

HEARING SCREENING



USER

MANUAL

# AUDIOLYSER® ADL CONNECT



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## 1. Introduction

The Audiolyser® ADL Connect is a computerized digital audiometer for the exploration of hearing function. The device presents different sounds to the patient, and, depending on what the patient perceives, it allows the detection of 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 immerse or spray with liquid the device.

**CAUTION:** Do not use the device if it 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 hearing 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

Do not perform audiometry without a prior examination of the ear by otoscopy.  
The patient is unable to understand and follow the 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.

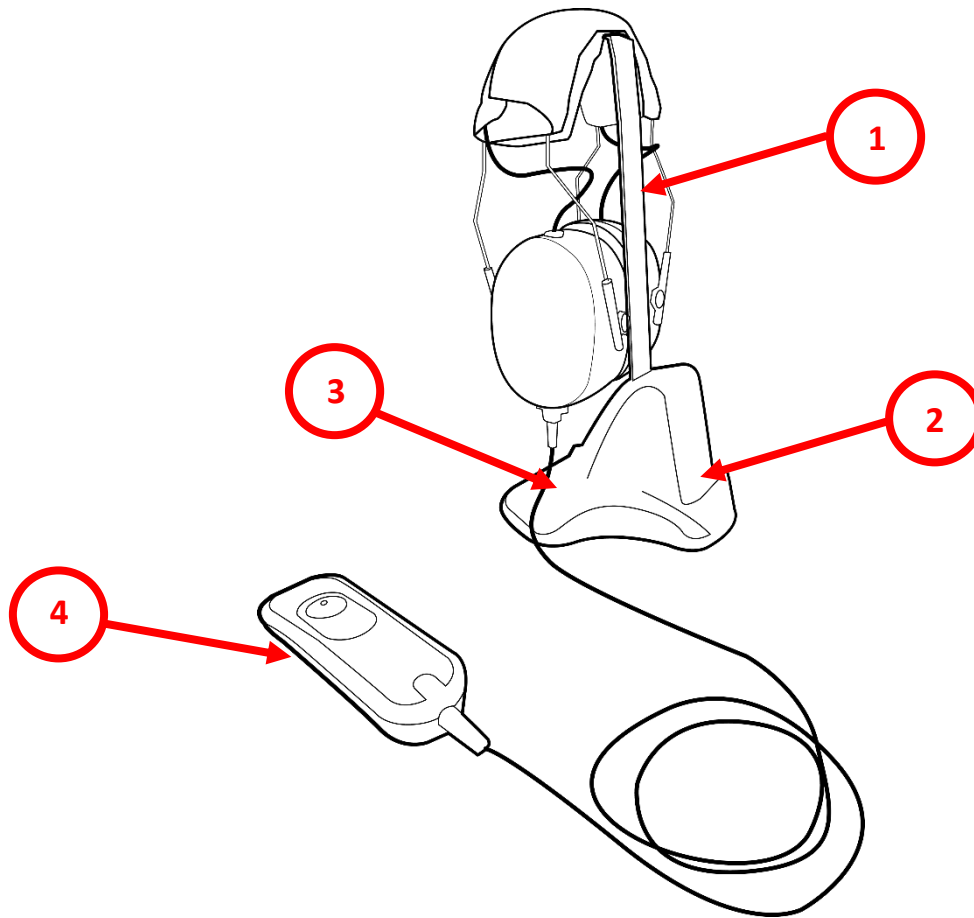
The precision of the audiometric measurements associated with the interpretation aids make it possible to diagnose the patient's deafness levels as well as the evolution of their hearing over the long term. The diagnostic assistance by detection of hearing loss allows a therapeutic orientation to improve 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 the headphones and the 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:

- Be connected to a computer in order to communicate with its dedicated 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

<b>Modes of use</b>	Manual mode or automatic		
<b>Sending sound</b>	Continuous, inverted or pulsed mode		
<b>Patient response time in automatic mode</b>	Adjustable, Between 15 and 30 tenths of a second		
<b>Harmonic distortion</b>	± 2.5%		
<b>Frequency accuracy</b>	± 2%		
<b>USB cable length</b>	3 m		
<b>Storage temperature</b>	-10 to 60°C		
<b>Temperature of use</b>	15 to 35°C		
<b>Humidity</b>	30 to 90%RH		
<b>Operating altitude</b>	< 2000 m		
<b>Tension</b>	5 VDC (via USB port)		
<b>Connectivity</b>	USB cable and/or Bluetooth BLE 2402 - 2480 MHz		
<b>Battery Type</b>	Rechargeable Lithium Polymer	Autonomy	Approx. 8h
<b>Battery capacity / voltage</b>	3.7V / 1500mAh		
<b>Battery charging time</b>	Approx. 3h	Cyclic endurance	≥ 500
<b>Current</b>	Typical power consumption: 350mA	Maximum power consumption: 1.1A	
<b>Compliance regulatory</b>	MDR 2017/745, ISO 10993, ISO 8253		
<b>Technical compliance</b>	IEC 60645-1, ANSI S3.6, ISO 389-1, ISO 389-8		
<b>Security Compliance</b>	EN 60601-1, EN 60601-1-2, IEC 62133, UN 38.3		
<b>Audiometer type</b>	4 (Pure-Tone)		
<b>Medical class</b>	Class IIa (rule 10)		
<b>Software class</b>	Class A		
<b>EMDN code</b>	Z121401 - Audiometers		
<b>GMDN code</b>	41187 - Tone audiometer, automated		
<b>Part applied</b>	Response box	Type BF	
<b>Dimensions / Weight</b>	255 x 210 x 100 mm, 800g		
<b>Device weight complete</b>	Between 500 and 850 g approximately (depending on the model)		
<b>Protection against electric shock</b>	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













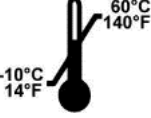



## AudioWin® software

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

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

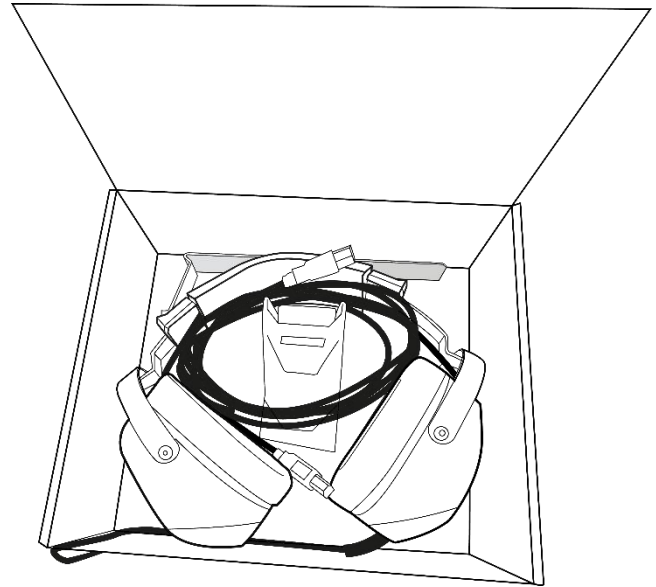
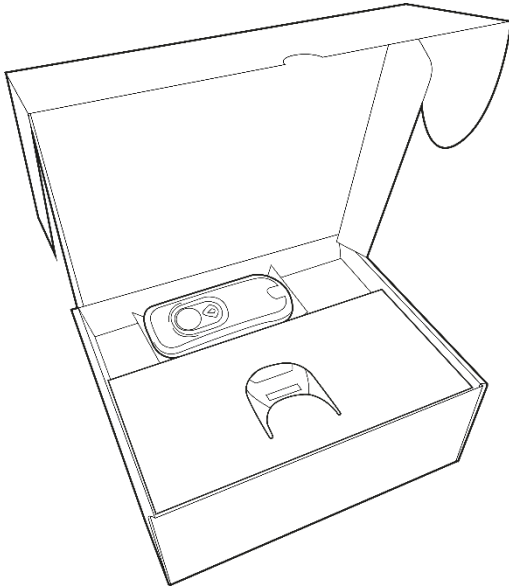
## 8. Installing the Audiolyser® ADL Connect

### Unpacking the device



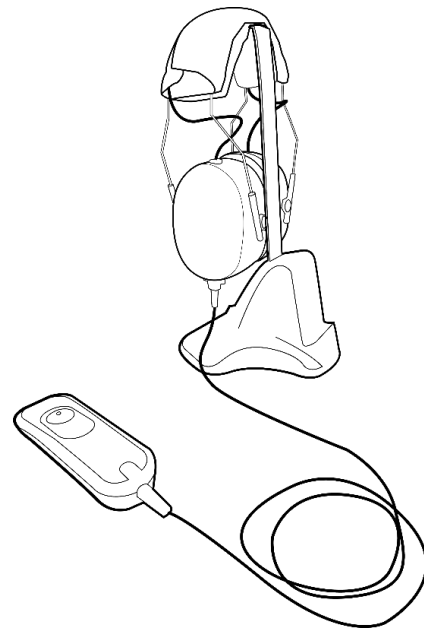
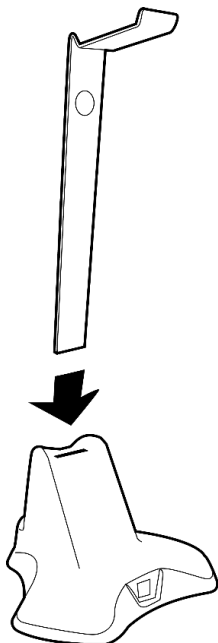
**NOTE:** The box and cables should be retained for maintenance.

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



### Assembling the docking station and headset holder

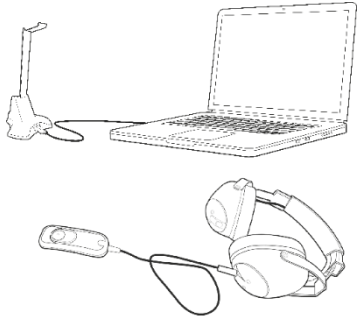
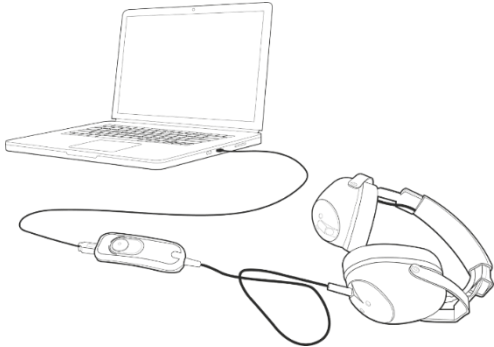
Insert the headset holder into the designated space on the back of the docking station. This will allow you to place your headset on it later.



## Connecting the cables



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

<p><b>Bluetooth configuration:</b></p> <p>Connect the USB cable from the docking station, Type B connector to the docking station, Type A to the PC.</p>	<p><b>Wired patient response remote configuration:</b></p> <p>Connect the USB cable of the response remote, 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 executable installation file of the AudioWin® software or the PDF version of the user manual by pressing and holding the response button for several seconds while simultaneously connecting the patient response remote to your computer using the cable supplied with your device.

The Audiolyser® ADL Connect will then be recognized by Windows as a mass storage device, automatically opening 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 of the 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

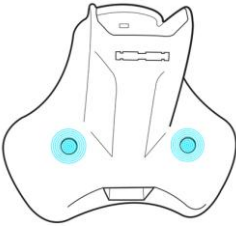

### Checking the connection between the Docking station and the response remote



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

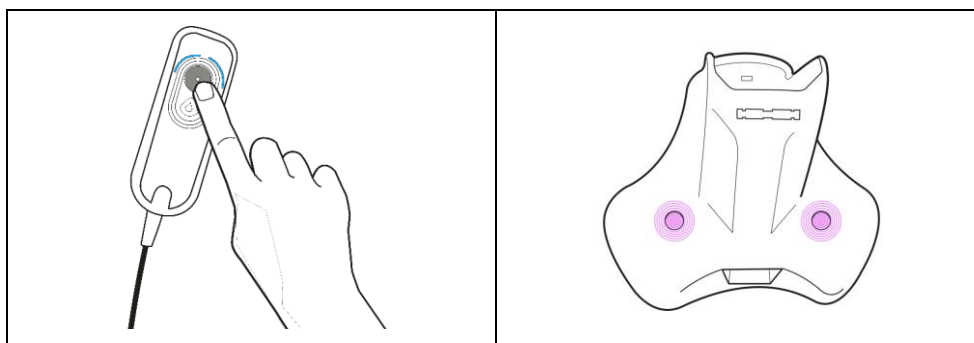
The operator will be informed, as the LEDs on the docking station will light up in pale purple.

**NOTE:** To switch the device back on, press and hold the button on the response remote for a few seconds, until the indicator lights on the docking station turn blue again.

<p>As soon as the Docking Station is connected to your computer, a flashing blue light indicates 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>	

### Indicator lights during the examination

The use of a patient response button is essential for the proper conduct of the examinations. To help you perform your tests under optimal conditions, the patient response button and the docking station are equipped with indicator lights that inform you of their use by the patient:

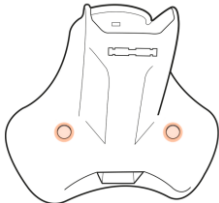
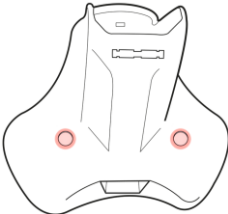
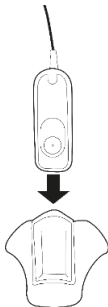




## Charging the response button



**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 »).

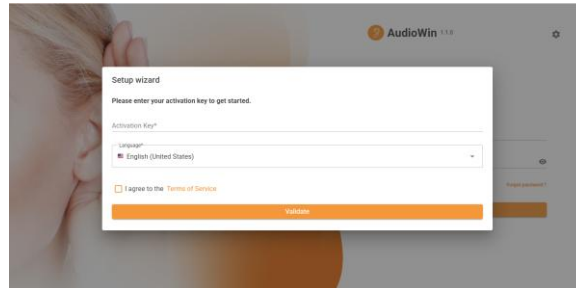
<p>Steady <b>ORANGE</b>: Indicates that the response remote battery is low (less than 20% charge).</p>	
<p>Steady <b>RED</b>: Indicates that the response remote battery is very low (less than 10% charge). The response remote needs to be charged immediately.</p>	
<p>To recharge the response remote, you must slide it into the small dedicated compartment at the front of the docking station.</p>	
<p>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.</p>	
<p>Flashing <b>GREEN</b>: response remote charging</p>	
<p>Steady <b>GREEN</b>: response remote fully charged</p>	

## 11. AudioWin® Software first connection

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

### Select your language and accept the Terms of Use.

Upon launching the software, enter the activation key. This key can be found on the information sheet provided with your device. Then select your preferred language. Please read the General Terms and Conditions of Use (available via the orange link), and accept them to continue.



### AudioWin® Software Login Page



1. **Interoperability Settings:** Settings that ensure communication between AudioWin® and your business software (EMR). This tab is detailed in the Interoperability section of the software settings.
2. **Remember Me:** Enables automatic login to the operator’s session during future uses of the software.
3. **Forgot Password?:** Allows password recovery in case of loss. To create a new password, you will need to answer the security question you defined when creating your account.

← **Forgot Password**

What was the name of your first pet?

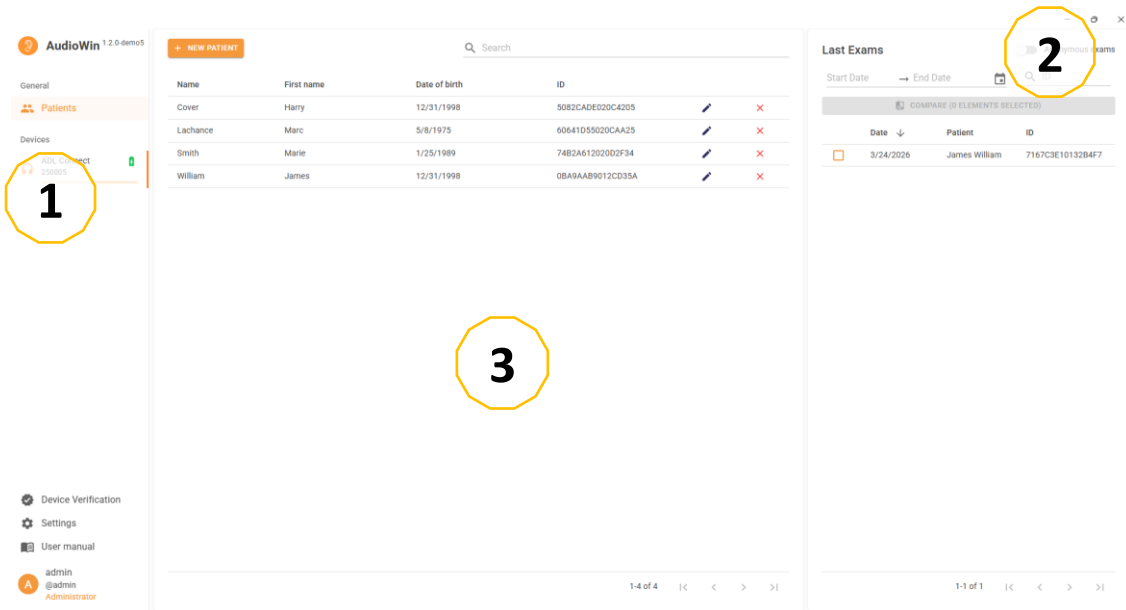
Answer\*

New password\*

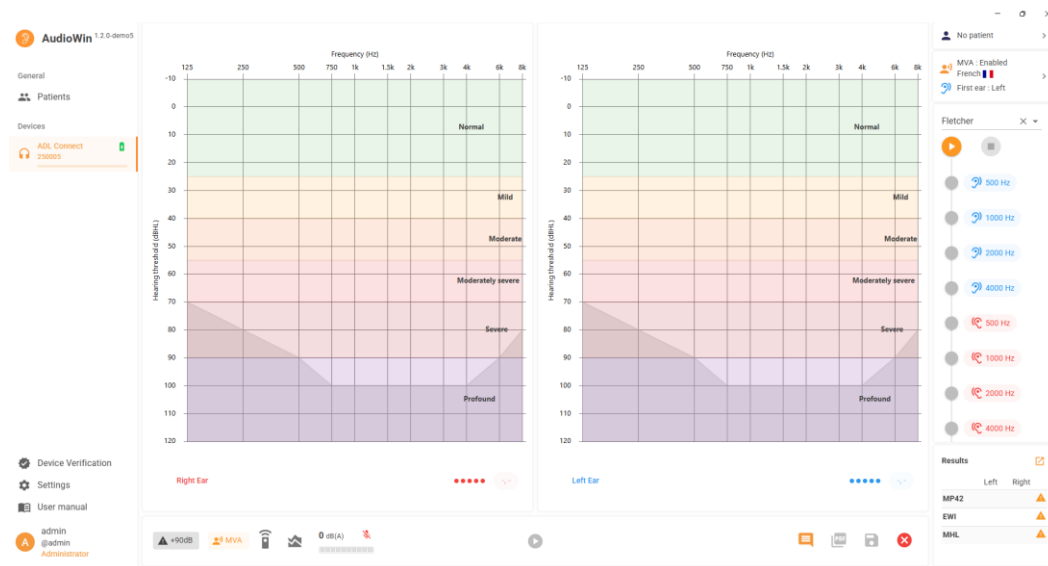
Confirm password\*

## 12.AudioWin® Software Home Page

### 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. Audiograms:** Display of the right and left ear audiograms, showing the measured frequencies and intensities.
- 5. Toolbar:** Access to audiogram display options, ambient noise level measurement, indicator lights, the comments section, report generation, and saving of the ongoing examination.

## Description of the icons

	Access settings
	Daily device check
	Patient list
	Patient undergoing the examination
	View user manual
	Edit profiles (Users, patients, etc.)
	Start a test
	Pause a test
	The patient does not press the response button
	The patient presses the response button
	Stop the test sequence
	Delete the selected profiles (Users, patients, etc.)
	Audiolyser® connected headset
	Restart uncertain answers
	Remote control battery level
	User profile
	Access the different presets
	Delete
	Microphone muted
	Microphone on
	Right ear
	Left ear
	Multi-device dashboard

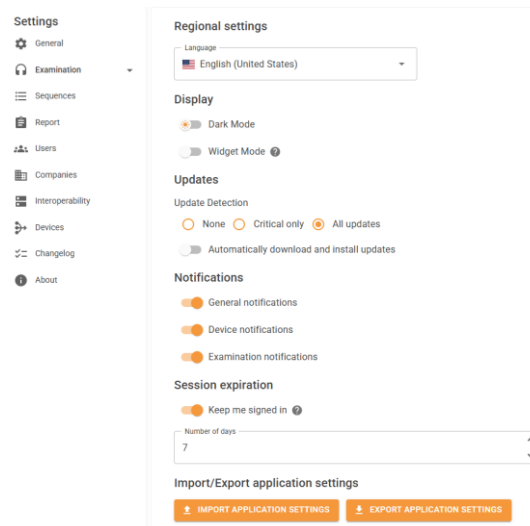
## AudioWin® Software settings

### General



**NOTE:** If you do not check the “Automatically download and install updates” box, when the software starts AudioWin® a window information will appear 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 appear at the top right corner of your AudioWin® software



**General settings are divided into six sections:**

#### **Regional settings:**

Allows you to change the display language.

#### **Display settings:**

Allows you to choose between light mode and dark mode, and to enable or disable widget mode (when enabled, the software appears as a shortcut in the lower-right corner of your screen, allowing you to monitor the progress of the examination while using other applications).

#### **Updates:**

Allows you to set your preferences for automatic updates of the AudioWin® software.

#### **Notifications:**

Choose whether you wish to receive notifications from the software, the connected device, or ongoing examinations.

#### **Session timeout:**

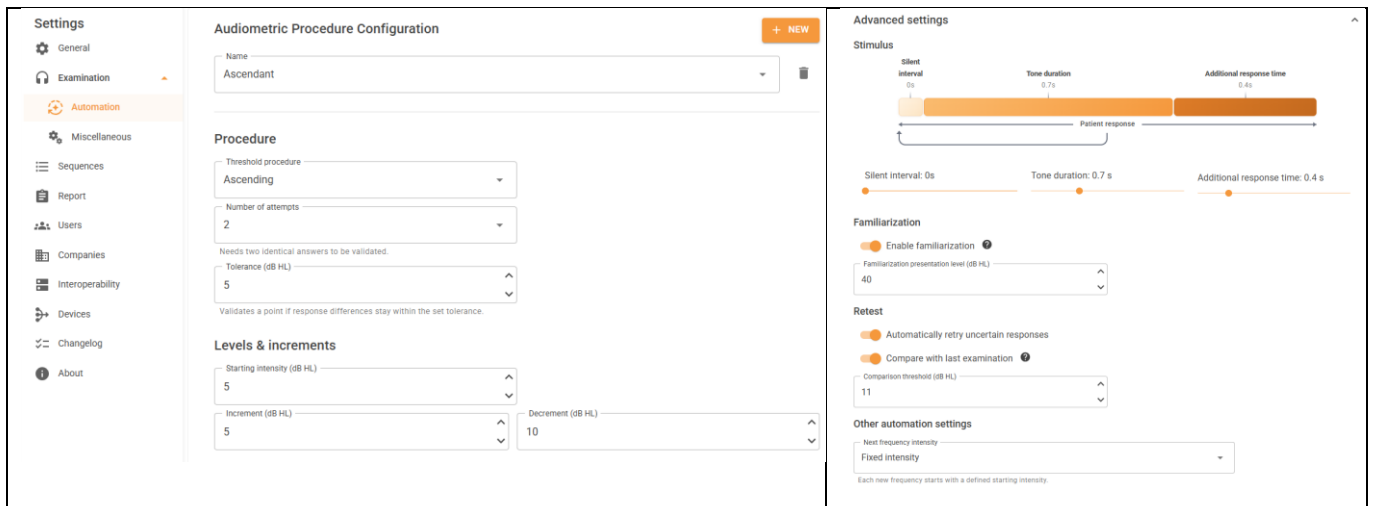
Allows you to enable or disable session expiration, controlling whether the user session automatically ends after a period of inactivity, and to specify the number of days before the session expires.

#### **IMPORT/EXPORT application settings:**

- **Import:** Allows the operator to import AudioWin® software settings.
- **Export:** Allows the operator to export AudioWin® software settings.

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

## Examination – Automatism



Gives you access to advanced examination configuration settings.

### All parameters:

Allows you to create, select, and delete custom test configurations.


To create a new custom test configuration:

- Click on the “New” button. Name your custom configuration; all parameters you modify in this tab will be saved automatically.

To modify a custom configuration:

- Select the name of the custom configuration from the drop-down menu, then directly adjust the various settings in this tab. All changes will be saved automatically.

To delete a custom configuration:

- Select the name of the custom configuration from the drop-down menu, then click the Delete button  .

Two preset configurations are available:

**Hughson–Westlake (Up-Down) method** → A standard audiometric procedure that consists of presenting a clearly audible tone, then decreasing the intensity in 10 dB steps until no response is obtained. The intensity is then increased in 5 dB steps until repeated responses are observed. The hearing threshold corresponds to the lowest level perceived at least two times out of three.

**Ascending method** → A procedure that begins below the presumed audibility threshold and increases the sound level in 5 dB steps until the tone is perceived. This method helps avoid anticipation bias and is generally quicker to perform. The hearing threshold is determined based on the subject’s first confirmed response.

### Procedure:

Allows you to define the parameters for running the audiometric test, including:

- **Threshold procedure:**
  - **Ascending presentation:** The intensity increases in steps as long as the patient does not hear the signal. The patient's first response then confirms the threshold.
  - **Bracketing presentation:** As long as the patient presses the response button, the intensity decreases in steps (these responses are not validated). When the patient no longer hears the signal, the intensity increases again in steps. The first press after this increase validates the threshold.
- **Number of attempts:** Maximum number of possible responses for each frequency.
- **Tolerance:** Maximum difference allowed between measurements of the same threshold to validate a frequency. If the values fall within this tolerance, the lowest value is retained.

#### Levels and Increments:

Allows you to specify the starting intensity of the first tested frequency, as well as amplitude variations during the test:

- Starting intensity: Level of the very first tone presented.
- Increment: Step increase in intensity when no response is obtained.
- Decrement: Step decrease in intensity when a positive response is obtained.

#### Advanced Settings:

Provides further customization of your test protocols.

#### Stimulus:

**Silent interval:** waiting time before the sound is emitted.

**Tone duration:** duration during which the sound is played.

**Additional response time:** additional time allowed for the patient to respond after the end of the sound stimulus for the tested frequency.

#### Familiarization:

The familiarization phase allows the patient to get used to the auditory signal before the actual test begins, helping reduce response errors.

You may:

- Enable or disable the familiarization phase.
- Set the intensity level (in dB HL) of the tone used during this phase.

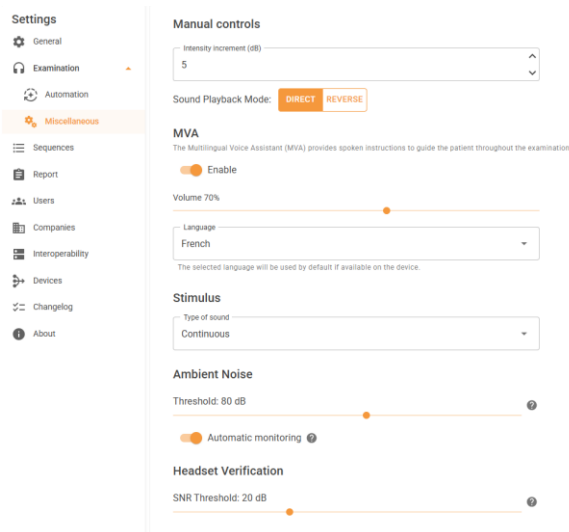
**Automatically retry uncertain responses** → When this option is enabled, the system automatically retests frequencies for which responses are uncertain.

**Compare with previous examination** → When this option is enabled, the system compares the frequencies measured during the current examination with those from the previous one. The comparison threshold defines the acceptable deviation; if this threshold is exceeded, the corresponding frequency is flagged as uncertain.

**Next Frequency Intensity:** Determines how the intensity of the first tone will be set for each new tested frequency:

- Decrement → The new frequency starts at a slightly lower intensity than the previous one (more comfortable and gradual).
- Fixed intensity → The new frequency starts at a predefined intensity.


## Examination – Miscellaneous




### Manual Controls:

**Intensity Increment (dB)** → Defines the step values used in the audiogram.

### Sound Playback Mode:

Direct → A sound signal is emitted after selecting a frequency on the audiogram and placing the cursor on the test start button .

Reverse → A sound signal is emitted as soon as you select a frequency on the audiogram. To stop the sound emission, place the cursor on the test pause button .

### MVA – Multilingual Voice Assistant:

The Multilingual Voice Assistant provides automated voice instructions to guide the patient throughout the examination (e.g., “Press the button when you hear the sound”). These are the default instructions and can be customized for each patient from the examination page.

You have the ability to:

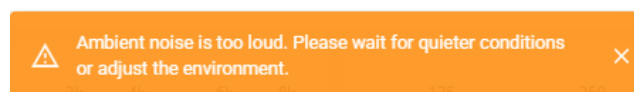
- Enable or disable the voice assistant during the test session.
- Set the volume level of the assistant’s voice.
- Select the language used by the voice assistant during the examination.

### Stimulus:

Type of sound → Defines the waveform of the acoustic signal used during the test (continuous or pulsed).

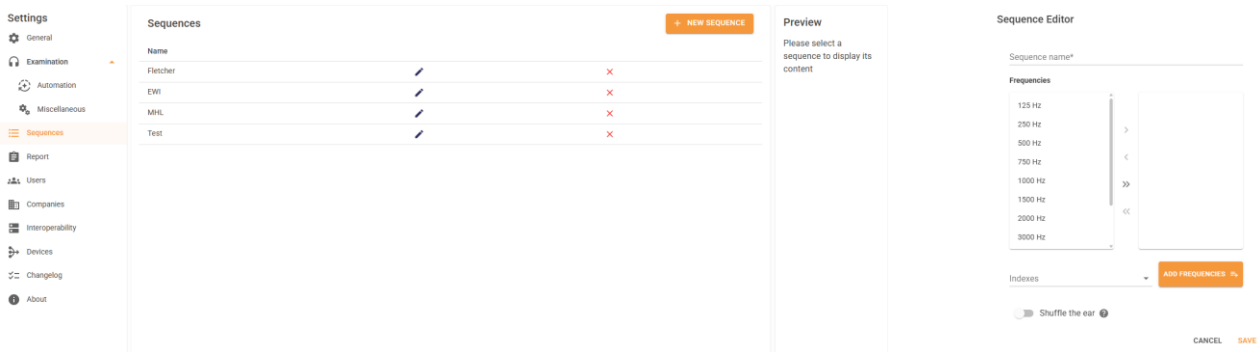
### Ambient noise:

Allows you to set the maximum acceptable noise level for the examination. If the ambient noise exceeds this threshold during the test, an alert will be displayed on the examination page.



**Headphone check:** SNR threshold (Signal-to-Noise Ratio): corresponds to the minimum signal-to-noise ratio required to validate the headphone check. The higher this value, the higher the required signal quality.

## Sequence

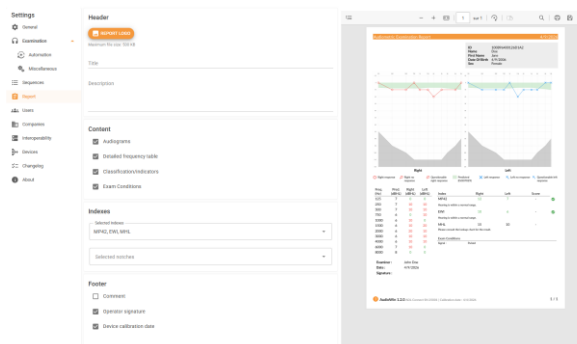


From this section, you can access all the sequences you have previously saved in the software, as well as modify or delete them, and view the frequencies included in each sequence.

To create a new sequence:

- Click on the “New sequence” button.
- Name your new sequence and select the frequencies you wish to test.
- Choose whether you want to alternate ears during the examination.
- You have the option to test only the frequencies used to calculate certain indices. To do so, select the indices from the dropdown menu and click on the “Add frequencies” button.
- Click on “Save”.

## Report



This tab allows you to customize your reports, for example by including information such as your logo and contact details, selecting the content to be displayed, choosing from the various available indices, and defining the information shown in the footer, among other options.

### Indices:

These are used for the automatic analysis of auditory test results. Activated indices enable the generation of scores or interpretations based on different assessment standards.

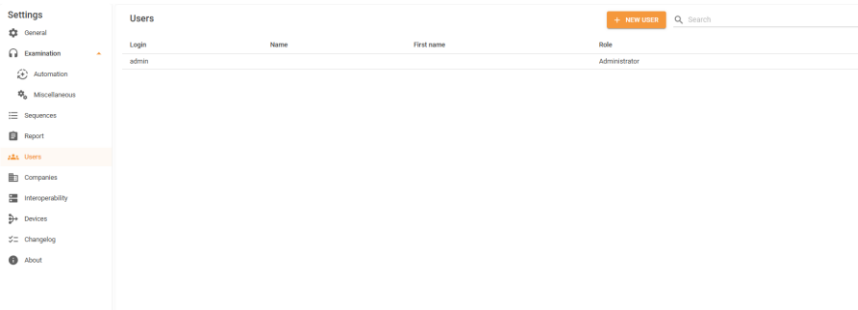
The following indices are available:

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

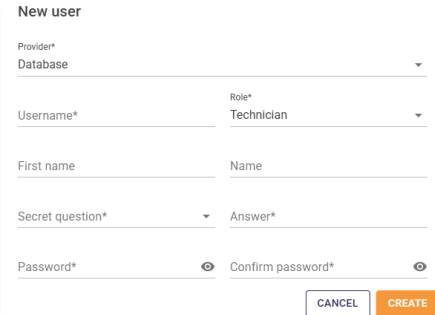
## Users



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



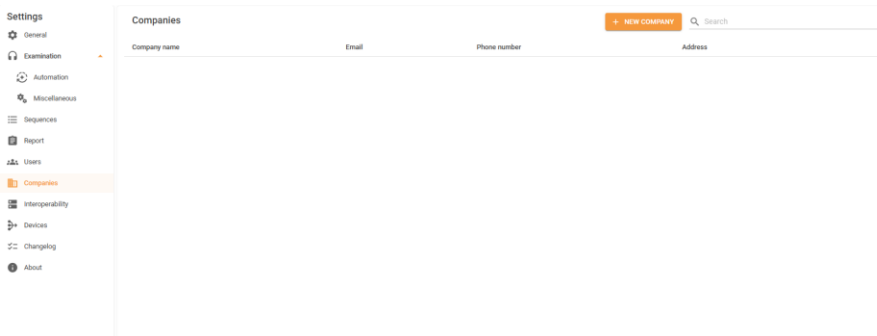
Login	Name	First name	Role
admin	Administrator		Administrator



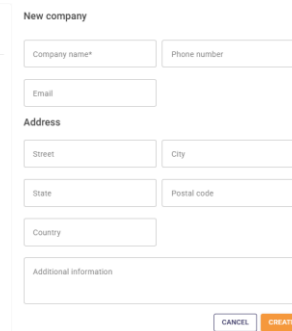
Displays the list of users already registered, and lets you add new users.

You also have access to LDAP, a protocol that allows different systems to connect to a centralized directory containing user identifiers and information, in order to authenticate users, assign appropriate access rights, and allow them to manage their own passwords.

## Companies

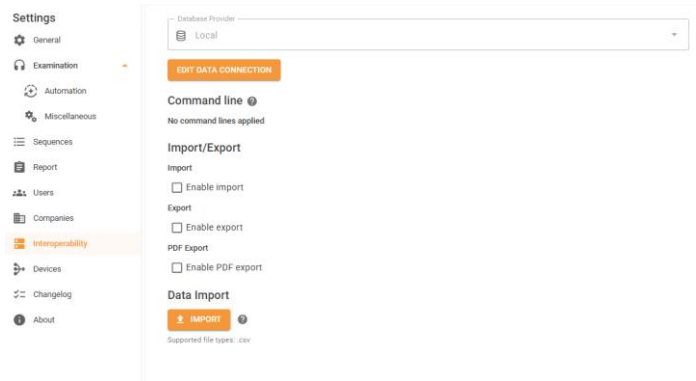


Company name	Email	Phone number	Address
--------------	-------	--------------	---------



Displays the list of facilities where examinations have already been conducted and allows new ones to be added.

## 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



**NOTE:** Patient response button updates are only available when it is directly connected via USB to a computer.

Type	S/N	Headset	Connection	Calibration Date	Device Version	Dock Version
ADL Connect	# 250005	Holmico PD-B1	Wired	7/22/2025 <span>Calibrated</span>	1.2.0	-
ADL 20	# 250046	Holmico PD-B1	-	2/26/2025 <span>Expired calibration</span>	1.9.0.0	-

Displays the list of all currently connected devices along with their associated information (model, serial number, firmware version, calibration date, availability of updates, etc.).

Once connected, the patient response button and the docking station can be updated. When an update is detected, a pop-up window will appear in the lower-right corner of your screen, asking whether you wish to update the equipment.

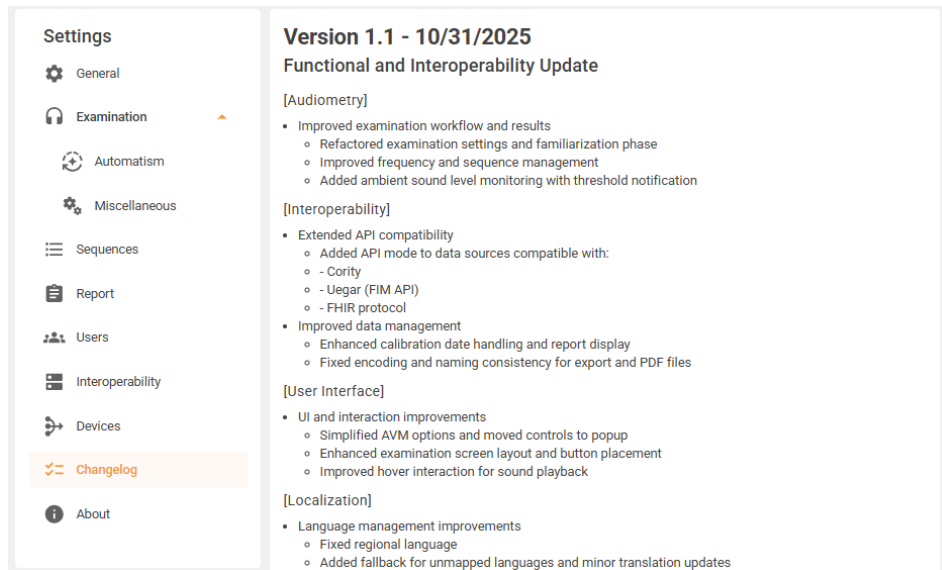
If the calibration date of your device has expired, a warning message will automatically appear when connecting to the software. This message informs you that it is necessary to contact FIM Medical or your local distributor to schedule the recalibration of the device.

### Warning

The calibration date of this device has expired. Please contact the device supplier for recalibration.

OK

## Changelog



The screenshot shows the 'Settings' menu with 'Changelog' selected. The main content area displays the following information:

**Version 1.1 - 10/31/2025**  
**Functional and Interoperability Update**

[Audiometry]

- Improved examination workflow and results
  - Refactored examination settings and familiarization phase
  - Improved frequency and sequence management
  - Added ambient sound level monitoring with threshold notification

[Interoperability]

- Extended API compatibility
  - Added API mode to data sources compatible with:
    - Cority
    - Uegar (FIM API)
    - FHIR protocol
- Improved data management
  - Enhanced calibration date handling and report display
  - Fixed encoding and naming consistency for export and PDF files

[User Interface]

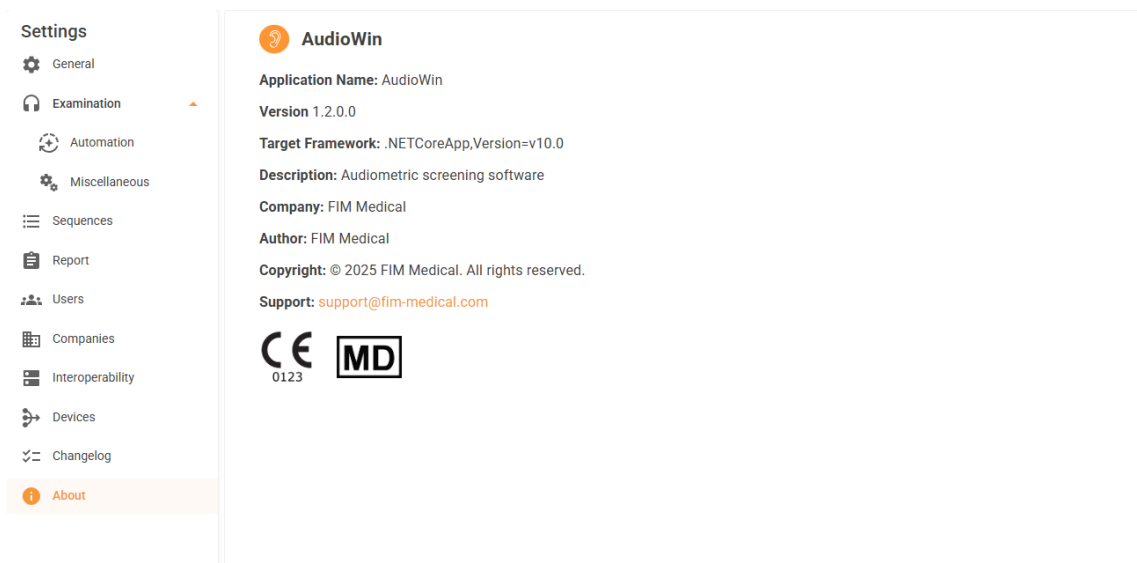
- UI and interaction improvements
  - Simplified AVM options and moved controls to popup
  - Enhanced examination screen layout and button placement
  - Improved hover interaction for sound playback

[Localization]

- Language management improvements
  - Fixed regional language
  - Added fallback for unmapped languages and minor translation updates

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


## About



The screenshot shows the 'Settings' menu with 'About' selected. The main content area displays the following information:

**AudioWin**

**Application Name:** AudioWin  
**Version:** 1.2.0.0  
**Target Framework:** .NETCoreApp,Version=v10.0  
**Description:** Audiometric screening software  
**Company:** FIM Medical  
**Author:** FIM Medical  
**Copyright:** © 2025 FIM Medical. All rights reserved.  
**Support:** [support@fim-medical.com](mailto:support@fim-medical.com)



Displays software information.

## Examination window



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



1. Audiograms for the right and left ears, showing frequencies and intensities.
2. Setting up sequences: this allows you to start, pause and restart a running sequence.
3. Displays a list of devices currently connected to the computer and the test progress bar.
4. Allows you to turn the microphone on or off and view the ambient noise level during the examination.
5. Define the examination parameters that depend on the patient (VMA settings, choice of the first ear to be tested, among others).

Button/Indicator	Meaning	Button/Indicator	Meaning
	Allows emission of sounds above 90 dB.		Additional patient information
	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
	Allows access to the Predicted settings and categorization zones.		Allows you to display more results.

## Displaying predictions

After selecting the predicted option by clicking the button, the graph will appear as follows:



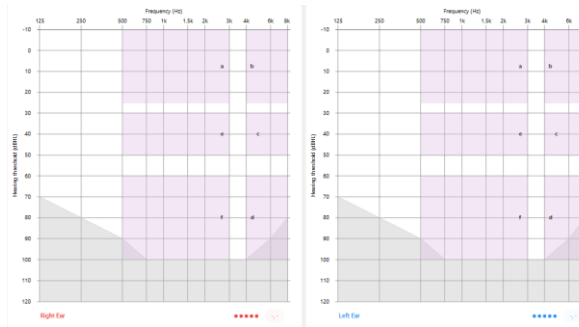
The calculation of these predictions is based on the ISO 7029:2017 standard.

### ✓ **Displaying categorization zones**

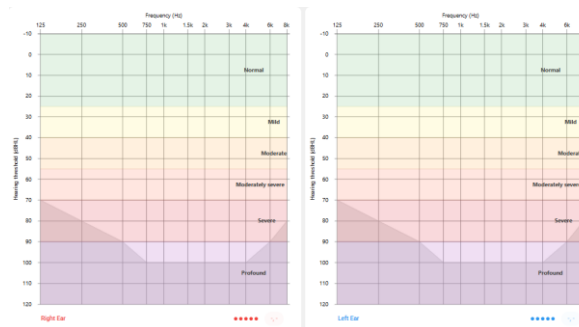
AudioWin® allows the display of categorization zones to help the operator quickly visualize the trend of the current test results.

Three types of zones are available:

#### ✓ **Merluzzi 1979 (Italy):**



#### ✓ **Degrees of hearing loss:**



#### ✓ **SIGYCOP:**

SIGYCOP is a medical evaluation system used by military physicians to assess fitness for service. It applies to:

- Candidates for enlistment or voluntary service in the armed forces
- Candidates for the reserve
- Active military personnel (career or contract)

#### ✓ **French Police:**

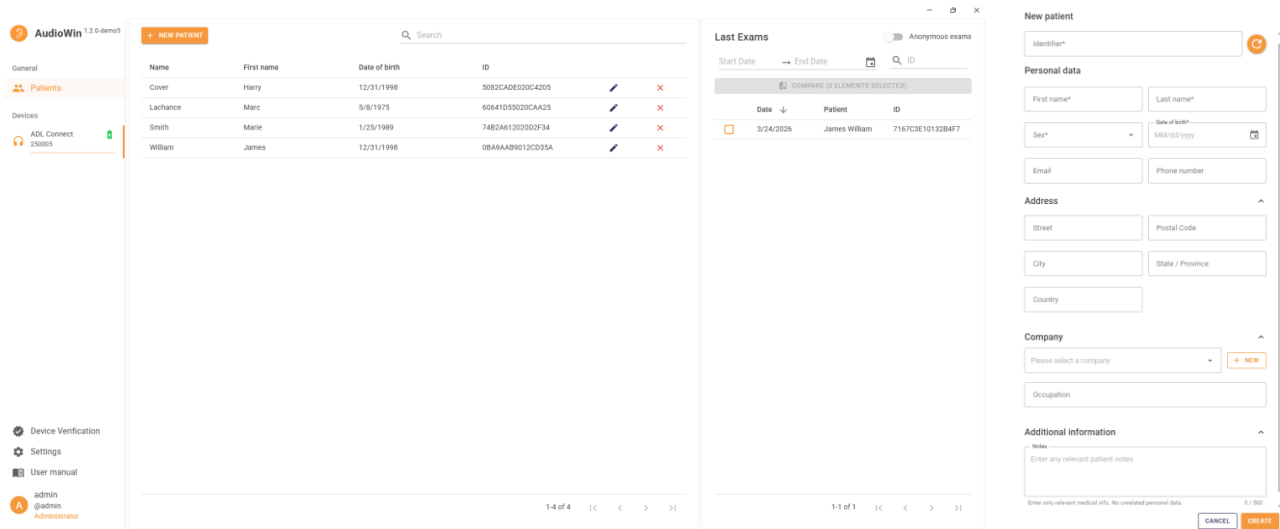
This is an assessment of the auditory fitness required to perform certain duties within the French National Police.




## 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.



Button	Meaning
	Filter the database to select an existing profile
	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 sound level above 80 dB for more than 15 minutes.



**NOTE:** If the patient is unable to become accustomed to the remote's operation, patient can confirm their 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 both automatic and manual modes.

In the Patients tab, double-click on the desired patient.

Check and update their information, then click on "Start" to begin the examination.

Examination Preparation
×

i
Please verify the patient information

Identifier\*

↻

**Personal data**

First name\*

Last name\*

Sex\*

Date of birth\*

Email

Phone number

**Address** ▼

**Company** ▼

**Additional information** ▼

**Notes**

Add a note about the audiometric test

Enter only relevant medical info. No unrelated personal data. 0 / 350

**Otoscopy information**

Not performed

**Left Ear**

Ear Condition

Wax

**Right Ear**

Ear Condition

Wax

CANCEL

START

FF1166.MUT.102 V01.02.00 AudioWin® Software V01.02.00

April 2026

33

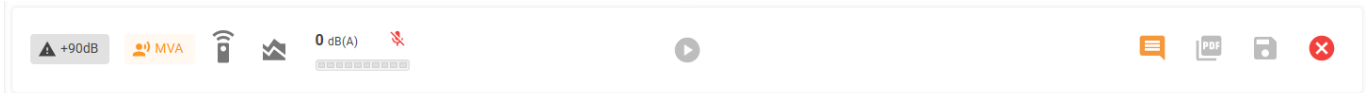
## Manual Mode





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

On audiograms, use the keyboard and/or the mouse to:

- Select the frequency.
- Select the intensity.



Click the button  to start the sound. You can also emit and pause a sound by pressing the space bar.

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

## Keyboard shortcuts

To facilitate the performance of examinations, you can use the following keyboard shortcuts:

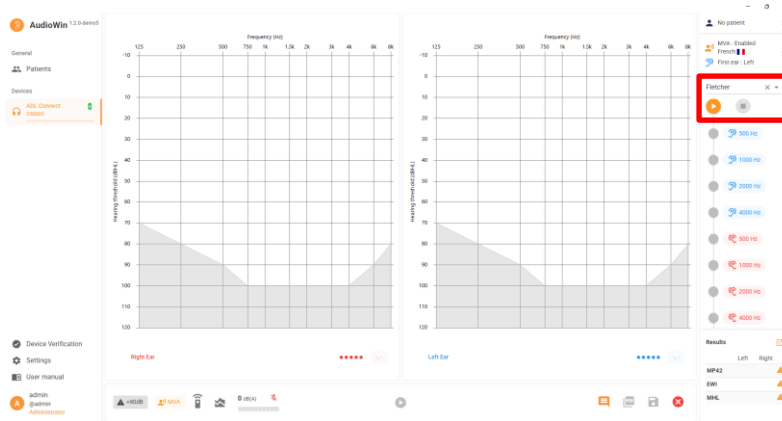
Key	Action
Enter	Record a patient response
Space	Play a sound
R	Start a sequence
P	Pause a sequence
Esc	Stop a sequence
Tab	Switch between audiograms
Delete	Delete the selected response from the audiogram

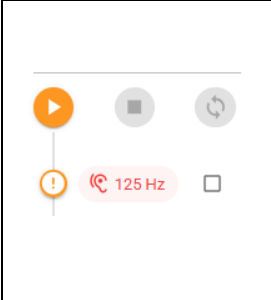




## Sequence Mode



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



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



	<p>Click the  button to start the sequence in automatic mode.</p>
	<p>The  button allows you to stop the sequence.</p>
	<p>The  button stops the sequence.</p>
	<p>The  button allows the selected frequencies to be retested.</p>

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

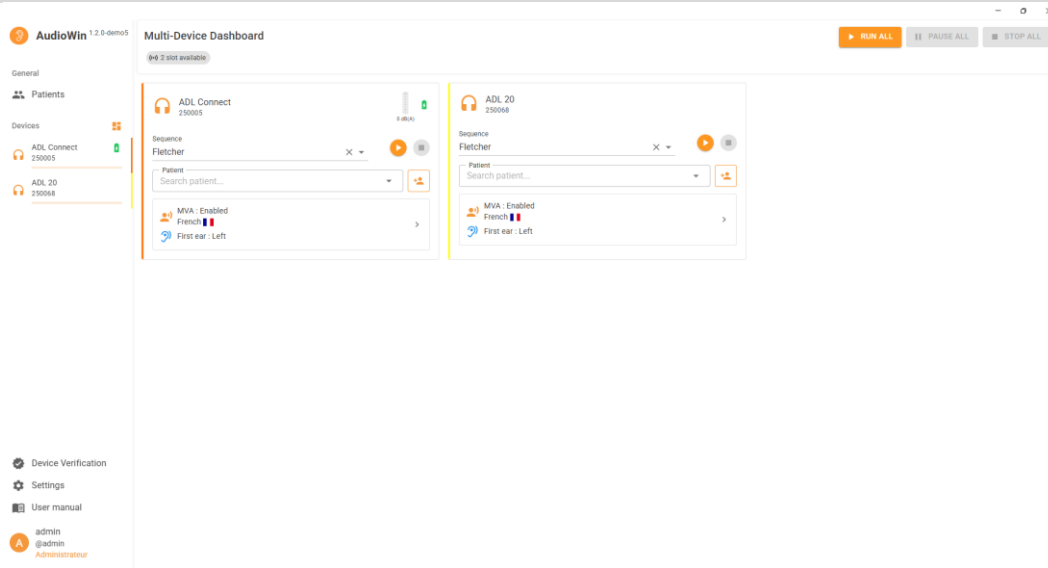
## Launching the automatic test


- 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 by pressing on the pause button 
- Finally, click "Save" to save the results.

## Multi-device mode











**NOTE:** Multi-device mode is available only when at least two devices are connected and recognized by the AudioWin® software.



When at least two devices are detected by the software, you can access the multi-device dashboard via the dedicated button .

- Assign a device to each patient (if the patient is already registered, they will appear in the dropdown menu; otherwise, you will need to create a new patient by clicking the dedicated button).
- N.B.:** To improve readability, a color is assigned to each device. This color appears on the patient response button when the patient presses it, as well as on the ADL Connect docking station when in Bluetooth mode.
- Assign a sequence to each patient.
- Configure the AVM using the dedicated button.
- Start the examinations individually or simultaneously using the “Start all” button.
- At any time, you can pause or stop the ongoing examination, either individually or simultaneously, using the dedicated buttons.
- Monitor the progress of the examinations using the progress bar associated with each patient.
- To save the results, go to the “Device” tab and click on the “Save” button.

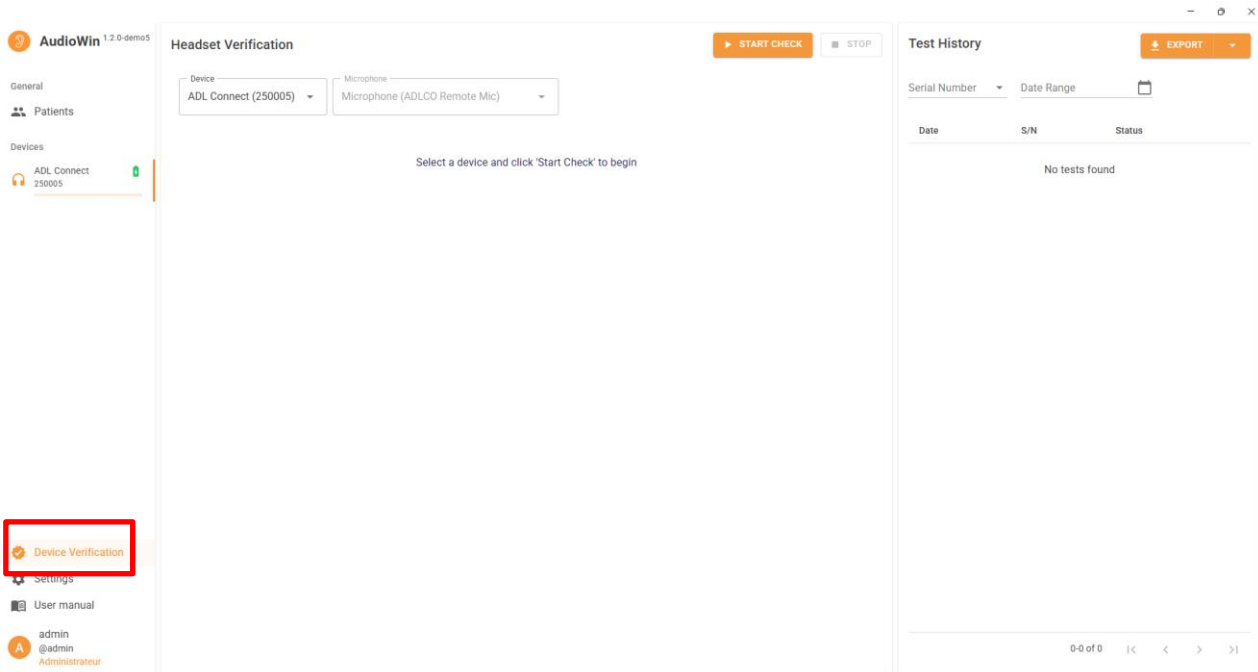
Button/Indicator	Meaning	Button/Indicator	Meaning
	Start a sequence		Pause a sequence
	Stop a sequence		AVM settings
	Create a patient		Edit a patient
	The first ear to be tested will be the left ear		The first ear to be tested will be the right ear

## 14. Device verification



**NOTE:** To ensure proper functioning of the headphones, FIM Medical recommends performing a daily check before conducting examinations.

**NOTE:** To ensure the reliability of the daily headphone check, it is recommended to perform it in a quiet environment so that ambient noise does not affect the results.



To perform the daily check:

- Go to the “Device Check” menu (highlighted in red).
- Select the device you wish to check from the list of available devices.
- Select the microphone associated with the selected device.
- Place the patient response button in its dedicated slot at the front of the docking station.
- Click on the “Start check” button.
- At any time, you can stop the check by clicking on the “Stop” button.
- Once the check is completed, the results are available in the right-hand tab “Test history”.
- You can export the results to your PC by clicking on “Export”, then selecting the desired file format.

## 15. Displaying results

### 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.



## 16. 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
- Bactynyl® 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.

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/calibration every year 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

FIM Medical estimates the service life of Audiolyser® ADL Connect at 10 years subject to proper compliance with cleaning conditions, maintenance and environmental conditions.

No liability for the lack of performance of the device can be attributed to FIM Medical in the event of non-compliance by the user with the maintenance recommendations and conditions of use.

## How to return a defective device



**NOTE:** When returning a device for maintenance, please include the charging station and the headset.

In case of a defective device, please contact FIM Medical with the serial number of the device for support.

Device shall be sent back to FIM Medical after an Return of Material Authorization has been issued to you.

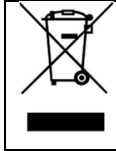
Before returning the device, please clean and disinfect it, as explained in the section “Cleaning and disinfection”.

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.



**NOTE:** In accordance with the REACH Regulation (EC) No. 1907/2006, Article 33, certain internal fastening components of the Holmco PD-81 headset used with the Audiolyser® ADL20 or ADL Connect contain more than 0.1% by weight of lead (CAS 7439-92-1) and imidazolidine-2-thione (CAS 96-45-7). Lead and imidazolidine-2-thione are classified as Substances of Very High Concern (SVHC).

**These components are fully enclosed and never come into contact with the user.**

### 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.

## 17. Troubleshooting and error messages

Issue	Probable cause	Solution
The remote control was connected via USB. This triggers the appearance of a File Explorer window.	The device is in "Mass Storage" mode, or it hasn't been woken from sleep.	Unplug the USB from the handset, press the response button to wake it up, then plug the USB back into the handset if you want to use it over USB.
No sound is perceived	Device is not connected to the software.	<ul style="list-style-type: none"> <li>• Check if the headset is connected.</li> <li>• Verify that the device information is displayed in the software interface.</li> </ul>
Response remote doesn't work: <ul style="list-style-type: none"> <li>• LEDs do not light up</li> <li>• Device is not detected by software</li> </ul>	Battery is discharged.	<ul style="list-style-type: none"> <li>• Charge the battery with the docking station</li> <li>• Alternatively, connect the remote directly to the PC</li> </ul>
Device is not detected by software.	Device is on sleep mode.	Press the button on the remote control. The base, initially lit in pale purple, then exits standby mode and lights up blue.
Bluetooth connection is not working: <ul style="list-style-type: none"> <li>• LEDs light up when patient button response is pressed</li> <li>• Device is not detected by software</li> </ul>	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 appears 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.