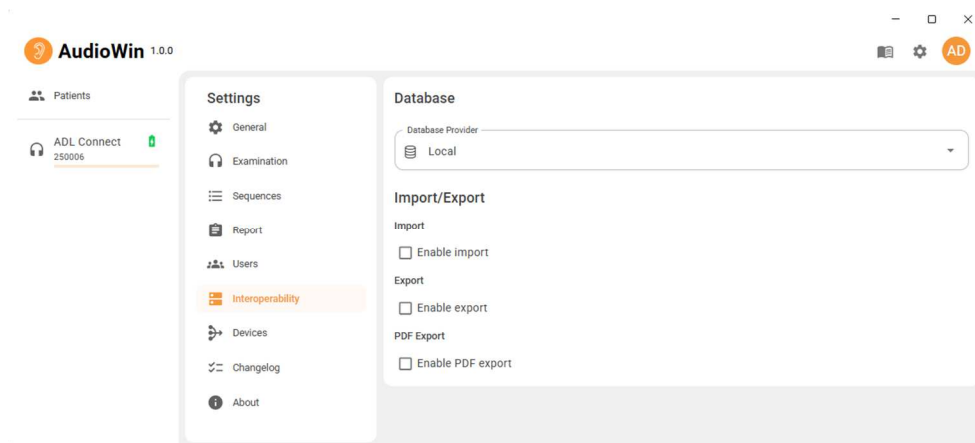
Users



Displays the list of users already registered, and lets you add new users.

You also have access to LDAP, which is a protocol that allows different systems to access a centralized database containing user identifiers and information, to authenticate them and give them the right access.

Interoperability

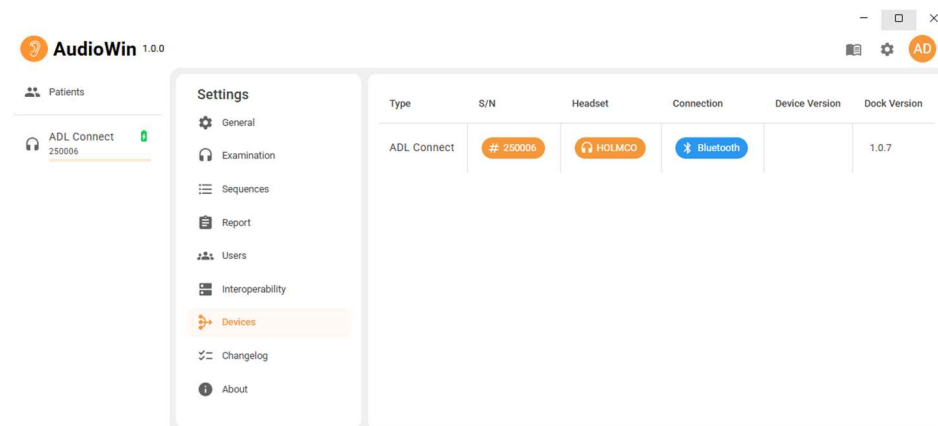


Selects the database supplier: local (directly on the software), remote (External database in PostgreSQL) or no database.

AudioWin® will then automatically perform the necessary presetting to facilitate data exchange. Available options:

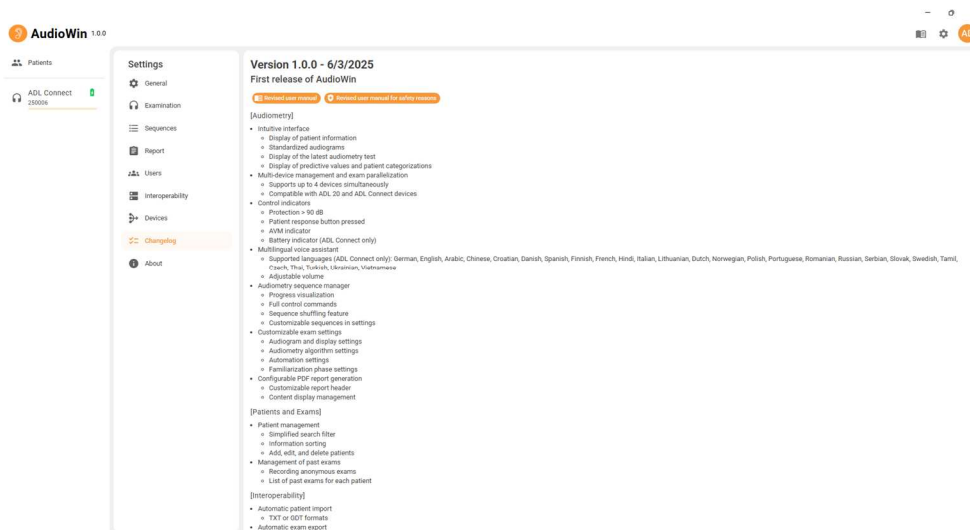
- Enable import: allows patient files to be imported from your EMR.
- Enable export: exports patient data and results to your EMR.
- Enable PDF export: saves examination reports in PDF format.

Devices



Displays all the connected devices and their relative information.

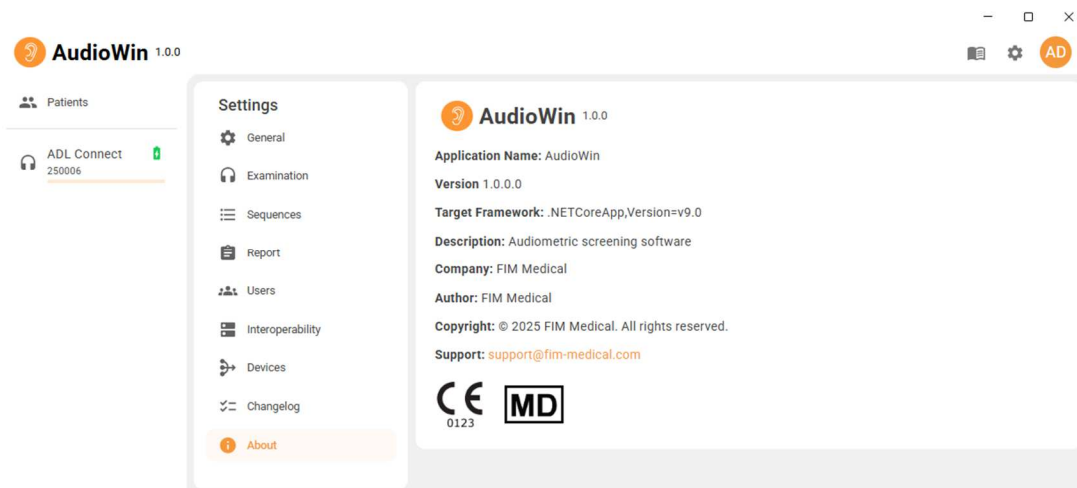
Changelog



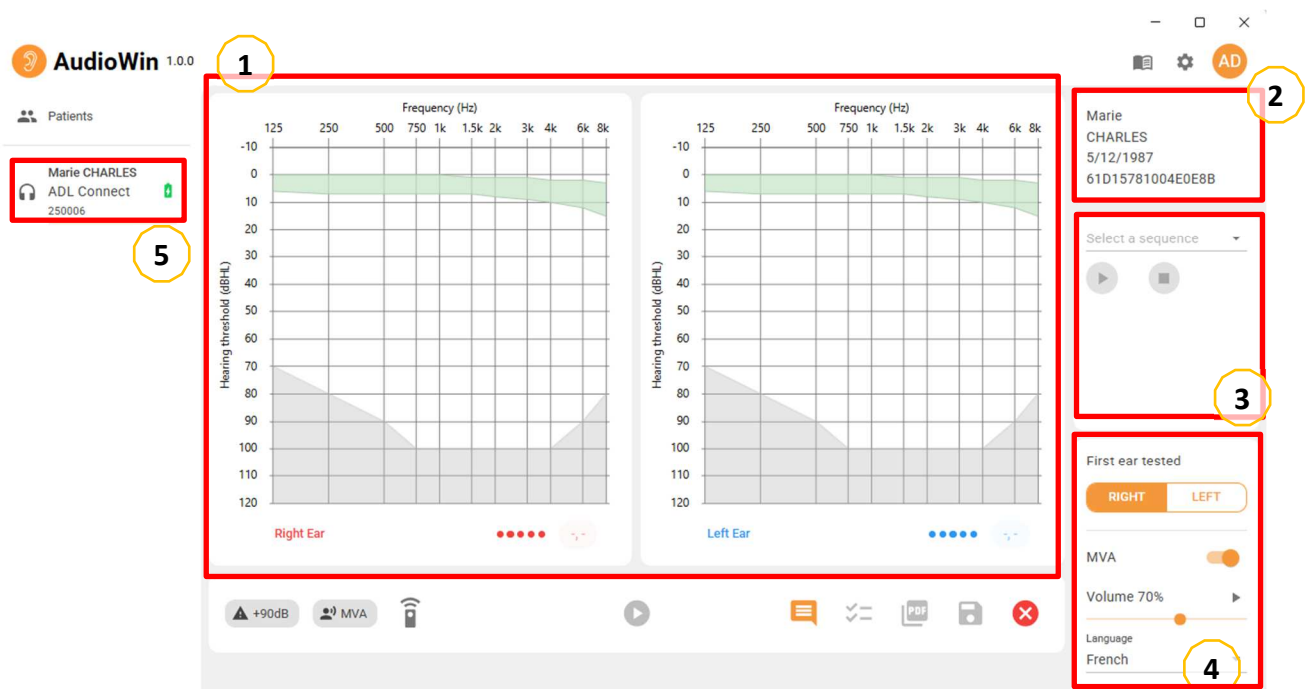
Displays all of the elements modified or added during an update.

About

Displays software information.












Examination window



1. Audiograms for the right and left ears, showing frequencies and intensities.
2. Patient information
3. Setting up sequences: this allows you to start, pause and restart a running sequence.
4. Test settings: Select the ear to be tested first, activate the MVA (Multilingual Voice Assistance), and set its volume and language.
5. Displays a list of devices currently connected to the computer.



NOTE: Even if no device is connected, test examinations can be carried out for functional testing purposes.

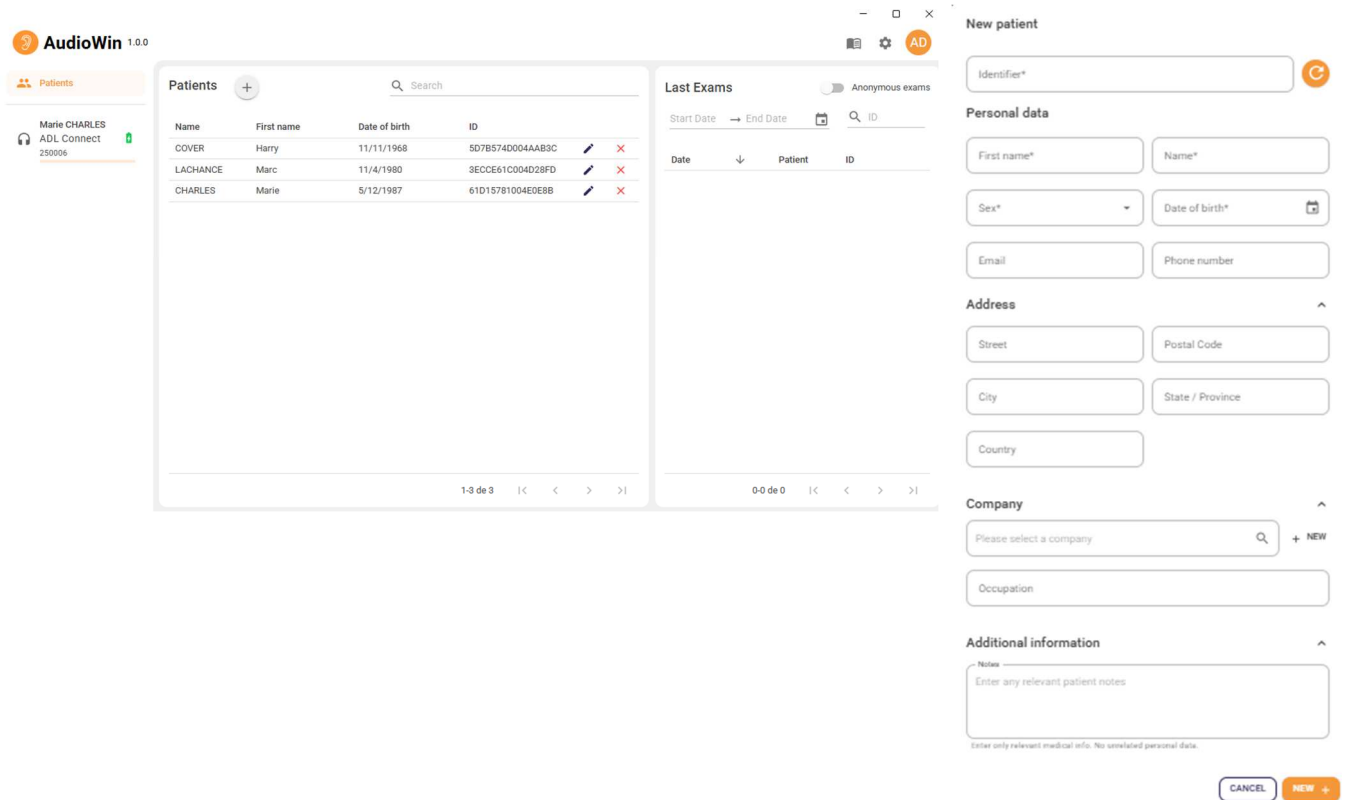
Button/Indicator	Meaning	Button/Indicator	Meaning
	Turns on if the sound emitted is greater than 90dB		Displays interpreted or calculated results, key indicators and details of measurements obtained.
	Turns on if the AVM is running		Generates an examination report in PDF format
	Turns green when the patient presses the response remote during the exam		Save an exam.
	To play a sound selected on the audiogram		Reset exam
	Comment area		

Patient profile management (excluding third-party software interface)





You can create a patient profile or select a specific patient profile for an examination.

If no patient is selected, the examination will be carried out anonymously.

From the side menu, click on the patient icon  to access the patient profile viewing interface.



The screenshot shows the AudiWin 1.0.0 interface. On the left, there is a sidebar with a 'Patients' icon and a list of patients: Marie CHARLES, ADL Connect, 250006. The main area is divided into two panels. The left panel, titled 'Patients', contains a table with columns: Name, First name, Date of birth, and ID. The table lists three patients: COVER Harry (11/11/1968, ID 5D7B574D004AAB3C), LACHANCE Marc (11/4/1980, ID 3ECCE61C004D28FD), and CHARLES Marie (5/12/1987, ID 61D15781004E0E8B). Each row has edit and delete icons. The right panel, titled 'Last Exams', has a search bar and a table with columns: Date, Patient, and ID. Below the table, there are navigation controls. On the far right, there is a 'New patient' form with fields for Identifier*, Personal data (First name*, Name*, Sex*, Date of birth*, Email, Phone number), Address (Street, Postal Code, City, State / Province, Country), Company (Please select a company, Occupation), and Additional information (Notes). At the bottom right of the form are 'CANCEL' and 'NEW' buttons.

Button	Meaning
	Filter the database to select an existing profile
	Create a new patient
	Edit the profile of the selected patient
	Delete the profile of the selected patient

When you select a patient, you will be able to view the history of that patient's exam results in the right window.

The window on the right can also be used to view previous examinations in anonymous mode, and to filter results according to various criteria.

To create a new patient profile, fill in the required information.

13. Conducting an exam



WARNING: There is a risk of cross-contamination if earpad covers are not changed or reused between two patients.



CAUTION: Do not expose the patient to a 80db or 100dB sound for more than 15 minutes.



NOTE: If the patient is unable to become accustomed to the remote's operation, patient can confirm his perception of the sound by raising his hand. The operator then validates the threshold by clicking on "Validate" or by pressing the "Enter" key.

AudioWin® is designed to perform audiometry in automatic mode, but also in manual mode.


Manual Mode

In the Review tab, use the keyboard and/or mouse to:

- Select the frequency.
- Select the intensity.



Click the button  to start the sound

Once the exam is complete, click on the *Save button* 

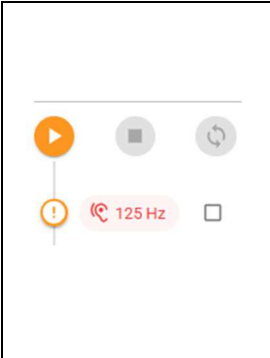





NOTE: To avoid handling errors, the software can automatically restrict direct changes of too great an amplitude to avoid damaging the patient's ear.

Sequence Mode

To use automatic mode from the exam page, choose a sequence from the drop-down menu.




	Click the button  to start the sequence in automatic mode.
	The button  allows you to stop the sequence.
	<p>The button  allows you to retest a frequency.</p> <p>This button appears when the patient gives different responses for the same frequency tested and/or when the patient gives no response when a frequency is tested. An exclamation mark will be shown next to the concerned frequency.</p>

Once the exam is complete, click on the “Save” button







NOTE: If the headphones are disconnected accidentally, the examination is interrupted and the operator is warned.







Launching the automatic test

- Click the button  to start the test.
- The AVM guides the patient with voice messages.
- The test begins with a familiarization phase at 40 dB as default (configurable in settings). This allows us to check that the patient presses the button when he hears a sound.
- As soon as the familiarization phase is completed, the test will start.
- The device then measures the hearing thresholds automatically for each frequency and each ear.
- If the answer is uncertain, a question mark (?) is displayed. The frequency will be retested at the end. (If enabled in the Option section of the Examination parameters)
- You can also manually rerun a test if necessary.
- The test can be paused at any time.
- Finally, click “Save” to save the results.

14. Displaying results

Audiwin automatically analyses the results of hearing tests. Activated cues can be used to generate scores or interpretations for different contexts. To do this, press the *Indexes button* 

Results

Frequency (Hz)	Predict (dBHL)	Right Ear (dBHL)	Left Ear (dBHL)
125	6		
250	7		
500	7		
750	7		
1000	7		
1500	7		
2000	8		
3000	9		
4000	10		
6000	12		
8000	15		


Index	Right (dBHTL)	Left (dBHTL)	Score	Interpretation
MP42				The index could not be calculated due to missing responses.
EWI				The index could not be calculated due to missing responses.
MHL				The index could not be calculated due to missing responses.

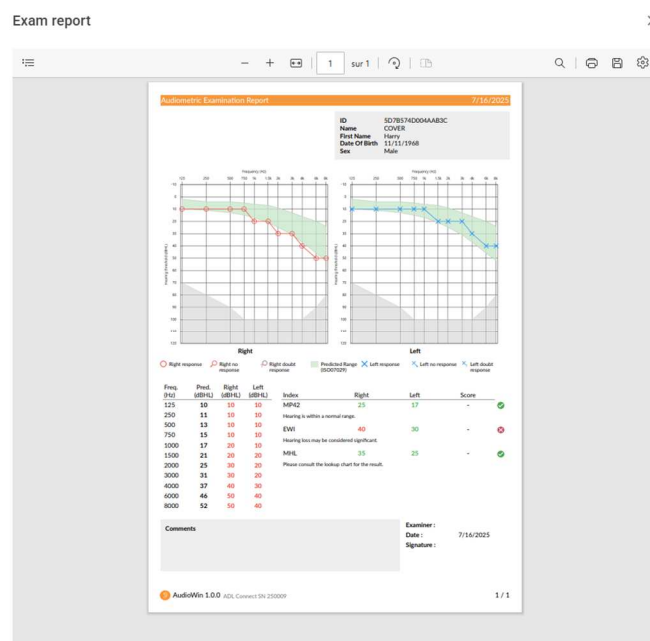
All the available indices are listed in the Indices section of the Examination parameters.

Visualizing the results examination

Review report

Once the exam is completed, click the *Save button* to save the exam results in PDF format. Exams can then be printed or exported to third-party software.

Click on  to access the PDF report viewer.



15. Maintenance of the Audiolyser® ADL Connect

Cleaning and disinfection



- **WARNING:** The device must be cleaned after each use with a damp cloth and a generic bactericidal-fungicidal product.
- **WARNING:** The company FIM MEDICAL have validated, for the decontamination of its Audiolyser® ADL Connect, the use of the wipes or rags soaked below:

- Clorox® Healthcare Bleach	- Mikrozyd® Universal wipes premium
- Clorox® Disinfecting Wipes	- Mikrozyd® AF Wipes
- Bactinyl® Disinfecting Wipes	- Mikrozyd® Sensitive wipes premium
- Sani-Cloth® Bleach / Plus / HB / AF3	- Aseptonet® Biocide
- Sani-Cloth Active wipes	- Anios® Quick wipes
- Super Sani-Cloth®	- Anios® Excel wipes
- Formula 409®	- Incidin™ Alcohol Wipe
- Virex® Plus	- ICB® France Klorxitol
- Sterimed® 100	- Ethanol wipes
- PURELL® Healthcare Surface Disinfecting Wipes	- Isopropyl alcohol 70% wipes

It is recommended to ask the patient to disinfect their hands before handling the device.

After each patient, the parts accessible to patients must be cleaned:

- The earphone cushions,
- The headset hoop,
- The patient response remote.

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

Maintenance



CAUTION: Device shall not be maintained or serviced while in use.

Daily routine check:



NOTE: The daily routine check of the device can be done with the software.

After using the device,

- clean and disinfect the device as described in the section 8. Cleaning and disinfection”,
- check the general condition of the equipment,
- check that the audiometer output is in good working order throughout its frequency range, check the patient's response system.

Annual maintenance:



CAUTION: Calibration of audiometers can only be carried out by FIM MEDICAL or a distributor if they have been authorized by FIM MEDICAL for maintenance. In France, no distributor or third party is authorized to calibrate the Audiolyser® ADL connect.

Annual maintenance must be done with equipment such as a sound level meter, artificial ear, frequency meter, soundproof box, all in an environment with controlled temperature and humidity.

Manufacturer annual standard maintenance operation:

- Check for the absence of false contacts
- Check the condition of the cables
- Check the headphones/earcups
- Check the different functionalities
- Check the push button
- Proceed to verification/adjustment

A maintenance every 3 years is required to ensure test reliability and expected service life.

Warranty

FIM Medical warrants that:

- Audiolyser® ADL Connect is free from defects under normal use and service for a period of 2 years from the date of delivery to the first purchaser.
- The contractual guarantee covers repairs only.

During the annual maintenance, a certain number of preventive operations are carried out. The revision cannot constitute a guarantee of coverage for any breakdown that may occur after this revision.

Service life

The expected service life of the Audiolyser® ADL Connect is 10 years, provided that the user carries out the compulsory maintenance required.

FIM Medical will not be held responsible for any loss of performance of the device in the event of failure to carry out this compulsory maintenance.

How to return a defective device

In case of a defective device, you can send back to FIM MEDICAL your device.

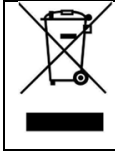
Before returning the device, please clean and disinfect it, as explained in the section “Cleaning and disinfection”.

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

Information for disposal for private users, companies and healthcare institutions

Device disposal:

In accordance with the WEEE directive 2012/19/EU, used electronic devices must be treated separately from household waste. The devices must be deposited in specific collection sites (waste disposal centers). For more information, you can contact FIM Medical or your authorized distributor.



This symbol specifies that this device is considered as an electrical equipment and must not be disposed as a common garbage.

This type of equipment can have potential effects on the environment and human health.

Earpad covers disposal:

Hygienic earpad covers must be disposed of in a separate collection for bio-soiled waste, DASRI (Déchets d'Activités de Soins à Risques Infectieux/Waste from Healthcare Activities with an Infectious Risk).

User information

Incident Reporting

If a **serious incident** occurs in relation to the use of the device, it shall be promptly **reported to the Manufacturer** using the contacts below and to the **Competent Authority** of the country where the incident occurred.

Other User Assistance Information

For other information and requests of technical support, please contact your local distributor using the contacts below.



MANUFACTURER:
FIM MEDICAL

51 rue Antoine Primat
69100 Villeurbanne
FRANCE

Tel: +33 4 72 34 89 89
Fax: +33 4 72 33 43 51

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

TECHNICAL ASSISTANCE /
LOCAL DISTRIBUTOR

(Contacts and/or company's stamp)

Other information



NOTE: The names of the people mentioned in this document are purely fictitious. Any similarity with real individuals, living or deceased, is entirely coincidental and unintentional.

User manual in paper format

A paper version of this user manual is available on request from FIM Medical (see support section above).

Declaration of conformity

The present device is classified as a medical device class IIa according to the European Regulation MDR 2017/745. The device has been designed in accordance with the requirements of the IEC 60601-1. Year of 1st CE marking: 2025.

FF1166.MUT.102 V01.01.00

July 2025

16. Troubleshooting and error messages

Issue	Probable cause	Solution
The device is not detected by software when directly connected to a PC and a file explorer window with software installation files opens.	The device is on "Masstorage Mode".	Reconnect the device but don't push on the response button remote at the same time of the connection.
No sound is perceived	Device is not connected to the software.	<ul style="list-style-type: none"> Check if the headset is connected. Check the indicator cone of headset presence on the software interface is colored blue
Response remote doesn't work: <ul style="list-style-type: none"> LEDs do not light up Device is not detected by software 	Battery is discharged.	<ul style="list-style-type: none"> Charge the battery with the docking station Alternatively, connect the remote directly to the PC
Device is not detected by software.	Device is on sleep mode.	Push the response remote button.
Bluetooth connection is no working: <ul style="list-style-type: none"> LEDs light up when patient button response is pressed Device is not detected by software 	Docking station is not connected to PC.	Connect the docking station to the PC. Its connection is mandatory for proper device operation.
A username is needed for connection but no username was created.	During installation, an admin account was automatically created and a password was chosen by the user.	The default username is admin , and the password is the one entered during installation .
Error message "apbuttons" at recording	« Identification incomplete »	Ensure all mandatory identification fields are completed.
	« 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.
Patient management page is not accessible.	Database mode is not activated.	Go to the Settings tab → under Interoperability , select Local as the Database Provider.

If the problem persists or for any other problem, contact FIM Medical or your authorized distributor.